sartorius stedim
b i o t e c h

Products and Solutions for the Biopharmaceutical Industry

turning science into solutions

Products and Solutions for the Biopharmaceutical Industry

4. Edition

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▶ A Profile of Sartorius Stedim Biotech

Sartorius Stedim Biotech is a leading provider of cutting-edge equipment and services for the development, quality assurance and production processes of the biopharmaceutical industry. Its integrated solutions covering fermentation, filtration, purification, fluid management and lab technologies are supporting the biopharmaceutical industry around the world to develop and produce drugs safely, timely and economically. Sartorius Stedim Biotech focuses on single-use technologies and value-added services to meet the rapidly changing technology requirements of the industry it serves. Strongly rooted in the scientific community and closely allied with customers and technology partners, the company is dedicated to its philosophy of 'turning science into solutions'. Headquartered in Aubagne, France, Sartorius Stedim Biotech is listed on the Eurolist of Euronext Paris. With its own manufacturing and R&D sites in Europe, North America and Asia and a global network of sales companies, Sartorius Stedim Biotech enjoys a worldwide presence. Its key manufacturing and R&D site is in Germany.

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► Integrated Solutions

From the URS to the Final Qualification

Sartorius Stedim Biotech is capable to supply fully single-use, hybrid or traditional stainless steel systems which are „fit for purpose" and not just fulfilling a URS. Our thorough understanding of the biopharmaceutical manufacturing processes and of our customers specific needs, enables us to add value into the design of engineered solutions, adding cost efficiency and security to our customers manufacturing processes. Our world wide supply chain concept, with manufacturing sites all over the world, makes us the supplier with the highest level of security of supply for reusable and single-use systems and components.

As a „full solution provider" we're bringing together one of the broadest portfolios of single-use components and services with our unique engineering and manufacturing capabilities, allowing us to provide fully integrated process solutions to the biopharmaceutical market.

▷ Consulting

Discover® Application Support
A team of specialists is at your service to support you in your process development tasks, ranging from feasibility trials to full plant surveys.

Process Simulation
Cost calculation and process simulation programs allow you to evaluate the impact of different technologies on your specific process and expansion plans.

▷ Design

Platform Concepts
for defined biotech processes are available out of the box, enabling you to evaluate cost, equipment and utility consumption during the pre conceptual phase of your project.

Competence
from pre conceptual phase to detailed engineering and facility design is given by the experience gained in more than four decades of technological leadership in engineering and single-use product development.
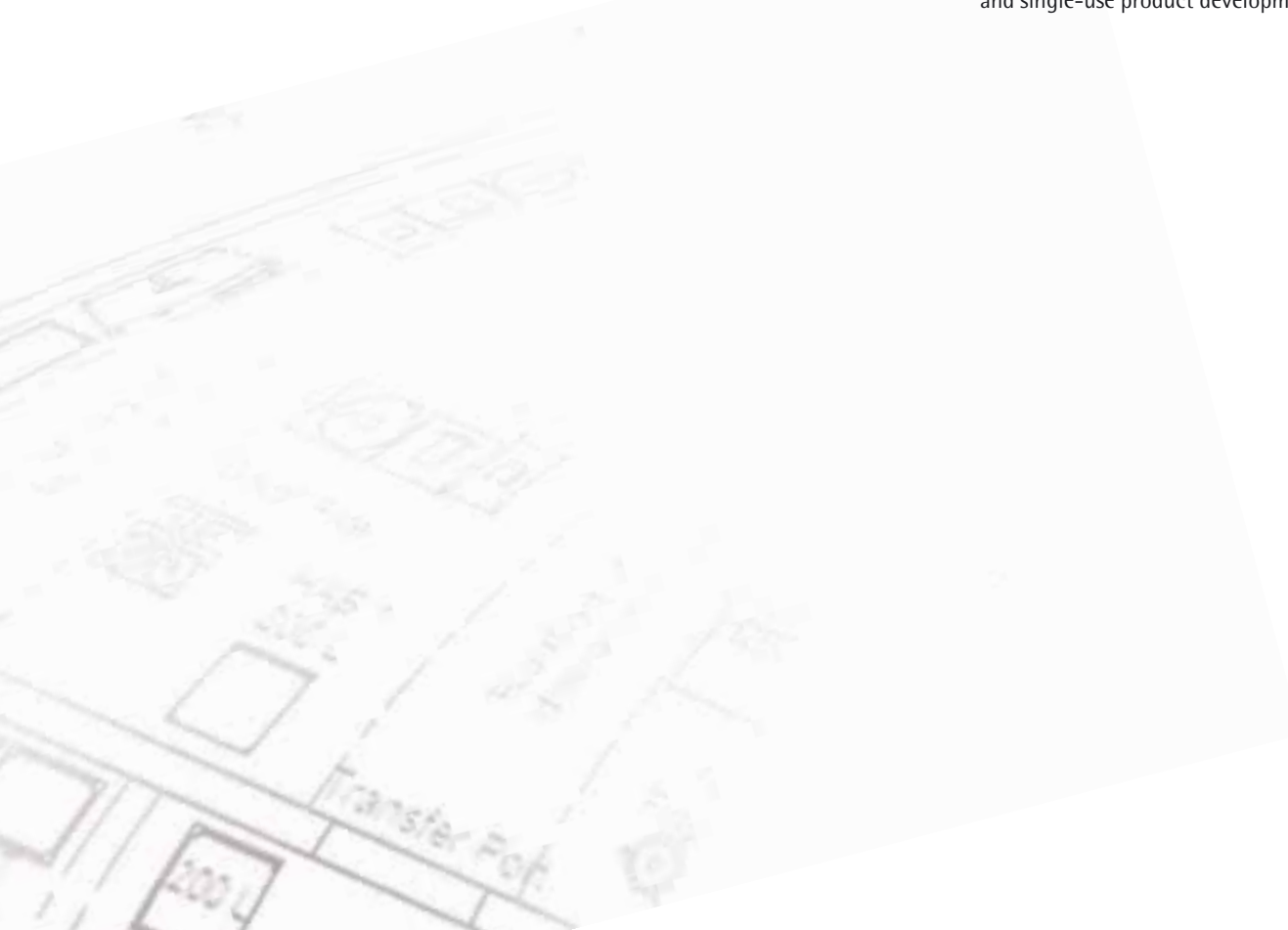
▷ Manufacturing

Dedicated Project Management,
experienced lead engineers and certified
workshop personnel as well as our own QA
personnel accompanying the project during
all phases of the execution are the key factors
which led to 1000's of successfully executed
projects.

Manufacturing Sites
in all areas of the world ensure the highest
possible level of security of supply for re-use-
able and single-use components and systems.

▷ Qualification

Our Own QA Personnel
accompany each project from the start to
ensure continuity and easy IQ |OQ later on.
Most of the Installation Tests are already
performed during the Factory Acceptance
Test to reduce time and cost.

Powerful Simulation Tools
are used to 100% pretest all DCS functions
according to the Functional Specification
allowing a more efficient execution of the
Factory Acceptance Test.

Performance Qualification
is supported by our application specialists
ensuring that you get the most out of the
equipment and to identify further potential
for process optimization.

▷ Services

Our full servicing concept
for instruments and equipment covers
not just FAT, Installation and SAT but also
provides preventive maintenance plans
and service contracts.

Confidence®
Validation Service includes extractables and
leachables studies as well as Physio-Chemical
studies on single-use components which
come in contact with your product, making
sure that your process is in full regulatory
compliance.

Expand®
seminars, workshops and courses are inte-
grated into the Sartorius Stedim Biotech
service program. They cover all different
areas from operator training to hands on
Cell Cultivation and Microbiology trainings.
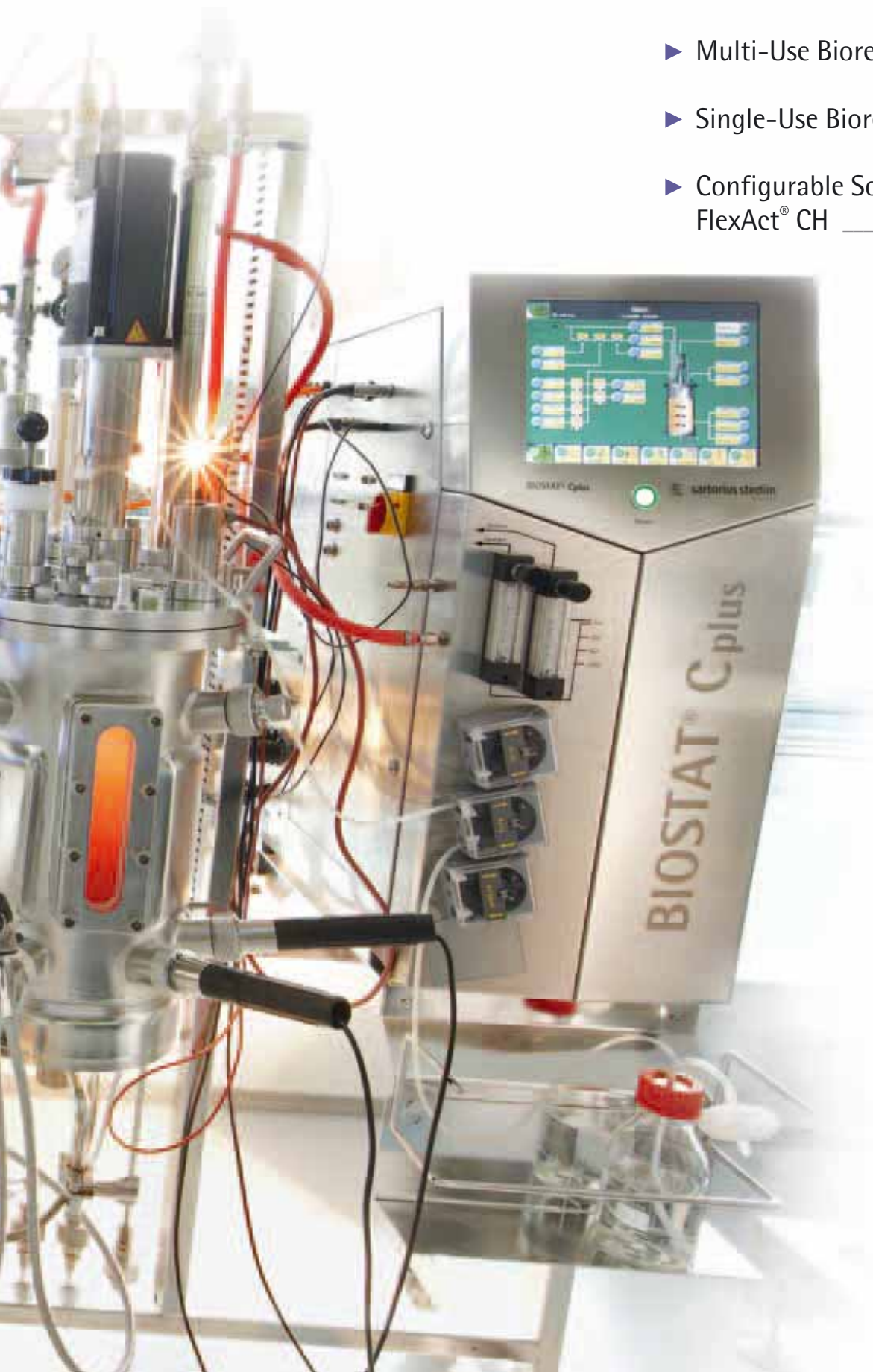
▶ BIOSTAT® Aplus

The Compact, Autoclavable Fermentor│Bioreactor

The BIOSTAT® Aplus is a compact, autoclavable fermentor│bioreactor system specially designed for educational use and preliminary or investigational R&D applications. The single-housing design concept with integrated measurement and control hardware, pumps, temperature, gassing and motor system, saves valuable laboratory bench space.

The application-driven, configured packages for microbial and cell culture include everything needed to get started immediately. The BIOSTAT® Aplus is available with interchangeable 1 L, 2 L, or 5 L working volume single-wall culture vessels. Select the size that meets your needs today! Each system also includes a powerful Notebook PC with local control software, as well as our BioPAT® MFCS/DA software package for simultaneous control and data collection.

The BIOSTAT® Aplus is Ideal for:

– Microbial culture – growth of bacteria, yeast and fungi

– Cell culture – growth of animal, insect and plant cells

– Transition from shake or tissue culture flasks

– Small-scale protein expression

– Education and research

Features

– Ready-to-use packages for microbial or cell culture applications

– Inclusive Notebook PC for operation

– Control of temperature, pH, DO, stirrer speed, gas mixing, Foam│Level and substrate

– 2-stage DO controller configurable via stirrer speed, gas mixing or substrate addition

– In-line pH calibration

– Trend display

– Flexible 4-gas mixing system with individual gas flow path for cell culture packages

– Oxygen enrichment capability for microbial packages

– Interchangeable culture vessels with 1 L, 2 L or 5 L working volume

– Industry proven hardware

– Powerful PC operating software – capable of handling up to four units

– BioPAT® MFCS/DA data storage and plotting software package

– Easy-to-follow step-by-step installation and user guide

– Installation Video

▷ Specifications

Technical Specifications

Space Requirements	Dimensions
Bench space requirement 1 L│2 L│5 L [W×H×D]	840│870│900×580│640│750×425 [mm]
Space requirement autoclave ∅×H per culture vessel 1 L│2 L│5 L	220×500*│250×550*│280×700* [mm]
Ambient temperature│relative humidity (non condensating)	5–40°C│85%

Operating PC	Detailed specification on request

Basic Unit	
Housing material	Coated sheet metal│aluminum│acrylic glass
Host communication	Ethernet

Measurement Ranges	
Agitation motor speed 1 L│2 L│5 L	20–1200│20–1200│20–800 rpm
Temperature	0–150°C
pH	2–12
pO_2	0–100%

Gassing System	
Microbial version	Air aeration with O_2 Supplementation via Sparger outlet
Cell culture version	4-gas mixing system with 4 gas outlets
Outlet design	Hose tube OD 6 mm
Flowmeter	Air calibrated @ 1.21 bara 20°C
Gas flow range Microbial Version 1 L│2 L│5 L	0.16–1.6│0.42–4.2│1.3–13 [l/min]
Gas flow range Cell culture Version 1 L│2 L│5 L	Air, N2: 16–166│33–333│50–500 [ml/min] O2, CO2: 3.3–33│16–166│33–333 [ml/min]
Accuracy	+/– 5% FS

Agitation Motor	Maintenance free drive
Performance	150 W

Integrated Pumps	Digital pulse width modulated controlled
Pump head	Watson Marlow 102R
Rotation speed speed	20 rpm
Flow rate integrated pumps	0.04–33 [ml/min]

* Optional flexible adapter for the exhaust cooler (BB-8844593) is available to reduce autoclave height requirements

Temperature Control System	Dry heating system via heating blanket and automatic cooling water control valve
Temperature control range	8 °C above cooling water to 60 °C
Heating blanket performance 1 L | 2 L | 5 L	100 | 170 | 400 [W]
Connections to culture vessel	Quick couplings for exhaust cooler and cooling finger (CC packages optional)

External Connections \| per Vessel

Balance connection	RS232		
Feed pump connection	0–10 V unused integrated pump can be configured to substrate controller		
2 × External inputs	0–10 V		
Culture Vessel	**1 L**	**2 L**	**5 L**
Total volume	1.6	3	6.6 [L]
Working volume	0.4–1	0.6–2	0.6–5 [L]
Headplate ports 19 mm | 12 mm | 6 mm	3 | 2 | 6	3 | 2 | 9	3 | 3 | 8
Volume storage bottles	3 × 250	3 × 250	250 & 2 × 500 [mL]
Design	Single-wall glass vessel with stainless steel head and vertical lifting handles		
pO$_2$ electrode	Polarographic		
pH electrode	Gel filled		
Temperature probe	Pt100		
Material (product wetted parts)	Borosilicat glass | Stainless steel AISI 316L | EPDM		

Utilities Requirements \| Housing Connection

Power supply	120 VAC or 230 VAC
Gasses	Controlled @ 1.5 barg dry, particle and oil free | hose connector OD 6 mm
Water	Controlled @ 2 barg | hose connector OD 6 mm
Drain	Gravity drain with zero backpressure required | hose connector OD 6 mm

Ordering Information

Description	BIOSTAT® Aplus Microbial Packages			BIOSTAT® Aplus Cell Culture Packages		
Culture vessel	1 L	2 L	5 L	1 L	2 L	5 L
Cat. No. 120 VAC	RAP-M01L OTRDM1	RAP-M02L OTRDM1	RAP-M05L OTRDM1	RAP-C01L FTSDM1	RAP-C02L FTSDM1	RAP-C05L FTSDM1
Cat. No. 230 VAC	RAP-M01L OTRDM2	RAP-M02L OTRDM2	RAP-M05L OTRDM2	RAP-C01L FTSDM2	RAP-C02L FTSDM2	RAP-C05L FTSDM2

Basic Unit

Digital controller	•			•		
Control capabilities for temperature, pH, DO (2 stage cascade), agitation speed, combined Level|Foam controller, substrate	•			•		
Air aeration with O_2-supplementation capability	•			•		
4-Gas mixing with individual gas flow path	–			•		
Peristaltic pumps (integrated)	3			3		

Control PC and Software

Notebook PC for operation	•			•		
PC operation software package	•			•		
SCADA Software MFCS/DA	•			•		

Culture Vessel — Single wall UniVessel®

Culture vessel tripod	•			•		
Stirrer shaft with Single Mechanical Seal	•			•		
6-blade disk impeller	2			–		
3-blade segment impeller	–			1		
150 Watt agitation motor	•			•		
Storage bottle	3			3		
Air inlet and exhaust filter	2			3		
Aeration tube with ring-sparger	•			–		
Aeration tube with µ-sparger	–			•		
Inoculation port	•			•		
Exhaust cooler	•			•		
4-Way addition fitting	•			•		
Fitting for overlay aeration	–			•		
Sample|Harvest pipe	•			•		
Manual sampler	•			•		
Cooling finger	•			BB-8846456	BB-8847819	BB-8847827
Heating blanket	•			•		
pH Electrode, cable	•			•		
DO Electrode, cable	•			•		
Temperature sensor with sleeve	•			•		
Foam|Level probe, cable	•			•		
Tubing, O-Ring spare set	•			•		

Options

Baffle cage	○BB-8846375	BB-8846812	BB-8846820	○BB-8846375	BB-8846812	BB-8846820
Bottle holder	○BB-8846464	BB-8847428	BB-8847436	○BB-8846464	BB-8847428	BB-8847436
Balance for weight measurement of culture vessel	○BB-8843513	BB-8843513	BB-8843513	○BB-8843513	BB-8843513	BB-8843513

Broad range of accessories available, please contact us for further information.

• = included, – = not included, Cat. No. = option

▶ BIOSTAT® Bplus

O$_2$ Enrichment

The BIOSTAT® Bplus with integrated O$_2$-Enrichment gassing capability enables high oxygen transfer for high cell density cultures. The Air flow can be automatically enriched by Oxygen depending on the culture demands and is routed to the sparger line. O$_2$ Enrichment is ideal for multi purpose microbial cultures in R&D applications. Connected to a Nitrogen source it can also be used for anaerobic cultivation.

Digital Controller

– Graphical user interface with color display and touch-screen operation

– Measurement and control for Temperature, pH, DO, agitation, Foam & Level (Twin: combined Foam | Level control)

– Multi-stage DO cascade control

– 2× feed controller per vessel

– Level control via Level probe or balance

– Totalizers with digital calibration for valves and pumps

– In-process pH-recalibration

– Trend display with up to 6 process values

– Up to 2 direct balance connections

– Space for internal Redox and Turbidity amplifier (Single only)

O$_2$–Enrichment Gassing System

– Gas mixing of Air and O$_2$

– O$_2$-Enrichment capability controlled via DO controller

– Optional mass flow controller for total flow

Pumps

– Up to 4 integrated pumps per side

– Configurable to feed controller

– Up to 2 external feed pumps per side

– Optional integrated speed controlled pump

Temperature System

– Powerful heater

– Integrated controlled cooling water valve

– Circulation pump

– Temperature range 8°C above cooling water up to 80°C

Agitation System

– Speed range from 20 up to 2,000 rpm

– Maintenance-free

– High torque for powerful mixing

– Gear-free for quiet operation

UniVessel® Culture Vessel
Jacketed culture vessel fully equipped with:

– Probes for Temperature, DO, pH, Foam and Level

– Stirrer shaft with single mechanical seal

– Rushton impeller

– Baffle assembly

– Aeration tube with ring sparger, sterile filters and exhaust cooler

– Manual sampler with sampling pipe

– Removable bottle support holder

– Addition bottles with stainless steel head piece and sterile filters

– Inoculation | addition port

– Four-way addition port

– Tubing, O-rings and tool kit

SCADA Software BioPAT® MFCS/DA

– Plug and Play configuration

– Online data acquisition

– Sample Data Management

– Enhanced plotting functions

– Export functions

– Easy to use programming interface

The BIOSTAT® Bplus O₂–Enrichment Packages are Applicable for:

– Culture of microorganisms

– Batch, fed batch and continuous culture

– High-cell density culture

– Culture of filamentous microorganisms

– Small-scale cell mass and protein production

– Anaerobic | microaeriphilic culture, on request

Key Features

– Integrated system design

– Single or Twin configuration

– Independent vessel control

– Small footprint

– Automatically controlled O₂-Enrichment

– Graphical user interface with touch screen operation

– Totalizers with digital calibration for valves and pumps

– One high-performance stirrer motor for all UniVessel® sizes

– Trend display with up to 6 process values

– Direct balance connection

– Pre-configured firmware for system extensions

▷ Specifications

Technical Specifications

Space Requirements	Dimensions
Bench space requirement Single Version 1 L | 2 L | 5 L | 10 L [W × H × D]	560 | 590 | 620 × 730 × 565 | 670 × 820 × 565 [mm]
Bench space requirement Twin Version 1 L | 2 L | 5 L | 10 L [W × H × D]	800 | 860 | 920 × 730 × 565 | 1,040 × 820 × 565 [mm]
Space requirement autoclave × H per culture vessel 1 L | 2 L | 5 L | 10 L	240 × 500* | 270 × 550* | 300 × 700* | 350 × 820* [mm]

Basic Unit

Housing material	Stainless steel AISI 304
Display	Touch Screen 10.4"
Resolution	800 × 600 dpi
Host communication	Ethernet | RS422 | RS232

Measurement Ranges

Agitation motor speed 1 L | 2 L | 5 L | 10 L	20–2,000 | 20–2,000 | 20–1,500 | 20–800 rpm
Temperature	0–150℃
pH	2–12
pO₂	0–100%
Turbidity (option)	0–6 AU
Redox (optional)	–1,000 – 1,000 mV

Gassing System	Air aeration with O_2 supplementation
Outlet design	Hose tube OD 6 mm

Flowmeter	Air calibrated @ 1.21 bara 20℃
Gas flow range "Sparger" 1 L | 2 L | 5 L | 10 L	0.16–1.6 | 0.42–4.2 | 1.3–13 | 2–20 [l/min]
Accuracy	+/– 5% FS

Thermal Mass Flow Controller (Option)	Air calibrated
Flow range "Sparger" Total Flow 1 L | 2 L | 5 L | 10 L	0.06–3 | 0.06–3 | 0.4–20 | 0.4–20 [slpm]
Accuracy	+/– 1% FS

Agitation Motor	Maintenance and gear-free servo drive
Performance	200 W

* Optional flexible adapter for the exhaust cooler (BB-8844593) is available to reduce autoclave height requirements.

Integrated Pumps	Digital pulse-width modulated controlled
Pump head	Watson Marlow 102R
Rotation speed	20 rpm
Flow rate integrated pumps	0.04 – 33.2 [ml/min]

Integrated Feed Pump (Option)	Speed controlled
Pump head	Watson Marlow 102R
Rotation speed	5–50 rpm
Flow rate integrated speed controlled pumps	1–83 [ml/min]

Temperature Control System	Thermostat system with recirculation pump and automatic cooling water control valve
Temperature control range	8°C above cooling water to 80°C
Electrical heater	1,000 W │ culture vessel
Connections to culture vessel	Quick couplings

External Connections │ per Vessel	
Balance connection	RS232
2 × Feed pump connection	0–10 V
2 × External input	0–10 V

Culture Vessel	1 L	2 L	5 L	10 L
Total volume	1.6	3	6.6	13 [L]
Working volume	0.4–1	0.6–2	0.6–5	1.5 │ 5–10 [L]
Headplate ports 19 mm │ 12 mm │ 6 mm	3 │ 2 │ 6	3 │ 2 │ 9	3 │ 3 │ 8	5 │ 2 │ 9
Volume storage bottles	250	250	500	500 [mL]
Design	Jacketed glass vessel with stainless steel head and vertical lifting handles			
pO_2 electrode	Polarographic			
pH electrode	Gel-filled			
Temperature probe	Pt 100			
Redox electrode (option)	Gel-filled			
Turbidity probe (option)	Single Channel NIR Absorption Probe, OPL 10 mm			
Material (product wetted parts)	Borosilicate glass │ Stainless steel AISI 316L │ EPDM			

Utilities Requirements │ Housing Connection	
Power supply	120 VAC or 230 VAC
Gasses	Controlled @ 1.5 barg dry, particle and oil-free │ hose connector OD 6 mm
Water	Controlled @ 2 barg │ hose connector OD 10 mm
Drain	Gravity drain with zero backpressure required │ hose connector OD 10 mm

Ordering Information

Description	BIOSTAT® Bplus–MO O$_2$–Enrichment with Jacketed UniVessel®				BIOSTAT® Bplus–TWIN–MO O$_2$–Enrichment with 2× Jacketed UniVessel®			
	1 L	2 L	5 L	10 | 1.5 L 10 | 5 L	1 L	2 L	5 L	10 | 1.5 L 10 | 5 L
Cat. No. 120 VAC	RBP1M01L OTRDG1	RBP1M02L OTRDG1	RBP1M05L OTRDG1	RBP1M1AL OTRDG1, BB-8843486	RBP2M01L OTRDG1	RBP2M02L OTRDG1	RBP2M05L OTRDG1	RBP2M1AL OTRDG1, BB-8843747
Cat. No. 230 VAC	RBP1M01L OTRDG2	RBP1M02L OTRDG2	RBP1M05L OTRDG2	RBP1M1AL OTRDG2, BB-8843485	RBP2M01L OTRDG2	RBP2M02L OTRDG2	RBP2M05L OTRDG2	RBP2M1AL OTRDG2, BB-8843746
Basic Unit								
Digital controller color display with touch screen	•				•			
Control capabilities listing per vessel								
Temperature, pH, DO (2-stage cascade), Stirrer speed	•				•			
Level and Foam via probe	•				Combined Level | Foam controller			
Level via balance	•				•			
Substrate A and Substrate B	•				•			
Gasmixing (integrated)	O$_2$-Enrichment							
Rotameter Sparger	•				•			
Solenoid Valve for O$_2$-Enrichment	•				•			
Peristaltic pumps (integrated)	4				3 per side			
Thermostat system (integrated)	•				•			
Supervisory Process Control Software								
BioPAT® MFCS/DA for data storage	•				•			
Culture Vessel Listing per Vessel	Jacketed UniVessel®							
Culture vessel tripod	•				•			
Stirrer shaft with single mechanical seal	•				•			
6–blade disk impeller	2	2	2	3	2	2	2	3
200–watt servo motor	•				•			
Storage bottle	3	3	3	3	3	3	3	3
Air Inlet and Exhaust filter	2				2			
Aeration tube with Ring-sparger	•				•			
Inoculation | addition port	•				•			
Exhaust Cooler	•				•			
4–Way addition fitting	•				•			
Sample- | Harvest pipe	•				•			
Manual sampler	•				•			
Baffles	•				•			
pH Electrode, cable	•				•			
DO Electrode, cable	•				•			
Level sensor, cable	•				•			
Foam sensor, cable	•				•			
Temperature sensor Pt 100	•				•			
Tubing, O-Ring spare set	•				•			
Options								
MFC (Sparger total flow)	○ 0.06–3 [l/min] BB-8847770		0.4–20 [l/min] BB-8847797		○ 0.06–3 [l/min] BB-8847770		0.4–20 [l/min] BB-8847797	
Feed pump (integrated) speed controlled	–				○ BB-8843468			
Balance for culture vessel	○ BB-8843513				○ BB-8843513			
Turbidity measurement	○ BB-8843472	BB-8843473	BB-8843474	BB-8843474	on request			
Redox measurement	○ BB-8843469	BB-8843470	BB-8803471	BB-8843471	on request			

Broad range of accessories available, please contact us for further information.

• = included,   — = not included,   — — = unavailable,   ○ = option

▶ BIOSTAT® Bplus

Gas Flow Ratio Control

The BIOSTAT® Bplus Gas Flow Ratio Control (GFRC) comes with two integrated mass flow controllers for Air and Oxygen. It allows for advanced process control and easy gas balancing. The system combines two operation modes for advanced gassing control of Air and O_2:

– Constant flow: Percentage alteration

– Constant ratio: Alteration of flow rates

Digital Controller

– Graphical user interface with color display and touch screen operation

– Measurement and control for Temperature, pH, DO, agitation, Foam & Level (Twin: combined Foam | Level control)

– Multi-stage DO cascade control

– 2× feed controller per vessel

– Gas Flow Ratio Controller

– Level control via Level probe or balance

– Space for Redox and Turbidity amplifier (Single only)

– Totalizers with digital calibration for pumps

– In-process pH-recalibration

– Trend display for up to 6 process values

– Up to 2 direct balance connections

Gas Flow Ratio Control Gassing System

– Gas mixing of Air and O_2

– Mass-flow controllers for Air and O_2 controlled via DO controller

Pumps

– Up to 4 integrated pumps per side

– Configurable to substrate controller

– Up to 2 external feed pumps per side

– Optional integrated speed controlled pump

Temperature System

– Powerful heater

– Integrated controlled cooling water valve

– Circulation pump

– Temperature range 8°C above cooling water up to 80°C

Agitation System

– Speed range from 20 up to 2,000 rpm

– Maintenance-free

– High torque for powerful mixing

– Gear-free for quiet operation

UniVessel® Culture Vessel

Jacketed culture vessel fully equipped with:

– Probes for Temperature, DO, pH, Foam and Level

– Stirrer shaft with single mechanical seal

– Rushton impeller

– Baffle assembly

– Aeration tube with ring sparger, sterile filters and exhaust cooler

– Manual sampler with sampling pipe

– Removable bottle holder

– Addition bottles with stainless steel head piece and sterile filters

– Inoculation | addition port

– Four-way addition port

– Tubing, O-rings and tool kit
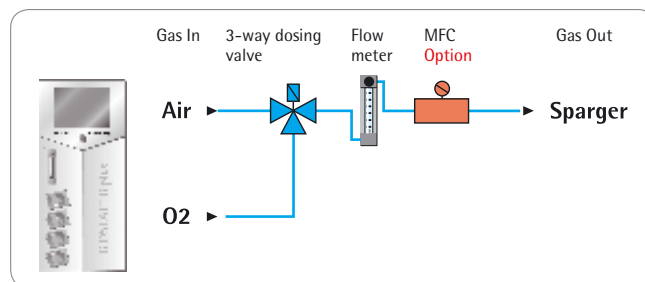
SCADA Software BioPAT® MFCS/DA

– Plug and Play configuration

– Online data acquisition

– Sample Data Management

– Enhanced plotting functions

– Export functions

– Easy-to-use programming interface

**The BIOSTAT® Bplus GFRC
Packages are Applicable for:**

– Culture of microorganisms

– Batch, fed batch and continuous culture

– Small scale cell mass and protein
  production

– High-cell density culture

– Culture of filamentous microorganisms

– Anaerobic | microaerophilic culture,
  on request

Key Features

– Single or Twin configuration

– Independent vessel control

– Small footprint

– Mass-flow controller for Air and Oxygen

– Gas Flow Ratio control strategy

– Graphical user interface with touch screen
  operation

– Totalizers with digital calibration for
  valves and pumps

– One high-performance stirrer motor for
  all UniVessel® sizes

– Trend display with up to 6 process values

– Direct balance connection

– Pre-configured firmware for system
  extensions

▷ Specifications

Technical Specifications

Space Requirements	Dimensions
Bench space requirement Single Version 1 L	2 L	5 L	10 L [W × H × D]	560	590	620 × 730 × 565	670 × 820 × 565 [mm]
Bench space requirement Twin Version 1 L	2 L	5 L	10 L [W × H × D]	800	860	920 × 730 × 565	1,040 × 820 × 565 [mm]
Space requirement autoclave × H per culture vessel 1 L	2 L	5 L	10 L	240 × 500*	270 × 550*	300 × 700*	350 × 820* [mm]

Basic Unit

Housing material	Stainless steel AISI 304
Display	Touch Screen 10.4"
Resolution	800 × 600 dpi
Host communication	Ethernet	RS422	RS232

Measurement Ranges

Agitation motor speed 1 L	2 L	5 L	10 L	20–2,000	20–2,000	20–1,500	20–800 rpm
Temperature	0–150°C
pH	2–12
pO_2	0–100%
Turbidity (option)	0–6 AU
Redox (optional)	–1,000 – 1,000 mV

Gassing System	Gas Flow Ratio Control via two mass flow controller
Outlet design	Hose tube OD 6 mm

Flowmeter	Air calibrated @ 1.21 bara 20°C
Gas flow range "Sparger" 1 L	2 L	5 L	10 L	0.16–1.6	0.42–4.2	1.3–13	2–20 [l/min]
Accuracy	+/– 5% FS

Thermal Mass Flow Controller	Integrated for Air and O_2
Air: Flow ranges 1 L	2 L	5 L	10 L	0.06–3	0.06-3	0.4-20	0.4-20 [slpm]
O_2: Flow ranges 1 L	2 L	5 L	10 L	0.06–3	0.06-3	0.4-20	0.4-20 [slpm]
Accuracy	+/– 1% FS

Agitation Motor	Maintenance and gear-free servo drive
Performance	200 W

* Optional flexible adapter for the exhaust cooler (BB-8844593) is available to reduce autoclave height
  requirements.

Integrated Pumps	Digital pulse-width modulated controlled
Pump head	Watson Marlow 102R
Rotation speed	20 rpm
Flow rate integrated pumps	0.04 – 33.2 [ml/min]

Integrated Feed Pump (Option)	Speed controlled
Pump head	Watson Marlow 102R
Rotation speed	5–50 rpm
Flow rate integrated speed controlled pumps	1–83 [ml/min]

Temperature Control System	Thermostat system with recirculation pump and automatic cooling water control valve
Temperature control range	8°C above cooling water to 80°C
Electrical heater	1,000 W │ culture vessel
Connections to culture vessel	Quick couplings

External Connections │ per Vessel	
Balance connection	RS232
2 × Feed pump connection	0–10 V
2 × External input	0–10 V

Culture Vessel	1 L	2 L	5 L	10 L
Total volume	1.6	3	6.6	13 [L]
Working volume	0.4–1	0.6–2	0.6–5	1.5 │ 5–10 [L]
Headplate ports 19 mm │ 12 mm │ 6 mm	3 │ 2 │ 6	3 │ 2 │ 9	3 │ 3 │ 8	5 │ 2 │ 9
Volume storage bottles	250	250	500	500 [mL]
Design	Jacketed glass vessel with stainless steel head and vertical lifting handles			
pO$_2$ electrode	Polarographic			
pH electrode	Gel-filled			
Temperature probe	Pt 100			
Redox electrode (option)	Gel-filled			
Turbidity probe (option)	Single Channel NIR Absorption Probe, OPL 10 mm			
Material (product wetted parts)	Borosilicate glass │ Stainless steel AISI 316L │ EPDM			

Utilities Requirements │ Housing Connection	
Power supply	120 VAC or 230 VAC
Gasses	Controlled @ 1.5 barg dry, particle and oil-free │ hose connector OD 6 mm
Water	Controlled @ 2 barg │ hose connector OD 10 mm
Drain	Gravity drain with zero backpressure required │ hose connector OD 10 mm

Ordering Information

Description	BIOSTAT® Bplus–MO GFRC with Jacketed UniVessel®				BIOSTAT® Bplus–TWIN–MO GFRC with 2× Jacketed UniVessel®			
	1 L	2 L	5 L	10 | 1.5 L 10 | 5 L	1 L	2 L	5 L	10 | 1.5 L 10 | 5 L
Cat. No. 120 VAC	BB-8843490	BB-8843492	BB-8843494	BB-8843498, BB-8843496	BB-8843751	BB-8843753	BB-8843755	BB-8843760, BB-8843757
Cat. No. 230 VAC	BB-8843489	BB-8843491	BB-8843493	BB-8843497, BB-8843495	BB-8843750	BB-8843752	BB-8843754	BB-8843758, BB-8843756

Basic Unit

Digital controller color display with touch screen	•				•			
Control capabilities listing per vessel								
Temperature, pH, DO (2-stage cascade), Stirrer speed	•				•			
Level and Foam via probe	•				Combined Level | Foam controller			
Level via balance	•				•			
Substrate A and Substrate B	•				•			
200-watt servo motor	•				•			
Gasmixing (integrated)	Gas Flow Ratio Control via MFC for Air and O$_2$							
Rotameter Sparger	•				•			
Air MFC	•				•			
O$_2$ MFC	•				•			
Peristaltic pumps (integrated)	4				3 per side			
Thermostat system (integrated)	•				•			

Supervisory Process Control Software

BioPAT® MFCS/DA for data storage	•				•			

Culture Vessel Listing per Vessel — Jacketed UniVessel®

Culture vessel tripod	•				•			
Stirrer shaft with Single Mechanical Seal	•				•			
6-blade disk impeller	2	2	2	3	2	2	2	3
Storage bottle	3	3	3	3	3	3	3	3
Air Inlet and Exhaust filter	2				2			
Aeration tube with Ring-sparger	•				•			
Inoculation | addition port	•				•			
Exhaust Cooler	•				•			
4-Way addition fitting	•				•			
Sample- | Harvest pipe	•				•			
Manual sampler	•				•			
Baffles	•				•			
pH Electrode, cable	•				•			
DO Electrode, cable	•				•			
Level sensor, cable	•				•			
Foam sensor, cable	•				•			
Temperature sensor Pt 100	•				•			
Tubing, O-Ring spare set	•				•			

Options

Feed pump (integrated) speed controlled	–				○ BB-8843468			
Balance for culture vessel	○ BB-8843513				○ BB-8843513			
Turbidity measurement	○ BB-8843472	BB-8843473	BB-8843474	BB-8843474	on request			
Redox measurement	○ BB-8843469	BB-8843470	BB-8803471	BB-8843471	on request			

Broad range of accessories available, please contact us for further information.

• = included,   — = not included,   — — = unavailable,   ○ = option

▶ BIOSTAT® Bplus

Additive Flow

The BIOSTAT® Bplus Additive Flow packages with single-wall culture vessels are specially configured for cell-culture applications. The integrated, automatically-controlled gas mixing system provides Sparger and Overlay gassing. Air is routed to Overlay. Air, O_2, N_2 and CO_2 are routed to Sparger. Each gas has its own rotameter for individual flow rate adjustment. Easy-to-upgrade culture vessel components and Rotameter flow rates allow for dual use accomodating cell culture and microbial cultures. Additive Flow provides the highest flexibility in controlling gas flow and gas composition for the bioprocess.

Digital Controller

– Graphical user interface with color display and touch screen operation

– Integrated amplifiers for Temperature, pH, DO, Foam and Level

– Space for Redox and Turbidity amplifier (single only)

– Integrated digital control loops for Temperature, pH, DO, agitation, gas mixing, Overlay flow and 2× substrate

– Level control via Level probe or balance

– Multi-stage DO cascade control

– Totalizers with digital calibration for valves and pumps

– In-process pH-recalibration

– Trend display for up to 6 process values

– Up to 2 direct balance connections

Additive Flow Gassing System

– Sparger and Overlay gas outlet

– Gasmixing of Air, O_2, N_2, CO_2 for Sparger gassing

– Air for Overlay gassing

– Controlled via pH | DO controller

– Optional mass flow controller for Overlay flow

Pumps

– 3× integrated pumps per side

– Configurable to substrate controller

– Up to 2 external feed pumps per side

– Optional integrated speed controlled pump

Temperature System

– Heating blanket

– Integrated controlled cooling water valve

– Temperature range up to 60°C

– Optional cooling finger

– Jacketed Vessels also available

Agitation System

– Speed range 20 up to 2,000 rpm

– Maintenance-free

– Gear-free for quiet operation

UniVessel® Culture Vessel
Single-wall culture vessel fully equipped with:

– Probes for Temperature, DO, pH, Foam and Level

– Stirrer shaft with single mechanical seal

– 3-blade segment impeller

– Aeration tube with micro Sparger, Overlay aeration fittings, sterile filters and exhaust cooler

– Manual sampler with sampling pipe

– Removable bottle support holder

– Addition bottles with stainless steel head piece and sterile filters

– Inoculation | addition port

– Four-way addition port

– Tubing, O-rings and tool kit

Gas In	3-way dosing valve	Flow meter	MFC Option	Gas Out
Air				Sparger
O2				

SCADA Software BioPAT® MFCS/DA

To accelerate your research activities, our powerful supervisory software BioPAT® MFCS/DA for extended visualization, data acquisition and trend display is included.

– Plug and Play configuration

– Batch-oriented software package

– Online data acquisition

– Sample Data Management

– Enhanced plotting functions

– Export functions

– Easy-to-use programming interface

The BIOSTAT® Bplus Additive Flow Packages are Applicable for:

– Cell culture of insect and mammalian cells

– Batch, fed batch and continuous culture

– Perfusion operation (easy to upgrade)

– Small-scale cell mass, protein, MAb & vaccine production

– High-cell density culture

– Suspension and micro-carrier cultures

Key Features

– Single or Twin configuration

– Independent vessel control

– Small footprint

– Automatically controlled gas mixing

– Sparger and Overlay gassing

– Graphical user interface with touch screen operation

– Totalizers with digital calibration for valves and pumps

– One high-performance stirrer motor for all UniVessel® sizes

– Trend display with up to 6 process values

– Direct balance connection

– Pre-configured firmware for system extension

▷ Specifications

Technical Specifications

Space Requirements	Dimensions
Bench space requirement Single Version 1 L | 2 L | 5 L | 10 L [W × H × D]	560 | 590 | 620 × 730 × 565 | 670 × 820 × 565 [mm]
Bench space requirement Twin Version 1 L | 2 L | 5 L | 10 L [W × H × D]	800 | 860 | 920 × 730 × 565 | 1,040 × 820 × 565 [mm]
Space requirement autoclave × H per culture vessel 1 L | 2 L | 5 L | 10 L	240 × 500* | 270 × 550* | 300 × 700* | 350 × 820* [mm]

Basic Unit

Housing material	Stainless steel AISI 304
Display	Touch Screen 10.4"
Resolution	800 × 600 dpi
Host communication	Ethernet | RS422 | RS232

Measurement Ranges

Agitation motor speed 1 L | 2 L | 5 L | 10 L	20–2,000 | 20–2,000 | 20–1,500 | 20–800 rpm
Temperature	0–150°C
pH	2–12
pO_2	0–100%
Turbidity (option)	0–6 AU
Redox (optional)	–1,000 – 1,000 mV

Gassing System	Additive Flow 4-gas mixing with Sparger and Overlay outlet
Outlet design	Hose tube OD 6 mm

Flowmeter	Air calibrated @ 1.21 bara 20°C
Gas flow range "Sparger" for Air, O_2, N_2, CO_2	0.003–0.033 [l/min]
Gas flow range "Overlay"	0.026–0.266 [l/min]
Accuracy	+/– 2% FS

Thermal Mass Flow Controller (Option)	Air calibrated
Flow range "Overlay"	0.006–0.3 slpm
Accuracy	+/– 1% FS

Agitation Motor	Maintenance and gear-free servo drive
Performance	200 W

* Optional flexible adapter for the exhaust cooler (BB-8844593) is available to reduce autoclave height requirements.

Integrated Pumps	Digital pulse-width modulated controlled
Pump head	Watson Marlow 102R
Rotation speed	20 rpm
Flow rate integrated pumps	0.04 – 33.2 [ml/min]

Integrated Feed Pump (Option)	Speed controlled
Pump head	Watson Marlow 102R
Rotation speed	5–50 rpm
Flow rate integrated speed controlled pumps	1–83 [ml/min]

Temperature Control System	Dry heating system via heating blanket and automatic cooling water control valve
Temperature control range	8°C above cooling water to 60°C
Heating blanket performance 1 L │ 2 L │ 5 L │ 10 L	100 │ 170 │ 400 │ 780 [W] │ culture vessel
Connections to culture vessel	Quick couplings for exhaust cooler and optional cooling finger

External Connections │ per Vessel

Balance connection	RS232
2 × Feed pump connection	0–10 V
2 × External input	0–10 V

Culture Vessel	**1 L**	**2 L**	**5 L**	**10 L**
Total volume	1.6	3	6.6	13 [L]
Working volume	0.4–1	0.6–2	0.6–5	1.5 │ 5–10 [L]
Headplate ports 19 mm │ 12 mm │ 6 mm	3│2│6	3│2│9	3│3│8	5│2│9
Volume storage bottles	250	250	500	500 [mL]
Design	Single wall glass vessel with stainless steel head and vertical lifting handles			
pO$_2$ electrode	Polarographic			
pH electrode	Gel-filled			
Temperature probe	Pt 100			
Redox electrode (option)	Gel-filled			
Turbidity probe (option)	Single Channel NIR Absorption Probe, OPL 20 mm			
Material (product wetted parts)	Borosilicate glass │ Stainless steel AISI 316L │ EPDM			

Utilities Requirements │ Housing Connection

Power supply	120 VAC or 230 VAC
Gasses	Controlled @ 1.5 barg dry, particle and oil-free │ hose connector OD 6 mm
Water	Controlled @ 2 barg │ hose connector OD 10 mm
Drain	Gravity drain with zero backpressure required │ hose connector OD 10 mm

Ordering Information

Description	BIOSTAT® Bplus–CC Additive Flow with Single Wall UniVessel®				BIOSTAT® Bplus–TWIN–CC Additive Flow with 2× Single Wall UniVessel®			
	1 L	2 L	5 L	10 | 1.5 L 10 | 5 L	1 L	2 L	5 L	10 | 1.5 L 10 | 5 L
Cat. No. 120 VAC	RBP1C01L ATSDM1	RBP1C02L ATSDM1	RBP1C05L ATSDM1	RBP1C1AL ATSDM1, RBP1C1BL ATSDM1	RBP2C01L ATSDM1	RBP2C02L ATSDM1	RBP2C05L ATSDM1	RBP2C1AL ATSDM1, RBP2C1BL ATSDM1
Cat. No. 230 VAC	RBP1C01L ATSDM2	RBP1C02L ATSDM2	RBP1C05L ATSDM2	RBP1C1AL ATSDM2, RBP1C1BL ATSDM2	RBP2C01L ATSDM2	RBP2C02L ATSDM2	RBP2C05L ATSDM2	RBP2C1AL ATSDM2, RBP2C1BL ATSDM2

Basic Unit

Digital controller color display with touch screen	•				•			
Control capabilities listing per vessel								
Temperature, pH, DO (2-stage cascade), Stirrer speed	•				•			
Combined Level | Foam controller	•				•			
Level via balance	•				•			
Substrate A and Substrate B	•				•			
200-watt servo motor	•				•			
Gasmixing	Additive Flow							
Rotameter Sparger	• Air, O$_2$, N$_2$, CO$_2$				• Air, O$_2$, N$_2$, CO$_2$			
Rotameter for Overlay	• Air				• Air			
Automatic gasmixing of Air, O$_2$, N$_2$, CO$_2$; Sparger	•				•			
Peristaltic pumps (integrated)	3				3 per side			
Temperature system with heating blanket	•				•			

Supervisory Process Control Software

BioPAT® MFCS/DA	•				•			

Culture Vessel Listing per Vessel	Single Wall UniVessel®							
Culture vessel tripod	•				•			
Stirrer shaft with Single Mechanical Seal	•				•			
3-blade segment impeller	1				1			
Storage bottle	3	3	3	3	3	3	3	3
Air Inlet and Exhaust filter	3				3			
Aeration tube with µ-sparger	•				•			
Inoculation port	•				•			
Exhaust Cooler	•				•			
4-Way addition fitting	•				•			
Universal Adaptor 3.2 mm for overlay aeration	•				•			
Sample- | Harvest pipe	•				•			
Manual sampler	•				•			
pH Electrode, cable	•				•			
DO Electrode, cable	•				•			
Level sensor, cable	•				•			
Foam sensor, cable	•				•			
Temperature sensor Pt 100	•				•			
Tubing, O-Ring spare set	•				•			

Options

Magnetic coupled agitation system	○ BB-8847339				○ BB-8847339			
Cooling finger	○ BB-8846456	BB-8847819	BB-8847827	BB-8847835	○ BB-8846456	BB-8847819	BB-8847827	BB-8847835
MFC (Overlay flow)	○ 0.003–0.3 [l/min] BB-8847746				○ 0.003–0.3 [l/min] BB-8847746			
Balance for culture vessel	○ BB-8843513				○ BB-8843513			
Turbidity measurement	○ BB-8843510	BB-8843511	BB-8843512	BB-8843512	on request			
Redox measurement	○ BB-8843469	BB-8843470	BB-8803471	BB-8843471	on request			

Broad range of accessories available, please contact us for further information.

• = included, — = not included, — — = unavailable, ○ = option

▶ BIOSTAT® Bplus

Exclusive Flow

The BIOSTAT® Bplus Exclusive Flow packages with single-wall culture vessels are specially configured for cell culture. The integrated four gas mixing system provides Overlay and Sparger gassing. Air is routed to Overlay. Air, O_2, N_2 and CO_2 are routed to Sparger. By an easy upgrade of culture vessel components and rotameter flow ranges, the system can be also used for microbial cultures. The system is ideal for beginners in cell culture who need an easy to use system that provides a certain amount of flexibility in gassing options.

Digital Controller

– Graphical user interface with color display and touch-screen operation

– Integrated amplifiers for Temperature, pH, DO, Foam & Level (Twin: combined Foam│Level amplifier)

– Space for Redox and Turbidity amplifier (single only)

– Integrated digital control loops for Temperature, pH, DO, agitation, gas mixing, total Sparger flow, total Overlay flow and 2× substrate

– Level control via Level probe or balance

– Multi-stage DO cascade control

– Totalizers with digital calibration for valves and pumps

– In-process pH-recalibration

– Trend display with up to 6 process values

– Up to 2 direct balance connections

Exclusive Flow Gassing System

– Sparger and Overlay gas outlet

– Gas mixing of Air, O_2, N_2, CO_2 for Sparger gassing

– Air for Overlay gassing

– Easily exchangeable rotameters

– Controlled via pH│DO controller

– Optional mass flow controllers for both total Sparger and Overlay flow

Pumps

– Up to 4 integrated pumps per side

– Configurable to substrate controller

– Up to 2 external feed pumps per side

– Optional integrated speed controlled pump

Temperature System

– Heating blanket

– Integrated controlled cooling water valve

– Temperature range up to 60°C

– Optional cooling finger

– Jacketed Vessels also available

Agitation System

– Speed range from 20 up to 2,000 rpm

– Maintenance-free

– Gear-free for quiet operation

UniVessel® Culture Vessel
Single-wall culture vessel fully equipped with:

– Probes for Temperature, DO, pH, Foam and Level

– Stirrer shaft with single mechanical seal

– 3-blade segment impeller

– Aeration tube with micro Sparger, Overlay aeration fittings, sterile filters and exhaust cooler

– Manual sampler with sampling pipe

– Removable bottle support holder

– Addition bottles with stainless steel head piece and sterile filters

– Inoculation│addition port

– Four-way addition port

– Tubing, O-rings and tool kit

SCADA Software BioPAT® MFCS/DA

– Plug and Play configuration

– Online data acquisition

– Sample Data Management

– Enhanced plotting functions

– Export functions

– Easy-to-use programming interface

The BIOSTAT® Bplus Exclusive Flow Packages are Applicable for:

– Cell culture of insect, mammalian and plant cells

– Culture of microorganisms

– Batch, fed batch and continuous culture

– Perfusion operation (easy to upgrade)

– Small-scale cell mass, protein, MAb & vaccine production

– High-cell density cultures

– Suspension and microcarrier cultures

Key Features

– Single or Twin configuration

– Independent vessel control

– Small footprint

– Automatically controlled gas mixing

– Sparger and Overlay gassing

– Graphical user interface with touch screen operation

– Totalizers with digital calibration for valves and pumps

– One high-performance stirrer motor for all UniVessel® sizes

– Trend display with up to 6 process values

– Direct balance connection

– Pre-configured firmware for system extensions

▷ Specifications

Technical Specifications

Space Requirements	Dimensions
Bench space requirement Single Version 1 L │ 2 L │ 5 L │ 10 L [W × H × D]	560 │ 590 │ 620 × 730 × 565 │ 670 × 820 × 565 [mm]
Bench space requirement Twin Version 1 L │ 2 L │ 5 L │ 10 L [W × H × D]	800 │ 860 │ 920 × 730 × 565 │ 1,040 × 820 × 565 [mm]
Space requirement autoclave × H per culture vessel 1 L │ 2 L │ 5 L │ 10 L	240 × 500* │ 270 × 550* │ 300 × 700* │ 350 × 820* [mm]

Basic Unit	
Housing material	Stainless steel AISI 304
Display	Touch Screen 10.4"
Resolution	800 × 600 dpi
Host communication	Ethernet │ RS422 │ RS232

Measurement Ranges	
Agitation motor speed 1 L │ 2 L │ 5 L │ 10 L	20–2,000 │ 20–2,000 │ 20–1,500 │ 20–800 rpm
Temperature	0–150℃
pH	2–12
pO_2	0–100%
Turbidity (option)	0–6 AU
Redox (optional)	–1,000 – 1,000 mV

Gassing System	Exclusive Flow 4-gas mixing with Sparger and Overlay outlet
Outlet design	Hose tube OD 6 mm

Flowmeter	Air calibrated @ 1.21 bara 20℃
Gas flow range "Sparger" 1 L │ 2 L │ 5 L │ 10 L	0.016–0.166 │ 0.016–0.166 │ 0.05–0.5 │ 0.1–1.0 [l/min]
Gas flow range "Overlay" 1 L │ 2 L │ 5 L │ 10 L	0.016–0.166 │ 0.16–1.6 │ 0.42–4.2 │ 0.83–8.3 [l/min]
Accuracy	+/– 5% FS

Thermal Mass Flow Controller (Option)	Air calibrated
Flow range "Sparger" Total Flow	0.02–1 slpm
Flow range "Overlay"	0.2–10 slpm
Accuracy	+/– 1% FS

Agitation Motor	Maintenance and gear-free servo drive
Performance	200 W

* Optional flexible adapter for the exhaust cooler (BB-8844593) is available to reduce autoclave height requirements.

Integrated Pumps	Digital pulse-width modulated controlled
Pump head	Watson Marlow 102R
Rotation speed	20 rpm
Flow rate integrated pumps	0.04 – 33.2 [ml/min]

Integrated Feed Pump (Option)	Speed controlled
Pump head	Watson Marlow 102R
Rotation speed	5–50 rpm
Flow rate integrated speed controlled pumps	1–83 [ml/min]

Temperature Control System	Dry heating system via heating blanket and automatic cooling water control valve
Temperature control range	8°C above cooling water to 60°C
Heating blanket performance 1 L │ 2 L │ 5 L │ 10 L	100 │ 170 │ 400 │ 780 [W] │ culture vessel
Connections to culture vessel	Quick couplings for exhaust cooler and optional cooling finger

External Connections │ per Vessel

Balance connection	RS232
2 × Feed pump connection	0–10 V
2 × External input	0–10 V

Culture Vessel	1 L	2 L	5 L	10 L
Total volume	1.6	3	6.6	13 [L]
Working volume	0.4–1	0.6–2	0.6–5	1.5 │ 5–10 [L]
Headplate ports 19 mm │ 12 mm │ 6 mm	3 │ 2 │ 6	3 │ 2 │ 9	3 │ 3 │ 8	5 │ 2 │ 9
Volume storage bottles	250	250	500	500 [mL]
Design	Single wall glass vessel with stainless steel head and vertical lifting handles			
pO$_2$ electrode	Polarographic			
pH electrode	Gel-filled			
Temperature probe	Pt 100			
Redox electrode (option)	Gel-filled			
Turbidity probe (option)	Single Channel NIR Absorption Probe, OPL 20 mm			
Material (product wetted parts)	Borosilicate glass │ Stainless steel AISI 316L │ EPDM			

Utilities Requirements │ Housing Connection

Power supply	120 VAC or 230 VAC
Gasses	Controlled @ 1.5 barg dry, particle and oil-free │ hose connector OD 6 mm
Water	Controlled @ 2 barg │ hose connector OD 10 mm
Drain	Gravity drain with zero backpressure required │ hose connector OD 10 mm

Ordering Information

Description	BIOSTAT® Bplus–CC Exclusive Flow with Single Wall UniVessel®				BIOSTAT® Bplus–TWIN Exclusive Flow with 2 × Single Wall UniVessel®			
	1 L	2 L	5 L	10 | 1.5 L 10 | 5 L	1 L	2 L	5 L	10 | 1.5 L 10 | 5 L
Cat. No. 120 VAC	BB-8843721	BB-8843723	BB-8843725	BB-8843729, BB-8843727	BB-8843783	BB-8843785	BB-8843787	BB-8843791, BB-8843789
Cat. No. 230 VAC	BB-8843720	BB-8843722	BB-8843724	BB-8843728, BB-8843726	BB-8843782	BB-8843784	BB-8843786	BB-8843790, BB-8843788

Basic Unit

Digital controller color display with touch screen	•				•			
Control capabilities listing per vessel								
Temperature, pH, DO (2 stage cascade), Stirrer speed	•				•			
Level and Foam via probe	•				Combined Level | Foam controller			
Level via balance	•				•			
Substrate A and Substrate B	•				•			
200-watt servo motor	•				•			
Gasmixing	Exclusive Flow							
Rotameter Sparger	•				•			
Rotameter for Overlay	• Air				• Air			
Automatic gasmixing of Air, O_2, N_2, CO_2; Sparger	•				•			
Peristaltic pumps (integrated)	4				3 per side			
Temperature system with heating blanket	•				•			

Supervisory Process Control Software

BioPAT® MFCS/DA for data storage	•				•			

Culture Vessel Listing per Vessel — Single Wall UniVessel®

Culture vessel tripod	•				•			
Stirrer shaft with Single Mechanical Seal	•				•			
3-blade segment impeller	1				1			
Storage bottle	3	3	3	3	3	3	3	3
Aeration tube with µ-sparger	•				•			
Air Inlet and Exhaust filter	3				3			
Inoculation port	•				•			
Exhaust Cooler	•				•			
4-Way addition fitting	•				•			
Universal Adaptor 3.2 mm for overlay aeration	•				•			
Sample- | Harvest pipe	•				•			
Manual sampler	•				•			
pH Electrode, cable	•				•			
DO Electrode, cable	•				•			
Level sensor, cable	•				•			
Foam sensor, cable	•				•			
Temperature sensor Pt 100	•				•			
Tubing, O-Ring spare set	•				•			

Options

Magnetic coupling	○ BB-8847339				○ BB-8847339			
Cooling finger	○ BB-8846456	BB-8847819	BB-8847827	BB-8847835	○ BB-8846456	BB-8847819	BB-8847827	BB-8847835
MFC (Sparger total flow)	○ 0.02–1 [l/min] BB-8847754				○ 0.02–1 [l/min] BB-8847754			
MFC (Overlay flow)	○ 0.2–10 [l/min] BB-8847789				○ 0.2–10 [l/min] BB-8847789			
Feed pump (integrated) speed controlled	–				○ BB-8843468			
Balance for culture vessel	○ BB-8843513				○ BB-8843513			
Turbidity measurement	○ BB-8843510	BB-8843511	BB-8843512	BB-8843512	on request			
Redox measurement	○ BB-8843469	BB-8843470	BB-8803471	BB-8843471	on request			

Broad range of accessories available, please contact us for further information.

• = included, — = not included, — — = unavailable, ○ = option

▶ BIOSTAT® B-DCU II

The BIOSTAT® B-DCU II is a new generation of a well proven fermentor | bioreactor system, designed for meeting demanding require-ments in both research and process develop-ment. Unrivalled for scale-down and scale-up modelling of various culture processes, the BIOSTAT® B-DCU II provides a new level of power and flexibility.

Features

– Independent process control for up to 6 culture vessels

– Superior gas mixing with up to 6 Rotameter and Mass Flow Controller

– Up to six integrated peristaltic pumps with choices for fixed and analogue speed pumps

– Validation support available, inclusive Logbook and 3-Level password protection

The BIOSTAT® B-DCU II is available for both microbial as well as cell culture applications.

Control Tower

The BioPAT® DCU control system belongs to the most proven and advanced bioprocess controllers ever developed. Utilizing proven technology and expert engineering, our existing in-house systems to bring powerful control capabilities to the sophisticated biotechnology market.

Supply Tower

Gassing Strategies
"O_2–Enrichment" Gassing Strategy
The "O_2-Enrichment" Gassing Strategy provides oxygen enrichment capability via solenoid valve controlled by DO controller.

"Gas Flow Ratio Control" Gassing Strategy
The "Gas Flow Ratio Control" Gassing Strategy provides on-line gas flow measurement and control of Air and O_2 via Mass Flow Con-troller. The gas flows are user adjustable or can be controlled via DO controller.

"Exclusive Flow" Gassing Strategy
The "Exclusive Flow" Gassing Strategy is a automatically controlled 4-gas mixing system providing Overlay and Sparger gassing.

Air is routed to Overlay. Air, O_2 and N_2 is routed to Sparger. CO_2 can be routed to Sparger or Overlay.

"Advanced Additive Flow" Gassing Strategy
The "Advanced Additive Flow" Gassing Strate-gy is an automatically controlled 4-gas mix-ing system providing Overlay and Sparger or Individual gas outlets. Each of the up to 6 gas flow path has its own rotameter and can be upgraded with Mass flow Controller.

Dosing Pumps
Up to 6 industrial proven easy-to-use peristaltic pumps for each culture vessel are infinitely controlled for addition of corrective agents, feeding, as well as culturing volume control. Up to four of the six can be analogue speed controlled pumps. Several pump speed ranges are available for both fixed and speed controlled pumps. Additionally, external pumps for feeding can be easily connected.

Temperature Control
Each culture vessel can be operated and automatically controlled at different temperatures. There are two choices offered. For single wall vessels, there is an electric heating blanket and cooling finger with solenoid valve. Alternatively, an integrated, high-efficiency thermostat system – with recirculation pump combined with jacketed culture vessels – features precise temperature control, even at minimum working volumes.

Agitation System
The high performance Servodrive motor assembly combines low shear, gentle agitation for cell cultures and high speed mixing for microbial high cell density cultivation.

Culture Vessel
Standard UniVessel® culture vessels, developed with over 40 years experience in up-scale and sterile design, are available as single wall or jacketed stirred tank vessels in 0.5, 1, 2, 5 and 10 L working volumes. Each UniVessel® can be supplied with a range of accessories and devices, including flexible couplings to allow the vessels to fit into tight autoclaves.

▷ Specifications

Technical Specification

Space Requirements | Enviromental Conditions:

Space requirement 1-fold	2-fold	3-fold	4-fold	5-fold	6-fold [W × H × D] (without options)	800	1200	1700	2050	2550	3000 × 780 (10 L: 820) × 800 [mm]
Space requirement autoclave ⌀ H (with BB-8844593 flexible adaptor for exhaust cooler) 0.5 L	1 L	2 L	5 L	10 L without tray for storage bottles	170 × 340 (N	A)	240 × 500 (340)	270 × 550 (400)	300 × 700 (510)	350 × 820 (620) [mm]
Ambient temperature	relative humidity (non-condensating)	5 - 40°C	85%
Control Tower	
Housing material	Stainless steel AISI 304
Display	Touch Screen 15"
Resolution	1024 × 768 dpi
Communication Control Tower/Supply Tower	Control Tower/Host	Ethernet	Ethernet
**Measurement Ranges	Resolution**	
Stirrer speed 0.5 L	1 L	2 L	5 L	10 L	tbd	20-2000	20-2000	20-1500	20-800 [rpm]	1 rpm
Temperature	0 – 150°C	0.1°C
pH	2–12	0.01 pH
pO_2	0–250%	1%
Foam and Level	on/off	4 user selecatable sensitivities
Turbidity	0 – 6 AU	0.01 AU
Redox	-2000–2000 mV	1 mV
Pressure	0-1000 mbarg	1 mbar
Gassing System	O_2-Enrichment, Gas Flow Ratio Control, Exclusive Flow, Advanced Additive Flow
Outlet design	Hose tube OD 6 mm
Flowmeter	Air calibrated @ 1.21 bara 20°C
Available gas flow ranges	1.5 – 15 mL/min to 2.3 – 23 L/min
Accuracy	+/- 2% FS
Thermal Mass Flow Controller	Calibrated to specific gas
Available gas flow ranges for Air/N_2, O_2 and CO_2	1.5 – 15 mL/min to 0.4 – 20 L/min
Accuracy	+/- 1% FS
Agitation	Maintenance and gear-free servo drive
Motor performance torque 0.5 L	1 L, 2 L, 5 L, 10 L	10 L	75/0.28	200/1.03	400/1.32 [W]/[Nm]
Integrated Pumps	on	off controlled, pulse-width modulated controlled
Pump head	Watson Marlow 102R, for tubing with 1.6 mm wall thickness
Rotation speed	2	20 [rpm]
Flow rate tube dependent (bore × wall tubing) 1.6 × 1.6/3.2 × 1.6 [mm]	0.04-0.44/0.16-1.62	0.4-4.4/1.6-16.2 [ml/min]
Integrated Feed Pump	Speed-controlled
Pump head	Watson Marlow 102R, for tubing with 1.6 mm wall thickness
Rotation speed	1–10	5–50 [rpm]
Flow rate tube dependent (bore × wall tubing) 1.6 × 1.6/3.2 × 1.6 [mm]	0.2 – 2/0.8 – 8	1.1–11/4 – 40 [ml/min]

Temperature Control System for Jacketed Culture Vessel	Connector for heating blanket and soleniod valve for cooling water
Temperature control range	8°C above cooling water to 80°C
Electrical heater	1000 W
Connections to culture vessel	exhaust cooler	Quick couplings	Quick couplings
Temperature Control for Single Wall Culture Vessel	Thermostat system with recirculation pump and soleniod valve for cooling water
Temperature control range	8°C above cooling water to 60°C
Haeting power of heating blankets 0.5 L	1 L	2 L	5 L	10 L	–	100	170	400	780 [W]
Connector heating blankets	Amphenol eco|mate 6-pol +PE

External Connections

Balance standard	option/interface/connector	2	4/RS232/M12
CO$_2$ exhaust analyzer interface/connector	1/RS232/M12
Feed pump connection qty./interface/connector	2/0-10 V/M12
External inputs qty./interface/connector	2/0-10 V/M12

Culture Vessel	**0.5 L**	**1 L**	**2 L**	**5 L**	**10 L**
Design	Single wall or jacketed glass vessel with stainless steel head pleate (0.5 L vessel jacketed only)				
Total volume	0.75	1.6	3	6.6	13 [L]
Working volume	0.15-0.5	0.4 -1	0.6-2	0.6-5	1.5-10 [L]
Headplate ports 19 mm	12 mm	6 mm	–	6	4	3	2	6	3	2	9	3	3	8	7	2	9
Volume storage bottles	250	250	250	500	500 [mL]

Sensors

pO$_2$ sensor	connector	Polarographic or optical	VP
pH sensor	connector	Gel-filled	VP
Temperature sensor	connector	Pt100 with pocket	M12
pH/Redox sensor	connector	Gel-filled	VP
Turbidity sensor	connector	Single Channel NIR Absorption Probe	Fischer 104
Pressure transmitter	connector	Piezoresistive	M12
Foam sensor	connector	Conductive	Clip
Level sensor	connector	Conductive	Clip
Material (product wetted parts)	Borosilicate glass	Stainless steel AISI 316L	EPDM

Utility Consumption

Power consumption max. DCU Tower	Supply Tower	200	2000 [W]
Water consumtion max. per Supply Tower	5 L/min
Gas consumption per Supply Tower	depending an installed Flow meter or Mass Flow controller

Utility Requirements | Housing Connection

Power supply DCU Tower	Supply Tower	110–230V/6A GFIC:32 mA	120V/15A or 230V/10A GFIC: 32 mA
Gasses	Controlled @ 1.5 barg (22 psig); dry, particle and oil-free	hose connector OD 6 mm
Water	Controlled @ 2–4 barg (29–58 psig)	hose connector OD 10 mm
Drain	Gravity drain with zero backpressure required	hose connector OD 10 mm
Regulatory compliance	CE (build according to UL & CSA requirements)

Ordering Information

Description	BIOSTAT® B–DCU II Individual
Control Unit	
Control Tower	Industrial PC with 15 " touch screen operation
Firmware capability	Overview vessel and single vessel display Trend display Guided calibration routines for sensors and media and gas totalizer Alarm massage display Process values: up to 200 Control loops: up to 128 Calibration routines up to 64 Configuration tool available
Measurement and Control capabilities	Agitation Temperature pH, Dual measurement possible DO (5 stage cascade), Dual measurement possible Foam Level Substrate pump controller Gravimetric Feed Control Culture vessel measurend and control Turbidity measurement Redox measurement Gravimetric Harvest Control Total Gas Flow Control "Sparger" Total Gas Flow Control "Overlay" Other on request
Validation support models	3-level Password Module Logbook Module
Supply Tower	
I │ O Tower components	Up to twelve (12) amplifier Up to 6 Mass flow Controller Up to 6 dosing │ shut off valves Up to 4 on │ off controlled pumps (integrated) Up to 4 speed controlled pumps Up to three (3) auxiliary inputs Up to 4 serial balance│scales connections Agitation motor control unit Up to one (1) pressure vessel controller
Gasmixing (integrated)	O_2-Enrichment │ Gas Flow Ratio Control │ Exclusive Flow │ Advanced Additive Flow 2 or 6 gas outlets
Rotameter	Various flow ranges available from 1.5–15 mL/min to 2.3–23 L/min
Mass Flow Controller	various flow ranges available from 0.15–15 mL/min to 0.4–20 L/min
Drive unit	75 W for 0.5 L UniVessel® 200 W for 1 L–10 L UniVessel® 400 W for 10 L UniVessel®
Peristaltic pumps (integrated)	Watson Marlow 102 pump head 2 rpm or 20 rpm on │ off controlled 1–10 rpm or 5-50 rpm speed controlled
Temperature control system (integrated)	Thermostat system or connector for heating blanket
Culture Vessel	UniVessel® single wall or jacketed vessel
Design	Single wall or jacketed vessel Stainless steel top plate with lifting handles Stainless steel stand (not for 0.5 L UniVessel)
Vessel working volume	0.5 L │ 1 L │ 2 L │ 5 L │ 10 L others on request
Stirrer shaft coupling	Direct coupling or Magnetic coupling
Stirrer shaft sealing	Single mechanical seal or magnetic drive
Impeller	6-blade impeller (ruston) │ 3-blage segment impeller │ Paddle impeller
Storage bottles	250 mL │ 500 mL
Aeration device	ring-sparger │ micro-sparger │ Overlay aeration fitting │ bubble free aeration
Deaeration	Exhaust fitting │ Exhaust cooler
Additions	1-way fiting │ 3-way fitting │ 4-way fitting │ septum ports
Dip tubes	Fixed length │ height adjustable │ Hight adjustable bended
Sampling systems	Bypass sampler │ Manual sampler
Perfusion device	Internal Spinfilter │ External Spinfilter
Sensors for	Pt 100 pH or pH/redox combined DO (Clark or Optical) Vessel pressure Turbidity sensor Foam sensor, 80 mm Level sensor, 150 mm or 300 mm
Supervisory Process Control Software	BioPAT® MFCS/DA or BioPAT® MFCS/win

▶ # BIOSTAT® B-DCU II

Advanced Additive Flow

The BIOSTAT® B-DCU II is the second genera-
tion of a well proven fermentor│bioreactor
system, designed for meeting demanding
requirements in both research and process
development. Unrivalled for scale-down
and scale-up modelling of various culture
processes, the BIOSTAT® B-DCU II provides
a new level of power and flexibility.
The BIOSTAT® B-DCU II Advanced Additive
Flow packages are specially configured for
cell culture. The integrated automatically-
controlled gas mixing system for up to 6 gas
flow path provides Sparger and Overlay or
optional individual gas out lets. Each gas has
its own rotameter for individual flow rate
adjustment.

Control Tower

– Graphical user interface with color display
  and touch screen operation

– Measurement and control for Temperature,
  pH, DO, agitation and Foam

– User configurable 5-stage DO cascade

– Up to 4 feed controller per vessel

– Automatic gas composition controlled
  by pH & pO_2 controller

– Level control via Level probe balance

– Totalizers with digital calibration for
  valves and pumps

– In-process pH-recalibration

– Trend display for up to 8 process values

– Up to 4 balance connections per vessel

– Culture vessel pressure measurement
  and control

Supply Tower

Advanced Additive Flow Gassing System

– Sparger and Overlay or optional individual
  gas out lets

– Gasmixing of Air, O_2, N_2, CO_2 for
  Sparger gassing via solenoid valves

– Air for Overlay gassing

– Additional optional gas flow path

– Optional gas switch Sparger to Overlay

– Up to 6 optional mass flow controller

Pumps

– 3 integrated pumps, expandable up to 6

– Up to 4 feeding pumps

Temperature System

– Powerful heater (1 kW)

– Integrated controlled cooling water valve

– Circulation pump

– Temperature range 8°C above cooling
  water up to 80°C

Agitation System

– Speed range 20 up to 2,000 rpm

– Maintenance free

– Gear-free for quiet operation

Culture Vessel
Jacketed culture vessel fully equipped with:

– Sensors for Temperature, DO, pH and Foam

– Stirrer shaft with single mechanical seal

– 3-blade segment impeller

– Aeration tube with micro Sparger,
  Overlay aeration fitting, sterile filters
  and exhaust cooler

– Manual sampler with sampling pipe

– Removable addition bottle support

– Addition bottles with stainless steel head
  piece and sterile filters

– Inoculation│addition septum port

– Multiple way addition port

– Tube, O-ring and tool kit

SCADA Software MFCS/DA

To accelerate your research activities, a powerful supervisory software MFCS/DA for extended visualization, data acquisition and trend display is included.

– Plug and Play configuration

– Batch-oriented software package

– Online data acquisition

– Sample Data Management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

Features

– Powerful industry rated BioPAT® DCU control system with 15" TFT color touch screen

– Independent process control for up to six culture vessels

– UniVessel® from 0.5 L to 10 L working volume

– Up to six integrated peristaltic pumps with choices for fixed and analogue speed pumps

– Choice of polarographic or optical pO_2-sensors

– Superior gas mixing with up to 6 Rotameter and Mass Flow Controller

– Culture vessel pressure control

– Easy on-site Supply Tower | Culture vessel upgrade

– Improved connectivity of utilities and probes

– Easy upgrade of cell culture packages for multi-purpose use

– Inclusive Supervisory Process control software

– Validation support available, inclusive Logbook and 3-Level password protection

▷ Specifications

Technical Specification

Space Requirements | Enviromental Conditions:

Space requirement 1-fold | 2-fold | 3-fold | 4-fold | 5-fold | 6-fold [W × H × D] (without options)	800 | 1200 | 1700 | 2050 | 2550 | 3000 × 780 (10L: 820) × 800 [mm]
Space requirement autoclave ∅ H (with BB-8844593 flexible adaptor for exhaust cooler) 0.5 L | 1 L | 2 L | 5 L | 10 L without tray for storage bottles	170 × 340 (N/A) | 240 × 500 (340) | 270 × 550 (400) | 300 × 700 (510) | 350 × 820 (620) [mm]
Ambient temperature | relative humidity (non-condensating)	5–40°C | 85%

Control Tower

Housing material	Stainless steel AISI 304
Display	Touch Screen 15"
Resolution	1024 × 768 dpi
Communication Control Tower/Supply Tower | Control Tower/Host	Ethernet | Ethernet

Measurement Ranges | Resolution

Stirrer speed 0.5 L | 1 L | 2 L | 5 L | 10 L	tbd | 20–2000 | 20–2000 | 20–1500 | 20–800 [rpm] | 1 rpm
Temperature	0–150°C | 0.1°C
pH	2–12 | 0.01 pH
pO_2	0–250% | 1%
Foam and Level	on/off | 4 user selecatable sensitivities
Turbidity (option)	0-6 AU | 0.01 AU
Redox (option)	-2000–2000 mV | 1 mV
Pressure (option)	0 - 1000 mbarg | 1 mbar

Gassing System „Advanced Additive Flow" with up to 6 Gas Flow Paths	4-gas mixing system with Spager and Overlay gas outlets
Outlet design	Hose tube OD 6 mm

Flowmeter — Air calibrated @ 1.21 bara 20°C

	0.5 L	1 L	2 L	5 L	10 L
Gas flow range „Sparger" for Air & N_2	0.53-53	0.53-53	13-133	13-133	26-266 [mL/min]
Gas flow range „Sparger" for O_2 & CO_2	1.5-15	1.5-15	3.3-33	3.3-33	13-133 [mL/min]
Gas flow range „Overlay" for Air [L/min]	0.11-1.05	0.11-1.05	0.16-1.6	0.42-4.2	1.3-13
Additional gas flow path to „Sparge" or „Overlay"	Various flow ranges available from 1.5–15 mL/min to 2.3–23 L/min				
Accuracy	+/– 2% FS				

Thermal Mass Flow Controller (Option) — Calibrated to specific gas

	0.5 L	1 L	2 L	5 L	10 L
Gas flow range „Sparger" for Air & N_2	0.5-50	0.5-50	3-150	3-150	6-300 [mL/min]
Gas flow range „Sparger" for O_2 & CO_2	0.15-15	0.15-15	0.6-30	0.6-30	3-150 [mL/min]
Gas flow range „Overlay" for Air	0.02-1.0	0.02-1.0	0.03-1.5	0.1-5	0.2-10 [L/min]
Additional gas flow path to „Sparge" or „Overlay"	Various flow ranges available from 1.5–15 mL/min to 0.4–20 L/min				
Accuracy	+/– 1% FS				

Agitation	Maintenance and gear-free servo drive
Motor performance torque 0.5 L | 1 L, 2 L, 5 L, 10 L	75/0.28 | 200/1.03 [W]/[Nm]
Integrated Pumps	on | off, pulse-width modulated controlled
Pump head	Watson Marlow 102R, for tubing with 1.6 mm wall thickness
Rotation speed speed	20 rpm
Flow rate tube dependent (bore × wall tubing) 1.6 × 1.6/3.2 × 1.6 [mm]	0.4-4.4 | 1.6-16.2 [ml/min]
Integrated Feed Pump (Option)	Speed-controlled
Pump head	Watson Marlow 102R, for tubing with 1.6 mm wall thickness
Rotation speed speed	1-10 | 5-50 [rpm]
Flow rate tube dependent (bore × wall tubing) 1.6 × 1.6/3.2 × 1.6 [mm] 0.2–2/0.8-8 | 1.1–11/4–40 [ml/min]	
Temperature Control System	Thermostat system with recirculation pump and soleniod valve for cooling water
Temperature control range	8°C above cooling water to 80°C
Electrical heater	1000 W
Connections to culture vessel | Exhaust cooler	Quick couplings | Quick couplings
External Connections	
Balance standard | option/interface/connector	2 | 4/RS232/M12
CO_2 exhaust analyzer interface/connector	1/RS232/M12
Feed pump connection qty./interface/connector	2/0–10 V/M12
External inputs qty./interface/connector	2/0-10 V/M12

Culture Vessel	**0.5 L**	**1 L**	**2 L**	**5 L**	**10 L**
Design	Jacketed glass vessel with stainless steel head pleate				
Total volume	0.75	1.6	3	6.6	13 [L]
Working volume	0.15-0.5	0.4 -1	0.6-2	0.6-5	1.5-10 [L]
Headplate ports 19 mm | 12 mm | 6 mm	– | 6 | 4	3 | 2 | 6	3 | 2 | 9	3 | 3 | 8	7 | 2 | 9
Volume storage bottles	250	250	250	500	500 [mL]
pO_2 sensor | connector	Polarographic or optical (option) | VP				
pH sensor | connector	Gel-filled | VP				
Temperature sensor | connector	Pt100 with pocket | M12				
pH | Redox sensor (option)	Gel-filled | VP				
Turbidity sensor (option)	Single Channel NIR Absorption Probe				
Pressure transmitter (option)	Piezoresistive | M12				
Material (product wetted parts)	Borosilicate glass | Stainless steel AISI 316L | EPDM				

Utility Consumption	
Power consumption max. DCU Tower | Supply Tower	200 | 2000 [W]
Water consumtion max. per Power Supply	5 L/min
Gas consumption max. per Power Supply 0.5 L | 1 L | 2 L | 5 L | 10 L	1 | 1.6 | 4.2 | 13 | 20 [L/min]
Utility Requirements | Housing Connection	
Power supply DCU Tower | Supply Tower	110 – 230 V/6 A GFIC: 32 mA | 120 V/15 A or 230 V/10 A GFIC: 32 mA
Gasses	Controlled @ 1.5 barg (22 psig); dry, particle and oil-free | hose connector OD 6 mm
Water	Controlled @ 2 – 4 barg (29 – 58 psig) | hose connector OD 10 mm
Drain	Gravity drain with zero backpressure required | hose connector OD 10 mm
Regulatory compliance	CE (build according to UL & CSA requirements)

Ordering Information

Description	BIOSTAT® B–DCU II Advanced Additive Flow				
Culture vessel working volume	0.5 L	1 L	2 L	5 L	10 L
Cat. No. 120 VAC					
BIOSTAT® B–DCU II Single	RBD1C5DLATSDG1	RBD1C01LATSDG1	RBD1C02LATSDG1	RBD1C05LATSDG1	RBD1C1ALATSDG1
BIOSTAT® B–DCU II Upgrade Kit (Vessel + Supply Tower)	RBD1C5DLATSDG1E	RBD1C01LATSDG1E	RBD1C02LATSDG1E	RBD1C05LATSDG1E	RBD1C1ALATSDG1E
Cat. No. 230 VAC					
BIOSTAT® B–DCU II Single	RBD1C5DLATSDG2	RBD1C01LATSDG2	RBD1C02LATSDG2	RBD1C05LATSDG2	RBD1C1ALATSDG2
BIOSTAT® B–DCU II Upgrade Kit (Vessel + Supply Tower)	RBD1C5DLATSDG2E	RBD1C01LATSDG2E	RBD1C02LATSDG2E	RBD1C05LATSDG2E	RBD1C1ALOTSDG2E
Control Unit					
Control Tower 15'' color display with touch screen operation	•				
Automatic pH and pO_2 calibration routine Single probe and group calibration	•				
Control Capabilities per Vessel					
Temperature, pH, DO (5-stage cascade), Stirrer speed, Foam, Substrate	•				
Vessel Pressure measurement | control	○ | ○				
Turbidity measurement	○				
Gravimetric Feed Control	○				
Gravimetric Harvest Control	○				
Extended Password Module	○				
Logbook Module	○				
Supply Tower					
Gas mixing (integrated)	Advanced Additive Flow				
Gas outlets Sparger & Overlay | Individual	• | ○				
Rotameter Sparger	• Air, O_2, N_2, CO_2				
Rotameter Overlay | Additional gas	• Air | ○ O_2 or CO_2 or N_2				
Solenoid valves for gas mixing of Air, O_2, N_2, CO_2	•				
Gas switch Sparger to Overlay	○				
Mass Flow Controller	○ (up to 6)				
Stirrer Motor	•				
Peristaltic Pumps (integrated)	3				
Feed Pumps speed controlled (integrated | external)	○ (up to 3) | ○ (up to 2)				
Thermostat system (integrated) Jacketed vessel | Single wall vessel	• | ○				
Supervisory Process Control Software					
MFCS/DA for data storage	•				
Culture Vessel	UniVessel®				
Jacketed vessel | Single wall vessel	• | –	• | ○	• | ○	• | ○	• | ○
Stirrer shaft with Single Mechanical Seal Direct coupling | Magnetic coupling	• | –	• | ○	• | ○	• | ○	• | ○
Magnetic drive	–	–	○	○	○
3-blade segment impeller	1				
Storage bottles	3	3	3	3	3
Air Inlet and Exhaust filter	3				
Aeration tube with µ-Sparger | Overlay port	•				
Inoculation | Addition port	•				
Exhaust Cooler	•				
Addition fitting	2 × 3-way	4-way	4-way	4-way	4-way
Sample- | Harvest pipe	•				
Manual sampler	•				
Tray for storage bottles	–	•	•	•	•
pH Electrode, cable	•				
DO Electrode , cable, Clark principle | Optical	○ | •				
Foam sensor, cable	•				
Level sensor, cable	○				
Temperature sensor Pt 100	•				
Turbidity sensor	○				
Exhaust CO2 sensor	○				
Pressure sensor | control	○ | ○				
Tubing, O-Ring (spare set)	•				

Broad range of accessories available; Configurable and customizable solutions are available outside of this package. Please contact us for further information.

• = standard, ○ = option, – = not available

▶ # BIOSTAT® B-DCU II

O$_2$ Enrichment

The BIOSTAT® B-DCU II is the second genera-tion of a well proven fermentor | bioreactor system, designed for meeting demanding requirements in both research and process development. Unrivaled for scale-down and scale-up modeling of various culture processes, the BIOSTAT® B-DCU II provides a new level of power and flexibility. The BIOSTAT® B-DCI II with integrated O$_2$-Enrichment gassing capability enables high oxygen transfer for high cell density cultures as well as for sheer-stress sensitive gassing for filamentous organisms. Furthermore, it may help to solve foaming problems due to reduced gassing rates.

Control Tower

– Intuitive touch screen operation

– Industrial controller hardware

– Controller for Agitation, Temperature, pH, pO$_2$, Foam

– Turbidity, Redox or culture vessel pressure measurement and control

– Automatic gas composition controlled by pO$_2$-controller

– User configurable 5-stage pO$_2$ cascade control via agitation speed, O$_2$-Enrichment with optional MFC's and substrate feeding

– Up to 4 feed controller per vessel

– Controller status indication

– Gas and pump totalizers

– Automatic single and group sensor calibration

– In-process pH-recalibration

– Trend display for up to 8 process values

– Up to 4 balance connections

Supply Tower

"O$_2$–Enrichment" Gassing System

– Gas mixing of Air and O$_2$

– O$_2$-Enrichment capability controlled via DO controller

– Optional mass flow controller for Total Sparger flow or for Air and O$_2$

Pumps

– 3 integrated pumps, expandable up to 6

– Up to 4 feeding pumps

Temperature System

– Powerful heater (1 kW)

– Integrated controlled cooling water valve

– Circulation pump

– Temperature range 8°C above cooling water up to 80°C

Agitation System

– Speed range 20 up to 2,000 rpm

– Maintenance free

– High torque for power full mixing

– Gear-free for quiet operation

Culture Vessel
Jacketed culture vessel fully equipped with:

– Sensors for Temperature, DO, pH and Foam

– Stirrer shaft with single mechanical seal

– Rushton impeller

– Baffle assembly (not for 0.5 L vessel)

– Aeration tube with ring Sparger, sterile filters and exhaust cooler

– Manual sampler with sampling pipe

– Removable addition bottle support (not for 0.5 L vessel)

– Addition bottles with stainless steel head piece and sterile filters

– Inoculation | addition septum port

– Multiple way addition port

– Tube, O-ring and tool kit

SCADA Software MFCS/DA

To accelerate your research activities, a powerful supervisory software MFCS/DA for extended visualization, data acquisition and trend display is included.

– Plug and Play configuration

– Batch-oriented software package

– Online data acquisition

– Sample Data Management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

Features

– Powerful industry rated DCU-4 control system with 15" TFT color touchscreen

– Independent process control for up to six culture vessels

– UniVessel® from 0.5 L to 10 L working volume

– Up to six integrated peristaltic pumps with choices for fixed and analogue speed pumps

– Choice of polarographic or optical pO_2-sensors

– Superior gas mixing with up to 2 Rotameter and Mass Flow Controller

– Culture vessel pressure control

– Easy on-site Supply Tower | Culture vessel upgrade

– Improved connectivity of utilities and probes

– Inclusive Supervisory Process control software

– Validation support available, inclusive Logbook and 3-Level password protection

▷ Specifications

Technical Specification

Space Requirements | Enviromental Conditions

Space requirement 1-fold	2-fold	3-fold	4-fold	5-fold	6-fold [W × H × D] (without options)	800	1200	1700	2050	2550	3000 × 780 (10L: 820) × 800 [mm]
Space requirement autoclave ∅ H (with BB-8844593 flexible adaptor for exhaust cooler) 0.5 L	1 L	2 L	5 L	10 L without tray for storage bottles	170 × 340 (N/A)	240 × 500 (340)	270 × 550 (400)	300 × 700 (510)	350 × 820 (620) [mm]
Ambient temperature	relative humidity (non-condensating)	5–40°C	85%

Control Tower

Housing material	Stainless steel AISI 304
Display	Touch Screen 15"
Resolution	1024 × 768 dpi
Communication Control Tower/Supply Tower	Control Tower/Host	Ethernet	Ethernet

Measurement Ranges | Resolution

Stirrer speed 0.5 L	1 L	2 L	5 L	10 L (200 W)	10 L (400 W)	tbd	20–2000	20–2000	20–1500	20–800	20–1200 [rpm]	1 rpm
Temperature	0-150°C	0.1°C
pH	2–12	0.01 pH
pO_2	0–250%	1%
Foam and Level	on/off	4 user selecatable sensitivities
Turbidity (option)	0–6 AU	0.01 AU
Redox (option)	–2000–2000 mV	1 mV
Pressure (option)	0 - 1000 mbarg	1 mbar

Gassing System „O_2–Enrichment" — Air aeration with O_2 supplementation

Outlet design	Hose tube OD 6 mm

Flowmeter — Air calibrated @ 1.21 bara 20°C

Gas flow range „Sparger" 0.5 L	1 L	2 L	5 L	10 L	0.11–1.05	0.16–1.6	0.42–4.2	1.3–13	2–20 [l/min]
Accuracy	+/– 2% FS

Thermal Mass Flow Controller (Option) — Air calibrated

Flow range „Sparger" Total Flow 1 L	2 L	5 L	10 L	0.02–1.0	0.06–3	0.06–3	0.2–10	0.4–20 [slpm]
Accuracy	+/– 1% FS

Agitation — Maintenance and gear-free Servo drive

Motor performance torque 0.5 L	1 L, 2 L, 5 L, 10 L	10 L	75/0.28	200/1.03	400/1.32 option [W]/[Nm]
Maximum impeller tip speed 0.5 L	1 L	2 L	5 L	10 L (200 W)	10 L (400 W)	tbd	4.7	5.6	5.0	3.1	4.7 [m/s]

Integrated Pumps — on | off controlled, pulse-width modulated controlled

Pump head	Watson Marlow 102R, for tubing with 1.6 mm wall thickness
Rotation speed	20 rpm
Flow rate tube dependent (bore × wall tubing) 1.6 × 1.6	3.2 × 1.6 [mm]	0.4-4.4	1.6-16.2 [ml/min]

Integrated Feed Pump (Option)	Speed controlled				
Pump head	Watson Marlow 102R, for tubing with 1.6 mm wall thickness				
Rotation speed	1-10 │ 5-50 [rpm]				
Flow rate tube dependent (bore × wall tubing) 1.6 × 1.6 │ 3.2 × 1.6 [mm]	0.2–2/0.8-8 │ 1.1–11/4–40 [ml/min]				
Temperature Control System	Thermostat system with recirculation pump and soleniod valve for cooling water				
Temperature control range	8°C above cooling water to 80°C				
Electrical heater	1000 W				
Connections to culture vessel │ Exhaust cooler	Quick couplings │ Quick couplings				
External Connections					
Balance standard │ option/interface/connector	2 │ 4/RS232/M12				
CO$_2$ exhaust analyzer interface/connector	1/RS232/M12				
Feed pump connection qty./interface/connector	2/0–10 V/M12				
External inputs qty./interface/connector	2/0–10 V/M12				
Culture Vessel	**0.5 L**	**1 L**	**2 L**	**5 L**	**10 L**
Design	Jacketed glass vessel with stainless steel head pleate				
Total volume	0.75	1.6	3	6.6	13 [L]
Working volume	0.15–0.5	0.4–1	0.6–2	0.6–5	1.5–10 [L]
Headpleate ports 19 mm │ 12 mm │ 6 mm	– │ 6 │ 4	3 │ 2 │ 6	3 │ 2 │ 9	3 │ 3 │ 8	7 │ 2 │ 9
Volume storage bottles	250	250	250	500	500 [mL]
pO$_2$ sensor │ connector	Polarographic or optical (option) │ VP				
pH sensor │ connector	Gel-filled │ VP				
Temperature sensor │ connector	Pt100 with pocket │ M12				
pH │ Redox sensor (option)	Gel-filled │ VP				
Turbidity sensor (option)	Single Channel NIR Absorption Probe				
Pressure transmitter (option)	Piezoresistive │ M12				
Material (product-wetted parts)	Borosilicate glass │ Stainless steel AISI 316L │ EPDM				
Utility Consumption					
Power consumption max. DCU Tower │ Supply Tower	200 │ 2000 [W]				
Water consumption max. per Supply Tower	5 L/min				
Gas consumption max. per Supply Tower 0.5 L │ 1 L │ 2 L │ 5 L │ 10 L	1 │ 1.6 │ 4.2 │ 13 │ 20 [L/min]				
Utility Requirements │ Housing Connection					
Power supply DCU Tower │ Supply Tower	110–230 V/6 A GFIC: 32 mA │ 120 V/15 A or 230 V/10 A GFIC: 32 mA				
Gasses	Controlled @ 1.5 barg (22 psig); dry, particle and oil-free │ hose connector OD 6 mm				
Water	Controlled @ 2–4 barg (29–58 psig) │ hose connector OD 10 mm				
Drain	Gravity drain with zero backpressure required │ hose connector OD 10 mm				
Regulatory compliance	CE (build according to UL&CSA requirements)				

Ordering Information

Description	BIOSTAT® B–DCU II O$_2$ Enrichment				
Culture vessel working volume	0.5 L	1 L	2 L	5 L	10 L
Cat. No. 120 VAC					
BIOSTAT® B–DCU II Single	RBD1M5DLOTRDG1	RBD1M01LOTRDG1	RBD1M02LOTRDG1	RBD1M05LOTRDG1	RBD1M1ALOTRDG1
BIOSTAT® B–DCU II Upgrade Kit (Vessel + Supply Tower)	RBD1M5DLOTRDG1E	RBD1M01LOTRDG1E	RBD1M02LOTRDG1E	RBD1M05LOTRDG1E	RBD1M1ALOTRDG1E
Cat. No. 230 VAC					
BIOSTAT® B–DCU II Single	RBD1M5DLOTRDG2	RBD1M01LOTRDG2	RBD1M02LOTRDG2	RBD1M05LOTRDG2	RBD1M1ALOTRDG2
BIOSTAT® B–DCU II Upgrade Kit (Vessel + Supply Tower)	RBD1M5DLOTRDG2E	RBD1M01LOTRDG2E	RBD1M02LOTRDG2E	RBD1M05LOTRDG2E	RBD1M1ALOTRDG2E
Control Unit					
Control Tower 15'' color display with touch screen operation	•				
Automatic pH and pO$_2$ calibration routine Single probe and group calibration	•				
Control Capabilities per Vessel					
Temperature, pH, DO (5-stage cascade), Stirrer speed; Foam, Level, Substrate	•				
Vessel Pressure measurement│control	○│○				
Turbidity measurement	○				
Redox measurement	○				
Gravimetric Feed Control	○				
Gravimetric Harvest Control	○				
Extended Password Module	○				
Logbook Module	○				
Supply Tower					
Gas mixing (integrated)	O$_2$-Enrichment				
Rotameter for Sparger [l/min]	•				
Solenoid Valve for O$_2$-Enrichment	•				
Mass Flow Controller Total Sparger Flow│Air and O$_2$	○│○				
Stirrer Motor	•				
Peristaltic Pumps (integrated)	3				
Feed Pumps speed controlled (integrated│external)	○ (up to 3)│○ (up to 2)				
Thermostat system (integrated)	•				
Supervisory Process Control Software					
MFCS/DA for data storage	•				
Culture Vessel	Jacketed UniVessel®				
Stirrer shaft with Single Mechanical Seal	•				
6-blade disk impeller	2	2	2	2	3
Baffles	–	•	•	•	•
Storage bottles	3	3	3	3	3
Air Inlet and Exhaust filter	2				
Aeration tube with Ring Sparger	•				
Inoculation│Addition port	•				
Exhaust Cooler	•				
Addition fitting	2 × 3-way	4-way	4-way	4-way	4-way
Sample-│Harvest pipe	•				
Manual sampler	•				
Tray for storage bottles	–	•	•	•	•
pH Electrode, cable	•				
DO Electrode, cable, Clark principle│Optical	○│•				
Foam sensor, cable	•				
Level sensor, cable	○				
Temperature sensor Pt 100	•				
Turbidity sensor	○				
pH│Redox sensor	○				
Pressure sensor│control	○│○				
Exhaust CO$_2$	○				
Tubing, O-Ring (spare set)	•				
Foam Disc (mechanical foam destroyer)	–	○	○	○	○

Broad range of accessories available; Configurable and customizable solutions are available outside of this package. Please contact us for further information.

• = standard, ○ = option, – = not available

▶ BIOSTAT® Qplus

12-fold Screening Fermentor│Bioreactor

System Description
The BIOSTAT® Qplus is a new generation of fermentor│bioreactor systems designed for parallel operation with high throughput capability.

The combination of a newly engineered control system launches small scale cultivation vessels into a new era of biotechnology screening. The BIOSTAT® Qplus has the capability to control fully independently up to twelve culture vessels with minimal manual operation.

Application-driven configured packages for microbial and cell culture provide everything to get started immediately. The BIOSTAT® Qplus is available with scaleable culture vessel working volumes of 0.5 L and 1 L.

The BIOSTAT® Qplus is delivered with a completely configured software package. A 3-fold, 6-fold, 9-fold system can be easily extended with a 3-fold vessel│supply tower extension kit up to a 12-fold system without expensive software extensions.

For further enhancement of system performance, a powerful supervisory process control software MFCS/DA for extended visualization, data acquisition and trend display is included.

The BIOSTAT® Qplus is Ideal for:

– Process development

– Process optimization

– Up- and Down-scale experiments

– Strain and Cell line characterization

– Quality control

– Parallel production process control

Applications

– Growth studies of microbial, mammalian, insect and plant cells

– Culture media composition and optimization

– Upscale migration, i. e. transition from shaking flasks

– Downscale of production process for process optimization

– Small scale protein and Mab expression

– High cell density cultivation

Features

– Space saving tower design

– Graphical user interface with touch screen operation

– Fully independent vessel control

– Integrated thermostat system

– Integrated gassing system with O2 supplementation for microbial packages

– Integrated 4-gas mixing system with Sparger and Overlay aeration for cell culture packages

– Top drive agitation system with maintenance-free motor

– Pre-configured software for up to 12-fold operation

– Control of pH, DO, temperature, foam | level, substrate addition, gas mixing and gas flow rate

– Scaleable vessel design

– Optional Turbidity or Redox measurement

– Easy upgrade of cell culture packages for multipurpose use

– Inclusive Supervisory Process control software

▷ Specifications

Technical Specification

Space Requirements | Environmental Conditions	Dimensions
Bench space requirement | weight | 0.5 L culture vessel 3-fold | 6-fold | 9-fold | 12-fold [W × H × D]	850 | 1320 | 1860 | 2400 × 900 × 750 [mm] | 95 | 155 | 216 | 278 [kg]
Bench space requirement | weight | 1 L culture vessel 3-fold | 6-fold | 9-fold | 12-fold [W × H × D]	1100 | 1800 | 2550 | 3300 × 900 × 800 [mm] | 114 | 194 | 274 | 355 [kg]
Space requirement autoclave ∅ × H 0.5 L per culture vessel | 3-fold vessel assembly with tray	170 × 340 | 480 × 340 [mm]
Space requirement autoclave ∅ × H 1 L per culture vessel | 3-fold vessel assembly	240 × 500 | 460 × 500 [mm]
Ambient temperature | relative humidity (non condensating)	5–40℃ | 85%

Control Tower

Housing material	Stainless steel AISI 304
Display	Touch Screen 15"
Resolution	1024 × 600 dpi
Communication Control Tower | Supply Tower | Host	Ethernet | Ethernet

Measurement Ranges

Agitation motor speed	50 – 1200 rpm
Temperature	0 – 150℃
pH	2 – 12
pO2	0 – 100%
Turbidity (optional)	0 – 6 AU
Redox (optional)	–1000 – 1000 mV

Supply Tower	Microbial Version	Cell Culture Version
Housing material	Stainless steel AISI 304	
Gassing System	Air areation with O2 supplementation Sparger outlet	4-gasmixing for Air N2, O2 CO2 Sparger and Overlay outlet
Outlet design	Hose connector OD 6 mm	Hose connector OD 6 mm

Flowmeter

Gas flow range „Sparger" 0.5 L | 1 L	0.1 – 1 | 0.16 – 1.6 [l/min]	0.005 – 0.05 | 0.016 – 0.166 [l/min]
Gas flow range „Overlay" 0.5 L | 1 L	––	0.05 – 0.5 | 0.16 – 1.6 [l/min]
Accuracy	+/– 5% FS	

Thermal Mass Flow Controller (Optional)

Flow range	0.03 – 1.5 slpm	0.003 – 0.150 slpm
Accuracy	+/– 1% FS	

Integrated Pumps

Pump head	Watson Marlow 102R
Rotation speed	20 rpm
Flow rate integrated pumps	0.04 – 33.2 [ml/min] (tube dependent)

Thermostate System

Temperature control range	8 °C above cooling water to 60 °C
Connections to culture vessel	Quick couplings

External Connections per Vessel

Feed pump connection │ External input	0 – 10 V │ 0 – 10 V

Culture Vessel

Culture Vessel	0.5 L	1 L
Design	Jacketed glass vessel with stainless steel head pleate	
Total volume	0.75 L	1.6 L
Working volume	0.15 – 0.5 L	0.4 – 1 L
Headpleate ports total 19 mm │ 12 mm │ 6 mm	– │ 6 │ 4	3 │ 2 │ 6
pO2 electrode	Polarographic	
pH electrode	Gel filled	
Temperature probe	Pt100	
Material (product wetted parts)	Borosilicat glass │ Stainless steel AISI 316L │ EPDM	
Volume storage bottles	250 mL	

Utilities Requirements │ Housing Connection

Power supply	120 VAC or 230 VAC
Gasses	Controlled @ 1.5 barg dry, particle and oil free │ hose connector OD 6 mm
Water	Controlled @ 2 barg │ hose connector OD 10 mm
Drain	Gravity drain with zero backpressure required │ hose connector OD 10 mm

Ordering Information

Description	BIOSTAT® Qplus Microbial Version		BIOSTAT® Qplus Cell Culture Version	
Culture vessel	0.5 L	1 L	0.5 L	1 L
Cat. No. 120 VAC				
BIOSTAT® Qplus 3-fold version	RQ-3M5DLOTRDG1	RQ-3M01LOTRDG1	RQ-3C5DLETSDG1	RQ-3C01LETSDG1
BIOSTAT® Qplus 6-fold version	RQ-6M5DLOTRDG1	RQ-6M01LOTRDG1	RQ-6C5DLETSDG1	RQ-6C01LETSDG1
BIOSTAT® Qplus 9-fold version	RQ-9M5DLOTRDG1	RQ-9M01LOTRDG1	RQ-9C5DLETSDG1	RQ-9C01LETSDG1
BIOSTAT® Qplus 12-fold version	RQ12M5DLOTRDG1	RQ12M01LOTRDG1	RQ12C5DLETSDG1	RQ12C01LETSDG1
3-fold MO upgrade to max 12 fold system without digital controller	RQ-3M5DLOTRDG1E	RQ-3M01LOTRDG1E	RQ-3C5DLETSDG1E	RQ-3C01LETSDG1
Cat. No. 230 VAC				
BIOSTAT® Qplus 3-fold version	RQ-3M5DLOTRDG2	RQ-3M01LOTRDG2	RQ-3C5DLETSDG2	RQ-3C01LETSDG2
BIOSTAT® Qplus 6-fold version	RQ-6M5DLOTRDG2	RQ-6M01LOTRDG2	RQ-6C5DLETSDG2	RQ-6C01LETSDG2
BIOSTAT® Qplus 9-fold version	RQ-9M5DLOTRDG2	RQ-9M01LOTRDG2	RQ-9C5DLETSDG2	RQ-9C01LETSDG2
BIOSTAT® Qplus 12-fold version	RQ12M5DLOTRDG2	RQ12M01LOTRDG2	RQ12C5DLETSDG2	RQ12C01LETSDG2
3-fold upgrade to max 12 fold system without digital controller	RQ-3M5DLOTRDG2E	RQ-3M01LOTRDG2E	RQ-3C5DLETSDG2E	RQ-3C01LETSDG2E
Control Unit				
Digital controller 15'' color display with touch screen	•	•	•	•
pH and pO2 calibration routine Single probe and group calibration	•	•	•	•
Control capabilities listing per vessel				
Temperature, pH, DO (multi stage cascade), Stirrer speed; Foam | Harvest, Substrate	•	•	•	•
Supply Tower				
Gasmixing (integrated)	O2-Enrichment		Exclusive Flow	
Rotameter for Sparger | Overlay [l/min]	• | – –		• | •	
Solenoid Valve for O2-Enrichment	•		4-gas mixing	
Gasmixing of Air, O2, N2, CO2	– –		•	
Mass Flow Controller Total Sparger Flow	○ 0.03 – 1.5 [l/min] 8848605		○ 0.003 – 0.150 [l/min] 8848606	
Peristaltic pumps (integrated)	3 per vessel		3 per vessel	
Thermostat system for independent vessel temperature control	•		•	
Tubing, O-Ring (spare set)	•		•	
Supervisory Process Control Software				
MFCS | DA for data storage	•		•	
Culture Vessel Listing per Vessel	**Jacketed UniVessel®**			
3-fold culture vessel tray	•	– –	•	– –
Individual culture vessel stand	– –	•	– –	•
Stirrer shaft with Single Mechanical Seal	•	•	•	•
6-blade disk impeller	2	2	–	–
3-blade segment impeller	–	–	1	1
3 shared storage bottles 250 mL with tray	•	–	•	–
3 storage bottles 250 mL with bottle holder	–	•	–	•
Air Inlet and Exhaust filter	2	2	3	3
Aeration tube with Ring-sparger	•	•	–	–
Aeration tube with Micro-sparger	–	–	•	•
Innoculation | addition kit	•	•	•	•
Exhaust Cooler	•	•	•	•
Addition fitting	2 × 3-way	4-way	2 × 3-way	4-way
Sample- | Harvest pipe	•	•	•	•
Manual sampler	•	•	•	•
Temperature probe	•	•	•	•
pH Electrode, cable	•	•	•	•
DO Electrode, cable	•	•	•	•
Level | Foam sensor, cable	•	•	•	•

• = included, — = not included, — — = unavailable, ○ = option

▶ # BIOSTAT® Cplus

O$_2$-Enrichment

The BIOSTAT® Cplus O$_2$-Enrichment packages are dedicated to microbial applications. The integrated O$_2$-Enrichment gassing capability enables high oxygen transfer for high cell density cultures as well as for sheer-stress sensitive gassing for filamentous organisms. It may help to solve foaming problems due to reduced gassing and agitation rates. Furthermore, each BIOSTAT® Cplus package comes with safety containment valves (Sacova), which eliminates the risky needle operation for e.g. inoculation and other liquid additions to the sterile culture vessel.

Digital Controller

– Graphical user interface with color touch screen display

– Measurement and control for Temperature, pH, DO, agitation, Foam|Level

– Multi-stage DO cascade control

– 2× feed controller

– High-Foam alarm with safety shut down of aeration and agitation

– Optional level control via level probe or culture vessel weight

– Totalizers with digital calibration for gassing valves and pumps

– In-process pH-recalibration

– Trend display for up to 6 process values

– Up to 2 direct balance connections

– Optional internal Redox and Turbidity measurement

– Optional automatic or manual pressure control

"O$_2$-Enrichment" Gassing System

– Gas mixing of Air and O$_2$

– Precise manual adjustable flow meter for sparger flow adjustment

– O$_2$-Enrichment capability controlled via DO controller

– Optional mass flow controller for total flow

Pumps

– Up to 4 integrated pumps

– Configurable to feed controller

– Up to 2 external feed pumps

– Optional integrated speed controlled pump

Temperature System

– Closed loop pressurized thermostat system with recirculation pump and two heat exchanger for heating and cooling, alternately electrical heating

– Temperature range 8°C above cooling water up to 90°C

– Sterilization temperatures up to 130°C

Agitation System

– Speed range 20 up to 1500 rpm

– Maintenance free

– High torque for power full mixing

– Gear-free for quiet operation

– Single or double mechanical seal (2 L Single mechanical seal only)

Culture Vessel

– Aspect ratio (H:D) 3:1 or 2:1 (2 L & 5 L 2:1 only)

– Jacketed culture vessel fully equipped with: Probes for Temperature, DO, pH, Foam|Level and High Foam

– Operation pressure gauge

– Stirrer shaft with single mechanical seal

– Rushton impellers

– Removable baffles

– Ring Sparger

– Stainless steel filter housing for aeration and exhaust with 0.2 μm grade sterile filters

– High efficiency exhaust cooler

– 1- Channel safety containment valve

– 3-channel safety containment valve

– Resterilizable sampling valve

– Bottom harvest valve

– Removable bottle support

– Addition bottles with stainless steel head piece and sterile venting filter

– Installation and start up kit

BioPAT® MFCS/DA Software Package

– Plug and Play configuration

– Online data acquisition

– Sample Data Management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

The BIOSTAT® Cplus O$_2$–Enrichment Packages are Applicable for:

– Culture of microorganisms

– Industrial and academic research

– Process development

– Process optimization

– Up- and Down-scale studies

– Batch, fed batch and continuous culture

– High-cell density culture

– Small scale production

– Anaerobic| microaeriphilic culture

Key Features

– Sanitary stainless steel design

– Small footprint

– Automatic SIP sequence

– Needle free operation via safety containment valves (Sacova)

– Culture vessels from 2 L to 30 L working volume

– Choice of steam or electrical heating

– High foam detection with safety shut-down

– Automatically controlled O$_2$ Enrichment

– Graphical user interface with color touch screen display

– Maintenance and gear free high-performance agitation motor

– Trend display with up to 6 process values

– Various process control possibilities

– Inclusive Supervisory Process control software (BioPAT® MFCS/DA)

– Validation support available

▷ Specifications

Technical Specifications

Space Requirements | Environmental Conditions Dimensions

BIOSTAT Cplus 2 L	5 L Bench space requirement [W × H × D]	1000 × 1300 × 750 [mm] Benchtop version
BIOSTAT Cplus 10–30 L Floor space requirement [W × H × D]	1020 × 1900 × 750 [mm] Floor standing
Ambient temperature	relative humidity (non condensating)	5–40℃	85%
Control Unit	
Housing material	Stainless steel AISI 304
Display	Touch Screen 10.4"
Resolution	800 × 600 dpi
Host communication	Ethernet	RS422	RS232
Measurement Ranges	
Agitation motor speed 2 L/5 L/10 L	15 L/20 L	30 L	20-1500	20-1000	20-600 rpm
Temperature	0–150℃
pH	2–12
pO$_2$	0-100%
Pressure (option)	-0.5–2 [barg]
Turbidity (option)	0–6 AU
Redox (optional)	-1000–1000 mV
Gassing System	Air aeration with O$_2$ supplementation
Outlet design	Hose tube OD 6 mm/Reinforced silicon tubing connected to aeration line
Flowmeter	Air calibrated @ 3 barg 20℃/scale lenght 65 mm
Gas flow range „Sparger" 2 L	5 L	10 L	15 L	20 L	30 L	0.42-4.2	1.3-13	2-20	3.6-36	3.6-36	5.5 - 55 [l/min]
Accuracy	+/- 4% FS
Thermal Mass Flow Controller (Option)	Air calibrated
Flow range „Sparger" Total Flow 2 L	5 L	10 L	15 L	20 L	30 L	0.2-10	0.2-10	0.6-30	0.6-30	0.6-30	1-50 [slpm]
Accuracy	+/- 1% FS
Agitation Motor	Maintenance and gear free servo drive
Performance 2 L/5 L	10 L/15 L	20 L/30 L	500	800	1200 [W]
Integrated Pumps	Digital pulse width modulated controlled
Pump head	Watson Marlow 102R
Rotation speed	20 rpm
Flow rate integrated pumps	0.04 - 33 [ml/min] (tube dependent)
Integrated Feed Pump (Option)	Speed controlled
Pump head	Watson Marlow 102R
Rotation speed	5-50 rpm
Flow rate integrated pumps	1 - 83 [ml/min] (tube dependent)
Temperature Control System	Closed loop thermostate system with recirculation pump, heat exchanger for cooling and heating or electrical heater
Temperature control range (operation	sterilization)	8℃ above cooling water to 90℃	up to 130℃
Temperature measurement (jacket)	Pt100
Heat exchanger (cooling	heating)	Stainless steel, copper soldered	Stainless steel, copper soldered (optional: Stainless steel welded)
Electrical heater 2 L/5 L	10 L-30 L (optional)	3 kW	6 kW

External Connections

Balance connection	RS232
2 × Feed pumps	0–10 V
4 × External inputs	0–10 V

Culture Vessel	**2 L**	**5 L**	**10 L**	**15 L**	**20 L**	**30 L**
H:D ratio	2:1	2:1	2:1 | 3:1	2:1 | 3:1	2:1 | 3:1	2:1 | 3:1
Total volume	3	6.8	15	22	30	42 [L]
Working volume	0.9–2	1.6–5	4.5–10 | 3.5–10	5.5–15 | 5.0–15	7.5–20 | 5.5–20	9.0–30 | 7.0–30 [L]
Top plate ports 19 mm Total/Used (Addition valves, Foam|Level Probe)/Spare ASME vessel: Additional 19 mm port	4/3/1	4/3/1	5/3/2 | 4/3/1	5/3/2	5/3/2	5/3/2
Top plate ports with fixed installations Sparger inlet/Exhaust cooler/Agitation system/sight glass for illumination (10–30 L only)/safety valve (PED vessel only)	5	5	5	5	5	5
Upper side ports 25 mm ASME vessel: Additional port for bursting disc	–	–	3	3	3	3
Lower side port 25 mm Total/Used (Pt100, pH, DO, sampling valve)/Spare (12 mm port for Pt 100)	5/1/ 3/1	5/1/ 3/1	5/1/ 3/1	5/1/ 3/1	5/1/ 3/1	5/1/ 3/1
Bottom port (harvest valve)	1	1	1	1	1	1
Vessel design	Jacketed stainless steel vessel with upper glass cylinder	Jacketed stainless steel vessel with vertical sight glass				
Volume storage bottles	500	500	1000	1000	1000	1000 [mL]
Material (product wetted parts)	Stainless steel AISI 316L | Borosilicat glass | EPDM					
Surface finish product wetted	Ra <= 0.8 µm, electropolished					
Pressure design criterria 2 L/ 5 L Vessel | Jacket	2.5 barg/–1 @ 150°C | 4 barg/–1 @ 150°C					
Pressure design criterria 10–30 L Vessel | Jacket	3 barg/–1 @ 150°C | 4 barg/–1 @ 150°C					
Fabrication 208 VAC | 400 VAC packages	ASME | PED (2 L & 5 L PED only)					

Probes

pO$_2$ electrode	Polarographic
pH electrode	Gel filled
Foam | Level probe	Conductive probe, stainless steel ceramic isolated
Temperature probe	Pt100
Redox electrode (option)	Gel filled
Pressure sensor (option)	Piezoresistive sensor
Turbidity probe (option)	Single Channel NIR Absorption Probe, Gap 10 mm

Utilities Requirements | Regulatory Compliance

Power supply	208 VAC (Plug: NEMA L 21-20P) or 400 VAC (Plug CEE)
Gases	4–6 barg; dry, particle and oil free
Process steam	2.5–3 barg, controlled, prefiltered
Clean steam	1.5–2 barg, controlled, prefiltered
Water return	Return to close loop cooling system
Condensate	Gravity drain with zero backpressure required
Regulatory compliance	CE

Ordering Information

Description	BIOSTAT® Cplus–MO O$_2$–Enrichment					
	2 L	5 L	10 L	15 L	20 L	30 L
Cat. No. 208 VAC | Culture vessel H:D ration	RCP-M02L OTRDS3 | 2:1	RCP-M05L OTRDS3 | 2:1	RCP-M10L OTRDS3 | 2:1	RCP-M15L OTRDS3 | 2:1	RCP-M20L OTRDS3 | 2:1	RCP-M30L OTRDS3 | 2:1
Cat. No. 400 VAC | Culture vessel H:D ration	RCP-M02L OTRDS4 | 2:1	RCP-M05L OTRDS4 | 2:1	RCP-M10L OTRDT4 | 3:1	RCP-M15L OTRDT4 | 3:1	RCP-M20L OTRDT4 | 3:1	RCP-M30L OTRDT4 | 3:1
Control Unit						
Digital controller, color display with touch screen	•	•	•	•	•	•
Control capabilities						
Temperature, pH, DO (2 stage cascade), Stirrer speed	•	•	•	•	•	•
Substrate A and Substrate B	•	•	•	•	•	•
Foam via conductive probe	•	•	•	•	•	•
High Foam alarm	•	•	•	•	•	•
Automatic sterilization sequence	•	•	•	•	•	•
Agitation motor (Servo drive)	•	•	•	•	•	•
Gasmixing	**O$_2$–Enrichment**					
Rotameter Sparger	•	•	•	•	•	•
Solenoid valve for O$_2$ Enrichment	•	•	•	•	•	•
Peristaltic pumps (integrated)	3 for Acid | Base | Afoam unused pump can be configured as substrate pump					
Supervisory Process Control Software						
MFCS/DA for data storage	•	•	•	•	•	•
Supply Frame	**Open Frame Design**					
Temperature control system	Closed loop system with recirculation pump and heat exchanger for heating and cooling – Alternative: Electrical heating					
Agitation motor holder	•					
Solenoid valves and steam traps for automatic in-situ sterilization	•					
Installation kit, Tubing, O-Ring (spare set)	•					
Culture Vessel	**Jacketed Stainless Steel Vessel with Upper Glass Cylinder**		**Jacketed Stainless Steel Vessel with Vertical Sight Glass**			
Stirrer shaft with Single Mechanical Seal	•	•	•	•	•	•
6–blade disk impeller	2	2	3	3	3	3
Stainless steel filter housing for Air Inlet and Exhaust filter incl. filter cartridges	•	•	•	•	•	•
Pressure gauge –1/3 barg	•	•	•	•	•	•
Aeration tube with Ring–sparger	•	•	•	•	•	•
Exhaust Cooler	•	•	•	•	•	•
4–Baffels (removable)	•	•	•	•	•	•
Resterilizable sampling valve; complete	•	•	•	•	•	•
1–Channel Sacova valve for needle free additions	•	•	•	•	•	•
3–Channel Sacova valve for needle free additions	•	•	•	•	•	•
Lamp for vessel illumination	–	–	•	•	•	•
Storage bottles	3	3	3	3	3	3
Removable tray for storage bottles	–	–	•	•	•	•
Harvest valve	•	•	•	•	•	•
pH Electrode, cable	•	•	•	•	•	•
DO Electrode, cable	•	•	•	•	•	•
Foam sensor, cable	•	•	•	•	•	•
Temperature sensor Pt 100	•	•	•	•	•	•
High–foam sensor with installation adaptor, cable	•	•	•	•	•	•
Options						
MFC (Sparger Total Flow)	○ 8847789 0.2-10 l/min	○ 8847789 0.2-10 l/min	○ 8848521 0.6-30 l/min	○ 8848521 0.6-30 l/min	○ 8848521 0.6-30 l/min	○ 8848556 1-50 l/min
Electrical heating instead of steam heat exchanger	○ 8842509	○ 8842509	○ 8842507	○ 8842507	○ 8842507	○ 8842507
Top plate lifting device	– –	– –	○ 8842516	○ 8842516	○ 8842516	○ 8842516
Pressure control Manual | Automatic	○ 8842512 | 8842513	○ 8842512 | 8842513	○ 8842512 | 8842514	○ 8842512 | 8842513	○ 8842512 | 8842513	○ 8842512 | 8842513
Vessel weight measurement	– –	– –	○ 8842514	○ 8842514	○ 8842514	○ 8842514
Feed pump (integrated); speed controlled	○ 8843468	○ 8843468	○ 8843468	○ 8843468	○ 8843468	○ 8843468
Feed pump integrated; digital	○ 8843466	○ 8843466	○ 8843466	○ 8843466	○ 8843466	○ 8843466
Turbibity measurement (amplifier + probe)	○ on request	○ 8846618 + 8846604	○ 8846618 + 8846604	○ 8846618 + 8846604	○ 8846618 + 8846604	○ 8846618 + 8846604
Redox measurement (amplifier + probe)	○ 8842744 + 8840237	○ 8842744 + 8840237	○ 8842744 + 8840237	○ 8842744 + 8840237	○ 8842744 + 8840237	○ 8842744 + 8840237

Broad range of accessories available, Please contact us for further details. Please note: Due to technical | space limitations may not all options can be combined

• = included, – = not included, – – = unavailable, ○ = option

▶ BIOSTAT® Cplus

Exclusive Flow

The BIOSTAT® Cplus Exclusive Flow packages are configured for cell culture applications. The integrated automatically controlled four gas mixing system provides Overlay and Sparger gassing. Air is routed to Overlay. Air, O_2, N_2 and CO_2 is routed to Sparger. By an easy upgrade of culture vessel components and rotameter flow range, the system can be also used for microbial cultures. Separate rotameters for gas to the Sparger and Overlay makes adjusting the flow rate easy. The gas composition is automatically controlled via DO and pH controller.

Furthermore, each BIOSTAT® Cplus package comes with safety containment valves (Sacova), which eliminates the risky needle operation for e.g. inoculation and other liquid additions to the sterile culture vessel.

Digital Controller

– Graphical user interface with color touch screen display

– Measurement and control for Temperature, pH, DO, agitation, Foam | Level

– Multi-stage DO cascade control

– 2 × feed controller

– High-Foam alarm with safety shut down of aeration and agitation

– Optional level control via Level probe or culture vessel weight

– Totalizers with digital calibration for gassing valves and pumps

– In-process pH-recalibration

– Trend display for up to 6 process values

– Up to 2 direct balance connections

– Optional internal Redox and Turbidity measurement

– Optional automatic or manual pressure control

"Exclusive Flow" Gassing System

– Sparger and Overlay gas outlet

– Gasmixing of Air, O_2, N_2, CO_2 for Sparger gassing

– Air for Overlay gassing

– Controlled via pH | DO controller

– Optional mass flow controller for total Sparger and Overlay flow

Pumps

– Up to 4 integrated pumps

– Configurable to feed controller

– Up to 2 external feed pumps

– Optional integrated speed controlled pump

Temperature System

– Closed loop pressurized thermostat system with recirculation pump and two heat exchanger for heating and cooling, alternately electrical heating

– Temperature range 8°C above cooling water up to 90°C

– Sterilization temperatures up to 130°C

Agitation System

– Speed range 20 up to 1500 rpm

– Maintenance free

– Gear-free for quiet operation

– Double mechanical seal

Culture Vessel

– Aspect ratio (H:D) 2:1

– Jacketed culture vessel fully equipped with: Probes for Temperature, DO, pH, Foam|Level and High Foam

– Operation pressure gauge

– Stirrer shaft with double mechanical seal

– 3-blade segment impellers

– µ-Sparger

– Stainless steel filter housing for aeration and exhaust with 0.2 µm grade sterile filters

– Overlay aeration assembly with stainless steel filter housing and 0.2 µm grade sterile filter

– High efficiency exhaust cooler

– 1- Channel safety containment valve

– 3-channel safety containment valve

– Resterilizable sampling valve

– Bottom harvest valve

– Removable bottle support

– Addition bottles with stainless steel head piece and sterile venting filters

– Installation and start up kit

BioPAT® MFCS/DA Software Package

– Plug and Play configuration

– Online data acquisition

– Sample Data Management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

The BIOSTAT® Cplus Exclusive Flow Packages are Applicable for:

– Cell culture of insect, mammalian and plant cells

– Microbial culture by easy upgrade

– Industrial and academic research

– Process development

– Process optimization

– Up- and Down-scale studies

– Batch, fed batch culture

– Easy upgrade to perfusion operation

– Small scale production

– High-cell density culture

– Suspension and micro carrier cultures

Key Features

– Sanitary stainless steel design

– Small footprint

– Easy multipurpose use upgrade

– Automatic SIP sequence

– Needle free operation via safety containment valves (Sacova)

– Culture vessels from 5 L to 30 L working volume

– Choice of steam or electrical heating

– High foam detection with safety shut-down

– Automatically controlled gas mixing

– Sparger and Overlay aeartion

– Graphical user interface with color touch screen display

– Maintenance and gear free high-performance agitation motor

– Trend display with up to 6 process values

– Various process control possibilities

– Inclusive Supervisory Process control software (BioPAT® MFCS/DA)

– Validation support available

▷ Specifications

Technical Specifications

Space Requirements	Environmental Conditions	Dimensions
BIOSTAT Cplus 5 L Bench space requirement [W × H × D]	1000 × 1300 × 750 [mm] Benchtop version
BIOSTAT Cplus 10-30 L Floor space requirement [W × H × D]	1020 × 1900 × 750 [mm] Floor standing
Ambient temperature│relative humidity (non condensating)	5–40°C │ 85%
Control Unit	
Housing material	Stainless steel AISI 304
Display	Touch Screen 10.4"
Resolution	800 × 600 dpi
Host communication	Ethernet │ RS422 │ RS232
Measurement Ranges	
Agitation motor speed 2 L/5 L/10 L │ 15 L/20 L │ 30 L	20-1500 │ 20-1000 │ 20-600 rpm
Temperature	0–150°C
pH	2–12
pO$_2$	0-100%
Pressure (option)	-0.5–2 [barg]
Turbidity (option)	0–6 AU
Redox (optional)	-1000–1000 mV
Gassing System	Exclusive Flow 4-gas mixing with Sparger and Overlay outlet
Outlet design	Hose tube OD 6 mm │ Reinforced silicon tubing connected to aeration line
Flowmeter	Air calibrated @ 3 barg 20°C/scale lenght 65 mm
Gas flow range „Sparger" 5 L │ 10 L │ 15 L │ 20 L │ 30 L	0.05-0.5 │ 0.1-1.0 │ 0.16-1.6 │ 0.16-1.6 │ 0.42-4.2 [l/min]
Gas flow range „Overlay" 5 L │ 10 L │ 15 L │ 20 L │ 30 L	0.42-4.2 │ 1.3-13 │ 1.3-13 │ 2-20 │ 3.6-36 [l/min]
Accuracy	+/- 4% FS
Thermal Mass Flow Controller (Option)	Air calibrated
Flow range „Sparger" Total Flow 5 L │ 10–30 L	0.01–0.5 slpm │ 0.06-3 slpm
Flow range „Overlay" 5 L │ 10–30 L	0.2–10 slpm │ 0.6 - 30 slpm
Accuracy	+/- 1% FS
Agitation Motor	Maintenance and gear free servo drive
Performance 5 L │ 10 L/15 L │ 20 L/30 L	500 │ 800 │ 1200 [W]
Integrated Pumps	Digital pulse width modulated controlled
Pump head	Watson Marlow 102R
Rotation speed	20 rpm
Flow rate integrated pumps	0.04–33 [ml/min] (tube dependent)
Integrated Feed Pump (Option)	Speed controlled
Pump head	Watson Marlow 102R
Rotation speed	5-50 rpm
Flow rate integrated pumps	1 - 83 [ml/min] (tube dependent)
Temperature Control System	Closed loop thermostate system with recirculation pump, heat exchanger for cooling and heating or electrical heater
Temperature control range (operation │ sterilization)	8°C above cooling water to 90°C │ up to 130°C
Temperature measurement	Pt100

Heat exchanger (cooling | heating)	Stainless steel, copper soldered | Stainless steel, copper soldered (optional: Stainless steel welded)				
Electrical heater 5 L | 10 L–30 L (optional)	3 kW | 6 kW				
External Connections					
Balance connection	RS232				
2 × Feed pumps	0–10 V				
4 × External inputs	0–10 V				
Culture Vessel	**5 L**	**10 L**	**15 L**	**20 L**	**30 L**
H:D ratio	2:1	2:1	2:1	2:1	2:1
Total volume	6.8	15	22	30	42 [L]
Working volume	1.6-5	3.5-10	5.5-15	7.5-20	9-30 [L]
Top plate ports 19 mm Total/Used (Addition valves, Foam/Level Probe, Overlay aeration)/Spare ASME vessel: Additional 19 mm port	4/4/–	5/4/1	5/4/1	5/4/1	5/4/1
Top plate ports with fixed installations Air inlet/Exhaust cooler/Agitation system/ sight glass for illumination (10–30 L only)/ safety valve (PED vessel only)	5	5	5	5	5
Upper side ports 25 mm ASME vessel: Additional port for bursting disc	–	3	3	3	3
Lower side port 25 mm Total/Used (Pt100, pH, DO, sampling valve)/Spare (12 mm port for Pt 100)	5/4/1	5/4/1	5/4/1	5/4/1	5/4/1
Bottom port (harvest valve)	1	1	1	1	1
Vessel design	Jacketed stainless vessel with vertical sight glass	Jacketed stainless steel steel vessel with upper glass cylinder			
Volume storage bottles	500	1000	1000	1000	1000 [mL]
Material (product wetted parts)	Stainless steel AISI 316L | Borosilicat glass | EPDM				
Surface finish product wetted	Ra <= 0.8 µm, electropolished				
Pressure design criterria 5 L Vessel | Jacket	2.5 barg/–1 @ 150°C | 4 barg/–1 @ 150°C				
Pressure design criterria 10-30 L Vessel | Jacket	3 barg/–1 @ 150°C | 4 barg/–1 @ 150°C				
Fabrication 208 VAC | 400 VAC packages	ASME | PED (5 L PED only)				
Probes					
pO_2 electrode	Polarographic				
pH electrode	Gel filled				
Foam | Level probe	Conductive probe, stainless steel ceramic isolated				
Temperature probe	Pt100				
Redox electrode (option)	Gel filled				
Pressure sensor (option)	Piezoresistive sensor				
Turbidity probe (option)	Single Channel NIR Absorption Probe, Gap 20 mm				
Utilities Requirements | Regulatory Compliance					
Power supply	208 VAC (Plug: NEMA L 21-20P) or 400 VAC (Plug CEE)				
Gases	4 – 6 barg; dry, particle and oil free				
Process steam	2.5 – 3 barg, controlled, prefiltered				
Clean steam	1.5 – 2 barg, controlled, prefiltered				
Water return	Return to close loop cooling system				
Condensate	Gravity drain with zero backpressure required				
Regulatory compliance	CE				

Ordering Information

Description	BIOSTAT® Cplus–MO Exclusive Flow				
	5 L	10 L	15 L	20 L	30 L
Cat. No. 208 VAC | Culture vessel H:D ration	RCP-C05L ETSES3 | 2:1	RCP-C10L ETSES3 | 2:1	RCP-C15L ETSES3 | 2:1	RCP-C20L ETSES3 | 2:1	RCP-C30L ETSES3 | 2:1
Cat. No. 400 VAC | Culture vessel H:D ration	RCP-C05L ETSES4 | 2:1	RCP-C10L ETSES4 | 2:1	RCP-C15L ETSES4 | 2:1	RCP-C20L ETSES4 | 2:1	RCP-C30L ETSES4 | 2:1
Control Unit					
Digital controller, color display with touch screen	•	•	•	•	•
Control capabilities					
Temperature, pH, DO (2 stage cascade), Stirrer speed	•	•	•	•	•
Substrate A and Substrate B	•	•	•	•	•
Foam via conductive probe	•	•	•	•	•
High Foam alarm	•	•	•	•	•
Automatic sterilization sequence	•	•	•	•	•
Agitation motor (Servo drive)	•	•	•	•	•
Gasmixing	Exclusive Flow				
Rotameter Sparger	•	•	•	•	•
Rotameter Overlay	•	•	•	•	•
Gasmixing of Air, O_2, N_2, CO_2; Sparger	•	•	•	•	•
Peristaltic pumps (integrated)	3 for Acid | Base | Afoam unused pump can be configured as substrate pump				
Supervisory Process Control Software					
MFCS/DA for data storage	•	•	•	•	•
Supply Frame	**Open Frame Design**				
Temperature control system	Closed loop system with recirculation pump and heat exchanger for heating and cooling – Alternative: Electrical heating				
Alternative: Electrical heating					
Agitation motor holder	•	•	•	•	•
Solenoid valves and steam traps for automatic in-situ sterilization	•	•	•	•	•
Installation kit, Tubing, O-Ring (spare set)	•	•	•	•	•
Culture Vessel	Jacketed Stainless Steel Vessel with Upper Glass Cylinder	Jacketed Stainless Steel Vessel with Vertical Sight Glass			
Stirrer shaft with Double Mechanical Seal	•	•	•	•	•
3-blade segment impeller	1	2	2	2	2
Stainless steel filter housing for Air Inlet and Exhaust filter incl. filter cartridges	•	•	•	•	•
Stainless steel filter housing for Overlay aeration incl. filter cartridges	•	•	•	•	•
Pressure gauge –1/3 barg	•	•	•	•	•
Aeration tube with micro-sparger	•	•	•	•	•
Exhaust Cooler	•	•	•	•	•
Resterilizable sampling valve; complete	•	•	•	•	•
1-Channel Sacova valve for needle free additions	•	•	•	•	•
3-Channel Sacova valve for needle free additions	•	•	•	•	•
Lamp for vessel illumination	– –	•	•	•	•
Storage bottles	3	3	3	3	3
Removable tray for storage bottles	– –	•	•	•	•
Combined Bottom harvest | sampling valve	•	•	•	•	•
pH Electrode, cable	•	•	•	•	•
DO Electrode, cable	•	•	•	•	•
Foam sensor, cable	•	•	•	•	•
Temperature sensor Pt 100	•	•	•	•	•
High-foam sensor with installation adaptor, cable	•	•	•	•	•
Options					
MFC (Sparger total flow)	○ 8848580 0.01-0.5 [l/min]	○ 8847770 0.06-3 [l/min]	○ 8847770 0.06-3 [l/min]	○ 8847770 0.06-3 [l/min]	○ 8847770 0.06-3 [l/min]
MFC (Overlay flow)	○ 8847789 0.2–10 [l/min]	○ 8848521 0.6-30 [l/min]	○ 8848521 0.6-30 [l/min]	○ 8848521 0.6-30 [l/min]	○ 8848521 0.6-30 [l/min]
Electrical heating instead of steam heat exchanger	○ 8845964	○ 8842507	○ 8842507	○ 8842507	○ 8842507
Top plate lifting device	– –	○ 8842516	○ 8842516	○ 8842516	○ 8842516
Pressure control Manual | Automatic	○ 8842512|8842513	○ 8842512|8842512	○ 8842512|8842512	○ 8842512|8842512	○ 8842512|8842512
Vessel weight measurement	– –	○ 8842514	○ 8842514	○ 8842514	○ 8842514
Feed pump (integrated); speed controlled	○ 8843468	○ 8843468	○ 8843468	○ 8843468	○ 8843468
Feed pump integrated; digital	○ 8843466	○ 8843466	○ 8843466	○ 8843466	○ 8843466
Turbibity measurement (amplifier + probe)	○ on request	○ on request	○ 8846618 + 8846605	○ 8846618 + 8846605	○ 8846618 + 8846605
Empty vessel sterilization	○ 8842508	○ 8842508	○ 8842508	○ 8842508	○ 8842508

Broad range of accessories available, Please contact us for further details. Please note: Due to technical | space limitations may not all options can be combined

• = included,   – = not included,   – – = unavailable,   ○ = option

▶ BIOSTAT® Cplus

Gas Flow Ratio Control

The BIOSTAT® Cplus Gas Flow Ratio Control (GFRC) packages are dedicated to microbial applications. The GFRC control loop with two integrated mass flow controllers (MFC) for Air and oxygen, controlled via DO cascade control loop allows advanced process control and easy gas balancing. The GFRC strategy enables highest oxygen transfer for high cell density cultures as well as for sheer stress sensitive gassing for filamentous organisms. It combines two operation modes for advanced gassing control of Air and O_2.

– Constant flow: Percentage alteration

– Constant ratio: Alteration of flow rates.

Furthermore, each BIOSTAT® Cplus package comes with safety containment valves (Sacova), which eliminates the risky needle operation for e.g. inoculation and other liquid additions to the sterile culture vessel.

Digital Controller

– Graphical user interface with color touch screen display

– Measurement and control for Temperature, pH, DO, agitation, Foam|Level

– Multi-stage DO cascade control

– 2 × feed controller

– High-Foam alarm with safety shut down of aeration and agitation

– Optional level control via Level probe or culture vessel weight

– Totalizers with digital calibration for pumps

– In-process pH-recalibration

– Trend display for up to 6 process values

– Up to 2 direct balance connections

– Optional internal Redox and Turbidity measurement

– Optional automatic or manual pressure control

"Gas Flow Ratio Control" Gassing System

– Gas mixing of Air and O_2

– Mass flow controllers for Air and O_2 controlled via DO controller

Pumps

– Up to 4 integrated pumps

– Configurable to feed controller

– Up to 2 external feed pumps

– Optional integrated speed controlled pump

Temperature System

– Closed loop pressurized thermostat system with recirculation pump and two heat exchanger for heating and cooling, alternately electrical heating

– Temperature range 8°C above cooling water up to 90°C

– Sterilization temperatures up to 130°C

Agitation System

– Speed range 20 up to 1500 rpm

– Maintenance free

– High torque for power full mixing

– Gear-free for quiet operation

– Single or double mechanical seal

Culture Vessel

– Aspect ratio (H:D) 3:1 or 2:1 (2 L & 5 L 2:1 only)

– Jacketed culture vessel fully equipped with: Probes for Temperature, DO, pH, Foam|Level and High Foam

– Operation pressure gauge

– Stirrer shaft with single mechanical seal

– Rushton impellers

– Removable baffles

– Ring Sparger

– Stainless steel filter housing for aeration and exhaust with 0.2 μm grade sterile filters

– High efficiency exhaust cooler

– 1- Channel safety containment valve

– 3-channel safety containment valve

– Resterilizable sampling valve

– Bottom harvest valve

– Removable bottle support

– Addition bottles with stainless steel head piece and sterile venting filters

– Installation and start up kit

BioPAT® MFCS/DA Software Package

– Plug and Play configuration

– Online data acquisition

– Sample Data Management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

The BIOSTAT® Cplus GFRC Packages are Applicable for:

– Culture of microorganisms

– Industrial and academic research

– Process development

– Process optimization

– Up- and Down-scale studies

– Batch, fed batch and continuous culture

– High-cell density culture

– Small scale production

– Anaerobic | microaeriphilic culture, on request

Key Features

– Sanitary stainless steel design

– Small footprint

– Automatic SIP sequence

– Needle free operation via safety containment valves (Sacova)

– Culture vessels from 2 L to 30 L working volume

– Choice of steam or electrical heating

– High foam detection with safety shut-down

– Integrated MFC for Air and O$_2$

– Gas Flow Ration Control loop

– Graphical user interface with color touch screen display

– Maintenance and gear free high-performance agitation motor

– Trend display with up to 6 process values

– Various process control possibilities

– Inclusive Supervisory Process control software (BioPAT® MFCS/DA)

– Validation support available

▷ Specifications

Technical Specifications

Space Requirements|Environmental Conditions	Dimensions
BIOSTAT Cplus 2 L | 5 L Bench space requirement [W × H × D]	1000 × 1300 × 750 [mm] Benchtop version
BIOSTAT Cplus 10-30 L Floor space requirement [W × H × D]	1020 × 1900 × 750 [mm] Floor standing
Ambient temperature|relative humidity (non condensating)	5–40°C | 85%
Control Unit	
Housing material	Stainless steel AISI 304
Display	Touch Screen 10.4"
Resolution	800 × 600 dpi
Host communication	Ethernet | RS422 | RS232
Measurement Ranges	
Agitation motor speed 2 L/5 L/10 L | 15 L/20 L | 30 L	20-1500 | 20-1000 | 20-600 rpm
Temperature	0–150°C
pH	2–12
pO$_2$	0-100%
Pressure (option)	-0.5–2 [barg]
Turbidity (option)	0–6 AU
Redox (optional)	-1000–1000 mV
Gassing System	Gas Flow Ratio Control via two mass flow controller for Air and O$_2$
Outlet design	Hose tube OD 6 mm/Reinforced silicon tubing connected to aeration line
Flowmeter	Air calibrated @ 3 barg 20°C/scale lenght 65 mm
Gas flow range „Sparger" 2 L | 5 L | 10 L | 15 L | 20 L | 30 L	0.42–4.2 | 1.3–13 | 2–20 | 3.6–36 | 3.6–36 | 5.5–55 [l/min]
Accuracy	+/- 4% FS
Thermal Mass Flow Controller	Integrated for Air and O$_2$
Flow ranges 2 L | 5 L | 10 L | 15 L | 20 L | 30 L	0.2-10 | 0.2-10 | 0.6-30 | 0.6-30 | 0.6-30 | 1-50 [slpm]
Accuracy	+/- 1% FS
Agitation Motor	Maintenance and gear free servo drive
Performance 2 L/5 L | 10 L/15 L | 20 L/30 L	500 | 800 | 1200 [W]
Integrated Pumps	Digital pulse width modulated controlled
Pump head	Watson Marlow 102R
Rotation speed	20 rpm
Flow rate integrated pumps	0.04 – 33 [ml/min] (tube dependent)
Integrated Feed Pump (Option)	Speed controlled
Pump head	Watson Marlow 102R
Rotation speed	5-50 rpm
Flow rate integrated pumps	1 – 83 [ml/min] (tube dependent)
Temperature Control System	Closed loop thermostate system with recirculation pump, heat exchanger for cooling and heating or electrical heater
Temperature control range (operation | sterilization)	8°C above cooling water to 90°C | up to 130°C
Temperature measurement (jacket)	Pt100

Heat exchanger (cooling │ heating)	Stainless steel, copper soldered │ Stainless steel, copper soldered (optional: Stainless steel welded)					
Electrical heater 2 L/5 L │ 10 L – 30 L (optional)	3 kW │ 6 kW					

External Connections

Balance connection	RS232
2 × Feed pumps	0–10 V
4 × External inputs	0–10 V

Culture Vessel	**2 L**	**5 L**	**10 L**	**15 L**	**20 L**	**30 L**
H:D ratio	2:1	2:1	2:1 │ 3:1	2:1 │ 3:1	2:1 │ 3:1	2:1 │ 3:1
Total volume	3	6.8	15	22	30	42 [L]
Working volume	0.9 -2	1.6-5	4.5-10 │ 3.5-10	5.5-15 │ 5.0-15	7.5- 20 │ 5.5- 20	9.0-30 │ 7.0-30 [L]
Top plate ports 19 mm Total/Used (Addition valves, Foam│Level Probe)/Spare ASME vessel: Additional 19 mm port	4/3/1	4/3/1	5/3/2 │ 4/3/1	5/3/2	5/3/2	5/3/2
Top plate ports with fixed installations Sparger inlet/Exhaust cooler/Agitation system/ sight glass for illumination (10–30 L only)/safety valve (PEO vessel only)	5	5	5	5	5	5
Upper side ports 25 mm ASME vessel: Additional port for bursting disc	–	–	3	3	3	3
Lower side port 25 mm Total/Used (Pt100, pH, DO, sampling valve)/Spare (12 mm port for Pt 100)	5/4/1	5/4/1	5/4/1	5/4/1	5/4/1	5/4/1
Bottom port (harvest valve)	1	1	1	1	1	1
Vessel design	Jacketed stainless steel vessel with upper glass cylinder	Jacketed stainless steel vessel with vertical sight glass				
Volume storage bottles	500	500	1000	1000	1000	1000[mL]
Material (product wetted parts)	Stainless steel AISI 316L │ Borosilicat glass │ EPDM					
Surface finish product wetted	Ra <= 0.8 μm, electropolished					
Pressure design criterria 2 L/5 L Vessel │ Jacket	2.5 barg/–1 @ 150°C │ 4 barg/–1 @ 150°C					
Pressure design criterria 10–30 L Vessel │ Jacket	3 barg/–1 @ 150°C │ 4 barg/–1 @ 150°C					
Fabrication 208 VAC │ 400 VAC packages	ASME │ PED (2 L & 5 L PED only)					

Probes

pO$_2$ electrode	Polarographic
pH electrode	Gel filled
Foam │ Level probe	Conductive probe, stainless steel ceramic isolated
Temperature probe	Pt100
Redox electrode (option)	Gel filled
Pressure sensor (option)	Piezoresistive sensor
Turbidity probe (option)	Single Channel NIR Absorption Probe, Gap 10 mm

Utilities Requirements │ Regulatory Compliance

Power supply	208 VAC (Plug: NEMA L 21-20P) or 400 VAC (Plug CEE)
Gases	4–6 barg; dry, particle and oil free
Process steam	2.5–3 barg, controlled, prefiltered
Clean steam	1.5–2 barg, controlled, prefiltered
Water return	Return to close loop cooling system
Condensate	Gravity drain with zero backpressure required
Regulatory compliance	CE

Ordering Information

Description	BIOSTAT® Cplus–MO Gas Flow Ratio Control					
	2 L	5 L	10 L	15 L	20 L	30 L
Cat. No. 208 VAC	Culture vessel H:D ration	RCP-M02L GTRDS3	2:1	RCP-M05L GTRDS3	2:1	RCP-M10L GTRDS3	2:1	RCP-M15L GTRDS3	2:1	RCP-M20L GTRDS3	2:1	RCP-M30L GTRDS3	2:1
Cat. No. 400 VAC	Culture vessel H:D ration	RCP-M02L GTRDS4	2:1	RCP-M05L GTRDS4	2:1	RCP-M10L GTRDT4	3:1	RCP-M15L GTRDT4	3:1	RCP-M20L GTRDT4	3:1	RCP-M30L GTRDT4	3:1
Control Unit						
Digital controller, color display with touch screen	•	•	•	•	•	•
Temperature, pH, DO (2 stage cascade),Stirrer speed	•	•	•	•	•	•
Substrate A and Substrate B	•	•	•	•	•	•
Foam via conductive probe	•	•	•	•	•	•
High Foam alarm	•	•	•	•	•	•
Automatic sterilization sequence	•	•	•	•	•	•
Agitation motor (Servo drive)	•	•	•	•	•	•
Gasmixing	Gas Flow ration Control via MFC for Air and O_2					
Rotameter Sparger	•	•	•	•	•	•
Air MFC	•	•	•	•	•	•
O_2 MFC	•	•	•	•	•	•
Peristaltic pumps (integrated)	3 for Acid/Base/Afoam unused pump can be configured as substrate pump					
Supervisory Process Control Software						
MFCS/DA for data storage	•	•	•	•	•	•
Supply Frame	**Open Frame Design**					
Temperature control system	Closed loop system with recirculation pump and heat exchanger for heating and cooling – Alternative: Electrical heating					
Agitation motor holder	•					
Solenoid valves and steam traps for automatic in–situ sterilization	•	•	•	•	•	•
Installation kit, Tubing, O–Ring (spare set)	•	•	•	•	•	•
Culture Vessel	**Jacketed Stainless Steel Vessel with Upper Glass Cylinder**		**Jacketed Stainless Steel Vessel with Vertical Sight Glass**			
Stirrer shaft with Single Mechanical Seal	•	•	•	•	•	•
6–blade disk impeller	2	2	3	3	3	3
Stainless steel filter housing for Air Inlet and Exhaust filter incl. filter cartridges	•	•	•	•	•	•
Pressure gauge –1/3 barg	•	•	•	•	•	•
Aeration tube with Ring–sparger	•	•	•	•	•	•
Exhaust Cooler	•	•	•	•	•	•
4–Baffels (removable)	•	•	•	•	•	•
Resterilizable sampling valve; complete	•	•	•	•	•	•
1–Channel Sacova valve for needle free additions	•	•	•	•	•	•
3–Channel Sacova valve for needle free additions	•	•	•	•	•	•
Lamp for vessel illumination	– –	– –	•	•	•	•
Storage bottles	3	3	3	3	3	3
Removable tray for storage bottles	–	–	•	•	•	•
Harvest valve	•	•	•	•	•	•
pH Electrode, cable	•	•	•	•	•	•
DO Electrode, cable	•	•	•	•	•	•
Foam sensor, cable	•	•	•	•	•	•
Temperature sensor Pt 100	•	•	•	•	•	•
High–foam sensor with installation adaptor, cable	•	•	•	•	•	•
Options						
Double mechanical seal	– –	○ 8845913	○ 8844968	○ 8844968	○ 8844968	○ 8844968
Electrical heating instead of steam heat exchanger	○ 8845964	○ 8845964	○ 8842507	○ 8842507	○ 8842507	○ 8842507
Top plate lifting device	– –	– –	○ 8842516	○ 8842516	○ 8842516	○ 8842516
Pressure control Manual	Automatic	○ 8842512	8842513	○ 8842512	8842513	○ 8842512	8842513	○ 8842512	8842513	○ 8842512	8842513	○ 8842512	8842513
Vessel weight measurement	– –	– –	○ 8842514	○ 8842514	○ 8842514	○ 8842514
Feed pump (integrated); speed controlled	○ 8843468	○ 8843468	○ 8843468	○ 8843468	○ 8843468	○ 8843468
Feed pump integrated; digital	○ 8843466	○ 8843466	○ 8843466	○ 8843466	○ 8843466	○ 8843466
Turbibity measurement (amplifier + probe)	○ on request	○ 8846618 + 8846604	○ 8846618 + 8846604	○ 8846618 + 8846604	○ 8846618 + 8846604	○ 8846618 + 8846604
Redox measurement (amplifier + probe)	○ 8842744 + 8840237	○ 8842744 + 8840237	○ 8842744 + 8840237	○ 8842744 + 8840237	○ 8842744 + 8840237	○ 8842744 + 8840237

Broad range of accessories available, Please contact us for further details. Please note: Due to technical | space limitations may not all options can be combined

• = included,   – = not included,   – – = unavailable,   ○ = option

▶ BIOSTAT® Cplus

Additive Flow

The BIOSTAT® C plus Additive Flow packages are specially configured for cell culture applications. The integrated, automatically controlled gas mixing system provides Sparger and Overlay gassing. Air is routed to Overlay. Air, O_2, N_2 and CO_2 is routed to Sparger, automatically controlled via DO and pH controller. Each gas has its own rotameter for individual flow rate adjustment. By an easy upgrade of culture vessel components and rotameter flow rates, the system can also be used for microbial culture.

Furthermore, each BIOSTAT® Cplus package comes with safety containment valves (Sacova), which eliminates the risky needle operation for e.g. inoculation and other liquid additions to the sterile culture vessel.

Digital Controller
– Graphical user interface with color touch screen display
– Measurement and control for Temperature, pH, DO, agitation, Foam | Level
– Multi-stage DO cascade control
– 2 × feed controller
– High-Foam alarm with safety shut down of aeration and agitation
– Optional level control via Level probe or culture vessel weight
– Totalizers with digital calibration for gassing valves and pumps
– In-process pH-recalibration
– Trend display for up to 6 process values
– Up to 2 direct balance connections
– Optional internal Redox and Turbidity measurement
– Optional automatic or manual pressure control

"Additive Flow" Gassing System
– Sparger and Overlay gas outlet
– Gasmixing of Air, O_2, N_2, CO_2 for Sparger gassing
– Air for Overlay gassing
– Controlled via pH | DO controller
– Optional mass flow controller for Overlay and Air Sparger flow

Pumps
– 3 integrated pumps
– Configurable to feed controller
– Up to 2 external feed pumps
– Optional integrated speed controlled pump

Temperature System
– Closed loop pressurized thermostat system with recirculation pump and two heat exchanger for heating and cooling, alternately electrical heating
– Temperature range 8°C above cooling water up to 90°C
– Sterilization temperatures up to 130°C

Agitation System
– Speed range 20 up to 1500 rpm
– Maintenance free
– Gear-free for quiet operation
– Double mechanical seal

Culture Vessel
– Aspect ratio (H:D) 2:1
– Jacketed culture vessel fully equipped with: Probes for Temperature, DO, pH, Foam|Level and High Foam
– Operation pressure gauge
– Stirrer shaft with double mechanical seal
– 3-blade segment impellers
– µ-Sparger
– Stainless steel filter housing for aeration and exhaust with 0.2 µm grade sterile filters
– Overlay aeration assembly with stainless steel filter housing and 0.2 µm grade sterile filter
– High efficiency exhaust cooler
– 1- Channel safety containment valve
– 3-channel safety containment valve
– Resterilizable sampling valve
– Bottom harvest valve
– Removable bottle support
– Addition bottles with stainless steel head piece and sterile venting filters
– Installation and start up kit

BioPAT® MFCS/DA Software Package

– Plug and Play configuration

– Online data acquisition

– Sample Data Management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

The BIOSTAT® Cplus Additive Flow Packages are Applicable for:

– Cell culture of insect, mammalian and plant cells

– Microbial culture by easy upgrade

– Industrial and academic research

– Process development

– Process optimization

– Up- and Down-scale studies

– Batch, fed batch and continuous culture

– Easy upgrade to perfusion operation

– Small scale production

– High-cell density culture

– Suspension and micro carrier cultures

Key Features

– Sanitary stainless steel design

– Small footprint

– Easy multipurpose use upgrade

– Automatic SIP sequence

– Needle free operation via safety containment valves (Sacova)

– Culture vessels from 5 L to 30 L working volume

– Choice of steam or electrical heating

– High foam detection with safety shut-down

– Automatically controlled gas mixing

– Individual gas flow rate adjustment

– Sparger and Overlay aeartion

– Graphical user interface with color touch screen display

– Maintenance and gear free high-performance agitation motor

– Trend display with up to 6 process values

– Various process control possibilities

– Inclusive Supervisory Process control software (BioPAT® MFCS/DA)

– Validation support available

▷ Specifications

Technical Specifications

Space Requirements | Environmental Conditions	Dimensions
BIOSTAT Cplus 5 L Bench space requirement [W × H × D]	1000 × 1300 × 750 [mm] Benchtop version
BIOSTAT Cplus 10–30 L Floor space requirement [W × H × D]	1020 × 1900 × 750 [mm] Floor standing
Ambient temperature | relative humidity (non condensating)	5–40°C | 85%
Control Unit	
Housing material	Stainless steel AISI 304
Display	Touch Screen 10.4"
Resolution	800 × 600 dpi
Host communication	Ethernet | RS422 | RS232
Measuremenr Ranges	
Agitation motor speed 2 L/5 L/10 L | 15 L/20 L | 30 L	20-1500 | 20-1000 | 20-600 rpm
Temperature	0–150°C
pH	2–12
pO$_2$	0-100%
Pressure (option)	-0.5–2 [barg]
Turbidity (option)	0–6 AU
Redox (optional)	-1000–1000 mV
Gassing System	Additive Flow 4-gas mixing with Sparger and Overlay outlet
Outlet design	Hose tube OD 6 mm/Reinforced silicon tubing connected to aeration line
Flowmeter	Air calibrated @ 3 barg 20°C/ scale lenght 120 mm
Gas flow range „Sparger" for Air & N$_2$ for 5 L | 10 L | 15 L | 20 L | 30 L	16-166 | 16-166 | 33-333 | 33-333 | 50-500 [mL/min]
Gas flow range „Sparger" for O$_2$ & CO$_2$ for 5 L | 10 L | 15 L | 20 L | 30 L	3.3-33 | 3.3-33 | 16-166 | 16-166 | 33-333 [mL/min]
Gas flow range „Overlay" 5 L | 10 L | 15 L | 20 L | 30 L	0.42-4.2 | 1.3-13 | 1.3-13 | 2-20 | 3.6-36 [l/min]
Accuracy	+/- 2 % FS
Thermal Mass Flow Controller (Option)	Air calibrated
Flow range „Overlay" 5 L | 10-30 L	0.1–5 slpm | 0.6–30 slpm
Flow range "Air Sparger flow"	0.2–10 slpm
Accuracy	+/- 1% FS
Agitation Motor	Maintenance and gear free servo drive
Performance 5 L | 10 L/15 L | 20 L/30 L	500 | 800 | 1200 [W]
Integrated Pumps	Digital pulse width modulated controlled
Pump head	Watson Marlow 102R
Rotation speed	20 rpm
Flow rate integrated pumps	0.04–33 [ml/min] (tube dependent)
Integrated Feed Pump (Option)	Speed controlled
Pump head	Watson Marlow 102R
Rotation speed	5–50 rpm
Flow rate integrated pumps	1–83 [ml/min] (tube dependent)
Temperature Control System	Closed loop thermostate system with recirculation pump, heat exchanger for cooling and heating or electrical heater

Temperature control range (operation | sterilization)	8°C above cooling water to 90°C | up to 130°C				
Temperature measurement (jacket)	Pt100				
Heat exchanger (cooling | heating)	Stainless steel, copper soldered | Stainless steel, copper soldered (optional: Stainless steel welded)				
Electrical heater 5 L | 10 L-30 L (optional)	3 kW | 6 kW				
External Connections					
Balance connection	RS232				
2 × Feed pumps	0–10 V				
4 × External inputs	0–10 V				
Culture Vessel	**5 L**	**10 L**	**15 L**	**20 L**	**30 L**
H:D ratio	2:1	2:1	2:1	2:1	2:1
Total volume	6.8	15	22	30	42 [L]
Working volume	1.6-5	3.5-10	5.5-15	7.5-20	9-30 [L]
Top plate ports with fixed installations Air inlet/Exhaust cooler/Agitation system/ sight glass for illumination (10–30 L only)/ safety valve (PEO vessel only)	5	5	5	5	5
Top plate ports 19 mm Total/Used (Addition valves, Overlay aeration, Foam/Level Probe)/Spare ASME vessel: Additional 19 mm port	4/4/–	5/4/1	5/4/1	5/4/1	5/4/1
Upper side ports 25 mm ASME vessel: Additional port for bursting disc	–	3	3	3	3
Lower side port 25 mm Total/Used (Pt100, pH, DO, sampling valve)/Spare (12 mm port for Pt 100)	5/4/1	5/4/1	5/4/1	5/4/1	5/4/1
Bottom port (harvest valve)	1	1	1	1	1
Vessel design	Jacketed stainless vessel with vertical sight glass	Jacketed stainless steel steel with upper glass cylinder			
Volume storage bottles	500	1000	1000	1000	1000 [mL]
Material (product wetted parts)	Stainless steel AISI 316L | Borosilicat glass | EPDM				
Surface finish product wetted	Ra <= 0.8 µm, electropolished				
Pressure design criterria 5 L Vessel | Jacket	2.5 barg/–1 @ 150°C | 4 barg/–1 @ 150°C				
Pressure design criterria 10–30 L Vessel | Jacket	3 barg/–1 @ 150°C | 4 barg/–1 @ 150°C				
Fabrication 208 VAC | 400 VAC packages	ASME | PED (5 L PED only)				
Probes					
pO_2 electrode	Polarographic				
pH electrode	Gel filled				
Foam/Level probe	Conductive probe, stainless steel ceramic isolated				
Temperature probe	Pt100				
Redox electrode (option)	Gel filled				
Pressure sensor (option)	Piezoresistive sensor				
Turbidity probe (option)	Single Channel NIR Absorption Probe, Gap 20 mm				
Utilities Requirements | Regulatory Compliance					
Power supply	208 VAC (Plug: NEMA L 21-20P) or 400 VAC (Plug CEE)				
Gases	4–6 barg; dry, particle and oil free				
Process steam	2.5–3 barg, controlled, prefiltered				
Clean steam	1.5–2 barg, controlled, prefiltered				
Water return	Return to close loop cooling system				
Condensate	Gravity drain with zero backpressure required				
Regulatory compliance	CE				

Ordering Information

Description	BIOSTAT® Cplus–MO Additive Flow				
	5 L	10 L	15 L	20 L	30 L
Cat. No. 208 VAC │ Culture vessel H:D ration	RCP-C05L ATSES3 │ 2:1	RCP-C10L ATSES3 │ 2:1	RCP-C15L ATSES3 │ 2:1	RCP-C20L ATSES3 │ 2:1	RCP-C30L ATSES3 │ 2:1
Cat. No. 400 VAC │ Culture vessel H:D ration	RCP-C05L ATSES4 │ 2:1	RCP-C10L ATSES4 │ 2:1	RCP-C15L ATSES4 │ 2:1	RCP-C20L ATSES4 │ 2:1	RCP-C30L ATSES4 │ 2:1
Control Unit					
Digital controller, color display with touch screen	•	•	•	•	•
Control capabilities					
Temperature, pH, DO (2 stage cascade), Stirrer speed	•	•	•	•	•
Substrate A and Substrate B	•	•	•	•	•
Foam via conductive probe	•	•	•	•	•
High Foam alarm	•	•	•	•	•
Automatic sterilization sequence	•	•	•	•	•
Agitation motor (Servo drive)	•	•	•	•	•
Gasmixing	Additive Flow				
Rotameter Sparger for Air; O_2; N_2; CO_2	•	•	•	•	•
Rotameter Overlay for Air	•	•	•	•	•
Automatic Gasmixing of Air, O_2, N_2, CO_2	•	•	•	•	•
Peristaltic pumps (integrated)	3 for Acid │ Base │ Afoam unused pump can be configured as substrate pump				
Supervisory Process Control Software					
MFCS/DA for data storage	•	•	•	•	•
Supply Frame	**Open Frame Design**				
Temperature control system	Closed loop system with recirculation pump and heat exchanger for heating and cooling – Alternative: Electrical heating				
Agitation motor holder	•	•	•	•	•
Solenoid valves and steam traps for automatic in-situ sterilization	•	•	•	•	•
Installation kit, Tubing, O-Ring (spare set)	•	•	•	•	•
Culture Vessel	**Jacketed Stainless Steel Vessel with Upper Glass Cylinder**	**Jacketed Stainless Steel Vessel with Vertical Sight Glass**			
Stirrer shaft with Double Mechanical Seal	•	•	•	•	•
3-blade segment impeller	1	2	2	2	2
Stainless steel filter housing for Air Inlet and Exhaust filter ' incl. filter cartridges	•	•	•	•	•
Stainless steel filter housing for Overlay aeration incl. filter cartridges	•	•	•	•	•
Filter assembly for Overlay aeration	•	•	•	•	•
Pressure gauge –1/3 barg	•	•	•	•	•
Aeration tube with micro-sparger	•	•	•	•	•
Exhaust Cooler	•	•	•	•	•
Resterilizable sampling valve; complete	•	•	•	•	•
1-Channel Sacova valve for needle free additions	•	•	•	•	•
3-Channel Sacova valve for needle free additions	•	•	•	•	•
Lamp for vessel illumination	– –	•	•	•	•
Storage bottles	3	3	3	3	3
Removable tray for storage bottles	– –	•	•	•	•
Combined Bottom harvest │ sampling valve	•	•	•	•	•
pH Electrode, cable	•	•	•	•	•
DO Electrode, cable	•	•	•	•	•
Foam sensor, cable	•	•	•	•	•
Temperature sensor Pt 100	•	•	•	•	•
High-foam sensor with installation adaptor, cable	•	•	•	•	•
Options					
MFC (Overlay flow)	○ 8847789 0.2–10 [l/min]	○ 8848521 0.6–30 [l/min]	○ 8848521 0.6–30 [l/min]	○ 8848521 0.6–30 [l/min]	○ 8848521 0.6–30 [l/min]
MFC (Air Sparger flow)	○ 8848580 0.05–0.5 [l/min]	○ 8848580 0.05–0.5 [l/min]	○ 8848580 0.05–0.5 [l/min]	○ 8848580 0.05–0.5 [l/min]	○ 8848580 0.05–0.5 [l/min]
Electrical heating instead of steam heat exchanger	○ 8845964	○ 8842507	○ 8842507	○ 8842507	○ 8842507
Top plate lifting device	– –	○ 8842516	○ 8842516	○ 8842516	○ 8842516
Pressure control Manual │ Automatic	○ 8842512 │ 8842513	○ 8842512 │ 8842513	○ 8842512 │ 8842513	○ 8842512 │ 8842513	○ 8842512 │ 8842513
Vessel weight measurement	– –	○ 8842514	○ 8842514	○ 8842514	○ 8842514
Feed pump (integrated); speed controlled	○ 8843468	○ 8843468	○ 8843468	○ 8843468	○ 8843468
Feed pump integrated; digital	○ 8843466	○ 8843466	○ 8843466	○ 8843466	○ 8843466
Turbibity measurement (amplifier + probe)	○ on request	○ on request	○ 8846618 + 8846605	○ 8846618 + 8846005	○ 8846618 + 8846605
Empty vessel sterilization	○ 8842508	○ 8842508	○ 8842508	○ 8842508	○ 8842508

Broad range of accessories available, Please contact us for further details. Please note: Due to technical │ space limitations may not all options can be combined

• = included,   – = not included,   – – = unavailable,   ○ = option

► BIOSTAT® PBR 2S

Hardware Description

The BIOSTAT® PBR 2S is a small scale photo bioreactor for photosynthetic applications, for up to 3 L culture volume.

The Control system presents an "easy-to-use" touch screen control system with integrated measurement and control hardware, pumps, temperature and four-gas mixing system for excellent process control. Incorporated in a single "tower" housing this design concept saves valuable laboratory bench space.

The powerful peristaltic recirculation pump provides high flow rates and is low shear. The pump is connected and controlled via the control system.

The photosynthesis module has been designed utilizing helix based geometry to produce optimum illumination efficiency per unit surface area. The recirculation vessel is provided with a range of measuring probes as temperature, pH, DO and turbidity probe and serves as a base unit for additional functions such as gassing|degassing and media conditioning. Both components are designed for high recirculation rates in order to prevent fouling.

Applications

The BIOSTAT PBR 2S incorporates a number of features enabling even the most shear sensitive cell types to be cultivated under optimum conditions. Easy to use and applicable for micro algae, moss, bacteria and plant cells, it is the ideal platform for academic and industrial research.

Illumination Control

Optimum illumination levels utilizing fluorescent lamps can be manually or automatically controlled via cell density turbidity measurement device.

MFCS/DA

For further enhancement of system performance a powerful supervisory process control software MFCS/DA for extended visualization, data acquisition and trend display is included.

▷ Specifications

Technical Specifications

	Dimensions
Basic housing W × H × D	320 × 735 × 565 mm
Photosynthesis device ∅ × H	390 × 500 mm
Recirculation pump W × H × D	169 × 138 × 256 mm
Space requirement autoclave ∅ × H (mm)	390 × 500 |*340 mm
Total volume	3.7 L
Working volume	3 L
Length photosynthesis module	6 m
Illuminated area	5350 cm^2
Fluorescent lamp Quantity | Wattage	8 | 18 W
Luminous flux per lamp	1200 lm
Light impact Photosynthetic active radiation (PHAR) @ 400–700 nm	5–480 µE/m^{2}s
Recirculation flow rate	50–5000 mL/min
Flow velocity photosynthesis module	16 m/min
Rotameter gas flow range „Sparger"	16-166 mL/min
Rotameter gas flow range „Overlay"	16-166 mL/min
Temperature	8 °C above cooling water –80 °C
pH	2–12
pO2	0–100 %, Air saturation
Turbidity	0–6 AU

Utility Requirements

Power supply	120 VAC or 230 VAC
Gasses	Controlled @ 1.5 barg dry, particle and oil free
Water	Controlled @ 2 barg
Drain	gravity drain with zero backpressure required

* with optional flexible adaptor for the exhaust cooler (8844593)

Ordering Information

Description	BIOSTAT® PBR 2S
Cat. No. 120 VAC	RPBRP02LECR-H1
Cat. No. 230 VAC	RPBRP02LECR-H2
Sterilization	autoclave
Basic Unit	
Digital controller color display with touch screen	•
Control capabilities	
Temperature, pH, DO	•
Recirculation rate	•
Illumination	•
Illumination via Turbidity	•
Substrate (Note: configurable via unused integrated pump)	•
Turbidity measurement	•
Gasmixing	Exclusive Flow
Gasmixing of Air, O_2, N_2, CO_2	•
Rotameter Sparger	•
Rotameter for Overlay	•
Peristaltic pumps (integrated)	2 (Acid | Base)
Thermostat system (integrated)	•
Recirculation Pump	
Peristaltic pump	•
Photosynthesis Device	
Illumination unit	•
Single wall glass pipe	•
Helix design	•
Recirculation Vessel Includes	
Stainless steel head plate	•
Jacketed glass vessel	•
Recirculation fitting	•
Air Inlet and Exhaust filter	•
Aeration tube with µ-sparger	•
Exhaust Cooler	•
4-Way addition fitting	•
Sample- | Harvest pipe	•
Manual sampler	•
pH Electrode, cable	•
DO Electrode, cable	•
Turbidity Electrode, cable	•
Temperature sensor Pt 100	•
Tubing, O-Ring spare set	•
Options	
MFC (Sparger)	○ 0.02 – 1 (l/min) BB-8847754
MFC (Overlay)	○ 0.02 – 1 (l/min) BB-8847754
Redox measurement	○ 8843469
Balance for culture vessel	○ 8843513

Broad range of accessories available, please contact us for further information.

Supervisor Process Control Software

MFCS/DA	•

• = included, ○ = option

▶ BIOSTAT® CultiBag RM 20 | 50

Packages

BIOSTAT® CultiBag RM 20 | 50 basic
The BIOSTAT® CultiBag RM 20 | 50 is a mid scale single-use bioreactor, for up to 25 L of culture volume. It utilizes rocking motion mixing technology. The basic system can be operated with two different Bag Holders which allow working volumes between 0.1 and 25 L. It is designed for standalone use with a heater mat and integrated aeration pump.

BIOSTAT® CultiBag RM 20 | 50 Optical
The basic version can be combined with the BIOSTAT® RM Control Tower for process optimization. These advanced optical packages utilize an intuitive touch screen for easy operation.

BIOSTAT® CultiBag RM 20 | 50 Perfusion
In perfusion mode continuous cultivation is possible. Five different perfusion options allow the use of exchange rates of 2 L up to 1100 liters per day depending on the chosen configuration.

Applications
Rocking motion technology is ideal for cell cultivation with low shear. Single-use CultiBags RM allow a reduction in validation costs, remove the need for cleaning and sterilizing, and reduce set-up time. Easy to use, this single-use bioreactor is hassle free and applicable to all cell types including mammalian cells, plant cells, insect cells and various microbial cells.

Operating Principle
All packages have an integrated aeration pump. Optical and perfusion packages include the BIOSTAT® RM Control Tower which is connected to the rocking unit for monitoring and controlling the culture, including DO, pH, agitation, and temperature in batch, fed batch or perfusion mode of operation. The superior gassing system consists of four rotameters (air, O_2, N_2, CO_2), one mass flow controller for total flow and one mass flow controller for CO_2. This allows two independent gassing strategies – either a constant CO_2 | air ratio or a automatic gas mix of air, O_2, N_2 and CO_2 for automatic feedback control from the pH and DO sensors. An overpressure control system is built-in for bag safety and culture integrity. The system will shut down gas flow when overpressure is breached and will then restart when the system pressure returns within range.

Flexibility
The BIOSTAT® CultiBag RM 20 | 50 is available in scalable formats with interchangeable Bag Holders and different bag sizes:

Bag Holder 20 for 1 L, 2 L, 10 L and 20 L CultiBags RM
Bag Holder 50 for 50 L CultiBags RM

Bags are operated at up to 50% of their total volume. Rocking angles and rocking rates can be adjusted to optimize culture conditions. Disposable CultiBags RM are available in basic, optical (with pH | DO sensors) and perfusion pro (with pH | DO sensors and internal perfusion membrane). Tube connections allow sterile addition of media to the cultivation chamber. For more information about disposable bioreactor chambers please refer to our datasheet CultiBag RM.

Intuitive Touchscreen

The BIOSTAT® RM Control Tower is available in optical and perfusion packages. Both systems incorporate industrial PC hardware-based technology with Sartorius Stedim Systems touchscreen interface. The easy to use principle reduces staff training time. The BIOSTAT® RM Control Tower includes a 6 parameter trend display and superior cultivation control.

Sensors

– Disposable optical chemical sensors for pH and DO are pre-installed in every optical and perfusion bag as a closed system

– Range: pH: 5.5–8.5
  DO: 0–100%

– pH and DO recalibration function

BioPAT® MFCS/DA

– Plug and Play configuration

– Online data acquisition

– Sample data management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

– Upgrade to advanced BioPAT® MFCS/Win control software possible

▷ Specifications

Technical Specifications

Power requirements	120 VAC, 230 VAC
Rocker with Bagholder 20 Dimensions (W × H × D): Weight:	710 × 400 × 560 mm 27 kg
Rocker with Bagholder 50 Dimensions (W × H × D): Weight:	1030 × 450 × 580 mm 32 kg
BIOSTAT® RM Control Tower Dimensions (W × H × D): Weight:	320 × 735 × 565 mm 60 kg
Housing	stainless steel
Interface	RS232, RS422, Ethernet
Temperature range	20°C – 40°C
Rocking angle	5 – 10 degrees
Rocking rate	8 – 42 rocks/min
Disposable Sensor: Optical Chemical pH: pO$_2$:	5.5 – 8.5 0 – 100%

Ordering Information

DH   020   L   B   RM   –   1

— Disposable Hardware

— Volume
020 = 20
050 = 50

— Units (Example: L = liter)

— Package Type
B = Basic
O = Optical
P = Perfusion

— RM = Rocking Motion Mixing Technology

— Special Additions
– = Tinted Lid
C = Clear Lid

— Voltage
1 = 120 VAC (50 | 60 Hz)
2 = 230 VAC (50 | 60 Hz)
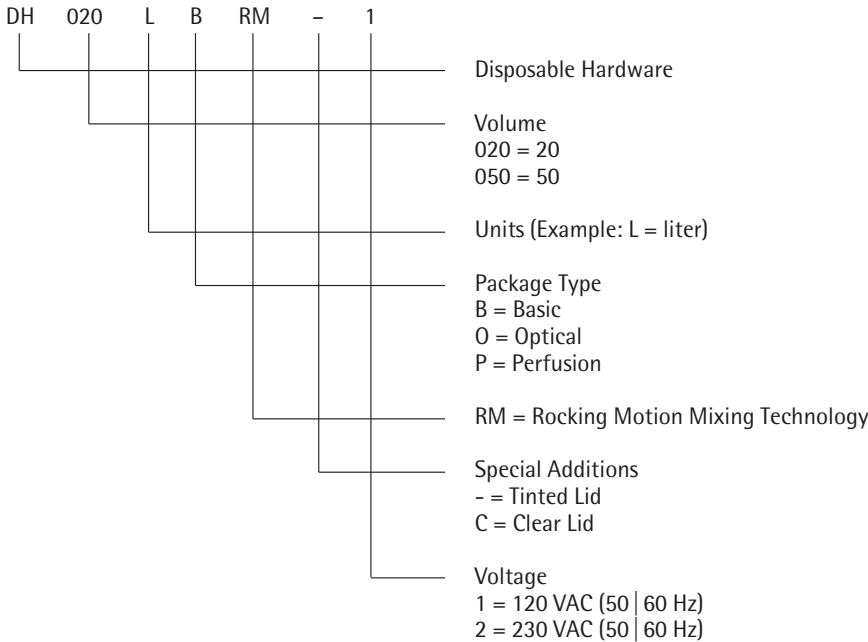
	Order Code	Description
Basic	DH-020LBRM-1│-2	Package BIOSTAT® CultiBag RM 20 basic – 120 VAC│230 VAC – Rocker 20│50 with Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic
Basic	DH-050LBRM-1│-2	Package BIOSTAT® CultiBag RM 50 basic – 120 VAC│230 VAC – Rocker 20│50 with Bag Holder 50 for CultiBags RM 50 L basic
Optical	DH-020LORM-1│-2	Package BIOSTAT® CultiBag RM 20 optical – 120 VAC│230 VAC – BIOSTAT® RM Control Tower 20 optical – Rocker 20│50 with Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic and optical
Optical	DH-050LORM-1│-2	Package BIOSTAT® CultiBag RM 50 optical – 120 VAC│230 VAC – BIOSTAT® RM Control Tower 50 optical – Rocker 20│50 with Bag Holder 50 for CultiBags RM 50 L basic and optical
Perfusion	Package BIOSTAT® CultiBag RM 20 perfusion – 120 VAC│230 VAC consists of:	
	DH-020LPRM-1│-2 + DH-----PRM**	BIOSTAT® RM Control Tower 20 perfusion Rocker 20│50 with Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic, optical and perfusion pro Perfusion Option according to process specifications as shown below
Perfusion	Package BIOSTAT® CultiBag RM 50 perfusion – 120 VAC│230 VAC consists of:	
	DH-050LPRM-1│-2 + DH-----PRM**	BIOSTAT® RM Control Tower 50 perfusion Rocker 20│50 with Bag Holder 50 for CultiBags RM 50 L basic, optical and perfusion pro Perfusion Option according to process specifications as shown below

Process Specifications for Perfusion Options 1–5

Order Code	Description	Perfusion Rate [L/Day]	Weighing Capacity Balances [kg]	Readability Balances [g]
DH-----PRM11	Perfusion Option 1 – 120 VAC	2 – 55	60	1
DH-----PRM12	Perfusion Option 1 – 230 VAC	2 – 55	60	1
DH-----PRM21	Perfusion Option 2 – 120 VAC	2 – 55	300	10
DH-----PRM22	Perfusion Option 2 – 230 VAC	2 – 55	300	10
DH-----PRM31	Perfusion Option 3 – 120 VAC	23 – 1100	300	10
DH-----PRM32	Perfusion Option 3 – 230 VAC	23 – 1100	300	10
DH-----PRM41	Perfusion Option 4 – 120 VAC	23 – 1100	600	20
DH-----PRM42	Perfusion Option 4 – 230 VAC	23 – 1100	600	20
DH-----PRM51	Perfusion Option 5 – 120 VAC	23 – 1100	1500	500
DH-----PRM52	Perfusion Option 5 – 230 VAC	23 – 1100	1500	500

▶ BIOSTAT® CultiBag RM 20 | 50 TWIN-Rocker

**The BIOSTAT® CultiBag
RM 20 | 50 TWIN-Rocker**
is a bench scale single-use bioreactor, consisting of two Rocker units, one BIOSTAT® RM TWIN-Rocker Control Tower and superior BioPAT® MFCS/DA data logging software.

Applications
Rocking motion mixing technology is ideal for cell cultivation with low shear. Easy to use, this disposable bioreactor is hassle free and applicable to all cell types including mammalian cells, plant cells, insect cells and various microbial cells. The TWIN-Rocker bioreactors can be used in R&D issues, inoculum production or manufacturing under GMP and non-GMP conditions.

Benefits
BIOSTAT® CultiBag RM bioreactor is a single-use bioreactor. It is flexible and easy to use. It reduces the risk of cross-contamination and set-up time, the time between the batches and investment costs. Single-use CultiBags RM remove the need for cleaning (CIP) and sterilizing (SIP). Validation requirements for single-use bioreactors are reduced. Additionally the TWIN-Rocker packages save valuable bench space as two rockers are controlled by one Control Tower.

Operating Principle
The Rocker unit moves back and forth generating a fluid movement in the cell culture and medium. In this way, the surface of the medium is continuously renewed by bubble-free aeration.

The control unit facilitates regulation of pH, DO, temperature, rocking rate and gas flow simultaneously in two CultiBag RM mounted on two Rockers.

Rocker 20 | 50
The Rocker 20 | 50 is controlled by BIOSTAT® RM TWIN-Rocker Control Tower. It is available in scalable formats with interchangeable Bag Holders for different bag sizes and heating capabilities: Bag Holder 20 for 1 L, 2 L, 10 L and 20 L CultiBags RM and Bag Holder 50 for 50 L CultiBags RM.

BIOSTAT® RM TWIN-Rocker Control Tower
has two independent control systems installed in one housing to control two CultiBag RM mounted on two independent Bag Holders. The Control Tower is connected to the rocking units for monitoring and controlling the culture, including pO2 (cascade control), pH, agitation, and temperature in batch, fed batch or perfusion mode of operation. The superior gassing system consists of four rotameters (air, O_2, N_2, CO_2), one mass flow controller for total flow and one mass flow controller for CO_2. This allows two independent gassing strategies – either a constant CO_2 | air ratio or an automactic mix of air, O_2, N_2 and CO_2 for automatic feedback control from the single-use pH and DO sensors. An overpressure control system is built-in for bag safety and culture integrity. The system will shut down gas flow when overpressure is breached and will then restart when the system pressure returns within range.

Sensors
– Disposable optical chemical sensors for pH and DO are pre-installed in every optical and perfusion bag as a closed system

– Range: pH: 5.5–8.5
  DO: 0–100%

– pH and DO recalibration function

Intuitive Touch Screen
The BIOSTAT® RM Control Tower incorporates industrial PC hardware-based technology with Sartorius Stedim Systems touch screen interface. The screen is intuitive, easy to use and reduces staff training time. The BIOSTAT® RM TWIN-Rocker Control Tower includes one trend display, which simultaneously plot up to six parameters from each CultiBag RM.

CultiBag RM
Single-use CultiBag RM bioreactor chamber is made of a multilayer film, USP class VI tested, with ethyl vinyl acetate (EVA) as the media contact layer. Bags are available in basic, optical (with pH | DO sensors) and perfusion pro (with pH | DO sensors and internal perfusion membrane) configurations. Sterile tube connections allow addition of media to the cultivation chamber. For more information about disposable bioreactor chambers please refer to our datasheet CultiBag RM.
CultiBag RM are not part of the packages and need to be ordered separately.

BioPAT® MFCS | DA

– Plug and Play configuration

– Online data acquisition

– Sample data management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

– Upgrade to advanced BioPAT® MFCS/Win control software possible

Packages

BIOSTAT® CultiBag RM 20 | 50 Optical TWIN-Rocker
The optical package consists of two rockers with a choice of either the same or different bag holders, one control unit for two rockers and a data acquisition software. It allows simultaneous monitoring and control of two CultiBag RM mounted on two independent rocker units for pH, DO, temperature, rocking angle and rocking rate. It is suitable for batch and fed-batch cultivation modes. Three optical packages are available: 20 optical | 20 optical, 20 optical | 50 optical and 50 optical | 50 optical.

BIOSTAT® CultiBag RM 20 | 50 Perfusion TWIN-Rocker
The perfusion package consists of optical package and two selected perfusion configurations. A choice of five different perfusion options allow medium exchange rates from 2 l up to 1100 liters per day depending on the chosen configuration. The perfusion configuration consists of an automated perfusion control software, two additional peristaltic pumps and two balances. Three perfusion packages are available: 20 perfusion | 20 perfusion, 20 perfusion | 50 perfusion and 50 perfusion | 50 perfusion.

BIOSTAT® CultiBag RM 20 | 50 Optical & Perfusion TWIN-Rocker
The optical & perfusion package allow the user to run simultaneously batch or fed-batch and perfusion cultivation. Four options are available: 20 optical | 20 perfusion, 20 optical | 50 perfusion, 20 perfusion | 50 optical and 50 optical | 50 perfusion.

▷ Specifications

Technical Specifications

Power requirements	120 VAC, 230 VAC
Rocker with Bagholder 20 Dimensions (W × H × D): Weight:	710 × 400 × 560 mm 27 kg
Rocker with Bagholder 50 Dimensions (W × H × D): Weight:	1030 × 450 × 580 mm 32 kg

BIOSTAT® RM Control Tower

Dimensions (W × H × D)	320 × 735 × 565 mm
Weight	70 kg
Housing	stainless steel
Interface	RS232, RS422, Ethernet
Temperature range	ambient – 40°C
Rocking angle	5 – 10 degrees
Rocking rate	8 – 42 rocks/min
Disposable Sensor	Optical Chemical
pH	5.5 – 8.5
pO$_2$	0 – 100%

Ordering Information

```
DH    020    L    0    R2    –    1
```

- Disposable Hardware

- Volume
  020 = 20
  050 = 50

- Units (Example: L = liter)

- Package Type
  O = Optical
  P = Perfusion
  R = Optical & perfusion
  L = Perfusion & optical

- R2 = Rocking Motion Mixing Technology
  with 2 Rockers

- Voltage
  1 = 120 VAC (50 | 60 Hz)
  2 = 230 VAC (50 | 60 Hz)

	Order Code	Description
Optical	DH-020LOR2-1│-2	Package BIOSTAT® CultiBag RM 20 optical TWIN-Rocker – 120 VAC │ 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 20 optical – 2 × Rocker 20 │ 50 with Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic and optical
Optical	DH-050LOR2-1│-2	Package BIOSTAT® CultiBag RM 50 optical TWIN-Rocker – 120 VAC │ 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 50 optical – 2 × Rocker 20 │ 50 with Bag Holder 50 for CultiBags RM 50 L basic and optical
Optical	DH-070LOR2-1│-2	Package BIOSTAT® CultiBag RM 20 & 50 optical TWIN-Rocker – 120 VAC │ 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 20&50 optical – 2 × Rocker 20 │ 50 with 1 × Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic and optical and 1 × Bag Holder 50 for CultiBags RM 50 l basic and optical
Perfusion	DH-020LPR2-1│-2 2 x DH-----PRM**	Package BIOSTAT® CultiBag RM 20 perfusion TWIN-Rocker – 120 VAC │ 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 20 perfusion – 2 × Rocker 20 │ 50 with Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic, optical and perfusion pro – 2 × Perfusion option according to process specification as shown on the next page
Perfusion	DH-050LPR2-1│-2 2 x DH-----PRM**	Package BIOSTAT® CultiBag RM 50 perfusion TWIN-Rocker – 120 VAC │ 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 50 perfusion – 2 × Rocker 20 │ 50 with Bag Holder 50 for CultiBags RM 50 L basic, optical and perfusion pro – 2 × Perfusion option according to process specification as shown on the next page
Perfusion	DH-070LPR2-1│-2 2 x DH-----PRM**	Package BIOSTAT® CultiBag RM 20 & 50 perfusion TWIN-Rocker – 120 VAC │ 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 20 & 50 perfusion – 2 × Rocker 20 │ 50 with 1 × Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic, optical and perfusion pro and 1 × Bag Holder 50 for CultiBags RM 50 L basic, optical and perfusion pro – 2 × Perfusion option according to process specification as shown on the next page

	Order Code	Description
Optical & perfusion	DH-020LRR2-1|-2 DH-----PRM**	Package BIOSTAT® CultiBag RM 20 optical & perfusion TWIN-Rocker – 120 VAC | 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 20 optical & perfusion – 2 × Rocker 20|50 with Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic, optical and perfusion pro – 1 × Perfusion option according to process specification as shown below
Optical & perfusion	DH-050LRR2-1|-2 2 x DH-----PRM**	Package BIOSTAT® CultiBag RM 50 optical & perfusion TWIN-Rocker – 120 VAC | 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 50 optical & perfusion – 2 × Rocker 20 | 50 with Bag Holder 50 for CultiBags RM 50 L basic, optical and perfusion pro – 1 × Perfusion option according to process specification as shown below
Optical & perfusion	DH-070LRR2-1|-2 2 x DH-----PRM**	Package BIOSTAT® CultiBag RM 20 & 50 optical & perfusion TWIN-Rocker – 120 VAC | 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 20 & 50 optical & perfusion – 2 × Rocker 20 | 50 with 1 × Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic, optical and perfusion pro and 1 × Bag Holder 50 for CultiBags RM 50 L basic, optical and perfusion pro – 1 × Perfusion option according to process specification as shown below
Perfusion & optical	DH-070LLR2-1|-2 2 x DH-----PRM**	Package BIOSTAT® CultiBag RM 20 & 50 perfusion&optical TWIN-Rocker – 120 VAC | 230 VAC – BIOSTAT® RM TWIN-Rocker Control Tower 20 & 50 perfusion & optical – 2 × Rocker 20 | 50 with 1 × Bag Holder 20 for CultiBags RM 1 L, 2 L, 10 L and 20 L basic, optical and perfusion pro and 1 × Bag Holder 50 for CultiBags RM 50 L basic, optical and perfusion pro – 1 × Perfusion option according to process specification as shown below

Process Specifications for Perfusion Options 1–5

Order Code	Description	Perfusion Rate [L/Day]	Weighing Capacity Balances [kg]	Readability Balances [g]
DH-----PRM11	Perfusion Option 1 – 120 VAC	2–55	60	1
DH-----PRM12	Perfusion Option 1 – 230 VAC	2–55	60	1
DH-----PRM21	Perfusion Option 2 – 120 VAC	2–55	300	10
DH-----PRM22	Perfusion Option 2 – 230 VAC	2–55	300	10
DH-----PRM31	Perfusion Option 3 – 120 VAC	23–1100	300	10
DH-----PRM32	Perfusion Option 3 – 230 VAC	23–1100	300	10
DH-----PRM41	Perfusion Option 4 – 120 VAC	23–1100	600	20
DH-----PRM42	Perfusion Option 4 – 230 VAC	23–1100	600	20
DH-----PRM51	Perfusion Option 5 – 120 VAC	23–1100	1500	500
DH-----PRM52	Perfusion Option 5 – 230 VAC	23–1100	1500	500

Packages "BIOSTAT® CultiBag RM perfusion TWIN-Rocker" require 2 × Perfusion Options.
Packages "BIOSTAT® CultiBag RM optical&perfusion and perfusion&optical TWIN-Rocker" require 1 × Perfusion Option.

▶ BIOSTAT® CultiBag RM 200

Single-Use Technology

BIOSTAT® CultiBag RM 200
The BIOSTAT® CultiBag RM 200 is a large scale single-use bioreactor for culturing up to 100 L of media. It utilizes rocking motion agitation and has an integrated Sartorius Stedim TWIN controller for independent control of two bags on one rocking platform. Superior BioPAT® MFCS│DA data logging software is included in this application driven package.

Applications
Rocking Motion is ideal for cell cultivation with low shear. Single-use bag technology improves validation costs, removes the need for cleaning, sterilizing, and reduces shear stress to cells. Easy to use, it is applicable to all cell types, including mammalian cells, plant cells, insect cells and various microbial cells. The BIOSTAT® CultiBag RM 200 bioreactor can be used for R&D, seed production or manufacturing under GMP.

Benefits
BIOSTAT® CultiBag RM bioreactor is a single-use bioreactor, which is flexible and easy to use. It does not require cleaning (CIP) or sterilizing (SIP) and reduces the risk of cross-contamination. Investment costs and set up time between batches are also reduced. Additionally, validation requirements for single-use bioreactors are low.

Operating Principle
The Rocker unit moves back and forth generating a fluid movement in the cell culture and medium. In this way, the surface of the medium is continuously renewed for bubble free aeration. The control unit, facilitates regulation of pH, DO, temperature, rocking rate and gas flow for optimal cell cultivation.

Rocker Unit
The Rocker unit with integrated bag holder can hold either one CultiBag RM 200 for cultivations of 20 to 100 L or up to two CultiBag RM 100 for cultivations of 10 to 50 L volume. The rocking unit is supplied with an integrated controller on the same platform which is mounted on casters for easy handling.

Control Tower
The BIOSTAT® CultiBag RM 200 has a TWIN controller which allows simultaneous monitoring & control of two bags mounted on one Rocker for pH, DO, T, rocking angle and rocking rate. The controller has a superior gassing system consisting of 4 rotameters (air, O_2, N_2, CO_2); 1 MFC for total flow and 1 MFC for CO_2 for both bags. This allows two independent gassing strategies to be employed: Either a constant CO_2│air ratio or a mixture of air, O_2, N_2 and CO_2 by automatic feedback control from the pH and DO sensors. When operated under automatic control, a four stage cascade control system can be utilized to increase productivity and extend batch age. An over-pressure control system is built-in for bag safety and culture integrity. The system will shut down gas flow when overpressure is breached and will then restart when the system pressure returns within range.

Intuitive Touch screen
The BIOSTAT® RM TWIN Control Tower incorporates industrial PC hardware with Sartorius Stedim touch screen interface. The screen is intuitive, easy to use and reduces staff training time. The TWIN Control Tower includes a trend display, which simultaneously plots up to six parameters from each CultiBag RM.

Sensors
– Disposable optical chemical sensors for pH and DO are pre-installed in every optical and perfusion bag as a closed system

– Range: pH: 5.5–8.5
  DO: 0–100%

– pH and DO recalibration function

Software BioPAT® MFCS | DA

– Plug and Play configuration

– Online data acquisition

– Sample data management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

– Upgrade to advanced BioPAT® MFCS/Win control software possible

CultiBag RM 100 L | 200 L
Single-use CultiBag RM bioreactor chamber is made of a multilayer film, USP class VI tested, with ethyl vinyl acetate (EVA) as the media contact layer. Bags are available in basic, optical (with pH | DO sensors) and perfusion pro (with pH | DO sensors and perfusion membrane) configurations. Sterile tube connections allow addition of media to the cultivation chamber. For more information about disposable bioreactor chambers please refer to our datasheet CultiBag RM.

Packages

BIOSTAT® CultiBag RM 200 Optical
The optical package consists of a rocker unit, a TWIN Control Tower and data acquisition software. It allows simultaneous monitoring and control of up to two cultivations for pH, DO, temperature, rocking angle and rocking rate. It is suitable for batch and fed-batch cultivation modes.

BIOSTAT® CultiBag RM 200 Perfusion
The perfusion package consists of the optical package and additionally two perfusion configurations. A choice of two different perfusion options allow medium exchange rates up to 1500 litres per day depending on the chosen configuration. The perfusion configuration consists of an automated perfusion control software, two additional peristaltic pumps and two balances. It is suitable for perfusion cultivation mode.

▷ Specifications

Technical Specifications

Power requirements	208 VAC	400 VAC
Dimensions (W × H × D)	1998 × 1241 × 830 mm
Weight	272 kg
Housing	Stainless steel
Interface	Ethernet, RS232
Temperature range	ambient -45 °C, ± 0.2 °C
Rocking angle	4–10 degrees, ± 0.3°
Rocking rate	6–20 rocks/min, ± 1 rocks/min

Disposable Sensor
Optical Chemical

pH	5.5–8.5
PO_2	0–100%

BIOSTAT® CultiBag RM – Ordering Information

DH – 200   L   O   RM   –   3

- Disposable Hardware
- Volume
- Units (Example: L = Liter)
- Package Type
  O = Optical
  P = Perfusion
- Rocking Motion Mixing Technology
- Voltage
  3 = 208 VAC (50 | 60 Hz)
  4 = 400 VAC (50 | 60 Hz)
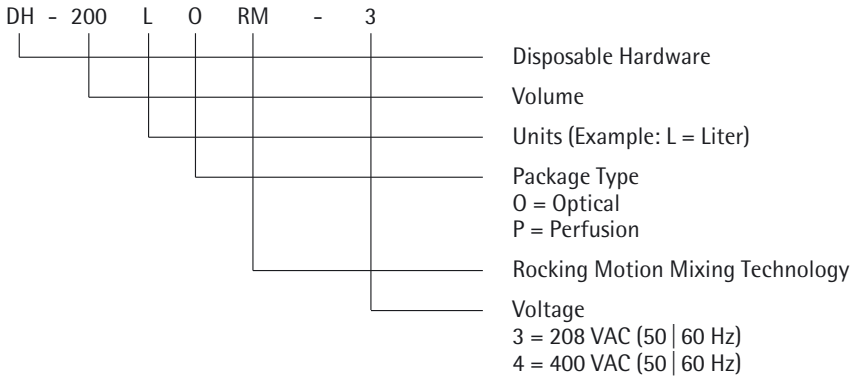
Order Code	Description
BIOSTAT® CultiBag RM 200 Optical:	
DH–200LORM-3 │ -4	Package BIOSTAT® CultiBag RM 200 optical – 208 VAC │ 400 VAC Rocker 200 with BIOSTAT® RM Twin Control Tower 200 optical
BIOSTAT® CultiBag RM 200 Perfusion: Consists of:	
DH–200LPRM-3 │ -4	Package BIOSTAT® CultiBag RM 200 perfusion – 208 VAC │ 400 VAC Rocker 200 with BIOSTAT® RM Twin Control Tower 200 perfusion +
DH-----PRM**	Perfusion option according to process specifications as shown below

Process Specifications for Perfusion Options 1–7

Order Code	Description	Perfusion Rate [L/Day]	Weighing Capacity Balances [kg]	Readability Balances [g]
DH-----PRM61	Perfusion Option 6 – 120 VAC Twin set up	23–1100	600	200
DH-----PRM62	Perfusion Option 6 – 230 VAC Twin set up	23–1100	600	200
DH-----PRM71	Perfusion Option 7 – 120 VAC Twin set up	23–1100	1500	500
DH-----PRM72	Perfusion Option 7 – 230 VAC Twin set up	23–1100	1500	500

▶ BIOSTAT® CultiBag RM 600 Optical

Single-Use Technology

Description
The BIOSTAT® CultiBag RM 600 optical is a large scale single-use bioreactor for culturing up to 300 L of media. It utilizes rocking motion agitation and has an integrated Sartorius Stedim controller. Superior BioPAT® MFCS│DA data logging software is included in this application driven package.

Applications
Rocking Motion is ideal for cell cultivation with low shear. Single-use bag technology reduces validation costs, removes the need for cleaning, sterilizing, and reduces shear stress to cells. Easy to use, it is applicable to all cell types, including mammalian cells, plant cells, insect cells and various microbial cells.

The BIOSTAT® CultiBag RM 600 bioreactor can be used for seed production or manu-facturing under GMP.

Benefits
BIOSTAT® CultiBag RM bioreactor is a single-use bioreactor, which is flexible and easy to use. It does not require cleaning in place (CIP) and sterilizing in place (SIP) and reduces the risk of cross-contamination. Investment costs and set up time between batches are also reduced. Additionally, validation require-ments for single-use bioreactors are low.

Operating Principle
The Rocker unit moves side to side generating a fluid movement in the cell culture. In this way, the surface of the medium is continu-ously renewed for bubble free aeration. The control unit facilitates regulation of pH, DO, temperature, rocking rate and gas flow for optimal cell cultivation.

Rocker Unit
The Rocker unit with integrated bag holder holds one CultiBag RM 600 for cultivations from 60 to 300 L volume. Two clamps fix the bag along two sides on the bag holder.

A continuous adjustment of the rocking angle at an angle range between 4° and 10° is possible. A laser scanner below the Rocker controls the movement of the Rocker to ensure the user´s safety.

Control Tower
The BIOSTAT® CultiBag RM 600 has an inte-grated controller which allows simultaneous monitoring & control for pH, DO, tempera-ture, rocking angle and rocking rate.

The controller has a superior gassing system consisting of 4 rotameters (air, O_2, N_2, CO_2), 1 MFC for total flow and 1 MFC for CO_2. This allows two gassing strategies to be employed: either a constant CO_2│air ratio or an automatic mixture of air, O_2, N_2 and CO_2 by automatic feedback control from the pH and DO sensors. When operated under automatic control, a four stage cascade control system can be utilized to increase productivity and extend batch age. An over-pressure control system is built-in for bag safety and culture integrity. The system will shut down gas flow when overpressure is breached and will then restart when the system pressure returns within range.

Intuitive Touch Screen
The BIOSTAT® RM Control Tower incorporates industrial PC hardware-based technology with Sartorius Stedim Systems touch screen interface. The screen is intuitive, easy to use and reduces staff training time. The Controller includes a trend display, which can plot up to six parameters at the same time.

Sensors

– Disposable optical chemical sensors for pH and DO are pre-installed in every optical and perfusion bag as a closed system

– Range: pH: 5.5–8.5
  DO: 0–100%

– pH and DO recalibration function

Software BioPAT® MFCS | DA

– Plug and Play configuration

– Online data acquisition

– Sample data management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

– Upgrade to advanced BioPAT® MFCS/Win
  control software possible

CultiBag RM 600
Single-use CultiBag RM bioreactor chamber
is made of a multilayer film, USP class VI
tested, with ethyl vinyl acetate (EVA) as the
media contact layer. Bags are available in
optical (with pH | DO sensors) configuration
only. Sterile tube connections allow addition
of media to the cultivation chamber.
For more information about disposable
bioreactor chambers please refer to our
datasheet CultiBag RM. CultiBag RM 600
is not part of the hardware package and
needs to be ordered separately.

▷ Specifications

Technical Specifications

Power requirements	208 VAC	400 VAC
Dimensions (W × D× H)	1790 × 1470 × 1330 cm
Weight	340 kg
Housing	Stainless steel
Interface	Ethernet, RS232
Temperature range	ambient -45 °C, ± 0.2 °C
Rocking angle	4–10 degrees, ± 0.3°
Rocking rate	2–16 rocks/min, ± 1 rocks/min

Disposable Sensor

Optical Chemical	
pH	5.5–8.5
PO_2	0–100%

BIOSTAT® CultiBag RM – Ordering Information

DH-600 L O RM - 4

Disposable Hardware

Volume

Units (Example: L = Liter)

Package Type
O = Optical

Rocking Motion Mixing Technology

Special Additions

Voltage
3 = 208 VAC (50 | 60 Hz)
4 = 400 VAC (50 | 60 Hz)
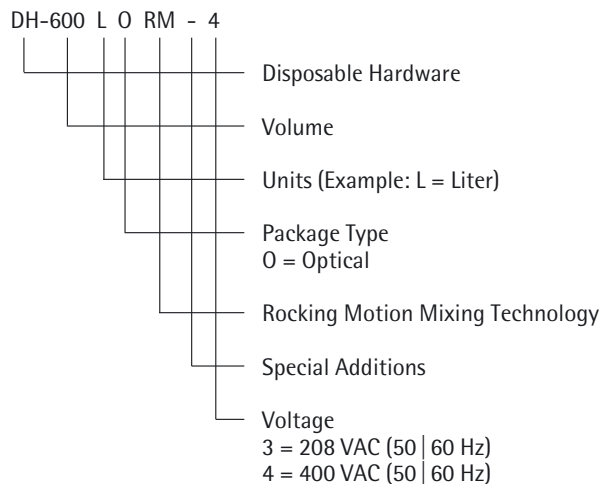
Order Code	Description
DH-600LORM-3	Package BIOSTAT® CultiBag RM 600 optical – 208 VAC Rocker 600 with BIOSTAT® RM Control Tower 600 optical
DH-600LORM-4	Package BIOSTAT® CultiBag RM 600 optical – 400 VAC

► CultiBag RM

Single-Use Technology
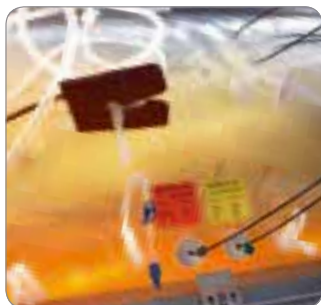
Description
The CultiBag RM is a disposable bag optimised for cell cultivation. Bags are available in multiple sizes and configurations depending on customer requirements. The inner layer of the disposable bioreactor bag is made of ethyl vinyl acetate (EVA), which shows excellent biocompatibility.

Applications
Our systems use rocking motion mixing technology which is ideal for cell cultivation with low shear stress. Easy to use, it is hassle free and applicable to all cell types, including mammalian cells, stem cells, plant cells, insect cells and microbial cells.

Cost Reduction and Risk Minimization
Disposable Bags and single-use systems in general used in biopharmaceutical manufacturing improve process safety and reduce costs at the same time. Time and capacity consuming CIP & SIP operations are minimized.

Flexibility
The CultiBag RM is available in 1 L, 2 L, 10 L, 20 L, 50 L, 100 L, 200 L and 600 L bag sizes. Bags are available as basic, optical (with pH | DO sensors) and perfusion pro (with pH | DO sensors and internal perfusion membrane).

Easy Implementation, Flexible Combinations
CultiBag RM Bags are supplied sterilized and ready to use. Setup times are kept to a minimum. The CultiBag RM can be mounted on the bag holder of the rocker easily and is secured on both sides with fixation clamps. Your process can be started right away. Media can be filled into the bag up to the required volume. A seed culture is added to the bag and cultivation is started under optimized conditions of aeration, temperature and mixing. Combining your basic rocker with our BIOSTAT® RM Control Tower will optimize your process for real culturing convenience.

Sterile connection and disconnection devices like the BioWelder® or the BioSealer®, which are also provided by Sartorius Stedim Biotech, can be used to make safe connections between the C-flex 374 thermoplastic tubings which are used on all CultiBag RM bags. Needle-free sampling ports allow easy and convenient sampling without the risk of contamination.

Sensors
Single-use sensors for pH and DO come pre-installed and pre-sterilized with the bag. This avoids risky insertion of traditional sensors.

An optical fibre connects to the sensor patch through a sterile barrier at the end of a sleeve in the bag. Sterility is maintained at all times. The optical fibre transmits light of specific wavelength to the sensor patch and returns the luminescence response from the sensor back to the measuring amplifier. Calibration is fast and easy.

▷ Specifications

Operating Volumes

Bag Size	Min [l]	Max [l]	Total [l]
1 L	0.1	0.5	1
2 L	0.2*	1	2
10 L	1.0*	5	10
20 L	2.0*	10	20
50 L	5.0*	25	50
100 L	10*	50	100
200 L	20*	100	200
600 L	60*	300	600

* Bags with sensors might require higher
   min. working volumes

Validation and Extractables Testing
CultiBag RM Bags have been qualified
applying the most complex and innovative
test regimes. Biological, chemical and physical
tests combined with extractable testing
proove lowest extractables and leechables
levels and excellent compatibilty to the
relevant pharmacopoeias and guidelines.
For more information, please refer to our
Validation Guide and Extractables Guide.
A leachables testing service is also available.
Please contact your local Sartorius Stedim
Biotech representative for further informa-
tion.

Quality Assurance
All relevant materials are selected following
applicable regulations and standards such as
FDA, CFR's, cGMPs and inhouse guidelines.
This includes the terms of delivery and
acceptance of our purchasing department.
Finished CultiBag RM bags undergo final
product quality control which is certified with
the Quality Assurance certificate included
with every bag.

Quality Management Systems
Sartorius Stedim Biotech has implemented
a certified Quality Management System
according to well established standards.
The complete Quality Systems Certificates
are continuosly updated and can be
downloaded on our website:
www.sartorius-stedim.com/qm-certificates.

Rapid Supply
All standard CultiBag RM Bags are available
from stock. Multiple warehouse locations
ensure fast delivery all over the world.

Bag Ports

CultiBag RM basic	Air Inlet | Air Outlet filter Sample port Fill | drain and spare ports Female luer, male luer, female MPC or male MPC connectors Ports with dip tubes Tubing material: C-Flex® 374; Silicone
CultiBag RM basic screw cap	Air Inlet | Air Outlet filter Sample port Fill | drain and spare ports Female luer, male luer, female MPC or male MPC connectors Ports with dip tubes Tubing material: C-Flex® 374; Silicone 38 mm screw cap
CultiBag RM optical	Air Inlet | Air Outlet filter Sample port Fill | drain and spare ports Female luer, male luer, female MPC or male MPC connectors Ports with dip tubes Optical chemical DO sensor Optical chemical pH sensor Tubing material: C-Flex® 374; Silicone
CultiBag RM perfusion pro	Air Inlet | Air Outlet filter Sample port Fill | drain and spare ports Female luer, male luer, female MPC or male MPC connectors Ports with dip tubes Optical chemical DO sensor Optical chemical pH sensor Feed | harvest ports Acid | base ports Tubing material: C-Flex® 374; Silicone; PharMed®

Ordering Information

DB B 002 L – – – – – – – –

Disposable Bags

Package Type
B = Basic
O = Optical
P = Perfusion
C = Customized

Total Volume
001 = 1 L
002 = 2 L
010 = 10 L
020 = 20 L
050 = 50 L
100 = 100 L
200 = 200 L
600 = 600 L

Units
L = Liter

Bag Version
– = 1.2 µm pore size (perfusion pro bag)
     or
     standard (basic and optical bag)
2 = Bag design fits Rocker 2
5 = 5 µm pore size (perfusion pro bag)

Vent Filter Type

Membrane
SM = Sartorius Stedim Biotech
         perfusion pro membrane

Design number

Design variation

	Order Code	Description
Basic Bags		
Example:	DBB020L	CultiBag RM 20 L basic for Rocker 20 | 50
	DBB002L2	CultiBag RM 2 L basic for Rocker 2
Optical Bags		
For Example:	DBO020L	CultiBag RM 20 L optical
Perfusion Pro Bags		
Example:	DBP020L--SM	CultiBag RM 20 L perfusion pro; 1.2 µm pore size
	DBP020L5-SM	CultiBag RM 20 L perfusion pro; 5 µm pore size
Customized Bags	Customer own bag design	
For Example:	DBC002L----01xx	CultiBag RM 2 L customized customer version

Bag Configurations
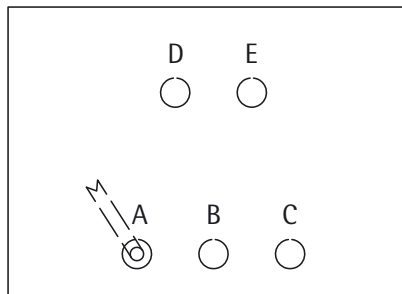
CultiBag RM 1 L basic | CultiBag RM 1L Basic (for Rocker 2)

DBB001L		
DBB001L2	**Ports**	
	Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port B	Septum for needle-free sampling, FM-Luer
	Port C	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port D	Gas Outlet Filter with Check Valve, M-Luer
	Port E	Gas Inlet Filter 1/4" Hose barb
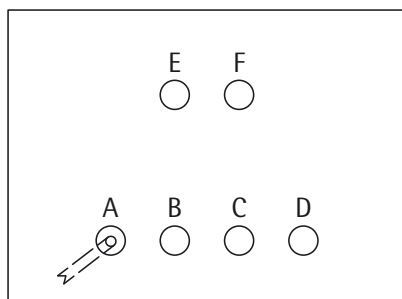
CultiBag RM 2L Basic | CultiBag RM 2L Basic (for Rocker 2)

DBB002L		
DBB002L2	**Ports**	
	Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port B	Septum for needle-free sampling, FM-Luer
	Port C; D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port E	Gas Outlet Filter with Check Valve, M-Luer
	Port F	Gas Inlet Filter 1/4" Hose barb

CultiBag RM 10L Basic | CultiBag RM 10L Basic (for Rocker 2)

DBB010L		
DBB010L2*	**Ports**	
	Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
	Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-luer
	Port C	Septum for needle-free sampling, FM-Luer
	Port D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port E	Gas Outlet Filter with Check Valve, M-Luer
	Port F	Gas Inlet Filter 1/4" Hose barb

CultiBag RM 20 L basic

DBB020L	**Ports**	
	Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
	Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-luer
	Port C	Septum for needle-free sampling, FM-Luer
	Port D; G	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port E	Gas Outlet Filter with Check Valve, M-Luer
	Port F	Gas Inlet Filter 1/4" Hose barb

* For bags that fit on the Rocker 2 the ports C and D are mounted vice versa.
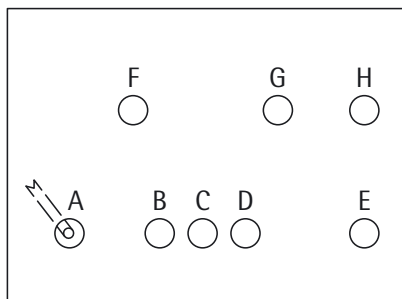
CultiBag RM 50L basic

DBB050L	Ports	
	Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
	Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port C	Septum for needle-free sampling, FM-Luer
	Port D; H	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port E	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), M-MPC
	Port F	Gas Outlet Filter with Check Valve, M-Luer
	Port G	Gas Inlet Filter 1/4" Hose barb
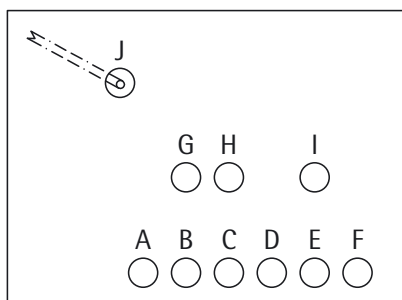
CultiBag RM 100 L basic

DBB100L	Ports	
	Port A; C	Silicone tubing 3/16" × 5/16" (50 mm)
	Port B	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
	Port D; E	Septum for needle-free sampling, FM-Luer
	Port F	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port G	Gas Outlet Filter, M-Luer
	Port H; I	Gas Inlet Filter 3/16" Hose barb
	Port J	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC

CultiBag RM 200 L basic

DBB200L	Ports	
	Port A; C	Silicone tubing 3/16" × 5/16" (50 mm)
	Port B	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
	Port D; E	Septum for needle-free sampling, FM-Luer
	Port F	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port G	Gas Outlet Filter, M-Luer
	Port H; I	Gas Inlet Filter 3/16" Hose barb
	Port J	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC

CultiBag RM 2L Basic Screw Cap

DBB002L----01SC **Ports**

Port	Description
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	Septum for needle-free sampling, FM-Luer
Port C; D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luerr
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1/4" Hose barb
Port G	Screw Cap 38 mm
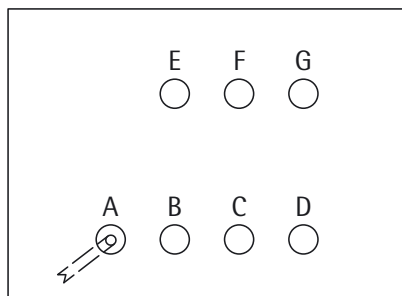
CultiBag RM 10L Basic Screw Cap

DBB010L----01SC **Ports**

Port	Description
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1/4" Hose barb
Port G	Screw Cap 38 mm

CultiBag RM 20L Basic Screw Cap

DBB020L----01SC **Ports**

Port	Description
Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port C	Septum for needle-free sampling, FM-Luer
Port D; G	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port E	Gas Outlet Filter with Check Valve, M-Luer
Port F	Gas Inlet Filter 1/4" Hose barb
Port H	Screw Cap 38 mm
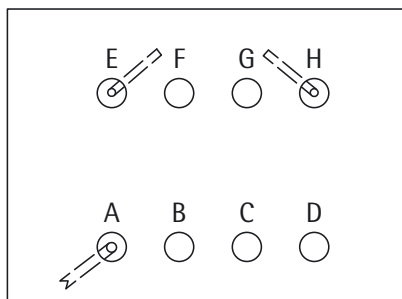
CultiBag RM 2L Optical

DBO002L	Ports	
	Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port B	Septum for needle-free sampling, FM-Luer
	Port C;D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port E	DO sensor
	Port F	Gas Outlet Filter with Check Valve, M-Luer
	Port G	Gas Inlet Filter 1/4" Hose barb
	Port H	pH sensor

CultiBag RM 10L Optical

DBO010L	Ports	
	Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
	Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port C	Septum for needle-free sampling, FM-Luer
	Port D	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port E	DO sensor
	Port F	Gas Outlet Filter with Check Valve, M-Luer
	Port G	Gas Inlet Filter 1/4" Hose barb
	Port H	pH sensor

CultiBag RM 20L Optical

DBO020L	Ports	
	Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
	Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port C	Septum for needle-free sampling, FM-Luer
	Port D	DO sensor
	Port E	pH sensor
	Port F	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port G	Gas Outlet Filter with Check Valve, M-Luer
	Port H	Gas Inlet Filter 1/4" Hose barb
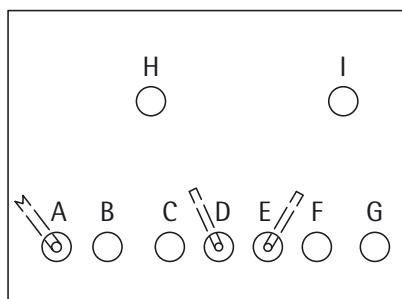
CultiBag RM 50L Optical

DBO050L	Ports	
	Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
	Port B	C-Flex® 374 tubing 1/8"× 1/4" (1000 mm), FM-Luer
	Port C	Septum for needle-free sampling, FM-Luer
	Port D	DO sensor
	Port E	pH sensor
	Port F	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port G	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), M-MPC
	Port H	Gas Outlet Filter with Check Valve, M-Luer
	Port I	Gas Inlet Filter 1/4" Hose barb
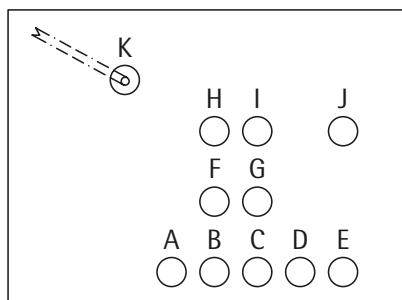
CultiBag RM 100L Optical

DBO100L	Ports	
	Port A	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
	Port B	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port C; D	Septum for needle-free sampling, FM-Luer
	Port E	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port F	DO sensor
	Port G	pH sensor
	Port H	Gas Outlet Filter, M-Luer
	Port I; J	Gas Inlet Filter 1/4" Hose barb
	Port K	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC

CultiBag RM 200L Optical

DBO200L	Ports	
	Port A	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
	Port B	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
	Port C; D	Septum for needle-free sampling, FM-Luer
	Port E	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port F	DO sensor
	Port G	pH sensor
	Port H	Gas Outlet Filter, M-Luer
	Port I; J	Gas Inlet Filter 1/4" Hose barb
	Port K	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC

CultiBag RM 600L Optical

Ports

Port A	Dip Tube Silicone, C-Flex® 374 tubing 3/8" x 5/8" (2000 mm), PharMed® tubing 3/8" × 5/8" (600 mm), FM-MPC
Port B; C	Septum for needle-free sampling, FM-Luer
Port D	DO sensor
Port E	pH sensor
Port F	Dip Tube Silicone, C-Flex® 374 tubing 3/8" x 5/8" (1000 mm), M-MPC
Port G	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
Port H	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port I	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), M-MPC
Port J	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (2000 mm), M-MPC
Port K; L; M	Gas Outlet Filter, M-Luer
Port N; O	Gas Inlet Filter 1/4" Hose barb
Port P	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (2500 mm), M-MPC
Port Q	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (2500 mm), FM-MPC
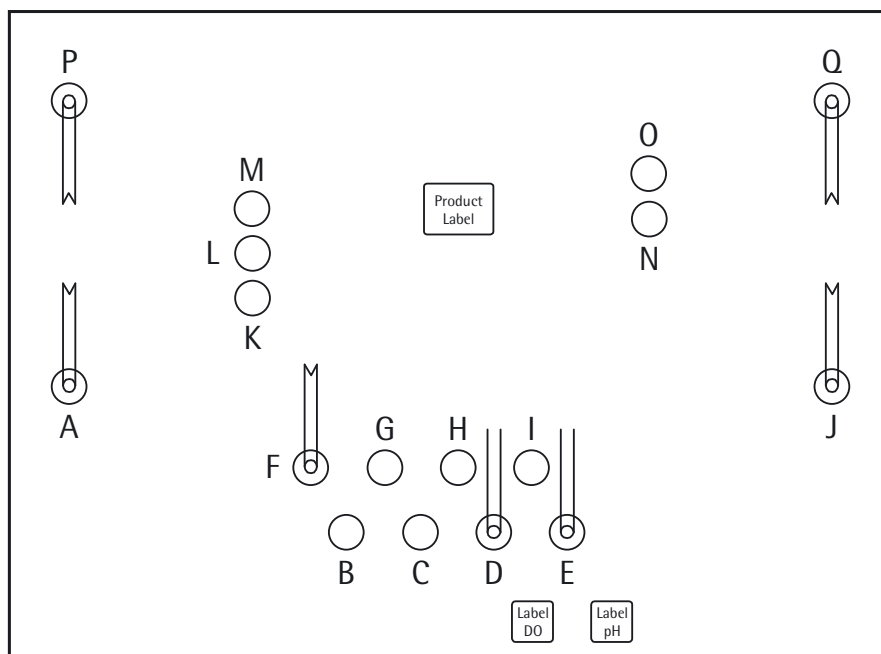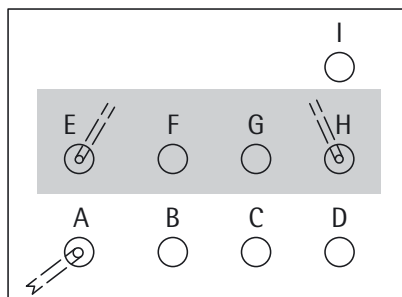
CultiBag RM 2L Perfusion Pro

**DBP002L--SM |
DBP002L5-SM**   **Ports**

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Feed)
Port B	Septum for needle-free sampling, FM-Luer
Port C	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port D	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/16" × 3/16" (300 mm), FM-Luer (Perfusion Harvest)
Port E	DO sensor
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter 1/4" Hose barb
Port H	pH sensor
Port I	Silicone tubing 3/16" × 5/16" (50 mm), FM-Luer
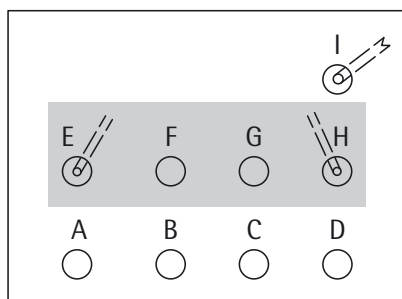
CultiBag RM 10L Perfusion Pro

**DBP010L--SM |
DBP010L5-SM**   **Ports**

Port A	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed®1/16" x 3/16" (300 mm), FM-Luer (Perfusion Feed)
Port C	Septum for needle-free sampling, FM-Luer
Port D	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed®1/16" × 3/16" (300 mm), FM-Luer (Perfusion Harvest)
Port E	DO sensor
Port F	Gas Outlet Filter with Check Valve, M-Luer
Port G	Gas Inlet Filter 1/4" Hose barb
Port H	pH sensor
Port I	Dip tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
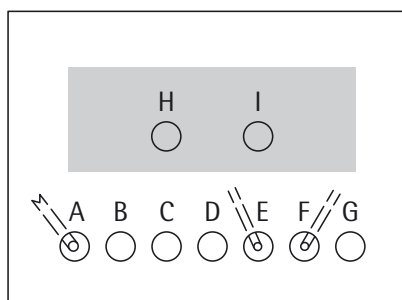
CultiBag RM 20L Perfusion Pro

**DBP020L--SM |
DBP020L5-SM**   **Ports**

Port A	Dip Tube Silicone, C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-luer
Port C	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/8" × 1/4" (300 mm), FM-Luer (Perfusion Feed)
Port D	Septum for needle-free sampling, FM-Luer
Port E	DO sensor
Port F	pH sensor
Port G	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/8" × 1/4" (300 mm), FM-Luer (Perfusion Harvest)
Port H	Gas Outlet Filter with Check Valve, M-Luer
Port I	Gas Inlet Filter 1/4" Hose barb
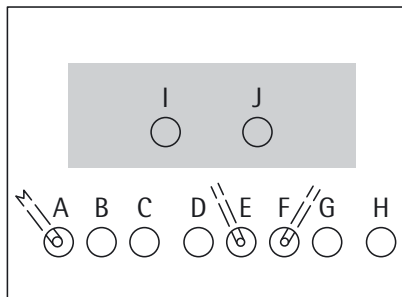
CultiBag RM 50L Perfusion Pro

DBP050L--SM | DBP050L5-SM	Ports	
	Port A	Dip Tube Silicone; C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), FM-MPC
	Port B	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port C	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/8"× 1/4" (300 mm), FM-Luer (Perfusion Feed)
	Port D	Septum for needle-free sampling, FM-Luer
	Port E	DO sensor
	Port F	pH sensor
	Port G	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), PharMed® 1/8" × 1/4" (300 mm), FM-Luer (Perfusion Harvest)
	Port H	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), M-MPC
	Port I	Gas Outlet Filter with Check Valve, M-Luer
	Port J	Gas Inlet Filter 1/4" Hose barb
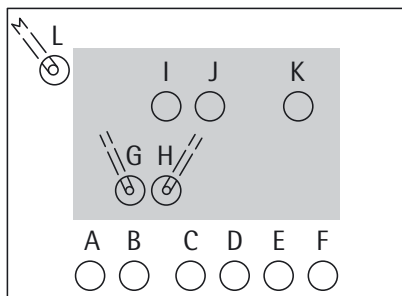
CultiBag RM 100L Perfusion Pro

DBP100L--SM | DBP100L5-SM	Ports	
	Port A	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port B	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), PharMed® 3/16" x 5/16" (300 mm), FM-Luer (Perfusion Feed)
	Port C	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
	Port D;E	Septum for needle-free sampling, FM-Luer
	Port F	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), PharMed® 3/16" x 5/16" (300 mm), FM-Luer (Perfusion Harvest)
	Port G	DO sensor
	Port H	pH sensor
	Port I	Gas Outlet Filter, M-Luer
	Port J;K	Gas Inlet Filter 1/4" Hose barb
	Port L	Dip Tube Silicone, C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC

CultiBag RM 200L Perfusion Pro

DBP200L--SM | DBP200L5-SM	Ports	
	Port A	C-Flex® 374 tubing 1/8" × 1/4" (1000 mm), FM-Luer
	Port B	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), PharMed® 3/16" x 5/16" (300 mm), FM-Luer (Perfusion Feed)
	Port C	C-Flex® 374 tubing 3/8" × 5/8" (1000 mm), M-MPC
	Port D;E	Septum for needle-free sampling, FM-Luer
	Port F	C-Flex® 374 tubing 1/4" × 7/16" (1000 mm), PharMed® 3/16" x 5/16" (300 mm), FM-Luer (Perfusion Harvest)
	Port G	DO sensor
	Port H	pH sensor
	Port I	Gas Outlet Filter, M-Luer
	Port J;K	Gas Inlet Filter 1/4" Hose barb
	Port L	Dip Tube Silicone, C-Flex 374 tubing 3/8" × 5/8" (1000 mm), M-MPC

Bag Accessories

Order Code	Description
DS-------GF	Light Conductor Cables for CultiBag RM optical and perfusion pro (2 pcs)
DS-------CGF	Clamps for Light Conductor Cable fixation (2 pcs)
DS-----RMFH	Filter Heater for outlet filter of CultiBag RM 1 L – 50 L
DS200L-RMFH	Filter Heater for outlet filter of CultiBag RM 100 L – 200 L
DS-------CV	Check Valves for outlet filter of CultiBag RM (50 pcs)

Temperature Control Unit RM 20 | 50

Description
The Temperature Control Unit RM 20|50 is an add-on module for the BIOSTAT® CultiBag RM 20|50, rocking platform bioreactor. It consists of a heating and cooling mechanism for precise temperature control of optical and perfusion systems. The system is ideally suited for cell cultivations below ambient conditions.

Applications
The Temperature Control Unit RM 20|50 is ideal for cell cultivation at low temperatures and environments where air conditioning is not available. It is also ideal for fermentations with high cell densities requiring cooling, and can be used under GMP conditions. The system is the ideal solution for cell culture applications which require superior temperature control. It is applicable to all cell types, including mammalian cells, plant cells, insect cells and microbial cells.

Operating Principle
The Temperature Control Unit RM 20 | 50 consists of a heating | cooling coil and a thermostat module. The thermostat module is located inside the BIOSTAT® RM Control Tower, and the heating | cooling coil is placed on the bag holder platform. The heating | cooling coil consists of two coil units. Water is circulated through the coil and the thermostat module – transferring energy from the circulating water within the coils to the cultivation chamber, CultiBag RM, or vice versa.

To increase the temperature, the heating element in the thermostat module, heats the circulating water to a calculated setpoint. To decrease temperature, a defined amount of tap water or external chilled water is injected into the circulation loop. Overflow of circulation water is vented to an outlet. The temperature is PID-Controlled. An additional PT-100 temperature sensor is installed in the thermostat module for monitoring and controlling the water temperature circulating in the coil, thereby avoiding bag overheating.

Benefits
The precise Temperature Control Unit RM 20|50 enables cultivation of micororganisms to high cell densities and cultivation of cells below ambient temperature. Easy to install, your BIOSTAT® CultiBag RM 20|50 system can be easily retrofitted with the Temperature Control Unit RM 20|50.

FRIGOMIX® 1000
The FRIGOMIX® 1000, recirculation water chiller can be applied when cooling water is either unavailable or when tap water is not cold enough to control temperature below ambient. Additionally, it can be used for rapid temperature shifts which are applicable to some processes. The FRIGOMIX® 1000 is cost effective and saves energy by recirculating the same clean water within the reservoir, compared to using a single stream of tap water or installing expensive cooling systems within the laboratory. The closed cooling cycle prevents deposits from the tap water supply from entering the cooling cycle and causing malfunction or damage to the cooling devices.

The FRIGOMIX® is flexible, easy to operate and reliable device. It allows inexpensive and precise temperature control below ambient temperature.

For more information please refer to our data sheet FRIGOMIX® 1000.

▷ Specifications

Technical Specifications Temperature Control Unit RM 20 | 50 Module

Effective energy transfer area of the heating	cooling coil (bag holder 20 and 50)	620 cm^2
Temperature range	8°C above the cooling water temperature up to 40°C
Water Circulation flow rate	2.5 l/min
Cooling water sources	– tab water or other cooling water sources (max. 2 barg) – Frigomix® 1000

Ordering Information

```
DH  –  050    L    T    RM    X    1    R
```

- Disposable Hardware
- Volume (050 = Bag holder 20 & 50)
- Units (Example: L = liter)
- Temperature Control Unit
- Mixing technology RM = rocking motion
- Placeholder
- Voltage
  1 = 120 VAC (50 | 60 Hz)
  2 = 230 VAC (50 | 60 Hz)
- Selection
  R = Retrofit RM System by Temperature Control Unit
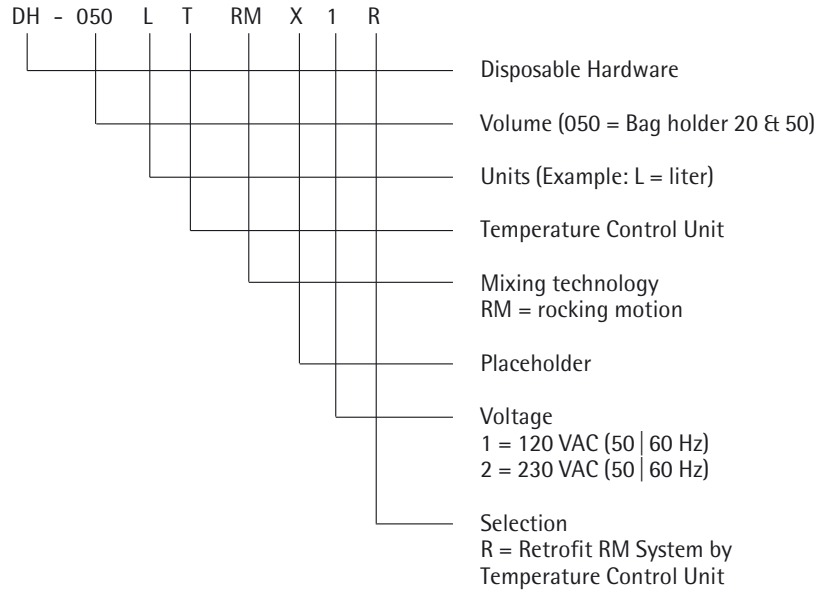
Order Code	Description
DH- 050 L TRMX1	Temperature Control Unit RM 20	50, 120 VAC
DH- 050 L TRMX2	Temperature Control Unit RM 20	50, 230 VAC
DH- 050 L TRMX1R	Retrofit Temperature Control Unit RM 20	50, 120 VAC
DH- 050 L TRMX2R	Retrofit Temperature Control Unit RM 20	50, 230 VAC

Order Number FRIGOMIX® 1000

BB-8522529

BIOSTAT® CultiBag STR Plus

Single-Use Technology

Packages

The BIOSTAT® CultiBag STR Plus single-use disposable bioreactor packages are specially configured for cell culture applications. The integrated, automatically-controlled gas mixing system provides advanced sparger and overlay aeration. Air and CO_2 are routed to Overlay. Air, N_2, O_2 and CO_2 are routed to Sparger. Control happens automatically via a DO and pH controller. Optional soft buttons the N_2 and O_2 can be used to redirect gases to overlay or sparger via manual selection.

Six rotameters are available for control of Air (2×), N_2, CO_2 (2×) and O_2. Up to 6 mass flow controllers may be added as options for individual flow rate adjustments of Air (2×), N_2, CO_2 (2×) and O_2.

BIOSTAT® STR Plus Control Tower

– For measurement & control hardware, pumps & gassing system

– Single and twin configurations for control of up to two single-use CultiBag STR cultivation vessels are available for 50 L and 200 L scale. 500 L and 1000 L available in single version.

– Installed on separate skid

Digital Control

– Graphical user interface with colour display and touch screen operation

– Integrated amplifiers for temperature, pressure, single-use DO and pH sensors

– Additional amplifiers for reusable DO & pH sensor available

– Integrated control loops for temperature, DO, pH, agitation, gas flow and substrate

– Multi-channel DO cascade control

– Calibration of DO and pH sensors

– In-process DO and pH recalibration

– Trend display for up to 6 process values

– Direct balance connections

Gassing Module

– 1 × Sparger outlet

– 1 × Overlay outlet

– 4-fold gasmixing of Air, N_2, O_2 and CO_2 for Sparger gassing

– Air and CO_2 for Overlay gassing

– Optional soft buttons allow for change of gassing direction for N_2 and O_2 from Sparger to Overlay

– Solenoid valves for Air (2×), N_2 (1×), O_2 (1×) and CO_2 (2×)

– Rotameters for Air (2×), N_2 (1×), O_2 (1×) and CO_2 (2×)

– Up to 6 optional Massflow Controllers* for Air (2×), N_2 (1×), O_2 (1×) and CO_2 (2×)

– Control via pH | DO controller

Pumps

– Integrated digital peristaltic pumps per side

– Configurable to pH or substrate controller

– Additional integrated or external feed pumps available on request

Temperature

Choice between heating only (for 50 L and 200 L scale) or heating | cooling (available for all sizes):

Heating Only

– 1 × 1.000 W and 2 × 500 W heating blankets around bag holder

– Temperature range: ambient - 40°C

– Automatic safety shutdown for prevention of overheating

– Filter Heater on exhaust filter

Heating | Cooling

– Jacketed vessel for cooling water

– Electrical heater:
  – 50 L & 200 L: 3.000 W
  – 500 L & 1000 L: 6.000 W

– Cooling water control valve

– Circulation pump

– Quick coupling connectors for the jacket of the bagholder

– Temperature range: 8°C above cooling water to 40°C

– Automatic safety shutdown for prevention of overheating

– Filter Heater on exhaust filter

Agitation System

– Magnetic drive

– Quiet operation

– Stirrer pre-installed inside single-use
  CultiBag STR

Bag Holder

– Installed on separate skid to the control
  tower; for easy connection and
  disconnection as required.

– Stainless Steel housing

– Electropolished

– Mobile

– 2 side windows for side ports

– 2 closable viewing windows

– Double door for installation of bags

Sensors

– Disposable optical chemical sensors for pH
  and DO are pre-installed in every bag

– Range: pH: 5.5 – 8.5
            DO: 0 – 100%

– PT100 reusable sensor for temperature
  measurement installed in a sleeve

– Additional probes available on request

**Disposable Cultivation Chamber:
CultiBag STR**

– Maximum working volume: 50 L, 200 L,
  500 L or 1000 L

– Minimum working volume: 25% of max.
  working volume

– Aspect Ratio (H:D) 1.8:1

– Stirrer pre-installed inside bag

– 2 × impellers

– Choice between 6-blade and 3-blade
  impellers

– Overlay and Sparger line

– Choice between ring and microsparger

– Dip tube

– Side Ports:
  – DO sensor
  – pH sensor
  – PT100 sensor
  – Needleless sampling device

– Bottom Drain Port

– Top Ports:
  – 2 × Gas IN, 1 × Gas OUT,
    including sterile filters
  – Feeding | Inoculation lines

– USP Class VI

SCADA Software BioPAT® MFCS/DA

– Plug and Play configuration

– Online data acquisition

– Sample data management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

– Upgrade to advanced BioPAT® MFCS/Win
  control software possible

Applications

– Cell culture of insect and mammalian cells

– Cell mass, protein, Mab & vaccine
  production

– Industrial and academic research

– Process development

– Process optimization

– Up- and down-scale studies

– Seed culture cultivation

– Large scale production up to 1000 L
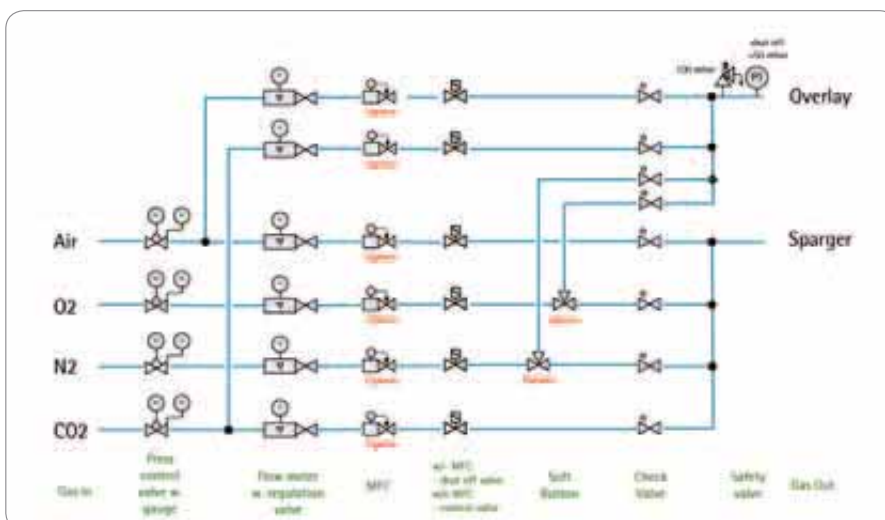
Features & Benefits

– Single & Twin configuration

– Single-use bioreactor in traditional reusable
  vessel design

– Large working volume range

– Flexible gassing system

– Individual gas flow adjustments via rotame-
  ters and optional mass flow controllers

– Disposable DO and pH sensors

– First completely single-use and scalable
  bioreactor on the market

– Bag holder design allows fast turn around
  from one cultivation to another

– Pressure safety control

– Advanced multi-channel cascaded
  DO control

– Intuitive touch screen interface for easy
  operation

– Traditional impeller and sparger types

– Convenient bag installation via double door

– Small footprint

– Supervisory Process Control software
  (BioPAT® MFCS/DA) included
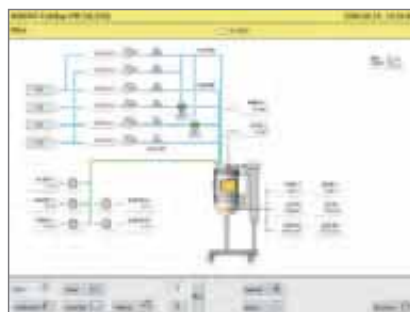
▷ Specifications

Technical Specifications

Hardware dimensions
W × H × D (mm)

BIOSTAT® CultiBag STR Plus,
single or double wall

BIOSTAT® CultiBag STR Plus 50 L
1723 × 1663 × 754

BIOSTAT® CultiBag STR Plus 200 L
1723 × 1663 × 754

BIOSTAT® CultiBag STR Plus 500 L
2148 × 2680 × 1204

BIOSTAT® CultiBag STR Plus 1000 L
2148 × 2680 × 1204

BIOSTAT® CultiBag STR Plus 50 L | 50 L
2652 × 1663 × 754

BIOSTAT® CultiBag STR Plus 200 L | 200 L
2652 × 1663 × 754

BIOSTAT® CultiBag STR Plus 50 L | 200 L
2652 × 1663 × 754

Technical Specifications

Description Hardware	"Pic STR Plus 50L" BIOSTAT® CultiBag STR Plus 50 L	"Pic STR Plus 200L" BIOSTAT® CultiBag STR Plus 200 L	"Pic STR Plus 500L" BIOSTAT® CultiBag STR Plus 500 L	"Pic STR Plus 1000L" BIOSTAT® CultiBag STR Plus 1000 L
Volume				
Total Volume	68 L	280 L	700 L	1300 L
Minimum Working Volume	12.5 L	50 L	125 L	250 L
Maximum Working Volume	50 L	200 L	500 L	1000 L
Power Supply				
208 VAC	×	×	×	×
400 VAC	×	×	×	×
Bag Holder				
Installed on skid	×	×	×	×
Electro-polished	×	×	×	×
Hemispherical doors	2	2	2	2
Holder for Air filters	×	×	×	×
Temperature Control	Only Heating or Heating|Cooling	Only Heating or Heating|Cooling	Heating|Cooling	Heating|Cooling
Viewing window	2	2	2	2
Opening for sideports	×	×	×	×
pT 100 probe	1	1	1	1
Pressure sensor	×	×	×	×
Sensor Clamps	×	×	×	×
Filter Heater	1	1	1	1
Top drive motor	×	×	×	×
Control Tower				
Single Version	×	×	×	×
Twin version	×	×	–	–
Installed on skid	×	×	×	×
Temperature Control, Single Wall	RT –40℃	RT –40℃	n|a	n|a
Temperature Control, Double Wall	8℃ above cooling water –40℃	8℃ above cooling water –40℃	8℃ above cooling water –40℃	8℃ above cooling water –40℃
Stirrer Speed	10 – 240 rpm	10 – 150 rpm	10 – 110 rpm*	10 – 90 rpm*
pH range	5.5 – 8.5	5.5 – 8.5	5.5 – 8.5	5.5 – 8.5
pH sensor in bag	1	1	2	2
DO range	0 – 100%	0 – 100%	0 – 100%	0 – 100%
DO sensor in bag	1	1	2	2
Amplifiers for:				
– Disposable DO sensor	1	1	1 | (2)	1 | (2)
– Disposable pH sensor	1	1	1 | (2)	1 | (2)
– Reusable DO sensor	(1)	(1)	(1 or 2)	(1 or 2)
– Reusable pH sensor	(1)	(1)	(1 or 2)	(1 or 2)
– Temperature	½	½	½	½
Multi-channel DO Cascade Control	×	×	×	×
Recalibration function for:				
– Disposable DO sensor	×	×	×	×
– Disposable pH sensor	×	×	×	×
Interface:				
– Ethernet	×	×	×	×
– RS232	2	2	4	4
– Analogue IN	2	2	4	4
– Analogue OUT	2	2	4	4
BioPAT® MFCS/DA	×	×	×	×
Gassing module Rotameter [L/min]:				
Sparger Line				
– O_2	0.7 – 5.5**	1.0 – 23**	6.0 – 56**	11.0 – 110**
– N_2	0.7 – 5.5**	1.0 – 23**	6.0 – 56**	11.0 – 110**
– CO_2	0.7 – 5.5**	1.0 – 23**	6.0 – 56**	11.0 – 110**
– Air	0.7 – 5.5**	1.0 – 23**	6.0 – 56**	11.0 – 110**
Overlay Line				
– Air	0.7 – 5.5**	1.0 – 23**	6.0 – 56**	11.0 – 110**
– CO_2	0.7 – 5.5**	1.0 – 23**	6.0 – 56**	11.0 – 110**
MFC for:				
Sparger Line				
– O_2	(0.1 – 5.0)**	(0.4 – 20)**	(1.0 – 50)**	(2.0 – 100)**
– N_2	(0.1 – 5.0)**	(0.4 – 20)**	(1.0 – 50)**	(2.0 – 100)**
– CO_2	(0.1 – 5.0)**	(0.4 – 20)**	(1.0 – 50)**	(2.0 – 100)**
– Air	(0.1 – 5.0)**	(0.4 – 20)**	(1.0 – 50)**	(2.0 – 100)**
Overlay Line				
– Air	(0.1 – 5.0)**	(0.4 – 20)**	(1.0 – 50)**	(2.0 – 100)**
– CO_2	(0.1 – 5.0)**	(0.4 – 20)**	(1.0 – 50)**	(2.0 – 100)**
Soft Button for:				
– N_2	(×)	(×)	(×)	(×)
– O_2	(×)	(×)	(×)	(×)
Pumps & Balances				
Digital Pumps WM102	3	3	–	–
Digital Pumps WM313D	–	–	3	3
Analogue Pumps (via Analogue OUT)	(up to 2)	(up to 2)	(up to 4)	(up to 4)
Balances (via RS232)	(up to 2)	(up to 2)	(up to 4)	(up to 4)

*　Valid in case 2 × 3-blade impellers are used. In case of 1 × 3-blade + 1 × 6-blade impeller maximum stirrer speed may be reduced depending on the filling level.
　　For more info please contact your local Sartorius Stedim Biotech representative.
**　Alternative lower flow ranges are available on request
( )　optional, needs to be ordered separately

▶ CultiBag STR
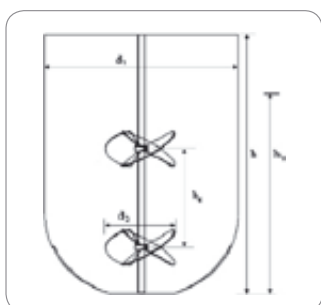
Description

The CultiBag STR is a cultivation chamber optimized for cell cultivation. Bags are available in various configurations depending on customer requirements. The CultiBag STR is available in working volumes of 12.5 L – 1000 L. The CultiBag STR utilizes stirred motion mixing technology and can be combined with the expert control capabilities of the Sartorius Stedim Biotech Controller.

Applications

Single-use bag technology results in improvements in validation costs, removes the need for cleaning and sterilization and reduces contamination risk. Easy to use, it is hassle-free and applicable to a large variety of cell types, such as insect cells and mammalian cells.

Single-Use Cultivation Chamber

The CultiBag STR has a working range of 12.5 to 1000 L depending on the bag type. Its vertically positioned stirrer is pre-installed inside the bag and contains two impellers. Both 3-blade pitched as well as 6-blade disk impellers are available. Traditional ring and micro spargers are available for integration inside the CultiBag STR. A dip tube allows gentle feeding without shear stress. Furthermore, various ports are available for feed, inoculation, harvest and sampling. Single-use optical chemical sensors for pH and DO are pre-installed in every CultiBag STR.

Bag Geometry and Ratios

The CultiBag STR design is entirely based on the gold standard coming from conventional stainless steel bioreactors. This allows for an easy transfer from stainless steel to single-use. Besides the above mentioned gassing and mixing solutions this approach is also applied to all dimensions and ratios applicable to the single-use vessel. Tabel 1 shows all relevant details and demonstrates clearly that these fall perfectly in line within the classical ranges.

CultiBag STR	50 L	200 L	500 L	1000 L
Volume				
Total Volume [L]	68	280	700	1300
Minimum Working Volume [L]	12.5	50	125	250
Maximum Working Volume [L]	50	200	500	1000
Bag Diameter d_1 [mm]	370	585	815	997
Bag Height h [mm]	666	1055	1467	1800
Ratio h/d_1	1.8	1.8	1.8	1.8
Liquid Height h_1 [mm]	480	783	1005	1360
Ratio h_1/d_1	1.29	1.34	1.23	1.36
Impeller Diameter d_2 [mm]	143	225	310	379
Ratio d_2/d_1	0.39	0.38	0.38	0.38
Distance between Impellers h_6 [mm]	186	300	403	493

Sensors

Single-use sensors for pH and DO come pre-installed and pre-sterilized with the bag. This avoids risky insertion of traditional sensors. An optical fibre connects to the sensor patch through a sterile barrier at the end of a sleeve in the bag. Sterility is maintained at all times. The optical fibre transmits light of specific wavelength to the sensor patch and returns the luminescence response from the sensor back to the measuring amplifier. Calibration is fast and easy. A PT100 reusable sensor for temperature is installed inside a special silicon sleeve.

Easy Implementation, Flexible Combinations

CultiBag STR bags are supplied sterilized and ready to use. This allows easy process implementation and setup times are kept to a minimum. The cylindrical bag holder is designed as two hemispherical doors which can be opened for easy installation of the CultiBag STR. Sterile connection and disconnection devices like the BioWelder® or the BioSealer®, also provided by Sartorius Stedim Biotech, can be used for safe transfer of your medium to the next process step. Needle-free sampling ports allow easy and convenient sampling without the risk of cross contamination.

Bag Material

The CultiBag STR has a multilayer film structure to provide a robust structure with low gas permeability and high chemical resistance. Polyethylene terephtalate (PET) acts as a light, strong and clear protective layer. PET provides robustness and contributes to the reduction of gas transition through the film.

Polyamide (PA) increases durability and strengthens the bag as well as reducing gas transition through the film.

Ethyl Vinyl Alcohol (EVOH) acts as the main gas barrier minimizing transmission of gases such as O_2 and CO_2 across the film.

The contact layer is made of ultra-low density polyethylene (ULDPE). ULDPE is in compliance with respective pharmacopoeias and provides a clean, inert and highly chemical resistant contact layer.

The different layers are linked together by a thermoset polymer in compliance with the FDA Regulation 21CFR § 177.1390 (c)(2)(VI).

Total film thickness is 200 ± 25 µm.

The bag material is certified BSE | TSE free and is in compliance with the EMEA's guidance (EMEA | 410 | 01) and the European Pharmacopoeia # 5.2.8. on minimizing the risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Product. Furthermore, it meets or exceeds the requirements of the USP Class VI – 70°C Plastic tests and is considered as non-cytotoxic and non-haemolytic.

Quality Assurance

For quality assurance, all materials are selected carefully in accordance with current regulations, such as FDA CFRs, cGMP's in-house guidelines and the specifications of our Research and Development Department. This includes the terms of delivery and acceptance of our Purchasing Department. Finished CultiBag STR bags undergo final product quality control.

Quality Management Systems

Sartorius Stedim Biotech implemented Quality Management Systems to assure consistent high quality of products for Biotechnology. Exemplary Quality Systems Certificates:

Quality Management System
SQS ISO 9001:2000

Quality Management System
TÜV Nord Certificate
DIN EN ISO 9001:2000

Quality Management System
Intertek Certificate
ISO 9001:2000

The complete Quality Systems Certificates are continuously updated and can be downloaded on our website:
www.sartorius-stedim.com/qm-certificates

Ordering Information

For more info on ordering a single-use CultiBag STR please contact your Sartorius Stedim Biotech representative.

Standard CultiBag STR 50 L & 200 L Design
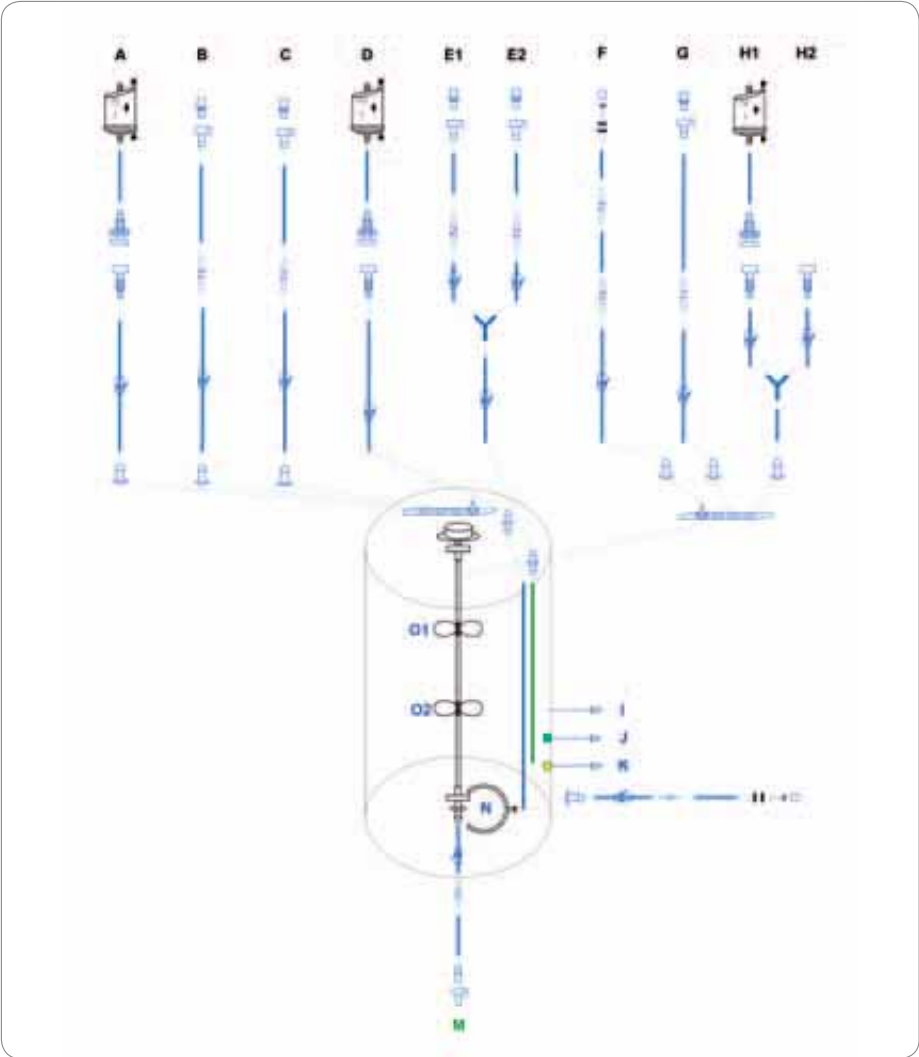
CultiBag STR 50 L, Article Number FRB114043

Pos.	Function	Description	Total Length*	Distal Connection
A	Overlay Aeration	Si(Pt) tube 1/2" ID × 3/4" OD (150 mm) + OPTA SFT-I aseptic connector 1/2" + Si(Pt) tube 1/2" ID × 3/4" OD (150 mm)	300 mm	0.2 sterile grade air filter
B	Feed	Si(Pt) tube 3/8" ID × 5/8" OD (2500 mm) connects to C-Flex® tube 3/8" ID × 5/8" OD (500 mm)	3000 mm	Quick Coupling Female 3/8" + plug
C	Feed	Si(Pt) tube 3/8" ID × 5/8" OD (2500 mm) connects to C-Flex® tube 3/8" ID × 5/8" OD (500 mm)	3000 mm	Quick Coupling Female 3/8" + plug
D	Sparging Aeration	Internal ring sparger connects to Si(Pt) tube 3/8" ID × 5/8" OD (650 mm) tube connects outside the bag to Si(Pt) tube 1/2" ID × 3/4" OD (150 mm) + OPTA SFT-I aseptic connector 1/2" + Si(Pt) tube 1/2" ID × 3/4" OD (150 mm)	950 mm	0.2 sterile grade air filter
E	Feed	Internal Si(Pt) tube 3/8" ID × 5/8" OD (500 mm) connects outside the bag to Si(Pt) tube 3/8" ID × 5/8" OD (1000 mm) splits to: E1: Si(Pt) tube 1/4" ID x 3/8" OD (750 mm) connects to C-Flex® tube 1/4" ID x 7/16" OD (500 mm) E2: Si(Pt) tube 3/8" ID x 5/8" OD (750 mm) connects to C-Flex® tube 3/8" ID x 5/8" OD (500 mm)	2750 mm	E1: Quick Coupling Female 1/4" + Plug E2: Quick Coupling Female 3/8" + plug
F	Addition base	Si(Pt) tube 1/4" ID × 3/8" OD (150 mm) connects to Si(Pt) tube 1/8" ID × 1/4" OD (500 mm) connects to C-Flex® 1/8" ID × 1/4" OD (500 mm)	1150 mm	Clave connector Female Luer 1/8"
G	Feed	Si(Pt) tube 1/4" ID × 3/8" OD (2500 mm) connects to C-Flex® tube 1/4" ID × 3/8" OD (500 mm)	3000 mm	Quick Coupling Female 1/4" + plug
H	Gas Out	Si(Pt) tube 1/2" x 3/4" OD (100 mm) splits to: H1: Si(Pt) tube 1/2" x 3/4" OD (150 mm) + OPTA SFT-I aseptic connector 1/2" + Si(Pt) tube 1/2" x 3/4" OD (150 mm) H2: Si(Pt) tube 1/2" x 3/4" OD (150 mm)	H1: 400 mm H2: 250 mm	H1: 0.2 sterile grade air filter H2: OPTA SFT-I aseptic connector 1/2", Male*
I	T sensor	Thermowell sensor port for pT100 sensor (Inside length 135 mm)	74 mm	/
J	DO sensor	Thermowell sensor port for glass fibre cable DO sensor (Inside length 75 mm)	50 mm	/
K	pH sensor	Thermowell sensor port for glass fibre cable pH sensor (Inside length 75 mm)	50 mm	/
L	Small volume sampling	Si(Pt) tube 1/4" ID × 3/8" OD (150 mm) reduced to C-Flex® tube 1/8" ID × 1/4" OD (500 mm)	650 mm	Clave connector Female Luer 1/8"
M	Bottom Drain Harvest	Si(Pt) tube 1/2" ID × 3/4" OD (2500 mm) connects to C-Flex® tube 3/8" ID × 5/8" OD (500 mm)	3000 mm	Quick Coupling Male 3/8" + plug
N	Sparger	Ring sparger	/	/
O	Stirrer	O1=3-blade pitched top bottom impellers + O2=3-blade pitched top bottom impellers	/	/

* A second exhaust filter line, article n° DS200L-SBFLO, can be ordered separately as an option for connection to line H2.
  This back-up filter line can than easily be installed during cell cultivation to line H2 in case a problem occurs on filter line H1.

CultiBag STR 200 L, Article Number FRB112855

Pos.	Function	Description	Total Length*	Distal Connection
A	Overlay Aeration	Si(Pt) tube 1/2" ID × 3/4" OD (150 mm) + OPTA SFT-I aseptic connector 1/2" + Si(Pt) tube 1/2" ID × 3/4" OD (150 mm)	300 mm	0.2 sterile grade air filter
B	Feed	Si(Pt) tube 3/8" ID × 5/8" OD (2500 mm) connects to C-Flex® tube 3/8" ID × 5/8" OD (500 mm)	3000 mm	Quick Coupling Female 3/8" + plug
C	Feed	Si(Pt) tube 3/8" ID × 5/8" OD (2500 mm) connects to C-Flex® tube 3/8" ID × 5/8" OD (500 mm)	3000 mm	Quick Coupling Female 3/8" + plug
D	Sparging Aeration	Internal ring sparger connects to Si(Pt) tube 3/8" ID × 5/8" OD (1250 mm) tube connects outside the bag to Si(Pt) tube 1/2" ID × 3/4" OD (150 mm) + OPTA SFT-I aseptic connector 1/2" + Si(Pt) tube 1/2" ID × 3/4" OD (150 mm)	1550 mm	0.2 sterile grade air filter
E	Feed	Internal Si(Pt) tube 3/8" ID × 5/8" OD (1000 mm) connects outside the bag to Si(Pt) tube 3/8" ID × 5/8" OD (1000 mm) splits to: E1: Si(Pt) tube 1/4" ID x 3/8" OD (750 mm) connects to C-Flex® tube 1/4" ID x 7/16" OD (500 mm) E2: Si(Pt) tube 3/8" ID x 5/8" OD (750 mm) connects to C-Flex® tube 3/8" ID × 5/8" OD (500 mm)	3250 mm	E1: Quick Coupling Female 1/4" + Plug E2: Quick Coupling Female 3/8" + plug
F	Addition base	Si(Pt) tube 1/4" ID × 3/8" OD (150 mm) connects to Si(Pt) tube 1/8" ID × 1/4" OD (500 mm) connects to C-Flex® 1/8" ID × 1/4" OD (500 mm)	1150 mm	Clave connector Female Luer 1/8"
G	Feed	Si(Pt) tube 1/4" ID × 3/8" OD (2500 mm) connects to C-Flex® tube 1/4" ID × 3/8" OD (500 mm)	3000 mm	Quick Coupling Female 1/4" + plug
H	Gas Out	Si(Pt) tube 1/2" x 3/4" OD (100 mm) splits to: H1: Si(Pt) tube 1/2" x 3/4" OD (150 mm) + OPTA SFT-I aseptic connector 1/2" + Si(Pt) tube 1/2" x 3/4" OD (150 mm) H2: Si(Pt) tube 1/2" x 3/4" OD (150 mm)	H1: 400 mm H2: 250 mm	H1: 0.2 sterile grade air filter H2: OPTA SFT-I aseptic connector 1/2", Male*
I	T sensor	Thermowell sensor port for pT100 sensor (Inside length 135 mm)	135 mm	/
J	DO sensor	Thermowell sensor port for glass fibre cable DO sensor (Inside length 75 mm)	75 mm	/
K	pH sensor	Thermowell sensor port for glass fibre cable pH sensor (Inside length 75 mm)	75 mm	/
L	Small volume sampling	Si(Pt) tube 1/4" ID × 3/8" OD (150 mm) reduced to C-Flex® tube 1/8" ID × 1/4" OD (500 mm)	650 mm	Clave connector Female Luer 1/8"
M	Bottom Drain Harvest	Si(Pt) tube 1/2" ID × 3/4" OD (2500 mm) connects to C-Flex® tube 1/2" ID × 3/4" OD (500 mm)	3000 mm	Quick Coupling Male 1/2" + plug
N	Sparger	Ring sparger	/	/
O	Stirrer	O1=3-blade pitched top bottom impellers + O2=3-blade pitched top bottom impellers	/	/

* A second exhaust filter line, article n° DS200L-SBFLO, can be ordered separately as an option for connection to line H2. This back-up filter line can than easily be installed during cell cultivation to line H2 in case a problem occurs on filter line H1.

CultiBag STR 500 L, Article Number FRB 115815 | CultiBag STR 1000 L, Article Number FRB 115573

Pos.	Function	Description	Total Length*	Distal Connection
A	Overlay Aeration	Si(Pt) tube 1/2" ID × 3/4" OD (50 mm) + OPTA SFT-I aseptic connector 1/2" + Si(Pt) tube 1/2" ID + 3/4" OD (150 mm)	650 mm	0.2 sterile grade air filter
B	Feed	Si(Pt) tube 1/2" ID + 3/4" OD (2500 mm) connects to C-Flex® tube 1/2" ID + 3/4" OD (500 mm)	3000 mm	MPX Quick Coupling Female 1/2" + plug
C	Feed	Si(Pt) tube 3/8" ID + 5/8" OD (2500 mm) connects to C-Flex® tube 3/8" ID + 5/8" OD (500 mm)	3000 mm	MPC Quick Coupling Female 3/8" + plug
D	Sparging Aeration	Internal ring sparger connects to C-Flex® tube 1/2" ID + 3/4" OD (1900 mm for 500 L | 2000 mm for 1000 L) tube connects outside the bag to Si(Pt) tube 1/2" ID + 3/4" OD (750 mm) + OPTA SFT-I aseptic connector 1/2" + Si(Pt) tube 1/2" ID + 3/4" OD (150 mm)	500 L: 2800 mm 1000 L: 2900 mm	0.2 sterile grade air filter
E	Feed	Internal C-Flex® tube 3/8" ID + 5/8" OD (1500 mm) connects outside the bag to Si(Pt) tube 1/2" ID + 3/4" OD (150 mm) splits to: E1: Si(Pt) tube 1/2" ID × 3/4" OD (2500 mm) connects to C-Flex® tube 3/8" ID × 5/8" OD (500 mm) E2: Si(Pt) tube 1/2" ID × 3/4" OD (2500 mm) connects to C-Flex® tube 1/2" ID × 3/4" OD (500 mm)	4650 mm	E1: MPC Quick Coupling Female 3/8" + Plug E2: MPX Quick Coupling Female 1/2" + plug

Pos.	Function	Description	Total Length	Distal Connection
F	Addition base	Si(Pt) tube 1/4" ID + 3/8" OD (2500 mm) connects to C-Flex® tube 1/4" ID + 3/8" OD (500 mm)	3000 mm	MPC Quick Coupling Female 1/4" + plug
G	Feed	Si(Pt) tube 1/4" ID + 3/8" OD (2500 mm) connects to C-Flex® tube 1/4" ID + 3/8" OD (500 mm)	3000 mm	MPC Quick Coupling Female 1/4" + plug
H	Gas Out	Si(Pt) tube 3/4" × 1" OD (500 mm) splits to: H1: Si(Pt) tube 3/4" × 1" OD (150 mm) + OPTA SFT-I aseptic connector 3/4" + Si(Pt) tube 3/4" × 1" OD (150 mm) H2: Si(Pt) tube 3/4" × 1" OD (150 mm)	H1: 800 mm H2: 650 mm	H1: 0.2 sterile grade air filter H2: OPTA SFT-I aseptic connector 3/4", Male*
I	T sensor	Thermowell sensor port for pT100 sensor (Inside length 135 mm)	74 mm	/
J	DO/pH sensor	Dual sensor port for pH and DO	/	/
K	Pressure sensor port	Si(Pt) tube 1/2" ID + 3/4" OD (750 mm) + OPTA SFT-I aseptic connector 1/2" + Si(Pt) tube 1/2" ID + 3/4" OD (150 mm)	900 mm	0.2 sterile grade air filter
L	Small volume sampling	Si(Pt) tube 1/4" ID + 3/8" OD (150 mm) reduced to C-Flex® tube 1/8" ID + 1/4" OD (500 mm)	650 mm	Clave connector Female Luer 1/8"
M	Bottom Drain Harvest	Si(Pt) tube 1/2" ID + 3/4" OD (2500 mm) connects to C-Flex® tube 1/2" ID + 3/4" OD (500 mm)	3000 mm	MPX Quick Coupling Male 1/2" + plug
N	Sparger	Ring sparger	/	/
O	Stirrer	O1 = 3-blade pitched top bottom impellers + O2 = 3-blade pitched top bottom impellers	/	/
P, Q, R, S	Feed	Si(Pt) tube 1/2" ID + 3/4" OD (500 mm)	500 mm	OPTA SFT-I aseptic connector 1/2", Female

* A second exhaust filter line, article n° DS001K-SBFLO, can be ordered separately as an option for connection to line H2. This back-up filter line can than easily be installed during cell cultivation to line H2 in case a problem occurs on filter line H1.

CultiBag STR Design Variations

Tubing Size	Specific tubing sizes are available on request
Tubing Length	Specific tubing lengths are available on request
Sparger Type	Choice between ring or microsparger
Impeller Type	Choice between 2 × 3-blade pitched impeller, 2 × 6-blade disk impeller or combination of both
Connectors	Specific connectors are available on request
Sensors	Additional or specific sensors may be available on request

Please note: not all variations are possible for all ports

▶ Foam Disc

Mechanial Foam Destroyer for Installation on Stirrer Shaft

Single-Use Technology

Introduction

In fermentation applications high oxygen transfer rates are achieved through high gassing and agitation rates. These disperse of the gas phase often results in foaming of the media.

Foam causes various problems such as blocking of the exhaust gas filter or discharge of the biomass from the liquid phase to the foam layer. Today, foaming is usually prevented by chemical anti-foaming agents, silicon oils or polyglycols. The use of antifoam agents is not only costly but also causes a reduction in oxygen transfer rates. Furthermore, the elimination of antifoam reagents in the downstream process is both difficult and expensive.

The foam disc, a mechanical foam destroyer, is the solution. This unique and patented device solves the foam problem where it starts, directly at the liquid surface.

In addition to that it allows for a substantial increase of the working volume in the culture vessel.

Design

The foam disc gets installed on the stirrer shaft, which makes retrofitting fast and easy. It is a two layer disc with four sections. Its lower layer has downwards positioned slots and paddles for foam skimming. Currently it is possible to install the device in autoclavable culture vessels in the working volume range from 1 L to 10 L. Designs for larger vessels will be available shortly.

Operating Principle

The rising foam enters the foam disc at the bottom side through four self-priming ports. With the rotation of the disc the foam is spun against the reactor wall causing the gas and liquid to separate into two phases. While the lighter gas phase leaves the reactor through the air exhaust the liquid phase drops back into the medium.

▷ Specifications

Technical Specifications

Dimensions disc | shaft	74 | 10 mm 84 | 10 mm 96 | 14 mm 96 | 16 mm
Material	Polyetheretherketon (PEEK)
Minimum required stirrer speed	300 rpm
Mounting	Stirrer shaft
Mounting position	close above liquid surface
Sterilization	autoclavable

Ordering Information

Description	Cat. No.	Diameter	For Shaft Diameter	Usage
Foam Disc 74 | 10	BB-8844465	74 mm	10 mm	UniVessel® 1 L MD2 vessel
Foam Disc 84 | 10	BB-8844466	84 mm	10 mm	UniVessel® 2 L B2 vessel
Foam Disc 96 | 14	BB-8844467	96 mm	14 mm	UniVessel® 5 L B10L
Foam Disc 96 | 16	BB-8844468	96 mm	16 mm	UniVessel® 10 L
Foam disc adaptor 16 | 11.5	BB-8844469	Foam disc 96 | 16 shaft diameter reducer		MD5, B5 vessel

▶ Hydrocyclone

Mammalian Cell Retention Device for Single-Use and Reusable Bioreactors

Single-Use Technology

Introduction

A majority of today's bioreactors in biopharmaceutical productions with mammalian cell cultures are mainly operated in fed-batch modes. In fed batch mode, media and other nutrients are added to the culture and the product is only harvested at the end of the run. This approach is well characterized, reliable and produces higher yields than simple batch modes. However, there are some potential disadvantages such as waste product accumulation, nutrients may become exhausted and the product may be degraded prior to harvest due to long residence times in the bioreactor. Perfusion mode is an alternative process operation methodology which eliminates the disadvantages of fed-batch modes and further increases the volumetric productivity.

In perfusion mode, the cells are retained while culturing media is continuously exchanged and therefore product is harvested throughout the culture period.

Capital and start-up costs are lower as smaller upstream and downstream capacity is required.

The key to successful perfusion operation is an efficient and scalable cell retention device such as the Hydrocyclone. Until now, Hydrocyclones have been used in biotechnology primarily for yeast separation. A completely new Hydrocyclone has been developed, designed for the retention of viable mammalian cells.

Design

The Hydrocyclone is a very simple device with very small dimensions and no moving parts. Furthermore, the disposable design of the Hydrocyclone eliminates cleaning requirements and cleaning validation.

Working Principle

Although the Hydrocyclone separation principle is identical to centrifuges (sedimentation in a centrifugal field), it has no movable parts. The centrifugal forces are performed by the fluid itself by being tangentially fed into the Hydrocyclone. Due to the conical design of its lower section the cells are concentrated and returned to the bioreactor via the Underflow, whereas the product, cell debris and used media are harvested via the Overflow.

Integration

Single-use and reusable bioreactors can be easily equipped with the Hydrocyclone. Two dip tubes or ports below liquid surface level are required, one for feeding the Hydrocyclone and one for the return flow (Underflow). The sterile connection of the pre-sterilized bioreactor and Hydrocyclone can be easily performed by using a sterile tube fuser (BioWelder®) or sterile connectors (Opta® SFT). For autoclavable culture vessels the Hydrocyclone can be installed prior autoclaving. For recirculation and harvest a low pulse peristaltic pumps is recommended. For feed flow adjustment an autoclavable pressure gauge is required.

Features

– Compact design

– Laboratory to Production scale

– Intermittent operation allows for easy scalability

– Perfusion rates of up to 720 L per day*

– Separation performance over 95% (Hybridoma)*

– Viable cell concentration 1.3 10^7 mL^{-1} (Hybridoma)*

– Extremely low residence time

– For single-use and reusable bioreactors

– No cleaning

Overflow (Harvest)

Feed   Feed

Underflow (Concentrate)
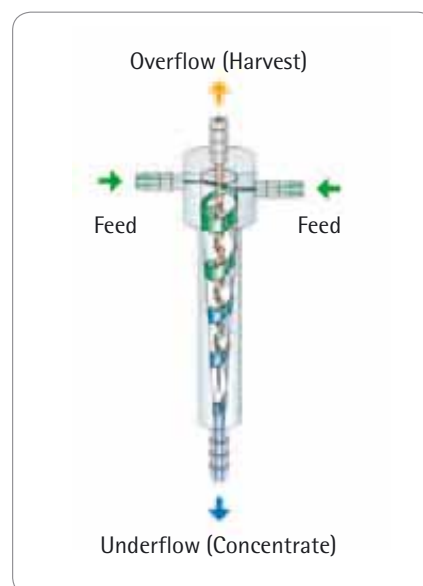
▷ Specifications

Product Specification

Material	Polyphenylenether (PPE) + Polystyrene (PS)
Dimensions (W × H × D)	72 × 147 × 43 [mm]; 2.83" × 5.79" × 1.69"
Weight	48 grams
Total Volume	3.1 cm^3
Maximum Operating Pressure	3 barg (43.5 psi) at 40°C (104°F)
Sterilization Methods Gamma irradiation Autoclaving	< 50 kGy 20 minutes at 121°C (250°F)
Connections	Hose barb OD 10 mm

Upscale

The Hydrcyclone can be used as perfusion device for bioreactors from laboratory to production scale.

The carefully optimized feed and harvest flow, which is required for optimal system performance, results in a maximum perfusion rate. When the required perfusions rate is lower the Hydrocyclone needs to be operated intermittently. Therefore, an upscale to a larger bioreactor is easy because only the operation interval needs to be extended. The minimum recommended operation time should be three minutes.

Initial Feed and Overflow Settings

The Hydrocyclone needs to be optimized for specific cell lines by carefully fine tuning the Feed and Overlay flow. Starting points are as follows: A: Feed flow 0.8–1.3 barg (approx. 1.2–1.6 L/min) B: Overflow (Harvest) 0.3–0.5 L/min.

Hydrocyclones for Mammalian Cell Culture in Use

HeLa-, SP/2, Hybridoma and human ATIII producing CHO cells where cultivated in a 6 L bioreactor as well as a mab producing Hybridoma cell line in a 20 L and 200 L bioreactor using the Hydrocyclone as perfusion device. No negative effect of the Hydrocyclone has been observed with respect to the cell viability and productivity using reference Spinner flaks. Cell viabilities between 85% (Hybridoma) and 95% (HaLa, CHO, SP/2) were observed. Maximum CHO cell concentrations of 1.2×10^7 per mL in the 6 L bioreactor and a Hybridoma cell concentration of 1.3×10^7 per mL in a 20 L and 200 L bioreactor has been published. A separation performance of over 95% of the viable cells in the 200 L bioreactors has been reached.*

* Source: BioTec 5–6, 38-39, 2006

Ordering Information

Description	Cat. No.	Pack Size
Hydrocyclone	PSHDH01	1

Required Accessories

– Tubing with an internal diameter of 8 mm or 9.6 mm, cable clips, tube clips, and Y-pieces and sampling systems if desired

– Autoclavable pressure measurement system

– Holder for Hydrocyclone and pressure measurement system (e.g., laboratory stand)

– 2 (two) low-pulsation pumps, e.g., Watson-Marlow 520 with 505 L pump head

Publications

A. Jockwer, R.A. Medhondro, R. Wagner, F.B. Anspach, W.-D. Deckwer
The Use of Hydrocyclones for Mammalian Cell Culture in Perfusion Bioreactors
Animal Cell Technology: From Target to Market, Kluwer Academic Publishers (2001)

E.A. Elsayed
Application of Hydrocyclone for Cell Separation in Mammalian Cell Perfusion Cultures
Dissertation: Technische Universität Braunschweig, Gemeins.Natw.Fak.: FB 4: Biowissenschaften, Psychologie, 2005

E.A. Elsayed, R.A. Medhondro, R. Wagner, W.-D. Deckwer
Use of Hydrocyclones for Mammalian Cell Retention:
Separation Efficiency and Cell Viability (Part1)
Engineering in Life Sciences (2006) 6, No4: 347–358

Rodrigo C.V. Pinto, Ricardo A. Medhondro, Leda R Castilho
Separation of CHO cells using Hydrocyclones
Cytotechnology (2008) 56: 57–67

R. Wagner, E.A. Elsayed, B. Schröder
Die Fliehkraft nutzen „Hydrodynamische Zellseparation als Perfusionssystem für industrielle Produktionsprozesse"
BioTec 5-6, 38–39, 2006

▶ BioPAT® MFCS SCADA Software

BioPAT® MFCS, provides various solutions to help you at every stage of your process. BioPAT® MFCS | DA is ideal for capturing, storing and visualizing process data, from 1 to 4 bioprocess units in a research & development setting.

BioPAT® MFCS | win is a feature-rich, GAMP category 4 software package capable of supporting the most demanding research or production environment, including S88- and 21CFRpart11-compliance.

Both systems are built upon batch-oriented data management, meaning all your process data will be traceable to a unique batch name | ID.

BioPAT® MFCS | DA
Designed as a "plug and play" tool when used in conjunction with our range of standard BIOSTAT® fermentors | bioreactors. This combination helps you get started acquiring and analyzing your important process data quickly.

Data may be acquired from 1 to 4 systems, either serially or via Ethernet. Features like the Sample Data Management function simplify the inclusion of external, manually-entered data (e.g., glucose analyzer, cell density, etc.) into your batch record. Visualization of the batch data is made possible with a powerful Plotting function, allowing for multiple variables, from multiple batches to be displayed simultaneously. The Export function may be used to export batch data to other data analysis programs.

– Up to 4 process units

– Batch oriented software package

– Sample Data Management

– Enhanced Plotting

– Export functions

– Easy to use programming interface

BioPAT® MFCS | win

BioPAT® MFCS | win provides advanced functionality for supervisory process control and data acquisition, including on-line and offline calculations, extensive batch reporting, software configuration management and multi-user network access to up to 16 systems.

BioPAT® MFCS | win is an open system, with an OPC (OLE for Process Control) interface, facilitating connectivity to other OPC-compliant, third-party software packages. For connectivity to legacy devices, a comprehensive driver library exists.

ISA-88 (Instrument Society of America) compliant batch management features allow for the utilization of procedural batch control, even in bench-scale applications. Resulting in consistent process operation for scale-down or scale-up activities.

Fully validatable, according to GAMP category 4 (Configurable System), and compliant with 21CFR part 11 electronic signatures and records. BioPAT® MFCS |win has all the necessary functionality for operation in a regulated cGMP production.

– Up to 16 process units

– Validatable

– 21 CFRPart 11 compliant

– ISA-S88 compliant

– OPC client and server interface

– Networking and Remote Alarming

► FlexAct® CH

Disposable Solution for Cell Harvest

Description

The FlexAct® CH is a standardized configurable disposable solution (CDS) dedicated to cell harvest steps in biopharmaceutical processes. The FlexAct® CH addresses the entire development cycle and production capacity needs from 50 to 1.000 L for cell harvest. The integration of monitoring & control features for pressure, pump speed and fluid level control is a further milestone for the implementation of process relevant single-use equipment. The integrated control allows end-users to perform other tasks during the cell harvest operation. Combined with a Palletank® and designed bag assemblies the multifunctional Central Operating Module enables the user the install, operate and monitor a fully single-use unit operation.

Features

– Multifunctional Central Operating Module

– Configurable system configurations

– 50–1,000 L working volumes

– Quick system set-up

– Integrated single-use presure sensor

– Controlled operation by pressure adjustment

Benefits

– Operator friendly

– Safe handling of L-drum filters

– Fully scalable

– Efficient equipment utilization

– Enables monitoring

– Highly flexible

Components

The FlexAct® CH configurable disposable cell harvest solution consists of:

– FlexAct® COM Central Operating Module with accessories

– L-drum trolley for up to 4 L-drums for easy and safe harvest operation

– Bag assembly configurations with integrated sterilizing grade filter and a transfer set with implemented single-use pressure sensor

– Weighing platforms or Palletanks® with load cells

1. FlexAct® COM Central Operating Module with Accessories

The FlexAct® COM Central Operating Module is designed for operational excellence in cell harvest processes. It features multiple work platforms that incorporate process equipment and user friendly monitoring & control capabilities. The integrated control instrumentation together with an ergonomically positioned 10" LCD touch screen enables the operator to have an overview about the main process parameters values such pressure, pH and temperature of the Protein A eluate whilst pH adjustment, incubation, neutralization and filtration. For secure fluid level management a weight signal is provided by either load cells that are integrated into the LevMixer® Palletanks® or floor scales provided individually. The three level Central Operating Unit is able to accommodate multiple process devices required in a single-use process environment. Depending on the process needs, thermal welding and sealing provided by the BioWelder® and BioSealer® as well as filter integrity testing by using a Sartocheck® 4 integrity tester will help to quick connect and test assemblies.

1.1 Sartocheck® 4

Filter Integrity Testing is an essential procedure to detect defective filter cartridges before or after use. Thus automatic integrity testers have to fulfil highest standards with respect to accuracy and reliability. At the same time the user-friendly interaction guarantees convenient handling. The Sartocheck® 4 offers solutions for all customer needs. With a comprehensive accessory package it allows highest flexibility for all integrity testing needs.

1.2 BioWelder® and BioSealer®

Sterile Fusing and Sealing of thermoplastic tubing are key technologies that offer most flexibility to the end users that are interested in getting a solution for multiple connection and disconnection cycles. Sartorius' BioWelder® and BioSealer® are devices that meet these requirements set by the industry. The ability of assuring quick and reliable connections and disconnections combined with the expertise of Wave Biotech Switzerland made BioWelder® and BioSealer® to the product of choice in the biopharmaceutical industry.

2. Sartoclear® L–Drum Technologies
– L-drum trolley

Two different moveable L-Drum support systems are available to assure an easy and safe handling of the capsules. The 1-way system can be connected to the 4 way support system so that a capsule can be easily transferred from one system to the other.

3. Bag Assemblies and Manifold

FlexAct® CH bag assemblies and manifolds are supplied to serve the need of a fully preconfigured, ready to install, single-use unit operation. Uniquely, the transfer set and Flexel® 3D storage bags are supplied in one package. The storage bag assemblies of the FlexAct® CH configurable disposable solution are tailored to suit the dedicated need for individual mAb solution volumes at the point of use. Supplied as single Flexel® 3D bags , the FlexAct® CH storage bag assemblies provide highest flexibility and efficiency.

4. Palletanks® for Intermediate mAb Solution Storage

The Palletank® for Storage or In-Process Handling are stainless steel container designed to perfectly fit with the Flexel® 3D LevMixer® bag assemblies.

5. Weighing Platforms

The IFS4 flat-bed scales are entirely constructed of stainless steel and have an extremely low height, making it ideally suited for floor installation without a pit or anchoring. The ramp is securely attached to the scale using special retainers for prevention of force shunt. This high-quality platform can be connected to any of a wide range of indicators, for use as a Class III legal measuring instrument or without legal verification. The CIS1 Combics 1 indicator allows strain gauge weighing with flat bad scales as well as with load cells to be connected.

FlexAct® Configurator

A configurator based selection system enables the user to flexibly create the FlexAct® CH solution that meets its process requirements in cell harvest operations. All components included in the configurator are standardized components that ensure highest performance, shortest lead times and highest quality. The following Configurable Disposable Solutions will gradually complete the FlexAct family:

Unit Operation	FlexAct® Configurable Disposable Solutions
Buffer Preparation	FlexAct® BP
Virus Inactivation	FlexAct® VI
Cell Harvest	FlexAct® CH
Media Preparation	FlexAct® MP
Virus Filtration	FlexAct® VR
Ultrafiltration|Diafiltration	FlexAct® UD
Polishing	FlexAct® PO
Form & Fill	FlexAct® FF
Form & Transfer	FlexAct® FT

Ease of Use

The primary driver behind the FlexAct® initiative is the development of disposable equipment which meets all process operations improving efficiency and speed. Sartorius Stedim specialists have analyzed the process environment and the operating procedure for cell harvest thoroughly and developed an operator friendly multifunctional Central Operating Unit. Tailored bag configurations with 30 L up to 650 L working volumes offer flexible solutions at full scalability. The system set-up is performed within minutes and needs less preparation time compared with existing solutions. Once the operation is performed, the system can be as fast rigged-off without the needs of tedious cleaning requirements. Set-up and rig-off ease allow for more efficient and faster equipment utilization adding to the overall process capacities. The monitoring on a 10" touch screen of all main process parameter is easily enabled by integrated disposable sensors.

Validation

Flexel® 3D bags have been qualified applying the most stringent and current test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® 3D bags with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Flexel® 3D bags are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes and state-of-the-art utilities. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a flexible and robust supply chain that can cope with strong market growth.

Subassembly 1

Subassembly 2

The schematic above shows the bag assemblies connected

▷ Specifications

1. FlexAct® CH Central Operating Module

Material	316 L Stainless Steel
Surface Finish	Optional: – Powder coated | coloured – Glass Bead Blasted, electropolished
Dimensions (W × D × H)	795 × 1410 × 1500 mm (31.3 × 55.51 × 59.06 inch)
Weight (approx.)	160 kg (352.74 lbs) (incl. Watson Marlow pump)
Control Unit	– Control unit with 10.4" touch screen

Pump

Watson Marlow	720UN | R
Specification	IP66 0.1 – 360 rpm
Pumphead	720R pumphead, 4 roller pumphead for maximum 2 bar. Accepts continuous tubing only (includes continuous tube clamp set)

BioWelder®

Power requirements	100 – 240 V │ 47 – 63 Hz
Dimensions	300 × 300 × 220 mm
Weight	0.5 kg
Housing	stainless steel
Interface	RS232 for printer
Blade	Cr-Ni-Alloy, single-use
Ambient temperature	20°C – 30°C (ideal: 22°C)
Relative Humidity	20% – 80% (ideal: 60%)
Temperature Sensor	Type K, calibration holder available
Max. Tube OD	¾"
Min. Tube OD	¼"
Welding Cycle	60 – 90 sec. depending on tube dimension
Standard settings for	C-Flex®, PHARMED® BPT, Sanipure® 60

BioSealer®

Power requirements	100 – 240 V │ 47 – 63 Hz
Dimensions	220 × 150 × 210 mm
Weight	3.0 kg
Housing	stainless steel
Compression head	Aluminum anodised
Ambient temperature	20°C – 30°C
Relative Humidity	35% – 65%
Max. Tube OD	¾"
Min. Tube OD	¼"
Sealing Cycle	1 – 4 minutes depending on tube size and quality
Tubing Types	Soft ThermoplasticTubing, (e.g. C-Flex®, SaniPure® 60 and Pharmed® BPT)

1: ext. reference tank
2: Venting 1
3: Out
4: Venting 2
5: Compressed Air In
A: external sensor
B: external valves

1: main switch
2: SD card reader
3: Serial Port TU
4: PLC Port
5: RJ45 Network
6: connection for optional
   barcode scanner

Sartocheck® 4 plus

Power requirements	100–240 V AC, 50	60 Hz
Maximum power input	74 watts
Maximum operating pressure	9999 mbar	145 psi
Minimum inlet pressure	4000 mbar	58 psi
Dimensions (W × D × H1 × H2)	460 × 390 × 140 × 245

Measuring ranges:

Test pressure	100–8000 mbar	1.5–116 psi
Pressure drop	1–2000 mbar	0.01–29 psi
System inlet volume – with internal ref. Vessel – with external ref. Vessel max.	14 L 150 L

Measuring accuracy:

Pressure	± 0.1% full scale
Pressure drop	± 1 mbar	0.015 psi
Volume determination	± 4%
Diffusion	± 5%
Water-Intrusion	± 5%
Bubble Point	± 50 mbar	± 0.7 psi

Operating conditions:

Ambient temperature	+15°C to +35°C
Rel. humidity	10–80%

Touch Screen:

Size	10.4" TFT
Features	256 colors

Comunication Ports:

Serial Port	TU RS232
Serial Port	MU RS485
PLC Port	binary signals 12 pins
Network	RJ45

Language option:

	English German French Spanish Italian

2. L–drum Technologies

2.1 L-drum trolley
Two different moveable L-Drum support
systems are available to assure an easy and
safe handling of the capsules. The 1-way
system can be connected to the 4 way
support system so that a capsule can be
easily transferred from one system to the
other. Customized support systems can
be made on request.

	1–Way Support System	**4–Way Support System**
Length	38 cm	71 cm
Width	57 cm	70 cm
Height	122 cm	130 cm
Weight	24 kg	52 kg

2.2 Sartoclear® L-drums
Sartoclear® P L-Drums are cellulose based
depth filters, especially developed for use in
the Biopharmaceutical industry. The depth
filter media provide a combined clarification
effect by both, size exclusion and adsorptive
mechanisms. The Sartoclear® P L-Drum is the
first production scale disposable depth filter
line, without the need for expensive clamping
systems. The "Plug and Play" filter capsules
reduce the set up time to a minimum and
provide 100% disposability of all fluid
contacting components.

Filtration volumes
Sartoclear® P L-Drum are used for the
filtration of 100 L up to 600 L per module,
depending on the application. The required
filtration area needs to be confirmed by small
scale tests using Sartoclear® P MaxiCaps®.

Water Flow Rate [l/L–Drum × min]

Differential Pressure [bar] ... PC1 | PC2 ... PB2 ... PB1 ... [psi]

Water Flow Rate [l/L-Drum × min]
ΔP = 1 bar
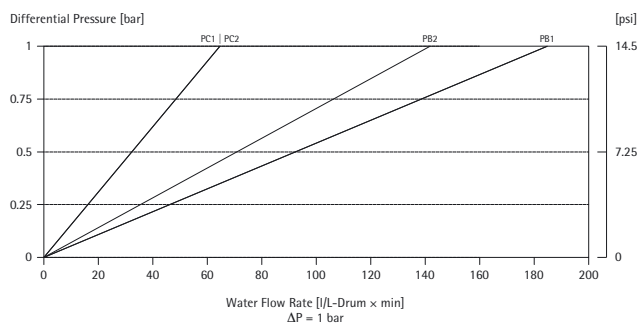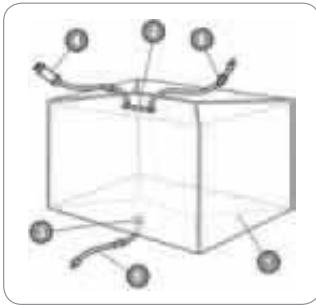
3. FlexAct® CH – Bag Assemblies and Transfer Sets

3.1 Flexel® 3D Bioprocessing Bag for Storage

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, ULDPE Contact Layer
Tubing material	C-Flex®, Silicone
Number of Ports	2 top ports, 1 bottom port
Filter	Sartopore® 2 gamma MidiCaps®	MaxiCaps®
Fittings	Tri-clamp, Luer Lock female female with needle free sampling port
Volumes	50 L, 100 L, 200 L, 500 L, 1000 L
Sterilization	by Gamma Irradiation

3.2. FlexAct® CH – Transfer set

3.2.1 Transfer set for CultiBag STR 50

– Transfer set FlexAct® CH (to be connected with outlet port MPC male of the CultiBag STR 50)

– MPC 3/8" ID inlet (female coupling) with sealing plug, 1/2"IDX7/8"OD, SI(Pt) APT, SU 1/2"(hose barb) pressure sensor, four TRI CLAMP connections with gasket, clamp and cap at the outlet. (see picture a)

– Four 11/2" TRI CLAMP Inlet with gaskets, clamps and caps, Tubing 1/2"IDX7/8"OD, SI(Pt) APT, 11/2" TRI CLAMP

– Outlet with gasket, clamp and cap. (see picture b)

3.2.2. Transfer set for CultiBag STR 100-1000

– MPX 1/2" ID inlet (female coupling) with sealing plug, 1/2"IDX7/8"OD, SI(Pt) APT, SU 1/2"(hose barb) pressure sensor, four TRI CLAMP connections with gasket, clamp and cap at the outlet. (see picture a)

– Four 11/2" TRI CLAMP Inlet with gaskets, clamps and caps, Tubing 1/2"IDX7/8"OD, SI(Pt) APT, 11/2" TRI CLAMP

– Outlet with gasket, clamp and cap (see picture b)
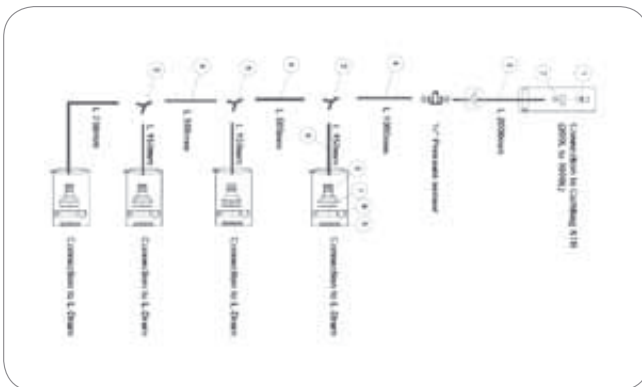
Picture a)
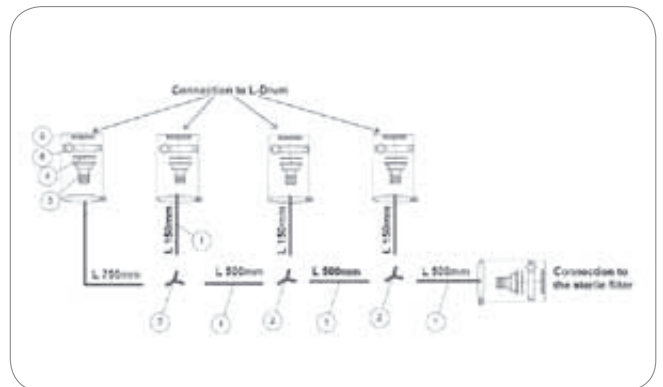
Picture b)

4. Palletank®

4.1 Palletank® for Storage

Material	304 L Stainless Steel
Surface Finish	Glass Bead Blasted
Stackable	3 (50-200 L) 2 (500 L)
Option	Dolly

Volume (L)	Dimensions (W × D × H)	Weight (kg) Palletank®
50 L	490 × 490 × 750	24
100 | 200 L	789 × 592 × 891	35
500 L	1192 × 792 × 1010	92
1,000	1260 × 1060 × 1443	145

5. Weighing Platforms – IFS Flat-Bed Scales

5.1 IFS4-300LI-I

Weighing capacity	300 kg
Platform size	1000 × 800
Height	standard
Load plate	AISI304/1.4301V2A bead-blasted
Resolution	30.000 d
Readability	10 g

5.2 IFS4-1500NN-I

Weighing capacity	1,500 kg
Platform size	1250 × 1250
Height	standard
Load plate	AISI304/1.4301V2A bead-blasted
Resolution	30.000 d
Readability	50 g

5.3 Combics CIS1 – Scale Indicator
Indicators for complex weighing tasks in 4 different versions.

Max. readability	31.250 digits
IP protection rate	IP67 (PG cable gland), IP44 (25-pol. D-SUB), (IP65 as option)

Ordering Information

1. FlexAct® Central Operating Module

Part Number	Description
4SZZNL201	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10,4" touch panel EU 230 V, st.steel version
4SZZNL501	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10,4" touch panel US 110 V, st.steel version
4SZZNL202	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10,4" touch panel EU 230 V, powder coated version
4SZZNL502	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10,4" touch panel US 110 V, powder coated version

2. L–Drum Technologies

2.1 L-drum trolleys

Order Number

2ZGB--0001	Trolley for 4 L-Drums, 70 cm × 70 cm × 120 cm (l × b × h)
2ZGB--0002	Trolley for 1 L-Drum, 70 cm × 70 cm × 120 cm (l × b × h)

2.2 Sartoclear® L-drums

Order Number	Grade	Retention Rating	Application
295PB1P13ALSS	PB1	11 µm | 4 µm	High Cell densitiy (>107/ml) Post Bioreactor*
295PB2P13ALSS	PB2	8 µm | 1 µm	Common Cell density (<107/ml) Post Bioreactor*
295PC1P13ALSS	PC1	1.0 µm | 0.3 µm	Particle containing Post Centrifuge applications, 100–150 FNU*
295PC2P13ALSS	PC2	0.3 µm | 0.3 µm	Post Centrifuge applications, <100 FNU*

* Value is an indication, the choice of media should be based on small scale tests.

3. Disposable Bag Assemblies

Legend:

Subassembly 1	Subassembly 2
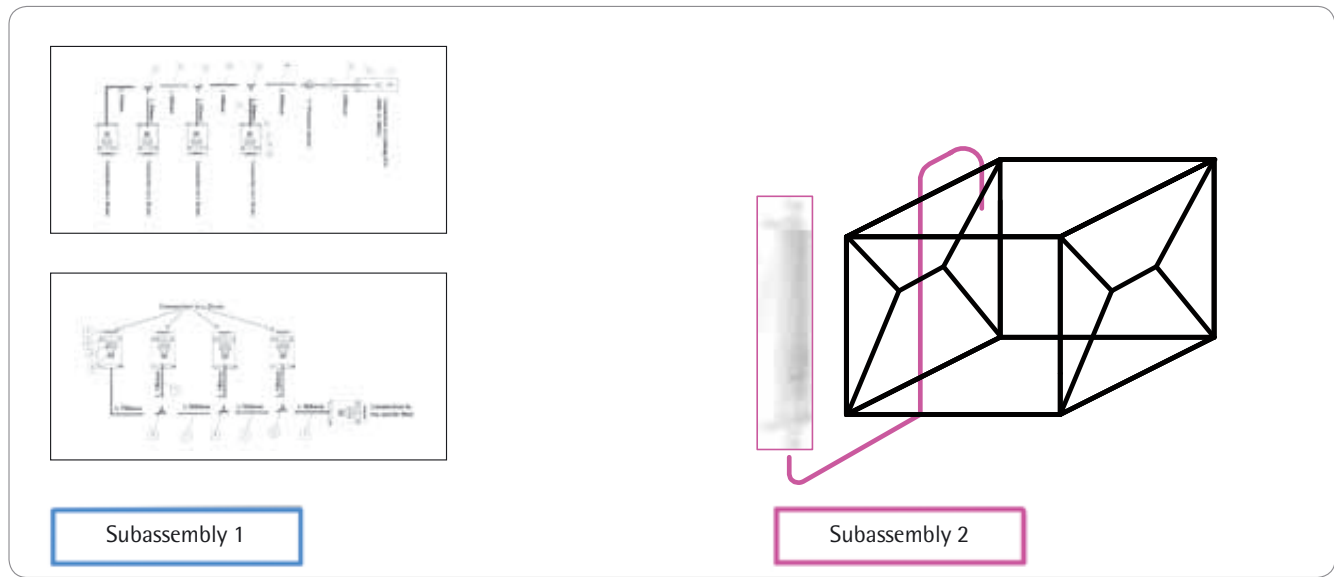
Part Number	Subassembly 1	Subassembly 2
4CH-----14AA10502	Transfer set FlexAct® CH (to be connected with outlet port MPC male of the CultiBag STR 50)[1]	50 L Flexel® 3-D bag with Sartopore® 2 Gamma height 7
4CH-----15AB11003	Transfer set FlexAct® CH (to be connected with outlet port MPX male of the CultiBag STR 100 – 1000)[2]	100 L Flexel® 3-D bag with Sartopore® 2 Gamma height 8
4CH-----15AC12004	Transfer set FlexAct® CH (to be connected with outlet port MPX male of the CultiBag STR 100 – 1000)[2]	200 L Flexel® 3-D bag with Sartopore® 2 Gamma height 9
4CH-----15AD15005	Transfer set FlexAct® CH (to be connected with outlet port MPX male of the CultiBag STR 100 – 1000)[2]	500 L Flexel® 3-D bag with Sartopore® 2 Gamma MaxiCaps® 10"
4CH-----15AD11T06	Transfer set FlexAct® CH (to be connected with outlet port MPX male of the CultiBag STR 100 – 1000)[2]	1000 L Flexel® 3-D bag with Sartopore® 2 Gamma MaxiCaps® 20"

[1] MPC 3/8" ID inlet (female coupling) with sealing plug, 1/2"IDX7/8"OD, SI(Pt) APT, SU 1/2" (hose barb) pressure sensor, four TRI CLAMP connections with gasket, clamp and cap at the outlet. (see picture a)
Four 11/2" TRI CLAMP Inlet with gaskets, clamps and caps, Tubing 1/2"IDX7/8"OD, SI(Pt) APT, 11/2" TRI CLAMP Outlet with gasket, clamp and cap.

[2] MPX 1/2" ID inlet (female coupling) with sealing plug, 1/2"IDX7/8"OD, SI(Pt) APT, SU 1/2"(hose barb) pressure sensor, four TRI CLAMP connections with gasket, clamp and cap at the outlet. (see picture a)
Four 11/2" TRI CLAMP Inlet with gaskets, clamps and caps, Tubing 1/2"IDX7/8"OD, SI(Pt) APT, 11/2" TRI CLAMP Outlet with gasket, clamp and cap (see picture b)

4. Palletank for Storage (50–1000 L) | In-Process Handling (1000 L)

Order Number	Palletank
FXC113946	Palletank® 50 L for storage stackable
FXA113988	Dolly for Palletank® 50 L (storage)
FXC110733	Palletank® 100 L for storage stackable
FXS102254	Dolly for Palletank® 100 L	200 L (storage & shipping)
FXC110733	Palletank® 200 L for storage stackable
FXS102254	Dolly for Palletank® 100 L	200 L (storage & shipping)
FXC110734	Palletank® 500 L for storage stackable
FXC100734	Dolly for Palletank® 500 L (storage & shipping)
FXC106223	Palletank® 1000 L for in-process fluid handling
FXS102259	Dolly for Palletank® 1000 L for in-Process fluid handling

5. Weighing Platforms

5.1 Floor Scales (Flat bed scales)

Part Number	Platform Dimensions (mm)	Weighing Capacity	Readability	Load Plate	Dust	Water Protection
IFS4-300LI-I floor scale (flat bed scale)	1000 × 800	300 kg	10 g	AISI304/1.4301 V2A bead-blasted	IP67	IP68
IFS4-1500NN-I floor scale (flat bed scale)	1250 × 1250	1500 kg	50 g	AISI304/1.4301 V2A bead-blasted	IP67	IP68

5.2 Combics CIS1 – Scale indicator

Combics 1 scale indicator, stainless steel housing, IP44	CISL1
Combics 1 plus scale indicator, stainless steel housing, IP44	CISL1N
Combics 2 scale indicator, stainless steel housing, IP44	CISL2
Combics 3 scale indicator, stainless steel housing, IP44	CISL3
Combics 1 scale indicator, stainless steel housing, IP67	CIS1
Combics 1 plus scale indicator, stainless steel housing, IP67	CIS1N
Combics 2 scale indicator, stainless steel housing, IP67	CIS2
Combics 3 scale indicator, stainless steel housing, IP67	CIS3

Optional Interfaces (UniCOM)

Interface module (RS-232C)	YDO01C-232
Interface module (RS-485 | 422)	YDO01C-485
Analog current output, 0–20 mA, 4–20 mA, 0–5 V, 16-bit	YDA01C-20MA
Profibus module	VDO01C-DP
Bluetooth® module (only for CIS models)	YDO01C-BT

Replace A | D Converter (WP1) with a Digital Interface

Interface (RS-232 | 485) for direct connection of a digital platform	YDI01C-WP

Printers and Printer Accessories

with functions for date, time and statistical evaluations	YDP03-0CE
Printer paper (5 rolls; length per roll: 50 m)	6906937
Replacement ink ribbon cartridge for printer	6906918
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 108 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator; only for use with flexible printout configuration (see "Software," next column)	YDP12IS-0CEUV
Printer paper (1 roll) for YDP12IS-0CE printer, 101 mm × 75 m, thermal sensitive paper	69Y03196
Labels for YDP12IS-0CE printer, extra large, 101 mm × 127 m, 305 labels	69Y03195
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 60 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator (see "Software," next column)	YDP04IS-0CEUV
Printer paper (3 rolls) for YDP12│04IS-0CE, 60 mm × 75 m, thermal sensitive paper	69Y03090
Labels for YDP12│04IS-0CE printer, small, 58 mm × 30 mm, 1000 labels	69Y03092
Labels for YDP12│04IS-0CE printer, medium, 58 mm × 76 mm, 500 labels	69Y03093
Labels for YDP12│04IS-0CE printer, large, 58 mm × 100 mm, 350 labels	69Y03094
Cable for direct connection of YDP12IS│YDP04IS-0CE printerto Combics CISL indicators	YCC01-01CISLM3

Electrical Accessories

External red│green│red display for Combics CISL indicators	YRD11Z
External red│green│red display for CIS indicators (12-pin round connector); connecting cable YCC02-R12F6 or Option M6 required	YRD14Z
Profibus connector for CISL... and CW...P... indicators (D-SUB 25-│9-pin)	IE10092
Second display for Combics CISL indicators	YRD02Z
Remote display, 7-segment, up to 45 mm characters	Information available on request
Bar code scanner, with cable for connection to Combics CISL scale indicator adapter cable, 120 mm scanning width	YBR02CISL
Bar code scanner for the Combics CIS model, with connecting cable, for connection with YCC02-R12F6	YBR02FC
Foot switch, incl. T-connector, D-SUB 25-pin	YFS01
Hand switch, incl. T-connector, D-SUB 25-pin	YHS02
External Alibi memory for electronic storage of weighing data	YAM01IS
Scanner for loading weighing data from YAM13IS Alibi memory cards to a PC	YAM02IS
Power supply for YAM01IS or YAM02IS Alibi memory	YAM11IS
Memory card for YAM01IS Alibi memory	YAM13IS
Cable for connecting Combics indicator to YAM01IS Alibi memory, 25-pin D-SUB to 9-pin D-SUB, 25 pol. D-SUB auf 9 pol. D-SUB	YCC01-10CIM3
Cable (D-SUB 9-pin, 2 m) for connecting YAM01IS Alibi memory to a PC	69EM0012
Flow rate controller for pumps with analog or digital pulse interface	YFC02Z-V2

Mechanical Accessories

Installation kit for pit frame installation (disconnectable plug-in cable for indicator)	YAS99I
Wall-mounting bracket, stainless steel	YDH01CIS
Wall-mounting bracket, stainless steel, tiltable	YDH02CIS
Floor-mounted column	YDH03CIP
Floor-mounted column, stainless steel	YDH03CIS
Base for installing floor-mounted column, stainless steel	YBP03CIS
Retainer for bar code scanner, for attachment to floor-mounted column, bench column or complete scale column	YBH01CWS
Plate for attaching printer to floor-mounted column or bench column	YPP01CWS

Software

Flexible printout configuration (e.g., bar codes, variable font sizes, embedding graphics, and similar) – Just ask your sales consultant	
Sartorius WinScale driver software for Windows® 95 │ 98 │ 2000 │ NT with current display of the weights and verifiable PC data memory, RS-232C, connecting cable 7357314 required	YSW03
SartoCollect software for the data communication between PC and any Sartorius instrument (incl. cable 26 Pin, 2 m)	YSC02

Power Supplies

24-V industrial power supply module	YAS02CI
External rechargeable battery pack, operates up to 40 hours, incl. battery charger	YRB10Z
External rechargeable battery pack, operates up to 40 hours, battery charger not included	YRB10Z-R
Connecting cable (25-pin, D-SUB) for YRB10Z rechargeable battery pack, 2 m	YCC02-RB01
Connecting cable with cable gland for YRB10Z rechargeable battery pack, 2 m*	YCC02-RB02
Connecting cable with cable gland, for car battery, 2 m*	YCC02-CB02

* only for CIS 1 │ 2 │ 3 indicator

Connecting Cables

with cable gland for YBR02FC bar code scanner*	YCC02-BR02
with cable gland for D09F6 printer, 9-pin D-SUB male connector, 6 m*	YCC02-D09M6
with cable gland for accessories, 9-contact D-SUB female connector, 6 m*	YCC02-D09F6
with cable gland for Sartorius scale, 25-contact D-SUB female connector, 1.5 m*	YCC02-D25F6
with cable gland for Sartorius scale, 25-pin D-SUB male connector, 6 m	YCC02-D25M6
with cable gland for accessories or IS platform, 12-pin round male connector, 6 m*	YCC02-R12M6
with cable gland, 12-contact round female connector, 1.5 m*	YCC02-R12F6
Cable for YDA01C-20MA power interface, with open cable ends e.g., 5 + = 5 m	6906926
Cable for connecting a PC, 25-pin, D-SUB, 1.5 m	7357312
Cable for connecting a PC, 9-pin, D-SUB, 1.5 m	7357314
Cable for connecting isi, QA│QC, FB│FC scales (25-pin D-SUB male connector to 12-pin round male connector), 3 m	YCC01-02ISM3
Connecting cable for scales, 25-contact D-SUB male connector (25-pin D-SUB female connector to 25-pin D-SUB male connector), 3 m	YCCDI-01M3
Connecting cable for scales to IS platform (25-pin D-SUB male connector to 12-contact round female connector), 3 m	YCC01-03CISLM3
Cable for connecting scale to platform, junction box or other weighing system equipment, approx. 8 mm outer diameter, shielded, with open ends; e.g., 5 + = 5 m	69YO1100

Other Accessories

In-use covers (set of 2)	YDC01CI
IP65 upgrade kit for the IP44 protected Combics CISL indicators	YAS01CISL
Anti-theft locking device	YTP01CI
Cable gland for Combics model CIS, IP67 protected*	YAS04CIS
Installation kit for integration in a control panel	YAS03CI

* only for CIS 1│2│3 indicator

6. Accessories

6.1 Sartocheck® 4 plus

Order Number	Order Code Description
26288	Sartocheck® 4 plus (following items included)
18104	Inlet tubing for compressed gas (included)
18103	Outlet tubing for compressed gas (included)
6982141	Ribbon cassette (included)
6982142	Rolls of printer paper (included) Test certificate (included) Calibration certificate (included) Installation and operating instructions (included)
16288---VP	Validation package Power cord (country specific)

Order Number	Accessories Sartocheck® 4 plus
26288---BS	Barcode Scanner
16288---TU	Multiunit
1ZE---0018	External pressure transducer
1ZE---0025	Set for external venting (1 valve)
1ZE---0026	Valve set for external filling (WIT) Serial Port Interface cable TU|TU
1ZE---0008	0.5 m
1ZE---0009	2 m
1ZE---0010	5 m Network Cable
1ZE---0029	2 m
1ZE---0030	5 m
1ZE---0031	10 m
1ZE---0032	20 m
26288---CK	Cleaning Kit
26288---PV	Pressure Tank for Cleaning
16288---RV	External reference vessel (10 L)
16288---PI	Profibus Interface
26288---VP	Validation Package
1ZE---0021	Clean Room Venting Adapter
1Z-LB-0002	Midisart Test Manifold 10

6.2 BioWelder®

Order Number	Order Code Description
16370	BioWelder®, Fully automated tube fusing unit
16372	Citizen Printer Print cable, AC adapter, paper roll and ribbon cassette
16373	Disposable Cutting Blades, with laser point 0.4 mm, 50 pcs./package,
16374	Calibration Kit With specifically designed holder, integrated temperature sensor type K and coding for calibration program recognition, calibration document for sensor included
16384	4-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16385	4-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16386	4-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16375	2-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16376	2-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16377	2-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16378	2-fould Tube Holder OD 7/16" (11.1 mm), ID 5/16" (8.0 mm), Wall 1/16" (1.6 mm)
16379	2-fould Tube Holder OD 1/2" (12.7 mm), ID 3/8" (9.5 mm), Wall 1/16" (1.6 mm)
16380	2-fould Tube Holder OD 5/8" (15.9 mm), ID 3/8" (9.5 mm), Wall 1/8" (3.2 mm)
16381	2-fould Tube Holder OD 3/4" (19 mm), ID 1/2" (12.7 mm), Wall 1/8" (3.2 mm)

6.3 BioSealer®

Order Number	Order Code Description
16360-P1 16360-P2 16360-P3 16360-P4 16360-P5 16360-P6	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 4"–1" and wall thickness 1/16"–3/32" Optional Parametersets: 1–6**
16361-P1 16361-P2 16361-P3 16361-P4 16361-P5 16361-P6	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 4"–1" and wall thickness 1/16"–3/32" Equipped with a removable Sealing Head Optional Parametersets: 1–6**
16362-P7 16362-P8 16362-P9 16362-P10 16362-P11 16362-P12	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8" Optional Parametersets: 7–12**
16363-P7 16363-P8 16363-P9 16363-P10 16363-P11 16363-P12	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8" Equipped with a removable Sealing Head Optional Parametersets: 7–12**
16365	IR Interface incl. Software CD
16366	Ceramic Heating Element Type 1 specified for BioSealer® 16360–16363

** The definition of each parameterset can be obtained in the parametersheet

7. Validation

CONFIDENCE®: Product and Process Specific Validation Services

Sartorius Stedim Biotech Validation Services conducts testing according to current regulatory requirements and guidance documents used in the industry such as PDA Technical Report No. 26 "Sterilizing Filtration of Liquids".

Testing is offered for filter elements, bags and other polymer-based components such as tubing, gaskets, stoppers, vials etc. Considering the process conditions, product formulation and process steps, the test scope (type of test, number of test filter elements or other test components) and complexity of the studies can vary.

Article No.	Description
861096	Validation protocol including one revision.

Microbiological Studies

Article No.	Description
861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria Brevundimonas diminuta
861015	Viability Test for determination of the bactericidal nature of the product (non-standard)
861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria Brevundimonas diminuta

Bacteria Challenge Test performed with 3 filter elements from different lots

Article No.	Description
861012	Bacteria Challenge Test using the standard test bacteria Brevundimonas diminuta
861016	Bacteria Challenge Test (non-standard)

Determination of Product Specific Integrity Test Limits

Product Integrity Test performed with minimum 3 filter elements from different lots

Article No.	Description
861020	Determination of product specific integrity test limits
862021	Determination of product specific integrity test limits (non-standard)

Chemical Compatibility Studies

Chemical Compatibility Test performed with 3 filter sets from different lots

Article No.	Description
861022	Chemical Compatibility Test
861024	Chemical Compatibility Test (non-standard)

Adsorption Studies (upon request)

Particle Release Studies

Particle Release Test typically includes 3 filter elements from different lots

Article No.	Description
861031	Particle Release Test

Leachables | Extractables Studies (analysis of drug product formulation usually requires sample preparation)

Extraction procedure always includes a blank, customer to decide on
1 or 3 filters | bags | components for extraction

861040	Static Extraction (out of box, without prior treatment)
861041	Extraction (including sterilization and | or flushing)
861044	Extraction (non-standard)

Two pretests may be required for complex products, e.g. formulation buffer and complete solution

861070	Analytical pre-test to identify product interference
861071	Analytical pre-test with sample preparation

Number of analyses normally reflects number of extract samples, including blank

861047	GC-MS Analysis without sample preparation
861048	GC-MS analysis with sample preparation
861051	HPLC analysis without sample preparation
861052	HPLC analysis with sample preparation

Following a standard approach HPLC and GC-MS are typical methods for the initial leachables analysis. If no peaks are detected no further study is performed. Additional analysis and type of analytical methods depend on the amount of peaks detected and their signal intensity.
A suitable analytical scheme is then developed in a second step case by case.

Flexel® for LevMixer® bag, using ATMI patented mixing technology

LevMixer® is a trademark or registered trademark of ATMI, Inc.
in the United States, other countries or both

▶ Sartopure® GA

Superior Venting Filter Cartridges

Description
Sartopure® GA and Sartofluor® GA are the ideal choice for air filtration in the biopharmaceutical industry. Sartopure® GA filters expand the service life time of sterilizing grade air filter systems by removal of particles from the air stream. In addition they can be used for all venting purposes that do not necessarily require an integrity testable membrane filter. Sartopure® GA offers an outstanding flow rate at low differential pressure.

Applications
Typically applications for Sartopure® GA air filters are:

– Prefiltration in front of Sartofluor® GA membrane filters or any other membrane air filter

– Venting of non pressure resistant vessels

– Particle removal from air streams, e.g. pressure supplies

Retention Efficiency
The excellent retention and therefore superior protection for stored products has been proven by particle retention filtration and bacteria challenge tests performed under worst case conditions. Sartopure® GA retained 10 million Bacillus subtilis var niger spores per cm^2 filtration area. Featuring a retention of 0.2 µm for gas, Sartopure® GA efficiently protects stored products, e.g. water, liquid sugar, oral solutions etc., in the pharmaceutical industry as well as the food and beverage industry.

Flow Rate
Due to the larger filter area of 0.7 m^2 | 10", Sartopure® GA delivers a flow rate of nearly 40 m^2/h at a differential pressure of 10 mbar. This means Sartopure® GA is the preferred product for high performance filling or draining of tanks | vessels.

Optimized Filter Material
Sartopure® GA's hydrophobic material guarantees an air flow recovery of 60-80% within 30 seconds after the filter has been wetted with water. The water prevents high differential pressures, ensuring fast recovery of air flow rate e. g. after cleaning the tank with hot water | agents.

Documentation
Sartopure® GA cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System.

Air Flow Rates for 10" and 20" Cartridges
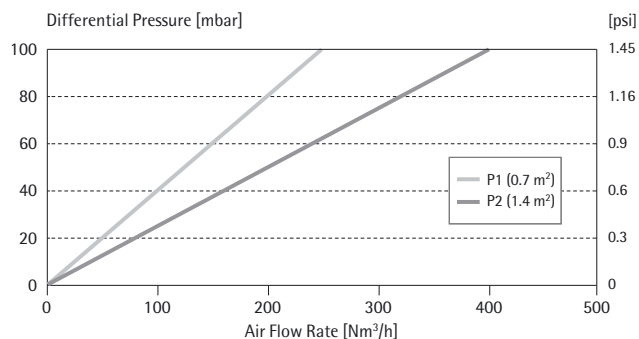
▷ Specifications

Materials

Filter Material	Hydrophobic Glass Fiber
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	Silicone (EPDM or Viton optional)

Pore Size
0.2 µm (nominal in Gases)

Available Sizes | Filtration Area
Size 1	10"	$0.7 \text{ m}^2 \mid 7 \text{ ft}^2$
Size 2	20"	$1.4 \text{ m}^2 \mid 14 \text{ ft}^2$
Size 3	30"	$2.1 \text{ m}^2 \mid 21 \text{ ft}^2$

Available Adapters Cartridges
25, 28

Operating Parameters

Max. allowable differential pressure	5 bar	75 psi at 20 °C
	2 bar	29 psi at 80 °C
Max. allowable back pressure	2 bar	29 psi at 20 °C

Regulatory Compliance
Filter material bacteria challenge tested with Bacillus subtilis var niger spores

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134 °C, 20 min. at max differential pressure of 0.5 bar | 7 psi

Autoclaving
134 °C, 2 bar | 29 psi, 30 min

Sterilization Cycles
In-Line Sterilization: Min. 50

Ordering Information

Order Code	Size	Pore Size [µm]
559**07P1----GA	1	0.2
559**07P2----GA	2	0.2
559**07P3----GA	3	0.2

Air Flow Recovery

Flow Rate (Nm³/h)

Air flow rate of a new 10" cartridge, Sartopure® GA

Air flow rate of a new 10" cartridge, Sartopure® GA, 30 sec. after it has been completely wetted with water

Differential Pressure 10 mbar [0.15 psi]
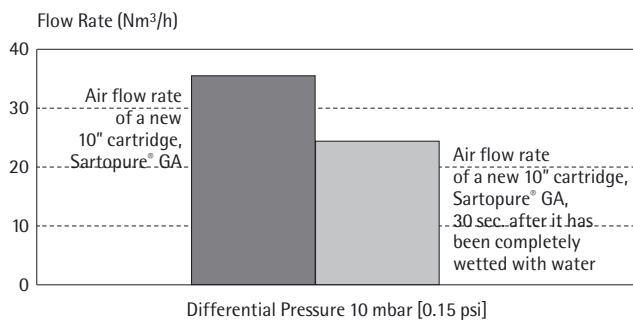
▶ Sartofluor® GA

Air Filter Cartridges for Bio-Pharmaceutical Applications

Description
Sartofluor® GA filter cartridges, manufactured with permanently hydrophobic PTFE membranes, are specially designed for sterile venting and gas applications where adherence to cGMP's is a must. Due to their permanent hydrophobicity, Sartofluor® GA cartridges offer the highest process security, even with high volume gas streams, extreme humidity and stringent in-line steam sterilizations.

Applications
Sartofluor® GA cartridges are ideally suited for application requiring a sterile, hydrophobic gas filter such as:

– Fermenter and bioreactor inlet gases

– Fermenter and bioreactor vents

– Autoclave vents

– Lyophilizer vents

– Purified water system storage tank vents

– In process storage tank vents

– Filling equipment process air

Performance
PTFE is the most hydrophobic of all membranes used in sterile filtration of gases. The inherent hydrophobicity of the PTFE membrane remains unaffected by repeated autoclaving or steaming. The sterile filtration of dry or moist gases is guaranteed. The unique single layer design is optimized for high flow rates at low differential pressures with short blow down times.

Stability
Sartofluor® GA can withstand high differential pressures in either the forward or reverse direction of flow. The mechanical stability and membrane structure are not affected by pulsation or high flow rates.

Water Intrusion Test (WIT) | Water Flow Test (WFT)
A Sartorius Stedim Biotech development, the WIT offers the first and only correlated in-situ integrity testing system for hydrophobic vent filters. WIT not only eliminates downstream intervention and preflushing, more importantly, it does not require a single drop of alcohol.

Quality Control
Each individual element is tested for integrity prior to released assuring absolute reliability.

Documentation
Sartofluor® GA cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Related Products
Sartopure® GA, page 130

Air Flow Chart Sartofluor® GA 0.2 µm
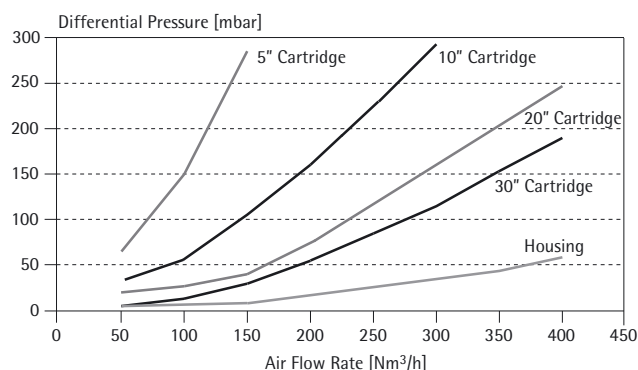
Under atmospheric pressure conditions

▷ Specifications

Materials

Membrane	PTFE
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	Silicone (EPDM or Viton optional)

Pore Size
0.2 µm
0.1 µm

Available Sizes | Filtration Area

Size 0	5"	0.375 m² | 4.04 ft²
Size 1	10"	0.75 m² | 8.1 ft²
Size 2	20"	1.5 m² | 16.1 ft²
Size 3	30"	2.25 m² | 24.2 ft²

Available Adapters Cartridges
25, 26, 27

Operating Parameters

Max. allowable differential pressure	5 bar | 75 psi at 20 °C 0.5 bar | 7 psi at 140 °C
Max. allowable back pressure	3 bar | 43.5 psi at 20 °C

Extractables
Sartofluor® GA filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test.

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134 °C, 20 min. at max differential pressure of 0.5 bar | 7 psi

Autoclaving
134 °C, 2 bar | 29 psi, 30 min

Sterilization Cycles
In-Line Sterilization: min 150
(in direction and in reverse direction of filtration)

Technical References
Validation Guide:
SPK 5711-e

Ordering Information

Order Code	Size	Pore Size [µm]
5182558T1----GA	10"	0.1
5182558T2----GA	20"	0.1
5182558T3----GA	30"	0.1
5182507T1----GA	10"	0.2
5182507T2----GA	20"	0.2
5182507T3----GA	30"	0.2
5182507T0----GA	5"	0.2

Blow-Down Time after WIT
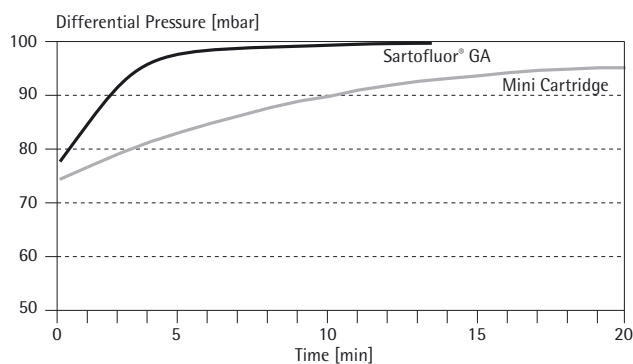
Differential pressure after steam sterilization measured at 200 mbar

▶ Sartofluor® 150 & 300

Superior Sterilizing Grade Air Filtration for Small Scale Bioreactors

Single-Use Technology

Description
Sartofluor® 150 and Sartofluor® 300 capsules are the ideal ready-to-use sterilizing grade air filter units for venting of small-scale bioreactors and vessels. Sartofluor® 150 and Sartofluor® 300 offer the highest safety for valuable products. The filtration area is optimized for high flow rates at low differential pressures required by R&D labs in pharmaceutical and biotechnology research.

Applications
Typical applications for Sartofluor® 150 and Sartofluor® 300 are particle removal and sterile filtration of air and gases for:

– Bioreactors

– Vessels

– Glass Bottles

The hydrophobic PTFE membrane is also suitable for liquid filtration of aggressive media:

– Acids

– Solvents

Flow Rate
The unique pleated filter construction offers superior flow rate at low differential pressures in comparison to conventional disk filter systems. Sartofluor® 150 (150 cm^2) and Sartofluor® 300 (300 cm^2) expand the portfolio of pleated membrane filters to fill the gap between small disk filters with 20 cm^2 filtration area and the smallest standard capsule with 500 cm^2 filtration area.

Microbiological Retention
Sartofluor® 0.2 μm rated 150 & 300 capsules are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is integrity tested prior to release, assuring absolute reliability.

Documentation
Sartofluor® 150 & 300 capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Air flow rate [l/min]

Sartofluor® 300

Sartofluor® 150

Differential Pressure [mbar]
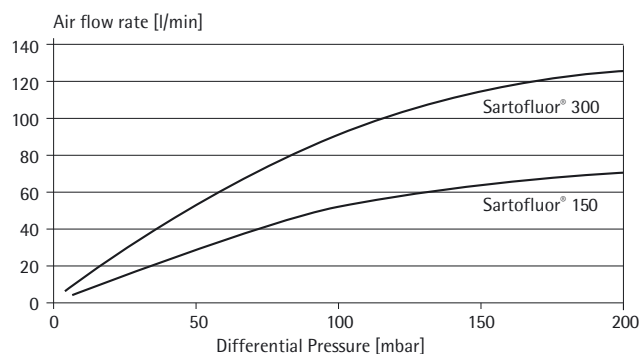
▷ Specifications

Materials

Membrane	PTFE
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
Housing	Polypropylene

Pore Size
0.2 μm

Available Sizes | Filtration Area
Size 4   0.015 m^2 | 0.16 ft^2
Size 5   0.03 m^2 | 0.32 ft^2

Available Connectors
SS, SO, OO   (150)
OO   (300)

Operating Parameters

Max. allowable differential pressure	4 bar | 58 psi at 20 °C 2 bar | 29 psi at 80 °C
Max. allowable back pressure	2 bar | 29 psi at 20 °C

Extractables
Sartofluor® 0.2 μm rated 150 & 300 filter capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

Sterilization

Autoclaving
134 °C, 2 bar | 29 psi, 30 min

Note
Sartofluor® 150 and Sartofluor® 300 capsules cannot be in-line steam sterilized

Sterilization Cycles
Autoclaving: Max. 3

Technical References
Validation Guide:
SPK 5732-e

Order Information

Order Code	Pore Size [μm]
Sartofluor® 150	
5181307T4--SS--B	0.2
5181304T4--SO--B	0.2
5181307T4--OO--B	0.2
Sartofluor® 300	
5181307T5--OO--D	0.2

▶ Sartofluor® MidiCaps and MaxiCaps

Single-Use Technology

Description
Sartofluor® MidiCaps and MaxiCaps 0.2 µm rated are self contained, ready to use, sterile filter units for sterilizing grade filtration in the pharma│biotech industry. Their unique hydrophobic PTFE membrane is ideally suited for particle removal and sterilizing grade filtration of gases and for filtration of highly aggressive liquids like solvents, acids and bases.

Applications
Typical applications include sterile venting of:

– Fermenters

– Vessels

– Glass Bottles

The hydrophobic PTFE membrane is also suitable for filtration of aggressive liquids like:

– Acids│Bases

– Solvents

Easy to Use
Sartofluor® MidiCaps and MaxiCaps are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

Flexibility
Sartofluor® MidiCaps and MaxiCaps are available with various filtration areas from 500 cm² │ 0.5 ft² up to 1.5 m² │ 16.1 ft² for easy adoption to any filtration process independent from the batch size.

Performance
The unique hydrophobic single layer PTFE membrane provides outstanding flow rates for gases and liquids at low differential pressure assuring most economic system design.

Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Microbiological Retention
Sartofluor® MidiCaps and MaxiCaps 0.2 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

Documentation
Sartofluor® MidiCaps and MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Air Flow Rates for Sartofluor® MidiCaps, 0.2 µm Rated with SS-Connector
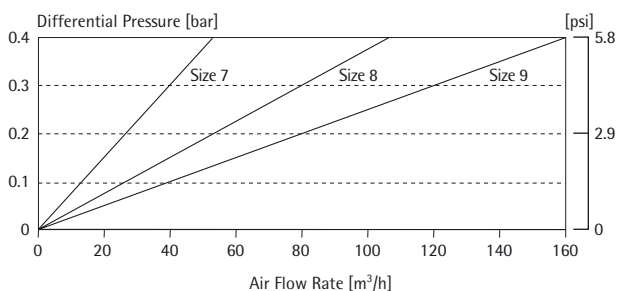
Water Flow Rates for Sartofluor® MidiCaps, 0.2 µm Rated with SS-Connector
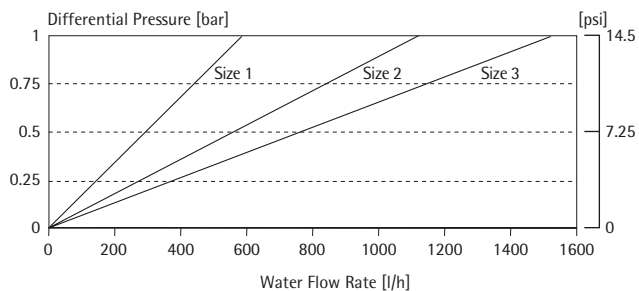
▷ Specifications

Materials

Membrane	PTFE
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	EPDM
Filling Bell	Polycarbonate

Pore Sizes
0.1 µm   (only MidiCaps)
0.2 µm   (MidiCaps & MaxiCaps)
0.45 µm   (only MidiCaps)

Available Sizes│Filtration Area

MidiCaps
Size 7   0.05 m²│0.5 ft²
Size 8   0.1 m²│1 ft²
Size 9   0.2 m²│2 ft²
Size 0   0.45 m²│5 ft²

MaxiCaps
Size 1   10"   0.5 m²│5.4 ft²
Size 2   20"   1.0 m²│10.8 ft²
Size 3   30"   1.5 m²│16.1 ft²

Available Connectors MidiCaps
SS, SO, OO, FF, FO, FH, HH (only for size 7)

Available Connectors MaxiCaps
SS, SO, OO, FF, BB

S: 1½" Tri-Clamp (Sanitary)
O: ½" Single stepped hose barb
F: ¾" Tri-Clamp (Sanitary)
H: ¼" Multiple stepped hose barb
          (with filling bell at the outlet)
B: ¾" – 1" Multiple stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar│72.5 psi at 20°C (MidiCaps) 4 bar│58 psi at 20°C (MaxiCaps) 2 bar│29 psi at 80°C
Max. allowable back pressure	2 bar│29 psi at 20°C

Extractables
Sartofluor® MidiCaps and MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to HIMA│ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

Autoclaving:
134°C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles
Autoclaving: Min. 25

Technical References
Validation Guide:
SPK5758-e (MidiCaps)

Order Information

Order Code	Pore Size [µm]	Pack Size [Pieces]	Test Pressure [bar│psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar│psi]
MidiCaps					
5185307T7--**--A	0.2	4	0.7│10.2	2	1.0│14.5
5185307T8--**--A	0.2	4	0.7│10.2	3	1.0│14.5
5185307T9--**--A	0.2	4	0.7│10.2	4	1.0│14.5
5185307T0--**--V	0.2	2	0.7│10.2	8	1.0│14.5
MaxiCaps					
5181307T1--**	0.2	1	0.7│10.2	7	1.0│14.5
5181307T2--**	0.2	1	0.7│10.2	14	1.0│14.5
5181307T3--**	0.2	1	0.7│10.2	21	1.0│14.5

**: Connector Styles

▶ Aerosart

Airfilter Cartridge for Industrial Applications

Description
Aerosart high performance air filter cartridges can significantly reduce operating costs. The Aerosart is a high flow rate, low differential pressure, hydrophobic membrane filter. The unique single layer filter construction also reduces Blow-Down-time. Both the high flow rate and the short Blow-Down-time lowers the energy cost of air supply operations.

Applications
The Aerosart is designed for large-scale fermentation inlet and exhaust gas filtration.

Microbiological Safety
Aerosart filter cartridges have been tested and passed aerosol bacterial and viral challenge tests. Tests were conducted using MS-2 coli phages (NCIMB 10 108) and B. subtils var. niger spores (NCTC 10073) at a challenge level of greater than 2.5×107 under worst case conditions of greater than 90% RH. No MS-2 coli phages or B. subtilis spores were detected on the downstream side of the Aerosart filter cartridges.

Performance
The unique single layer pleated filter construction of the highly hydrophobic PTFE membrane provides low differential pressures, excellent flow rates and the fastest blow down times of any gas service filter.

Long Service Life Time
The mechanical and thermal stresses experienced during steam in place sterilization pose the highest risk to any filter cartridge. In many cases, Aerosart filter cartridges will be used for more the 120 steaming cycles. Tests have shown Aerosart cartridges to pass integrity tests with greater than 150 steaming cycles.

Air Flow Rates Aerosart
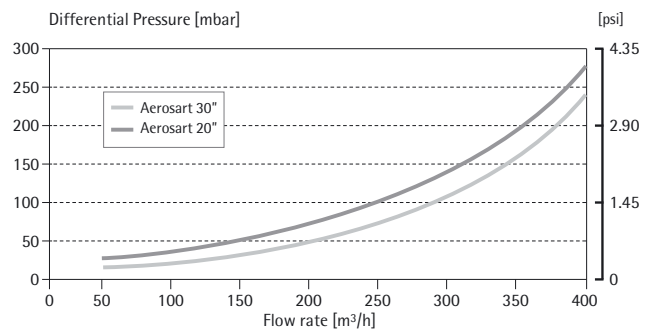
Air flow rate for Aerosart filter cartridges (0.2 μm) in relation to the filter cartridge heights at atmosphere pressure condition.

▷ Specifications

Materials

Filter Membrane	PTFE
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	EPDM

Pore Size
0.2 µm

Available Sizes│Filtration Area

Size 1	10"	0.7 m^2 │ 7.5 ft^2
Size 2	20"	1.5 m^2 │ 16.1 ft^2
Size 3	30"	2.25 m^2 │ 24.2 ft^2

Available Adapters
25

Packaging
6 cartridges per box

Operating Parameters

Max. allowable differential pressure	5 bar │ 75 psi at 20°C 0.5 bar │ 7 psi at 134°C
Max. allowable back pressure	3 bar │ 43.5 psi at 20°C 0.5 bar │ 7 psi at 134°C

Regulatory Compliance
Qualified for retention of aerosolized bacterial spores and viruses (coli-phages) in air

Non pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134°C, 20 min. at a maximum differential pressure of 0.5 bar │ 7 psi

Sterilization Cycles
Minimum of 150 In-Line Sterilization cycles

Ordering Information

Order Code	Size	Pore Size [µm]
5152507T1---E--C	10"	0.2
5152507T2---E--C	20"	0.2
5152507T3---E--C	30"	0.2
5152707T1---E--C	10"	0.2
5152707T2---E--C	20"	0.2
5152807T1---E--C	10"	0.2
5152807T2---E--C	20"	0.2

▶ Midisart® 2000

The Ready-to-Use Filter for Sterilizing Gases and Venting

Single-Use Technology

Midisart® 2000 filtration units are ideal tools in biotechnology, the pharmaceutical industry, research institutes and anywhere you need sterile vents, bioisolation or sterile air and gases.

Midisarts® are excellent for

– sterile venting of filling vessels and fermentation carboys, including culture vessels and CO_2 incubators (6 to 120 liters)

– venting of holding tanks for sterile, distilled water and liquid culture media

– autoclave venting

– in-line sterilization of and particulate removal from air and gases, such as sterilization of air for small fermenters

Midisart® 2000 filtration units have been specially designed for maximum handling ease and safety. Tapered hose barbs ensure a simple and secure hold for 6- to 12-mm inner diameter tubing. Other connector types such as a small hose barb (for tubings with 4–12 mm inner diameter), ⅛″ NPT thread and TriClamp are also available. Midisart® is lightweight – only 20 g – so it will not weigh down or kink tubing.

User Benefits

1. Maximum Handling Ease

– Midisart® 2000 comes individually packaged and presterilized – it's ready to connect!

2. Extra Reliability and Safety

– Midisart® 2000 is integrity testable and delivers reproducible results.

– The membrane is reinforced with polypropylene gauze, giving the Midisart® unit added stability and making it pressure resistant up to 3 bar (approx. 44 psi).

– Midisart® 2000 entirely eliminates moisture breakthrough because of its inherently hydrophobic PTFE material.

– In addition, Midisart® is biosafe because all materials of construction meet the requirements of the current USP Plastics Class VI testing.

– Midisart® 2000 units easily withstand at least 20 autoclaving cycles with no loss in performance. The convenient Memory Discs supplied with each Midisart® 2000 in UPN-coded boxes enable you to keep track of the number of autoclaving cycles by marking or clipping off each cycle. This feature is key in complying with GLP and ISO standards for traceable documentation.

3. Quality Control Certificate

– Each unit is automatically tested 100% for housing and membrane sealing during manufacture as part of our zero-defect quality control testing.

– The lot number and the individual unit number are imprinted on the top part of each Midisart® 2000 housing to ensure complete traceability.

Midisart® 2000 units are visually inspected before they are packaged. In addition to 100% leak testing, random samples taken from each lot undergo the following tests to assure compliance with Sartorius Stedim Biotech stringent in-house quality assurance standards:

– Housing burst pressure test

– Pressure-hold test

– Bubble point test

– Pyrogen test

– Sterile filtration capability

– Flow rate test

– Sterility test

Performance

– With a diameter measuring just 64 mm, Midisart® incorporates a filter area of 20 cm², which means that it is "packed" with high flow rate performance power!

– Midisarts® multiply filtration performance in more ways than one. They can be autoclaved at least 20 times at 134°C!

Chemical Compatibility
The materials used in Midisart® (PTFE and polypropylene) give it excellent compatibility with the solvents and other chemicals listed below:

– Acetic acid (concentrated), acetone, acetonitrile

– n-butanol

– Cellosolve (ethyl), chloroform

– Diethylacetamide, dimethyl formamide, dimethyl sulfoxide, dioxane

– Ethanol, ethyl acetate, ethylene glycol

– Freon TF

– Gasoline

– 1 N hydrochloric acid, hexane

– Isobutanol, isopropanol

– Methanol, methylene chloride, methyl ethyl ether, methyl ethyl ketone

– Sodium hydroxide (5%)

– Pentane

– Tetrahydrofuran, toluene, trichloroacetic acid, trichloroethane

– Water

– Xylene

However, its compatibility can be affected by various factors, such as temperature, concentration, composition, etc. We therefore recommend that you perform a trial filtration run to test whether Midisart® is compatible with the particular medium you wish to filter.

Midisart® 2000 can also be used to filter aqueous solutions. In this case, it must be first wetted with alcohol to overcome the membrane's hydrophobicity.

Standard Hose Barb

Small Hose Barb

⅛" NPT Thread

TriClamp

▷ Specifications

Technical Specifications

Filter material	PTFE – reinforced with polypropylene gauze
Housing material	Polypropylene
Filtration area	20 cm^2
Housing diameter	64 mm
Priming volume	Approx. 3 ml
Maximum operating pressure	300 kPa (3 bar = 44 psi)
Water penetration point (breakthrough)	0.2 µm – approx. 400 kPa (4 bar = 58 psi) 0.45 µm – approx. 300 kPa (3 bar = ~ 44 psi)
Max. autoclaving temperature	134°C
Max. autoclave cycles	20
Hold-up volume	Before the bubble point approx. 1.0 ml After the bubble point approx. 0.5 ml
Biosafety	USP Plastics Class VI
Bubble point with isopropanol (60%)	0.45 µm ≥ 0.9 bar (~13.1 psi) 0.2 µm ≥ 1.1 bar (~16 psi)
Flow rate for air at Δp = 0.1 bar (1.45 psi) (1 bar = 100 kPa = 14.5 psi)	0.2 µm pore size 5.0 l/min 0.45 µm pore size 8.5 l/min

Order Information

Order Numbers	Pore Size	Membrane	Connectors E|A	Pieces/Case	Sterile
17804 E	0.45 µm	PTFE	Hose Barb | Hose Barb	12	Yes
17804 G	0.45 µm	PTFE	Hose Barb | Hose Barb	25	Yes
17804 NPE	0.45 µm	PTFE	⅛" | ⅛" NPT	12	Yes
17804 NPG	0.45 µm	PTFE	⅛" | ⅛" NPT	25	Yes
17805 E	0.2 µm	PTFE	Hose Barb | Hose Barb	12	Yes
17805 G	0.2 µm	PTFE	Hose Barb | Hose Barb	25	Yes
17805 NPE	0.2 µm	PTFE	⅛" | ⅛" NPT	12	Yes
17805 NPG	0.2 µm	PTFE	⅛" | ⅛" NPT	25	Yes
17805 UPN	0.2 µm	PTFE	Hose Barb | Hose Barb	100	No
17805 UPQ	0.2 µm	PTFE	Hose Barb | Hose Barb	500	No
17809 UNN	0.2 µm	PTFE	⅛" | ⅛" NPT	100	No
17812 UNN	0.2 µm	PTFE	⅛" | Hose Barb	100	No
17805 TCN	0.2 µm	PTFE	TriClamp | TriClamp	100	No
17877 UPN	0.2 µm	PTFE	small Hose Barb | small Hose Barb	100	No

In the interest of further development of Sartorius Stedim Biotech products, we reserve the right to make changes without notice.

▶ Midisart® BV

Sterile Venting Filter on Disposable Bag and Tubing Assemblies

Single-Use Technology

Description
Midisart® BV disposable venting filter manu-factured with hydrophobic, reinforced PTFE membranes, are especially designed for sterile venting on disposable bag manifolds and tubing systems.

Applications
Midisart® BV filter elements used on disposable bags do prevent the collapsing of the bag chamber during draining by sterile venting.

Used on disposable bag manifolds Midisart® BV facilitate sterile drainage of the tubing in order to empty the tubing connection between the single bags of the bag manifold.

Stability
The reinforcement of the hydrophobic PTFE membrane by a Polyester fleece assures the full mechanical stability of the PTFE mem-brane for specified applications after gamma sterilization. Midisart® BV is integrity testable.

Quality Control
Each individual element is tested 100% for housing and membrane sealing during manu-facture. The lot number and the individual unit number are imprinted on the top part of each Midisart® BV housing to ensure complete traceability.

Documentation
Midisart® BV filter elements are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Manage-ment System. A Validation Guide is available for compliance with regulatory requirements.

▷ Specifications

Materials

Membrane	PTFE
Support fleece	Polyester
Housing	Polypropylene

Pore Size
0.2 µm

Article Codes
17805--------BVE (12 per box)
17805--------BVN (100 per box)
17805--------BVQ (500 per box)

Connectors
Multiple stepped hosebarb (in- and outlet)

Filtration Area
20 cm² | 3 square inch

Housing Diameter
64 mm | 2.5"

Sterilization
Gamma Irradiation
25 kGy (recommended)
50 kGy (max.)

Max. Operation Pressure

In direction of filtration	1.5 bar	22 psi
Opposite direction	0.5 bar	7 psi

▶ # Sartosteel

Removing Particles from Liquids, Gas and Steam

Description
Sartosteel are especially developed for removing particles from liquids, gas and steam.

Applications
Sartosteel is applied in biopharmaceutical process such as:

– Steam filtration

– Condensate filtration

– Water filtration

Further Applications
Chemical Industrie

– Polymer filtration (from 3 µm)

– Catalyst retention (10 µm)

– Gas filtration (≥ 80 ℃)

– Cleaning agents

Machine-building │ Automotive Industries

– Fuel filtration

– Hydraulic oils

Performance
Sartosteel stainless steel depth filter catridges contain sintered, homogeneous, 0.4 mm thick non woven stainless steel mesh layers, which are reinforced on both sides by mesh supports. These filters are used for removing particles from liquids and gases (steam). Sartosteel filter cartridges offer the user maximum security along with low filtration costs.

Product Benefits

– High dirt-handling capacity

– High mechanical stability

– Homogeneous material construction

– Absolutely leak-proof connections between end caps and filter unit

Quality Control
Sartocell are designed, developed and manu-factured in accordance with a DIN ISO 9001 certified Quality Management System.

Particle retention rating 3 µm Sartosteel

Retention capability in %
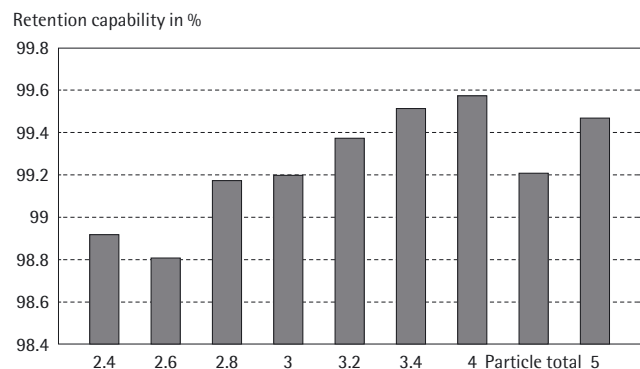
Particles: Latex particles in ethanol 96%

▷ Specifications

Materials
Sintered non woven stainless steel media, reinforced on both sides with sintered-on mesh

Filter Media	AISI 316 L
Support Mesh	AISI 304 | 316 L
Outer Support	AISI 304 | 316 L
Core	AISI 304 | 316 L
End Caps	AISI 304 | 316 L
Gaskets	Silicone*

* standard: also availabe in Viton and EPDM

Retention Rates
3 µm

Filter Area
10" element: 500 cm² (effective filter area)

Operation Parameters
Max. differential pressure:
≤ 20 bar, in the direction of filtration
≤ 1 bar, opposite to the direction
of filtration

Resistance | Compatibility

Thermal	up to 200 °C (not with silicone sealing)
Chemical	inert to caustic solutions, solvents not compatible with aggressive and relatively high concentrations of acid (≥ 5%)

Order Information

Cartriges

Order Code	Adapter Type	Retention Rate [µm]	Height
570▪▪02S1	25, 28	3	10"
570▪▪02S5	25, 28	3	20"
570▪▪02S3	25, 28	3	30"

▪▪: Please replace the blanks with the appropriate two-letter combination for the adapter type.

Sartosteel – sarturated steam (T = 121°C, P = 1 bar system pressure)
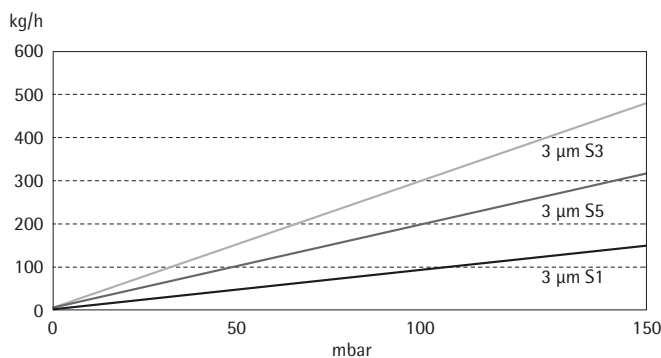
▶ Jumbo Star Sartopure® GF Plus

A "Giant" Step Forward in Pleated Depth Filters

Description
Jumbo Star Sartopure® GF Plus modular filter elements are ideal for removal of contaminates like colloids, lipids, protein aggregates (Host Cell Protein) and bioburden from bio-pharmaceutical fluids. They can be used for large-scale cell harvest clarification in lieu of lenticular filters and for aggregates removal in large-scale Protein Pool filtrations. They offer excellent protection to the membrane filters & chromatography columns in downstream processing. These filters do not contain any DE embedded in a loose cellulosic matrix. As a result, these GF Plus filters typically have significantly less Extractables compared to the Lenticular filters.

Application
Jumbo Star Sartopure® GF Plus are the ideal choice for large-scale prefiltration and clarification of:

– Harvested Cell Culture fluids

– Microbial Fermentation broths

– Serum free or serum containing cell culture media

– Process Intermediates containing lipids, colloids and protein aggregates as contaminants.

Effective Clarification
Jumbo Star Sartopure® GF Plus feature glass fiber layers for an effective clarification of fluid streams based on the combination of adsorption and sieve retention.

Economic Prefiltration
Based on a cutting-edge pleating technology; extremely high filter area is incorporated in each 10″ filter element. In addition, the 3-dimensional filter matrix of Sartopure® GF Plus depth filters ensures outstanding total throughput performance thus ensuring most economic design of your prefiltation scheme.

Reliable Operation
The new modular construction, coupled with effective combinations of nonwoven polypropylene and glass fibre layers, achieves the highest process reliability and reproducible results from batch to batch even under varying process conditions.

Cost Saving
The modular filter construction in combination with the expanded filter area results in a smaller filter housing, minimizing the required footprint. Jumbo Star filters are available in 4 different cartridge sizes to match a wide range of batch sizes.

Flexibility
Jumbo Star Sartopure® GF Plus filter elements are available in a modular design from 5 m^2 up to 20 m^2 of filter area. This flexibility facilitates an easy adoption to your filtration process, depending on the batch size.

Documentation
Jumbo Star Sartopure® GF Plus are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow 10″ Cartridge

Differential Pressure [mbar] · [psi] · Water Flow Rate [l/min]

— Jumbo Star Sartopure® GF Plus 0.65 µm
-- Jumbo Star Sartopure® GF Plus 1.2 µm
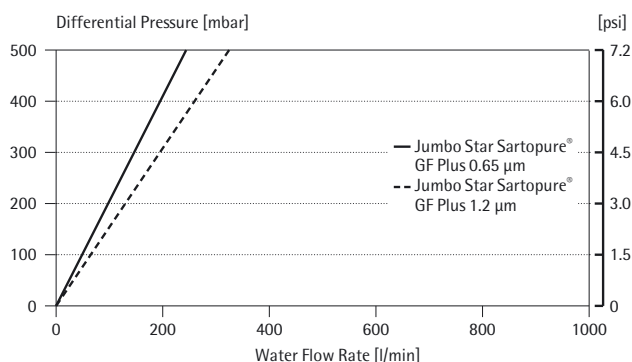
▷ Specifications

Materials

Filter Material	Multiple glass fibre layers
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	Silicone

Retention Rates
0.65 µm
1.2 µm

Available Sizes | Filtration Area
Size 1   10"   5 m²
Size 2   20"   10 m²
Size 3   30"   15 m²
Size 4   40"   20 m²

Available Adapter
40

Operating Parameters

Max. allowable differential pressure	4 bar | 58 psi at 20°C 1 bar | 14.5 psi at 80°C 0.5 bar | 7.2 psi at 120°C
Max. allowable back pressure	1.5 bar | 22 psi at 20°C

Extractables
Jumbo Star Sartopure® GF Plus meet or exceed the requirements for WFI quality standards set by current USP after WFI flush.

Regulatory Compliance
Non pyrogenic according to USP Bacterial Endotoxins Testing

Passed USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

Inline-Steam Sterilization
121°C, 30 min. at max differential pressure of 0.5 bar | 7 psi

Autoclaving
134°C, 30 min, 2 bar | 29 psi

Technical References
Validation Guide:
SPK5774-e09021
85034-537-52

Ordering Information

Order Code	Retention Rate
5554005JX	0.65 µm
5554003JX	1.20 µm

X = 1   Size 10"
X = 2   Size 20"
X = 3   Size 30"
X = 4   Size 40"

▶ # Jumbo Star Sartopure® PP2

A "Giant", Ready-to-Use Particulate Filtration & Bioburden Reduction Filter

Description
Jumbo Star Sartopure® PP2 modular filter elements can be used for a wide range of prefiltration applications. Retention of hard, non deformable particles and reduction of bioburden from liquids is achieved through fractionated defined depth filtration. Jumbo Star Sartopure® PP2 combine multiple layers of progressively finer polypropylene depth filter fleeces in a pleated format.

Application
Jumbo Star Sartopure® PP2 are the ideal choice for prefiltration and clarification of:

– Plasma Fractions

– LVP Solution

– Ophtalmics

– WFI

– Process water

Security
Jumbo Star Sartopure® PP2 filter elements ensure selective and defined particle retention. They are a valuable protection for the final membrane filter. The completely polypropylene construction offers a broad chemical compatibility.

Economic Prefiltration
Highest dirt loading capacities in combination with high flow rates make Jumbo Star Sartopure® PP2 filter elements an ideal choice for a variety of large-scale filtration applications in the Pharmaceutical industry. Filtration costs are reduced to a minimum as these filters provide a long service life in many applications.

Reliable Operation
The new modular construction together with effective combination of nonwoven polypropylene achieves highest process reliability and reproducible results from batch to batch even under varying process conditions.

Cost Saving
The modular filter construction in combination with the expanded filter area results in a smaller filter housing, minimizing the required footprint. Jumbo Star filters are available in 4 different cartridge sizes to match a wide range of batch sizes.

Flexibility
Jumbo Star Sartopure® PP2 filter elements are available in a modular design from 7 m^2 filter area up to 28 m^2 filter area. This flexibility facilitiates an easy adoption to your filtration process, depending on the batch size.

Documentation
Jumbo Star Sartopure® PP2 filter are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow 10" Cartridge
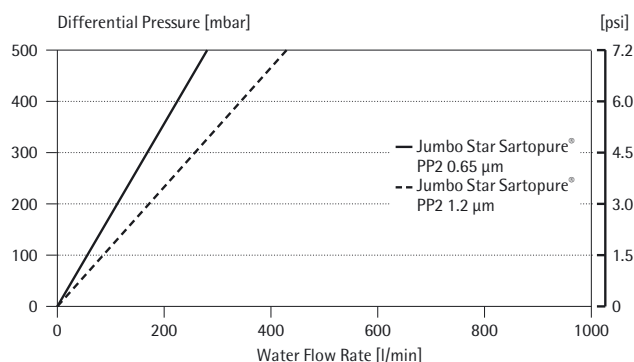
▷ Specifications

Materials

Filter Material	Multiple Polypropylene layers
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	Silicone

Retention Rates
0.65 µm, 1.2 µm, 3 µm, 8 µm, 20 µm

Available Sizes | Filtration Area
Size 1	10"	7 m^2
Size 2	20"	14 m^2
Size 3	30"	21 m^2
Size 4	40"	28 m^2

Available Adapter
40

Operating Parameters

Max. allowable differential pressure	4 bar | 58 psi at 20°C 1 bar | 14.5 psi at 80°C 0.5 bar | 7.2 psi at 120°C
Max. allowable back pressure	1.5 bar | 22 psi at 20°C

Extractables
Jumbo Star Sartopure® PP2 filter meet, or exceed the requirements for WFI quality standards set by current USP without the need for a WFI flush, prior to use.

Regulatory Compliance
Non pyrogenic according to USP Bacterial Endotoxins Testing

Pass USP Plastic Class VI Test

No fiber releasing according to 21 CFR

Sterilization

Inline-Steam Sterilization
121°C, 30 min. at max differential pressure of 0.5 bar | 7 psi

Autoclaving
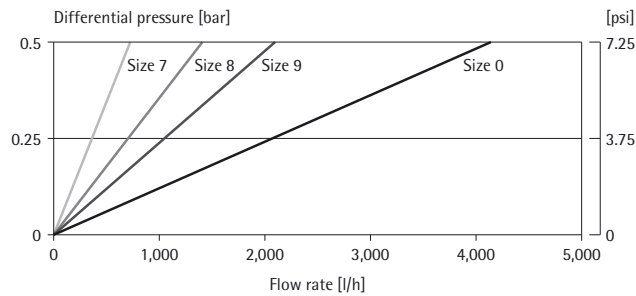134°C, 30 min, 2 bar | 29 psi

Technical References
Validation Guide:
SPK5774-e09021
85034-537-52

Ordering Information

Order Code	Retention Rate
5594005JX	0.65 µm
5594003JX	1.20 µm
5594002JX	3.00 µm
5594001JX	8.00 µm
5594020JX	20.0 µm

X = 1   Size 10"
X = 2   Size 20"
X = 3   Size 30"
X = 4   Size 40"

Water Flow 10" Cartridge

Differential Pressure [mbar] — [psi] — Water Flow Rate [l/min]
Jumbo Star Sartopure® PP2 3.0 µm
Jumbo Star Sartopure® PP2 8.0 µm
Jumbo Star Sartopure® PP2 20 µm
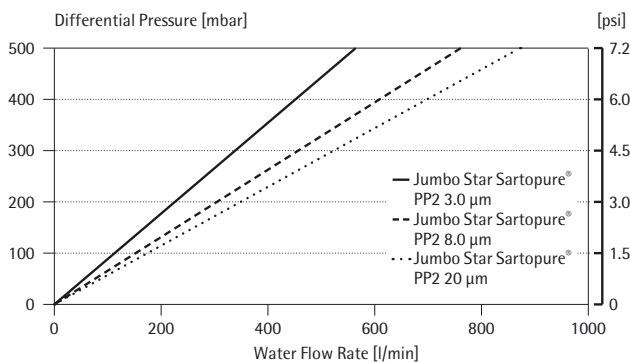
▶ Sartopure® PP2

Particle & Bioburden Reduction Filter Cartridges

Description
Sartopure® PP2 cartridges were optimized for the wide range of prefiltration. Retention of particles and reduction of bioburden from liquids as well as gases is ensured through fractionated defined depth filtration. Sartopure® PP2 filters combine multiple layers of progressively finer pleated polypropylene depth filter material. They are ideally suited for clarification and prefiltration prior to membrane filtration.

Applications
Typical applications for Sartopure® PP2 filters are particle removal from various media like:

– Plasma Fractions

– Vaccines

– MAB

– Diagnostics

– Purified Protein Solutions

– Biological Fluids

– Ophtalmics

– Solutions containing Preservatives

– WFI

Security
The Sartopure® PP2 filter elements ensure the selective, effective and defined particle retention. It is a valuable protection for the final filter. The all polypropylene construction offers a broad chemical compatibility.

Performance
The Sartopure® PP2 filter elements combine high dirt loading capacities with long service life and extremely high flow rates.

Economical Results
Considering all features and benefits, Sartopure® PP2 filters guarantee the maximum in process profitability.

Flexibility
Sartopure® PP2 filters are available as standard filter cartridges, mini cartridges, MaxiCaps, MidiCaps and in various sizes to allow for broadest choice and highest process flexibility.

Documentation
Sartopure® PP2 cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for 10" Cartridges and MaxiCaps
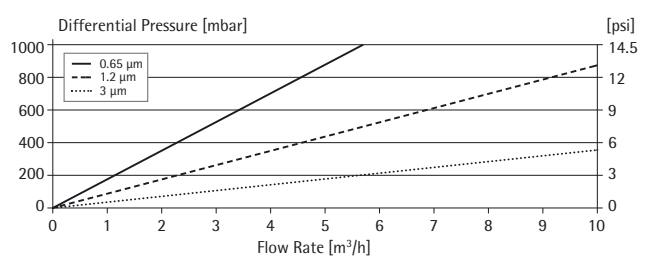
▷ Specifications

Materials

Filter Material	Multiple Poly-propylene layers
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Retention Rates
0.65 µm, 1.2 µm, 3 µm, 5 µm, 8 µm,
20 µm, 50 µm

Available Sizes│Filtration Area

Cartridges
Size 1	10"	0.6 m^2 │ 6 ft^2
Size 2	20"	1.2 m^2 │ 12 ft^2
Size 3	30"	1.8 m^2 │ 18 ft^2

Mini Cartridges
Size 7	0.05 m^2 │ 0.5 ft^2
Size 8	0.1 m^2 │ 1 ft^2
Size 9	0.2 m^2 │ 2 ft^2

Available Adapters Cartridges
21, 25, 27, 28

Available Adapter Mini Cartridges
15

Operating Parameters

Max. allowable differential pressure	5 bar │ 75 psi at 20 ℃ 2 bar │ 29 psi at 80 ℃
Max. allowable back pressure	2 bar │ 29 psi at 20 ℃

Extractables
Sartopure® PP2 cartrides meet, or exceed
the requirements for WFI quality standards
set by the current USP.

Regulatory Compliance
Non pyrogenic according to USP Bacterial
Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134 ℃, 20 min. at max differential pressure
of 0.5 bar │ 7 psi

Autoclaving
134 ℃, 2 bar │ 29 psi, 30 min

Sterilization Cycles
In-Line Sterilization: (only cartridges)	Min. 25
Autoclaving:	Min. 25

Technical References
Validation Guide:
SPK 5717-e

Extractables Guide:
SPK 5719-e

Order Information

Order Code	Pore Size [µm]
Cartridges	
559**05PX	0.65
559**03PX	1.2
559**02PX	3
559**42PX	5
559**01PX	8
559**20PX	20
559**50PX	50

**	= Adapter
X	= Height

Water Flow Rates for 10" Cartridges
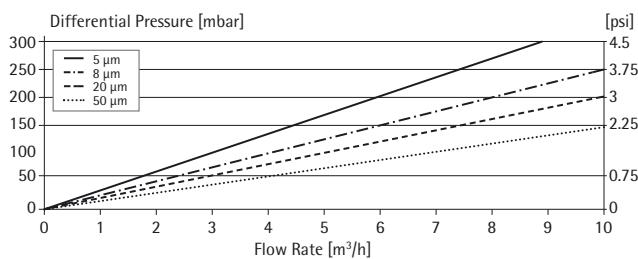
▶ Sartopure® PP 2 MidiCaps

Particle Filtration & Bioburden Reduction Filter Capsules

Single-Use Technology

Description
Sartopure® PP 2 MidiCaps and MaxiCaps are self-contained ready to use filter capsules for a wide range of prefiltration applications. Retention of hard, non derformable particles and reduction of bioburden from liquids as well as gases is ensured through fractionated defined depth filtration. Sartopure® PP 2 MidiCaps and MaxiCaps combine multiple layers of progressively finer pleated polypropylene depth filter materials. They are ideally suited for clarification and pre-filtration prior to membrane filtration.

Applications
Typical applications for Sartopure® PP2 MidiCaps and MaxiCaps are particle removal and bioburden reduction from various process media like:

– Plasma Fractions

– Vaccines

– MAB

– Diagnostics

– Purified Protein Solutions

– Biological Fluids

– Ophtalmics

– Solutions containing Preservatives

– WFI

Security
The Sartopure® PP 2 filter elements ensure the selective, effective and defined particle retention. They are a valuable protection for the final filter. The all polypropylene construction offers a broad chemical compatibility.

Performance
Sartopure® PP2 filter elements combine high dirt loading capacities with long service life and extremely high flow rates.

Economical Results
Considering all features and benefits, Sartopure® PP2 filters guarantee the maximum in process profitability.

Flexibility
Sartopure® PP2 MidiCaps and MaxiCaps are available with various filtration areas from 500 cm^2 | 0.5 ft^2 up to 1.8 m^2 | 18 ft^2 for easy adoption to any filtration process independ-ent from the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed as all Sartopure® PP 2 MidiCaps and MaxiCaps are produced with the same type of membrane and identical materials of construction.

Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Documentation
Sartopure® PP 2 MidiCaps & MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for Sartopure® PP 2 0.65 µm MidiCaps
with SS inlet and outlet

Differential pressure [bar]   [psi]

Size 7   Size 8   Size 9   Size 0
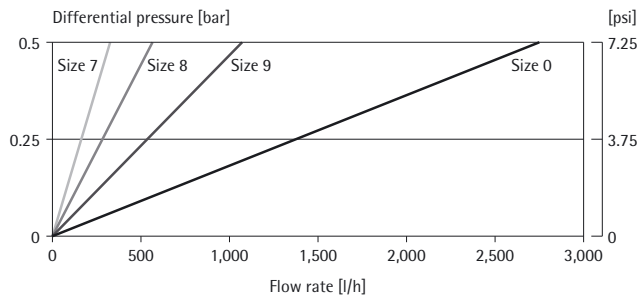
Flow rate [l/h]

Water Flow Rates for Sartopure® PP 2 1.2 µm MaxiCaps
with SS inlet and outlet

Differential pressure [bar]   [psi]

Size 7   Size 8   Size 9   Size 0

Flow rate [l/h]

▷ Specifications

Materials

Filter Matrial	Polypropylene fleeces
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

Retention Rates

0.65 µm, 1.2 µm, 3 µm, 5 µm, 8 µm, 20 µm

Available Sizes│Filtration Area

MidiCaps

Size 7		0.05 m²│0.5 ft²
Size 8		0.10 m²│1 ft²
Size 9		0.2 m²│2 ft²
Size 0		0.45 m²│5 ft²

MaxiCaps

Size 1	10"	0.6 m²│6 ft²
Size 2	20"	1.2 m²│12 ft²
Size 3	30"	1.8 m²│18 ft²

Available Connectors MidiCaps

SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps

SS, SO, OO, FF, BB

S:	1½" Tri-Clamp (Sanitary)
O:	½" Single stepped hose barb
F:	¾" Tri-Clamp (Sanitary)
H:	¼" Multiple stepped hose barb (with filling bell at the outlet)
B:	¾" – 1" Multiple stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar│72.5 psi at 20°C (MidiCaps) 2 bar│29 psi at 80°C (MidiCaps) 4 bar│58 psi at 20°C (MaxiCaps) 3 bar│43.5 psi at 20°C (MaxiCaps)
Max. allowable back pressure	2 bar│29 psi at 20°C

Extractables

Sartopure® PP 2 MidiCaps & MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

Autoclaving
134°C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles
Autoclaving: Min. 25

Technical References

Validation Guide
SPK5764-e
85030-532-48

Extractable Guide
SPK5719-e
85030-507-79

Order Information

Order Code	Retention Rate [µm]	Pack Size [Pieces]
MidiCaps		
5595305PX--XX--X	0.65 µm	4/2 (Size 0)
5595303PX--XX--X	1.2 µm	4/2 (Size 0)
5595302PX--XX--X	3 µm	4/2 (Size 0)
5595342PX--XX--X	5 µm	4/2 (Size 0)
5595301PX--XX--X	8 µm	4/2 (Size 0)
5595320PX--XX--X	20 µm	4/2 (Size 0)
MaxiCaps		
5591305PX--XX	0.65 µm	1
5591303PX--XX	1.2 µm	1
5591302PX--XX	3 µm	1
5591342PX--XX	5 µm	1
5591301PX--XX	8 µm	1
5591320PX--XX	20 µm	1

▶ Sartopure® GF Plus

The New Generation of Adsorptive Depth Filters

Description
Sartopure® GF Plus adsorptive depth filters are designed for removal of contaminants like colloids, lipids, protein aggregates (Host Cell Protein) and particles from biopharmaceutical fluids. They are used for protection of membrane filters, chromatography columns and ultrafiltration systems in pharmaceutical and biotechnological production processes.

Applications
Sartopure® GF Plus adsorptive depth filters are the ideal choice for prefiltration and clarification of:

– Cell Culture fluids after cell harvest

– Fermentation broths

– Serum free or serum containing cell culture media

– Serum

– Highly viscous opthalmic and LVP solutions

– All media containing lipids and colloids as contaminants

Effective Clarification
Sartopure® GF Plus adsorptive depth filters feature highly charged glass fiber layers for effective clarification of fluid streams based on the combination of adsorptive and mechanical retention.

Economic Prefiltration
The 3-dimensional filter matrix of Sartopure® GF Plus adsorptive depth filters assures outstanding total throughput performance of the filters thus ensuring most economic design of your prefiltration scheme.

Reliable Operation
The high and defined particle retention capability of Sartopure® GF Plus allows reliable operation and reproducible results from batch to batch even under varying process conditions.

Cost Saving
The efficient protection of downstream membrane filters and purification equipment saves filter costs and helps to increase the yield of biotech production processes.

Flexibility
Sartopure® GF Plus filters are available as standard cartridges and MaxiCaps. Cartridges are strong and robust and designed for maximum pressure differentials and multiple steaming cycles. Disposable MaxiCaps are designed for single use and are integral component of disposable manufacturing lines.

Documentation
Sartopure® GF Plus adsorptive depth filters are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for Sartopure® GF Plus
Sartopure® GF Plus 10" Standard Cartridges 0.65 µm, 1.2 µm
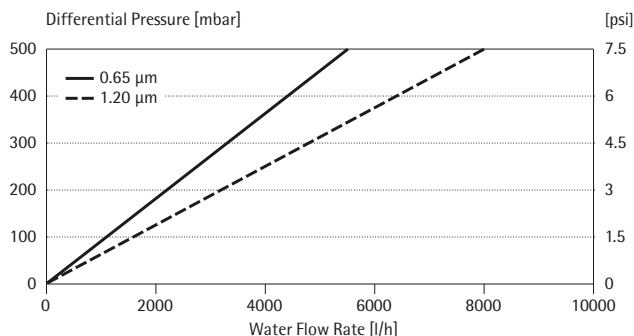
▷ Specifications

Materials

Filter Material	Glass Fiber Fleeces
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Retention Rates
0.65 µm, 1.2 µm

Available Sizes │ Filtration Area (Nominal)
Size 1	10"	0.4 m² │ 4 ft²
Size 2	20"	0.8 m² │ 8 ft²
Size 3	30"	1.2 m² │ 12 ft²
Size 4	40"	1.6 m² │ 16 ft²

Available Adapters Cartridges
21, 25, 27, 28

Operating Parameters

Max. allowable differential pressure	5 bar │ 75 psi at 20°C 2 bar │ 29 psi at 80°C
Max. allowable back pressure	2 bar │ 29 psi at 20°C

Extractables
Sartopure® GF Plus cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber relesaing according to 21 CFR

Sterilization
In-line Steam Sterilization:
134°C, 20 min. at max differential pressure of 0.5 bar

Note
MaxiCaps cannot be in-line steam sterilized!

Autoclaving:
134°C, 2 bar, 30 min

Sterilization Cycles
In-Line sterilization   Min. 25
Autoclaving: Min. 25

Technical References
Validation Guide:
SPK5753-e

Order Information

Order Code	Pore Size [µm]
Cartridges	
555**05PX	0.65
555**03PX	1.2

** = Adapter
X = Height 10", 20", 30", 40"

Product Comparision Data

Product Comparision (%/kg)
Turbidity Reduction (%)
Service Life (kg)
Sartopure® GF Plus, Product B, Product C, Product D
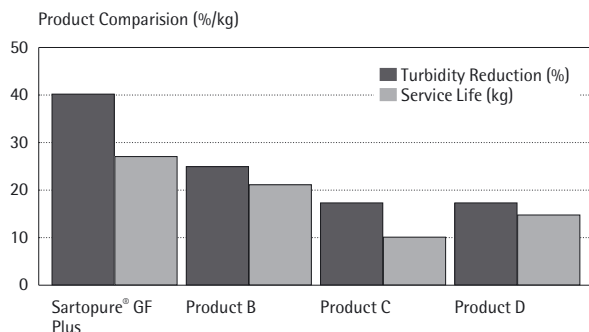
▶ Sartopure® GF Plus MidiCaps and MaxiCaps

The New Generation of Adsorptive Depth Filters

Single-Use Technology

Description
Sartopure® GF Plus MidiCaps and MaxiCaps are self-contained, ready to use filter units for removal of contaminants like colloids, lipids, protein aggregates (Host Cell Protein) and particles from bio-pharmaceutical fluids. They are used for protection of membrane filters, chromatography- and ultrafiltration systems in pharmaceutical and biotech production processes.

Applications
Sartopure® GF Plus MidiCaps & MaxiCaps are the ideal choice for prefiltration and clarification of:

– Cell Culture fluids after cell harvest

– Fermentation broths

– Serum free or serum containing cell culture media

– Serum

– All media containing lipids, colloids and protein aggregates as contaminants.

Effective Clarification
Sartopure® GF Plus MidiCaps & MaxiCaps feature highly charged glass fiber layers for effective clarification of fluid streams based on the combination of adsorptive and mechanical retention.

Economic Prefiltration
The 3-dimensional filter matrix of Sartopure® GF Plus adsorptive depth filters assures outstanding total throughput performance thus ensuring most economic design of your prefiltration scheme.

Reliable Operation
The high and defined particle retention capability of Sartopure® GF Plus allows reliable operation and reproducible results from batch to batch even under varying process conditions.

Cost Saving
The efficient protection of downstream membrane filters and purification equipment saves filter costs and helps to increase the yield of biotech production processes.

Flexibility
Sartopure® GF Plus MidiCaps and MaxiCaps are available with various filtration areas from 500 cm^2 | 0.5 ft^2 up to 1.2 m^2 | 12 ft^2 for easy adoption to any filtration process independent from the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed as all Sartopure® GF Plus MidiCaps and MaxiCaps are produced with the same type of membrane and identical materials of construction.

Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Documentation
Sartopure® GF Plus MidiCaps & MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for MidiCaps with SS inlet and outlet 0.65 µm

▷ Specifications

Materials

Filter Matrial	Glass fiber fleeces
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

Retention Rates
0.65 µm
1.2 µm

Available Sizes│Filtration Area (nominal)

MidiCaps
Size 7   0.04 m² │ 0.4 ft²
Size 8   0.08 m² │ 0.8 ft²
Size 9   0.12 m² │ 1.2 ft²
Size 0   0.25 m² │ 2.5 ft²

MaxiCaps
Size 1   10"   0.4 m² │ 4 ft²
Size 2   20"   0.8 m² │ 8 ft²
Size 3   30"   1.2 m² │ 12 ft²

Available Connectors MidiCaps
SS, SO, OO, FF, FO,
HH (only size 7)

Available Connectors MaxiCaps
SS, OO

S: 1½" Tri-Clamp (Sanitary)
O: ½" Single stepped hose barb
F: ¾" Tri-Clamp (Sanitary)
H: ¼" Multiple stepped hose barb
            (with filling bell at the outlet)
B: ¾" – 1" Multiple stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar │ 72.5 psi at 20°C (MidiCaps) 2 bar │ 29 psi at 80°C (MidiCaps) 4 bar │ 58 psi at 20°C (MaxiCaps) 3 bar │ 43.5 psi at 20°C (MaxiCaps)
Max. allowable back pressure	2 bar │ 29 psi at 20°C

Order Information

Order Code	Retention Rate [µm]	Pack Size [Pieces]
MidiCaps		
5555305PX--**--X	0.65 µm	4 │ 2 (size 0)
5555303PX--**--X	1.2 µm	4 │ 2 (size 0)
MaxiCaps		
5551305PX--**	0.65 µm	1
5551303PX--**	1.2 µm	1

Extractables
Sartopure® GF Plus MidiCaps & MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization
Autoclaving: 134°C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles
Autoclaving: Min. 25

Technical References
Validation Guide   SPK5760-e

Water Flow Rates for MidiCaps with SS inlet and outlet 1.2 µm
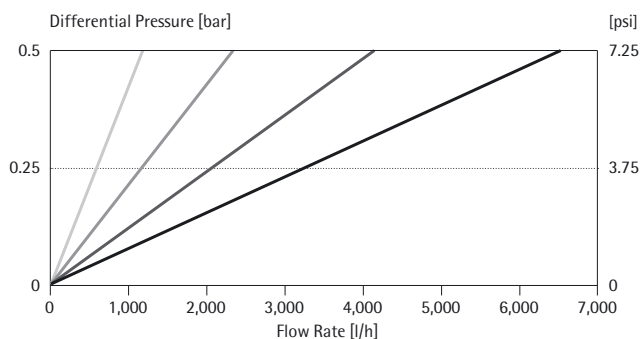
▶ Sartoclean® GF

Adsorptive Membrane Filter for Colloid and Bioburden Reduction

Description
Sartolclean® GF filter cartridges combine absolute retention performance by membrane filtration with high adsorptive power by glass fiber fleeces. Therefore Sartoclean® GF are ideally suited for removal of colloids and lipids as well as defined particle retention and bioburden reduction for a broad range of bio-pharmaceutical applications.

Applications
Sartoclean® GF filter cartridges are widely used for prefiltration in biotech manufacturing processes to protect subsequent downstream processing equipment. Typical applications include bioburden reduction as well as effective colloid and lipid removal from:

– Fermentation broths

– Serum

– Cell Culture Media

– Colloid and Lipid containing solutions

Process Safety
The removal of colloidal contaminants and lipids by adsorption allows an effective downstream processing and bioburden reduction by membrane filtration avoids formation of pyrogenes during the process resulting in an increased process safety especially for biotech derived fluids.

Performance
The combination of adsorptive glass fiber fleeces with membrane filters assures optimal total throughput performance and allow for economic filtration system design.

Flexibility
Sartoclean® GF filters are available as standard filter cartridges and mini cartrides and offering broadest choice for scale-up and easiest adoption to varying process volumes.

Documentation
Sartoclean® GF cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for 10″ Sartoclean® GF Cartridges

Standardized at 20°C

▷ Specifications

Materials

Prefilter Membrane	Cellulose Acetate
Endfilter Membrane	Cellulose Acetate
Filter active fleece	Glass Fiber
Support Fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Pore Sizes
0.8 + 0.65 µm
3.0 + 0.8 µm

Available Sizes | Filtration Area

Cartridges
Size 1	10"	0.6 m^2	6 ft^2
Size 2	20"	1.2 m^2	12 ft^2
Size 3	30"	1.8 m^2	18 ft^2

Mini Cartridges
Size 7	0.05 m^2	0.5 ft^2
Size 8	0.1 m^2	1 ft^2
Size 9	0.2 m^2	2 ft^2

Available Adapters Cartridges
21, 25, 27, 28

Available Adapter Mini Cartridges
15

Operating Parameters

Max. allowable differential pressure	5 bar	75 psi at 20 °C (Cartridges) 2 bar	29 psi at 80 °C (Cartridges and Capsules)
Max. allowable back pressure	2 bar	29 psi at 20 °C

Extractables
Sartoclean® GF cartrides, mini cartridges and capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134 °C, 20 min. at max differential pressure of 0.5 bar | 7 psi

Note:
Capsules cannot be in-line steam sterilized!

Autoclaving
134 °C, 2 bar | 29 psi, 30 min

Sterilization Cycles
In-Line Sterilization: (only cartridges)	Min. 25
Autoclaving:	Min. 25

Technical References
Validation Guide:
SPK5718-e

Order Information

Order Code	Pore Size [µm]
Cartridges	
560**05GX	0.65
560**04EX	0.8
Mini Cartridges	
5601305GX------B	0.65
5601304EX------B	0.8

▶ Sartoclean® CA

Particle & Bioburden Reduction Filter Cartridges

Description
Sartoclean® CA filter cartridges are the ideal choice for a broad range of prefiltration applications in the biopharmaceutical industry from particle removal to bioburden reduction. They offer a defined retention performance by size exclusion. The use of Sartoclean® CA prefilters avoids early blockage of downstream sterilizing grade membrane filters and contributes significantly to an economical design of your filtration system.

Applications
Featuring ultra low binding cellulose acetate membranes, Sartoclean® CA filters are typically used for membrane prefiltration of:

– Plasma Fractions

– Vaccines

– MAB

– Diagnostics

– Purified Protein Solutions

– Biological Fluids

– Solutions containing Preservatives

High Product Yield
Throughout the years the cellulose acetate membranes of the Sartoclean® CA filters have proven to be the membrane material with lowest unspecific binding capabilities, assuring highest protein yields and rapid preservative recovery enhancing your process efficiency.

Performance
Sartoclean® CA filters with heterogeneous double layer construction (3.0 | 0.8 µm & 0.8 | 0.65 µm) offer highest total throughput performance due to the "build-in prefiltration" to avoid filter change during filtration and assure economical system design. Single layer Sartoclean® CA filters (0.45 µm & 0.2 µm) offer highest flow rates for microbe retentive filtration.

Mechanical Strength
The reinforcement of the membrane results in increased mechanical and thermal resistance, especially of interest in applications with high differential pressure and with repeated steam sterilization of the filters.

Flexibility
Sartoclean® CA filters are available as standard filter cartridges, mini cartridges, capsules and MaxiCaps offering broadest choice for scale-up and easiest adoption to varying process volumes.

Documentation
Sartoclean® CA cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for Sartoclean® CA 10" cartridges

Standardized at 20°C

▷ Specifications

Materials

Prefilter Membrane	Cellulose Acetate
Endfilter Membrane	Cellulose Acetate
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Pore Sizes
3.0 + 0.8 µm
0.8 + 0.65 µm
0.45 µm
0.2 µm

Available Sizes│Filtration Area

Cartridges
Size 1   10"   0.74 m^2│7.4 ft^2
Size 2   20"   1.5 m^2│15 ft^2
Size 3   30"   2.2 m^2│22 ft^2

Mini Cartridges
Size 7   0.08 m^2│0.8 ft^2
Size 8   0.16 m^2│1.6 ft^2
Size 9   0.3 m^2│3 ft^2
Size 0   0.6 m^2│6 ft^2
                             (only Capsules)

Available Adapters Cartridges
21, 25, 27, 28

Available Adapter Mini Cartridges
15

Operating Parameters

Max. allowable differential pressure	5 bar│75 psi at 20 °C 2 bar│29 psi at 80 °C
Max. allowable back pressure	2 bar│29 psi at 20 °C

Extractables
Sartoclean® CA cartrides meet or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134 °C, 20 min. at max differential pressure of 0.5 bar│7 psi

Autoclaving
134 °C, 2 bar│29 psi, 30 min

Sterilization Cycles
In-Line Sterilization: Min. 25
Autoclaving: Min. 25

Technical References
Validation Guide:
SPK5718-e

Order Information

Order Code	Pore Size [µm]	Pack Size [Pieces]
Cartridges		
562**07AX	0.2	1
562**06AX	0.45	1
562**05GX	0.65	1
562**04EX	0.8	1
Mini Cartridges		
5621505GX------B	0.65	5
5621504EX------B	0.8	5

Water Flow Rates for Sartoclean® CA 10" cartridges
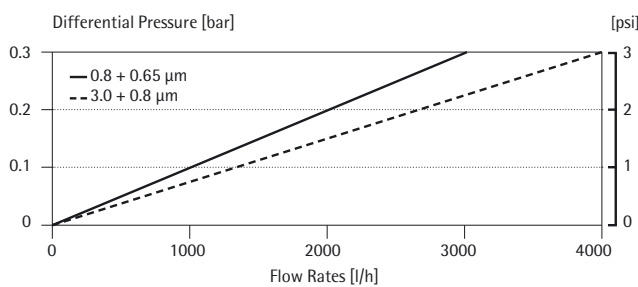
Standardized at 20 °C

▶ Sartoguard PES

Membrane Prefiltration Filter Cartridges

Description

Sartoguard PES filter cartridges are especially designed for effective bioburden control and reliable removal of particles from a broad range of fluid streams. They provide the finest, most efficient and reliable perform-ance for critical prefiltration applications. They can be used for protection of Mycoplas-ma retentive or sterilizing grade filters. They allow for downsizing of filtration systems and cost saving in applications where the use of validated sterilizing grade filters is not required, but reliable bioburden and turbidity reduction is.

Applications

Typical applications of Sartoguard PES filter cartridges include prefiltration of:

– Buffers

– Downstream Intermediates (before and after UF | DF and chromatography steps)

– Clarified cell culture harvest

– Cell Culture Media

– Aseptically filled Small Volume Parenterals (SVP)

Economy

Sartoguard PES filter cartridges feature a unique heterogeneous double layer membrane construction in combination with an increased filtration area of 0.8 m²/10" cartridge. By providing outstanding total throughput and flow rate performance, they ensure highest process efficiency, minimized overall filtration costs and short filtration cycle times.

Reliable Retention

Sartoguard PES filters are available with 0.1 µm and 0.2 µm nominal retention rating. The 0.1 µm rated filters typically provide a LRV of 6 per cm² filtration area for Brevundimonas Diminuta, while the 0.2 µm rated filters typi-cally provide a LVR of 6 per cm² filtration area for Serratia Marcescens.

Compatibility

Sartoguard PES filter elements are designed for broad chemical compatibility from pH 1 to pH 14 and low extractable levels. They are compatible with multiple in line steam sterilization cycles up to 134 °C.

Quality & Security

Sartoguard PES filter cartridges are individu-ally tested for integrity during production. The integrity of the filters can be verified onside before and after use by a diffusion or bubble-point test.

Scalability

Sartoguard PES filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

Documentation

Sartoguard PES cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Manage-ment System. A Validation Guide is available for compliance with regulatory requirements.

Soy Peptone Supplemented Cell Culture Media
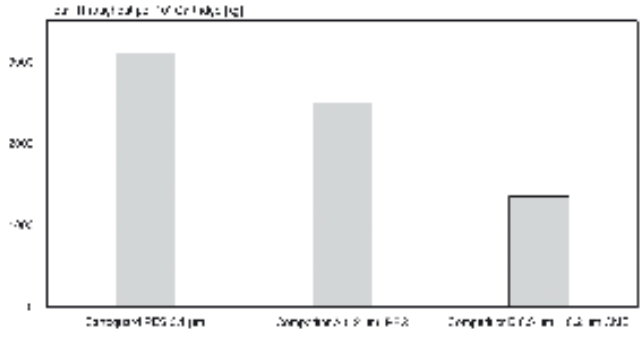
Soy Peptone Supplemented Cell Culture Media
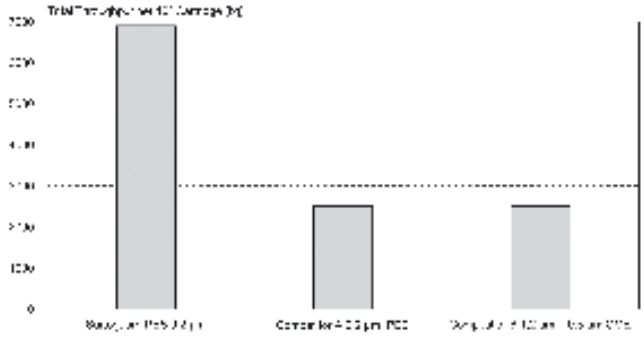
▷ Specifications

Materials

Prefilter Membrane	PES, asymmetric
Endfilter Membrane	PES, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone

Pore Size Combinations
0.8 μm + 0.1 μm nominally
1.2 μm + 0.2 μm nominally

Available Sizes│Filtration Area
Size 1   10"   0.8 m^2│8.6 ft^2
Size 2   20"   1.6 m^2│17.2 ft^2
Size 3   30"   2.4 m^2│25.8 ft^2

Available Adapters
25

Operating Parameters

Max. allowable differential pressure	5 bar│72.5 psi at 20°C 2 bar│29 psi at 80 °C
Max. allowable back pressure	2 bar│29 psi at 20 °C

Extractables
Sartoguard PES filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity tested during production

Onside integrity testable by diffusion or bubble-point test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization
In-Line Steam Sterilization:
134°C, 20 min. at max differential pressure of 0.5 bar

Autoclaving:
134°C, 2 bar, 30 min

Sterilization Cycles
In-Line Sterilization   Min. 25
Autoclaving   Min. 25

Technical References
Validation Guide:
SPK5782-e

Order Codes

Cartridges	Pore Size Nominally [μm]	Test Pressure [bar│psig]	Max. Diffusion [ml/min]	Min. Bubble Point [bar│psig]
5472558G1	0.1 μm	1.5│22	25	2.8│40.5
5472558G2	0.1 μm	1.5│22	50	2.8│40.5
5472558G3	0.1 μm	1.5│22	75	2.8│40.5
5472507F1	0.2 μm	1.2│17,5	18	1.8│26
5472507F2	0.2 μm	1.2│17,5	36	1.8│26
5472507F3	0.2 μm	1.2│17,5	54	1.8│26

▶ # Sartoclean® GF MidiCaps & MaxiCaps

Colloid & Bioburden Reduction Filter Capsules

Single-Use Technology

Description
Sartolclean GF MidiCaps & MaxiCaps are self-contained, ready to use filter units for a broad range of prefiltration applications in the biopharmaceutical industry. Sartoclean® GF MidiCaps & MaxiCaps combine absolute retention performance by membrane filtration with high adsorptive power by glass fiber fleeces. Therefore the filters are ideally suited for removal of colloids, lipids, defined particle retention and bioburden reduction.

Applications
Sartoclean® GF MidiCaps & MaxiCaps are widely used for prefiltration in biotech manufacturing processes to protect subsequent downstream processing equipments. Sartoclean® GF MidiCaps & MaxiCaps are ideally suited for the biodurden reduction as well as effective colloid and lipid removal from:

– Fermentation Broth

– Serum

– Plasma

– Cell Culture Media

– Colloid and Lipid containing solutions

Performance
Due to the combination of high adsorptive glass fiber fleeces with membrane filters Sartoclean® GF MidiCaps & MaxiCaps assure optimal total throughput performance. Therefore the MidiCaps & MaxiCaps allows a more economical filtration system design.

Process Safety
The removal of collodial contaminations and lipids by adsorption allows an effective downstream processing and bioburden reduction by membrane filtration prevents the formation of pyrogenes during the process – resulting in an increased process safety, especially for biotech derived fluids.

Flexibility
Sartoclean® GF MidiCaps & MaxiCaps are available with various filtration areas from 500 cm² | 0.5 ft² up to 1.8 m² | 18 ft² for easy adoption to any filtration process independent from the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed as all Sartoclean® GF MidiCaps & MaxiCaps are produced with the same type of membrane and identical materials of construction.

Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Documentation
Sartoclean® GF MidiCaps & MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for Sartoclean® GF 0.65 μm MidiCaps with SS inlet an outlet
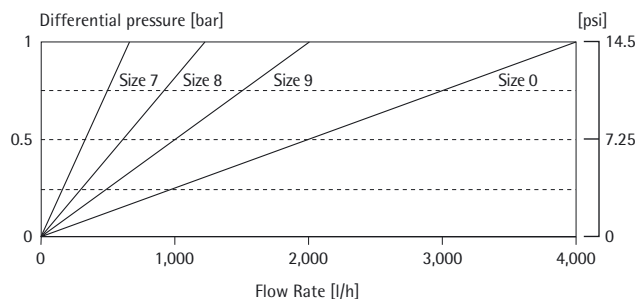
▷ Specifications

Materials

Prefilter Membrane	Cellulose Acetate
Endfilter Membrane	Cellulose Acetate
Filter active fleece	Glass fiber
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone
Filling Bel*	Polycarbonate

* only Size 7

Pore Sizes
0.8 + 0.65 µm, 3.0 + 0.8 µm

Available Sizes│Filtration Area

MidiCaps
Size 7	0.05 m^2│0.5 ft^2
Size 8	0.1 m^2│1 ft^2
Size 9	0.2 m^2│2 ft^2
Size 0	0.45 m^2│5 ft^2

MaxiCaps
Size 1	10"	0.6 m^2│6. ft^2
Size 2	20"	1.2 m^2│12 ft^2
Size 3	30"	1.8 m^2│18 ft^2

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, SO, OO

S:	1½" Tri-Clamp (Sanitary)
O:	Hose Barb
F:	¾" Tri-Clamp (Sanitary)
H:	Small, multiple stepped hose barb (with filling bell at the outlet)

Operating Parameters

Max. allowable differential pressure	5 bar│72.5 psi at 20°C (MidiCaps) 4 bar│58 psi at 20°C (MaxiCaps) 3 bar│43.5 psi at 50°C
Max. allowable back pressure	2 bar│29 psi at 20°C

Extractables
Sartoclean® GF MidiCaps & MaxiCaps meet or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

Autoclaving
134°C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles
Autoclaving: Min. 25

Technical References
Validation Guide:
SPK5763-e

Order Information

Order Code	Pore Size [µm]	Pack Size [Pieces]
MidiCaps		
5605305GX--**--X	0.65 µm	4
5605304EX--**--X	0.8 µm	2
MaxiCaps		
5601305GX--**	0.65 µm	1
5601304EX--**	0.8 µm	1

Water Flow Rates for Sartoclean® GF 0.65 µm MaxiCaps with SS inlet an outlet
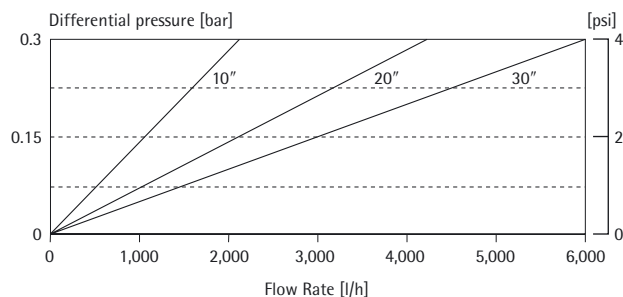
▶ ## Sartoclean® CA MidiCaps & MaxiCaps

Particle & Bioburden Reduction Filter Capsules

Single-Use Technology

Description
Sartoclean® CA filter are the ideal choice for a broad range of prefiltration applications in the biopharmaceutical industry from particle removal to bioburden reduction. They offer a defined retention performance by size exclusion. The use of Sartoclean® CA prefilters avoids early blockage of downstream steriliz-ing grade membrane filters and contributes significantly to an economical design of your filtration system.

Applications
Featuring ultra low binding cellulose acetate membranes, Sartoclean® CA filters are typically used for membrane prefiltration of:

– Plasma Fractions

– Vaccines

– MAB

– Diagnostics

– Purified Protein Solutions

– Biological Fluids

– Solutions containing Preservatives

High Product Yield
Throughout the years the cellulose acetate membranes of the Sartoclean® CA filters have proven to be the membrane material with lowest unspecific binding capabilities, assuring highest protein yields and rapid preservative recovery enhancing your process efficiency.

Performance
Sartoclean® CA filters with heterogeneous double layer construction (3.0 | 0.8 µm & 0.8 | 0.65 µm) offer highest total throughput performance due to the "build-in prefiltra-tion" to avoid filter change during filtration and assure economical system design. Single layer Sartoclean® CA filters (0.45 µm & 0.2 µm) offer highest flow rates for microbe retentive filtration.

Mechanical Strength
The reinforcement of the membrane results in increased mechanical and thermal resistance, especially of interest in applications with high differential pressure and with repeated steam sterilization of the filters.

Flexibility
Sartoclean® CA filters are available as standard filter cartridges, mini cartrides, MidiCaps and MaxiCaps offering broadest choice for scale-up and easiest adoption to varying process volumes.

Documentation
Sartoclean® CA cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for Sartoclean® CA 10" cartridges

Standardized at 20°C

▷ Specifications

Materials

Prefilter Membrane	Cellulose Acetate
Endfilter Membrane	Cellulose Acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone

Pore Sizes
0.8 + 0.65 µm, 3.0 + 0.8 µm

Available Sizes│Filtration Area

MidiCaps
Size 7	0.08 m² │ 0.8 ft²
Size 8	0.16 m² │ 1.6 ft²
Size 9	0.3 m² │ 3 ft²
Size 0	0.6 m² │ 6 ft²

MaxiCaps
Size 1	10"	0.74 m² │ 7.4 ft²
Size 2	20"	1.5 m² │ 15 ft²
Size 3	30"	2.2 m² │ 22 ft²

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, SO, OO

S:	1½" Tri-Clamp (Sanitary)
O:	Hose Barb
F:	¾" Tri-Clamp (Sanitary)
H:	Small, multiple stepped hose barb (with filling bell at the outlet)

Operating Parameters

Max. allowable differential pressure	5 bar │ 72.5 psi at 20°C (MidiCaps) 4 bar │ 58 psi at 20°C (MaxiCaps) 3 bar │ 43.5 psi at 50°C
Max. allowable back pressure	2 bar │ 29 psi at 20°C

Extractables
Sartoclean® CA silk meet or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134 °C, 20 min. at max differential pressure of 0.5 bar │ 7 psi

Autoclaving
134°C, 2 bar │ 29 psi, 30 min

Sterilization Cycles
Autoclaving: Min. 25

Order Information

Order Code	Pore Size [µm]	Pack Size [Pieces]
MaxiCaps		
562**07AX--XX	0.2	1
562**06AX--XX	0.45	1
562**05GX--XX	0.65	1
562**04EX--XX	0.8	1
5625304EX--XX--☐		
5625305GX--XX--☐		
5625307AX--XX--☐		
5625306AX--XX--☐		

XX = Connector Styles
X = Size
☐ = Pack Size

Water Flow Rates for Sartoclean® CA 10" cartridges
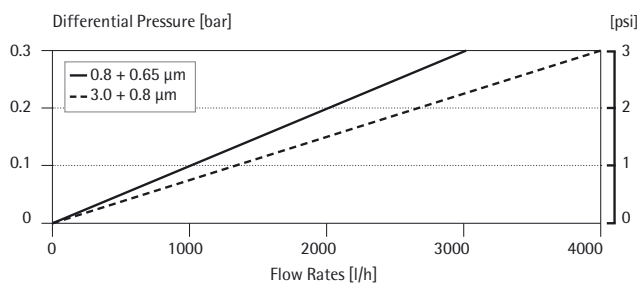
Standardized at 20°C

▶ Sartofine PP

Particle & Bioburden Reduction Filter Cartridges

Description
Sartofine filter cartridges contain no pleated filter layers. For application purposes, they feature a 14 mm thick multilayer, consisting of 4 to 7 different filter zones. The number of zones depends on the type of cartridge. Each zone, made up of polypropylene filter layers is a homogeneous depth filter itself. The nominal retention rating of the respective filter zones becomes increasingly finer in the direction of filtration. Therefore Sartofine PP filters are ideally suited for all applications requirering exceptional high dirt holding capacities with added benefit of high total throughput.

Applications
Whether in the bio-pharmaceutical or chemical industry, Sartofine PP filter cartridges are used wherever liquids with a wide range of particle sizes need to be prefiltered or clarified. You can choose from 7 different retention ratings (0.5 µm to 40 µm), depending on the size of the particles to be removed. This variety allows you to select the filter type which best suits your particular application.

Efficiency
Particle removal by fractionated depth filtration ensures optimal use of the entire multiplayer which results in a long service life of the filter. The filtration efficiency is enhanced by the filter cake that can be build up within the depths of each filter zone. This filter cake allows colloids to be retained in the finer filter zones.

Mechanical Stability
Sartofine PP filter cartridges have been designed for daily routine use. Our special production method of wrapping the filter layers tightly around the supportive core of the cartridge provides high mechanical stability and eliminates the common problem of breakthrough right from the start. The thermally bonded exterior layer and our special welding technique for joining filter layers and end caps allow you to easily backflush the cartridges during cleaning at a pressure up to 3 bar (44 psi).

Documentation
Sartofine PP cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Sartofine 10" Standard Cartridges, 0.5 µm, 0.7 µm, 1 µm
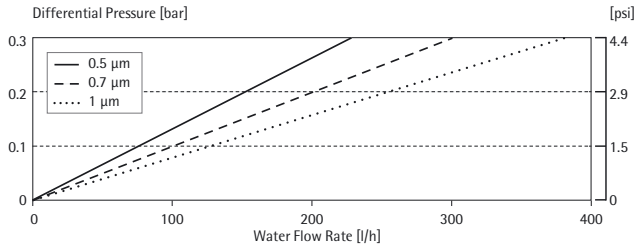
Sartofine 10" Standard Cartridges, 3 µm, 5 µm, 10 µm
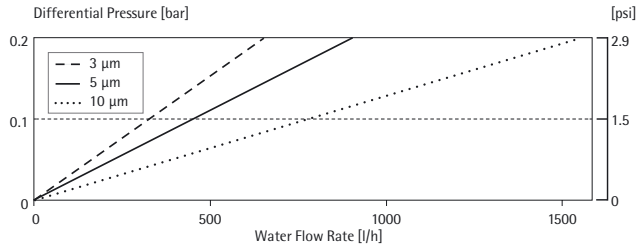
▷ Specifications

Materials

Filter Material	Multiple Poly-propylene layers
Support Fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Retention Rates

0.5 µm, 0.7 µm, 1 µm, 3 µm, 5 µm, 10 µm, 15 µm, 20 µm, 40 µm

Available Sizes│Filtration Area

Cartridges

Size 1	10"	0.05 m² │ 0.5 ft²
Size 2	20"	0.1 m² │ 1 ft²
Size 3	30"	0.15 m² │ 1.5 ft²
Size 4	40"	0.2 m² │ 2 ft²

Available Adapters Cartridges
00, 03, 05, 07, 08

Operating Parameters

Max. allowable differential pressure	5 bar │ 75 psi at 20 °C 2 bar │ 29 psi at 80 °C
Max. allowable back pressure	2 bar │ 29 psi at 20 °C

Extractables
Sartofine PP cartrides meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134 °C, 20 min. at max differential pressure of 0.5 bar │ 7 psi

Autoclaving
134 °C, 2 bar │ 29 psi, 30 min

Sterilization Cycles
In-Line Sterilization: (only cartridges)	Min. 25
Autoclaving:	Min. 25

Technical References
Validation Guide:
SPK 5707-e

Order Information

Order Code	Pore Size [µm]
Cartridges	
558**06WX	0.5
558**05WX	0.7
558**03WX	1
558**02WX	3
558**42WX	5
558**10WX	10
558**15WX	15
558**20WX	20
558**40WX	40

Legende
** = Adapter
X = Size

Sartofine 10" Standard Cartridges, 20 µm, 40 µm
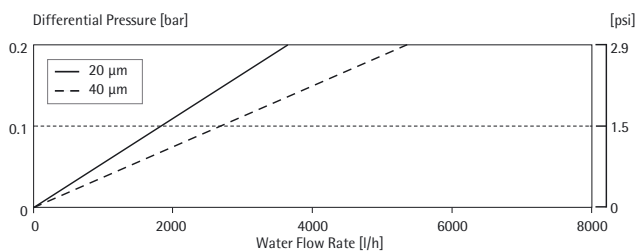
▶ ## SartoScale

Filter Test Disposables for Use in the Biopharmaceutical Industry

Single-Use Technology

Description
SartoScale filter test disposables are designed to perform reliable filterability trials with 47 mm flat filter discs of original filter cartridge material. The use of disposables for filtration trials avoids time consuming preparation of filter discs in stainless steel filter holders and prevents installation mistakes of the flat filter discs.

Applications
SartoScale filter test disposables are ideally suited to perform all kind of filterability trials with the target to select the optimal membrane material for a certain application or to determine the ideal combination of prefilters and final filters with minimum product volumes.

Original Filter Material
SartoScale filter test disposables contain the original filter active material of the respective filter cartridges in order to assure reproducible test results.

Scale-Up
After material selection or determination of a prefilter│final filter scheme with SartoScale filter test disposables a scale-up for flow rate and total throughput performance of the selected materials should be done using small scale pleated capsule devices (e. g. capsules of type 150).

Optimized Design
SartoScale filter test disposables feature ultra low hold up and dead volumes in order to perform filterability trials with minimized product volumes.

Reliability
SartoScale filter test disposables containing integrity testable membrane filters can be tested for integrity by a bubble-point test to assure reliable test results.

Zero-T-Test System
We recommend to use SartoScale filter test disposables together with our Zero-T Filter Test System in order to perform filtration trials effectively. The Zero-T-System consists of hardware and software modules which allow easy handling and installation of the SartoScale filter test disposables. Automatic data acquisition is achieved by the connection of a balance to a laptop. The software analyses automatically the incoming data for scale-up calculations.

Availabilility
SartoScale filter test disposables will become available for all filter materials of Sartorius Stedim Biotech including:

– Sartopore® 2 544...

– Sartobran® P 523..

– Sartolon® 510...

– Sartofluor® 518...

– Sartoclean® CA 562...

– Sartoclean® GF 560...

– Sartopure® PP2 559...

– Sartopure® GF Plus 555...

– Sartoguard® 547...

▷ Specifications

Materials

Capsule housing	Polypropylene
Filter materials	All common filter materials of Sartorius Stedim Biotech

Available Sizes│Filtration Area
Size S   13 cm^2

Available Connectors Styles
FF, FH, HH

F: ½″ Tri-Clamp (Sanitary)
H: Small, multiple stepped hose barb
        (with filling bell at the outlet)

Operating Parameters

Max. allowable differential pressure	5 bar │ 72.5 psi at 20 ℃ 2 bar │ 29 psi at 80 ℃

SartoScale filter test disposables cannot be used in reverse direction of filtration!

Extractables
SartoScale filter test disposables meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
All sterilizing grade and mycoplasma retentive SartoScale filter test disposables are randomly tested for integrity during production.

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization
Autoclaving:
134 ℃, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles
Autoclaving: 1 Cycle

Integrity Test Parameters
(Water wetted)

Filtertyp	Pore Size	Bubble-Point [bar│psi]
Sartopore® 2, XLG, XLI	0.2 µm	3.2 │ 46
Sartopore® 2	0.45 µm	2.2 │ 32
Sartobran® P	0.1 µm	3.8 │ 55
Sartobran® P	0.2 µm	3.2 │ 46
Sartobran® P	0.45 µm	2.0 │ 29
Sartolon®	0.2 µm	3.0 │ 43.5

Pack Size
3 Pieces per pack

Ordering Information

Sartopore® 2 0.2 µm	5445307HS--**--M
Sartopore® 2 0.1 µm	5445358KS--**--M
Sartopore® 2 0.45 µm	5445306GS--**--M
Sartopore® 2 XLG	5445307GS--**--M
Sartopore® 2 XLI	5445307IS--**--M
Sartobran® P 0.2 µm	5235307HS--**--M
Sartobran® P 0.1 µm	5235358HS--**--M
Sartobran® P 0.45 µm	5235306DS--**--M
Sartolon® 0.2 µm	5105307HS--**--M
Sartoclean® CA 0.65 µm	5625305GS--**--M
Sartoclean® CA 0.8 µm	5625304ES--**--M
Sartoclean® GF 0.65 µm	5605305GS--**--M
Sartoclean® GF 0.8 µm	5605304ES--**--M
Sartopure® PP2 0.65 µm	5595305PS--**--M
Sartopure® PP2 1.2 µm	5595303PS--**--M
Sartopure® PP2 3 µm	5595302PS--**--M
Sartopure® PP2 5 µm	5595342PS--**--M
Sartopure® PP2 8 µm	5595301PS--**--M
Sartopure® GF Plus 0.65 µm	5555305PS--**--M
Sartopure® GF Plus 1.2 µm	5555303PS--**--M
Sartoguard® PES 0.1 µm nominally	5475358GS--**--M
Sartoguard® PES 0.2 µm nominally	5475307FS--**--M

**: Connector Styles

▶ Sartobran® P 0.2 µm

Sterilizing Grade Filter Cartridges and Mini Cartridges

Description
Sartobran® P sterilizing grade filter cartridges have proven throughout the years to be the first choice in the biopharmaceutical industry for all applications requiring low adsorption capabilities. The unique ultra-low unspecific binding capacity of the cellulose acetate membranes assures highest protein yield and rapid preservative recovery. Sartobran® P filters are ideally suited for processing high-value biological solutions like dilute protein solutions and pharmaceuticals sensitive to adsorption like dilute preservative solutions.

Applications
Sartobran® P filters are ideally suited for all applications that require highest product recovery rates such as:

– Coagulation factors, albumine, IgG

– Bacterial and viral vaccines

– MAB's

– Bio-processed pharmaceuticals

– Diagnostics

– Purified protein solutions

– Biological fluids

– Solutions containing preservatives

Highest Product Yield
The Sartobran® P's cellulose acetate membrane provides the lowest unspecific adsorption of any membrane material available, ensuring the highest product recovery rates.

Performance
Due to the "built-in prefiltration" by a 0.45 µm membrane, Sartobran® P 0.2 µm filters provide excellent total throughputs and higher flow rates at low differential pressure for gentle product treatment.

Flexibility
Sartobran® P 0.2 µm filters are available in traditional cartridge formats and disposable capsules from 150 cm² to 1.8 m² for simple linear scale up and process flexibility.

Microbiological Retention
Sartobran® P 0.2 µm rated filter cartridges are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-05 guidelines.

Quality Control
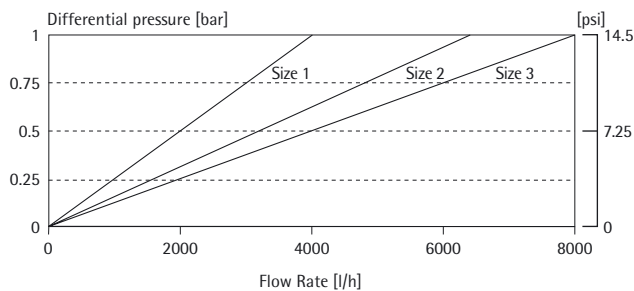Each individual element is integrity-tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation
Sartobran® P cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for Standard Cartridges and MaxiCaps

Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Cellulose acetate
Endfilter membrane	Cellulose acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Pore Size
0.45 µm + 0.2 µm

Available Sizes | Filtration Area

Cartridges

Size 1	10"	0.6 m²	6.5 ft²
Size 2	20"	1.2 m²	12.9 ft²
Size 3	30"	1.8 m²	19.4 ft²

Mini Cartridges

Size 7	0.05 m²	0.54 ft²
Size 8	0.1 m²	1.1 ft²
Size 9	0.2 m²	2.2 ft²

Available Adapter Cartridges
21, 25, 27, 28

Available Adapter Mini Cartridges
15, 18

Operating Parameters

Max. allowable differential pressure	5 bar	75 psi at 20°C
2 bar	29 psi at 80°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartobran® P 0.2 µm rated filter cartridges meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134°C, 20 min. at max differential pressure of 0.5 bar | 7 psi

Autoclaving
134°C, 2 bar | 29 psi, 30 min

Sterilization Cycles

In-line sterilization	Min. 25
Autoclaving	Min. 25

Technical References

Validation Guide	SPK5726-e
Extractables Guide	SPK5720-e

Ordering Information

Order Code	Size	Pore Size [µm]
Cartridges		
523**07H1----P	1	0.2
523**07H2----P	2	0.2
523**07H3----P	3	0.2
Mini Cartridges		
5231507H7------B	7	0.2
5231507H8------B	8	0.2
5231507H9------B	9	0.2

Total Throughput Comparison
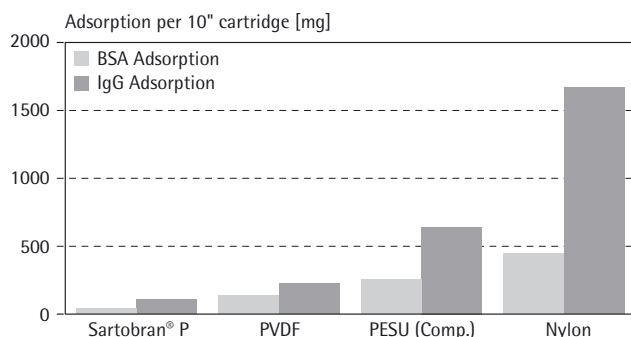
10" Cartridge format

▶ Sartobran® P 0.2 µm

Sterilizing Grade MidiCaps and MaxiCaps

Single-Use Technology

Description
Sartobran® P membrane filter MidiCaps and MaxiCaps are self-contained, ready-to-use, sterile filter units for sterilizing grade filtration in the pharma│biotech industry. The extremely low unspecific adsorption of their cellulose acetate membranes assures highest protein yields and rapid preservative recovery.

Applications
Sartobran® P filter elements have proven throughout the years to be the first choice for all applications in the biopharmaceutical industry requiring low adsorption capabilities. They are typically used for sterilizing grade filtration of:

– Coagulation factors, albumin, IgG

– Bacterial & viral vaccines

– MAB

– Bio-processed pharmaceuticals

– Diagnostics

– Purified protein solutions

– Biological fluids

– Fluids containing preservatives

Easy to Use
Sartobran® P MidiCaps and MaxiCaps are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

Flexibility
Sartobran® P 0.2 µm MidiCaps and MaxiCaps are available with various filtration areas from 500 cm²│0.5 ft² up to 1.8 m²│18 ft² for easy adoption to any filtration process, independent of the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed as all Sartobran® P MidiCaps and MaxiCaps are produced with the same type of membrane and identical materials of construction.

Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Microbiological Retention
Sartobran® P MidiCaps and MaxiCaps 0.2 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control
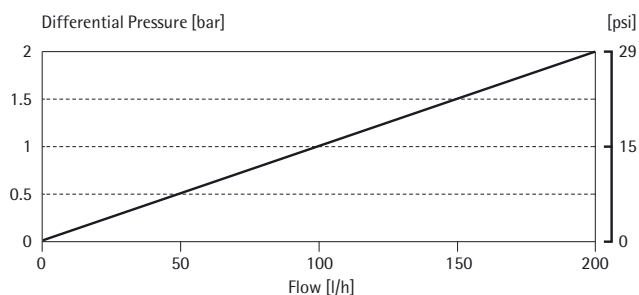Each individual element is tested for integrity by B.-P. and Diffusion Test prior to being released, assuring absolute reliability.

Documentation
Sartobran® P MidiCaps and MaxiCaps are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for MidiCaps with SS Inlet and Outlet

Water Flow Rates for MaxiCaps

Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Cellulose acetate
Endfilter membrane	Cellulose acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone
Filling bell	Polycarbonate

Pore Size
0.45 µm + 0.2 µm

Available Sizes | Filtration Area

MidiCaps
Size 7   0.05 m² | 0.5 ft²
Size 8   0.1 m² | 1 ft²
Size 9   0.2 m² | 2 ft²
Size 0   0.45 m² | 5 ft²

MaxiCaps
Size 1   0.6 m² | 6 ft²
Size 2   1.2 m² | 12 ft²
Size 3   1.8 m² | 18 ft²

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, SO, OO, BB, FF

S: 1½" Tri-clamp (sanitary)
O: ½" Hose Barb
F: ¾" Tri-clamp (sanitary)
H: Small, multiple-stepped hose barb
          (with filling bell at the outlet)
B: ¾"–1" Multiple-stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar │ 72.5 psi at 20°C (MidiCaps) 2 bar │ 29 psi at 80°C (MidiCaps) 4 bar │ 58 psi at 20°C (MaxiCaps) 3 bar │ 43.5 psi at 20°C (MaxiCaps)
Max. allowable back pressure	2 bar │ 29 psi at 20°C

Extractables
Sartobran® P 0.2 µm rated filter MidiCaps and MaxiCaps meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

Autoclaving
134°C, 2 bar, 30 min

No in-line steam-sterilization

Sterilization Cycles
Autoclaving   Min. 25

Technical References
Validation Guide
– SPK5760-e (MidiCaps)
– SPK5726-e (MaxiCaps)

Extractables Guide
– SPK5720-e

Order Information

Order Code	Pore Size [µm]	Pack Size [Pieces]	Test Pressure [bar │ psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar │ psi]
MidiCaps					
5235307H7--**--A	0.2	4	2.5 │ 36	3	3.2 │ 46
5235307H8--**--A	0.2	4	2.5 │ 36	4	3.2 │ 46
5235307H9--**--A	0.2	4	2.5 │ 36	5	3.2 │ 46
5235307H0--**--V	0.2	2	2.5 │ 36	10	3.2 │ 46
MaxiCaps					
5231307H1--**	0.2	1	2.5 │ 36	15	3.2 │ 46
5231307H2--**	0.2	1	2.5 │ 36	30	3.2 │ 46
5231307H3--**	0.2	1	2.5 │ 36	45	3.2 │ 46

**: Connector Styles

▶ # Sartobran® P 150 & 300 0.2 µm

Sterilizing Grade Filter Capsules

Single-Use Technology

The Sartobran® 150 & 300 are disposable, sterile ready-to-use membrane filter capsules. They are designed for use in small-scale production of high-value pharmaceutical and biotech products, due to the ultra-low binding of their cellulose acetate membrane for proteins and preservatives. The Sartobran® 150 and 300 feature the same materials and type of construction as any other Sartobran® P filter element, for easy scale-down and scale-up, making them perfect for R&D labs in pharmaceutical development.

Applications
Typical applications include sterilizing grade filtration of any solution sensitive to adsorption such as:

– Therapeutics

– Bioprocessed pharmaceuticals

– Serum

– Injectables

– Media

– Buffers

Performance
The unique pleated filter construction and the "built-in-prefiltration" offers excellent flow rates and superior total throughput performance, especially in comparison to conventional stacked disc filter systems.

High Product Yield
The highest product yields are realized by the combination of extremely low residual volume in the capsule housing and ultra-low unspecific adsorption of the cellulose acetate membrane.

Automatic Venting
A hydrophobic PTFE vent filter membrane positioned at the highest point upstream allows easy venting of the capsule and prevents product loss during the venting process.

Scalability
Featuring the same materials and type of construction as any other Sartobran® P filter element, Sartobran® P 150 & 300 are ideally suited for R&D labs in pharmaceutical development. Filtration trials can be performed using extremely small volumes of high-value products.

Microbiological Retention
Sartobran® P 0.2 µm rated 150 & 300 capsules are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is integrity-tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation
Sartobran® P 150 & 300 capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rate Sartobran® 300

Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Cellulose acetate
Endfilter membrane	Cellulose acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Housing	Polypropylene

Pore Size
0.45 μm + 0.2 μm

Available Sizes | Filtration Area
Size 4 $\quad$ 0.015 m² | 0.16 ft²
Size 5 $\quad$ 0.03 m² | 0.32 ft²

Available Connectors
SS, SO, OO $\qquad$ (Type 150)
OO $\qquad$ (Type 300)

Operating Parameters

Max. allowable differential pressure	4 bar	58 psi at 20 °C
2 bar	29 psi at 80 °C
Max. allowable back pressure	2 bar	29 psi at 20 °C

Extractables
Sartobran® P 0.2 μm rated 150 & 300 filter capsules meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

Autoclaving
134 °C, 2 bar | 29 psi, 30 min

No in-line steam-sterilization

Sterilization Cycles
Autoclaving $\qquad$ Min. 25 (Type 300)
$\qquad\qquad\qquad$ Max. 3 (Type 150)

Technical References
Validation Guide $\qquad$ SPK5726-e
Extractables Guide $\qquad$ SPK5720-e

Ordering Information

Order Code	Pore Size [μm]
Sartobran® 150	
5231307H4--OO--B	0.2
5231307H4--SO--B	0.2
5231307H4--SS--B	0.2
Sartobran® 300	
5231307H5--OO--B	0.2

Water Flow Rate Sartobran® 150
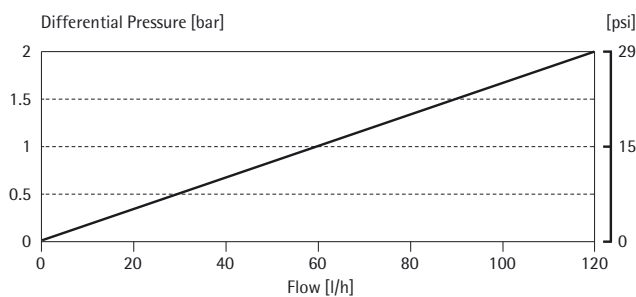
Standardized at 20 °C

▶ Sartobran® P 0.1 µm

Sterilizing Grade Filter Cartridges, MidiCaps & MaxiCaps

Description
Sartobran® P 0.1 µm rated, high-flow filter elements are designed to give enhanced sterility assurance for applications with microorganisms present that can pass through 0.2 µm rated sterilizing grade filters. The Sartobran® P's cellulose acetate membrane offers ultra-low binding properties for proteins and preservatives, making Sartobran® P filters the ideal choice for filtration of high-value biopharmaceutical products.

Applications
All applications which require sterilizing grade filtration with retention finer than conventional 0.2 µm sterilizing grade filters for removal of unusually small microorganisms. This typically includes:

– Bio-processed pharmaceuticals

– Long-term filling operations

– Filtration in pharmaceutical water systems

Any other application requiring sub 0.2 µm filtration for enhanced sterility assurance.

Flow Rates
Higher flow rates than other 0.1 µm rated filters provide short filtration time and gentle product treatment, even if replacement of conventional 0.2 µm rated filters is necessary.

Total Throughput
Due to the "built-in prefiltration" by a 0.45 µm membrane, Sartobran® P 0.1 µm filters provide higher total throughputs than any other 0.1 µm rated filter for economical process design.

Highest Product Yield
The ultra-low adsorption characteristic of the Sartobran® P's cellulose acetate membrane provides the highest product yield - especially important for high-value proteins.

Flexibility
Sartobran® P 0.1 µm filters are available in traditional cartridge formats and disposable capsules from 150 cm^2 to 1.8 m^2 for simple linear scale up and process flexibility.

Quality Control
Each individual element is integrity-tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation
Sartobran® P cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for 10", 20" and 30" Cartridges
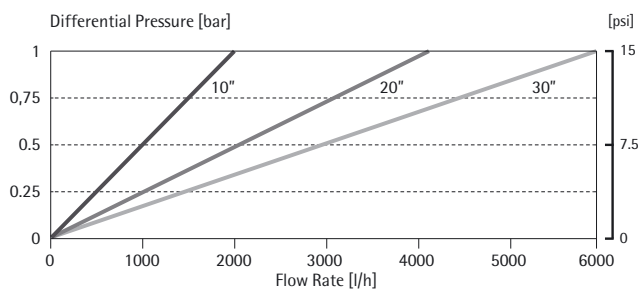
Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Cellulose acetate
Endfilter membrane	Cellulose acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Pore Size
0.45 µm + 0.1 µm

Available Sizes | Filtration Area

Cartridges | MaxiCaps
Size 1	10"	0.6 m^2	6 ft^2
Size 2	20"	1.2 m^2	12 ft^2
Size 3	30"	1.8 m^2	18 ft^2

MidiCaps | Mini Cartridges
Size 7	0.05 m^2	0.5 ft^2
Size 8	0.1 m^2	1 ft^2
Size 9	0.2 m^2	2 ft^2
Size 0	0.45 m^2	5 ft^2

Available Adapter Cartridges
21, 25, 27, 28

Available Adapter Mini Cartridges
15

Total Throughput Comparison

Total Throughput at 95% blockage [kg]

10" Cartridge format

Operating Parameters

Max. allowable differential pressure	5 bar	75 psi at 20°C (cartridges) 4 bar	58 psi at 20°C (capsules) 2 bar	29 psi at 80°C (cartridges and capsules)
Max. allowable back pressure	2 bar	29 psi at 20°C

Available Connectors MaxiCaps
SS, SO, OO, BB, FF

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Extractables
Sartobran® P 0.1 µm rated filter cartridges meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test.

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134°C, 20 min. at max differential pressure of 0.5 bar | 7 psi

Note
Capsules cannot be in-line steam-sterilized.

Autoclaving
134°C, 2 bar | 29 psi, 30 min

Sterilization Cycles
In-line sterilization (only cartridges)	Min. 25
Autoclaving	Min. 25

Technical References
Validation Guide	SPK5726-e
Extractables Guide	SPK5720-e

Ordering Information

Order Code	Size	Pore Size [µm]
Cartridges		
523**58H1----P	1	0.1
523**58H2----P	2	0.1
523**58H3----P	3	0.1
MaxiCaps		
5231358H1--**	1	0.1
5231358H2--**	2	0.1
5231358H3--**	3	0.1
Mini Cartridges		
5231558H7------B	7	0.1
5231558H8------B	8	0.1
5231558H9------B	9	0.1
MidiCaps		
5235358H7--**--A	7	0.1
5235358H8--**--A	8	0.1
5235358H9--**--A	9	0.1
5235358H0--**--V	0	0.1
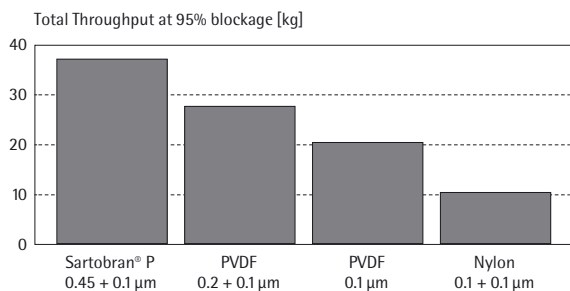
▶ Sartobran® P 0.45 µm

Bioburden and Particle Reductive Filter Cartridges

Description
Sartobran® P 0.45 µm rated filter cartridges are ideally suited for bioburden and particle removal from biopharmaceutical solutions for protection of subsequent downstream processing equipment or sterilizing grade filters. The unique low unspecific binding capacity of the cellulose acetate membranes assures highest protein yield and rapid preservative recovery.

Applications
Sartobran® P filters are ideally suited for prefiltration of high-value biological solutions and pharmaceuticals sensitive to adsorption, as well as for final filtration of LVP´s and Buffers. Typical applications are filtration of:

– Coagulation factors, albumine, IgG

– Bacterial and viral vaccines

– MAB's

– Bio-processed pharmaceuticals

– Diagnostics

– Purified protein solutions

– LV P

– Buffers

Highest Product Yield
The cellulose acetate membrane of the Sartobran® P filters provides the lowest unspecific adsorption of all membrane materials available for highest product recovery rates.

Performance
Due to the "built-in prefiltration" by a 0.65 µm membrane, Sartobran® P 0.45 µm filters provide excellent total throughputs and higher flow rates at low differential pressure for gentle product treatment.

Flexibility
Sartobran® P 0.45 µm filters are available in traditional cartridge formats and disposable capsules from 150 cm^2 to 1.8 m^2 for simple linear scale up and process flexibility.
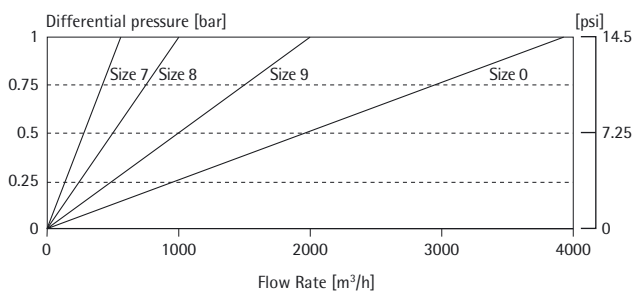
Quality Control
Each individual element is tested for integrity by diffusion and bubble point test prior to being released, assuring absolute reliability.

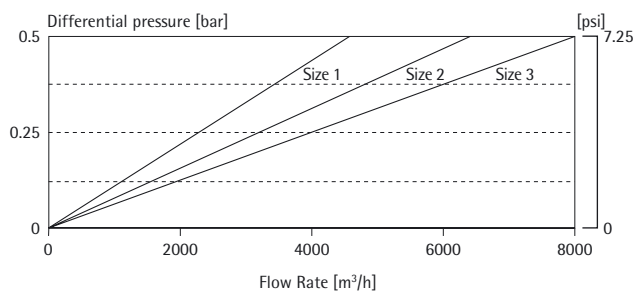**Documentation**
Sartobran® P cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for Standard Cartridges and MaxiCaps
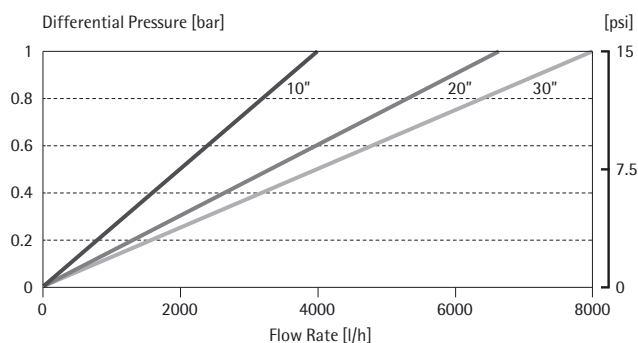
Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Cellulose acetate
Endfilter membrane	Cellulose acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Pore Size
0.65 μm + 0.45 μm

Available Sizes | Filtration Area

Cartridges

Size 1	10"	0.6 m²	6.5 ft²
Size 2	20"	1.2 m²	12.9 ft²
Size 3	30"	1.8 m²	19.4 ft²

Mini Cartridges

Size 7	0.05 m²	0.5 ft²
Size 8	0.1 m²	1.1 ft²
Size 9	0.2 m²	2.2 ft²

Available Adapter Cartridges
21, 25, 27, 28

Available Adapter Mini Cartridges
15

Operating Parameters

Max. allowable differential pressure	5 bar	75 psi at 20°C 2 bar	29 psi at 80°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartobran® P 0.45 μm rated filter cartridges meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134°C, 20 min. at max differential pressure of 0.5 bar | 7 psi

Note
Capsules and MaxiCaps cannot be in-line steam-sterilized.

Autoclaving
134°C, 2 bar | 29 psi, 30 min

Sterilization Cycles

In-line sterilization	Min. 25
Autoclaving	Min. 25

Technical References

Validation Guide	SPK5726-e
Extractables Guide	SPK5720-e

Ordering Information

Order Code	Size	Pore Size [μm]
Standard Cartridges		
523**06D1----P	1	0.45
523**06D2----P	2	0.45
523**06D3----P	3	0.45
Mini Cartridges		
5231506D7------B	7	0.45
5231506D8------B	8	0.45
5231506D9------B	9	0.45

Total Throughput Comparison

Adsorption per 10" cartridge [mg]

- BSA Adsorption
- IgG Adsorption
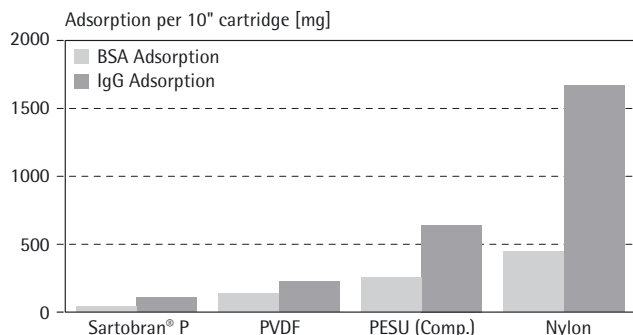
10" Cartridge format

▶ Sartobran® P 0.45 µm

Bioburden and Particle-Retentive MidiCaps and MaxiCaps

Single-Use Technology

Description
Sartobran® P membrane filter MidiCaps and MaxiCaps 0.45 µm rated are ideally suited for bioburden and defined particle reduction from biopharmaceutical solutions. They can be used for protecting sterilizing grade membrane filters or subsequent downstream processing equipment in biotech production processes.

Applications
Featuring extremely low adsorptive cellulose acetate membranes, Sartobran® P filter elements are ideally suited for filtration of highly valuable protein solutions or solutions containing preservatives. They assure highest protein yield and rapid preservative recovery.

Typical applications include:

– Coagulation factors, albumin, IgG

– Bacterial & viral vaccines

– MAB

– Bio-processed pharmaceuticals

– Diagnostics

– Purified protein solutions

– Biological fluids

– Fluids containing preservatives

Easy to Use
Sartobran® P MidiCaps and MaxiCaps are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

Flexibility
Sartobran® P 0.45 µm MidiCaps and MaxiCaps are available with various filtration areas from 500 cm² | 0.5 ft² up to 1.8 m² | 18 ft² for easy adoption to any filtration process, independent of the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed, as all Sartobran® P MidiCaps and MaxiCaps are produced with the same type of membrane and identical materials of construction.

Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Quality Control
Each individual element is tested for integrity by B.-P. and diffusion test prior to being released, assuring absolute reliability.

Documentation
Sartobran® P MidiCaps and MaxiCaps are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for MidiCaps with SS Inlet and Outlet

Water Flow Rates for MaxiCaps

Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Cellulose acetate
Endfilter membrane	Cellulose acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone
Filling bell	Polycarbonate

Pore Size Combination
0.65 µm + 0.45 µm

Available Sizes | Filtration Area

MidiCaps
Size 7   0.05 m² | 0.5 ft²
Size 8   0.1 m² | 1 ft²
Size 9   0.2 m² | 2 ft²
Size 0   0.45 m² | 5 ft²

MaxiCaps
Size 1   0.6 m² | 6 ft²
Size 2   1.2 m² | 12 ft²
Size 3   1.8 m² | 18 ft²

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, SO, OO, FF, BB

S: 1½" Tri-clamp (sanitary)
O: ½" Hose Barb
F: ¾" Tri-clamp (sanitary)
H: Small, multiple-stepped hose barb
         (with filling bell at the outlet)
B: ¾"-1" Multiple-stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar	72.5 psi at 20°C (MidiCaps) 2 bar	29 psi at 80°C (MidiCaps) 4 bar	58 psi at 20°C (MaxiCaps) 3 bar	43.5 psi at 50°C (MaxiCaps)
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartobran® P 0.45 µm rated filter MidiCaps and MaxiCaps meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity-tested

Non-pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

Autoclaving
134°C, 2 bar, 30 min

No in-line steam-sterilization

Sterilization Cycles
Autoclaving   Min. 25

Technical References
Validation Guide
– SPK 5760-e (MidiCaps)
– SPK 5726-e (MaxiCaps)

Extractables Guide
– SPK5731-e

Order Information

Order Code	Pore Size [µm]	Pack Size [Pieces]	Test Pressure [bar	psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar	psi]
MidiCaps					
5235306D7--**--A	0.45	4	1.5	22	3	2.0	29
5235306D8--**--A	0.45	4	1.5	22	4	2.0	29
5235306D9--**--A	0.45	4	1.5	22	5	2.0	29
5235306D0--**--V	0.45	2	1.5	22	10	2.0	29
MaxiCaps					
5231306D1--**	0.45	1	1.5	22	15	2.0	29
5231306D2--**	0.45	1	1.5	22	30	2.0	29
5231306D3--**	0.45	1	1.5	22	45	2.0	29

**: Connector Styles

▶ # Sartopore® 2 0.2 µm

Sterilizing Grade Filter Cartridges and Mini Cartridges

Description

Sartopore® 2 0.2 µm rated sterilizing grade filter cartridges are designed for filtration of a broad range of pharmaceutical products where compliance with cGMP requirements has to be fulfilled. Sartopore® 2 cartridges feature a unique hydrophilic heterogeneous double-layer polyethersulfone membrane with broad chemical compatibility, high thermal resistance and higher throughput arld flow rate than any other sterilizing grade filter cartridge.

Applications

Typical applications include sterilizing grade filtration of:

– Therapeutics

– Biological fluids

– Opthalmics

– SVPs, LVPs

– Antibiotics

– WFI

– Chemicals

– Cleaning and sanitizing agents

– Bulk pharmaceutical products

Compatibility

The polyethersulfone membrane is compatible with a pH range from pH 1 to pH 14 and unaffected by steam sterilization cycles, making Sartopore® 2 cartridges ideal for filtration of solutions with high│low pH and for SIP│Cl P-cycles.

Performance

Sartopore® 2 cartridges provide an exceptionally high total throughput by fractionated filtration due to the "built-in prefiltration" of the 0.45 µm membrane. The asymmetric pore structure of the polyethersulfone membrane provides high flow rates at low pressure drops.

Wettability

Sartopore® 2 cartridges can be easily wetted out for integrity testing even after drying at 80°C for 12 hours.

Microbiological Retention

Sartopore® 2 filter cartridges are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-05 guidelines.

Quality Control

Each individual element is integrity-tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation

Sartopore® 2 cartridges are designed, developed and manufactured in accordance with an IS0 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for 10", 20" and 30" Cartridges
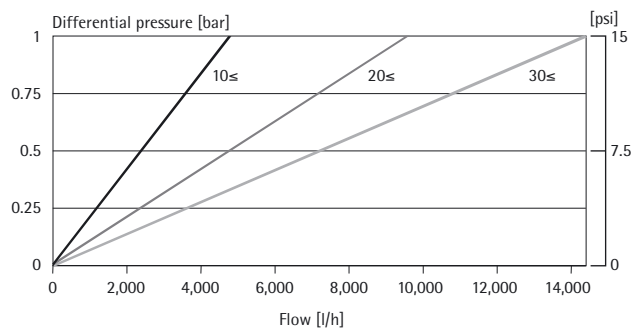
Standardized at 20°C

Total Throughput Comparison
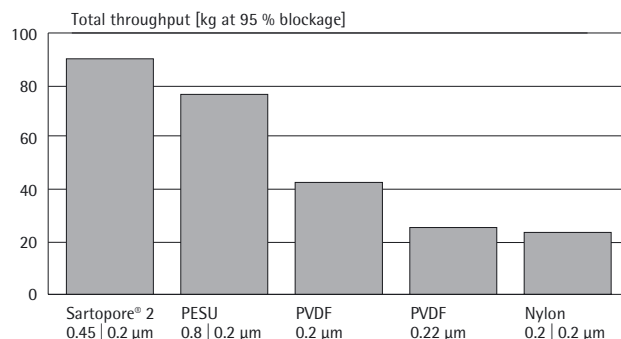
10" Cartridge format

▷ Specifications

Materials

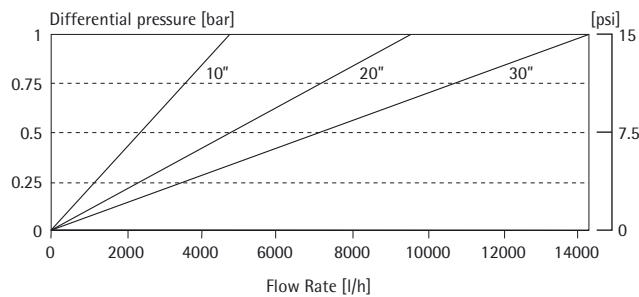|	
Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Pore Size
0.45 µm + 0.2 µm

Available Sizes | Filtration Area

Standard Cartridges

Size 0	5"	0.3 m^2	3 ft^2
Size 1	10"	0.6 m^2	6 ft^2
Size 2	20"	1.2 m^2	12 ft^2
Size 3	30"	1.8 m^2	18 ft^2

Mini Cartridges

Size 7	0.05 m^2	0.5 ft^2
Size 8	0.1 m^2	1 ft^2
Size 9	0.2 m^2	2 ft^2

Available Adapter Cartridges
21, 25, 27, 28

Available Adapter Mini Cartridges
15

Operating Parameters

Max. allowable differential pressure	5 bar	58 psi at 20°C 2 bar	29 psi at 80°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartopore® 2 0.2 µm rated filter cartridges meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Integrity Test Limits
Maximum allowable diffusion at 2.5 bar | 36 psi at 20°C

Cartridge Size	Maximum Diffusion	Minimum Bubble Point
Size 0	10 ml	min	3.2 bar	46 psi
Size 1	18 ml	min	3.2 bar	46 psi
Size 2	36 ml	min	3.2 bar	46 psi
Size 3	54 ml	min	3.2 bar	46 psi
Size 7	4 ml	min	3.2 bar	46 psi
Size 8	5 ml	min	3.2 bar	46 psi
Size 9	7 ml	min	3.2 bar	46 psi

Sterilization

In-Line Steam Sterilization
134°C, 20 min. at max differential pressure of 0.5 bar | 7.25 psi

Autoclaving
134°C, 2 bar | 29 psi, 30 min

Sterilization Cycles

In-line sterilization	Min. 25
Autoclaving	Min. 25

Technical References

Validation Guide	SPK5732-e
Extractables Guide	SPK5731-e

Ordering Information

Order Code	Pore Size [µm]	Test Pressure [bar	psi]	Max. Diffusion [ml/min]	Min. B.P. [bar	psi]
Cartridges				
544**07H1	0.2	2.5	36	18	3.2	46
544**07H2	0.2	2.5	36	36	3.2	46
544**07H3	0.2	2.5	36	54	3.2	46
Mini Cartridges				
544**07H7------B	0.2	2.5	36	4	3.2	46
544**07H8------B	0.2	2.5	36	5	3.2	46
544**07H9------B	0.2	2.5	36	7	3.2	46

▶ Sartopore® 2 0.2 μm

Sterilizing Grade MidiCaps and MaxiCaps

Single-Use Technology

Description
Sartopore® 2 0.2 μm membrane filter MidiCaps and MaxiCaps are self-contained, ready-to-use, sterile filter units for sterilizing grade filtration in the pharma│biotech industry. Made of a unique hydrophilic heterogeneous double-layer polyethersulfone membrane, Sartopore® 2 capsules are designed for convenient sterile filtration of a broad range of pharmaceutical products.

Applications
Typical applications include sterilizing grade filtration of:

– Therapeutics

– Biological fluids

– Injectables

– Media

– Buffers

– Chemicals

– Cleaning and sanitizing agents

Compatibility
The polyethersulfone membrane is compatible with a pH-range from pH 1 to pH 14 making Sartopore® 2 MidiCaps and MaxiCaps ideal for filtration of solutions with high│low pH.

Easy to Use
Sartopore® 2 MidiCaps are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

Flexibility
Sartopore® 2 0.2 μm MidiCaps and MaxiCaps are available with various filtration areas from 500 cm^2│0.5 ft^2 up to 1.8 m^2│18 ft^2 for easy adoption to any filtration process independent of the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed as all Sartopore® 2 MidiCaps and MaxiCaps are produced with the same type of membrane and materials and identical construction.

Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Microbiological Retention
Sartopore® 2 filter MidiCaps and MaxiCaps 0.2 μm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is tested for integrity by bubble point and diffusion test prior to being released, assuring absolute reliability.

Documentation
Sartopore® 2 MidiCaps and MaxiCaps are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for MidiCaps with SS Inlet and Outlet

Water Flow Rates for MaxiCaps

Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone
Filling bell	Polycarbonate

Pore Size
0.45 µm + 0.2 µm

Available Sizes | Filtration Area

MidiCaps
Size 7   0.05 m^2 | 0.5 ft^2
Size 8   0.1 m^2 | 1 ft^2
Size 9   0.2 m^2 | 2 ft^2
Size 0   0.45 m^2 | 5 ft^2

MaxiCaps
Size 1   0.6 m^2 | 6 ft^2
Size 2   1.2 m^2 | 12 ft^2
Size 3   1.8 m^2 | 18 ft^2

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, SO, OO, FF, BB

S: 1½" Tri-clamp (sanitary)
O: ½" Single stepped hose barb
F: ¾" Tri-clamp (sanitary)
H: Small, multiple-stepped hose barb
        (with filling bell at the outlet)
B: ¾"–1" Multiple-stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar	58 psi at 20°C (MidiCaps) 3 bar	43.5 psi at 50°C (MaxiCaps) 2 bar	29 psi at 80°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartopore® 2 0.2 µm rated filter MidiCaps and MaxiCaps meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

Autoclaving
134°C, 2 bar, 30 min

No in-line steam-sterilization

Sterilization Cycles
Autoclaving   Min. 25

Technical References
Validation Guide
– SPK5751-e (MidiCaps)
– SPK5732-e (MaxiCaps)

Extractables Guide
– SPK5731-e

Order Information

Order Code	Pore Size [µm]	Pack Size [Pieces]	Test Pressure [bar	psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar	psi]
MidiCaps					
5445307H7--**--A	0.2	4	2.5	36	4	3.2	46
5445307H8--**--A	0.2	4	2.5	36	5	3.2	46
5445307H9--**--A	0.2	4	2.5	36	7	3.2	46
5445307H0--**--V	0.2	2	2.5	36	14	3.2	46
MaxiCaps					
5441307H1--**	0.2	1	2.5	36	18	3.2	46
5441307H2--**	0.2	1	2.5	36	36	3.2	46
5441307H3--**	0.2	1	2.5	36	54	3.2	46

**: Connector Styles

▶ ## Sartopore® 2 0.2 μm T-Style MaxiCaps

Sterilizing Grade γ-Irradiatable or Autoclavable T-Style MaxiCaps

Single-Use Technology

Description
Sartopore® 2 0.2 μm - γ irradiatable or auto-clavable T-Style MaxiCaps feature a new and innovative capsule housing design. The T-Style design is ideal for easy installation of multiple filters in series or parallel configu-rations to reduce overall footprint and hold-up volumes. Sartopore® 2 0.2 μm T-Style MaxiCaps can be sterilized by autoclaving or gamma-irradiation. The opportunity to sterilize by gamma irradiation allows the use of these filters in flexible-bag-container-systems.

Applications
Typical applications include sterilizing grade filtration of:

– Biologicals

– Pharmaceuticals

– Cell Culture Media

– Culture Media Components

– Serum

– Buffer

Compatibility
Sartopore® 2 T-Style MaxiCaps are designed for sterilizing by gamma irradiation at a maximum dosage of ≤ 50kGy or by auto-claving at 134°C and 2 bar. The PES mem-brane offers a broad chemical compatibility from pH 1 – pH 10 and make them ideally suited for processing in biopharmaceutical industry. The innovative design allows a maximum forward differential pressure of 5 bar | 72.5 psi at 20°C.

Flexible Integration
The variety of different connector styles, dimensions and filter sizes facilitates an easy integration into any process.

Economy
The combination of a built-in 0.45 μm pre-filter in front of the a 0.2 μm final filter and the asymmetric membrane structure provide outstanding total throughput performance.

Cost Savings
The use of T-Style design concept avoids investment in stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation. They also avoid investment in additional tubing required to connect mulitple filters in serie.

Microbiological Retention
Sartopore® 2 0.2 μm T-Style MaxiCaps rated are fully validated as sterilizing grade filters according to ASTM F-838-05 guidelines.
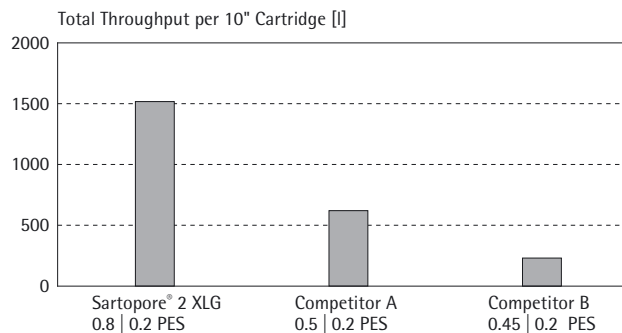
Quality Control
Each individual filter is tested for integrity by B.P. and Diffusion-Test prior to being released assuring absolute reliability.

Documentation
Sartopore® 2 0.2 μm T-Style MaxiCaps are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Vailidation Guide is available for compliance with regulatory requirements.
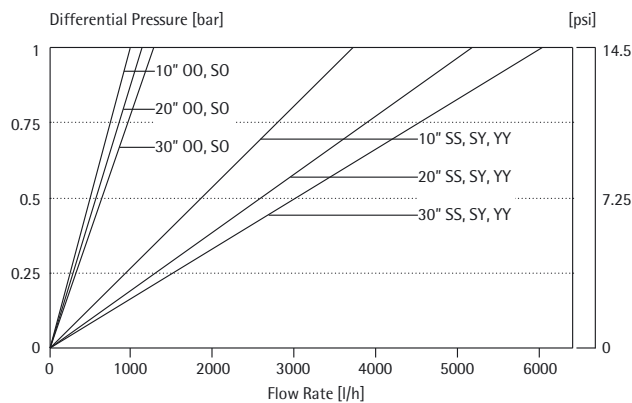
Differential Pressure [bar]   [psi]

- 10" OO, SO
- 20" OO, SO
- 30" OO, SO
- 10" SS, SY, YY
- 20" SS, SY, YY
- 30" SS, SY, YY

Flow Rate [l/h]

▷ Specifications

Materials

Prefilter Membrane	Polyethersulfone, asymmetric
Endfilter Membrane	Polyethersulfone, asymmetric
Support Fleece	Polyester
Core	Polypropylene
End Caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone

Pore Size Combinations
0.45 μm + 0.2 μm

Available Sizes | Filtration Area
Size 1   0.6 m^2 | 6 ft^2
Size 2   1.2 m^2 | 12 ft^2
Size 3   1.8 m^2 | 18 ft^2

Available Connectors
SS, SO, OO, YY, SY

S: 1 ½" Tri-Clamp (Sanitary)
0: ½" Single stepped hose barb
Y: 1" Single stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar	72.5 psi at 20°C 2 bar	29 psi at 80°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartopore® 2 0.2 μm T-Style MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP after γ-irradiation with < 50 kGy, or autoclaving.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to ASTM F 838-05 Bacterial Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization
1 × γ-irradiation ≤ 50 kGy irradiational dosage
or
3 × autoclaving, 134°C, 2 bar, 30 min

Sartopore® 2 0.2 μm T-Style MaxiCaps can not be In-line steam sterilized!

Sterilization Cycles
γ-irradiation   1 Cycle
or
autoclaving   3 Cycles

Technical References
Validation Guide

Order Code	Pore Size [μm]	Test Pressure [bar | psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar | psi]
5448307H1G-**	0.2	2.5 | 36	18	3.2 | 46
5448307H2G-**	0.2	2.5 | 36	36	3.2 | 46
5448307H3G-**	0.2	2.5 | 36	54	3.2 | 46

**: Connector Style

▶ Sartopore® 2 XLG 0.2 µm

Sterilizing Grade Filter Cartridges

Description
Sartopore® 2 XLG filter cartridges are especially designed for sterilizing grade filtration in special applications of cell culture processes. The unique heterogeneous double layer PES membrane combination of Sartopore® 2 XLG cartridges is specifically developed to deal with the broad variety of contaminants in up- and downstream processing of biotech applications. They provide consistently high total throughput performance for biological fluid streams independent from media and process variations.

Applications
Typical applications of Sartopore® 2 XLG cartridges include sterilizing grade filtration of:

– Plant peptone or yeast supplemented cell culture media

– Serum containing cell culture media

– Other cell culture media used in biotech manufacturing

– Clarified cell culture harvest

– Downstream Intermediates (before and after UF | DF and chromatography steps)

Economy
The combination of the build in 0.8 µm pre-filter in front of a 0.2 µm final filter together with an exceptionally high effective filtration area of 0.8 m²/10″ cartridge provide outstanding total throughput and flow rate performance in the target applications. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Compatibility
The PES membrane of Sartopore® 2 XLG cartridges provides broad chemical compati-bility from pH 1 to pH 14 and low extractable levels. They are compatible with multiple in line steam sterilization cycles up to 134°C.

Scalability
Sartopore® 2 XLG filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

Microbiological Retention
Sartopore® 2 XLG filter cartridges are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.
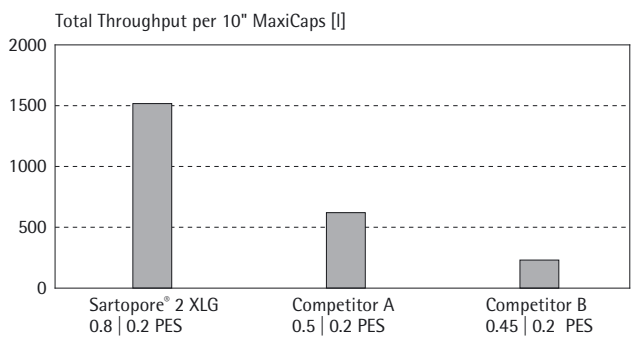
Quality Control
Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

Documentation
Sartopore® 2 XLG cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Manage-ment System. A Validation Guide is available for compliance with regulatory requirements.

Soy Peptone Supplemented Cell Culture Media

Total Throughput per 10″ Cartridge [l]

Sartopore® 2 XLG 0.8 | 0.2 PES	~1520
Competitor A 0.5 | 0.2 PES	~610
Competitor B 0.45 | 0.2 PES	~220

▷ Specifications

Materials

Prefilter Membrane	PES, asymmetric
Endfilter Membrane	PES, asymmetric
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	Silicone

Pore Size Combination
0.8 µm + 0.2 µm

Available Sizes │ Filtration Area
Size 1	10"	0.8 m^2 │ 8.6 ft^2
Size 2	20"	1.6 m^2 │ 17.2 ft^2
Size 3	30"	2.4 m^2 │ 25.8 ft^2

Available Adapters
25

Operating Parameters

Max. allowable differential pressure	5 bar │ 72.5 psi at 20°C 2 bar │ 29 psi at 80°C
Max. allowable back pressure	2 bar │ 29 psi at 20°C

Extractables
Sartopore® 2 XLG 0.2 µm rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization:
134°C, 20 min. at max differential pressure of 0.5 bar

Autoclaving:
134°C, 2 bar, 30 min

Sterilization Cycles
In-Line Sterilization:	Min. 25
Autoclaving:	Min. 25

Technical References
Validation Guide:
SPK5772-e

Extractables Guide:
SPK5775-e

Order Codes

Cartridges	Pore Size [µm]	Test Pressure [bar │ psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar │ psi]
5442507G1	0.8 + 0.2	2.5 │ 36	23	3.2 │ 46
5442507G2	0.8 + 0.2	2.5 │ 36	46	3.2 │ 46
5442507G3	0.8 + 0.2	2.5 │ 36	69	3.2 │ 46

Monoclonal Antibody Pool
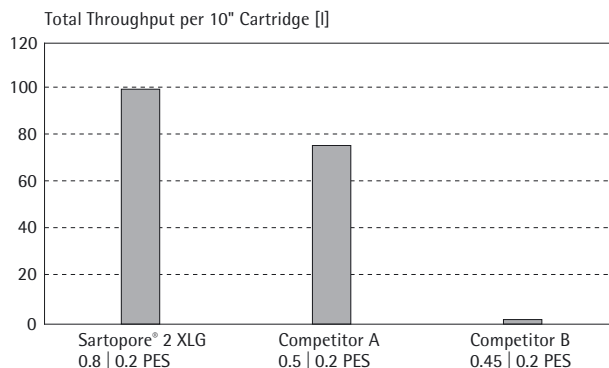
Antibody Concentration: 47.5 mg/ml

▶ # Sartopore® 2 XLG 0.2 μm

Sterilizing Grade MidiCaps®, MaxiCaps® and Capsules

Single-Use Technology

Description
Sartopore® 2 XLG MidiCaps®, MaxiCaps® and Capsules are self contained filter units that are especially designed for sterilizing grade filtration in special applications of cell culture processes. The unique heterogeneous double layer PES membrane combination of Sartopore® 2 XLG MidiCaps®, MaxiCaps® and Capsules is specifically developed to deal with the broad variety of contaminants in up- and downstream processing of biotech applications. They provide consistently high total throughput performance for biological fluid streams independent from media and process variations.

Applications
Typical applications of Sartopore® 2 XLG MidiCaps®, MaxiCaps® and Capsules include sterilizing grade filtration of:

– Plant peptone or yeast supplemented cell culture media

– Serum containing cell culture media

– Other cell culture media used in biotech manufacturing

– Clarified cell culture harvest

– Downstream Intermediates (before and after UF | DF and chromatography steps)

Economy
The combination of the built-in 0.8 μm pre-filter in front of a 0.2 μm final filter together with the 30% enlarged effective filtration area per XLG filter element provide an outstanding total throughput and flow rate performance in the target applications. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Compatibility
The PES membrane of Sartopore® 2 XLG MidiCaps®, MaxiCaps® and Capsules provide broad chemical compatibility from pH 1 to pH 14 and low extractable levels. They are compatible with multiple autoclaving cycles up to 134°C.

Scalability
Sartopore® 2 XLG filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

Cost Saving
The use of the capsule design concept avoids investment in stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Microbiological Retention
Sartopore® 2 XLG MidiCaps®, MaxiCaps® and Capsules are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is tested for integrity by B.P. and Diffusion-Test prior to being released assuring absolute reliability.

Documentation
Sartopore® 2 XLG MidiCaps®, MaxiCaps® and Capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Soy Peptone Supplemented Cell Culture Media

Total Throughput per 10" MaxiCaps [l]

| | Sartopore® 2 XLG 0.8 | 0.2 PES | Competitor A 0.5 | 0.2 PES | Competitor B 0.45 | 0.2 PES |

Monoclonal Antibody Pool

Total Throughput per 10" MaxiCaps [l]

| | Sartopore® 2 XLG 0.8 | 0.2 PES | Competitor A 0.5 | 0.2 PES | Competitor B 0.45 | 0.2 PES |

Antibody Concentration: 47.5 mg/ml

▷ Specifications

Materials

Prefilter Membrane	Polyethersulfone, asymmetric
Endfilter Membrane	Polyethersulfone, asymmetric
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

Pore Size
0.8 µm + 0.2 µm

Available Sizes | Filtration Area

Capsules
Size 4   0.021 m² | 0.22 ft²

MidiCaps
Size 7   0.065 m² | 0.7 ft²
Size 8   0.13 m² | 1.4 ft²
Size 9   0.26 m² | 2.8 ft²
Size 0   0.52 m² | 5.6 ft²

MaxiCaps
Size 1   0.8 m² | 8.6 ft²
Size 2   1.6 m² | 17.2 ft²
Size 3   2.4 m² | 25.8 ft²

Available Connectors

Capsules Size 4
SS, SO, OO

MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

MaxiCaps
SS, SO, OO, FF, BB

S: 1½" Tri-Clamp (Sanitary)
O: ½" Single stepped hose barb
F: ¾" Tri-Clamp (Sanitary)
H: ¼" Multiple stepped hose barb
         (with filling bell at the outlet)
B: ¾" – 1" Multiple stepped hose barb
S: ½" Tri-Clamp (only Capsule Size 4)
O: Multiple stepped hose barb
         (only Capsule Size 4)

Operating Parameters

Max. allowable differential pressure	5 bar | 75 psi at 20°C (MidiCaps) 4 bar | 58 psi at 20°C (MaxiCaps and Capsules) 3 bar | 43.5 psi at 50°C
Max. allowable back pressure	2 bar | 29 psi at 20°C

Extractables
Sartopore® 2 XLG 0.2 µm rated MidiCaps®, MaxiCaps® and Capsules meet or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

Autoclaving:
134°C, 2 bar, 30 min

Sterilization Cycles (MaxiCaps® and MidiCaps®)
Autoclaving: Min. 25

No In-Line Steam Sterilization

Technical References
Validation Guide:
SPK5772-e08121
85034-536-30

Order Codes

	Pore Size [µm]	Pack Size (pieces)	Test Pressure [bar | psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar | psi]
XLG MidiCaps®					
5445307G7--**--A	0.8 + 0.2	4	2.5 | 36	5	3.2 | 46
5445307G8--**--A	0.8 + 0.2	4	2.5 | 36	6	3.2 | 46
5445307G9--**--A	0.8 + 0.2	4	2.5 | 36	9	3.2 | 46
5445307G0--**--V	0.8 + 0.2	2	2.5 | 36	18	3.2 | 46
XLG MaxiCaps®					
5441307G1--**	0.8 + 0.2	1	2.5 | 36	23	3.2 | 46
5441307G2--**	0.8 + 0.2	1	2.5 | 36	46	3.2 | 46
5441307G3--**	0.8 + 0.2	1	2.5 | 36	69	3.2 | 46
XLG Capsules Size 4					
5441307G4--**--B	0.8 + 0.2	5	2.5 | 36	1.1	3.2 | 46

▶ Sartopore® 2 XLI 0.2 µm

Sterilizing Grade Filter Cartridges

Description
Sartopore® 2 XLI filter cartridges are especially designed for sterilizing grade filtration of pharmaceutical solutions with a homogenous particle spectrum. The unique heterogeneous double layer PES membrane combination of Sartopore® 2 XLI cartridges is specifically developed to provide exceptional high total throughputs and outstanding flow rates for totally chemically defined process fluids and other process fluids of biotech manufacturing processes with small particle spectrum.

Applications
Typical applications of Sartopore® 2 XLI cartridges include sterilizing grade filtration of:

– Ophthalmic solutions

– Chemically defined cell culture media

– High viscous large volume parenterals

– Any fully chemically defined media

Economy
The combination of the build in 0.35 µm pre-filter in front of a 0.2 µm final filter together with an exceptionally high effective filtration area of 0.8 m^2/10" cartridge provide outstanding total throughput and flow rate performance in the target applications. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Compatibility
The PES membrane of Sartopore® 2 XLI cartridges provides broad chemical compatibility from pH 1 to pH 14 and low extractable levels. They are compatible with multiple in line steam sterilization cycles up to 134°C.

Scalability
Sartopore® 2 XLI filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

Microbiological Retention
Sartopore® 2 XLI filter cartridges are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.
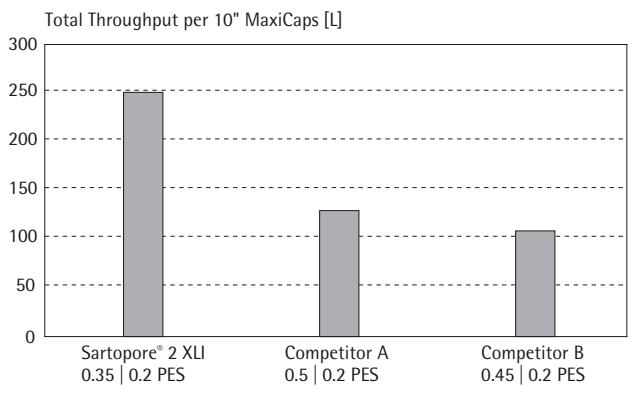
Quality Control
Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.
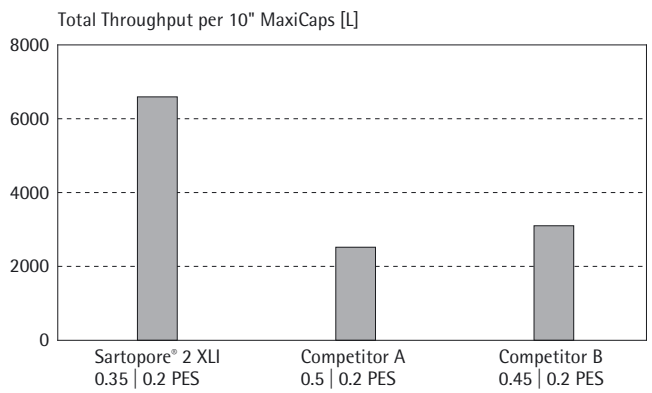
Documentation
Sartopore® 2 XLI cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Chemically Defined Cell Culture Media

Total Throughput per 10" Cartridge [l]

	Sartopore® 2 XLI 0.35 | 0.2 PES	Competitor A 0.5 | 0.2 PES	Competitor B 0.45 | 0.2 PES
Value	~248	~127	~105
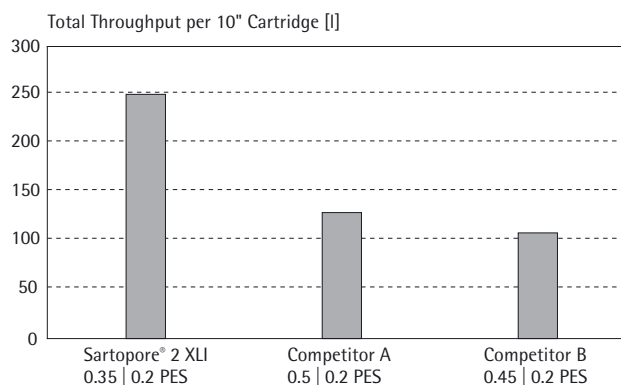
▷ Specifications

Materials

Prefilter Membrane	PES, asymmetric
Endfilter Membrane	PES, asymmetric
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
O-Rings	Silicone

Pore Size Combination
0.35 µm + 0.2 µm

Available Sizes | Filtration Area
Size 1   10"   0.8 m² | 8.6 ft²
Size 2   20"   1.6 m² | 17.2 ft²
Size 3   30"   2.4 m² | 25.8 ft²

Available Adapters
25

Operating Parameters

Max. allowable differential pressure	5 bar	72.5 psi at 20°C 2 bar	29 psi at 80°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartopore® 2 XLI 0.2 µm rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization:
134°C, 20 min. at max differential pressure of 0.5 bar

Autoclaving:
134°C, 2 bar, 30 min

Sterilization Cycles
In-Line Sterilization: Min. 25
Autoclaving: Min. 25

Technical References
Validation Guide:
SPK5768-e

Extractables Guide:
SPK5766-e

Order Codes

Cartridges	Pore Size [µm]	Test Pressure [bar	psig]	Max. Diffusion [ml/min]	Min. Bubble Point [bar	psig]
5442507I1	0.35 + 0.2	2.5	36	21	3.2	46
5442507I2	0.35 + 0.2	2.5	36	42	3.2	46
5442507I3	0.35 + 0.2	2.5	36	63	3.2	46

Ophthalmic Solution
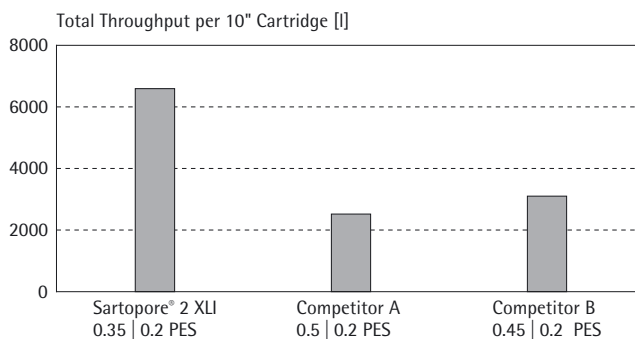
Total Throughput per 10" Cartridge [l]

▶ Sartopore® 2 XLI 0.2 µm

Sterilizing Grade MidiCaps®, MaxiCaps® and Capsules

Single-Use Technology

Description
Sartopore® 2 XLI MidiCaps®, MaxiCaps® and Capsules are self contained filter units that are especially designed for sterilizing grade filtration of pharmaceutical solutions with a homogenous particle spectrum. The unique heterogeneous double layer PES membrane combination of Sartopore® 2 XLI filters is specifically developed to provide exceptional high total throughputs and outstanding flow rates for totally chemically defined process fluids and other process fluids of biotech manufacturing processes with small particle spectrum.

Applications
Typical applications of Sartopore® 2 XLI MidiCaps®, MaxiCaps® and Capsules include sterilizing grade filtration of:

– Ophthalmic solutions

– Chemically defined cell culture media

– High viscous large volume parenterals

– Any fully chemically defined media

Economy
The combination of the built-in 0.35 µm pre-filter in front of a 0.2 µm final filter together with the 30% enlarged effective filtration area per XLI filter element provide an outstanding total throughput and flow rate performance in the target applications. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Compatibility
The PES membrane of Sartopore® 2 XLI MidiCaps®, MaxiCaps® and Capsules provide broad chemical compatibility from pH 1 to pH 14 and low extractable levels. They are compatible with multiple autoclaving cycles up to 134°C.

Scalability
Sartopore® 2 XLI filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

Cost Saving
The use of the capsule design concept avoids investment in stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Microbiological Retention
Sartopore® 2 XLI MidiCaps®, MaxiCaps® and Capsules are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is tested for integrity by B.P. and Diffusion-Test prior to being released assuring absolute reliability.

Documentation
Sartopore® 2 XLI MidiCaps®, MaxiCaps® and Capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Chemically Defined Cell Culture Media

Total Throughput per 10" MaxiCaps [L]

	Sartopore® 2 XLI 0.35 | 0.2 PES	Competitor A 0.5 | 0.2 PES	Competitor B 0.45 | 0.2 PES
Throughput (L)	~248	~128	~105

Ophthalmic Solution

Total Throughput per 10" MaxiCaps [L]

	Sartopore® 2 XLI 0.35 | 0.2 PES	Competitor A 0.5 | 0.2 PES	Competitor B 0.45 | 0.2 PES
Throughput (L)	~6600	~2500	~3050

▷ Specifications

Materials

Prefilter Membrane	Polyethersulfone, asymmetric
Endfilter Membrane	Polyethersulfone, asymmetric
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

Pore Size
0.35 µm + 0.2 µm

Available Sizes | Filtration Area
Capsules Size 4   0.021 m² | 0.22 ft²

MidiCaps
Size 7	0.065 m²	0.7 ft²
Size 8	0.13 m²	1.4 ft²
Size 9	0.26 m²	2.8 ft²
Size 0	0.52 m²	5.6 ft²

MaxiCaps
Size 1	0.8 m²	8.6 ft²
Size 2	1.6 m²	17.2 ft²
Size 3	2.4 m²	25.8 ft²

Available Connectors Capsules Size 4
SS, SO, OO

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, SO, OO, FF, BB

S: 1½" Tri-Clamp (Sanitary)
O: ½" Single stepped hose barb
F: ¾" Tri-Clamp (Sanitary)
H: ¼" Multiple stepped hose barb (with filling bell at the outlet)
B: ¾" – 1" Multiple stepped hose barb
S: ½" Tri-Clamp (only Capsule Size 4)
O: Multiple stepped hose barb (only Capsule Size 4)

Operating Parameters

Max. allowable differential pressure	5 bar	75 psi at 20°C (MidiCaps) 4 bar	58 psi at 20°C (MaxiCaps) 3 bar	43.5 psi at 50°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartopore® 2 XLI 0.2 µm rated MidiCaps®, MaxiCaps® and Capsules meet or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

Autoclaving:
134°C, 2 bar, 30 min

Sterilization Cycles (MaxiCaps® & MidiCaps®)
Autoclaving: Min. 25

No In-Line Steam Sterilization

Technical References
Validation Guide: SPK5768-e

Extractables Guide: SPK5776-e

Order Codes

	Pore Size [µm]	Test Pressure [bar	psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar	psi]
XLI MidiCaps®				
5445307I7--**--A	0.35 + 0.2	2.5	36	5	3.2	46
5445307I8--**--A	0.35 + 0.2	2.5	36	6	3.2	46
5445307I9--**--A	0.35 + 0.2	2.5	36	9	3.2	46
5445307I0--**--V	0.35 + 0.2	2.5	36	18	3.2	46
XLI MaxiCaps®				
5441307I1--**	0.35 + 0.2	2.5	36	23	3.2	46
5441307I2--**	0.35 + 0.2	2.5	36	46	3.2	46
5441307I3--**	0.35 + 0.2	2.5	36	69	3.2	46
XLI Capsules Size 4				
5441307I4--**--B	0.35 + 0.2	2.5	36	1.1	3.2	46

▶ # Sartopore® 2 HF 0.2 µm

Sterilizing Grade Filter Cartridges

Description
Sartopore® 2 High Flow sterilizing grade filter cartridges are developed for filtration of water-based pharmaceutical formulations. Sartopore® 2 HF cartridges feature a unique single-layer, hydrophilic polyethersulfone membrane. This membrane is characterized by broadest chemical compatibility, highest thermal resistance, increased mechanical stability and higher flow rates than any other sterilizing grade filter cartridge offers.

Applications
Typical applications include sterilizing grade filtration of:

– Large Volume Parenterals (LVP)

– Buffers

– WFI

– Cleaning and sanitizing agents

– Bulk pharmaceutical products

– Any application requiring exceptional high flow rates

Compatibility
The polyethersulfone membrane is compatible with a pH-range from pH 1 to pH 14 and to multiple steam sterilization cycles, making Sartopore® 2 HF cartridges ideal for filtration of solutions with high | low pH and for SIPICIP-cycles.

Performance
The increased effective filtration area of Sartopore® 2 HF filter cartridges allows for highest flow rates and assures thereby the most economic design of filtration systems.

Wettability
Sartopore® 2 HF cartridges can be easily wetted out for integrity testing even after drying cycles with 80°C for 12 hours.

Microbiological Retention
Sartopore® 2 HF filter cartridges 0.2 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.
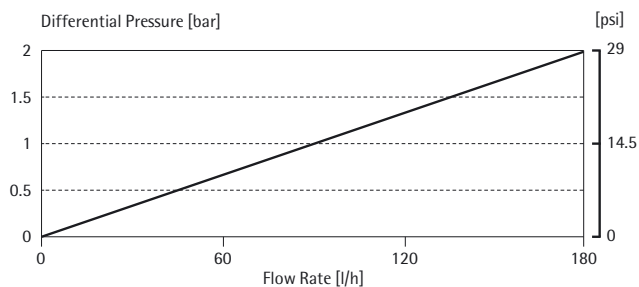
Quality Control
Each individual element is tested for integrity by bubble point and diffusion test prior to release, assuring absolute reliability.

Documentation
Sartopore® 2 HF cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and an Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for 10", 20" and 30" Cartridges
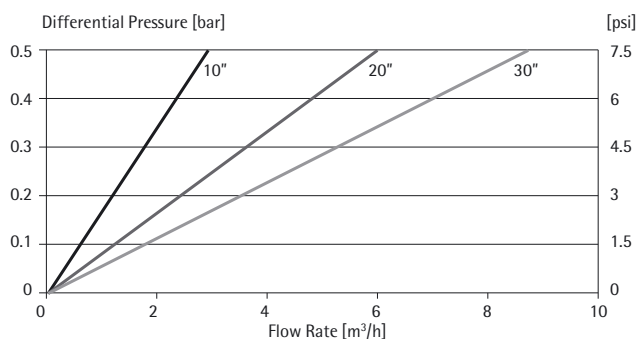
Standardized at 20°C

Flow Rate Comparison
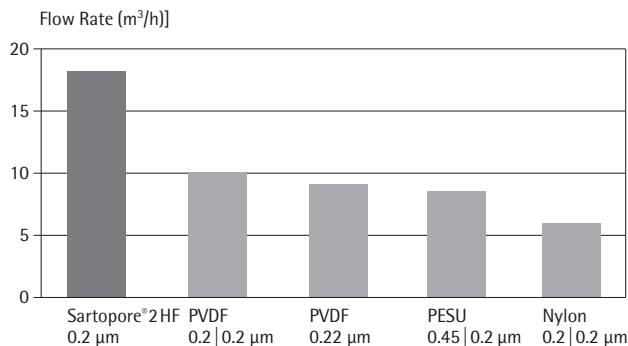
30" Filter cartridges at 1 bar | 14.5 psi differential pressure (20°C)

▷ Specifications

Materials

Filter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone

Pore Size
0.2 μm

Available Sizes | Filtration Area

Size 1	10"	0.7 m²	7 ft²
Size 2	20"	1.4 m²	14 ft²
Size 3	30"	2.1 m²	21 ft²

Available Adapters
25

Operating Parameters

Max. allowable differential pressure	5 bar	75 psi at 20°C 2 bar	29 psi at 80°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartopore® 2 HF 0.2 μm rated filter cartridges meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134°C, 20 min. at max differential pressure of 0.5 bar | 7 psi

Autoclaving
134°C, 2 bar, 30 min

Sterilization Cycles

In-line sterilization	Min. 25
Autoclaving	Min. 25

Technical References

Validation Guide	SPK 5741-e
Extractables Guide	SPK 5742-e

Integrity Test Limits
Maximum allowable diffusion at 2.5 bar | 36 psi at 20°C

Cartridge Size	Maximum Diffusion	Minimum Bubble Point
Size 1	21 ml	min	3.2 bar	46 psi
Size 2	42 ml	min	3.2 bar	46 psi
Size 3	63 ml	min	3.2 bar	46 psi

Ordering Information

Order Code	Pore Size [μm]	Test Pressure [bar	psi]	Max. Diffusion [ml/min]	Min. B.P. [bar	psi]
544**07H1	0.2	2.5	36	18	3.2	46
544**07H2	0.2	2.5	36	36	3.2	46
544**07H3	0.2	2.5	36	54	3.2	46

▶ # Sartopore® 2 150 & 300 0.2 μm

Sterilizing Grade Filter Capsule

Single-Use Technology

Description
Sartopore® 2 150 and Sartopore® 2 300 are disposable, sterile, ready-to-use membrane filter capsules for convenient sterilizing grade filtration. Sartopore® 2 150 and Sartopore® 2 300 capsules are made with a unique hydrophilic polyethersulfone membrane providing outstanding total throughput, flow rate, low extractables and broadest chemical compatibility.

Applications
Typical applications include sterilizing grade filtration of:
– Therapeutics
– Biological fluids
– Injectables
– Purified water
– Media
– Buffers

Compatibility
The polyethersulfone membrane is compatible with a pH range from pH 1 to pH 14 making Sartopore® 2 150 ideal for filtration of solutions with high | low pH.

Performance
The unique pleated filter construction combined with the highly asymmetric pore structure of the polyethersulfone membrane offers excellent flow rates and superior total throughput performance, especially in comparison to conventional stacked-disc filter systems.

Easy to Use
Sartopore® 2 150 and 300 capsules are available with hose barb, ¼ inch NPT thread or ½ inch tri-clamp connectors for simple installation in your filtration system. The tri-clamp connection assures secure and reliable integrity testing.

Automatic Venting
The new vent design enables easy access to the venting valve. A hydrophobic PTFE membrane positioned on the highest point upstream allows an easy venting of the capsule and prevents product loss during the venting process.

Scalability
Featuring the same materials and type of construction as any other Sartopore® 2 filter element, Sartopore® 2 150 and 300 are ideally suited for R&D Labs in pharmaceutical development. Filtration trials can be performed using extremely small volumes of high-value products.

Microbiological Retention
Sartopore® 2 150 and 300 0.2 μm rated capsules are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is integrity-tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation
Sartopore® 2 150 and 300 capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide is available for compliance with regulatory requirements.

Water Flow Rate

Standardized at 20 ℃

▷ Specifications

Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Housing	Polypropylene

Pore Size
0.45 µm + 0.2 µm

Available Sizes | Filtration Area
Size 4   0.015 m^2 | 0.15 ft^2
Size 5   0.03 m^2 | 0.32 ft^2

Available Connectors
SS, SO, OO (Type 150)
OO (Type 300)

Operating Parameters

Max. allowable differential pressure	4 bar	58 psi at 20 °C
2 bar	29 psi at 80 °C
Max. allowable back pressure	2 bar	29 psi at 20 °C

Extractables
Sartopore® 2 150 and 300 filter capsules meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

Sterilization

Autoclaving
134 °C, 2 bar | 29 psi, 30 min

No in-line steam-sterilization

Technical references
Validation Guide   SPK5732-e
Extractables Guide   SPK5731-e

Ordering Information

Order Code	Pore Size [µm]
Sartopore® 2 150	
5441307H4--OO--B	0.2
5441307H4--SO--B	0.2
5441307H4--SS--B	0.2
Sartopore® 2 300	
5441307H5--OO--B	0.2

Total Throughput Comparison

Total Throughput at 95% blockage [kg]
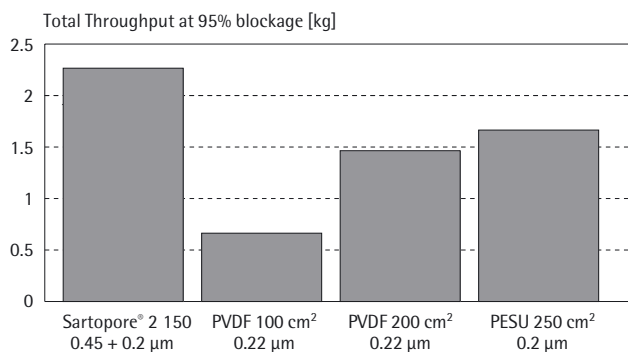
▶ Sartopore® 2 0.1 µm

Sterilizing Grade and Mycoplasma Retentive Filter Cartridges

Description
Sartopore® 2 0.1 µm rated filter cartridges are especially developed for validated sterile filtration and reliable mycoplasma removal from any media likely to contain it, such as those originating from animal sources. In addition, these elements are ideally suited for removal of unusually small microorganisms that have been shown to pass through a 0.2 µm rated sterilizing grade filter.

Applications
Typical applications include sterilizing grade filtration and mycoplasma removal from:

– Animal sera

– Cell culture media

– Media components

– Bioprocessed pharmaceuticals

– Biological fluids

– Any other application requiring sub 0.2 µm filtration for enhanced sterility assurance.

Compatibility
Featuring a unique hydrophilic polyether-sulfone membrane, Sartopore® 2 0.1 µm cartridges are compatible from pH 1 to pH 14 and to numerous steam sterilization cycles. Therefore, they are also ideally suited for filtration of solutions with high│low pH and for multiple SIP│CIP cycles.

Performance
Sartopore® 2 0.1 µm cartridges provide exceptionally high flow rates, resulting in economical sizing of filtration systems. Due to the "built-in prefiltration" by a 0.2 µm membrane, Sartopore® 2 0.1 µm rated cartridges achieve outstanding total throughputs.

Wettability
Sartopore® 2 cartridges can be easily wetted out for integrity testing even after drying at 80°C for 12 hours

Microbiological Retention
Sartopore® 2 0.1 µm rated filter cartridges are validated as sterilizing grade filters according to ASTM F 838-05 standard and for mycoplasma removal with a Log Reduction Value (LRV) of 7 for Acholeplasma laidlawii.
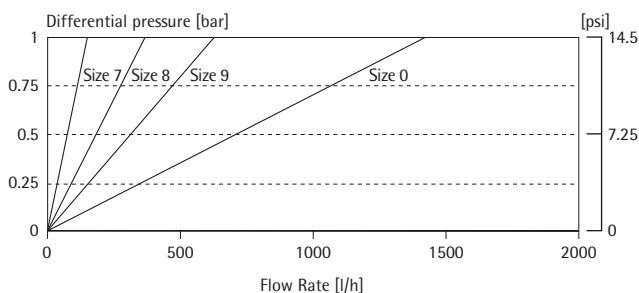
Quality Control
Each individual element is tested for integrity by diffusion test prior to being released, assuring absolute reliability.
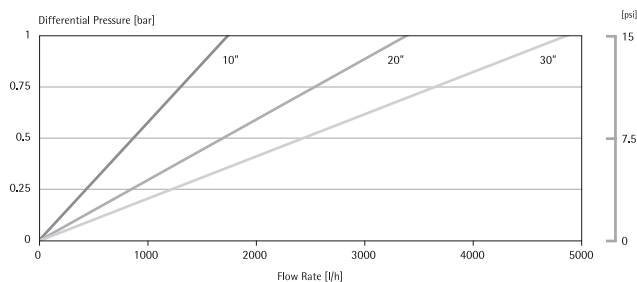
Documentation
Sartopore® 2 0.1 µm rated cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for 10", 20" and 30" Cartridges

Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Pore Size
0.2 µm + 0.1 µm

Available Sizes | Filtration Area

Cartridges

Size 1	10"	0.6 m²	6 ft²
Size 2	20"	1.2 m²	12 ft²
Size 3	30"	1.8 m²	18 ft²

Mini Cartridges

Size 7	0.05 m²	0.5 ft²
Size 8	0.1 m²	1 ft²
Size 9	0.2 m²	2 ft²

Available Adapters Cartridges
21, 25, 27, 28

Available Adapters Mini Cartridges
15

Operating Parameters

Max. allowable differential pressure	5 bar	75 psi at 20 °C 2 bar	29 psi at 80 °C
Max. allowable back pressure	2 bar	29 psi at 20 °C

Extractables
Sartopore® 2 0.1 µm rated filter cartridges meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test and mycoplasma removal.

Non-pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134 °C, 20 min. at max differential pressure of 0.5 bar | 7.25 psi

Autoclaving
134 °C, 2 bar | 29 psi, 30 min

Sterilization Cycles

In-line sterilization	Min. 25
Autoclaving	Min. 25

Technical References

Validation Guide	SPK5735-e
Extractables Guide	SPK5731-e

Ordering Information

Order Code	Pore Size [µm]
Cartridges	
544**58K1	0.1
544**58K2	0.1
544**58K3	0.1
Mini Cartridges	
5441558K7------B	0.1
5441558K8------B	0.1
5441558K9------B	0.1

Total Throughput Comparison
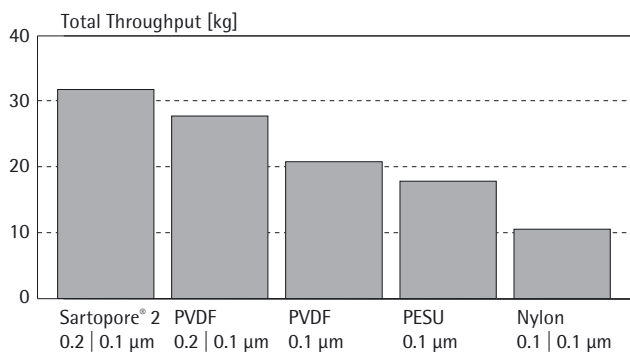
10" Cartridge format

▶ Sartopore® 2 0.1 µm

Sterilizing Grade and Mycoplasma Retentive MidiCaps & MaxiCaps

Single-Use Technology

Description
Sartopore® 2 0.1 µm rated MidiCaps and MaxiCaps are self-contained, ready-to-use membrane filter units for validated sterile filtration and reliable Mycoplasma removal in the pharma | biotech industry.

Applications
Typical applications include sterilizing grade filtration and Mycoplasma removal from:

– Animal Sera

– Cell Culture Media

– Media Components

– Bioprocessed Pharmaceuticals

– Prefiltration infront of virus filters

– Biological Fluids

and any other application requiring sub 0.2 µm filtration for enhanced sterility assurance.

Compatibility
The polyethersulfone membrane is compatible with a pH-range from pH 1 to pH 14 making Sartopore® 2 MidiCaps and MaxiCaps ideal for filtration of solutions with high | low pH.

Easy to Use
Sartopore® 2 MidiCaps are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

Flexibility
Sartopore® 2 0.1 µm MidiCaps and MaxiCaps are available with various filtration areas from 500 cm^2 | 0.5 ft^2 up to 1.8 m^2 | 18 ft^2 for easy adoption to any filtration process independent from the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed as all Sartopore® 2 MidiCaps and MaxiCaps are produced with the same type of membrane and materials and identical construction.

Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Microbiological Retention
Sartopore® 2 0.1 µm MidiCaps and MaxiCaps are validated as sterilizing grade filters according to ASTM F 838-05 standard and for Mycoplasma removal with a Log Reduction Value (LRV) of 7 for Acholeplasma laidlawii.

Quality Control
Each individual element is tested for integrity by Diffusion-Test prior to be released assuring absolute reliability.

Documentation
Sartopore® 2 MidiCaps and MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for MidiCaps with SS inlet and outlet

Water Flow Rates for MaxiCaps

▷ Specifications

Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone
Filling bell	Polycarbonate

Pore Size
0.2 µm + 0.1 µm

Available Sizes | Filtration Area

MidiCaps
Size 7   0.05 m^2 | 0.5 ft^2
Size 8   0.1 m^2 | 1 ft^2
Size 9   0.2 m^2 | 2 ft^2
Size 0   0.45 m^2 | 5 ft^2

MaxiCaps
Size 1   0.6 m^2 | 6 ft^2
Size 2   1.2 m^2 | 12 ft^2
Size 3   1.8 m^2 | 18 ft^2

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, SO, OO, FF, BB

S: 1½" Tri-Clamp (Sanitary)
O: ½" Stepped hose barb
F: ¾" Tri-Clamp (Sanitary)
H: Small, multiple stepped hose barb
          (with filling bell at the outlet)
B: ¾"– 1" Multiple stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar	58 psi at 20°C (MidiCaps) 4 bar	43.5 psi at 20°C (MaxiCaps) 3 bar	43.5 psi at 50°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartopore® 2 0.1 µm rated filter MidiCaps and MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test and Mycoplasma removal.

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

Autoclaving
134 °C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles
Autoclaving: Min. 25

Technical References
Validation Guide
– SPK5751-e (MidiCaps)
– SPK5735-e (MaxiCaps)

Extractables Guide
– SPK5731-e

Ordering Information

Order Code	Pore Size [µm]	Pack Size [Pieces]	Test Pressure [bar	psi]	Max. Diffusion [ml/min]
MidiCaps				
5445358K7--**--A	0.1	4	4.0	58	4
5445358K8--**--A	0.1	4	4.0	58	6
5445358K9--**--A	0.1	4	4.0	58	9
5445358K0--**--V	0.1	2	4.0	58	18
MaxiCaps				
5441358K1--**	0.1	1	4.0	58	24
5441358K2--**	0.1	1	4.0	58	48
5441358K3--**	0.1	1	4.0	58	72

**: Connector Styles

▶ # Sartopore® 2 150 & 300 0.1 μm

Sterilizing Grade Filter and Mycoplasma Retentive Capsule

Single-Use Technology

Description
Sartopore® 2 150 & 300 are disposable, sterile, ready-to-use membrane filter capsules for convenient sterilizing grade filtration and reliable mycoplasma removal from any media likely to contain it such ans originating form animal sources. Sartopore® 2 150 & 300 capsules are made with a unique hydrophilic Polyethersulfone membrane providing outstanding total throughput, flow rate, low extractables and broadest chemical compatibility.

Applications
Typical applications include sterilizing grade filtration of:

– Animal Sera

– Cell Culture Media

– Media Components

– Bioprocessed Pharmaceuticals

– Biological Fluids

Any other application requiring sub 0.2 μm filtration for enhanced sterility assurance.

Compatibility
The polyethersulfone membrane is compatible with a pH range from pH 1 to pH 14 making Sartopore® 2 150 & 300 ideal for filtration of solutions with high|low pH.

Performance
The unique pleated filter construction combined with the highly asymmetric pore structure of the polyethersulfone membrane offers excellent flow rates and superior total throughput performance, especially in comparison to conventional stacked disc filter systems.

Easy to Use
Sartopore® 2 150 & 300 capsules are available with hose barb, ¼ inch NPT-thread or ½ inch Tri-Clamp connectors for simple installation in your filtration system. The Tri-Clamp connection assures secure and reliable integrity testing.

Automatic Venting
The new vent design enables easy access to the venting valve. A hydrophobic PTFE membrane positioned on the highest point upstream allows an easy venting of the capsule and prevents product loss during the venting process.

Scalability
Featuring the same materials and type of construction as any other Sartopore® 2 filter element, Sartopore® 2 150 & 300 are ideally suited for R&D Labs in pharmaceutical development. Filtration trials can be performed using extremely small volumes of high value products.

Microbiological Retention
Sartopore® 2 150 & 300 0.1μm rated capsules are validated as sterilizing grade filters according to HIMA and ASTM F-838-05 standard and for Mycoplasma removal with Log Reduction Value (LRV) of 7 for Acholeplasma laidlawi.
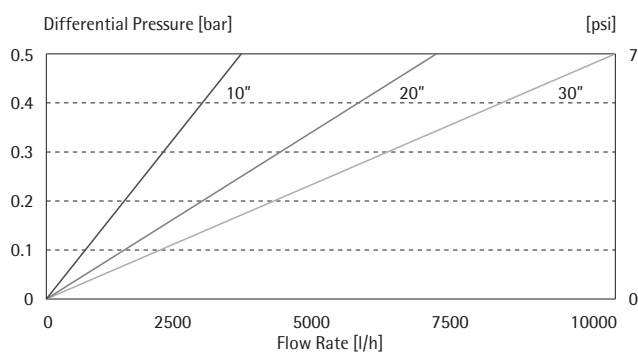
Quality Control
Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation
Sartopore® 2 150 & 300 capsules are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide is available for compliance with regulatory requirements.

▷ Specifications

Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Housing	Polypropylene

Pore Size
0.2 µm + 0.1 µm

Available Sizes│Filtration Area
Size 4   0.015 m²│0.15 ft²
Size 5   0.03 m²│0.32 ft²

Available Connectors
SS, SO, OO (Type 150)
OO (Type 300)

Operating Parameters

Max. allowable differential pressure	4 bar│58 psi at 20°C 2 bar│29 psi at 80°C
Max. allowable back pressure	2 bar│29 psi at 20°C

Extractables
Sartopore® 2 150 & 300 0.1 µm rated filter capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test and Mycoplasma removal

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

Autoclaving
134°C, 2 bar│29 psi, 30 min
No In-Line Steam Sterilization

Technical References
Validation Guide   SPK5735-e
Extractables Guide   SPK5731-e

Ordering Information

Order Code	Pore Size [µm]
Sartopore® 2 150	
5441358K4--OO--B	0.1
5441358K4--SO--B	0.1
5441358K4--SS--B	0.1
Sartopore® 2 300	
5441358K5--OO--B	0.1

▶ Sartopore® 2 0.45 µm

Bioburden & Particle Reductive Filter Cartridges

Description

Sartopore® 2 0.45 µm rated filter cartridges are designed for bioburden reduction and particle removal from a broad range of pharmaceutical products. They offer extremely high flow rates and total throughputs and are therefore ideally suited for membrane prefiltration of aqueous solutions and highly viscous, difficult to filter pharmaceutical products.

Applications

Typical applications include bioburden reduction and particle removal from:

– Buffers

– Biological fluids

– Opthalmics

– LVP

– Antibiotics

– Bulk pharmaceutical products

Compatibility

Featuring a unique hydrophilic polyethersulfone membrane, Sartopore® 2 0.45 µm cartridges are compatible with solutions from pH 1 to pH 14 and are unaffected by numerous steam sterilization cycles. They are ideally suited for filtration of solutions with high|low pH and for multiple SIP|CIP cycles.

Performance

Sartopore® 2 0.45 µm cartridges provide exceptional high flow rates, resulting in economical sizing of filtration systems. Due to the "built-in prefiltration" by a 0.8 µm membrane , Sartopore® 2 0.45 µm rated cartridges offer outstanding total throughputs.

Wettability

Sartopore® 2 cartridges can be easily wetted out for integrity testing even after drying at 80°C for 12 hours.

Microbiological Retention

Sartopore® 2 0.45 µm rated filter cartridges are validated for removal of Serratia marcessens with a Log Reduction Value (LRV) of 7 according to HIMA and ASTM F-838-05 guidelines.

Quality Control

Each individual element is integrity-tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation

Sartopore® 2 cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for Standard Cartridges

Standardized at 20°C

▷ Specifications

Materials

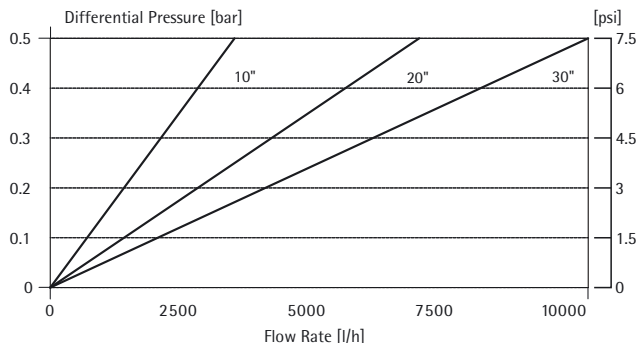|	
Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Pore Size
0.8 μm + 0.45 μm

Available Sizes | Filtration Area

Cartridges
Size 1	10"	0.6 m² | 6.5 ft²
Size 2	20"	1.2 m² | 12.9 ft²
Size 3	30"	1.8 m² | 19.4 ft²

Mini Cartridges
Size 7	0.05 m² | 0.5 ft²
Size 8	0.1 m² | 1 ft²
Size 9	0.2 m² | 2 ft²

Available Adapters Cartridges
21, 25, 27, 28

Available Adapters Mini Cartridges
15

Operating Parameters

Max. allowable differential pressure	5 bar | 75 psi at 20 ℃ 2 bar | 29 psi at 80 ℃
Max. allowable back pressure	2 bar | 29 psi at 20 ℃

Extractables
Sartopore® 2 0.45 μm rated filter cartridges meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test using Serratia marcescens

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134℃, 20 min. at max differential pressure of 0.5 bar | 7.25 psi

Autoclaving
134℃, 2 bar | 29 psi, 30 min

Sterilization Cycles
In-line sterilization	Min. 25
Autoclaving	Min. 25

Technical References
Validation Guide	SPK 5732-e
Extractables Guide	SPK 5731-e

Ordering Information

Order Code	Pore Size [μm]
Cartridges	
544**06G1	0.45
544**06G2	0.45
544**06G3	0.45
Mini Cartridges	
5441506G7------B	0.45
5441506G8------B	0.45
5441506G9------B	0.45

Total Throughput Comparison

Total Throughput at 95% blockage [kg]
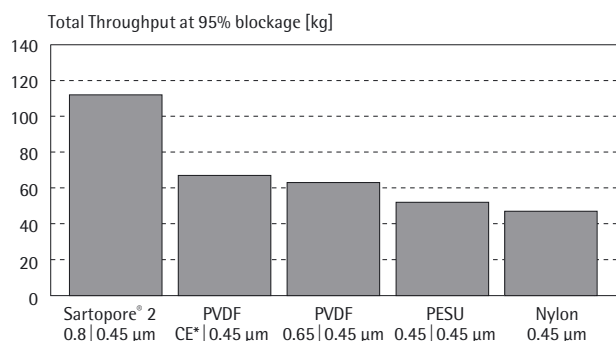
10" Cartridges

* Cellulose Ester prefilter

▶ Sartopore® 2 0.45 µm

Bioburden & Particle Retentive MidiCaps & MaxiCaps

Single-Use Technology

Description
Sartopore® 2 0.45 µm membrane filter MidiCaps and MaxiCaps are self contained, ready to use filter units for bioburden reduction and particle removal from a broad range of pharmaceutical products. Membrane prefiltration of aqueous solutions and highly viscous pharmaceutical products difficult to filter can effectively be accomplished due to the outstanding total throughput and flow rate performance of Sartopore® 2 0.45 µm MidiCaps and MaxiCaps.

Applications
Typical applications include bioburden reduction and particle removal from:
– Therapeutics
– Injectables
– Buffers
– Biological Fluids
– Tissue Culture Media
– Acetic and basic solutions

Compatibility
The polyethersulfone membrane is compatible with a pH-range from pH 1 to pH 14 making Sartopore® 2 MidiCaps and MaxiCaps ideal for filtration of solutions with high│low pH.

Easy to Use
Sartopore® 2 MidiCaps are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

Flexibility
Sartopore® 2 0.45 µm MidiCaps and MaxiCaps are available with various filtration areas

from 500 cm²│0.5 ft² up to 1.8 m²│18 ft² and various connector styles for easy adoption to any filtration process independent from the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed as all Sartopore® 2 MidiCaps and MaxiCaps are produced with the same type of membrane and materials and identical construction.

Cost Saving
The use of the disposalbe capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Microbiological Retention
Sartopore® 2 filter MidiCaps and MaxiCaps 0.45 µm rated are fully validated with a Log Reduction Value (LRV) of 7 for Serratia Marcescens according to HIMA and ASTM F-838-05 procedures.

Quality Control
Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

Documentation
Sartopore® 2 MidiCaps and MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for MidiCaps with SS inlet and outlet
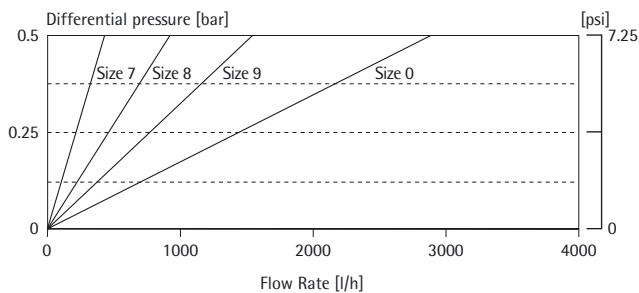
Water Flow Rates for Sartopore® 2 MaxiCaps

Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene
O-Rings	Silicone
Filling bell	Polycarbonate

Pore Size
0.8 µm + 0.45 µm

Available Sizes | Filtration Area

MidiCaps
Size 7   0.05 m^2 | 0.5 ft^2
Size 8   0.1 m^2 | 1 ft^2
Size 9   0.2 m^2 | 2 ft^2
Size 0   0.45 m^2 | 5 ft^2

MaxiCaps
Size 1   0.6 m^2 | 6 ft^2
Size 2   1.2 m^2 | 12 ft^2
Size 3   1.8 m^2 | 18 ft^2

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, SO, OO, FF, BB

S: 1½" Tri-Clamp (Sanitary)
O: ½" Stepped hose barb
F: ¾" Tri-Clamp (Sanitary)
H: Small, multiple stepped hose barb (with filling bell at the outlet)
B: ¾"–1" Multiple stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar	58 psi at 20 °C (MidiCaps) 4 bar	43.5 psi at 20 °C (MaxiCaps) 3 bar	43.5 psi at 50 °C
Max. allowable back pressure	2 bar	29 psi at 20 °C

Extractables
Sartopore® 2 0.45 µm rated MidiCaps and MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to Bacteria Challenge Test using Serratia marcescens following HIMA/ASTM methodologies.

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

Autoclaving
134 °C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles
Autoclaving: Min. 25

Technical References
Validation Guide
– SPK5751-e (MidiCaps)
– SPK5732-e (MaxiCaps)

Extractables Guide
– SPK5731-e

Ordering Information

Order Code	Pore Size [µm]	Pack Size [Pieces]	Test Pressure [bar	psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar	psi]
MidiCaps					
5445306G7--**--A	0.45	4	1.7	25	3	2.2	32
5445306G8--**--A	0.45	4	1.7	25	4	2.2	32
5445306G9--**--A	0.45	4	1.7	25	6	2.2	32
5445306G0--**--V	0.45	2	1.7	25	12	2.2	32
MaxiCaps					
5441306G1--**	0.45	1	1.7	25	12	2.2	32
5441306G2--**	0.45	1	1.7	25	24	2.2	32
5441306G3--**	0.45	1	1.7	25	36	2.2	32

**: Connector Styles

▶ Sartopore® 2 300 0.45 µm

Bioburden & Particle Retentive Capsule

Single-Use Technology

Description
Sartopore® 2 300 is a disposable, sterile, ready-to-use membrane filter capsules for bioburden reduction an particle removal from a broad range of pharmaceutical products. Membrane prefiltration of aqueous solutions and highly viscous pharmaceutical products difficult to filter can effectively be accomplished due to the outstanding total throughput and flow rate performance. Sartopore® 2 300 capsules are made with a unique hydrophilic Polyethersulfone membrane providing outstanding total throughput, flow rate, low extractables and broadest chemical compatibility.

Applications
Typical applications include bioburden reduction and particle removal of:

– Therapeutics

– Injectables

– Buffers

– Tissue Culture Media

– Biological Fluids

– Acetic and basic solutions

Any other application requiring sub 0.2 µm filtration for enhanced sterility assurance.

Compatibility
The polyethersulfone membrane is compatible with a pH range from pH 1 to pH 14 making Sartopore® 2 300 ideal for filtration of solutions with high|low pH.

Performance
The unique pleated filter construction combined with the highly asymmetric pore structure of the polyethersulfone membrane offers excellent flow rates and superior total throughput performance, especially in comparison to conventional stacked disc filter systems.

Easy to Use
Sartopore® 2 300 capsules are available with hose barb for simple installation in your filtration system.

Automatic Venting
The new vent design enables easy access to the venting valve. A hydrophobic PTFE membrane positioned on the highest point upstream allows an easy venting of the capsule and prevents product loss during the venting process.

Scalability
Featuring the same materials and type of construction as any other Sartopore® 2 filter element, Sartopore® 2 300 are ideally suited for R&D Labs in pharmaceutical development. Filtration trials can be performed using extremely small volumes of high value products.

Microbiological Retention
Sartopore® 2 300 0.45 µm rated capsules are validated with a Log Reduction Value (LRV) of 7 of Serratia Marcescens according to HIMA and ASTM F-838-05 procedures.

Quality Control
Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation
Sartopore® 2 300 capsules are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Manage-ment System. A Validation Guide and Extractables Guide is available for compliance with regulatory requirements.

▷ Specifications

Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Housing	Polypropylene

Pore Size
0.8 µm + 0.45 µm

Available Sizes│Filtration Area
Size 5   0.03 m^2│0.32 ft^2

Available Connectors
OO

Operating Parameters

Max. allowable differential pressure	4 bar│58 psi at 20°C 2 bar│29 psi at 80°C
Max. allowable back pressure	2 bar│29 psi at 20°C

Extractables
Sartopore® 2 300 0.45 µm rated filter capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% Individually integrity tested

Integrity test correlated Bacteria Challenge using Serritia marcescens following Test to HIMA/ASTM F 838-05

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

Autoclaving
134°C, 2 bar│29 psi, 30 min
No In-Line Steam Sterilization

Technical References

Validation Guide	SPK5735-e
Extractables Guide	SPK5731-e

Ordering Information

Order Code	Pore Size [µm]
5441306G5--OO--B	0.45

▶ Sartopore® 2 0.2 µm & 0.1 µm

Sterilizing Grade & Mycoplasma Retentive γ-Irradiatable MidiCaps

Single-Use Technology

Description
Sartopore® 2-γ-MidiCaps are designed for connection to flexible-bag-container-systems prior to sterilization by gamma-irradiation. They are available with 0.2 µm & 0.1 µm final membranes for sterilizing grade filtration and Mycoplasma removal.

Applications
Typical applications include sterilizing grade filtration and Mycoplasma removal of:

– Biologicals

– Pharmaceuticals

– Cell Culture Media
 (serum free or serum containing)

– Culture Media Components

– Serum

– Buffers

Compatibility
Sartopore® 2-γ-MidiCaps are designed for sterilization by gamma irradiation ≤ 50 kGy irradiation dosage. The Polyethersulfone membrane of the Sartopore® 2-γ-MidiCaps offers a broad chemical compatibility from pH 1 to pH 10 making them ideally suited for filtration of high and low pH-buffers in the Pharma|Biotech field.

Performance
Due to the superior construction including a "build-in" prefiltration by a heterogeneous double layer membrane Sartopore® 2-γ-MidiCaps achieve outstanding total through-puts and excellent flow rates.

Flexibility
Sartopore® 2-γ-MidiCaps are available with various filtration areas from 500 cm² | 0.5 ft² up to 0.45 m² | 4.8 ft² and a broad range of different connector styles to allow an easy integration into any bag-container system.

Microbiological Retention
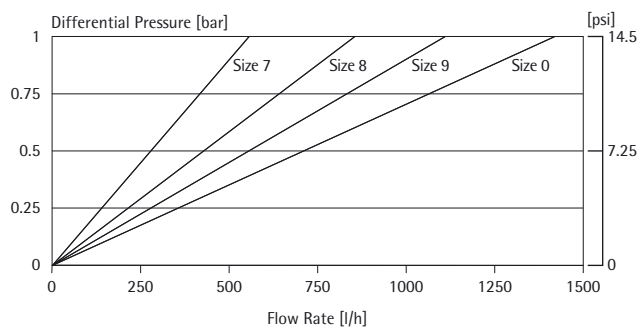Sartopore® 2-γ-MidiCaps 0.2 µm & 0.1 µm rated elements are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines. In addition Sartopore® 2-γ-MidiCaps with 0.1 µm final membranes are validated for Mycoplasma removal with a LRV of 7 for Acholeplasma Laidlawii.

Quality Control
Each individual element is tested for integrity by B.-P. (0.2 µm only) and Diffusion-Test prior to be released assuring absolute reliability.

Documentation
Sartopore® 2-γ-MidiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Sartopore® 2 0.2 µm. Water Flow Rates for γ-MidiCaps
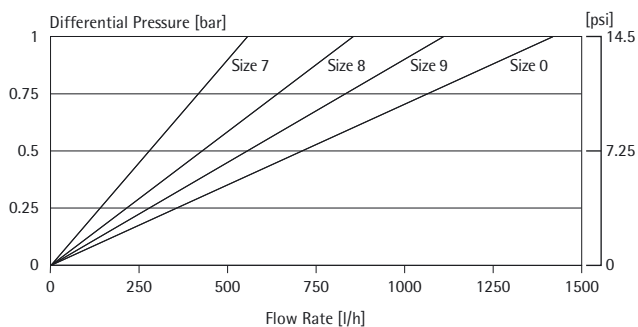
Sartopore® 2 0.1 µm. Water Flow Rates for γ-MidiCaps
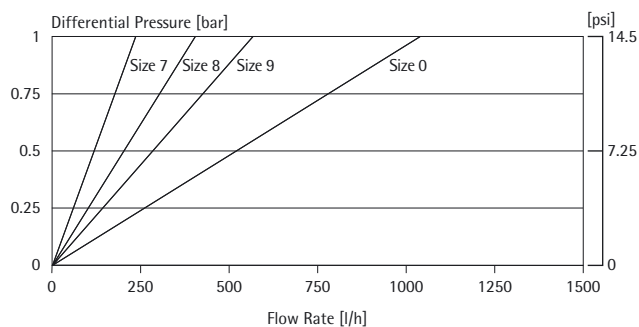
Standardized at 20°C

▷ Specifications

Materials

Prefilter Membrane	Polyethersulfone, asymmetric
Endfilter Membrane	Polyethersulfone, asymmetric
Support fleece	Polyester
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Ring	Silicone

Pore Size Combinations
0.2 µm + 0.1 µm
0.45 µm + 0.2 µm

Available Sizes│Filtration Area
Size 7	0.05 m^2│0.5 ft^2
Size 8	0.1 m^2│1.1 ft^2
Size 9	0.2 m^2│2.2 ft^2
Size 0	0.45 m^2│4.8 ft^2

Available Connectors
SS, SO, OO, FO, FO, HH (only Size 7)

S: 1½" Tri-Clamp (Sanitary)
O: ½" Single stepped hose barb
F: ¾" Tri-Clamp (Sanitary)
H: ¼" Multiple stepped hose barb
   (with filling bell at the outlet)
B: ¾" – 1" Multiple stepped hose barb

Operating Parameters
Max. allowable differential pressure	5 bar│72.5 psi at 20°C 2 bar│29 psi at 80°C
Max. allowable back pressure	2 bar│29 psi at 20°C

Extractables
Sartopore® 2-γ-MidiCaps meet, or exceed the requirements for WFI quality standards set by the current USP after γ-irradiation with ≤ 50 kGy.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to HIMA│ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization
γ-irradiation ≤ 50 kGy irradiation dosage

Sartopore® 2-γ-MidiCaps cannot be autoclaved or in-line steam sterilized

Sterilization Cycles
γ-Irradiation: 1 Cycle

Technical References
Validation Guide
SPK5743

Order Information

Order Code.	Pore Size [µm]	Test Pressure [bar│psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar│psi]
5445307H7G-**	0.2	2.5│36	4	3.2│46
5445307H8G-**	0.2	2.5│36	5	3.2│46
5445307H9G-**	0.2	2.5│36	7	3.2│46
5445307H0G-**	0.2	2.5│36	14	3.2│46
5445358K7G-**	0.1	4.0│58	4	not applicable
5445358K8G-**	0.1	4.0│58	6	not applicable
5445358K9G-**	0.1	4.0│58	9	not applicable
5445358K0G-**	0.1	4.0│58	18	not applicable

**: Connector Styles

▶ Sartopore® 2 0.2 µm

Sterilizing Grade γ-Irradiatable MidiCaps & MaxiCaps

Single-Use Technology

Description
Sartopore® 2-γ-MidiCaps & MaxiCaps are 0.2 µm rated sterilizing grade filter capsules designed for connection to flexible bag container systems prior to sterilization by gamma irradiation.

Applications
Typical applications include sterilizing grade filtration of:

– Pharmaceuticals

– Biologicals

– Cell culture media

– Culture media components

– Serum

– Buffers

– Diagnostic reagents

Compatibility
Sartopore® 2-γ-MidiCaps & MaxiCaps are designed for sterilization by gamma irradiation ≤ 50 kGy irradiation dosage. The polyethersulfone membrane of the Sartopore® 2-γ-MidiCaps & MaxiCaps offers a broad chemical compatibility from pH 1 to pH 14 (depending on process conditions) making them ideally suited for a broad range of applications in the pharma | biotech field.

Performance
Due to the superior construction, including a "built-in prefiltration" by a 0.45 µm membrane, Sartopore® 2-γ-MidiCaps & MaxiCaps offer outstanding total through-puts and excellent flow rates.

Flexibility
Sartopore® 2-γ-MidiCaps & MaxiCaps are available with filtration areas from 0.015 m² | 0.15 ft² up to 0.45 m² | 5 ft² for easy use in any bag filtration process, independent of the batch size.

Microbiological Retention
Sartopore® 2-γ-MidiCaps & MaxiCaps 0.2 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is integrity-tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation
Sartopore® 2 Gamma MidiCaps & MaxiCaps are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Sartopore® 2 0.2 µm. Water Flow Rates for γ-MidiCaps

Differential Pressure [bar] / [psi]

Size 7   Size 8   Size 9   Size 0

Flow Rate [l/h]

Standardized at 20°C

▷ Specifications

Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene

Pore Size
0.45 µm + 0.2 µm

Available Sizes | Filtration Area

MidiCaps
Size 4   0.015 m² | 0.15 ft²
Size 5   0.03 m² | 0.3 ft²
Size 7   0.05 m² | 0.5 ft²
Size 8   0.1 m² | 1 ft²
Size 9   0.2 m² | 2 ft²
Size 0   0.45 m² | 5 ft²

MaxiCaps
Size 1   0.6 m² | 6 ft²
Size 2   1.2 m² | 12 ft²
Size 3   1.8 m² | 18 ft²

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, OO, BB, FF

Operating Parameters

Max. allowable differential pressure	4 bar	58 psi at 20°C 3 bar	43.5 psi at 50°C
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartopore®-γ-MidiCaps & MaxiCaps meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization
γ-irradiation ≤ 50 kGy irradiation dosage

Autoclaving
134°C, 2 bar | 29 psi, 30 min

No in-line steam sterilization

Sterilization Cycles
γ-Irradiation   Max. 1
Autoclaving   Max. 3

Technical References
Validation Guide   SPK5734-e
Extractables Guide   SPK5740-e

Ordering Information

Order Code	Pore Size [µm]
MidiCaps	
5445307H7G--**--B	0.2
5445307H8G--**--B	0.2
5445307H9G--**--A	0.2
5445307H0G--**--V	0.2
MaxiCaps	
5441307H1G--**	0.2
5441307H2G--**	0.2
5441307H3G--**	0.2

Sartopore® 2 0.1 µm. Water Flow Rates for γ-MidiCaps
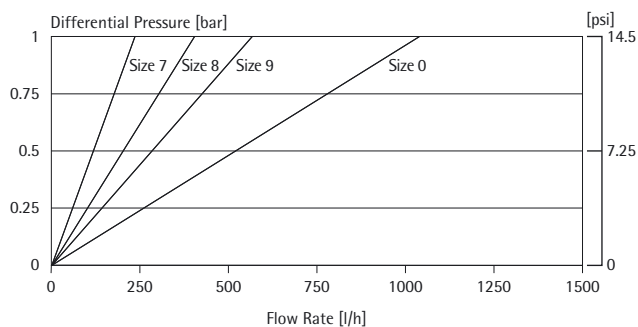
▶ Sartopore® 2 0.1 μm

Sterilizing Grade and Mycoplasma Retentive γ-Irradiatable
MidiCaps & MaxiCaps

Description
Sartopore® 2 0.1 μm rated γ-irradiatable MidiCaps & MaxiCaps are designed for sterilizing grade filtration and mycoplasma removal in bag filtration processes. Prior or after connection to flexible bag container systems they can be sterilized by γ-irradiation ≤ 50 kGy.

Applications
Typical applications for Sartopore® 2-γ-MidiCaps & MaxiCaps include combined sterilizing grade filtration and mycoplasma removal from

– Cell culture media

– Culture media components

– Serum

They are ideally suited for bioprocessed pharmaceuticals and any other applications requiring sub 0.2 μm filtration for enhanced sterility assurance.

Compatibility
Sartopore® 2-γ-MidiCaps & MaxiCaps are designed for sterilization by gamma irradiation ≤ 50 kGy irradiation dosage. The polyethersulfone membrane of the Sartopore® 2-γ-MidiCaps & MaxiCaps offers a broad chemical compatibility from pH 1 to pH 14 making them ideally suited for a broad range of applications in the pharma│biotech field.

Performance
Due to the superior construction, including a "built-in" prefiltration by a heterogeneous double-layer membrane, Sartopore® 2-γ-MidiCaps & MaxiCaps achieve outstanding total throughputs and excellent flow rates.

Flexibility
Sartopore® 2-γ-MidiCaps & MaxiCaps are available with filtration areas from 0.03 m²│0.3 ft² up to 0.45 m²│5 ft² for easy adaption to any bag-filtration process, independent of the batch size.

Microbiological Retention
Sartopore® 2-γ-MidiCaps & MaxiCaps 0.1 μm rated are validated as sterilizing grade filters according to ASTM F 838-05 standard and for mycoplasma removal with a Lock Reduction Value (LRV) of 7 for Acholeplasma laidlawii.

Quality Control
Each individual element is tested for integrity by diffusion test prior to being released, assuring absolute reliability.
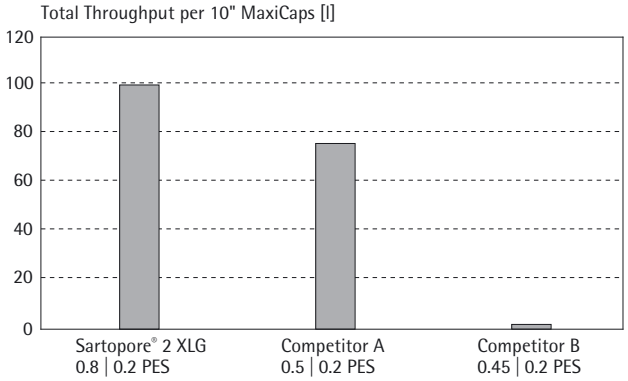
Documentation
Sartopore® 2 Gamma MidiCaps & MaxiCaps are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Water Flow Rates for 0.2 m² and 0.45 m² Capsules

▷ Specifications

Materials

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule housing	Polypropylene

Pore Size
0.2 µm + 0.1 µm

Available Sizes | Filtration Area

MidiCaps
Size 7	0.05 m² | 0.5 ft²
Size 8	0.1 m² | 1 ft²
Size 9	0.2 m² | 2 ft²
Size 0	0.45 m² | 5 ft²

MaxiCaps
Size 1	0.6 m² | 6 ft²
Size 2	1.2 m² | 12 ft²
Size 3	1.8 m² | 18 ft²

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Available Connectors MaxiCaps
SS, OO, FF, BB

Operating Parameters

Max. allowable differential pressure	4 bar | 58 psi at 20°C 3 bar | 43.5 psi at 50°C
Max. allowable back pressure	2 bar | 29 psi at 20°C

Extractables
Sartopore®-γ-MidiCaps & MaxiCaps meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
Individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization
γ-irradiation ≤ 50 kGy irradiation dosage

Autoclaving
134 °C, 2 bar | 29 psi, 30 min

No in-line steam sterilization

Sterilization Cycles
γ-Irradiation	Max. 1
Autoclaving	Max. 3

Technical References
Validation Guide	SPK5734-e
Extractables Guide	SPK5740-e

Order Information

Order Code	Pore Size [µm]
MidiCaps	
5445358K7G-**--B	0.1
5445358K8G-**--B	0.1
5445358K9G-**--A	0.1
5445358K0G-**	0.1
MaxiCaps	
5441358K1G-**	0.1
5441358K2G-**	0.1
5441358K3G-**	0.1

** Inlet | Outlet connectors

Water Flow Rates for 0.03 m², 0.05 m² and 0.1 m² Capsules
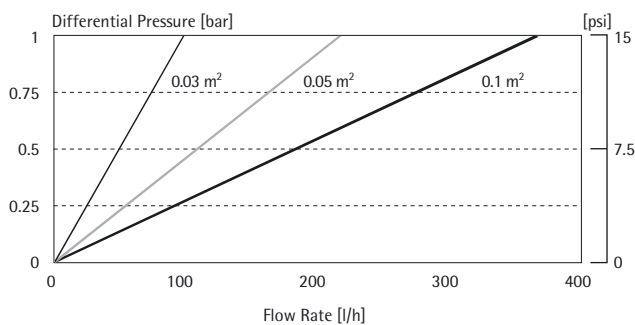
► Sartopore® 2 XLG 0.2 μm

Sterilizing Grade γ-Irradiatable MaxiCaps®

Single-Use Technology

Description
Sartopore® 2-XLG-γ-MaxiCaps® are designed for connection to flexible-bag-container-systems prior to sterilization by gamma-irradiation. The unique heterogeneous double layer PES membrane combination of Sartopore® 2-XLG-γ-MaxiCaps® is specifically developed to deal with the broad variety of contaminants in up- and downstream pro-cessing of biotech applications. They provide consistently high total throughput perform-ance for biological fluid streams independent from media and process variations.

Applications
Typical applications include sterilizing grade filtration of:

– Plant peptone or yeast supplemented cell culture media

– Serum containing cell culture media

– Other cell culture media used in biotech manufacturing

– Clarified cell culture harvest

– Downstream Intermediates (before and after UF│DF and chromatography steps)

Compatibility
Sartopore® 2-XLG-γ-MaxiCaps® are designed for sterilization by gamma irradiation ≤ 50 kGy irradiation dosage. The Polyether-sulfone membrane of the Sartopore® 2-XLG-γ-MaxiCaps® offers a broad chemical compatibility from pH 1 to pH 10 making them ideally suited for filtration of high and low pH-buffers in the Pharma│Biotech field.

Economy
The combination of the built-in 0.8 μm prefilter in front of a 0.2 μm final filter together with the 30% enlarged effective filtration area per XLG filter element provide an outstanding total throughput and flow rate performance in the target applications. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Flexibility
Sartopore® 2-XLG-γ-MaxiCaps® are ideally suited to be used in large scale filtration applications in combination with flexible bag containers due to their superior effective filtration area of up to 2.4 m^2 │ 25.8 ft^2 per 30" element.

Microbiological Retention
Sartopore® 2-XLG-γ-MaxiCaps® 0.2 μm are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is tested for integrity by B.-P. (0.2 μm only) and Diffusion-Test prior to be released assuring absolute reliability.

Documentation
Sartopore® 2-XLG-γ-MaxiCaps® are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Manage-ment System. A Validation Guide is available for compliance with regulatory requirements.

Soy Peptone Supplemented Cell Culture Media

Total Throughput per 10" MaxiCaps [l]

	Sartopore® 2 XLG 0.8 │ 0.2 PES	Competitor A 0.5 │ 0.2 PES	Competitor B 0.45 │ 0.2 PES
	~1520	~620	~230

Monoclonal Antibody Pool

Total Throughput per 10" MaxiCaps [l]

	Sartopore® 2 XLG 0.8 │ 0.2 PES	Competitor A 0.5 │ 0.2 PES	Competitor B 0.45 │ 0.2 PES
	~99	~75	~2

Antibody Concentration: 47.5 mg/ml

▷ Specifications

Materials

Prefilter Membrane	Polyethersulfone, asymmetric
Endfilter Membrane	Polyethersulfone, asymmetric
Support fleece	Polyester
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Ring	Silicone

Pore Size Combinations
0.8 µm + 0.2 µm

Available Sizes│Filtration Area
Size 1	0.8 m² │ 8.6 ft²
Size 2	1.6 m² │ 17.2 ft²
Size 3	2.4 m² │ 25.8 ft²

Available Connectors
SS, SO, OO, FF, BB

S:	1½" Tri-Clamp (Sanitary)
O:	½" Single stepped hose barb
F:	¾" Tri-Clamp (Sanitary)
B:	¾" – 1" Multiple stepped hose barb

Operating Parameters

Max. allowable differential pressure	4 bar │ 58 psi at 20°C 3 bar │ 43.5 psi at 50°C
Max. allowable back pressure	2 bar │ 29 psi at 20°C

Extractables
Sartopore® 2-XLG-γ-MaxiCaps® meet, or exceed the requirements for WFI quality standards set by the current USP after γ-irradiation with ≤ 50 kGy.

Regulatory Compliance
Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization
γ-irradiation ≤ 50 kGy irradiation dosage

Sartopore® 2-XLG-γ-MaxiCaps® cannot be autoclaved or in-line steam sterilized

Sterilization Cycles
γ-Irradiation: 1 Cycle

Technical References
Validation Guide

Order Information

Order Code.	Pore size [µm]	Test Pressure [bar│psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar│psi]
5441307G1G-**	0.8 + 0.2	2.5 │ 36	23	3.2 │ 46
5441307G2G-**	0.8 + 0.2	2.5 │ 36	46	3.2 │ 46
5441307G3G-**	0.8 + 0.2	2.5 │ 36	69	3.2 │ 46

**: Connector Styles

▶ Sartolon®

Sterilizing Grade Filter Cartridges, MidiCaps & MaxiCaps

Description
Sartolon® sterilizing grade filter cartridges, MaxiCaps and capsules are designed for broad chemical compatibility for specific applications in the pharmaceutical and chemical industry. Their superior filtration performance compared to competitive nylon membrane filters allow more economical design of your filtration process.

Applications
Featuring a unique hydrophillic nylon membrane, Sartolon® filters are ideally suited for sterilizing grade filtration of:

– Solvents

– Antibiotics

– Bulk pharmaceutical chemicals

– LVP

Compatibility
Sartolon® filter elements are ideal for filtration of a broad range of solvents and liquids containing solvents. The nylon membrane material provides a broad chemical compatibility, especially for aggressive solvent solutions.

Performance
Sartolon® filter elements offer higher total throughputs than any other sterilizing grade nylon filter element on the market. The heterogeneous double-layer construction provides higher total throughputs than homogeneous double-layer types due to the "built-in prefiltration."

Microbiological Retention
Sartolon® 0.2 µm rated filter elements are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-05 guidelines.

Quality Control
Each individual element is integrity-tested by diffusion and bubble point test prior to release, assuring absolute reliability.

Documentation
Sartolon® filter elements are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for 10", 20" and 30" Cartridges
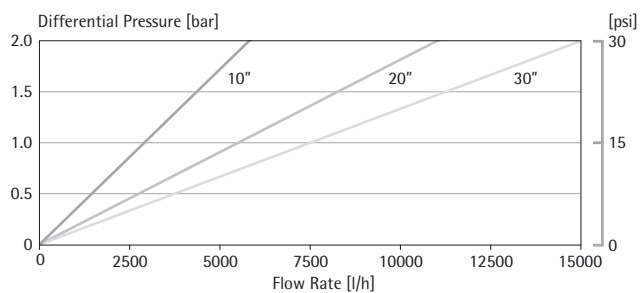
Standardized at 20 °C

▷ Specifications

Materials

Prefilter membrane	Nylon
Endfilter membrane	Nylon
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	Silicone (optional EPDM or Viton)

Pore Size
0.45 µm + 0.2 µm

Available Sizes | Filtration Area

Cartridges | MaxiCaps
Size 1	10"	0.6 m²	6 ft²
Size 2	20"	1.2 m²	12 ft²
Size 3	30"	1.8 m²	18 ft²

Mini Cartridges | MidiCaps
| Size 9 | | 0.2 m² | 2 ft² |

Available Adapters Cartridges
21, 25, 27, 28

Available Adapter Mini Cartridges
15

Available Connectors MaxiCaps
SS, SO, OO, FF, BB

Available Connectors MidiCaps
SS, SO, OO, FF, FO, HH (only size 7)

Operating Parameters

Max. allowable differential pressure	5 bar	75 psi at 20°C (cartridges) 4 bar	58 psi at 20°C (MaxiCaps & capsules) 3 bar	43.5 psi at 50°C (MaxiCaps) 2 bar	29 psi at 80°C (cartridges and capsules)
Max. allowable back pressure	2 bar	29 psi at 20°C

Extractables
Sartolon® cartridges, MaxiCaps and capsules meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization
134°C, 20 min. at max differential pressure of 0.5 bar | 7 psi

Note
Capsules and MaxiCaps cannot be in-line steam-sterilized!

Autoclaving
134°C, 2 bar | 29 psi, 30 min

Sterilization Cycles
In-line sterilization (only cartridges)	Min. 25
Autoclaving	Min. 25

Technical References
Validation Guide	SPK5716-e
Extractables Guide	SPK5729-e

Ordering Information

Order Code	Size	Pore Size [µm]
Cartridges		
510**07H1	1	0.2
510**07H2	2	0.2
510**07H3	3	0.2
MaxiCaps		
5101307H1--**	1	0.2
5101307H2--**	2	0.2
5101307H3--**	3	0.2
MidiCaps		
5105307H9--**--A	4	0.2
Mini Cartridges		
5101507H9------B	4	0.2

Total Throughput Comparison

Total throughput (kg filtrate at 90% blockage)

40
30
20
10
0

Sartolon® 0.45 | 0.2 µm   Nylon N66 0.2 | 0.2 µm
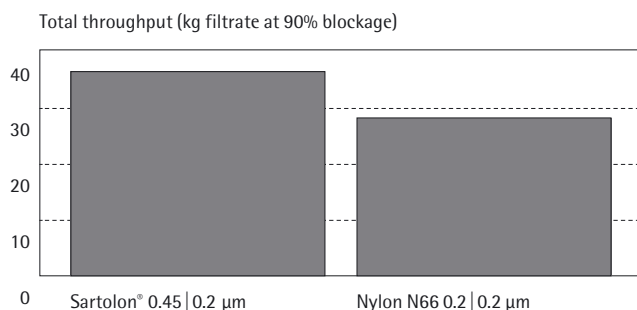
10" Cartridge format

▶ Sartofluor® LG MaxiCaps

Membrane Filtration of Aggressive Media

Single-Use Technology

Description
MaxiCaps are a unique new housing design concept from Sartorius Stedim Biotech that brings the benefits of single-use filter elements to process scale. The incorporation of standard filter cartridges into self-contained, high-quality polypropylene housings makes it possible to operate large-scale filter installations without the need for filter housings.

Applications
Sartofluor® LG MaxiCaps improve the process security of sterile filtration of aggressive media (acids and bases) and solvents. There is no need to open the filter housing after filtration. The capsule design allows filtration of such media without any handling of the contaminated filter cartridge post use.

Speed of Operation
MaxiCaps are ready-to-use, saving time and money. No more backup filtration rigs to prepare. MaxiCaps can be easily replaced, should any operational difficulties occur.

Process Security
By relying on established process validation data for standard cartridge elements, MaxiCaps can easily be implemented into current filtration processes.

Cleaning Validation
As these capsules are single-use filter elements, there is no need to spend time and money for validating the efficiency of your cleaning procedure for filter housing.

Cost
Sartofluor® LG MaxiCaps remove the need for investment in stainless steel or PVDF filter housings and an inventory of spare parts such as valves and O-rings.

Water Flow Rates* for Sartofluor® LG MaxiCaps 0.2 µm with Sanitary Flanges
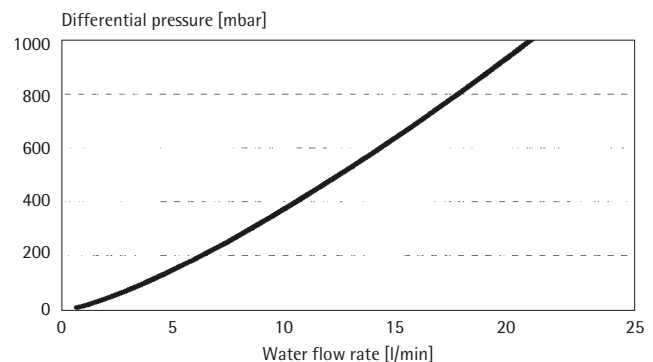
* Prewetted with IPA | water

▷ Specifications

Materials

Filter membrane	PTFE
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
O-Rings	EPDM (Viton as accessory in the package)

Pore Size
0.2 µm

Available Sizes│Filtration Area
Size 1	10"	0.5 m²│5.4 ft²
Size 2	20"	1.0 m²│10.8 ft²
Size 3	30"	1.5 m²│16.1 ft²

Available Adapters Connectors
SS, SO, OO, FF, FO, HH

Operating Parameters

Max. allowable differential pressure	3 bar│43.5 psi at 20°C
Max. allowable back pressure	2 bar│29 psi at 20°C

Extractables
Sartofluor® LG MaxiCaps meet, or exceed, the requirements for WFI quality standards set by the current USP.

Regulatory Compliance
100% individually integrity-tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

Sterilization

Autoclaving
134°C, 2 bar│29 psi, 30 min

No in-line steam sterilization

Sterilization Cycles
Autoclaving	min 25

Ordering Information

Order Code	Size	Pore Size [µm]
Capsules		
5181307T1--**	1	0.2
5181307T2--**	2	0.2
5181307T3--**	3	0.2

▶ ## Multi-Rounds

Multi-Rounds Filter Housings

Introduction
Quality gas or liquid filtration systems require both quality housings and quality filter cartridges. To meed this need, Sartorius Stedim Biotech has been producing a sanitary line of housings with quality as the primary objective. Sartorius Stedim Biotech multi-round housings have been designed to meet the scale-up requirements of pharmaceutical and biotechnology processing. These housings are designed specifically for sterile filtration with special attention taken with the choice of materials, durability, cleanability, ease of use and quality control.

Quality of Materials
Only 316L Stainless steel is used for all wetted surfaces to provide maximum durability. Supplied O-rings and gaskets are compounded only from FDA approved materials that meet the requirements for direct contact with food and pharmaceutical products.

Quality Surface Finishes
All Sartorius Stedim Biotech Sanitary housings come standard with internal finishes of at least 0.5 micron Ra and are electropolished. Electropolishing removes surface impurities in stainless steel left over from the machining and the finishing processes. Such impurities are sites for future initiation of corrosion and possible sources of contaminates leaching into the product. Electropolishing also smoothes the microscratches left by mechanical polishing, thus reducing the total surface area the product will contact, and making it harder for bacteria or contaminates to lodge on leaves a highly corrosion resistant, passive film on the surface of the steel (passivation). Thus electropolishing is the recommended finish for all applications where cleanliness and corrosion resistance are critical.

Ease in Cleaning
Sartorius Stedim Biotech utilizes a unique filter cup design that is conductive for allowing a thorough cleaning. The raised filter cup design eliminates small grooves and tight spaces that might be difficult to verify or validate the cleaning while still permitting free complete drainage of the filter housing. The entire housing is cleaned, even under the receiver plate. CIP caps are also available.

Quality Control and Documentation
An important feature of pharmaceutical process validation is documentation. All our housings are given stringent inspections during and after manufacturing including dimensional checks, weld inspections, surface measurements and hydrostatic testing. Each housing is labled by laser with a matching serial number on the bell and base. This serial number provides complete tractability for the Quality Control Certificate, Material Test Reports, and Weld Logs

Ease of Installation
Sartorius Stedim Biotech housings are sold ready to install with all gaskets, o-rings and clamps. All that is required are the components needed to connect to your existing hardware.

PED 97/23/EC Standard
Sartorius Stedim Biotech Stainless Steel Housings are designed and manufactured according the Pressure Equipment Directive PED 97/23/EC. Our manufacturing process follows the highest quality standards and is monitored by an internal quality control system as well as by independent notified bodies on a regular basis.

▷ Specifications

Materials

All Wetted Surfaces	316L
Clamps	304
Seals	Silicone (Viton or EPDM optional)

Available Heights
3-Round   10", 20", 30", 40"
5, & 7 Round   10", 20", 30", 40"

Surface Finishes
Interior   Ra <0.5 μm EP
Exterior   Ra <1.6 μm EP

Housing Ratings
Pressure   −1 + 10 bar
Temperature   −10 + 150°C

▶ Single Rounds

Mini & 1 Element Filter Housings

Introduction
There has been, and is, an increasing demand for quality filter cartridge systems for steriliz-ing and polishing filtration processes. A large emphasis has been placed on the integrity of construction of the filter cartridges. How-ever, the filter cartridge housing is just as an important part of any filtration system. Without a proper housing the cartridge is useless. Even the best cartridge cannot do the job if enclosed in a housing that allows fluid to bypass the filter, has external leaks, are not chemically or mechanically compatible with the application. Quality gas or liquid filtration systems require both quality housings and quality filter cartridges. To meed this need, Sartorius Stedim Biotech has been producing a sanitary line of housings with quality as the primary objective.

Quality of Materials
Only 316L Stainless steel is used for all wetted surfaces to provide maximum durability. Sup-plied O-rings and gaskets are compounded only from FDA approved materials that meet the requirements for direct contact with food and pharmaceutical products.

Quality Surface Finishes
All Sartorius Stedim Biotech Sanitary hous-ings come standard with internal finishes of at least 0.5 micron Ra and are electropolished. Electropolishing removes surface impurities in stainless steel left over from the machining and the finishing processes. Such impurities are sites for future initiation of corrosion and possible sources of contaminates leaching into the product. Electropolishing also smoothes the microscratches left by mechanical polish-ing, thus reducing the total surface area the product will contact, and making it harder for bacteria or contaminates to lodge on the housing surface.

Finally, electropolishing leaves a highly cor-rosion resistant, passive film on the surface of the steel (passivation). Thus electropolishing is the recommended finish for all applications where cleanliness and corrosion resistance are critical.

Ease in Cleaning
Sartorius Stedim Biotech utilizes a unique filter cup design that is conductive for allow-ing a thorough cleaning. The raised filter cup design eliminates small grooves and tight spaces that might be difficult to verify or validate the cleaning while still permitting free complete drainage of the filter housing.

Flexibility
Sartorius Stedim Biotech offers the widest range of housing sizes and design options to exactly match your flow rate and pressure differential requirements. Connections are available in many styles and sizes. Custom designs and unique configurations are available upon request.

Quality Control and Documentation
An important feature of pharmaceutical process validation is documentation. All our housings are given stringent inspections during and after manufacturing including dimensional checks, weld inspections, surface measurements and hydrostatic testing. Each housing is labled by laser with a matching serial number on the bell and base. This serial number provides complete tractability for the Quality Control Certificate, Material Test Reports, and Weld Logs.

Ease of Installation
Sartorius Stedim Biotech housings are sold ready to install with all gaskets, o-rings and clamps. All that is required are the components needed to connect to your existing hardware.

PED 97/23/EC Standard
Sartorius Stedim Biotech Stainless Steel Housings are designed and manufactured according the Pressure Equipment Directive PED 97/23/EC. Our manufacturing process follows the highest quality standards and is monitored by an internal quality control system as well as by independent notified bodies on a regular basis.

▷ Specifications

Materials

All Wetted Surfaces	316L
Clamps	304
Seals	Silicone (Viton or EPDM optional)

Available Heights
Mini	5"
Single Round	5", 10", 20", 30", 40"

Surface Finishes
Interior	Ra <0.5 μm EP
Exterior	Ra <1.6 μm EP

Housing Ratings
Pressure	−1 + 10 bar
Temperature	−10 + 150 °C

▶ Jumbo Filter Housings

Filter Housing for Biopharmaceutical Applications

New Sanitary Baseplate Design

Introduction

Sartorius Stedim Biotech Jumbo P Filter Housings are specifically designed for liquid filtration applications of the Biopharmaceutical Industry. Manufactured in an PED 97│23│EC certified facility, special attention has been paid to choice of materials, durability, cleanability, ease of use and quality control. They are the clear choice of pharmaceutical and biotech manufacturers. Sartorius Stedim Biotech Jumbo Filter Housings are made to support the high expectations and standards of our customers.

Applications

Sartorius Stedim Biotech Jumbo Pharma Filter Housings are ideally suited for liquid filtration, including:

– Harvested Cell Culture fluids

– Microbial Fermentation broths

– Serum free or serum containing cell culture media

– Plasma Fractions

– LVP Solution

– Ophtalmics

– WFI

– Process water

Quality of Material

Only 316L grade stainless steel is used for all wetted surfaces to provide maximum durability and resistance to corrosion. All supplied gaskets and O-rings meet FDA regulatory requirements.

Quality of Surface Finishes

Jumbo P Filter Housings come standard with internal finishes of at least 0.8 micron (µm) Ra and are nitric electropolished and passivated. Electropolishing of stainless steel Filter Housings is the recommended finishing process for all applications where cleanliness and corrosion resistance are critical.
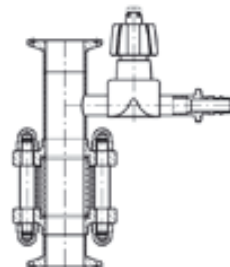
Ease in Cleaning

Jumbo P Filter Housings are designed to allow for a more thorough cleaning. Sprayball assembly is available for all Jumbo P housings. CIP caps are also available.

Complete Flexibility

Sartorius Stedim Biotech offers the widest range of Filter Housing design options to exactly match your specific application requirements. Custom designs are available upon request.

Quality Control and Documentation

Premium document package as standard includes as-built drawing(s), BOM, MTRs, elastomer certs., hydrotest certs., surface finish certs., EP│passivation certs.,weld log, etc. Each Filter Housing is also labled with a matching serial number on the base and bell for complete traceability

Ease of Installation

Sartorius Stedim Biotech Filter Housings are sold ready-to-install with the gasket(s), O-Ring (s) and clamp included.

CE PED 97│23│EC Standard

Sartorius Stedim Biotech Stainless Steel Housings are designed and manufactured according the Pressure Equipment Directive PED 97│23│EC. Our manufacturing process follows the highest quality standards and is monitored by an internal quality control system as well as by independent notified bodies on a regular basis. ASME design on request.

Vent Assembly

▷ Specifications

Technical Specifications

Product Contact Surfaces	316L
Gasket Materials	EPDM (Viton or Silicone available)
CFR Compliance	All gasket materials comply with the FDA regulations 21 CFR 17.2600
Closure System	Clamp closure
Height	10" High, 20" High, 30" High, 40" High
Adapter	Jumbo Double O-Ring Bayonet Connector
Surface Finishes	Ra <0.8 μm internal (epolished) Ra <1.6 μm external (epolished)

Order Codes

7J11LSZ00001	1 Module, Premium Documentation, Gasket Material Silicone
7J12LSZ00001	2 Modules, Premium Documentation, Gasket Material Silicone
7J13LSZ00001	3 Modules, Premium Documentation, Gasket Material Silicone
7J14LSZ00001	4 Modules, Premium Documentation, Gasket Material Silicone
7J11LEZ00001	1 Module, Premium Documentation, Gasket Material EPDM
7J12LEZ00001	2 Modules, Premium Documentation, Gasket Material EPDM
7J13LEZ00001	3 Modules, Premium Documentation, Gasket Material EPDM
7J14LEZ00001	4 Modules, Premium Documentation, Gasket Material EPDM
7J11LVZ00001	1 Module, Premium Documentation, Gasket Material Viton
7J12LVZ00001	2 Modules, Premium Documentation, Gasket Material Viton
7J13LVZ00001	3 Modules, Premium Documentation, Gasket Material Viton
7J14LVZ00001	4 Modules, Premium Documentation, Gasket Material Viton

Accessories

Membrane Gauge with Tri Clamp 1.5"– 1–10 bar	7ZMA--0024
Vent Assembly with sight glass and membrane valve	7ZM-B-0041
90° 2" OD bend with welding ends	292ZALBV0006
90° 2" OD Bend with Tri Clamp 1.5"	292ZALBV0003
90° 2" OD Bend with Tri Clamp 2.0"	292ZALBV0001
90° 2" OD Bend with 11864-2 Aseptic screw joint	292ZALBV0002
90° 2" OD Bend with 11864-3 Aseptic Tri Clamp	292ZALBV0004
Others on request	

In– and Outlet

Aseptic threaded connection 2" DIN 11864-1 (pipe size 50.8 × 1.6 mm).
Vent connection 1.5 Tri clamp (pipe size 38 × 1.6 mm).

Measurements, Weights and Volume

Jumbo Pharma Housings

Modules		1	2	3	4
Volume	ltr	25.1	42.8	60.4	78.1
Total Height (A)	mm	870	1120	1370	1620
Height (C)	mm	388	388	388	388
Diameter (B)	mm	306	306	306	306
Weight	kg	68	75	82	89

▶ Sartoclear® P Filter Housings

1 Self draining baseplate design.
2 Replaceable adapter Flat│Double O-Ring.
3 In– and outlet aseptic threaded connection 2" DIN 11864-1 (pipe size 50.8 × 1.6 mm)

Introduction
Sartorius Stedim Biotech Sartoclear® P Filter Housings are specifically designed for liquid filtration applications of the Bio-Pharmaceutical Industry. Manufactured in an PED 97│23│EC certified facility, special attention has been paid to choice of materials, durability, cleanability, ease of use and quality control. They are the clear choice of pharmaceutical and biotech manufacturers and equipment providers of bioreactors, CIP skids, autoclaves, lyophilizers and process tanks. Sartorius Stedim Biotech Sartoclear® P Filter Housings are made to support the high expectations and standards of our customers.

Applications
Sartorius Stedim Biotech Sartoclear® P Filter Housings are ideally suited for liquid filtration, including:

– Cell harvest & clarification of cell culture and other fermentation media

– Upstream filtration of growth media

– Particle and colloid removal serum and plasma

– Removal of cryoprecipitants

Typical process volumes for Sartoclear® P depth filter modules are regularly higher than 100 liters.

Quality of Material
Only 316L grade stainless steel is used for all wetted surfaces to provide maximum durability and resistance to corrosion. All supplied gaskets and O-rings meet FDA regulatory requirements.

Quality of Surface Finishes
Sartoclear® P Filter Housings come standard with internal finishes of at least 0.8 micron (µm) Ra and are nitric electropolished and passivated. Electropolishing of stainless steel Filter Housings is the recommended finishing process for all applications where cleanliness and corrosion resistance are critical.

Ease in Cleaning
Sartoclear® P Filter Housings are designed to allow for a more thorough cleaning. The secure center post assembly conceals small grooves and threads from the process fluid making cleaning easier. While some of the internal components must be washed separately, riboflavin testing utilizing a sprayball assembly is available for all Sartoclear® P housings. CIP caps are also available.

Complete Flexibility
Sartorius Stedim Biotech offers the widest range of Filter Housing design options to exactly match your specific application requirements. Custom designs are available upon request.

Quality Control and Documentation
Premium document package includes as-built drawing(s), BOM, MTRs, elastomer certs., hydrotest certs., surface finish certs., EP│passivation certs.,weld log, etc. Each Filter Housing is also labled with a matching serial number on the base and bell for complete traceability.

Ease of Installation
Sartorius Stedim Biotech Filter Housings are sold ready-to-install with the gasket(s), O-Ring (s) and clamp included.

CE PED 97│23│EC Standard
Sartorius Stedim Biotech Stainless Steel Housings are designed and manufactured according the Pressure Equipment Directive PED 97│23│EC. Our manufacturing process follows the highest quality standards and is monitored by an internal quality control system as well as by independent notified bodies on a regular basis. ASME design on request.

▷ Specifications

Technical Specifications

Product Contact Surfaces	316L
Gasket Materials	EPDM (Viton or Silicone available)
CFR Compliance	All gasket materials comply with the FDA regulations 21 CFR 17.2600
Closure System	Bolt clamps
Height 12", 16"	1 High, 2 High, 3 High, 4 High
Adapter	Flat and Double O-Ring
Surface Finishes	Ra <0.8 µm internal (epolished) Ra <1.6 µm external (epolished)

Measurements, Weights and Volume

Housing for 12" Modules (Dia. 320 mm (B))

| Elements		1	2	3	4
Filtration Area	m^2	1.8	3.6	5.4	7.2
Volume	ltr	36	57	78	100
Total Height (A)	mm	1010	1280	1550	1820
Height (C)	mm	430	430	430	430
Weight	kg	60	67	73	81

Housing for 16" Modules (Dia. 450 mm (B))

Elements		1	2	3	4
Filtration Area	m^2	3.6	7.2	10.8	14.4
Volume	ltr	73	115	157	198
Total Height (A)	mm	1023	1293	1563	1833
Height (C)	mm	430	430	430	430
Weight	kg	97	108	117	126

Accessories

90° 2" OD bend with welding ends	292ZALBV0006
90° 2" OD Bend with Tri Clamp 1.5"	292ZALBV0003
90° 2" OD Bend with Tri Clamp 2.0"	292ZALBV0001
90° 2" OD Bend with 11864-2 Aseptic screw joint	292ZALBV0002
90° 2" OD Bend with 11864-3 Aseptic Tri Clamp	292ZALBV0004

Others on request

Ordering Information

29V   12   018   10   D   B   E   L   Z

Sartoclear® Module Housing
Standard

Module Diameter
12   = 12"
16   = 16"

Filtration Area, 12"   **Filtration Area, 16"**
018 = 1.8 m^2 036 = 3.6 m^2
036 = 3.6 m^2 072 = 7.2 m^2
054 = 5.4 m^2 108 = 10.8 m^2
072 = 7.2 m^2 144 = 14.4 m^2

Max. Operation Pressure
10   = 10 bar | 145 psi

Module Adapter
D   = Double O-Ring Adapter
F   = Flat Adapter

Connectors
B   = Aseptic Screw Pipe Connectors DIN 11864-1

Gasket
E   = EPDM
S   = Silicone
V   = Viton

Housing Material
L   = 1.4404 | 1.4435 (AISI 316L)

Certificate
N   = Materials Certificate 3.1 to DIN EN 10204 + gasket material according to FDA Regulations (Standard) + original material documentation

Z   = Premium Documentation

▶ Sanitary Junior Filter Housing

Introduction

Sartorius Stedim Biotech Sanitary Junior Filter Housings are specifically designed for air | gas filtration applications of the Bio-Pharmaceutical Industry. Sterilizing grade filter cartridges for air and gas are installed in the production process, as one of the standard procedures to reduce the contamination risk for the product. Sterilizing grade air filters are an essential part of fermentation processes, where they are used for sterile inlet and off-gas filtration. Furthermore, filters are typically used for sterile venting of autoclaves, freeze dryers and WFI tanks. Sartorius Stedim Biotech Sanitary Junior Filter Housings are made to support the high expectations and standards of our customers.

Applications

Housings are ideally suited for sterile air and gas filtration, including:

— Fermenter and bioreactor inlet gases

— Fermenter and bioreactor vents

— Autoclave vents

— Lyophilizer vents

— Purified water system storage tank vents

— In process storage tank vents

— Filling equipment process air

Quality of Materials

Only 316L grade stainless steel is used for all wetted surfaces to provide maximum durability and resistance to corrosion. All supplied gaskets and O-rings meet FDA and USP Class VI regulatory requirements.

Quality of Surface Finishes

Junior Filter Housings come standard with internal finishes of at least 0.5 micron (µm) Ra and are nitric electropolished and passivated. Electropolishing of stainless steel Filter Housings is the recommended finishing process for all applications where cleanliness and corrosion resistance are critical.

Ease in Cleaning

Sartorius Stedim Biotech utilizes a unique plugin adapter design that is conducive to a thorough cleaning. The plug-in adapter design eliminates small grooves and tight spaces that might be difficult to validate for cleaning, while still allowing complete drainage of the housing.

Complete Flexibility

Sartorius Stedim Biotech offers the widest range of Filter Housing design options to exactly match your specific application requirements. Custom designs are available upon request.

Quality Control and Documentation

Premium document package includes as-built drawing(s), BOM, MTRs, elastomer certs., hydrotest certs., surface finish certs., EP | passivation certs., weld log, etc. Each Filter Housing is also labled with a matching serial number on the base and bell for complete traceability.

Ease of Installation

Sartorius Stedim Biotech Filter Housings are sold ready-to-install with the gasket(s), O-ring(s) and clamp included.

CE PED 97 | 23 | EC Standard

Sartorius Stedim Biotech Stainless Steel Housings are designed and manufactured according the Pressure Equipment Directive PED 97 | 23 | EC. Our manufacturing process follows the highest quality standards and is monitored by an internal quality control system as well as by independent notified bodies on a regular basis.

▷ Specifications

Product Contact Surfaces	316L SS
Gasket Material	EPDM (Viton or Silicone available)
CFR Compliance	All gasket materials compliy with the FDA and USP Cl VI
Closure System	Clamp Closure
Adapter	Plug in Ad. 14
Surface internal Surface external	Ra ≤ 0.5 μm EP Ra ≤ 1.2 μm EP
Max. Pressure Max. Temperatur	10 bar 140°C

Ordercode

7U17LEN00002	½" Pipe diameter 12.70 × 1.65 mm
7U17LEN00003	¾" Pipe diameter 19.05 × 1.65 mm
In– and outlet	Sanitary TC Flange 25 mm diameter

▶ Series 7 | Single Round Housings

Air | Gas and Liquid Filtration
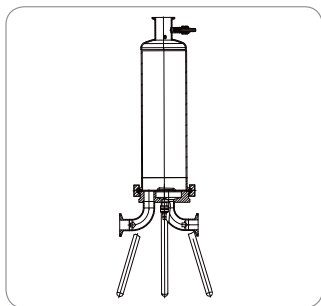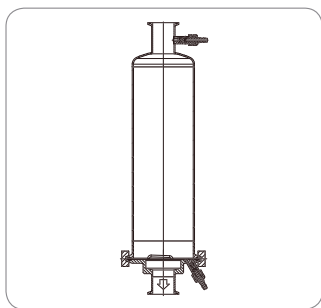
Introduction
Sartorius Stedim Biotech Series 7 Single Round Housings are specifically designed for air | gas and liquid filtration applications of the Bio-Pharmaceutical Industry. Manufactured in an ASME-certified facility, special attention has been paid to choice of materials, durability, cleanability, ease of use and quality control. They are the clear choice of pharmaceutical and biotech manufacturers and equipment providers of bioreactors, CIP skids, autoclaves, lyophilizers and process tanks. Sartorius Stedim Biotech Series 7 Single Round Housings are made to support the high expectations and standards of our customers.

Applications
Sartorius Stedim Biotech Series 7 Single Round Housings are ideally suited for sterile air | gas and liquid filtration, including:

– Bulk gases

– Fermenter off-gases

– Tank venting

– Pharmaceutical preparations

– High-purity water

– Human and veterinary drugs

– Diagnostic reagents

– Sera

– Blood fractions

– Cell cultures

Quality of Materials
Only 316L grade stainless steel is used for all wetted surfaces to provide maximum durability and resistance to corrosion. All supplied gaskets and O-rings meet FDA and USP Class VI regulatory requirements.

Quality Surface Finishes
Sartorius Stedim Biotech filter housings come standard with internal finishes of at least 15 micro-inch Ra and are nitric electropolished and passivated. Electropolishing of stainless steel Filter Housings is the recommended finishing process for all applications where cleanliness and corrosion resistance are critical.

Ease in Cleaning
Sartorius Stedim Biotech utilizes a unique filter cup design that is conducive for allowing a thorough cleaning. The raised filter cup design eliminates small grooves and tight spaces that might be difficult to verify or validate the cleaning while still permitting free complete drainage of the filter housing.

Flexibility
Sartorius Stedim Biotech offers the widest range of housing sizes and design options to exactly match your flow rate and pressure differential requirements. Connections are available in many styles and sizes. Custom designs are available upon request. Acc. to Sartorius M.D.S. Software (Modular Design System).

Quality Control and Documentation
ISO 9001 | 2008 registered or current. Standard 20 pt documentation package includes GA drawing(s), BOM, Final Test Report | Certs, MTRs, and welding records. Each Filter Housing is also electro-etched with a matching serial number on the base and bell for complete traceability.

Ease of Installation
Sartorius Stedim Biotech filter housings are sold ready-to-install with the gasket(s), O-ring(s) and clamp included.

Design Code
Acc. to current ASME BPE standards. cGMP | GEP-compliant sanitary design.

▷ Specifications

Materials

Product Contact Surfaces	316L
Clamps	304
Seals, USP clVI	Silicone (Viton®, EPDM or PTFE enveloped optional)

Adapter
25 (Cd 7)

Available Heights
5", 10", 20", 30", 40"

Surface Finishes
Interior   Ra ≤ 15 µin EP
Exterior   Ra ≤ 32 µin EP

Housing Ratings
Pressure   −14.5 –145 psi
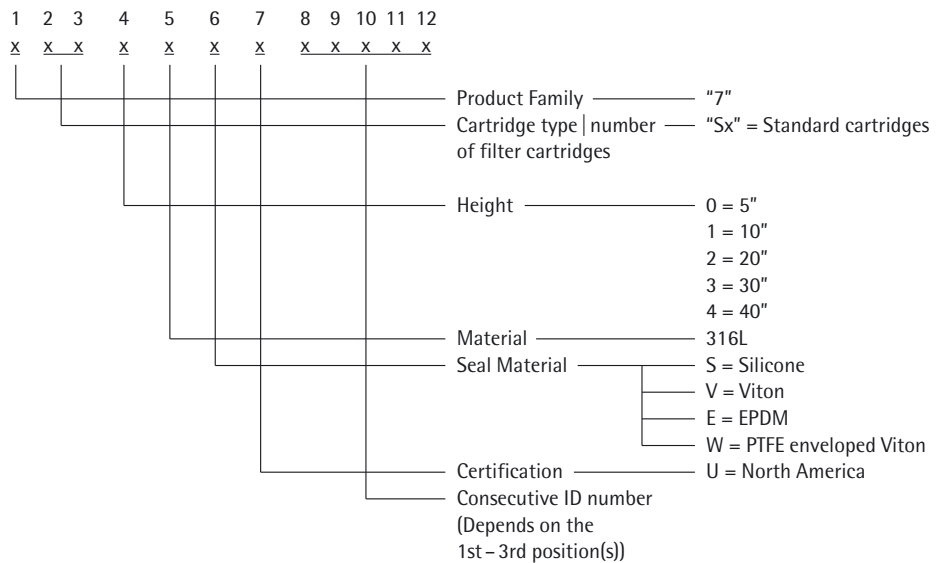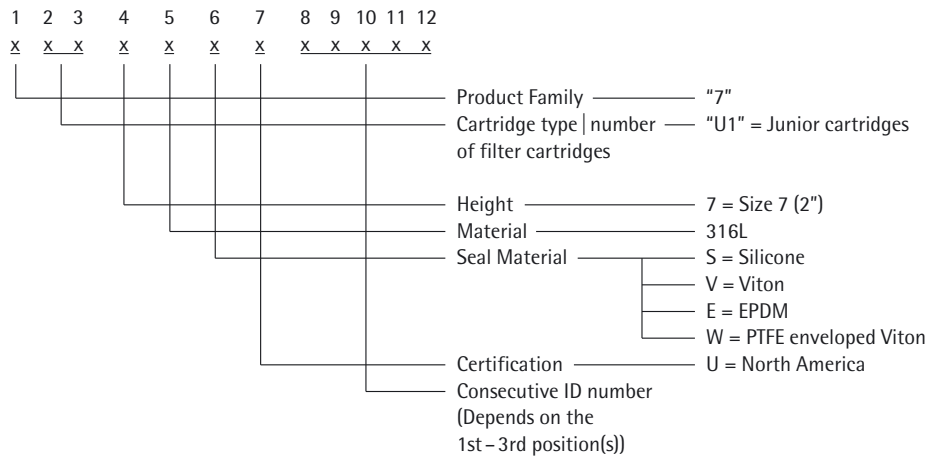Temperature   14 – 302°F

Standard Order Codes

7S11LSUS0839	1 × 10" STD I-type, Pharma valve vent│drain, 1.5" TC
7S11LSUS1677	1 × 10" STD T-type, Pharma valve vent│drain, 1" TC
7S11LEUS1681	1 × 10" STD T-type│C-line base, Pharma valve vent│drain, 1.5" TC (Pressure gas)
7S10LEUS0414	1 × 5" STD I-type, 1.5" TC (Vent, no pressure)
7S11LEUS0414	1 × 10" STD I-type, 1.5" TC (Vent, no pressure)

Spare Parts and Accessories

4" Base│Bell Gasket, USP clVI:
Silicone   7EDSCV0007
Viton®   7EDVCV0007
EPDM   7EDECV0007
PTFE enveloped Viton®   7EDWCV0007
Sanitary clamp   7ZSB--0023
Pharma valve   7EVD--0003

Ordering Information

```
1   2   3    4    5    6    7    8  9  10 11 12
x   x   x    x    x    x    x    x  x  x  x  x
```

Product Family ———————— "7"
Cartridge type│number —— "Sx" = Standard cartridges
of filter cartridges

Height ———————————— 0 = 5"
1 = 10"
2 = 20"
3 = 30"
4 = 40"

Material ———————————— 316L
Seal Material ——————— S = Silicone
V = Viton
E = EPDM
W = PTFE enveloped Viton

Certification ——————— U = North America
Consecutive ID number
(Depends on the
1st – 3rd position(s))

▶ Series 7 | Junior Housings

Sterile Air | Gas Filtration
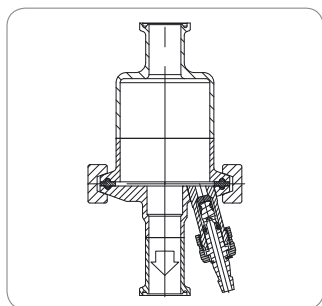
Introduction
Sartorius Stedim Biotech Series 7 Junior Housings are specifically designed for sterile air | gas filtration applications of the Bio-Pharmaceutical Industry. Sterilizing grade filter cartridges for air and gas are installed in the production process, as one of the standard procedures to reduce the contamination risk for the product. Sterilizing grade air filters are an essential part of fermentation processes, where they are used for sterile inlet and off-gas filtration. Furthermore, filters are typically used for sterile venting of autoclaves, freeze dryers and WFI tanks. Sartorius Stedim Biotech Series 7 Junior Housings are made to support the high expectations and standards of our customers.

Applications
Sartorius Stedim Biotech Series 7 Junior Housings are ideally suited for sterile air | gas filtration, including:

– Fermentor and bioreactor inlet gases

– Fermentor and bioreactor vents

– Autoclave vents

– Lyophilizer vents

– Purified water system storage tank vents

– In process storage tank vents

– Filling equipment process air

Quality of Materials
Only 316L grade stainless steel is used for all wetted surfaces to provide maximum durability and resistance to corrosion. All supplied gaskets and O-rings meet FDA and USP Class VI regulatory requirements.

Quality Surface Finishes
Sartorius Stedim Biotech filter housings come standard with internal finishes of at least 15 micro-inch Ra and are nitric electropolished and passivated. Electropolishing of stainless steel Filter Housings is the recommended finishing process for all applications where cleanliness and corrosion resistance are critical.

Ease in Cleaning
Sartorius Stedim Biotech utilizes a unique plug-in adapter design that is conducive for allowing a thorough cleaning. The plug-in adapter design eliminates small grooves and tight spaces that might be difficult to verify or validate the cleaning while still permitting free complete drainage of the filter housing.

Flexibility
Sartorius Stedim Biotech offers the widest range of housing sizes and design options to exactly match your flow rate and pressure differential requirements. Connections are available in many styles and sizes. Custom designs are available upon request. Acc. to Sartorius M.D.S. Software (Modular Design System).

Quality Control and Documentation
ISO 9001 | 2008 registered or current. Standard 20 pt documentation package includes GA drawing(s), BOM, Final Test Report | Certs, MTRs, and welding records. Each Filter Housing is also electro-etched with a matching serial number on the base and bell for complete traceability.

Ease of Installation
Sartorius Stedim Biotech filter housings are sold ready-to-install with the gasket(s), O-ring(s) and clamp included.

Design Code
Acc. to current ASME BPE standards. cGMP | GEP-compliant sanitary design.

▷ Specifications

Materials

Product Contact Surfaces	316L
Clamps	304
Seals, USP clVI	Silicone (Viton®, EPDM or PTFE enveloped optional)

Adapter
Plug-in Ad. 14

Filter Cartridge
Sartofluor Junior

Surface Finishes
Interior   Ra ≤ 15 µin EP
Exterior   Ra ≤ 32 µin EP

Housing Ratings
Pressure   −14.5 −145 psi
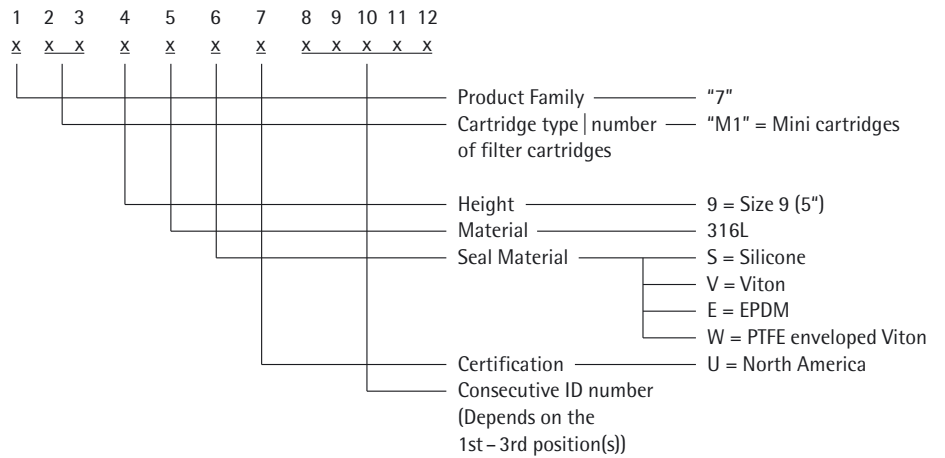Temperature   14 − 302°F

Standard Order Codes

7U17LSUS0005	1 × 7 Junior I-type, Pharma valve drain, 3/4" TC
7U17LSUS0003	1 × 7 Junior I-type, No vent⏐drain, 3/4" TC

Spare Parts and Accessories

2" Base⏐Bell Gasket, USP clVI:
Silicone   7EDSCV0004
Viton®   7EDVCV0004
EPDM   7EDECV0004
PTFE enveloped Viton®   7EDWCV0004
Sanitary clamp   7ZSB--0012
Pharma valve   7EVD--0003

Ordering Information

1   2   3   4   5   6   7   8   9   10 11 12
x   x   x   x   x   x   x   x   x   x   x   x

Product Family —————— "7"
Cartridge type⏐number — "U1" = Junior cartridges
of filter cartridges

Height —————————— 7 = Size 7 (2")
Material ————————— 316L
Seal Material ———————— S = Silicone
                                          V = Viton
                                          E = EPDM
                                          W = PTFE enveloped Viton
Certification —————————— U = North America
Consecutive ID number
(Depends on the
1st – 3rd position(s))

▶ Series 7 | Mini Housings

Air | Gas and Liquid Filtration
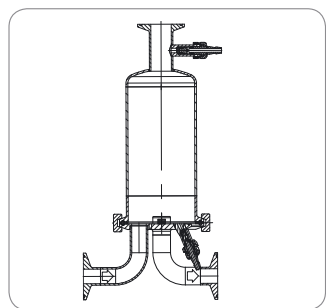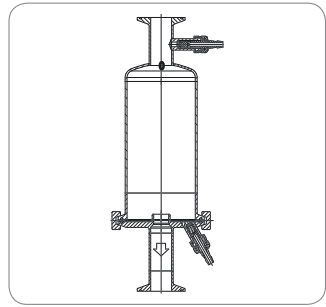
Introduction
Sartorius Stedim Biotech Series 7 Mini Housings are specifically designed for air | gas and liquid filtration applications of the Bio-Pharmaceutical Industry. They are the clear choice of pharmaceutical and biotech manufacturers and equipment providers of bioreactors, CIP skids, autoclaves, lyophilizers and process tanks. Sartorius Stedim Biotech Series 7 Mini Housings are made to support the high expectations and standards of our customers.

Applications
Sartorius Stedim Biotech Series 7 Mini Housings are ideally suited for sterile air | gas and liquid filtration, including:

– Bulk gases

– Fermenter off-gases

– Tank venting

– Pharmaceutical preparations

– High-purity water

Quality of Materials
Only 316L grade stainless steel is used for all wetted surfaces to provide maximum durability and resistance to corrosion. All supplied gaskets and O-rings meet FDA and USP Class VI regulatory requirements.

Quality Surface Finishes
Sartorius Stedim Biotech filter housings come standard with internal finishes of at least 15 micro-inch Ra and are nitric electropolished and passivated. Electropolishing of stainless steel Filter Housings is the recommended finishing process for all applications where cleanliness and corrosion resistance are critical.

Ease in Cleaning
Sartorius Stedim Biotech utilizes a unique plug-in adapter design that is conducive for allowing a thorough cleaning. The plug-in adapter design eliminates small grooves and tight spaces that might be difficult to verify or validate the cleaning while still permitting free complete drainage of the filter housing.

Flexibility
Sartorius Stedim Biotech offers the widest range of housing sizes and design options to exactly match your flow rate and pressure differential requirements. Connections are available in many styles and sizes. Custom designs are available upon request. Acc. to Sartorius M.D.S. Software (Modular Design System).

Quality Control and Documentation
ISO 9001 | 2008 registered or current. Standard 20 pt documentation package includes GA drawing(s), BOM, Final Test Reportˇ | Certs, MTRs, and welding records. Each Filter Housing is also electro-etched with a matching serial number on the base and bell for complete traceability.

Ease of Installation
Sartorius Stedim Biotech filter housings are sold ready-to-install with the gasket(s), O-ring(s) and clamp included.

Design Code
Acc. to current ASME BPE standards. cGMP | GEP-compliant sanitary design.

▷ Specifications

Materials

Product Contact Surfaces	316L
Clamps	304
Seals, USP clVI	Silicone (Viton®, EPDM or PTFE enveloped optional)

Adapter
15 (Plug-in with interlocking tabs)

Filter Sizes
Mini 7, 8, 9

Surface Finishes
Interior   Ra ≤ 15 µin EP
Exterior   Ra ≤ 32 µin EP

Housing Ratings
Pressure   –14.5 –145 psi
Temperature   14 –302 °F

Standard Order Codes

7M19LSUS0584	1 × 9 Mini T-type, Pharma valve vent │ drain, 1.5" TC (Pipe 3/4")
7M19LSUS0148	1 × 9 Mini I-type, Pharma valve vent │ drain, 1" TC
7M19LEUS0567	1 × 9 Mini T-type │ C-line base (Pressure Gas), Pharma valve vent │ drain, 1.5" TC (Pipe 3/4")

Spare Parts and Accessories

3" Base │ Bell Gasket, USP clVI:
Silicone   7EDSCV0006
Viton®   7EDVCV0006
EPDM   7EDECV0006
PTFE enveloped Viton®   7EDWCV0006
Sanitary clamp   7ZSB--0020
Pharma valve   7EVD--0003

Ordering Information

```
1   2   3     4     5     6     7     8  9  10 11 12
x   x   x     x     x     x     x     x  x  x  x  x
```

Product Family ——————— "7"
Cartridge type │ number ——— "M1" = Mini cartridges
of filter cartridges

Height ———————————— 9 = Size 9 (5")
Material ——————————— 316L
Seal Material ——————— S = Silicone
                       V = Viton
                       E = EPDM
                       W = PTFE enveloped Viton
Certification ———————— U = North America
Consecutive ID number
(Depends on the
1st – 3rd position(s))

▶ # Series 48 │ Filter Housing Heaters

For Superior Thermal Control

Introduction

Series 48 Filter Housing Heaters are a cost-effective and low maintenance solution for Biopharmaceutical processes requiring superior thermal control. Series 48 Heaters prevent vapor condensation in sterile vent and process filters and piping systems and help maintain preferred material viscosities. Series 48 Heaters offer tight temperature control and advanced functionality, while complying with strict safety regulations.

Series 48 Heaters feature a unique temperature controller which integrates a temperature process controller, a high-low temperature alert, and power switching with a safety high limit - all inside a NEMA 4X enclosure. The controller features a user-friendly digital display and an optional Modbus RTU Communications module allows users to remotely adjust parameters through its RS485 interface.

Applications

Series 48 Housing Heaters are used in onjunction with sterile vent and process filter housings and are ideally suited for processes such as:

– Bioprocessing and Pharmaceutical Process Fluids

– Fermentation

– Product Recovery

– Water for Injection

– Filtration and Purification Processes

– Skidded Systems

– Tanks and Vessels

Improved Heater Design

– Specially designed heater jackets for optimum performance and increased thermal uniformity

– Thermocouple embedded in heater mat for tight temperature control

– Corrosion-resistant stainless steel snaps for easy installation or removal

– Contoured foam insulator covers dome section to prevent heat loss

– External heater surfaces safe to touch

– UL listed and CE tested and marked for both electrical and thermal safety

Advanced Temperature Control

– User-adjustable and resettable temperature setpoints for advanced process control

– User-friendly communication and display options provide greater temperature control versatility and functionality

– Adjustable and resettable safety limit device integrated into controller circuitry eliminates the need for a thermal fuse

– Optional Modbus communications allows for remote display, control, and diagnostics of individual heater status

– No-arc relay ensures long controller lifetime and increased reliability

– Programmable Low Temperature Alert │ High Temperature Alert (LTA/HTA) integrated into controller circuitry

– Multiple LEDs display controller │ heater operating and alert conditions and status

NEMA 4X Compliance

– Heater jacket, controller and cables are certified to NEMA 4X requirements

– Water and dust resistant

– Corrosion resistant

– Resists damage from ice buildup

The NEMA rated heaters allow for installation in the harshest of environments. The units can be mounted in any location where moisture is present, including clean-in-place (CIP) washdown areas.

Additional Features

– Control components reside inside controller, away from heat source, extending heater life

– Increased energy efficiency outperforms steam-jacketed housings

– Optional Series 48 software adjusts control parameters on individual heaters from a remote location quickly and easily

– Software monitors temperatures, provides graphical output and offers data logging capability

▷ Specifications

Materials

Heater Jacket	Molded Silicone Foam, Fiberglass Reinforced Silicone, Teflon Insulated Wire
Snaps	Stainless Steel
Controller	Polycarbonate Lid, ABS Base

Number of Cartridges (Round)
1

Height
Junior, Mini, 5", 10", 20", 30"

Interior Temperature Range
Ambient to 185°C (365°F)

Standard Order Codes

48FHH1778-17	1 × 7 Junior Heater KIT, NEMA 4X, 5-15P Power Plug, Display, 120 V, LTA
48FHH1758-19	1 × 9 Mini Heater KIT, NEMA 4X, 5-15P Power Plug, Display, 120 V, LTA
48FHH1802-10	1 × 5" Heater KIT, NEMA 4X, 5-15P Power Plug, Display, 120 V, LTA
48FHH1805-11	1 × 10" Heater KIT, NEMA 4X, 5-15P Power Plug, Display, 120 V, LTA
48FHH1808-12	1 × 20" Heater KIT, NEMA 4X, 5-15P Power Plug, Display, 120 V, LTA
48FHH18011-13	1 × 30" Heater KIT, NEMA 4X, 5-15P Power Plug, Display, 120 V, LTA

Notes
1. Communication option available upon request.
2. Multi-Round heater designs are available upon request.
3. 240 V, Cable w/ flying leads available upon request.

Heater Specifications

Pre-Set Temperature Points	95°C (203°F)
Exterior Range Temperature	Ambient to 43°C (109°F) based on 95°C set point
Foam Thickness	0.5 in. (12.7 mm)
Connectors	Bulgin Mini Buccaneer
Weight Range	1 to 5 lbs (0.45 to 2.27 kg)
Product Safety	UL®/C-UL Listed, CE, Semi S2, NEMA 4X

Controller Specifications

Power Requirements	120 VAC input
Power Consumption	0.3 W
Relay Contact Rating	SPDT, 2 A @ 50 VAC resistive, 1 A @ 30 VDC
Dimensions	4.69" × 2.72" × 4.61" (119 × 69 × 117 mm)
Product Safety	UL®/C-UL Listed, CE, Semi S2, NEMA 4X

▶ Sprayball Cleaning System SCS
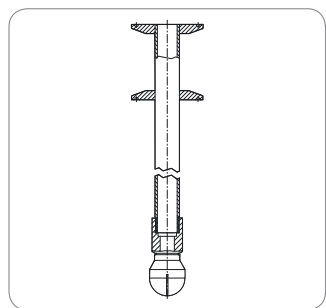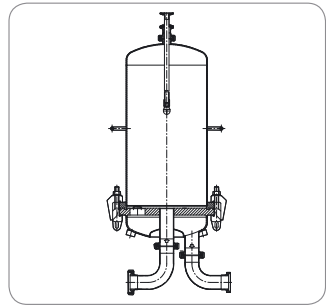
Description
The Sartorius Stedim Biotech Sprayball Cleaning System has been specially designed for preliminary cleaning before sterilisation of housing bells, which – due to their size – cannot be cleaned in a traditional cleaning system.

The Sprayball System is a compact, axial rotating cleaning system, which is driven by the through-flow of the cleaning agent.

Because of the sophisticated location of the spray nozzles, this system can clean all cylindrical housing bells of the Sartorius Stedim Biotech brand without any spray shadow.

The axis of the cleaning head has a double ball bearing and therefore guarantees the highest performance safety in all positions of installation.

Operating Principle
The axial system works on the basis of spectral distribution. Using the operating pressure of the cleaning agent, the spray head rotates and thus reaches all areas within the housing bell over 360°.

The large volume jet nozzles ensure that the cleaning agent is focused and thus a high mechanical cleansing effect with a great flushing velocity is achieved.

Installation
Due to the small diameter of the lance, the SCS can be used in nearly every Sartorius Stedim Biotech housing bell. The Sprayball System is mounted on the vent valve port The spray lance has a mm diameter fitting for this purpose. It is possible to use other fittings to attach the Sprayball System, however. These are available as special accessories. To use the Sprayball System, you will need a line pressure of 1-6 bar (1 bar = 100 kPa).

The cleaning results will depend on the kind of pollution, the cleaning agent itself and the working pressure and temperature of the cleaning agent.

Sartorius Stedim Biotech cannot provide any explicit cleaning recommendations due to the great variety of conditions that are possible.
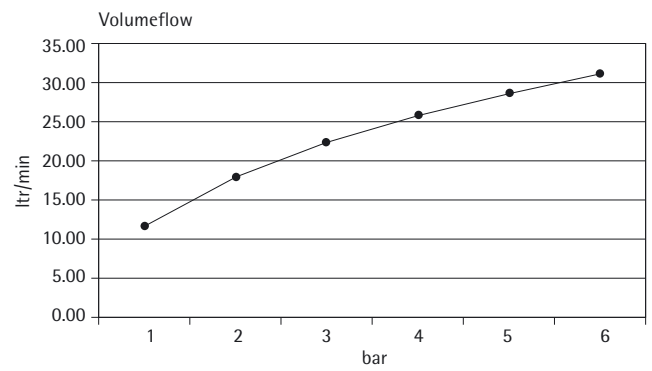
Volumeflow

▷ Specifications

Technical Data SCS 360°

Material	316L
Max. operating temperature	194°F
Max. bell diameter	40"
Volume flow	see Flow Curve
Operating pressure	14.5 psi – 87 psi
Max. lance diameter	3/4"
Connection	1.5" TC

Other adapters on request

Order Numbers

Spray lance for 10" housing	7ZALA-0191
Spray lance for 20" housing	7ZALA-0192
Spray lance for 30" housing	7ZALA-0193

► Sartocheck® mini

Filter Integrity Tester for Food & Beverage Applications

Description
The automatic filter integrity tester
Sartocheck® mini can be used to verify the
integrity of membrane filters which are
used in the food & beverage environment.

Taken those specific needs into account,
this unit offers the following main features:

– Automatic filter integrity tester

– Pressure Drop Test &

– Diffusion Test

– Small, portable unit

– 19 different test programs

– 100 test results to be stored

– LCD display

– Automatic venting after the test

– Thermo-printer (57 mm paper)

– Easy and reliable data transfer to PC

– High capacity batteries for up to 4 hrs work

– Protection rating IP50

– Incl. bag and case

Test Result Documentation
Test results are automatically printed using
the built-in thermo printer. An additional
port allows the connection of an external
printer.

Data Storage
The unit stores up to 100 test results in the
internal memory. To avoid the oldest data
to be overwritten, electronic data can be
stored on a connected PC with user-friendly
software. The same software can be used
for programming the device.

▷ Specifications

Technical Specifications

Power requirements	100–240 V AC, 50│60 Hz
Max. Power Input	20 W
Max. inlet pressure	4500 mbar
Dimensions	315×150×280 mm
Weight	ca. 3.900 g
Languages	German, English, French, Italian, Spanish, Portuguese

Operating Conditions

Temperature	3–30°C.
Humidity	5–95% rel.

Measuring Ranges

Test pressure	0–3900 mbar
Max. inlet pressure	0–4500 mbar
Net volume	0.1–999 L

Measuring Accuracy

Rel. deviation pressure measurement	< 0.2%
Abs. deviation pressure measurement	max. ±4 mbar (@20°C)

Interfaces

External printer	Centronics 25 pol
Communication port	232, 9 pole male

Equipment Supplied

– Sartocheck® mini integrity test unit

– Low volume adapter for net volumes <5 L

– Printer paper (4 rolls)

– Pressure inlet tubing (18104)

– Pressure outlet tubing (18103)

– Carrier bag (soft case)

– Hard case

Order Information
26292---01

▶ Sartocheck® 3 Plus

Description

This unit supports all established integrity test methods and is characterized by its intuitive and easy handling. The Sartocheck® 3 Plus is not encumbered by the 21 CFR part 11 code as it is a paper based system and does not store test results electronically.

Main Features:

– Smart design

– Large colour TFT display

– User-friendly menu structure

– On-screen assistance

– Paper-based result documentation
  (21CFR part 11 not applicable)

– Up to 250 different test programs
  to be stored

– Password protected access

– Individual user profiles | rights to be defined

– SD card reader for storing | transferring
  test programs

– Reliable cleaning of the complete
  internal pneumatics

**Sartocheck® 3 Plus Performs the
Following Tests:**

– Bubble Point Test

– Diffusion Test

– Bubble Point and Diffusion Test
  (combined test)

– Pressure Drop Test

– Water Intrusion Test

– Water Flow Test

– Multipoint Diffusion Test

Data Storage

As a pure paper-based system the Sartocheck® 3 Plus does not have an electronic result database. However, the system allows to store up to 250 test programs within its internal memory. Test programs can be stored | archived on standard SD cards (Secure Digital memory Card).

Cleaning Function Guarantees Highest Process Security

The cleaning function of Sartocheck® 3 Plus allows you to flush all internal pneumatic parts completely. On-screen instructions guide you through all necessary steps. The automatic drying function guarantees that no cleaning liquid remains inside.

Because only stainless steel and PTFE is used for the internal pneumatic parts, the unit can be cleaned even with aggressive cleaning fluids (e.g. 1 M NaOH). This guarantees highest cleaning efficacy and therefore enhances the safety of the integrity testing procedure.

▷ Specifications

Power requirements	100–240 V AC, 50 | 60 Hz
Max. Power Input	74 watts
Max. operating pressure	9999 mbar | 145 psi
Minimum inlet pressure	4000 mbar | 58 psi
Dimensions (W × D × H)	460 × 390 × 212 mm

Measuring Ranges

Test pressure	100–8000 mbar | 1.5–116 psi
Pressure drop	1–2000 mbar | 0.01–29 psi
System inlet volume – with internal ref. Vessel – with external ref. Vessel	9000 ml max. 100 l

Measuring Accuracy

Pressure	± 0.1% full scale ± 9.5 mbar
Pressure drop	± 1 mbar
Volume determination	± 4%
Diffusion	± 5%
Water-Intrusion	± 5%
Bubble Point	± 50 mbar | ± 0.7 psi

Operating Conditions

Ambient temperature	+15 °C to +35 °C
Rel. humidity	10–80%

Colour Display

Size	8.4"
Resolution	640 × 480 pixel

Language Option | English German French Spanish Italian

Equipment Supplied

Sartocheck® 3 Plus	16290
Tubing for compressed gas inlet	18104
Tubing for compressed Gas outlet	18103
Ribbon cassette	6982141
Rolls of printer paper	6982142
Test certificate	
Calibration certificate	
Operating Instructions	
Validation Package	16290---VP
Mains lead (country specific)	

Accessories

Cleaning Kit	26288---CK
Ext. Reference Vessel (10 L)	16288---RV

1: external reference tank
2: Venting 1
3: Out
4: Venting 2
5: In

1: main switch
2: Service TU
3: Service MU

▶ Sartocheck® 4 plus

Fully Automatic Integrity Testing Device

Description

The Sartocheck® 4 plus is the result of Sartorius' 30 years experience in developing automatic filter integrity testers. Valuable productivity enhancing features and robust build quality have been combined with incredible ease of use to make the Sartocheck® 4 plus the only logical choice for integrity testing. The Sartocheck® 4 plus provides the following unique combination of benefits:

– Barcode Scanner for easy and reliable data entry (optional)

– Intelligent selection of test program after scanning the filter

– Combination of large, color touchscreen display with keypad

– External pressure sensor and external valves (optional)

– Automated cleaning function eliminates expensive service calls

– Sophisticated Cleaning Kit available (optional)

– Automatic detection of improper test setup (e.g. disconnected filters)

– Multitasking menu

– Electronic test reports in PDF format

– no thermo paper but dot matrix printer (longer print preservation)

– SD card reader for easy test program proliferation to other Sartocheck® testers

– Profibus communication (interface as accessory)

– Unparalleled accuracy and repeatability of results for all test types

– World class documentation, training, applications, and service support

– Allows concurrent filter testing by controlling up to four additional test units (optional MultiUnits)

– Fully compliant with 21 CFR Part 11

– Developed in accordance with GAMP

Integrity Test Methods

– Bubble Point Test (BPT)

– Diffusion Test (Diff)

– Combined Test (Diff + BPT)

– Pressure Drop Test

– Water Intrusion Test (WIT)

– Water Flow Test (WFT)

– Multipoint Diffusion Test

– Customer Specific Tests

– Automatic Test Time function for intelligent optimization of test times

Barcode Scanning

Using the optional barcode scanner allows easy and error-free entry of filter data into the unit. Sartocheck® 4 plus automatically locates the suitable test program that matches the scanned cartridge.

Cleaning Function

The patented cleaning function of Sartocheck® 4 plus allows the user to perform reliable cleaning of the complete internal pneumatics even with aggressive cleaning agents (up to 1 M NaOH). This unique feature provides highest security of the integrity testing procedure while eliminating the need for costly down time and service calls.

Network Concept

The network solution for the Sartocheck® 4 plus incorporates the TCP-IP and FTP protocol standards, with data being transmitted via the Ethernet standard. Via standard RJ45 connection, all data can be easily up-loaded on a FTP server. Profibus communication can be used to allow bidirectional communication with process control system as a basis for complete automation.

Multiunit Concept

In order to increase productivity through parallel filter testing, up to four additional MultiUnits can be easily connected to the Sartocheck® 4 plus. This provides the equiva-lent testing capacity of five Sartochecks operating concurrently at a significant cost savings to the end user.

Qualification

Sartocheck® 4 plus ensures that all integrity tests are carried out with highest precision and accuracy. Our comprehensive Sartocheck® 4 plus validation documentation and world-class Service Team provide exemplary support for the user.

▷ Specifications

Technical Specification

Power requirements	100 – 240 V AC 50 | 60 Hz
Max. Power Input	74 watts
Max. operating pressure	9999 mbar | 145 psi
Min. inlet pressure	4000 mbar | 58 psi
Dimensions (W × D × H1 × H2)	460 × 390 × 140 × 245

Measuring Ranges

Test Pressure	100-8000 mbar | 1.5-116 psi
Pressure drop	1-2000 mbar | 0.01-29 psi
System inlet volume	
– with int. reference vessel	14 L
– with ext. reference vessel	150 L

Measuring Accuracy

Pressure	± 0.1 % full scale
Pressure Drop	± 1 mbar (0.015 psi)
Volume Determination	± 4 %
Diffusion	± 5 %
Water Intrusion	± 5 %
Bubble Point	± 50 mbar ± 0.7 psi

Operating Conditions

Ambient temperature	+15℃ to +35℃
Rel. humidity	10-80%

Touch Screen

Size	10.4″ TFT
Features	256 colors

Communication Ports

Serial Port TU	RS232
Serial Port MU	RS485
PLC Port	binary signals 12 pins
Network	RJ45

Language Option	English German French Spanish Italian

Equipment Supplied

Sartocheck® 4 plus	26288
Inlet tubing for compressed gas	18104
Outlet tubing	18103
Ribbon cassette	6982141
Rolls of printer paper	6982142
Test certificate	
Calibration certificate	
Installation and operating instructions	
Validation package	26288---VP
Power cord	

Accessories

Barcode Scanner	26288---BS
Multiunit	16288---TU
External pressure transducer	1ZE---0018
Set for external venting (1 valve)	1ZE---0025
Valve set for external filling (WIT)	1ZE---0026
Serial Port Interface cable TU | TU	
0.5 m	1ZE---0008
2 m	1ZE---0009
5 m	1ZE---0010
Network Cable	
2 m	1ZE---0029
5 m	1ZE---0030
10 m	1ZE---0031
20 m	1ZE---0032
Cleaning Kit	26288---CK
Pressure Tank for Cleaning	26288---PV
External reference vessel (10 L)	16288---RV
Profibus Interface	16288---PI
Validation Package	26288---VP
Clean Room Venting Adapter	1ZE---0021
Midisart® Test Manifold 10×	1Z-LB-0002
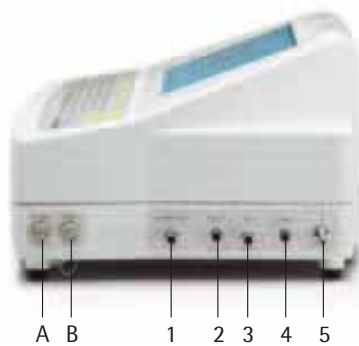
A   B   1   2   3   4   5

1: ext. reference tank
2: Venting 1
3: Out
4: Venting 2
5: Compressed Air In
A: external sensor
B: external valves

6 5   1   2   3   4

1: main switch
2: SD card reader
3: Serial Port TU
4: PLC Port
5: RJ45 Network
6: connection for optional barcode scanner

▶ Sartocheck® 4 MultiUnit

Next Generation of Filter Integrity Testing

Description
The Sartocheck® 4 MultiUnit has been developed to enable parallel integrity testing of multiple filters in the biopharmaceutical industry. The MultiUnit is an identical copy of the Sartocheck® 4, without the user interface and the data management system. Each MultiUnit connected to a Sartocheck® 4 or Sartocheck® 4 plus is operated and controlled by this Sartocheck® 4 (plus) via a RS485 connection.

Efficiency
Up to 4 MultiUnits can be connected to one Sartocheck® 4 (plus) allowing to integrity test up to 5 different filter systems in parallel including the testing capabilities of the Sartocheck® 4 (plus) itself. Testing up to 5 filters in parallel allows to reduce the time required for filter integrity testing in biopharmaceutical production significantly and increases the efficiency of your production process.

Flexibility
There is no relevant distance limitation between the Sartocheck® 4 (plus) and the connected MultiUnits. The MulitUnits can be placed all over your production facility and are centrally controlled and operated by the Sartocheck® 4 (plus). A printout of the test results of the MultiUnit is made by the printer of the Sartocheck® 4 (plus) and the test data can be transferred to a network for review and achiving.

Data Transfer Security
The Sartocheck® 4 MultiUnit is an independent test unit with its own power supply, electronics and pneumatics. It will maintain the test results even if switched off or if the connection is lost until the handshake communication with the Sartocheck® 4 (plus) confirms that the test results have been transferred successfully. If the MultiUnit is switched off during the test it will transfer a corresponding error message as soon as the communication has been automatically reestablished.

Traceability
The Sartocheck® 4 (plus) test result printout contains the serial number of the MultiUnit, the user name (log-on identity), a unique file name and all the information that has been entered in the batch protocol.

Patent Pending Thermal Insulation
The Sartocheck® 4 (plus) and its MultiUnit feature a unique, patent pending separation of the electronic components and the temperature sensitive pneumatics in addition to the efficient vent fan. This superior solution avoids any thermal influence on the integrity test measurement from the unit itself.

Clean Room Venting Adapter
The Sartocheck® 4 (plus) and its MultiUnit can be equipped with an optional venting fan adapter that allows to contain the out coming air in order to avoid any dispersion of particles in a clean room.

Sartorius Stedim Biotech Validation Package
The MultiUnit is delivered with a comprehensive validation package including an IQ & OQ protocol that can be accomplished by qualified Sartorius Stedim Biotech personnel. Assistance for PQ can also be provided from the Sartorius Stedim Biotech Technical Support team.

▷ Specifications

Technical Specifications

Power requirements	100 – 240 V AC 50 | 60 Hz
Maximum operating pressure	9999 mbar | 145 psi
Minimum inlet pressure	4000 mbar | 58 psi

Measuring Ranges

Test pressure	100 – 8000 mbar | 1.5 – 116 psi
Pressure drop	1 – 2000 mbar | 0.01 – 29 psi
System net volume	
– with internal ref. vessel	14 l
– with external ref. vessel	150 l

Measuring Accuracy

Pressure	± 0.1% full scale ± 9.5 mbar
Pressure drop	± 1 mbar
Volume determination	± 4%
Diffusion	± 5%
Water intrusion	± 5%
Bubble point	± 50 mbar | 0.7 psi

Operating Conditions

Ambient temperature	+15 to + 35℃
Relative humidity	10 – 80%
Max distance between SC4 and multiunit (RS485)	100 m

Order Information

Order number	16288---TU

Equipment Supplied

MultiUnit	16288---TU
Tubing for compressed gas inlet	18104
Tubing for test gas	18103
Test certificate	
Calibration certificate	
Installation and operating instructions	
Validation package	16288---VPTU
Mains lead (country specific)	

Accessories

External pressure Transducer	1ZE---0018
Valve kit for ext. venting (1 valve)	1ZE---0025
Valve kit for WIT and | or external pressure sensor (3 valves)	1ZE---0026
Cleaning kit	26288---CK
Clean room venting adapter	1ZE---0021

1. MultiUnit RS485 in \| out
2. MultiUnit RS485 in \| out
3. MultiUnit PLC in \| out
4. Sartocheck® 4 PLC in \| out
5. Sartocheck® 4 RS485 in \| out
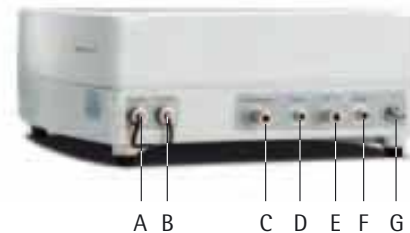
A. Ext. sensor
B. Ext. valve
C. Ext. reference tank
D. Venting 1
E. Outlet (test gas)
F. Venting 2
G. Inlet comp. gas

▶ WIT Trolley

Description
The WIT Trolley has been developed to make integrity testing of hydrophobic sterilizing grade filters safe and easy in the pharmaceutical industry. Both Water Intrusion and Water Flow tests can be performed. The Sartocheck® 4 (plus) pilots all the pneumatic valves via the integrated SIEMENS PLC. A PT100 sensor measures the water temperature in the water tank and avoids testing with water out of the predefined temperature range.

Installation
Due to its unique design and its fully automatic two step filling procedure the WIT Trolley can test all HIMA correlated hydrophobic sterilizing grade membrane filters at a horizontal distance of more than 100 m and a vertical distance of more than 15 m. The external thermal compensated pressure sensor is installed on the top of the housing and measures the pressure drop exactly where the intrusion│water flow take place. Moving the WIT Trolley during the measurement will have no incidence on the test value.

No Cross Contamination
The Trolley uses the principle of one way flow. Once the Sartocheck® 4 (plus) has pressurized the water tank and filled the housing to a stable pressure the filter housing is isolated by the filling valve. The gas overpressure in the water tank is vented directly at the water tank and does not go back via the Sartocheck® 4 (plus).

At the end of the integrity test the test water is drained via the draining valve directly at the housing and does not get in contact with neither the filling tubing nor the water tank.

In-Line Steam Decontamination
The Trolley can be steamed at max temperature of 134°C (266°F). The SIEMENS PLC supervises the steaming temperature at the lowest point using a second PT100 sensor. If the steaming temperature increases too much the inlet valve is closed. If the steaming temperature decreases too much the steaming cycle is interrupted and an error message is given. An optional extended steaming version of the Trolley allows for steaming of the filling hose.

Test Flexibility
Although connected to the Trolley the Sartocheck® 4 (plus) can perform all types of standard integrity testing via the auxiliary output thus giving a total test flexibility. It can also be connected to up to four MultiUnits (please see separate data sheet) in order to perform an additional test in parallel.

PLC Connector and Integration
The Sartocheck® 4 (plus) may be triggered by a 24V dry signal from a PLC. The Sartocheck® 4 (plus) printout clearly shows the difference between an integrity test that has been started by an operator from the Sartocheck® 4 (plus) touch screen│key board and via the PLC contact.

The WIT Trolley can thus be integrated into an automated process and deliver a "GO" or a "NO GO" for the following process steps.

Sartorius Stedim Biotech Validation Package
The Sartocheck® 4 (plus) and its Trolley are both delivered with a comprehensive validation package including an IQ & OQ protocol that can be accomplished by qualified Sartorius Stedim Biotech personnel. Assistance for PQ can also be provided from the Sartorius Stedim Biotech Technical Support team.

▷ Specifications

Technical Specifications

Power requirements	110 – 230 V AC 50 | 60 Hz
Maximum operating pressure	9999 mbar 145 psi
Minimum inlet pressure	4000 mbar 58 psi

Measuring Ranges

Test pressure	100 – 8000 mbar 1.5 – 116 psi
Pressure drop	1 – 2000 mbar 0.01 – 29 psi
System net volume	
- with internal ref. vessel	9000 ml
- with external ref. vessel	100 l

Order Information

Order number	17005A---L--5301

Measuring Accuracy

Pressure	± 0.1% full scale ± 9.5 mbar
Pressure drop	± 1 mbar
Volume determination	± 4%
Diffusion	± 5%
Water intrusion	± 5%
Bubble point	± 50 mbar 0.7 psi

Operating Conditions

Ambient temperature	+15 to + 35 °C
Relative humidity	10 – 80%
Max distance between SC4 and filter housing (horizontal)	100 m
Max distance between SC4 and filter housing (SC4 below)	25 m
Max distance between SC4 and filter housing (SC4 above)	15 m

Equipment Supplied

Trolley

Hose with valve battery for filling

Steam trap

Installation and operating instructions

Validation package

Mains lead (country specific)

Accessories

External pressure transducer*	1ZE---0018
Sartocheck® 4 plus*	26288

Optional Version

Extended steaming version	17005A---L--5501

* to be ordered separately;
  not part of 17005A---L--5301

1: Sartocheck® 4
2: Pneumatic & hydraulic compartment
3: Electrical compartment
4: OP7 screen

▶ Opta® SFT

Sterile Connector to be Integrated Into Sartorius Stedim Biotech Fluid Management Assemblies (Opta® SFT-I) and Also Available as Individual Device for End-User Assembly with Silicone Tubing (SFT-I) or TPE Tubing (SFT-D) and Autoclave Sterilization

Single-Use Technology

Description

The Opta® SFT Sterile Connector is a single-use device that allows a sterile connection between two separate, pre-sterilized components in biopharmaceutical manufacturing processes. Opta® SFT Sterile Connectors are quick and easy to use, and are backed by extensive validation work and 100% in house integrity testing.

The Opta® SFT-D is available as individual device for end-user assembly with TPE tubing and autoclave sterilization.

Ultra Safe Hose Barb Design

The dimensions of Opta® SFT-I hose barbs have been specifically designed to assure the robustness and the integrity of the engagement between hose barb and various types of tubing. This is a key requirement for sterile fluid transfer in critical biopharmaceutical applications. Special tools in manufacturing guarantee the proper attachment to any type of tubing. Thus the Opta® SFT-I Sterile Connector is supplied with Flexel® 3D and Flexboy® bags as part of integrated Sartorius Stedim Biotech Fluid Management assemblies. The Opta® SFT-I is also available as individual device for end-user assembly with silicone tubing and autoclave sterilization.

Ready to Autoclave or Gamma sterilised transfer sets with Opta® SFT-I are also available to ensure the counter connection to customers process equipment.

Features & Benefits

Male and female connector couplings sealed with sterilizing grade membrane	Allows for sterile fluid transfer in non classified & classified environments
Male and female connector couplings	Allows for "error proofing" of designs to prevent mistaken connections.
Sterilizable by Gamma irradiation & Autoclave	Flexible implementation of Hybrid single-use and multiple use technologies.
100% integrity tested	Highest security
Claimed size equivalent to tubing ID size	No flow restriction
3-step operation	Easy, Robust, Repeatable Operation
All hose barb connections intensively qualified (SFT-I only)	Safe and robust tubing connections
Fully integrated supply chain for Opta® SFT-I incorporating single-use assemblies from Sartorius Stedim Biotech	Streamlined supply chain, high security of supply

▷ **Specifications**

Operating Sequences

Materials for Male and Female Coupling

Connector body & collar	Polycarbonate
Seal	Santoprene
Membrane	Hydrophobic polyethersulfone
Protective cap	Polypropylene

Connections

Small connector body	¼", ³/₈" and ½" Hose Barb
Large connector body	½" and ¾" Hose Barb

Pressure Resistance

Max. operating pressure	3 bar (43.5 psi) at 40°C (104°F)

Sterilization Methods

Gamma irradiation	≤ 50 kGy
Autoclaving	20 minutes at 121°C (250°F)

Simple & Fast Operation Principle
The Opta® SFT Sterile Connector consists of a female and a male coupling body that once assembled create the sterile fluid path via an easy 3-step operation. The removal of the protective plastic caps attached to each coupling prepares for assembly. After sliding the male and female coupling heads together, the sterile barrier membrane is pulled out to create the sterile fluid path. Finally, the locking collar is screwed into place. The Opta® SFT Sterile Connector is now ready for the sterile fluid transfer.

1. Remove protective cap and connect the Opta® SFT male and female connectors – correct connection validated by a click

2. Remove membranes

3. Screw the collar – correct screwing validated by a click

Transfer fluid

Gamma sterilised

Gamma sterilised

Gamma sterilised

Gamma sterilised

Ready to autoclave

Customer process
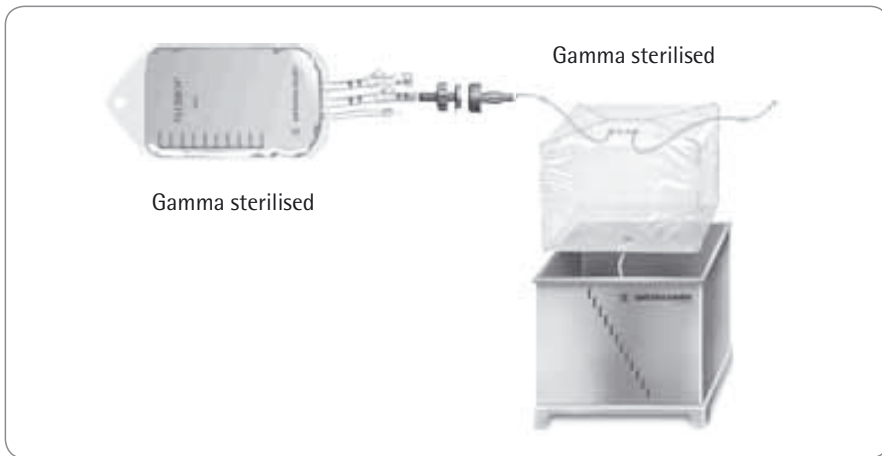
Integration
All Opta® SFT-I connectors can be integrated into custom Sartorius Stedim Biotech assembly including a full range of additional disposable components.

Opta® SFT-I are pre-assembled to bags, filters and tubing and then Gamma sterilised to offer a ready to use solution. They can also be assembled on tubing and filtration sets without Gamma sterilisation to offer ready to autoclave solutions to end users when autoclaving is required in the process.

100% Integrity Tested
All Opta® SFT Sterile Connectors are 100% integrity tested to assure the highest quality for critical applications like sterile fluid transfer.

Qualification
Opta® SFT Sterile Connector has been qualified applying the most stringent and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Opta® SFT sterile connectors with data representing a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Opta® SFT Sterile Connectors are tested for compliance to:

– USP <85>: Bacterial Endotoxin testing

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <645>: pH and conductivity

– USP <788> and E.P. 2.9.19: Particulate

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Details on methodologies and equipment used as well as further tests performed are available in the Validation Guide.
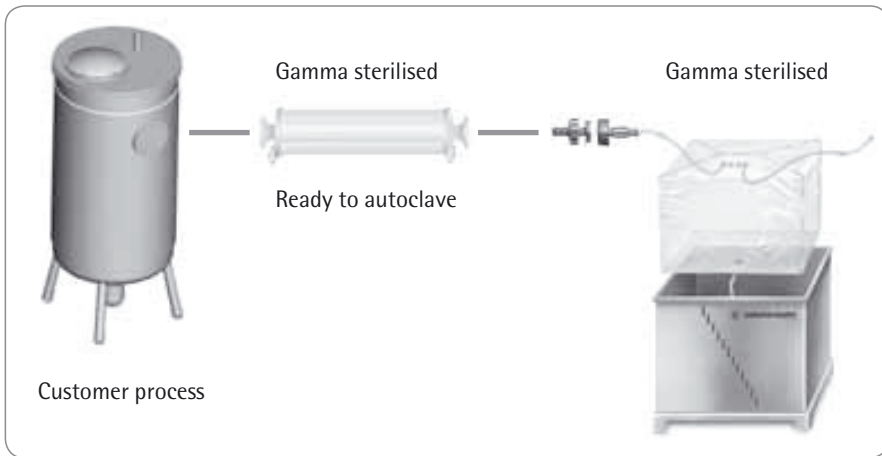
Sterile Fluid Transfer Validation

Opta® SFT Sterile Connectors has been validated to provide a sterile fluid transfer path under worst case conditions. In order to provide the assurance that the Opta® SFT can provide a sterile fluid path in your process, a comprehensive validation, including immersion of the male and female connector bodies in a bacterial suspension prior to connection, followed by the transfer and subsequent incubation of growth promotion medium has been performed. Complete details of this validation are available in our validation guide.

Applications

Opta® SFT Sterile Connectors are used to create a sterile fluid path between two presterilized components in classified as well as non classified production environments. All operations in Up – and Downstream Processing that are using single-use or hybrid equipment can benefit from the Opta® SFT Sterile Connector from Sartorius Stedim Biotech.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes for its fully integrated disposable assemblies. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Ordering Information

Part Number to be Specified in FMT Assembly Specifications	Description
640MS014M	OPTA® SFT-I Sterile Connector, 1/4" Hose Barb, Male Small Connector Body
640FS014M	OPTA® SFT-I Sterile Connector, 1/4" Hose Barb, Female Small Connector Body
640MS038M	OPTA® SFT-I Sterile Connector, 3/8" Hose Barb, Male Small Connector Body
640FS038M	OPTA® SFT-I Sterile Connector, 3/8" Hose Barb, Female Small Connector Body
640MS012M	OPTA® SFT-I Sterile Connector, 1/2" Hose Barb, Male Small Connector Body
640FS012M	OPTA® SFT-I Sterile Connector, 1/2" Hose Barb, Female Small Connector Body
640ML012M	OPTA® SFT-I Sterile Connector, 1/2" Hose Barb, Male, Large Connector Body
640FL012M	OPTA® SFT-I Sterile Connector,1/2" Hose Barb, Female, Large Connector Body
640ML034M	OPTA® SFT-I Sterile Connector, 3/4" Hose Barb, Male, Large Connector Body
640FL034M	OPTA® SFT-I Sterile Connector, 3/4" Hose Barb, Female, Large Connector Body

Product Code	Description	Pack Size
640MS014M---D	OPTA® SFT-I Sterile Connector, 1/4" Hose Barb, Male Small Connector Body, For assembly with silicone tubing.	10
640FS014M---D	OPTA® SFT-I Sterile Connector, 1/4" Hose Barb, Female Small Connector Body, For assembly with silicone tubing.	10
640MS038M---D	OPTA® SFT-I Sterile Connector, 3/8" Hose Barb, Male Small Connector Body, For assembly with silicone tubing.	10
640FS038M---D	OPTA® SFT-I Sterile Connector, 3/8" Hose Barb, Female Small Connector Body, For assembly with silicone tubing.	10
640MS012M---D	OPTA® SFT-I Sterile Connector, 1/2" Hose Barb, Male Small Connector Body, For assembly with silicone tubing.	10
640FS012M---D	OPTA® SFT-I Sterile Connector, 1/2" Hose Barb, Female Small Connector Body, For assembly with silicone tubing.	10
640ML012M---D	OPTA® SFT-I Sterile Connector, 1/2" Hose Barb, Male, Large Connector Body, For assembly with silicone tubing.	10
640FL012M---D	OPTA® SFT-I Sterile Connector, 1/2" Hose Barb, Female, Small Connector Body, For assembly with silicone tubing.	10
640ML034M---D	OPTA® SFT-I Sterile Connector, 3/4" Hose Barb, Male, Large Connector Body, For assembly with silicone tubing.	10
640FL034M---D	OPTA® SFT-I Sterile Connector, 3/4" Hose Barb, Female, Small Connector Body, For assembly with silicone tubing.	10
641MS014M---D	OPTA® SFT-D Sterile Connector, Male Small Connector Body, 1/4" Hose Barb, For assembly with TPE tubing	10
641FS014M---D	OPTA® SFT-D Sterile Connector, Female Small Connector Body, 1/4" Hose Barb, For assembly with TPE tubing	10
641MS038M---D	OPTA® SFT-D Sterile Connector, Male Small Connector Body, 3/8" Hose Barb, For assembly with TPE tubing	10
641FS038M---D	OPTA® SFT-D Sterile Connector, Female Small Connector Body, 3/8" Hose Barb, For assembly with TPE tubing	10
641MS012M---D	OPTA® SFT-D Sterile Connector, Male Small Connector Body, 1/2" Hose Barb, For assembly with TPE tubing	10
641FS012M---D	OPTA® SFT-D Sterile Connector, Female Small Connector Body, 1/2" Hose Barb, For assembly with TPE tubing	10

► Standard Flexboy® Bioprocessing Bags

Description
Standard Flexboy® Bioprocessing bags are designed for the preparation, storage and transport of biopharmaceutical solutions, intermediates and final bulk products. They provide a single-use alternative to traditional glass, stainless steel and rigid plastic carboys in a large variety of applications.

Applications
The broad chemical compatibility of Flexboy® Bags assures the safe processing of a wide range of biopharmaceutical fluids in a variety of applications:

– Buffers and Media sterile
  filtration & storage

– Bulk Harvest

– Product pooling

– Fraction collection

– Sample collection

– Bulk intermediate hold

– Final Product transport

Cost Reduction and Risk Reduction
Single-Use Systems used in biopharmaceutical manufacturing improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Cost and time consuming CIP & SIP operations are minimized. This results not only in significant cost savings within the entire manufacturing process, but also in the optimization of capacity utilization.

Flexibility
Standard Flexboy® bags are available as stand-alone bags and filter & bag assemblies incorporating a variety of filter and bag sizes allowing easy adaptation to process volume and media. Multiple configurations that also integrate thermoweldable TPE tubing are provided for flexible incorporation into your process. Thus, sterile connection and disconnection devices like the BioWelder® and the BioSealer® can be used to allow safe connections and disconnections from and to another process step.

Female luer fittings with a needle-free sampling port allow easy and convenient sampling, quick connects may be attached directly or adapted to a variety of connections and mini triclamps that are constantly used in industrial environment assure maximum flexibility.

Easy Implementation
Standard Flexboy® Bags are available in bag chamber volumes between 5 mL and 50 L. They are supplied sterilized and ready to use. This allows an easy and convenient process implementation. A series of associated systems such as Flexboy® Trays and Racks facilitate an easy bag handling. Sartorius Stedim Biotech supports users already at the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation of Single-Use Manufacturing.

Features	Benefits
Multiple manufacturing sites	High security of supply
100% integrity testing of bag and immediate connection	Process safety and integrity
All connections extensively qualified	Safe and robust
Full compliance with ISO11137	Highest sterility assurance level
Standard design	Most designs available from stock

▷ Specifications

Bag Chamber	Multiple Film Construction, EVA Fluid Contact Layer
Tubing	EVA, TPE
Fittings	Female Luer Lock, MPC Male Coupling, Mini Triclamp, Needle free sampling port
Filters	Sartopore® 2 Gamma Filter Capsule
Number of Ports	3 (except for 5 mL: 1 Port)
Volumes	5 mL – 50 L
Sterilization	by Gamma Irradiation

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Validation
Flexboy® bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexboy® with data representing the widest range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows sterility assurance level validation of 10^{-6} for each Single-Use System over its entire shelf life.

Quality Assurance
Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Flexboy® bags are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Rapid Supply
The majority of Standard Flexboy® storage systems are available from stock.

Dimensions

5 mL – 3 L

Volume	5 mL	50 mL	150 mL	250 mL	500 mL	1 L	2 L	3 L
Length (L) mm	70 (2.76")	134 (5.28")	205 (8.07")	230 (9.06")	241 (9.49")	299 (11.77")	319 (12.56")	381 (15.00")
Width (W) mm	59 (2.32")	95 (3.74")	85 (3.35")	94 (3.70")	130 (5.12")	155 (6.10")	223 (8.78")	223 (8.78")
Length inc. Tubing (T) mm	110 (4.33")	231 (9.09")	302 (11.89")	327 (12.88")	338 (13.31")	396 (15.59")	416 (16.39")	478 (18.82")
Film Surface Area cm^2	21 (3.3 in^2)	143 (22.2 in^2)	275 (42,6 in^2)	329 (51.0 in^2)	452 (70.0 in^2)	707 (109.6 in^2)	1103 (171.0 in^2)	1346 (208.7 in^2)

5 L – 50 L

Volume	5 L	10 L	20 L	50 L
Length (L) mm	376 (14.80")	621 (24.45")	654 (25.75")	790 (31.10")
Width (W) mm	332 (13.07")	300 (11.81")	431 (16.97")	580 (22.83")
Length inc. Tubing (T) mm	473 (18.62")	718 (28.27")	749 (29.57")	887 (34.92")
Film Surface Area cm^2	1929 (299.0 in^2)	3528 (546.9 in^2)	4826 (748.0 in^2)	8106 (1256.4 in^2)

Ordering Information

1. Standard Flexboy® with EVA Tubes

1.1. Standard Flexboy® with EVA Tubes (5 mL with Luer® Lock Connection) (All Countries Except USA and Canada)
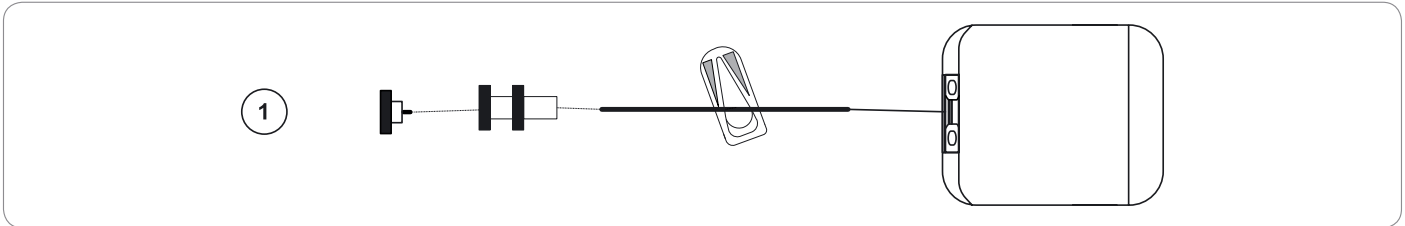
Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB115270	Flexboy® 5 mL	EVA	3/16" × 1/4" × 5 cm (2") Female LL + plug, slide clamp	NA	NA	100

1.2. Standard Flexboy® with EVA Tubes (50 mL to 3 L with Luer Lock Connection)
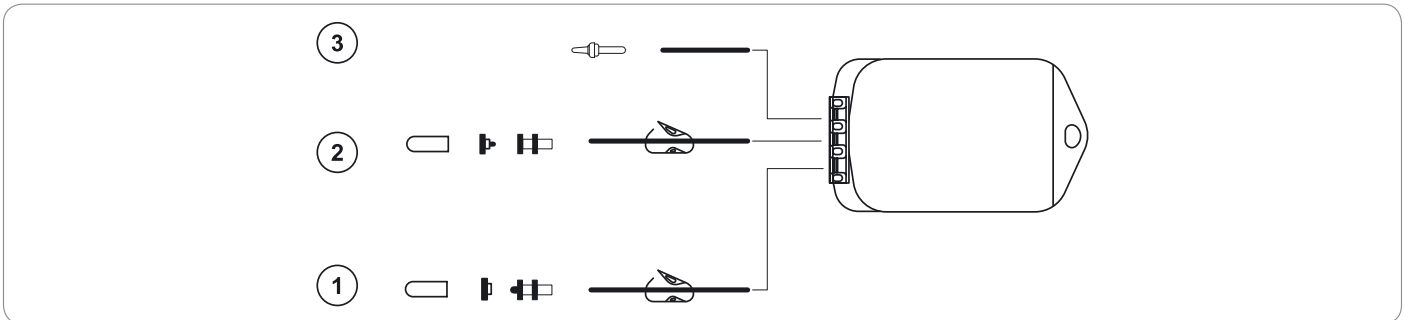
Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB102603	Flexboy® 50 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102643	Flexboy® 150 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102670	Flexboy® 500 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB103547	Flexboy® 1000 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102812	Flexboy® 3000 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20

1.3. Standard Flexboy® with EVA Tubes (50 mL to 3 L with Luer Lock Connection) (USA and Canada)

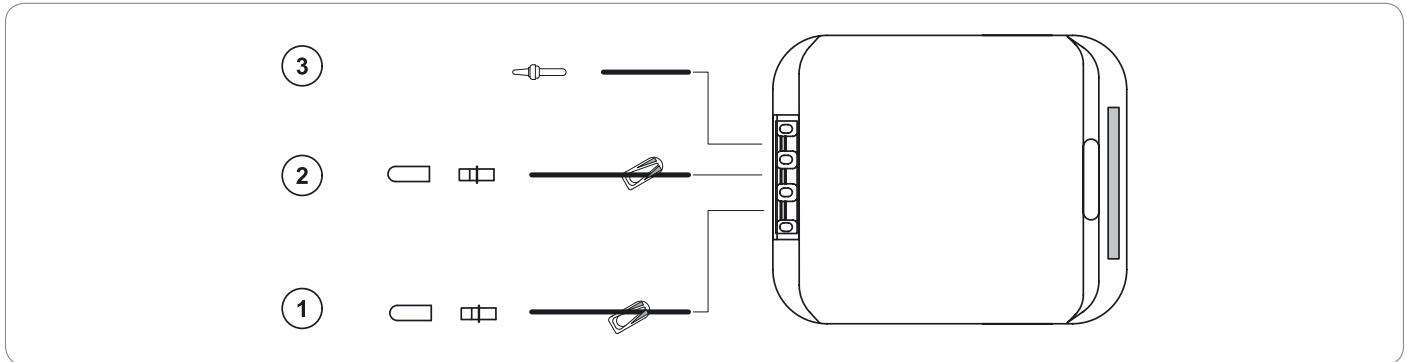| Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB207567	Flexboy® 50 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	50
FFB207568	Flexboy® 150 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	50
FFB207569	Flexboy® 250 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	50
FFB207570	Flexboy® 500 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	50
FFB207571	Flexboy® 1000 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	50
FFB207572	Flexboy® 2000 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	50
FFB207573	Flexboy® 3000 ml	EVA	1/4" × 5/16" × 10 cm (4") LL male + Cap, pinch clamp	1/4" × 5/16" × 10 cm (4") LL female + Cap, pinch clamp	3/16" + 1/4" + 5 cm (1,97 in.) + septum	50

Ordering Information (All Countries)

1.4. Standard Flexboy® with EVA Tubes (50 mL to 3 L with MPC Connection)
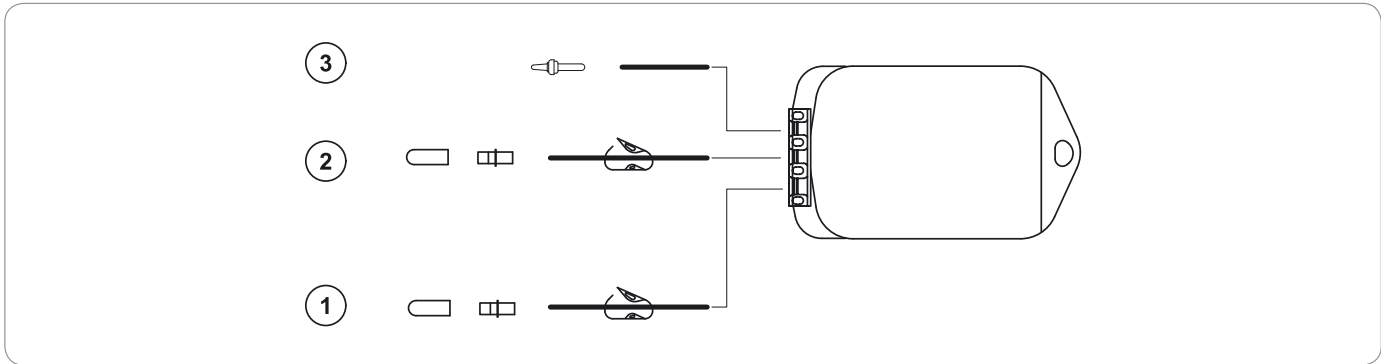
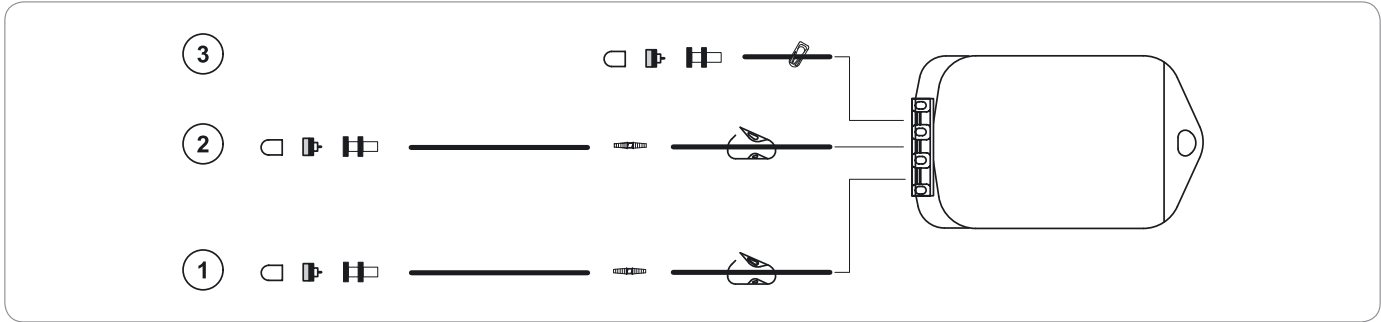| Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB102640	Flexboy® 50 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102877	Flexboy® 150 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB103398	Flexboy® 500 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102606	Flexboy® 1000 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102704	Flexboy® 3000 ml	EVA	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	1/4" × 5/16" × 10 cm (4") MPC male + dust cap, pinch clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20

Ordering Information

1.5. Standard Flexboy® with EVA Tubes (5 L to 50 L with MPC Connection) (All Countries Except USA and Canada)

Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB102025	Flexboy® 5 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB101974	Flexboy® 10 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB101961	Flexboy® 20 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB102340	Flexboy® 50 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20

1.6. Standard Flexboy® with EVA Tubes (5 L to 50 L with MPC Connection) (USA and Canada)

Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB207582	Flexboy® 5 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB207583	Flexboy® 10 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB207584	Flexboy® 20 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20
FFB207586	Flexboy® 50 liter	EVA	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/8" × 15/32" × 10 cm (4") MPC Male + dust cap, slide clamp	3/16" × 1/4" × 5 cm (1,97 in.) + septum	20

Ordering Information (All Countries)

2. Standard Flexboy® with TPE Tubes

2.1.Standard Flexboy® with TPE Tubes (150 mL)

Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB110898	Flexboy® 150 ml	EVA + Clear C-Flex 374	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, dust cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, dust cap, pinch clamp	EVA port tube + slide clamp + LL female + needle free sampling port, dust cap	50

2.2. Standard Flexboy® with TPE Tubes (1 L to 3 L)
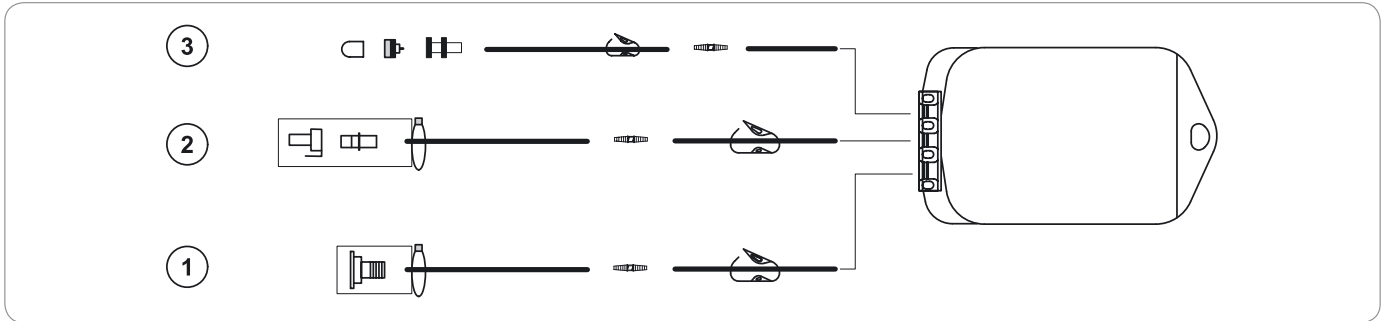
Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB110900	Flexboy® 1000 ml	EVA + Clear C-Flex 374	1/4" × 7/16" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/4" × 7/16" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110902	Flexboy® 3000 ml	EVA + Clear C-Flex 374	1/4" × 7/16" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/4" × 7/16" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20

Ordering Information (All Countries)
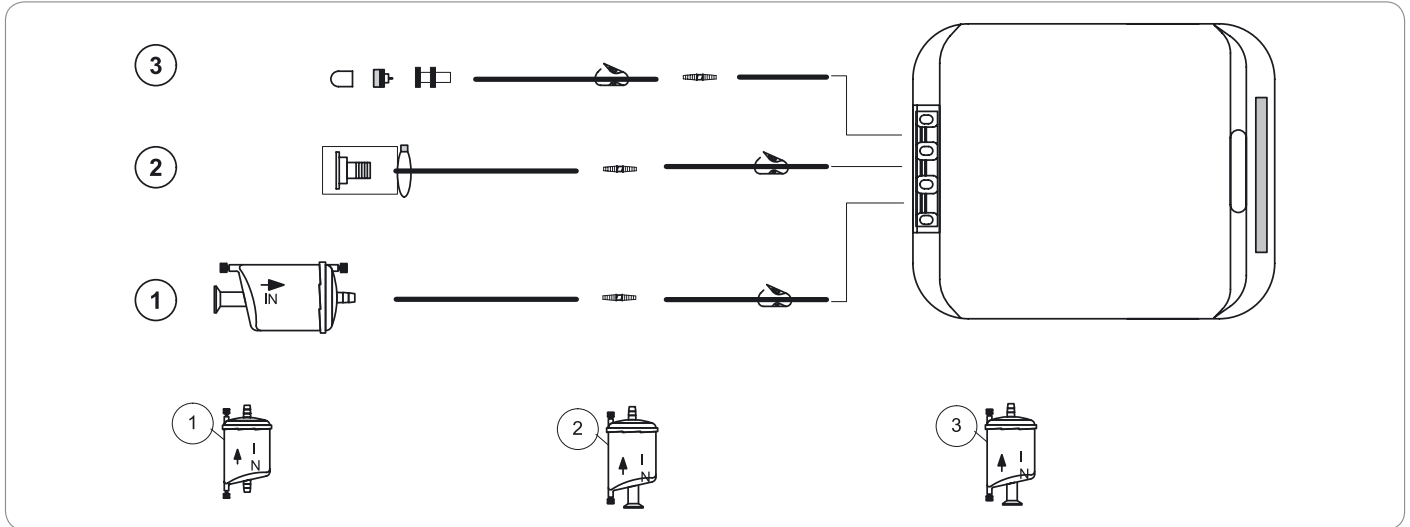
2.3. Standard Flexboy® with TPE Tubes (5 L to 50 L)
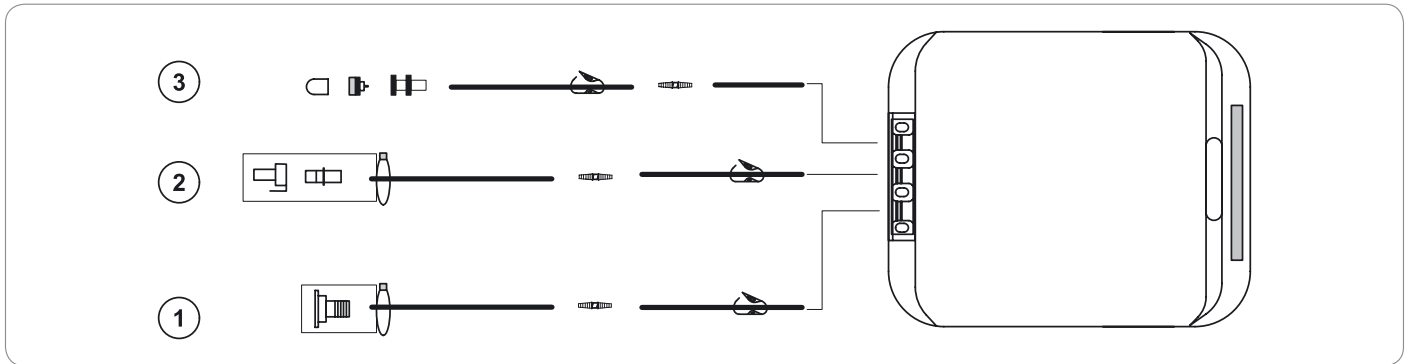
Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB110904	Flexboy® 5 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	3/8" × 5/8" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110905	Flexboy® 10 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	3/8" × 5/8" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110906	Flexboy® 20 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	3/8" × 5/8" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10
FFB110907	Flexboy® 50 liter	EVA + Clear C-Flex 374	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	3/8" × 5/8" × 50 cm (20") MPC Male + sealing cap, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10

Ordering Information (All Countries)

3. Standard Flexboy® with TPE Tubes & Sartopore® 2 Gamma Capsules

3.1. Standard Flexboy® with TPE Tubes (1 L to 3 L)

Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB110908	Flexboy® 1000 ml	EVA + Clear C-Flex 374	1/4" × 7/16" × 50 cm (20") 5441307H4G-OO, Sartopore 2, 0.2 µm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 150 cm^2, pinch clamp	1/4'' × 7/16'' × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110909	Flexboy® 3000 ml	EVA + Clear C-Flex 374	1/4" × 7/16" × 50 cm (20") 5441307H4G-OO, Sartopore 2, 0.2 µm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 150 cm^2, pinch clamp	1/4'' × 7/16'' × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20

Ordering Information (All Countries)

3.2.Standard Flexboy® with TPE Tubes (5 L to 50 L)

Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Qty/Box
FFB110910	Flexboy® 5 liter	EVA + Clear C-Flex 374	3/8'' × 5/8'' × 50 cm (20") 5441307H5G-OO, Sartopore 2, 0.2 μm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 300 cm², pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110911	Flexboy® 10 liter	EVA + Clear C-Flex 374	3/8'' × 5/8'' × 50 cm (20") 5441307H5G-OO, Sartopore 2, 0.2 μm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 300 cm², pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	20
FFB110912	Flexboy® 20 liter	EVA + Clear C-Flex 374	3/8'' × 5/8'' × 50 cm (20") 5441307H5G-OO, Sartopore 2, 0.2 μm, filter inlet: 1/4" stepped Hose Barb filter outlet: 1/4" stepped Hose Barb; 300 cm², pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10
FFB110913	Flexboy® 50 liter	EVA + Clear C-Flex 374	1/2'' × 3/4'' × 50 cm (20") 5441307H7G-SM, Sartopore 2, 0.2 μm, filter inlet: 1.5" Sanitary flange filter outlet: 5/8" Hose Barb; 500 cm², pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10
FFB110915	Flexboy® 50 liter	EVA + Clear C-Flex 374	1/2'' × 3/4'' × 50 cm (20") 5441358K7G-SM, Sartopore 2, 0.1 μm, filter inlet: 1.5" Sanitary flange filter outlet: 5/8" Hose Barb; 500 cm², pinch clamp	3/8" × 5/8" × 50 cm (20") 3/4" Triclamp, pinch clamp	1/8" × 1/4" × 50 cm (20") LL female + needle free sampling port, pinch clamp	10

► Flexboy® Tray and Rack System

Description
The Flexboy® Tray and Rack Systems are designed to facilitate handling of both individual and manifold Flexboy® Single-Use Bioprocessing Bags (5 L–20 L) within bio-pharmaceutical manufacturing processes.

Applications
The Flexboy® Tray and Rack Systems are designed to support Flexboy bags for the safe processing & transfer of a wide range of biopharmaceutical fluids in applications such as:

– Buffer and Media storage

– Bulk harvest

– Product pooling

– Fraction collection

– Sample collection

– Bulk intermediate hold

– Final product transport

Flexibility
The modular Tray and Rack System offers the possibility to expand the system according to process needs. Swivel wheels integrated in the rack allow individual or manifold Flexboy® bags to be easily moved around the facility.

Additional rack systems focused on specific application demands are available upon request.

Safety
Smooth finish and integrated handles make the system both user friendly and safe. This allows reliable stacking of additional modules by maintaining highest safety levels.

Technology Integration Support
Sartorius Stedim Biotech supports users already at the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation and validation of Single-Use Manufacturing.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of design-ing Single-Use solutions based on collabora-tive supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Quality Assurance
The Flexboy® Tray and Rack Systems are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. They undergo extensive testing before shipping.

Available from Stock
Flexboy® Tray and Rack Systems are available from stock.

▷ Specifications

Specifications Tray & Lid

Material	Stainless Steel 304L
Surface Finish	Bead Blasted
Volumes	5 L, 10 L and 20 L

Dimensions	
5 L	475 × 330 × 117 mm (18.7" × 12.9" × 4.6")
10 L	760 × 330 × 117 mm (29.9" × 12.9" × 4.6")
20 L	770 × 404 × 170 mm (30" × 15.9" × 6.7")

Weight of Tray | bag & Lid
(Bag filled to nominal volume)

5 L	8.6 kg
10 L	15.7 kg
20 L	28.6 kg
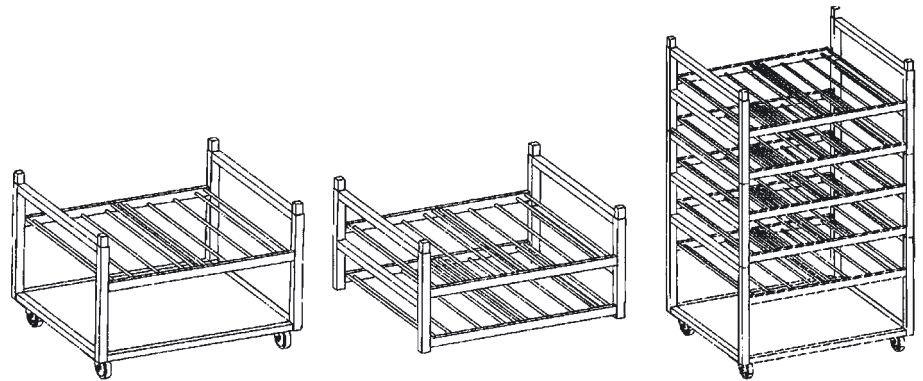
Base module 1
H: 772 mm × L: 887 mm × W: 775 mm
(30.4" × 34.9" × 30.5")

Module 2
H: 640 mm × L: 887 mm × W: 775 mm
(25.2" × 34.9" × 30.5")

Full version
H: 1980 mm × L: 887 mm × W: 775 mm
(77.9" × 34.9" × 30.5")

	Base Module 1	Additional Module 2	Full System
Material	Stainless steel 304	Stainless steel 304	Stainless steel 304
Surface finish	Blast	Blast	Blast
Weight	30.5 kg	26 kg	82.5 kg
Flexboy® tray compartments	2 places for 20 L Trays or 4 places for 5 or 10 L Trays	4 places for 20 L Trays or 8 places for 5 or 10 L Trays	10 places for 20 L Trays or 20 places for 5 or 10 L Trays
Peristaltic pumps Compartment	Yes – Dimension: 887 × 775 × 300 mm (34.9" × 30.5" × 11.8")	No	Yes – Dimension: 887 × 775 × 300 mm (34.9" × 30.5" × 11.8")
Wheels	4 swivel wheels (two with brakes)	–	4 swivel wheels (two with brakes)
Additional features	Built in wheels (non autoclavable)	–	Full = 1 base + 2 additional modules

Ordering Information

Order Code	Description
Flexboy® Racks	
FFA102707	Flexboy® Rack	Base Module 1
FFA102714	Flexboy® Rack	Module 2
Flexboy® Trays	
FFA102705	Flexboy® Tray + Lid 5 L
FFA102715	Flexboy® Tray + Lid 10 L
FFA102716	Flexboy® Tray + Lid 20 L

Please note: Custom versions are available upon request.

▶ Standard Flexel® 3D Bioprocessing Bags for Palletank®

Single-Use Technology

Description
Flexel® 3D standard bags are designed for processing, storage and transport of large volume biopharmaceutical solutions in Sartorius Stedim Biotech's proven Palletank® containers. They provide a single-use alternative to traditional stainless steel vessels in a large variety of applications.

Cost Reduction and Risk Reduction
Single-use systems used in biopharmaceutical manufacturing improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Costly and time consuming CIP & SIP operations are minimized. This results not only in significant cost savings within the entire manufacturing process, but also in the optimization of capacity utilization.

Applications
The multi-layer film construction of different materials provides a strong structure with low gas permeability and high chemical resistance for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications such as:

– Buffers and media filtration & storage

– Bulk harvest

– Product pooling

– Fraction collection

– Sample collection

– Bulk intermediate filtration & hold

– Final product storage and transport

Flexibility
Standard Flexel® 3D bags are available as stand-alone bags with silicone tubing, stand-alone bags with C-Flex tubing and filter & bag assemblies incorporating a variety of filter and bag sizes allowing easy adoption to process volume and media. Multiple configurations that also integrate thermoweldable TPE tubing are provided for flexible incorporation into your process. Thus, sterile connection and disconnection devices like the BioWelder® and the BioSealer® can be used to allow safe connections and disconnections from and to another process step.

Female luer fittings with a needle free sampling port may be used for easy and convenient sampling, quick connects may be attached directly or adapted to a variety of connections and tri-clamps that are widely used in a production environment assure maximum flexibility.

Fast Operation
The new defined range of standard Flexel® 3D bag systems incorporates 1,000 L standard bag solutions that enable the user to empty the bags quickly through a ¾" ID tubing.

Features	Benefits
Multiple manufacturing sites	High security of supply
All connections extensively qualified	Safe and robust
Full compliance with ISO11137	Highest sterility assurance level
Standard design	Most designs available from stock
Designed to fit Palletank®	Market leading space saving bag containment system
¾" ID bottom drain	Quick transfer of process fluid
Various bag & filter sizes	High flexibility

▷ Specifications

Standard Flexel® 3D for Palletank®

Bag Chamber	Multiple layer film construction, including EVOH gas barrier layer ULDPE contact layer
Tubing	Silicone, TPE
Fittings	MPX Couplings, Female Luer Lock, MPC Male Coupling, Triclamp, Needle-less sampling port
Filters	Sartopore® 2 Gamma Filter Capsule
Volumes	100 L–1,000 L
Number of Ports	Standard silicone: 100 L–1,000 L: 3 (2 top, 1 bottom)
	Standard TPE: 100 L–1,000 L: 4 (3 top, 1 bottom)
	Standard TPE & Sartopore® 2: 100 L–1,000 L: 4 (3 top, 1 bottom)
Sterilization	by Gamma Irradiation

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions combined with collaborative supplier management and customer demand planning assures a state of the art product supported by a robust supply chain that can cope with strong market growth.

Validation

Flexel® bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testings provide users of Flexel® 3D bags with data representing the widest range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-use products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Flexel® 3D bags for Palletank® are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Supply Chain

The majority of standard Flexel® 3D bags for Palletank® systems are available from stock.

Ordering Information (All Countries Except USA and Canada)

1. Standard Flexel® 3D Bags with Silicone Tubes
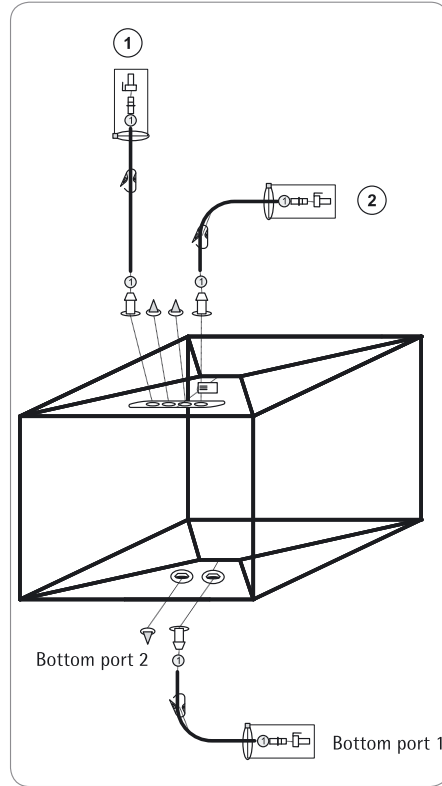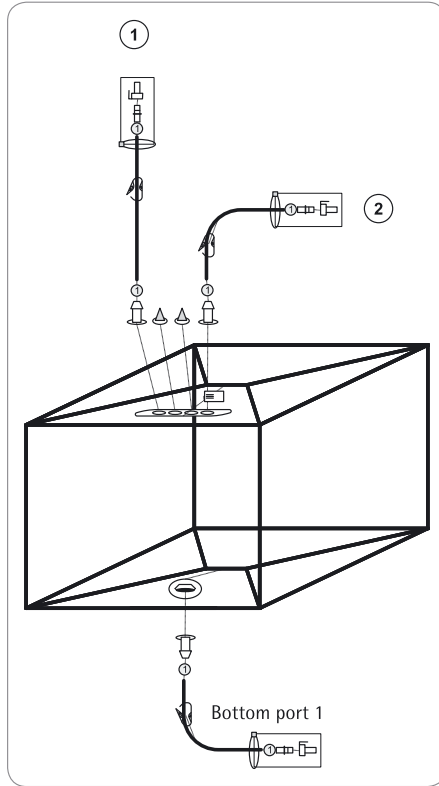
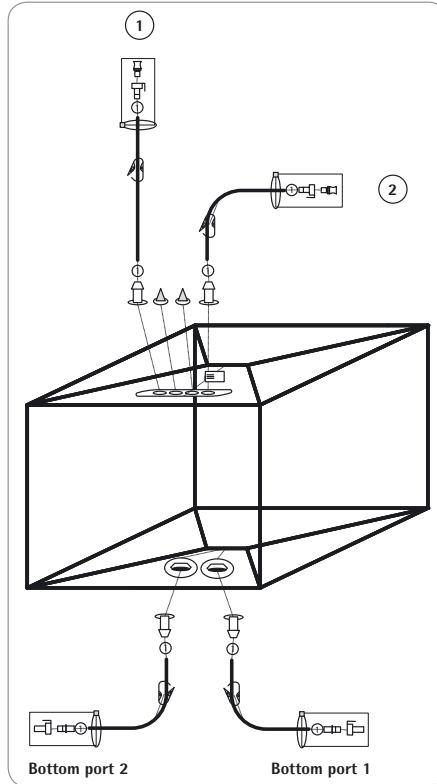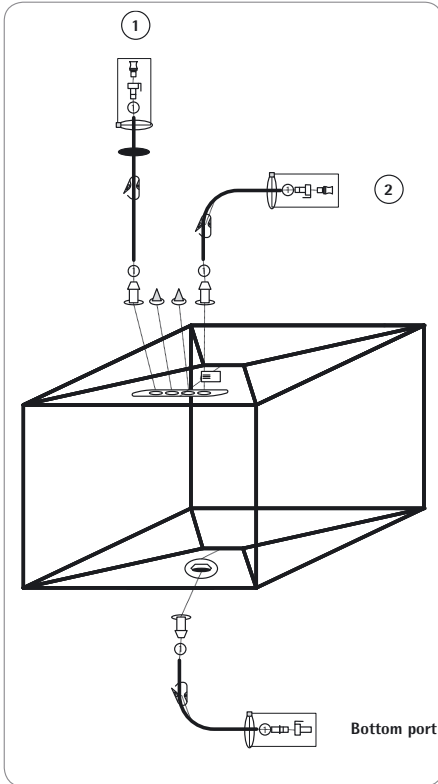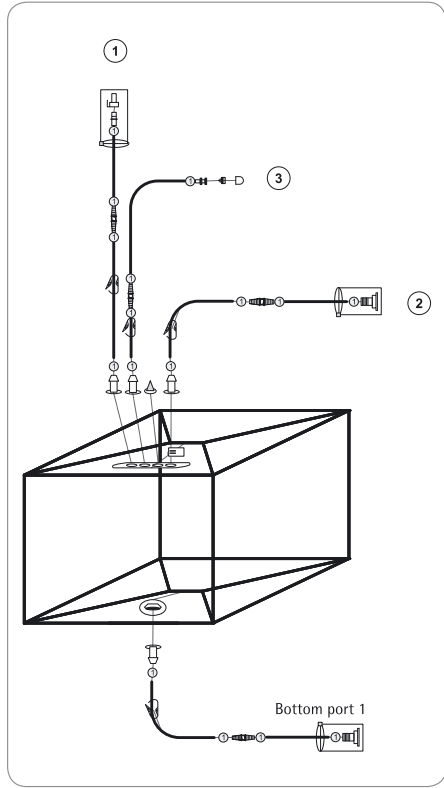Standard Flexel® 3D bags with silicone tubes (100 L to 500 L)   Standard Flexel® 3D bags with silicone tubes (1,000 L)

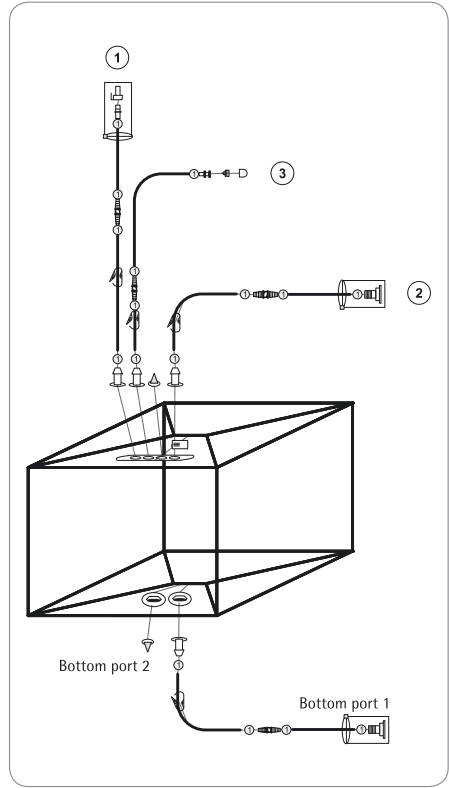| Part Number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Qty/Box
FXB103341	Flexel® 100 L for Palletank® – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	5
FXB103364	Flexel® 200 L for Palletank® – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	5
FXB103376	Flexel® 500 L for Palletank® – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	5

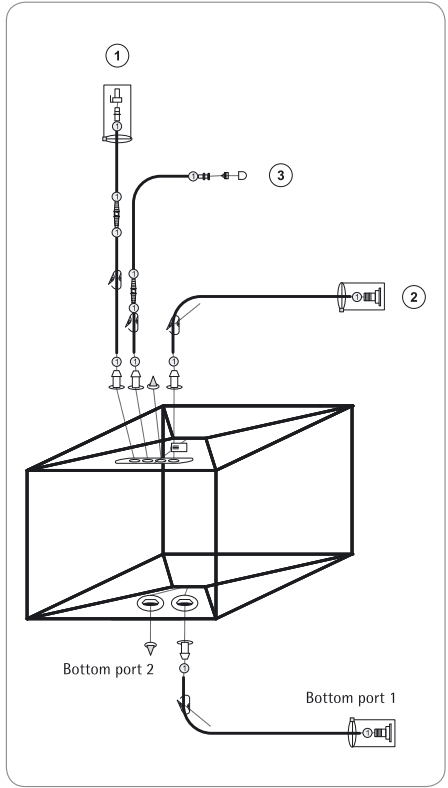| Part Number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Bottom Port 2	Qty/Box
FXB103426	Flexel® 1000 L for Palletank® – Silicone	Silicone	1/2" × 11/16" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 11/16" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 11/16" × 1 m (40") 1/2" MPX male + sealing cap	Plug	5

Ordering Information (USA and Canada)

1. Standard Flexel® 3D Bags with Silicone Tubes

Standard Flexel® 3D bags with silicone tubes (100 L to 500 L)   Standard Flexel® 3D bags with silicone tubes (1,000 L)

Part Number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Qty/Box
FXB207591	Flexel® 100 L for Palletank® with GammaTag™	Silicone	1/2" × 11/16" × 1.5 m (60"), 1/2" MPX female + sealing plug	1/2" × 11/16" × 1.5 m (60"), 1/2" MPX female + sealing plug	1/2" × 11/16" × 1 m (40") 1/2" MPX male + sealing cap	10
FXB207592	Flexel® 200 L for Palletank® with GammaTag™	Silicone	1/2" × 11/16" ×1.5 m (60"), 1/2" MPX female + sealing plug	1/2" × 11/16" × 1.5 m (60"), 1/2" MPX female + sealing plug	1/2" × 11/16" × 1 m (40"), 1/2" MPX male + sealing cap	10
FXB207593	Flexel® 500 L for Palletank® with GammaTag™	Silicone	1/2" × 11/16" × 1.5 m (60"), 1/2" MPX female + sealing plug	1/2" × 11/16" × 1.5 m (60"), 1/2" MPX female + sealing plug	1/2" × 11/16" × 1 m (40"), 1/2" MPX male + sealing cap	3

Part Number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Bottom Port 2	Qty/Box
FXB207595	Flexel® 1000 L for Palletank® – Silicone	Silicone	1/2" × 11/16" × 1.5 m (60") 1/2" MPX female + sealing plug	1/2" × 11/16" × 1.5 m (60") 1/2" MPX male + sealing plug	1/2" × 11/16" × 1 m (40") 1/2" MPX male + sealing cap	1/2" × 11/16" × 1 m (40") 1/2" MPX male + sealing cap	5

Ordering Information (All Countries)

2. Standard Flexel® 3D Bags with TPE Tubes

Standard Flexel® 3D bags with TPE tubes (100 L to 500 L)
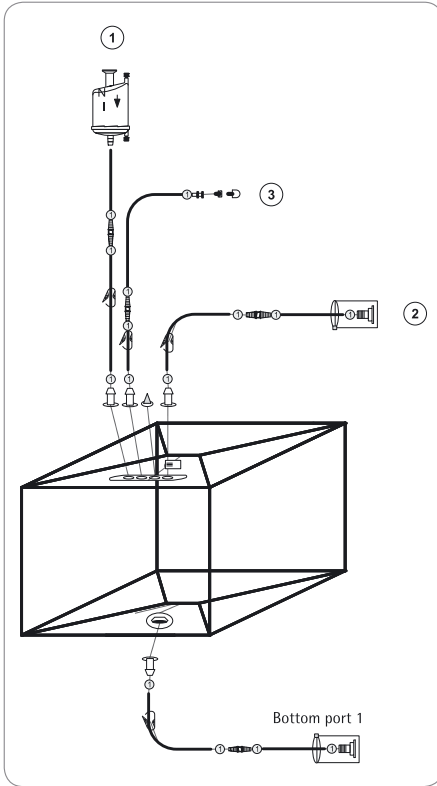
Standard Flexel® 3D bags with TPE tubes (1,000 L)

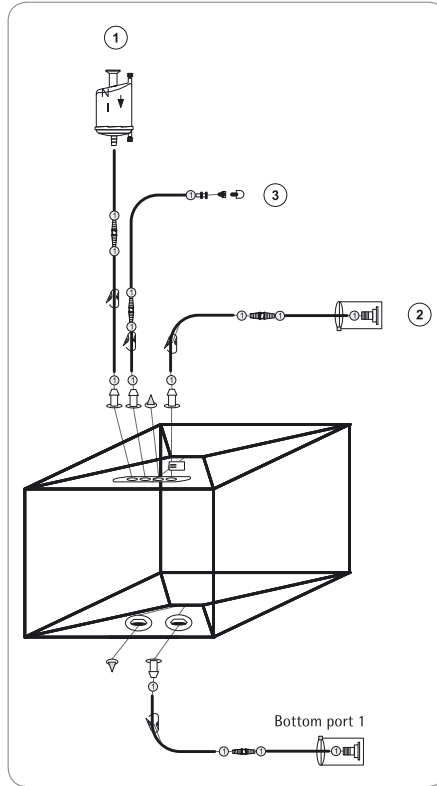Standard Flexel® 3D bags with TPE tubes
High Flow Rate(1,000 L)

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110925	Flexel® 100 L for Palletank® – PTE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	4
FXB110927	Flexel® 200 L for Palletank® – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FXB110929	Flexel® 500 L for Palletank® – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FXB110930	Flexel® 1000 L for Palletank® – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FXB111157	Flexel® 1,000 L for Palletank® – HIGH FLOW – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	3/4" × 1-1/8" × 1.5 m (60") silicone 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	3/4" × 1-1/8" × 1.5 m (60") silicone 1-1/2" Tri-Clamp	2

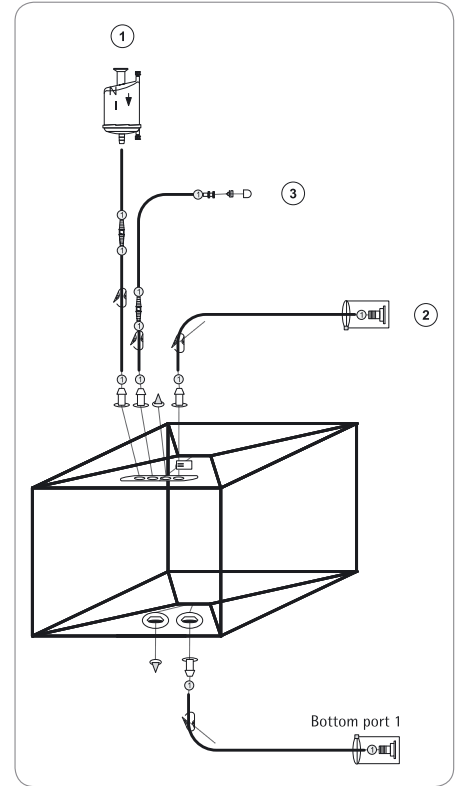## Ordering Information (All Countries)

3. Standard Flexel® 3D Bags with TPE Tubes and Sartopore® 2 Gamma MidiCaps

Standard Flexel® 3D bags with TPE tubes and
Sartopore® 2 Gamma MidiCaps (100 L to 500 L)

Standard Flexel® 3D bags with TPE tubes and
Sartopore® 2 Gamma MaxiCaps (1,000 L)

Standard Flexel® 3D bags with TPE tubes and
Sartopore® 2 Gamma MaxiCaps – High Flow rate (1,000 L)

Standard Flexel® 3D Bags with TPE Tubes and Sartopore® 2 Gamma MidiCaps, 0.2 μm (100 L to 500 L)

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110962	Flexel® 100 L for Palletank® – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 8, 0.2 μm, filter inlet 1.5" sanitary flange 1,000 cm²	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	3
FXB110964	Flexel® 200 L for Palletank® – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 9, 0.2 μm, filter inlet 1.5" sanitary flange 2,000 cm²	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FXB110966	Flexel® 500 L for Palletank® – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 0, 0.2 μm, filter inlet 1.5" sanitary flange 4,500 cm²	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2

Ordering Information (All Countries)

Standard Flexel® 3D Bags with TPE Tubes and Sartopore® 2 Gamma MidiCaps, 0.1 µm (100 L to 500 L)

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110975	Flexel® 100 L for Palletank® – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 8, 0.1 µm, filter inlet 1.5" sanitary flange 1,000 cm²	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	3
FXB110976	Flexel® 200 L for Palletank® – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 9, 0.1 µm, filter inlet 1.5" sanitary flange 2,000 cm²	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FXB110977	Flexel® 500 L for Palletank® – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 0, 0.1 µm, filter inlet 1.5" sanitary flange 4,500 cm²	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2

Standard Flexel® 3D Bags with TPE Tubes and Sartopore® 2 Gamma MaxiCaps, 0.2 and 0.1 µm (1,000 L)

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110967	Flexel® 1,000 L for Palletank® – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MaxiCaps size 2, 0.2 µm, filter inlet 1.5" sanitary flange 1.2 m²	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1
FXB110978	Flexel® 1,000 L for Palletank® – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MaxiCaps size 2, 0.1 µm, filter inlet 1.5" sanitary flange 1.2 m²	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1

Ordering Information (All Countries)

Standard Flexel® 3D Bags with TPE Tubes and Sartopore® 2 Gamma MaxiCaps (1,000 L – High Flow Rate)

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB111153	Flexel® 1,000 L for Palletank® HIGH FLOW – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MaxiCaps size 2, 0.2 µm, filter inlet 1.5" sanitary flange 1.2 m²	3/4" × 1–1/8" × 1.5 m (60") silicone 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	3/4" × 1–1/8" × 1.5 m (60") silicone 1–1/2" Tri-Clamp	1
FXB111154	Flexel® 1,000 L for Palletank® HIGH FLOW – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MaxiCaps size 2, 0.1 µm, filter inlet 1.5" sanitary flange 1.2 m²	3/4" × 1" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	3/4" × 1" × 1.5 m (60") 1–1/2" Tri-Clamp Silicone	1

▶ Standard Flexel® 3D Bioprocessing Bags for Drums

Single-Use Technology

Description
Flexel®3D standard bags are designed for processing, storage and transport of large volume biopharmaceutical solutions in drums. They provide a single-use alternative to traditional stainless steel vessels in a large variety of applications.

Cost Reduction and Risk Reduction
Single-use Systems used in biopharmaceutical manufacturing improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Costly and time consuming CIP & SIP operations are minimized. This results not only in significant cost savings within the entire manufacturing process, but also in the optimization of capacity utilization.

Applications
The multi-layer film construction of different materials provides a strong structure with low gas permeability and high chemical resistance for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications such as:

– Buffers and Media filtration & storage

– Bulk harvest

– Product pooling

– Fraction collection

– Sample collection

– Bulk intermediate filtration & hold

– Final product storage and transport

Flexibility
Standard Flexel® bags for drums are available as stand-alone bags with Silicone tubing, stand-alone bags with C-Flex tubing and Filter & Bag assemblies incorporating a variety of filter and bag sizes allowing easy adoption to process volume and media. Multiple configurations that also integrate thermoweldable TPE tubing are provided for flexible incorporation into your process. Thus, sterile connection and disconnection devices like the BioWelder® and the BioSealer® can be used to allow safe connections and disconnections from and to another process step.

Female luer fittings with a needle free sampling port may be used for easy and convenient sampling, quick connects may be attached directly or adapted to a variety of connections and tri-clamps that are widely used in a production environment assure maximum flexibility.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions combined with collaborative supplier management and customer demand planning assures a state of the art product supported by a robust supply chain that can cope with strong market growth.

Features	Benefits
Multiple manufacturing sites	High security of supply
All connections extensively qualified	Safe and robust
Full compliance with ISO11137	Highest sterility assurance level
Standard design	Most designs available from stock
Various bag & filter sizes	High flexibility

▷ Specifications

Standard Flexel®3D for Drum

Bag Chamber	Multiple layer film construction, including EVOH gas barrier layer, ULDPE Contact Layer
Tubing	Silicone, TPE
Fittings	MPX Couplings, Female Luer Lock, MPC Male Coupling, Triclamp, Needle free sampling port
Filters	Sartopore® 2 Gamma Capsule
Volumes	50 L – 560 L
Sterilization	by Gamma Irradiation

Validation
Flexel® bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® with data representing the widest range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Quality Assurance
Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror bio-pharmaceutical operations and meet cGMP requirements.

Flexel® 3D bags are tested for compliance to:
– USP <87>: Biological reactivity tests, in Vitro
– USP <88>: Biological reactivity tests, in Vivo
– USP <661>: Tests for plastic
– USP <788> and E.P. 2.9.19: Particulate
– ISO 11737: Bioburden
– ISO 11137: Sterilization of Medical devices

Supply Chain
The majority of Standard Flexel® 3D bags for drum systems are available from stock.

Ordering Information

1. Standard Flexel® 3D Bags for Drum with Silicone Tubes (All Countries Except USA and Canada)
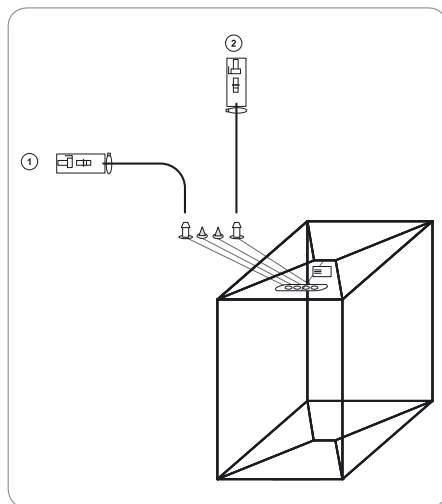
Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Top Port 4	Qty/Box
FXB103162	Flexel® 50 L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB102464	Flexel® 100 L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB102465	Flexel® 200 L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB103294	Flexel® 300 L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB103367	Flexel® 370 L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB102167	Flexel® 560 L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB102508	Flexel® 1,000 L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5

Ordering Information (USA and Canada)
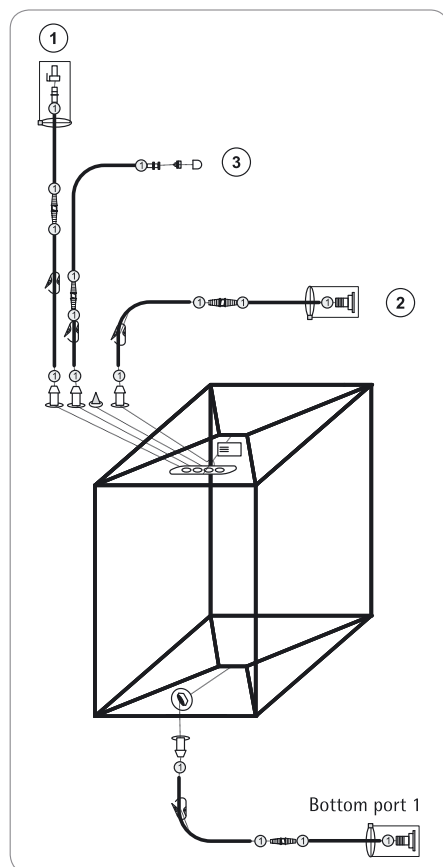
1. Standard Flexel® 3D Bags for Drum with Silicone Tubes
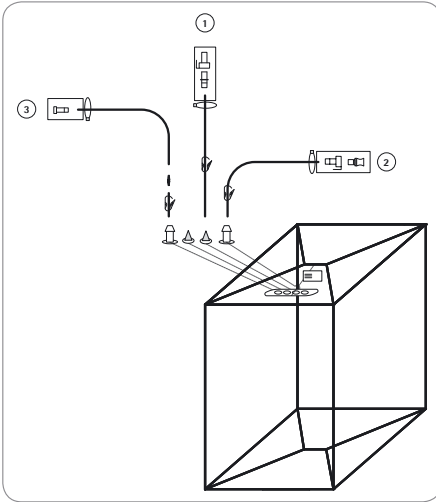
Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Top Port 4	Qty/Box
FXB207614	Flexel® 50 L for drum – Silicone	Silicone	1/2" × 3/4" × 0.75 m (30"), 1/2" MPX male + sealing cap	1/2" × 3/4" × 0.75 m (30"), 1/2" MPX female + sealing plug	1/8" × 1/4" × 0.45 (30") TPE, sealing plug	Plug	10
FXB207615	Flexel® 100 L for drum – Silicone	Silicone	1/2" × 3/4" × 0.75 m (30"), 1/2" MPX male + sealing cap	1/2" × 3/4" × 0.75 m (30"), 1/2" MPX female + sealing plug	1/8" × 1/4" × 0.45 (30") TPE, sealing plug	Plug	10
FXB207616	Flexel® 200 L for drum – Silicone	Silicone	1/2" × 3/4" × 0.75 m (30"), 1/2" MPX male + sealing cap	1/2" × 3/4" × 0.75 m (30"), 1/2" MPX female + sealing plug	1/8" × 1/4" × 0.45 (30") TPE, sealing plug	Plug	5
FXB207630	Flexel® 650 L for drum – Silicone	Silicone	1/2" × 3/4" × 0.75 m (30"), 1/2" MPX male + sealing cap	1/2" × 3/4" × 0.75 m (30"), 1/2" MPX female + sealing plug	1/8" × 1/4" × 0.45 (30") TPE, sealing plug	Plug	4

Ordering Information (All Countries)

**2. Standard Flexel® 3D Bags for Drum with Silicone & TPE Tubes**

2.1. Standard Flexel® 3D Bags for Drum with Silicone & TPE Tubes with Side Bottom Drain

Bottom port 1

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110917	Flexel® 50 L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110919	Flexel® 100 L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110920	Flexel® 200 L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m. (60") 1-1/2" Tri-Clamp	5
FXB111626	Flexel® 300 L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB111631	Flexel® 370 L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110921	Flexel® 560 L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2

Ordering Information (All Countries)

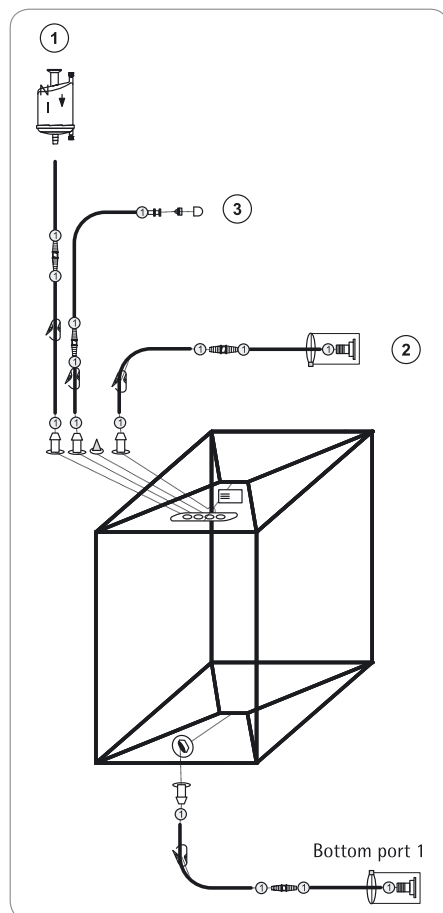**2.2. Standard Flexel® 3D Bags for Drum with Silicone & TPE Tubes**
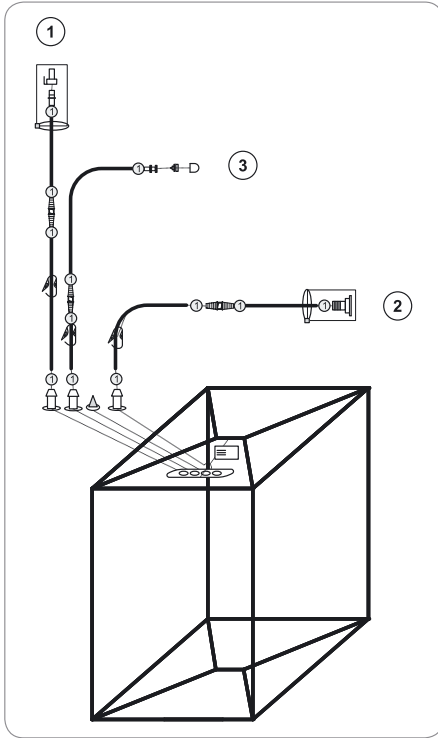
Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110922	Flexel® 50 L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110923	Flexel® 100 L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110924	Flexel® 200 L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5

Ordering Information (All Countries)

3. Standard Flexel® 3D Bags for Drum with Silicone & TPE Tubes & Sartopore® 2 Gamma MidiCaps

3.1. Standard Flexel® 3D Bags for Drum with Silicone & TPE Tubes with Side Bottom Drain & Sartopore® 2 Gamma MidiCaps 0.2 μm (50 L to 370 L)

Bottom port 1

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110954	Flexel® 50 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2'' × 3/4'' × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 7, 0.2 μm; filter inlet 1.5" sanitary flange 500 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110958	Flexel® 100 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2'' × 3/4'' × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 8, 0.2 μm; filter inlet 1.5" sanitary flange 1000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110960	Flexel® 200 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2'' × 3/4'' × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 9, 0.2 μm; filter inlet 1.5" sanitary flange 2000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5

Ordering Information (All Countries)

3.1. Standard Flexel® 3D Bags for Drum with Silicone & TPE Tubes with Side Bottom Drain & Sartopore® 2 Gamma MidiCaps 0.2 µm (50 L to 370 L)
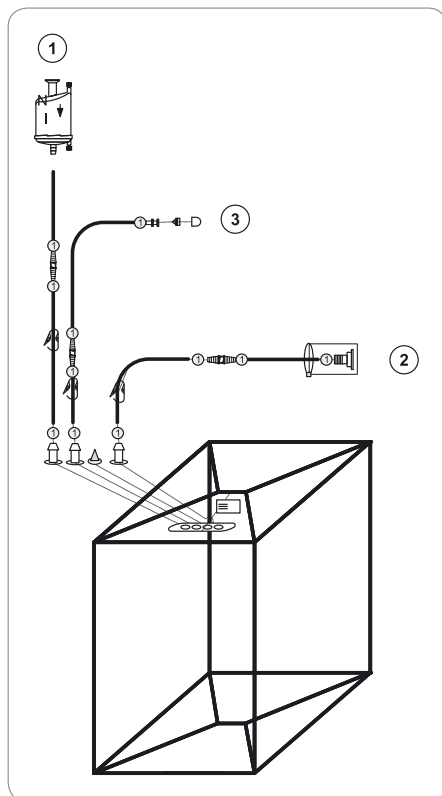
Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB111629	Flexel® 300 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") filter inlet 1.5" sanitary flange Sartopore® 2 Gamma, MidiCaps size 9, 0.2 µm, 2000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111633	Flexel® 370 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") filter inlet 1.5" sanitary flange Sartopore® 2 Gamma, MidiCaps size 9, 0.2 µm, 2000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2

3.2. Standard Flexel® 3D Bags for Drum with Silicone & TPE Tubes with Side Bottom Drain & Sartopore® 2 Gamma MidiCaps 0.1 µm (50 L to 370 L)

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110969	Flexel® 50 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") filter inlet 1.5" sanitary flange Sartopore® 2 Gamma, MidiCaps size 7, 0.1 µm, 500 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110971	Flexel® 100 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") filter inlet 1.5" sanitary flange Sartopore® 2 Gamma, MidiCaps size 8, 0.1 µm, 1000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110973	Flexel® 200 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") filter inlet 1.5" sanitary flange Sartopore® 2 Gamma, MidiCaps size 9, 0.1 µm, 2000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB111630	Flexel® 300 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") filter inlet 1.5" sanitary flange Sartopore® 2 Gamma, MidiCaps size 9, 0.1 µm, 2000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111634	Flexel® 370 L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") filter inlet 1.5" sanitary flange Sartopore® 2 Gamma, MidiCaps size 9, 0.1 µm, 2000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2

Ordering Information (All Countries)

3.3. Standard Flexel® 3D Bags for Drum with Silicone & TPE Tubes & Sartopore® 2 Gamma MidiCaps 0.2 µm (50 L to 200 L)

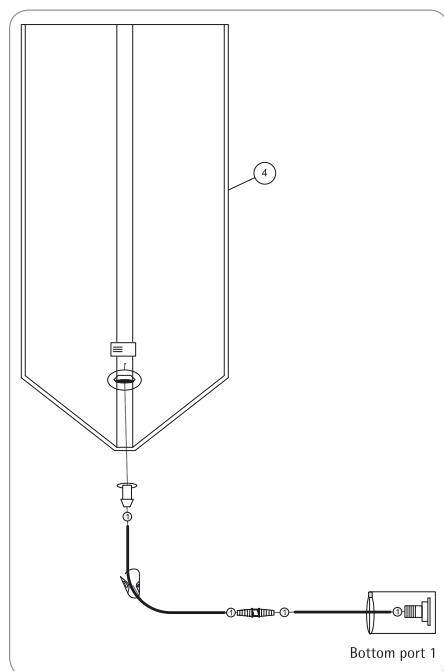| Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110955	Flexel® 50L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2'' × 3/4'' × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 7, 0.2 µm; filter inlet 1.5" sanitary flange 500 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp + needle free sampling port	1/8" × 1/4" × 1.1 m (40") LL female	No bottom drain	5
FXB110959	Flexel® 100L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2'' × 3/4'' × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 8, 0.2 µm; filter inlet 1.5" sanitary flange 1000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110961	Flexel® 200L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2'' × 3/4'' × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 9, 0.2 µm; filter inlet 1.5" sanitary flange 2000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5

Ordering Information (All Countries)

3.3. Standard Flexel® 3D Bags for Drum with Silicone & TPE Tubes & Sartopore® 2 Gamma MidiCaps 0.1 μm (50 L to 200 L)

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110970	Flexel® 50L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 7, 0.1 μm; filter inlet 1.5" sanitary flange 500 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110972	Flexel® 100L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 8, 0.1 μm; filter inlet 1.5" sanitary flange 1000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110974	Flexel® 200L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") Sartopore® 2 Gamma, MidiCaps size 9, 0.1 μm; filter inlet 1.5" sanitary flange 2000 cm²	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5

Ordering Information (All Countries)

4. Standard Flexel® Tank Liners for Drum

4.1. Standard Sterile Flexel® Tank Liners for Drum with Side Bottom Drain

Bottom port 1

| Part Number	Description	Tubing	Bottom Port 1	Qty/Box
FXB110931	Flexel® 30 L liner – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB110934	Flexel® 50 L liner – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB110936	Flexel® 100 L liner – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB110937	Flexel® 200 L liner – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB111636	Flexel® 300 L liner – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB111637	Flexel® 370 L liner – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB110939	Flexel® 560 L liner – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110940	Flexel® 1,000 L liner – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5

Ordering Information (All Countries Except USA and Canada)

4.2. Standard Flexel® Tank Liners for Drum
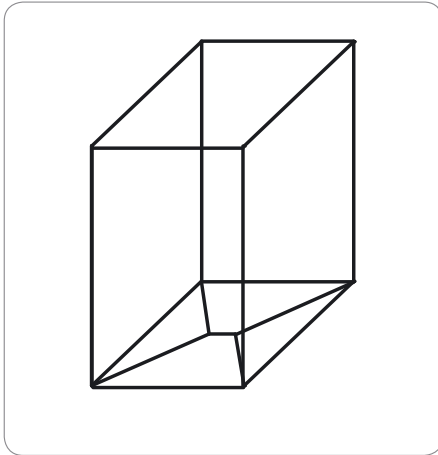
Part Number	Description	Sterility	Qty/Box
FXB102120	Flexel® 50 L liner	Non sterile	20
FXB102116	Flexel® 100 L liner	Non sterile	20
FXB102117	Flexel® 200 L liner	Non sterile	20
FXB102119	Flexel® 300 L liner	Non sterile	20
FXB103406	Flexel® 370 L liner	Non sterile	20
FXB103357	Flexel® 560 L liner	Non sterile	20
FXB111118	Flexel® 30 L liner	Sterile	10
FXB103126	Flexel® 50 L liner	Sterile	40
FXB103087	Flexel® 100 L liner	Sterile	20
FXB102965	Flexel® 200 L liner	Sterile	20
FXB103132	Flexel® 300 L liner	Sterile	10
FXB103318	Flexel® 370 L liner	Sterile	15
FXB103368	Flexel® 560 L liner	Sterile	20

Ordering Information (USA and Canada)

4.2. Standard Flexel® Tank Liners for Drum
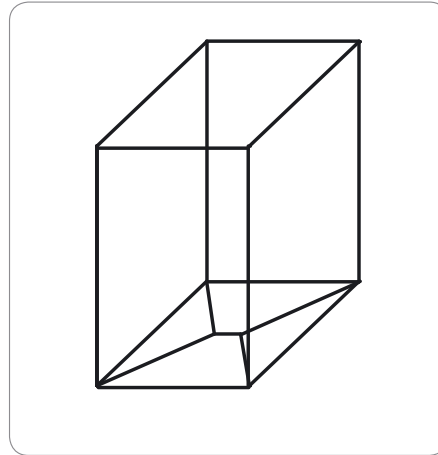
Part Number	Description	Sterility	Qty/Box
FXB207551	Flexel® 50 L liner	Non sterile	20
FXB207552	Flexel® 100 L liner	Non sterile	20
FXB207553	Flexel® 200 L liner	Non sterile	20
FXB207554	Flexel® 300 L liner	Non sterile	20
FXB207555	Flexel® 370 L liner	Non sterile	20
FXB207556	Flexel® 560 L liner	Non sterile	10
FXB207557	Flexel® 750 L liner	Non sterile	10
FXB207558	Flexel® 1,000 L liner	Non sterile	10
FXB207559	Flexel® 50 L liner	Sterile	20
FXB207560	Flexel® 100 L liner	Sterile	20
FXB207561	Flexel® 200 L liner	Sterile	20
FXB207562	Flexel® 300 L liner	Sterile	20
FXB207563	Flexel® 370 L liner	Sterile	20
FXB207564	Flexel® 560 L liner	Sterile	10
FXB207565	Flexel® 750 L liner	Sterile	10
FXB207084	Flexel® 1,000 L liner	Sterile	10

▶ Standard Scalable Flexel® 3D Bioprocessing Bags

Single-Use Technology

Description

Standard Scalable Flexel® 3D Bioprocessing Bags are designed for processing and storage of small volume biopharmaceutical solutions. They provide a single-use alternative to traditional glass, stainless steel and rigid plastic carboys in a large variety of applications. With a volume range of 5 L to 50 L, the Standard Scalable Flexel® 3D Bags are routinely used in bioresearch, process development and in small volume biomanufacturing. These bags are manufactured with very high quality standards for applications requiring remarkable levels of robustness, reliability and security.

Scaling-up operations to very large volume (up to 3000 L) is straightforward starting with Scalable Flexel® 3D Bags as they are manufactured with the same S40 film, same 3D bag technology and same port technology as the very large volume Flexel® 3D Bags. Standard Scalable Flexel® 3D Bags are available with an extensive range of accessories (trays, racks, Palletank, reusable handle, BioWelder®, BioSealer®, GammaTag®) for a rapid and functional deployment of a complete single-use engineered liquid handling and storage solutions in your process.

Cost Reduction and Risk Reduction

Single-use systems used in biopharmaceutical manufacturing improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Costly and time consuming CIP & SIP operations are minimized. This results not only in significant cost savings within the entire manufacturing process, but also in the optimization of capacity utilization.

Applications

Standard Scalable Flexel® 3D Bioprocessing Bags are constructed from S40, a multi-layer film that provides a strong structure with low gas permeability and high chemical resistance for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications.

Typical applications requiring robust container storage include:

– Buffers and cell culture media filtration and storage

– Product harvest

– Product pooling

– Fraction collection

– Viral inactivation & filtration

– Bulk intermediate filtration & hold

– Final product storage

Features	Benefits
Multiple manufacturing sites	High security of supply
All connections extensively qualified	Safe and robust
Full compliance with ISO11137	Highest sterility assurance level
Standard design	Most designs available from stock
Various bag size	High flexibility
Designed to fit standard tray and Palletank®	Space saving containment systems
Scalable S40 film	Process scalability with the same product contact materials from 5 L to 3000 L

Flexibility
Standard Scalable Flexel® 3D Bags are available for a fast implementation in a customer process, using pre-defined bag configurations. The bag configurations may be readily customized to optimize the integration into a specific application and process using pre-qualified and off the shelf OPUS components. Sartorius Stedim Biotech supports user design with a comprehensive support program that ensures successful design implementation of Single-Use Manufacturing.

Easy Implementation
Standard Scalable Flexel® 3D Bags are available with volume of 5 L, 10 L, 20 L and 50 L. They are supplied sterilized and ready to use for easy and convenient process implementation. A 50 L configuration with thermoweldable TPE tubing is provided for flexible incorporation into your process. Sterile connection and disconnection devices like the BioWelder® and the BioSealer® can be used to allow safe connections and disconnections from and to another process step.

A series of associated systems such as reusable handle, plastic and stainless steel Trays, Racks and Palletanks® facilitates bag handling, transportation and storage. 50 L Flexel® 3D Bag assembly is equipped with a GammaTag® RFID tag that enables the user to reliably read and write all relevant product, process and lifecycle information directly on the Sartorius Stedim Biotech single-use system, providing instantaneous data recall.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing single-use solutions combined with collaborative supplier management and customer demand planning assures a state of the art product supported by a robust supply chain that can cope with strong market growth.

Validation
Standard Scalable Flexel® 3D Bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Standard Scalable Flexel® 3D Bags with data representing a wide range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Quality Assurance
Sartorius Stedim Biotech Quality Systems for single-use products follow applicable ISO and FDA regulations. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements. Standard Scalable Flexel® 3D Bags are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate matters in injections

– USP<85> and E.P.2.6.14: Bacterial endotoxins

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Supply Chain
The majority of Standard Scalable Flexel® 3D Bag systems are available from stock.

▷ Specifications

1. Standard Scalable Flexel® 3D Bags

Bag Chamber	Multiple layer film construction, including EVOH gas barrier layer and a PE contact layer
Tubing	Silicone, TPE
Fittings	MPC and MPX Male & Female Couplings, Female Luer Lock, Needle-less sampling port
Volumes	5 L, 10 L, 20 L and 50 L
Number of Ports	3 ports (5 L, 10 L & 20 L) 3 top ports and 3 bottom ports (50 L)
Sterilization	By Gamma irradiation

2. Reusable Handle

Description	Removable handle for Flexel® 3D 5-10-20 L
Material of Construction	Silicone | PA Coated Steel

3. Plastic Trays

Material of Construction	Polypropylene
Tray Capacity	5 L, 10 L and 20 L
Lids available for	5 L, 10 L
Stackable	Yes

Dimensions	
5 L	400 × 300 × 175 mm – (15.8 × 11.8 × 6.9")
10 L	600 × 400 × 175 mm – (23.63 × 15.8 × 6.9")
20 L	1000 × 400 × 214 mm – (39.4 × 11.8 × 8.4")

Weight of Tray | Bag & Lid (Bag filled to nominal volume)	
5 L	6.2 Kg – 13.7 lbs
10 L	12.4 Kg – 27.3 lbs
20 L	24.1 Kg – 53.0 lbs

4. Stainless Steel Trays

Material	304L Stainless Steel
Surface Finish	Bead Blasted
Tray Capacity	5 L (for Flexel® 3D 5 L) 10 L (for Flexel® 3D 10 L & 20 L)
Lid available for	5 L, 10 L

Dimensions	
5 L	475 × 330 × 117 mm – (18.7" × 12.9" × 4.6")
10 L	760 × 330 × 117 mm – (29.9" × 12.9" × 4.6")

Weight of Tray | Bag & Lid (Bag filled to nominal volume)	
5 L	8.6 Kg (18.9 lbs)
10 L	15.7 Kg (34.5 lbs)
20 L in 10 L Tray	25.7 Kg (56.5 lbs)

5. Rack System

(Please consult the Flexboy® Tray and Rack System Datasheet)

|	Base Module 1	Additional Module 2	Full System
Material	304 Stainless Steel	304 Stainless Steel	304 Stainless Steel
Surface Finish	Bead Blasted	Bead Blasted	Bead Blasted
Weight	30.5 Kg (67.1 Lbs)	26 Kg (57.2 Lbs)	82.5 Kg (181.5 Lbs)
Stainless Steel Tray Compartments	4 Places for 5 or 10 L Stainless Steel Trays – (2 Places for 20 L Stainless Steel Trays)	8 Places for 5 or 10 L Stainless Steel Trays – (4 Places for 20 L Stainless Steel Trays)	20 Places for 5 or 10 L Stainless Steel Trays – (10 Places for 20 L Stainless Steel Trays)
Plastic Tray Compartments	2 Places for 20 L Plastic Trays or 2 Places for 10 L Plastic Trays or 4 Places for 5 L Plastic Trays	4 Places for 20 L Plastic Trays or 4 Places for 10 L Plastic Trays or 8 Places for 5 L Plastic Trays	10 Places for 20 L Plastic Trays or 10 Places for 10 L Plastic Trays or 20 Places for 5 L Plastic Trays
Peristaltic Pumps Compartment	Yes – Dimensions: 887 × 775 × 300 mm (34.9" × 30.5" × 11.8")	No	Yes – Dimensions: 887 × 775 × 300 mm (34.9" × 30.5" × 11.8")
Wheels	4 Swivel Wheels (Two With Brakes)	–	4 Swivel Wheels (Two With Brakes)
Additional Features	Built In Wheels (Non Autoclavable)	–	Full = 1 Base + 2 Additional Modules

6. Palletank® for Storage

Description	Palletank® 50 L for storage stackable
Bag Volume	50 L
Construction Material	304L Stainless Steel
Surface Finishing	Bead Blasted
Dimensions (Approx.)	490 × 490 × 750 mm (19.3 × 19.3 × 29.5")
Sliding Gate	1
Stackability (static)	Yes (3)
Weight (Approx.)	24 kg (52.8 lb)

Accessories

Description	Dolly for Palletank 50 L for storage
Weight (Approx.)	7 kg (15.4 lb)

Ordering Information

1. Scalable Flexel® 3D Bioprocessing Bags
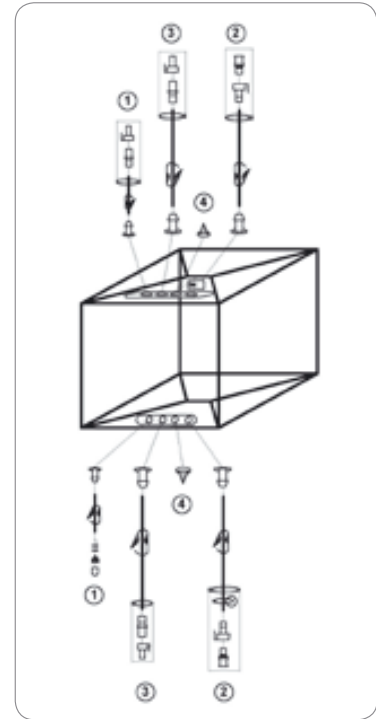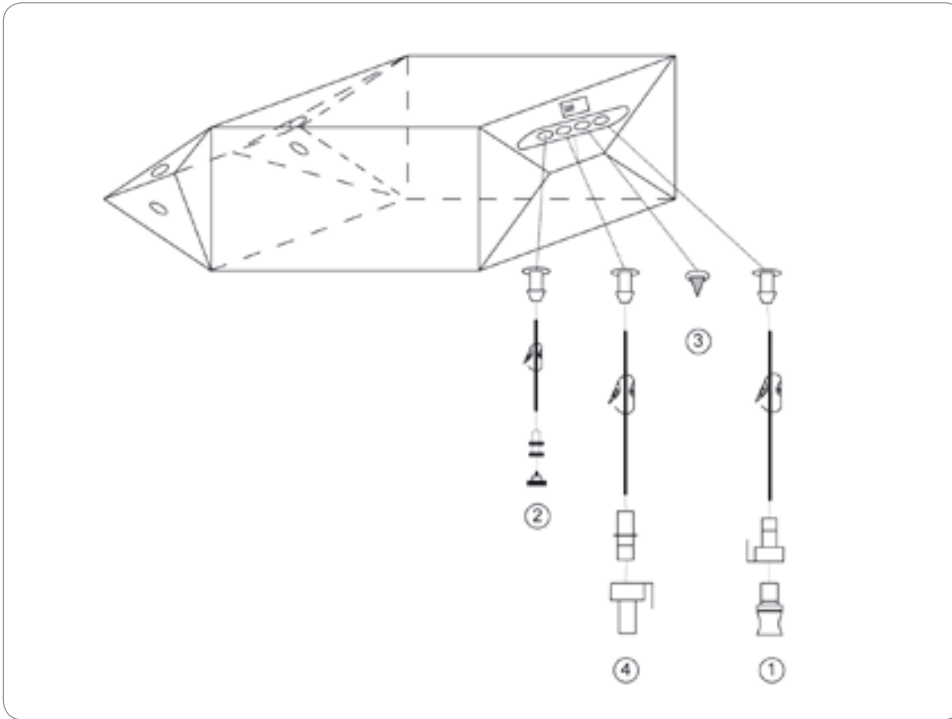
Part Number	Description	Tubing	Bag Port 1	Bag Port 2	Bag Port 3	Bag Port 4	Qty/Box
FXB112850	STD Flexel® 5 L	Silicone	3/8" × 5/8" × 150 mm (6") 3/8" MPC female + plug	1/4" × 3/8" × 100 mm (4") LL female + plug	Plug	3/8" × 5/8" × 150 mm (6") 3/8" MPC male + cap	12
FXB112852	STD Flexel® 10 L	Silicone	3/8" × 5/8" × 150 mm (6") 3/8" MPC female + plug	1/4" × 3/8" × 100 mm (4") LL female + plug	Plug	3/8" × 5/8" × 150 mm (6") 3/8" MPC male + cap	12
FXB112853	STD Flexel® 20 L	Silicone	3/8" × 5/8" × 150 mm (6") 3/8" MPC female + plug	1/4" × 3/8" × 100 mm (4") LL female + plug	Plug	3/8" × 5/8" × 150 mm (6") 3/8" MPC male + cap	12

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Top Port 4	Qty/Box
FXB113153	STD Flexel® Cubical 50 L	Silicone & Clear C-Flex® 374	1/4" × 3/8" × 10 cm (4") + male MPC + sealing cap	1/2" × 3/4" × 50 cm (20") + female MPX + sealing cap	1/2" × 3/4" × 50 cm (20") + male MPX + sealing cap	Plug	4
			Bottom Port 1	**Bottom Port 2**	**Bottom Port 3**	**Bottom Port 4**	
			1/4" × 3/8" × 10 cm (4") + LL female + needle free sampling port	1/2" × 3/4" × 50 cm (20") + GammaTag™ + female MPX + sealing cap	1/2" × 3/4" × 50 cm (20") + male MPX + sealing cap	Plug	

2. Reusable Handle

Part Number	Description	Qty/Box
FXA113036	Removable Handle For Flexel® 3D 5–10–20 L	3

3. Plastic Trays

Part Number	Description	Qty/Box
FFA113141	Plastic Tray Flexel® │ Flexboy® 5 L + Lid	1
FFA113142	Plastic Tray Flexel® │ Flexboy® 10 L – 20 L + Lid	1
FFA113143	Plastic Tray Flexel® 20 L	1

4. Stainless Steel Trays

Part Number	Description	Qty/Box
FFA102705	Flexboy® Tray + Lid 5 L	1
FFA102715	Flexboy® Tray + Lid 10 L	1

5. Rack System

Part Number	Description	Qty/Box
FFA102707	Flexboy® Rack │ Base Module 1	1
FFA102714	Flexboy® Rack │ Module 2	1

6. Palletank® for Storage 50 L

Part Number	Description	Qty/Box
FXC113946	Std Palletank® Storage 50 L (Stackable)	1
FXA113988	Std Palletank® Accessory Dolly 50 L (Storage)	1

▶ Integrity Testing of Flexel® 3D

Bioprocessing Bags for Drum and for Palletank®

Description

Flexel® 3D Bioprocessing Bags are designed for processing, storage and transport of large volume biopharmaceutical solutions in drum and Palletank®. They provide a single-use alternative to traditional stainless steel vessels in a large variety of applications. Normal process validation and in process control of the manufacturing provides a high degree of reliability of Flexel® 3D Bioprocessing Bags.

For critical storage and processing applications that require a higher degree of assurance, the integrity of each Flexel® 3D Bioprocessing Bag can be controlled with an optional test performed at Sartorius Stedim Biotech manufacturing plant.

Integrity Testing

Large volume, single-use Flexel® 3D Bags are increasingly used for the handling, storage and transport of high value products, such as bulk drug substances and vaccines. For these applications, an in-process bag chamber integrity test can be performed during manufacturing at Sartorius Stedim Biotech. This in-process physical control, in combination with the microbial challenge validation study is essential to provide the highest assurance level of the bag integrity. This optional test is performed on customer request for customized bag configurations.

The integrity test method is derived from ASTM F2095: "Standard Leak Test for Nonporous Flexible Packages with Restraining Plates". A pressure decay leak test is used to detect small channel defects in the seals or pinholes in the walls of the flexible bag.

The test method is non destructive and compatible with a 100% on-line implementation in Sartorius Stedim Biotech grade C clean rooms. The in-process test is performed on sealed bag chambers after the welding of the bag port and before assembly with the fill and drain lines.

Features & Benefits

Applicable to Flexel® 3D Bags for Drum and Palletank® (50 L – 200 L)	Covers most common volume bags for critical applications.
Non destructive testing	Safe and robust 100% testing is performed
High resolution, reproducibility, repeatability	High assurance level of the bag chamber integrity
Rapid, online testing	100% testing
Validated	High assurance level of bag integrity
Traceable	Documented batch record and certificate of release

▷ Specifications

Integrity Tested Flexel® 3D Bags for Drum

Bag Chamber	S40 multiple layer film construction, including EVOH gas barrier layer, and a PE contact layer
Volumes	50 L, 100 L & 200 L
Port tubing	Top port: 4 × port tubing with a ½″ hose barb in position 1 Bottom port: No port
Tubing	Silicone, TPE

Integrity Tested Flexel® 3D Bags for Palletank®

Bag Chamber	S40 multiple layer film construction, including EVOH gas barrier layer, and a PE contact layer
Volumes	100 L & 200 L
Port tubing	Top port: 4 × port tubing with a ½″ hose barb in position 1 Bottom port: 1 port tubing
Tubing	Silicone, TPE

Applications

Flexel® 3D Bioprocessing Bags are constructed from S40, a multi-layer film that provides a strong structure with low gas permeability and high chemical resistance for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications. Typical applications requiring a 100% in-process integrity testing include:

– Bulk intermediate filtration & hold

– Bulk drug substance storage and transport

– Final fill and finish operations

The integrity of large volume sterile single-use bags is of paramount importance for the handling and storage of biopharmaceutical products. The single-use container must act as an effective barrier to microorganism to insure the sterility of the stored solutions. The integrity testing performed during the manufacturing of Flexel® 3D Bioprocessing Bags considerably increases the security and safety of single-use biopharmaceutical processes.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions combined with collaborative supplier management and customer demand planning assures a state of the art product supported by a robust supply chain that can cope with strong market growth.

Validation

Flexel® 3D Bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® 3D Bags with data representing a wide range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

The objective of the air leak test is to check the integrity of the bag seals and port welds and identify possible damages of the film. This in-process test is performed during manufacturing on a 100% basis for each type of bag, using 0.2 µm filtered clean air. The pressure decay during the test is measured and compared to an acceptance criteria determined during the qualification of the method.

The test can securely distinguish between integral and non-integral bags. In order to define the acceptance criteria, measurements were evaluated with a large range of calibrated defects. Pinholes are associated with slight pressure decay during the test period. Large pressure decays are generated by large sealing defects.

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-use products follow applicable ISO and FDA regulations. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements. Flexel® 3D Bags for Palletank® and for Drum are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate matters in injections

– USP<85> and E.P.2.6.14: Bacterial endotoxins

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Implementation

Integrity testing is implemented for customized Flexel® 3D Bags upon customer request.

The integrity test can be applied to new or existing Flexel® 3D Bag configurations. For an existing configuration, implementation of the integrity test in production is initiated with a "Product Modification Request (PMR)". For a new bag configuration, the demand for the integrity test is reported in the user requirements of the new product.

Ordering Information

Contact your local Sartorius Stedim Biotech sales representative for ordering information.

▶ Flexel® 3D Palletank® for Storage

Introduction
The Palletank® for storage are stainless steel containers designed for the safe and robust storage of biopharmaceutical fluids contained in Flexel® 3D Bags. They are available in volumes of 50 L, 200 L and 500 L to be used with 50 L, 100 L | 200 L and 500 L Flexel® 3D bags. The Flexel® 3D Bag are manufactured according to a patented design that precisely fits the Palletank®.

Applications
Palletank® Systems that incorporate Flexel® 3D Bags have been designed for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications such as:

– Buffers and media storage

– Bulk harvest

– Product pooling

– Fraction collection

– Sample collection

– Bulk intermediate hold

– Final product transport

Space-Saving
The stackable version of the Flexel® 3D Palletank® for storage enables users to meet the complex in-process demands as well as the high requirements for storage while maximizing the utilization of the available clean room area. It saves up to 50% of the space required for cylindrical drums.

Safety
Flexel® 3D Bags coupled with the rigid structure of Palletank® provide a stable and secure solution for processing, storage and transportation of buffers, media, intermediates and final bulk products.

Palletank® Family
Besides the Palletank® for storage, the product range of Palletank® container includes the following lines specifically developed for the various application requirements on fluid management in the biopharmaceutical industry:

– Palletank® for shipping

– Palletank® for in-process fluid handling

– Palletank® for weighing

– Palletank® for recirculation mixing

Technology Integration Support
Sartorius Stedim Biotech supports users from the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation and validation of Single-Use Manufacturing.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Quality Assurance
Flexel® 3D Palletank® Systems are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. They undergo extensive testing before shipping.

Key Features & Benefits

Patented system	Perfect fit and protection of the Flexel® 3D Bag in its Palletank®
Standard design	Most design are available from stock
Stackable version	Space saving containment system
Technology integration support	For a successful Single-Use manufacturing implementation and validation

▷ Specifications

1. Palletank® for Storage

Description	Palletank® 200 L for Storage	Palletank® 500 L for Storage
Bag Volume(s)	100 L or 200 L	500 L
Construction Material	304L Stainless Steel	
Surface Finishing	Bead Blasted	
Dimensions (w × d × h)	789 × 592 × 891 mm (31.2 × 23.3 × 35.1 in)	1192 × 792 × 1010 mm (46.9 × 31.2 × 39.7 in)
Weight	35 kg (77.17 lb)	92 kg (202.8 lb)
Bottom Gate	1	1
Stackability	No	No

2. Palletank® for Storage Stackable

Description	Palletank® 50 L for Storage Stackable	Palletank® 200 L for Storage Stackable	Palletank® 500 L for Storage Stackable
Bag Volume(s)	50 L	100 L or 200 L	500 L
Construction Material	304L Stainless Steel		
Surface Finishing	Bead Blasted		
Dimensions (w × d × h)	490 × 490 × 750 mm (19,3 × 19,3 × 29,5 in)	789 × 592 × 915 mm (31.2 × 23.3 × 36 in)	1192 × 792 × 1060 mm 46.9 × 31.2 × 41.7 in
Weight	24 kg (52.8 lb)	48.4 kg (106.7 lb)	87.5 kg (192.9 lb)
Bottom Gate | Sliding Gate	1	1	1
Stackability (Static)	3 high	3 high	2 high

3. Ancillary Products

3.1. Dolly

Description	Dolly for Palletank® 50 L for Storage and Shipping	Dolly for Palletank® 200 L for Storage and Shipping	Dolly for Palletank® 500 L for Storage and Shipping
Construction Material	304L and polyamide (wheels)		
Surface Finishing	Glass Bead blasted		
Dimensions (w × d × h)	490 × 490 × 185 mm (19.3 × 19.3 × 7.3 in)	815 × 615 × 188 mm (32.1 × 24.2 × 6.4 in)	1215 × 815 × 161 mm (47.8 × 32.1 × 6.4 in)
Weight (approx.)	7 kg (15.4 lb)	10 kg (22 lb)	18 kg (39.7 lb)

3.2. Weighing Platforms

The IFS4 flat-bed scales are entirely constructed of stainless steel and have an extremely low height, making it ideally suited for floor installation without a pit or anchoring. The ramp is securely attached to the scale using special retainers for prevention of force shunt. This high-quality platform can be connected to any of a wide range of indicators, for use as a Class III legal measuring instrument or without legal verification. The CIS1 Combics 1 indicator allows strain gauge weighing with flat bed scales as well as with load cells to be connected.

	IFS4-150GG-I	IFS4-300LI-I	IFS4-1000RN-I
Weighing capacity	150 kg (330.7 lb)	300 kg (661.4 lb)	1000 kg (2204.6 lb)
Platform size	600 × 600 mm (23.6 × 23.6 in)	1000 × 800 mm (39.3 × 31.5 in)	1500 × 1250 mm (59 × 49.2 in)
Height	Standard: 35 mm	Standard: 35 mm	Standard: 45 mm
Load Plate	AISI304 | 1.4301 (V2A) bead-blasted	AISI304 | 1.4301 (V2A) bead-blasted	AISI304 | 1.4301 (V2A) bead-blasted
Resolution	30.000 d	30.000 d	30.000 d
Readability	5 g	10 g	50 g
Suitable with Palletank® Storage and Storage Stackable	50 L	200 L	500 L

Refer to specific Sartorius Mechatronics datasheet for Combics indicators ranges, printers and other accessories specifications and ordering information.

Integrated Features

Features	Benefits	Palletank® for Storage	Palletank® for Storage Stackable
Level marks	allow rapid visual monitoring of the fluid level in the bag	•	• *
Integrated pallet	allows easy carriage by pallet-jack or forklift	•	•
Tubing & Fitting Tray	simplifies fluid handling operations & provides a convenient and secure place for inlet & outlet tubing assemblies during transport.	•	•
Lid	protects the bag against dust and light		• *
Bottom gate | Sliding gate	allows passage of large bore tubing, 1,5" tri clamps, QC bags and filters; facilitates bag positioning and maintain in position	•	•
Stacking corner	enables the stacking of Flexel® 3D Systems in order to maximise the utilisation of available clean room area		•
Dolly (accessory)	facilitates the movement of material throughout a facility	•	•

* Except 50 L volume

Ordering Information

Order Code	Description
FXC110888	Palletank® 200 L for storage
FXC110889	Palletank® 500 L for storage
FXC113946	Palletank® 50 L for storage stackable
FXC110733	Palletank® 200 L for storage stackable
FXC110734	Palletank® 500 L for storage stackable
FXA113988	Dolly for Palletank® 50 L for storage
FXS102254	Dolly for Palletank® 100 L	200 L for storage & shipping
FXS102256	Dolly for Palletank® 500 L for storage & shipping

► Flexel® 3D Palletank® for In-Process Fluid Handling

Introduction
The Palletank® for in-process fluid handling are specifically developed for users who wish to leave the containers in close proximity to process equipment. Palletank® and Flexel® 3D bags for in-process fluid handling are available in 200 L, 500 L, 1000 L, 1500 L, 2000 L, 2500 L and 3000 L volumes. The Flexel® 3D Bags are manufactured according to a patented design that precisely fits the Palletank®.

Applications
– In-process product hold
– Storage and distribution of media and buffers.
– Solution distribution in Flexel® 3D Bag manifold
– Waste Collection
– Feed & harvest from bioreactor

Easy Operation
The double hinged front doors allow bag replacement, installation and manipulation whilst Palletank® are stacked up in the process area (up to 1000 L) thus enabling continuous processing without movement of the containers. As a result a forklift is not routinely required in the manufacturing area. A specially designed dolly up-to 1000 L (accessory) facilitates the convenient movement of material throughout the facility.

Ready for Large Volumes
The unique lifting system for large volume tanks provides optimal bag unfolding and filling. A specially designed bottom gate allows safe passage of large bore tubing, 1,5" tri clamps, QC bags and filters. The front and side bin access additionally eases the bag deployment in the container when filling.

Palletank® Family
Besides the Palletank® for in-process fluid handling the product range of Palletank® container includes the following lines specifically developed for the various application requirements on fluid management in the biopharmaceutical industry:

– Palletank® for shipping
– Palletank® for storage
– Palletank® for weighing
– Palletank® for recirculation mixing

Technology Integration Support
Sartorius Stedim Biotech supports users from the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation and validation of Single-Use Manufacturing.

Features and Benefits
– Easy operation due to continuous processing without movement of the containers
– Easy access through double hinged front door with safety latches
– Optimal bag unfolding and filling through a lifting system for large size containers

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Quality Assurance
Flexel® 3D Palletank® Systems are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. They undergo extensive testing before shipping.

▷ Specifications

Palletank® for In-Process Fluid Handling

Description	Palletank® 200 L for In-Process Fluid Handling	Palletank® 500 L for In-Process Fluid Handling	Palletank® 1000 L for In-Process Fluid Handling
Bag Volume(s)	100 L or 200 L	500 L	1000 L
Construction Material		304L Stainless Steel	
Surface Finishing		Glass Bead Blasted	
Dimensions (w×d×h)	860 × 660 × 929 mm (33.9 × 26 × 36.6 in)	1260 × 860 × 989 mm (49.6 × 33.9 × 38.9 in)	1260 × 1060 × 1443.5 mm (49.6 × 41.7 × 59.3 in)
Weight (approx.)	50 kg (110.2 lb)	89 kg (196.2 lb)	120 kg (264.6 lb)
Bottom gate	1	1	2
Stackability	3 high	3 high	2 high
Total Weight (approx.)	68 kg (150.2 lb)	111 kg (244.7 lb)	144.5 kg (317.9 lb)

Palletank® for In-Process Fluid Handling

Description	Palletank® 1500 L for In-Process Fluid Handling	Palletank® 2000 L for In-Process Fluid Handling	Palletank® 2500 L for In-Process Fluid Handling	Palletank® 3000 L for In-Process Fluid Handling
Bag Volume(s)	1500 L	2000 L	2500 L	3000 L
Construction Material	304L Stainless Steel			
Surface Finishing	Glass Bead Blasted			
Dimensions (w×d×h)	1200 × 1000 × 2043 mm (47.2 × 39.4 × 80.4 in)	1200 × 1000 × 2543 mm (47.2 × 39.4 × 100.1 in)	1200 × 1000 × 3043 mm (47.2 × 39.4 × 119.8 in)	1200 × 1000 × 3543 mm (47.2 × 39.4 × 139.5 in)
Weight (approx.)	300 kg (661.4 lb)	350 kg (771.6 lb)	400 kg (881.8 lb)	450 kg (992 lb)
Bottom gates	3			
Tubing access in front of Palletank®	3			
Stackability	No			

Accessories

Description	Dolly for Palletank® 200 L for In-Process Fluid Handling	Dolly for Palletank® 500 L for In-Process Fluid Handling	Dolly for Palletank® 1000 L for In-Process Fluid Handling
Weight	18 kg (40 lb)	22 kg (48.5 lb)	24.5 kg (54 lb)

Ordering Information

Order Code	Description
FXC106230	Palletank® 200 L for in-process fluid handling
FXC106235	Palletank® 500 L for in-process fluid handling
FXC106223	Palletank® 1000 L for in-process fluid handling
FXC109797	Palletank® 1500 L for in-process fluid handling
FXC109798	Palletank® 2000 L for in-process fluid handling
FXC109799	Palletank® 2500 L for in-process fluid handling
FXC109764	Palletank® 3000 L for in-process fluid handling
FXS102255	Dolly for Palletank® 200 L for in-Process fluid handling
FXS102257	Dolly for Palletank® 500 L for in-Process fluid handling
FXS102259	Dolly for Palletank® 1000 L for in-Process fluid handling

► Flexel® 3D Palletank® for Shipping

Introduction
The Palletank® for Shipping is a patented system that is specifically developed for secure and convenient shipment of sterile bulk pharmaceutical fluids. It is available in volumes of 100 L, 200 L and 500 L. The system is composed of two basic elements, the Palletank® container and the associated shipping kit. The Flexel® 3D Bags are manu-factured according to a patented design that precisely fits the Palletank® to assure highest safety during shipping.

Applications
Bulk shipment of sterile biopharmaceutical fluids such as:

– Bulk drug substance

– Product intermediates

– Media

– Buffers

Safe and Validated Shipping
The shipping kit acts as a compression unit to firmly secure the filled Flexel® 3D Bag whilst in transit. Top and bottom tubing are protect-ed to prevent damage and a rigid lid is locked securely prior to shipping. For optimum use, the Palletank® for Shipping can be moved around with a palletjack, forklift or it can be fitted with a dolly, available separately.

Space–Saving
The Palletank® for shipping can be stacked up-to 3 high to maximize the utilization of the available clean room area. When not in use or upon return, the Palletank® is foldable and stackable up-to 5 high.

Easy Cleanability
In order to simplify the cleaning|disinfection cycles, all movable parts of the Palletank® for shipping can be dismantled (including door hinges).

Palletank Family
The Palletank® for shipping is part of the family of Palletank® containers includes the following lines specifically developed for the various application requirements on fluid management in the biopharmaceutical industry:

– Palletank® for in process fluid handling

– Palletank® for storage

– Palletank® for weighing

– Palletank® for recirculation mixing

Technology Integration Support
Sartorius Stedim Biotech supports users from the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation and validation of Single-Use Manufacturing.

Features & Benefits

– Validated shipping system that provides highest safety during transportation of single-use bag containments

– Immobilisation of Flexel® 3D Bag by compression assures system integrity

– Dismountable construction improves space utilization on site before and after usage

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of design-ing Single-Use solutions based on collabora-tive supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Quality Assurance
Flexel® 3D Palletank® systems are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Manage-ment System. They undergo extensive testing before shipping.

▷ Specifications

Description	Palletank® 100 L for Shipping	Palletank® 200 L for Shipping	Palletank® 500 L for Shipping
Bag Volume(s)	100 L	200 L	500 L
Construction Material	304L		
Dimensions (w × d × h)			
Unfolded	800 × 600 × 688 mm (31.5 × 23.6 × 27.1 in)	800 × 600 × 935 mm (31.5 × 23.6 × 36.8 in)	1206 × 806 × 1050 mm (47.5 × 31.7 × 41.33 in)
Folded	800 × 600 × 510 mm (31.5 × 23.6 × 20.1 in)	800 × 600 × 510 mm (31.5 × 23.6 × 20.1 in)	1206 × 806 × 540 mm (47.5 × 31.7 × 21.26 in)
Weight (Incl. Lid)	63.5 kg (140 lb)	84 kg (185.18 lb)	129 kg (284.4 lb)
Bottom gates	1	1	1
Stackability			
Unfolded	3	3	2
Folded	5	5	3

Accessories

Description	Shipping Kit 100 L	Shipping Kit 200 L	Shipping Kit 500 L
Weight	16 kg (35.27 lb)	16 kg (35.27 lb)	28 kg (61.8 lb)

Ordering Information

Order Code	Description
FXC106362	Palletank® 100 L for shipping
FXC103133	Palletank® 200 L for shipping
FXC106609	Palletank® 500 L for shipping
FXC102475	Palletank® 100 L shipping kit
FXC102477	Palletank® 200 L shipping kit
FXC102478	Palletank® 500 L shipping kit
FXS102254	Dolly for Palletank® 100 L/200 L for shipping
FXS102256	Dolly for Palletank® 500 L for shipping

► Flexel® 3D Palletank® for Weighing

Introduction
The Palletank® for weighing are developed for optimized fluid management control in biopharmaceutical process applications. They are available in volumes of 200 L and 500 L. The Flexel® 3D Bags are manufactured according to a patented design that precisely fits the Palletank® to assure highest bag security.

Applications
The Palletank® for weighing provides additional process security to applications like:

– In-process product hold

– Storage and distribution of media and buffers.

– Solution distribution in Flexel® 3D Bag manifold

– Waste collection

– Feed & harvest from bioreactor

High-Performance Weight Measurement System Provided by Sartorius Mechatronics
The Palletank® for weighing are configured with built-in load cells that are electronically linked to a control panel and printer for stream-lined operation. The control panel provides an easy-to-read user interface and overall system control and the printer facilitates documentation including weight, batch number and operator signature.

Palletank® Family
The Palletank® for weighing is part of the family of Palletank® containers which includes the following lines specifically developed for the various application requirements on fluid management in the biopharmaceutical industry:

– Palletank® for shipping

– Palletank® for storage

– Palletank® for in process fluid handling

– Palletank® for recirculation mixing

Feature	Benefits
Highest process control and security due to accurate weight measurement by Sartorius Mechatronics load cells	Patented bag design that precisely fits the Palletank® to enhance process security

▷ Specifications

Description	Palletank® 200 L for weighing	Palletank® 500 L for weighing
Bag Volume(s)	200 L	500 L
Construction Material	304 L	304 L
Dimensions (w × d × h)	1186 × 587 × 895 mm (46.7 × 23.4 × 35.2 in)	1586 × 787 × 997 mm (62.4 × 31 × 39.2 in)
Weight (approx.)	60 kg (132 lb)	70 kg (154.3 lb)
Bottom gates	1	1
Stackability	No	No

Technology Integration Support
Sartorius Stedim Biotech supports users from the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation and validation of Single-Use Manufacturing.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Quality Assurance
Flexel® 3D Palletank® Systems are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. They undergo extensive testing before shipping.

Ordering Information

Order Code	Description
FXC110692	Palletank® 200 L for weighing
FXC110695	Palletank® 500 L for weighing

▶ BioSealer®

For Permanent and Consistent Leak Free Seals

Description
The BioSealer® is a fully automated device, designed to produce permanent and consistent leak free seals on thermoplastic tubing.

Applications
The BioSealer® is used to disconnect thermo-plastic tubing such as C-Flex®, Advantaflex®, FluiSoft®, SaniPure® and Pharmed®, on disposable bag assemblies used in biopharma-ceutical manufacturing processes. Individual bags or bag assemblies can be disconnected in a non sterile environment by maintaining sterility of the product.

Operating Principle
The inserted empty or liquid filled tube will be compressed and heated between two ceramic heating elements. The liquid will be evacuated from the internal tube section. The heat and the compression force will fuse the tube to a homogeneous section. This section can be cut in the middle by using sharp scissors.

Flexibility
The unit is sealing from ¼" OD tubing up to ¾" OD tubing which makes it ideal for the implementation of Single Use Bag Technology.

Easy to Use
The BioSealer® is optional available with a removable sealing head. The sealing head can be used 3 m away form the actual device. This ensures an easy adaptation to various space requirements.

Short Sealing Cycles
Depending on the tubing size and quality the average sealing cycle times are between 1 to 4 minutes. A contribution to overall short processing times.

Stability
The thermal seal produced by the BioSealer® ensures an extraordinary level of stability and guarantees sterile disconnections. All units are individually tested before dispatch to ensure maximum reliability.

▷ Specifications

Technical Specification

Power requirements	100–240 V/47–63 Hz
Dimensions	220 × 150 × 210 mm
Weight	3.0 kg
Housing	stainless steel
Compression head	Aluminum anodised
Ambient temperature	20°C – 30°C
Relative Humidity	35% – 65%
Max. Tube OD	¾"
Min. Tube OD	¼"
Sealing Cycle	1 – 4 minutes depending on tube size and quality
Tubing Types	Soft Thermoplastic Tubing, (e.g. C-Flex®, SaniPure® 60, Raumedic® FluiSoft™ and Pharmed® BPT), Advantapure Advantaflex®

Ordering Information

Article Code	Description
16360-P1 16360-P2 16360-P3 16360-P17 16360-P5 16360-P6 16360-P19 16360-P8 16360-P21	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD ¼" – ½" and wall thickness 1/16" – 3/32" Optional Parametersets**
16361-P1 16361-P2 16361-P3 16361-P17 16361-P5 16361-P6 16361-P19 16361-P8 16361-P21	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD ¼" – ½" and wall thickness 1/16" – 3/32" Equipped with a removable Sealing Head Optional Parametersets**
16362-P18 16362-P8 16362-P9 16362-P10 16362-P11 16362-P12 16362-P20 16362-P22 16362-P23	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8" – 3/4" and wall thickness 1/8" Optional Parametersets**
16363-P18 16363-P8 16363-P9 16363-P10 16363-P11 16363-P12 16363-P20 16363-P22 16363-P23	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8" – 3/4" and wall thickness 1/8" Equipped with a removable Sealing Head Optional Parametersets**
16365	IR Interface incl. Software CD
16366	Ceramic Heating Element Type 1 specified for BioSealer® 16360–16363

** The definition of each parameterset can be obtained in the parametersheet 425S00.
   The article code specifies which parameterset will be installed.

▶ BioWelder®

Fully Automated Tube Fusing Device

Description
The BioWelder® is a fully automated device for connecting thermoplastic tubing in a sterile welding operation.

Applications
The BioWelder® is used to connect thermo-plastic tubing such as C-Flex®, FluiSoft™, AdvantaFlex®, Sanipure® and Pharmed®, used on disposable bags or bag assemblies within biopharmaceutical manufacturing processes.

Operating Principle
The two hoses are inserted into interchange-able holders. The inserted hoses will be cut by a blade and fused together. The blade is kept sterile and antitoxin free throughout the entire process. Sterile connections can easily be made in an non sterile environment.

Flexibility
The different interchangeable tube holders in the sizes between ¼" to ¾" OD allow a quick and easy adaptation to the process needs. The unit identifies each holder on an implemented chip. This ensures superior connections with a minimum risk of any operator errors.

Ease of Use
A LCD programming display with keypads guides the user through the operator menu. Each process step can easily be followed and monitored by the information provided. A printer can be connected in order to print the protocols of the last welding cycles.

Fast Process Times
Depending on the tubing diameter the average welding cycle times are between 60 and 90 seconds. This provides enormous time savings along the process chain.

Stability
The thermal weld produced by the BioWelder® ensures an extraordinary level of stability and guarantees sterile connec-tions. All units are individually tested before dispatch to ensure maximum reliability.

▷ Specifications

Technical Specification

Power requirements	100–240 V | 47–63 Hz
Dimensions	300 × 300 × 220 mm
Weight	10.5 kg
Housing	stainless steel
Interface	RS232 for printer
Blade	Cr-Ni-Alloy, single-use
Ambient temperature	20°C–30°C (ideal: 22°C)
Relative Humidity	20%–80% (ideal: 60%)
Temperature Sensor	Type K, calibration holder available
Max. Tube OD	3/4"
Min. Tube OD	1/4"
Welding Cycle	60–90 sec. depending on tube dimension
Standard settings for	C-Flex®, FluiSoft™, AdvantaFlex®, PHARMED® BPT, Sanipure® 60

The BioWelder® unit can be programmed with maximum 3 parameter sets. When ordered without any mention, the BioWelder® comes with C-Flex®, PHARMED® BPT and Sanipure® 60. The unit can be ordered with other parameter sets. In that case, please specify the parameter sets you want to have in the unit and the ones you want to have removed.

Ordering Information

Order Code	Description
16370	BioWelder®, Fully automated tube fusing unit
16372-EU	Printer CBM for EU Incl. Software licence, print cable, AC adapter, paper roll and ribbon cassette
16372-US	Printer CBM for US Incl. Software licence, print cable, AC adapter, paper roll and ribbon cassette
16372-GB	Printer CBM for GB Incl. Software licence, print cable, AC adapter, paper roll and ribbon cassette
16372-IEC	Printer CBM, IEC Incl. Software licence, print cable, AC adapter, paper roll and ribbon cassette
16373	Disposable Cutting Blades, With laser point 0.4 mm, 50 pcs./package
16374	Calibration Kit With specifically designed holder, integrated temperature sensor type K and coding for calibration program recognition, calibration document for sensor included
16384	4-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16385	4-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16386	4-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16375	2-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16376	2-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16377	2-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16378	2-fould Tube Holder OD 7/16" (11.1 mm), ID 5/16" (8.0 mm) Wall 1/16" (1.6 mm)
16379	2-fould Tube Holder OD 1/2" (12.7 mm), ID 3/8" (9.5 mm) Wall 1/16" (1.6 mm)
16380	2-fould Tube Holder OD 5/8" (15.9 mm), ID 3/8" (9.5 mm) Wall 1/8" (3.2 mm)
16381	2-fould Tube Holder OD 3/4" (19 mm), ID 1/2" (12.7 mm) Wall 1/8" (3.2 mm)
16387	Protective cover for cleaning purposes

▶ Standard Flexel® for Magnetic Mixer

Description

Flexel® for Magnetic Mixer is a new single-use mixing solution using the market leading ATMI patented Magnet Mixer Technology, Sartorius Stedim Biotech Flexel® 3D Bag and the proven Palletank® technology. Major improvements in bag installation and handling paired with the efficiency and speed of impeller mixing systems make Flexel® for Magnetic Mixer the disposable mixing system of choice for powder│liquid mixing, buffer and media formulation and large volume liquid│liquid homogenization.

Components

1. Palletank® for Magnetic Mixer is a stainless steel cubical container designed to perfectly fit with the Flexel® Bag for Magnetic Mixer with its integrated impeller. It includes a railed port for coupling the mobile Magnetic Mixer Drive Unit with the Palletank® for Magnetic Mixer and a clamp holder to facilitate powder transfer. The hinged door allows easy installation of the bag system whereas the front bottom gate facilitates easy tubing installation and access. Windows on lateral and rear sides enable the user to visually control the mixing process. The cubical shape improves the mixing efficiency and offers scalability from 50 L to 1000 L.

2. Magnetic Mixer Drive Unit generates the rotation of the single-use magnetic impeller coupled to a non-shedding ceramic bearing, enabling Flexel® for Magnetic Mixer to efficiently dissolve and disperse powders, suspensions, solutions or mix emulsions. The Magnetic Mixer Drive Unit is mobile, cart-mounted and designed to interface with Palletank® for Magnetic Mixer of different volumes.

3. Flexel® Bag for Magnetic Mixer contains an in center magnetic impeller assembly. Its unique sided K-weld design simplifies installation and facilitates the unfolding and folding of the bag during filling and draining operations. The patented protection cap prevents contact of the impeller with the film during transport. It also offers a large diameter port for powder transfer.

Clean and Sterile Mixing Operation

Flexel® for Magnetic Mixer is a compact and non-invasive single-use mixing system with a bottom-mounted magnetically-driven impeller capable of providing efficient high-torque mixing for all powder-liquid and liquid-liquid mixing applications. The impeller rotates on a low-friction, inert bearing assembly designed to ensure low particle shedding while allowing high mixing efficient in large liquid volumes.

Features & Benefits

50 L to 1000 L Flexel® for Magnetic Mixer	Full scalability
Low-friction, inert bearing assembly	Low particle shedding, high-torque mixing
Side K-Welds on Flexel® Bag for Magnetic Mixing	Easy installation and unfolding, walk away filling process
HDPE impeller protection Triclamp cap	Prevents film damage during packaging and transport. Offers large diameter port for powder transfer. Provides connection to Powder Bag (with a reducer).
Face bottom port	Easy installation and access to tubing
Standard designs of Flexel® Bag for Magnetic Mixer	Most designs are available from stock
Hinged door on Palletank® for Magnetic Mixer	Easy installation
Mobile Magnetic Mixer Drive Unit	Single drive unit can serve multiple mixing Palletanks® of different volumes
Rear and lateral windows	Visual check of correct bag installation and mixing process
Full compliance with ISO 11137	Highest sterility assurance level

Flexibility

The Magnetic Mixer Drive Unit operates independently of the Palletank® for Magnetic Mixer so that a single drive unit can serve multiple Palletanks® of different sizes. Standard Flexel® Bags for Magnetic Mixer are available from stock. Expert design service is available on-site through Sartorius Stedim Biotech process development engineers on a worldwide basis.

Validation

Flexel® Bags for Magnetic Mixer have been qualified applying the most stringent and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® Bags for Magnetic Mixer with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech Single-Use Products with a sterility assurance level of 10^{-6} over the shelf life.

Flexel® Bags for Magnetic Mixer are tested for compliance with:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Containers-Physicochemical tests - Plastics

– USP <788> Particulate matter in injections – Large-volume injections and E.P. 2.9.19: Particulate contamination-sub-visible particles

– USP<85> and EP 2.1.14: Bacterial endotoxins test

– ISO 11737: Microbiological methods- Determination of a population of microorganisms on products

– ISO 11137: Sterilization of Health care products-Radiation

Quality Assurance
Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of design-ing Single-Use solutions based on collabora-tive supplier management and customer demand planning assures a state-of-the-art and robust supply chain that can cope with strong market growth.

Applications
The Magnetic Mixer Drive Unit delivers strong torque for efficient mixing in a wide variety of biopharmaceutical applications. With its efficient high-torque impeller, Flexel® Bags for Magnetic Mixer can ideally be applied for powder-liquid and liquid-liquid mixing applications, requiring high mixing intensity such as:

– Buffer preparation

– Media preparation

– Hydration and dissolution of hydrophobic powders

– Large volume Bulk intermediate resuspension and homogenization

– Large volume product formulation

▷ Specifications

1. Magnetic Mixer Drive Unit

Power:	
EU	Single Phase 230 V, 50│60 Hz
USA	USA Single Phase 110 V, 60 Hz
Japan	Japan Single Phase 230 V, Transformer (110 V Input), 50│60 Hz
Input Wattage	< 150 Watts
Footprint	84 × 41 cm (33 in × 16 in)
Drive Unit Height	104 cm (41 in), to top of handle
Weight	25 kg (55 lb)
Ambient Temperature	4° to 30℃
Max. Humidity	85% (non-condensing), *avoid condensation, *for indoor use
Mobility	Mounted on stainless cart with four clean room wheels and push handle
IP Rating	NEMA 4X, IP 65
Impeller Speed	0–300 RPM
Initial Set-up Time	Not applicable
Vessel Changeover	< 7 Minutes
CE Mark	Compliant
Material for External Surfaces	Stainless Steel #316L

2. Flexel® Bag for Magnetic Mixer

Bag Chamber	S40 Flexel® 3D Bag Chamber with Multi-Layer Film, including EVOH gas barrier layer and PE contact layer
Impeller Position	Bottom Centered
Impeller Size	161 mm (6.35″)
Tubing Material	Silicone, C-Flex®
Number of Ports	1 top port, 4 front bottom ports
Fittings	MPC Quick Connect Coupling, Tri-clamp, needleless sampling port

Volumes	50 L, 100 L, 200 L, 400 L, 650 L and 1000 L
Nominal Filling Volume	Minimum – Maximum Volume
50 L	30 L – 60 L
100 L	40 L – 120 L
200 L	60 L – 230 L
400 L	120 L – 420 L
650 L	160 L – 720 L
1,000 L	250 L – 1060 L
Sterilization	by Gamma Irradiation

3. Palletank® for Magnetic Mixer

Material	304L Stainless Steel
Surface Finish	Glass Bead Blasted
Door	Front Hinged Door
Windows	Plexiglas
Ports	Railed port for drive unit Front bottom port for bag line access
Volumes	50 L, 100 L, 200 L, 400 L, 650 L and 1000 L
Dimensions	W × D × H
50 L	825 × 570 × 1051 mm (32.5 × 22.4 × 41.4 inch)
100 L	825 × 570 × 1126 mm (32.5 × 22.4 × 44.3 inch)
200 L	777 × 726 × 1230 mm (30.6 × 28.6 × 48.4 inch)
400 L	941 × 891 × 1325 mm (37 × 35.1 × 58.3 inch)
650 L	998 × 1025 × 1480 mm (39.3 × 40.4 × 58.3 inch)
1000 L	1139 × 1167 × 1650 mm (44.8 × 45.9 × 65.0 inch)
Weight (approx.)	
50 L	43 kg (95 lb)
100 L	49 kg (108 lb)
200 L	63 kg (139 lb)
400 L	88 kg (196 lb)
650 L	103 kg (227 lb)
1000 L	156 kg (344 lb)

Palletank® are compatible with the LevMixer® drive unit.

Ordering Information

1. Flexel® Bags for Magnetic Mixer

Part Number	Description	Tubing	Bottom Port 1	Bottom Port 2	Bottom Port 3	Bottom Port 4	Qty/Box
FMB114867	STD Flexel® Cubical Magnetic Mix Bag 50 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FMB114870	STD Flexel® Cubical Magnetic Mix Bag 100 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FMB114893	STD Flexel® Cubical Magnetic Mix Bag 200 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FMB114894	STD Flexel® Cubical Magnetic Mix Bag 400 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FMB114895	STD Flexel® Cubical Magnetic Mix Bag 650 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2
FMB114896	STD Flexel® Cubical Magnetic Mix Bag 1000 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1–1/2" Tri-Clamp	2

2. Palletank® for Magnetic Mixer

Part Number	Description
FXC110820	Palletank® 50 L for Impeller Mixing incl. Adaptation Set and Clamp Holder
FXC112230	Palletank® 100 L for Impeller Mixing incl. Adaptation Set and Clamp Holder
FXC110821	Palletank® 200 L for Impeller Mixing incl. Adaptation Set and Clamp Holder
FXC111135	Palletank® 400 L for Impeller Mixing incl. Adaptation Set and Clamp Holder
FXC110822	Palletank® 650 L for Impeller Mixing incl. Adaptation Set and Clamp Holder
FXC113384	Palletank® 1000 L for Impeller Mixing incl. Adaptation Set and Clamp Holder

3. Magnetic Mixer Drive Units

Part Number	Description
LT-DU-005-US	Magnetic Mixer Drive Unit, 110 V, US Power Cord
LT-DU-006-EU	Magnetic Mixer Drive Unit, 230 V, EU Power Cord
LT-DU006-UK	Magnetic Mixer Drive Unit, 230 V, UK Power Cord
LT-DU006-SW	Magnetic Mixer Drive Unit, 230 V, Swiss Power Cord
LT-DU006-AU	Magnetic Mixer Drive Unit, 230 V, Australian Power Cord
LT-DU006-JA	Magnetic Mixer Drive Unit, 230 V, Japanese Power Cord and Transformer

4. Spare Parts

Part Number	Description
FXA112559	Clamp Holder for Palletank® 50 L for Impeller Mixing
FXA112560	Clamp Holder for Palletank® 100 L for Impeller Mixing
FXA112074	Adaptation Set for Palletank® for Impeller Mixing
FXA112083	Clamp Holder for Palletank® 200 L for Impeller Mixing
FXA112086	Clamp Holder for Palletank® 400 L for Impeller Mixing
FXA112085	Clamp Holder for Palletank® 650 L for Impeller Mixing

5. Other Literature
Powder Transfer Bag details are available on the datasheet SPT2018-e10021

▶ Flexel® Palletank® for LevMixer®[1]

Description

The Flexel® Palletank® for LevMixer® is a new single-use mixing solution using the market leading LevTech® levitated impeller and Sartorius Stedim Biotech Flexel® 3D Bag. The newly designed cubical mixing tank is based on the proven Palletank® technology. Major improvements in bag installation and handling paired with the efficiency and speed of impeller mixing systems make the Flexel® Palletank® for LevMixer® the disposable mixing system of choice in the biopharmaceutical industry.

Components

1. Palletank® for LevMixer® is a stainless steel cubical container designed to perfectly fit with the Flexel® Bags for LevMixer® with its integrated impeller. It includes a railed port for coupling the mobile LevMixer® drive unit with the Flexel® Bags for LevMixer® and a clamp holder to facilitate powder transfer. The hinged door allows easy installation of the bag system whereas the front bottom gate facilitates easy tubing installation and access. Windows on lateral and rear sides enable the user to visually control the mixing process. The cubical shape improves the mixing efficiency and offers scalability from 50 L to 1,000 L.

2. LevMixer® drive unit generates the levitation and rotation of the single-use magnetic impeller without surface contact. This allows the Flexel® Palletank® for LevMixer® to efficiently mix powders, suspensions, solutions or emulsions. The LevMixer® drive unit is mobile, cartmounted and designed to interface with Palletank® for LevMixer® of different volumes.

3. Flexel® Bags for LevMixer® contains an in center magnetic impeller assembly. Its unique sided K-weld design simplifies installation and facilitates the unfolding and folding of the bag during filling and draining operations. The patented protection cap provides robustness avoiding contact of the impeller with the film during transport. It also offers a large diameter port for powder transfer.

Clean and Sterile Mixing Operation

A patented superconductor technology is utilized to levitate and drive the single-use impeller inside sterile Single-Use Flexel® Bags for LevMixer®. The LevMixer® drive unit causes the impeller to levitate, lock in position and rotate. Thus it generates no friction or mechanical stress on the bag during mixing and avoids unwanted particle shedding that will affect the purity of the product.

Features & Benefits

50 L to 1,000 L Flexel® for LevMixer®	Full scalability
Levitated mixing technology	Ultra clean mixing operation
Side K-Welds on Flexel® Bags for LevMixer®	Easy installation, unfolding and walk away filling process
HDPE impeller protection Triclamp cap	Prevents film damage during packaging and transport Offers large diameter port for powder transfer
Face bottom port	Easy installation and access to tubing
Standard Flexel® Bags for LevMixer® designs	Most designs are available from stock
Hinged door on Palletank® for LevMixer®	Easy installation
Mobile drive unit	Single drive unit can serve multiple mixing tanks of different volumes
Rear and lateral windows	Visual check of correct bag installation and mixing process
Full compliance with ISO 11137	Highest sterility assurance level

[1] LevMixer is a trademark or registered trademark of ATMI, inc in the United States, other countries or both and this product uses ATMI patented LevMixer technology.
[2] using ATMI patented mixing technology

Applications

The LevMixer® drive unit delivers strong torque for efficient mixing of a wide variety of solutions from process intermediate to final drug product in the biopharmaceutical industry. Due to its cubical design the Flexel® Bags for LevMixer® can ideally be applied for liquid in liquid mixing and solid – liquid mixing operations that require moderate to high mixing intensity such as:

– Buffer & media preparation

– Product formulation|reformulation

– Hydration|Dissolution of hydrophobic powders

– Bulk intermediate resuspension

– Viral inactivation

– Final formulation

Flexibility

The LevMixer® drive unit operates independently of the Palletank® for LevMixer® so that a single drive unit can serve multiple Palletank® of different sizes. Standard Flexel® Bags for LevMixer® are available from stock. They may be readily customized to optimize the integration into specific processes. Expert design service is available on-site through Sartorius Stedim Biotech application engineers on a worldwide basis.

Validation

Flexel® Bags for LevMixer® have been qualified applying the most stringent and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® Bags for LevMixer® with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech Single-Use Products with a sterility assurance level of 10^{-6} over the shelf life.

Flexel® Bags for LevMixer® are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Containers-Physicochemical tests – Plastics

– USP <788> Particulate matter in injections-Large-volume injections and E.P. 2.9.19: Particulate contamination-sub-visible particles

– USP<85> and EP 2.1.14: Bacterial endotoxins test

– ISO 11737: Microbiological methods-Determination of a population of micro-organisms on products

– ISO 11137: Sterilization of Health care products-Radiation

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state-of-the-art and robust supply chain that can cope with strong market growth.

▷ Specifications

1. LevMixer® Drive Unit

Power:	
EU	Single Phase 230 V, 50/60 Hz
USA	Single Phase 110 V, 60 Hz
Japan	Single Phase 230 V, Transformer (110 V Input), 50/60 Hz
Input Wattage	< 350 Watts
Footprint	94 cm + 41 cm (37 inch + 16 inch)
Weight	47 kg (103 lb)
Ambient Temperature	4° to 30°C
Ambient Humidity	Less than 75%
Mobility	Mounted on stainless cart with four clean room wheels and push handles
IP Rating	IP23
Impeller Speed	0 – 180 RPM
Initial Set-up Time	45 Minutes
Vessel Changeover Time	< 7 Minutes
CE Mark	Compliant
Material for External Surfaces	Stainless Steel #316L

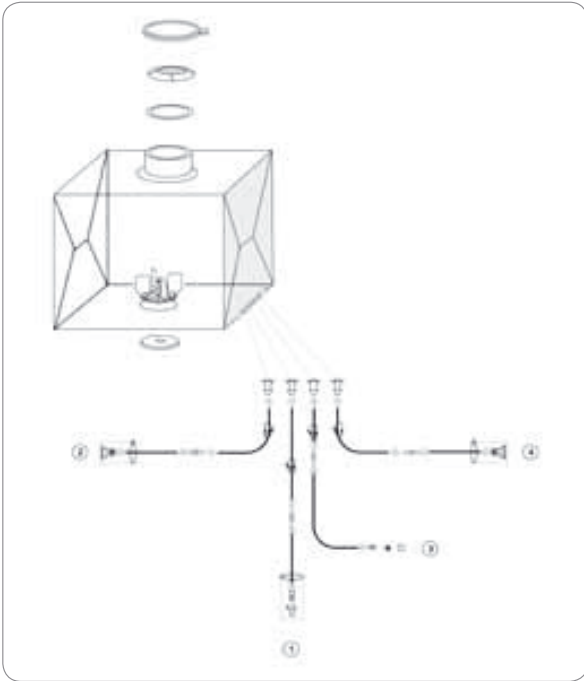## 2. Flexel® Bags for LevMixer® Specifications

Bag Chamber	S40 Flexel 3D Bag Chamber with Multi-Layer Film, including EVOH gas barrier layer and PE contact layer
Impeller Position	Centered
Impeller Size (50 L – 100 L)	4.95" (126 mm)
Impeller Size (200 L to 1,000 L)	6.35" (161 mm)
Tubing Material	Silicone, C-Flex®
Number of Ports	1 top port, 4 front bottom ports
Outlet Fittings	MPC Quick Connect Coupling, Tri-clamp, Needless sampling port
Volumes	50 L, 100 L, 200 L, 400 L, 650 L and 1,000 L
Nominal Filling Volume: 50 L 100 L 200 L 400 L 650 L 1,000 L	Minimum – Maximum Volume: 30 L – 60 L 40 L – 120 L 60 L – 230 L 120 L – 420 L 160 L – 720 L 250 L – 1,060 L
Sterilization	by Gamma Irradiation

3. Palletank® for LevMixer®

Material	304L Stainless Steel
Surface Finish	Glass Bead Blasted
Door	Front Hinged Door
Windows	Plexiglass
Ports	Railed port for drive unit Front bottom port for bag line access
Volumes	50 L, 100 L, 200 L, 400 L, 650 L and 1,000 L
Dimensions: 50 L 100 L 200 L 400 L 650 L 1,000 L	W × D × H 825 × 570 × 1051 mm (32.5 × 22.4 × 41.4 inch) 825 × 570 × 1126 mm (32.5 × 22.4 × 44.3 inch) 777 × 726 × 1230 mm (30.6 × 28.6 × 48.4 inch) 941 × 891 × 1325 mm (37 × 35.1 × 58.3 inch) 998 × 1025 × 1480 mm (39.3 × 40.4 × 58.3 inch) 1139 × 1167 × 1650 mm (44.8 × 45.9 × 65.0 inch)
Weight (approx.): 50 L 100 L 200 L 400 L 650 L 1,000 L	43 kg (95 lb) 49 kg (108 lb) 63 kg (139 lb) 88 kg (196 lb) 103 kg (227 lb) 156 kg (344 lb)

Ordering Information

1. Flexel® Bags for LevMixer®

Part Number	Description	Tubing	Bottom Port 1	Bottom Port 2	Bottom Port 3	Bottom Port 4	Qty/Box
FXB111567	STD Flexel® Cubical Mix Bag 50 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111568	STD Flexel® Cubical Mix Bag 100 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111420	STD Flexel® Cubical Mix Bag 200 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111421	STD Flexel® Cubical Mix Bag 400 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111565	STD Flexel® Cubical Mix Bag 650 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111569	STD Flexel® Cubical Mix Bag 1,000 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2

2. Palletank® for LevMixer®

Part Number	Description
FXC110820	STD Palletank® Cubical Mix 50 L (Impeller) incl. Adaptation Set and Clamp Holder
FXC112230	STD Palletank® Cubical Mix 100 L (Impeller) incl. Adaptation Set and Clamp Holder
FXC110821	STD Palletank® Cubical Mix 200 L (Impeller) incl. Adaptation Set and Clamp Holder
FXC111135	STD Palletank® Cubical Mix 400 L (Impeller) incl. Adaptation Set and Clamp Holder
FXC110822	STD Palletank® Cubical Mix 650 L (Impeller) incl. Adaptation Set and Clamp Holder
FXC113384	STD Palletank® Cubical Mix 1,000 L (Impeller) incl. Adaptation Set and Clamp Holder

3. Drive Units

For 50 L – 400 L Flexel® Palletank® for LevMixer®

Part Number	Description
LT-DBTL002 US	LevMixer® drive machine for US and Canada on cart with two latches for 8" and 15" ports. Control panel (110 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL003 Europe	LevMixer® drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL004 Japan	LevMixer® drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories. Includes Japanese transformer.
LT-DBTL005 UK	LevMixer® drive machine with European certification on cart with UK-Plug and two latches for 8" and 15" ports. Control panel (220V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL010 Australia	LevMixer® drive machine with European certification on cart with Australian plug and two latches for 8" and 15" ports. Control panel (220V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.

For 50 L – 1,000 L Flexel® Palletank® for LevMixer®

Part Number	Description
LT-DBTL006 US	LevMixer® drive machine for US and Canada on cart with three latches for 8", 15" and 20" ports. Control panel (110 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL007 Europe	LevMixer® drive machine with European certification on cart with three latches for 8", 15" and 20" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL008 Japan	LevMixer® drive machine with European certification on cart with three latches for 8", 15" and 20" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories. Includes Japanese transformer.
LT-DBTL009 UK	LevMixer® drive machine with European certification on cart with UK-Plug and three latches for 8", 15" and 20" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL011 Australia	LevMixer® drive machine with European certification on cart with Australian plug and three latches for 8", 15" and 20" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.

4. Spare Parts

Part Number	Description
FXA112559	Clamp Holder for STD Palletank® Cubical Mix 50 L (Impeller)
FXA112560	Clamp Holder for STD Palletank® Cubical Mix 100 L (Impeller)
FXA112083	Clamp Holder for STD Palletank® Cubical Mix 200 L (Impeller)
FXA112086	Clamp Holder for STD Palletank® Cubical Mix 400 L (Impeller)
FXA112085	Clamp Holder for STD Palletank® Cubical Mix 650 L (Impeller)
FXA113527	Clamp Holder for STD Palletank® Cubical Mix 1,000 L (Impeller)
FXA112074	Adaptation Set for STD Palletank® Cubical Mix (Impeller)

▶ Palletank® Jacketed for LevMixer® | Magnetic Mixer

Introduction

The Palletank® Jacketed for LevMixer® combined with Flexel® 3D mixing bag assemblies provides state of the art fluid management control in biopharmaceutical process applications. This mobile jacketed and insulated Palletank® has been designed for an efficient heating | cooling of the bag content along with efficient single-use mixing systems with Flexel® for LevMixer®[1] and Flexel® for Magnetic Mixer[2]. The excellent heat-transfer characteristics make this Palletank® suitable for a large variety of biopharmaceutical process applications. It is available in standard sizes from 50 L to 650 L, covering cooling and heating requirements ranging from lab | pilot operation to full-scale production.

High Performance Heating and Cooling

The temperature of the bag content is controlled by the heating | cooling of the heat transfer fluid circulated within the jacket. The dimple jacket is directly in contact with the Flexel® Bag for LevMixer® or Flexel® Bag for Magnetic Mixer thus providing an efficient heat transfer. The turbulences generated by the dimples inside the jacket provides excellent heat-transfer characteristics. The high heat transfer fluid velocity and the fluid flow directed by the baffles inside the jacket provide excellent temperature uniformity. The fluid temperature homogeneity is improved by the mixing. The Palletank® Jacketed for LevMixer® range is designed with maximized heat transfer surface. All faces are insulated; all faces are jacketed except the front for the access door (200 L to 650 L) and the lid.

Easy Implementation

The dimple jacket rated for a working pressure of 10 bars (150 psi) and generates a low pressure drop – 0.2 and 0.5 bars. The Palletank® heat fluid transfer circuit directly to an internal water network system using industry standard inlet | outlet tri clamp port. It can also be used in combination with an external heating | cooling system.

Applications

The Palletank® Jacketed provides excellent heat transfer performances and is available standard from 50 L to 650 L which make it suitable to a large range of biopharmaceutical applications:

– Chilling and cold storage of bioreactor harvest

– Maintaining temperature of bioreactor harvest

– Cold storage of bulk intermediate product

– Cold storage of cell culture media and chromatography buffer

– Buffer preparation – heating solution for powder dissolution

Features & Benefits

Insulated dimple jacket	High heat transfer efficiency
Jacketed bottom	High heating	cooling efficiency for low filling volumes or flow rate
Compliant with ASME and PED directives	Process security
Standard Tri Clamp connection	Easy implementation with direct connection to the facility's water network
Face bottom port	Easy installation including pre-connected bags and easy access to tubing
Compatible with Magnetic Mixer®[1] and LevMixer® Drive Unit	Suitable for a large variety of process applications
Multiple manufacturing sites for Flexel® 3D Bags	High Security of supply

[1] LevMixer® is trademark or registered trademarks of ATMI, Inc. in the United States, other countries or both.

[2] This product uses ATMI patented Magnet Mixer technology using ATMI patented mixing technology

Cost Reduction and Risk Reduction
Single-use systems used in biopharmaceutical manufacturing improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Costly and time consuming CIP & SIP operations are eliminated. This results not only in significant cost savings within the entire manufacturing process, but also in the optimization of capacity utilization.

Technology Integration Support
Sartorius Stedim Biotech supports users from the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation and validation of Single-Use Manufacturing.

Palletank® Ranges
Besides the Palletank® for LevMixer®, the product range of Palletank® container includes the following lines specifically developed for the various application requirements on fluid management in the biopharmaceutical industry:

– Palletank® for storage

– Palletank® for shipping

– Palletank® for in-process fluid handling

– Palletank® for weighing

– Palletank® for recirculation mixing

– Palletank® for impeller mixing

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

▷ Specifications

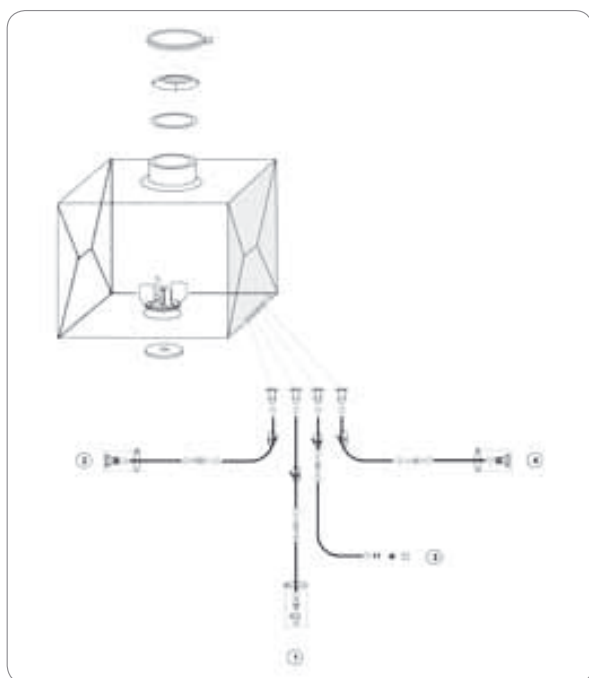|	
Material of construction	Stainless Steel 304 Glascofoam and polyfoam (insulation)
Surface Finish	Glass bead blasted
Door	Front insulated hinged door (except 50 L and 100 L)
Port	Railed port for coupling LevMixer®|Magnetic Mixer® drive unit
Bag tubing gate	Insulated front bottom port for bag line access
Mobility	Mounted on stainless cart with four clean room wheels and push handles
Operating temperature	0 – 50°C
Maximum operating pressure	10 bars (150 psi)
Test pressure	15 bars (225 psi)
ASME and PED	Compliant
Insulated	Yes – the 4 sides, the bottom and the lid
Jacketed	4 sides and bottom (50 L and 100 L) 3 sides and bottom (200 L to 650 L)
Volumes	50 L, 100 L, 200 L, 400 L, and 650 L
Dimensions	(W × D × H) 50 L: 654 × 610 × 1085 mm (25,7 × 24.0 × 42.7 in.) 100 L: 740 × 696 × 1190 mm (29.1 × 27.4 × 46.9 in.) 200 L: 861 × 817 × 1290 mm (33.8 × 32.2 × 50.8 in.) 400 L: 1103 × 982 × 1440 mm (43.4 × 38.7 × 56.7 in.) 650 L: 1263 × 1091 × 4546 mm (49.7 × 43.0 × 60.9 in.)
Weight	50 L: 140 Kg (308 lb) 100 L: 157 Kg (346 lb) 200 L: 180 Kg (396 lb) 400 L: 298 Kg (656 lb) 650 L: 374 Kg (824 lb)

Ordering Information

1. Palletank® Jacketed for LevMixer® or Magnetic Mixer

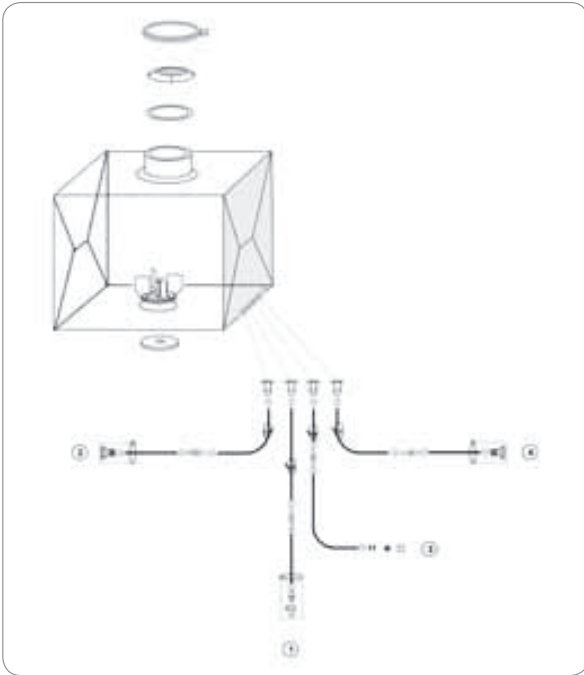| Order Code	Description
FXC114525	STD Palletank® Cubical Jacketed-Mix 50 L (Impeller) incl. Adaptation Set and Clamp Holder
FXC113382	STD Palletank® Cubical Jacketed-Mix 100 L (Impeller) incl. Adaptation Set and Clamp Holder
FXC113383	STD Palletank® Cubical Jacketed-Mix 200 L (Impeller) incl. Adaptation Set and Clamp Holder
FXC114524	STD Palletank® Cubical Jacketed-Mix 400 L (Impeller) incl. Adaptation Set and Clamp Holder
FXC114526	STD Palletank® Cubical Jacketed-Mix 650 L (Impeller) incl. Adaptation Set and Clamp Holder

2. Spare Parts

Part Number	Description
FXA112559	Clamp holder for STD Palletank® Cubical Jacketed-Mix 50 L (Impeller)
FXA112560	Clamp holder for STD Palletank® Cubical Jacketed-Mix 100 L (Impeller)
FXA112083	Clamp holder for STD Palletank® Cubical Jacketed-Mix 200 L (Impeller)
FXA112086	Clamp holder for STD Palletank® Cubical Jacketed-Mix 400 L (Impeller)
FXA112085	Clamp holder for STD Palletank® Cubical Jacketed-Mix 650 L (Impeller)
FXA112074	Adaptation Set for Palletank® Cubical Jacketed-Mix

3. Flexel® Bags for LevMixer®

Part Number	Description	Tubing	Bottom Port 1	Bottom Port 2	Bottom Port 3	Bottom Port 4	Qty/Box
FXB111567	STD Flexel® Cubical Mix Bag 50 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111568	STD Flexel® Cubical Mix Bag 100 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111420	STD Flexel® Cubical Mix Bag 200 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111421	STD Flexel® Cubical Mix Bag 400 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111565	STD Flexel® Cubical Mix Bag 650 L	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2

4. Flexel® Bags for Magnetic Mixer

Part Number	Description	Tubing	Bottom Port 1	Bottom Port 2	Bottom Port 3	Bottom Port 4	Qty/Box
FMB114867	STD Flexel® Cubical Magnetic Mix Bag 50 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FMB114870	STD Flexel® Cubical Magnetic Mix Bag 100 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FMB114893	STD Flexel® Cubical Magnetic Mix Bag 200 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FMB114894	STD Flexel® Cubical Magnetic Mix Bag 400 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FMB114895	STD Flexel® Cubical Magnetic Mix Bag 650 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FMB114896	STD Flexel® Cubical Magnetic Mix Bag 1000 L TPE	Silicone + Clear C-Flex 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 0.6 m (23.6") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2

5. LevMixer® Drive Unit

For Palletank® Jacketed for LevMixer® 50 L, 100 L and 200 L

Part Number	Description
LT–DBTL002 US	Superconducting drive machine for US and Canada on cart with two latches for 8" and 15" ports. Control panel (110 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL003 Europe	Superconducting drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL004 Japan	Superconducting drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories. Includes Japanese transformer.
LT–DBTL005 UK	Superconducting drive machine with European certification on cart with UK–Plug and two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL010 Australia	Superconducting drive machine with European certification on cart with Australian plug and two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.

For Palletank® Jacketed for LevMixer® 50 L, 100 L, 200 L, 400 L and 650 L

Part Number	Description
LT–DBTL006 US	Superconducting drive machine for US and Canada on cart with three latches for 8", 15" and 20" ports. Control panel (110 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL007 Europe	Superconducting drive machine with European certification on cart with three latches for 8", 15" and 20" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL008 Japan	Superconducting drive machine with European certification on cart with three latches for 8", 15" and 20" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories. Includes Japanese transformer.
LT–DBTL009 UK	Superconducting drive machine with European certification on cart with UK–Plug and three latches for 8", 15" and 20" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL011 Australia	Superconducting drive machine with European certification on cart with Australian plug and three latches for 8", 15" and 20" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.

6. Magnetic Mixer Drive Units

Part Number	Description
LT-DU-005-US	Magnetic Mixer Drive Unit, 110 V, US Power Cord
LT-DU-006-EU	Magnetic Mixer Drive Unit, 230 V, EU Power Cord
LT-DU006-UK	Magnetic Mixer Drive Unit, 230 V, UK Power Cord
LT-DU006-SW	Magnetic Mixer Drive Unit, 230 V, Swiss Power Cord
LT-DU006-AU	Magnetic Mixer Drive Unit, 230 V, Australian Power Cord
LT-DU006-JA	Magnetic Mixer Drive Unit, 230 V, Japanese Power Cord and Transformer

▶ Powder Transfer Bag System

Single-Use Technology

Description
Standard Powder Transfer Bag System is designed for powder delivery applications where high containment, high product recovery and ease of use are important. Standard Powder Transfer Bags provide a single-use alternative to traditional rigid reusable containers and plastic pouches in a large variety of powder containment and delivery applications. With a volume range of 15 L and 30 L, the Standard Powder Transfer Bags are routinely used at all process scales from process development to commercial bio-manufacturing.

These bags are manufactured with very high quality standards for applications requiring remarkable levels of robustness, reliability and security.

With an extensive range of accessories, Standard Powder Transfer Bag System facilitates the delivery and discharge of powders into Sartorius Stedim Biotech single-use mixing systems (Flexel® for LevMixer®[1] and for Magnetic Mixer). The Standard Powder Transfer Bag System is based on the market leading Sartorius Stedim Biotech Flexel® 3D Bag, the proven Palletank® technology and the patent-pending PSD film technology from ATMI.

[1] LevMixer® is a trademark or registered trademark of ATMI, Inc. in the United States, other countries or both.

Cost Reduction and Risk Reduction
Single-use systems used in biopharmaceutical manufacturing improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Costly and time consuming CIP & SIP operations are eliminated. This results not only in significant cost savings within the entire manufacturing process, but also in the optimization of capacity utilization.

Applications
Standard Powder Transfer Bags are constructed from a Permanently Static Dissipative (PSD) LDPE film that provides a strong structure with high flexibility and transparency for the safe containment and delivery of powders into a wide range of applications.

Typical applications requiring a high containment for the transport and delivery of a powder into a single-use mixing systems includes:

– Media preparation
  (dry powder media, dry powder feed)

– Buffer preparation (dry powder buffer)

– Formulation (API, Excipient)

Features	Benefits
Antistatic film	Dissipating static reduces powder loss and explosion risk
Tapered funnel shape	High product recovery
Flexible transparent film	Bag contents is clearly visible
Standard design	References available from stock
Industry-standard triclamp interface	Broad compatibility and superior process seal to single-use systems
Reinforced handle	Easy to manipulate – good ergonomics
Rotary powder holder	Easy access to the hook – good ergonomics

Flexibility
Standard Powder Transfer Bags are available for a fast implementation in a customer process using industry-standard Triclamp interface.

Sartorius Stedim Biotech supports user design with a comprehensive support program that ensures successful design implementation of Single-Use Manufacturing.

Easy Implementation
Standard Powder Transfer Bags are available in volumes of 15 L and 30 L. They are supplied gamma irradiated and ready to use.
A series of associated systems such as pinch clamp, 4-inch triclamp cap and powder bag holders for Palletanks® for LevMixer® facilitate handling and processing.

Validation
Standard Powder Transfer Bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests provide users of Standard Powder Transfer Bags with data representing a wide range of products in a variety of processing conditions.

Quality Assurance
Sartorius Stedim Biotech Quality Systems for single-use products follow applicable ISO and FDA regulations. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements. Standard Powder Transfer Bags are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate matters in injections

– ISO 11737: Bioburden

The film is certified animal derived component free.

Supply Chain
Standard Powder Transfer Bags are available from stock.

▷ Specifications

1. Standard Powder Transfer Bags

Bag Chamber	Multiple layer film construction, including Permanently Static Dissipative (PSD) LDPE contact layer
Fittings	4-inch triclamp
Accessory	Pinch clamp
Volumes	15 L and 30 L
Number of Port	1 port
Irradiation	25–45 kGy

2. Triclamp Reducer

Description	8-inch to 4-inch triclamp reducer with a 4-inch triclamp plug, 4-inch triclamp gasket and 4-inch triclamp union
Material of Construction	Reducer: polyethylene, Plug: polyethylene, Gasket: platinum cured silicone, 4-inch triclamp union: glass reinforced polyamide
Non sterile	

3. Accessories

Description	4-inch triclamp plug, 4-inch triclamp gasket, 4-inch triclamp union
Material of Construction	Plug: polyethylene, Gasket: platinum cured silicone, 4-inch triclamp union: glass reinforced polyamide
Non sterile	

4. Powder Bag Holders
Two Vertical Positions for 15 L and 30 L Powder Bags.

Description	Powder holder accessory for Palletank® for LevMixer®, 50–100 L	Powder holder accessory for Palletank® for LevMixer®, 200–400–650 L	Powder holder accessory for Palletank® for LevMixer®, 1000 L
Construction Material	304L Stainless Steel and Nylon		
Surface Finishing	Glass Bead Blasted		
Weight (Approx.)	8 kg	9 kg	9 kg
Overall dimensions (Approx.) w × d × h	442 × 400 × 1080 mm 17.4 × 15.7 × 42.5 in.	743 × 400 × 1080 mm 29.2 × 15.7 × 42.5 in.	857 × 400 × 1080 mm 33.7 × 15.7 × 42.5 in.
Height above Palletank with 15 L Powder Bag with 30 L Powder Bag	726 mm │ 28.6 in. 986 mm │ 38.8 in.		
Additional features	Two vertical positions for 15 L and 30 L Powder bags. Rotary powder holder for easy access to the hook		

Ordering Information

1. Standard Powder Transfer Bags

Part Number	Description	Bag Port 1	Qty/Box
FMA114008	STD POWDER BAG 15 L (PWD PORT) with pinch clamp	4-inch triclamp	5
FMA114009	STD POWDER BAG 30 L (PWD PORT) with pinch clamp	4-inch triclamp	5

2. Components

Part Number	Description	Qty/Box
FMA114007	COMPONENT (TC8"-4")	1
FMA114179	COMPONENT FOR TC4" (CAP │ GASKET │ UNION)	5

3. Powder Bag Holders

Part Number	Description	Qty/Box
FXA114343	STD PALLETANK® CUBICAL ACCESSORY POWDER HOLDER 50–100 L	1
FXA114344	STD PALLETANK® CUBICAL ACCESSORY POWDER HOLDER 200–400–650 L	1
FXA114419	STD PALLETANK® CUBICAL ACCESSORY POWDER HOLDER 1000 L	1

▶ Flexel® Drum for LevMixer®

Description

The Flexel® Drum for LevMixer® [1] is a unique single-use mixing solution utilizing cylindrical tank geometries combined with the market leading LevTech® levitated impeller and Sartorius Stedim Biotech Flexel® 3D Bag technologies.

Components

1. LevMixer® Drum-PE are designed to fit perfectly with the Flexel® Drum Bags for LevMixer® and the integrated impeller. The tanks are positioned on a stainless steel LevMixer® Dolly to ensure a safe operation as well as easy access and drainage. The LevMixer® Dolly contains a railed port for coupling the LevMixer® Drive Unit with the Flexel® Drum Bag for LevMixer®. They are available in 50 L, 100 L, 200 L, 300 L, 370 L and 560 L volumes to be used with the 50 L to 560 L Flexel® Drum Bag for LevMixer®.

2. LevMixer® Drum-Stainless Steel are available in 50 L, 100 L, 200 L, 300 L and 370 L. The tanks are positioned on a stainless steel LevMixer® Dolly to ensure a safe operation as well as easy access and drainage. In the volumes of 560 L, 750 L and 1,000 L the tanks are mounted on legs that are equipped with cleanroom wheels for increased mobility. They incorporate an interface railed port for coupling the LevMixer® Drive Unit with the impeller inside the bag.

3. LevMixer® Drive Unit levitates and rotates the single-use magnetic impeller without seals, bearings or surface contact. This allows the Flexel® Drum for LevMixer® to efficiently mix powders, suspensions, solutions or emulsions. The LevMixer® Drive Unit is mobile, cart-mounted and designed to interface with mixing tanks of different volumes.

4. Flexel® Drum Bags for LevMixer® contain a magnetic impeller assembly positioned for maximum flexibility and performance for all applications. They offer scalability, ease of use and robustness.

Clean and Sterile Mixing Operation

A patented superconducting technology is utilized to levitate and drive the single-use impeller inside sterile single-use Flexel® Drum Bags for LevMixer®. When aligned with the specially designed LevMixer® impeller, the LevMixer® Drive Unit causes the impeller to levitate and lock in position. Thus it generates no friction or mechanical stress on the bag during mixing and avoids unwanted particle shedding that will influence the purity of the product.

Applications

The LevMixer® Drive Unit delivers strong torque for efficient mixing of a wide variety of solutions from process intermediate to final drug product in the biopharmaceutical industry. Due to its cylindrical design the Flexel® Drum Bags for LevMixer® can ideally be applied for liquid in liquid mixing and solid in liquid mixing operations such as:

– Buffer & media preparation

– Hydration | Dissolution of hydrophobic powders

– Viral inactivation

– Product suspension

– Final formulation

Features & Benefits

Levitated mixing technology	Ultra clean mixing operation
Various bag & tank sizes	High flexibility
Standard Flexel® Drum Bags for LevMixer® designs	Most designs are available from Stock
All connections are intensively qualified	Safe and robust
Multiple manufacturing sites	High security of supply
Full compliance with ISO 11137	Highest sterility assurance level

[1] LevMixer is a trademark or registered trademark of ATMI, inc in the United States, other countries or both and this product uses ATMI patented LevMixer technology. Using ATMI patented mixing technology.

Flexibility

The LevMixer® Drive Unit operates independ-ently of the cylindrical tank with the Flexel® Drum Bags for LevMixer® so that a single LevMixer® Drive Unit can serve multiple tanks of different sizes.

Flexel® Drum Bags for LevMixer® are available from stock. They can be readily customized to optimize the integration into specific proc-esses. Expert design service is available on-site through Sartorius Stedim Biotech Application Specialists on a worldwide basis.

Validation

Flexel® Drum Bags for LevMixer® have been qualified applying the most stringent and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® Drum Bags for LevMixer® with data repre-senting the widest range of process fluids in a variety of processing conditions.

The validation of the Gamma Irradiation for all Sartorius Stedim Biotech single-use products is done in full compliance with ISO11137 to ensure a sterility assurance level of 10^{-6} over their shelf life.

Flexel® Drum Bags for LevMixer® are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of design-ing Single-Use solutions based on collabora-tive supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

▷ Specifications

1. LevMixer® Drive Unit

Power:	
EU	Single Phase 230 V, 50/60 Hz
USA	Single Phase 110 V, 60 Hz
Japan	Single Phase 230 V, Transformer (110 V Input), 50/60 Hz
Input Wattage	< 350 Watts
Footprint	37 inches+16 inches (94 cm+41 cm)
Weight	103 lb (47 kg)
Ambient Temperature	4° to 30°C
Ambient Humidity	Less than 75%
Mobility	Mounted on Stainless Cart with Four Clean Room Wheels and Push Handles
IP Rating	IP23
Impeller Speed	0–180 RPM
Initial Set-up Time	45 Minutes
Vessel Changeover Time	< 7 Minutes
CE Mark	Compliant
Material for External Surfaces	Stainless Steel #316

2. LevMixer® Drum–PE

Material	HDPE
Volumes	50 L–560 L

Dimensions & weight:	Height | Diameter
50 L	22" (559 mm) | 14.75" (374 mm) 8 lbs (3,6 kgs)
100 L	35" (635 mm) | 18.25" (463 mm) 9 lbs (4 kgs)
200 L	37" (940 mm) | 21.50" (546 mm) 22 lbs (10 kgs)
300 L	46" (1,168 mm) | 23.25" (590 mm) 35.5 lbs (16.1 kgs)
370 L	41" (1,041 mm) | 27.37" (695 mm) 38.5 lbs (17.5 kgs)
560 L	53" (1,346 mm) | 23.31" (744 mm) 53 lbs (24 kgs)

3. LevMixer® Drum–Stainless Steel

Material	Stainless Steel # 316L
Volumes	50 L–1,000 L

Dimensions:	Height | Diameter
50 L	22" (559 mm) | 14.75" (374 mm)
100 L	35" (635 mm) | 18.25" (463 mm)
200 L	37" (940 mm) | 21.50" (546 mm)
300 L	46" (1,168 mm) | 23.25" (590 mm)
370 L	41" (1,041 mm) | 27.37" (695 mm)
560 L	53" (1,346 mm) | 23.31" (744 mm)
750 L	48.5" (1,232 mm) | 35.875" (911 mm)
1,000 L	48.5" (1,232 mm) | 42.125" (1,070 mm)

4. LevMixer® Dolly

|	
Material	Stainless Steel # 316L
Finish	Bead Blasting
Wheels	Clean Room Wheels
Dimensions: LT-DBMC034 LT-DBMC036	34" (860 mm) W × 40" (1010 mm) L × 36" (945 mm) H 26" (660 mm) W × 44" (1117 mm) L × 34" (864 mm) H
Weight	80 lb (36.5 kg)
Load capacity	1,250 lb (570 kg)

5. Flexel® Drum Bags for LevMixer®

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, ULDPE Contact Layer
Impeller position	Off-center
Impeller size	50 – 100 liter – 4.95" (126 mm) 200 – 1,000 liter – 6.35" (161 mm)
Tubing material	Silicone, TPE
Number of Ports	3 top ports, 1 bottom port
Outlet Fittings	MPC Quick Connect Coupling, Tri-clamp, Luer Lock female septum
Volumes	50 L – 1000 L
Sterilization	by Gamma Irradiation

6. Flexel® Liners for LevMixer®

|	
Bag Chamber	Multiple Film Construction, ULDPE Contact Layer (No Gas Barrier)
Impeller position	Off-center
Impeller size	50 – 100 liter – 4.95" (126 mm) 200 – 1,000 liter – 6.35" (161 mm)
Number of Ports	No Bottom Drain Port, Bottom Drain Port
Outlet Fittings (w/Bottom Drain Port)	Tri-clamp
Tubing material	Silicone, C-Flex® (w/Bottom Drain Port)
Volumes	50 L – 1000 L
Sterilization	by Gamma Irradiation

Ordering Information

1. Flexel® Drum Bags for LevMixer®
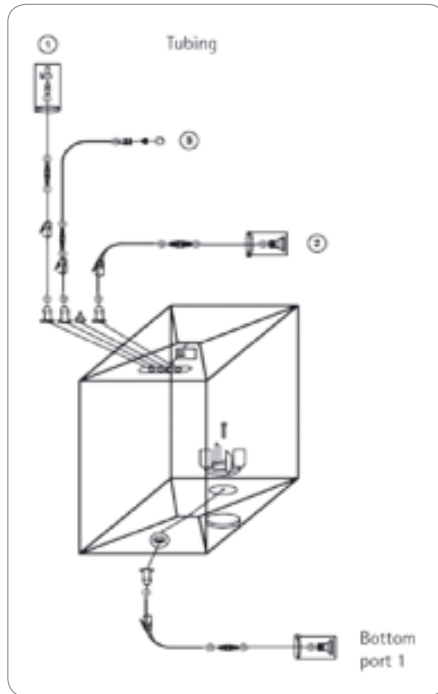
Part Number	Description	Qty/Box	Tubing	Top Filling Port 1	Top Filling Port 2	Top Sampling Port 3	Bottom Draining Port 1
FXB111067	Flexel® 50 L – LevMixer® Drum Bag	4	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1/2" MPX male + cap	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40"). LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111101	Flexel® 100 L – LevMixer® Drum Bag	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1/2" MPX male + cap	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40"). LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111103	Flexel® 200 L – LevMixer® Drum Bag	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1/2" MPX male + cap	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40"). LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111104	Flexel® 300 L – LevMixer® Drum Bag	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1/2" MPX male + cap	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40"). LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111106	Flexel® 370 L – LevMixer® Drum Bag	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1/2" MPX male + cap	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40"). LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111108	Flexel® 560 L – LevMixer® Drum Bag	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1/2" MPX male + cap	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40"). LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111109	Flexel® 750 L – LevMixer® Drum Bag	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1/2" MPX male + cap	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40"). LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60"). 1-1/2" Tri-Clamp
FXB111110	Flexel® 1000 L – LevMixer® Drum Bag	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1/2" MPX male + cap	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40"). LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp

Front side Bottom port 1
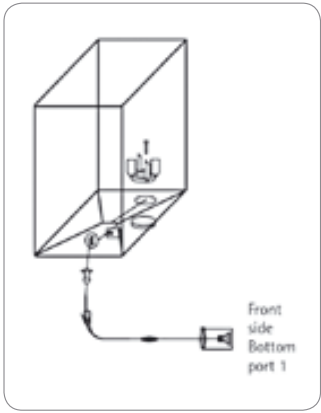
2. Flexel® Liners for LevMixer® with Silicone and TPE tubes

Part Number	Description	Qty/Box	Tubing	Bottom Draining Port 1
FXB111123	Flexel® 50 L – LevMixer® Liner	4	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111129	Flexel® 100 L – LevMixer® Liner	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111131	Flexel® 200 L – LevMixer® Liner	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111132	Flexel® 300 L – LevMixer® Liner	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111133	Flexel® 370 L – LevMixer® Liner	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111138	Flexel® 560 L - LevMixer® Liner	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111139	Flexel® 750 L - LevMixer® Liner	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
FXB111140	Flexel® 1000 L - LevMixer® Liner	2	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60"). 1–1/2" Tri-Clamp
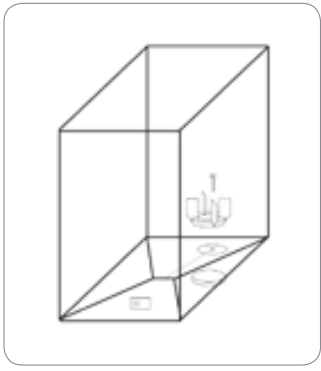
3. Flexel® Liners for LevMixer®

Part Number	Description	Qty/Box	Tubing	Bottom Draining Port 1
FXB111141	Flexel® 50 L – LevMixer® Liner	4	na	na
FXB111143	Flexel® 100 L – LevMixer® Liner r	2	na	na
FXB111144	Flexel® 200 L – LevMixer® Liner	2	na	na
FXB111145	Flexel® 300 L – LevMixer® Liner	2	na	na
FXB111146	Flexel® 370 L – LevMixer® Liner	2	na	na
FXB111147	Flexel® 560 L – LevMixer® Liner	2	na	na
FXB111149	Flexel® 750 L – LevMixer® Liner	2	na	na
FXB111150	Flexel® 1000 L – LevMixer® Liner	2	na	na

4. LevMixer® Drive Unit and LevMixer® Dolly

LT–DBTL002 US	Superconducting drive machine for US and Canada on cart with two latches for 8" and 15" ports. Control panel (110 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories and spare part pouch (Requires Dolly LT–DBMC034)
LT–DBTL003 Europe	Superconducting drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories and spare part pouch (Requires Dolly LT–DBMC034)
LT–DBTL004 Japan	Superconducting drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories and spare part pouch. Includes Japanese transformer (Requires Dolly LT–DBMC034)
LT–DBTL005 UK	Superconducting drive machine with European certification on cart with UK plug and two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories and spare part pouch (Requires Dolly LT–DBMC034)
LT–DBTL010 Australia	Superconducting drive machine with European certification on cart with Australian plug and two latches for 8" and 15" ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories and spare part pouch (Requires Dolly LT–DBMC034)
LT–DBMC034	Elevated 316 stainless steel tank support dolly on clean room wheels, with two drive port positions (8" and 15"), push handle and guide rail for drive positioning and lifting.
LT–DBMC036	Elevated stainless steel dolly (316L) with partial handle on clean room wheels, with guide port and impeller ports. Design to support jacketed and non–jacketed stainless steel tanks in volumes between 200 L and 370 L.

5. LevMixer® Drum–PE

Order–No	Volume	Drive Port Off Center	Side & Bottom Drain
LT–DBMC032	30 liter	x	x
LT–DBMC057	50 liter	x	x
LT–DBMC106	100 liter	x	x
LT–DBMC208	200 liter	x	x
LT–DBMC303	300 liter	x	x
LT–DBMC370	370 liter	x	x
LT–DBMC560	560 liter	x	x

6. LevMixer® Drum–Stainless Steel

Order–No	Volume	Non Jacketed–Cylindrical	Jacketed	With Insulation–Cylindrical	Non–Insulated Cylindrical	Bottom & Side Drain Port	With Door	OD Finish: Beadblast
LT–JTBB059	50 liter	x				x		x
LT–JTBB059A	50 liter	x		x		x		x
LT–JTBB059B	50 liter		x		x	x		x
LT–JTBB059C	50 liter		x	x		x		x
LT–JTBB110	100 liter	x				x		x
LT–JTBB111	100 liter	x		x		x		x
LT–JTBB112	100 liter		x		x	x		x
LT–JTBB113	100 liter		x	x		x		x
LT–JTBB216	200 liter	x				x		x
LT–JTBB217	200 liter	x		x		x		x
LT–JTBB218	200 liter		x		x	x		x
LT–JTBB219	200 liter		x	x		x		x
LT–JTBB308	300 liter	x				x	x	x
LT–JTBB309	300 liter	x		x		x	x	x
LT–JTBB310	300 liter		x		x	x	x	x
LT–JTBB311	300 liter		x	x		x	x	x
LT–JTBB370	370 liter	x				x	x	x
LT–JTBB371	370 liter	x		x		x	x	x
LT–JTBB372	370 liter		x		x	x	x	x
LT–JTBB373	370 liter		x	x		x	x	x
LT–JTBB560	560 liter	x				x	x	x
LT–JTBB561	560 liter	x		x		x	x	x
LT–JTBB562	560 liter		x		x	x	x	x
LT–JTBB563	560 liter		x	x		x	x	x
LT–JTBB752	750 liter	x				x	x	x
LT–JTBB753	750 liter	x		x		x	x	x
LT–JTBB754	750 liter		x		x	x	x	x
LT–JTBB755	750 liter		x	x		x	x	x
LT–JTTL027	1,000 liter	x				x	x	x
LT–JTTL028	1,000 liter	x		x		x	x	x
LT–JTTL029	1,000 liter		x		x	x	x	x
LT–JTTL030	1,000 liter		x	x		x	x	x

7. Accessories

LT-DBCI001	Magnetic charger with bearing for use with 6-magnet oriented impellers (4.95")
LT-DBCI002	Replacement bearing for magnetic charger LT-DBCI001
LT-DBCI005	Magnetic charger with bearing for use with 4-magnet oriented impellers (6.35")
LT-DBAK004	Testing Impeller for use with 6-magnet oriented impellers (4.95")
LT-DBAK007	Testing Impeller for use with 4-magnet oriented impellers (6.35")
LT-DBBI002	Centering aligner
LT-DBBI008	Plastic component for interfacing process bag with retaining tank – DB-200E/EA
LT-DBBI007	Magnetic Clamp to hold Locking Dish in place
LT-DBBI004	Rubber O-Ring to secure Drive-Bag Interface

► # Flexel® 3D System for Recirculation Mixing

Introduction

The Flexel® 3D System for recirculation mixing combines the versatility and convenience of a fully integrated Palletank® system with the advantages of Flexel® 3D Single-Use Bag technology. It can be supplied as full unit operation including all components like dolly, Sartorius Mechatronics load cells supplied with control panel and pre-connected mixing loops Flexel® 3D Bag. The modular design of the Flexel® 3D Palletank® for recirculation mixing also allows for separate operation of a mobile Palletank® and separate stationary flatbed scale.

Applications

The Flexel® 3D Palletank® for mixing has been specifically developed for sterile liquid–liquid blending applications such as:

– Re-homogenization prior to filling

– Temperature equilibration

- Mixing of bulk intermediates in DSP

– UF | DF applications

– Media supplement preparation

– Fraction pooling

– Homogenization of protein solutions

– pH adjustment

– Viral inactivation

– Suspension of adjuvant gel

Increased Safety Through Pre-Connected Mixing Loops Flexel® 3D Bags

The Flexel® 3D Bag is equipped with either one or two pre-connected mixing loops. No additional connection is required, thus preventing any risk of contamination due to operator manipulation. The large loop diameter allows for high flow rates and maximizes mixing intensity.

Key Features & Benefits

Patented integrated tubing protection channels	Increased safety through pre-connected mixing loops Flexel® 3D Bag
Tubing access in front of Palletank®	Easy passage of large filters, Biosafe® RAFT system & manifolded bags
Pump position above the Palletank®	Easy installation, start-up & maintenance
ASME and DESP 97/23/ CE compliant double jacket	Efficient cooling & heating of bag contents
Built-in load cells	Precise fluid management
Multiple manu-facturing sites for Flexel® 3D bags	High Security of supply
All connections extensively qualified	Safe & robust
Full compliance with ISO11137	Highest sterility assurance level

Flexibility
The Flexel® 3D Palletank® for recirculation mixing can be assembled according to end-user's requirements. Thanks to its modular construction load cells with controller, support frames and temperature control can be easily integrated by using standardized components.

– Integrated or roll-up configuration
Two configurations provide optimal process versatility: a single unit with integrated weighing and mixing functionalities, or a modular unit with mobile Palletank® and separate stationary flatbed scale.

– Jacketed
The Palletank® container can be configured to include an ASME and DESP 97/23/CE compliant double jacket and insulation system. The temperature of the bag content is controlled by the heating | cooling of the heat transfer fluid circulated within the jacket. The jacketed container provides excellent heat transfer characteristics due to the turbulence generated by the dimples augmented by increasing jacket velocities through the use of jacket baffles.

– Weight monitoring
A high-performance weight measurement system provided by Sartorius Mechatronics. The Palletank® for recirculation mixing can be configured with built-in load cells that are electronically linked to a control panel and printer for stream-lined operation.

Palletank® Family
Besides the Palletank® for recirculation mixing the product range of Palletank® container includes the following lines specifically developed for the various application requirements on fluid management in the biopharmaceutical industry:

– Palletank® for storage

– Palletank® for shipping

– Palletank® for in-process fluid handling

– Palletank® for weighing

– Palletank® for Impeller Mixing (LevMixer®)

Technology Integration Support
Sartorius Stedim Biotech supports users from the design & implementation phase of a new production facility with the most comprehensive support program that ensures successful design implementation and validation of Single-Use Manufacturing.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

The Flexel® 3D recirculation mixing bags are made to order.

Quality Assurance
Flexel® 3D Palletank® Systems are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. They undergo extensive testing before shipping.

Flexel® 3D Bags for Palletank® are Tested for Compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Containers-Physicochemical tests - Plastics

– USP <788> Particulate matter in injections Large-volume injections and E.P. 2.9.19: Particulate contamination-sub-visible particles

– USP<85> and EP 2.1.14: Bacterial endotoxins test

– ISO 11737: Microbiological methods-Determination of a population of microorganisms on products

– ISO 11137: Sterilization of Health care products-Radiation

Sartorius Stedim Biotech Flexel® 3D System is composed of a single-use sterile bag, the Flexel® 3D Bag and the Palletank® rigid container. The two make up the System and must be used together. Sartorius Stedim Biotech Flexel® 3D recirculation mixing Bags must be used with Palletank® for recirculation mixing.

▷ Specifications

Flexel® 3D Recirculation Mixing Bags

Bag Chamber	Multiple layer film construction, including EVOH gas barrier layer, ULDPE contact layer
Tubing	Silicone, TPE
Fittings	MPX Couplings, Female Luer Lock, MPC Male Coupling, KPC Connector, Triclamp, Needle free sampling port
Volumes	50 L–1,000 L
Number of Ports	Standard silicone:
200 L	4 (2 top, 2 bottom)
50 L–500 L–1,000 L	3 (2 top, 1 bottom)
Sterilization	by Gamma Irradiation

Palletank® for Recirculation Mixing

Bottom Gates	3
Tubing access in front of Palletank®	3
Construction material	Stainless Steel 304 L
Finishing	Glass Bead Blasted
Not stackable	

	Palletank® Volume	Bag Volume(s)	Dimensions (w × d × h)	Weight (approx.)
Palletank® for recirculation mixing	50 L	50 L	519 × 543 × 734 mm (20.4 × 21.4 × 28.9 in)	Not available
	200 L	100 L | 200 L	849 × 649 × 924 mm (33.4 × 25.6 × 36.7 in)	55 kg (121.3 lb)
	500 L	500 L	1335 × 863 × 1003 mm (50 × 34 × 39.5 in)	200 kg (441 lb)
	1000 L	1000 L	1341 × 1071 × 1461 mm (52.8 × 45.2 × 57.5 in)	Not available
Palletank® for recirculation mixing with integrated frame	500 L	500 L	1500 × 863 × 1553 mm (59 × 33.98 × 61.1 in)	260 kg (485 lb)
	1000 L	1000 L	1500 × 1071 × 2008 mm (59 × 45.2 × 79.1 in)	Not available
Palletank® for recirculation mixing & weighing	200 L	100 L | 200 L	1265 × 649 × 1019 mm (49.8 × 25.6 × 40.1 in)	60 kg (132 lb)
Palletank® for recirculation mixing & weighing with integrated frame	500 L	500 L	1500 × 863 × 1798 mm (59 × 16.1 × 70.8 in)	240 kg (529 lb)
	1000 L	1000 L	1500 × 1071 × 2037 mm (59 × 45.2 × 80.2 in)	Not available
Palletank® jacketed & recirculation mixing	200 L	100 L | 200 L	945 × 733 × 1119 mm (37.2 × 28.9 × 44.1 in)	Not available
	500 L	500 L	1430 × 858 × 1274 mm (56 × 33.8 × 50,2 in)	200 kg (441 lb)
	1000 L	1000 L	1430 × 1050 × 1800 mm (56 × 41.3 × 70.6 in)	Not available
Palletank® jacketed & recirculation mixing with integrated frame	500 L	500 L	1600 × 856 × 1845 mm (63 × 33.7 × 72.6 in)	Not available
	1000 L	1000 L	1600 × 1050 × 2390 mm (63 × 41.3 × 94.1 in)	Not available
Palletank® jacketed, recirculation mixing & weighing	200 L	100 L | 200 L	1331 × 733 × 1264 mm (52.4 × 28.9 × 49.8 in)	200 kg (441 lb)
Palletank® jacketed, recirculation mixing & weighing with integrated frame	500 L	500 L	1600 × 856 × 1972 mm (63 × 33.7 × 77.6 in)	Not available
	1000 L	1000 L	1600 × 1050 × 2250 mm (63 × 41.3 × 88.6 in)	Not available

Frame for Pump

|	Dimensions (w × d × h)	Weight (approx.)	Corresponding Palletank® PN
Frame for pump (Small)	675 × 570 × 818 mm (26.6 × 23.6 × 32.2 in)	Not available	FXC111319
Frame for pump (Medium)	1090 × 830 × 1670 mm (42.9 × 32.7 × 65.7 in)	35 kg (77 lb)	FXC113085, FXC107087
Frame for pump (Large)	1600 × 830 × 1845 mm (63 × 32.7 × 72.6 in)	40 kg (88.2 lb)	FXC113086, FXC113087, FXC113090, FXC107092, FXC109987, FXC107088

Ordering Information

1. Palletank® for Recirculation Mixing

Order Code	Description
FXC111319	Palletank® 50 L for recirculation mixing
FXC107087	Palletank® 200 L for recirculation mixing
FXC107092	Palletank® 500 L for recirculation mixing
FXC109987	Palletank® 1000 L for recirculation mixing
FXC107094	Palletank® 500 L for recirculation mixing with integrated frame
FXC110226	Palletank® 1000 L for recirculation mixing with integrated frame
FXC107088	Palletank® 200 L for recirculation mixing and weighing (Sartorius Mechatronics)
FXC110568	Palletank® 500 L for recirculation mixing and weighing (Sartorius Mechatronics) with integrated frame
FXC110698	Palletank® 1000 L for recirculation mixing and weighing (Sartorius Mechatronics) with integrated frame
FXC113085	Palletank® 200 L jacketed & recirculation mixing
FXC113086	Palletank® 500 L jacketed & recirculation mixing
FXC113087	Palletank® 1000 L jacketed & recirculation mixing
FXC113088	Palletank® 500 L jacketed & recirculation mixing with integrated frame
FXC113089	Palletank® 1000 L jacketed & recirculation mixing with integrated frame
FXC113090	Palletank® 200 L jacketed, recirculation mixing & weighing (Sartorius Mechatronics)
FXC113091	Palletank® 500 L jacketed, recirculation mixing & weighing (Sartorius Mechatronics) with integrated frame
FXA110873	Frame for pump (small)
FXA107091	Frame for pump (medium)
FBA106932	Frame for pump (large)

2. Flexel® 3D Recirculation Mixing Bags
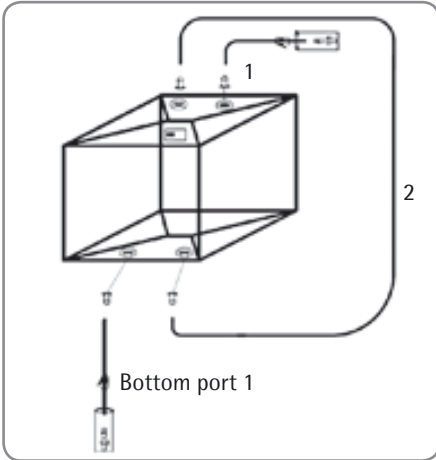
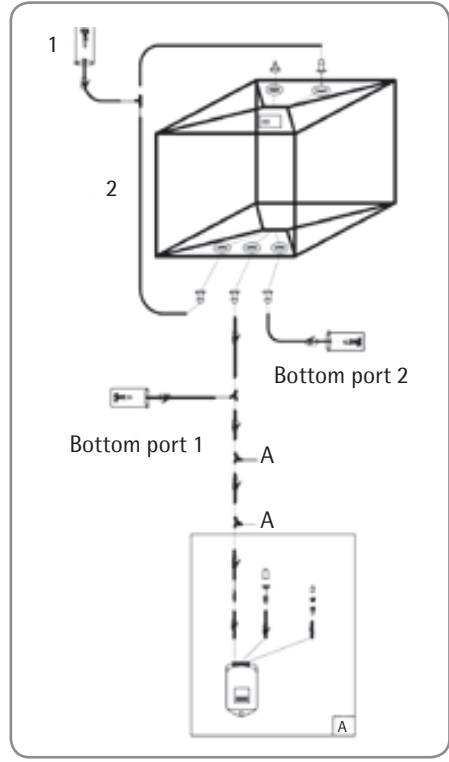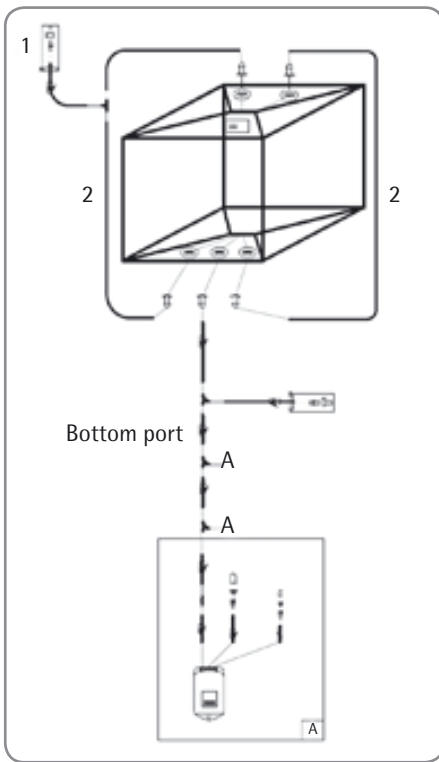Flexel® 3D recirculation mixing Bag 50 L
with MPC connector
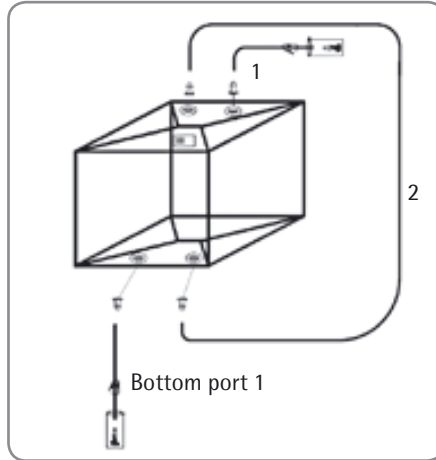
Flexel® 3D recirculation mixing Bag 50 L
with KPC connector

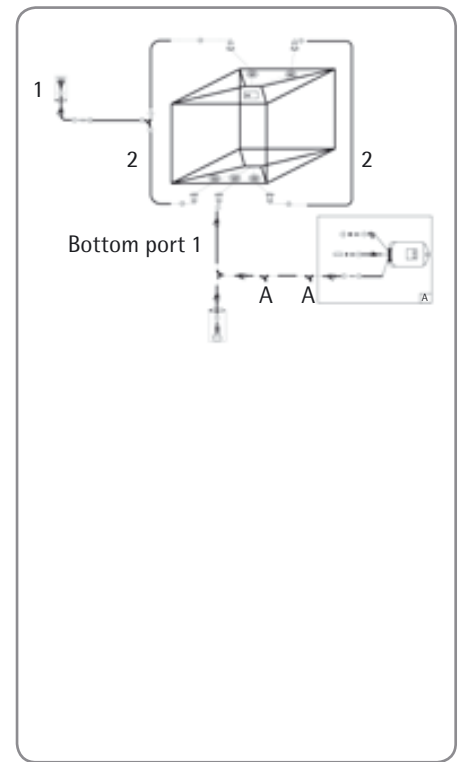| Part Number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Qty/Box
FXB111711	Flexel® 3D recirculation mixing Bag 50 L	silicone	3/8 × 5/8 × 1.0 m (40")	3/4 × 1–1/8 × 2.0 m (80")	3/8 × 5/8 × 1.0 m (40")	5
			3/8 MPC male × sealing cap		3/8 MPC male × sealing cap	
FXB111773	Flexel® 3D recirculation mixing Bag 50 L	silicone	3/8 × 5/8 × 1.0 m (40")	3/4 × 1–1/8 × 2.0 m (80")	3/8 × 5/8 × 1.0 m (40")	
			3/8 KPC male aseptic connector		3/8 KPC male aseptic connector	

Sartopore® 2 Gamma filter capsules can be integrated upon request.
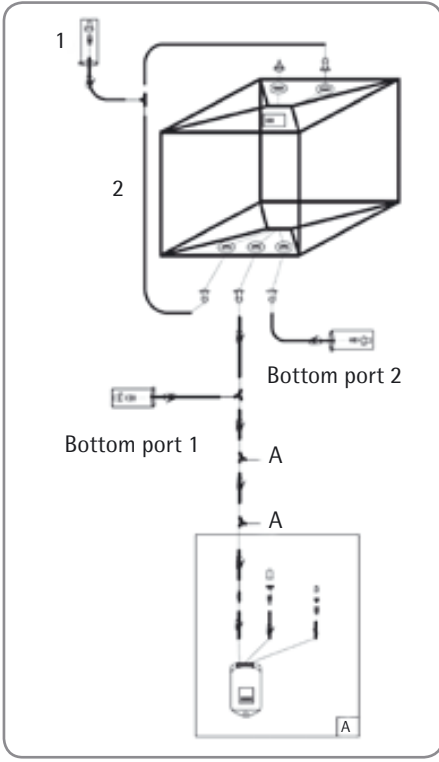
Flexel® 3D recirculation mixing Bag 200 L
with MC connector

Flexel® 3D recirculation mixing Bag 200 L
with KPC

Part Number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Bottom Port 2	Qty/Box
FXB107394	Flexel® 3D recirculation mixing Bag 200 L	silicone	1/2 × 11/16 × 0.5 m (20")	3/4 × 1-1/8 × 3.0 m (120")	1/2 × 11/16 × 1.5 m (60")	1/2 × 11/16 × 1.0 m (40")	2
			1/2 MPX male × sealing cap		1/2 MPX male × sealing cap 3 × 150 ml QC bags	1/2 MPX male × sealing cap	
FXB107402	Flexel® 3D recirculation mixing Bag 200 L	silicone	1/2 × 11/16 × 0.5 m (20")	3/4 × 1-1/8 × 3.0 m (120")	1/2 × 11/16 × 1.5 m (60")	1/2 × 11/16 × 1.0 m (40")	2
			1/2 KPC male aseptic connector		1/2 KPC male aseptic connector 3 × 150 ml QC bags	1/2 KPC male aseptic connector	

Sartopore® 2 Gamma filter capsules can be integrated upon request.

Flexel® 3D recirculation mixing Bag
500 L | 1000 L with MPC connector
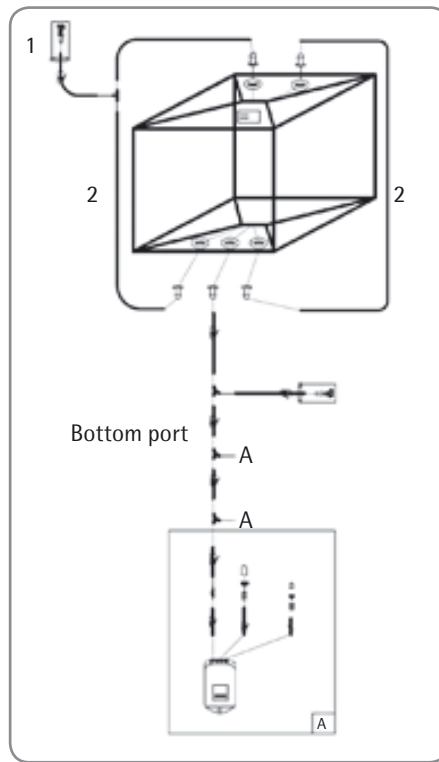
Flexel® 3D recirculation mixing Bag
500 L | 1000 L with KPC connector

Flexel® 3D recirculation mixing Bag
500 L with OPTA connector

Part Number	Description	Tubing	Top Port 1	Top Port 2	Bottom Port 1	Qty/Box
FXB107404	Flexel® 3D recirculation mixing Bag 500 L	silicone	1/2 × 11/16 × 0.5 m (20")	3/4 × 1–1/8 × 3.0 m (120")	1/2 × 11/16 × 1.5 m (60")	2
			1/2 MPX male × sealing cap		1/2 MPX male × sealing cap 3 × 150 ml QC bags	
FXB107403	Flexel® 3D recirculation mixing Bag 500 L	silicone	1/2 × 11/16 × 0.5 m (20")	3/4 × 1–1/8 × 3.0 m (120")	1/2 × 11/16 × 1.5 m (60")	2
			1/2 KPC male aseptic connector		1/2 KPC male aseptic connector 3 × 150 ml QC bags	
FXB113320	Flexel® Palletank Mix 500 L (Loop|Opta|QC)	silicone	3/4 × 1–1/8 × 0.3 m (12") + 1/2 × 3/4 × 0.15 m (6")	3/4 × 1–1/8 × 3 m (119")	1/2 × 3/4 × 1.15 m (60")	2
			1/2 OPTA female aseptic connector		1/2 OPTA male aseptic connector + 3× 150 mL QC bags	
FXB111766	Flexel® 3D recirculation mixing Bag 1000 L	silicone	1/2 × 3/4 × 0.5 m (20")	3/4 × 1–1/8 × 3.5 m (138")	1/2 × 3/4 × 1.5 m (60")	2
			1/2 MPX male × sealing cap		1/2 MPX male × sealing cap 3 × 150 ml QC bags	
FXB111762	Flexel® 3D recirculation mixing Bag 1000 L	silicone	1/2 × 3/4 × 0.5 m (20")	3/4 × 1–1/8 × 3.5 m (138")	1/2 × 3/4 × 1.5 m (60")	2
			1/2 KPC male aseptic connector		1/2 KPC male aseptic connector 3 × 150 ml QC bags	

Sartopore® 2 Gamma filter capsules can be integrated upon request.

▶ Celsius® FFT

Single-Use Container for Flexible Freeze-Thaw Processes

Single-Use Technology

Description
Celsius® FFT combines a unique design of a flexible bag with an integral protective shell. The robustness of this single-use assembly ensures protection, support and ease of handling.

Applications
Celsius® FFT is specifically designed for freezing, thawing and long term frozen storage of biopharmaceuticals such as

– Process intermediates

– Bulk drug substances

– Product in clinical phases (pre, I, II +)

– Vaccines

Single-Use System for Freeze-Thaw Operation
Celsius® FFT is designed for used with common chest and upright freezers. Celsius® FFT is constructed from S71 film, a multi-layer co-extruded high gas barrier film containing EVAM (ethylene vinyl acetate copolymer, monomaterial) as fluid contact layer and EVOH (ethylene vinyl alcohol) as gas barrier layer. The shell provides protection to the contents during all processes, making the assembly robust and reliable and simplifying the handling, storage and shipping of the singe-use containers.

Celsius® FFTp for Plate Freezer
Celsius® FFTp has been especially designed to be used with plate freezers. It also combines the flexible bag with an integral protective shell design. The design is compact and flat to offer a good contact with heat exchange freezer plates.

Celsius® FFT Shippers
The Celsius® FFT Shippers allows shipment of individual or multiple Celsius® FFT to remote locations. The shipper provides adequate insulation and refrigeration to maintain the Celsius® FFT below –40°C for at least 96 h.

Key Features
– Integral container with

  – A S71 bag

  – A HDPE protective shell

– Ready-to-use

  – Pre-assembled

  – Clean, pre-sterilized and QC tested

– Robust

– Single-use

▷ Specifications

Nominal Volume	2 L, 4 L, 6 L and 12 L
Sampling Port	Luer® lock
Inlet & Outlet Port	MPC Quick Coupling
Sterilization	Gamma Irradiation (25–45 kGy)

Materials

Film	S71, 360 μm
Product Contact Layer	EVA (ethylene vinyl acetate copolymer)
Gas Barrier Layer	EVOH (Ethylene Vinyl Alcohol)
Fill and Drain Ports	EVA (Ethylene Vinyl Acetate copolymer)
Fill, Drain and Sampling	C-Flex® 374
MPC Quick Coupling	PC (Polycarbonate) with Silicone O-ring
Shell	HDPE (High-Density Polyethylene)
Fasteners	304 stainless steel

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of design-ing Single-Use solutions based on collabora-tive supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Validation

Celsius® FFT bags have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Celsius® with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows sterility assurance level validation of 10^{-6} for each Single-Use System over its entire shelf life.

Quality Assurance

Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements. A type III drug master file (DMF) is on record with the FDA.

Dimensions L × W × H

Celsius® FFT 6 L	57.8 × 42.6 × 11.7 cm 22.8" × 16.8" × 4.6"
Shipper; Celsius® FFT 6 L 1-unit Shipper	74.4 × 59.2 × 42.7 cm 29.3" × 23.3" × 16.8"
Shipper; Celsius® FFT 6 L 4-unit Shipper	112.1 × 78.3 × 72.5 cm 44.1" × 30.8" × 28.6"
Celsius® FFT 2 L	38.6 × 32.8 × 12.4 cm 15.2" × 12.9" × 4.9"
Celsius® FFT 4 L	43.4 × 42.4 × 12.6 cm 17.1" × 16.7" × 5.0"
Celsius® FFTp 6 L	56.6 × 40.4 × 5.1 cm 22.3" × 15.9" × 2.00"
Celsius® FFT 12 L	69.8 × 53.4 × 13.1 cm 27.5" × 21.0" × 5.23"
Celsius® FFTp 12 L	67.8 × 51.3 × 6.9 cm 26.7" × 21.0" × 2.72"
Shipper; Celsius® FFT 4 L 1-unit Shipper	61.5 × 58.9 × 52.8 cm 24.2" × 23.2" × 0.8"
Shipper; Celsius® FFT 4 L 4-unit Shipper	110.5 × 64.3 × 79.2 cm 43.5" × 25.3" × 31.2"
Shipper; Celsius® FFT 12 L 1-unit Shipper	90.7 × 74.9 × 51.6 cm 35.7" × 29.5" × 20.3"

Ordering Information

Part Number	Description	Qty/Box
FZB114906	Celsius® FFT 2 L (3T, TPE)	6
FZB212401	Celsius® FFT 4 L (3T, TPE)	6
FZB212241	Celsius® FFT 6 L (3T, TPE)	6
FZB114079	Celsius® FFTp 6 L (2T, MPC)	6
FZB212435	Celsius® FFT 12 L (3T, TPE)	3
FZB115991	Biopharm bag 2 L (3T, TPE)	10
FZB212530	Biopharm bag 4 L (3T, TPE)	10
FZB212521	Biopharm bag 6 L (3T, TPE)	10
FZB212916	Biopharm bag 12 L (3T, TPE)	10
FTH-SM00103-0003	Celsius® FFT 4 L 1-unit shipper	1
FTH-SM00103-0004	Celsius® FFT 4 L 4-unit shipper	1
FTH-SM00103-0001	Celsius® FFT 6 L 1-unit shipper	1
FTH-SM00103-0002	Celsius® FFT 6 L 4-unit shipper	1
FTH-SM00103-0005	Celsius® FFT 12 L 1-unit shipper	1
FZB115784	Celsius® FFTp 12 L (MPCx2)	2

Ordering Information

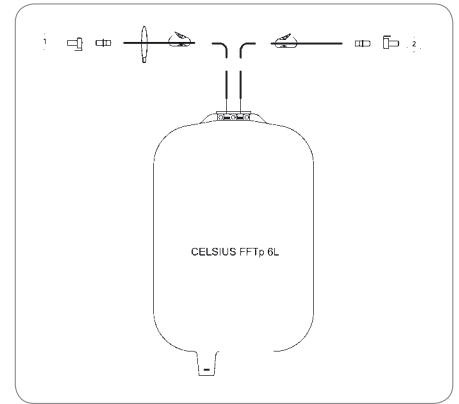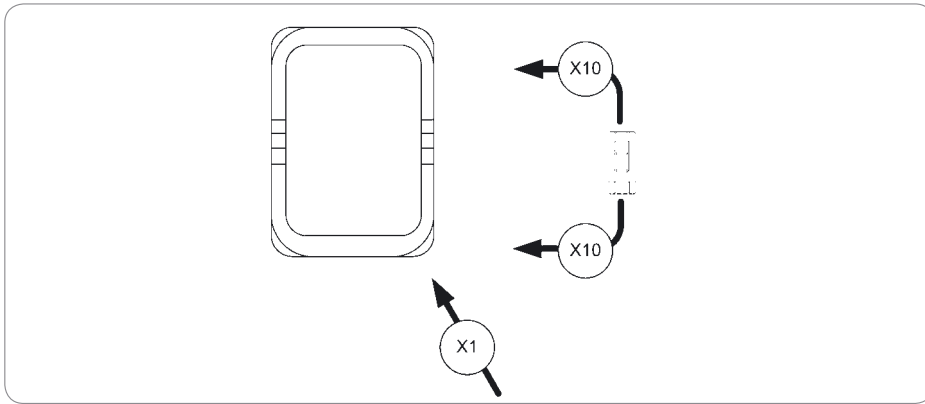| Part Number	Description	Tubing	Port 1	Port 2	Port 3	Qty per Box
FZB212401	Celsius® FFT 4 L (3T, TPE)	TPE|Clear C-Flex® 374	3/8" × 5/8" × 50 cm (20") and male MPC + sealing cap	3/8" × 5/8" × 10 cm (4") + 1/8" × 1/4" × 50 cm (20") and female Luer® Lock with plug	3/8" × 5/8" × 50 cm (20") and male MPC + sealing cap	6
FZB212435	Celsius® FFT 12 L (3T, TPE)	TPE|Clear C-Flex® 374	3/8" × 5/8" × 50 cm (20") and male MPC + sealing cap	3/8" × 5/8" × 10 cm (4") + Clear C-Flex® 374 1/8" × 1/4" × 50 cm (20") and female Luer Lock with plug	3/8" × 5/8" × 50 cm (20") and male MPC + sealing cap	3
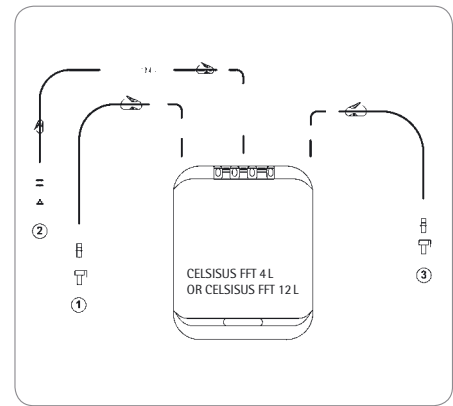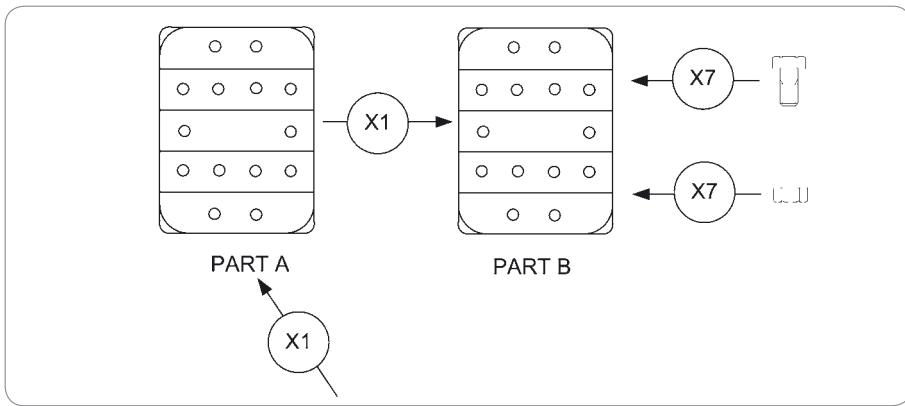
| Part Number	Description	Tubing	Port 1	Port 2	Qty per Box
FZB212241	Celsius® FFT 6 L (3T, TPE)	TPE|Clear C-Flex® 374	3/8" × 5/8" × 75 cm (30") and male MPC + sealing cap	3/8" × 5/8" × 75 cm (30") and male MPC + sealing cap + 3/8" × 5/8" × 15 cm (6") + 1/8" × 1/4" × 75 cm (30") and female Luer® Lock with plug	6
FZB114906	Celsius® FFT 2 L (3T, TPE)	TPE|Clear C-Flex® 374	3/8" × 5/8" × 50 cm (20") and male MPC + sealing cap	3/8" × 5/8" × 50 cm (20") and male MPC + sealing cap + 3/8" × 5/8" × 30 cm (12") + 1/8" × 1/4" × 50 cm (20") and female Luer® Lock with plug	6
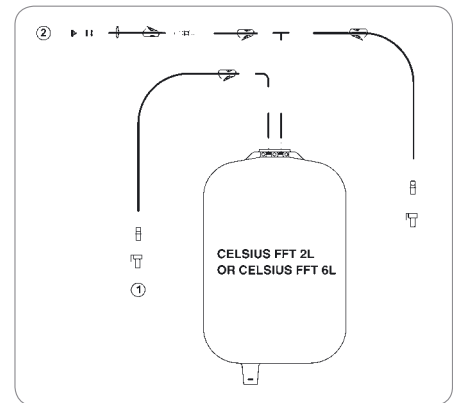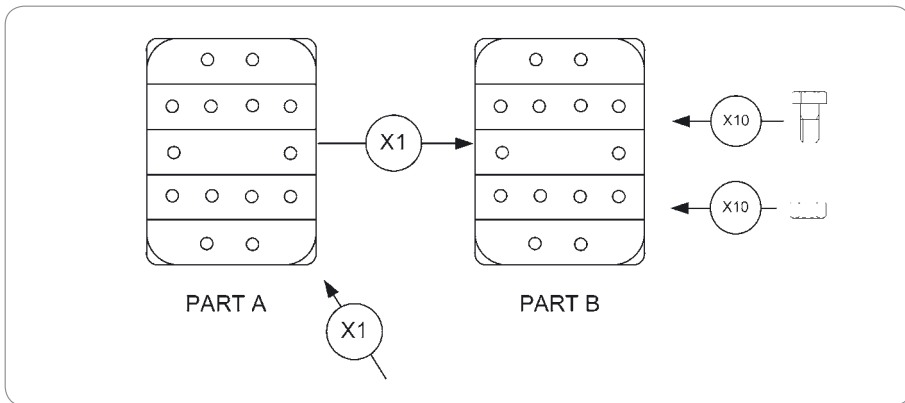
Ordering Information

Part Number	Description	Tubing	Port 1	Port 2	Qty per Box
FZB114079	Celsius® FFTp 6 L (2T, MPC)	EVA	3/8" × 15/32" × 40 mm (1.57") + 3/8" × 15/32" × 150 mm (6") + male MPC + sealing cap	3/8" × 15/32" × 40 mm (1.57") + 3/8" × 15/32" × 150 mm (6") + male MPC + sealing cap	6

Part Number	Description	Tubing	Port 1	Port 2	Port 3	Qty per Box
FZB115784	Celsius® FFTp 12L (MPCx2)	EVA	3/8" × 15/32" × 40 mm (1.57") + 3/8" × 15/32" × 300 mm (12") + male MPC + sealing cap	3/8" × 15/32" × 40mm (1.57") + plug	3/8" × 15/32" × 40 mm (1.57") + 3/8" × 15/32" × 300 mm (12") + female MPC + sealing plug	2
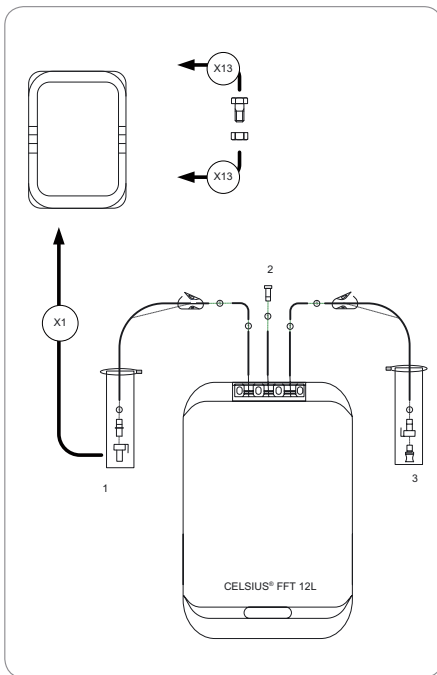
▶ Celsius®-Pak

Disposable Containers for Controlled Freeze-Thaw

Celsius®-Pak combines unique design in disposable container with a protective structural frame. The robustness of the assembly ensures protection, support and ease of handling. Celsius®-Pak provides uniform and reproducible freeze and thaw processes for biopharmaceuticals in manufacturing and process development.

The new Celsius®-Paks 1 & 2 L combines a unique design of a disposable container with an integral protective structural holder.

The new 8.3 L and 16.6 L Celsius®-Pak Frame 2G offers and improved robustness over the first generation design by adding bumpers to withstand tip-over, adding curved cross section to grip the ice block and eliminating sharps.

Celsius®-Pak are specifically designed for controlled freezing, thawing and long term frozen storage of biopharmaceuticals such as:

– Process intermediates

– Bulk drug substances

– Product in clinical phases (pre, I, II +)

– Vaccines

Single-Use System for Controlled Freeze and Thaw Operation
Celsius®-Paks are specifically designed to be used with the Celsius® Freeze-Thaw Modules, the only Controlled Freeze-Thaw System in disposable containers. Celsius®-Paks are constructed from S71 film, a multi-layer co-extruded high gas barrier film containing EVAM (ethylene vinyl acetate copolymer, monomaterial) as fluid contact layer and EVOH (ethylene vinyl alcohol) as gas barrier layer. Celsius®-Pak frames provide protection to the contents during all processes, making the assembly robust and reliable and simplifying the handling, storage and shipping of the disposable containers.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Key Features

– Single-use

– Scalable

– Robust

– Facilitated Validation

– Complete Logostical Solution

– Clean, pre-sterilized and integrity tested

Validation
Celsius®-Paks have been qualified applying the most complex and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Celsius®-Pak with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows sterility assurance level validation of 10^{-6} for each Single-Use product over its entire shelf life. A type III drug master file (DMF) is on record with the FDA.

Quality Assurance
Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Available from Stock
The entire range of Celsius®-Pak is available from stock.

▷ Specifications

Specifications	30 mL Celsius®–Pak	100 mL Celsius®–Pak	1 L Celsius®–Pak	2 L Celsius®–Pak	8.3 L Celsius®–Pak	16.6 L Celsius®–Pak
Inlet Port	1 on top with female Luer Lock	1 on top with female Luer Lock	MPC Quick Coupling	MPC Quick Coupling	1 on top with MPC or KPC connector and Y splitter with male Luerlock or vent filter	1 on top with MPC or Opta connector and Y splitter with male Luerlock or vent filter
Outlet Port	1 on top with female Luer Lock	1 on top with female Luer Lock	MPC Quick Coupling	MPC Quick Coupling	1 on bottom with MPC or KPC connector	1 on bottom with MPC or Opta connector
Vent Filter	–	–	20 cm² Hydrophobic Sterilizing Vent Filter	20 cm² Hydrophobic Sterilizing Vent Filter	–	–
Film	S71	S71	S71	S71	S71	S71
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation

Materials	30 mL Celsius®–Pak	100 mL Celsius®–Pak	1 L Celsius®–Pak	2 L Celsius®–Pak	8.3 L Celsius®–Pak	16.6 L Celsius®–Pak
Product Contact Layer	EVAM®[1]	EVAM®	EVAM®	EVAM®	EVAM®	EVAM®
Gas & Moisture Barrier Layout	EVA	EVOH	EVA[2]	EVA| EVOH	EVA	EVA	EVOH	EVA	EVA	EVOH	EVA	EVA	EVOH	EVA	EVA	EVOH	EVA
External Robust, Handling Layer	EVA	EVA	EVA	EVA	EVA	EVA
Fill & Drain Ports	EVA	EVA	EVA	EVA	EVA	EVA
Fill & Drain Transfer Line	N	A	N	A	Platinum-Cured Silicone or C-Flex	Platinum-Cured Silicone or C-Flex	Platinum-Cured Silicone	Platinum-Cured Silicone
Thermowell	EVA	EVA	–	–	EVA	EVA
Holder	–	–	HDPE[3]	HDPE	–	–

Frames	8.3 L Celsius®–Pak Frame 2G	16.6 L Celsius®–Pak Frame 2G
Ends	HDPE	HDPE
Plate & Rods	316 Stainless Steel	316 Stainless Steel
Dimensions (H × W × D)	92.5 cm × 27.5 cm × 19.5 cm (36.4" × 10.8" × 7.7")	92.5 cm × 42.5 cm × 19.5 cm (36.4" × 16.7" × 7.7")

1. Ethylene Vinyl Acetate Monomaterial
2. EVA-Ethylene Vinyl Acetate, EVOH-Ethylene Vinyl Alcohol
3. High Density Polyethylene
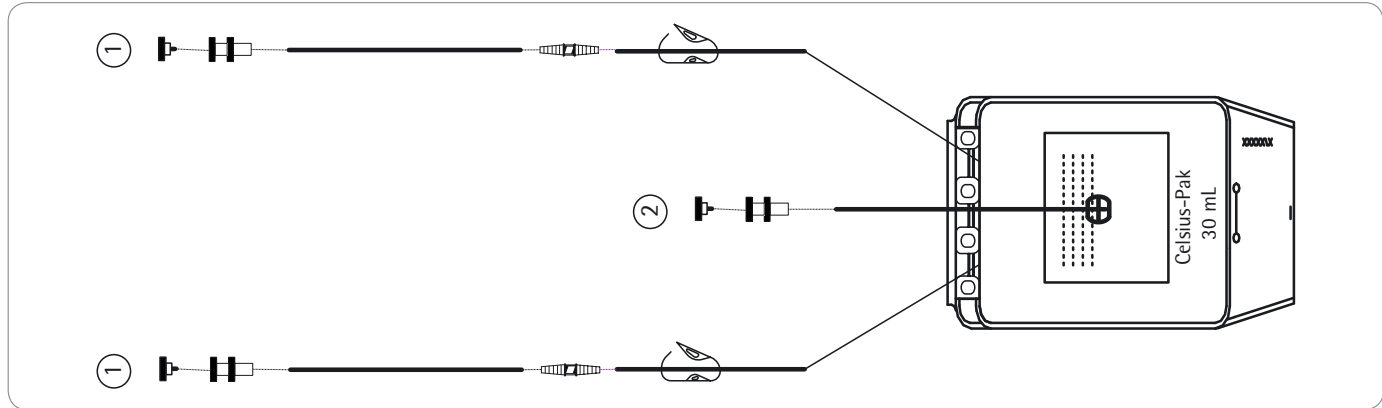Specifications and material are subject to change.

Ordering Information

Equipment

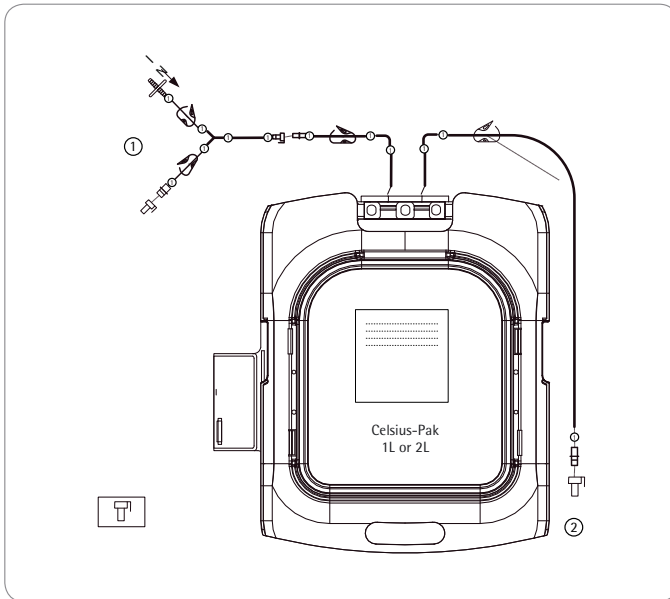| Part Number	Description	Qty
FTH-CF00016-0009	16.6 L Celsius®-Pak Frame 2G	1
FTH-CF00008-0015	8.3 L Celsius®-Pak Frame 2G	1
FTH-CF00000-0029	Celsius®-Pak Frame 2G RTD Holder	1

Ordering Information

Disposables

Celsius®-Pak 30 mL with Thermowell & C-Flex®

Part Number	Description	Tubing	Port 1	Port 2	Qty per Box
FZB114804	Celsius®-Pak 30 mL with Thermowell	EVA	1/4" × 5/16" × 10 cm (4") Female LL + plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4" × 10 cm (4") Female LL + plug	10
FZB114866	Celsius®-Pak 30 mL with Thermowell and C-Flex	EVA + Clear C-Flex® 374	1/8" × 1/4" × 15 cm (6") + Female LL + Plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4" × 10 cm (4") Female LL + plug	10
FDP102653	Overpouch, Celsius®-Pak 30 mL	Alu Foil	N|A	N|A	250
FZB114839	Celsius®-Pak 100 mL with Thermowell	EVA	1/4" × 5/16" × 10 cm (4") Female LL + plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4" × 10 cm (4") Female LL + plug	10
FZB114908	Celsius®-Pak 100 mL with Thermowell, C-Flex	EVA + Clear C-Flex® 374	1/8" × 1/4" × 15 cm (6") + Female LL + Plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4" × 10 cm (4") Female LL + plug	10
FDP102667	Overpouch, Celsius®-Pak 100 mL	Alu Foil	N|A	N|A	100

Ordering Information

Disposables

Celsius®-Pak 1 L or 2 L with MPC

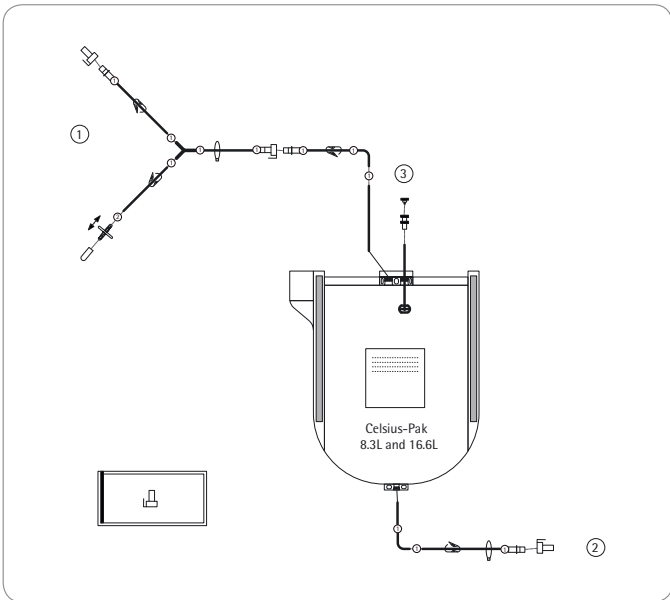| Part Number	Description	Tubing	Port 1	Port 2	Qty per Box
FZB115358	Celsius®-Pak, 1 L, TPE, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 4 cm (1.57") + C-Flex 1/4" × 3/8" × 30 cm (12") + Silicone (pt) 1/2" × 11/16" × 15 cm (6"), Silicone (pt) 1/4" × 3/8" L100 (L4") and Midisart vent filter	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 25 cm (10") + C-Flex 1/4" × 3/8" × 50 cm (20")	8
FZB115319	Celsius®-Pak, 1 L, MPC connectors, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and Midisart vent filter + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 30 cm (12") and male MPC + sealing cap	8
FZB115366	Celsius®-Pak, 2 L, TPE, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 4 cm (1.57") + C-Flex 1/4" × 3/8" × 30 cm (12") + Silicone (pt) 1/2" × 11/16" × 15 cm (6"), Silicone (pt) 1/4" × 3/8" L100 (L4") and Midisart vent filter	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 25 cm (10") + C-Flex 1/4" × 3/8" × 50 cm (20")	4
FZB115322	Celsius®-Pak, 2 L, MPC connectors, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") + Silicone (pt) 1/4" × 3/8" 10 cm (4") and Midisart vent filter + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 1/4" × 3/8" × 30 cm (12") and male MPC + sealing cap	4

Ordering Information
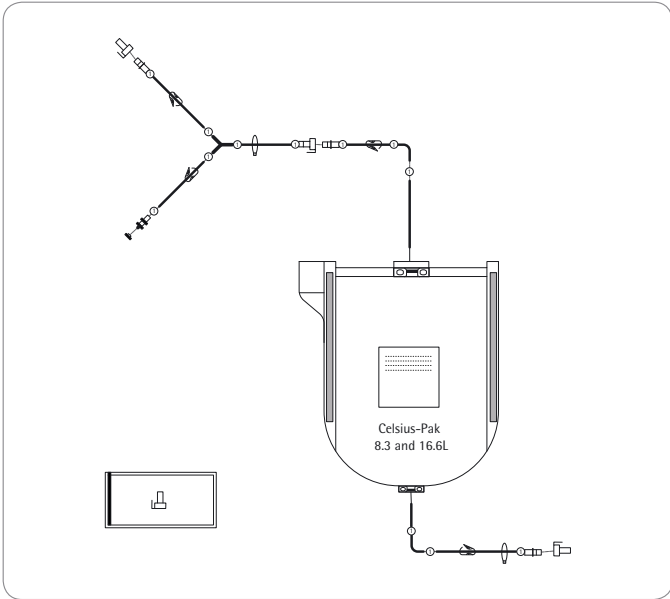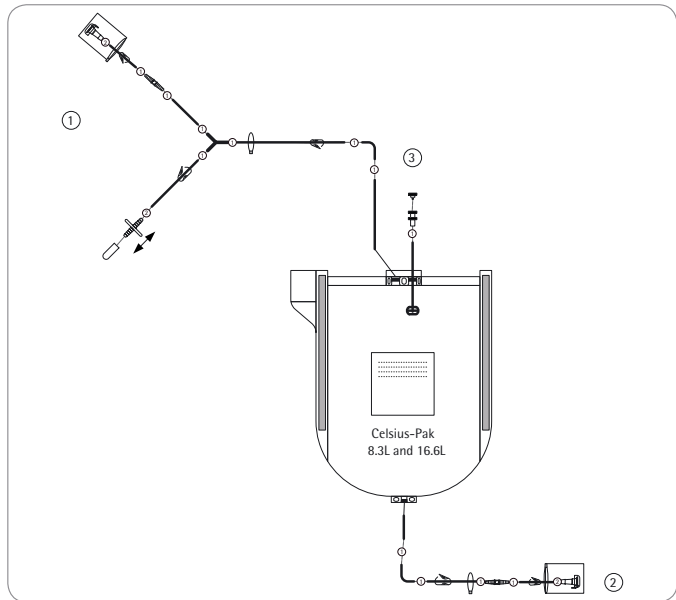
Disposables

Celsius®-Pak 8.3 L or 16.6 L without thermowell
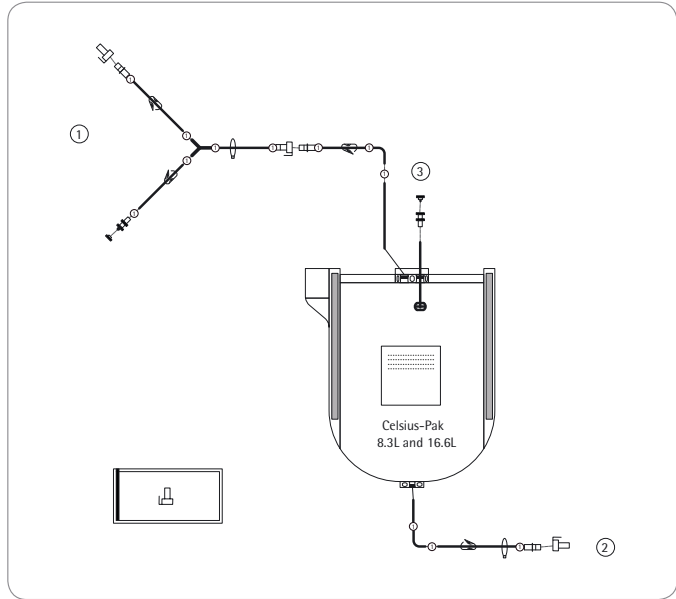
Celsius®-Pak 8.3 L or 16.6 L with thermowell

Celsius®-Pak 8.3 L or 16.6 L with vent filter

Celsius®-Pak 8.3 L or 16.6 L with thermowell, aseptic connection device and vent filter

Ordering Information

Disposables

Part Number	Description	Tubing	Port 1	Port 2	Port 3	Qty per Box
FZB115327	Celsius®-Pak, 8.3 L, without Thermowell	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 40 cm (15,8") + Silicone (pt) 3/8" × 5/8" × 50 cm (20") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and female LL + cap + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC × sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 200 cm (79") and male MPC + sealing cap	–	12
FZB114851	Celsius®-Pak, 8.3 L, Thermowell	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 40 cm (15,8") + Silicone (pt) 3/8" × 5/8" × 50 cm (20") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and female LL + cap + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 200 cm (79") and male MPC + sealing cap	–	12
FZB115370	Celsius®-Pak, 8.3 L, Thermowell, Aseptic Connection Device, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 75 cm (30") + Silicone (pt) 3/8" × 5/8" × 15 cm (6") and Midisart vent filter + Silicone (pt) 3/8" × 5/8" × 10 cm (4") + Silicone (pt) 1/2" × 11/16" × 15 cm (6") and female aseptic connector	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 110 cm (43") and female aseptic connector	3/16" × 1/4" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	12
FZB115334	Celsius®-Pak, 8.3 L, Thermowell, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 30 cm (12") + Silicone (pt) 3/8" × 5/8" × 60 cm (23.6") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and Midisart vent filter + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 175 cm (69") and male MPC + sealing cap	3/16" × 1/4" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	12
FZB115373	Celsius®-Pak, 16.6 L, without Thermowell	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 40 cm (15,8") + Silicone (pt) 3/8" × 5/8" × 50 cm (20") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and female LL + cap + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 200 cm (79") and male MPC + sealing cap		6
FZB114861	Celsius®-Pak, 16.6 L, Thermowell	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 40 cm (15,8") + Silicone (pt) 3/8" × 5/8" × 50 cm (20") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and female LL + cap + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 200 cm (79") and male MPC + sealing cap		6
FZB115289	Celsius®-Pak, 16.6 L, Thermowell, Aseptic Connection Device, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 75 cm (30") + Silicone (pt) 3/8" × 5/8" × 15 cm (6") and Midisart vent filter + Silicone (pt) 3/8" × 5/8" × 10 cm (4") + Silicone (pt) 1/2" × 11/16" × 15 cm (6") and female aseptic connector	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 110 cm (43") and female aseptic connector	3/16" × 1/4" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	6
FZB115377	Celsius®-Pak, 16.6 L, Thermowell, Vent Filter	EVA + Silicone (pt)	EVA 3/8" × 15/32" × 10 cm (4") + Silicone (pt) 3/8" × 5/8" × 30 cm (12") + Silicone (pt) 3/8" × 5/8" × 60 cm (23.6") + Silicone (pt) 1/4" × 3/8" × 10 cm (4") and Midisart vent filter + Silicone (pt) 3/8" × 5/8" × 10 cm (4") and male MPC + sealing cap	EVA 3/8" × 15/32" × 4 cm (1.57") + Silicone (pt) 3/8" × 5/8" × 175 cm (69") and male MPC + sealing cap	3/16" × 1/4" × 43 cm (17") + Female LL + plug (thermowell sealed end tube)	6

► FT 100

Freeze-Thaw Module

Robust and reliable, the FT100 Freeze-Thaw Module gives flexibility to the Controlled Freeze-Thaw and Hold processes in disposable Celsius®-Paks. The FT100, controlled by the CU5000 Thermal Control Unit, optimizes the freezing and thawing processes while minimizing adverse effects in biopharmaceutical products.

Ergonomic Design, Maximum Flexibility
The FT100 Freeze-Thaw Module consists in three separate bays designed to hold two 16.6 L Celsius®-Pak or four 8.3 L Celsius®-Pak each. This structure provides complete flexibility of operations, allowing Freeze-Thaw processes between 8.3 L and 100 L per cycle.

The Heat Transfer Fluid circulates inside heat transfer plates mounted on each bay. Once a freeze or thaw cycle is initiated, the plates close over the Celsius®-Paks ensuring good contact between the plates and the Celsius®-Pak surface optimizing the heat transfer.

Conceived to minimize the operator efforts, each bay of the FT100 has a docking locator to align the Transfer Cart or the Storage Module to simplify the transfer of the Celsius®-Paks to and from the FT100 Freeze-Thaw Module.

The FT100 is mounted on rockers that allow the module to rock back and forward during thawing processes. This rocking movement optimizes the mixing of the liquid and solid phases of the product, improving thawing time and ensuring product homogeneity.

Key Features

– Pre-Sterilized, Disposable,
  Close Container System

– Minimize Operation Handling

– Scalable

– Robust and Reliable

– Complete Logistical Solution

▷ Specifications

Specifications	FT100 Freeze–Thaw Module	FT100 Power Panel
Dimensions (H × W × D)	88" × 83" × 81" (2240 mm × 2111 mm × 2006 mm)[1]	36" × 24" × 10" (914 mm × 610 mm × 254 mm)
Weight	Empty: 4000 lbs. (1814 kg) Loaded: 4600 lbs. (2087 kg)	160 lbs. (72.6 kg)
Exterior Material	Type AISI 316 Stainless Steel – Polished	

1. Top mounted control panel not included. Dimensions (H×W×D): 24" × 20" × 8" (61 cm × 50.8 cm × 20.3 cm)

Power Requirements	Single Power Feed	Dual Power Feed	
Voltage	460V	460V	120V
Circuit	1	1	2
Frequency	60Hz	60Hz	60Hz
Phase	3 Phase	3 Phase	1 Phase
Minimum Circuit Amperage	5.3A	5.3A	9A

Celsius® System Floor Plan
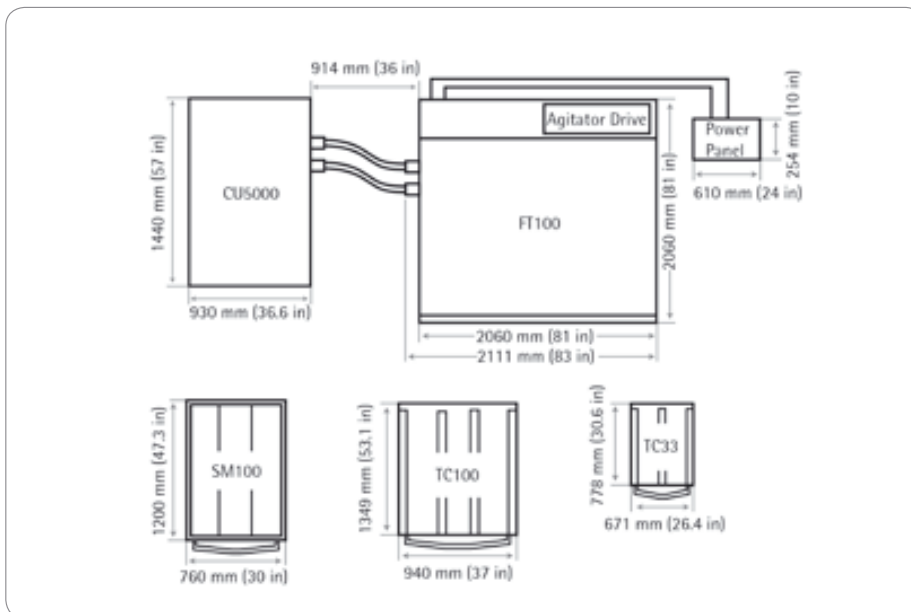
▶ FT 16

Freeze–Thaw Module

Designed to offer Controlled Freeze-Thaw operations for pilot and clinical manufacturing scales, the FT16 Freeze–Thaw Module allows freezing and thawing of disposable 8.3 L and 16.6 L Celsius®-Paks with the same profile characteristics as the production scale FT100 Freeze-Thaw Module.

Freeze–Thaw Flexibility and Control
The FT16 enables optimum freezing and thawing processes, thus minimizing the adverse effects of uncontrolled freezing and thawing on biopharmaceutical products.

The FT16 Freeze-Thaw Module consists of a single bay designed to hold one 16.6 L Celsius®-Pak or two 8.3 L Celsius®-Paks.

In the same manner as the FT100 Freeze-Thaw Module, Heat Transfer Fluid circulates inside heat exchange plates mounted in the bay. During freezing and thawing, the plates close onto the Celsius®-Paks ensuring optimal contact and heat transfer between the surface of the plates and the Celsius®-Paks.

The FT16 is mounted on a rocker assembly that enables controlled mixing during the thawing process. Mixing reduces thaw time and ensures product homogeneity.

Transfer Carts and Storage Modules designed for efficient movement of liquid and frozen material are used to transfe product to and from the FT16 with minimal operator handling of the Celsius®-Paks. Customized, insulated shipping containers can be used to ship frozen and liquid Celsius®-Paks between facilities.

Key Features

– Pre-Sterilized, Disposable, Closed Container System

– Simple to Operate

– Scalable

– Robust and Reliable

– Complete Logistical Solution

▷ Specifications

Specifications	FT16 Freeze-Thaw Module	CryoPilot B with Transformer (US)	CryoPilot B without Transformer (EU)
Dimensions (H × W × D)	66.50" × 49.82" × 66.14" (169 cm × 126.5 cm × 168 cm)	61" × 35" × 26" (155 cm × 90 cm × 67 cm)	53" × 35" × 26" (135 cm × 90 cm × 67 cm)
Weight	Empty: 2000 lbs. (907.2 kg) Loaded: 2100 lbs. (952.5 kg)	Empty: 585 lbs. (266 kg) Loaded: 662 lbs. (301 kg)	Empty: 462 lbs. (210 kg) Loaded: 539 lbs. (245 kg)
Exterior Material	Type AISI 316 Stainless Steel - Polished		

| CryoPilot B	Heat Transfer Fluid (Refrigerant) & Additional Supplies
Heat Transfer Fluid (HTF)	Dow Corning HF
Volume/Flow	15 gallons (60 liters)
Temperature Range	-94°F to 95°F (-70°C to 35°C)
Compressed Dry Gas	3-5 Bar (45-87 PSIG) with -58oF (-50oC) Dew Point
Condenser Cooling Water	Up to 1.5 gallons/min at 59oF (15oC), 30 psi differential

Power Requirements	FT16 Freeze-Thaw Module	CryoPilot B with Transformer (US)	CryoPilot B without Transformer (EU)
Voltage	230V	208V	400V
Circuit	1	1	1
Frequency	60Hz	60Hz	60Hz
Phase	3 Phase	3 Phase	3 Phase
Minimum Circuit Amperage	5.3A	30A[1]	16A

1. For operations in North America, the CryoPilot B has been shipped with a step up transformer. This transformer is rated for 208V, 60Hz, 3 Phase, 33.8A. This rating relates to the maximum output possible for the transformer but this maximum output is not required for the proper operation of the CryoPilot B. A 30A breaker minimum will allow for proper operation.
Specifications and material are subject to change.

FT16/CryoPilot B System Floor Plan
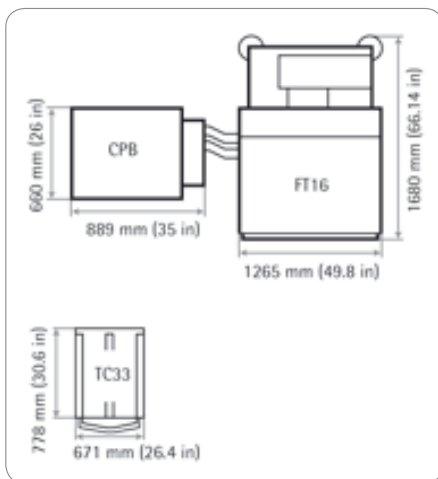
▶ Celsius® Logistic Accessories

Transfer Carts
The Celsius® System Transfer Carts are designed to minimize the operator efforts when transferring Celsius®-Pak from and to the Freeze-Thaw Modules. The Transfer Carts have a docking system that perfectly aligns with the bays in the Freeze-Thaw Modules allowing the Celsius®-Pak to easily slide in or out the modules with minimum effort and complete safety for both operator and product. The Transfer Carts area available in two sizes: TC33 with a maximum carrying capacity of 33 L and TC100 with a maximum carrying capacity of 100 L.

Celsius® SSM Shipper
The Celsius® SSM can be shipped to remote locations by using the Celsius® SSM Shipper. The shipper provides adequate insulation and refrigeration to maintain all Celsius®-Paks in a maximally or minimally loaded SSM below –30°C for at least 72h during ISTA 7D summer or winter temperature profiles.

Celsius® SSM
The Celsius® Shippable Storage Module (SSM) allows storage of up to 100 L of product in frozen Celsius®-Paks. The Celsius® SSM is mounted on a Celsius® SSM trolley that permits the easy rolling of the module into freezers while allowing removing the SSM for storage. The Celsius® SSM Trolley can also be docked with the Freeze-Thaw module or Transfer Cart for easy transfer of frozen Celsius®-Paks.

The Celsius® Shipper allows shipment of individual Celsius®-Pak to remote locations. The shipper provides adequate insulation and refrigeration to maintain the Celsius®-Pak below –30°C for at least 72 h.

Celsius®-Pak Carrier
The **Celsius**®-Pak Carrier allows processing the Celsius®-Pak 1 L or 2 L in the Celsius® FT16 and FT100 modules. The Celsius®-Pak Carrier can receive up to 8 Celsius®-Paks 1 L or 4 Celsius®-Pak 2 L or a mix of both.

SSM Trolley

Filling Station
The FS16 Filling Station optimizes the logistics of filling and pressurization of the Celsius®-Paks. The elevated mounting platform includes a docking system that allows the perfect aligning of the transfer carts to ensure the easy sliding of the Celsius®-Paks with no efforts for the operator and no risks for the contents. The Filling Station reproduces the placement and pressure of the Freeze-Thaw Modules plates over the Celsius®-Paks optimizing the container shape when filling and pressurizing. The Scale Terminal Controller allows automatic filling process with minimal operator intervention.

Filling Station Insert
The Filling Station Insert allows using the FS16 to fill and pressurize Celsius®-Pak 1 L and 2 L.

▷ Specifications

Transfer Carts	TC33	TC100
Materials	Type AISI 304 Stainless Steel (Polished)	Type AISI 304 Stainless Steel (Polished)
Dimensions (w × d × h)	30" × 35.5" × 54.6" (76 × 90 × 139 cm)	37" × 54" × 55" (94 × 137 × 139 cm)
Weight	111 lbs (50.4 Kg)	323 lbs (146.5 kg)

Filling Station	FS16
Materials	Type AISI 304 Stainless Steel (Polished)
Dimensions (w × d × h)	20" × 23" × 53" (50 × 58 × 134 cm)
Weight	250 lbs (114 kg)

Shippable Storage

Module	SSM
Materials	HDPE pallet and dunnage, XLPE foam, stainless steel hardware
Dimensions (w × d × h)	80 × 120 × 62 cm (collapsed) | 80 × 120 × 127 cm (assembled)
	32" × 47" × 25" (collapsed) | 32" × 47" × 50" (assembled)
Weight	155 lbs (70 kg) empty, 462 lbs (210 kg) loaded

Celsius® SSM Shipper

Materials	Aluminum pallet base, LLDPE exterior, fiberglass interior, polyurethane insulation
Dimensions (w × d × h)	48" × 61" × 70" (123 × 156 × 177 cm)
Weight	550 lbs (250 kg) empty, 1619 lbs (735 kg) loaded

Celsius® Shipper

Materials	Corrugated plastic exterior, HDPE-lined polyurethane foam insulation, polyethylene and polyurethane foam
Dimensions (w × d × h)	33" × 57" × 26" (84 × 144 × 65 cm)
Weight	44 lbs (20 kg) empty, 180 lbs (82 kg) loaded

Part Number	Description
FTH–TC00033–0001	TC33 – Transfer Cart 33 L
FTH–TC00100–0001	TC100 – Transfer Cart 100 L
FTH–FS00016–0001	FS16 – Filling Fixture
FTH–SM00101–0024	Shippable Storage Module
FTH–SM00101–0028	SSM Shipper
FTH–SM00101–0020	SSM Trolley
FTH–SM00101–0027	SSM Insulated Cover
FTH–SM00102–0002	Celsius® Shipper
FTH–CF00004–0020	Celsius®-Pak 1 L and 2 L Carrier
FTH–CF00004–0050	Filling Station Insert for 1 L and 2 L Celsius®-Pak

Process Cycle
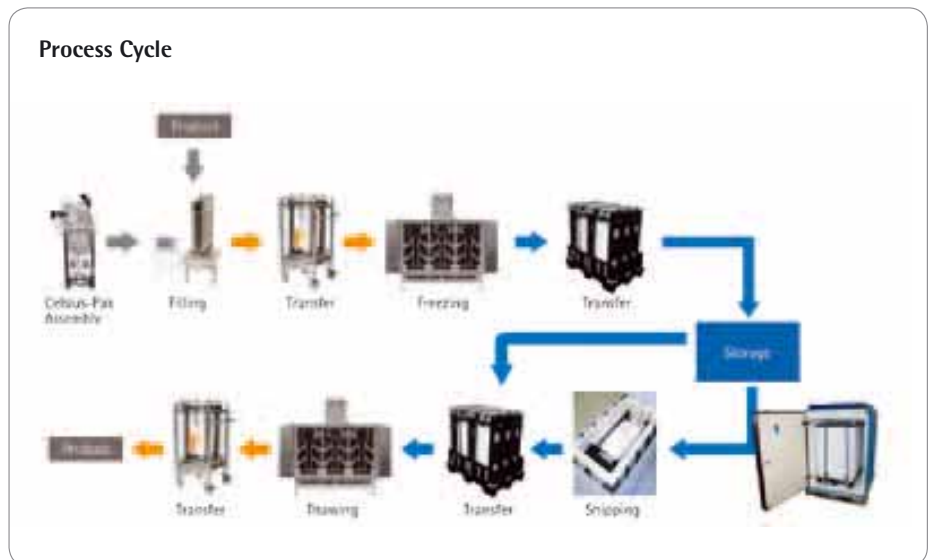
▶ Celsius® S³ System

The Celsius® S³ is the only small-volume Controlled Freeze-Thaw System in disposable containers that is scalable to production volume. This system is a tool to execute freeze-thaw process development and stability studies using a minimal amount of product.

Scalability
The Celsius® S³ System models a 16.6 L pilot-scale and 100 L production system with a minimal amount of product. Using the same freeze and thaw pathlength and identical materials of construction in all Celsius®-Pak containers, the Celsius® S³ System ensures unmatched scalability between all scale systems.

Key Features
– Scale-up
– Scale-down
– Stability studies
– Development studies

Ease of Use
The CryoPilot Control Unit provides automated operation and data collection. The Celsius® S³ System freezes and thaws from 1 to 10 product samples per run. Celsius®-Paks are available in 30 mL and 100 mL with different filling port and thermowell configurations.

Improved Process Validation
Celsius® S³ System offers excellent batch to batch reproducibility and consistent product stability after freezing, thawing and storing. The Celsius® S³ System provides documented and reproducible freeze-thaw processes, thus facilitating validation of your freeze-thaw operations.

Typical Celsius® Freeze Profile
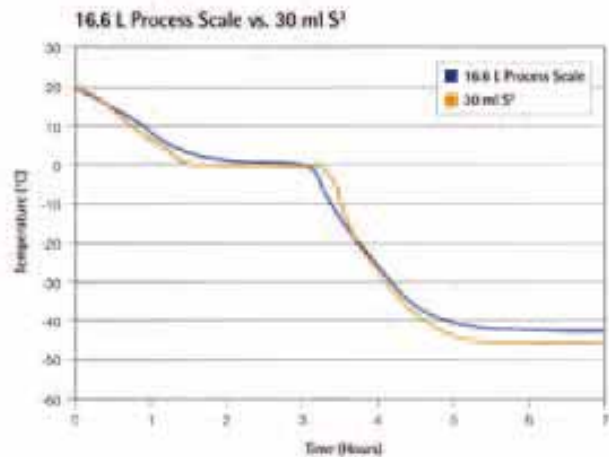
▷ Specifications

Specifications	Celsius® S³ Freeze-Thaw Unit	CryoMixer Jr.
Dimensions	With mounting base 16.75" × 14" × 21" (42.5 cm × 35.6 cm × 53.3 cm)	19.75" × 23" × 3.5" (50.2 cm × 58.4 cm × 8.9 cm)
Weight	40 lb (18 Kg)	52 lb (24 Kg)
Electrical	N/A	EU: 230 V, 50 Hz, 5 A, 1 Phase USA: 110 V, 60 Hz, 5 A, 1 Phase
Exterior Material	302/304 Stainless Steel Shell; Clear	PVC Enclosure Hood

Specifications	CryoPilot	Control Unit
Dimensions	18.5" × 16.75" × 28.5"	(470 mm × 426 mm × 724 mm)
Weight	205 lb (93 Kg)	
Exterior Material	304 Stainless Steel and PVC	
Heat Transfer Fluid (HTF)	Dow Syltherm HF	
Temperature Range	CryoPilot nominal: +40°C to -70°C	
Power Requirements	EU: 230 V, 50 Hz, 16 A breaker minimum, 1 Phase USA: 230 V, 60 Hz, 20 A breaker minimum, 1 Phase	

Specifications	30 mL Celsius®-Pak	100 mL Celsius®-Pak
Film	S71	S71
Product Contact Layer	EVAM®[1]	EVAM®[1]
Gas & Moisture Barrier Layer	EVA/EVOH/EVA[2]	EVA/EVOH/EVA[2]
External Robust, Handling Layer	EVA	EVA

1. Ethylene Vinyl Acetate Monomaterial
2. EVA-Ethylene Vinyl Acetate, EVOH-Ethylene Vinyl Alcohol. A type III DMF is on records with the FDA.

Ordering Information
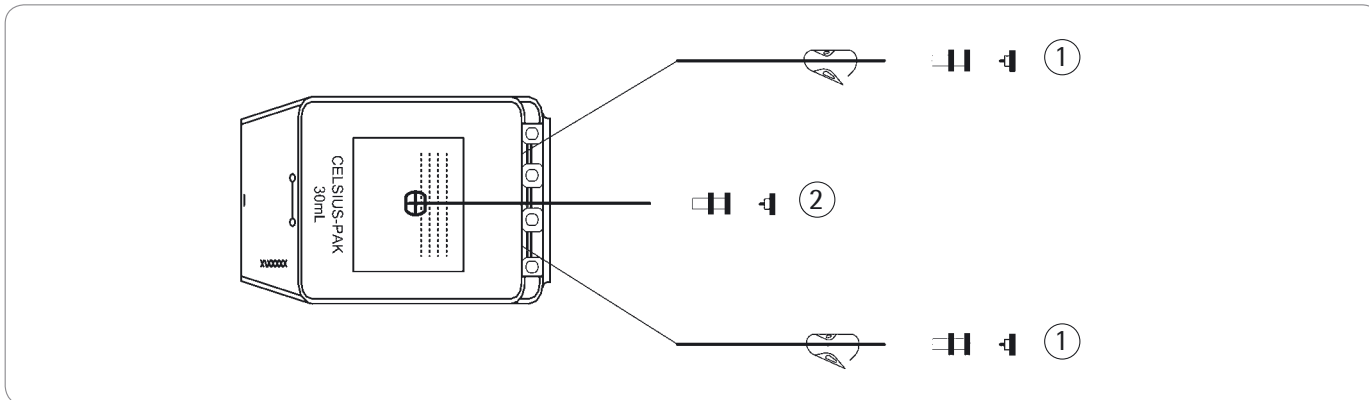
Part Number	Old Part Number	Description	Tubing	Port 1	Port 2	Qty/Box
FZB103484	DB-00030-4	Celsius®-Pak 30 mL with Thermowell	EVA	1/4 „ × 5/16" × 10 cm (4") Female LL + plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4 „ × 10 cm (4") Female LL + plug	10
FZB103494	DB-00100-8	Celsius®-Pak 100 mL with Thermowell	EVA	1/4 „ × 5/16" × 10 cm (4") Female LL + plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4 „ × 10 cm (4") Female LL +plug	10
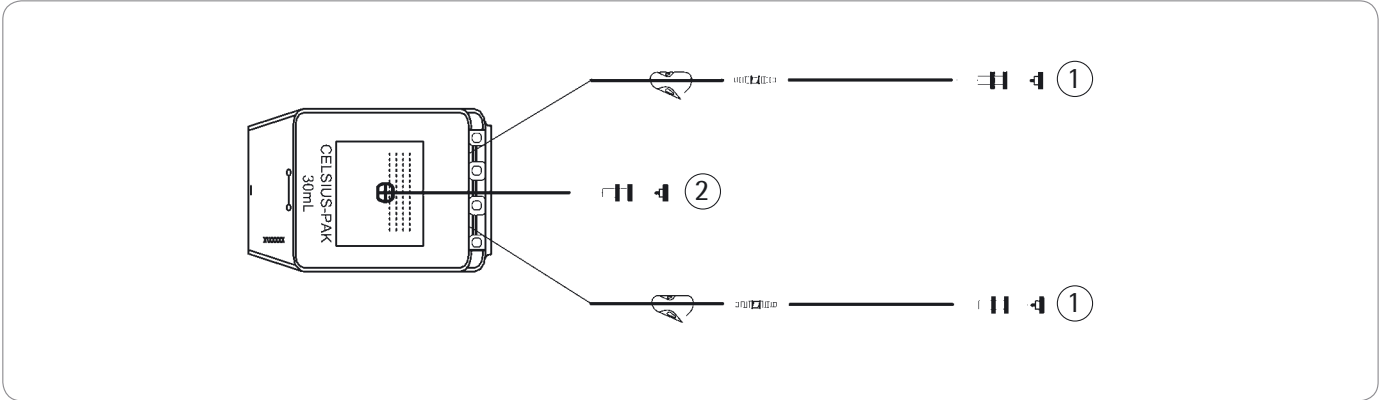
Part Number	Old Part Number	Description	Tubing	Port 1	Port 2	Qty/Box
FZB103492	DB-00030-6	Celsius®-Pak 30 mL with Thermowell and C-Flex	EVA + Clear C-Flex 374	1/8" × 1/4" × 15 cm (6") + Female LL + plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4 „ × 10 cm (4") Female LL + plug	10
FZB103498	DB-00100-3	Celsius®-Pak 100 mL with Thermowell and C-Flex	EVA + Clear C-Flex 374	1/8" × 1/4 „ × 15 cm (6") + Female LL + plug, pinch clamp	Thermowell sealed end tube 3/16" × 1/4 „ × 10 cm (4") Female LL + plug	10

Some configurations are made to order. Specifications and material are subject to change.

▶ Cryo Fin | Cryovessel

Controlled Freeze-Thaw System

Introduction
Sartorius Stedim Biotech patented Freeze-Thaw Technology has been an integral part of the Biopharmaceutical processes since 1996.

The CryoFin family of products offers reproducible and validatable Freeze-Thaw processes and a robust means of handling intermediates and bulk substance. The CryoFin components: CryoVessels, Thermal Control Units and Mixers offer a complete logistical solution for the storage and shipping of high value biopharmaceutical products. The Thermal Control Unit monitors and documents all critical parameters, which ensures a validated process.

Freezing & Thawing
The controlled freeze-thaw rate in the CryoVessel is accomplished through active and passive heat transfer surfaces, which helps minimize adverse effects and maximize production yields.

The Volume Compartmentalization divides the effective volume of the CryoVessel in equal compartments, reducing the freezing path lengths and maximizing the heat removal. This compartmentalization is also the basis for the CryoWedge Scale Down System designed to model and evaluate the production scale levels with a minimal volume of product.

Key Figures

– Robust Construction: Stainless Steel and other alloys

– Reproducible Freeze-Thaw Processes

– Documented Freeze-Thaw Cycles

– Secure Containment

– Designed for air cargo and surface shipments

– Compatible with Sterile Filling Operations

– CIP and SIP Compatible

– Volumes of 20 L, 60 L, 125 L, 200 L & 300 L

Features	CryoVessel
Interior	316L Stainless Steel, Ra std = 10 micro-inch/ 0.254 micrometers, electropolished
Exterior	316L Stainless Steel, Ra std = 30 micro-inch/ 0.762 micrometers
Ports	Tri-clamp style ferrules, CIP spray rings, vent filter, pressure gauge, sight glass, rupture disk
Diptube	Tri-clamp end for product inlet
Thermowell	1/4 inch (0.635 cm) diameter dual element RTD temperature probe for product temperature recording and monitoring
Quick Disconnect Fittings	Self-sealing connectors on CryoVessel jacket and core heat exchanger
Outlet Valve	NovAseptic® diaphragm valve, platinum coated silicon

▷ Specifications

Specifications	20 L	60 L	125 L
Model Designation	CV-0020	CV-0060	CV-0125
Working Volumes (min/max)	2 Liters/20 Liters	11 Liters/60 Liters	11 Liters/125 Liters
Weight (empty/full)	340 lbs. (154 kg) 437 lbs. (198 kg)	460 lbs. (209 kg) 653 lbs. (296 kg)	1060 lbs. (481 kg) 1411 lbs. (640 kg)
Inner Diameter	12" (31 cm)	20" (51 cm)	20" (51 cm)
Dimensions W × H × D (in/cm)	24" × 24" × 44" 61 cm × 61 cm × 112 cm	38" × 38" × 49" 97 cm × 97 cm × 125 cm	38" × 38" × 60" 97 cm × 97 cm × 153 cm

Specifications	200 L	300 L
Model Designation	CV-0200	CV-0300
Working Volumes (min/max)	27 Liters/200 Liters	46 Liters/300 Liters
Weight (empty/full)	1465 lbs. (665 kg) 1997 lbs. (906 kg)	1800 lbs. (816 kg) 2266 lbs. (1028 kg)
Inner Diameter	30" (76 cm)	34" (86 cm)
Dimensions W × H × D (in/cm)	38" × 42" × 61" 97 cm × 107 cm × 155 cm	43" × 52" × 61" 110 cm × 130 cm × 155 cm

20 L & 60 L Vessel System Floor Plan
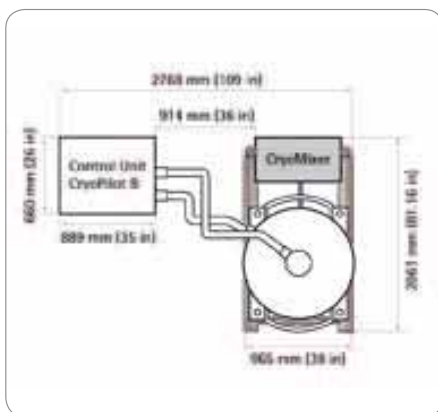
125 L, 200 L & 300 L Vessel System Floor Plan
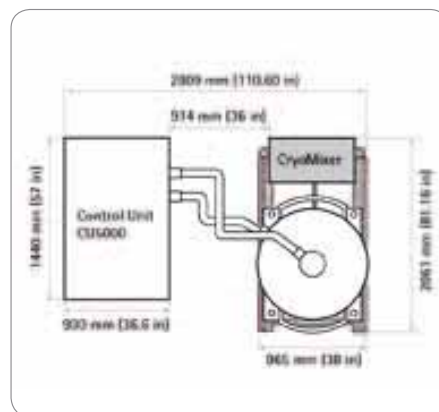
▶ # CU 5000

Thermal Control Unit

The CU5000 Thermal Control Unit allows simple access to the complete Controlled Freeze-Thaw and Hold parameters and functions while securely monitors and stores all critical parameters of the process.

Simple, Friendly and Secure
The entire automatic freeze, thaw and hold operations are controlled by the CU5000 Thermal Control Unit. The critical parameters of all processes are commanded, monitored and stored in an automatic manner with minimal operator intervention.

The CU5000 controls the freeze-thaw process by controlling the temperature and fl ow rate of the heat transfer fluid according to a predefi ned profi le.

The CU5000 Thermal Control Unit is user-friendly and simple to operate. It securely stores customized freeze-thaw profi les, data output and all process records that can be retrieved by a touch of the screen. New profiles can be created and used in seconds.

The full process documentation offered by the CU5000 Thermal Control Unit simplify validation and verifi cation and allows incomparable repeatability of processes.

The Thermal Control Unit is password protected with different levels of access allowing full control of operations.

Celsius® System Floor Plan
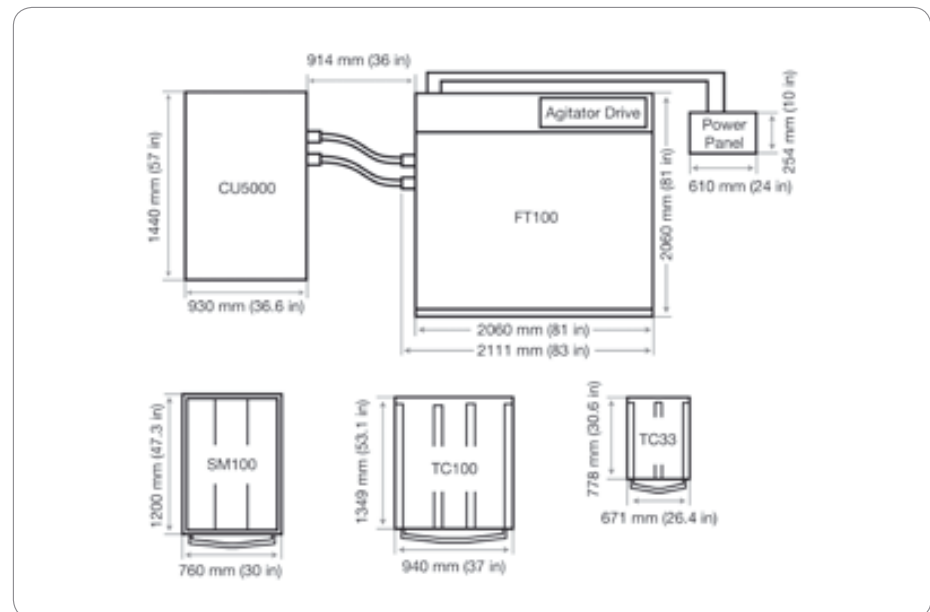
Key Features

– Easy Process Repeatability

– Simple Touch Screen Operation

– Dependable and Secure

– Robust Construction

– Complete Logistical Solution

▷ Specifications

Specifications	CU5000 Thermal Control Unit
Dimensions	(HxWxD) 80" × 37" × 57" (2032 mm × 940 mm × 1448 mm)
Weight Empty	1700 lbs. (771.1 kg)
Loaded	1815 lbs. (823.3 kg)
Sound Level	85 dB
Ambient Conditions	Temperature: 32°F to 104°F (0°C to 40°C) Humidity: Non-Condensing
Exterior Materials	Type AISI 304 Stainless Steel. Approximately #4 finish

Specifications	Heat Transfer Fluid (Refrigerant)
Fluid	Dow Syltherm HF or Dow Corning 200 Fluid 5cSt grade
Volume/Flow	Total system capacity: approximately 20 gallons (76 liters) nominal, including plumbing and components Stainless steel resevoir max volume: 19 gallons (72 liters) Maximum recirculation fl ow, pressure: 31.7 gallons/min (120 liters/min) at 14.7 psi
Temperature Range	-94°F to 95°F (-70°C to 35°C)

Additional Supplies	CU5000 Thermal Control Unit
Dry Gas Supply	6 to 9 bar (87 to 125 psi)
Condenser Cooling Water	up to 5.5 gallons/min at 70oF (21°C), 20 psi differential

Power Requirements	Single Power Feed	Dual Power Feed	
Voltage	460V	460V	120V
Circuit	1	1	2
Frequency	60Hz	60Hz	60Hz
Phase	3 Phase	3 Phase	1 Phase
Minimum Circuit Amperage	67.1A	62.9A	16.6A

Specifications and material are subject to change.

Cryofin System Foor Plan
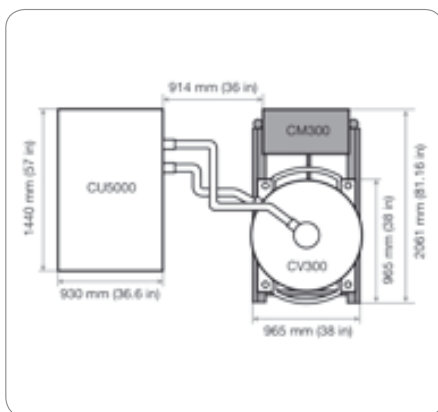
▶ Biosafe® Ports

Contained Aseptic Transfer of Components, Fluids and Powders

Description

The Biosafe® range of Aseptic Transfer Ports offers reliable and easy-to-use solutions for the secure transfer of components, fluids and powders while maintaining the integrity of the critical area – isolators, RABS and cleanrooms.

Features & Benefits

– Enhanced sterility assurance and viral segregation in aseptic processing

– Easy to use

– Process safety

– Versatile technology

– Simplified maintenance and sterilization

– Cost effective

1. Biosafe® 110 Monolever Port; 2. Biosafe® 110 Automatic Port; 3. Biosafe® 110 Three-lever Port;
4. Biosafe® Biosteam® P Port; 5. Biosafe® Biosteam® S Port

Applications	Upstream and Downstream Processing		Aseptic Processing	

Applications	Transfer of large volume support solutions held in lower classified environments to higher classification process zones. Examples of applications:
	– Media feed to N-2│N-1│bioreactor
	– Buffer feed to chromatography columns
	– Transfer out of higher classified zones:
	  – fraction collection
	  – bulk intermediates
	  – bulk final product transferring
	    out of purification
		Transfer into formulation vessel
		– Powder (buffer
		  and media)
			Discharge from autoclave
			– Stoppers
				Transfer into isolators or RABS
				– Drug products
				– Entry of stoppers
				– Entry and removal of QC test
				  devices, tools and pumps
				– Waste removal

Biosafe® 110 Three-lever Port	•	–	–	–
Biosafe® 110 Monolever Port	•	–	–	•[1]
Biosafe® 110 Automatic Port	–	–	–	•[1]
Biosafe® Biosteam® P Port	–	•	–	–

Biosafe® Bags (All Biosafe® Bags are designed for connection to any Biosafe® Port.)	Rapid Aseptic Fluid Transfer (RAFT) Systems preassembled with other Sartorius Stedim Biotech technologies such as Flexel® 3D and Flexboy® system. Complete assembly is Gamma sterile.	Closed Gamma sterile	Double connector Gamma sterile	– Open autoclavable to be filled
				  by end-users prior to autoclave
				  sterilization and aseptic transfer.
				– Prefilled autoclavable delivered
				  ready-to-sterilize via component
				  suppliers.
				  – Prefilled delivered Gamma
				    sterile by component suppliers.
				– Closed Gamma sterile for the
				  removal of waste, tools, pumps and
				  QC test devices.

Biosafe® Biosteam® S Port	–	–	•	–

[1] Biosafe® Port with outside opening is the best choice to prevent air turbulence in RABS and glove usage in isolator.

Operating Sequences

Connecting a Biosafe® Bag
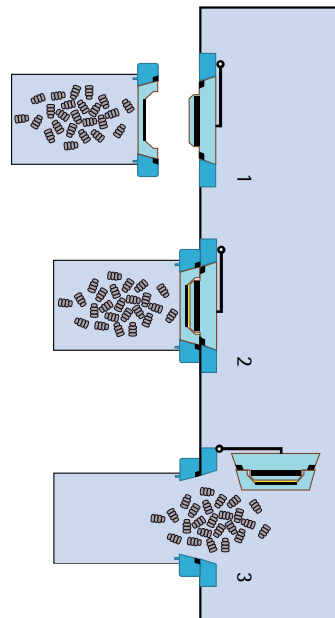
Approach
– Wipe down the Biosafe® Port
– Open package of the Biosafe® Bag and remove the protecting pouch

Docking
– Docking is secured by magnetic guidance on the Biosafe® Port
– The magnetic connection is further secured by mechanical locks.

Opening and Transfer
– Open the double-door either from inside or outside the critical area.
– Aseptic transfer of components, fluids or powders.

Prior to the connection, the pins on the Biosafe® connector are in the "out" position (see beside). This is a proof that the Biosafe® Bag is ready to be connected to the Port and that it has not been used before.
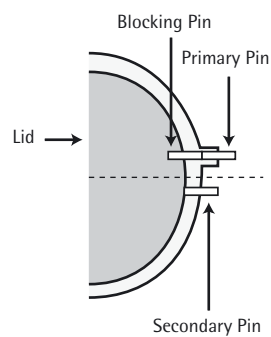
Step 1: Biosafe® Bag prior to connection
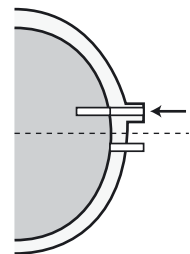
Step 2: Handles to "open" position
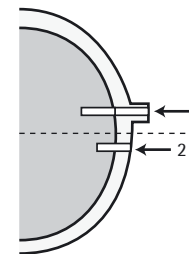
Step 3: Handles to "close" position

Outside View

Inside View

Maintenance, Decontamination and Sterilization of the Biosafe® Port
When connected to the Biosafe® Port, the dummy service connector allows the door to be opened for the sterilization of the critical area and the inner side of the Biosafe® Port as well as for maintenance operations such as gasket replacement.

▷ Specifications

	Biosafe® 110 Three–Lever Port	Biosafe® 110 Monolever Port	Biosafe® 110 Automatic Port	Biosafe® Biosteam® P Port	Biosafe® Biosteam® S Port
Installation Requirements	Wall thickness: 2-8 mm | 0.08-0.31 in.	Wall thickness: 2-8 mm | 0.08-0.31 in.	Wall thickness: 2-8 mm | 0.08-0.31 in.	N|A	N|A
	– If the wall thickness exceeds 8 mm | 0.31 in., the Biosafe® Port must be installed on a Biosafe® support which is then integrated into the wall. – If outside opening is chosen, the Biosafe® Port is systematically supplied on a Biosafe® support which is then integrated into the wall.	N|A	N|A	N|A	N|A
	– We highly recommend setting the port below or on a window so that the operator can see the other side. – Height of port for accessibility: for good access, the port axis must be 1.1 m to 1.4 m (43.3 in. to 52.12 in.) high from the operator standing reference.			N|A	N|A
Weight (approx.)	10 KG| 22.05 lb.	15 KG| 33.07 lb.	45 KG| 99.21 lb.	80 KG| 176.37 lb.	80 KG| 176.37 lb.
Operating Temp Range	5°C to 30°C 41°F to 86°F	5°C to 30°C 41°F to 86°F	10°C to 30°C 50°F to 86°F	5°C to 30°C 41°F to 86°F	5°C to 30°C 41°F to 86°F
Maximum Temp During Autoclave Cycle	N|A	N|A	N|A	150°C | 302°F	150°C| 302°F
Pressure Range During Autoclave Cycle	N|A	N|A	N|A	–1 to +6 bars	–1 to +3 bars
Power Requirements (Europe and U.S.)	100 V to 240 V; 50 to 60 Hz (required only if the vacuum option is chosen)		90 V to 240 V; 50 to 60 Hz	N|A	N|A
Materials of Construction[1]	Stainless Steel 316L; PETP; Silicone | EPDM for gaskets			Stainless Steel 316L; PETP; PEEK; EPDM for gaskets	
Passage Diameter	110 mm| 4.3 in.	110 mm| 4.3 in.	110 mm| 4.3 in.	110 mm| 4.3 in.	110 mm| 4.3 in.
Quality Standards	– All materials are compliant with 21 CFR Part 177.2600 (EPDM|Silicone), 21 CFR Part 177.1630 (PETP) and 21 CFR Part 177.2470 (PEEK) – The Biosafe® Biosteam® P and S Ports meet the requirements given by European Pressure Equipment directive 97/23/EC and the European explosive atmosphere Directive 94/9/EC 'ATEX' – Vacuum box meets the requirements for Low Voltage European Directive 73/23/EC – Automatic Port meets the requirements for Machinery Directive 98/37/EC; Low Voltage European Directive 73/23/EC; Electromagnetic Compatibility Directive 89/336/EC				
FAT|SAT	Factory Acceptance Tests (FAT) and Site Acceptance Tests (SAT) are performed on each Biosafe® Port. – Air-tightness at several points of control: gasket, locking screws, handles positioning, vacuum circuit (if the option is chosen) – Functional: positioning of gasket, positioning and manipulation of external and internal handle(s), lockers, mechanical securities				
Cleaning and Decontamination Agents	– Purified water (WFI) or any neutral pH detergent – Ethanol or isopropyl alcohol (70% v|v) – Peracetic acid solution (2% v|v) – Hydrogen peroxide solution (2% v|v)				

[1] The list provides construction materials in contact with the critical area (isolators, RABS, cleanrooms).

Ordering Information

Biosafe® Ports

FAA109720	Biosafe® 110 Three-lever TTI Port[1]
FAA109857	Biosafe® 110 Three-lever TTI Port[2]
FAA109856	Biosafe® 110 Three-lever TTI Port[3]
FAA109858	Biosafe® 110 Three-lever TTI Port[4]
FAA109722	Biosafe® 110 Monolever Port[1]
FAA109860	Biosafe® 110 Monolever Port[2]
FAA109861	Biosafe® 110 Monolever Port[3]
FAA109862	Biosafe® 110 Monolever Port[4]
FAA109723	Biosafe® 110 Automatic Port[1]
FAA109869	Biosafe® 110 Automatic Port[2]
FAA109871	Biosafe® 110 Automatic Port[3]
FAA109872	Biosafe® 110 Automatic Port[4]
FAA109728	Biosafe® Biosteam® P Port
FAA113645	Biosafe® Biosteam® S Port

Accessories, Options & Support for Biosafe® Ports

FAA109724	Biosafe® Dummy Service Connector for Manual Port
FAA109725	Biosafe® Dummy Service Connector for Automatic Port
FAA112940	Biosafe® Dummy Service Connector for Biosafe® Biosteam® P Port
FAA113646	Biosafe® Dummy Service Connector for Biosafe® Biosteam® S Port
FAA109727	Biosafe® vertical support device for Biosafe® 110 Three-lever Port
FAA112077	Biosafe® inclined support device for Biosafe® 110 Monolever Port
FAA112080	Biosafe® inclined support device for Biosafe® 110 Three-lever Port
FAA112081	Biosafe® inclined support device for Biosafe® 110 Automatic Port
FAA109726	Biosafe® Vacuum Box
S87078SAT 110	Site Acceptance Tests (SAT) and training at final customers

[1] Inside right opening
[2] Inside left opening
[3] Outside right opening
[4] Outside left opening.

Dimensions

	A	B	C	D	E	F	G	H	I
Biosafe® 110 Three-lever Port	400 mm 15.7 in.	118 mm 4.65 in.	200 mm 7.9 in.	250 mm 9.8 in.	N|A	N|A	N|A	N|A	63 mm 2.5 in.
Biosafe® 110 Monolever Port	500 mm 19.7 in.	–	375 mm 14.8 in.	245 mm 9.7 in.	N|A	N|A	320 mm 12.6 in.	500 mm 12.7 in.	N|A
Biosafe® 110 Automatic Port	560 mm 22.1 in.	–	405 mm 15.9 in.	195 mm 7.7 in.	326 mm 12.8 in.	300 mm 11.8 in.	240 mm 9.5 in.	560 mm 22.0 in.	N|A

Front View
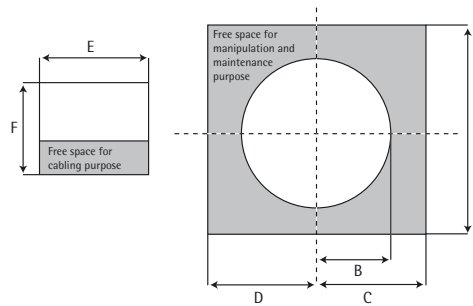
Side View
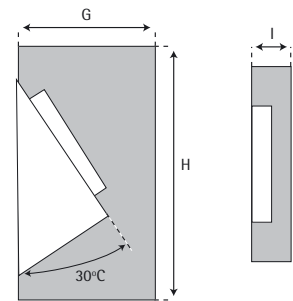
Spare Parts for Biosafe® Ports

Upon order of Biosafe® Ports, you will receive a complete technical package including the list and prices of spare parts.

▶ Biosafe® Aseptic Transfer Bags

Introduction

A complete range of Biosafe® aseptic transfer Bags is designed to best fit your requirements for aseptic transfer of components into clean rooms, isolators or RABS and for contained transfer of potent powders.

For use with the Biosafe® aseptic transfer Bags, the Biosafe® aseptic transfer Ports are available in a variety of design to meet specific needs and applications.

Applications

The Biosafe® range of aseptic transfer Bags is designed to best fit your requirements for aseptic transfer of stoppers, pumps, tools, QC test devices between two environments with different classifications and for contained transfer of highly potent powders from isolator to vessel. They provide a single-use alternative to traditional stainless steel rigid transfer containers in a large variety of applications.

Features and Benefits

Aseptic and contained single-use technology	Enhanced sterility assurance
Various bag materials & sizes	High flexibility
Standard Biosafe® bag	Short delivery leadtime
Multiple manufacturing sites	High security of supply

Biosafe® Aseptic Transfer Bag Configurations

Applications		Gamma Sterile	Autoclavable
Prefillable syringe components		Prefilled and Ready-to-Use (RTU) components[1]	Prefilled and Ready-to-Sterilize (RTS) components[1]
Vial & Cartridge components		Prefilled and Ready-to-Use (RTU) components[2]	Prefilled and Ready-to-Sterilize (RTS) components[2]
		Bulk components discharged from the autoclave processor into a Biosafe® aseptic transfer Bag with double-connector	Bulk components to be processed and autoclaved by end-user
QC Test devices	IN	Prefilled Petri dishes[3]	N|A
	OUT	Sequential removal of Petri dishes	N|A
Waste	OUT	Removal	N|A
Samples	OUT	Removal	N|A
Tools|Filling parts	IN	N|A	Entry
	OUT	Removal	N|A
Powders	IN|OUT	Filling from an isolator and discharging into a formulation vessel of high potent powders in a Biosafe® aseptic transfer Bag with double-connector	N|A

Gamma sterilizable Biosafe® Bag can be supplied upon request.

[1] Exclusively supplied in BD TSCF™ packaging with components chosen by the end-user
[2] Supplied by component suppliers who validated the Biosafe® aseptic transfer Bags (West Pharma, Stelmi, Helvöet)
[3] Supplied gamma sterile and validated by AES Chemunex

Cost Reduction and Risk Reduction
Single-Use Biosafe® aseptic transfer Bags improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Cost and time consuming cleaning and sterilization required for traditional transfer containers are eliminated.

Safety and Ease of Use
The Biosafe® aseptic transfer Bags feature an inner sleeve that is deployed in the critical area to guide the components during their passage in the Biosafe® Port while covering the critical line (ring of concern). Over protective pouch around the Biosafe® connector protects from particle contamination up to connection.

The Biosafe® aseptic transfer Bag connector assemblies are 100% air leak tested.

Aseptic Transfer Lines of Products
Besides the Biosafe® aseptic transfer Bags for transfer of components and powders, the SART System™ and the Biosafe® RAFT system allow for aseptic transfer of liquids between area with different classifications.

Technology Integration Support
Sartorius Stedim Biotech supports users at the preliminary design phase of a new production facility with the most comprehensive program to ensure successful design, implementation and validation of Single-Use Manufacturing.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state-of-the-art and robust supply chain that can cope with strong market growth.

Quality Assurance
Biosafe® aseptic transfer Bags are designed, developped and manufactured in accordance with a ISO 9001 and ISO 13485 Quality Management. Manufacture and Gamma sterilization processes are conducted under conditions that mirror Biopharmaceutical operations and meet cGMP requirements.

▷ Specifications

Biosafe® Aseptic Transfer Bag Gamma Sterile

Description		Biosafe® Bag BIO324	Biosafe® Bag BIO365	Biosafe® Bag BIO346
Dimensions	Film (L × W)	1200 × 300 mm 47.2 × 11.8 in.	740 × 475 mm 29.1 × 18.5 in.	2400 × 180 mm 94.5 × 7.0 in.
	Passage diameter	110 mm │ 4.3 in.		
Material of construction	Film	PE│PA│PE[1] 100 µm	STD71[2] 300 µm	PE│PA│PE[1] 80 µm
	Connector	ABS[4] port, HDPE[5] ring		
	Inner sleeve	N│A	N│A	N│A
Biosafe® connector		× 1	× 1	× 1
Working volume		23 L	50 L	16 L
Sterilization		Gamma sterile		

Description		Biosteam® P Bag BIO360	Biosteam® P Bag BIO364	Biosteam® S Bag BIO377TRMM
Dimensions	Film (L × W)	2000 × 300 mm 78.7 × 11.8 in.	2000 × 300 mm 78.7 × 11.8 in.	1000 × 350 mm 39.4 × 11.8 in.
	Passage diameter	110 mm │ 4.3 in.		
Material of construction	Film	LDPE[3] anti static	LDPE[3] anti static	PE│PA│PE[1] 100 µm
	Connector	ABS[4] port, HDPE[5] ring		
	Inner sleeve	LDPE[3] anti static	LDPE[3] anti static	HDPE[5]
Biosafe® connector		× 2	× 1	× 2
Working volume		10 L	10 L	25 L
Sterilization		Gamma sterile		

[1] PE│PA│PE: Polyethylene │ Polyamide │ Polyethylene
[2] STD71: Stedim 71 film
[3] LDPE: Low Density Polyethylene
[4] ABS: Acronytryle Butadiene Styrene
[5] HDPE: High Density Polyethylene
[6] PC: Polycarbonate

Biosafe® Aseptic Transfer Bag Autoclavable

Description		Biosafe® Bag BIO352	Biosafe® Bag BIO352TY	Biosafe® Bag BIO352MM	Biosafe® Bag BIO352TYMM
Dimensions	Film (L × W)	1100 × 400 mm 43.3 × 15.7 in.			
	Passage diameter	110 mm │ 4.3 in.			
Material of	Film	Tyvek® and HDPE[5] 80 µm			
	Connector	PC[6] port, HDPE[5] ring			
	Inner sleeve	N │ A	Tyvek®, HDPE[5]	N │ A	Tyvek®, HDPE[5]
	Protective cover	N │ A	N │ A	Tyvek®	Tyvek®
Biosafe® connector		× 1			
Working volume		30 L			
Sterilization		One steam sterilization cycle at 121°C for 30 minutes			

Description		Biosafe® Bag BIO352TR	Biosafe® Bag BIO352TRMM	Biosafe® Bag BIO363	Biosafe® Bag BIO363TY
Dimensions	Film (L × W)	1100 × 400 mm 43.3 × 15.7 in.			
	Passage diameter	110 mm │ 4.3 in.			
Material of	Film	Tyvek® and HDPE[5] 80 µm			
	Connector	PC[6] port, HDPE[5] ring			
	Inner sleeve	PC[6]	PC[6]	N │ A	Tyvek®, HDPE[5]
	Protective cover	N │ A	Tyvek®	N │ A	N │ A
Biosafe® connector		× 1			
Working volume		35 L	35 L	30 L	30 L
Sterilization		One steam sterilization cycle at 121°C for 30 minutes			

Description		Biosafe® Bag BIO363TYMM	Biosafe® Bag BIO363TR	Biosafe® Bag BIO363TRMM	Biosafe® Bag BIO363MM
Dimensions	Film (L × W)	1100 × 400 mm 43.3 × 15.7 in.			
	Passage diameter	110 mm │ 4.3 in.			
Material of	Film	Tyvek® and HDPE[5] 80 µm			
	Connector	PC[6] port, HDPE[5] ring			
	Inner sleeve	Tyvek®, HDPE[5]	PC[6]	PC[6]	N │ A
	Protective cover	Tyvek®	N │ A	Tyvek®	Tyvek®
Biosafe® connector		× 1			
Working volume		30 L			
Sterilization		One steam sterilization cycle at 121°C for 30 minutes			

[1] PE │ PA │ PE: Polyethylene │ Polyamide │ Polyethylene
[2] STD71: Stedim 71 film
[3] LDPE: Low Density Polyethylene
[4] ABS: Acronytryle Butadiene Styrene
[5] HDPE: High Density Polyethylene
[6] PC: Polycarbonate

Ordering Information

Order Code	Designation	Application	Pack Size (Pieces)
BIO324	Biosafe® Aseptic Transfer Bag Gamma sterile	Removal of components	30
BIO365	Biosafe® Aseptic Transfer Bag Gamma sterile	Removal of waste	24
BIO346	Biosafe® Aseptic Transfer Bag Gamma sterile	Removal of Petri dishes	30
BIO377TRMM	Biosafe® Aseptic Transfer Bag with double-connector Gamma sterile	Discharging and transfer of components	20
BIO360	Biosafe® Aseptic Transfer Bag with double-connector Gamma sterile	Filling & discharging of powders	30
BIO364	Biosafe® Aseptic Transfer Bag Gamma sterile	Discharging of powders	20
BIO352	Biosafe® Aseptic Transfer Bag autoclavable	Entry of components	36
BIO352TY	Biosafe® Aseptic Transfer Bag autoclavable with inner sleeve	Entry of components	36
BIO352MM	Biosafe® Aseptic Transfer Bag autoclavable with protective cover	Entry of components	36
BIO352TYMM	Biosafe® Aseptic Transfer Bag autoclavable with inner sleeve and protective cover	Entry of components	36
BIO352TR	Biosafe® Aseptic Transfer Bag autoclavable with inner sleeve	Entry of components	20
BIO352TRMM	Biosafe® Aseptic Transfer Bag autoclavable with inner sleeve and protective cover	Entry of components	20
BIO363	Biosafe® Aseptic Transfer Bag autoclavable	Entry of components	24
BIO363TY	Biosafe® Aseptic Transfer Bag autoclavable with inner sleeve	Entry of components	24
BIO363MM	Biosafe® Aseptic Transfer Bag autoclavable with protective cover	Entry of components	24
BIO363TYMM	Biosafe® Aseptic Transfer Bag autoclavable with inner sleeve and protective cover	Entry of components	24
BIO363TR	Biosafe® Aseptic Transfer Bag autoclavable with inner sleeve	Entry of components	20
BIO363TRMM	Biosafe® Aseptic Transfer Bag autoclavable with inner sleeve and protective cover	Entry of components	20

Library
Further documentations are available upon request:

– Biosafe® Aseptic Transfer Ports

– Biosafe® Rapid Aseptic Fluid Transfer (RAFT) System

– SART System™

► # Biosafe® RAFT System

Biosafe® Rapid Aseptic Fluid Transfer (RAFT) System

Introduction

The Biosafe® Rapid Aseptic Fluid Transfer (RAFT) system provides easy-to-use and reliable through-the-wall aseptic transfer of liquid between clean rooms of different environmental classification while ensuring a total confinement. When pre-assembled and pre-sterilized with Flexel® 3D or Flexboy® bags with flexibility in volumes, from a few liters up-to 3000 L, the Biosafe® RAFT System opens up opportunities for modularity within the facility.

For use with the Biosafe® RAFT System, the Biosafe® aseptic transfer Ports are available in a variety of design to meet specific needs and applications.

Applications

– Solutions supplied through the wall from unclassified area into process suites:

  - Transfer of cell culture media and other solution to bioreactor

  - Transfer of buffers to centrifugation, clarification and chromatography

  - Transfer of buffers to recovery operations and purification

– Sterile solutions transfer between segregated process areas - for example between live viral and inactivated viral suites.

– Outsourced ready-to-use buffers and media can be docked and fed directly to the process without having to enter the main facility.

Risk Reduction

As a single-use system, the Biosafe® RAFT System improves process safety as it reduces the risk of cross contamination from batch-to-batch and product-to-product.

Optimized Facility Design and Cost Reduction

The Biosafe® RAFT System allows the user to segregate the preparation and supply of support solutions from the process areas. This results not only in substantial reduction of higher classification clean rooms but also in optimization of material and operators flows. As a single-use system, cost and time consuming CIP and SIP are minimized with a direct impact on capacity utilization.

Aseptic Transfer Lines of Products

Besides the Biosafe® RAFT System for transfer of liquid, a complete range of Biosafe® Bags is available for aseptic transfer of components (stoppers, pumps, tools, QC test devices) and powders into critical areas - clean rooms, isolators, RABS or vessels.

Technology Integration Support

Sartorius Stedim Biotech supports users at the preliminary design phase of a new production facility with the most comprehensive program to ensure successful design, implementation and validation of Single-Use Manufacturing.

Features and Benefits

Aseptic and contained single-use technology	Enhanced sterility assurance
Segregated preparation and manufacturing areas	Substantial reduction of higher classification areas
Various bag sizes pre-assembled on Biosafe® RAFT system	High flexibility in process
Multiple manufacturing sites	High security of supply

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Quality Assurance
Biosafe® RAFT System is designed, developed and manufactured in accordance with ISO 9001 and ISO 13485 Quality Management. Manufacture and Sterilization processes are conducted under conditions that mimic Biopharmaceutical operations and meet cGMP requirements.

Biosafe® RAFT System fluid paths are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Containers-Physicochemical tests - Plastics

– USP<85>and EP 2.1.14: Bacterial endotoxins test

– USP <788>Particulate matter in injections-Large-volume injections and E.P. 2.9.19: Particulate contamination-sub-visible particles

– ISO 11737: Microbiological methods-Determination of a population of micro-organisms on products

– ISO 11137: Sterilization of Health care products-Radiation

▷ Specifications

Standard Specifications

Biosafe® Connector

Material	ABS[1] port, HDPE[2] ring	a
Opening diameter	110 mm / 4 in.	a

Film

Dimensions (L × W)	400 × 800 mm | 15,7 × 31,5 in.	b
Material	PE/PA/PE[3] 100 µm	b

Fittings

	Inlet Outside of the Biosafe® Bag		Outlet In the Biosafe® Bag	
Tubing				
Internal Diameter	3/8" or 1/2"	c	3/8" or 1/2"	d
Length	No restriction	c	Max. length = 2 m / 78 in	d
Material	Silicone Pt or Clear C-Flex ADCF	c	Silicone Pt or Clear C-Flex ADCF	d
Bag | Filter	Flexel® 3D Bag (100 L to 3000 L) or Flexboy® Bag (5 L to 50 L) Sartopore® 2 Gamma Capsule	e	N/A	
Connection	Female MPC or MPX, Tri clamp, Steam-thru connector, Opta® sterile connector	f	Male MPC or MPX, Tri clamp, Steam-thru connector, Opta® sterile connector, Open end tube	g

Sterilization by Gamma irradiation

[1] ABS: Acronytryle Butadiene Styrene
[2] HDPE: High Density Polyethylene
[3] PE/PA/PE: Polyethylene/Polyamide/ Polyethylene


Ordering Information
Single-use systems configured with Biosafe® RAFT System are customized upon request following the above-mentioned standard specifications. Please consult your sales representative for ordering details.

Library
Further documentation is available upon request:

– Biosafe® range of Aseptic Transfer Ports

– Biosafe® Aseptic Transfer Bags

– SART System™
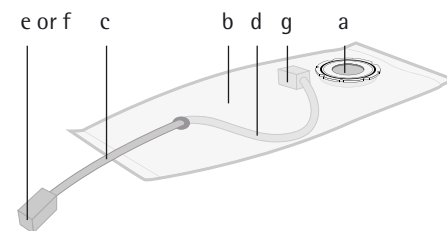
► SART System™

Sartorius Stedim Biotech Aseptic Rapid Transfer System

Single-Use Technology

Description
The SART System™ is designed to allow aseptic liquid transfer between two areas with different containment classifications. The SART System™ consists of an external port, an internal port and a disposable connection device – Gammasart ATD™ –

Operating Principle
Applying RTP technology at the port as well as the disposable connector the SART system™ utilizes a well established and accepted aseptic connection technology. The principle of the connection is based on the alpha-beta concept using 4 V-shaped profiles matching exactly at the tip. The small size allows accurate matching of the V-shaped profiles.

Applications
The SART System™ has been developed to facilitate an aseptic transfer from:

– a clean room into a protected environment (Isolator, Restricted Access Barrier System | RABS).

– a lower classified clean room or even corridor into a class A/ISO 5 clean room

The disposable Gammasart ATD™ connector may be sterilized by autoclave or gamma irradiation, enabling use for either traditional vessels or fully disposable fluid handling technologies.

Flexibility
The disposable Gammasart ATD™ connector may be opened and re-used up to five times. Multiple transfers of different volumes can be processed without the need of re-sterilization. In the event of a stoppage on a filling line, the Gammasart ATD™ connector allows that the bulk can be safely removed from the line, stored and re-connected later.

Safety
The port is equipped with mechanical interlock systems that prevent an accidental opening of the port in without the Gammasart ATD™ connector in place and accidental release of the outer part of the connector. The Gammasart ATD™ connector is 100% air leak tested as a condition of lot release.

Qualification
The SART System™ and the Gammasart ATD™ connector have been extensively qualified for use in critical applications within bio-pharmaceutical manufacturing processes. A validation guide is available.

▷ Specifications

Technical Specification

External Port

Port Material	Stainless Steel 316L
Sealing Material	Silicone
Thickness requirement for wall	10 mm

Internal Port

Material	Stainless Steel 316L

Gammasart ATD™ Connector

Connector Body Material	PBT Celanex Grade 2404MT
Overmolded Seal Material	Santoprene Grade 281–64

Ordering Information

Part Number	Description	Qty/Box
AN-CON-202025	SART System™, Sartorius Stedim Biotech Aseptic Rapid Transfer System, incl. external port, external port cover, internal port and internal stopper	1
AN-CON-102025	Gammasart ATD™, Non sterile disposable connector for aseptic liquid transfer, incl. connector body and connector cover	50
AN-CON-101025	Gammasart ATD™, Sterile disposable connector for aseptic liquid transfer, incl. connector body and connector cover	10

Please note: Validation information can be obtained in the validation guide SLO5701-e.

FlexAct® BP

Disposable Solution for Buffer Preparation

Description

The FlexAct® BP configurable disposable buffer preparation solution is a standardized configurable disposable solution (CDS) dedicated to buffer preparation steps in biopharmaceutical processes. The FlexAct® BP addresses the entire development cycle and production capacity needs from 50 to 1,000 L for buffer preparation. The integration of monitoring & control features for pH, pump speed and fluid level control is a further milestone for the implementation of process relevant single-use equipment. The integrated controls allow end-users to perform other tasks during the buffer preparation operation. Combined with a Flexel® for LevMixer® System and multiple Palletanks® the multifunctional Central Operating Module enables the user the install, operate and monitor a fully single use unit operation.

Features

– Multifunctional Central Operating Module
– Tailored bag configurations
– 50 – 1,000 L buffer preparation
– Quick system set-up
– Integrated disposable sensors
– Bidirectional operation

Benefits

– Operator friendly
– Flexible buffer supply
– Fully scalable
– Efficient equipment utilization
– Enables monitoring
– Highly flexible

Components

The FlexAct® BP configurable disposable buffer preparation solution consists of:

– Flexel® for LevMixer® System for Palletank®
– Weighing platforms
– FlexAct® BP Central Operating Module with accessories
– Multiple bag assembly configurations with Palletanks®

1. Flexel® for LevMixer® System for Palletank®
The Flexel® 3D for LevMixer® system for Palletank® includes

– Cubical Palletank® available in 50 L, 100 L, 200 L, 400 L, 650 L and 1,000 L volumes
– Superconducting drive unit

1.1. Palletank® for Impeller Mixing is a stainless steel cubical container designed to perfectly fit with the Flexel® 3D for LevMixer® bag assemblies with its integrated impeller. It includes a railed port for coupling the mobile Drive Unit with the Flexel® 3D for LevMixer® bag cubical. For reliable fluid level control the Palletanks® for Impeller Mixing are optionally equipped with in-house load cells. The hinged door allows easy installation of the bag assembly whereas the front bottom gate facilitates easy tubing installation and access. Windows on lateral and rear sides enable the user to visually control the mixing process. The cubical shape improves the mixing efficiency and offers scalability from 50 L to 1,000 L.

1.2. LevTech® Superconducting Drive Unit generates the levitation and rotation of the single-use magnetic impeller without surface contact. This allows the Flexel® 3D for LevMixer® system to efficiently mix powders, suspensions, solutions or emulsions. The drive unit is mobile, cart-mounted and designed to interface with Palletank® For Impeller Mixing of different volumes. The LevTech® drive unit operates independently of the cubical tank with the Flexel® mixing bag so that a single drive unit can serve multiple Palletank® of different sizes. Flexel® 3D for LevMixer® bag assemblies for FlexAct® BP operations are available from stock.

2. Weighing Platforms

The IFS4 flat-bed scales are entirely constructed of stainless steel and have an extremely low height, making it ideally suited for floor installation without a pit or anchoring. The ramp is securely attached to the scale using special retainers for prevention of force shunt. This high-quality platform can be connected to any of a wide range of indicators, for use as a Class III legal measuring instrument or without legal verification. The CIS1 Combics 1 indicator allows strain gauge weighing with flat bad scales as well as with load cells to be connected.

3. FlexAct® BP Central Operating Module with Accessories

The FlexAct® BP Central Operating Module is designed for operational excellence in buffer preparation processes. It features multiple work platforms that incorporate process equipment and user friendly monitoring & control capabilities. The integrated control instrumentation together with an ergonomically positioned 10" LCD touch screen enables the operator to have an overview about the main process parameters values such as pH and temperature of the buffer whilst preparation and filtration. For secure fluid level management a weight signal is provided by either load cells that are integrated into the LevMixer® Palletanks® or floor scales provided individually. The three level Central Operating Unit is able to accommodate multiple process devices required in a single-use process environment. Depending on the process needs, thermal welding and sealing provided by the BioWelder® and BioSealer® as well as filter integrity testing by using a Sartocheck® 4 integrity tester will help to quick connect and test assemblies.

3.1 Sartocheck® 4

Filter Integrity Testing is an essential procedure to detect defective filter cartridges before or after use. Thus automatic integrity testers have to fulfil highest standards with respect to accuracy and reliability. At the same time the user-friendly interaction guarantees convenient handling.

The Sartocheck® 4 offers solutions for all customer needs. With a comprehensive accessory package it allows highest flexibility for all integrity testing needs.

3.2 BioWelder® and BioSealer®

Sterile Fusing and Sealing of thermoplastic tubing are key technologies that offer most flexibility to the end users that are interested in getting a solution for multiple connection and disconnection cycles. Sartorius' BioWelder® and BioSealer® devices that meet these requirements set by the industry. The ability of assuring quick and reliable connections and disconnections combined with the expertise of Wave Biotech Switzerland made BioWelder® and BioSealer® to the product of choice in the biopharmaceutical industry.

4. Buffer Bag Assemblies with Palletank® for Intermediate Buffer Storage

FlexAct® BP bag assemblies are supplied to serve the need of a fully preconfigured, ready to install, single-use unit operation. Uniquely, the Flexel® 3D for LevMixer® bag and Flexel® 3D storage bags are supplied in one package.

The Flexel® 3D for LevMixer® bag assembly for Palletank® contains a centred magnetic impeller. Its unique sided K-weld design simplifies installation and facilitates the unfolding and folding of the bag during filling and draining operations. The patented protection cap provides robustness avoiding frictions of the impeller with the film during transport before bag use. It also offers a large 8" diameter port for powder transfer and allows for continuous mixing during fluid transfer operations and avoids hold up volume for 100% fluid recovery. The storage bag assemblies of the FlexAct® BP Configurable Disposable Solution are tailored to suit the dedicated need for individual buffer volumes at the point of use. Supplied as single Flexel® 3D bags or Flexel® 3D bag manifolds, the FlexAct® BP buffer storage bag assemblies provide highest flexibility and efficiency. The Palletank® for Storage or In-Process Handling are stainless steel container designed to perfectly fit with the Flexel® 3D for LevMixer® bag assemblies.

4.1 Powder Bags

Powder Bags provide a cost-effective and efficient system for handling pharmaceutical powders in a safe and contained manner. They incorporate antistatic film, ergonomic handles and industry-standard triclamp connectors.

FlexAct® Configurator

A configurator based selection system enables the user to flexibly create the FlexAct® BP solution that meets its process requirements in buffer preparation. All components included in the configurator are standardized components that ensure highest performance, shortest lead times and highest quality. The following Configurable Disposable Solutions will gradually complete the FlexAct® family:

Unit Operation	FlexAct® Configurable Disposable Solutions
Buffer Preparation	FlexAct® BP
Media Preparation	FlexAct® MP
Cell Harvest	FlexAct® CH
Ultrafiltration | Diafiltration	FlexAct® UD
Virus Removal	FlexAct® VR
Virus Inactivation	FlexAct® VI
Polishing	FlexAct® PO
Form & Fill	FlexAct® FF

Ease of Use

The primary driver behind the FlexAct® initiative is the development of disposable equipment which meets all process operations improving efficiency and speed. Sartorius Stedim specialists have analyzed the process environment and the operating procedure for buffer preparations thoroughly and developed an operator friendly multifunctional Central Operating Unit. Tailored bag configurations with 50 L up to 1,000 L buffer preparation offer a flexible buffer supply at full scalability. The system set-up is performed within minutes and needs less preparation time compared with existing solutions. Once the operation is performed, the system can be as fast rigged-off without the needs of tedious cleaning requirements. Set-up and rig-off ease allow for more efficient and faster equipment utilization adding to the overall process capacities. The monitoring on a 10" touch screen of all main process parameter is easily enabled by integrated disposable sensors.

Validation

Flexel® 3D bags have been qualified applying the most stringent and current test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® 3D bags with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Flexel® 3D bags are tested for compliance to:

– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes and state-of-the-art utilities. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a flexible and robust supply chain that can cope with strong market growth.

Flexel® Storage bag(s) with tubing and Sartopore® 2 Gamma Midicaps | Maxicaps

Flexel® for LevMixer® bag with tube and 1½" TC connector

The schematic above shows the bag assemblies connected

▷ Specifications

1. Superconducting Drive Unit

Power: – EU – USA – Japan	 Single Phase 230 V, 50 | 60 Hz Single Phase 110 V, 60 Hz Single Phase 230 V, Transformer (110 V Input), 50 | 60 Hz
Input Wattage	< 350 Watts
Footprint	37 inches + 16 inches (94 cm + 41 cm)
Weight	103 lb (47 kg)
Ambient Temperature	4° to 30℃
Ambient Humidity	Less than 75%
Mobility	Mounted on Stainless Cart with Four Clean Room Wheels and Push Handles
IP Rating	IP23
Impeller Speed	0–180 RPM
Initial Set-up Time	45 Minutes
Vessel Changeover Time	< 7 Minutes
CE Mark	Compliant
Material for External Surfaces	Stainless Steel #316L

2. Flexel® 3D Bag Assemblies

2.1 LevMixer® Bags for Palletank®

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, ULDPE Contact Layer
Impeller position	Centered
Impeller size	50–100 L: 4.95" (126 mm) 200–1,000 L: 6.35" (161 mm)
Tubing material	Silicone
Number of Ports	1 top port, 4 front bottom ports
pH probe	Single-use glass electrode
T probe	PT element (reusable)
Outlet Fittings	Tri-clamp, Luer Lock female septum
Volumes	50 L; 100 L; 200 L; 400 L; 650 L; 1,000 L
Sterilization	by Gamma Irradiation

2.2 Powder Bags
Safe and Easy Contained Transfer of Powder Containment or the protection of operators and their surrounding environment by isolating powders has always been a priority for the pharmaceutical industry. In addition, the need to assure product integrity combined with stringent Health & Safety regulations, demands guaranteed segregation at all stages.

Today, customers are using the contained powder transfer bags to transfer media, buffers, filter aids and other powders. Applications include transport from suppliers to customers or in-house supply from dispensary of preparation area to end-users. If sterility or aseptic processing is a requirement, the contained powder transfer bags and accessories are delivered gamma irradiated (> 25 kGy).

All powder bags are equipped with Tri-Clamp connectors for powder charging. For buffer preparation, the contained powder transfer bags can be connected to the mixing bag. After discharge, bags remain connected to the mixing bags in order to minimize the operator exposure.

Standard Powder Transfer Bags provide:

– High product recovery with an ultra clean, antistatic, <USP> Class VI, LDPE film

– High containment to protect the operator, eliminate potential safety risk and avoid the contamination of the work environment during handling, transfer or transport of the fine powder

– Good ergonomics with an extensive range of accessories (complete solution)

– Comprehensive validation package

Applications
Typical applications requiring a high containment for the transport and delivery of powders into a single-use mixing system includes:

– Media preparation (dry powder media, dry powder feed)

– Buffer preparation (dry powder buffer)

– Formulation (API, Excipient)

Powder Transfer Bag Systems are also used for powder transfer into reusable mixing vessels (buffer and media prep).

Standard Powder Transfer Bags

Bag Chamber	Multiple layer film construction, including Permanently Static Dissipative (PSD) LDPE contact layer
Fittings	4-inch triclamp
Accessory	Pinch clamp
Volumes	15 L and 30 L
Number of Port	1 port
Irradiation	25–45 kGy

Triclamp Reducer

Description	8-inch to 4-inch triclamp reducer with a 4-inch triclamp plug, 4-inch triclamp gasket and 4-inch triclamp union
Material of Construction	Reducer: polyethylene, Plug: polyethylene, Gasket: platinum cured silicone, 4-inch triclamp union: glass reinforced polyamide
Non sterile	

Accessories

Description	4-inch triclamp plug, 4-inch triclamp gasket, 4-inch triclamp union
Material of Construction	Plug: polyethylene, Gasket: platinum cured silicone, 4-inch triclamp union: glass reinforced polyamide
Non sterile	

Powder Bag Holders
Two vertical positions for 15 L and 30 L Powder bags.

Description	Powder holder accessory for Palletank® for LevMixer®, 50–100 L	Powder holder accessory for Palletank® for LevMixer®, 200–400–650 L	Powder holder accessory for Palletank® for LevMixer®, 1,000 L
Construction Material	304 L Stainless Steel and Nylon		
Surface Finishing	8 kg	9 kg	9 kg
Overall dimensions (Approx.) w × d × h	442 × 400 × 1,080 mm 17.4 × 15.7 × 42.5 in.	743 × 400 × 1,080 mm 29.2 × 15.7 × 42.5 in.	857 × 400 × 1,080 mm 33.7 × 15.7 × 42.5 in.
Height above Palletank® with 15 L Powder Bag with 30 L Powder Bag	726 mm | 28.6 in. 986 mm | 38.8 in.		
Additional features	Two vertical positions for 15 L and 30 L Powder bags. Rotary powder holder for easy access to the hook		

2.3 Flexel® 3D Bag for Storage

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, ULDPE Contact Layer
Tubing material	C-Flex®, Silicone
Number of Ports	2 top ports, 1 bottom port
Outlet Fittings	Tri-clamp, Luer Lock female septum
Volumes	20 L; 50 L; 100 L; 200 L; 500 L; 1,000 L
Sterilization	by Gamma Irradiation

3. Palletank®

3.1 For Impeller Mixing w │ or w │ o load cells

Material	304 L Stainless Steel
Surface Finish	Glass Bead Blasted
Door	Front Hinged Door
Windows	Plexiglass
Ports	Railed port for drive unit Front bottom port for bag line access

Volume (L)	Dimensions (W × D × H)	Weight (kg) Palletank®
50	825 × 570 × 1,051	43
100	825 × 570 × 1,126	49
200	775 × 699 × 1,250	63
400	921 × 824 × 1,345	88
650	1,040 × 930 × 1,500	103
1,000	1,090 × 1,120 × 1,650	156

4. FlexAct® BP Central Operating Module

Material	316 L Stainless Steel
Surface Finish	Optional: – Powder coated | coloured – Glass Bead Blasted, electropolished
Dimensions	W × D × H 795 × 1,410 × 1,500 mm (31.3 × 55.51 × 59.06 inch)
Weight (approx.)	160 kg (352.74 lb) (incl. Watson Marlow pump)
Control Unit	– Control unit with 10.4" touch panel

4.1 Pump

Watson Marlow	720UN | R
Specification	IP66 0.1–360 rpm
Pumphead	720R pumphead, 4 roller pumphead for maximum 2 bar. Accepts continuous tubing only (includes continuous tube clamp set)

4.2 BioWelder®

Power requirements	100–240 V │ 47–63 Hz
Dimensions	300 × 300 × 220 mm
Weight	0.5 kg
Housing	stainless steel
Interface	RS232 for printer
Blade	Cr-Ni-Alloy, single-use
Ambient temperature	20°C–30°C (ideal: 22°C)
Relative Humidity	20%–80% (ideal: 60%)
Temperature Sensor	Type K, calibration holder available
Max. Tube OD	¾"
Min. Tube OD	¼"
Welding Cycle	60–90 sec. depending on tube dimension
Standard settings for	C-Flex®, PHARMED® BPT, Sanipure® 60

4.3 BioSealer®

Power requirements	100–240 V │ 47–63 Hz
Dimensions	220 × 150 × 210 mm
Weight	3.0 kg
Housing	stainless steel
Compression head	Aluminum anodised
Ambient temperature	20°C–30°C
Relative Humidity	35%–65%
Max. Tube OD	¾"
Min. Tube OD	¼"
Sealing Cycle	1–4 minutes depending on tube size and quality
Tubing Types	Soft ThermoplasticTubing, (e.g. C-Flex®, SaniPure® 60 and Pharmed® BPT)

4.4 Sartocheck® 4

Power requirements	100–240 V AC, 50 | 60 Hz
Maximum power input	74 watts
Maximum operating pressure	9,999 mbar | 145 psi
Minimum inlet pressure	4,000 mbar | 58 psi
Dimensions	W × D × H1 × H2 460 × 390 × 140 × 245

Measuring ranges:

Test pressure	100–8,000 mbar | 1.5–116 psi
Pressure drop	1–2,000 mbar | 0.01–29 psi
System inlet volume – with internal ref. Vessel – with external ref. Vessel max.	 9,000 ml 100 l

Measuring accuracy:

Pressure	± 0.1% full scale, ± 9.5 mbar
Pressure drop	± 1 mbar
Volume determination	± 4%
Diffusion	± 5%
Water-Intrusion	± 5%
Bubble Point	±50 mbar | ± 0.7 psi

Operating conditions:

Ambient temperature	+15°C to +35°C
Rel. humidity	10–80%

Touch Screen:

Size	10.4" TFT
Features	256 colors

Comunication Ports:

Serial Port	TU RS232
Serial Port	MU RS485
PLC Port	binary signals12 pins
Network	RJ45

Language option:

	English German French Spanish Italian

5. IFS Flat-Bed Scales

5.1 IFS4-300LI-I

Weighing capacity	300 kg
Platform size	1000 × 800
Height	standard
Load plate	AISI304 │ 1.4301V2A bead-blasted
Resolution	30.000 d
Readability	10 g

5.2 IFS4-1500NN-I

Weighing capacity	1,500 kg
Platform size	1250 × 1250
Height	standard
Load plate	AISI304 │ 1.4301V2A bead-blasted
Resolution	30.000 d
Readability	50 g

5.3 Combics CIS1 – Scale Indicator
Indicators for complex weighing tasks in 4 different versions.

Max. readability	31.250 digits
IP protection rate	IP67 (PG cable gland), IP44 (25-pol. D-SUB), (IP65 as option)

Ordering Information

1. Flexel® 3D Palletanks®

1.1 Flexel® 3D for LevMixer® Palletank® – Without Load Cells

Order Number	LevMixer® Palletank® w│o Load Cells
FXC110820	Palletank® 50 L for Impeller Mixing
FXC112230	Palletank® 100 L for Impeller Mixing
FXC110821	Palletank® 200 L for Impeller Mixing
FXC111135	Palletank® 400 L for Impeller Mixing
FXC110822	Palletank® 650 L for Impeller Mixing
FXC113384	Palletank® 1,000 L for Impeller Mixing

1.2 Spare parts for Flexel® 3D for LevMixer® Palletank®

Order Number	Spare Parts LevMixer® Palletank®
FXA112559	Clamp Holder for Palletank® 50 L for Impeller Mixing
FXA112560	Clamp Holder for Palletank® 100 L for Impeller Mixing
FXA112083	Clamp Holder for Palletank® 200 L for Impeller Mixing
FXA112086	Clamp Holder for Palletank® 400 L for Impeller Mixing
FXA112085	Clamp Holder for Palletank® 650 L for Impeller Mixing
FXA113527	Clamp Holder for Palletank® 1,000 L for Impeller Mixing
FXA112074	Adaptation Set for Palletank® for Impeller Mixing

1.3 Palletank® for Storage (50–650 L)│In-Process Handling (1,000 L)

Order Number	Palletank®
FXC113946 FXA113988	Palletank® 50 L for storage stackable Dolly for Palletank® 50 L (storage)
FXC110733 FXS102254	Palletank® 100 L for storage stackable Dolly for Palletank® 100 L │ 200 L (storage & shipping)
FXC110733 FXS102254	Palletank® 200 L for storage stackable Dolly for Palletank® 100 L │ 200 L (storage & shipping)
FXC110734 FXC100734	Palletank® 500 L for storage stackable Dolly for Palletank® 500 L (storage & shipping)
FXC106223 FXS102259	Palletank® 1,000 L for in-process fluid handling Dolly for Palletank® 1,000 L for in-Process fluid handling

1.4 Floor Scales (Flat Bed Scales)

Part Number	Platform Dimensions (mm)	Weighing Capacity	Readability	Load Plate	Dust│Water Protection
IFS4-300LI-I floor scale (flat bed scale)	1,000 × 800	300 kg	10 g	AISI304│1.4301 V2A beadblasted	IP67│IP68
IFS4-1500NN-I floor scale (flat bed scale)	1,250 × 1,250	1,500 kg	50 g	AISI304│1.4301 V2A beadblasted	IP67│IP68

1.5 Combics CIS1 – Scale Indicator

Combics 1 scale indicator, stainless steel housing, IP44	CISL1
Combics 1 plus scale indicator, stainless steel housing, IP44	CISL1N
Combics 2 scale indicator, stainless steel housing, IP44	CISL2
Combics 3 scale indicator, stainless steel housing, IP44	CISL3
Combics 1 scale indicator, stainless steel housing, IP67	CIS1
Combics 1 plus scale indicator, stainless steel housing, IP67	CIS1N
Combics 2 scale indicator, stainless steel housing, IP67	CIS2
Combics 3 scale indicator, stainless steel housing, IP67	CIS3

Optional Interfaces (UniCOM)

Interface module (RS-232C)	YDO01C-232
Interface module (RS-485│422)	YDO01C-485
Analog current output, 0–20 mA, 4–20 mA, 0–5 V, 16-bit	YDA01C-20MA
Profibus module	VDO01C-DP
Bluetooth® module (only for CIS models)	YDO01C-BT

Replace A│D Converter (WP1) with a Digital Interface

Interface (RS-232│485) for direct connection of a digital platform	YDI01C-WP

Printers and Printer Accessories

with functions for date, time and statistical evaluations	YDP03-0CE
Printer paper (5 rolls; length per roll: 50 m)	6906937
Replacement ink ribbon cartridge for printer	6906918
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 108 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator; only for use with flexible printout configuration (see "Software," next column)	YDP12IS-0CEUV
Printer paper (1 roll) for YDP12IS-0CE printer, 101 mm × 75 m, thermal sensitive paper	69Y03196
Labels for YDP12IS-0CE printer, extra large, 101 mm × 127 m, 305 labels	69Y03195
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 60 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator (see "Software," next column)	YDP04IS-0CEUV
Printer paper (3 rolls) for YDP12│04IS-0CE, 60 mm × 75 m, thermal sensitive paper	69Y03090
Labels for YDP12│04IS-0CE printer, small, 58 mm × 30 mm, 1000 labels	69Y03092
Labels for YDP12│04IS-0CE printer, medium, 58 mm × 76 mm, 500 labels	69Y03093
Labels for YDP12│04IS-0CE printer, large, 58 mm × 100 mm, 350 labels	69Y03094
Cable for direct connection of YDP12IS│YDP04IS-0CE printerto Combics CISL indicators	YCC01-01CISLM3

Electrical Accessories

External red│green│red display for Combics CISL indicators	YRD11Z
External red│green│red display for CIS indicators (12-pin round connector); connecting cable YCC02-R12F6 or Option M6 required	YRD14Z
Profibus connector for CISL... and CW...P... indicators (D-SUB 25-│9-pin)	IE10092
Second display for Combics CISL indicators	YRD02Z
Remote display, 7-segment, up to 45 mm characters	Information available on request
Bar code scanner, with cable for connection to Combics CISL scale indicator adapter cable, 120 mm scanning width	YBR02CISL
Bar code scanner for the Combics CIS model, with connecting cable, for connection with YCC02-R12F6	YBR02FC
Foot switch, incl. T-connector, D-SUB 25-pin	YFS01
Hand switch, incl. T-connector, D-SUB 25-pin	YHS02
External Alibi memory for electronic storage of weighing data	YAM01IS
Scanner for loading weighing data from YAM13IS Alibi memory cards to a PC	YAM02IS
Power supply for YAM01IS or YAM02IS Alibi memory	YAM11IS
Memory card for YAM01IS Alibi memory	YAM13IS
Cable for connecting Combics indicator to YAM01IS Alibi memory, 25-pin D-SUB to 9-pin D-SUB, 25 pol. D-SUB auf 9 pol. D-SUB	YCC01-10CIM3
Cable (D-SUB 9-pin, 2 m) for connecting YAM01IS Alibi memory to a PC	69EM0012
Flow rate controller for pumps with analog or digital pulse interface	YFC02Z-V2

Mechanical Accessories

Installation kit for pit frame installation (disconnectable plug-in cable for indicator)	YAS99I
Wall-mounting bracket, stainless steel	YDH01CIS
Wall-mounting bracket, stainless steel, tiltable	YDH02CIS
Floor-mounted column	YDH03CIP
Floor-mounted column, stainless steel	YDH03CIS
Base for installing floor-mounted column, stainless steel	YBP03CIS
Retainer for bar code scanner, for attachment to floor-mounted column, bench column or complete scale column	YBH01CWS
Plate for attaching printer to floor-mounted column or bench column	YPP01CWS

Software

Flexible printout configuration (e.g., bar codes, variable font sizes, embedding graphics, and similar) – Just ask your sales consultant	
Sartorius WinScale driver software for Windows® 95│98│2000│NT with current display of the weights and verifiable PC data memory, RS-232C, connecting cable 7357314 required	YSW03
SartoCollect software for the data communication between PC and any Sartorius instrument (incl. cable 26 Pin, 2 m)	YSC02

Power Supplies

24-V industrial power supply module	YAS02CI
External rechargeable battery pack, operates up to 40 hours, incl. battery charger	YRB10Z
External rechargeable battery pack, operates up to 40 hours, battery charger not included	YRB10Z-R
Connecting cable (25-pin, D-SUB) for YRB10Z rechargeable battery pack, 2 m	YCC02-RB01
Connecting cable with cable gland for YRB10Z rechargeable battery pack, 2 m*	YCC02-RB02
Connecting cable with cable gland, for car battery, 2 m*	YCC02-CB02

* only for CIS 1│2│3 indicator

Connecting Cables

with cable gland for YBR02FC bar code scanner*	YCC02-BR02
with cable gland for D09F6 printer, 9-pin D-SUB male connector, 6 m*	YCC02-D09M6
with cable gland for accessories, 9-contact D-SUB female connector, 6 m*	YCC02-D09F6
with cable gland for Sartorius scale, 25-contact D-SUB female connector, 1.5 m*	YCC02-D25F6
with cable gland for Sartorius scale, 25-pin D-SUB male connector, 6 m	YCC02-D25M6
with cable gland for accessories or IS platform, 12-pin round male connector, 6 m*	YCC02-R12M6
with cable gland, 12-contact round female connector, 1.5 m*	YCC02-R12F6
Cable for YDA01C-20MA power interface, with open cable ends e.g., 5 + = 5 m	6906926
Cable for connecting a PC, 25-pin, D-SUB, 1.5 m	7357312
Cable for connecting a PC, 9-pin, D-SUB, 1.5 m	7357314
Cable for connecting isi, QA│QC, FB│FC scales (25-pin D-SUB male connector to 12-pin round male connector), 3 m	YCC01-02ISM3
Connecting cable for scales, 25-contact D-SUB male connector (25-pin D-SUB female connector to 25-pin D-SUB male connector), 3 m	YCCDI-01M3
Connecting cable for scales to IS platform (25-pin D-SUB male connector to 12-contact round female connector), 3 m	YCC01-03CISLM3
Cable for connecting scale to platform, junction box or other weighing system equipment, approx. 8 mm outer diameter, shielded, with open ends; e.g., 5 + = 5 m	69YO1100

* only for CIS 1│2│3 indicator

Other Accessories

In-use covers (set of 2)	YDC01CI
IP65 upgrade kit for the IP44 protected Combics CISL indicators	YAS01CISL
Anti-theft locking device	YTP01CI
Cable gland for Combics model CIS, IP67 protected*	YAS04CIS
Installation kit for integration in a control panel	YAS03CI

* only for CIS 1│2│3 indicator

2. Superconducting Drive Unit

2.1 Drive Units for Flexel® 3D for LevMixer® System 50 L – 400 L

Part Number	Description
LT-DBTL002	Superconducting drive machine for US and Canada on cart with two latches for 8" and 15" ports. Control panel (110 V) and US lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL003	Superconducting drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) Europe and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL004	Superconducting drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) Europe and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL005	Superconducting drive machine with European certification on cart with UK-Plug and two latches for 8" and 15" ports. UK Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL010	Superconducting drive machine with European certification on cart with Australian plug and two latches for 8" and 15" ports. Australia Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.

2.2 Drive Units for Flexel® 3D for LevMixer® System 50 L – 1,000 L

| Part Number	Description
LT–DBTL006	Superconducting drive machine for US and Canada on cart with three latches for 8", 15" and 20" ports. Control panel (110 V) US and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL007	Superconducting drive machine with European certification on cart with three latches for 8", 15" and 20" ports. Europe Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL008	Superconducting drive machine with European certification on cart with three latches for 8", 15" and 20" ports. Japan Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories. Includes Japanese transformer.
LT–DBTL009	Superconducting drive machine with European certification on cart with UK–Plug and three latches for 8", 15" and 20" ports. UK Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL011	Superconducting drive machine with European certification on cart with Australian plug and three latches for 8", 15" and 20" Australia ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.

2.3 Spare Parts

Part Number	Description
FXA112559	Clamp Holder for Palletank® 50 L for Impeller Mixing
FXA112560	Clamp Holder for Palletank® 100 L for Impeller Mixing
FXA112083	Clamp Holder for Palletank® 200 L for Impeller Mixing
FXA112086	Clamp Holder for Palletank® 400 L for Impeller Mixing
FXA112085	Clamp Holder for Palletank® 650 L for Impeller Mixing
FXA113527	Clamp Holder for Palletank® 1,000 L for Impeller Mixing

3. FlexAct® Central Operating Module

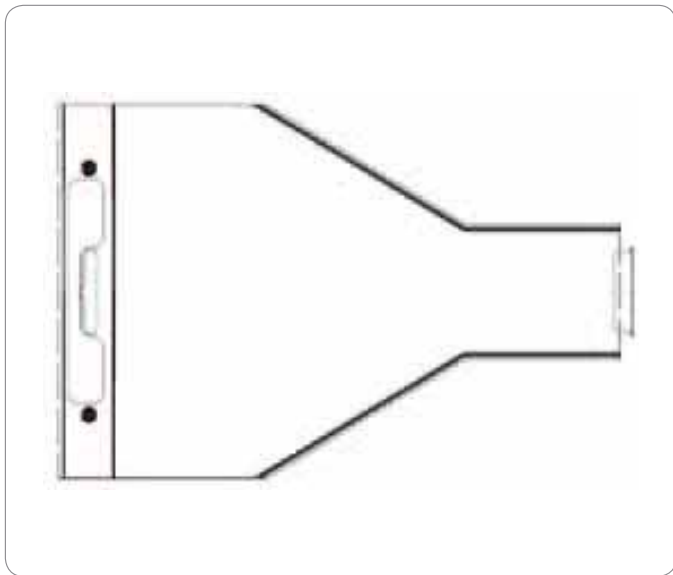| Part Number	Description
4SZZNL201	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10.4" touch panel EU 230 V, st. steel version
4SZZNL501	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10.4" touch panel US 110 V, st. steel version
4SZZNL202	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10.4" touch panel EU 230 V, powder coated version
4SZZNL502	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN/R – Control unit with 10.4" touch panel US 110 V, powder coated version

4. Disposable Bag Assemblies

Legend:

Subassembly 1

Subassembly 2

Thermowell
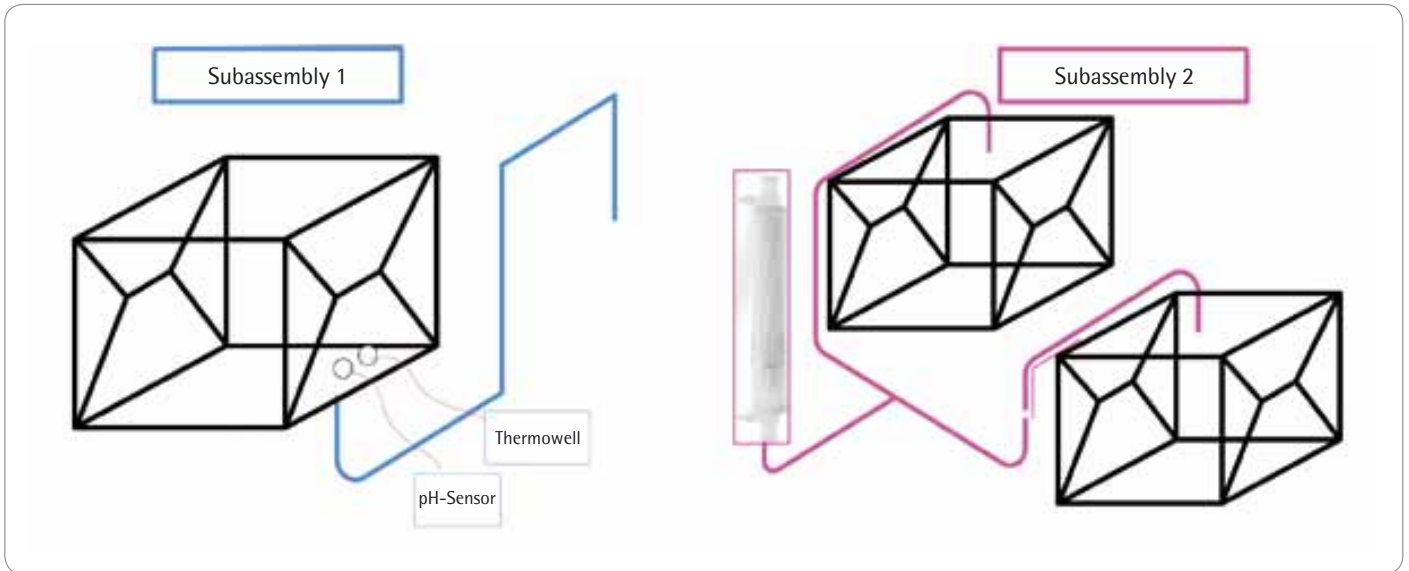
pH-Sensor

Part Number	Subassembly 1	Subassembly 2
4BP105B01AA10502	50 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	50 L Flexel® 3-D bag with Sartopore 2 Gamma height 7
4BP105B01AA3AA02	50 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	3 × 20 L manifold with Sartopore 2 Gamma height 7 on inlet
4BP110B01AB11003	100 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	100 L Flexel® 3-D bag with Sartopore 2 Gamma height 8
4BP110B01AB2AB03	100 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 2 × 50 L (TPE | Sartopore® | QC) – MidiCaps® size 8
4BP110B01AB5AC03	100 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	5 × 20 L manifold with Sartopore 2 Gamma height 8 on inlet
4BP120B01AC12004	200 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	200 L Flexel® 3-D bag with Sartopore 2 Gamma height 9
4BP120B01AC2AD04	200 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 2 × 100 L (TPE | Sartopore® | QC) – MidiCaps® size 9
4BP120B01AC3AE04	200 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 1 × 100L + 2 × 50L (TPE | Sartopore® | QC) – MidiCaps® size 9

Part Number	Subassembly 1	Subassembly 2
4BP120B01AC4AF04	200 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 4 × 50 L (TPE | Sartopore® | QC) – MidiCaps® size 9
4BP150B01AD15005	400 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	500 L Flexel® 3-D bag with Sartopore 2 Gamma MaxiCaps® 10"
4BP150B01AD-2AG05	400 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 2 × 200 L (TPE | Sartopore® | QC) – MaxiCaps® 10"
4BP150B01AD-3AH05	400 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 1 × 200 L + 2 × 100 L (TPE | Sartopore® | QC) – MaxiCaps® 10"
4BP150B01AD4AI05	400 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 4 × 100 L (TPE | Sartopore® | QC) – MaxiCaps® 10"
4BP150B01AD5AK05	400 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 3 × 100 L + 2 × 50 L (TPE | Sartopore® | QC) – MaxiCaps® 10"
4BP165B01AD11T05	650 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	1000L Flexel® 3-D bag with Sartopore 2 Gamma MaxiCaps® 10"
4BP165B01AD3AL05	650 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 1 × 500 L + 1 × 100 L + 1 × 50 L (TPE | Sartopore® | QC) – MaxiCaps® 10"
4BP165B01AD-4AM05	650 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 3 × 200 L + 1 × 50 L (TPE | Sartopore® | QC) – MaxiCaps® 10"
4BP165B01AD-5AN05	650 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 2 × 200 L + 2 × 100 L + 1 × 50 L (TPE | Sartopore® | QC) – MaxiCaps® 10"
4BP11TB01AE11T06	1,000 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	1,000 L Flexel® 3-D bag with Sartopore 2 Gamma MaxiCaps® 20"
4BP11TB01AE2AO06	1,000 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 2 × 500 L (TPE | Sartopore® | QC) – MaxiCaps 20"
4BP11TB01AE5AP06	1,000 L LevMixer® bag with pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® Manifold 5 × 200 L (TPE | Sartopore® | QC) – MaxiCaps 20"

4.1 Powder Bags

Standard Powder Transfer Bags

Part Number	Description	Bag Port 1	Oty/Box
FMA114008	STD Powder bag 15 L (PWD Port) with pinch clamp	4-inch triclamp	5
FMA114009	STD Powder bag 30 L (PWD Port) with pinch clamp	4-inch triclamp	5

Components

Part Number	Description	Oty/Box
FMA114007	Component (TC8"-4")	1
FMA114179	Component for TC4" (CAP | Gasket | Union) with pinch clamp	5

Powder Bag Holders

Part Number	Description	Oty/Box
FXA114343	STD Palletank® Cubical Accessory Powder Holder 50–100 L	1
FXA114344	STD Palletank® Cubical Accessory Powder Holder 200–400–650 L	1
FXA114419	STD Palletank® Cubical Accessory Powder Holder 1000 L	1

5. Accessories

5.1 Sartocheck® 4

Order Number	Order Code Description
16288	Sartocheck® 4 (following items included)
18104	Tubing for compressed gas inlet (included)
18103	Tubing for compressed gas outlet (included)
6982141	Ribbon cassette (included)
6982142	Rolls of printer paper (included) Sartocontrol CD (included) Test certificate (included) Calibration certificate (included) Installation and operating instructions (included)
16288---VP	Validation package Mains lead (country specific)

Order Number	Accessories Sartocheck® 4
1ZE---0018	External pressure transducer
1ZE---0025	Valve set for external venting
1ZE---0026	Valve set for external filling (WIT) Serial Port Interface cable TU | TU:
1ZE---0008	0.5 m
1ZE---0009	2 m
1ZE---0010	5 m
16288---VP	Validation Package
16288---TU	Multiunit
16288---CK	Cleaning Kit

5.2 BioWelder®

Order Number	Order Code Description
16370	BioWelder®, Fully automated tube fusing unit
16372	Citizen Printer, Print cable, AC adapter, paper roll and ribbon cassette
16373	Disposable Cutting Blades, With laser point 0.4 mm, 50 pcs. | package
16374	Calibration Kit With specifically designed holder, integrated temperature sensor type K and coding for calibration program recognition, calibration document for sensor included
16384	4-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16385	4-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16386	4-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16375	2-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)

Order Number	Order Code Description
16376	2-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16377	2-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16378	2-fould Tube Holder OD 7/16" (11.1 mm), ID 5/16" (8.0 mm), Wall 1/16" (1.6 mm)
16379	2-fould Tube Holder OD 1/2" (12.7 mm), ID 3/8" (9.5 mm), Wall 1/16" (1.6 mm)
16380	2-fould Tube Holder OD 5/8" (15.9 mm), ID 3/8" (9.5 mm), Wall 1/8" (3.2 mm)
16381	2-fould Tube Holder OD 3/4" (19 mm), ID 1/2" (12.7 mm), Wall 1/8" (3.2 mm)

5.3 BioSealer®

Order Number	Order Code Description
16360-P1 16360-P2 16360-P3 16360-P4 16360-P5 16360-P6	BioSealer® Fully automated Tube Sealing Device Seals tubes with OD 4"–1" and wall thickness 1/16" – 3/32" Optional Parametersets: 1–6**
16361-P1 16361-P2 16361-P3 16361-P4 16361-P5 16361-P6	BioSealer® Fully automated Tube Sealing Device Seals tubes with OD 4"–1" and wall thickness 1/16" – 3/32" Equipped with a removable Sealing Head Optional Parametersets: 1–6**
16362-P7 16362-P8 16362-P9 16362-P10 16362-P11 16362-P12	BioSealer® Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8" Optional Parametersets: 7–12**
16363-P7 16363-P8 16363-P9 16363-P10 16363-P11 16363-P12	BioSealer® Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8" Equipped with a removable Sealing Head Optional Parametersets: 7–12**
16365	IR Interface incl. Software CD
16366	Ceramic Heating Element Type 1 specified for BioSealer® 16360–16363

** The definition of each parameterset can be obtained in the parametersheet

6. Validation

6.1 CONFIDENCE®: Product and Process Specific Validation Services
Sartorius Stedim Biotech Validation Services conducts testing according to current regulatory requirements and guidance documents used in the industry such as PDA Technical Report No. 26 "Sterilizing Filtration of Liquids".

Testing is offered for filter elements, bags and other polymer-based components such as tubing, gaskets, stoppers, vials etc. Considering the process conditions, product formulation and process steps, the test scope (type of test, number of test filter elements or other test components) and complexity of the studies can vary.

Article No.	Description
861096	Validation protocol including one revision.

Microbiological Studies

Article No.	Description
861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria Brevundimonas diminuta
861015	Viability Test for determination of the bactericidal nature of the product (non-standard)
861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria Brevundimonas diminuta Bacteria Challenge Test performed with 3 filter elements from different lots
861012	Bacteria Challenge Test using the standard test bacteria Brevundimonas diminuta
861016	Bacteria Challenge Test (non-standard) Determination of Product Specific Integrity Test Limits Product Integrity Test performed with minimum 3 filter elements from different lots
861020	Determination of product specific integrity test limits
862021	Determination of product specific integrity test limits (non-standard) Chemical Compatibility Studies Chemical Compatibility Test performed with 3 filter sets from different lots
861022	Chemical Compatibility Test
861024	Chemical Compatibility Test (non-standard) Adsorption Studies (upon request)

Particle Release Studies
Particle Release Test typically includes 3 filter elements from different lots

Article No.	Description
861031	Particle Release Test

Leachables│Extractables Studies
(analysis of drug product formulation usually requires sample preparation)
Extraction procedure always includes a blank, customer to decide on 1 or 3 filters│bags│components for extraction

861040	Static Extraction (out of box, without prior treatment)
861041	Extraction (including sterilization and │ or flushing)
861044	Extraction (non-standard)

Two pretests may be required for complex products, e.g. formulation buffer and complete solution

861070	Analytical pre-test to identify product interference
861071	Analytical pre-test with sample preparation

Number of analyses normally reflects number of extract samples, including blank

861047	GC-MS Analysis without sample preparation
861048	GC-MS analysis with sample preparation
861051	HPLC analysis without sample preparation
861052	HPLC analysis with sample preparation

Following a standard approach HPLC and GC-MS are typical methods for the initial leachables analysis. If no peaks are detected no further study is performed. Additional analysis and type of analytical methods depend on the amount of peaks detected and their signal intensity. A suitable analytical scheme is then developed in a second step case by case.

Flexel® for LevMixer® bag, using ATMI patented mixing technology

LevMixer® is a trademark or registered trademark of ATMI, Inc.
in the United States, other countries or both

▶ FlexAct® MP

Disposable Solution for Media Preparation

Description

The FlexAct® MP is a standardized configurable disposable solution (CDS) dedicated to media preparation in biopharmaceutical processes. The FlexAct® MP addresses the entire development cycle and production capacity needs from 50 to 1,000 L for media preparation. The integration of monitoring & control features for pH, temperature, pressure, pump speed and fluid level control is a further milestone for the implementation of process relevant single-use equipment. The integrated control allows end-users to perform other tasks during the media preparation operation. Combined with a Flexel® for Magnetic Mixer[1] and Palletank® the multifunctional Central Operating Module enables the user to install, operate and monitor a fully single-use unit operation.

Features

– Multifunctional Central Operating Module

– Tailored bag configurations

– 50 – 1,000 L working volumes

– Quick system set-up

– Integrated disposable sensors (p, pH, T)

– Bidirectional operation

Benefits

– Operator friendly

– Flexible media supply

– Fully scalable

– Efficient equipment utilization

– Enables monitoring

– Highly flexible

Components

The FlexAct® MP configurable media preparation solution consists of:

– Flexel® for Magnetic Mixer

– Weighing platforms or Palletank® for Magnetic Mixer with load cells

– FlexAct® COM Central Operating Module with accessories

– Multiple bag assembly configurations with Palletank®

1. Overview: Flexel® for Magnetic Mixer

Flexel® for Magnetic Mixer is a single-use, high performance mixing solution using Sartorius Stedim Biotech Flexel® 3D Bags, the proven Palletank® technology and ATMI patented Mixing Technology. The system consists of three separate components designed to fit together to offer a maximum process flexibility.

1.1 Palletank® for Magnetic Mixing – These stainless steel containers are designed to perfectly fit with the Flexel® 3D bags for Magnetic Mixer integrated with the bottom centered impeller and include a railed port interface for the coupling of the mobile Drive Unit.

1.2 Magnetic Drive Unit – Magnetic Mixer Drive Unit generates the rotation of the single-use magnetic impeller coupled to a non-shedding ceramic bearing, enabling Flexel® for Magnetic Mixer to efficiently dissolve and disperse powders, suspensions, solutions or mix emulsions. The Magnetic Mixer Drive Unit is mobile, cart-mounted and designed to interface with Palletank® for Magnetic Mixer of different volumes.

1.3 Flexel® 3D Bag for Magnetic Mixer for FlexAct® MP operations are available from stock in configuration of 50 L to 1,000 L volumes.

2. Weighing Platforms

The IFS4 flat-bed scales are entirely constructed of stainless steel and have an extremely low height, making it ideally suited for floor installation without a pit or anchoring. The ramp is securely attached to the scale using special retainers for prevention of force shunt. This high-quality platform can be connected to any of a wide range of indicators, for use as a Class III legal measuring instrument or without legal verification. The CIS1 Combics 1 indicator allows strain gauge weighing with flat bed scales as well as with load cells to be connected.

3. FlexAct® COM Central Operating Module with Accessories

The FlexAct® COM Central Operating Module is designed for operational excellence in media preparation processes. It features multiple work platforms that incorporate process equipment and user friendly monitoring & control capabilities. The integrated control instrumentation together with an ergonomically positioned 10" LCD touch screen enables the operator to have an overview about the main process parameters values such as pressure, pH and temperature. For secure fluid level management a weight signal is provided by either load cells that are integrated into the Palletanks® or floor scales provided individually. The three level Central Operating Unit is able to accommodate multiple process devices required in a single-use process environment. Depending on the process needs, thermal welding and sealing provided by the BioWelder® and BioSealer® as well as filter integrity testing, using a Sartocheck® 4 plus integrity tester, will help to quick connect disconnect and test assemblies.

3.1 Sartocheck® 4 plus

Filter Integrity Testing is an essential procedure to detect defective filter cartridges before or after use. Thus automatic integrity testers have to fulfill highest standards with respect to accuracy and reliability. The Sartocheck® 4 plus is the result of Sartorius' 30 years experience in developing automatic filter integrity testers. Valuable productivity enhancing features and robust build quality have been combined with incredible ease of use to make the Sartocheck® 4 plus the only logical choice for integrity testing.

3.2 BioWelder® and BioSealer®

Sterile Fusing and Sealing of thermoplastic tubing are key technologies that offer most flexibility to the end users that are interested in getting a solution for multiple connection and disconnection cycles. Sartorius' BioWelder® and BioSealer® are devices that meet these requirements set by the industry. The ability of assuring quick and reliable connections and disconnections combined with the expertise of Sartorius Stedim Biotech made BioWelder® and BioSealer® to the product of choice in the biopharmaceutical industry.

4. FlexAct® MP Bag Assemblies with Palletank® for Media Storage

FlexAct® MP bag assemblies are supplied to serve the need of a fully preconfigured, ready to install, single-use unit operation. Uniquely, the Flexel® Bag for Magnetic Mixer and Flexel® 3D Bioprocessing Bags are supplied in one package.

The Flexel® Bag assemblies for Magnetic Mixer contains a centred magnetic impeller. Its unique sided K-weld design simplifies installation and facilitates the unfolding and folding of the bag during filling and draining operations. The patented protection cap provides robustness avoiding frictions of the impeller with the film during transport and before bag use. It also offers a large 8" diameter port for powder transfer and allows for continuous mixing during fluid transfer operations and minimizes hold up volume for 100% fluid recovery. The storage bag assemblies of the FlexAct® MP Configurable Disposable Solution are tailored to suit the dedicated need for individual media solution volumes at the point of use. The Palletank® for Storage or for In-Process Handling are stainless steel container designed to perfectly fit with the Flexel® 3D Bioprocessing Bag assemblies.

4.1 Powder Bags

Powder Bags provide a cost-effective and efficient system for handling pharmaceutical powders in a safe and contained manner. They incorporate antistatic film, ergonomic handles and industry-standard triclamp connectors.

FlexAct® Configurator

A configurator based selection system enables the user to flexibly create the FlexAct® solution that meets its process requirements in buffer preparation. All components included in the configurator are standardized components that ensure highest performance, shortest lead times and highest quality. The following Configurable Disposable Solutions will gradually complete the FlexAct® family:

Unit Operation	FlexAct® Configurable Disposable Solutions
Buffer Preparation	FlexAct® BP
Virus Inactivation	FlexAct® VI
Cell Harvest	FlexAct® CH
Media Preparation	FlexAct® MP
Virus Filtration	FlexAct® VR
Ultrafiltration	Diafiltration	FlexAct® UD
Polishing	FlexAct® PO
Form & Fill	FlexAct® FF
Form & Transfer	FlexAct® FT

Ease of Use

The primary driver behind the FlexAct® initiative is the development of disposable equipment which meets all process operations improving efficiency and speed. Sartorius Stedim Biotech specialists have analyzed the process environment and the operating procedure for media preparation thoroughly and developed an operator friendly multifunctional Central Operating Unit. Tailored bag configurations with 50 L up to 1,000 L working volumes offer flexible solutions at full scalability. The system set-up is performed within minutes and needs less preparation time compared with existing solutions. Once the operation is performed, the system can be as fast rigged-off without the needs of tedious cleaning requirements. Set-up and rig-off ease allow for more efficient and faster equipment utilization adding to the overall process capacities. The monitoring on a 10" touch screen of all main process parameter is easily enabled by integrated disposable sensors.

Validation

Flexel® Bag for Magnetic Mixer and Flexel® 3D Bioprocessing Bags have been qualified applying the most stringent and current test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® Bag for Magnetic Mixer and Flexel® 3D Bioprocessing Bags with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Flexel® Bag for Magnetic Mixer and Flexel® 3D Bioprocessing Bags are tested for compliance to:
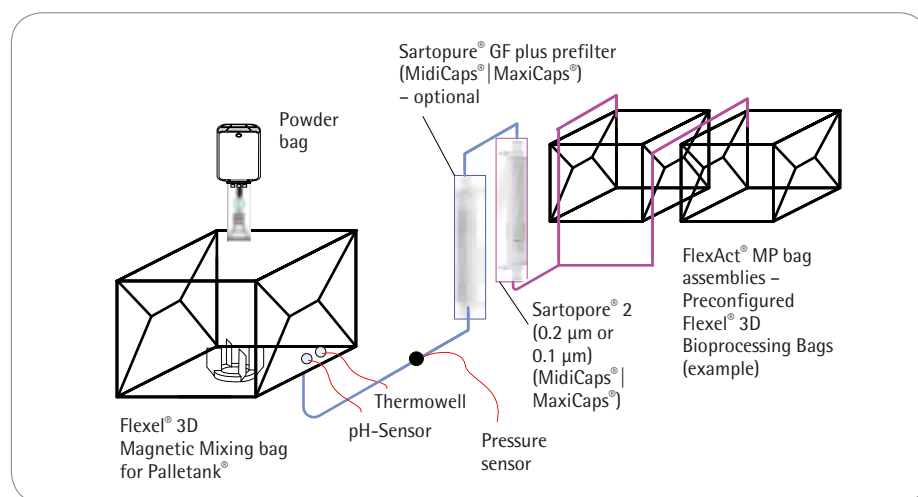
– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes and state-of-the-art utilities. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a flexible and robust supply chain that can cope with strong market growth.

The schematic below shows the bag assemblies connected. As an option a Sartopure® GF plus prefilter is connected with the Sartopore® 2 sterilizing grade filter (also configurable with Sartopore® 2 Mycoplasma retentive filter).

Due to the type of media and feed the filterability may be different. Therefore filterability and scaleup trials are recommended to define the appropriate prefilter in retention rate and size.

▷ Specifications
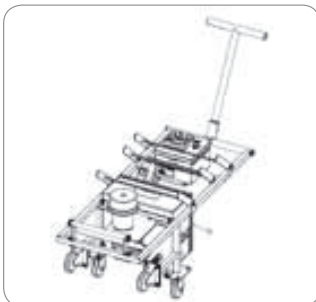
1. Magnetic Mixer Drive Unit
The Magnetic Mixer Drive Unit generates the rotation of the single-use magnetic impeller located inside the single-use bag assemblies. The Magnetic Mixer Drive Unit is mobile, cart-mounted and designed to interface with Palletank® for Magnetic Mixer of different volumes.

Power: EU Japan	Single Phase 230 V, 50	60 Hz Single Phase 230 V, Transformer (110 V Input), 50	60 Hz
Input Wattage	< 150 Watts
Footprint	84 × 41 cm (33 in × 16 in)
Drive Unit Height	104 cm (41 in), to top of handle
Weight	25 kg (55 lb)
Ambient Temperature	4° to 30℃
Max. Humidity	85% (non-condensing), avoid condensation, for indoor use
Mobility	Mounted on stainless cart with four clean room wheels and push handle
IP Rating	NEMA 4X, IP 65
Impeller Speed	0–300 RPM
Initial Set-up Time	Not applicable
Vessel Changeover	< 7 Minutes
CE Mark	Compliant
Material for External Surfaces	Stainless Steel #316L

2. FlexAct® MP Bag Assemblies

2.1. Flexel® Bags for Magnetic Mixer

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, PE Contact Layer
Impeller position	Centered
Impeller size	50 – 1,000 L: 6.35" (161 mm)
Tubing material	Silicone
Number of Ports	4 front bottom ports, 1 powder port
pH probe	Single-use glass pH electrode
Thermowell	Silicone thermowell for T probe element (reusable)
Fittings	Tri-clamp, Quick Connector, Luer Lock female with needle free sampling port
Volumes	50 L, 100 L, 200 L, 400 L, 650 L and 1,000 L
Sterilization	by Gamma Irradiation

2.2. Flexel® 3D Bioprocessing Bag for Storage

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, PE Contact Layer
Tubing material	C-Flex®, Silicone
Number of Ports	2 top ports, 1 bottom port
Filter	Sartopore® 2 gamma MidiCaps®	MaxiCaps®
Fittings	Tri-clamp, Luer Lock female female with needle free sampling port
Volumes	50 L, 100 L, 200 L, 500 L and 1,000 L
Sterilization	by Gamma Irradiation

2.3 Powder bags

Bag Chamber	Multiple layer film construction, including Permanently Static Dissipative (PSD) LDPE contact layer
Fittings	4-inch triclamp
Accessory	Pinch clamp
Volumes	15 L and 30 L
Number of Port	1 port
Irradiation	25–45 kGy

Powder Transfer Bag and Accessories

Standard Powder Transfer Bag System is designed for powder delivery applications where high containment, high product recovery and ease of use are important. Standard Powder Transfer Bags provide a single-use alternative to traditional rigid reusable containers and plastic pouches in a large variety of powder containment and delivery applications. With a volume range of 15 L and 30 L, the Standard Powder Transfer Bags are routinely used at all process scales from process development to commercial bio-manufacturing.

These bags are manufactured with very high quality standards for applications requiring remarkable levels of robustness, reliability and security.

With an extensive range of accessories, Standard Powder Bag Transfer System facilitates the delivery and discharge of powders into Sartorius Stedim Biotech single-use mixing systems (Flexel® for LevMixer® and for Magnetic Mixer). The Standard Powder Bag Transfer System is based on the market leading Sartorius Stedim Biotech Flexel® 3D Bag, the proven Palletank® technology and the patent-pending PSD film technology from ATMI.

All powder bags are equipped with Tri-Clamp connectors for powder charging. For media preparation, the contained powder transfer bags can be connected to the mixing bag. After discharge, bags remain connected to the mixing bags in order to minimize the operator exposure.

Standard Powder Transfer Bags provide:

– High product recovery with an ultra clean, antistatic, <USP> Class VI, LDPE film

– High containment to protect the operator, eliminate potential safety risk and avoid the contamination of the work environment during handling, transfer or transport of the fine powder

– Good ergonomics with an extensive range of accessories (complete solution)

– Comprehensive validation package

Powder Bag Holders

Description	Powder holder accessory for 50–100 L Palletank® for Magnetic Mixer	Powder holder accessory for 200–400–650 L Palletank® for Magnetic Mixer	Powder holder accessory for 1,000 L Palletank® for Magnetic Mixer
Construction Material	304 L Stainless Steel and Nylon		
Surface Finishing	Glass Bead Blasted		
Weight (Approx.)	8 kg	9 kg	9 kg
Overall dimensions (Approx.) w × d × h	442 × 400 × 1,080 mm 17.4 × 15.7 × 42.5 in.	743 × 400 × 1,080 mm 29.2 × 15.7 × 42.5 in.	857 × 400 × 1,080 mm 33.7 × 15.7 × 42.5 in.
Height above Palletank® with 15 L Powder Bag: with 30 L Powder Bag:	726 mm │ 28.6 in. 986 mm │ 38.8 in.	986 mm │ 38.8 in. 726 mm │ 28.6 in.	726 mm │ 28.6 in. 986 mm │ 38.8 in.
Additional features	Two vertical positions for 15 L and 30 L Powder bags. Rotary powder holder for easy access to the hook		

Filterability of Media and Feed
Media and feed have different filterabilities due to various components and concentrations. Therefore filterability and scale-up trials can optimize the economics of the filtration train by selecting appropriate prefilter retention rates and sizes.

Sartorius Stedim Biotech has a large filterability database due to the partnership with SAFC. It is always recommended to perform indication and verification filterability trials to find the optimal filter combination for the media type and volume.

Filterability and scale-up trials with SartoScale filtration units performed by SSB's application specialists simplify the optimization process.

2.4 Sartopure® GF plus prefilters
Sartopure® GF Plus absorptive depth filter are designed for removal of contaminates like colloids, lipids, protein aggregates (Host Cell Protein) and particles from biopharmaceutical fluids. They are used for protection of membrane filters, chromatography columns, ultra-filtration systems in pharmaceutical and biotechnological production processes.

Cost Saving
The efficient protection of downstream membrane filters and purification equipment saves filter costs and helps to increase the yield of biotech production processes. Moreover, the use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Flexibility
Sartopure® GF Plus MaxiCaps® are available with various filtration areas from 0.4 m² | 4 ft² up to 1.6 m² | 18 ft² for easy adoption to any filtration process independent from the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed as all Sartopure® GF Plus filter elements are produced with the same type of membrane and identical materials of construction.

Documentation
Sartopure® GF Plus MaxiCaps® are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

2.5 Sartopore® 2 Gamma – MidiCaps® and MaxiCaps®
Sartopore® 2 Gamma Midicaps® and MaxiCaps® are designed for connection to flexible-bagcontainer-systems prior to sterilization by gamma-irradiation.

They are available with 0.2 µm & 0.1 µm final membranes for sterilizing grade filtration and Mycoplasma removal.

– Applications: Typical applications include sterilizing grade filtration and Mycoplasma removal of:
 – Biologicals
 – Pharmaceuticals
 – Cell Culture Media (serum free or serum containing)
 – Culture Media Components
 – Serum
 – Buffers

– Compatibility: Sartopore® 2 Gamma MidiCaps® and MaxiCaps® are designed for sterilization by gamma irradiation < 50 kGy irradiation dosage. The Polyethersulfone membrane of the Sartopore® 2 Gamma MaxiCaps® offers a broad chemical compatibility from pH 1 to pH 14 making them ideally suited forfiltration of high and low pH-buffers in the Pharma | Biotech field.

– Performance: Due to the superior construction including a "built-in" prefiltration by a heterogeneous double layer membrane Sartopore® 2 Gamma MidiCaps® and MaxiCaps® achieve outstanding total throughputs and excellent flow rates.

– Flexibility: Sartopore® 2 Gamma MaxiCaps® are ideally suited to be used in small and large scale filtration applications in combination with flexible bag containers due to their superior effective filtration area of up to 1.8 m² | 18 ft² per 30" element.

– Microbiological Retention: Sartopore® 2 Gamma MidiCaps® and MaxiCaps® 0.2 µm & 0.1 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines. In addition Sartopore® 2 Gamma MidiCaps® and MaxiCaps® are validated for Mycoplasma removal with a LRV of 7 for Acholeplasma Laidlawii.

– Quality Control: Each individual element is tested for integrity by B.-P. (0.2 µm only) and Diffusion-Test prior to be released assuring absolute reliability.

– Documentation: Sartopore® 2 Gamma MidiCaps® and MaxiCaps® are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

3. Palletank®

3.1 For Magnetic Mixer with or without load cells

Material	304 L Stainless Steel
Surface Finish	Glass Bead Blasted
Door	Front Hinged Door
Windows	Plexiglass
Ports	Railed port for drive unit Front bottom port for bag line access

Volume (L)	Dimensions (W × D × H)	Weight (kg) Palletank®
50	825 × 570 × 1,051	43
100	825 × 570 × 1,126	49
200	775 × 699 × 1,250	63
400	921 × 824 × 1,345	88
650	1,040 × 930 × 1,500	103
1,000	1,090 × 1,120 × 1,650	156

3.2 Palletank® for Storage

Material	304 L Stainless Steel
Surface Finish	Glass Bead Blasted
Stackable	3 (50 – 200 L) 2 (500 L)
Option	Dolly

Volume (L)	Dimensions (W × D × H)	Weight (kg) Palletank®
50	490 × 490 × 750	24
100 | 200	789 × 592 × 891	35
500	1,192 × 792 × 1,010	92
1,000	1,260 × 1,060 × 1,443	145

4. FlexAct® MP Central Operating Module

Material	316 L Stainless Steel
Surface Finish	Optional: – Powder coated │ coloured – Glass Bead Blasted, electropolished
Dimensions (W × D × H)	795 × 1,410 × 1,500 mm (31.3 × 55.51 × 59.06 inch)
Weight (approx.)	160 kg (352.74 lbs) (incl. Watson Marlow pump)
Control Unit	– Control unit with 10.4" touch screen

Pump

Watson Marlow	720UN │ R
Specification	IP66 0.1 – 360 rpm
Pumphead	720R pumphead, 4 roller pumphead for maximum 2 bar. Accepts continuous tubing only (includes continuous tube clamp set)

BioWelder®

Power requirements	100 – 240 V │ 47 – 63 Hz
Dimensions	300 × 300 × 220 mm
Weight	0.5 kg
Housing	stainless steel
Interface	RS232 for printer
Blade	Cr-Ni-Alloy, single-use
Ambient temperature	20°C – 30°C (ideal: 22°C)
Relative Humidity	20% – 80% (ideal: 60%)
Temperature Sensor	Type K, calibration holder available
Max. Tube OD	¾"
Min. Tube OD	¼"
Welding Cycle	60 – 90 sec. depending on tube dimension
Standard settings for	C-Flex®, PHARMED® BPT, Sanipure® 60

BioSealer®

Power requirements	100 – 240 V │ 47 – 63 Hz
Dimensions	220 × 150 × 210 mm
Weight	3.0 kg
Housing	stainless steel
Compression head	Aluminum anodised
Ambient temperature	20°C – 30°C
Relative Humidity	35% – 65%
Max. Tube OD	¾"
Min. Tube OD	¼"
Sealing Cycle	1 – 4 minutes depending on tube size and quality
Tubing Types	Soft ThermoplasticTubing, (e.g. C-Flex®, SaniPure® 60 and Pharmed® BPT)

1: ext. reference tank
2: Venting 1
3: Out
4: Venting 2
5: Compressed Air In
A: external sensor
B: external valves

1: main switch
2: SD card reader
3: Serial Port TU
4: PLC Port
5: RJ45 Network
6: connection for optional
   barcode scanner

Sartocheck® 4 plus

Power requirements	100 – 240 V AC, 50	60 Hz
Maximum power input	74 watts
Maximum operating pressure	9999 mbar	145 psi
Minimum inlet pressure	4000 mbar	58 psi
Dimensions (W × D × H1 × H2)	460 × 390 × 140 × 245

Measuring ranges:

Test pressure	100 – 8000 mbar	1.5 – 116 psi
Pressure drop	1 – 2000 mbar	0.01 – 29 psi
System inlet volume – with internal ref. Vessel – with external ref. Vessel max.	14 L 150 L

Measuring accuracy:

Pressure	± 0.1% full scale
Pressure drop	± 1 mbar	0.015 psi
Volume determination	± 4%
Diffusion	± 5%
Water-Intrusion	± 5%
Bubble Point	± 50 mbar	± 0.7 psi

Operating conditions:

Ambient temperature	+15℃ to +35℃
Rel. humidity	10 – 80%

Touch Screen:

Size	10.4" TFT
Features	256 colors

Comunication Ports:

Serial Port	TU RS232
Serial Port	MU RS485
PLC Port	binary signals 12 pins
Network	RJ45

Language option:

	English German French Spanish Italian

5. IFS Flat-Bed Scales

5.1 IFS4-300LI-I

Weighing capacity	300 kg
Platform size	1000 × 800
Height	standard
Load plate	AISI304 │ 1.4301V2A bead-blasted
Resolution	30.000 d
Readability	10 g

5.2 IFS4-1500NN-I

Weighing capacity	1,500 kg
Platform size	1250 × 1250
Height	standard
Load plate	AISI304 │ 1.4301V2A bead-blasted
Resolution	30.000 d
Readability	50 g

5.3 Combics CIS1 – Scale Indicator
Indicators for complex weighing tasks in 4 different versions.

Max. readability	31.250 digits
IP protection rate	IP67 (PG cable gland), IP44 (25-pol. D-SUB), (IP65 as option)

Ordering Information

1. Flexel® 3D Palletank®

1.1 Palletank® for Magnetic Mixer – without load cells

Order Number	Palletank® for Magnetic Mixer w/o Load Cells
FXC110820	Palletank® 50 L for Impeller Mixing
FXC112230	Palletank® 100 L for Impeller Mixing
FXC110821	Palletank® 200 L for Impeller Mixing
FXC111135	Palletank® 400 L for Impeller Mixing
FXC110822	Palletank® 650 L for Impeller Mixing
FXC113384	Palletank® 1,000 L for Impeller Mixing

1.2 Palletank® for Magnetic Mixer – with load cells

Order Number	Palletank® for Magnetic Mixer w/ Load Cells and Combics 1 Controller
FXC114153	Palletank® 50 L for Impeller Mixing with load cells and CIS1 Combics controller
FXC114154	Palletank® 100 L for Impeller Mixing with load cells and CIS1 Combics controller
FXC114155	Palletank® 200 L for Impeller Mixing with load cells and CIS1 Combics controller
FXC114156	Palletank® 400 L for Impeller Mixing with load cells and CIS1 Combics controller
FXC114157	Palletank® 650 L for Impeller Mixing with load cells and CIS1 Combics controller
FXC114158	Palletank® 1,000 L for Impeller Mixing with load cells and CIS1 Combics controller

1.3 Spare parts for Palletank® for Magnetic Mixer

Order Number	Spare Parts LevMixer® Palletank®
FXA112559	Clamp Holder for Palletank® 50 L for Impeller Mixing
FXA112560	Clamp Holder for Palletank® 100 L for Impeller Mixing
FXA112083	Clamp Holder for Palletank® 200 L for Impeller Mixing
FXA112086	Clamp Holder for Palletank® 400 L for Impeller Mixing
FXA112085	Clamp Holder for Palletank® 650 L for Impeller Mixing
FXA113527	Clamp Holder for Palletank® 1,000 L for Impeller Mixing
FXA112074	Adaptation Set for Palletank® for Impeller Mixing

1.4 Palletank® for storage (50-500 L) | in-process handling (1,000 L)

Order Number	Palletank®
FXC113946	Palletank® 50 L for storage stackable
FXA113988	Dolly for Palletank® 50 L (storage)
FXC110733	Palletank® 100 L for storage stackable
FXS102254	Dolly for Palletank® 100 L│200 L (storage & shipping)
FXC110733	Palletank® 200 L for storage stackable
FXS102254	Dolly for Palletank® 100 L│200 L (storage & shipping)
FXC110734	Palletank® 500 L for storage stackable
FXC100734	Dolly for Palletank® 500 L (storage & shipping)
FXC106223	Palletank® 1,000 L for in-process fluid handling
FXS102259	Dolly for Palletank® 1,000 L for in-Process fluid handling

1.5 Floor Scales (Flat bed scales)

Part Number	Platform Dimensions (mm)	Weighing Capacity	Readability	Load Plate	Dust│Water Protection
IFS4-300LI-I floor scale (flat bed scale)	1000 × 800	300 kg	10 g	AISI304│1.4301 V2A bead-blasted	IP67│IP68
IFS4-1500NN-I floor scale (flat bed scale)	1250 × 1250	1500 kg	50 g	AISI304│1.4301 V2A bead-blasted	IP67│IP68

1.6 Combics CIS1 – Scale indicator

Combics 1 scale indicator, stainless steel housing, IP44	CISL1
Combics 1 plus scale indicator, stainless steel housing, IP44	CISL1N
Combics 2 scale indicator, stainless steel housing, IP44	CISL2
Combics 3 scale indicator, stainless steel housing, IP44	CISL3
Combics 1 scale indicator, stainless steel housing, IP67	CIS1
Combics 1 plus scale indicator, stainless steel housing, IP67	CIS1N
Combics 2 scale indicator, stainless steel housing, IP67	CIS2
Combics 3 scale indicator, stainless steel housing, IP67	CIS3

Optional Interfaces (UniCOM)

Interface module (RS-232C)	YDO01C-232
Interface module (RS-485│422)	YDO01C-485
Analog current output, 0–20 mA, 4–20 mA, 0–5 V, 16-bit	YDA01C-20MA
Profibus module	VDO01C-DP
Bluetooth® module (only for CIS models)	YDO01C-BT

Replace A│D converter (WP1) with a Digital Interface

Interface (RS-232│485) for direct connection of a digital platform	YDI01C-WP

Printers and Printer Accessories

with functions for date, time and statistical evaluations	YDP03-0CE
Printer paper (5 rolls; length per roll: 50 m)	6906937
Replacement ink ribbon cartridge for printer	6906918
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 108 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator; only for use with flexible printout configuration (see "Software," next column)	YDP12IS-0CEUV
Printer paper (1 roll) for YDP12IS-0CE printer, 101 mm × 75 m, thermal sensitive paper	69Y03196
Labels for YDP12IS-0CE printer, extra large, 101 mm × 127 m, 305 labels	69Y03195
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 60 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator (see "Software," next column)	YDP04IS-0CEUV
Printer paper (3 rolls) for YDP12│04IS-0CE, 60 mm × 75 m, thermal sensitive paper	69Y03090
Labels for YDP12│04IS-0CE printer, small, 58 mm × 30 mm, 1000 labels	69Y03092
Labels for YDP12│04IS-0CE printer, medium, 58 mm × 76 mm, 500 labels	69Y03093
Labels for YDP12│04IS-0CE printer, large, 58 mm × 100 mm, 350 labels	69Y03094
Cable for direct connection of YDP12IS│YDP04IS-0CE printerto Combics CISL indicators	YCC01-01CISLM3

Electrical Accessories

External red│green│red display for Combics CISL indicators	YRD11Z
External red│green│red display for CIS indicators (12-pin round connector); connecting cable YCC02-R12F6 or Option M6 required	YRD14Z
Profibus connector for CISL... and CW...P... indicators (D-SUB 25-│9-pin)	IE10092
Second display for Combics CISL indicators	YRD02Z
Remote display, 7-segment, up to 45 mm characters	Information available on request
Bar code scanner, with cable for connection to Combics CISL scale indicator adapter cable, 120 mm scanning width	YBR02CISL
Bar code scanner for the Combics CIS model, with connecting cable, for connection with YCC02-R12F6	YBR02FC
Foot switch, incl. T-connector, D-SUB 25-pin	YFS01
Hand switch, incl. T-connector, D-SUB 25-pin	YHS02
External Alibi memory for electronic storage of weighing data	YAM01IS
Scanner for loading weighing data from YAM13IS Alibi memory cards to a PC	YAM02IS
Power supply for YAM01IS or YAM02IS Alibi memory	YAM11IS
Memory card for YAM01IS Alibi memory	YAM13IS
Cable for connecting Combics indicator to YAM01IS Alibi memory, 25-pin D-SUB to 9-pin D-SUB, 25 pol. D-SUB auf 9 pol. D-SUB	YCC01-10CIM3
Cable (D-SUB 9-pin, 2 m) for connecting YAM01IS Alibi memory to a PC	69EM0012
Flow rate controller for pumps with analog or digital pulse interface	YFC02Z-V2

Mechanical Accessories

Installation kit for pit frame installation (disconnectable plug-in cable for indicator)	YAS99I
Wall-mounting bracket, stainless steel	YDH01CIS
Wall-mounting bracket, stainless steel, tiltable	YDH02CIS
Floor-mounted column	YDH03CIP
Floor-mounted column, stainless steel	YDH03CIS
Base for installing floor-mounted column, stainless steel	YBP03CIS
Retainer for bar code scanner, for attachment to floor-mounted column, bench column or complete scale column	YBH01CWS
Plate for attaching printer to floor-mounted column or bench column	YPP01CWS

Software

Flexible printout configuration (e.g., bar codes, variable font sizes, embedding graphics, and similar) – Just ask your sales consultant	
Sartorius WinScale driver software for Windows® 95 │ 98 │ 2000 │ NT with current display of the weights and verifiable PC data memory, RS-232C, connecting cable 7357314 required	YSW03
SartoCollect software for the data communication between PC and any Sartorius instrument (incl. cable 26 Pin, 2 m)	YSC02

Power Supplies

24-V industrial power supply module	YAS02CI
External rechargeable battery pack, operates up to 40 hours, incl. battery charger	YRB10Z
External rechargeable battery pack, operates up to 40 hours, battery charger not included	YRB10Z-R
Connecting cable (25-pin, D-SUB) for YRB10Z rechargeable battery pack, 2 m	YCC02-RB01
Connecting cable with cable gland for YRB10Z rechargeable battery pack, 2 m*	YCC02-RB02
Connecting cable with cable gland, for car battery, 2 m*	YCC02-CB02

* only for CIS 1│ 2│3 indicator

Connecting Cables

with cable gland for YBR02FC bar code scanner*	YCC02-BR02
with cable gland for D09F6 printer, 9-pin D-SUB male connector, 6 m*	YCC02-D09M6
with cable gland for accessories, 9-contact D-SUB female connector, 6 m*	YCC02-D09F6
with cable gland for Sartorius scale, 25-contact D-SUB female connector, 1.5 m*	YCC02-D25F6
with cable gland for Sartorius scale, 25-pin D-SUB male connector, 6 m	YCC02-D25M6
with cable gland for accessories or IS platform, 12-pin round male connector, 6 m*	YCC02-R12M6
with cable gland, 12-contact round female connector, 1.5 m*	YCC02-R12F6
Cable for YDA01C-20MA power interface, with open cable ends e.g., 5 + = 5 m	6906926
Cable for connecting a PC, 25-pin, D-SUB, 1.5 m	7357312
Cable for connecting a PC, 9-pin, D-SUB, 1.5 m	7357314
Cable for connecting isi, QA | QC, FB | FC scales (25-pin D-SUB male connector to 12-pin round male connector), 3 m	YCC01-02ISM3
Connecting cable for scales, 25-contact D-SUB male connector (25-pin D-SUB female connector to 25-pin D-SUB male connector), 3 m	YCCDI-01M3
Connecting cable for scales to IS platform (25-pin D-SUB male connector to 12-contact round female connector), 3 m	YCC01-03CISLM3
Cable for connecting scale to platform, junction box or other weighing system equipment, approx. 8 mm outer diameter, shielded, with open ends; e.g., 5 + = 5 m	69YO1100

Other Accessories

In-use covers (set of 2)	YDC01CI
IP65 upgrade kit for the IP44 protected Combics CISL indicators	YAS01CISL
Anti-theft locking device	YTP01CI
Cable gland for Combics model CIS, IP67 protected*	YAS04CIS
Installation kit for integration in a control panel	YAS03CI

* only for CIS 1 \| 2 \| 3 indicator

2. Magnetic Mixer Drive Unit

Part Number	Description
LT-DU-005-US	Magnetic Mixer Drive Unit, 110 V, US Power Cord
LT-DU-006-EU	Magnetic Mixer Drive Unit, 230 V, EU Power Cord
LT-DU006-UK	Magnetic Mixer Drive Unit, 230 V, UK Power Cord
LT-DU006-SW	Magnetic Mixer Drive Unit, 230 V, Swiss Power Cord
LT-DU006-AU	Magnetic Mixer Drive Unit, 230 V, Australian Power Cord
LT-DU006-JA	Magnetic Mixer Drive Unit, 230 V, Japanese Power Cord and Transformer

3. FlexAct® Central Operating Module

Part Number	Description
4SZZNL201	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN│R – Control unit with 10.4" touch panel EU 230 V, st.steel version
4SZZNL501	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN│R – Control unit with 10.4" touch panel US 110 V, st.steel version
4SZZNL202	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN│R – Control unit with 10.4" touch panel EU 230 V, powder coated version
4SZZNL502	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN│R – Control unit with 10.4" touch panel US 110 V, powder coated version

4. FlexAct® MP Bag Assemblies

Legend:

Sartopure® GF plus prefilter (MidiCaps®│MaxiCaps®) – optional

Powder bag

FlexAct® MP bag assemblies – Preconfigured Flexel® 3D Bioprocessing Bags (example)

Sartopore® 2 (0.2 µm or 0.1 µm) (MidiCaps®│MaxiCaps®)

Thermowell

pH–Sensor

Pressure sensor

Flexel® 3D Magnetic Mixing bag for Palletank®
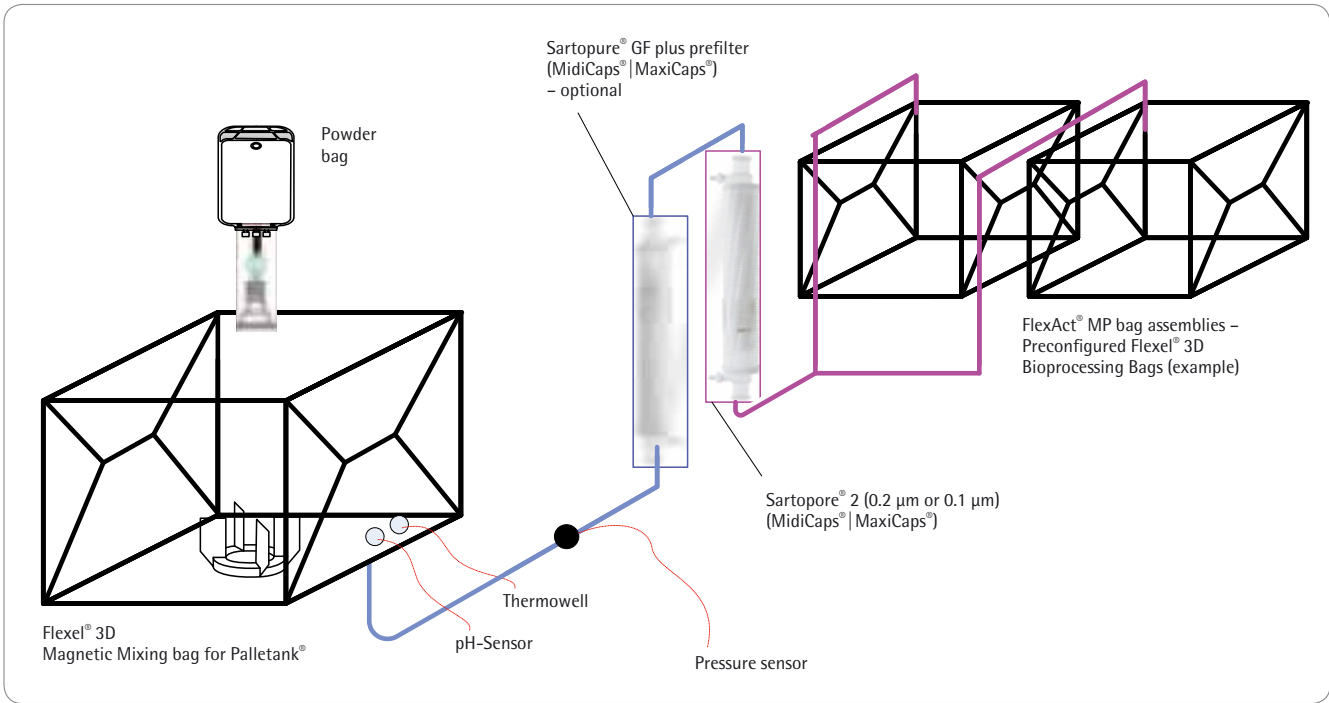
Bag Assemblies with Sartopure® 2 Gamma MidiCaps® and MaxiCaps® 0.45 µm | 0.2 µm

Part Number	Subassembly 1	Subassembly 2
4MP105E01AC10504	50 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 50 L (TPE|Sartopore®) Gamma size 9 (0.45 | 0.2 µm)
4MP105E01AC3AA04	50 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® (Palletank®) manifold 3 × 20 L (TPE|Sartopore®) Gamma size 9 (0.45 | 0.2 µm)
4MP110E01AG11010	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 100 L (TPE|Sartopore®) Gamma – MidiCaps® size 0 (0.45 | 0.2 µm)
4MP110E01AG2AB10	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 50 L (TPE|Sartopore®) – MidiCaps® size 0 (0.45 | 0.2 µm)
4MP110E01AG5AC10	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® (Palletank®) manifold 5 × 20 L (TPE|Sartopore®) – Gamma – MidiCaps® size 0 (0.45 | 0.2 µm)
4MP120E01AD12005	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 200 L (TPE|Sartopore®) Gamma – MaxiCaps® 10" (0.45 | 0.2 µm)
4MP120E01AD2AD05	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 100 L (TPE|Sartopore®) – MaxiCaps® 10" (0.45 | 0.2 µm)
4MP120E01AD3AE05	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 100 L + 2 × 50 L (TPE|Sartopore®) – MaxiCaps® 10" (0.45 | 0.2 µm)
4MP120E01AD4AF05	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 4 × 50 L (TPE|Sartopore®) – MaxiCaps® 10" (0.45 | 0.2 µm)
4MP140E01AE15006	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 500 L (TPE|Sartopore®) Gamma – MaxiCaps® 20" (0.45 | 0.2 µm)
4MP140E01AE2AG06	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 200 L (TPE|Sartopore®) – MaxiCaps® 20" (0.45 | 0.2 µm)
4MP140E01AE3AH06	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 200 L + 2 × 100 L (TPE|Sartopore®) – MaxiCaps® 20" (0.45 | 0.2 µm)
4MP140E01AE4AI06	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 4 × 100 L (TPE|Sartopore®) – MaxiCaps® 20" (0.45 | 0.2 µm)
4MP140E01AE5AK06	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 3 × 100 L + 2 × 50 L (TPE|Sartopore®) – MaxiCaps® 20" (0.45 | 0.2 µm)
4MP165E01AF11T16	650 L LevMixer® bag with pressure sensor, pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® 1,000 L (TPE|Sartopore®) Gamma – MaxiCaps® 30" (0.45 | 0.2 µm)
4MP165E01AF3AL16	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 500 L + 1 × 100 L + 1 × 50 L (TPE|Sartopore®) – MaxiCaps® 30" (0.45 | 0.2 µm)
4MP165E01AF4AM16	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 3 × 200 L + 1 × 50 L (TPE|Sartopore®) – MaxiCaps® 30" (0.45 | 0.2 µm)
4MP165E01AF5AN16	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 200 L + 2 × 100 L + 1 × 50 L (TPE|Sartopore®) – MaxiCaps® 30" (0.45 | 0.2 µm)
4MP11TE01AF11T16	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 1,000 L (TPE|Sartopore®) Gamma – MaxiCaps® 30" (0.45 | 0.2 µm)
4MP11TE01AF2AO16	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 500 L (TPE|Sartopore®) – MaxiCaps® 30" (0.45 | 0.2 µm)
4MP11TE01AF5AP16	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 5 × 200 L (TPE|Sartopore®) – MaxiCaps® 30" (0.45 | 0.2 µm)

Bag Assemblies with Sartopure® 2 Gamma MidiCaps® and MaxiCaps® 0.2 μm│0.1 μm

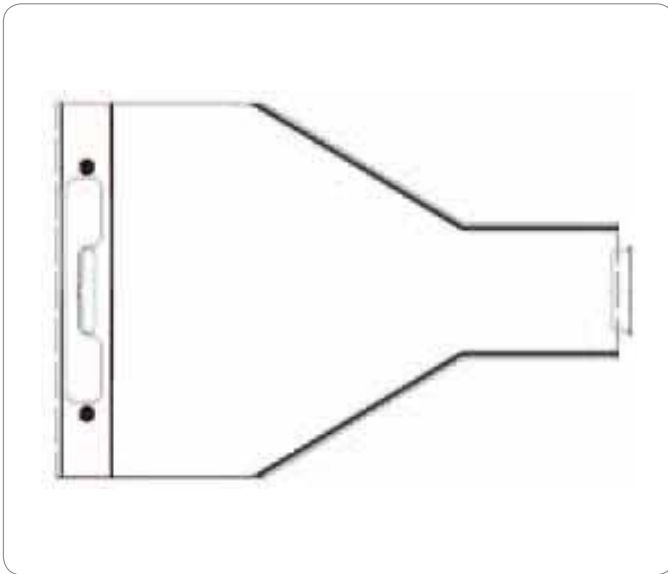| Part Number	Subassembly 1	Subassembly 2
4MP05E01AH10517	50 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 50 L (TPE│Sartopore®) Gamma size 9 (0.2│0.1 μm)
4MP105E01AH3AA17	50 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® (Palletank®) manifold 3 × 20 L (TPE│Sartopore®) Gamma size 9 (0.2│0.1 μm)
4MP110E01AI11018	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 100 L (TPE│Sartopore®) Gamma – MidiCaps® size 0 (0.2│0.1 μm)
4MP110E01AI2AB18	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 50 L (TPE│Sartopore®) – MidiCaps® size 0 (0.2│0.1 μm)
4MP110E01AI5AC18	100 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® (Palletank®) manifold 5 × 20 L (TPE│Sartopore®) – Gamma – MidiCaps® size 0 (0.2│0.1 μm)
4MP120E01AJ12019	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 200 L (TPE│Sartopore®) Gamma – MaxiCaps® 10" (0.2│0.1 μm)
4MP120E01AJ2AD19	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 100 L (TPE│Sartopore®) – MaxiCaps® 10" (0.2│0.1 μm)
4MP120E01AJ3AE19	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 100 L + 2 × 50 L (TPE│Sartopore®) – MaxiCaps® 10" (0.2│0.1 μm)
4MP120E01AJ4AF19	200 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 4 × 50 L (TPE│Sartopore®) – MaxiCaps® 10" (0.2│0.1 μm)
4MP140E01AK15020	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 500 L (TPE│Sartopore®) Gamma – MaxiCaps® 20" (0.2│0.1 μm)
4MP140E01AK2AG20	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 200 L (TPE│Sartopore®) – MaxiCaps® 20" (0.2│0.1 μm)
4MP140E01AK3AH20	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 200 L + 2 × 100 L (TPE│Sartopore®) – MaxiCaps® 20" (0.2│0.1 μm)
4MP140E01AK4AI20	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 4 × 100 L (TPE│Sartopore®) – MaxiCaps® 20" (0.2│0.1 μm)
4MP140E01AK5AK20	400 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 3 × 100 L + 2 × 50 L (TPE│Sartopore®) – MaxiCaps® 20" (0.2│0.1 μm)
4MP165E01AL11T21	650 L LevMixer® bag with pressure sensor, pH sensor, thermowell, 4" to 8" adaptor	Flexel® Palletank® 1,000 L (TPE│Sartopore®) Gamma – MaxiCaps® 30" (0.2│0.1 μm)
4MP165E01AL3AL21	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 1 × 500 L + 1 × 100 L + 1 × 50 L (TPE│Sartopore®) – MaxiCaps® 30" (0.2│0.1 μm)
4MP165E01AL4AM21	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 3 × 200 L + 1 × 50 L (TPE│Sartopore®) – MaxiCaps® 30" (0.2│0.1 μm)
4MP165E01AL5AN21	650 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 200 L + 2 × 100 L + 1 × 50 L (TPE│Sartopore®) – MaxiCaps® 30" (0.2│0.1 μm)
4MP11TE01AL11T21	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® 1,000 L (TPE│Sartopore®) Gamma – MaxiCaps® 30" (0.2│0.1 μm)
4MP11TE01AL2AO21	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 2 × 500 L (TPE│Sartopore®) – MaxiCaps® 30" (0.2│0.1 μm)
4MP11TE01AL5AP21	1,000 L Flexel® Bag for Magnetic Mixer with pressure sensor, pH sensor, thermowell	Flexel® Palletank® manifold 5 × 200 L (TPE│Sartopore®) – MaxiCaps® 30" (0.2│0.1 μm)

4.1 Powder Bags

Ordering Information

1. Standard Powder Transfer Bags

Part Number	Description	Bag Port 1	Oty/Box
FMA114008	STD Powder bag 15 L (PWD Port) with pinch clamp	4-inch triclamp	5
FMA114009	STD Powder bag 30 L (PWD Port) with pinch clamp	4-inch triclamp	5

2. Components

Part Number	Description	Oty/Box
FMA114007	Component (TC8"-4")	1
FMA114179	Component for TC4" (CAP | Gasket | Union) with pinch clamp	5

3. Powder Bag Holders

Part Number	Description	Oty/Box
FXA114343	STD Palletank® Cubical Accessory Powder Holder 50–100 L	1
FXA114344	STD Palletank® Cubical Accessory Powder Holder 200–400–650 L	1
FXA114419	STD Palletank® Cubical Accessory Powder Holder 1,000 L	1

5. Accessories

5.1 Sartocheck® 4 plus

Order Number	Order Code Description
26288	Sartocheck® 4 plus (following items included)
18104	Inlet tubing for compressed gas (included)
18103	Outlet tubing for compressed gas (included)
6982141	Ribbon cassette (included)
6982142	Rolls of printer paper (included) Test certificate (included) Calibration certificate (included) Installation and operating instructions (included)
16288---VP	Validation package Power cord (country specific)

Order Number	Accessories Sartocheck® 4 plus
26288---BS	Barcode Scanner
16288---TU	Multiunit
1ZE---0018	External pressure transducer
1ZE---0025	Set for external venting (1 valve)
1ZE---0026	Valve set for external filling (WIT) Serial Port Interface cable TU│TU
1ZE---0008	0.5 m
1ZE---0009	2 m
1ZE---0010	5 m Network Cable
1ZE---0029	2 m
1ZE---0030	5 m
1ZE---0031	10 m
1ZE---0032	20 m
26288---CK	Cleaning Kit
26288---PV	Pressure Tank for Cleaning
16288---RV	External reference vessel (10 L)
16288---PI	Profibus Interface
26288---VP	Validation Package
1ZE---0021	Clean Room Venting Adapter
1Z-LB-0002	Midisart® Test Manifold 10

5.2 BioWelder®

Order Number	Order Code Description
16370	BioWelder®, Fully automated tube fusing unit
16372	Citizen Printer Print cable, AC adapter, paper roll and ribbon cassette
16373	Disposable Cutting Blades, with laser point 0.4 mm, 50 pcs./package
16374	Calibration Kit With specifically designed holder, integrated temperature sensor type K and coding for calibration program recognition, calibration document for sensor included
16384	4-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16385	4-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16386	4-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16375	2-fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16376	2-fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16377	2-fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16378	2-fould Tube Holder OD 7/16" (11.1 mm), ID 5/16" (8.0 mm), Wall 1/16" (1.6 mm)
16379	2-fould Tube Holder OD 1/2" (12.7 mm), ID 3/8" (9.5 mm), Wall 1/16" (1.6 mm)
16380	2-fould Tube Holder OD 5/8" (15.9 mm), ID 3/8" (9.5 mm), Wall 1/8" (3.2 mm)
16381	2-fould Tube Holder OD 3/4" (19 mm), ID 1/2" (12.7 mm), Wall 1/8" (3.2 mm)

5.3 BioSealer®

Order Number	Order Code Description
16360-P1 16360-P2 16360-P3 16360-P4 16360-P5 16360-P6	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 4"–1" and wall thickness 1/16"–3/32" Optional Parametersets: 1–6**
16361-P1 16361-P2 16361-P3 16361-P4 16361-P5 16361-P6	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 4"–1" and wall thickness 1/16"–3/32", Equipped with a removable Sealing Head Optional Parametersets: 1–6**
16362-P7 16362-P8 16362-P9 16362-P10 16362-P11 16362-P12	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8" Optional Parametersets: 7–12**
16363-P7 16363-P8 16363-P9 16363-P10 16363-P11 16363-P12	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8", Equipped with a removable Sealing Head Optional Parametersets: 7–12**
16365	IR Interface incl. Software CD
16366	Ceramic Heating Element Type 1 specified for BioSealer® 16360–16363

** The definition of each parameterset can be obtained in the parametersheet

6. Validation

CONFIDENCE®: Product and Process Specific Validation Services

Sartorius Stedim Biotech Validation Services conducts testing according to current regulatory requirements and guidance documents used in the industry such as PDA Technical Report No. 26 "Sterilizing Filtration of Liquids".

Testing is offered for filter elements, bags and other polymer-based components such as tubing, gaskets, stoppers, vials etc. Considering the process conditions, product formulation and process steps, the test scope (type of test, number of test filter elements or other test components) and complexity of the studies can vary.

Article No.	Description
861096	Validation protocol including one revision.

Microbiological Studies

Article No.	Description
861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria Brevundimonas diminuta
861015	Viability Test for determination of the bactericidal nature of the product (non-standard)
861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria Brevundimonas diminuta

Bacteria Challenge Test performed with 3 filter elements from different lots

Article No.	Description
861012	Bacteria Challenge Test using the standard test bacteria Brevundimonas diminuta
861016	Bacteria Challenge Test (non-standard)

Determination of Product Specific Integrity Test Limits

Product Integrity Test performed with minimum 3 filter elements from different lots

Article No.	Description
861020	Determination of product specific integrity test limits
862021	Determination of product specific integrity test limits (non-standard)

Chemical Compatibility Studies

Chemical Compatibility Test performed with 3 filter sets from different lots

Article No.	Description
861022	Chemical Compatibility Test
861024	Chemical Compatibility Test (non-standard)

Adsorption Studies (upon request)

Particle Release Studies

Particle Release Test typically includes 3 filter elements from different lots

Article No.	Description
861031	Particle Release Test

Leachables│Extractables Studies (analysis of drug product formulation usually requires sample preparation)

Extraction procedure always includes a blank, customer to decide on 1 or 3 filters│bags│components for extraction

Article No.	Description
861040	Static Extraction (out of box, without prior treatment)
861041	Extraction (including sterilization and│or flushing)
861044	Extraction (non–standard)

Two pretests may be required for complex products, e.g. formulation buffer and complete solution

861070	Analytical pre-test to identify product interference
861071	Analytical pre-test with sample preparation

Number of analyses normally reflects number of extract samples, including blank

861047	GC-MS Analysis without sample preparation
861048	GC-MS analysis with sample preparation
861051	HPLC analysis without sample preparation
861052	HPLC analysis with sample preparation

Following a standard approach HPLC and GC-MS are typical methods for the initial leachables analysis. If no peaks are detected no further study is performed. Additional analysis and type of analytical methods depend on the amount of peaks detected and their signal intensity.
A suitable analytical scheme is then developed in a second step case by case.

This product uses ATMI patented Magnet Mixer technology

Flexel® for LevMixer® bag, using ATMI patented mixing technology

LevMixer® is a trademark or registered trademark of ATMI, Inc.
in the United States, other countries or both

SARTOFLOW®
Alpha plus SU

▶ Sartoclear® P Caps

Screening for the Right Filter Media

Single-Use Technology

Description
Sartoclear® P Caps are small scale depth filter products for screening applications in the Biopharmaceutical industry. The cellulose based depth filters combine high dirt holding capacities with electro kinetic adsorption in a single closed filtration system.

Applications
The specific characteristics of Sartoclear® P depth filters have proven to be valuable in a variety of clarification applications like:

– Cell harvest & Cell debris clarification

– Lysates from bacteria and yeasts

– Removal of precipitates from sera and plasma

– Particle and colloid removal

Sartoclear® P Depth Filter Media
Offering a maximal performance for every application, Sartoclear® P filter media are available in 6 different grades. The different variations of special selected cellulose fibres and diatomaceous earth provide a range of filters, each having its own dirt holding and contaminant adsorption characteristics. Small scale, 25 cm², Sartoclear® P Caps are available to screen for the most optimal filter grade per application.

Sartoclear® P Multilayer Combinations
Typical applications often require two or more filter media grades. The 4 most common media combinations have been selected and put together in one capsule. Multilayer filters combine two process steps in one, which results in faster processing, reduced buffer costs and reduced footprint.

Product Benefits

– Fast & easy media screening

– Minimised product loss due to very small surface area

– Scale up possibilities with MaxiCaps®

Validation
All Sartoclear® P products are validated according to the quality standards for WFI, set by the current USP. Detailed information on the methods and the validation data can be found in the Validation Guide for Sartoclear® P Sheets and Modules.

Water Flow Rate [ml/Capsule × min]
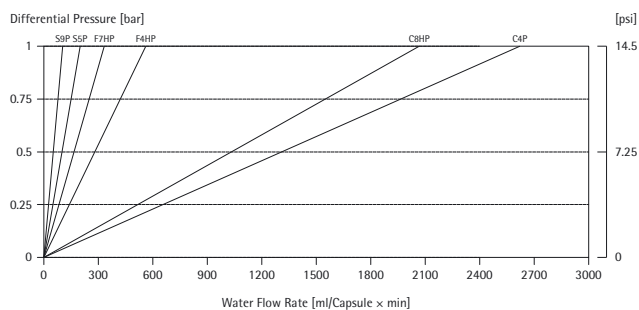
▷ Specifications

Materials

Depth Filter media	Cellulose depth filter media with inorganic filter aids
End caps	Polypropylene

Operating Parameters

Max. allowable differential pressure	2.0 bar | 36 psi
Max. allowable back pressure	0.03 bar | 0.4 psi

Sterilization
1 cycle of wet autoclaving 121°C at
1 bar for 30 min.
Sartoclear® P Caps may not be in line
steam sterilized!

Biosafety

All materials of this filter element meet
the requirements of the current USP <88>
Class VI test for plastics.

LAL level	< 0.25 EU/ml
Metal extractables see corresponding validation guide.	

Connectors

Inlet	¾" Sanitary flange
Outlet	¾" Sanitary flange

Grade	Nominal Retention µm	Thickness mm	Weight kg/m²	Ash Content %	Water Flow L/m²/min
C4-P	8	4.1	0.93	20	1,250
C8HP	4	4.1	1.08	35	700
F4HP	1.5	4.1	1.26	45	205
F7HP	1.0	4.0	1.42	50	100
S5-P	0.3	4.0	1.55	50	70
S9-P	0.1	4.0	1.64	48	42

Media Grade	Application	Media Combination
PB1	Post Bioreactor fluids with high cell densities and low viabilities	C3 + C8H
PB2	Post Bioreactor fluids with common cell densities and viabilities	C4 + F7H
PC1	Post Centrifuge applications (100–150 FNU)	F7H + S5
PC2	Post Centrifuge applications (<100 FNU)	S5 + S5

Ordering Information
All Sartoclear® P Caps do have ¾" Triclamp connectors at the in- and outlet.

Order No.	Grade	Description	Qty.
293C4-P13ACFF--M	C4HP	Single Layer 25 cm² Cap, Cell Harvest	3
293C8HP13ACFF--M	C8HP	Single Layer 25 cm² Cap, Cell Harvest	3
293F4HP13ACFF--M	F4HP	Single Layer 25 cm² Cap, Clarification	3
293F7HP13ACFF--M	F7HP	Single Layer 25 cm² Cap, Clarification	3
293S5-P13ACFF--M	S5P	Single Layer 25 cm² Cap, Bioburden reduction	3
293S9-P13ACFF--M	S9P	Single Layer 25 cm² Cap, Bioburden reduction	3
295PB1P13ACFF--M	PB1	Post Bioreactor 1, Multilayer 25 cm² Cap	3
295PB2P13ACFF--M	PB2	Post Bioreactor 2, Multilayer 25 cm² Cap	3
295PC1P13ACFF--M	PC1	Post Centrifuge 1, Multilayer 25 cm² Cap	3
295PC2P13ACFF--M	PC2	Post Centrifuge 2, Multilayer 25 cm² Cap	3

▶ Sartoclear® P MaxiCaps®

Cell Clarification and Contaminant Removal

Single-Use Technology

Description

Sartoclear® P MaxiCaps® are medium scale depth filter capsules for scale up studies and small scale production processes in the Biopharmaceutical industry. The cellulose based depth filters combine high dirt holding capacities with electro kinetic adsorption in a single closed filtration system.

Applications

The specific characteristics of Sartoclear® P depth filters have proven to be valuable in a variety of clarification applications like:

– Cell harvest & Cell debris clarification

– Lysates from bacteria and yeasts

– Removal of precipitates from sera and plasma

– Particle and colloid removal

Sartoclear® P Depth Filter Media

Offering a maximal performance for every application, Sartoclear® P filter media are available in 6 different grades. The different variations of special selected cellulose fibres and diatomaceous earth provide a range of filters, each having its own dirt holding and contaminant adsorption characteristics. Small scale, 25 cm², Sartoclear® P Caps are available to screen for the most optimal filter grade per application.

Sartoclear® P Multilayer Combinations

Typical applications often require two or more filter media grades. The 4 most common media combinations have been selected and put together in one capsule. Multilayer filters combine two process steps in one, which results in faster processing, reduced buffer costs and reduced footprint.

Product Benefits

– Fast & easy scale up from the lab to process scale

– Fully disposable fluid pathway
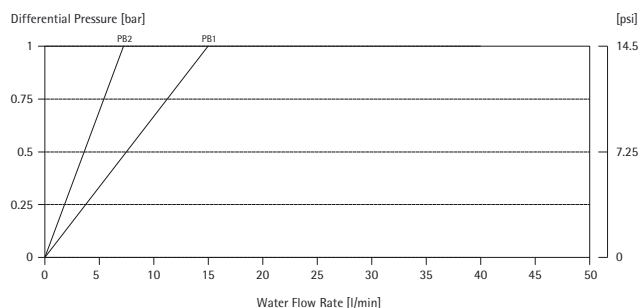
– Maximal flexibility

Validation

All Sartoclear® P products are validated according to the quality standards for WFI, set by the current USP. Detailed information on the methods and the validation data can be found in the Validation Guide for Sartoclear® P Sheets and Modules.

Water Flow Rates for Sartoclear® P
5" MaxiCaps®
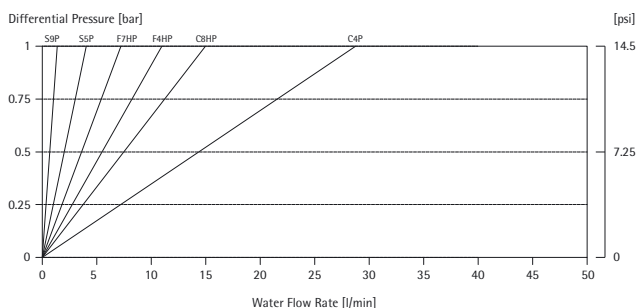
Water Flow Rates for Sartoclear® P
5" MaxiCaps®

▷ Specifications

Materials

Depth Filter media	Cellulosic depth filter media with inorganic filter aids
Sealing media	Silicone
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene

Operating Parameters

Max. operating pressure	2.5 bar | 36 psi
Max. allowable differential pressure	2.0 bar | 29 psi
Max. allowable back pressure	2.0 bar | 29 psi

Sterilization
1 cycle of wet autoclaving 121°C at
1 bar for 30 min.
Sartoclear® MaxiCaps® may not be
in line steam sterilized!

Filtration Area MaxiCaps®

	Single Layer	Multi Layer
5"	600 cm²	400 cm²
10"	1,100 cm²	–
20"	2,200 cm²	1,500 cm²

Biosafety

All materials of this filter element meet the requirements of the current USP <88> Class VI test for plastics	
LAL content	< 0.25 EU/ml

Metal extractables see corresponding
Validation guide.

Grade	Nominal Retention µm	Thickness mm	Weight kg/m²	Ash Content %	Water Flow L/m²/min
C4-P	8	4.1	0.93	20	1,250
C8HP	4	4.1	1.08	35	700
F4HP	1.5	4.1	1.26	45	205
F7HP	1.0	4.0	1.42	50	100
S5-P	0.3	4.0	1.55	50	70
S9-P	0.1	4.0	1.64	48	42

Media Grades	Application	Media Combination
PB1	Post Bioreactor fluids with high cell densities and low viabilities	C3 + C8H
PB2	Post Bioreactor fluids with common cell densities and viabilities	C4 + F7H
PC1	Post Centrifuge applications (100–150 FNU)	F7H + S5
PC2	Post Centrifuge applications (<100 FNU)	S5 + S5

Dimensions and Connections

Capsule Type	Single Layer 5"	Single Layer 10"	Single Layer 20"
Connector	3/4" Sanitary Flange	1½" Sanitary Flange	1½" Sanitary Flange
Capsule (height × diameter)	250 × 100 mm	365 × 100 mm	620 × 100 mm
Inlet and outlet connector	25 mm outer ∅ 14 mm inner ∅	50.5 mm outer ∅ 36 mm inner ∅	50.5 mm outer ∅ 36 mm inner ∅

Capsule Type	Multi Layer 5"	Multi Layer 20"
Connector	3/4" Sanitary Flange	3/4" Sanitary Flange
Capsule (height × diameter)	250 × 100 mm	620 × 100 mm
Inlet and outlet connector	25 mm outer ∅ 14 mm inner ∅	25 mm outer ∅ 14 mm inner ∅

Ordering Information

Order No.	Grade	Nominal Pore Size	Quantity	Adapter Inlet and Outlet	Filtration Area
Single Layer Products					
Sartoclear® P 5" MaxiCaps®					
293C4-P13AFFF--V	C4-P	8 µm	2	¾" Sanitary Flange	600 cm²
293C8HP13AFFF--V	C8HP	4 µm	2	¾" Sanitary Flange	600 cm²
293F4HP13AFFF--V	F4HP	1.5 µm	2	¾" Sanitary Flange	600 cm²
293F7HP13AFFF--V	F7HP	1.0 µm	2	¾" Sanitary Flange	600 cm²
293S5-P13AFFF--V	S5-P	0.3 µm	2	¾" Sanitary Flange	600 cm²
293S9-P13AFFF--V	S9-P	0.1 µm	2	¾" Sanitary Flange	600 cm²
Sartoclear® P 10" MaxiCaps®					
293C4-P13A1SS	C4-P	8 µm	1	1½" Sanitary Flange	1,100 cm²
293C8HP13A1SS	C8HP	4 µm	1	1½" Sanitary Flange	1,100 cm²
293F4HP13A1SS	F4HP	1.5 µm	1	1½" Sanitary Flange	1,100 cm²
293F7HP13A1SS	F7HP	1.0 µm	1	1½" Sanitary Flange	1,100 cm²
293S5-P13A1SS	S5-P	0.3 µm	1	1½" Sanitary Flange	1,100 cm²
293S9-P13A1SS	S9-P	0.1 µm	1	1½" Sanitary Flange	1,100 cm²
Sartoclear® P 20" MaxiCaps®					
293C4-P13A2SS	C4-P	8 µm	1	1½" Sanitary Flange	2,200 cm²
293C8HP13A2SS	C8HP	4 µm	1	1½" Sanitary Flange	2,200 cm²
293F4HP13A2SS	F4HP	1.5 µm	1	1½" Sanitary Flange	2,200 cm²
293F7HP13A2SS	F7HP	1.0 µm	1	1½" Sanitary Flange	2,200 cm²
293S5-P13A2SS	S5-P	0.3 µm	1	1½" Sanitary Flange	2,200 cm²
293S9-P13A2SS	S9-P	0.1 µm	1	1½" Sanitary Flange	2,200 cm²

Ordering Information

Order No.	Grade	Nominal Pore Size	Quantity	Adapter Inlet and Outlet	Filtration Area
Multi Layer Products					
Sartoclear® P 5" MaxiCaps®					
295PB1P13AFFF--V	PB1	11 µm | 4 µm	2	¾" Sanitary Flange	400 cm²
295PB2P13AFFF--V	PB2	8 µm | 1 µm	2	¾" Sanitary Flange	400 cm²
295PC1P13AFFF--V	PC1	1 µm | 0.3 µm	2	¾" Sanitary Flange	400 cm²
295PC2P13ACFF--V	PC2	0.3 µm | 0.3 µm	2	¾" Sanitary Flange	400 cm²
Sartoclear® P 20" MaxiCaps®					
295PB1P13A2FF	PB1	11 µm | 4 µm	1	¾" Sanitary Flange	1,500 cm²
295PB2P13A2FF	PB2	8 µm | 1 µm	1	¾" Sanitary Flange	1,500 cm²
295PC1P13A2FF	PC1	1 µm | 0.3 µm	1	¾" Sanitary Flange	1,500 cm²
295PC2P13A2FF	PC2	0.3 µm | 0.3 µm	1	¾" Sanitary Flange	1,500 cm²

Accessories

Order No.	Description
5ZGI—0001	Stainless steel holder for one 5", 10" or 20" MaxiCap®, 3 legs
5ZGLG-0004	Stainless steel holder for one 5", 10" or 20" MaxiCap®, 3 legs

▶ Sartoclear® L-Drum Technologies

Disposable Cell Clarification and Contaminant Removal

Single-Use Technology

Description
Sartoclear® P L-Drums are cellulose based depth filters, especially developed for use in the Biopharmaceutical industry. The depth filter media provide a combined clarification effect by both, size exclusion and adsorptive mechanisms.

The Sartoclear® P L-Drum is the first production scale disposable depth filter line, without the need for expensive clamping systems. The "Plug and Play" filter capsules reduce the set up time to a minimum and provide 100% disposability of all fluid contacting components.

Applications
– Cell harvest & Cell debris clarification

– Lysates from bacteria and yeasts

– Removal of precipitates from sera and plasma

– Particle and colloid removal

Sartoclear® P Multilayer Combinations
Typical applications often require two or more filter media grades. The 4 different Sartoclear® Multilayer media combinations have been optimised for typical post bio-reactor (PB1 and PB2) and post centrifuge (PC1 and PC2) applications. Multilayer filters combine two process steps in one, which results in faster processing, reduced buffer costs and reduced footprint.
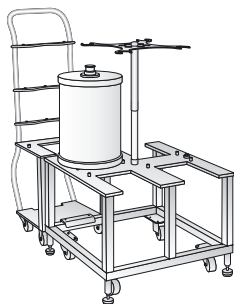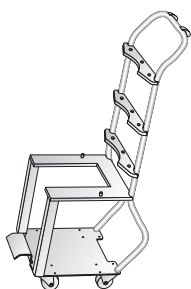
Filtration Volumes
Sartoclear® P L-Drum are used for the filtration of 100 L up to 600 L per module, depending on the application. The required filtration area needs to be confirmed by small scale tests using Sartoclear® P Maxicaps.
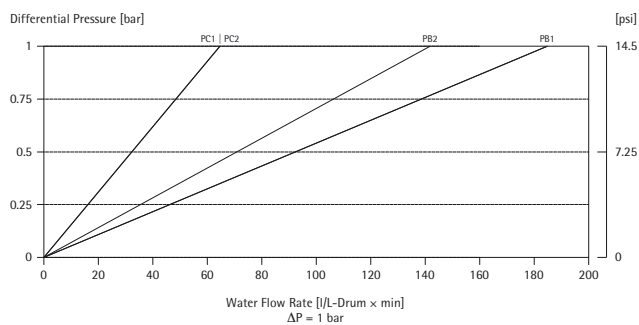
Support Systems
Two different moveable L-Drum support systems are available to assure an easy and safe handling of the capsules. The 1-way system can be connected to the 4 way support system so that a capsule can be easily transferred from one system to the other. Customized support systems can be made on request.

Product Benefits
– Large scale disposable processing

– "Plug and Play" system

– Fully disposable fluid pathway

– Maximal flexibility

Water Flow Rate [l/L–Drum × min]

Differential Pressure [bar]

| | | PC1 | PC2 | | PB2 | | PB1 | | [psi] |

Water Flow Rate [l/L-Drum × min]
ΔP = 1 bar

▷ Specifications

Materials

Depth Filter media	Cellulosic depth filter media with inorganic filter aids
Sealing media	Silicone
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene

Operating Parameters

Max. operating pressure	2.5 bar | 36 psi
Max. allowable differential pressure	2.0 bar | 29 psi
Max. allowable back pressure	2.0 bar | 29 psi

Sterilization
1 cycle of dry autoclaving 121°C at 1 bar for 30 min.
Sartoclear® P L-Drums may not be in line steam sterilized!

Technical Data L-Drum

Filtration area	2 m^2
Height	60 cm
Diameter	31 cm
Weight	16 kg

Biosafety

All materials of this filter element meet the requirements of the current USP <88> Class VI test for plastics	
LAL content	< 0.25 EU/ml

Metal extractables see corresponding Validation guide.

Connectors

Inlet	1½" Sanitary flange
Outlet	1½" Sanitary flange

Support Systems

	1–Way Support System	4–Way Support System
Length	38 cm	71 cm
Wide	57 cm	70 cm
Height	122 cm	130 cm
Weight	24 kg	51 kg

Media Grades	Application	Media Combination
PB1	Post Bioreactor fluids with high cell densities and low viabilities	C3 + C8HP
PB2	Post Bioreactor fluids with common cell densities and viabilities	C4-P + F7HP
PC1	Post Centrifuge applications (100–150 FNU)	F7HP + S5-P
PC2	Post Centrifuge applications (<100 FNU)	S5-P + S5-P

Specifications of Used Filter Media

Grade	Nominal Retention µm	Thickness mm	Weight kg/m^2	Ash Content %	Water Flow L/m^2/min
C4-P	8	4.1	0.93	20	1,250
C8HP	4	4.1	1.08	35	700
F7HP	1.0	4.0	1.42	50	100
S5-P	0.3	4.0	1.55	50	70

Ordering Information for Sartoclear® L–Drums

Order No.	Grade	Retention Rating	Application
295PB1P13ALSS	PB1	11 µm | 4 µm	High Cell densitiy (>10^7/ml) Post Bioreactor*
295PB2P13ALSS	PB2	8 µm | 1 µm	Common Cell density (<10^7/ml) Post Bioreactor applications*
295PC1P13ALSS	PC1	1.0 µm | 0.3 µm	Particle containing Post Centrifuge applications, 100–150 FNU*
295PC2P13ALSS	PC2	0.3 µm | 0.3 µm	Post Centrifuge applications, <100 FNU*

* Value is an indication, the choice of media should be based on small scale tests.

Accessories for L–Drum

2ZGB--0001	Trolley for 4 L-Drums, 70 cm × 70 cm × 120 cm (l × b × h)
2ZGB--0002	Trolley for 1 L-Drum, 70 cm × 70 cm × 120 cm (l × b × h)

▶ Sartoclear® P Single Layer Depth Filter Modules

Cell Clarification and Contaminant Removal Technologies

Description

Sartoclear® P depth filter products are cellulose based depth filters, especially developed for use in the Biopharmaceutical industry. They combine high dirt holding capacities with electro kinetic adsorption in a single closed filtration unit.

Applications

The specific characteristics of Sartoclear® P depth filters have proven to be valuable in a variety of clarification applications like:

– Cell harvest & Cell debris clarification

– Lysates from bacteria and yeasts

– Removal of precipitates from sera and plasma

– Particle and colloid removal

Sartoclear® P Depth Filter Media

Offering a maximal performance for every application, Sartoclear® P filter media are available in 6 different grades. The different variations of special selected cellulose fibres and diatomaceous earth provide a range of filters, each having its own dirt holding and contaminant adsorption characteristics. Small scale, 25 cm^2, Sartoclear® P Caps are available to screen for the most optimal filter grade per application.

Housings

Sartoclear® P filter housings are optimized for Sartoclear® P lenticular modules in pharmaceutical applications. The 12" and 16" diameter housings come with a self draining baseplate design and a replaceable adapter for the use of O-ring and flat gasket adapters. A detailed datasheet for Sartoclear® P filter housings is available.
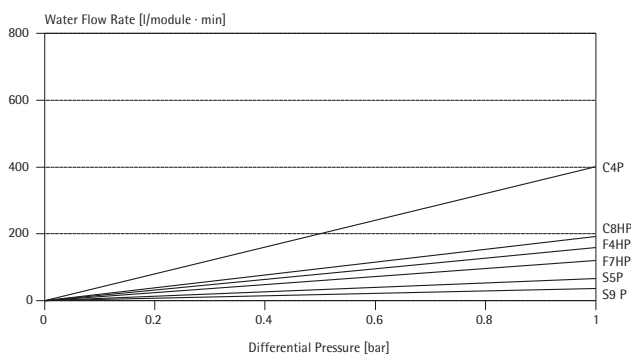
Validation

All Sartoclear® P products are validated according to the quality standards for WFI, set by the current USP. Detailed information on the methods and the validation data can be found in the Validation Guide for Sartoclear® P Sheets and Modules.
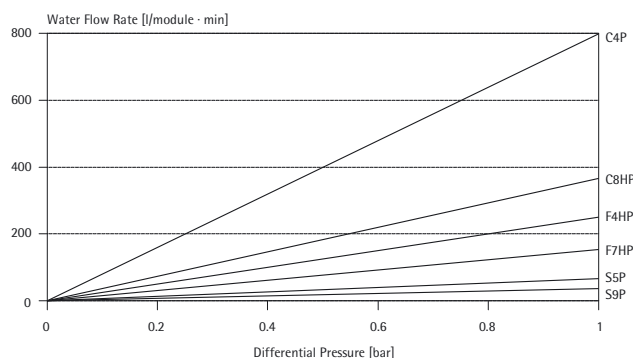
Product Benefits

– Large scale applications

– Secure and Economical processing

Water Flow Rate
12" module, 16 cells

Water Flow Rate [l/module · min]

Differential Pressure [bar]

Curves: C4P, C8HP, F4HP, F7HP, S5P, S9 P

Water Flow Rate
16" module, 16 cells

Water Flow Rate [l/module · min]

Differential Pressure [bar]

Curves: C4P, C8HP, F4HP, F7HP, S5P, S9P

▷ Specifications

Materials

Depth Filter media	Cellulosic depth filter media with inorganic filter aids
O-Rings	EPDM
Core	Polypropylene
End caps	Polypropylene

Operating Parameters

Max. allowable differential pressure	2.0 bar | 36 psi
Max. allowable back pressure	0.03 bar | 0.4 psi

Sanitization

Steam sterilization	121℃ at 1 bar for 60 min.
Hot water flush	80℃ at 1 bar for 30 min.

Biosafety

All materials of this filter element meet the requirements of the current USP <88> Class VI test for plastics.

LAL level	< 0.25 EU/ml

Metal extractables see corresponding validation guide.

Dimensions and Connections

12" Filter Modules

Filtration area	1.8 m^2
Diameter	286 mm
Height DO-Adapter	330 mm
Height FA-Adapter	272 mm

16" Filter Modules

Filtration area	3.6 m^2
Diameter	402 mm
Height DO-Adapter	330 mm
Height FA-Adapter	272 mm

Grade	Nominal Retention µm	Thickness mm	Weight kg/m^2	Ash Content %	Water Flow L/m^2/min
C4-P	8	4.1	0.93	20	1,250
C8HP	4	4.1	1.08	35	700
F4HP	1.5	4.1	1.26	45	205
F7HP	1.0	4.0	1.42	50	100
S5-P	0.3	4.0	1.55	50	70
S9-P	0.1	4.0	1.64	48	42

Ordering Information

Adapter Media Grade	12" Lenticular Module 1.8 m^2 Flat Gasket	Double O-Ring	16" Lenticular Module 3.6 m^2 Flat Gasket	Double O-Ring
C4-P	293C4-P12-1FA--V	293C4-P12-1DO--V	293C4-P16-1FA	293C4-P16-1DO
C8HP	293C8HP12-1FA--V	293C8HP12-1DO--V	293C8HP16-1FA	293C8HP16-1DO
F4HP	293F4HP12-1FA--V	293F4HP12-1DO--V	293F4HP16-1FA	293F4HP16-1DO
F7HP	293F7HP12-1FA--V	293F7HP12-1DO--V	293F7HP16-1FA	293F7HP16-1DO
S5-P	293S5-P12-1FA--V	293S5-P12-1DO--V	293S5-p16-1FA	293S5-p16-1DO
S9-P	293S9-P12-1FA--V	293S9-P12-1DO--V	293S9-P16-1FA	293S9-P16-1DO

▶ New Sartocon® ECO

New Hydrosart® Ultrafiltration Cassettes

Description

The Hydrosart® High Performance Membrane
is a stabilized cellulose based membrane that has been optimized for the biotechnological and pharmaceutical industry. The Hydrosart® membrane is a stable polymer that features the capability of operating in a broad pH range. Hydrosart® is also extremely hydrophilic, making it non-protein binding and generally non-fouling. Hydrosart® exhibits extremely high flux under extreme protein loads. Membrane cleaning, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures and concentrations. These features make Hydrosart® an ideal membrane for biological applications. Hydrosart® ECO ultrafiltration cassettes are available in the following nominal molecular weight cutoffs: 10 kD | 30 kD | 100 kD

Applications
Hydrosart® ultrafiltration membranes are designed for use in the biotechnological and pharmaceutical industries. They can be used for the following applications:

– Oligonucleotides

– Proteins
   Albumin, even with 40% EtOH
   – Vaccines
      Tetanus
      Diphtheria

– Monoclonal antibodies

Product Profile
Hydrosart® shows minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use.

The Hydrosart® ultrafiltration membrane can be re-used without loss of integrity or performance.

Feature	Benefits
Low feed flow requirements (low cross flow flux)	Low pump energy consumption
Competable with competitive pump capacity	Excellent performance in all crossflow systems
Thin channel design	High mass transfer at low feed flow rates
Non protein binding	Easy to clean
Non adsorptive membrane	High product yield
Non fouling	High sustained flux
Broad pH and temperature range	Wide choices of cleaning and sanitizing agents
Self sealing cassette	No need for gaskets
No use of glues	Low extractables
Enlarged feed and retentate ports	Lower system pressure drops

▷ Specifications

Materials of Construction

Membrane	Hydrosart® (stabilized cellulose based membrane)
Integrated gasket	Polypropylene
Spacer	Polypropylene
Sealing compound	Silicone white

Pore Size | Retention Rate
Hydrosart® ultrafiltration cassettes are available in a choice of the following nominal molecular weight cut offs:
10 kD | 30 kD | 100 kD

Available Sizes
Sartorius Stedim Biotech Crossflow Cassettes are available in **Standard Cassette** size for pilot- and production scale, and in **Sartocon® Slice** format for reduced volume handling.

Available Filter Holder
Sartorius Stedim Biotech Crossflow Cassettes are designed to fit standard Sartorius Stedim Biotech filter holders like Sartocon® Slice, Sartocon® 2 Plus, and SARTOFLOW® 10 and 20 holders.

Filtration Area
Filter area Sartocon® Cassette   0.7 m²
Filter area Sartocon® Slice Cassette   0.14 m²

Operating Parameters

Feed pressure, P_{in}	58 psi	4 bar maximum
Operating temperature	50 °C maximum
Max. air diffusion rates at 20°C at P_{in} = 15 psi	1 bar	15 ml air/min for 0.7 m² filter area 5 ml air/min for 0.14 m² filter area
Cleaning	NaOH, 1 M, 40 °C
Disinfection	NaOH, 1 M, 40 °C, 30 min
Storage	NaOH, 0.1 M

Sanitization
NaOH, 1 M, 40°C, 30 min

Regulatory Compliance
All materials have passed the USP Biological Test and the in Vivo Biological reactivity test according to USP Plastic Class Test VI. The filtrate meets or exceeds the currently valid USP and EP for sterile Water for Injection, with respect to bacteria endotoxins, particulate matter, oxidizable substances, pH dependent conductivity, extractable substances such as ammonia, chloride, sulfate, calcium and nitrate.

Quality Control
Each filter cassette is individually assigned a serial number, integrity tested and certified.

Each filter complies with cGMP requirements for non-fibre-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

Average Dynamic Water Flux*

Nominal Molecular Weight Cut Off (kD)	10 kD	30 kD	100 kD
Permeate Flow Hydrosart® l/h/m²	45	100	380

* (Feed pressure, P_{feed} = 29 psi | 2 bar; Retentate pressure, P_{ret} = 7 psi | 0.5 bar; $P_{Filtrate}$ = open valve)

Retention Rates Hydrosart®

Substance	Approx. Mol. Wt.	10 kD	30 kD	100 kD
Cytochrome C	12,400	>97.5%	–	–
Albumin	67,000	–	≥97.5%	≤60%
γ Globulin	169,000	–	–	≥96%

Order Information
Available types and order numbers

Type	Filter Area	Cut Off	Order No.
Sartocon® Cassettes	0.7 m²	10 kD	3M2 144 39 07 E--SW
Sartocon® Cassettes	0.7 m²	30 kD	3M2 144 59 07 E--SW
Sartocon® Cassettes	0.7 m²	100 kD	3M2 144 68 07 E--SW
Sartocon® Slice Cassettes	0.14 m²	10 kD	3M5 144 39 01 E--SW
Sartocon® Slice Cassettes	0.14 m²	30 kD	3M5 144 59 01 E--SW
Sartocon® Slice Cassettes	0.14 m²	100 kD	3M5 144 68 01 E--SW

For further assistance, please contact your local Sartorius Stedim Biotech application specialist or our Goettingen-based Applications Department in Germany.

Technical References
Validation Guide
Publication No.: SPC5709-e

Directions for Use (Sartocon® ECO Cassettes and Sartocon® Slice ECO Cassettes)
Publication No.: SPC6040-a

▶ Polyethersulfone Microfiltration Cassettes

Cell Removal and Mycoplasma Reduction

Description

The Polyethersulfone Membrane
The polyethersulfone membrane (PESU) is a membrane polymer that is well established in the biotechnological and pharmaceutical industries. The PESU membrane is a stable polymer that features a broad pH and temperature range. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. Because of these features, the PESU membrane is ideally suited for biotechnological applications. PESU cassettes are available in 0.1 µm. Polyethersulfone membranes are designed for applications in the biotechnological and pharmaceutical industries.

They can be used to remove the following cells from liquids:

– mammalian cells

– clostridia

– yeasts

– salmonella

– mycoplasma reduction

Product Profile
Membrane retention is unaffected by repeated re-use.

Feature	Benefits
Low adsorption	Minimal loss of proteins
Low protein-binding	High product yield
Wide pH and a wide variety of temperature range	Chemicals can be used for the removal of foulants
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

▷ Specifications

Materials of Construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone white

Pore Size | Retention Rate

PESU microfiltration cassettes are available in 0.1 µm pore size.

Available Sizes

Sartorius Stedim Biotech Crossflow Cassettes are available in **Standard Cassette** size for pilot- | production scale and in **Sartocon® Slice** format for reduced volume handling.

Available Filterholder

Sartorius Stedim Biotech Crossflow Cassettes are designed for Sartorius Stedim Biotech filter holders like Sartocon® Slice (0.1 m² Cassettes only), Sartocon®, Sartocon® 2 Plus, Sartocon® 3, and different SARTOFLOW® holder.

Filtration Area

Filter area Sartocon® Cassette	0.6 m²
Filter area Sartocon® Slice Cassette	0.1 m²

Operating Parameters

Feed pressure, P_{in}	58 psi	4 bar maximum
Operating temperature	50 °C maximum
pH stabilty	1–14
Air diffusion rates at P_{in} = 15 psi	1 bar	15 ml air/min for 0.6 m² filter area 5 ml air/min for 0.1 m² filter area
Cleaning	NaOH, 1M, max. 40 °C
Disinfection	NaOH, 1 M, max. 50 °C, 30 min
Storage	NaOH, 0.1 M

Thermal Sterilization

t.b.d.

Regulatory Compliance

All materials have passed the USP Biological Test. The filtrate meets or exceeds the currently valid USP and EP for sterile Water for Injection, with respect to particulate matter, extractable substances oxidizable substances, pH dependent maximum conductivity, Ammonia, Chloride, Sulfate, Calcium and Bacteria Endotoxins.

Quality Control

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

For further assistance, please contact your local Sartorius Stedim Biotech field engineer or our Goettingen- based Applications Department in Germany.

Technical References

Validation Guide
Publication No.: SPC5705-e

Directions for Use (Sartocon® Cassettes and Sartocon® Slice Cassettes)
Publication No.: SPC6019-a

Average Dynamic Water Flux

Permeate*	1450 l/h/m²

* Feed pressure, P_{in} = 29 psi | 2.0 bar; retentate pressure, P_{out} = 7 psi | 0.5 bar

Protein Retention PESU

Substance	Approx. Mol. Wt.	1 kD [%]	5 kD [%]	8 kD [%]	10 kD [%]	PESU$_{max}$ kD [%]	30 kD [%]	50 kD [%]	100 kD [%]	300 kD [%]
Vitamin B12	1,200	>70	50–80	–	–	–	–	–	–	–
Cytocrome C	12,400	–	–	≥99	>95	–	60-90	–	–	–
Albumin	67,000	–	–	–	–	>99.9	–	>95	<80	–
γ-Globulin	169,000	–	–	–	–	–	–	>99	≥98	<70
Dextran	2,000,000	–	–	–	–	–	–	–	–	>95

Retention Coefficient

Marker	Retention (Static Conditions)
Mycoplasmen	LRV ≥ 7
Brevundimonas diminuta	LRV ≥ 7

Order Information

Available types and order numbers

Type	Filter Area	Pore Size	Order No.
Sartocon® Cassettes	0.6 m²	0.1 µm	302 154 58 06 W--SW
Sartocon® Slice Cassettes	0.1 m²	0.1 µm	305 154 58 01 W--SW

▶ Hydrosart® Microfiltration Cassettes

Cell Harvest and Bacteria Concentration

Description

The Hydrosart® Membrane

Hydrosart® is a stabilized cellulose derivative membrane polymer that has been optimized for the biotechnological and pharmaceutical industries. The Hydrosart® membrane is a stable polymer that features a broad pH and temperature range. Hydrosart® is also extremely hydrophilic, making it non-protein-binding and virtually non-fouling. As a result, it has extremely high flux. Hydrosart®'s wide temperature range makes it possible to sterilize the membrane by either steam or autoclaving. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures.

Applications

Hydrosart® membranes are designed for use in the biotechnological and pharmaceutical industries. They can be used to remove the following from liquids:

– Mammalian cells
   CHO
   BHK

– Bacteria
   E. coli
   Pasteurella
   C. diphtheria

– Yeasts

– Cell lysates

Product Profile

Hydrosart® has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use. Hydrosart® has been validated to withstand in-line steam sterilization without any loss of integrity or changes in membrane retention.

Feature	Benefits
Non-adsorptive	No loss of proteins, easy to clean, sustained flux
Non-protein-binding	High product yield
Wide pH and temperature range	More choices in sanitizing agents
High flow rates	Economical filtration runs
Steam-resistant polymer	Withstands repeated steam-sterilization cycles
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

Because of these features, Hydrosart® is ideal for biological applications.
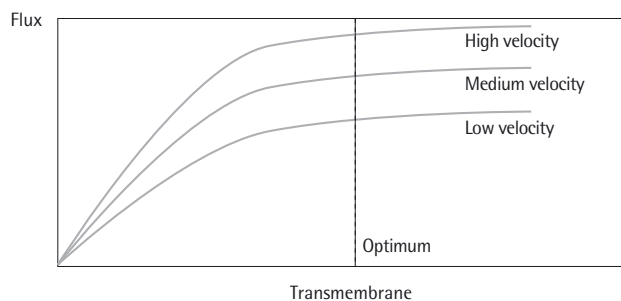
Effect of Transmembrane Pressure (TMP) and crossflow velocity on flux rates

▷ Specifications

Materials of Construction

Membrane	Hydrosart® (stabilized cellulose based membrane)
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone white

Pore Size│Retention Rate
Hydrosart® Microfilter Cassettes are available in a choice of 0.2 µm and 0.45 µm pore sizes.

Available Sizes
Sartorius Stedim Biotech Crossflow Cassettes are available in **Standard Cassette** size for pilot-│production scale and in **Sartocon® Slice** format for reduced volume handling.

Available Filter Holder
Sartorius Stedim Biotech Crossflow Cassettes are designed for Sartorius Stedim Biotech filter holders like Sartocon® Slice (0.1 m^2 Cassettes only), Sartocon® 2 Plus, Sartocon® 3, and different SARTOFLOW® holder.

Filtration Area
Filter area Sartocon® Cassette   0.6 m^2
Filter area Sartocon® Slice Cassette   0.1 m^2

Operating Parameters

Feed pressure, P_{in}	58 psi│4 bar maximum
Operating temperature	50 °C maximum
pH stability	2–14
Air diffusion rates at P_{in} = 15 psi (1 bar)	50 ml air/min for 0.6 m^2 filter area 15 ml air/min for 0.1 m^2 filter area
Cleaning	NaOH, 1 M; 40 °C, 60 min
Disinfection	NaOH, 1 M, max. 50 °C, 30 min
Storage	NaOH, 0.1 M

Sterilization
Sterilization 121 °C, 30 min, steaming
               121 °C, 30 min, auloclaving

Regulatory Compliance
All materials have passed the USP Biological Test. The filtrate meets or exceeds the currently valid USP and EP for sterile Water for Injection, with respect to particulate matter, extractable substances, oxidizable substances, pH dependent conductivity, Ammonia, Chloride, Sulfate, Calcium and Bacteria Endotoxins.

Quality Control
Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

Average Dynamic Water Flux

Pore Size	Sartocon® Cassettes Permeate*
0.2 µm	2,100 l/h/m^2
0.45 µm	2,300 l/h/m^2

* (Feed pressure, P_{in} = 29 psi│2.0 bar; retentate pressure, P_{out} = 7 psi│0.5 bar)

Order Information
Available types and order numbers

Type	Filter Area	Pore Size	Order No.
Sartocon® Cassettes	0.6 m^2	0.2 µm	302 186 07 06 W--SW
Sartocon® Cassettes	0.6 m^2	0.45 µm	302 186 06 06 W--SW
Sartocon® Slice Cassettes	0.1 m^2	0.2 µm	305 186 07 01 W--SW
Sartocon® Slice Cassettes	0.1 m^2	0.45 µm	305 186 06 01 W--SW

Retention Coefficient

Marker	Retention (Static Conditions)
Bacteria	>99%
Mammalian cells	>99%

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

For further assistance, please contact your local Sartorius Stedim Biotech field engineer or our Goettingen- based Applications Department in Germany.

Technical References
Validation Guide
Publication No.: SPC5705-e

Directions for Use (Sartocon® Cassettes and Sartocon® Slice Cassettes)
Publication No.: SPC6019-a

▶ # Sartocon® Single-Use Cassettes

Protein Purification, Concentration and Diafiltration | Cell Removal

Single-Use Technology

Description

The Polyethersulfone Membrane
The polyethersulfone membrane (PESU) is a membrane polymer that is well established in the biotechnological and pharmaceutical industries. The PESU membrane is a stable polymer that features a broad pH and temperature range. Its wide temperature range makes it possible to sterilize some of the membrane by either steam or autoclaving. Because of these features, the PESU membrane is ideally suited for biotechnological applications. Polyethersulfone membranes are designed for Single-Use applications use in the biotechnological and pharmaceutical industries.

They can be used for the following applications:

– IgG

– Blood factors

– Enzymes

– Peptides

Product Profile
The polyethersulfone membrane in Sartocon® Single-Use Cassettes has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by always out of the box performance. Some PESU ultrafiltration | microfiltration cassettes have been validated to withstand in-line steam sterilization without any loss or changes in membrane retention.

Feature	Benefits
New Filter-Cassette in each production run	Reproducability – Consistent process economics "Ready to use	easy to use conditions" – High Target Protein rejection "Consistent Yield" – Sustained Performance (Lot-to-Lot) – Batch-to-Batch Consistency "Always out of the box performance"
Single-use	Eliminate cleaning Validation Reduced down time
Alcohol	Glycerol storage	Consistently low TOC limits
Consistent performance	Minimal processing time
Self sealing cassette	No gaskets required
Silicone sealing internal	external	No glue No Polyurethane extractables
Opimized Cassette construction	Lower pressure drop across the Cassette

▷ ## Specifications

Materials of Construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone grey

Pore Size | Retention Rate
PESU ultrafiltration and microfiltration cassettes are available in a choice of the following ultrafilters with nominal molecular weight cut offs: 1 kD, 5 kD, 8 kD, 10 kD, 30 kD, 50 kD, 100 kD, 300 kD and microfilters with a pore size of 0.1 µm.

Available Sizes
Sartorius Stedim Biotech Sartocon® Single-Use Crossflow Cassettes are available in **Standard Cassette** format size for pilot- | production scale.

Available Filterholder
Sartorius Stedim Biotech Sartocon® Single-Use Crossflow Cassettes are designed for Sartorius Stedim Biotech filter holders like Sartocon®, Sartocon® 2 Plus, Sartocon® 3, and different SARTOFLOW® holder.

Filtration Area
Filter area
Sartocon® Cassette 0.7 m² UF
0.6 m² MF

Operating Parameters

Feed pressure, P_{in}	58 psi | 4 bar maximum
Operating temperature	50 °C maximum
Air diffusion rates at P_{in} = 15 psi | 1 bar	Ultrafilters: 1 kD–300 kD: 50 ml 50 ml air/min for 0.7 m² filter area | Microfilters: 15 ml air/min for 0.6 m² filter area

Sterilization
only 30 kD | 100 kD | 300 kD and 0.1 µm,
121 °C, 30 min., steaming;
121 °C, 110 min, autoclaving

Regulatory Compliance
All materials have passed the current USP
Biological Test. The filtrate meets or exeeds
USP and EP requirements for Sterile
Water for Injection with respect to total
solids, oxidizable substances, particulate
matter, ammonia, chloride, nitrate, sulfate
and heavy metals.

Quality Control
Each filter cassette is individually assigned a
serial number, integrity tested and certified.

It complies with cGMP requirements for
non-fiber-releasing filters and is filed under
the Drug Master File Number DMF 5967
by the Food and Drug Administration,
Washington, DC. Validation information
is available upon request.

If you use holding devices from other
suppliers, please contact our Applications
Department. A different torque might be
needed due to specific variations in design.

For further assistance, please contact
your local Sartorius Stedim Biotech
field engineer or our Goettingen-based
Applications Department in Germany.

Technical References
Validation Guide
Publication No.: SPC5701-e

Directions for Use
Publication No.: SPC6001-a

Retention Rates Polyethersulfone Ultrafilter

Substance	Approx. Mol. wt	1 kD	5 kD	8 kD	10 kD	30 kD	50 kD	100 kD	300 kD
Vitamin B12	1.200	>70	>50	<45	–	–	–	–	–
Inulin	5.000	>85	>70	–	–	–	–	–	–
Cytochrome C	12.400	–	>99	>99	>95	>60	–	–	–
Myoglobin	17.000	–	–	–	>99	>98	>95	<80	–
Albumin	67.000	–	–	–	>95	–	–	–	–
g-Globulin	169.000	–	–	–	–	–	>99	>98	<70
Dextran	2,000.000	–	–	–	–	–	–	–	>95

Retention Coefficient Polyethersulfone Microfilter

Marker	Retention (Static Conditions)
Mycoplasma	LRV ≥ 7
Brevundimonas diminuta	LRV > 7

Typical Water Flux Release Data

Cutoff	Pore Size	Sartocon® Single-Use Cassettes [l/h]
1 kD		9
5 kD		21
8 kD		125
10 kD		160
30 kD		280
50 kD		460
100 kD		530
300 kD		630
	0.1 µm	850

* (Feed pressure, P_{in} = 22 psi \| 1.5 bar; Retentate pressure, P_{out} = closed valve; $P_{Filtrate}$ = open valve)

Order Information
Available types and order numbers

Cutoff	Pore Size	Sartocon® Single-Use Cassettes
1 kD		3021460907E--SUD
5 kD		3021462907E--SUD
8 kD		3021463407E--SUD
10 kD		3021463907E--SUD
30 kD		3021465907E--SUD
50 kD		3021465007E--SUD
100 kD		3021466807E--SUD
300 kD		3021467907E--SUD
	0.1 µm	3021545806W--SUD

▶ Polyethersulfone Ultrafiltration Cassettes

Protein Purification, Concentration and Diafiltration

Description

The Polyethersulfone Membrane
The polyethersulfone membrane (PESU) is a membrane polymer that is well established in the biotechnological and pharmaceutical industries. The PESU membrane is a stable polymer that features a broad pH and temperature range. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. Because of these features, the PESU membrane is ideally suited for biotechnological applications. Polyethersulfone membranes are designed for use in the biotechnological and pharmaceutical industries.

They can be used for the following applications:

– IgG

– Blood factors

– Enzymes

– Peptides

Product Profile
The polyethersulfone membrane has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use.

Feature	Benefits
Low adsorption	Minimal loss of proteins
Low protein-binding	High product yield
Wide pH and a wide variety of temperature range	Chemicals can be used for the removal of foulants
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet hole	Lower pressure drop

▷ Specifications

Materials of Construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone white

Pore Size│Retention Rate
PESU ultrafiltration cassettes are available in a choice of the following nominal molecular weight cut offs: 1 kD, 5 kD, 8 kD, 10 kD, 30 kD, 50 kD, 100 kD, 300 kD

Available Sizes
Sartorius Stedim Biotech Crossflow Cassettes are available in **Standard Cassette** size for pilot-│production scale and in **Sartocon® Slice** format for reduced volume handling.

Available Filterholder
Sartorius Stedim Biotech Crossflow Cassettes are designed for Sartorius Stedim Biotech filter holders like Sartocon® Slice (0.1 m^2 Cassettes only), Sartocon®, Sartocon® 2 Plus, Sartocon® 3, and different SARTOFLOW® holder.

Filtration Area
Filter area Sartocon® Cassette   0.7 m^2
Filter area Sartocon® Slice Cassette   0.1 m^2

Operating Parameters

Feed pressure, P_{in}	58 psi | 4 bar maximum
Operating temperature	50 °C maximum
Air diffusion rates at P_{in} = 15 psi | 1 bar	1 k–300 kD: 50 ml air/min for 0.7 m² filter area | 15 ml air/min for 0.1 m² filter area
Cleaning	NaOH, 1 M; 40 °C
Disinfection	NaOH, 1 M, max. 50 °C, 30 min
Storage	NaOH, 0.1 M

Thermal Sterilization
t.b.d.

Regulatory Compliance
All materials have passed the USP Biological Test. The filtrate meets or exceeds the currently valid USP and EP for sterile Water for Injection, with respect to particulate matter, extractable substances, oxidizable substances, pH dependent maximum conductivity, Ammonia, Chloride, Sulfate, Calcium and Bacteria Endotoxins.

Quality Control
Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

For further assistance, please contact your local Sartorius Stedim Biotech field engineer or our Goettingen- based Applications Department in Germany.

Technical References
Validation Guide
Publication No.: SPC5705-e

Directions for Use (Sartocon® Cassettes and Sartocon® Slice Cassettes)
Publication No.: SPC6019-a

Retention Rates Polyethersulfone

Substance	Approx. Mol. Wt.	1 kD [%]	5 kD [%]	8 kD [%]	10 kD [%]	PESU$_{max}$ kD [%]	30 kD [%]	50 kD [%]	100 kD [%]	300 kD [%]
Vitamin B12	1,200	>70	50–80	–	–	–	–	–	–	–
Cytocrome C	12,400	–	–	≥99	>95	–	60–90	–	–	–
Albumin	67,000	–	–	–	–	>99.9	–	>95	<80	–
γ-Globulin	169,000	–	–	–	–	–	–	>99	≥98	<70
Dextran	2,000,000	–	–	–	–	–	–	–	–	>95

Average Dynamic Water Flux
Permeate flow rate P_{in} = 2 bar, P_{ret} = 0,5 bar, $P_{filtrate}$ = open

Cut Off | Pore Size	Polyethersulfone l/h/m²
1 kD	13
5 kD	42
8 kD	220
10 kD	300
30 kD	610
50 kD	720
100 kD	800
300 kD	1260

Order Information
Available types and order numbers

Cut Off | Pore Size	Sartocon® Cassettes, 0.7 m² Filter Area	Sartocon® Slice Cassettes, 0.1 m² Filter Area
1 kD	3021460907E--SW	3051460901E--SW
5 kD	3021462907E--SW	3051462901E--SW
8 kD	3021463407E--SW	3051463401E--SW
10 kD	3021463907E--SW	3051463901E--SW
30 kD	3021465907E--SW	3051465901E--SW
50 kD	3021465007E--SW	3051465001E--SW
100 kD	3021466807E--SW	3051466801E--SW
300 kD	3021467907E--SW	3051467901E--SW

▶ Sartocube® – Hydrosart® Ultrafilter Cassette

Protein Purification, Concentration and Diafiltration

Description

The Hydrosart® Membrane

Hydrosart® is a stabilized cellulose based membrane that has been optimized for the biotechnological and pharmaceutical industry. The Hydrosart® membrane is a stable polymer that features a broad pH range. Hydrosart® is also extremely hydrophilic, making it non-protein binding, virtually non-foul, and has extremely high flux. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. These features make Hydrosart® an ideal membrane for biological applications. Hydrosart® ultrafiltration Sartocube® cassettes are available in the following nominal molecular weight cutoffs: 2 kD│5 kD│10 kD│30 kD│100 kD

Applications

Hydrosart® ultrafiltration membranes are designed for use in the biotechnological and pharmaceutical industries. They can be used for the following applications:

– Oligonucleotide

– Proteins
  Albumin, even with 40% EtOH
  Hemoglobin

– Coagulation factors
  Factor VIII
  Factor III

– Vaccines
  Tetanus
  Diphteria

– Monoklonal Antibodies

Product Profile

Hydrosart® shows minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use.

The Hydrosart® ultrafiltration membrane can be re-used without any loss of integrity or performance.

Feature	Benefits
Non-adsorptive	No loss of proteins, easy to clean, sustained flux
Non-protein binding	High product yield
Wide pH and temperature range	More choices in sanitizing agents
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

Better solvent resistance than Polyethersulfone and Cellulose Triacetate

▷ Specifications

Materials of Construction

Membrane	Hydrosart® (stabilized cellulose based membrane)
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone white

Pore Size│Retention Rate
Hydrosart® ultrafiltration cassettes are available in a choice of the following nominal molecular weight cut offs:
2 kD│5 kD│10 kD│30 kD│100 kD

Available Sizes
Sartorius Stedim Biotech Crossflow Cassettes are available in **Standard Cassette** size for pilot-│production scale and in **Sartocon® Slice** format for reduced volume handling.

Available Filterholder
Sartocube® Cassettes are designed for Sartorius Stedim Biotech filter holders like, Sartocon® 2 Plus and different SARTOFLOW® holder.

Filtration Area
Filter area Sartocube® Cassette is 3.0 m^2

Operating Parameters

Feed pressure, P_{in}	58 psi│4 bar maximum
Operating temperature	50 °C maximum
Max. air diffusion rates at P_{in} = 15 psi│1 bar	50 ml air/min for 3.0 m^2 filter area
Cleaning	NaOH, 1 M, 50 °C
Disinfection	NaOH, 1 M, 40 °C, 30 min
Storage	NaOH, 0.1 M

Sanitisation
NaOH, 1 M, 40 °C, 30 min

Regulatory Compliance
All materials have passed the USP Biological Test. The filtrate meets or exceeds the currently valid USP and EP for sterile Water for Injection, with respect to particulate matter, extractable substances, oxidizable substances, pH dependent conductivity, Ammonia, Chloride, Sulfate, Calcium and Bacteria Endotoxins.

Quality Control
Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

Average Dynamic Water Flux
Permeate flow rate P_{in} = 2 bar, P_{ret} = 0.5 bar, $P_{filtrate}$ = open

Cut Off	Hydrosart® 3.0 m^2 l/h
2 kD	27
5 kD	70
10 kD	170
30 kD	500
100 kD	1200

Retention Rates Hydrosart®

Substance	Approx. Mol. Wt.	2 kD	5 kD	10 kD	30 kD	100 kD
Vitamin B12	1,200	≥88%	–	–	–	
Inulin	5,000	–	≥96%	–	–	
Cytochrome C	12,400	–	–	>97.5%	–	
Albumin	67,000	–	–	–	≥97.5%	≤60%
γ Globulin	169,000	–	–	–	–	≥96%

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

For further assistance, please contact your local Sartorius Stedim Biotech field engineer or our Goettingen- based Applications Department in Germany.

Technical References
Validation Guide
Publication No.: SPC5704-e

Directions for Use (Sartocube® Cassettes)
Publication No.: SPC6018-a

Order Information
Available types and order numbers

Type	Filter Area	Cut Off	Order No.
Sartocube® Cassettes	3.0 m^2	2 kD	302 144 19 30 E–BSW
Sartocube® Cassettes	3.0 m^2	5 kD	302 144 29 30 E–BSW
Sartocube® Cassettes	3.0 m^2	10 kD	302 144 39 30 E–BSW
Sartocube® Cassettes	3.0 m^2	30 kD	302 144 59 30 E–BSW
Sartocube® Cassettes	3.0 m^2	100 kD	302 144 68 30 E–BSW

▶ Hydrosart® Ultrafiltration Cassettes

Protein Purification, Concentration and Diafiltration

Description

The Hydrosart® Membrane
Hydrosart® is a stabilized cellulose based membrane that has been optimized for the biotechnological and pharmaceutical industry. The Hydrosart® membrane is a stable polymer that features a broad pH range. Hydrosart® is also extremely hydrophilic, making it non-protein binding, virtually non-foul, and has extremely high flux. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. These features make Hydrosart® an ideal membrane for biological applications. Hydrosart® ultrafiltration cassettes are available in the following nominal molecular weight cutoffs: 2 kD | 5 kD | 10 kD | 30 kD | 100 kD

Applications
Hydrosart® ultrafiltration membranes are designed for use in the biotechnological and pharmaceutical industries. They can be used for the following applications:

– Oligonucleotide

– Proteins
  Albumin, even with 40% EtOH
  Hemoglobin

– Coagulation factors
  Factor VIII
  Factor III

– Vaccines
  Tetanus
  Diphteria

– Monoklonal Antibodies

Product Profile
Hydrosart® shows minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use.

The Hydrosart® ultrafiltration membrane can be re-used without any less cleaning loss of integrity or performance.

Feature	Benefits
Non-adsorptive	No loss of proteins, easy to clean, sustained flux
Non-protein binding	High product yield
Wide pH and temperature range	More choices in sanitizing agents
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

Better solvent resistance than Polyethersulfone and Cellulose Triacetate

▷ Specifications

Materials of Construction

Membrane	Hydrosart® (stabilized cellulose based membrane)
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone white

Pore Size | Retention Rate
Hydrosart® ultrafiltration cassettes are available in a choice of the following nominal molecular weight cut offs:
2 kD | 5 kD | 10 kD | 30 kD | 100 kD

Available Sizes
Sartorius Stedim Biotech Crossflow Cassettes are available in **Standard Cassette** size for pilot- | production scale and in **Sartocon® Slice** format for reduced volume handling.

Available Filterholder
Sartorius Stedim Biotech Crossflow Cassettes are designed for Sartorius Stedim Biotech filter holders like Sartocon® Slice (0.1 m² Cassettes only), Sartocon® 2 Plus, and different SARTOFLOW® holder.

Filtration Area
Filter area Sartocon® Cassette   0.6 m²
Filter area Sartocon® Slice Cassette   0.1 m²

Operating Parameters

Feed pressure, P_{in}	58 psi │ 4 bar maximum
Operating temperature	50 °C maximum, at 20 °C
Max. air diffusion rates at P_{in} = 15 psi │ 1 bar	15 ml air/min for 0.6 m² filter area 5 ml air/min for 0.1 m² filter area
Cleaning	NaOH, 1 M, 40 °C
Disinfection	NaOH, 1 M, 40 °C, 30 min
Storage	NaOH, 0.1 M

Sterilization
NaOH, 1 M, 40 °C, 30 min

Regulatory Compliance
All materials have passed the USP Biological Test. The filtrate meets or exceeds the currently valid USP and EP for sterile Water for Injection, with respect to particulate matter, extractable substances, oxidizable substances, pH dependent conductivity, Ammonia, Chloride, Sulfate, Calcium and Bacteria Endotoxins.

Quality Control
Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

For further assistance, please contact your local Sartorius Stedim Biotech field engineer or our Goettingen- based Applications Department in Germany.

Technical References
Validation Guide
Publication No.: SPC5705-e

Directions for Use (Sartocon® Cassettes and Sartocon® Slice Cassettes)
Publication No.: SPC6019-a

Average Dynamic Water Flux*

Nominal Molecular Weight Cutoff (kD)	2 kD	5 kD	10 kD	30 kD	100 kD
Permeate Flow Hydrosart® l/h/m²	10	25	60	170	550

* (Feed pressure, P_{in} = 22 psi │ 1.5 bar; Retentate pressure, P_{out} = closed valve; $P_{Filtrate}$ = open valve)

Retention Rates Hydrosart®

Substance	Approx. Mol. Wt.	2 kD	5 kD	10 kD	30 kD	100 kD
Vitamin B12	1,200	≥88%	–	–	–	
Inulin	5,000	–	>97%	–	–	
Cytochrome C	12,400	–	–	>97.5%	–	
Albumin	67,000	–	–	–	>97.5%	≤60%
γ Globulin	169,000	–	–	–	>97.5%	≥96%

Order Information
Available types and order numbers

Type	Filter Area	Cut Off	Order No.
Sartocon® Cassettes	0.6 m²	2 kD	302 144 19 06 E--SW
Sartocon® Cassettes	0.6 m²	5 kD	302 144 29 06 E--SW
Sartocon® Cassettes	0.6 m²	10 kD	302 144 39 06 E--SW
Sartocon® Cassettes	0.6 m²	30 kD	302 144 59 06 E--SW
Sartocon® Cassettes	0.6 m²	100 kD	302 144 68 06 E--SW
Sartocon® Slice Cassettes	0.1 m²	2 kD	305 144 19 01 E--SW
Sartocon® Slice Cassettes	0.1 m²	5 kD	305 144 29 01 E--SW
Sartocon® Slice Cassettes	0.1 m²	10 kD	305 144 39 01 E--SW
Sartocon® Slice Cassettes	0.1 m²	30 kD	305 144 59 01 E--SW
Sartocon® Slice Cassettes	0.1 m²	100 kD	305 144 68 01 E--SW

▶ ## Albumin Ultrafiltration Cassettes "PESU-MAX"

Albumin Concentration

Description

The PESU-MAX Membrane
The PESU-MAX membrane is made out of polyethersulfone (PESU). This membrane polymer is well established in the bio-technological and pharmaceutical industries. The PESU-MAX cassette, is designed for use in the blood market specially for ALBUMIN rejectable applications. The PESU-MAX membrane is a stable polymer that features a broad pH and temperature range. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. Because of these features, the PESU membrane is ideally suited for blood market applications.

Product Profile
The polyethersulfone membrane has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use. PESU ultrafiltration cassettes have been validated to withstand in-line steam sterilization without any loss or changes in membrane retention.

Feature	Benefits
Low adsorption	Minimal loss of proteins
Low protein-binding	High product yield
Wide pH and a wide variety of temperature range	Chemicals can be used for the removal of foulants
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet hole	Lower pressure drop

▷ ## Specifications

Materials of Construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone white

Pore Size│Retention Rate
PESU-MAX ultrafiltration cassette is available in a retention rate of >99.99% for Albumin.

Available Sizes
Sartorius Stedim Biotech Crossflow Cassettes are available in **Standard Cassette** size for pilot-│production scale and in **Sartocon® Slice** format for reduced volume handling.

Available Filterholder
Sartorius Stedim Biotech Crossflow Cassettes are designed for Sartorius Stedim Biotech filter holders like Sartocon® Slice (0.1 m^2 Cassettes only), Sartocon® 2 Plus, Sartocon® 3, and different SARTOFLOW® holder.

Filtration Area
Filter area Sartocon® Cassette   0.7 m^2
Filter area Sartocon® Slice Cassette   0.1 m^2

Operating Parameters

Feed pressure, P_{in}	58 psi | 4 bar maximum
Operating temperature	50°C maximum
Air diffusion rates at P_{in} = 14.5 psi | 1 bar	20 ml air/min for 0.7 m² filter area | 5 ml air/min for 0.1 m² filter area
Cleaning	NaOH, 1M, 40°C, 60 min
Disinfection	NaOH, 1 M, max. 50°C, 30 min
Storage	NaOH, 0.1 M

Sterilization
Sterilization NaOH, 1 M, max. 50°C, 30 min

The Sartorius Stedim Biotech Design "Stress Test" as an Indication of Cassette Cleaning Cycles

Purpose
The goal of this test is to establish that Sartorius Stedim Biotech Cassette is resistent to NaOH exposure as is recommended in this Guide for cleaning and storage.

Test Procedure
PESUmax Sartocon® cassette (Mat. No. 302146AL07K--SW) are tested under stress test conditions according to demonstrate compatibility with caustic. The test conditions are: feed pressure in 4 bar; retentate pressure 0 bar and permeate open; pH is 14 with 1 N NaOH at above 50°C for minimum 200 hours.

Results
All released and published Sartocon® cassettes are validated according to this procedure. All cassettes passed the integrity test after minimum 50 hours.

Regulatory Compliance
All materials have passed the USP Biological Test. The filtrate meets or exceeds the currently valid USP and EP for sterile Water for Injection, with respect to particulate matter, extractable substances, oxidizable substances, pH dependent conductivity, Ammonia, Chloride, Sulfate, Calcium and Bacteria Endotoxins.

Quality Control
Each filter cassette is individually assigned a serial number, integrity tested and certified. It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

For further assistance, please contact your local Sartorius Stedim Biotech field engineer or our Goettingen- based Applications Department in Germany.

Technical References
Validation Guide Publication No.: SPC5701-e

Directions for Use (Sartocon® Cassettes and Sartocon® Slice Cassettes) Publication No.: SPC6001-a

Average Dynamic Water Flux

Permeate

l/h/m²	per Cassette 0.7 m²	per Cassette 0.1 m²
approx. 350	250	50

(P_{feed} = 29 psi \| 2.0 bar, $P_{retentate}$ = 7 psi \| 0.5 bar)

Retention Rates PESU–MAX
Polyethersulfone

Retention Coefficient

Marker	Retention
Albumin	>99.9%

Ordering Information
Available types and order numbers

Cutoff	Sartocon® Cassettes 0.7 m² Filter Area	Sartocon® Slice Cassettes 0.1 m² Filter Area
Albumin	302146AL07K--SW	305146AL01K--SW

▶ ## Sartocon® Slice 200 Stainless Steel Holder

Low Hold-Up Volume Crossflow Holder for Sartocon® Slice 200 Cassettes

Description

Sartocon® Slice 200 Holder
The Sartocon® Slice 200 stainless steel holder is optimized for the use with up to two Slice 200 Crossflow cassettes (max. 0.04 m²). It is designed for low volume applications from 20 ml to 5 l.

Target use:

– scaling studies

– product discovery

– pre-clinical trials

– small pilot lots

Sartocon® Slice 200 cassettes with a filter area of 200 cm² each, are available with Hydrosart and Polyethersulfone membrane types.

The Sartocon® Slice 200 system covers the whole range of pharmaceutical and biotechnological crossflow applications like concentration and diafiltration of proteins, vaccines, viruses, antibodies, oligo nucleotides, endotoxin removal etc. The system is suitable for cell harvesting and clarification processes.

The family of Sartorius Stedim Biotech Crossflow holders feature the latest advances in crossflow design:

– vertical orientation

– self draining systems

– low minimal hold-up volumes

The Sartocon® Slice 200 cassette (filter area: 200 cm²) has the same hydrodynamic flow path design and identical materials like the larger Sartocon® Slice (0.1 m²) and production scale Sartocon® Cassettes (0.6 or 0.7 m²). This uniform design within the Sartocon® family provides the user with predictable performance for scaling studies. The Slice 200 holder completes the Slice 200 cassette in an ideal way and gives the perfect tool for every low volume crossflow application.

The Slice 200 holder uses female stainless steel Luer lock connectors. This ensures a safe and reliable connection to additional equip-ment. The stainless steel luer lock thread allows the use of even polypropylene adapters without the risc of damaging. The feed and retentate ports as well as the two filtrate ports are located each on one side of the holder. This allows, together with the small footprint design, a compact system with low minimum working volume. The adjustable feet guarantees a firm stand of the holder on the bench.

The bores of the ports are widened up to the cassettes side, to avoid air locks and to ensure a proper cleaning in place behaviour of the Slice 200 system.

Feature	Benefits
Vertical position	self draining self venting
Low hold up volume	minimized working volume
Female Luer lock threads	safe fit of the adapters
Small footprint	compact system
Unique optimized In- and Outlets	no air lock
Adjustable feet	secure stand
Fits up to two Slice 200 cassettes	high flexibility for up to 5 l working volume

▷ Specifications

Materials of Construction

Filterplate	316L (1.4404│1.4435) Stainless steel
Connectors	female luer lock threads, 316L (1.4404│1.4435) Stainless steel
O-Ring	Silicone
Nuts for tie rods	Nickel coated bronze
Feet	Polyethylene
Other components	316L (1.4404│1.4435) Stainless steel

Technical Data

Holder Hold-up volume Feed│Retentate ports	<2 ml
Holder Hold-up volume permeate ports	<2 ml
Maximum number of cassettes	2 Slice 200 cassettes (200 cm² each)
Dimensions (L×W×H)	160×120×275 mm
Weight	5.8 kg

Accessories and Ordering Informations

Slice200 stainless steel holder	17525--01
Pressure gauge, 0–6 bar, oil damped	17525---001
SARTOFLOW® Slice 200 benchtop system (240V)	17525SYS-BT2
SARTOFLOW® Slice 200 benchtop system (120V)	17525SYS-BT1

Ordering Information
Available Slice 200 types and order numbers

Ultrafiltration Cassettes 200 cm²

Membrane	MWCO	Order Numbers Sartocon® Slice 200
PESU	1 kD	308 146 09 02 E--SW
	5 kD	308 146 29 02 E--SW
	8 kD	308 146 34 02 E--SW
	10 kD	308 146 39 02 E--SW
	30 kD	308 146 59 02 E--SW
	50 kD	308 146 50 02 E--SW
	100 kD	308 146 68 02 E--SW
	300 kD	308 146 79 02 E--SW
Hydrosart®	2 kD	308 144 19 02 E--SW
	5 kD	308 144 29 02 E--SW
	10 kD	308 144 39 02 E--SW
	30 kD	308 144 59 02 E--SW
	100 kD	308 144 68 02 E--SW

Microfiltration Cassettes 200 cm²

Membrane	Pore Size	Order Numbers Sartocon® Slice 200
PESU	0.1 µm	308 154 58 02 E--SW
Hydrosart®	0.2 µm	308 186 07 02 E--SW
	0.45 µm	308 186 06 02 E--SW

The preservation liquid is either 20% Ethanol or Glycerin.

▶ Sartocon® Slice Stainless Steel Holder

Low Hold-Up Volume Crossflow Holder for Sartocon® Slice Cassettes

Description

Sartocon® Slice Holder
The Sartocon® Slice stainless steel holder is optimized for the use with up to five Slice Crossflow cassettes (0.1–0.5 m²). It is designed for low to medium volume applications from 1–100 L.

Target use:

– process development

– pre-clinical trials

– clinical trials

– scaling studies

– pilot scale and small volume production

Sartocon® Slice cassettes have a surface area of 0.1 m² each and are available with Polyethersulfone and Hydrosart membrane types.

The filterholder can be thermally sterilized by autoclaving or inline steaming if the pressure compensation tools are used. Typical applications for Sartocon® Slice covers the whole range of pharmaceutical and biotechnological crossflow applications like concentration and diafiltration of proteins, vaccines, viruses, antibodies, oligo nucleotides, endotoxin removal etc. The system is suitable for cell harvesting and clarification processes.

The Sartocon® Slice Filterholder features the latest advances in crossflow design:

– vertical orientation

– self draining system

– low minimal hold-up volume

– monolithic design

– large retentate channels

– cGMP construction and operation

The Sartocon® Slice cassette (filter area: 0.1 m²) has the same hydrodynamic flow path design and identical materials like the larger Sartocon® Cassette (Hydrosart 0.6 m², PESU 0.7 m²). This unique design within the Sartocon® family provides the user with predictable performance for scaling studies. The Silce holder completes the Slice cassette in an ideal way and gives the perfect tool for every low volume crossflow application. The Slice holder has sanitary tri-clamp connections. This ensures a safe and reliable connection to other equipment. The feed and retentate ports as well as the two filtrate ports are located on one side. This allows fixed piping and a compact system with low minimum working volume. The adjustable feet guarantees a firm stand of the holder on the bench.

Port locations are situated to avoid air locks and to ensure proper cleaning and product recovery.

Feature	Benefits
Cassettes in vertical position	self draining self venting
Unique optimized In- and Outlets	no air lock
Fits up to five cassettes	provides process flexibility
Low hold up volume	minimized working volume
Adjustable feet	secure stand

▷ Specifications

Technical Specifications

Number of cassettes	1–5
Surface area	0.1–0.5 m^2
Material	AISI 316 L stainless steel (German standard 1.4435), electropolished
Surface finish Product contact	Ra ≤0.4 µm
Support plate	AISI 316 L stainless steel
Port connection	outer diameter 25 mm (TC25); inner diameter 10 mm (DN10); (DIN11850, Reihe 2)
Max. operating pressure at 20 °C	4 bar (58 psi)

Spare Parts and Accessories

Accessories and Ordering Information

Sartocon® Slice Holder	17521---002
Pressure compensation tools	17521---028
Sartocon® microfiltration set	17521---105
Sartocon® ultrafiltration set	17521---106
Sartojet membrane pump	17521---110
Sartocon® Slice Flush Plate PP-DWST	305030C
Sartocon® Slice Adapter Plates	17521---029 17521---920

Ordering Information

Ultrafilter Membrane	Area	MWCO	Part Number
Hydrosart® UF	0.1 m^2	2 kD	30 5 144 19 01 E--SW
Hydrosart® UF	0.1 m^2	5 kD	30 5 144 29 01 E--SW
Hydrosart® UF	0.1 m^2	10 kD	30 5 144 39 01 E--SW
Hydrosart® UF	0.1 m^2	30 kD	30 5 144 59 01 E--SW
Hydrosart® UF	0.1 m^2	100 kD	30 5 144 68 01 E--SW
PESU UF	0.1 m^2	1 kD	30 5 146 09 01 E--SW
PESU UF	0.1 m^2	5 kD	30 5 146 29 01 E--SW
PESU UF	0.1 m^2	8 kD	30 5 146 34 01 E--SW
PESU UF	0.1 m^2	10 kD	30 5 146 39 01 E--SW
PESU UF	0.1 m^2	30 kD	30 5 146 59 01 E--SW
PESU UF	0.1 m^2	Albumin	30 5 146 AI 01 K--SW
PESU UF	0.1 m^2	50 kD	30 5 146 50 01 E--SW
PESU UF	0.1 m^2	100 kD	30 5 146 68 01 E--SW
PESU UF	0.1 m^2	300 kD	30 5 146 79 01 E--SW

Microfilter Membrane	Area	Pore Size	Part Number
Hydrosart® MF	0.1 m^2	0.2 µm	30 5186 07 01 W--SW
Hydrosart® MF	0.1 m^2	0.45 µm	30 5186 06 01 W--SW
PESU MF	0.1 m^2	0.1 µm	30 5154 58 01 W--SW

Steamable Sartocon® Slice Cassettes	Area	Pore Size | MWCO	Part Number
PESU UF	0.1 m^2	30 kD	30 5146 59 01 E--SG
PESU UF	0.1 m^2	100 kD	30 5146 68 01 E--SG
PESU UF	0.1 m^2	300 kD	30 5146 79 01 E--SG
PESU MF	0.1 m^2	0.1 µm	30 5154 58 01 W--SG
Hydrosart® MF	0.1 m^2	0.2 µm	30 5186 07 01 W--SG 30 5186 07 01 O--SG
Hydrosart® MF	0.1 m^2	0.45 µm	30 5186 06 01 W--SG 30 5186 06 01 O--SG

▶ Sartocon® 2 plus

Description
The Sartocon® 2 plus 1.4404 or 1.4435 stainless steel holder is optimized for the use with Sartocon® production scale Crossflow cassettes 0.6 to 7 m². It is suitable for applications from 30 l to >2000 l volume. Easy handling design and high quality materials make this holder the perfect tool.

Thermal sterilization in an autoclave or steaming in place is possible.

Target use:
– process development
– preclinical trials
– clinical trials
– pilot lots
– production

Outstanding Design for Full Flexibility

– self draining and self venting due to the vertical orientation
– large, oval retentate channels for low pressure drops
– easy installation
– low hold-up volume
– monolithic design
– all ports are located on the product plate
– fixed piping with low hold-up volume

Order Information

Filter Holder & Filtration Sets

Microfiltration Set Sartocon® 2 Plus

| 17546---201 | Sartocon® Microfiltration Set (316L) – 7 m², Filter Holder, Pressure Gauges, Valves, Clamps, Permeate Manifold, Torque wrench |

Ultrafiltration Set Sartocon® 2 Plus

| 17546---202 | Sartocon® Ultrafiltration Set (316L) – 7 m², Filter Holder, Pressure Gauges, Valves, Clamps, Permeate Manifold, Torque wrench |

Sartocon® 2 plus, 1.4404

SAP	Norm	F/R	P	E–Polished	Mirror –Inverted
		[mm]	[mm]		
17546ID260160--	DIN	26	16		
17546ID260160E-	DIN	26	16	X	
17546IZ221157--	Zoll	22.1	15.7		
17546IZ221157E-	Zoll	22.1	15.7	X	
17546II297181--	ISO	29.7	18.1		
17546II297181E-	ISO	29.7	18.1	X	
17546IJ230230--	JIS-G	23	23		
17546IJ230230E-	JIS-G	23	23	X	
17546ID260160-M	DIN	26	16		X
17546ID260160EM	DIN	26	16	X	X
17546IZ221157-M	Zoll	22.1	15.7		X
17546IZ221157EM	Zoll	22.1	15.7	X	X
17546II297181-M	ISO	29.7	18.1		X
17546II297181EM	ISO	29.7	18.1	X	X
17546IJ230230-M	JIS-G	23	23		X
17546IJ230230EM	JIS-G	23	23	X	X

Sartocon® 2 plus, 1.4435

SAP	Norm	F/R	P	E–Polished	Mirror –Inverted
		[mm]	[mm]		
17546DD260160--	DIN	26	16		
17546DD260160E-	DIN	26	16	X	
17546DZ221157--	Zoll	22.1	15.7		
17546DZ221157E-	Zoll	22.1	15.7	X	
17546DI297181--	ISO	29.7	18.1		
17546DI297181E-	ISO	29.7	18.1	X	
17546DJ230230	JIS-G	23	23		
17546DJ230230E	JIS-G	23	23	X	
17546DD260160-M	DIN	26	16		X
17546DD260160EM	DIN	26	16	X	X
17546DZ221157-M	Zoll	22.1	15.7		X
17546DZ221157EM	Zoll	22.1	15.7	X	X
17546DI297181-M	ISO	29.7	18.1		X
17546DI297181EM	ISO	29.7	18.1	X	X
17546DJ230230-M	JIS-G	23	23		X
17546DJ230230EM	JIS-G	23	23	X	X

▶ SARTOCON® Single-Use Adapter Plates

Crossflow Adapter Plates for Sartocon® Cassettes

Single-Use Technology

Description
Sartorius Stedim Biotech single-use adapter plates for Sartocon® cassettes are used in fully disposable crossflow production scale systems. The adapter plates fit in existing Sartorius Stedim Biotech SARTOCON® 2 plus or SARTOFLOW® 10 crossflow holders. A single-use adapter plate set consists of a feed | retentate and a permeate plate machined from polypropylene. The single use Sartocon® crossflow cassettes are placed in a clamping device between the adapter plates and sealed by the clamping force achieved by the closure system.

These components can be completed with single-use recirculation bags, peristaltic pumps, single-use pressure gauges and valves to obtain a complete disposable crossflow system for up to five Sartocon® cassettes respectively one Sartocube® (max. 3.5 m² filter area). Microfiltration and Ultrafiltration applications from 30 l to 500 l are covered.

Feature	Benefits
No contact of product with reused components	no cleaning no cleaning validation no cross contamination
Made of Polypropylene	steamable
Cassettes in vertical position	self draining
Tri-Clamp connectors	safe fit to standard accessories
Modular system	high flexibility

The single-use SARTOCON® system covers the whole range of pharmaceutical and biotechnological crossflow applications like concentration and diafiltration of proteins, vaccines, viruses, antibodies, oligo nucleotides, endotoxin removal etc. The system is also suitable for cell harvesting and clarification processes.

Single-use Sartocon® cassettes with a filter area of up to 0.7 m² each, are available with Polyethersulfone membrane type.

▷ Specifications

Materials of Construction

Feed|Retentate and Permeate plates	Polypropylene, compliant USP class VI Plastics test
Connectors Feed|Retentate	1"–1½" sanitary Tri Clamp flange (DN25)
Connectors Permeate	¾" sanitary Tri Clamp flange (DN10)

Technical Data

Surface finish	Ra ≤ 0.8 μm
Feed|Retentate Plate Dimensions (L×W×H) Weight	208×54×216 mm 1.8 kg
Permeate Plate Dimensions (L×W×H) Weight	203×38×216 mm 1.3 kg

Ordering Informations and Accessories

SARTOCON® Single-Use Adapter Plate set (1× Feed|Retentate plate, 1× Permeate plate)	17546---113
SARTOFLOW® 10 Holder with manual oil hydraulic closure system	on request
SARTOCON® 2 plus	on request

Single-Use Cassettes, 0.7 m² Filter Area

Cutoff|Pore Size	Order Numbers
1 kD	3021460907E--SUD
5 kD	3021462907E--SUD
8 kD	3021463407E--SUD
10 kD	3021463907E--SUD
30 kD	3021465907E--SUD
50 kD	3021465007E--SUD
100 kD	3021466807E--SUD
300 kD	3021467907E--SUD
0.1 μm	3021545806W--SUD

▶ SARTOFLOW® 10 Stainless Steel Holder

Hydraulic Crossflow Holder for Sartocon® Cassettes

Description

SARTOFLOW® 10 Holder
The SARTOFLOW® 10 stainless steel holder is optimized for the use with up to ten Sartocon® production scale Crossflow cassettes or two Sartocubes® (max. 7 m²). It is designed for applications from 30 l to 1000 l volume.

Target use:

– process development

– preclinical trials

– clinical trials

– pilot lots

– production

Sartocon® cassettes with a filter area of up to 0.7 m² each, are available with Hydrosart®, and Polyethersulfone, membrane types.

SARTOFLOW® 10 systems cover the whole range of pharmaceutical and biotechnological crossflow applications like concentration and diafiltration of proteins, vaccines, viruses, antibodies, oligo nucleotides, endotoxin removal etc. The system is also suitable for cell harvesting and clarification processes. The family of Sartorius Stedim Biotech Crossflow holders feature the latest advances in crossflow design:

– vertical orientation of cassettes

– self draining systems

– inline steamable

– no welds

– minimized hold up volume

The SARTOFLOW® 10 filter holder is part of a modular micro- and ultrafiltration system and fits up to ten Sartocon® filter cassettes. It is designed for process development and pilot scale production in biopharmaceutical applications.

The Sartocon® cassettes are placed between filter and clamping plate without a need for additional gaskets. It's not even necessary to remove the clamping plate for installation of the cassettes. Just place the cassettes on the guide rods and close the holder with the manual driven oil hydraulic pump. The crossflow holder and the hydraulic pump are optionally mounted on a stainless steel skid for easy handling.

The clamping pressure can be controlled by an integrated oil pressure gauge. This allows very accurate and reproducable clamping conditions. Defined clamping conditions are essential, especially for steaming in place applications but it is also very valuable when cassettes have to be changed frequently. The SARTOFLOW® 10 holder offers high performance production scale technology for every process development and small scale production facility.

The vertical positioning of the cassettes allows complete draining of retentate and permeate channels by gravity during harvesting and steaming procedures.

The SARTOFLOW® 10 flow distribution plate is machined from a single piece of stainless steel. It's sanitary tri-clamp connections are not welded but machined from the same plate. This eliminates potentially problems associated with welds and ensures long service life and safe and reliable connection to other equipment. The feed and retentate connectors are located on one side of the plate. This allows easy integration into any skid design and assures a compact system with low minimum working volume.

Connectors are situated to eliminate potential air locks and to assure thorough cleaning and total product recovery.

Feature	Benefits
Vertical position	self draining self venting
Tri-clamp connectors	safe fit of accessories
No welds	no corrosion
Steamable	no cross contamination
Fits up to 10 cassettes or 2 Sartocubes®	up to 1000 l working volume
Hydraulic closure	precise and reproducible clamping conditions

▷ Specifications

Materials of Construction

Filter and Clamping plate	316L (1.4435) stainless steel, grinded
Connectors	sanitary Tri Clamp flange (DN25)
Other components	316L stainless steel

Technical Data

Surface finish, grinded	Ra ≤ 0.4 μm
Closure	Lukas Hydraulic ram ACM 10/150
Oil pressure gauge	0–400 bar | 0–6000 psi
Pressure limit	430 bar
Maximum number of cassettes	10 Sartocon® cassettes
Dimensions (L × W × H)	680 × 420 × 508 mm
Weight	approx. 70 kg

Accessories and Ordering Informations

Handhydraulic Set for SF 10 or SF 20 Set: Handhydraulic pump manometer, pressure hose, needle valve	1ZW---0004
Pressure gauge, 0-6 bar, 1–1½"	17546---003
Diaphragm valve, 1–1½"	17546---005
Silicone gasket (FDA), 1–1½"	17546---012
Clamp for 1–1½" Tri-clamp	17033
Sartocon® manifold for permeate outlet	17546---016
Hose connector to 1–1½" Tri-clamp flange	17546---018
Sartocon® Adapterplate (round to oval adapter)	302020A
Sartocon® Single-Use Adapter Plates	17546---113
Sartocon® Flush Plate PP-DWST	302030C
Sartocon® Dummy Modules PP-DWST 20 mm 40 mm 100 mm	302020D 302040D 302100D

Ultrafiltration

Membrane Material	MWCO	Order Numbers Sartocon®	Order Numbers Sartocube®
Hydrosart®	2 kD	3021441906E--SW	3021441930E-BSW
	5 kD	3021442906E--SW	3021442930E-BSW
	10 kD	3021443906E--SW	3021443930E-BSW
	30 kD	3021445906E--SW	3021445930E-BSW
	100 kD	3021446806E--SW	3021446830E-BSW
PESU	1 kD	3021460907E--SW	n.a.
	5 kD	3021462907E--SW	n.a.
	8 kD	3021463407E--SW	n.a.
	10 kD	3021463907E--SW	3021463935E-BSW
	Albumin	30214AL07K--SW	n.a.
	30 kD	3021465907E--SW	3021463935E-BSW
	50 kD	3021465007E--SW	3021463035E-BSW
	100 kD	3021466807E--SW	3021466835E-BSW
	300 kD	3021467907E--SW	3021467935E-BSW

Microfiltration

Membrane Material	Pore Size	Order Numbers Sartocon®	Order Numbers Sartocube®
Hydrosart®	0.2 μm	3021860706W--SW	3021860730W-BSW
	0.45 μm	3021860606W--SW	3021860630W-BSW
PESU	0.1 μm	3021545806W--SW	3021545830W-BSW

SARTOFLOW® 10, 316L (1.4435)

Order Number	Norm	F/R [mm]	P [mm]	E–Polished	Mirror – Inverted
179-6DD260160--	DIN	26	16		
179-6DD260160E-	DIN	26	16	×	
179-6DZ221157--	Zoll	22.1	15.7		
179-6DZ221157E-	Zoll	22.1	15.7	×	
179-6DI297181--	ISO	29.7	18.1		
179-6DI297181E-	ISO	29.7	18.1	×	
179-6DJ230230--	JIS-G	23	23		
179-6DJ230230E-	JIS-G	23	23	×	
179-6DD260160-M	DIN	26	16		×
179-6DD260160EM	DIN	26	16	×	×
179-6DZ221157-M	Zoll	22.1	15.7		×
179-6DZ221157EM	Zoll	22.1	15.7	×	×
179-6DI297181-M	ISO	29.7	18.1		×
179-6DI297181EM	ISO	29.7	18.1	×	×
179-6DJ230230-M	JIS-G	23	23		×
179-6DJ230230EM	JIS-G	23	23	×	×

▶ # SARTOFLOW® 20 Stainless Steel Holder

Hydraulic Crossflow Holder for Sartocon® Cassettes

Description

SARTOFLOW® 20 Holder
The SARTOFLOW® 20 stainless steel holder is optimized for the use with up to twenty Sartocon® production scale Crossflow cassettes or four Sartocubes® (max. 14 m²). It is designed for applications from 200 L to 2500 L volume.

Target use:

– process development

– preclinical trials

– clinical trials

– pilot lots

– production

Sartocon® cassettes are available with Hydrosart® or Polyethersulfone membrane types.

The SARTOFLOW® 20 system covers the whole range of pharmaceutical and biotechnological crossflow applications like concentration and diafiltration of proteins, vaccines, viruses, antibodies, oligo nucleotides, endotoxin removal etc. The system is also suitable for cell harvesting and clarification processes. The family of Sartorius Stedim Biotech Crossflow holders feature the latest advances in crossflow design:

– vertical orientation of cassettes

– self draining systems

– inline steamable

– no welds

– minimized hold up volume

The selfdraining SARTOFLOW® 20 filter holder is part of a modular micro- and ultrafiltration system and fits up to twenty Sartocon® filter cassettes.

The Sartocon® cassettes are placed between filter and clamping plate without a need for additional gaskets. It's not even necessary to remove the clamping plate for installation of the cassettes. Just place the cassettes on the guide rods and close the holder with the oil hydraulic system. Manual driven hydraulic pump and automatic hydraulic pumps are available.

The clamping pressure can be controlled by an oil pressure gauge of a manual or automatic hydraulic pump. This allows very accurate and reproducable clamping conditions. Defined clamping conditions are essential, especially for steaming in place applications but it is also very valueable when cassettes have to be changed frequently. The SARTOFLOW® 20 holder offers high performance production scale technology for every pilot and production scale facility.

The vertical positioning of the cassettes allows complete draining of retentate and permeate channels by gravity during harvesting and steaming procedures.

The SARTOFLOW® 20 flow distribution plate is machined from a single piece of stainless steel. It's sanitary tri-clamp connections are not welded but machined from the same plate. This eliminates potentially problems associated with welds and ensures long service life and safe and reliable connection to other equipment. The feed and retentate connectors are located on one side of the plate. This allows easy integration into any skid design and assures a compact system with low minimum working volume.

Connectors are situated to eliminate potential air locks and to assure thorough cleaning and total product recovery.

Feature	Benefits
Vertical orientation	self draining, self venting
Tri-clamp connectors	safe fit of accessories
No welds	no corrosion
Steamable	no cross contamination
Fits up to twenty Sartocon® cassettes 4 Sartocubes®	high flexibility for up to 2500 l working volume
Hydraulic closure	precise and reproducible clamping conditions

▷ Specifications

Materials of Construction

Filter and Clamping plate	316L (1.4435) stainless steel, grinded or electro polished
Connectors	sanitary Tri-clamp flange

Technical Data

Surface finish, grinded	Ra ≤ 0.4 μm
Closure	Lukas Hydraulic ram ACM 10 │ 150
Maximum number of cassettes	20 Sartocon® cassettes (max. 14 m²) 4 Sartocubes®
Dimensions (L×W×H)	1230×240× 348 mm
Weight	approx. 80 kg

Accessories and Ordering Informations

Sartocon® Single-Use Adapter Plates	17546---113
Sartocon® Flush Plate PP-DWST	302030C
Sartocon® Dummy Modules PP-DWST 20 mm 40 mm 100 mm	302020D 302040D 302100D
Handhydraulic Set for SF 10 or SF 20 Set: Handhydraulic pump manometer, pressure hose, needle valve	1ZW---0004
Sartocon® Adapter plate (round to oval adapter)	302020A

Ultrafiltration

Membrane Material	Nominal Molecular Weight Cutoff [NMWCO]	Order Numbers Sartocon®	Order Numbers Sartocube®
Hydrosart® 0.6 m²	2 kD 5 kD 10 kD 30 kD 100 kD	3021441906E--SW 3021442906E--SW 3021443906E--SW 3021445906E--SW 3021446806E--SW	3021441930E-BSW 3021442930E-BSW 3021443930E-BSW 3021445930E-BSW 3021446830E-BSW
PESU 0.7 m²	1 kD 5 kD 8 kD 10 kD Albumin 30 kD 50 kD 100 kD 300 kD	3021460907E--SW 3021462907E--SW 3021463407E--SW 3021463907E--SW 30214AL07K--SW 3021465907E--SW 3021465007E--SW 3021466807E--SW 3021467907E--SW	n.a. n.a. n.a. 3021463935E-BSW n.a. 3021463935E-BSW 3021463035E-BSW 3021466835E-BSW 3021467935E-BSW

Microfiltration

Membrane Material	Pore Size	Order Numbers Sartocon®	Order Numbers Sartocube®
Hydrosart® 0.6 m²	0.2 μm 0.45 μm	3021860706W--SW 3021860606W--SW	3021860730W-BSW 3021860630W-BSW
PESU 0.7 m²	0.1 μm	3021545806W--SW	3021545830W-BSW

SARTOFLOW® 20, 316L (1.4435) 1.4435

Order Number	Norm	F/R [mm]	P [mm]	E-Polished	Mirror – Inverted
179-2DD380260--	DIN	38	26		
179-2DD380260E-	DIN	38	26	×	
179-2DZ348221--	Zoll	34.8	22.1		
179-2DZ348221E-	Zoll	34.8	22.1	×	
179-2DI384237--	ISO	38.4	23.7		
179-2DI384237E-	ISO	38.4	23.7	×	
179-2DJ357230--	JIS-G	35.7	23		
179-2DJ357230E-	JIS-G	35.7	23	×	
179-2DD380260-M	DIN	38	26		×
179-2DD380260EM	DIN	38	26	×	×
179-2DZ348221-M	Zoll	34.8	22.1		×
179-2DZ348221EM	Zoll	34.8	22.1	×	×
179-2DI384237-M	ISO	38.4	23.7		
179-2DI384237EM	ISO	38.4	23.7	×	×
179-2DJ357230-M	JIS-G	35.7	23		×
179-2DJ357230EM	JIS-G	35.7	23	×	×

▶ ## SARTOFLOW® Slice 200 Benchtop Crossflow System

Protein Purification, Concentration and Diafiltration

Design Description
The family of Sartorius Stedim Biotech Benchtop Crossflow Systems feature the latest advances in crossflow technology from Sartorius Stedim Biotech. The SARTOFLOW® Slice 200 Benchtop System is designed around our Sartocon® Slice 200 (filter area: 200 cm²) cassette and is perfectly suited for R&D, process development, pre-clinical and small pilot lots.

The SARTOFLOW® Slice 200 Benchtop system features

– Sartocon® Slice 200 filter cassette holder fits up to two Sartocon® Slice 200 filter cassettes

– 500 ml feed reservoir with sealed cap

– 900 rpm magnetic stirrer

– Peristaltic Pump

– Three pressure transmitters

– Display of process parameters (Pressures, TMP, Flow rates, Volume)

– 3 modes of operation (Manual | TMP Control | Constant Flow)

– 5 built-in independent alarms

– Win Wedge PC interface Software with custom Excel macros for data logging process analysis complete with graphs.

The flow characteristics of the Sartocon® Slice 200 filter cassettes are the same as larger Sartorius Stedim Biotech Sartocon® 0.1 or 0.7 m² production scale cassettes. Therefor it provides the user with linear scale-up and predictable performance for future production requirements.

Sartorius Stedim Biotech offers standard and custom crossflow system designs. Standard designs include our line of Benchtop Systems

which is comprised of the SARTOFLOW® Slice 200 Benchtop™, SARTOFLOW® Alpha™ and SARTOFLOW® Alpha Plus. Sartorius Stedim Systems also provides custom turn-key designs for laboratory, pilot plant and manufacturing.

The features of the SARTOFLOW® Slice 200 Benchtop System allow users to automate, optimize and document the crossflow processes:

– Reliable operation through the use of sensors & user-definable alarms

– On-board application programs that automate and optimize the filtration

– Finger-tip control via the front panel with menu-driven software

– Interfaces directly to PC

– Optically-encoded and servo-controlled pump motors

– Real-time verification and documentation of process parameters

The SARTOFLOW® Slice 200 Crossflow System
is ideal for developing, characterizing and optimizing all MF | UF | DF processes

– Compact Foot Print

– Very low operating and hold-up volumes < 20 ml

– 3 Automatic modes of operation

– The vessel's lid can be sealed for automatic constant volume diafiltration

– User set point alarms

– Process scalable

– Display of process parameters

– PC data logging, analysis and graphing
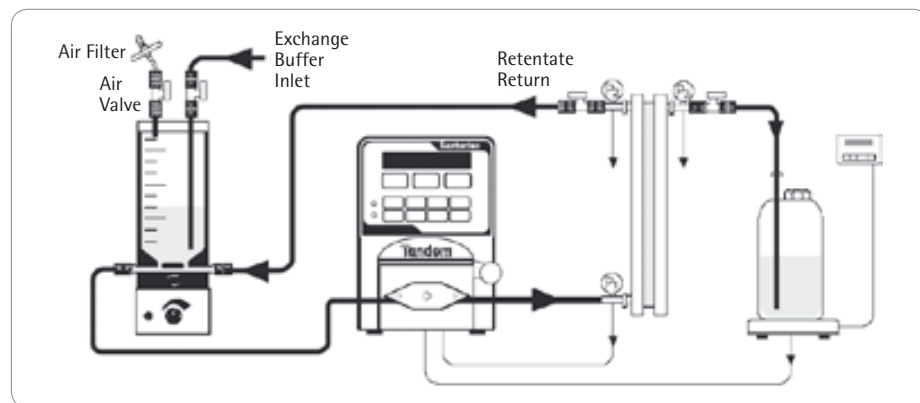
▷ Specifications

Technical Specifications

Pump Output	50–2,200 ml/min @ 40 psi | 2.5 bar
Filter Area	200 to 400 cm²
Tank Volume	500 ml
Min. Operating Volume	<20 ml
Max. System Pressure	58 psi | 4 bar
Connections	Luer
Dimensions (W × D)	60 cm × 40 cm

RS232 Communications

Quality and Documentation
Sartorius Stedim Biotech Crossflow filtration systems are manufactured from high quality components and are supplied complete with Operating Manual and Spare Parts List.

Major Components
– Tandem 1082 Peristaltic Pump

– 500 ml Graduated Polysulfone Feed Vessel

– 316L (1.4404 \| 1.4435) Stainless Steel Sartocon® Slice 200 Filter holder

– Sartorius Laboratory Balance Talent TE 4100

– Medical Grade Pressure Transmitters

– 900 RPM Integral Stir Plate and stir bar

– Luer Fittings, T-pieces, Valves and Vents

– Pinch Valve for back pressure control

– Phar Med #15 Tubing

– Balance and Pump RS232 Interface cables

– Win Wedge \| SartoWedge PC Software

Standards and Codes
All components comply with CE, EPL and CSA.

Ordering Information

SARTOFLOW® Slice 200 Benchtop System (120V)	17525SYS-BT1
SARTOFLOW® Slice 200 Benchtop System (220V)	17525SYS-BT2
Pack of 1 Pressure Transmitter	17525SP-01
Spare parts kit (replacement Luer valves and fittings)	17525SP-02
Pump BT 240 V	17525SP-03
Pump BT 120 V	17525SP-04
Pack of 3 Pressure Transmitters	17525SP-10
Stirrer Subassembly	17525SP-11

Mircofiltration Cassettes

Order Code	Material	Membrane Area	Pore Size
3081860702W--SW	Hydrosart®	200 cm²	0.20 µm
3081860602W--SW	Hydrosart®	200 cm²	0.45 µm
3081545802W--SW	PESU	200 cm²	0.10 µm

Ultrafiltration Cassettes

Order Code	Material	Membrane Area	Cut–Off
3081441902E--SW	Hydrosart®	200 cm²	2 kDa
3081442902E--SW	Hydrosart®	200 cm²	5 kDa
3081443902E--SW	Hydrosart®	200 cm²	10 kDa
3081445902E--SW	Hydrosart®	200 cm²	30 kDa
3081446802E--SW	Hydrosart®	200 cm²	100 kDa
3081460902E--SW	PESU	200 cm²	1 kDa
3081462902E--SW	PESU	200 cm²	5 kDa
3081463402E--SW	PESU	200 cm²	8 kDa
3081463902E--SW	PESU	200 cm²	10 kDa
3081465902E--SW	PESU	200 cm²	30 kDa
3081465002E--SW	PESU	200 cm²	50 kDa
3081466802E--SW	PESU	200 cm²	100 kDa
3081467902E--SW	PESU	200 cm²	300 kDa

▶ SartoJet Pump

Four-Piston Diaphragm Pump for Sartocon® Slice Crossflow
Filtration System

SartoJet four piston diaphragm pump

Sartocon® Slice Filter holder

1. Liquid level in storage tank, M8 socket
2. Pressure, M12 socket
3. External signal, M12 connector
4. Power input
5. Switch ON|OFF

The SartoJet is a powerful 4-piston diaphragm pump for all biopharmaceutical down stream applications from the laboratory right up to pilot scale production. Optimal for shear sensitive products.

Sartocon® Slice microfiltration or ultrafiltration Sets supply up to five Slice Cassettes with 0.1m² filter area each. All pressurized parts of the system are hard piped and can be connected directly to the SartoJet pump head.

Applications
– Transfer of biopharmaceutical solutions and suspensions
– Feedpump for crossflow and cartridge filtration applications
– Dosing and mixing pump for chromatography systems
– Feedpump for centrifuges, separators and homogenizers

The pump design is especially suited for:
– Protein solutions
– Polymer solutions
– Cell and cell debris suspensions
– Mammalian and insect cell suspensions
– Vaccines
– Monoclonal antibodies

The unique pump technology ensures high reliability and very low energy uptake even at high flow rates with shear sensitive cell suspensions. Therefore, in cell harvest crossflow applications no cooling of the suspension is necessary. The pump is self priming and can be combined with severall different accessories.

The pump is easy to operate. Pump and control pad are mounted in an easy-to-clean stainless steel cabinet.

A special designed Sartocon® Slice crossflow set fits directly to the feed adapter of the pump. All pressurized parts of the system are hard piped and connected via sanitary Tri Clamp adapters. This system supplies up to five Sartocon® Slice Cassettes with 0.1 m² filter area each.

An optional pressure switch with local digital pressure read out shuts the pump down when a predefined pressure is triggered. This accessory protects the user and the process by shutting down the pump automatically when the maximum operation pressure of a cartridge or a crossflow system is obtained. The pressure switch is easily programmed by the user.

Additional control is achieved by using an inductive level sensor. This small sensor is placed outside of a glass or plastic vessel and is not in contact with the product. It switches the pump off when a predefined level of liquid in the vessel is detected.

Features
– Easy to clean, no shaft seals
– Can run dry, self priming
– Low noise, constant flow
– Compact
– Adjustable flow up to 1,380 l/h
– Pressure up to 6.0 bar|90 psi, 5.0 bar|75 psi in permanent use
– Temperature up to 60°C, CIP up to 90°C (short time), SIP up to 135°C

Max. Flow at 100% (1 cP)
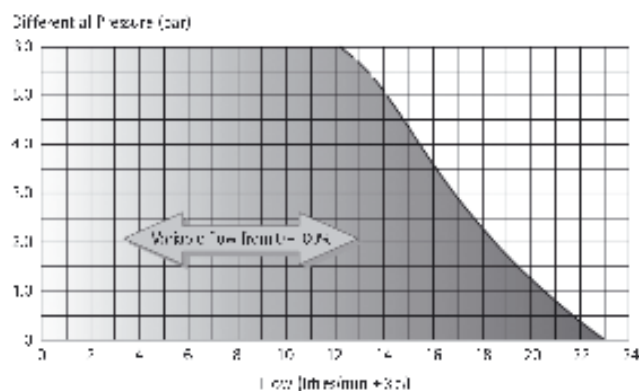
▷ Specifications

Product Wetted Components

Pump head	AISI 316L stainless steel
Surface finish	Ra < 0.8 µm
Diaphragm	Santoprene®
Valves & O-Ring	EPDM & BUNA
Valve chamber & pistons	Polypropylene
Ports	Tri-Clamp ¾"

Documents
3.1B material certificates, surface finish protocol, pump performance chart and FDA conformity documents are supplied with the pump.

Electrical Details

Power supply	intelligent controls enable operation at most single phase supplies 115–240 V AC 50 Hz or 60 Hz
Controls voltage	24 V, DC
Controls (ON | OFF)	Touch Pad 0–100 %
External Control	0...10 V DC is possible

Dimension

L × W × H	415 × 300 × 385 mm

Drive

Motor	24 V DC
Variable speed	0–3,000 rpm
Torque	0.59 Nm at 3,000 rpm
Motor power	185 Watt, 8.7 Amp.

Ordering Informations

SartoJet four piston diaphragm pump	7521---110
Sartocon® Slice Microfiltration Set for the SartoJet Pump	17521---105
Sartocon® Slice Ultrafiltration Set for SartoJet Pump	17521---106
Pressure switch with local display mounted on a DN10 Tee with 3/4"	17521---111
TC connectors for use with Sartorius SartoJet pump (17521---110).	
Level Switch for use with Sartorius SartoJet pump	17521---112
Drain Valve - T-piece with membrane valve set for use with Sartorius SartoJet pump	17521---113
Sartocon® Slice Flush Plate PP-DWST	305030C

Accessories

Pressure gauge 0-4 bar oil damped DN10	17521---033
Diaphragm valve with Tri-clamp adapter DN10	17521---032
Permeate manifold with Tri-clamp adapter DN10	17521---034
Hose barb adapters DN10 Suitable for hoses with 13 mm innerdiameter	17521---035
Clamp for 25 mm Tri-clamp adapters	17521---010
EPDM Gaskets (5 pieces)	17521---036

Ultrafilter Membrane	Area	MWCO	Part Number
Hydrosart® UF	0.1 m^2	2 kD	305 144 19 01 E--SW
Hydrosart® UF	0.1 m^2	5 kD	305 144 29 01 E--SW
Hydrosart® UF	0.1 m^2	10 kD	305 144 39 01 E--SW
Hydrosart® UF	0.1 m^2	30 kD	305 144 59 01 E--SW
Hydrosart® UF	0.1 m^2	100 kD	305 144 68 01 E—SW
PESU UF	0.1 m^2	1 kD	305 146 09 01 E--SW
PESU UF	0.1 m^2	5 kD	305 146 29 01 E--SW
PESU UF	0.1 m^2	8 kD	305 146 34 01 E--SW
PESU UF	0.1 m^2	10 kD	305 146 39 01 E--SW
PESU UF	0.1 m^2	30 kD	305 146 59 01 E--SW
PESU UF	0.1 m^2	Albumin	305 146 AI 01 K--SW
PESU UF	0.1 m^2	50 kD	305 146 50 01 E--SW
PESU UF	0.1 m^2	100 kD	305 146 68 01 E--SW
PESU UF	0.1 m^2	300 kD	305 146 79 01 E—SW

Microfilter Membrane	Area	Pore Size	Part Number
Hydrosart® UF	0.1 m^2	0.2 µm	305 186 07 01 W--SW
Hydrosart® UF	0.1 m^2	0.45 µm	305 186 06 01 W--SW
PESU MF	0.1 m^2	0.1 µm	305 154 58 01 W--SW

▶ SARTOFLOW® Alpha plus

Crossflow System with DCU4 Control

Recirculation bag

Description

The SARTOFLOW® Alpha plus is a modular bench-top crossflow system for semi-automatic micro- and ultrafiltration applications. The system can be used at cGMP facilities for process development, clinical trials and for running small-scale production batches. A number of standardized options are available to ensure that the system exactly meets each user's needs.

The system can also be upgraded with additional options if the requirements are revised during process development or production. This crossflow unit is equipped with a DCU4 control unit that can communicate with Sartorius Stedim Biotech SCADA MFCS/win data acquisition and control software. The crossflow filter holder takes up to five Sartocon® Slice cassettes, each with 0.1 m² filter area. The cassette is designed with the same hydrodynamic flow path as larger production scale filter cassettes, thereby enabling linear scale-up to larger filter areas. The unique compact design allows small volumes to be run on a laboratory bench even under aseptic conditions. All optional modules are designed to achieve the smallest possible recirculation volume of 300 ml (with one Sartocon® Slice cassette, 0.1 m²).

Thanks to the IP54 rating for pump and control unit, the whole system, including control unit, can be run in cool rooms or in harsh production environments. The unit and its touch screen are splash-proof and hold up under continuous use in both laboratory and production.

The system is easy to install in the production area. You just need to supply power, cooling water and optional steam. No other hook-ups, such as for pressurized air, are required for operation. The control unit and pump unit are separate components, to make handling more convenient. A stand for single-use Sartorius Stedim Biotech recirculation bags is available for the SARTOFLOW® Alpha plus.

Filtration Module

– Sanitary rotary lobe pump

– TMP control

– Flow rates up to 500 L/h vs. 4 bar

– Dry-run protection sensor

– 3 pressure sensors, 1 temperature probe

– Permeate flow meter

– Pump head heat exchanger

Tank Module

– Conical 10-liter stainless steel vessel; optionally supplied with double jacket

– Minimum recirculation volume of 300 ml

– Vortex breaker

– Replaceable dip tube to prevent foaming

– Visual control through one full-length sight glass on the side and a round one on the top

The recirculation tank utilizes a load cell for level control and can be replaced by an optional recirculation bag stand. All level control functions work whether the system is run with a stainless steel tank or a single-use bag.

Steaming–in–Place (SIP) Module

The SIP module offers the unique capability of running all kinds of crossflow processes aseptically. Special steamable Sartocon® Slice microfiltration and ultrafiltration filter cassettes are available that stay in place during steaming. External product loading, adding diafiltration volume and product recovery can be safely performed after SIP. Gamma-irradiated bags from Sartorius Stedim Biotech, pre-equipped with in-line steamable Steam-Thru® couplings from CPC Colder, ensure aseptic connections at these critical junctions.

Control Unit

All control and alarm functions are set and displayed on the 15" touch screen. This screen shows all signal readouts, a set point control-ler and trend curve to ensure comfortable operation and enable immediate process control even when you change parameters. Active controllers and alarms are visualized in the main display.

The logbook function stores alarms, set points and user logs. All logbook entries are transferable to the optional MFCS/win SCADA software and can be personalized with three-level password protection.

Process Sequences

Predefined sequences for concentration and diafiltration allow semiautomatic operation with predefined parameters.

– Concentration

– Diafiltration

– SIP

– CIP

– Permeate flush

– Retentate flush

All SARTOFLOW® Alpha plus units are equipped with a feed pressure and level controller for running the system at defined set points. The feed pressure controller keeps the feed pressure constant by controlling the pump speed (feed pressure is the defined value). The level controller can run one or two integrated peristaltic pumps to keep the volume in the recirculation tank or bag constant.

The TMP permits control of the retentate and the permeate pressure at predefined levels by acting on electronic positioning valves (retentate and permeate pressure are given values).

The TMP controller keeps TMP constant by adjusting the retentate valve and feed pump speed (TMP and ∆P are defined values).

The retentate flow option relies on an addi-tional flow meter in the retentate piping. This feature enables the user to run processes at specified retentate flow rates by simply adjusting the feed pump speed.

When both options are chosen, retentate flow and TMP controller can even be combined, allowing optimization trials to be run at con-stant recirculation flow rates and TMP values.

Semiautomatic optimization trials at constant retentate flow rates and automatic step-by-step or ramp variation of the TMP are possible in conjunction with MFCS/win.

Data Acquisition

Data acquisition is performed on an external PC connected to the system over an ethernet interface. SCADA MFCS software for data acquisition, batch management and visualiza-tion is included in the package. The system can be easily integrated into existing MFCS networks with Sartorius Stedim Biotech fermenters and incubation shakers.

cGMP Production Environment

Optional validated MFCS/win software can be upgraded with the 21 CFR Part 11 and S88 recipe option.

DCU4-Touchscreen

Slice Filterholder

▷ Specifications

Technical Specifications

Pump output	500 L/h @ 4bar (60 psi)
Filter area	0.1–0.5 m²
Max. inlet pressure	4 bar (60 psi)
Piping connections	Tri-clamp
Electrical requirements	230 VAC │ 60 Hz 120 VAC │ 50 Hz
Dimensions	1100 mm × 800 mm × 960 mm
Weight	Approx. 150 kg
Minimum volume	< 300 ml

SARTOFLOW® Alpha plus is a modular semi-automatic system offering numerous standard and optional features:

Modules
– Standard module
– Tank module (10 L)
– SIP module

Options
– Retentate flow meter
– Permeate and │ or retentate conductivity probe
– Permeate and │ or retentate pH probe
– Permeate UV probe
– Second peristaltic pump
– Steam inlet safety device
– Cooling device
– Double jacket vessel
– Bag Stand

Data Acquisition
– MFCS/Win Standard Software Package
– Recipe Control (S88) Software Module
– 21 CFR part 11 software module

Bags
–   5 L FBB111332
– 10 L FBB111333
– 20 L FBB111334

Abbreviations
– $\Delta d = P_{feed} - P_{retentate}$
– MFCS: Multi Fermenter Control Software
– DCU4: Digital control unit
– cGMP: current Good Manufacturing Practice
– $TMP = \left(\dfrac{P_{feed} + P_{retentate}}{2} \right) - P_{permeate}$
  (TMP: Trans Membrane Pressure)

Ultrafilter Membrane	Area	MWCO	Part Number
Hydrosart® UF	0.1 m^2	2 kD	30 5 144 19 01 E -- SW
Hydrosart® UF	0.1 m^2	5 kD	30 5 144 29 01 E -- SW
Hydrosart® UF	0.1 m^2	10 kD	30 5 144 39 01 E -- SW
Hydrosart® UF	0.1 m^2	30 kD	30 5 144 59 01 E -- SW
Hydrosart® UF	0.1 m^2	100 kD	30 5 144 68 01 E -- SW
PESU UF	0.1 m^2	1 kD	30 5 146 09 01 E -- SW
PESU UF	0.1 m^2	5 kD	30 5 146 29 01 E -- SW
PESU UF	0.1 m^2	8 kD	30 5 146 34 01 E -- SW
PESU UF	0.1 m^2	10 kD	30 5 146 39 01 E -- SW
PESU UF	0.1 m^2	30 kD	30 5 146 59 01 E -- SW
PESU UF	0.1 m^2	50 kD	30 5 146 50 01 E -- SW
PESU UF	0.1 m^2	100 kD	30 5 146 68 01 E -- SW
PESU UF	0.1 m^2	300 kD	30 5 146 79 01 E -- SW
PESU UF	0.1 m^2	Albumin	30 5 146 AL 01 K -- SW

Microfilter Membrane

Hydrosart® MF	0.1 m^2	0.2 µm	30 2 186 07 01 W-- SW
Hydrosart® MF	0.1 m^2	0.45 µm	30 5 186 06 01 W-- SW
PESU MF	0.1 m^2	0.1 µm	30 5 154 58 01 W-- SW

▶ New SARTOFLOW® Alpha plus SU

Outstanding Crossflow Filtration Performance and Efficient Single-Use Technology Combined

Single-Use Technology

Stand with recirculation bag

Description

The SARTOFLOW® Alpha plus SU combines innovative Single-use technology with excellence in Crossflow performance – to meet your process needs and to supply you with an easy to use solution. Bag Loop assemblies for the SARTOFLOW® Alpha plus SU are supplied sterile and ready to use. Each assembly is optimized for ultrafiltration, microfiltration and diafiltration applications used in many downstream processes like purification of vaccines, monoclonal antibodies or recombinant proteins. The SARTOFLOW® Alpha plus SU is a bench-top Crossflow system for micro- and ultrafiltration applications. All product wetted parts of the System are supplied sterile and made from Single-use components.

The system is suitable for use in cGMP environments for process development, clinical trials and for small-scale production batches.

The system is an ideal choice for Contract Manufacturers, research and development applications and all companies with multi-product through-put.

The SARTOFLOW® Alpha plus SU is equipped with a gamma pre-sterilized loop consisting of a self contained UF or MF unit, pump tubing pressure domes, flow meters, valves, bags and tubing.

This Crossflow system control unit is equipped with our DCU4 control unit that can communicate with Sartorius Stedim Biotech's SCADA, MFCS software. The Crossflow filter holder is specially designed for Sartorius' Sartocon® Slice Self Contained unit with membrane areas up to 0.3 m². The cassette is designed with the same hydrodynamic flow path as our larger production scale filter cassettes, enabling linear scale-up to larger filter areas. The unique compact design allows small volumes to be run on a laboratory bench even under aseptic conditions.

Thanks to the IP54 rating for the pump and control unit, the whole system, including control unit, can be run in harsh production environments. The unit and its touch screen are splash-proof and can withstand continuous use in both laboratory and production conditions.

The system is easy to install in the production area. The control unit and filtration module are separate components, to make handling more convenient.

Filtration Module

Filtration Module includes a Sartocon® Slice Holder – optional hydraulic closure – for Sartocon® Slice Self Contained operation, a bag holder, TMP control, delta P control, four pressure transmitters, two flow transmitters, two positioning actuators for the back pressure control valves, overpressure protection, peristaltic recirculation pump (0.3 m³/h vs. 3 bar), a temperature transmitter and level control.

SARTOFLOW® Alpha plus Tower
DCU4 control includes a 15" Siemens Touch Panel. Two peristaltic feed pumps are integrated in to the control tower making it possible to load product and buffer as discrete process steps.

Bag Loop with Sartocon® Slice Self Contained
For Single-Use processing the SARTOFLOW® Alpha plus SU is supplied with a gamma sterilized loop consisting of a PESU Self Contained Filter Unit, four pressure domes, retentate and permeate flow meters, two valve bodies for back pressure control in either the retentate or permeate lines, and a 10 l recirculation bag with vent filter and tubing.

The Sartocon® Slice Self Contained – available in 0.1, 0.2 or 0.3 m² membrane area – is part of the gamma sterilized loop assembly. The system is suitable for use in laboratory and cGMP environments. Ultrafilters are available in a 10 kDa and 30 kDa cut-off in PESU and with a pore size of 0.1 µm for microfiltration applications. OPTA sterile connectors with colored tags make it easy to connect to the bag loop while maintaining the sterile envelope.

The Single-use pressure domes are located in feed, retentate, permeate line and for over pressure protection of the recirculation bag. The pressure domes are simply snapped on to the reusable pressure transducer SARTOFLOW® Alpha plus SU features flow meters in the permeate and retentate line.

Bag Stand
A bag stand for the SARTOFLOW® Alpha plus SU is designed for Crossflow operations. During process the slope of the bag can be changed to optimize the recirculation volume. The stand is mounted on to a load cell for accurate level control.

Control Unit
All control and alarm functions are set and displayed on the 15" touch screen. The screen displays all signal readouts, set point controllers and trend curves to ensure user friendly operation. It enables immediate process control even when you change parameters on the fly. Active controllers and alarms are visualized in the main display.

The logbook function stores alarms, set points and user logs. All logbook entries are transferable to the optional MFCS/win SCADA software and can be personalized with three-level password protection.

Process Sequences
Predefined sequences provide operation for membrane conditioning, Concentration, Dia-filtration (UF | DF), Rinsing and CIP steps using predefined parameters. All SARTOFLOW® Alpha plus SU units are equipped with a feed pressure and level controllers for running the system at user defined set points. The feed pressure controller keeps the feed pressure constant by controlling the pump speed (feed pressure is the defined value). Delta P and the retentate flow are controlled by the recirculation pump speed.

The TMP option permits control of the retentate and the permeate pressure at predefined set points using the valves electrically driven positioning actuators.

The retentate flow option enables the user to run processes at specified retentate flow rates by adjusting the feed pump speed. The level controller can run two integrated peristaltic pumps to keep the volume in the recirculation bag constant. The systems' software architecture is designed to allow one to conduct optimization trials at constant recirculation flow rates and TMP values.

– DCU4-Touchscreen

– Stand with recirculation bag

– Step by step TMP and Feed Flow rate

Optimization trials can be customized using our MFCS/win SCADA software.

Data Acquisition
Data acquisition is accomplished using an external PC connected to the system over an ethernet interface. SCADA MFCS software for data acquisition, batch management and visualization is included in the package. The system can be easily integrated into existing MFCS networks with Sartorius Stedim Biotech fermentors and incubation shakers.

cGMP Production Environment
Optional validated MFCS/win software can be upgraded with the 21 CFR Part 11 and S88 recipe option.
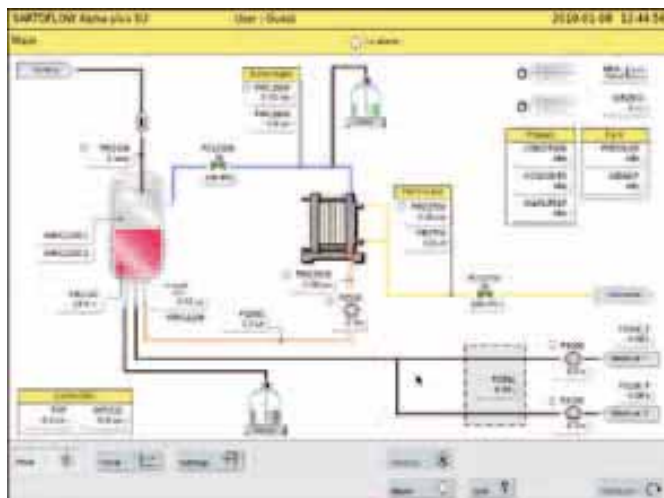
DCU4-Touchscreen

Sartocon® Slice Self Contained

▷ Specifications

Technical Specifications

Pump output	300 L/h @ 3bar (43 psi)
Filter area Sartocon® Slice Self Contained	0.1–0.3 m²
Level control via load cell	0–100 kg
Max. inlet pressure	3 bar (43 psi) sterile OPTA connectors with colored tags
Electrical requirements	230 VAC/60 Hz; 120 VAC/50 Hz
Dimensions	1100 mm × 800 mm × 960 mm
Weight Approx.	150 kg
PESU Sartocon® Slice Self Contained	up to 0.3 m² membrane area

SARTOFLOW® Alpha plus SU modules	Filtration module with standard filter holder	Filtration module with hydraulic filter holder
DCU4 Tower	230 VAC/60 Hz	120 VAC/50 Hz

Consumables

Order Number	Description
SFA-SU-1463901	UF 10 kDa PESU, 0.1 m^2
SFA-SU-1463921	UF 10 kDa PESU, 0.2 m^2
SFA-SU-1463931	UF 10 kDa PESU, 0.3 m^2
SFA-SU-1465901	UF 30 kDa PESU, 0.1 m^2
SFA-SU-1465921	UF 30 kDa PESU, 0.2 m^2
SFA-SU-1465931	UF 30 kDa PESU, 0.3 m^2
TBD	MF 0.1 µm PESU, 0.1 m^2
TBD	MF 0.1 µm PESU, 0.2 m^2
TBD	MF 0.1 µm PESU, 0.3 m^2

components of bag assembly:
10 l recirculation bag, pressure domes,
flow meter, valve bodies,
OPTA connectors and tubing

Data Acquisition
– MFCS/Win Standard Software Package
– Recipe Control (S88) Software Module
– 21 CFR part 11 Software Module

Abbreviations
– $\Delta d = P_{feed} - P_{retentate}$
– MFCS: Multi Function Control Software
– DCU4: Digital control unit
– cGMP: current Good
  Manufacturing Practice
– $TMP = \left(\dfrac{P_{feed} + P_{retentate}}{2}\right) - P_{permeate}$
  (TMP: Trans Membrane Pressure)

▶ # SARTOFLOW® Beta plus

Crossflow System with DCU4 Control

SARTOFLOW® Beta plus Feed line

SARTOFLOW® Beta plus Filtration skid

Description

The SARTOFLOW® Beta plus is a modular crossflow system for semiautomatic micro- and ultrafiltration applications. The system can be used at cGMP facilities for process development, clinical trials and for running production batches. A number of standardized options are available to ensure that the system exactly meets each user's needs. The system can also be upgraded with additional options if the requirements are revised during process development or production. This crossflow unit is equipped with a DCU4 control unit that communicates with Sartorius Stedim Biotechs SCADA MFCS/win data acquisition and control software.

The crossflow filter holder takes up to ten Sartocon filter cassettes, each with 0.7 m² filter area.

The unique compact design allows small volumes to be run under aseptic conditions.

All optional modules are designed to achieve the smallest possible recirculation volume.

Thanks to the high rating for Pump and control unit, the whole system, including control unit, can be run in cool rooms or in harsh production environments. The unit and its touch screen are splash-proof and hold up under continuous use in both laboratory and production.

The system is easy to install in the production area. You just need to supply power, cooling water and optional steam. No other hook-ups, such as for pressurized air, are required for operation. The filtration unit and the tank system are separate standalone carts, to make handling more convenient.

Filtration Module

– Sanitary rotary lobe pump

– Flow rates up to 7 m³/h vs. 4 bar

– SARTOFLOW® 10 filter holder (up to 7 m² filter area)

– Dry-run protection sensor

– 3 pressure sensors (–1 … 5 bar)

– 1 temperature probe (retentate)

– Peristaltic pump (approx. 600 L/h) for media supply

– DCU4 control unit

– TMP control

– Surface Cleaning│desinfection

– Clean-room-desinfection with Formalin

– Hydraulic Clamping Unit

Tank Module (Different Sizes)

– 50 liter (total: 75 L) stainless steel vessel with conical bottom shape

– 100 liter (total: 130 L) stainless steel vessel with torospherical bottom

– 150 liter (total: 175 L) stainless steel vessel with torospherical bottom

– 200 liter (total: 225 L) stainless steel vessel with torospherical bottom

All vessels are optionally supplied with double jacket and insulation. A magnetic stirrer is also available as an option. Level control by guided radar. Vessels including NA-Connect sampling port.

For external filling or media transfer (only without SIP module) the vessel and instrumentation are mounted on a mobile skid that can be easily connected to the filtration unit.

Steaming-in-Place (SIP) Module

The SIP module offers the unique capability of running all kinds of crossflow processes aseptically. Special steamable Sartocon® microfiltration and ultrafiltration filter cassettes are available that stay in place during steaming. External product loading, adding diafiltration volume and product recovery can be safely performed after SIP. Gammairradiated bags from Sartorius Stedim Biotech, pre-equipped with in-line steamable Steam-Thru® couplings from CPC Colder, ensure aseptic connections at these critical junctions.

Control Unit

All control and alarm functions are set and displayed on the 15″ touch screen. This screen shows all signal readouts, a set point controller and trend curve to ensure comfortable operation and enable immediate process control even when you change parameters. Active controllers and alarms are visualized in the main display. The logbook function stores alarms, set points and user logs. All logbook entries are transferable to the optional MFCS/win SCADA software and can be personalized with three-level password protection.

Process Sequences
Predefined sequences for concentration and diafiltration allow semiautomatic operation with predefined parameters.

– Tank Filling & re-filling

– Concentration

– Diafiltration

– SIP

– CIP

– Permeate flush

– Retentate flush

– Product Recovery

– Draining

All SARTOFLOW® Beta plus units are equipped with pressure sensors and a level controller for running the system at defined set points. The pressure controller keeps the pressure constant by controlling the pump speed (feed pressure is the defined value) or by position-ing the permeate or retentate valve. The level controller can run one or two integrated peri-staltic pumps to maintain the volume in the recirculation tank.

The integrated TMP option permits control of the retentate and the permeate pressure at predefined levels by acting on electronic positioning valves (retentate and permeate pressure are given values). The TMP controller keeps TMP constant by adjusting the reten-tate valve and feed pump speed (TMP and ΔP are defined values).

The retentate flow option relies on an additional flow meter in the retentate piping. This feature enables the user to run processes at specified retentate flow rates by simply adjusting the feed pump speed.

When retentate flow option is chosen, retentate flow and TMP controller can even be combined, allowing optimization trials to be run at constant recirculation flow rates and TMP values. Semiautomatic optimization trials at constant retentate flow rates and automatic step-by-step or ramp variation of the TMP are possible in conjunction with MFCS/win.

Data Acquisition
Data acquisition is performed on an external PC connected to the system over an Ethernet interface. SCADA MFCS/DA software for data acquisition, batch management and visualiza-tion is included in the package. The system can be easily integrated into existing MFCS networks with Sartorius Stedim Biotech fermenters and incubation shakers.

cGMP Production Environment
Optional validated MFCS/win software can be upgraded with the 21 CFR Part 11 and S88 recipe option.

The basic system is designed such, that all basic operation Phases Like Filling, Filtration, Concentration, diafiltration, Product recov-ery, Cleaning, rinsing and draining will be performed in automated mode.

Moreover, the basic SF Beta Plus System is equipped with all safety equipment, required for as safe operation.

▷ Specifications

Technical Specifications

Pump output	7 m³/h @ 4 bar (60 psi)
Filter area	0.7 – 7.0 m²
Max. inlet pressure	4 bar (60 psi)
Piping connections	Tri-clamp
Electrical requirements	400 VAC/50 Hz 208 VAC/60 Hz
Dimensions	2500 mm × 800 mm × 2500 mm
Weight	Approx. 600 kg

SARTOFLOW® Beta plus is a modular semi-automatic system offering numerous standard and optional features.

The basic SARTOFLOW® Beta plus system is a Completely equipped system, designed for performing the Following operation steps (Phases):

– Filling | Re-Filling

– Filtration

– Concentration

– Product Recovery

– Retentate Flush

– Permeate Flush

– CIP

– Rinsing

– Draining

– Water Flux measurement

– SIP (optional)

Most of the several options offered are additional instruments to meet the Customers' requirements.
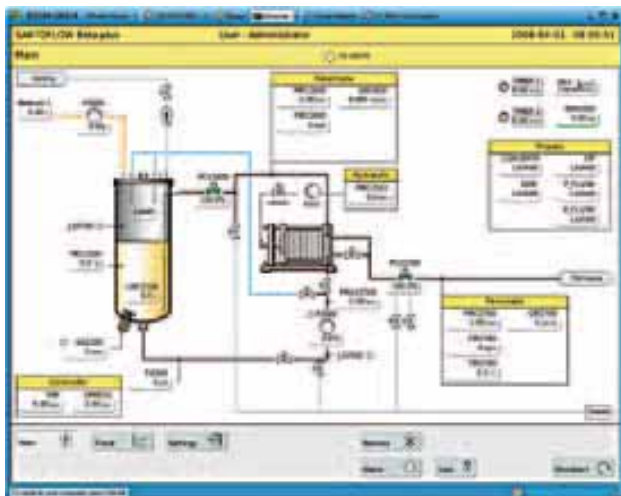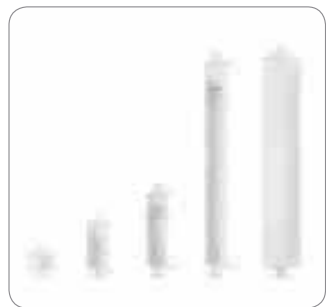

DCU4-Touchscreen

▶ Sartobind® Ion Exchange Chromatography

Membrane Adsorber Capsules, 4 mm Bed Height

Single-Use Technology

Sartobind Q and S capsules

Sartobind STIC capsules

Sartobind SingleSep® ion exchange capsules are designed to remove contaminants from therapeutic proteins at accelerated flow rates. This is a direct result of negligible mass transfer effects and is made possible by the >3 µm macroporous membrane. The design allows for robust chromatographic separations and drastically reduced validation costs.

Applications in Flowthrough Mode
Efficient removal of:

– DNA below detection limit

– Host cell proteins up to 99%

– Endotoxins up to >5 log

– Viruses up to >6 log

Economical:

– No hardware investment & maintenace

– No column packing, testing, regeneration

– No re-use validation

– Less unspecific binding – higher yield

– Less labor

– 95% buffer savings

Easy:

– Ready-to-use and disposable

– No trouble with air entrapment, channeling or bed cracking

– Simple and fast set-up

– High flow rates: up to 30 bed volumes per minute

– No need for dilution of e.g. CEX pools with Sartobind STIC, removes contaminants also at high conductivity

Quality Control
Sartobind SingleSep capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. They have passed Plastic Class VI, particles and extractables test according to current United States Pharmacopoeia (USP) and are tested for protein binding capacity prior to release. Each package contains a certificate of quality assurance.

Sartobind®, Sartobind STIC® and SingleSep® are trademarks of Sartorius Stedim Biotech GmbH.

▷ Specifications

Base membrane	Stabilized reinforced cellulose
Membrane thickness	275 µm
Pore size	>3 µm
Membrane types	– Strong cation exchanger S (sulfonic acid) – Strong anion exchanger Q (quaternary ammonium) – Sartobind STIC®: Salt Tolerant Interaction Chromatography, anion exchanger (primary amine) for operation at high salt conditions up to 20 mS/cm
Capsule design	Cylindrical
Number of layers	15
Bed height	4 mm
Housing material	Polypropylene
Max. pressure	0.4 MPa (4 bar | 58 psi)
Sanitisation	1 N NaOH 30 – 60 min

Related Products
Sartobind MA units laboratory scale
Sartobind capsules with 8 mm bed height
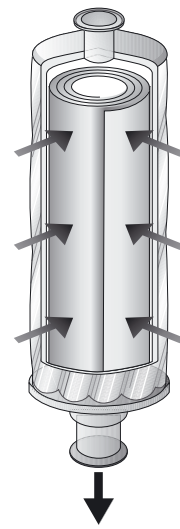
Technical Data

Order No.	Description	Connector	Quantity	Bed Volume [ml]	Typical Protein Binding Capacity* [g]	Rec. Flow Rate [l/min]
92IEXQ42DN-11	Sartobind Q SingleSep nano 1 ml	Luer female	1	1	0.029	0.03
92IEXQ42DN-11--A	Sartobind Q SingleSep nano 1 ml	Luer female	4	1	0.029	0.03
92IEXS42DN-11	Sartobind S SingleSep nano 1 ml	Luer female	1	1	0.025	0.03
92IEXS42DN-11--A	Sartobind S SingleSep nano 1 ml	Luer female	4	1	0.025	0.03
92STPA42DN-11--A	Sartobind STIC PA nano 1 ml	Luer female	4	1	0.05	0.03
92IEXQ42D4-OO--A	Sartobind Q SingleSep mini capsules	hose barb	4	7	0.2	0.2
92IEXS42D4-OO--A	Sartobind S SingleSep mini capsules	hose barb	4	7	0.175	0.2
92IEXQ42D4-SS--A	Sartobind Q SingleSep mini capsules	sanitary	4	7	0.2	0.2
92IEXS42D4-SS--A	Sartobind S SingleSep mini capsules	sanitary	4	7	0.175	0.2
92IEXQ42D9-OO--A	Sartobind Q SingleSep 5" capsules	hose barb	4	70	2	1.9
92IEXS42D9-OO--A	Sartobind S SingleSep 5" capsules	hose barb	4	70	1.75	1.9
92IEXQ42D9-SS--A	Sartobind Q SingleSep 5" capsule	sanitary	4	70	2	1.9
92IEXS42D9-SS--A	Sartobind S SingleSep 5" capsules	sanitary	4	70	1.75	1.9
92IEXQ42D1-SS	Sartobind Q SingleSep 10" capsules	sanitary	1	180	5.3	5
92IEXS42D1-SS	Sartobind S SingleSep 10" capsule	sanitary	1	180	4.6	5
92IEXQ42D2-SS	Sartobind Q SingleSep 20" capsule	sanitary	1	360	10.6	10
92IEXQ42D3-SS	Sartobind Q SingleSep 30" capsule	sanitary	1	540	16	15
92IEXS42D3-SS	Sartobind S SingleSep 30" capsule	sanitary	1	540	14	15
92IEXQ42DC3SS	Sartobind Q SingleSep mega capsule	sanitary	1	1620	48	50

Sartobind STIC PA sizes coming up soon: 5", 70 ml, 10", 180 ml, 30" 540 ml and mega 1.6 l capsules

	* Typical Dynamic Binding Capacity at 10 % Breakthrough [mg/cm²]	[mg/ml]	Reference Protein	Loading Buffer
S	0.7	25	hen egg white lysozyme	10 mM potassium phosphate, pH 7.0
Q	0.8	29	bovine serum albumin	20 mM Tris│HCl, pH 7.5
Sartobind STIC PA	1.4	50	bovine serum albumin	20 mM Tris│HCl with 150 ml NaCl, pH 7.5

▶ Sartobind® Ion Exchange Chromatography

Membrane Adsorber Capsules, 8 mm Bed Height

Single-Use Technology

The Sartobind Q or S capsules with 8 mm bed height are membrane chromatography devices for large scale capturing and impurity removal at high flow rates.

Sartobind strong cation (S) and anion ligands (Q) are covalently attached as a flexible hydrogel onto the stabilized reinforced cellulose. The membrane pore size of >3 µm allows large proteins, bioparticles and viruses to enter the macroporous structure and achieve high binding capacity without size exclusion effects.

The membrane is rolled up to form a cylinder with a bed height of 8 mm around a central solid core.

The optimized design of the fluid channels reduces the void volume significantly, resulting in sharp breakthrough curves with minimal elution volumes. The recommended flow rate of Jumbo 5 l is 25 liters per minute.

The internal support structures and the outer shell of the Sartobind Jumbo are made from polypropylene.

Sartobind nano 3 ml is the recommended scale down model for the Sartobind Jumbo. The membrane geometry and the materials of construction are identical in all three devices.

Applications

Polishing
– Virus clearance >6 log
– DNA below detection limit
– Endotoxins >5 log
– Host cell proteins >99%
– Leached ligand materials
– Aggregates

Capture
– Large proteins
– Viruses
– Vaccines
– Proteins from large feed streams

Benefits
– Designed for large scale flow through polishing as well as bind and elute chromatography
– Small elution volumes at 2 membrane volumes
– 8 mm bed height for increased binding capacity
– Scale down model with Sartobind nano 3 ml with 8 mm bed height
– Recommended flow rate of 5 bed volumes per minute
– Easy and simple handling (like a filter)
– Autoclaveable or CIP with 1 N NaOH 1 h
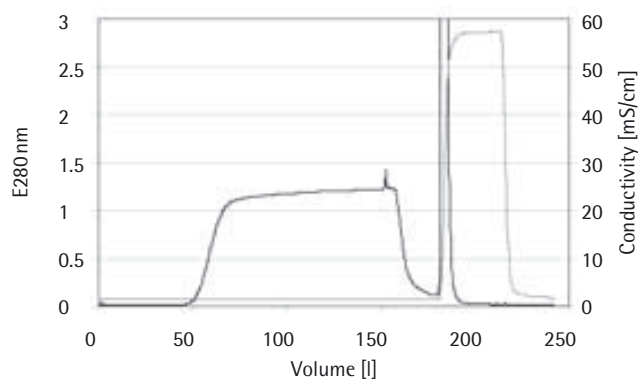
Bovine serum albumin (BSA) 2 g/l was loaded onto a 5 l Sartobind Q Jumbo. Dynamic binding capacity at 10 % breakthrough was achieved at ~53 liters, equivalent to 106 g of protein. Elution volume accounted for 10 liters, equivalent to only 2 membrane volumes.

Technical Data

Description	Sartobind Q nano 3 ml	Sartobind S nano 3 ml	Sartobind Q 150 ml	Sartobind S 150 ml
Order number	96IEXQ42EUC11--A	96IEXS42EUC11--A	96IEXQ42E9BFF	96IEXS42E9BFF
Shipment	4 × Sartobind Q nano 3 ml, 2 Luer male to UNF 10–32 adapters PEEK, manual	4 × Sartobind S nano 3 ml, 2 Luer male to UNF 10–32 adapters PEEK, manual	Sartobind Q 150 ml, manual, certificate	Sartobind S 150 ml, manual, certificate
Membrane material	Stabilized reinforced cellulose			
Ligand	Strong basic anion exchanger: quaternary ammonium $(R\text{-}CH_2\text{-}N^+(CH_3)_3)$	Strong acidic cation exchanger: sulfonic acid $(R\text{-}CH_2\text{-}SO_3^-)$	Strong basic anion exchanger: quaternary ammonium $(R\text{-}CH_2\text{-}N^+(CH_3)_3)$	Strong acidic cation exchanger: sulfonic acid $(R\text{-}CH_2\text{-}SO_3^-)$
Pore size	>3 µm	>3 µm	>3 µm	>3 µm
Bed height	8 mm	8 mm	8 mm	8 mm
Bed volume	3 ml	3 ml	150 ml	150 ml
Nominal adsorption area	110 cm^2	110 cm^2	5500 m^2	5500 m^2
Typical dyn. binding capacity 10% – per cm^2 – per ml – per unit	0.8 mg BSA 29 mg 88 mg	0.7 mg lysozyme 25.5 mg 77 mg	0.8 mg BSA 29 mg 4.4 g	0.7 mg lysozyme 25.5 mg 3.9 g
Recommended flow rate	0.015 l/min	0.015 l/min	0.75 l/min	0.75 l/min
Void volume*	4 ml	4 ml	0.2 l	0.2 l
Maximum pressure	0.4 MPa (4 bar, 58 psi)	0.4 MPa (4 bar, 58 psi)	0.4 MPa (4 bar, 58 psi)	0.4 MPa (4 bar, 58 psi)
Housing material	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Weight	10 g	10 g	400 g	400 g
Connectors	Luer female	Luer female	Sanitary 25 mm ¾"	Sanitary 25 mm ¾"
pH stability (short term)	2–14	3–14	2–14	3–14
pH stability (long term)	2–12	4–13	2–12	4–13

* Includes the porosity of the membrane which is approximately 80%.

Technical Data

Description	Sartobind Q Jumbo 5 l	Sartobind S Jumbo 5 l
Order number	96IEXQ42E3ESS	96IEXS42E3ESS
Shipment	Sartobind Q Jumbo 5 l, 15 membrane discs $\varnothing$ 30 mm, manual, certificate	Sartobind S Jumbo 5 l, 15 membrane discs $\varnothing$ 30 mm, manual, certificate
Membrane material	Stabilized reinforced cellulose	
Ligand	Strong basic anion exchanger: quaternary ammonium $(R-CH_2-N^+(CH_3)_3)$	Strong acidic cation exchanger: sulfonic acid $(R-CH_2-SO_3^-)$
Pore size	>3 µm	>3 µm
Bed height	8 mm	8 mm
Bed volume	5 l	5 l
Nominal adsorption area	18.2 m^2	18.2 m^2
Typical dyn. binding capacity 10% – per cm^2 – per ml – per unit	0.8 mg BSA 29 mg 145 g	0.7 mg lysozyme 25.5 mg 127 g
Recommended flow rate	25 l/min	25 l/min
Void volume*	7 l	7 l
Maximum pressure	0.3 MPa (3 bar, 44 psi)	0.3 MPa (3 bar, 44 psi)
Housing material	Polypropylene	Polypropylene
Weight	16 kg dry, 20 kg wet, 23 kg filled	16 kg dry, 20 kg wet, 23 kg filled
Connectors	Sanitary 50.5 mm 1 ½"	Sanitary 50.5 mm 1 ½"
pH stability (short term)	2 – 14	3 – 14
pH stability (long term)	2 – 12	4 – 13

* Includes the porosity of the membrane which is approximately 80%.

Accessories for Sartobind Capsules

Order Number	Description	Quantity
1ZA---0004	Adapter Luer male to UNF-10 – 32 female, PEEK	1
1ZAOGV0003	Adapter sanitary 25 mm to UNF 10 – 32 female, polyoxymethylene	2
7ZSB--0001	Clamp TC 25, stainless steel	1
7EDECV0001	Clamp gasket TC 25, EPDM	2
7ZSB---0009	Clamp TC 50.5, stainless steel	2
7EDECV0003	Clamp gasket TC 50.5, EPDM	2
7ZSB---0012	Clamp TC 64, stainless steel	2
7EDECV0004	Clamp gasket TC 64, EPDM	2
5ZGI--0001	Holder for 1 ×10", 20" or 30" capsule, stainless steel, 3 legs	1
5ZGLG-0004	Holder for 3 ×10", 20" and 30" capsules, stainless steel, 3 legs	1
5ZALB-0002	Distribution adapter for 3 capsules, stainless steel 1 × 64 mm, 2 × 50.5 mm sanitary	1
7ZAL-V0013	Reducing adapter 1½"–¾"; 50.5/25 mm, sanitary	2
7ZAL-V0010	Reducing adapter 2"–1½"; 64/50.5 mm, sanitary	2
7ZAL--0011	Sanitary 25 mm adapter to hose barb, stainless steel	1
7ZAL--0012	Sanitary 50.5 mm adapter to hose barb, stainless steel	1
9ZAIAM0001	Stainless steel legs for mega	3
9ZGL--0102	Trolley for Jumbo 5 l, stainless steel	1
16290	Sartocheck® 3 Plus	1
26288	Sartocheck® 4 Plus	1
16288---RV	External stainless steel vessel (10 l) for diffusion testing of Sartobind mega capsule	1

▶ Sartobind® Phenyl Hydrophobic Interaction Chromatography

Membrane Adsorber Capsules, 8 mm Bed Height

The Sartobind Phenyl capsules with 8 mm bed height are membrane chromatography devices for large scale capturing and impurity removal at typical hydrophobic interaction conditions known from HIC columns but at much higher flow rates.

The hydrophobic interaction phenyl ligand is covalently attached directly onto an enlarged surface of stabilized reinforced cellulose. The membrane pore size of >3 µm allows large proteins and aggregates to enter the macroporous structure achieving high binding capacity without size exclusion effects.

The membrane is rolled up to a cylinder with a bed height of 8 mm around a central solid core.

The miniaturized design of fluid channels reduce the void volume significantly. The recommended flow rate is 5 bed volumes per minute.

The internal support structures and the outer shell of the capsules are made from polypropylene.

Sartobind nano 3 ml is the recommended scale down model to start with. A 50 fold scale up device can be chosen with the 150 ml capsule and 1666 fold to the Jumbo.

The membrane geometry and the materials of construction are identical in all devices.

Applications

Polishing
– Aggregates
– Host cell proteins
– Viruses
– Endotoxins
– Lipids, dyes and anti foam agents
– Leached chromatography ligands

Capture
– Monoclonal antibodies
– Conjugated vaccines, viruses and phages
– Oligonucleotides

Benefits
– Binds aggregates and hydrophobic contaminants
– Designed for large scale flow through polishing as well as bind and elute chromatography
– 8 mm bed height for increased binding capacity
– Scale down model with Sartobind nano 3 ml with 8 mm bed height
– Cleaning in place with 1 N NaOH 1 h at 20°C
– Recommended flow rate of 5 bed volumes/min
– Easy and simple handling (like a filter)

Technical Data

Description	Sartobind Phenyl nano 3 ml	Sartobind Phenyl 150 ml	Sartobind Phenyl Jumbo 5 l
Order number	96HICP42EUC11--A	96HICP42E9BFF	96HICP42E3ESS
Shipment	4 × Sartobind Phenyl nano 3 ml, 2 Luer male to UNF 10–32 adapters PEEK, manual	Sartobind Phenyl 150 ml, manual, certificate	Sartobind Phenyl Jumbo 5 l, manual, certificate
Membrane material	Stabilized reinforced cellulose		
Ligand	Phenyl	Phenyl	Phenyl
Pore size	>3 µm	>3 µm	>3 µm
Bed height	8 mm	8 mm	8 mm
Bed volume	3 ml	150 ml	5 l
Nominal adsorption area	110 cm^2	5500 cm^2	18.2 m^2
Typical dynamic binding capacity10% per cm^2 Per ml Per device	0.4 mg IgG 14.6 mg IgG 44 mg IgG	0.4 mg IgG 14.6 mg IgG 2.2 g IgG	0.4 mg IgG 14.6 mg IgG 72.8 g IgG
Recommended flow rate	0.015 l/min	0.75 l/min	25 l/min
Void volume*	4 ml	0.2 l	7 l
Maximum pressure	0.4 MPa (4 bar, 58 psi)	0.4 MPa (4 bar, 58 psi)	0.3 MPA (3 bar, 44 psi)
Housing material	Polypropylene	Polypropylene	Polypropylene
Weight	10 g	400 g	16 kg dry, 20 kg wet, 23 kg filled
Connectors	Luer female	Sanitary 25 mm ¾"	Sanitary 50.5 mm 1 ½"
pH stability (short term)	2–14	2–14	2–14
pH stability (long term)	3–13	3–13	3–13

* Includes the porosity of the membrane which is approximately 80%

▶ Virosart® CPV MidiCaps

The 20 nm PESU Virus Filter for the Robust and Efficient Removal
of Small Non-Enveloped and Large Enveloped Viruses

Single-Use Technology

Description

Virus filtration with Virosart® CPV is an integral part of the orthogonal viral clearance technology platform of Sartorius Stedim Biotech. This orthogonal technology platform features virus filtration, virus inactivation and virus adsorption. Virosart® CPV targets the removal of both small non-enveloped viruses (20 nm) e.g. PPV, MVM and larger enveloped viruses (> 50 nm) e.g. MuLV from a biopharmaceutical feed stream.

Application & Positioning of Virosart® CPV

Virosart® CPV is being used at the end of the purification process for the virus filtration of the biopharmaceutical product. At this stage the purity of the biopharmaceutical product is the highest and virus filter blockage due to contaminants (DNA, CHOP, aggregates & lipoproteins) is the lowest.

Product Benefits

Virosart® CPV provides highest virus safety to the biopharmaceutical product. This filter retains more than 4 $\log_{10}$ of small non-enveloped viruses (e.g. PPV, MVM) and more than 6 $\log_{10}$ of large enveloped viruses (e.g. MuLV). Based on the unique double layer 20 nm PESU membrane, Virosart® CPV provides excellent flow rates and superior capacity. This filter offers highest virus safety over the entire flow decay profile of up to 90%.

Scalability

Scale down work is being realised using the Virosart® CPV Minisart (5 cm² capsule) to enable filtration work for flow and capacity studies as well as for GLP virus spiking studies. Scale up studies are being performed using Virosart® capsule and | or MidiCaps (180 cm² | 2.000 cm²) to reliably scale up into larger scale manufacturing. Large scale manufacturing is being operated with Virosart® CPV MaxiCaps® or cartridges. Typical batch sizes of products being subject to virus filtration with this Virosart® CPV MidiCaps are 5 to 50 liter.

Integrity Testing

Virosart® CPV MidiCaps are being tested for integrity using a water based integrity test with the Sartocheck® 4 technology of Sartorius Stedim Biotech. Virosart® CPV MidiCaps have been validated for 4 $\log_{10}$ removal of small non-enveloped viruses using bacteriophage PP7 as the model virus. Validation data is shown in the validation guide of Virosart® CPV.
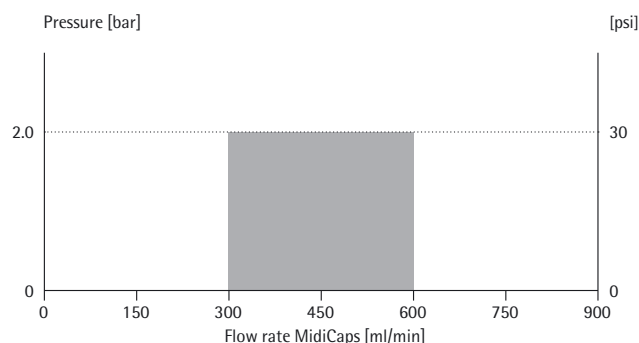
Quality Control

Each individual Virosart® CPV MidiCap is autoclaved and integrity tested during manufacture assuring highest product reliability.

Documentation

Virosart® CPV MidiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Characteristic Water Flow Rates for Virosart® CPV MidiCaps

▷ Specifications

Materials

Membrane	Double layer Polyethersulfone, symmetric
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
Capsule Housing	Polypropylene

Pore Size
CPV (20 nm nominal)

Available Sizes | Filtration Area

MidiCaps
Size 9   0.2 m² | 2 ft²

Available Connectors for Virosart® CPV MidiCaps

FF	¾" Tri-Clamp (Sanitary) inlet & outlet

Operating Parameters

In the direction of filtration	At 20°C (Capsules) max. 5.0 bar | 72.5 psi At 80°C max. 2.0 bar | 29 psi
In the reversed direction of filtration	20°C max. 0.2 bar | 2.9 psi

Extractables
Virosart® CPV filters meet, or exceed the requirements for WFI quality standards set by the USP 26

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization
Autoclaving:
121°C @ 1 bar | 14.5 psi for 30 min

No In-Line Steam Sterilization of Capsules!

Technical References
Validation Guide:
SPK5754-e | 85030-522-02

Brochure:
SPK1509-e | 85030-521-89

Virus Information Guide:
SPK5752-e | 85030-521-91

Order Information

	Pore Size	Pack Size	Test Pressure	Max. Diffusion
5455328V9--FF--V	CPV (20 nm nom.)	2 capsules/ box	4.5 bar | 65.2psi	10 ml/min/ capsule

▶ Virosart® CPV MaxiCaps® and Cartridges

The 20 nm PESU Virus Filter for the Robust and Efficient Removal
of Small Non-Enveloped and Large Enveloped Viruses

Single-Use Technology

Description
Virus filtration with Virosart® CPV is an integral part of the orthogonal viral clearance technology platform of Sartorius Stedim Biotech. This orthogonal technology platform features virus filtration, virus inactivation and virus adsorption. Virosart® CPV targets the removal of both small non-enveloped viruses (20 nm) e.g. PPV, MVM and larger enveloped viruses (> 50 nm) e.g. MuLV from a biopharmaceutical feed stream.

Application & Positioning of Virosart® CPV
Virosart® CPV is being used at the end of the purification process for the virus filtration of the biopharmaceutical product. At this stage the purity of the biopharmaceutical product is the highest and virus filter blockage due to contaminants (DNA, CHOP, aggregates & lipoproteins) is the lowest.

Product Benefits
Virosart® CPV provides highest virus safety to the biopharmaceutical product. This filter retains more than 4 $\log_{10}$ of small non-enveloped viruses (e.g. PPV, MVM) and more than 6 $\log_{10}$ of large enveloped viruses (e.g. MuLV). Based on the unique double layer 20 nm PESU membrane, Virosart® CPV provides excellent flow rates and superior capacity. This filter offers highest virus safety over the entire flow decay profile of up to 90%.

Scalability
Scale down work is being realised using the Virosart® CPV Minisart (5 cm² capsule) to enable filtration work for flow and capacity studies as well as for GLP virus spiking studies. Scale up studies are being performed using Virosart® capsule and | or MidiCaps (180 cm² | 2.000 cm²) to reliably scale up into larger scale manufacturing. Large scale manufacturing is being operated with Virosart® CPV MaxiCaps® or cartridges. Typical batch sizes of products being subject to virus filtration with Virosart® CPV MaxiCaps® and cartridges are ≥ 50 liter.

Integrity Testing
Virosart® CPV filters are being tested for integrity using a water based integrity test with the Sartocheck® 4 technology of Sartorius Stedim Biotech. Virosart® CPV filters have been validated for 4 $\log_{10}$ removal of small non- enveloped viruses using bacteriophage PP7 as the model virus. Validation data is shown in the validation guide of Virosart® CPV.
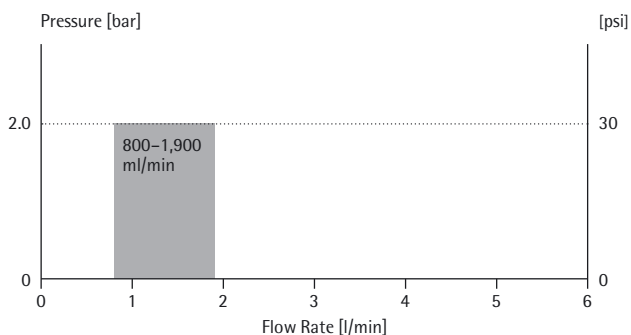
Quality Control
Each individual Virosart® CPV filter is autoclaved and integrity tested during manufacture assuring highest product safety.
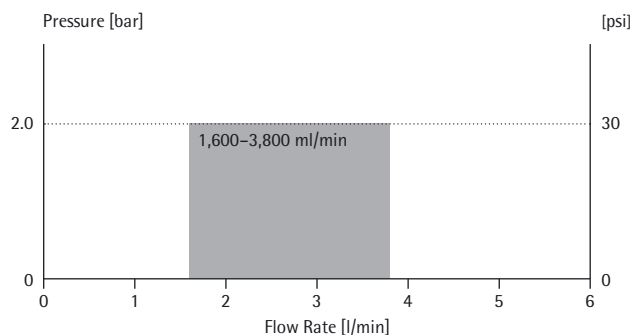
Documentation
Virosart® CPV filter capsules are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Characteristic Water Flow Rates for
Virosart® CPV 10" Standard Filter Cartridges & 10" MaxiCaps®

Pressure [bar]   [psi]

2.0 ········ 800–1,900 ml/min ········   30

0   0
  0   1   2   3   4   5   6
            Flow Rate [l/min]

Characteristic Water Flow Rates for
Virosart® CPV 20" Standard Filter Cartridges & 20" MaxiCaps®

Pressure [bar]   [psi]

2.0 ········ 1,600–3,800 ml/min ········   30

0   0
  0   1   2   3   4   5   6
            Flow Rate [l/min]

▷ Specifications

Materials

Membrane	Double layer Polyethersulfone, symmetric
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
Capsule Housing	Polypropylene

Pore Size
CPV (20 nm nominal)

Available Sizes│Filtration Area

MaxiCaps
Size 1	0.7 m^2│7 ft^2
Size 2	1.4 m^2│14 ft^2
Size 3	2.1 m^2│21 ft^2

Standard Filter Cartridges
Size 1	0.7 m^2│7 ft^2
Size 2	1.4 m^2│14 ft^2
Size 3	2.1 m^2│21 ft^2

Available Connectors
Sanitary for MaxiCaps® & code 7 for cartridges

Operating Parameters

In the direction of filtration	At 20°C (Capsules) max. 5.0 bar│72.5 psi At 80°C max. 2.0 bar│29 psi
In the reversed direction of filtration	20°C max. 0.2 bar│2.9 psi

Extractables
Virosart® CPV filters meet, or exceed the requirements for WFI quality standards set by the USP 26

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization
Steaming│Autoclaving:
121°C @ 1 bar│14.5 psi for 30 min

No In-Line Steam Sterilization of MaxiCaps®

Technical References
Validation Guide:
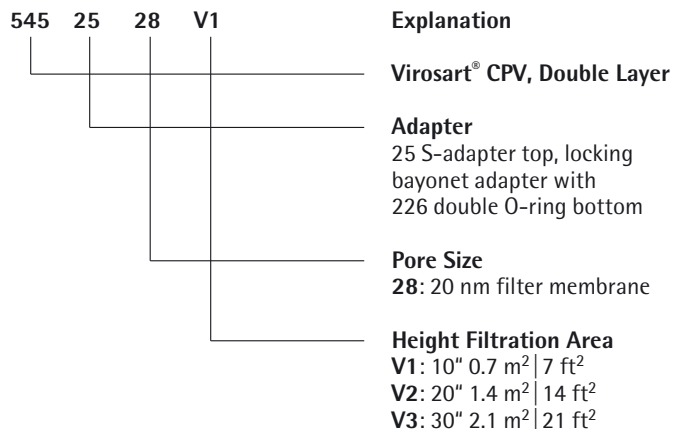SPK5754-e│85030-522-02
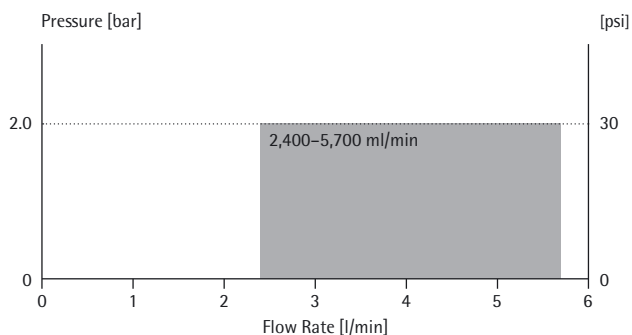
Brochure:
SPK1509-e│85030-521-89
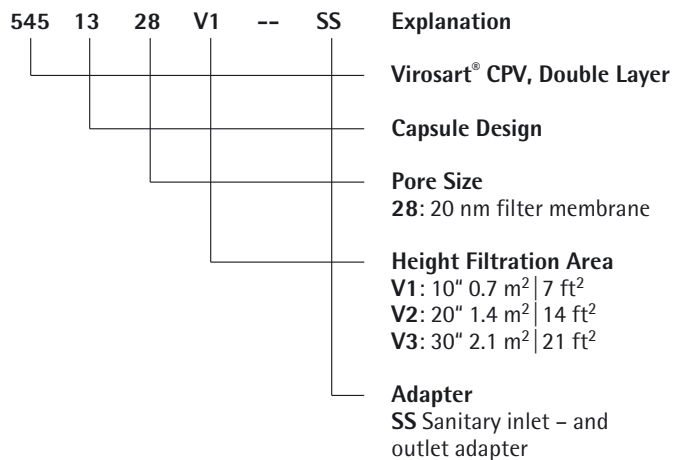
Virus Information Guide:
SPK5752-e│85030-521-91

Ordering Information Virosart® CPV Standard Filter Cartridges

545	25	28	V1	**Explanation**

Virosart® CPV, Double Layer

Adapter
25 S-adapter top, locking bayonet adapter with 226 double O-ring bottom

Pore Size
28: 20 nm filter membrane

Height Filtration Area
V1: 10" 0.7 m^2│7 ft^2
V2: 20" 1.4 m^2│14 ft^2
V3: 30" 2.1 m^2│21 ft^2

Characteristic Water Flow Rates for
Virosart® CPV 30" Standard Filter Cartridges & 30" MaxiCaps®

Ordering Information Virosart® CPV MaxiCaps®

545	13	28	V1	--	SS	**Explanation**

Virosart® CPV, Double Layer

Capsule Design

Pore Size
28: 20 nm filter membrane

Height Filtration Area
V1: 10" 0.7 m^2│7 ft^2
V2: 20" 1.4 m^2│14 ft^2
V3: 30" 2.1 m^2│21 ft^2

Adapter
SS Sanitary inlet – and outlet adapter

▶ ## UVivatec® Lab System

Virus Inactivation Based on UV-C Irradiation

Description
Virus inactivation with UVivatec® is an integral part of the orthogonal virus clearance technology platform of Sartorius Stedim Biotech. This orthogonal platform features virus filtration, virus inactivation and virus adsorption. UVivatec® shows efficient (> 4 log) inactivation of both small non-enveloped viruses (20 nm) e.g. PPV, MVM and larger enveloped viruses (> 50 nm) e.g. MuLV from biopharmaceutical feed stream by UV-C irradiation (254 nm) while maintaining product integrity.

Applications
Inactivation of viruses in

– Fermentation media

– Blood & plasma products

– Therapeutic proteins and | or Mabs

– Proteins | enzymes out of tissue extracts

– Vaccines

Features

– Novel helical reactor with optimized hydrodynamic design

– Uniform irradiation through efficient radial mixing based on dean vortices

– Narrow residence time distribution

– Exact control of irradiation dosage without over | under exposure

– Effective inactivation of viruses with sensitive product treatment

Scalability
Consistent and predictable scaling performance based on UV-C dose concept. The UVivatec® lab system has been designed for:

– Bench scale | Feasibility studies

– Spiking studies

– Pilot scale studies

– Process optimization

Small scale manufacturing can be performed in the UVivatec® GMP lab system.
Large scale manufacturing can be performed with the UVivatec® process system.

Technical Specifications

– Bench top system

– Irradiation intensity: 60 W/m^2

– 9W UV-C low-pressure mercury lamp (254 nm)

– Low pulsation peristaltic pump

– Operating flow rate with aqueous systems 6 – 20l/h

– Process control with touch-sensitive panel

– UV-C sensor

– Pressure sensor

– Flow meter

– Serial interface for connection to Windows-PC

– Level sensor for leakage monitoring

– MS-Windows compatible software for data control and recording (optional)

▷ Specifications

External dimensions (W × H × D)	600 × 875 × 400 mm
Weight	approx. 61 kg
Operating voltage	100 ... 240 VAC
Input frequency	45 ... 65 Hz
Current consumption	0.52 A (110 VAC | 60 Hz) 0.32 A (230 VAC | 50 Hz)
Control voltage	24 V DC
Adjustable pump volume	6 ... 20 l/h
Adjustable pump rate	2 ... 20 l/h
Operational flow rate	6 ... 20 l/h
Dead volume	< 100 ml
Pump speed	max. 100 rpm
Hose dimensions	∅ 4.8 mm inside Wall thickness 2.4 mm
Lamp power	9 W
Wavelength	254 nm
UV sensor work range	4 ... 20 mA = 0 ... 9 W/m^2
Max. operating pressure	< 2 bar

Accessories

Modules
Scalable UVivatec® lab modules with helically designed PTFE channel lined with quartz glass for single-use.

Software
UVivatec® lab monitoring software for online data collection (optional).

Ordering Information
UVivatec® lab system:
UVCLABSYSTEM

UVivatec® lab module:
UVCLABMODULE

UVivatec® lab software:
UVCLABSOFTWARE

UVivatec® lab spare part UV-C lamp:
UVCLABLAMP

▶ UVivatec® GMP Lab System

Virus Inactivation Based on UV-C Irradiation

Description

Virus inactivation with UVivatec® is an integral part of the orthogonal virus clearance technology platform of Sartorius Stedim Biotech. This orthogonal platform features virus filtration, virus inactivation and virus adsorption. UVivatec® shows efficient (> 4 log) inactivation of both small non-enveloped viruses (20 nm) e.g. PPV, MVM and larger enveloped viruses (> 50 nm) e.g. MuLV from biopharmaceutical feed stream by UV-C irradiation (254 nm) while maintaining product integrity.

Applications

Inactivation of viruses in

– Fermentation media

– Blood & plasma products

– Therapeutic proteins and│or Mabs

– Proteins│enzymes out of tissue extracts

– Vaccines

Features

– Novel helical reactor with optimized hydrodynamic design

– Uniform irradiation through efficient radial mixing based on dean vortices

– Narrow residence time distribution

– Exact control of irradiation dosage without over│under exposure

– Effective inactivation of viruses with sensitive product treatment

Scalability

Consistent and predictable scaling performance based on UV-C dose concept. The UVivatec® lab system has been designed for:

– Bench scale│Feasibility studies

– Spiking studies

– Pilot scale studies

– Process optimization

Small scale manufacturing can be performed in the UVivatec® GMP lab system. Large scale manufacturing can be performed with the UVivatec® process system.

Technical Specifications

– Bench top system

– GMP compliant design

– System for small scale manufacturing

– Irradiation intensity: 60 W/m2

– 9W UV-C low-pressure mercury lamp (254 nm)

– Low pulsation peristaltic pump

– Operating flow rate with aqueous systems 6 – 20l/h

– Process control with touch-sensitive panel

– UV-C sensor

– Pressure sensor

– Flow meter

– Level sensor for leakage monitoring

– Serial interface for connection to Windows-PC

– Extra splitter ports for direct signal transfer to PCS

– GMP documentation package and qualification support

– MS-Windows compatible software for data control and recording (optional)

▷ Specifications

External dimensions (W × H × D)	600 × 875 × 400 mm
Weight	approx. 61 kg
Operating voltage	100 ... 240 VAC
Input frequency	45 ... 65 Hz
Current consumption	0.52 A (110 VAC | 60 Hz) 0.32 A (230 VAC | 50 Hz)
Control voltage	24 V DC
Adjustable pump volume	6 ... 20 l/h
Adjustable pump rate	2 ... 20 l/h
Operational flow rate	6 ... 20 l/h
Dead volume	< 100 ml
Pump speed	max. 100 rpm
Hose dimensions	$\varnothing$ 4.8 mm inside Wall thickness 2.4 mm
Lamp power	9 W
Wavelength	254 nm
UV sensor work range	4 ... 20 mA = 0 ... 9 W/m^2
Max. operating pressure	< 2 bar

Accessories

Modules
Scalable UVivatec® lab modules with helically designed PTFE channel lined with quartz glass for single-use.

Software
UVivatec® lab monitoring software for online data collection (optional).

Ordering Information
UVivatec® GMP lab system:
UVCGMPLABSYSTEM

UVivatec® lab module:
UVCLABMODULE

UVivatec® lab software:
UVCLABSOFTWARE

UVivatec® lab spare part UV-C lamp:
UVCLABLAMP

▶ UVivatec® Modules

Disposable Modules for UVivatec® Systems

Single-Use Technology

Description

Virus inactivation with UVivatec® is an integral part of the orthogonal virus clearance technology platform of Sartorius Stedim Biotech. This orthogonal platform features virus filtration, virus inactivation and virus adsorption. UVivatec® shows efficient (> 4 log) inactivation of both small non-enveloped viruses (20 nm) e.g. PPV, MVM and larger enveloped viruses (> 50 nm) e.g. MuLV from biopharmaceutical feed stream by UV-C irradiation (254 nm) while maintaining product integrity.

Applications

Inactivation of viruses in

– Fermentation media

– Blood & plasma products

– Therapeutic proteins and│or Mabs

– Proteins│enzymes out of tissue extracts

– Vaccines

Features

– Novel helical reactor with optimized hydrodynamic design

– Uniform irradiation through efficient radial mixing based on dean vortices

– Narrow residence time distribution

– Disposable concept

– Quick and simple to install and replace

Scalability

Consistent and predictable scaling performance based on UV-C dose concept. Bench top and spiking studies can reliably be performed using UVivatec® lab modules. They feature the identical design and flow performance like the UVivatec® process modules for large scale production. Small scale manufacturing can be realised with the UVivatec® lab modules.

Quality Control

Each individual module is tested for flow through, leakage and UVC transparency before release assuring absolute reliability.

▷ Specifications

Materials

Outer channel	PTFE
Inner channel	Quartz Glass
End Caps	PVDF
O-Rings	Silicone

Available Sizes │ Module Volume

Lab module	~ 24 ml
Process module	~140 ml

Operating Parameters

Flow Rates
UVivatec® lab module	6 – 20 l/h
UVivatec® process module	30 –120 l/h

Extractables
UVivatec® modules meet the requirements of USP Plastic Class VI.

Non-pyrogenic according to USP bacterial endotoxins.

UVivatec® modules meet, or exceed the requirements for WFI quality standards set by the current USP.

Ordering Information
UVivatec® lab module:
UVCLABMODULE

UVivatec® process module:
UVCPROMODULE

▶ UVivatec® Process System (Customized)

Virus Inactivation Based on UV-C Irradiation

Description

Virus inactivation with UVivatec® is an integral part of the orthogonal virus clearance technology platform of Sartorius Stedim Biotech. This orthogonal platform features virus inactivation, virus adsorption and virus filtration. UVivatec® shows efficient (> 4 log) inactivation of both small non-enveloped viruses (20 nm) e.g. PPV, MVM and larger enveloped viruses (> 50 nm) e.g. MuLV from biopharmaceutical feed stream by UV-C irradiation (254 nm) while maintaining product integrity.

Applications

Inactivation of viruses in

– Fermentation media

– Blood & plasma products

– Therapeutic proteins and|or MAbs

– Proteins|enzymes out of tissue extracts

– Vaccines

Features

– Novel helical reactor with optimized hydrodynamic design

– Uniform irradiation through efficient radial mixing based on dean vortices

– Narrow residence time distribution

– Exact control of irradiation dosage without over|under exposure

– Effective inactivation of viruses with sensitive product treatment

– Full automation

– Single or multi-modular design

– Single-use module concept

Scalability

Consistent and predictable scaling performance based on UV-C dose concept. The UVivatec® lab system has been designed for:

– Bench scale|Feasibility studies

– Spiking studies

– Pilot scale studies

– Process optimization

Small scale manufacturing can be performed in the UVivatec® GMP lab system.
Large scale manufacturing can be performed with the UVivatec® process system.

▷ Specifications

Technical Specifications
Customized process scale system for virus inactivation based on UV-C irradiation at 254 nm wavelength.

Systems for one or several UVivatec® process modules according to process requirements.

– Customized process scale system based on process requirements

– GMP compliant design

– Irradiation intensity per lamp | module: 194 W/m²

– 30 W UV-C low-pressure mercury lamp

– Operating flow rate with aqueous systems 30 to 120 l/h per module

– High-grade finished piping

– Solenoid valves

– Linear drive for UV lamp

– Rotary lobe pump

– Process control system with touch screen panel

– Position sensing for UVivatec® process module or dummy installation

– Mass flow control

– UV, air, pressure, temperature and conductivity sensor

– Level sensor for leakage monitoring

– Paperless recorder for documentation (FDA 21 CFR Part 11 compliant)

Accessories

Modules
Scalable UVivatec® process modules with helically designed PTFE channel lined with quartz glass for single-use.

Ordering Information
UVivatec® process system:
Project based

UVivatec® process module:
UVCPROMODULE

UVivatec® process spare part UV-C lamp:
UVCPROLAMP

▶ FlexAct® VI

Disposable Solution for Low pH Virus Inactivation

Single-Use Technology

Description
The FlexAct® VI is a standardized configurable disposable solution (CDS) dedicated to low pH virus inactivation steps in biopharmaceutical processes. The FlexAct® VI addresses the entire development cycle and production capacity needs from 30 to 650 L for low pH virus inactivation. The integration of monitoring & control features for pH, temperature, pressure, pump speed and fluid level control is a further milestone for the implementation of process relevant single-use equipment. The integrated control while pH adjustment, incubation and neutralization steps allows end-users to perform other tasks during the low pH virus inactivation operation. Combined with a Flexel® Palletank® for LevMixer®[1] and Palletanks® the multifunctional Central Operating Module enables the user the install, operate and monitor a fully single-use unit operation.

Features
– Multifunctional Central Operating Module
– Configurable system configurations
– 30 – 650 L working volumes
– Quick system set-up
– Integrated disposable sensors (p, pH, T)
– Controlled pH adjustment by FlexAct® DCU

Benefits
– Operator friendly
– One and two step operation available
– Fully scalable
– Efficient equipment utilization
– Enables monitoring
– Highly flexible

Components
The FlexAct® VI configurable low pH virus inactivation solution consists of:

– Flexel® Palletank® for LevMixer®
– Weighing platforms or Palletanks® for LevMixer® with load cells
– FlexAct® COM Central Operating Module with accessories
– Acid | Base peristaltic dosing pumps for controlled pH adjustment
– Bag assembly configurations with Palletanks®

1. Flexel® Palletank® for LevMixer®
The Flexel® Palletank® for LevMixer® includes

Palletank® for LevMixer® available in 50 L, 100 L, 200 L, 400 L and 650 L volumes LevMixer® drive unit

1.1. Palletank® for LevMixer® is a stainless steel cubical container designed to perfectly fit with the Flexel® Bag for LevMixer® with its integrated impeller. It includes a railed port for coupling the mobile Drive Unit with the Flexel® Bag for LevMixer®. For reliable fluid level control the Palletanks® for LevMixer® are optionally equipped with in-house load cells. The hinged door allows easy installation of the bag assembly whereas the front bottom gate facilitates easy tubing installation and access. Windows on lateral sides enable the user to visually control the mixing process. The cubical shape improves the mixing efficiency and offers scalability from 50 L to 650 L.

1.2. The LevMixer® Drive Unit generates the levitation and rotation of the single-use magnetic impeller without surface contact. This allows the Flexel® for LevMixer® to efficiently mix powders, suspensions, solutions or emulsions. The LevMixer® drive unit is mobile, cart-mounted and designed to interface with Palletanks® for LevMixer® of different volumes. The LevMixer® drive unit operates independently of the cubical tank with the Flexel® mixing bag so that a single LevMixer® drive unit can serve multiple Palletanks® of different sizes. Flexel® Bags for LevMixer® for FlexAct® VI operations are available in standard configurations.

2. Weighing Platforms
The IFS4 flat-bed scales are entirely constructed of stainless steel and have an extremely low height, making it ideally suited for floor installation without a pit or anchoring. The ramp is securely attached to the scale using special retainers for prevention of force shunt. This high-quality platform can be connected to any of a wide range of indicators, for use as a Class III legal measuring instrument or without legal verification. The CIS1 Combics 1 indicator allows strain gauge weighing with flat bad scales as well as with load cells to be connected.

3. FlexAct® COM Central Operating Module with Accessories
The FlexAct® COM Central Operating Module is designed for operational excellence in low pH virus inactivation processes. It features multiple work platforms that incorporate process equipment and user friendly monitoring & control capabilities. The integrated control instrumentation together with an ergonomically positioned 10" LCD touch screen enables the operator to have an overview about the main process parameters values such pressure, pH and temperature of the Protein A eluate whilst pH adjustment, incubation, neutralization and filtration. For secure fluid level management a weight signal is provided by either load cells that are integrated into the LevMixer® Palletanks® or floor scales provided individually. The three level Central Operating Unit is able to accommodate multiple process devices required in a single-use process environment. Depending on the process needs, thermal welding and sealing provided by the BioWelder® and BioSealer® as well as filter integrity testing by using a Sartocheck® 4 integrity tester will help to quick connect and test assemblies.

3.1 Sartocheck® 4 plus
Filter Integrity Testing is an essential procedure to detect defective filter cartridges before or after use. Thus automatic integrity testers have to fulfil highest standards with respect to accuracy and reliability. The Sartocheck® 4 plus is the result of Sartorius' 30 years experience in developing automatic filter integrity testers. Valuable productivity enhancing features and robust build quality have been combined with incredible ease of use to make the Sartocheck® 4 plus the only logical choice for integrity testing.

3.2 BioWelder® and BioSealer®
Sterile Fusing and Sealing of thermoplastic tubing are key technologies that offer most flexibility to the end users that are interested in getting a solution for multiple connection and disconnection cycles. Sartorius' BioWelder® and BioSealer® are devices that meet these requirements set by the industry. The ability of assuring quick and reliable connections and disconnections combined with the expertise of Wave Biotech Switzerland made BioWelder® and BioSealer® to the product of choice in the biopharmaceutical industry.

4. Acid|Base Peristaltic Dosing Pumps for Controlled pH Adjustment
Watson Marlow peristaltic pumps WM 520 are preconfigurated for automated acid and base dosing. The pump provides a 0.1% set speed accuracy at 220 rpm giving flow rates from 4 µl/min to 3.5 litre/min. It provides precision dosing and metering, and excellent, uninterrupted batch consistency.

5. Bag Assemblies with Palletank® for LevMixer® for Quick pH Adjustment and Incubation and Palletanks® for Intermediate mAb Solution Storage
FlexAct® VI bag assemblies are supplied to serve the need of a fully preconfigured, ready to install, single-use unit operation. Uniquely, the Flexel® Bag for LevMixer® and Flexel® 3D Bioprocessing Bags are supplied in one package.

The Flexel® Bag assemblies for LevMixer® contains a centred magnetic impeller. Its unique sided K-weld design simplifies installation and facilitates the unfolding and folding of the bag during filling and draining operations. The patented protection cap provides robustness avoiding frictions of the impeller with the film during transport and before bag use. It also offers a large 8" diameter port for powder transfer and allows for continuous mixing during fluid transfer operations and minimizes hold up volume for 100% fluid recovery. The storage bag assemblies of the FlexAct® VI Configurable Disposable Solution are tailored to suit the dedicated need for individual mAb solution volumes at the point of use. The Palletank® for Storage or for In-Process Handling are stainless steel container designed to perfectly fit with the Flexel® 3D bioprocessing bag assemblies.

FlexAct® Configurator
A configurator based selection system enables the user to flexibly create the FlexAct® VI solution that meets its process requirements in buffer preparation. All components included in the configurator are standardized components that ensure highest performance, shortest lead times and highest quality. The following Configurable Disposable Solutions will gradually complete the FlexAct® family:

Unit Operation	FlexAct® Configurable Disposable Solutions
Buffer Preparation	FlexAct® BP
Virus Inactivation	FlexAct® VI
Cell Harvest	FlexAct® CH
Media Preparation	FlexAct® MP
Virus Filtration	FlexAct® VR
Ultrafiltration|Diafiltration	FlexAct® UD
Polishing	FlexAct® PO
Form & Fill	FlexAct® FF
Form & Transfer	FlexAct® FT

Ease of Use

The primary driver behind the FlexAct® initiative is the development of disposable equipment which meets all process operations improving efficiency and speed. Sartorius Stedim specialists have analyzed the process environment and the operating procedure for low pH virus inactivation thoroughly and developed an operator friendly multifunctional Central Operating Unit. Tailored bag configurations with 30 L up to 650 L working volumes offer flexible solutions at full scalability. The system set-up is performed within minutes and needs less preparation time compared with existing solutions. Once the operation is performed, the system can be as fast rigged-off without the needs of tedious cleaning requirements. Set-up and rig-off ease allow for more efficient and faster equipment utilization adding to the overall process capacities. The monitoring on a 10" touch screen of all main process parameter is easily enabled by integrated disposable sensors.

Validation

Flexel® Bag for LevMixer® and Flexel® 3D Bioprocessing Bags have been qualified applying the most stringent and current test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® Bag for LevMixer® and Flexel® 3D Bioprocessing Bags with data representing the widest range of process fluids in a variety of processing conditions. Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

Flexel® Bag for LevMixer® and Flexel® 3D Bioprocessing Bags are tested for compliance to:
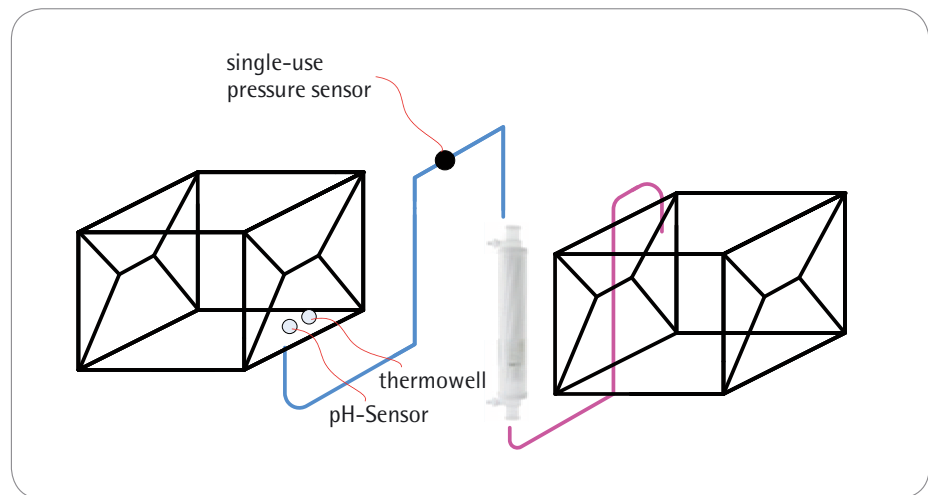
– USP <87>: Biological reactivity tests, in Vitro

– USP <88>: Biological reactivity tests, in Vivo

– USP <661>: Tests for plastic

– USP <788> and E.P. 2.9.19: Particulate

– ISO 11737: Bioburden

– ISO 11137: Sterilization of Medical Devices

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes and state-of-the-art utilities. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a flexible and robust supply chain that can cope with strong market growth.
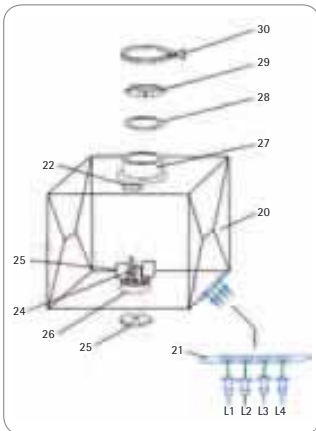

The schematic above shows the bag assemblies connected

▷ Specifications
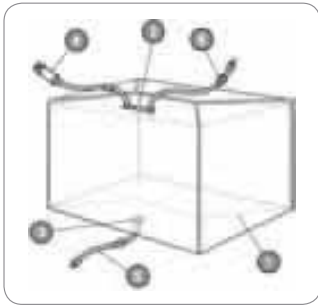
1. LevMixer® Drive Unit

Power:	
EU	Single Phase 230 V, 50 │ 60 Hz
USA	Single Phase 110 V, 60 Hz
Japan	Single Phase 230 V, Transformer (110 V Input), 50 │ 60 Hz
Input Wattage	< 350 Watts
Footprint	37 inches +16 inches (94 cm + 41 cm)
Weight	103 lb (47 kg)
Ambient Temperature	4° to 30℃
Ambient Humidity	Less than 75%
Mobility	Mounted on Stainless Cart with Four Clean Room Wheels and Push Handles
IP Rating	IP23
Impeller Speed	0–180 RPM
Initial Set-up Time	45 Minutes
Vessel Changeover Time	< 7 Minutes
CE Mark	Compliant
Material for External Surfaces	Stainless Steel #316L

2. FlexActl® VI Bag Assemblies

2.1. Flexel® Bags for LevMixer®

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, ULDPE Contact Layer
Impeller position	Centered
Impeller size	50–100 L: 4.95″ (126 mm) 200–650 L: 6.35″ (161 mm)
Tubing material	Silicone
Number of Ports	2-top port, 4 front bottom ports, 1 powder port
pH probe	Single-use glass pH electrode
Thermowell	Silicone thermowell for T probe PT element (reusable)
Fittings	Tri-clamp, Quick Connector, Luer Lock female with needle free sampling port
Volumes	50 L, 100 L, 200 L, 400 L, 650 L
Sterilization	by Gamma Irradiation

2.2. Flexel® 3D Bioprocessing Bag for Storage

Bag Chamber	Multiple Film Construction, including EVOH gas barrier layer, ULDPE Contact Layer
Tubing material	C-Flex®, Silicone
Number of Ports	2 top ports, 1 bottom port
Filter	Sartopore® 2 gamma MidiCaps®	MaxiCaps®
Fittings	Tri-clamp, Luer Lock female female with needle free sampling port
Volumes	50 L, 100 L, 200 L, 500 L, 1000 L
Sterilization	by Gamma Irradiation

2.3 Sartopure® GF plus prefilters

The chemical reaction of protein A eluate with acid and base during the low pH inactivation steps results in a forming of hydrolysates. Therefor a prefiltration step in front of the sterilizing grade filter is indicated. Sartopure® GF Plus absorptive depth filter are designed for removal of contaminates like colloids, lipids, protein aggregates (Host Cell Protein) and particles from biopharmaceutical fluids. They are used for protection of membrane filters, chromatography columns, ultrafiltration systems in pharmaceutical and biotechnological production processes.

Cost Saving

The efficient protection of downstream membrane filters and purification equipment saves filter costs and helps to increase the yield of biotech production processes. Moreover, the use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

Flexibility

Sartopure® GF Plus MaxiCaps are available with various filtration areas from 0.4 m² | 4 ft² up to 1.6 m² | 18 ft² for easy adoption to any filtration process independent from the batch size.

Scalability

Consistent and predictable scale-up and down trials can reliably be performed as all Sartopure® GF Plus filter elements are produced with the same type of membrane and identical materials of construction.

Documentation

Sartopure® GF Plus MaxiCaps are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Volume (L)	Prefilter type Sartopure® GF plus 0.65 µm	Prefilter type Sartopure® GF plus 1.2 µm	Height
50	5551305P1--SS	5551303P1--SS	10"
100	5551305P1--SS	5551303P1--SS	10"
200	5551305P2--SS	5551303P2--SS	20"
400	5551305P3--SS	5551303P3--SS	30"
400	2 × 5551305P2--SS	2 × 5551303P2--SS	2×20"
650	2 × 5551305P3--SS	2 × 5551303P3--SS	2×30"

3. Palletank®

3.1 For LevMixer® w/ or w/o load cells

Material	304 L Stainless Steel
Surface Finish	Glass Bead Blasted
Door	Front Hinged Door
Windows	Plexiglass
Ports	Railed port for drive unit Front bottom port for bag line access

Volume (L)	Dimensions (W × D × H)	Weight (kg) Palletank®
50	825 × 570 × 1,051	43
100	825 × 570 × 1,126	49
200	775 × 699 × 1,250	63
400	921 × 824 × 1,345	88
650	1,040 × 930 × 1,500	103
1,000	1,090 × 1,120 × 1,650	156

3.2. Palletank® for Storage

Material	304 L Stainless Steel
Surface Finish	Glass Bead Blasted
Stackable	3 (50 – 200 L) 2 (500 L)
Option	Dolly

Volume (L)	Dimensions (W × D × H)	Weight (kg) Palletank®
50	490 × 490 × 750	24
100 │ 200	789 × 592 × 891	35
500	1192 × 792 × 1010	92
1,000	1260 × 1060 × 1443	145

4. FlexAct® VI Central Operating Module

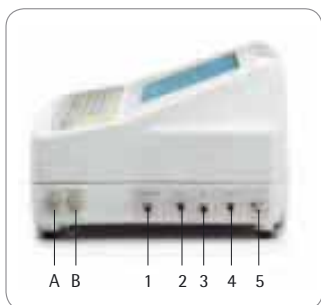|	
Material	316 L Stainless Steel
Surface Finish	Optional: – Powder coated │ colour – Glass Bead Blasted, electropolisheded
Dimensions (W × D × H)	795 × 1410 × 1500 mm (31.3 × 55.51 × 59.06 inch)
Weight (approx.)	160 kg (352.74 lbs) (incl. Watson Marlow pump)
Control Unit	– Control unit with 10.4" touch screen

Pump

Watson Marlow	720UN │ R
Specification	IP66 0.1 – 360 rpm
Pumphead	720R pumphead, 4 roller pumphead for maximum 2 bar. Accepts continuous tubing only (includes continuous tube clamp set)

BioWelder®

Power requirements	100 – 240 V │ 47 – 63 Hz
Dimensions	300 × 300 × 220 mm
Weight	0.5 kg
Housing	stainless steel
Interface	RS232 for printer
Blade	Cr-Ni-Alloy, single-use
Ambient temperature	20°C – 30°C (ideal: 22°C)
Relative Humidity	20% – 80% (ideal: 60%)
Temperature Sensor	Type K, calibration holder available
Max. Tube OD	3/4"
Min. Tube OD	1/4"
Welding Cycle	60 – 90 sec. depending on tube dimension
Standard settings for	C-Flex®, PHARMED® BPT, Sanipure® 60

BioSealer®

Power requirements	100 – 240 V │ 47 – 63 Hz
Dimensions	220 × 150 × 210 mm
Weight	3.0 kg
Housing	stainless steel
Compression head	Aluminum anodised
Ambient temperature	20°C – 30°C
Relative Humidity	35% – 65%
Max. Tube OD	3/4"
Min. Tube OD	1/4"
Sealing Cycle	1 – 4 minutes depending on tube size and quality
Tubing Types	Soft ThermoplasticTubing, (e.g. C-Flex®, SaniPure® 60 and Pharmed® BPT)

1: ext. reference tank
2: Venting 1
3: Out
4: Venting 2
5: Compressed Air In
A: external sensor
B: external valves

1: main switch
2: SD card reader
3: Serial Port TU
4: PLC Port
5: RJ45 Network
6: connection for optional
    barcode scanner

Sartocheck® 4 plus

Power requirements	100 – 240 V AC, 50 │ 60 Hz
Maximum power input	74 watts
Maximum operating pressure	9999 mbar │145 psi
Minimum inlet pressure	4000 mbar │58 psi
Dimensions (W × D × H1 × H2)	460 × 390 × 140 × 245

Measuring ranges:

Test pressure	100 – 8000 mbar │1.5 – 116 psi
Pressure drop	1 – 2000 mbar │0.01 – 29 psi
System inlet volume – with internal ref. Vessel – with external ref. Vessel max.	14 L 150 L

Measuring accuracy:

Pressure	± 0.1% full scale
Pressure drop	± 1 mbar │0.015 psi
Volume determination	± 4%
Diffusion	± 5%
Water-Intrusion	± 5%
Bubble Point	± 50 mbar │± 0.7 psi

Operating conditions:

Ambient temperature	+15°C to +35°C
Rel. humidity	10 – 80%

Touch Screen:

Size	10.4" TFT
Features	256 colors

Comunication Ports:

Serial Port	TU RS232
Serial Port	MU RS485
PLC Port	binary signals 12 pins
Network	RJ45

Language option:

	English
	German
	French
	Spanish
	Italian

5. IFS Flat-Bed Scales

5.1 IFS4-300LI-I

Weighing capacity	300 kg
Platform size	1000 × 800
Height	standard
Load plate	AISI304 │ 1.4301V2A bead-blasted
Resolution	30.000 d
Readability	10 g

5.2 IFS4-1500NN-I

Weighing capacity	1,500 kg
Platform size	1250 × 1250
Height	standard
Load plate	AISI304 │ 1.4301V2A bead-blasted
Resolution	30.000 d
Readability	50 g

5.3 Combics CIS1 – Scale Indicator
Indicators for complex weighing tasks in 4 different versions.

Max. readability	31.250 digits
IP protection rate	IP67 (PG cable gland), IP44 (25-pol. D-SUB), (IP65 as option)

6. Acid│Base Peristaltic Dosing Pump

WM 520U│R2

Specification

Weight	9.6 kg
Operational Temperature Range	5°C to 40°C
Noise	< 70 dBd(A) at 1 m
Control Ratio	2200:1
Standards	CE, C ETL US
Supply	110 V│230 V 1ph, 50│60 Hz

Materials of Construction

Drive Casework	Pressure die-cast aluminium LM24
Casework Coating	Alocrom pre-treatment, exterior grade polyester powder coat
Keypad	Polyester
Switch Plate	Glass filled ABS plastic
Rear Blanking Plate	Stainless Steel 304
Gearbox Nose	Aluminium LM24M
Drive Shaft	Electroless nickel plated carbon steel

Flow Rate Ranges (ml/min) — **Tube Bore and Flow Rates (ml/min)**

Tube Material	Speed	0.5 mm	0.8 mm	1.6 mm	3.2 mm	4.8 mm	6.4 mm	8.0 mm	9.6 mm
Neoprene, Sta-Pure, Chem-Sure, Tygon, Platinum-cured silicone	0.1 to 220 rpm	0.004–9.5	0.01–24	0.04–97	0.18–390	0.40–870	0.70–1500	1.1–2400	1.6–3500
Marprene│Bioprene TL	0.1 to 220 rpm	0.004–9.0	0.01–23	0.04–92	0.17–370	0.38–830	0.67–1500	1.1–2300	1.5–3500

276
158
150
All dimensions in mm

385
80
238
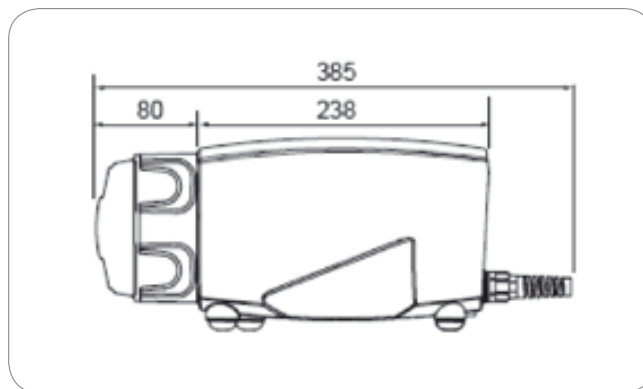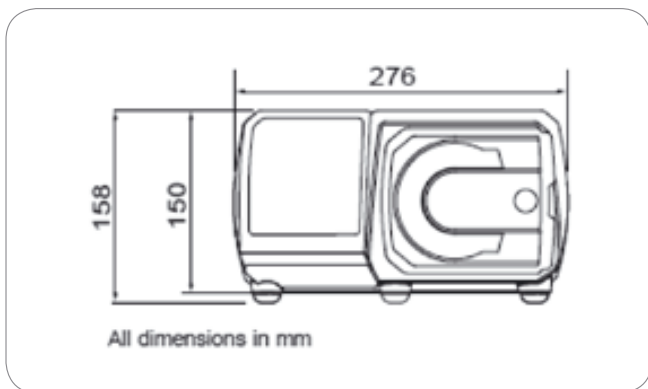
Ordering Information

1. Flexel® 3D Palletank®

1.1 Palletank® for LevMixer® – without load cells

Order Number	Palletank® for LevMixer® w/o Load Cells
FXC110820	Palletank® 50 L for Impeller Mixing
FXC112230	Palletank® 100 L for Impeller Mixing
FXC110821	Palletank® 200 L for Impeller Mixing
FXC111135	Palletank® 400 L for Impeller Mixing
FXC110822	Palletank® 650 L for Impeller Mixing

1.2 Palletank® for LevMixer® – with load cells

Order Number	Palletank® for LevMixer® w/ Load Cells and Combics 1 Controller
FXC114153	Palletank® 50 L for Impeller Mixing with load cells and CIS1 Combics controller
FXC114154	Palletank® 100 L for Impeller Mixing with load cells and CIS1 Combics controller
FXC114155	Palletank® 200 L for Impeller Mixing with load cells and CIS1 Combics controller
FXC114156	Palletank® 400 L for Impeller Mixing with load cells and CIS1 Combics controller
FXC114157	Palletank® 650 L for Impeller Mixing with load cells and CIS1 Combics controller

1.3 Spare parts for Palletank® for LevMixer®

Order Number	Spare Parts LevMixer® Palletank®
FXA112559	Clamp Holder for Palletank® 50 L for Impeller Mixing
FXA112560	Clamp Holder for Palletank® 100 L for Impeller Mixing
FXA112083	Clamp Holder for Palletank® 200 L for Impeller Mixing
FXA112086	Clamp Holder for Palletank® 400 L for Impeller Mixing
FXA112085	Clamp Holder for Palletank® 650 L for Impeller Mixing
FXA112074	Adaptation Set for Palletank® for Impeller Mixing

1.4 Palletank® for storage (50-650 L) │ in-process handling (1000 L)

Order Number	Palletank®
FXC113946	Palletank® 50 L for storage stackable
FXA113988	Dolly for Palletank® 50 L (storage)
FXC110733	Palletank® 100 L for storage stackable
FXS102254	Dolly for Palletank® 100 L│200 L (storage & shipping)
FXC110733	Palletank® 200 L for storage stackable
FXS102254	Dolly for Palletank® 100 L│200 L (storage & shipping)
FXC110734	Palletank® 500 L for storage stackable
FXC100734	Dolly for Palletank® 500 L (storage & shipping)
FXC106223	Palletank® 1000 L for in-process fluid handling
FXS102259	Dolly for Palletank® 1000 L for in-Process fluid handling

1.5 Floor Scales (Flat bed scales)

Part Number	Platform Dimensions (mm)	Weighing Capacity	Readability	Load Plate	Dust│Water Protection
IFS4-300LI-I floor scale (flat bed scale)	1000 × 800	300 kg	10 g	AISI304 │ 1.4301 V2A bead-blasted	IP67│IP68
IFS4-1500NN-I floor scale (flat bed scale)	1250 × 1250	1500 kg	50 g	AISI304 │ 1.4301 V2A bead-blasted	IP67│IP68

2. LevMixer® Drive Unit

2.1 LevMixer® Drive units for Flexel® for LevMixer® 50 L – 400 L

Part Number	Description
LT–DBTL002	Superconducting drive machine for US and Canada on cart with two latches for 8" and 15" ports. Control panel (110 V) and US lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL003	Superconducting drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) Europe and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL004	Superconducting drive machine with European certification on cart with two latches for 8" and 15" ports. Control panel (220 V) Europe and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL005	Superconducting drive machine with European certification on cart with UK-Plug and two latches for 8" and 15" ports. UK Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT–DBTL010	Superconducting drive machine with European certification on cart with Australian plug and two latches for 8" and 15" ports. Australia Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.

2.2 LevMixer® Drive units for Flexel® for LevMixer® 50 L – 650 L

Part Number	Description
LT-DBTL006	Superconducting drive machine for US and Canada on cart with three latches for 8", 15" and 20" ports. Control panel (110 V) US and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL007	Superconducting drive machine with European certification on cart with three latches for 8", 15" and 20" ports. Europe Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL008	Superconducting drive machine with European certification on cart with three latches for 8", 15" and 20" ports. Japan Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories. Includes Japanese transformer.
LT-DBTL009	Superconducting drive machine with European certification on cart with UK-Plug and three latches for 8", 15" and 20" ports. UK Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.
LT-DBTL011	Superconducting drive machine with European certification on cart with Australian plug and three latches for 8", 15" and 20" Australia ports. Control panel (220 V) and lifting mechanism on handle and welded body. Includes tool kit with accessories.

2.3 Spare Parts

Part Number	Description
FXA112559	Clamp Holder for Palletank® 50 L for Impeller Mixing
FXA112560	Clamp Holder for Palletank® 100 L for Impeller Mixing
FXA112083	Clamp Holder for Palletank® 200 L for Impeller Mixing
FXA112086	Clamp Holder for Palletank® 400 L for Impeller Mixing
FXA112085	Clamp Holder for Palletank® 650 L for Impeller Mixing
FXA113527	Clamp Holder for Palletank® 1000 L for Impeller Mixing

2.4 Combics CIS1 – Scale indicator

Combics 1 scale indicator, stainless steel housing, IP44	CISL1
Combics 1 plus scale indicator, stainless steel housing, IP44	CISL1N
Combics 2 scale indicator, stainless steel housing, IP44	CISL2
Combics 3 scale indicator, stainless steel housing, IP44	CISL3
Combics 1 scale indicator, stainless steel housing, IP67	CIS1
Combics 1 plus scale indicator, stainless steel housing, IP67	CIS1N
Combics 2 scale indicator, stainless steel housing, IP67	CIS2
Combics 3 scale indicator, stainless steel housing, IP67	CIS3

Optional Interfaces (UniCOM)

Interface module (RS-232C)	YDO01C-232
Interface module (RS-485 | 422)	YDO01C-485
Analog current output, 0–20 mA, 4–20 mA, 0–5 V, 16-bit	YDA01C-20MA
Profibus module	VDO01C-DP
Bluetooth® module (only for CIS models)	YDO01C-BT

Replace A | D Converter (WP1) with a Digital Interface

Interface (RS-232 | 485) for direct connection of a digital platform	YDI01C-WP

Printers and Printer Accessories

with functions for date, time and statistical evaluations	YDP03-0CE
Printer paper (5 rolls; length per roll: 50 m)	6906937
Replacement ink ribbon cartridge for printer	6906918
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 108 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator; only for use with flexible printout configuration (see "Software," next column)	YDP12IS-0CEUV
Printer paper (1 roll) for YDP12IS-0CE printer, 101 mm × 75 m, thermal sensitive paper	69Y03196
Labels for YDP12IS-0CE printer, extra large, 101 mm × 127 m, 305 labels	69Y03195
Verifiable strip and label printer with "thermo-direct" print head, paper width up to 60 mm, with 100–240 V external power supply (EU and US) and power cord. Adapter cable YCC01-01CISLM3 required for Combics CISL indicator; adapter cables YCC02-R12F6 and 69Y03142 required for Combics CIS indicator (see "Software," next column)	YDP04IS-0CEUV
Printer paper (3 rolls) for YDP12 │ 04IS-0CE, 60 mm × 75 m, thermal sensitive paper	69Y03090
Labels for YDP12 │ 04IS-0CE printer, small, 58 mm × 30 mm, 1000 labels	69Y03092
Labels for YDP12 │ 04IS-0CE printer, medium, 58 mm × 76 mm, 500 labels	69Y03093
Labels for YDP12 │ 04IS-0CE printer, large, 58 mm × 100 mm, 350 labels	69Y03094
Cable for direct connection of YDP12IS │ YDP04IS-0CE printerto Combics CISL indicators	YCC01-01CISLM3

Electrical Accessories

External red │ green │ red display for Combics CISL indicators	YRD11Z
External red │ green │ red display for CIS indicators (12-pin round connector); connecting cable YCC02-R12F6 or Option M6 required	YRD14Z
Profibus connector for CISL... and CW...P... indicators (D–SUB 25- │ 9-pin)	IE10092
Second display for Combics CISL indicators	YRD02Z
Remote display, 7-segment, up to 45 mm characters	Information available on request
Bar code scanner, with cable for connection to Combics CISL scale indicator adapter cable, 120 mm scanning width	YBR02CISL
Bar code scanner for the Combics CIS model, with connecting cable, for connection with YCC02-R12F6	YBR02FC
Foot switch, incl. T-connector, D–SUB 25-pin	YFS01
Hand switch, incl. T-connector, D–SUB 25-pin	YHS02
External Alibi memory for electronic storage of weighing data	YAM01IS
Scanner for loading weighing data from YAM13IS Alibi memory cards to a PC	YAM02IS
Power supply for YAM01IS or YAM02IS Alibi memory	YAM11IS
Memory card for YAM01IS Alibi memory	YAM13IS
Cable for connecting Combics indicator to YAM01IS Alibi memory, 25-pin D–SUB to 9-pin D–SUB, 25 pol. D–SUB auf 9 pol. D–SUB	YCC01-10CIM3
Cable (D–SUB 9-pin, 2 m) for connecting YAM01IS Alibi memory to a PC	69EM0012
Flow rate controller for pumps with analog or digital pulse interface	YFC02Z-V2

Mechanical Accessories

Installation kit for pit frame installation (disconnectable plug-in cable for indicator)	YAS99I
Wall-mounting bracket, stainless steel	YDH01CIS
Wall-mounting bracket, stainless steel, tiltable	YDH02CIS
Floor-mounted column	YDH03CIP
Floor-mounted column, stainless steel	YDH03CIS
Base for installing floor-mounted column, stainless steel	YBP03CIS
Retainer for bar code scanner, for attachment to floor-mounted column, bench column or complete scale column	YBH01CWS
Plate for attaching printer to floor-mounted column or bench column	YPP01CWS

Software

Flexible printout configuration (e.g., bar codes, variable font sizes, embedding graphics, and similar) – Just ask your sales consultant	
Sartorius WinScale driver software for Windows® 95 │ 98 │ 2000 │ NT with current display of the weights and verifiable PC data memory, RS-232C, connecting cable 7357314 required	YSW03
SartoCollect software for the data communication between PC and any Sartorius instrument (incl. cable 26 Pin, 2 m)	YSC02

Power Supplies

24-V industrial power supply module	YAS02CI
External rechargeable battery pack, operates up to 40 hours, incl. battery charger	YRB10Z
External rechargeable battery pack, operates up to 40 hours, battery charger not included	YRB10Z-R
Connecting cable (25-pin, D-SUB) for YRB10Z rechargeable battery pack, 2 m	YCC02-RB01
Connecting cable with cable gland for YRB10Z rechargeable battery pack, 2 m*	YCC02-RB02
Connecting cable with cable gland, for car battery, 2 m*	YCC02-CB02

* only for CIS 1 │ 2 │ 3 indicator

Connecting Cables

with cable gland for YBR02FC bar code scanner*	YCC02-BR02
with cable gland for D09F6 printer, 9-pin D-SUB male connector, 6 m*	YCC02-D09M6
with cable gland for accessories, 9-contact D-SUB female connector, 6 m*	YCC02-D09F6
with cable gland for Sartorius scale, 25-contact D-SUB female connector, 1.5 m*	YCC02-D25F6
with cable gland for Sartorius scale, 25-pin D-SUB male connector, 6 m	YCC02-D25M6
with cable gland for accessories or IS platform, 12-pin round male connector, 6 m*	YCC02-R12M6
with cable gland, 12-contact round female connector, 1.5 m*	YCC02-R12F6
Cable for YDA01C-20MA power interface, with open cable ends e.g., 5 + = 5 m	6906926
Cable for connecting a PC, 25-pin, D-SUB, 1.5 m	7357312
Cable for connecting a PC, 9-pin, D-SUB, 1.5 m	7357314
Cable for connecting isi, QA│QC, FB│FC scales (25-pin D-SUB male connector to 12-pin round male connector), 3 m	YCC01-02ISM3
Connecting cable for scales, 25-contact D-SUB male connector (25-pin D-SUB female connector to 25-pin D-SUB male connector), 3 m	YCCDI-01M3
Connecting cable for scales to IS platform (25-pin D-SUB male connector to 12-contact round female connector), 3 m	YCC01-03CISLM3
Cable for connecting scale to platform, junction box or other weighing system equipment, approx. 8 mm outer diameter, shielded, with open ends; e.g., 5 + = 5 m	69YO1100

Other Accessories

|	
In-use covers (set of 2)	YDC01CI
IP65 upgrade kit for the IP44 protected Combics CISL indicators	YAS01CISL
Anti-theft locking device	YTP01CI
Cable gland for Combics model CIS, IP67 protected*	YAS04CIS
Installation kit for integration in a control panel	YAS03CI

* only for CIS 1│2│3 indicator

3. FlexAct® Central Operating Module

Part Number	Description
4SZZNL201	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN│R – Control unit with 10.4" touch panel EU 230 V, st.steel version
4SZZNL501	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN│R – Control unit with 10.4" touch panel US 110 V, st.steel version
4SZZNL202	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN│R – Control unit with 10.4" touch panel EU 230 V, powder coated version
4SZZNL502	FlexAct® Central Operation Module Universal working platform equipped with: – Peristaltic pump type Watson Marlow 720 UN│R – Control unit with 10.4" touch panel US 110 V, powder coated version

4. Flexel® Bag Assemblies for LevMixer®

Legend:

Subassembly 1

SU pressure sensor

Thermowell

pH-Sensor
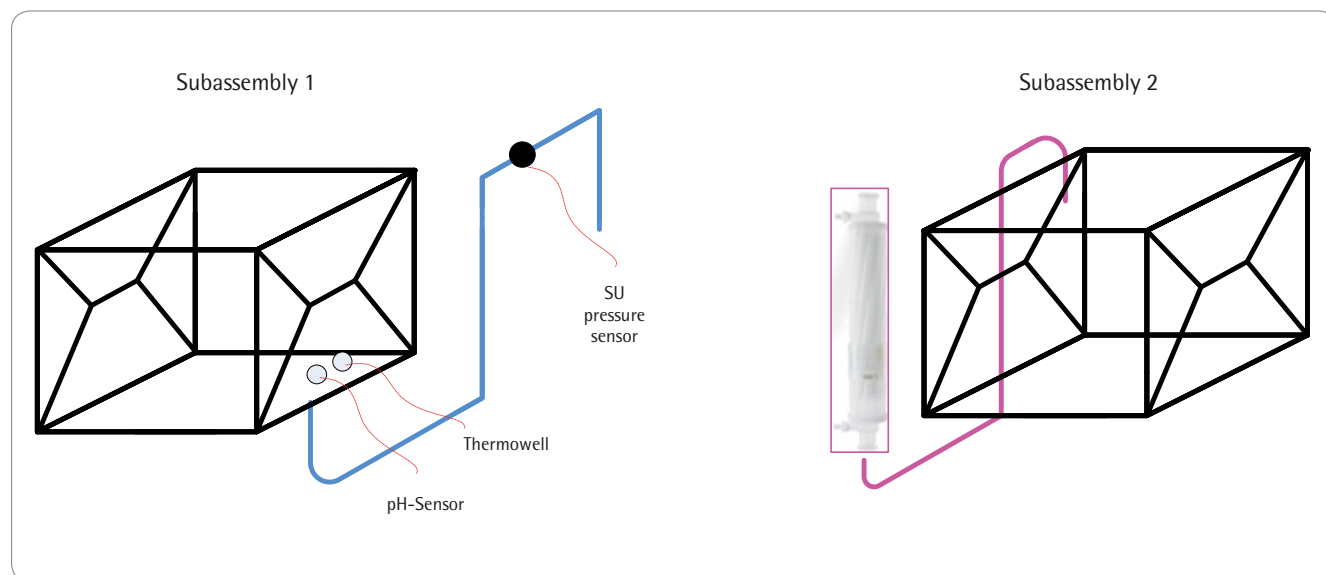
Subassembly 2

Part Number	Subassembly 1	Subassembly 2
4VI105E08AC10509	Flexel® Cubical LevMixer® Bag 50 L (Probe pH, Pressure)	Flexel® Palletank® 50 L (TPE │ Sartopore®), with Transfer Sets
4VI110E08AG11010	Flexel® Cubical LevMixer® Bag 100 L (Probe pH, Pressure)	Flexel® Palletank® 100 L (TPE │ Sartopore®) with Transfer Sets
4VI120E08AD12011	Flexel® Cubical LevMixer® Bag 200 L (Probe pH, Pressure)	Flexel® Palletank® 200 L (TPE │ Sartopore®) with Transfer Sets
4VI140E08AE15012	Flexel® Cubical LevMixer® Bag 400 L (Probe pH, Pressure)	Flexel® Palletank® 500 L (TPE │ Sartopore®) with Transfer Sets
4VI165E08AF11T13	Flexel® Cubical LevMixer® Bag 650 L (Probe pH, Pressure)	Flexel® Palletank® 1000 L (TPE │ Sartopore®) with Transfer Sets

5. Accessories

5.1 Sartocheck® 4 plus

Order Number	Order Code Description
26288	Sartocheck® 4 plus (following items included)
18104	Inlet tubing for compressed gas (included)
18103	Outlet tubing for compressed gas (included)
6982141	Ribbon cassette (included)
6982142	Rolls of printer paper (included) Test certificate (included) Calibration certificate (included) Installation and operating instructions (included)
16288---VP	Validation package Power cord (country specific)

Order Number	Accessories Sartocheck® 4 plus
26288---BS	Barcode Scanner
16288---TU	Multiunit
1ZE---0018	External pressure transducer
1ZE---0025	Set for external venting (1 valve)
1ZE---0026	Valve set for external filling (WIT) Serial Port Interface cable TU|TU
1ZE---0008	0.5 m
1ZE---0009	2 m
1ZE---0010	5 m Network Cable
1ZE---0029	2 m
1ZE---0030	5 m
1ZE---0031	10 m
1ZE---0032	20 m
26288---CK	Cleaning Kit
26288---PV	Pressure Tank for Cleaning
16288---RV	External reference vessel (10 L)
16288---PI	Profibus Interface
26288---VP	Validation Package
1ZE---0021	Clean Room Venting Adapter
1Z-LB-0002	Midisart Test Manifold 10

5.2 BioWelder®

Order Number	Order Code Description
16370	BioWelder®, Fully automated tube fusing unit
16372	Citizen Printer Print cable, AC adapter, paper roll and ribbon cassette
16373	Disposable Cutting Blades, with laser point 0.4 mm, 50 pcs./package,
16374	Calibration Kit With specifically designed holder, integrated temperature sensor type K and coding for calibration program recognition, calibration document for sensor included
16384	4–fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16385	4–fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16386	4–fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16375	2–fould Tube Holder OD 1/4" (6.4 mm), ID 1/8" (3.2 mm), Wall 1/16" (1.6 mm)
16376	2–fould Tube Holder OD 5/16" (8.0 mm), ID 3/16" (4.8 mm), Wall 1/16" (1.6 mm)
16377	2–fould Tube Holder OD 3/8" (9.5 mm), ID 1/4" (6.4 mm), Wall 1/16" (1.6 mm)
16378	2–fould Tube Holder OD 7/16" (11.1 mm), ID 5/16" (8.0 mm), Wall 1/16" (1.6 mm)
16379	2–fould Tube Holder OD 1/2" (12.7 mm), ID 3/8" (9.5 mm), Wall 1/16" (1.6 mm)
16380	2–fould Tube Holder OD 5/8" (15.9 mm), ID 3/8" (9.5 mm), Wall 1/8" (3.2 mm)
16381	2–fould Tube Holder OD 3/4" (19 mm), ID 1/2" (12.7 mm), Wall 1/8" (3.2 mm)

5.3 BioSealer®

Order Number	Order Code Description
16360-P1 16360-P2 16360-P3 16360-P4 16360-P5 16360-P6	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 4"–1" and wall thickness 1/16"–3/32" Optional Parametersets: 1–6**
16361-P1 16361-P2 16361-P3 16361-P4 16361-P5 16361-P6	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 4"–1" and wall thickness 1/16"–3/32", Equipped with a removable Sealing Head Optional Parametersets: 1–6**
16362-P7 16362-P8 16362-P9 16362-P10 16362-P11 16362-P12	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8" Optional Parametersets: 7–12**
16363-P7 16363-P8 16363-P9 16363-P10 16363-P11 16363-P12	BioSealer®, Fully automated Tube Sealing Device Seals tubes with OD 5/8"–3/4" and wall thickness 1/8", Equipped with a removable Sealing Head Optional Parametersets: 7–12**
16365	IR Interface incl. Software CD
16366	Ceramic Heating Element Type 1 specified for BioSealer® 16360–16363

** The definition of each parameterset can be obtained in the parametersheet

6. Acid │ Base Peristaltic Dosing Pump

WM 520U │ R2 Pump

Order Number	Order Code Description
	Watson Marlow 520

7. Validation

CONFIDENCE®: Product and Process Specific Validation Services

Sartorius Stedim Biotech Validation Services conducts testing according to current regulatory requirements and guidance documents used in the industry such as PDA Technical Report No. 26 „Sterilizing Filtration of Liquids".

Testing is offered for filter elements, bags and other polymer-based components such as tubing, gaskets, stoppers, vials etc. Considering the process conditions, product formulation and process steps, the test scope (type of test, number of test filter elements or other test components) and complexity of the studies can vary.

Article No.	Description
861096	Validation protocol including one revision.

Microbiological Studies

Article No.	Description
861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria Brevundimonas diminuta
861015	Viability Test for determination of the bactericidal nature of the product (non-standard)
861010	Viability Test for determination of the bactericidal nature of the product in contact with the standard test bacteria Brevundimonas diminuta

Bacteria Challenge Test performed with 3 filter elements from different lots

Article No.	Description
861012	Bacteria Challenge Test using the standard test bacteria Brevundimonas diminuta
861016	Bacteria Challenge Test (non-standard)

Determination of Product Specific Integrity Test Limits

Product Integrity Test performed with minimum 3 filter elements from different lots

861020	Determination of product specific integrity test limits
862021	Determination of product specific integrity test limits (non-standard)

Chemical Compatibility Studies

Chemical Compatibility Test performed with 3 filter sets from different lots

861022	Chemical Compatibility Test
861024	Chemical Compatibility Test (non-standard)

Adsorption Studies (upon request)

Particle Release Studies

Particle Release Test typically includes 3 filter elements from different lots

861031	Particle Release Test

Leachables│Extractables Studies (analysis of drug product formulation usually requires sample preparation)

Extraction procedure always includes a blank, customer to decide on
1 or 3 filters│bags│components for extraction

861040	Static Extraction (out of box, without prior treatment)
861041	Extraction (including sterilization and│or flushing)
861044	Extraction (non-standard)

Two pretests may be required for complex products, e.g. formulation buffer and complete solution

861070	Analytical pre-test to identify product interference
861071	Analytical pre-test with sample preparation

Number of analyses normally reflects number of extract samples, including blank

861047	GC-MS Analysis without sample preparation
861048	GC-MS analysis with sample preparation
861051	HPLC analysis without sample preparation
861052	HPLC analysis with sample preparation

Following a standard approach HPLC and GC-MS are typical methods for the initial leachables analysis. If no peaks are detected no further study is performed. Additional analysis and type of analytical methods depend on the amount of peaks detected and their signal intensity.
A suitable analytical scheme is then developed in a second step case by case.

Flexel® for LevMixer® bag, using ATMI patented mixing technology

LevMixer® is a trademark or registered trademark of ATMI, Inc.
in the United States, other countries or both

▶ Air Sampler for Critical Applications

The system consists of the MD8 airscan® air sampler and disposable gelatine filter units. The system is routinely used for the quantitative detection of air-borne organisms, mainly at filling lines in sterile areas of class A (classification according to "EU Guide for GMP"), isolators, or blow-fill-seal machines.

The exceptionally high air flow rate of 8 m³/h enables isokinetic sampling at flow rates that are usual in laminar flow as well as filtration of 1 m³ air very quickly (less than 8 minutes). The filter unit can be placed separately from the air sampler for remote sampling.

The MD8 airscan® air sampler allows to adjust selectively and easily air flow rate and sample removal speed. By means of a specially developed calibration unit (see accessories), the user can calibrate the MD8 airscan® locally, e.g. within the scope of validation steps.

After removing the sample, the gelatine filter can be placed directly on the agar culture medium for incubation and colony growth.

▷ Specifications

Specifications for the MD8 airscan® Air Sampler

Air flow rate	2.0 m³/h – 8 m³/h adjustable in 100-liter steps
Timer	1–99 minutes, adjustable in 1-minute steps
Max. deviation	±5% in a temperature range of 15°–35℃
Noise level	For gelatine membrane filters, max. 62 dB (A)
Weight	Approx. 6.5 kg
Dimensions (L×W×H)	375×242×228 mm
Correction of the air flow rate setting	When the entered air flow rate cannot be attained, the display shows the max. attainable flow rate for a corresponding new setting below this value.
By-packed filter holder	17655 (Gelatine disc filters)

Ordering Information for the MD8 airscan® Air Sampler

Order Number

16746	MD8 airscan® air sampler, 230 V, 50 Hz
16747	MD8 airscan® air sampler, 115 V, 60 Hz
16748	MD8 airscan® air sampler, 100 V, 50–60 Hz

Each version can be switched from 50 to 60 Hz and back.

Accessories for the MD8 airscan® Air Sampler

Order Number

17801	Holder for disposable gelatine filter units

Ordering Information for Consumables
Disposable gelatine units, sterile, pack of 10

Order Number

17528--80----ACD	Individually packed in 1 polyethylene bag each
17528--80----BZD	Individually packed in 3 polyethylene bags each
17528--80----VPD	Individually packed in 3 polyethylene bags each, but label on innermost bag

Special brochures available on request. Order no. SLF3001-e│SM-3011-e

▶ AirPort MD8

Battery-Powered Portable Air Sampler

AirPort MD8 is the air sampler for the pharmaceutical industry, the biotechnology, the food and beverage industry, for hospitals' environmental care and for work safety.

AirPort MD8 Offers the Following Benefits

– Battery-powered and portable for universal use.

– Battery power level clearly indicated so constant performance during sampling is guaranteed.

– Ergonomic design and easy to clean.

– Flexible adjustment possibilities of the volume flow and the sample volume.

– User-friendly prompting with the option of four languages; English, French, German and Spanish.

– Parameters last used stored even after automatic shut-off.

– The device can be calibrated locally.

For guaranteeing reliable and exact measurement results AirPort MD8 uses the gelatine membrane filter method or the Impaction method with BACTair™.

▷ Specifications

Specifications for AirPort MD8

Volume flow regulation	By an integrated impeller wheel.
Volume flow adjustable	30 l/min., 40 l/min., 50 l/min. and 125 l/min.
Fixed given sample volumes	25, 50, 100, 250, 500, 750 and 1000 liters. In addition, the sample volume can be chosen manually in 5-liter steps.
Operational life with one battery charge	Approx. 4.5 hours for 50 l/min
Noise level	For gelatine membrane filters 48 dB (A)
Weight	Approx. 2.5 kg
Dimensions (L×W×H)	300×135×165 mm
By-packed adapter	17801 (for disposable gelatine filter units) 17803 (for BACTair™ Plates)

Power Supply

Battery	NiMH 16.8 Volt/3800 mAh
Battery charger input	100–240 V/47–63 Hz/600 mA
Battery charger output	24 V/1000 mA
Charging time	Approx. 4.5 hours for empty battery

Ordering Information for the AirPort MD8

Order Number

16757	AirPort MD8, complete with two adapters (17801 and 17803) and battery charger (69898525).

Accessories and Replacement Parts for the AirPort MD8

Order Number

17803	Adapter for BACTair™ on the AirPort MD8 air sampler
1ZPX-D0002	Covers for BACTair™ Culture Media Plates, 10×2 units individually, sterile packaged
17801	Holder for disposable gelatine filter units
69898525	Battery charger

Ordering Information for Consumables
Please refer to the following pages.

Special brochures available on request. Order no. SM-1502-e and SM-4023-e

▶ Gelatine Membrane Filters
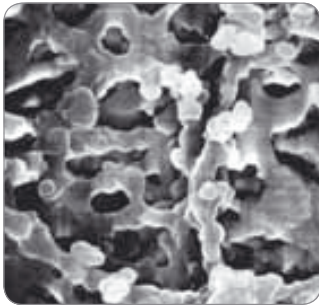
Gelatine filters in conjunction with the MD8 air samplers (gelatine filter method) are used for collecting of airborne microbes and viruses. Gelatine filter disposables are individually packed, pre-sterilized and ready-to-connect units, each consisting of a gelatine membrane filter and a holder. Gelatine membrane filters are still available as filter discs, suitable for the filter holder 17655 (80 mm diameter) supplied with the MD8 airscan® air samplers, as well as in smaller diameters.

Gelatine filters in conjunction with the MD8 air samplers offer the following features and benefits:

– "Absolute" retention rate (99.9995% for Bac. sub. niger spores, 99.94% for T3 phages).

– The filter maintains the viability of collected microorganisms for a relevant and meaningful sampling time.

– Gelatine filters are completely water-soluble. Therefore, microbes in one sample can be cultivated in | on different nutrient media or low and high bacteria counts can be measured. The sample is not affected by inhibitors.

– The solubility of the gelatine filter is a prerequisite for virus sampling.

▷ Specifications

Specifications of Gelatine Filters

Gelatine filters	Water soluble, pore size 3 µm, 80 mm diameter, thickness approx. 250 µm
Thermal resistance	Max. 60°C
Residual dampness content	46-49%
Air flow rate	Approx. 2.7 l/min./cm² at ΔP = 0.05 bar
Retention rates	1. Bac. subtilis niger spores 99.9995% at 0.25 m/s inlet velocity. 2. Coli phages: phage T1, 99.9% at 0.3 m/s inlet velocity and 50% rel. air humidity. Phage T3, 99.94% at 0.3 m/s inlet velocity and 80% rel. humidity.
Filtration area	38.5 cm²
Conditions for use	Room temperature, max. 30°C, max. air humidity 85%
Sterilization	Supplied pre-sterilized by gamma irradiation

Disposable Gelatine Units, Sterile, Pack of 10

Order Number	
17528--80----ACD	Individually packed in 1 polyethylene bag each
17528--80----BZD	Individually packed in 3 polyethylene bags each
17528--80----VPD	Individually packed in 3 polyethylene bags each, but label on innermost bag

Gelatine Disc Filter, Sterile, Sealed in Units of Five Each in a Polyethylene Bag

Order Number	Diameter	Package Size
12602--80----ALK	80 mm	50
12602--50----ALN	50 mm	100
12602--50----ALK	50 mm	50
12602--47----ALN	47 mm	100
12602--47----ALK	47 mm	50
12602--37----ALK	37 mm	50

Special brochure available on request. Order no. SLF3001-e | SM-3011-e

▶ BACTair™ – Big Impact

Microbiological Air Monitoring by the Impaction Method

A new developed system for sampling airborne organisms that allows impaction onto culture media plates, where the plates function directly as collection heads. This means that the collection properties are integrated right into the culture media plates. Metal sieve plates or metal collection heads with slots, which have to be sterilized for routine samplings on a regular basis, are eliminated. Now, non-sterile sieves or slots have become a thing of the past.

The geometry of the culture medium plate and the 400 holes in the sieve plate yield exceptional sampling efficiency, which is generally higher than that of other impaction samplers.

This new method uses the AirPort MD8 air sampler to pump the air stream. BACTair™ is ready-to-connect to the AirPort MD8.

BACTair™ offers the following benefits
– Individually, sterile packaged
– Integrated disposable sieve
– Pre-filled with agar media
– Samples 1 m^3 in just 8 min
– Optimized geometry

▷ Specifications

Specifications for BACTair™

Material	Polystyrene
Dimensions	116 × 24 mm
Number of impaction holes	400 holes, ⌀ 0.47 mm each
High retention of particles	> 0.65 μm
Sterilization	Gamma irradiation

BACTair™ Culture Media Plates with Agar, 110 mm, Individually, Sterile Packaged, 10 Units

Order Number	Determination of	Medium Type
14320-110----ACD	Total Count	Tryptic Soy Agar (TSA)
14321-110----ACD	Yeasts and molds	Sabouraud Agar (acc. USP)

Other BACTair™ Culture Media types on request.

Air Sampler

16757	AirPort MD8 Air Sampler for BACTair™ incl. charger

Accessories

17803	Adapter for BACTair™ on the AirPort MD8 air sampler
1ZPX-D0002	Covers for BACTair™ Culture Media Plates, 10 × 2 units individually, sterile packaged
14301-110------K	BACTair™ Plates, sterile, without media

Special brochures are available on request. Order no. SM-4023-e and SL-2047-e

▶ # Accessories

For the MD8 Air Samplers

New Calibration Unit

The user can calibrate the MD8 airscan® and AirPort MD8 directly on the job by means of the calibration unit*.

This is absolutely necessary above all within the scope of validation steps, for which it is important that the shown air flow rate (desired value at the MD8) corresponds to the actual air amount (actual value at the calibration device). The calibration unit is supplied complete with battery charger | power supply unit (specific for the country in which it is used), filter holder, connectors set and connection tube (PVC, 2 m).

* Alternatively, a maintenance agreement can be signed. Within the scope of the contractual services, Sartorius Stedim Biotech technicians will carry out a calibration of the MD8 at regular intervals

▷ ## Specifications

Specifications for Calibration Unit

Dimensions	Length, 300 mm (without filter holder), Width, 390 mm with handles Height, 182 mm min., 200 mm max. (adjustable feet)
Connectors	Quick locks (bayonet principle)
Operational life with full battery	Approx. 4 hours
Charge time for empty battery	Approx. 10 hours
Measuring range	1–16 m³/h
Max. error	1–16 m³/h, ±2%
Type of protection	IP 40
Allowable ambient temperature	Min. 0°C, max. 40°C
Weight	Approx. 11 kg

Special brochure available on request.
Order no. SL-2028-e

Tubing and Connectors Set

If the disposable gelatine filter unit is not placed directly at the MD8 airscan®, but at a distance from it, a flexible plastic hose (2 m or 5 m), a connectors set and, if not available, a holder (tripod 16970, double socket 16976, clamp 17037) are necessary for the connection between filter and MD8 airscan®. The autoclavable silicone hose is used instead of the flexible plastic hose, if the MD8 airscan® has to be used in sterile rooms, operating rooms, isolators, blow-fill-seal machines, etc. With this hose attached to the air outlet connector (exhaust), the waste air can be led off into another room.

Case

A stable case for the transport and the storage of a MD8 airscan®, incl. accessories.

Aluminum Stack

It consists of a middle part, 10 numbered filter holders and 2 end caps. The stack is first sterilized (by 180°C dry heat, 2 h), and then equipped with the filters under sterile conditions (LF cleanbench). The prepared filter holders are put on one side of the middle part. After removing the sample, the inserted filter holders are put on the other side of the middle part, so that used and unused filter holders are separated from each other.

Accessories for Isolator Application

For the monitoring of isolators with MD8 airscan®, we recommend using stainless steel accessories such as adapters 17016 (DN25) or 17030 (DN30), clamps 17033 for sanitary flanges, connector 17659---001 or 17659---003 (for tri clamp) and the filter holder for gelatine filter disposables 17801---001 as well as a Sartofluor® capsule with PTFE membrane and sanitary flange inlet and outlet, for sterile air filtration inserted between the MD8 airscan® and isolator. This construction makes it possible that the MD8 air sampler remains outside the critical work area (the barrier function between different clean-room classes is maintained).

Accessories for Remote Control Function
Users of the MD8 airscan® now have the possibility of operating this air sampler from a distance, using either of two remote control configurations:

a) Via a PC (with Microsoft 95/98 or higher) with MD8 airscan® dialog system and cable connection to the MD8 airscan® (1ZE---0004).

b) Via a PLC interface unit (1ZE---0003).

Gelatine Membrane Filter, 80 mm, Sterile, Pack of 50 for Use with Stack
Gelatine membrane filters are still available as 80 mm filter discs, suitable for the filter holder supplied with the MD8 airscan®. The filters are sterile-supplied, but the filter holders have to be sterilized by dry heat (180°C, 2h) and then equipped with the filters under sterile conditions. For performing routine check-ups, a stack is recommended in this case.

Further Consumables for Air Monitoring
If gelatine filters cannot be used (high humidity, high temperature), it is recommended to use cellulose nitrate filters.

Accessories for the MD8 Air Samplers

Order Numbers

16756	Calibration unit for the MD8 air samplers
17208	Case for MD8 airscan®
17656	Aluminum stack for MD8 air samplers

Replacement Parts for the Stack

Order Numbers

17655	Individual filter holders for gelatine filter type 12602--80----ALK
17660	Middle part
17661	End cap

Tubing and Connectors Set

Order Numbers

17085	Flexible PVC hose with reinforced ends (2 m)
17088	Flexible PVC hose with reinforced ends (5 m)
17662	Silicone tubing, sterilizable (1 m, state length required)
17657	Set of connectors (consisting of 17658 and 17659), aluminum
17658	Connector (air sampler inlet to flexible hose), aluminum
17659	Connector (flexible hose to filter holder│adapter), aluminum

Accessories for Isolator Application

Order Numbers

17016	Adapter (DN 25 hose barb to 1"–1 1/2" sanitary flange) to connect MD8 airscan® to an isolator via silicone tubing and a filter capsule, stainless steel
17030	Adapter (DN 30 hose barb to 1"–1 1/2" sanitary flange) to connect MD8 airscan® to an isolator via flexible PVC hose and filter capsule, stainless steel
17033	Clamp for 1"–1 1/2" sanitary flanges, stainless steel
17659---001	Connector (flexible hose to filter holder│adapter), hose nipple, stainless steel
17659---003	Connector (flexible hose to filter holder│adapter), tri clamp, stainless steel
17801---001	Adapter for gelatine filter disposables, stainless steel
5181307T9-----SS	Sartofluor® Capsule with PTFE membrane and sanitary flange inlet and outlet, for sterile air filtration inserted between the MD8 airscan® and isolator

Accessories for Remote Control Function

Order Numbers

1ZE---0003	Remote control (Interface) for MD8 airscan® designed for PLC units
1ZE---0004	Remote control for MD8 airscan® for use with PC (dialog system software)

Consumables Used with Stack
Gelatine disc filters, 3 µm pore size, 80 mm, 50 pieces/pack

Order Numbers

12602-080 ALK	Gelatine disc filter, sterile, sealed in units of five each in a polyethylene bag

Further Consumables for Air Monitoring
Cellulose nitrate membrane filters, 80 mm diameter, 100 pieces/pack

Order Numbers

11404--80----ALN	Cellulose nitrate membrane filters, 0.8 µm, white with black grid, pre-sterilized in bags of 5
13004--80----ALN	Cellulose nitrate membrane filters, 0.8 µm, gray with white grid, pre-sterilized in bags of 5
11301--80----ALN	Cellulose nitrate membrane filters, 8 µm, white no grid, pre-sterilized in bags of 5

▶ # Gridded Membrane Filters from Cellulose Nitrate (Cellulose Ester) acc. to ISO Standards

Sterile and Individually Packaged, for Colony Counting

Sterile, individually packed filters have long become standard for routine microbiological quality control because of the user benefits they offer.

They are pre-sterilized and ready-to-use and save preparatory time. As they are individually packed, they avoid the possibility of contamination of remaining filters in opened packs and conform with GLP, having filter identification and lot number printed on each individual envelope.

The increasing demand on these filters required the construction of a new packaging machine with ultra-modern stamping. Each membrane is checked to ensure it is not damaged in any way, is positioned correctly with no slippage under the edge seal, has perfect grid printing and is free of particles. Each envelope is checked for readable lettering. Quality control par excellence!

These membrane filters are in accordance with the following norms: ISO 7704, ISO 7899-2, ISO 8199, ISO 9308-1 and ISO 16266. In addition to this they have been manufactured for use especially at the same time with Sartorius Stedim Biotech Nutrient Pads in accordance with the AFNOR (French Standards), the American Petroleum Institute, the American Society for Microbiology, the APHA Standard Methods, the Association of Official Analytical Chemists, the British Drinking Water Guideline, the British Standards, the DGHM (German Association of Hygiene and Microbiology), the DIN Guidelines (German Standards), the European Brewery Community, the European Drinking Water Guideline 98/83, the European Pharmacopoeia, the German Pharmacopoeia, the International Commission for Uniform Methods of Sugar Analysis, the International Dairy Federation, the International Fruit Juice Producers, the ISO Guidelines, the LMBG (German food law), the method described by Lanaridris & Lafon-Lafourcade, the method described in the journal of Food Protection, the method described in the journal of the Institute of Brewing, the methods of the Central European Brewery Commission, the MNO (Mineral|Table Water Guideline), the National Canners Association, the testing procedures for packaging stuff, the U.S. Environmental Protection Agency, the United States Pharmacopoeia, the US Department of Agriculture, the VLB (German Institute of Brewery), the Zentralblatt für Hygiene (Journal of Hygiene), the US Federal Drug Administration and Internal Standard Operation Procedures.

▷ Specifications

The Membrane Filters
All membranes are made of cellulose nitrate,
a material which assures effective retention
with high flow rates and optimum colony
growth. The printed grid with a size of
3.1×3.1 mm makes the counting easier,
especially for higher bacteria counts and for
microcolonies, but does not influence the
growth. The various filter colors allow the
best contrast to the colonies and particles.

High Flow Membranes
The standard membrane filter for micro-
biological analysis is an 0.45 µm filter. One
special variant is the High Flow membrane. It
provides 30% higher flow rates in comparison
to traditional 0.45 µm membranes. The special
pore structure of the new 0.45 µm HighFlow
membrane filters allows shorter filtration
times due to higher flow rates and through-
puts. Especially E. coli shows best growth
promotion on High Flow Membranes. As every
Sartorius Stedim Biotech 0.45 µm membrane
filter lot, these membranes are also tested
and released according to ISO 7704.

Additional Membrane Filters
Cellulose nitrate (cellulose ester) membrane
filters, gridded, non-sterile packaged
(page 556).

Cellulose nitrate (cellulose ester) and cellulose
acetate membrane filters, white, individually,
sterile packaged (page 558).

Hydrophobic edge membranes are used
mainly in the sterility testing of solutions
containing antibiotics (page 560).

▶ Microsart® e.motion Dispenser

Fully automated membrane filter dispenser for individually sterile cellulose nitrate filter discs.

The membrane filters are automatically removed from their sterile package – either in a touch-free mode via an optical sensor or at the touch of a button. A pedal switch can be optionally connected to the dispenser. Thanks to their new motorized traction roller, each filter is quickly and reliably dispensed. Membranes that accidentally slide out of their packaging or that even get damaged in the process are now problems of the past.

The controller specially developed for the Microsart® e.motion prevents unwanted dispensing of several membrane filters at a time – it's simple, "fail-safe," and fast.

The clear, compact design of the dispenser allows quick and easy cleaning. The Microsart® e.motion has an interface port available so that other sensor systems can be connected to control the dispenser.

The dispenser's low weight makes it easy to transport. Both its functions and design are ideal, giving you the versatility and flexibility you need in your lab.

Applications
Membrane filters for colony counting, particle testing and microscopy

Some of the advantages you will benefit from when using the Microsart® e.motion dispenser:

– Fully automated membrane filter dispenser

– Works hands-free by an optical sensor

– Works by touch button

– Compact design

– Rapid and reliable transport due to sprocket feed roll technology

– Easy insertion of the filter band

– Easy-to-clean

▷ Specifications

Specifications of the Microsart® e.motion Dispenser

Dimensions (L×H×W) in mm	204×213×165
Weight	2.9 kg
Operating voltage	110 V/230 V optional
Frequency	50–60 Hz
Max. power	Consumption 10 W
Dispensing speed	0.5 sec
Dispenser delay	5 sec
Certificates	CE Mark and EMC Directive, European Standards EN 50081-1 and –2, EN 50082-1 and -2, EN 61010

Order Number for Microsart® e.motion Dispenser

16712	Microsart® e.motion dispenser, fully automated membrane filter dispenser.
1ZE---0028	Pedal (foot switch) for Microsart® e.motion dispenser

▶ Microsart® e.motion Membrane Filters

The membrane filter band specially designed for the Microsart® e.motion can be conveniently inserted, and changed easily and rapidly as needed, even without having to completely use up a complete package quantity. Each box contains 100 membrane filters individually sealed on a special pleated band, and is designed so that it is easy to open and seal for storage. Microsart® e.motion – reliable help in your lab.

Some of the advantages you will benefit from when using the Microsart® e.motion membrane filters:

– Outstanding recovery rates for microorganisms

– 0.45 µm are acc. to ISO 7704

– Multi-fit: Fits into various dispensers

– Protective paper-free

– Packaged on a special pleated band

– Product data are printed on

– High Flow membranes available

– Gamma irradiated, 25kGray

▷ Specifications

Please refer to the membrane type:
Cellulose nitrate (cellulose ester), gridded, individually, sterile packaged.

Order Numbers for Microsart® e.motion Membrane Filters
Diameter 47 mm or 50 mm, in Pack of 3 × 100 Membranes, Individually,
Sterile Packaged, Without Protective Paper

White│black	11407Z-47----SCM	0.2 µm
White│black	11407Z-50----SCM	0.2 µm
White│black	114H6Z-47----SCM	0.45 µm High Flow
White│black	114H6Z-50----SCM	0.45 µm High Flow
White│black	11406Z-47----SCM	0.45 µm
White│black	11406Z-50----SCM	0.45 µm
White│black	11404Z-47----SCM	0.8 µm
White│black	11403Z-47----SCM	1.2 µm
White│black	11403Z-50----SCM	1.2 µm
White│black	11402Z-47----SCM	3 µm
White│green	139H6Z-47----SCM	0.45 µm High Flow
White│green	13906Z-47----SCM	0.45 µm
White│green	13906Z-50----SCM	0.45 µm
Green│dark green	13806Z-47----SCM	0.45 µm
Green│dark green	13806Z-50----SCM	0.45 µm
Gray*│white	130H6Z-50----SCM	0.45 µm High Flow
Gray*│white	13006Z-47----SCM	0.45 µm
Gray*│white	13006Z-50----SCM	0.45 µm
Gray*│white	13005Z-47----SCM	0.65 µm
Gray*│white	13005Z-50----SCM	0.65 µm
Gray*│white	13004Z-47----SCM	0.8 µm
Gray*│white	13004Z-50----SCM	0.8 µm

* Gray membranes after wetting black

Microsart® e.motion Membrane Filters are also available together with Nutrient Pads.

▶ # Cellulose Nitrate (Cellulose Ester) Membrane Filters

Gridded, Individually, Sterile Packaged
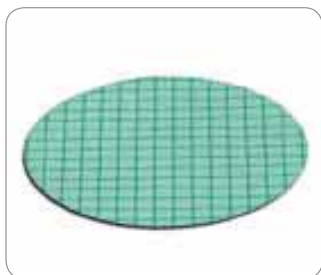
Applications
Membrane filters for colony counting, particle testing and microscopy

Some of the advantages you will benefit from when using this type of membrane filter:

– Outstanding recovery rates for microorganisms

– 0.45 µm are acc. to ISO 7704

– High Flow membranes available

– Three different colors available

– Certified quality

– Gamma irradiated, 25kGray

▷ ## Specifications

Design	47 or 50 mm in diameter, white, grey or green and gridded
Growth Promotion Test acc. to ISO 7704	– No enhancement or inhibition by the grid lines – No enhancement or inhibition due to chemical extractables – No enhancement or inhibition by the sterilization process
Sterility test	Sterile
Thermal resistance	130°C max.
Thickness acc. to DIN 53105	115–145 µm
Chemical compatibility	Aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents. Detailed information in section "Chemical Compatibility" under Cellulose Nitrate type 113 (page 622).

Typical Performance Rates for Various Pore Sizes

Pore size		0.2 µm*	0.45 µm**	0.45 µm High Flow**	0.65 µm
Flow rate for water per cm² at 1 bar acc. to DIN 58355	in ml/min	20	70	100	130
Coliform retention	in %	100	100	100	n. a.
Recovery rate lot-released acc. to ISO 7704	in %	≥ 90	≥ 90	≥ 90	≥ 90

*) Pore size determined by quantitative retention of Brevundimonas diminuta in accordance with the ASTM Document F 838-83 (1993) Standard test method for determining bacterial retention of membrane filters utilized for liquid filtration.
**) Pore size determined by quantitative retention of Serratia marcescens in accordance with the Standard Methods of Water and Waste Water

White Membrane with Black Grid, for Detection of Bacteria with Dyed Media, Particle Count & Microscopy, Type 114, Individually, Sterile Packaged

Pore Size	Order No.	Diameter	Pack Size
0.2 µm	11407--47----ACN	47 mm	100
	11407--47----ACR	47 mm	1,000
	11407--50----ACN	50 mm	100
	11407--50----ACR	50 mm	1,000
0.45 µm	11406--47----ACN	47 mm	100
	11406--47----ACR	47 mm	1,000
	11406--50----ACN	50 mm	100
	11406--50----ACR	50 mm	1,000
0.45 µm High Flow*	114H6--47----ACN	47 mm	100
	114H6--47----ACR	47 mm	1,000
	114H6--50----ACN	50 mm	100
	114H6--50----ACR	50 mm	1,000
0.65 µm	11405--47----ACN	47 mm	100
	11405--50----ACN	50 mm	100
0.8 µm	11404--47----ACN	47 mm	100
	11404--47----ACR	47 mm	1,000
	11404--50----ACN	50 mm	100
1.2 µm	11403--47----ACN	47 mm	100
	11403--47----ACR	47 mm	1,000
	11403--50----ACN	50 mm	100
	11403--50----ACR	50 mm	1,000

White Membrane with Green Grid, for Detection of Bacteria with Dyed Media, Particle Count and Microscopy, Type 139, Individually, Sterile Packaged

0.45 µm	13906--47----ACN	47 mm	100
	13906--47----ACR	47 mm	1,000
	13906--50----ACN	50 mm	100
	13906--50----ACR	50 mm	1,000
0.45 µm High Flow*	139H6--47----ACN	47 mm	100
	139H6--47----ACR	47 mm	1,000
	139H6--50----ACN	50 mm	100
0.65 µm	13905--47----ACN	47 mm	100
1.2 µm	13903--47----ACN	47 mm	100

Green Membrane with Dark-Green Grid, Providing Optimal Contrast to Light-Colored or Transparent Bacteria Colonies, Type 138, Individually, Sterile Packaged

0.45 µm	13806--47----ACN	47 mm	100
	13806--47----ACR	47 mm	1,000
	13806--50----ACN	50 mm	100
	13806--50----ACR	50 mm	1,000

Gray Membrane (After Wetting, Black) with White Grid, for Detection of Yeasts and Molds, Particle Count and Microscopy, Type 130, Individually, Sterile Packaged

0.45 µm	13006--47----ACN	47 mm	100
	13006--47----ACR	47 mm	1,000
	13006--50----ACN	50 mm	100
	13006--50----ACR	50 mm	1,000
0.65 µm	13005--47----ACN	47 mm	100
	13005--50----ACN	50 mm	100
	13005--50----ACR	50 mm	1,000
0.8 µm	13004--47----ACN	47 mm	100
	13004--47----ACR	47 mm	1,000
	13004--50----ACN	50 mm	100

▶ ## Cellulose Nitrate (Cellulose Ester) Membrane Filters

Gridded, Non-Sterile Packaged
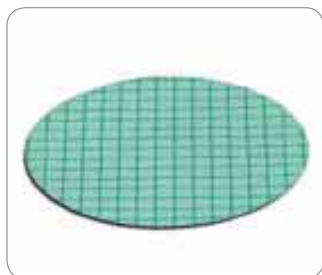
Applications
Membrane filters for colony counting, particle testing and microscopy

Some of the advantages you will benefit from when using this type of membrane filter:

– Outstanding recovery rates for microorganisms

– 0.45 µm are acc. to ISO 7704

– Three different colors available

▷ ## Specifications

Design	25, 47 or 50 mm in diameter, white, grey or green and gridded
Growth Promotion Test acc. to ISO 7704	– No enhancement or inhibition by the grid lines – No enhancement or inhibition due to chemical extractables
Thermal resistance	130°C max.
Thickness acc. to DIN 53105	115–145 µm
Chemical compatibility	Aqueous solutions (pH 4-8), hydrocarbons and several other organic solvents. Detailed information in section "Chemical Compatibility" under Cellulose Nitrate type 113 (page 622).

Typical Performance Rates for Various Pore Sizes

Pore size		0.2 µm*	0.45 µm**	0.65 µm
Flow rate for water per cm² at 1 bar acc. to DIN 58355	in ml/min	20	70	130
Coliform retention	in %	100	100	n. a.
Recovery rate lot-released acc. to ISO 7704	in %	≥ 90	≥ 90	≥ 90

*) Pore size determined by quantitative retention of Brevundimonas diminuta in accordance with the ASTM Document F 838-83 (1993) Standard test method for determining bacterial retention of membrane filters utilized for liquid filtration.
**) Pore size determined by quantitative retention of Serratia marcescens in accordance with the Standard Methods of Water and Waste Water

White Membrane with Black Grid, for Detection of Bacteria with Dyed Media, Particle Count & Microscopy, Type 114, Non–Sterile

Pore Size	Order No.	Diameter	Pack Size
0.2 µm	11407--25------N	25 mm	100
	11407--47------N	47 mm	100
	11407--47------R	47 mm	1,000
	11407--50------N	50 mm	100
0.45 µm	11406--25------N	25 mm	100
	11406--47------N	47 mm	100
	11406--47------R	47 mm	1,000
	11406--50------N	50 mm	100
	11406--50------R	50 mm	1,000
0.65 µm	11405--47------N	47 mm	100
0.8 µm	11404--25------N	25 mm	100
	11404--47------N	47 mm	100
	11404--50------N	50 mm	100
1.2 µm	11403--25------N	25 mm	100
	11403--47------N	47 mm	100
	11403--50------N	50 mm	100

White Membrane with Green Grid, for Detection of Bacteria with Dyed Media, Particle Count and Microscopy, Type 139, Non–Sterile

0.45 µm	13906--47------N	47 mm	100
	13906--47------R	47 mm	1,000
	13906--50------N	50 mm	100
	13906--50------R	50 mm	1,000

Green Membrane with Dark–Green Grid, Providing Optimal Contrast to Light–Colored or Transparent Bacteria Colonies, Type 138, Non–Sterile

0.45 µm	13806--47------N	47 mm	100
	13806--47------R	47 mm	1,000
	13806--50------N	50 mm	100
	13806--50------R	50 mm	1,000

Gray Membrane (After Wetting, Black) with White Grid, for Detection of Yeasts and Molds, Particle Count and Microscopy, Type 130, Non–Sterile

0.45 µm	13006--25------N	25 mm	100
	13006--47------N	47 mm	100
	13006--47------R	47 mm	1,000
	13006--50------N	50 mm	100
0.65 µm	13005--47------N	47 mm	100
	13005--50------N	50 mm	100
0.8 µm	13004--47------N	47 mm	100
	13004--50------N	50 mm	100

▶ Cellulose Nitrate (Cellulose Ester) and Cellulose Acetate Membrane Filters

White, Individually, Sterile Packaged

Sterile, individually packed filters have long become standard for routine microbiological quality control because of the user benefits they offer. They are pre-sterilized and ready-to-use and save preparatory time. As they are individually packed, they avoid the possibility of contaminating remaining filters in opened packs and conform with GLP, having filter identification and lot number printed on each individual envelope.

Materials
The membranes are made of even cellulose nitrate (cellulose ester), a material which assures effective retention with high flow rates and optimum colony growth or cellulose acetate, a material which combines high flow rates and thermal stability with very low adsorption characteristics.

Additional Applications
11301, a white CN membrane filter with a pore size of 8 µm is used as a prefilter in a special prefilter attachment (16807) for bacteriological analyses. It retains the coarse suspended particles, whereas it allows microorganisms to pass through. These microbes are trapped on the surface of the underlying bacteria-retentive membrane filter (e. g. 0.45 µm).

11107, a white CA membrane filter with a pore size of 0.2 µm is the filter of choice for sterile filtration, such as nutrient media, buffer and sera. This membrane is validated by the Bacteria Challenge Test.

Applications
Membrane filters for colony counting, sterility testing, particle testing and microscopy

Some of the advantages you will benefit from when using this type of membrane filter:

– Outstanding recovery rates for microorganisms

– Defined particle retention

– 0.45 µm are acc. to ISO 7704

– 0.2 µm are validated by BCT

– Certified quality

– Gamma-irradiated, 25kGray

▷ Specifications

Design	25, 47 or 50 mm in diameter, white
Growth Promotion Test acc. to ISO 7704	– No enhancement or inhibition by the sterilization process – No enhancement or inhibition due to chemical extractables
Sterility test	Sterile
Thermal resistance	CN: 130°C max. | CA: 180°C max.
Thickness acc. to DIN 53105	CN: 115–145 µm | CA: 120 µm (average value)
Chemical compatibility	Aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents. Detailed information in section "Chemical Compatibility" under Cellulose Nitrate type 113 and Cellulose Acetate type 111 (page 622).

Cellulose Nitrate Membrane Filters, White, for Colony Counting, Sterility Testing, Particle Count & Microscopy, Type 113, Individually, Sterile Packaged

Pore Size	Order No.	Diameter	Pack Size
0.45 µm	11306--25----ACN 11306--47----ACN 11306--50----ACN	25 mm 47 mm 50 mm	100 100 100
0.65 µm	11305--47----ACN 11305--50----ACN	47 mm 50 mm	100 100
0.8 µm	11304--47----ACN 11304--50----ACN	47 mm 50 mm	100 100
1.2 µm	11303--47----ACN 11303--50----ACN	47 mm 50 mm	100 100
3 µm	11302--47----ACN 11302--50----ACN	47 mm 50 mm	100 100
8 µm	11301--47----ACN 11301--50----ACN	47 mm 50 mm	100 100

Cellulose Acetate* Membrane Filters, White, for Colony Counting, Sterility Testing, Particle Count & Microscopy, Type 111, Individually, Sterile Packaged

0.2 µm	11107--47----ACN 11107--50----ACN	47 mm 50 mm	100 100
0.45 µm	11106--47----ACN 11106--50----ACN	47 mm 50 mm	100 100

* If cellulose nitrate is not compatible

▶ Hydrophobic Edged Cellulose Nitrate (Cellulose Ester), Cellulose Acetate and Regenerated Cellulose Membrane Filters

Individually, Sterile Packaged & Non-Sterile

Hydrophobic edge membranes are used mainly for colony counting and sterility testing of solutions containing substances with antibiotic characteristics. The hydrophobic edge avoids the penetration of any growth-inhibitory substance into the membrane clamp zone wherefrom it could not be rinsed out and the substance could inhibit microbial growth during incubation.

Materials
The membranes are available in three different materials:

– Cellulose nitrate (cellulose ester), a material which assures effective retention with high flow rates and optimum colony growth

– Cellulose acetate, a material which combines high flow rates and thermal stability with very low adsorption characteristics

– Regenerated cellulose, a material which combines excellent chemical resistance and thermal stability with very low adsorption characteristics.

Applications
Membrane filters for colony counting and sterility testing

Some of the advantages you will benefit from when using this type of membrane filter:

– Outstanding retention rates for microorganisms

– 0.45 µm are acc. to ISO 7704

– 0.2 µm are validated by BCT

– Certified quality

▷ Specifications

Design	25, 47 or 50 mm in diameter, white or white with black grid
Growth Promotion Test acc. to ISO 7704	– No enhancement or inhibition by the grid lines – No enhancement or inhibition due to chemical extractables – No enhancement or inhibition by the sterilization process
Sterility test	Sterile
Thermal resistance	CN: 130°C max. │ CA and RC: 180°C max.
Thickness acc. to DIN 53105	CN: 115–145 µm │ CA: 120 µm (average value) │ RC: 160–200 µm
Chemical compatibility	Aqueous solutions (pH 4–8), hydrocarbons and several other organic solvents, RC is resistant to almost all solvents and is compatible in a pH-range of 3-12. Detailed information in section "Chemical Compatibility" under Cellulose Nitrate type 113, page 622, Cellulose Acetate type 111 and Regenerated Cellulose type 184.

Cellulose Nitrate Membrane Filters, White with Black Grid, 3 mm Hydrophobic Edge, for Colony Counting & Sterility Testing, Type 131, Individually, Sterile Packaged

Pore Size	Order No.	Diameter	Pack Size
0.2 µm	13107--47----ACN	47 mm	100
	13107--50----ACN	50 mm	100
0.45 µm	13106--47----ACN	47 mm	100
	13106--50----ACN	50 mm	100

Cellulose Nitrate Membrane Filters, White with Black Grid, 6 mm Hydrophobic Edge, for Colony Counting & Sterility Testing, Type 131, Individually, Sterile Packaged

0.45 µm	13106--47----HEN	47 mm	100

Cellulose Nitrate Membrane Filters, White with Black Grid, 3 mm Hydrophobic Edge, for Colony Counting & Sterility Testing, Type 131, Non–Sterile

0.2 µm	13107--25------N	25 mm	100
	13107--47------N	47 mm	100
	13107--50------N	50 mm	100
0.45 µm	13106--25------N	25 mm	100
	13106--47------N	47 mm	100
	13106--50------N	50 mm	100
8 µm	13101--47------N	47 mm	100
	13101--50------N	50 mm	100

Cellulose Nitrate Membrane Filters, White, 3 mm Hydrophobic Edge, for Colony Counting & Sterility Testing, Type 131, Non–Sterile

8 µm	13101--50----AHN	50 mm	100

Cellulose Nitrate Membrane Filters, White with Black Grid, 6 mm Hydrophobic Edge, for Colony Counting & Sterility Testing, Type 131, Non–Sterile

0.2 µm	13107--47----HCN	47 mm	100
0.45 µm	13106--47----HCN	47 mm	100

Cellulose Acetate* Membrane Filters, White with Black Grid, 3 mm Hydrophobic Edge, for Colony Counting & Sterility Testing, Type 135, Individually, Sterile Packaged

0.2 µm	13507--47----ACN	47 mm	100
0.45 µm	13506--47----ACN	47 mm	100
	13506--50----ACN	50 mm	100

Cellulose Acetate* Membrane Filters, White with Black Grid, 3 mm Hydrophobic Edge, for Colony Counting & Sterility Testing, Type 135, Sterile, Packaged of 10 Discs per Sleeve

0.45 µm	13506--47----ALS	47 mm	100

Cellulose Acetate* Membrane Filters, White with Black Grid, 3 mm Hydrophobic Edge, for Colony Counting & Sterility Testing, Type 135, Non–Sterile

0.2 µm	13507--47------N	47 mm	100
0.45 µm	13506--47------N	47 mm	100

Cellulose Acetate* Membrane Filters, White with Black Grid, 6 mm Hydrophobic Edge, for Colony Counting & Sterility Testing, Type 135, Non–Sterile

0.45 µm	13506--47----HCN	47 mm	100

Regenerated Cellulose* Membrane Filters, White, Hydrophobic Edged, for Colony Counting & Sterility Testing, Type 184, 100 Membranes per Box, Individually, Sterile Packaged

0.45 µm	18406--47----ACN	47 mm	3 mm hydropho. edge
	18406--47----HDN	47 mm	4 mm hydropho. edge

* If cellulose nitrate is not compatible

▶ Nutrient Pad Sets

Dehydrated Media Pads in Petri Dishes, with Matching Membrane Filters for Economical, Time-Saving Microbiological Quality Control
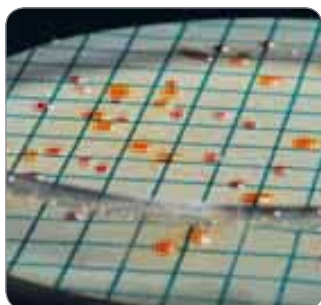
Sartorius Stedim Biotech Nutrient Pad Sets have been used successfully in the membrane filter method for 20 years. Practical and easy to handle, they reduce labor and simplify many microbiological testing procedures.

Nutrient pads are sterile, dehydrated culture media. Once they are moistened with 3.0–3.5 ml of sterile and demineralized (or distilled) water they are ready to use immediately.

Ready–to–Use up to 24 Months
The standard NPS box contains 100 sterile nutrient pads, each of which is individually inserted in a petri dish and sterilized. Ten each of these petri dishes are sealed in an aluminum bag. This special packaging in bags protects the sensitive formula constituents of the nutrient pads during transport and storage from fluctuations in humidity and temperature. As a result, it guarantees the high quality of our NPS throughout their entire shelf life up to 24 months. This makes the Sartorius Stedim Biotech Nutrient Pads Sets unique: No other ready-to-use culture media around the globe assures such consistently high quality and reproducible results up to 24 months.

Compliance with International Standards
Currently, Sartorius Stedim Biotech offers more than 30 different Nutrient Pad Set types to meet the diverse objectives of micro-biological analysis. Aside from the European drinking water directive, they comply with other international regulations and recommendations: international pharmacopoeias, DIN and ISO standards, the American Standards for Water and Foods, mineral water regulations, brewery guidelines, such as MEBAC or EBC, and recommendations of the food industry, such as LMBG, NCA and ICUMSA, etc.

By–Packed Membranes
All Nutrient Pad Set types are supplied with the appropriate membrane filters, which are also pre-sterilized and individually packaged. The membrane filters tailored to meet the special requirements of microbial detection are available with 47 mm or 50 mm diameters.

Benefits for the User

Economy
No time-consuming and labor-intensive preparation of the nutrient media (sterilization, cleaning, etc.).

Easy Handling
Nutrient Pad Sets can also be used in laboratories without comprehensive microbiological equipment.

Consistently Quality
During the production, each nutrient pad set batch is compared with the corresponding agar medium, in order to guarantee consistently quality and reproducible results.

Trouble–Free Storage
Nutrient Pad Sets can be stored at room temperature in a warehouse, up to 24 months.

Order Numbers for Nutrient Pad Sets in Petri Dishes

Nutrient Pad Sets for Total Colony Counting,
individually, sterile packaged in petri dishes, 100 per box, with 100 individually,
sterile packaged 47 mm membrane filters

Determination of	NPS Type (Filter Type)[1]	Order No.[2]
Total count	Caso (1)	14063--47------N
Total count	R2A (1)	14084--47------N
Total count	Standard TTC (1)	14055--47------N
Total count	Standard TTC I mod. (1)	14085--47------N
Total count	Standard (1)	14064--47------N
Total count	TGE (1) | Tryptone Glucose Extract	14076--47------N
Total count	Yeast Extract (1)	14090--47------N

Nutrient Pad Sets for E. coli, Coliforms and Enterobacteria,
individually, sterile packaged in petri dishes, 100 per box, with 100 individually,
sterile packaged 47 mm membrane filters

E. coli and coliforms	Chromocult (7)	14087--47------N
E. coli	ECD (2)	14082--47------N
E. coli and coliforms	Endo (9)	14053--47------N
Enterobacteria, E. coli	MacConkey (2)	14097--47------N
E. coli and coliforms	m FC (2)	14068--47------N
E. coli and coliforms	m FC in closed petri dishes (2)	14068--50----PDN
E. coli and coliforms	Teepol | Lauryl Sulphate (2)	14067--47------N
E. coli and coliforms	Tergitol TTC (2)	14056--47------N

Nutrient Pad Sets for Other Faecal Bacteria,
individually, sterile packaged in petri dishes, 100 per box, with 100 individually,
sterile packaged 47 mm membrane filters

Enterococci	Azide (1) | KF Strep	14051--47------N
Salmonellae	Bismuth Sulfite (1)	14057--47------N

Nutrient Pad Sets for Non–Faecal, Pathogenic Bacteria,
individually, sterile packaged in petri dishes, 100 per box, with 100 individually,
sterile packaged 47 mm membrane filters

Pseudomonas aeruginosa	Cetrimide (2)	14075--47------N
Staphylococci, Staph. aureus	Chapman (2)	14074--47------N

Nutrient Pad Sets for Yeasts and Molds,
individually, sterile packaged in petri dishes, 100 per box, with 100 individually,
sterile packaged 47 mm membrane filters

Determination of	NPS Type (Filter Type)[1]	Order No.[2]
Wild yeasts	Lysine (3)	14061--47------N
Yeasts and molds	Malt Extract (8)	14086--47----CCN
Yeasts and molds	Malt Extract (6)	14086--47------N
Yeasts and molds	Sabouraud (10)	14069--47------N
Yeasts and molds	Schaufus Pottinger| m green yeast and mold (4)	14070--47------N
Yeasts and molds	Schaufus Pottinger| m green yeast and mold (5)	14072--47------N
Yeasts and molds	Schaufus Pottinger| m green yeast and mold (6)	14080--47------N
Yeasts and molds	Schaufus Pottinger| m green yeast and mold (3)	14083--47------N
Yeasts and molds	Schaufus Pottinger| m green yeast and mold (8)	14091--47------N
Yeasts and molds and bacteria	Wallerstein Nutrient| WL Nutrient (2)	14089--47------N
Yeasts and molds	Wort (3)	14058--47------N

Nutrient Pad Sets for Product–Spoiling Microorganisms,
individually, sterile packaged in petri dishes, 100 per box, with 100 individually, sterile packaged
47 mm membrane filters

Thermophilic spore formers and mesophilic bacteria	Glucose Tryptone (2)	14066--47------N
Leuconostoc oenos and other wine-spoiling organ.	Jus de Tomate|Tomato Juice (1)	14079--47------N
Lactobacilli and other soft drink-spoiling microorganisms	MRS (1)	14077--47------N
Acid-tolerant microorganisms	Orange Serum|pH 5.5 (1)	14062--47------N
Acid-tolerant microorganisms	Orange Serum|pH 3.2 (6)	14096--47------N
Lactobacilli and Pediococci and other beer-spoiling microorganisms	VLB-S7-S (2)	14059--47------N
Mesophilic slime-forming bacteria esp. Leu. mesenteroides	Weman (1)	14065--47------N

Nutrient Pad Sets Starter Kit,
individually, sterile packaged in petri dishes, 100 per box, with 100 individually,
sterile packaged 47 mm membrane filters

E. coli and coliforms, total count, yeasts and molds	Mixed types: Endo, Standard, Wort (1, 2, 3)	14095--47------N

Sterile Water in Ampoules,
for moistening NPS, 3.5 ml each, 100 per box

100 ampoules with sterile water   1ZZ—K0001

Special brochure available on request f.o.c. Order no. SM-4017-e.

1) The membrane filters are selected for optimum growth, together with the
   corresponding nutrient media. The supplied membrane filter type is listed
   within brackets:
   (1) = Green with dark-green grid, 0.45 µm pore size
   (2) = White with green grid, 0.45 µm pore size
   (3) = Gray (after wetting black) with white grid, 0.65 µm pore size
   (4) = White with green grid, 0.65 µm pore size
   (5) = White with green grid, 1.2 µm pore size
   (6) = Gray (after wetting black) with white grid, 0.8 µm pore size
   (7) = White with black grid, 0.45 µm pore size
   (8) = Gray (after wetting black) with white grid, 0.45 µm pore size
   (9) = White with green grid, 0.45 µm pore size, High Flow, (ideal for E.coli)
   (10) = Gray (after wetting black) with white grid, 0.45 µm pore size, High Flow

2) Diameter of the membrane filter, 47 mm. Order number for
   Nutrient Pad Set with 50 mm membrane filter as above,
   but --47------N replaced by --50------N.

Most of the NPS types are also available with Microsart® e.motion Membrane Filters:
Order number as above, but ---N replaced by -RDN.

Other NPS types on request.

Nutrient Pad Set Poster
The photo shows a poster, original size
70 cm × 50 cm, with growth patterns
and typical applications for the Nutrient
Pad Sets, described on the previous page.
On request, you can obtain this poster
free of charge. Order no. SM-0001-e.

► Culture Media in Bottles and Tubes

Absorbent Pads and Petri Dishes

Agar Media
The traditional culture media for microorganisms is agar media. This can be used for the membrane filtration method or for direct incubation. There are two different forms available: Agar media in tubes are for pouring agar plates. The content of one tube is sufficient for two 90 mm or three 60 mm petri dishes. Agar media in bottles are the cost-effective alternative for casting plates.

Liquid Broth Media
Liquid culture media broth for direct incubation or for wetting an absorbent pad before a membrane filter is placed on it. They are available in tubes and in bottles.

Absorbent Pads
Sartorius Stedim Biotech 1.4 mm thick absorbent pads are wetted with the appropriate liquid culture medium before a membrane filter is placed on them. They come pre-sterilized in plastic magazines, which fit onto the Sartorius Stedim Biotech manual dispensing device. The absorbent pads are available in two diameters:

– 47 mm with approx. 3 ml absorption capacity and

– 50 mm with approx. 3.5 ml absorption capacity.

Agar Media in 250 ml Bottles, 4 Bottles per Box

Determination of	Agar Type	Order No.
Total count	Nutrient	14144----------A
Yeasts and molds	Wort	14157----------A
Wild yeasts	Lysine	14143----------A
Lactobacilli and Pediococci and other beer-spoiling organisms	VLB-S7-S	14148----------A

Agar Media in 20 ml Tubes, 50 Tubes per Box

Determination of	Agar Type	Order No.
Total count	Nutrient	14137----------K
Total count	Standard	14131----------K
Yeasts and molds	Wort	14138----------K
Acid-tolerant microorganisms	Orange serum	14130----------K
Leuconostoc oenos and other wine-spoiling organ.	Jus de tomate (tomato juice)	14140----------K

Lactose Broth Media, Bottled Concentrate, for Drinking Water Analysis

Concentration Factor	Packaging	Order No.
Two times concentrated	4 bottles à 100 ml	14155----------A

Broth Media in 20 ml Tubes, 50 Tubes per Box

Determination of	Broth Type	Order No.
Lactobacilli and Pediococci and other beer-spoiling organisms	VLB-S7-S	14127----------K

Absorbent Pads, 47 mm, Sterile Packaged in 10 Magazines, Each with 100 Pads

Description	Packaging	Order No.
Absorbent Pads, 10×100 pads	1,000 per box, incl. one dispenser	15410--47----ALR
Absorbent Pad Set, 10×100 pads plus 1,000 membrane filters (0.45 µm, white⎪green)	1,000 per box, incl. two dispensers	13906--47----APR

Absorbent Pads, 47 mm, Sterile Packaged of 10 Discs per Sleeve

Description	Packaging	Order No.
Absorbent Pad Set, 10×10 pads in sleeves plus 100 membrane filters (0.2 µm, white⎪black)	100 per box	13707--47----ALN
Absorbent Pad Set, 10×10 pads in sleeves plus 100 membrane filters (0.45 µm, white⎪black)	100 per box	13706--47----ALN

Absorbent Pads, 50 mm, Sterile–Packaged in 10 Magazines, Each with 100 Pads

Description	Packaging	Order No.
Absorbent Pads, 10×100 pads	1,000 per box, incl. one dispenser	15410--50----ALR

Absorbent Pads, 50 mm, Sterile–Packaged in Petri Dishes

Description	Packaging	Order No.
Absorbent Pad Set, 100 pads in petri dishes, sterile packaged	100 per box	15400--50------N
Absorbent Pad Set, 100 pads in petri dishes plus 100 membrane filters (0.45 µm, green⎪dark green)	100 per box	15400--50----FRN

Disposable Petri Dishes, Auto–Sterile, 100 per Box

Diameter	Order No.
60 mm	14311--60------N
90 mm	14311--90------N

▶ Biosart® 100 Monitors

The membrane filtration method is the suitable technique for microbiological analysis of pharmaceuticals, water, cosmetics, foods and beverages. The use of ready-to-use disposable units is optimal for these applications.

Biosart® 100 Monitors
Biosart® 100 Monitors have been specifically designed for the detection and enumeration of microorganisms in pharmaceuticals, cosmetics, food, beverages, water and other liquids. These sterile disposables with an incorporated membrane filter and cellulose pad are ready to use. After filtration, just remove the 100 ml funnel to convert the Monitor into a petri dish eliminating the need for membrane manipulation. Culture media for wetting the pad are available in individually sterilized, convenient plastic ampoules. Biosart® 100 Monitors are ready-to-use filter units designed to be placed onto the bases of a vacuum manifold, eliminating the cleaning and sterilization required of reusable funnels.

Compliance with International Standards
The membrane filter method is worldwide accepted and the preferred method of choice for the analysis of microbial contamination in liquid samples. Biosart® 100 Monitors and Media are in compliance with the membrane filtration procedures referenced in the:

– European drinking water directive (Council Directive 98/83/EC on the quality of water)

– Standard Methods for the Examination of Water and Waste Water, 20th edition

– U.S. Environmental Protection Agency, 600/8-78-017.

– International Standard's microbiological methods, such as ISO 7704, ISO 9308-1, DIN EN ISO 16266, ISO 8199

– WHO Guidelines for Drinking Water Quality, 1997

– International Pharmacopoeia, such as the current editions of the USP and EP

High Flow Membranes
Biosart® 100 Monitors are also available with the new 0.45 µm High Flow membranes. The special pore structure allows shorter filtration times due to 30% higher flow rates. Especially E. coli shows best growth promotion on High Flow Membranes.

Applications
Colony counting, particle testing and microscopy

Some of the advantages you will benefit from when using Biosart® 100 Monitors:

Superior Performance
– High flow rate
– High total throughput

Safe & Reliable
– Sterile or individually, sterile packaged
– Consistently recovery
– Membranes meet ISO 7704
– Membranes available in various colors
– Without any hydrophobic adhesive areas

Economical
– Ready to connect and easy to use
– Minimal amount of equipment needed

▷ Specifications

Housing	Polystyrene
Membrane filter	Cellulose nitrate (cellulose ester): choice of white, green or grey, with grid; Regenerated cellulose: white; membranes removable for filing
Plug and adapter	Polyethylene
Pad	Cellulose
Capacity	100 ml, 10 ml graduations
Pore size	0.2 µm, 0.45 µm or 0.8 µm
Filter diameter	47 mm
Filtration area	14.5 cm²
Max. operating pressure	Vacuum only
Outlet	6.5 × 1.5 mm
Lot certificates	Recovery rate, sterility and specifications

Biosart® 100 Monitors, 100 ml, 47 mm, Individually Packaged, Sterile, 48 Units

Pore Size	Membrane Filter* Color | Grid Color	Order No.
0.2 µm	CN white | black	16401-47-07--ACK
0.45 µm	CN white | black	16401-47-06--ACK
0.45 µm	CN green | dark green	16402-47-06--ACK
0.45 µm	CN gray | white**	16403-47-06--ACK

Biosart® 100 Monitors, 100 ml, 47 mm, Packaged in Trays, Sterile, 48 Units

0.2 µm	CN white | black	16401-47-07----K
0.45 µm High Flow	CN white | black	16401-47-H6----K
0.45 µm	CN white | black	16401-47-06----K
0.45 µm	CN green | dark green	16402-47-06----K
0.45 µm	CN gray | white**	16403-47-06----K
0.8 µm	CN gray | white**	16403-47-04----K
0.45 µm	RC white	16404-47-06----K

Biosart® 100 Monitors, 100 ml, 47 mm, Sterile, 48 Units

0.45 µm High Flow	CN white | black	16401-47-H6-V--K
0.45 µm	CN white | black	16401-47-06-V--K
0.45 µm	CN gray | white**	16403-47-06-V--K
0.8 µm	CN gray | white**	16403-47-04-V--K

Biosart® 100 Monitors, 100 ml, 47 mm, Sterile, 48 Units, Membrane Fixed
available only in the U.S. and Canada

0.45 µm High Flow	CN white | black	16401-47-H6-VWMK
0.45 µm	CN white | black	16401-47-06-VWMK
0.45 µm High Flow	CN gray | white**	16403-47-H6-VWMK
0.45 µm	CN gray | white**	16403-47-06-VWMK

* CN = Cellulose Nitrate (Cellulose ester)
  RC = Regenerated Cellulose
** Gray membranes after wetting black

Biosart® 100 Monitor Adapters and Membrane Lifter

Description	Adaptation	Order No.
Biosart® 100 Adapter, silicone	Biosart® 100 Monitor onto Sartorius Stedim Biotech stainless steel frits e. g. 16840 (Combisart® single base, 50 mm) or onto 16841 (individual base)	16414
Biosart® 100 Adapter, polypropylene	Biosart® 100 Monitor onto 50 mm supports	16415
Biosart® 100 Adapter, polypropylene	Biosart® 100 Monitor onto 56 mm supports and vacuum pumps	16416
Biosart® 100 Membrane Lifter, ABS	for easy transfer of the membrane onto agar	16417

▶ Biosart® 100 Nutrient Media

Each box of Biosart® 100 Nutrient Media con-tains 50 ampoules with sterile media, each with 2.5 ml and a lot certificate. If stored under proper conditions (+4°C), the culture media have a shelf life of 12 month (except for Endo, KF Strep, Lauryl Sulfate and Tergitol which have a 9-month shelf life). Biosart® 100 Nutrient Media comply with international regulations and recommendations: Interna-tional pharmacopoeias, DIN and ISO stand-ards, the American Standards for Water and Foods, mineral water regulations, guidelines of the food and beverage industries.

Within the scope of the quality assurance procedure and the stringent quality control standards every batch has passed Sartorius Stedim Biotech in-house tests of growth promotion, sterility, physical and technical parameters have been passed successfully. Biosart® 100 Nutrient Media are convenient in use and eliminating the handling of glass ampoules.

Application
Colony counting

Some of the advantages you will benefit from when using Biosart® 100 Media:

Safe & Reliable

– Pre-sterilized media

– Certificate of Quality for every batch

– In compliance with international standards

– Consistently recovery

Economical

– Ready-to-use

– Long shelf life

Biosart® 100 Nutrient Media, 2.5 ml, Individually, Sterile-Packaged in Ampoules, 50 Units

Determination of	Media Type	Order No.
Total count	Caso (acc. USP)	16400-02----CA-K
Total count	R2A (acc. EP)	16400-02----RA-K
Total count	TGE|Total Count	16400-02----TC-K
Total count	Total Count TTC	16400-02----TZ-K
E. coli and coliforms	m Endo	16400-02----EN-K
E. coli and coliforms	m FC	16400-02----MF-K
E. coli and coliforms	Lauryl Sulfate|Teepol	16400-02----LS-K
E. coli and coliforms	Tergitol TTC	16400-02----TT-K
Enterococci	KF Strep|Azide	16400-02----KF-K
Pseudomonas aeruginosa	Cetrimide	16400-02----CE-K
Yeasts and molds	Sabouraud (acc. USP)	16400-02----SB-K
Yeasts and molds	m Green yeast and mold|Schaufus Pottinger	16400-02----MG-K
Yeasts and molds	m Green yeast and mold selective	16400-02----GS-K
Yeasts and molds	Wort	16400-02----WZ-K
Yeasts and molds and bacteria	WL Nutrient|Wallerstein Nutrient	16400-02----WN-K
Bacteria in fermentation processes	WL Differential|Wallerstein Differential	16400-02----WL-K
Acid-tolerant microorganisms	Orange Serum	16400-02----OS-K

▶ # Microsart® @filter 100
Microsart® @filter 250

Sterile Disposable Filter Units with Click-Fit

The key to manufacture competitive products and maintaining conformity is the effective quality assurance and control in the highly regulated pharmaceutical industry. Products and raw materials used in the pharmaceutical or biotech industry require control of microbial levels during processing and handling. Microorganisms in liquids are quantified by the membrane filtration method. Use of this membrane filtration method allows accurate quantification of bacteria, yeasts and molds when low counts in a high sample volume are anticipated. All components of the filtration system must comply with international guidelines, such as USP, EP or ISO standards.

Description
Ready-to-use, sterile Microsart® @filter units combine a funnel and a gridded membrane filter in one unit. They have been specifically developed for the detection and enumeration of microorganisms in pharmaceuticals, cosmetics, food, beverages, water and other liquids.

For sample volumes up to 100 ml Microsart® @filter 100 is the ideal device, larger sample sizes could be easily filtered by Microsart® @filter 250. Marked graduations allow accurate sample volumes.

The optimized design permits thorough rinsing of the system subsequent to filtration. No liquid is retained in the filter funnel. Optimal sealing to the Microsart® Base 47 mm guarantees the Click-Fit closure.

Microsart® @vance
The Microsart® @filter unit kicks off the new product family Microsart® @vance. Microsart® @vance stands for innovative products for microbiological analyses based on colony count determination. Only a few steps from taking the sample until incubation by eliminating the risk of secondary contamination excel this product line.

All Microsart® products meet the most stringent quality assurance standards and also impress users with reliable results and simple, time-saving handling. However Microsart® @vance – this is advanced colony counting by Sartorius Stedim Biotech GmbH.

Combisart® Systems
The Microsart® @filter Base is the perfect addition to existing Combisart stainless steel manifolds. The slightly recessed frit ensures the plane positioning of the membrane filter. Thus wrinkled membranes, which make the counting of the colony growth difficult, are eliminated. Lateral notches make sure that the membrane can be removed easily after filtration.

Microsart® Funnel Dispenser
Microsart® @filter units are available as packaged in trays for the use in clean benches. The packaging in bags is specially developed for the use with the Microsart® Funnel Dispenser. The Funnel Dispenser for secure removal of single, sterile Microsart® @filter has proven itself in practice. Even after opening the bag, the remaining funnels are protected from secondary contamination. The Microsart® Funnel Dispenser is made of high-grade stainless steel, the dispenser opening is made of polypropylene and contains a silicone O-ring. All these materials guarantee reliable autoclaving.

Applications
Colony counting, particle testing and microscopy

Some of the advantages you will benefit from when using Microsart® @filter units:

Safe and Reliable

– **Sterile Packaged**
Sterilization at the point of use is not required

– **Fully Disposable Base and Funnel**
Preparation-and sterilization-free procedure reduces the risk of secondary contamination

– **Optimized Design and Materials**
No liquid remains after filtration, eliminates the need of rinsing

Easy Handling

– **Click-Fit Closure**
Fast in routine analysis, eliminates the risk of leakage

Economy

– **Adaptable on Combisart®**
Given flexibility, no additional investment required

– **Transparent Funnel Material**
Visibility of the complete filtration

▷ Specifications

Materials	Funnel: Polypropylene, Base: Polypropylene Membrane filter: Cellulose Nitrate (C. Ester); choice of various colors and grids
Capacity	100 ml, graduations at 20, 50 and 100 ml 250 ml, 50, 100, 200 and 250 ml graduations
Filter diameter	47 mm, prefilter 40 mm (particle testing only)
Filtration area	13.2 cm^2
Max. operating pressure	Vacuum only
Sterilization	Ethylene oxide
Lot certificate	Recovery rate, sterility and performance test

Microsart® @filter 100, Sterile Disposable Filter Units, 47 mm, 100 ml, Packaged in Trays, Ideal for the Use in Clean Benches, 24 Units

Pore Size	Membrane Filter* Color | Grid Color	Order No.
0.2	CN white | black	16D01--10-07--TG
0.45, High Flow	CN white | black	16D01--10-H6--TG
0.45, High Flow	CN gray | white**	16D03--10-H6--TG
0.45	CN green | dark green	16D02--10-06--TG
0.45	CN white (w/o grid)	16D05--10-06--TG

Microsart® @filter 250, Sterile Disposable Filter Units, 47 mm, 250 ml, Packaged in Trays, Ideal for the Use in Clean Benches, 16 Units

Pore Size	Membrane Filter* Color | Grid Color	Order No.
0.2	CN white | black	16D01--25-07--TF
0.45, High Flow	CN white | black	16D01--25-H6--TF
0.45, High Flow	CN gray | white**	16D03--25-H6--TF
0.45	CN green | dark green	16D02--25-06--TF
0.65	CN gray | white**	16D03--25-05--TF

Microsart® @filter 100, Sterile Disposable Filter Units, 47 mm, 100 ml, Packaged in Bags, Ideal for the Use with Microsart® Funnel Dispenser, 60 Units

Pore Size	Membrane Filter* Color | Grid Color	Order No.
0.2	CN white | black	16D01--10-07--BL
0.45, High Flow	CN white | black	16D01--10-H6--BL
0.45, High Flow	CN gray | white**	16D03--10-H6--BL
0.45	CN green | dark green	16D02--10-06--BL
0.45	CN white (w/o grid)	16D05--10-06--BL

Microsart® @filter 250, Sterile Disposable Filter Units, 47 mm, 250 ml, Packaged in Bags, Ideal for the Use with Microsart® Funnel Dispenser, 48 Units

Pore Size	Membrane Filter* Color | Grid Color	Order No.
0.2	CN white | black	16D01--25-07--BK
0.45, High Flow	CN white | black	16D01--25-H6--BK
0.45, High Flow	CN gray | white**	16D03--25-H6--BK
0.45	CN green | dark green	16D02--25-06--BK
0.65	CN gray | white**	16D03--25-05--BK

* CN = Cellulose Nitrate (Cellulose ester)
** Gray membranes after wetting black

► Microsart® Funnel 100
Microsart® Funnel 250

Sterile Disposable Funnels with Click-Fit

In microbiological quality control, sterility of the equipment used for processing samples is a necessary basic requirement. The re-useable funnels made of stainless steel or other materials which are used for membrane filtration are usually sanitized between samples by flaming or with hot water. Both of these methods can be insufficiently reliable if not properly performed. Alternatively, the funnels can be sterilized by autoclaving, but this is too laborious for routine use. A disposable filter funnel is the ideal combination for reliability and time saving.

Description
Microsart® Funnels are sterile plastic funnels, which are available for the filtration of various sample volumes. They allow quick performance of the filtration steps required in the routine testing of water, food and beverages, pharmaceutical and cosmetic products.

A Sartorius Stedim Biotech 47 mm gridded membrane is placed on a stainless steel filter support. A Microsart® Funnel is simply and practically fitted on. The sample is filtered.

The funnel is made of polypropylene and thus is elastic enough for optimal sealing with a Click-Fit closure. Graduations are marked to allow accurate sample volumes. The large inner diameter ensures a high flow rate. The optimized shape allows thorough rinsing of the system subsequent to filtration. No liquid is retained in the filter funnel.

Microsart® Base 47 mm
The Microsart® Base 47 mm is the perfect addition to existing Combisart® and Microsart® Combi.jet stainless steel manifolds. The slightly recessed frit ensures the plane positioning of the membrane filter. Thus wrinkled membranes, which make the counting of the colony growth difficult, are eliminated. Lateral notches make sure that the membrane can be removed easily after filtration.

Microsart® Funnel Dispenser
The Funnel Dispenser for secure removal of single, sterile Microsart® Funnels has proven itself in practice. Even after opening the bag, the remaining funnels are protected from secondary contamination. The Microsart® Funnel Dispenser is made of high-grade stainless steel, the dispenser opening is made of polypropylene and contains a silicone O-ring. All these materials guarantee reliable autoclaving.

Applications
Colony counting, particle testing and microscopy

Some of the advantages you will benefit from when using Microsart® Funnel 100:

– **Reliable Results**
Use a new, sterile funnel for each test for certain prevention of cross contamination!

– **Time-Saving**
Just change the funnel, rather than spending time sanitizing it!

– **Simpler Handling**
No more holding hot funnels! And, you can see when filtration has been completed, particularly useful when using manifolds in routine testing.

▷ Specifications

Material	Polypropylene
Capacity	100 ml, graduations at 20, 50 and 100 ml 250 ml, graduations at 50, 100, 200 and 250 ml
Filter diameter	47 mm, prefilter 40 mm (particle testing only)
Filtration area	13.2 cm^2
Max. operating pressure	Vacuum only
Sterilization	Ethylene oxide
Lot certificate	Sterility and performance test

Microsart® Funnel 100, Sterile Disposable Funnel, 100 ml, 100 Units

Description	Order No.
Microsart® Funnel 100, sterile in 5 sealed bags	16A07--10------N

Microsart® Funnel 250, Sterile Disposable Funnels, 250 ml, 96 Units

Description	Order No.
Microsart® Funnel 250, sterile in 6 sealed bags	16A07--25------N

Accessories and Replacement Parts

Description	Order No.
Microsart® Funnel Dispenser Funnel dispenser for secure removal of single, sterile Microsart® Funnels	16A08
Microsart® Base 47 mm, with frit, stainless steel, optimal for the use with 47 mm membranes, Click-Fit closure for Microsart® Funnel and Microsart® @filter (other funnel types sealed by bayonet closure)	1ZU---0002
Silicone O-ring for Microsart® Base 47 mm male thread (pack size 3)	6980274
Replacement frit, stainless steel	1ZU---0001

Further information about Microsart® Combi.jet and Combisart® stainless steel manifolds you will find on the following pages.

▶ Biosart® 250 Funnels

In microbiological quality control, sterility of the equipment used for processing samples is a necessary basic requirement. The reuseable funnels made of stainless steel or other materials which are used for membrane filtration are usually sanitized between samples by flaming or with hot water. Both of these methods can be insufficiently reliable when not properly performed. Alternatively, the funnels could be sterilized by autoclaving, but this is too laborious for routine use. A disposable sterile funnel in a certified quality is the ideal solution.

Description
The Biosart® 250 Funnel has been specifically designed for microbiological and analytical quality assurance. Biosart® 250 are sterile funnels which allows for fast filtration required in the routine testing of pharmaceutical and cosmetic products, water, food and beverages and other liquids. A Sartorius Stedim Biotech gridded membrane is placed on a stainless steel filter support. A Biosart® 250 Funnel is simply fitted on and the sample is filtered. The funnel is made of polypropylene and is sufficiently elastic for optimal sealing with a bayonet-type closure. Graduations are marked at 50, 100, 150, 200 and 250 ml for exact sample volumes. The large inner diameter ensures a high flow rate. The conical form allows a thorough rinsing of the system subsequent to filtration. No liquid is retained in the filter funnel.

Applications
Colony counting, particle testing and microscopy

Some of the advantages you will benefit from when using Biosart® 250 Funnels:

Superior Performance
– High flow rate
– High total throughput

Safe & Reliable
– Sterile or individually, sterile packaged
– No risk of cross contaminations
– No leakages due to proven closure technique
– No holding of hot funnels
– Visibility of the complete filtration

Economical
– Ready to connect and easy to use
– Minimal amount of equipment needed
– Autoclavable (to a limited extend)

▷ Specifications

Material	Polypropylene
Capacity	250 ml, 50 ml graduations
Filter diameter	47 mm (or 50 mm), prefilter 40 mm
Filtration area	12.5 cm^2
Max. operating pressure	Vacuum only
Sterilization	Ethylene oxide
Lot certificates	Sterility and performance tests

Biosart® 250 Funnels, Ready to Use Filter Funnels, 250 ml, 50 Units

Description	Order No.
Biosart® 250 Funnel, 50 units, individually, sterile-packaged	16407--25----ACK
Biosart® 250 Funnel, 50 units, sterile-packaged	16407--25----ALK

Further information available on request f.o.c. Order no. SL-3017-e

► ## Combisart® – The Sterile Vented Filter Station

Individual and Multi-Branch Systems

The Sartorius Stedim Biotech Combisart®, system enables you to select the optimal hardware and consumables for your needs in microbiological analysis or particle count in quality assurance. Combisart® features a modular design and field-proven standard accessories to make your choice easier.

Description
At the heart of the Combisart® system is a high-grade stainless steel manifold or individual system designed to accommodate all types of filter holders and funnels such as:

– Ready-to-use units like Microsart® Funnels 100 and 250, Microsart® @filter 100 and 250, Biosart® 100 Monitors and Biosart® 250 Funnels

– Flammable units such as stainless steel funnels for colony counting

– Autoclavable reusable funnels made of glass or polycarbonate

The outlet of the manifolds are newly Quick Connection Nipples, which could be used together with Quick Connection Couplings (more information under Microsart® Combi.jet) or as hose nipples for vacuum tubings. The low height of the manifold ports is particularly advantageous for working on a clean bench. For low number of samples, we recommend the use of the 1-branch manifold 16844 or the individual base 16841 on the top of a suction flask. For large number of samples, we recommend the 3- or 6-branch manifolds.

Sterile Venting
A special feature of the Combisart® system is the stainless steel three-way valve (tap). They allows the vacuum for each filter holder to be individually controlled and each filter station to be sterilely vented. This rules out secondary contamination of the underside of the filter.
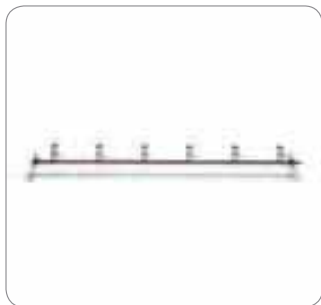
Sterilization
The system is compliant with ISO 8199 with regards to the sterilization methods of the equipment described in the "General Guide to enumeration of micro-organisms by culture". Since the most reliable sterilization method is autoclaving, the Combisart® design offers a unique advantage for this method. After inserting the membrane filters in the filter holders, you can simply unscrew them as an entire unit from each workstation and autoclaved them. This method increases reliability and saves sterilization capacity.

The Right Equipment for Your Application
In connection with the single base 16840 (for 50 mm membranes) the manifolds are flexible to adapt disposable Biosart® 250 or stainless steel funnels. The stainless steel filter support of the single base 16840 allows a homogenous distribution of the residues on the membrane filter surface.

Alternatively to 16840 the Microsart® Base 47 mm is highly recommended for all 47 mm membrane filters, Microsart® Funnels and for Microsart® @filter.

The Biosart® 100 adapter 16414 ensures that the Monitors are positioned perfectly, minimizing the risk of contamination during filtration.

3 or 6 polycarbonate holders of the type 16511 can be screwed onto the manifold directly.

Glass units (16306 or 16307) can be fitted by using corresponding adapter-│stopper-combinations.

Maximum Flexibility

The turnable single base for 50 mm membranes 16840 or the Microsart® Base 47 mm features additional advantages you will benefit from:

– You can pour out a non-filterable sample from each unit

– Filtration equally easy for left- or right handed users in your laboratory, because funnels can be positioned to suit the individual user

Some of the advantages you will benefit from when using the Combisart® System:

Safe & Reliable

– Sterile venting of each membrane after filtration

– Sterilization acc. to ISO 8199

– Special polished stainless steel surfaces allow easy cleaning & rinsing

– Low height is advantageous for working on a clean bench

Saves Time

– Filtration of 3 or 6 samples in parallel

– Easy pouring out of non-filterable samples

– Equally easy for right- and left-handed users

Economical

– Maximum flexibility due to different set-ups

– Space-saving in the autoclave

– Stainless steel 304 – long lifecycle

Combisart® Hardware–Setups

Filtration systems fast and easy completed at www.sartorius-stedim.com/microbio

▷ Specifications

Stainless steel quality	High-grade stainless steel: B.S. 304S31 │ AISI 304
Dimensions in mm (L│H│D)	3-branch manifold: 435│103│120 6-branch manifold: 910│103│120
Max. operating pressure	Vacuum only
Sterilization	By autoclaving (max. 134°C), By dry heat (max. 180°C), By flaming, By other methods acc. to ISO 8199
Parts and materials	Lid, funnel, base part, filter support, clamp and tap made of stainless steel. Silicone flat gasket. Silicone lid seal
Flow rate per filter station for water at 90% vacuum	200 ml/min with 0.2 µm membrane filter 600 ml/min with 0.45 µm membrane filter
Filtration area	12.5 cm² (if using stainless steel funnels)
Suitable membrane filter diameter	50 mm (47 mm, if using a 47 mm frit 6980103)
Outlet spout (individual system)	10 mm outer diameter
Inlet (branches only)	Female thread, TR 20×2
Outlet (branches only)	Quick Connection Nipple DN 7 (tubings with DN 10 are max. connectable)

Combisart® Individual System and Multi–Branch Manifolds, Made of High–Grade Stainless Steel, Pre–Assembled with Stainless Steel Funnels and Lids

Description	Capacity	Order No.
Combisart® individual filter holder, stainless steel, 100 ml	1×100 ml	16219-CS
Combisart® individual filter holder, stainless steel, 500 ml	1×500 ml	16201-CS
Combisart® 1-branch stainless steel manifold 100 ml	1×100 ml	16844-CS
Combisart® 1-branch stainless steel manifold, 500 ml	1×500 ml	16845-CS
Combisart® 3-branch stainless steel manifold 100 ml	3×100 ml	16824-CS
Combisart® 3-branch stainless steel manifold 500 ml	3×500 ml	16828-CS
Combisart® 6-branch stainless steel manifold 100 ml	6×100 ml	16832-CS
Combisart® 6-branch stainless steel manifold 500 ml	6×500 ml	16831-CS

Combisart® Individual and Multi–Branch Bases, Made of High–Grade Stainless Steel, Without Funnels and Lids, to Accommodate Various Funnel Types

Description	Order No.
Combisart® individual base, stainless steel, with frit (50 mm), to accommodate stainless steel funnels and Biosart® 100│250	16841
Combisart® 1-branch stainless steel manifold, without frit	16844
Combisart® 3-branch stainless steel manifold, without frits	16842
Combisart® 6-branch stainless steel manifold, without frits	16843
Combisart® Single base with frit (for 50 mm membranes), stainless steel, accommodate stainless steel funnels and Biosart® 100│250	16840
Microsart® Base 47 mm, with frit, stainless steel, optimal for the use with 47 mm membranes, Click-Fit closure for Microsart® Funnel and Microsart® @filter (other funnel types sealed by bayonet closure)	1ZU---0002

Replacement Parts for Combisart® Individual Filter Holders

6981001
stainless steel lid

6981003
silicone lid seal

6981002
stainless steel funnel 500 ml
with clamp

6980264
clamp

6981063
stainless steel lid

6981064
silicone lid seal

6981065
stainless steel funnel 100 ml
with clamp

6980264
clamp

6981004
stainless steel
funnel 40 ml
with clamp

6980102 stainless steel frit 50 mm
6980103 stainless steel frit 47 mm

6980124 silicone flat gasket
6980104 PTFE flat gasket

17012-E
Plug Luer Lock
(pack of 12)

17575-ACK
Minisart SRP
(pack of 50)

6980267 3-way tap
6980268 knurled nut

6980225
Plug conical
(pack of 10)

16841
individual
stainless
steel base

Replacement Parts for Combisart® Manifolds

6981004
funnel 40 ml
with clamp

6981063
stainless steel lid

6981064
silicone lid seal

6981065
funnel 100 ml
with clamp

6980264
clamp

16840*
single base

6981001
stainless steel lid

6981003
silicone lid seal

6981002
funnel 500 ml with clamp

6980264 clamp

6980271
silicone O-ring
16 × 2 mm

16840*
single base

6980270
stainless steel cap

6980102 stainless steel frit 50 mm
6980103 stainless steel frit 47 mm

6980124 silicone flat gasket
6980104 PTFE flat gasket

16840* stainless steel single base
(incl. 50 mm frit and silicone gasket)

6980274 silicone O-ring 8 × 20

6980235 silicone O-ring (pack of 3)

6980268
knurled nut

17575–ACK
Minisart SRP
(pack of 50)

17012–E
Plug Luer Lock
(pack of 12)

Manifolds
without base
supports and
funnels:
16844 1–branch
16842 3–branch
16843 6–branch

1EAS—0026 quick connection nipple
6980272 hose nipple

6980271
silicone O-ring
16 × 2 mm

6980267
stainless steel
3–way tap

6980225
Plug conical
(pack of 10)

*) Alternatively to 16840 the Microsart® Base 47 mm is highly recommended
   for all 47 mm membrane filters, Microsart® Funnels and Microsart® @filter units.

Accessories and Replacement Parts for the Combisart® System

Description	Quantity	Order No.
Minisart® SRP25, sterile filter for venting, 0.2 µm, individually sterile-packaged, could be autoclaved 5 times.	50	17575--------ACK
Plug luer lock, to close the Minisart® inlet, if sterile venting is not required	12	17012----------E
Plug, conical, to close the venting hole beside the 3-way-valve, if sterile venting is not required	10	6980225
Silicone O-ring for single base 16840 male thread	3	6980274
Silicone O-ring for manifold female threads	3	6980235
Silicone flat gasket underneath the frit	1	6980124
PTFE flat gasket underneath the frit	1	6980104
Stainless steel frit, 50 mm diameter	1	6980102
Stainless steel frit, 47 mm diameter	1	6980103
Quick Connection Nipple, stainless steel	1	1EAS--0026
Hose nipple, stainless steel, DN 10	1	6980272
Replacement frit for Microsart® Base 47 mm, stainless steel	1	1ZU---0001

Funnels, Lids, Seals and Filter Holders to Connect on the Combisart® System

Description	Capacity	Membrane Filter Diameter	Order No.
Stainless steel funnel with closure clamp	100 ml	47 | 50 mm	6981065
Lid, stainless steel	for 100 ml funnel		6981063
Lid seal, silicone	for 100 ml funnel		6981064
Stainless steel funnel with closure clamp	500 ml	47 | 50 mm	6981002
Lid, stainless steel	for 500 ml funnel		6981001
Lid seal, silicone	for 500 ml funnel		6981003
Stainless steel funnel with closure clamp	40 ml	47 | 50 mm	6981004
Polycarbonate filter holder, complete with filter support and funnel	250 ml	47 mm	16511
Glass filter holder, complete with filter support, funnel and metal clamp	30 ml	25 mm	16306
Glass filter holder, complete with filter support, funnel and metal clamp	250 ml	47 | 50 mm	16307

Combisart® Adapter, to Accommodate Various Funnel Types

Description	Adaptation	Order No.
Biosart® 100 Adapter, silicone	Biosart® 100 Monitors onto 16840 (Combisart® single base) or onto 16841 (individual base)	16414
Biosart® 100 Adapter, stainless steel with silicone stopper	Biosart® 100 Monitors onto Combisart® manifolds 16844, 16842 and 16843	16835
Glass funnel Adapter, stainless steel with silicone stopper	16306 | 15 (glass funnel, 30 ml) onto Combisart® manifolds 16844, 16842 and 16843	16836
Glass funnel Adapter, stainless steel with silicone stopper	16307 (glass funnel, 250 ml) onto Combisart® manifolds 16844, 16842 and 16843	16837

▶ # Microsart® Combi.jet

2-Branch Stainless Steel Manifold for Microbiological Analysis

The Microsart® Combi.jet is a 2-branch manifold, made of high-grade stainless steel. The manifold has been specifically designed for the use together with the Microsart® e.jet Transfer Pump. The system is able to create sufficient vacuum for vacuum filtration concomitantly transferring the filtered liquid directly to waste. Microsart® Combi.jet and Microsart® e.jet can be easily connected and disassembled by the innovative Quick Connection technology.

Compact Design
The complete traditional equipment, such as connectors, tubes, suction flask, protection filter, Woulff's bottle and a vacuum pump, requires a lot of laboratory space and is time consuming to operate and maintain. Microsart® Combi.jet reduces operating complexity due to its small and compact design. The Transfer Pump Microsart® e.jet fits visually and ergonomically into this design.

Quick Connection
Building-up the vacuum filtration system is easy and fast thanks to the innovative Quick Connection Coupling and Nipples at the Microsart® Combi.jet manifold and Microsart® e.jet Transfer Pump. Simply push-to-connect for assembling and pull-to-disassembling the whole system within seconds.

Sterile Venting
A special feature of the Microsart® Combi.jet manifold are the stainless steel three-way valves (taps). They allow the vacuum for each filter holder to be individually controlled and each filter station to be sterilely vented. This rules out secondary contamination of the underside of the filter.

Maximum Flexibility
The Microsart® Combi.jet enables you to select the optimal hardware and consumables for your needs in microbiological analysis in quality assurance. Microsart® Combi.jet features a modular design and field-proven standard accessories to make your choice easier. At the heart of the whole system is the Microsart® Combi.jet, the stainless steel 2-branch manifold, designed to accommodate all types of filter holders and funnels such as:

– Ready-to-use units Microsart® @filter 100 and 250

– Ready-to-use units Microsart® Funnel 100 and 250

– Ready-to-use units Biosart® 100 Monitors

– Ready-to-use units Biosart® 250 Funnels

– Flammable units such as stainless steel funnels

– Autoclavable glass filter holders

– Autoclavable polycarbonate

Reliability: Ideal for Microbiology Applications

– Sterile venting after filtration

– Easy to clean and sanitize

– Smooth and reliable filtration

Economically Efficient

– Saving time due to Quick Connection technology

– Saving work space

– No need of suction flasks and water traps

▷ Specifications

Stainless steel quality	High-grade stainless steel: B.S. 304S31 | AISI 304
Dimensions in mm (L | H | D)	246 | 98 | 130
Max. operating pressure	Vacuum only
Sterilization	By autoclaving (max. 134°C)
Parts and materials	Manifold: stainless steel, silicone O-ring
Quick Connection Coupling	PVDF, closure: stainless steel, sealing: FKM | FPM
Inlet (manifold)	Female thread, TR 20×2
Outlet	Quick Connection Coupling (female), inner diameter NW 7, non-shut-off

Microsart® Base 47 mm

Materials	stainless steel, silicone O-ring
Suitable membrane filter diameter	47 mm
Filtration area (e. g. for the use with Microsart® Funnels)	12.5 cm²

Microsart® Combi.jet 2–Branch Manifold, Made of High–Grade Stainless Steel, Without Frits and Funnels, to Accommodate Various Funnel Types

Description	Order No.
Microsart® Combi.jet 2-branch manifold, without frits	16848-CJ
Microsart® Base 47 mm, with frit, stainless steel, optimal for the use with 47 mm membranes, Click-Fit closure for Microsart® Funnel and Microsart® @filter (other funnel types closure by bayonet or adapter)	1ZU---0002

Accessories and Replacement Parts for Microsart® Combi.jet

Description	Quantity	Order No.
Minisart® SRP25, sterile filter for venting, 0.2 µm, individually sterile-packaged, could be autoclaved 5 times	50	17575--------ACK
Plug luer lock, to close the Minisart inlet, if sterile venting is not required	12	17012----------E
Plug, conical, to close the venting hole beside the 3-way-valve, if sterile venting is not required	10	6980225
Silicone O-ring for Microsart® Base 47 mm male thread	3	6980274
Silicone O-ring for manifold female threads	3	6980235
Combisart® single base, stainless steel, optimal for the use with 50 mm membrane filters, funnel closure by bayonet or adapter	1	16840
Microsart® Combi.jet Coupling, Quick Connection, PVDF	1	1EAS--0022

Funnels and filter holders to connect onto the Microsart® Combi.jet manifold are equivalent to those for the use with the Combisart® system (page 578).

▶ How to Set-up a Vacuum Filtration System

Microsart® Combi.jet 2-Branch Stainless Steel Manifold plus Microsart® e.jet
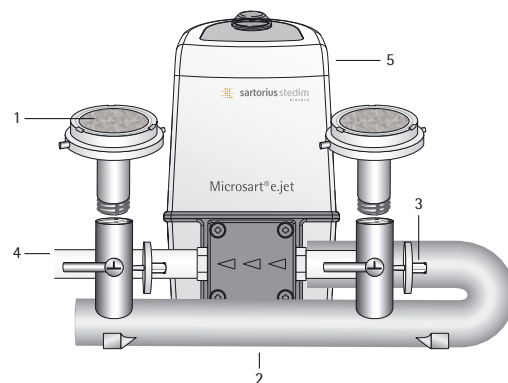
The filter stations are directly connected to a Transfer Pump for simultaneous transfer of the filtrate to waste. Easy assembling by Quick Connection technique.

Order Information

Pos.	Description	Order Qty.	Order No.	Detailed Information on Page
	Microsart® Combi.jet stainless steel equipment:			583
1	Microsart® Base 47 mm	2	1-ZU---0001	
2	Microsart® Combi.jet 2-branch manifold	1	16848-CJ	
	Sterile venting of the filter station:			581
3	Minisart® SRP25, 0.2 μm	1	17575--------ACK	
4	Silicone tubing, 1 m	2*	1ZAS--0007	595
	Vacuum Pump:			594
5	Microsart® e.jet Transfer Pump, 230 V, 50 Hz	1	166MP-4	
	Additional accessories:			
	Microsart® @filter 100, sterile filter units	1	16D01--10-H6--TG	572
	Microsart® e.motion Dispenser	1	16712	552
	Stainless steel tweezers	1	16625	599
	Colony Counter	1	17649	598
	Incubator	1	18113	598
	Stainless steel prefilter attachment	1	16807	599
	Container for anaerobic incubation	1	16671	599

* required length depends on distance between Transfer Pump and drain

Combisart® 1-Branch Stainless Steel Manifold Plus Microsart® mini.vac
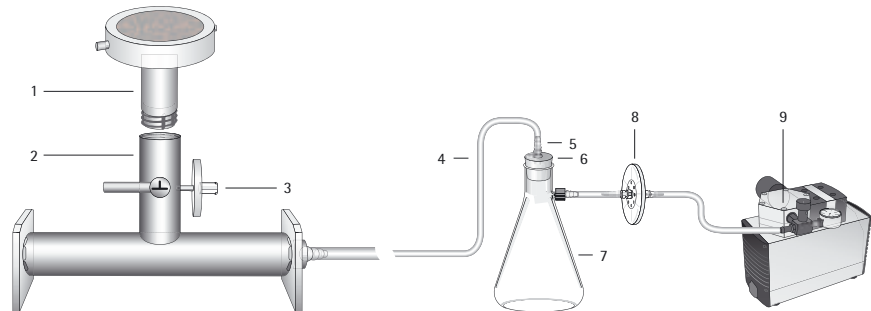
The filter station is connected to a suction flask, which is connected to a filtrate-protected vacuum pump.

Order Information

Pos.	Description	Order Qty.	Order No.	Detailed Information on Page
	Combisart® stainless steel equipment:			578
1	Combisart® single base, 50 mm	1	16840	
2	Combisart® 1-branch manifold	1	16844	
	Sterile venting of the filter station:			581
3	Minisart® SRP25, 0.2 µm	1	17575--------ACK	
4	Rubber vacuum hose, 1 m	3*	16623	591
	Suction flask and stopper:			590
5	Tube connector	1	17204	
6	Silicone stopper	1	17173	
7	Suction flask, 2 liters	1	16672	
	Water trap for pump protection:			591
8	Vacusart®, 0.45 µm	1	17804----------M	
	Vacuum Pump:			592-595
9	Microsart® mini.vac, 230 V, 50 Hz	1	16694-2-50-06	
	Additional accessories:			
	Microsart® e.motion Dispenser	1	16712	552
	Stainless steel tweezers	1	16625	599
	Colony Counter	1	17649	598
	Incubator	1	18113	598
	Stainless steel prefilter attachment	1	16807	599
	Container for anaerobic incubation	1	16671	599

* required length depends on distance between the filter station and the vacuum source

Combisart® 1–Branch Stainless Steel Manifold plus Microsart® e.jet
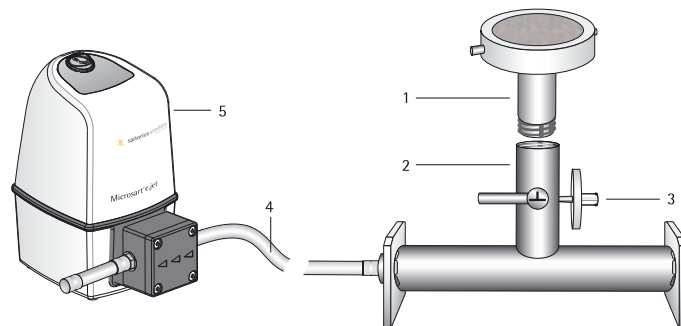
The filter station is directly connected to a vacuum fluid pump for simultaneous transfer of the filtrate to waste.

Order Information

Pos.	Description	Order Qty.	Order No.	Detailed Information on Page
	Combisart® stainless steel equipment:			578
1	Combisart® single base, 50 mm	1	16840	
2	Combisart® 1–branch manifold	1	16844	
	Sterile venting of the filter station:			581
3	Minisart® SRP25, 0.2 µm	1	17575--------ACK	
4	Rubber vacuum hose, 1 m	3*	16623	591
	Vacuum Pump:			594
5	Microsart® e.jet Transfer Pump	1	166MP–4	
	Additional accessories:			
	Microsart® e.motion Dispenser	1	16712	552
	Stainless steel tweezers	1	16625	599
	Colony Counter	1	17649	598
	Incubator	1	18113	598
	Stainless steel prefilter attachment	1	16807	599
	Container for anaerobic incubation	1	16671	599

* required length depends on distance between the filter station and the vacuum source

▶ Traditional Multi-Branch Manifolds and Individual Filter Holders

Made of Stainless Steel, Glass and Polycarbonate

Individual Filter Holders
The three stainless steel holder types differ only in the funnel capacity (either 40 ml, 100 ml or 500 ml). They have been designed specifically for applications in which the particles or microorganisms retained on the membrane filter surface are of interest. The stainless steel frit filter support ensures a uniform distribution of the residues. Simple handling is very important regarding routine examinations. Stainless steel taps in the base allow the vacuum to be turned on and off. The special closure clamps simplify the addition or removal of the funnels adding to the ease of use.

Multi-Branch Manifolds
The manifold systems are available with 100 ml or 500 ml capacity funnels. The three or six separate filter holders save time when mass examinations have to be carried out. Due to the stainless steel taps on the manifold ports, the vacuum for each holder can be turned on and off individually. The stainless steel frit allows homogenous distribution of the residues on the membrane filter surface. Funnel and filter support can be disinfected by flaming.

Glass Filter Holders
These filter holders are available for the filtration of small volumes with a 30 ml top part and for larger volumes with a 250 ml top part. They can be sterilized by autoclaving (max. 134 °C) or by dry heat (max. 180 °C). The glass frit ensures uniform distribution of retained residue.

Polycarbonate Filter Holders
Type 16510 is complete with receiver flask, and can be operated with vacuum as well as with slight overpressure (0.5 bar is recommended for highest standing times). Type 16511 is like 16510, but without receiver flask. It is used on a suction flask or a vacuum manifold e. g. Combisart® systems. Both devices can be sterilized by autoclaving (max. 121 °C).

▷ Specifications

Stainless Steel Multi-Branch Manifolds and Individual Filter Holders

Stainless steel quality	High-grade stainless steel: B.S. 304S31 │ AISI 304
Dimensions in mm (W│H│D)	3-branch manifold: 3 × 100 ml: 432 │ 184 │ 120 3 × 500 ml: 442 │ 262 │ 132 6-branch manifold: 6 × 100 ml: 906 │ 268 │ 120 6 × 500 ml: 916 │ 329 │ 132
Max. operating pressure	Vacuum or max. 2 bar pressure (29 psi)
Sterilization	By autoclaving (max. 134 °C), By dry heat (max. 180 °C), By flaming, By other methods acc. to ISO 8199
Parts and materials	Lid, funnel, base part, – filter support, clamp and tap made of stainless steel. Silicone flat gasket. Silicone lid seal
Flow rate per filter station for water at 90 % vacuum	200 ml/min with 0.2 µm membrane filter 600 ml/min with 0.45 µm membrane filter
Filtration area	12.5 cm²
Suitable membrane filter diameter	50 mm (47 mm, if using a 47 mm frit filter support 6980103)
Outlet spouts (individual system)	10 mm outside diameter
Outlet (branches only)	Hose nipple, DN 10

Replacement Parts for Traditional Individual Filter Holders

6981001
stainless steel lid

6981003
silicone lid seal

6981002
stainless steel funnel 500 ml
with clamp

6980264
clamp

6980102 stainless steel frit 50 mm
6980103 stainless steel frit 47 mm

6980124 silicone flat gasket
6980104 PTFE flat gasket

6982119 spare parts
(leaf spring, washer, lock washer)

6980101 stainless steel base

6981063
stainless steel lid

6981064
silicone lid seal

6981065
stainless steel funnel 100 ml
with clamp

6980264
clamp

6981004
stainless steel funnel 40 ml
with clamp

Replacement Parts for Traditional Manifolds

6981004
funnel 40 ml
with clamp

6980271
silicone O-ring
16 + 2 mm

6980270
stainless steel cap

6982119 spare part
kit for tap
(leaf spring, washer,
lock washer)

6981063
stainless steel lid

6981064
silicone lid seal

6981065
stainless steel
funnel 100 ml
with clamp

6980264
clamp

Manifolds
without funnels:

16824-----1 3-branch
16831-----1 6-branch

6981001
stainless steel lid

6981003
silicone lid seal

6981002
stainless steel funnel 500 ml
with clamp

6980264
clamp

6980102 stainless steel frit 50 mm
6980103 stainless steel frit 47 mm

6980124 silicone flat gasket
6980104 PTFE flat gasket

6980272
hose nipple

6980271
silicone O-ring

Individual Stainless Steel Filter Holders, Pre-Assembled with Stainless Steel Funnels and Lids

Description	Capacity	Order No.
Individual stainless steel filter holder, 100 ml	1 × 100 ml	16219
Individual stainless steel filter holder, 500 ml	1 × 500 ml	16201
Individual stainless steel filter holder without lid, 40 ml	1 × 40 ml	16220

Multi-Branch Manifolds, Stainless Steel, with Stainless Steel Funnels and Lids

Description	Capacity	Order No.
3-branch stainless steel manifold, 100 ml	3 × 100 ml	16824
3-branch stainless steel manifold, 500 ml	3 × 500 ml	16828
6-branch stainless steel manifold, 100 ml	6 × 100 ml	16832
6-branch stainless steel manifold, 500 ml	6 × 500 ml	16831

Glass Filter Holders

Description	Capacity	Membrane Filter Diameter	Order No.
Glass filter holder, complete with filter support, funnel and metal clamp	30 ml	25 mm	16306
Glass filter holder, complete with filter support, funnel and metal clamp	250 ml	47 | 50 mm	16307

Polycarbonate Filter Holder

Description	Capacity	Membrane Filter Diameter	Order No.
Polycarbonate filter holder, with 250 ml top part and receiver flask, for vacuum or pressure filtration	250 ml	47 mm	16510
Polycarbonate filter holder, with 250 ml top part, for vacuum filtration only	250 ml	47 mm	16511

▶ Accessories for Vacuum Filter Holders
and Manifold Systems

Suction Flasks and Stoppers

Suction Flask, 2 Liter Capacity
Vacuum-resistant flask made of duran
50 glass with plastic safety hose nipple
according to the – German Industrial
Standard No. 12476. Outer diameter of the
hose nipple, 9 mm. Inner diameter of the
opening, 60 mm. Stoppers are not enclosed.

A 1-liter capacity flask is available for
countries which do not have safety
restrictions on glass hose nipples.

Order Numbers for Suction Flasks

Description	Order No.
Suction flask, 5 liters acc. to DIN 12476, incl. stopper 75 D and glass tube	16672-----1
Suction flask, 2 liters acc. to DIN 12476, without stopper	16672
Tube connector for connecting a Combisart® stainless steel manifold to a suction flask 1 or 2 liters (not necessary when a Vacusart® is connected directly to the bored stopper)	17204
Suction flask, 1 liter (not available in countries which have safety restrictions on glass hose nipples)	16606

Replacement Parts for Suction Flasks

Description	Order No.
Glass tube for silicon stopper 75 D for suction flask 5 liters 16672-----1	1EAQ--0017
Bored stopper 75 D for suction flask 5 liters 16672-----1	1EAS--0019
Assembling kit for hose barb for suction flask 5 liters 16672-----1	1EA---0018
Hose barb, complete, Polypropylene, for suction flask 2 liters 16672	6983003

Order Numbers for Bored Stoppers for Suction Flask 2 Liters 16672

Description	Adaptation	Order No.
Silicone stopper	Combisart® individual base 16841 or other individual stainless steel filter holders (16201, 16219, 16220) onto the suction flask 16672	17173
Silicone stopper	16306│15 (glass funnels, 30 ml) onto the suction flask 16672	17174
Silicone stopper	16307 (glass funnel, 250 ml) onto the suction flask 16672	17175

Order Numbers for Bored Stoppers for Suction Flask 1 Liter 16606

Description	Adaptation	Order No.
Silicone stopper	Combisart® individual base 16841 or other individual stainless steel filter holders (16201, 16219, 16220) onto the suction flask 16606	17004
Silicone stopper	16306│15 (glass funnels, 30 ml) onto the suction flask 16606	17005
Silicone stopper	16307│16 (glass funnel, 250 ml) onto the suction flask 16606	17006

Water Traps
Used between suction flask and vacuum source, in order to prevent overflow of filtrate into an electric vacuum pump

Vacusart®
Vacusart® is a ready-to-connect filtration unit, consisting of a polypropylene housing and a hydrophobic, but air-permeable PTFE membrane with a pore size of 0.45 µm. Vacusart® is perfectly suitable for the protection of vacuum pumps. It could be put directly into the hole of the bored stopper and connected with the rubber hose to the vacuum pump.

Description	Order No.
Vacusart® water trap, pack of 3	17804----------M

Woulff's Bottle, 500 ml
Used between suction flask and vacuum source. Allows simple control of the vacuum with glass units without a separate tap and prevents furthermore the filtrate from overflowing from the suction flask.

Description	Order No.
Woulff's bottle, 500 ml	16610

Rubber Vacuum Hose (1 Meter)
Thick-walled rubber hose for connecting the system components, e. g. suction flasks, vacuum pumps, etc. When ordering, please state length required in meters.

Description	Order No.
Rubber vacuum hose (1 meter)	16623

▶ Electric Vacuum Pumps

Microsart® mini.vac
Microsart® maxi.vac
Neoprene membrane pumps with low noise level, oil- and maintenance-free; reliable sources of vacuum.

The new vacuum pump series provides up to date technology for daily use in the Microbiology laboratory environment.

The vacuum produced by the new pumps is controlled and can be easily adjusted to your specifications. Thus damageable cells (e.g. bacteria) are concentrated on the surface or a membrane filter under better conditions, which results in decreased sub lethals, higher recovery rates and shorter incubation times.

▷ Specifications

Specifications of Electric Vacuum Pumps

	Microsart® maxi.vac 16694-2-50-22 16694-1-60-22	Microsart® mini.vac 16694-2-50-06 16694-1-60-06
Delivery	22 l/min	6 l/min
Ultimate Vacuum	100 mbar	100 mbar
Noise level [100 mbar]	57.5–59.0 dBA	53.5 dBA
Operating Pressure	1 bar	2.5 bar
Materials (contact with filtrate possible)	Aluminum, CR (Neoprene), NBR (Perbunan)	PPS, EPDM, FPM (Viton)
Connectors for Tube (mm)	ID 9	ID 4
Ambient Temperature	5…40℃	5…40℃
Mains	16694-2-50-22: 230 V │ 50 Hz 16694-1-60-22: 115 V │ 60 Hz	16694-2-50-06: 230 V │ 50 Hz 16694-1-60-06: 115 V │ 60 Hz
Motor Protection	IP 44	IP 20
Power P1	130 W	65 W
Operating Current	0.9 A	0.63 A
Weight	7.1 kg	1.9 kg
Dimensions W │ H │ D (mm)	261 │ 204 │ 110	164 │ 141 │ 90
Recommended application	Multiple filtration runs with multi-branch manifolds	Single filtration run with individual filter station

Order Numbers

Description	Order No.
Microsart® maxi.vac for multiple filtration runs, 230 V, 50 Hz	16694-2-50-22
Microsart® maxi.vac for multiple filtration runs, 115 V, 60 Hz	16694-1-60-22
Microsart® mini.vac for single filtration run, 230 V, 50 Hz	16694-2-50-06
Microsart® mini.vac for single filtration run, 115 V, 60 Hz	16694-1-60-06

Replacement Parts	Order No.
Replacement kit for 16694-2-50-22 and -1-60-22, set of one membrane, two valve springs and two head seals	1ED---0055
Replacement kit for 16694-2-50-06 and -1-60-06, set of one membrane, two valve springs and two head seals	1ED---0054
Sound absorber for 16694-2-50-22 and -1-60-22	1EH---0002
Sound absorber for 16694-2-50-06 and -1-60-06	1EH---0001
Fine adjustment head for 16694-2-50-22 and -1-60-22	1EV---0002
Fine adjustment head for 16694-2-50-06 and -1-60-06	1EV---0001
Fine adjustment head for 16694-2-50-06 and -1-60-06, for pressure filtration	1EV---0003

Microsart® e.jet Transfer Pump with Quick Connection Now

The Microsart® e.jet is a new vacuum laboratory pump able to create sufficient vacuum for vacuum filtration and concomitantly transferring the filtered liquid directly to waste. The Microsart® e.jet is ideal for sample preparation in Microbiology achieving a trans membrane pressure of 600 mbar and a flow rate of > 3.5 Nl/min (3.5 Normliters water displacement by air in one minute). Constant flow rates and a defined maximum vacuum guarantee smooth and reliable filtration.

Reducing Operating Complexity

Until now vacuum equipment for the Membrane Filtration Method consists of numerous parts including connectors, tubes, vacuum containers, protection filter, Woulff's bottle and a vacuum pump. After several samples the vacuum must be broken to empty the filtrate collection container. The complete traditional equipment requires far more laboratory space and is time consuming to operate and maintain. Microsart® e.jet will eliminate the need for side-arm flasks or Woulff's bottles from the laboratory filtration bench.

The Microsart® e.jet pump is an ideal accessory for manifolds up to 3 filter stations. Compared to traditional equipment Microsart® e.jet and a stainless steel manifold require only 30% of the average space meaning in particular less congestion working in Laminar Flow Cabinets.

Traditional vacuum pumps often loose their efficiency and capability to generate sufficient vacuum, when liquid is drawn into the pump head. The Microsart® e.jet is designed to pump both gas and liquids, meaning no loss of efficiency or malfunctions from water drawn into the pump head.

Quick Connection

Building-up the vacuum filtration system is easy and fast thanks to the innovative Quick Connections. The Microsart® e.jet Transfer Pump is equipped with Quick Connection Nipples assembled to Quick Connection Couplings on hose nipples for DN 10 tubings. Simply push-to-connect for assembling and pull-to-disassembling the whole system within seconds. The Quick Connections are non-shut-off.

Some of the advantages you will benefit from when using the Microsart® e.jet

– Ideal for microbiology applications

– No need of suction flasks and water traps

– Saving 70% of work space while saving money – that's economic efficiency

▷ Specifications

Technical Specifications

Flow rate	> 3.5 Nl/min
Max. Vacuum	0.4 bar
Max. Pressure	1.0 bar
Mains	100–240 V │ 50-60 Hz
Materials (in contact with filtrate)	PTFE, ETFE, Polypropylene, EPDM, POM, PSU
Weight	Pump: 1425.3 g Power supply: 202.8 g
Dimensions (W│L│H)	120 × 170 × 190 mm
Max. ambient Temp.	+5...+40℃
Max. Temp of liquid	+5...+80℃
Max. viscosity	<150 cSt
Protection type	IP 64
Protection class	III
Inlet │ Outlet	Quick Connection on hose nipples for DN 10 tubings

Order Information

Description	Order Number
Microsart® e.jet Transfer Pump	166MP-4

Accessories	Order Number
Tubing with Quick Connection Coupling (PSU), silicone, 20 cm, for vacuum-sided connection, inner diameter DN 10, outer diameter DN 20, wall thickness 5 mm	1ZA---0006
Silicone tubing, 1 m, for pressure-sided connection, inner diameter DN 10, outer diameter DN 14, wall thickness 2 mm	1ZAS--0007

Replacement Parts

Description	Order Number
Pump head complete for 166MP-3 and 166MP-4	1EP---0001
Power supply complete for 166MP-3 and 166MP-4	1EE---0007

Threaded Fittings

Quick Connection set, 2 Nipples (POM) on R3/8" male thread and 2 Couplings (PSU) on DN 10 hose nipple	1EAS--0027
DN 10 hose nipple on R3/8" male thread	1EAF--0020

Order Numbers Traditional Pumps

Description	Order No.
Multiple filtration runs: 13 mbar final vacuum, 26 l/min max., 220 V, 50 Hz	16612
Multiple filtration runs: 13 mbar final vacuum, 26 l/min max., 110 V, 60 Hz	16615
Individual filtration run: 100 mbar final vacuum, 20 l/min max., 220 V, 50 Hz	16692
Individual filtration run: 100 mbar final vacuum, 20 l/min max., 110 V, 60 Hz	16695

Replacement Parts	Order No.
Set of two neoprene membranes, four valve springs and two neoprene head seals for 16612/16615	6986017
Set of one neoprene membrane, two valve springs and one neoprene head seal for 16692/16695	6986105

Water Jet Pump
Simple vacuum source. For connection to
a water tap with G3/4 male thread.

Description	Order No.
Water jet pump, with G 3/4 female thread	16611

Hand–Operated Vacuum Pump
Practical vacuum source, also outside of
a laboratory. Up to 80% vacuum can be
obtained. The body is of PVC. Supplied
completely with gauge, vacuum release lever
and a 60-cm length of clear plastic tubing.

Description	Order No.
Hand-operated vacuum pump with gauge	16673

Dosing Syringe
The most convenient way to moisten the NPS
with water is to use a dosing syringe with an
adapted Minisart® syringe filter. Simultaneous
sterilization and dispensing of demineralized
water in 3.5 ml steps is easily done by dropping
the sinker at the end of the suction tubing
into the water, then filling the dosing syringe
and dispensing sterile water by operating the
twigger automatically.

Description	Order No.
Dosing syringe, 0.5–5 ml	16685-2
Minisart®, 0.2 µm, individually, sterile-packaged	17597----------K
Replacement part: tubing with sinker for 16685-2 and 16685	6986125
Service Kit for Dosing Syringe 16685-----2	1EP---0002

Colony Counter
Compact, handy battery-operated colony counter, it is as simple to use as a ball-point pen, and has a 4-digit LCD-display. The counter is supplied with an additional marker refill.

Description	Order No.
Colony counter	17649
Replacement part: Black marker refill	6981540
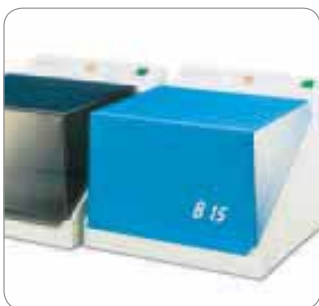
Incubator
Compact, space-saving incubator for the incubation of membrane filters on nutrient pads or other nutrient media. The incubator has a capacity of 15 liters and is designed to hold the following numbers and sizes of petri dishes: 200×47 mm or 160×56 mm | 60 mm or 72×90 mm.

The swing-up cover and removable insertion plate simplify loading and unloading. The cover is opaque, avoiding light penetration into the chamber.

▷ Specifications

Incubator	18113
Voltage	230 V
Frequency	50	60 Hz
Rated power	0.2 kW
Weight	5.5 kg (12 lbs)
Max. load for insertion plate	5 kg (12 lbs)
Dimensions W	H	D (mm)	Inner 270	205	288 Outer 340	270	431
Temperature range	20°C (or 5°C above room temperature) to 50°C
Temperature deviation	Less than ±0.2°C (at 37°C and RT 20°C)
Spacial temperature deviation	Less than ±0.8°C
Capacity	approx. 15 liters

Description	Order No.
Incubator	18113

Stainless Steel Tweezers
Membrane filters should only be handled
with suitable tweezers to avoid contamination
which can result from hand contact. Sartorius
Stedim Biotech stainless steel tweezers can be
flamed and they are autoclavable. They have
blunt-edged tips for a careful, firm hold of the
membrane filter.

Description	Order No.
Stainless steel tweezers	16625

Stainless Steel Prefilter Attachment
The stainless steel prefilter holder allows
the removal of coarse, solid particles from
samples for microbiological analysis before
and during the actual bacteria retentive fil-
tration. The device is clipped between funnel
and base of the stainless steel vacuum filter
holders. It can be autoclaved and flamed.
11301, a white cellulose nitrate (cellulose
ester) membrane filter with a pore size of
8 µm is used as the prefilter and it retains
the coarse suspended particles from the
sample, whereas it allows microorganisms
to pass through. These microbes are trapped
on the surface of the underlying bacteria-
retentive membrane filter (e. g. 0.45 µm).
After filtration is complete, the test filter
is incubated, and the colonies can grow on
the filter surface without disturbance from,
or being hidden by, an excess of particles.

Description	Order No.
Stainless steel prefilter attachment	16807
Cellulose nitrate membranes with 50 mm diameter and 8 µm pore size for the prefilter holder, pack of 100, individually, sterile packaged	11301--50----ACN
Replacement part: support plate, autoclavable, flammable	6981139

Container for Anaerobic Incubation
Stainless steel container with 11.8 cm inner
diameter, 10.7 cm depth and a with metal
insert for convenient insertion and removal of
petri dishes. The plastic lid holds two taps for
the vacuum exhaust and for cleaning with
inert gas, with 6 mm hose nipples (for 16623),
vacuum gauge and sealing ring. For up to
fourteen 60 mm, or up to six 90 mm petri
dishes.

Description	Order No.
Anaerobic container	16671

▶ Sterility Testing Systems
Sterisart® Universal Pump

International pharmacopeias require the complete sterility of pharmaceutical products that are injected into the blood stream or that otherwise enter the body below the skin surface. As a manufacturer of such products, you are required to supply proof of sterility of the final product batch.

The new Sterisart® Universal Pump is available in two versions: as basic version 16419 and as an upgraded version 16420 with display and user software. The pump can be used in clean rooms, integrated into clean benches, or installed countersunk in the working surface of isolators. Its low, compact design has a space-saving footprint – a great benefit for most clean room benchtops and isolators.

Additional Features and Benefits

– Closed system – no ventilation for enhanced safety

– Robust and maintenance free

– Compact and ergonomic construction

– Modular design

– Pump available with special software (operator-guided menus; all process sequences can be logged; barcode recognition)

Special brochures available on request.
Order no. SLD1003-e, SLD2010

▷ Specifications

Technical Specifications for Sterisart® Universal Pump

Pump flow rate	70–650 ml/min
Power requirements	100–240 VAC
Frequency	50–60 Hz
Power consumption	100 W
Dimensions Pump Pump with holding ring for bottles, container	approx. 336×260×210 mm (with lever) (W×D×H) approx. 440×365×485 mm (W×D×H)
Weight Basic version 16419 Upgraded version 16420 with display and user software	approx. 13.5 kg approx. 14.6 kg

Ordering Information

Order No.	Description
16419	Sterisart® Universal pump, basic version
16420	Sterisart® Universal pump, upgraded version with display｜user software

Accessories

Order Number	Description
1ZE---0033	Footswitch
1ZG---0014	Adapter for Sterisart® container for draining for usage with Millipore Equinox pump
1ZG---0025	Adapter for Sterisart® container for draining for usage with new Millipore Equinox pump
1ZE---0039	Transport trolley
1ZE---0040	Communication kit
1ZE---0041	Installation kit for isolators

Further accessories are available on request.

▶ Sterility Testing Systems
Sterisart® NF

Sterisart® NF is a completely closed system for the sterility testing of pharmaceutical products. It is based on the membrane filter method, however it eliminates the procedure of manipulating the filters. By this the main risk of a secondary contamination and false positive results is eliminated. A peristaltic pump transfers the sample into the filtration units, and after rinsing, the filtration units are filled with media and used for incubation of the filters without any contact to the environment.

Special brochures available on request. Order no. SLD1002-e, SL-2019-e, SLD2006-e, SLD2005-e, SLD2007-e, S--2019-e, SLD2009-e, SLDS2001

Sterisart® NF Offers the Following Features and Benefits

– Reliable, Sartochem® membrane:
  – High retention of microbes
  – Low adsorption
  – High mechanical stability

– Easy to use:
  – Pre-installed color-coded tube clamps
  – Easy-to-read graduated marks
  – User-friendly, several practical adapters available
  – Product-|lot number identification

– Secure:
  – Gas-impermeable packaging for protection against sterilants

▷ Specifications

Technical Specifications for Sterisart® NF

Pore size of the Sartochem® membrane filter	0.45 µm, tested with Serratia marcescens
Filter area	15.7 cm² in each Sterisart® container
Flow rate (for water)	500 ml/min at 1 bar (approx. 15 psi)
Pore size of the air filters	0.2 µm PTFE, validated acc. to HIMA for the retention of B. diminuta
Sample container capacity	120 ml (graduation marks at 50, 75 and 100 ml)
Max. operating pressure	3 bar (approx. 44 psi) at 20°C
Max. operating temperature	50°C
Sterilization	ETO (ethylene oxid gas) or gamma irradiation

Ordering Information

Sterisart® NF alpha Disposable Units for Sterility Testing in Clean Rooms, Individually, Sterile Packaged, ETO–Sterilized, Needles Made of Flamable Stainless Steel, Pack Size 10

Type of Sample	Type of Sample Container	Description	Order No.
LVPs	Closed glass bottles with septum	Sterisart® NF alpha with long dual-needle spike, sterile vented	16466--------ACD
LVPs SVPs	Open containers, i.e. glass ampoules, glass bottles Collapsible bags	Sterisart® NF alpha with long needle, by-packed sterile venting needle	16467--------ACD
Medical devices	Tubing systems and bags with Luer or Luer Lock connectors	Sterisart® NF alpha with Luer (Lock) connection, by-packed long needle and sterile venting needle	16468--------ACD

Sterisart® NF gamma Disposable Units for Sterility Testing in Isolators, Individually Sterile, Double-Packaged, Gamma Irradiated, Needles Made of Flamable Stainless Steel, Pack Size 10

Type of Sample	Type of Sample Container	Description	Order No.
LVPs	Closed glass bottles with septum	Sterisart® NF gamma with long dual-needle spike, sterile vented	16466--------GBD
SVPs	Closed glass vials with septum	Sterisart® NF gamma with short dual-needle spike, sterile vented	16476--------GBD
LVPs, SVPs, Eye drops	Closed plastic containers│vials│ ampoules, plastic containers of Blow-Fill-Seal fillings	Sterisart® NF gamma with long needle, side opening, with solid pointed tip, non-coring, by-packed sterile venting needle	16477--------GBD
LVPs SVPs	Open containers, i.e. glass ampoules, glass bottles Collapsible bags	Sterisart® NF gamma with long needle, by-packed sterile venting needle	16467--------GBD
Lyophillisates, Soluble powders, Liquid antibiotics	Closed glass vials with septum	Sterisart® NF gamma with two dual-needle spikes of different length, one is sterile vented	16475--------GBD
Pre-filled syringes	Syringes with and without needles	Sterisart® NF gamma with universal Luer adapter and long dual-needle spike, sterile vented	16469--------GBD
Medical devices	Tubing systems and bags with Luer or Luer Lock connectors	Sterisart® NF gamma with Luer (Lock) connection, by-packed long needle and sterile venting needle	16468--------GBD
NEW Medical devices	Containers│bags with Luer Lock male connectors	Sterisart® NF gamma with female Luer Lock connection	16478--------GBD

Sterisart® NF gamma Septum, Disposable Units for Sterility Testing in Isolators, Sterisart® NF Containers with Integrated Septum for Reliable Sample Drawing, Individually Sterile, Double-Packaged, Gamma Irradiated, Needles Made of Flamable Stainless Steel, Pack Size 10

LVPs	Closed glass bottles with septum	Sterisart® NF gamma Septum with long dual-needle spike, sterile vented	16466--------GSD
LVPs SVPs	Open containers, i.e. glass ampoules, glass bottles Collapsible bags	Sterisart® NF gamma Septum with long needle, by-packed sterile venting needle	16467--------GSD
Lyophillisates, Soluble powders, Liquid antibiotics	Closed glass vials with septum	Sterisart® NF gamma Septum with two dual-needle spikes of different length, one is sterile vented	16475--------GSD
Pre-filled syringes	Syringes with and without needles	Sterisart® NF gamma Septum with universal Luer adapter and long dual-needle spike, sterile vented	16469--------GSD

Accessories

Application	Description	Order No.
Difficult-to-dissolve powders in closed glass vials with septum, non-vacuo	Sterisart® NF gamma tubing system with two dual-needle spikes of different length, needles made of flamable stainless steel	16470--------GBD
Sterile venting of containers with rinsing solution and nutrient media, additional sterile venting needles, equal to the by-packed needles of the Sterisart® NF units i.e. type 16467, 16468 and 16477	Needle with venting filter, 4 cm, stainless steel, individually sterile packaged, gamma irradiated, pack size 50	16596--------HNK

Further units (16464--------ACD│GBD) on request.

▶ Reusable Sterility Test System

Reusable sterility test system for the sterility testing of injection and infusion solutions. The filter holders are easy to clean, dish-watersafe and autoclavable. The system can be designed according to the needs of the user, and the membrane filter can be chosen according to requirements.

▷ Specifications

Specifications of the Filter Holders

Material	Glass cylinder; polypropylene base and sealing plug; anodized aluminum closing cap.
Sealing	Silicone gasket, 36/47 mm (6980573) Silicone O-ring, 40.5×3.5 mm (6980574)
Filter diameter	47 mm
Filtration area	12.5 cm^2
Capacity	16523: 130 ml (56 ml up to the mark for aerobic incubation at a level of 60 mm, 110 ml up to the mark at the 115-mm level).
Operating pressure	Vacuum only
Sterilization	Autoclaving at 121℃

General Accessories for the Reusable Sterility Test System

Description	Order Numbers
Filter holder with 130 ml capacity	16523
Stainless steel manifold	16826
Stainless-steel adapter	17756
T-distributor for 2 filter holders	16966
Filling cap with filling needle	16967
Silicone adapter	16968
Peristaltic pump	16696
Silicone tubing, 4×1.5 mm	16699
Holding rod for inlet tube | needle	16974
Incubation rack	16975
Tube clamps (tubing clips)	16978
Venting filters, pack size 50	17574----------K

Additional Accessories for Reusable Sterility Test System (for Ampoule Testing)

Description	Order Numbers
Inlet tube	16963
Holding tongs	16973
Ampoule breaker	16969
Clamp holder	16976
Support stand	16970

**Additional Accessories for Reusable Sterility Testing System
(for Testing Infusion Solutions in Bottles)**

Description	Order Numbers
Inlet needle (long)	16964
Inlet needle (short)	16964-----3

**Consumables (Membrane Filters, 47 mm, 100 Pieces/pack)
for the Reusable Sterility Test System**

Order Numbers	Pore Size	Description	Application
11306--47------N	0.45 µm	Cellulose nitrate membrane filter	pH 4-8, most hydrocarbons
13106--47----HCN	0.45 µm	Cellulose nitrate membrane filter with hydrophobic edge	pH 4-8, most hydrocarbons
11106--47------N	0.45 µm	Cellulose acetate membrane filter	pH 4-8, most alcohols, hydrocarbons and oils
13506--47----HCN	0.45 µm	Cellulose acetate membrane filter with hydrophobic edge	pH 4-8, most alcohols, hydrocarbons and oils
18406--47------N	0.45 µm	Regenerated cellulose membrane filter	pH 3-12, solvent-resistant
11407--47------N	0.2 µm	Cellulose nitrate membrane filter	pH 4-8, most hydrocarbons
13107--47----HCN	0.2 µm	Cellulose nitrate membrane filter with hydrophobic edge	pH 4-8, most hydrocarbons
11107--47------N	0.2 µm	Cellulose acetate membrane filter	pH 4-8, most alcohols, hydrocarbons and oils
13507--47----HCN	0.2 µm	Cellulose acetate membrane filter with hydrophobic edge	pH 4-8, most alcohols, hydrocarbons and oils
18407--47------N	0.2 µm	Regenerated cellulose membrane filter	pH 3-12, solvent-resistant

Peristaltic Pump

Specifications

Rotor speed	1.5–220 rpm
Operating voltages and frequencies	110–240 V 50/60 Hz
Speed control ratio	147:1
Power rating	100 VA
Operating temperature	4°C to 40°C
Storage temperature range	−40°C to 70°C
Weight	5.5 kg | 12.1 lbs
Noise	<70 dBA at 1 m
Standards	IEC 335-1, EN 60529 (IP31)
Machinery Directive	98/37/EC EN 60204-1
Low Voltage Directive	73/23/EG EN 61010-1
EMC Directive	89/336/EG EN 50081-1/EN 50082-1
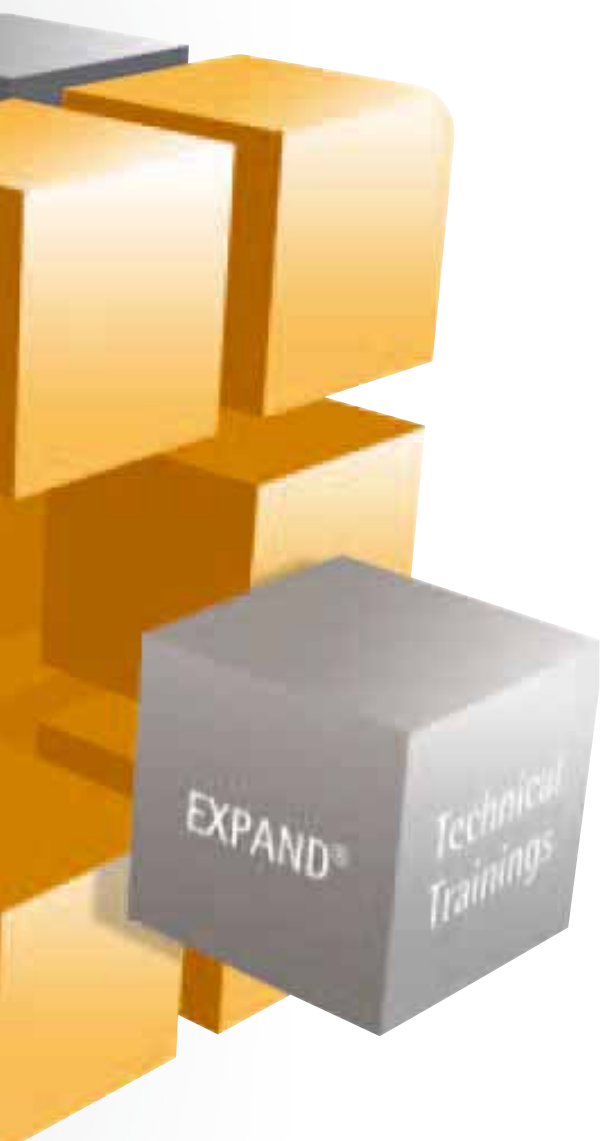
Order Number

16696

We think in processes. It is possible to add value only if products and services are effectively intertwined. As a capable service partner, Sartorius Stedim Biotech offers you a truly comprehensive spectrum of services applicable to both Sartorius projects and also other manufacturer's equipment and products.

Our services program covers all aspects for ensuring efficient and reliable processes in the lab and in production. A closely knit global network of experienced specialists will provide everything from installing and maintaining your equipment (including qualification and validation), to training your staff.

▶ Instrument Services

Our Mission is Your Productivity
We are well aware of how important smooth-running equipment is for efficient production processes and working routines.

That is why we at Sartorius Stedim Biotech offer you our full-scale Instrument Service. This service covers a diverse range of instruments and equipment used in the different applications in the biopharmaceutical industry.

Adherence to cGMP requirements and our ISO 9001:2008 certified Quality Management System ensures that our customers receive services that meet the strictest quality requirements for reliable operation.

In today's strongly competitive market, such services play a critical role and require a complex infrastructure to meet the current customer requirements. Accordingly, our organization places great emphasis on the core competence of our service offering.

Sartorius Stedim Biotech has a local presence worldwide. A training department with vast practical experience, highly qualified specialists, well-versed technicians and fast delivery times on replacement parts are not just empty catchphrases, but practiced everyday with every customer by every member of our service staff.

Rely on people with an in-depth knowledge of the biopharmaceuticals industry: Count on Sartorius Stedim Biotech and its Instrument Service Department.
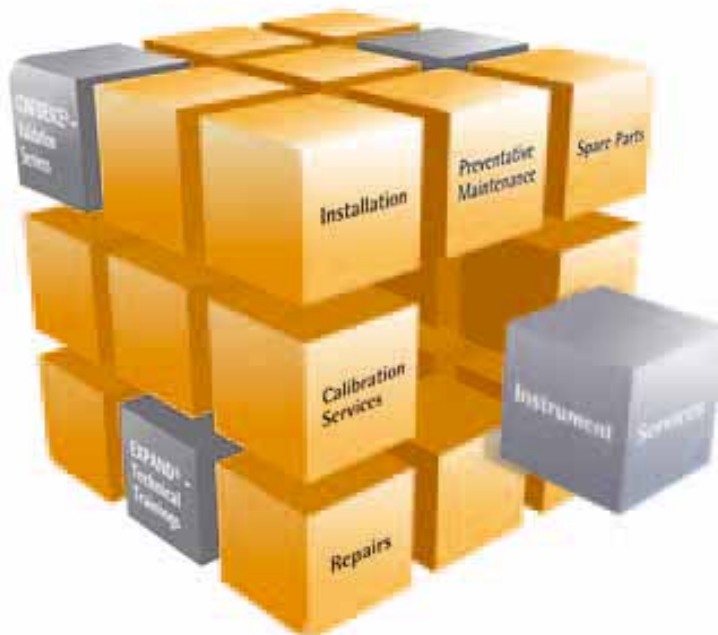
Full Servicing of Instruments and Equipment
Single-source and Full-range. No matter whether an air sampler or a bioreactor or peripheral devices for single-use technology are involved, we service all of these systems for you.

– FAT and SAT

– Installation

– IQ | OQ support and documentation

– Calibration services

– Spare part sales

– Preventative maintenance

– Instrument repairs

– Technical and application support

– Practical and technical operator training

Customer–Specific Maintenance Contracts
Only pay for what you really need.

	Basic	Standard	Advanced
Priority handling of emergency calls	•	•	•
Technical phone support		•	•
On–site support through dedicated engineers	•	•	•
Preventative maintenance at regular intervals (PM)	•	•	•
Replacement of pre–defined PM spare parts	•	•	•
Comprehensive maintenance|repair documentation	•	•	•
10% discount on all spare parts	•	•	
Software and hardware updates*		•	•
10% discount on labor and travel for all repair visits		•	
Unlimited number of emergency calls			•
Replacement of worn or damaged spare parts			•

* Does not include requalification of non–standard systems

▶ # EXPAND®

Training Courses and Seminars

We call it the EXPAND® Technical Training Program. EXPAND® seminars, workshops and courses are integrated into the Sartorius Stedim Biotech service program. These training programs are designed to ensure that each course participant has a proper understanding of the theoretical subject matter and acquires the necessary hands-on, practical skills. The ultimate aim and purpose is to enable technicians and specialists to perform their work safely and efficiently. Continuing education of staff has become one of the many worldwide regulatory requirements. So, to help our customers keep up with the latest standards, we have created EXPAND®, a comprehensive series of technical training courses with a strong emphasis on hands-on, practical exercises. These training programs are essential for all supervisors, managers, operators, technicians and specialists working in R&D, Production and Quality Assurance Departments.

For our current trainings and seminar program please visit us at:
www.sartorius-stedim.com/expand

Cell Cultivation │ Cell Biology
Animal Cell Culture; Mycoplasms; Flow Cytometry; Viability, Cytotoxicity and Proliferation; Virus Detection; Microscopy

Fermentation │ Cell culture
From Cryo Culture to Bioreactor; Production of Viruses; Monoclonal Antibodies; Serum-free Cultivation; Process Analytical Technology

Downstream Processing
Downstream Processing; Virus │ Prion Safety

Filtration
Sterilization and Integrity Testing; Filter Optimization and Scale-up; Crossflow Filtration; Single-Use Technologies

Microbiology
Microbiology in the Beverage Industry; Sterility Testing; Light Microscopy in the microbiological Quality Control

Molecular Biology
Cloning and Expression; RNA Technologies; Quantitative Real-time PCR

Proteomics
Protein Expression and Purification; ELISA Technologies; Immunhistochemistry and Immunofluorescence; Antibodies in Analysis

Lab– │ Quality Management
Balances as test divices in QM; Gravimetric Pipette Calibration; Qualification and validation in the cell culture lab

Professional Education
Life Sciences Assistant
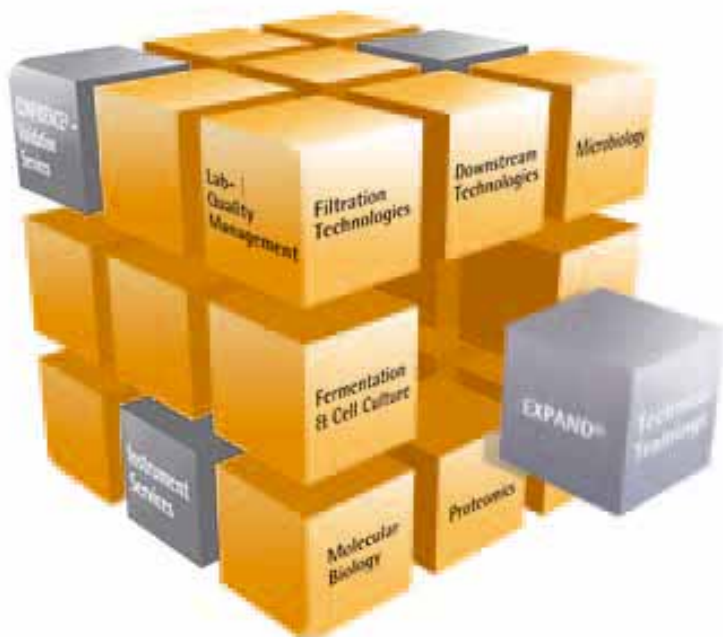
Abstract of Our Training Program

▷ Cell Cultivation | Cell Biology

 # 862055 Basics of Animal Cell Culture
Target group: Technicians and scientists without any or with little previous knowl-edge, career changers and those returning to work after a career break.

Beginners of cell cultivation often start by looking over the shoulders of their colleagues, who don't have the time during the busy day-to-day routine to teach all the basic principles and background information on each subject in depth. This seminar will teach you the fundamental prerequisites and techniques for everyday work with animal cells and let you establish, optimize and standardize your proprietary cell cultures.

Theoretical Aspects Include:

– Equipping and maintaining a cell culture lab

– Cell cultivation: Composition of media, required additives, culture vessels and disposables, origin of cell lines including the required documentation

– Routine methods in cell cultivation: Morphological cell evaluation, handling the microscope, passage | subcultivation, cell counting, viability tests, cryopreservation (freeze | thaw technologies)

– Aseptic techniques and biological contamination

Practical Exercises:

– Inverse microscopy of cells

– Passage | subcultivation, cell counting including viability testing

– Freezing | thawing cells

– Detection of contamination

 # 862056 Advanced Course Animal Cell Culture | Trouble Shooting
Target group: Technicians and scientists with experience in cell cultivation.

Even in experienced cell culture labs, cell growth problems can crop up suddenly and apparently without reason and affect the sterility or reproducibility of results. This sem-inar will teach you how to use practicable methods to ensure the quality of your animal cell cultures over the short and long term and solve any emergent difficulties.

Theoretical Aspects Include:

– Detection of poor cell growth and cause analysis, e.g. physiological relationships in the cell culture, effect of media compo-nents, material surfaces and cell handling on cell growth

– Biological and chemical contamination: Sources, diagnosis, treatment and prevention

– Required documentation and standardi-zation of cell lines, creating proprietary cell banks (cell banking), viability tests, check lists

Practical Exercises:

– Routine methods as causes for bad cell growth including cryopreservation and viability tests

– Detection of poor cell growth and contaminated cells

▷ Fermentation |
  Cell Culture Technologies

**# 862077 Basic Course Fermentation |
Cell Culture**
Target group: Technicians and scientists without any or with little previous knowledge.

This course teaches you the fundamentals of different fermentation systems and how to monitor fermentation to obtain the desired product.

This course covers:

– Chemical and microbiological principles of fermentation

– Basic principles of reactor technique and different fermentation systems (batch and continuous culture)

– Strain maintenance and testing organisms

– Cultivation conditions and growth kinetics

– Measurement and control during fermentation process

– Monitoring | In-line controls

 # 862021 High Cell Density Cultivation of *Escherichia coli*
Target group: Technicians and scientists with basic knowledge of microbiology, cultivation of microorganisms and of molecular biology and who are in charge of managing bioreactors or willing to do this in future.

Small groups will perform high cell density cultivation in the laboratory bioreactor and learn about the related theoretical and practical aspects.

The main aspects include efficient cultivation to obtain high cell densities (High Cell Density Cultivation, HCDC), safe handling of laboratory bioreactors, avoiding sterility problems. Consideration is given to dissolved nutrients and oxygen supply, to balancing equation fundamentals and realization in feeding strategies.

Theoretical and practical aspects include:

– Virtual bioreactor (simulation)

– Laboratory bioreactors, handling, preparation and cell harvesting

– Media composition for high cell density cultivation

– Cultivation strategies

– Feeding profile calculation

– Oxygen demand of growing cells

– Oxygen transfer aspects

**# 862086 Animal Cell Culture Workshop:
From Cryo Culture to Bioreactor (Part 1)**
Target group: Technicians and scientists without any or with little previous knowledge.

This workshop provides you with hands-on training in various cell cultivation systems to enable you to perform every step of the process yourself – from thawing cell cultures (cryo culture) to fermentation in bioreactors (seed train).

Theoretical aspects include:

– Basic principles of cell cultivation and special features of production processes using animal cells

– Media for production

– Cultivation systems for production

– Monitoring and data analysis

– Strategies for scaling-up cultivation

Practical exercises:

– Preparation of reusable and single-use bioreactors for cell cultivation (autoclaving, in situ-steam sterilization, disposable bioreactors)

– Thawing and cultivation of antibody-producing CHO cell lines in different cultivation systems

– Aseptic transfer of cell culture during the production process (seed train) and sterile sampling

– Monitoring cell cultivation

▷ Downstream Processing

 # 862087 Animal Cell Culture Workshop: Downstream Processing (Part 2)
Target group: Technicians and scientists without any or with little previous knowledge.

This workshop provides you with hands-on training in different strategies and methods for purification of your products using an antibody producing CHO cell line.

Theoretical aspects include:
– Methods for product purification and critical process parameters
– Development of strategies for proprietary applications
– Virus inactivation and virus removal

Practical exercises:
– Cell harvesting and clarification of the fermentation product by depth filtration and crossflow filtration (microfiltration)
– Purification using column chromatography, membrane chromatography, ultrafiltration (crossflow filtration)
– Removal of contaminants by membrane chromatography
– Quantification and quality control
– Scale up strategies

▷ Filtration

 # 862024 Sterilization and Integrity Testing of Membrane Filters
Target group: Technicians and scientists with or without previous knowledge.

In this training course, participants learn theoretical knowledge and practical skills in handling the filters employed for sterile filtration.

The theoretical aspects include:
– Basic principles of filtration
– Depth filters | membrane filters
– Hydrophobic | hydrophilic filters
– Retention mechanisms
– Integrity testing of membrane filters
– Regulatory requirements
– Integrity testing methods
– Testing equipment
– Physical theoretical principles of steam sterilization of filter lines

Practical exercises:
– Manual determination of bubble point | diffusion
– Automated integrity testing
– Bubble point test | diffusion test
– Integrity testing of hydrophobic filters using the water intrusion test (WIT)
– Trouble shooting
– Hands-on exercises for in-line steam sterilization of filter cartridges

 # 862037 Filter Optimization and Scale–Up
Target group: Technicians and scientists without any or with little previous knowledge.

There is always room for improvement in any process. Reducing costs per liter, improving yield and implementing efficient process times while increasing product and process reliability are the major success factors for any company. This course can help you to find the optimal process solution for your specific application.

Theoretical aspects include:
– Depth and membrane filter
– Construction and formats
– Filter clogging mechanisms
– Selection of pre- and final filter materials
– Evaluation of the test results

Practical exercises:
– Constant flow and constant pressure trials
– Pre- and final filter optimization trials
– Small scale filterability trials
– Confirmation of test results with small pleated filter elements
– Introduction to Zero-T software
– Scale up calculations

 # 862008 Crossflow Filtration
Target group: Technicians and scientists with or without previous knowledge.

This course is designed to give participants state-of-the-art knowledge about GMP-compliant processing using crossflow filtration.

Theoretical aspects include:
– Crossflow filtration theory
– Membrane characterization | membrane selection
– Factors influencing performance
– Scale up
– Operating conditions
– Cleaning-in-place (CIP)
– Steaming-in-place (SIP)
– Integrity testing
– Applications in biotechnology

Practical exercises:
– Operational set-up of the systems
– Determination of clean water flux
– Cell retention by microfiltration (model solution)
– Concentration of a protein solution by ultrafiltration
– Removal of low-molecular weight contaminants by diafiltration
– Cleaning
– Demonstration of steaming-in-place (optional)
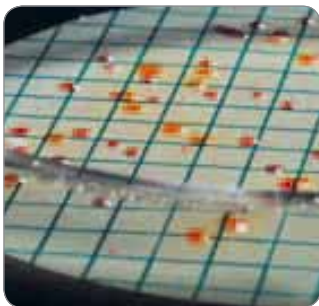
▷ Microbiology

 # 862001 Basic Course Microbiology
Target group: Technicians and scientists
without any or with little previous knowl-
edge, career changers and those returning
to work after a career break.

Theoretical aspects include:

– Introduction to microbiology

– Growth conditions

– Microbiological detection methods

– The microbiological lab

– Microbiological examination of water and
  drinking water: Regulations and methods

– Introduction to personnel hygiene

Practical exercises:

– Introduction to microbiological work

– Pour plate, streak plate

– Sample filtration run with various media:
  water, particulate media, oil-containing
  media

– Evaluation of different growth samples

 # 862034 Sterility Testing
Target group: Technicians and scientists with
previous knowledge.

"Because sterility testing is a very exacting
procedure, where asepsis of the procedure
must be ensured for a correct interpretation
of results, it is important that personnel be
properly trained and qualified" USP <71>.

This workshop is designed to give participants
theoretical knowledge and practical experi-
ence in the handling of sterility testing in
clean rooms and isolators.

Theoretical aspects include:

– Sterility testing

– Regulation and guidance

– Sterility test methods | test limitations

– Validation

– Interpretation of sterility test results

– Microbial identification of isolates
  recovered from a sterility test

– Microbiological monitoring

– Sterility test isolators

– Standards and regulations

– Design

– H_2O_2 decontamination

Practical exercises:

– Sterility testing of different sterile products
  (LVPs | SVPs | ampoules | antibiotics |
  syringes | medical devices)

– Performing sterility test in isolators

– Visual inspection and evaluation of
  sterile test samples

▷ Molecular Biology

 # 862042 Molecular Biology
Target group: Technicians and scientists without any or with little previous knowledge, career changers and those returning to work after a career break.

In this seminar, you will learn the basic theory and practice of molecular biological methods. After completing this seminar, you will know how the latest methods for DNA and RNA analysis work and be able to apply them in your own lab.

Practical exercises:

– DNA isolation and analysis: Isolation of DNA from different sources, concentration measurement, restriction digestion and analysis in agarose gel (gel electrophoresis)

– RNA isolation and analysis: handling and quality assessment of RNA

– Establishing and optimizing a PCR

– Controls and trouble shooting

▷ Proteomics

 # 862052 Proteins: Isolation, Purification and Analysis
Target group: Technicians and scientists without any or with little basic knowledge, career changers and those returning to work after a career break.

Proteins have variable biochemical structures preventing them from being isolated and purified according to a standard protocol. This turns every new target protein into a new challenge for experimenters.

Theoretical aspects include:

– Biochemical properties of proteins like structure, function, modification and stability

– Protein isolation and purification techniques like ion exchange and affinity chromatography, gel filtration, protein precipitation, ultrafiltration and gel electrophoresis including staining

– Immunological methods like Western Blot and ELISA

Practical exercises:

– Liquid chromatographic purification methods

– Isolation of a recombinant fusion proteins

– Protein quantification

– Separation and analysis using SDS-PAGE, staining of polyacrylamide gels (e.g. Coomassie and silver), Western Blot

 # 862053 Advanced Course Protein Expression and Purification
Target group: Technicians and scientists with previous knowledge.

Even the most experienced users repeatedly encounter unanticipated difficulties with the expression and purification of natural and recombinant proteins. In this course you will learn the important practical aspects in protein expression and purification, alternative strategies will be discussed.

This course covers:

– Production of native and recombinant proteins: Expression systems, their advantages and disadvantages (quantity and quality of proteins, glycosylation and other protein modifications)

– Biochemical characteristics of protein purification and processing, recombinant tags for purification

– Protein processing: How buffers, temperature and detergents influence the stability, solubility and aggregation behavior of purified proteins

– Optimization of process sequences including trouble shooting

▶ CONFIDENCE®

Validation Services

Focus on regulatory compliance, time to market and cost efficiency with CONFIDENCE®.

We respect our customers' individuality. The diversity of today's manufacturing processes on a global scale requires an approach which considers the critical success factors for each company scenario.

You can relax knowing that your needs are being met with our risk-based validation strategies. We work in partnership with you to develop the appropriate test scope based on a risk assessment for processing and packaging materials used.

Whether you conduct conventional manufacturing in a stainless steel environment or implement single-use fluid management, we will test any and all process components, regardless of the manufacturer.

Various regulations for pharmaceutical products call for monitoring of impact factors on the drug product's safety and efficacy. This includes the evaluation of possible contaminants such as bacteria, toxic substances or particles but also verification of adsorption effects of drug product components to fluid contact surfaces.

We will help interpreting the regulatory documents which are the basis for your business and define applicable test conditions for your product formulation based on your actual process conditions.

Confidentiality is taken seriously when we interact with you regarding:

– Risk assessment consultancy

– Grouping | bracketing support

– Customized validation protocol development

Complete your testing requirements with CONFIDENCE® Validation Services
Our program includes but is not limited to:

Microbiological Studies	– Filter elements
	– Single-use fluid management containers
Physico-Chemical Studies	– Filter elements
	– Single-use fluid management containers
Extractables	Leachables Studies	– Filter elements
Analytical Techniques used include e.g. NVR, TOC, HPLC-UV, GC-MS, LC-MS, LC-MS-MS, LC-Q-tof, FTIR, ICP-MS, ICP-OES	– Single-use fluid management containers and assemblies
	– Freeze and thaw bags
	– Mixing systems
	– Transfer systems
	– Tubing	connectors	gaskets
	– Polymer-based syringes	vials	ampoules	bottles (including labels, ink or glue)

Benefit from the expertise supplied by our specialists:

– Science-driven consulting services

– Long history of regulatory expertise

– Unique product and process specific test approach

– In-depth knowledge of actual drug product testing

– Pioneers with polymer and elastomer extractables | leachables knowledge

– Modern state-of-the art laboratories

– Fast turnaround by effective and dedicated project management

Thinking globally and acting locally – we are where you need us with the same degree of competence, reliability and focus on your critical success factors.

Make the choice that helps bring your products to market rapidly – on time, every time. Ask us about our 30-day commitment program.

We continue to lead and innovate in the field of validation studies.
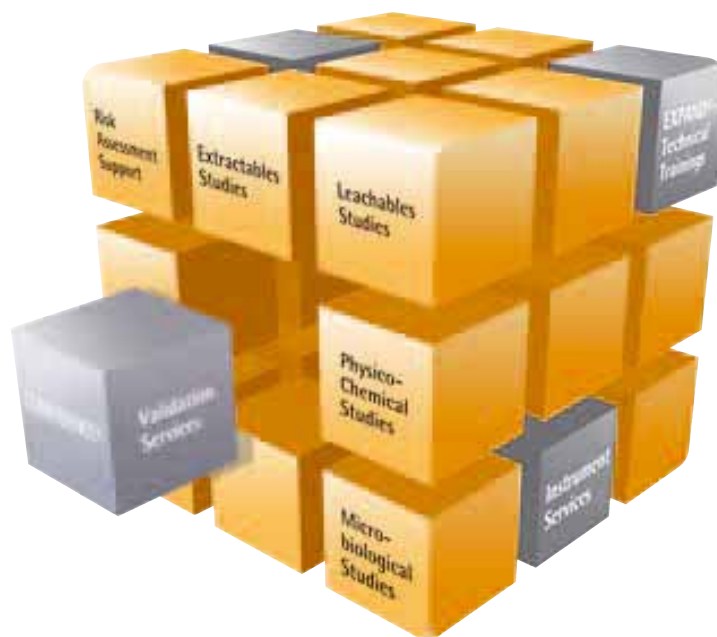
▶ DISCOVER®

Plant, Process and System Survey

There is room for improvement in any process. Within the scope of our DISCOVER® service segment, the following areas | aspects are competently and critically analyzed:

– Quality management system
  Filter handling, ranging from incoming inspection, storage in the warehouse and use, to disposal

– Filtration systems and plants |
  Filtration processes

– System analysis for preventive maintenance

– Qualification | Validation status

The results of a DISCOVER® survey and analysis and specific suggestions for improvement will be documented in a comprehensive report for you.
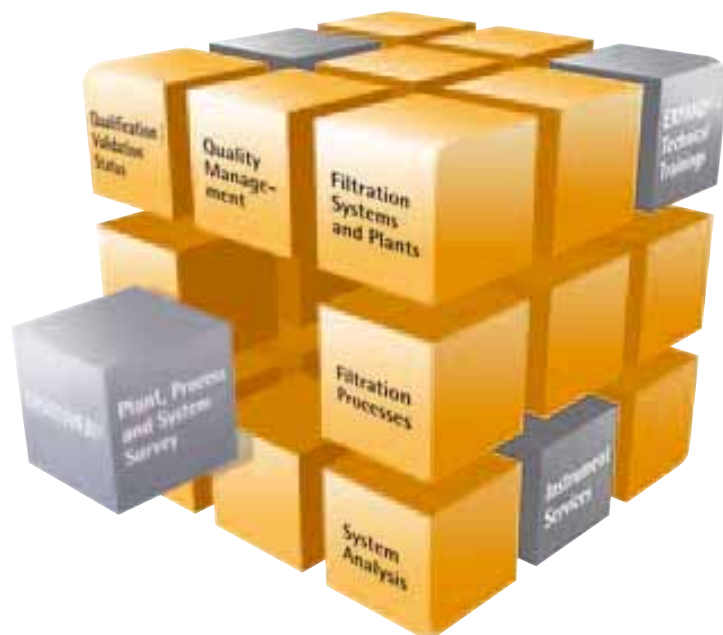
▶ # INCREASE®

Process Optimization

There's always room for improvement in any process. An INCREASE® study will systematically implement the potential identified by process analysis to achieve maximum yields. Use the extensive application know-how of our specialists.

Process Development and Optimization
The INCREASE® process optimization program supports a wide variety of aspects of your business activities – technical, organizational and GMP compliance. Within the scope of technical process development and optimization, our specialists understand that achieving high yields and efficient process times are the key to success.

Benefit from the expertise provided by our specialists:

– Selection of the optimal filtration material

– Performance of filterability studies

– Development support for purification processes

– Sizing and designing of production-scale plants – scale-up

– Technical consultation for perfusion reactors

Scale–Up | Technology Transfer
Converting from pilot to process scale and transferring technology to another location require considerable organizational and communication efforts for a certain time. Moreover, the requirements of the particular regulatory authorities and GMP standards have to be complied with.

Let Sartorius Stedim Biotech reduce your effort:

– You take a make-or-buy decision

– For all the rest of the details, we offer our full support together with our BioPharm-Alliance partners

GMP Compliance
Lack of familiarity or non-compliance with GMP requirements represents a business risk. Together with our BioPharm-Alliance partners, we can help to minimize your risk by offering support in the following areas:

– Optimization of quality or process control system

– Corrective actions guidance

– Optimization of approval procedures

– Post-approval change support

– Preparation for inspections
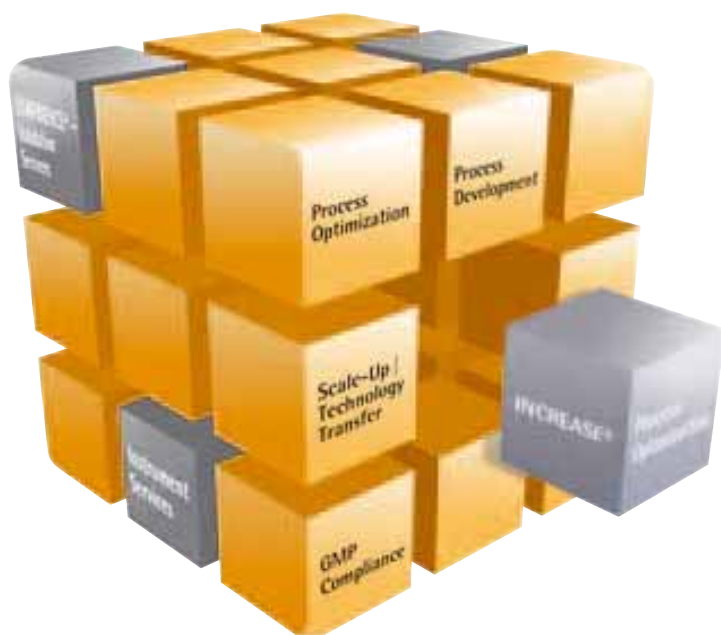
▶ Chemical Compatibility
1. Filter Materials and Mini Cartridges

Solvents	Cellulose Acetate	Cellulose Nitrate	Reg. Cellulose	PTFE	Poly–amide	Glass Fiber	Polycar–bonate	Poly–ether–sulfone	Sartobran® P Cartridge	Sartofluor® Cartridge
	111	113	184	118	250	134	230	154		
Acetone	–	–	●	●	–	●	○	–	–	E
Acetonitrile	?	?	●	●	–	?	?	●	?	?
Gasoline	●	●	●	●	●	●	●	●	V	–
Benzene	●	●	●	●	●	●	?	●	–	–
Benzyl alcohol	○	○	●	●	●	●	?	–	○	●
n–Butyl acetate	○	–	●	●	●	●	●	●	E	?
n–Butanol	●	●	●	●	●	●	●	●	●	●
Cellosolve	●	–	●	●	?	●	–	●	–	–
Chloroform	–	●	●	●	●	●	–	–	–	–
Cyclohexane	○	○	●	●	?	●	●	–	○	V
Cyclohexanone	–	–	●	●	●	●	?	?	–	–
Diethylacetamide	–	–	●	●	●	●	?	?	–	?
Diethyl ether	●	–	●	●	●	●	●	?	–	–
Dimethyl formamide	–	–	○	●	○	●	–	?	–	●
Dimethylsulfoxide	–	–	●	●	●	●	–	–	—	●
Dioxane	–	–	●	●	●	●	–	●	–	●
Ethanol, 98%	●	○	●	●	●	●	●	●	●	●
Ethyl acetate	–	–	●	●	●	●	?	–	–	–
Ethylene glycol	●	○	●	●	?	●	●	●	●	●
Formamide	?	?	?	●	?	●	–	?	–	●
Glycerine	●	●	●	●	●	●	●	●	●	●
n–Heptane	●	●	●	●	?	●	?	?	●	V
n–Hexane	●	●	●	●	●	●	●	?	V	–
Isobutanol	○	○	●	●	●	●	●	?	–	●
Isopropanol	●	○	●	●	●	●	●	●	●	●
Isopropyl acetate	○	–	●	●	?	●	?	●	–	●
Methanol, 98%	●	–	●	●	?	●	●	●	●	●
Methyl acetate	–	–	●	●	●	●	?	–	–	●
Methylene chloride	–	○	●	●	●	●	–	–	–	–
Methyl ethyl ketone	–	–	●	●	●	●	?	–	–	●
Methyl isobutyl ketone	●	–	●	●	●	●	?	?	–	–
Monochlorobenzene	●	●	●	●	●	●	–	?	V	V
Nitrobenzene	●	○	●	●	●	●	–	?	–	–
n–Pentane	●	●	●	●	●	●	●	?	V	V
Perchloroethylene	●	●	●	●	●	●	●	?	V	V
Pyridine	–	–	●	●	●	●	–	–	–	–
Carbon tetrachloride	○	●	●	●	●	●	?	●	–	?
Tetrahydrofuran	–	–	●	●	●	●	–	–	–	–
Toluene	●	●	●	●	●	●	?	●	–	–

Key to symbols see next page.

	Cellulose Acetate	Cellulose Nitrate	Reg. Cellulose	PTFE	Poly–amide	Glass Fiber	Polycar–bonate	Poly–ether–sulfone	Sartobran® P Cartridge	Sartofluor® Cartridge
Solvents	111	113	184	118	250	134	230	154		
Trichloroethane	○	●	●	●	?	●	?	?	–	?
Trichloroethylene	●	●	●	●	●	●	–	●	–	?
Xylene	●	●	●	●	●	●	●	●	–	–
Acids										
Acetic acid, 25%	●	●	●	●	○	?	○	●	●	?
Acetic acid, 96%	–	–	●	●	–	?	?	●	–	●
Hydrofluoric acid, 25%	●	○	○	●	–	?	●	?	–	–
Hydrofluoric acid, 50%	●	○	–	●	–	?	●	?	–	–
Perchloric acid, 25%	–	○	○	●	–	?	?	?	–	●
Phosphoric acid, 25%	●	○	○	●	–	?	?	?	●	●
Phosphoric acid, 85%	○	○	○	●	–	?	–	?	–	V/E
Nitric acid, 25%	–	○	–	●	–	?	●	●	–	V
Nitric acid, 65%	–	–	–	●	–	?	●	●	–	–
Hydrochloric acid, 25%	–	○	–	●	–	?	●	●	–	V/E
Hydrochloric acid, 37%	–	–	–	●	–	?	●	●	–	V/E
Sulfuric acid, 25%	–	○	○	●	–	●	?	●	–	●
Sulfuric acid, 98%	–	–	–	●	–	?	–	?	–	–
Trichloroacetic acid, 25%	–	○	●	●	–	?	?	?	–	●
Bases										
Ammonium, 1N	●	●	○	●	●	●	–	●	E	●
Ammonium hydroxide, 25%	–	○	–	○	●	○	–	●	–	●
Potassium hydroxide, 32%	–	–	○	●	○	○	–	●	–	●
Sodium hydroxide, 32%	–	–	○	●	○	○	–	●	–	●
Sodium, 1N	○	–	○	●	●	●	–	●	–	●
Aqueous Solutions										
Formaline, 30%	○	●	○	●	○	●	●	●	–	●
Sodium hypochlorite, 5%	●	○	●	●	○	●	?	?	–	●
Hydrogen peroxide, 35%	●	●	○	●	○	?	?	?	●	●

Key to Symbols
● = compatible   ○ = limited compatibility
– = not compatible   ? = not tested

E = compatible after replacing silicone O-ring with an EPDM O-ring
V = compatible after replacing the silicone O-ring with a Viton O-ring

Contact time: 24 hours at 20°C
Chemical compatibilities can be influenced by various factors.
Therefore, we recommend that you confirm compatibility with the
liquid you wish to filter by performing a trial filtration run before
you begin with actual filtration.

▶ 2. Filter Holder, Cartridge Housing and O-ring Materials

	Glass	Poly-carbonate	Poly-propylene	PTFE	Stainless Steel	EPDM O-ring	PTFE O-ring	Silicone O-ring	Viton O-ring
Solvents									
Acetone	●	○	●	●	●	●	●	–	–
Acetonitrile	●	?	●	●	●	○	●	–	●
Gasoline	●	○	●	●	●	–	●	–	●
Benzene	●	–	–	●	●	–	●	–	●
Benzyl alcohol	●	–	●	●	●	○	●	●	●
n-Butyl acetate	●	–	○	●	●	●	●	–	–
n-Butanol	●	●	●	●	●	●	●	●	●
Cellosolve	●	–	–	●	●	○	●	–	–
Chloroform	●	–	–	●	●	–	●	–	●
Cyclohexane	●	○	●	●	●	–	●	–	●
Cyclohexanone	●	–	●	●	●	–	●	–	–
Diethylacetamide	●	–	?	●	●	?	●	●	–
Diethyl ether	●	–	○	●	●	–	●	–	–
Dimethyl formamide	●	–	●	●	●	●	●	○	–
Dimethylsulfoxide	●	?	?	●	●	?	●	○	–
Dioxane	●	–	○	●	●	●	●	–	–
Ethanol, 98%	●	●	●	●	●	●	●	●	●
Ethyl acetate	●	–	●	●	●	●	●	–	–
Ethylene glycol	●	●	●	●	●	●	●	●	●
Formamide	●	–	●	●	●	●	●	–	○
Glycerine	●	○	●	●	●	●	●	●	●
n-Heptane	●	●	●	●	●	–	●	●	●
n-Hexane	●	●	●	●	●	–	●	–	●
Isobutanol	●	●	●	●	●	●	●	●	●
Isopropanol	●	○	●	●	●	●	●	●	●
Isopropyl acetate	●	●	●	●	●	●	●	–	–
Methanol, 98%	●	–	●	●	●	●	●	●	●
Methyl acetate	●	?	●	●	●	●	●	–	–
Methylene chloride	●	–	–	●	●	–	●	–	○
Methyl ethyl ketone	●	–	●	●	●	●	●	–	–
Methyl isobutyl ketone	●	–	?	●	●	–	●	–	–
Monochlorobenzene	●	–	●	●	●	–	●	–	●
Nitrobenzene	●	–	○	●	●	–	●	–	–
n-Pentane	●	●	●	●	●	–	●	–	●
Perchloroethylene	●	–	○	●	●	–	●	–	●
Pyridine	●	–	○	●	●	–	●	–	–
Carbon tetrachloride	●	–	○	●	●	–	●	–	●
Tetrahydrofuran	●	–	○	●	●	–	●	–	–
Toluene	●	–	●	●	●	–	●	–	○

Key to symbols see next page.

	Glass	Poly-carbonate	Poly-propylene	PTFE	Stainless Steel	EPDM O-ring	PTFE O-ring	Silicone O-ring	Viton O-ring
Solvents									
Trichloroethane	•	–	?	•	•	–	•	–	•
Trichloroethylene	•	–	–	•	•	–	•	–	•
Xylene	•	–	○	•	•	–	•	–	○
Acids									
Acetic acid, 25%	•	•	•	•	•	•	•	•	–
Acetic acid, 96%	•	–	•	•	•	•	•	?	–
Hydrofluoric acid, 25%	–	–	•	•	–	○	•	–	○
Hydrofluoric acid, 50%	–	–	•	•	–	○	•	–	○
Perchloric acid, 25%	•	○	•	•	–	•	•	–	•
Phosphoric acid, 25%	•	○	•	•	○	•	•	–	•
Phosphoric acid, 85%	•	○	•	•	○	•	•	–	•
Nitric acid, 25%	•	–	•	•	–	○	•	–	•
Nitric acid, 65%	•	–	–	•	–	–	•	–	•
Hydrochloric acid, 25%	•	○	•	•	–	○	•	–	•
Hydrochloric acid, 37%	•	–	•	•	–	•	•	–	•
Sulfuric acid, 25%	•	•	•	•	○	•	•	–	•
Sulfuric acid, 98%	•	–	–	•	–	–	•	–	•
Trichloroacetic acid, 25%	•	○	•	•	–	•	•	–	–
Bases									
Ammonium, 1N	•	–	•	•	•	•	•	–	–
Ammonium hydroxide, 25%	•	–	•	•	•	•	•	•	–
Potassium hydroxide, 32%	•	–	•	•	•	•	•	○	○
Sodium hydroxide, 32%	•	–	•	•	•	•	•	○	•
Sodium, 1N	•	–	•	•	•	•	•	•	•
Aqueous Solutions									
Formaline, 30%	•	•	•	•	•	•	•	○	•
Sodium hypochlorite, 5%	•	•	•	•	•	•	•	•	•
Hydrogen peroxide, 35%	•	•	•	•	•	•	•	•	•

Key to Symbols

• = compatible ○ = limited compatibility
– = not compatible ? = not tested

Contact time: 24 hours at 20℃
Chemical compatibilities can be influenced by various factors.
Therefore, we recommend that you confirm compatibility with the
liquid you wish to filter by performing a trial filtration run before
you begin with actual filtration.

▶ 3. Ready-to-Connect Filtration Units

	Midisart® 2000	Minisart®	Minisart® HY	Minisart® RC	Minisart® SRP	Sartobran® 300	Sartobran® P Capsule	Sartofluor® Capsule	Sartolab® P20
Solvents									
Acetone	•	–	–	•	–	–	–	•	–
Acetonitrile	•	–	?	•	•	?	?	?	?
Gasoline	•	•	•	•	•	•	•	•	○
Benzene	•	–	–	?	•	–	–	○	–
Benzyl alcohol	•	?	?	?	•	○	○	•	–
n-Butyl acetate	•	–	–	?	•	•	•	•	–
n-Butanol	•	○	○	•	•	•	•	•	•
Cellosolve	○	–	–	•	○	–	–	○	–
Chloroform	•	–	–	•	•	–	–	•	–
Cyclohexane	•	–	–	?	•	○	○	•	○
Cyclohexanone	•	–	–	?	•	–	–	•	–
Diethylacetamide	•	–	–	•	•	–	–	•	–
Diethyl ether	•	?	?	?	•	○	○	•	–
Dimethyl formamide	•	–	–	?	•	–	–	•	–
Dimethylsulfoxide	•	–	–	•	•	–	–	•	–
Dioxane	•	–	–	•	•	–	–	○	–
Ethanol, 98%	•	–	–	•	•	•	•	•	•
Ethyl acetate	•	○	○	•	•	–	–	○	–
Ethylene glycol	•	?	?	•	•	•	•	•	•
Formamide	•	?	?	?	•	?	?	•	–
Glycerine	•	•	•	?	•	•	•	•	○
n-Heptane	•	•	•	?	•	•	•	•	•
n-Hexane	•	•	•	•	•	•	•	•	•
Isobutanol	•	○	○	•	•	○	○	•	○
Isopropanol	•	○	○	–	•	•	•	•	○
Isopropyl acetate	•	○	○	?	•	○	○	•	○
Methanol, 98%	•	–	–	•	•	•	•	•	–
Methyl acetate	•	–	–	?	•	–	–	•	–
Methylene chloride	•	–	–	•	•	–	–	○	–
Methyl ethyl ketone	•	–	–	•	•	–	–	•	–
Methyl isobutyl ketone	•	?	?	?	•	?	?	•	–
Monochlorobenzene	•	?	?	?	•	•	•	•	–
Nitrobenzene	•	?	?	?	•	○	○	•	–
n-Pentane	•	•	•	•	•	•	•	•	•
Perchloroethylene	•	○	○	?	•	○	○	•	–
Pyridine	•	–	–	?	•	–	–	•	–
Carbon tetrachloride	•	○	○	?	•	○	○	•	–
Tetrahydrofuran	•	–	–	•	•	–	–	○	–
Toluene	•	–	–	•	•	•	•	•	–

Key to symbols see next page.

	Midisart® 2000	Minisart®	Minisart® HY	Minisart® RC	Minisart® SRP	Sartobran® 300	Sartobran® P Capsule	Sartofluor® Capsule	Sartolab® P20
Solvents									
Trichloroethane	•	○	○	•	•	?	?	•	–
Trichloroethylene	○	?	?	?	○	–	–	–	–
Xylene	•	–	–	•	•	○	○	•	–
Acids									
Acetic acid, 25%	•	○	○	?	?	•	•	•	•
Acetic acid, 96%	•	–	–	?	•	–	–	•	–
Hydrofluoric acid, 25%	•	○	○	?	•	•	•	•	–
Hydrofluoric acid, 50%	•	○	○	?	•	–	–	•	–
Perchloric acid, 25%	•	?	?	?	•	–	–	•	–
Phosphoric acid, 25%	•	•	•	?	•	•	•	•	•
Phosphoric acid, 85%	–	?	?	?	–	○	○	–	○
Nitric acid, 25%	•	–	–	?	•	–	–	•	–
Nitric acid, 65%	•	–	–	?	•	–	–	○	–
Hydrochloric acid, 25%	•	–	–	?	•	–	–	•	–
Hydrochloric acid, 37%	•	–	–	?	•	–	–	•	–
Sulfuric acid, 25%	•	–	–	?	•	–	–	•	–
Sulfuric acid, 98%	•	–	–	?	•	–	–	•	–
Trichloroacetic acid, 25%	•	–	–	•	•	–	–	•	–
Bases									
Ammonium, 1N	•	•	•	?	•	•	•	•	–
Ammonium hydroxide, 25%	•	○	○	?	•	○	○	•	–
Potassium hydroxide, 32%	•	–	–	?	•	–	–	•	–
Sodium hydroxide, 32%	•	–	–	?	•	–	–	•	–
Sodium, 1N	•	○	○	?	•	○	○	•	–
Aqueous Solutions									
Formaline, 30%	•	–	–	?	•	○	○	•	○
Sodium hypochlorite, 5%	•	•	•	?	•	–	–	•	•
Hydrogen peroxide, 35%	•	•	•	?	•	•	•	•	•

Key to Symbols

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Contact time: 24 hours at 20°C
Chemical compatibilities can be influenced by various factors. Therefore, we recommend that you confirm compatibility with the liquid you wish to filter by performing a trial filtration run before you begin with actual filtration.

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