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

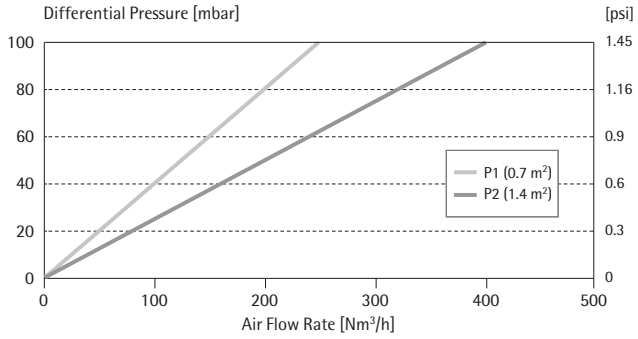
Retention Efficiency
The excellent retention and therefore superior protection for stored products has been proven by particle retention filtration and bacteria challenge tests performed under worst case conditions. Sartopure® GA retained 10 million Bacillus subtilis var niger spores per cm^2 filtration 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 m^2 | 7 ft^2
Size 2	20"	1.4 m^2 | 14 ft^2
Size 3	30"	2.1 m^2 | 21 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

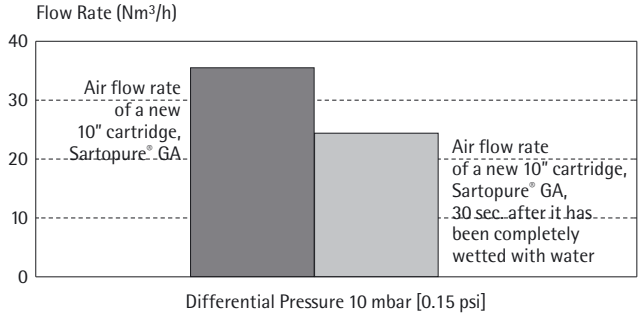
Autoclaving
134 °C, 2 bar | 29 psi, 30 min

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



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.

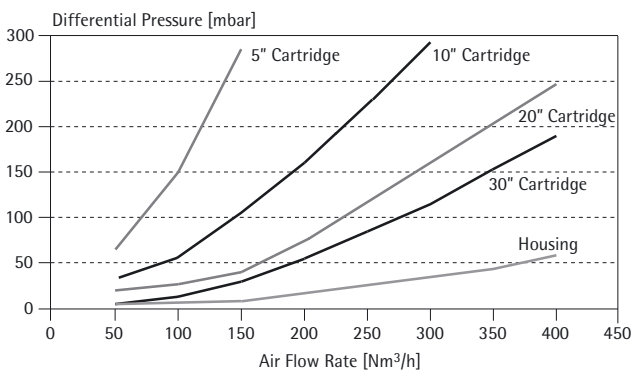
Water Intrusion Test (WIT) | Water Flow Test (WFT)
A Sartorius Stedim Biotech development, the WIT offers the first and only correlated in-situ integrity testing system for hydrophobic vent filters. WIT not only eliminates downstream intervention and preflushing, more importantly, it does not require 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 m^2 | 4.04 ft^2
Size 1	10″	0.75 m^2 | 8.1 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 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

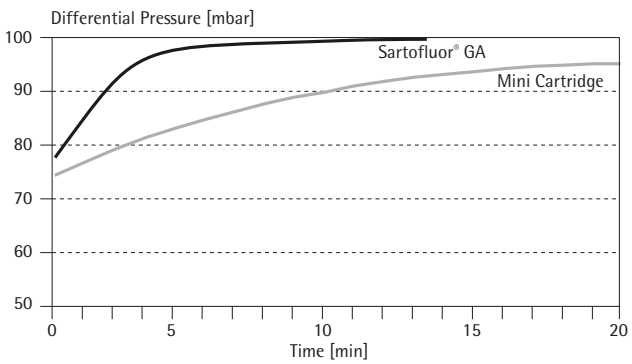
Sterilization Cycles
In-Line Sterilization: min 150 (in direction and in reverse direction of filtration)

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

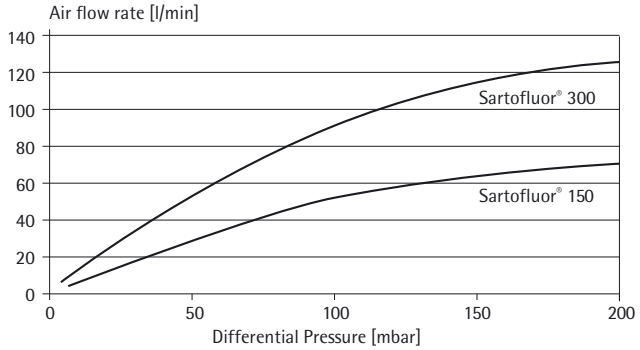
– Solvents

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.



▷ 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 cm^2 | 0.5 ft^2 up to 1.5 m^2 | 16.1 ft^2 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.

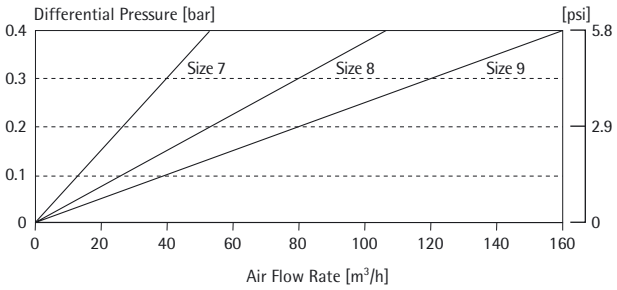
Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

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.

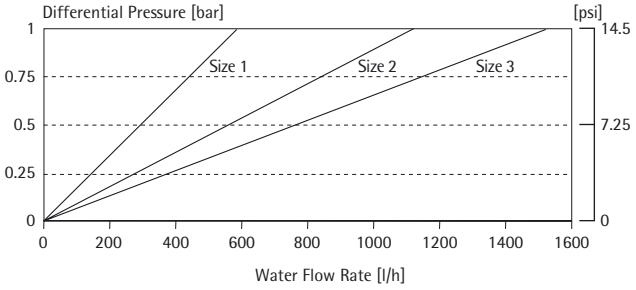
Quality Control
Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

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 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" 0.5 m^2 | 5.4 ft^2
Size 2 20" 1.0 m^2 | 10.8 ft^2
Size 3 30" 1.5 m^2 | 16.1 ft^2

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.

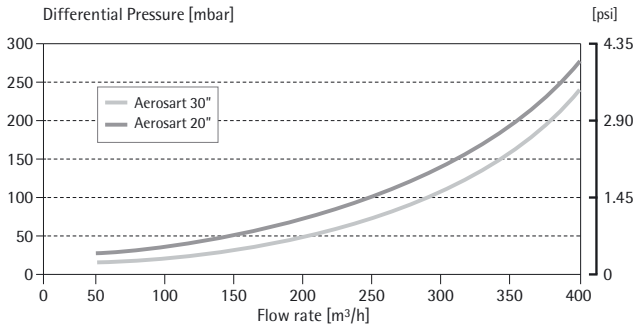
Applications
The Aerosart is designed for large-scale fermentation inlet and exhaust gas filtration.

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 cm^2, 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

1/8" 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 After the bubble point	approx. 1.0 ml approx. 0.5 ml
Biosafety	USP Plastics Class VI	
Bubble point with isopropanol (60%)	0.45 µm 0.2 µm	≥ 0.9 bar (~13.1 psi) ≥ 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 0.45 µm pore size	5.0 l/min 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	1/8" | 1/8" NPT	12	Yes
17804 NPG	0.45 µm	PTFE	1/8" | 1/8" 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	1/8" | 1/8" NPT	12	Yes
17805 NPG	0.2 µm	PTFE	1/8" | 1/8" 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	1/8" | 1/8" NPT	100	No
17812 UNN	0.2 µm	PTFE	1/8" | 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 manufactured 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 membrane 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 manufacture. 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 Management 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 cm^2 | 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 °C)
- Cleaning agents

Machine-building | Automotive Industries

- Fuel filtration
- Hydraulic oils

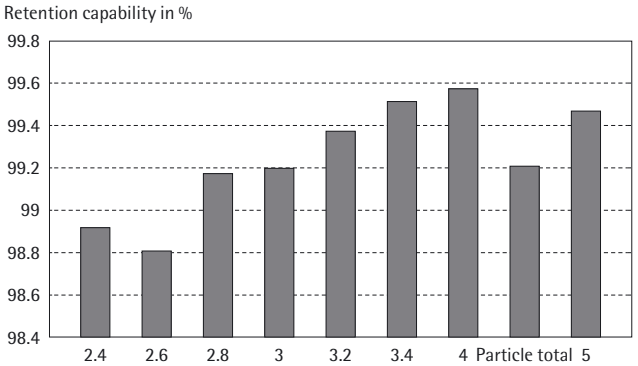
Performance
Sartosteel stainless steel depth filter catridges contain sintered, homogeneous, 0.4 mm thick non woven stainless steel mesh layers, which are reinforced on both sides by mesh supports. These filters are used for removing particles from liquids and gases (steam). Sartosteel filter cartridges 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 manufactured in accordance with a DIN ISO 9001 certified Quality Management System.

Particle retention rating 3 µm Sartosteel



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 cm^2 (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%)

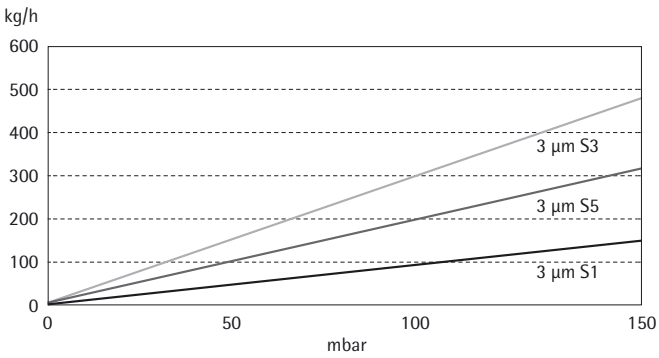
Order Information

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.

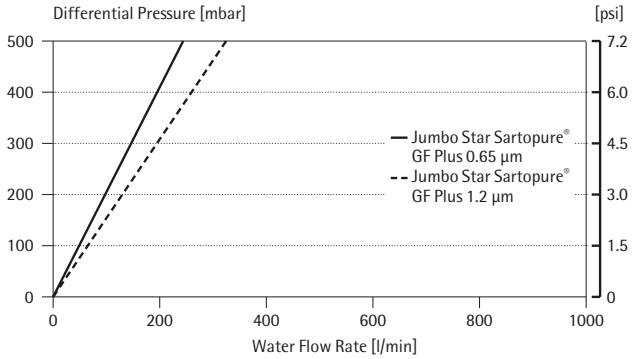
Reliable Operation
The new modular construction, coupled with effective combinations of nonwoven polypropylene and glass fibre layers, achieves the highest process reliability and reproducible results from batch to batch even under varying process conditions.

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 facilitiates 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



▷ 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 m^2
Size 2	20"	10 m^2
Size 3	30"	15 m^2
Size 4	40"	20 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® 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.

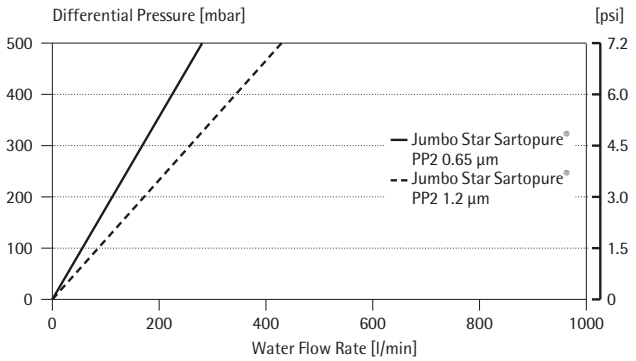
Reliable Operation
The new modular construction together with effective combination of nonwoven polypropylene achieves highest process reliability and reproducible results from batch to batch even under varying process conditions.

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

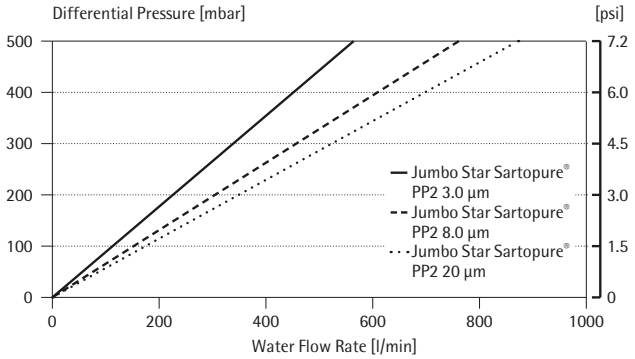
Technical References
Validation Guide:
SPK5774-e09021
85034-537-52

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



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.

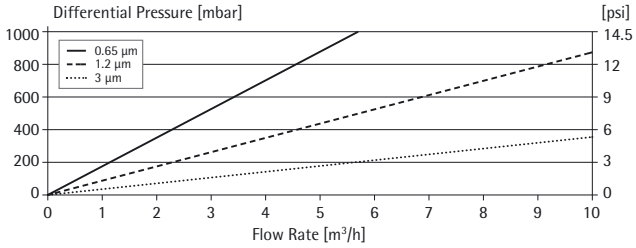
Performance
The Sartopure® PP2 filter elements combine high dirt loading capacities with long service life and extremely high flow rates.

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 Polypropylene 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 °C 2 bar | 29 psi at 80 °C
Max. allowable back pressure	2 bar | 29 psi at 20 °C

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 °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 (only cartridges)
Autoclaving: Min. 25

Technical References
Validation Guide:
SPK 5717-e

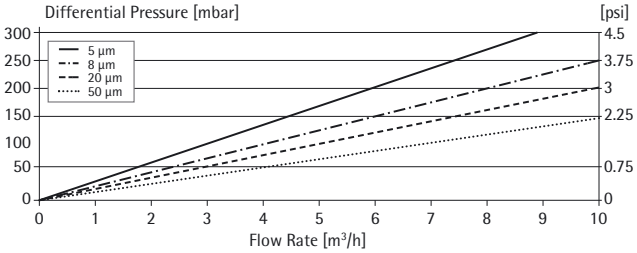
Extractables Guide:
SPK 5719-e

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.

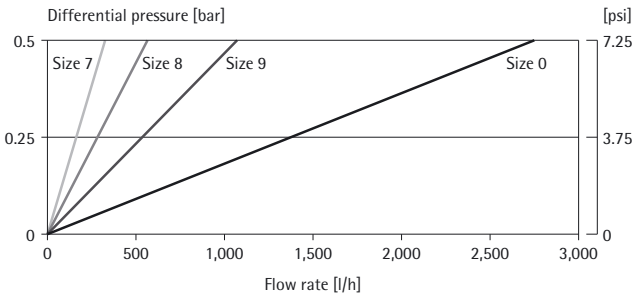
Flexibility
Sartopure® PP2 MidiCaps and MaxiCaps are available with various filtration areas from 500 cm^2 | 0.5 ft^2 up to 1.8 m^2 | 18 ft^2 for easy adoption to any filtration process independent from the batch size.

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.

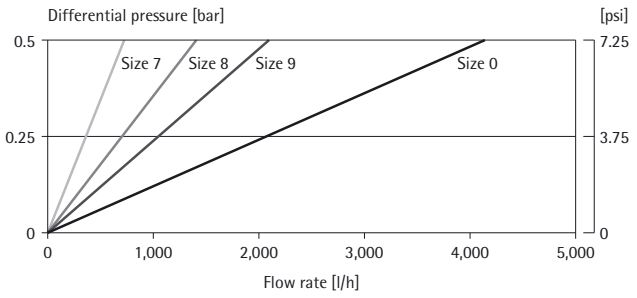
Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

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



Water Flow Rates for Sartopure® PP 2 1.2 µm MaxiCaps with SS inlet and outlet



▷ 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 m^2 | 0.5 ft^2
Size 8		0.10 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, 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.

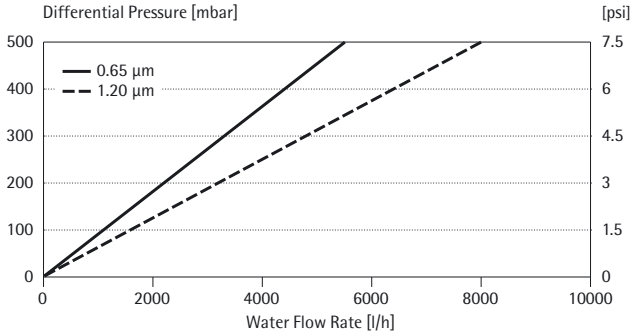
Reliable Operation
The high and defined particle retention capability of Sartopure® GF Plus allows reliable operation and reproducible results from batch to batch even under varying process conditions.

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 m^2 | 4 ft^2
Size 2	20"	0.8 m^2 | 8 ft^2
Size 3	30"	1.2 m^2 | 12 ft^2
Size 4	40"	1.6 m^2 | 16 ft^2

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

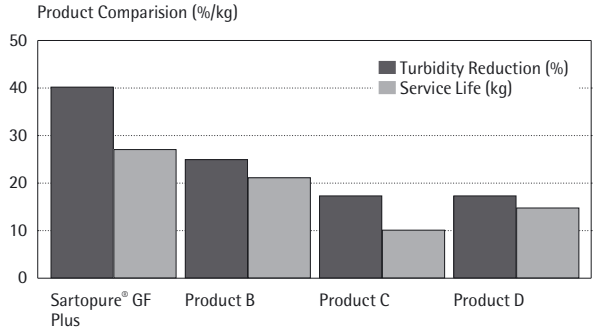
Technical References
Validation Guide:
SPK5753-e

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



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.

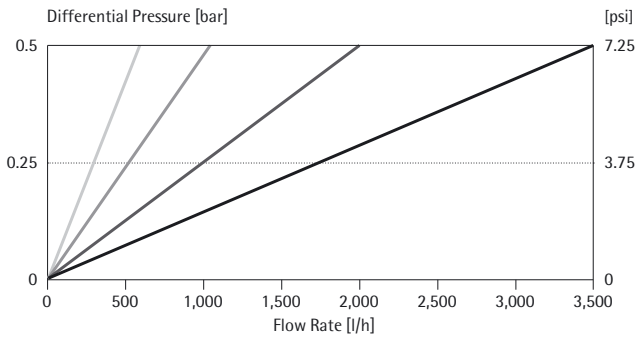
Flexibility
Sartopure® GF Plus MidiCaps and MaxiCaps are available with various filtration areas from 500 cm^2 | 0.5 ft^2 up to 1.2 m^2 | 12 ft^2 for easy adoption to any filtration process independent from the batch size.

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 m^2 | 0.4 ft^2
Size 8	0.08 m^2 | 0.8 ft^2
Size 9	0.12 m^2 | 1.2 ft^2
Size 0	0.25 m^2 | 2.5 ft^2

MaxiCaps

Size 1	10"	0.4 m^2 | 4 ft^2
Size 2	20"	0.8 m^2 | 8 ft^2
Size 3	30"	1.2 m^2 | 12 ft^2

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

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

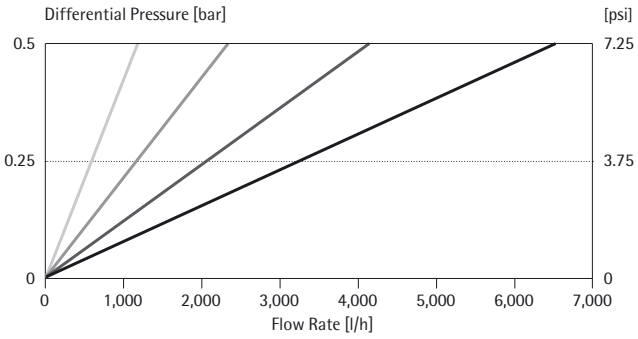
Sterilization Cycles
Autoclaving: Min. 25

Technical References
Validation Guide SPK5760-e

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

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

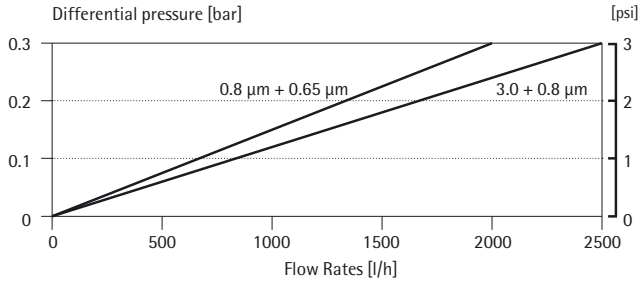
Process Safety
The removal of colloidal contaminants and lipids by adsorption allows an effective downstream processing and bioburden reduction by membrane filtration avoids formation of pyrogenes during the process resulting in an increased process safety especially for biotech derived fluids.

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.

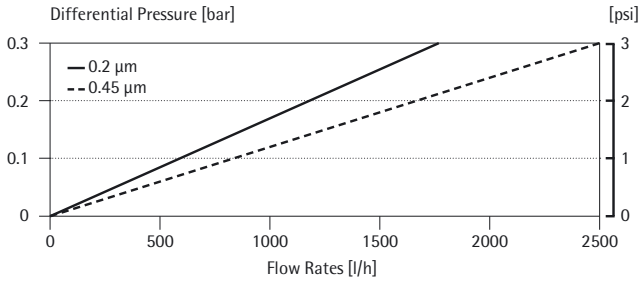
Performance
Sartoclean® CA filters with heterogeneous double layer construction (3.0 | 0.8 µm & 0.8 | 0.65 µm) offer highest total throughput performance due to the "build-in prefiltration" to avoid filter change during filtration and assure economical system design. Single layer Sartoclean® CA filters (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 cartrides, 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

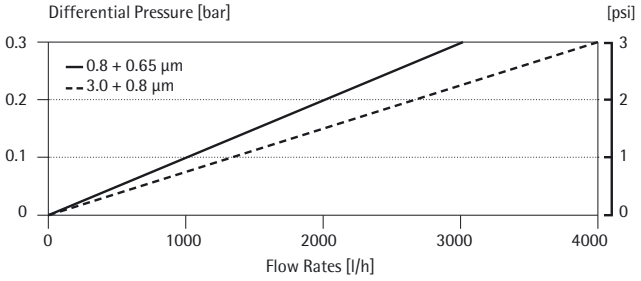
Sterilization Cycles
In-Line Sterilization: Min. 25
Autoclaving: Min. 25

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 performance for critical prefiltration applications. They can be used for protection of Mycoplasma 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 m^2/10" 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 cm^2 filtration area for Brevundimonas Diminuta, while the 0.2 µm rated filters typically provide a LVR of 6 per cm^2 filtration area for Serratia Marcescens.

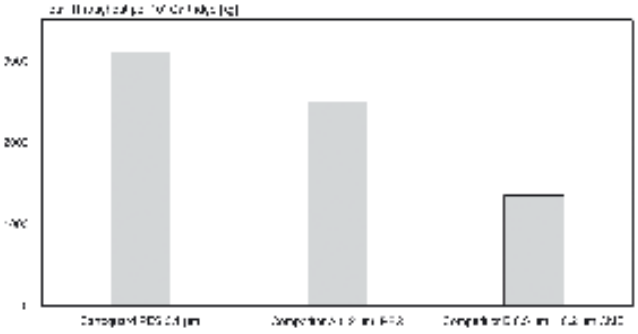
Compatibility
Sartoguard PES filter elements are designed for broad chemical compatibility from pH 1 to pH 14 and low extractable levels. They are compatible with multiple in line steam sterilization cycles up to 134 °C.

Quality & Security
Sartoguard PES filter cartridges are individually 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.

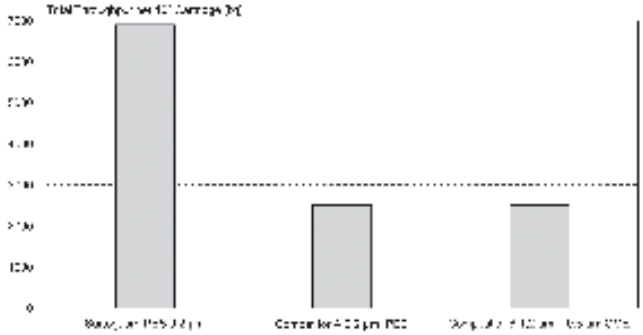
Scalability
Sartoguard PES filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

Documentation
Sartoguard PES cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management 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.

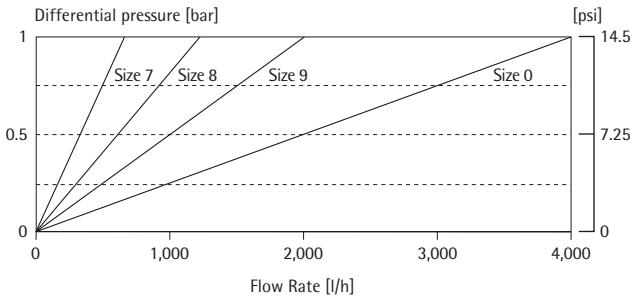
Flexibility
Sartoclean® GF MidiCaps & MaxiCaps are available with various filtration areas from 500 cm^2 | 0.5 ft^2 up to 1.8 m^2 | 18 ft^2 for easy adoption to any filtration process independent from the batch size.

Scalability
Consistent and predictable scale-up and down trials can reliably be performed as all 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

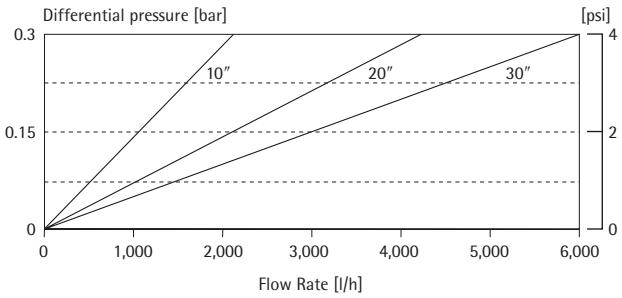
Sterilization Cycles
Autoclaving: Min. 25

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 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.

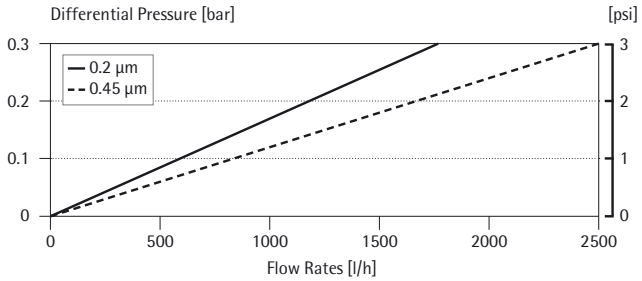
Performance
Sartoclean® CA filters with heterogeneous double layer construction (3.0 | 0.8 µm & 0.8 | 0.65 µm) offer highest total throughput performance due to the "build-in prefiltration" to avoid filter change during filtration and assure economical system design. Single layer Sartoclean® CA filters (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 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 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

MaxiCaps

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

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

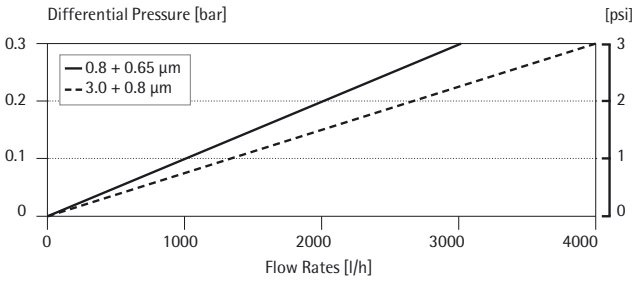
Order Information

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.

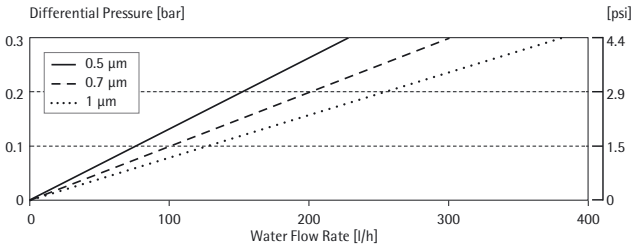
Applications
Whether in the bio-pharmaceutical or chemical industry, Sartofine PP filter cartridges are used wherever liquids with a wide range of particle sizes need to be prefiltered or clarified. You can choose from 7 different retention ratings (0.5 µm to 40 µm), depending on the size of the particles 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.

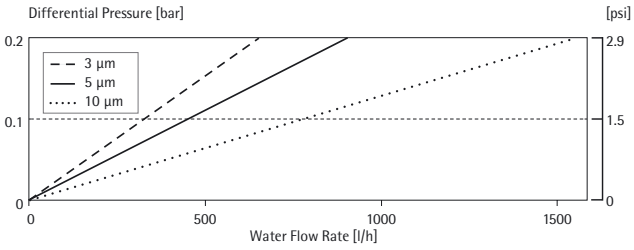
Mechanical Stability
Sartofine PP filter cartridges have been designed for daily routine use. Our special production method of wrapping the filter layers tightly around the supportive core of the cartridge provides high mechanical stability and eliminates the common problem of breakthrough right from 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 Polypropylene 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 m^2 | 0.5 ft^2
Size 2	20"	0.1 m^2 | 1 ft^2
Size 3	30"	0.15 m^2 | 1.5 ft^2
Size 4	40"	0.2 m^2 | 2 ft^2

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: Min. 25
(only cartridges)
Autoclaving: Min. 25

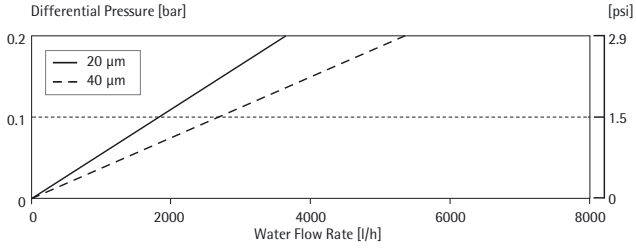
Technical References
Validation Guide:
SPK 5707-e

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°C 2 bar | 29 psi at 80°C

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°C, 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.

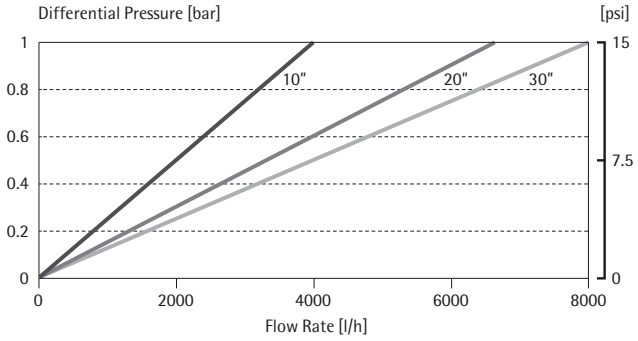
Flexibility
Sartobran® P 0.2 µm filters are available in traditional cartridge formats and disposable capsules from 150 cm^2 to 1.8 m^2 for simple linear scale up and process flexibility.

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 m^2 | 6.5 ft^2
Size 2	20"	1.2 m^2 | 12.9 ft^2
Size 3	30"	1.8 m^2 | 19.4 ft^2

Mini Cartridges

Size 7	0.05 m^2 | 0.54 ft^2
Size 8	0.1 m^2 | 1.1 ft^2
Size 9	0.2 m^2 | 2.2 ft^2

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

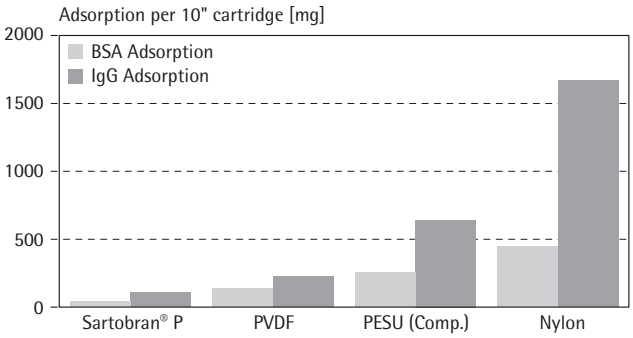
Technical References

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 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 Sartobran® P MidiCaps and MaxiCaps are produced with the same type of membrane and identical materials of construction.

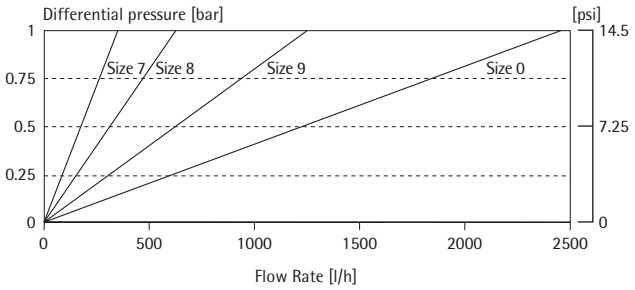
Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

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.

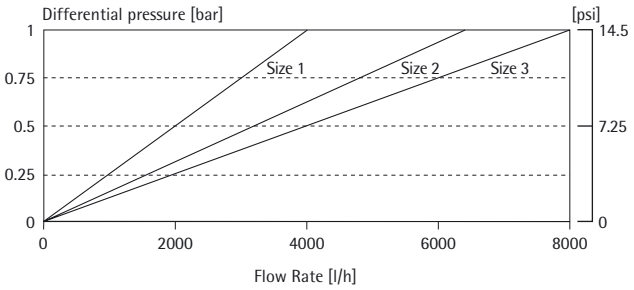
Quality Control
Each individual element is tested for integrity by B.-P. and Diffusion Test prior to being released, assuring absolute reliability.

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 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, 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.

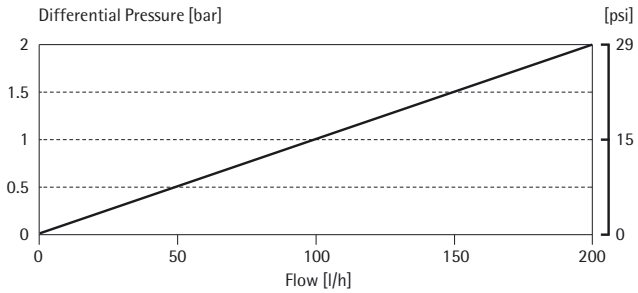
Scalability
Featuring the same materials and type of construction as any other Sartobran® P filter element, Sartobran® P 150 & 300 are ideally suited for R&D labs in pharmaceutical development. Filtration trials can be performed using extremely small volumes of high-value products.

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	0.015 m^2 | 0.16 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
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	Min. 25 (Type 300) Max. 3 (Type 150)

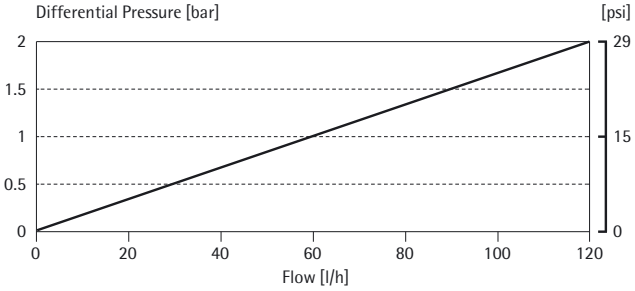
Technical References

Validation Guide	SPK5726-e
Extractables Guide	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.

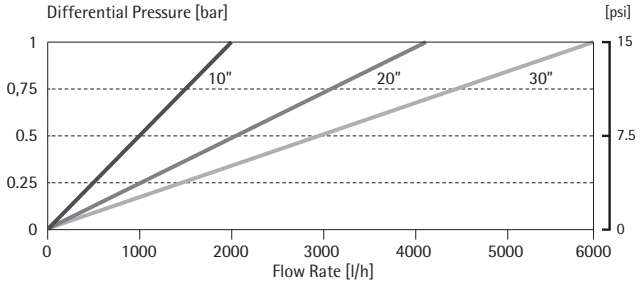
Highest Product Yield
The ultra-low adsorption characteristic of the Sartobran® P's cellulose acetate membrane provides the highest product yield - especially important for high-value proteins.

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

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

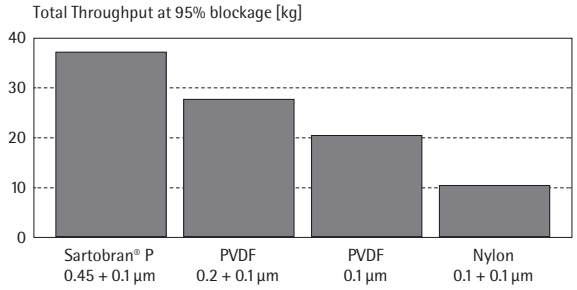
Technical References

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

Total Throughput Comparison



10" Cartridge format

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.

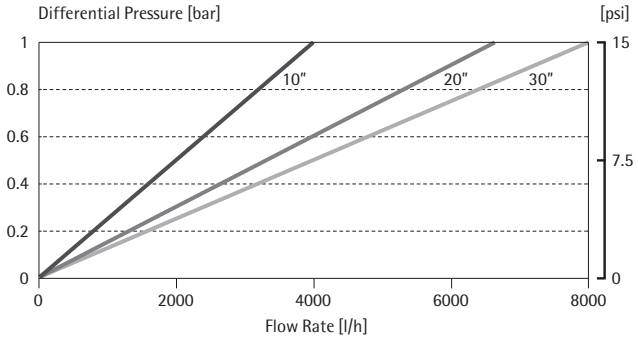
Performance
Due to the "built-in prefiltration" by a 0.65 µm membrane, Sartobran® P 0.45 µm filters provide excellent total throughputs and higher flow rates at low differential pressure for gentle product treatment.

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 m^2 | 6.5 ft^2
Size 2	20"	1.2 m^2 | 12.9 ft^2
Size 3	30"	1.8 m^2 | 19.4 ft^2

Mini Cartridges

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

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

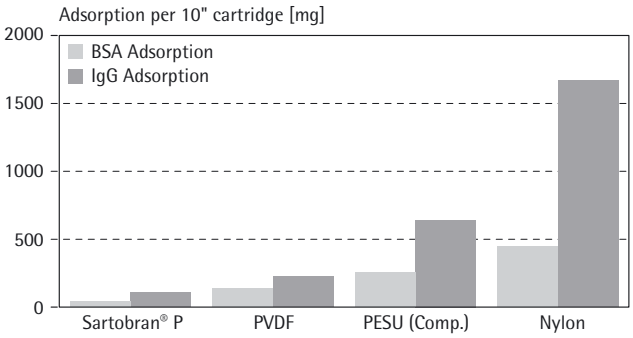
Technical References

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



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 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.

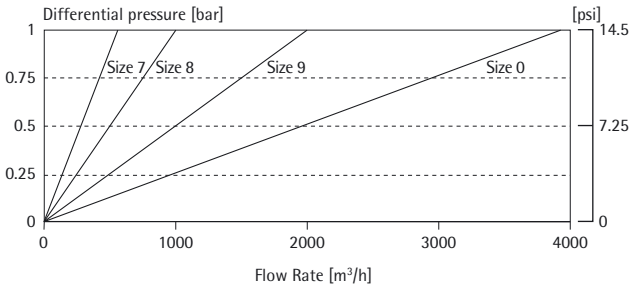
Scalability
Consistent and predictable scale-up and down trials can reliably be performed, as all Sartobran® P MidiCaps and MaxiCaps are produced with the same type of membrane and identical materials of construction.

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.

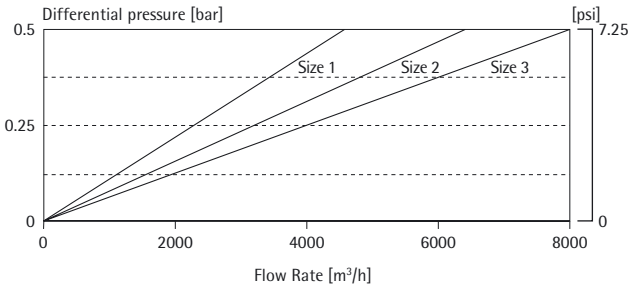
Quality Control
Each individual element is tested for integrity by B.-P. and diffusion test prior to being released, assuring absolute reliability.

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 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" 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 | CI 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.

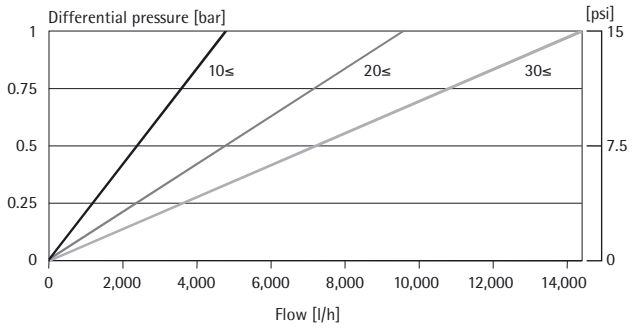
Wettability
Sartopore® 2 cartridges can be easily wetted out for integrity testing even after drying at 80°C for 12 hours.

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.

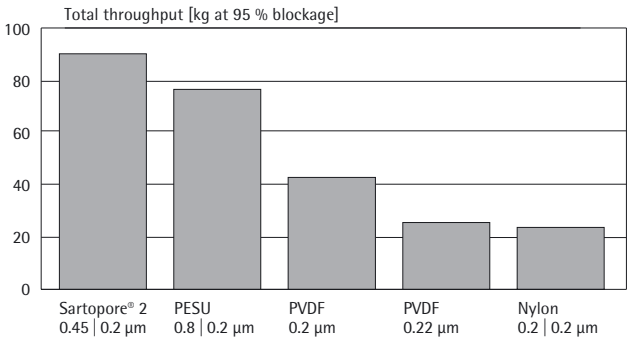
Documentation
Sartopore® 2 cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20°C

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

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

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

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.

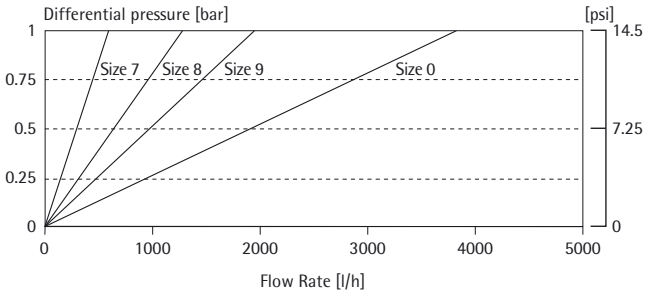
Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

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.

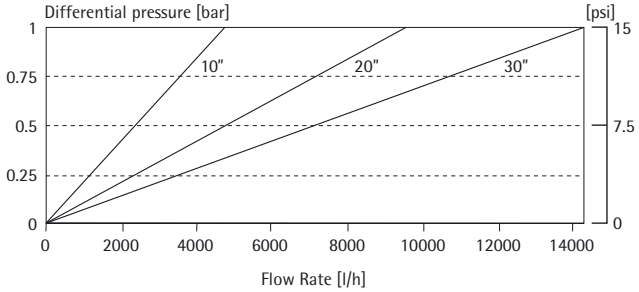
Quality Control
Each individual element is tested for integrity by bubble point and diffusion test prior to being released, assuring absolute reliability.

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 autoclavable 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 configurations 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 autoclaving at 134°C and 2 bar. The PES membrane 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.

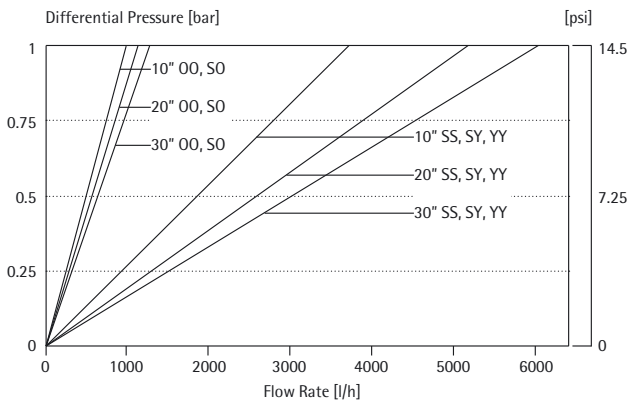
Economy
The combination of a built-in 0.45 µm pre-filter in front of the a 0.2 µm final filter and the asymmetric membrane structure provide outstanding total throughput performance.

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.



▷ Specifications

Materials

Prefilter Membrane	Polyethersulfone, asymmetric
Endfilter Membrane	Polyethersulfone, asymmetric
Support Fleece	Polyester
Core	Polypropylene
End Caps	Polypropylene
Capusle 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)
O: 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 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 XLG 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.

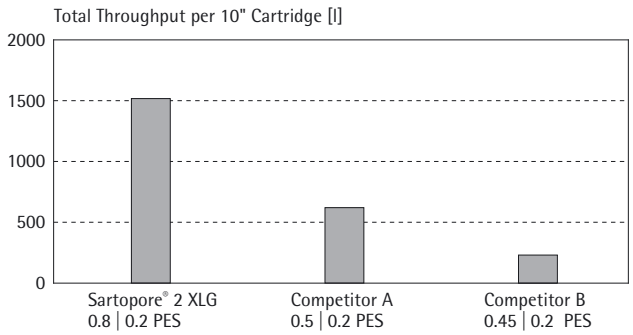
Scalability
Sartopore® 2 XLG filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

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 Management System. A Validation Guide is available for compliance with regulatory requirements.

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 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

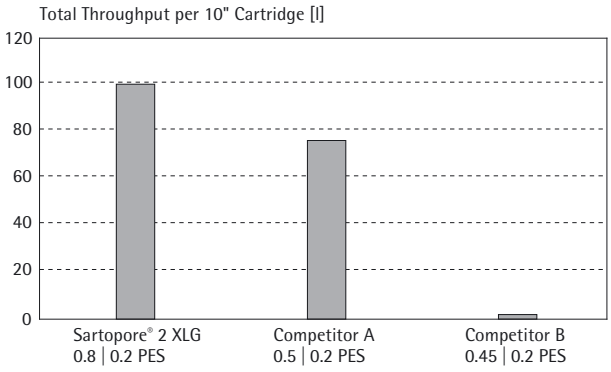
Technical References
Validation Guide:
SPK5772-e

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.

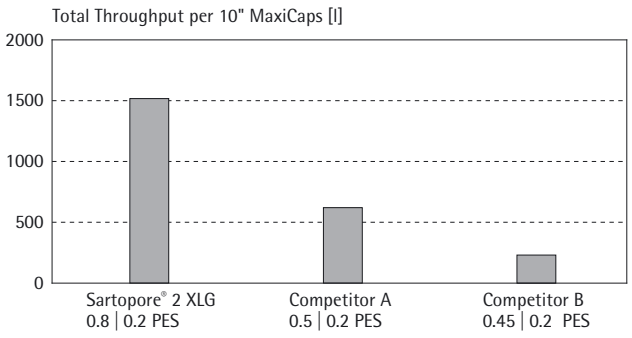
Cost Saving
The use of the capsule design concept avoids investment in stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

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.

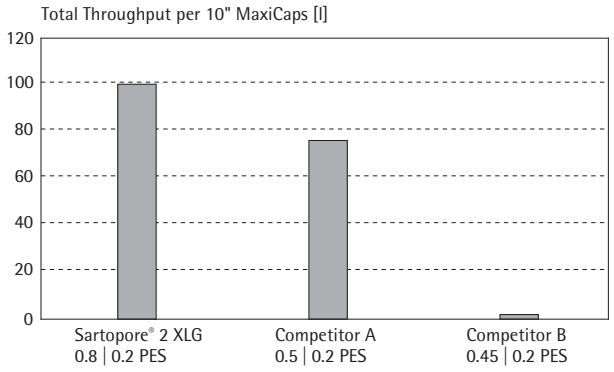
Quality Control
Each individual element is tested for integrity by B.P. and Diffusion-Test prior to being released assuring absolute reliability.

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



Monoclonal Antibody Pool



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 m^2 | 0.22 ft^2

MidiCaps
Size 7 0.065 m^2 | 0.7 ft^2
Size 8 0.13 m^2 | 1.4 ft^2
Size 9 0.26 m^2 | 2.8 ft^2
Size 0 0.52 m^2 | 5.6 ft^2

MaxiCaps
Size 1 0.8 m^2 | 8.6 ft^2
Size 2 1.6 m^2 | 17.2 ft^2
Size 3 2.4 m^2 | 25.8 ft^2

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.

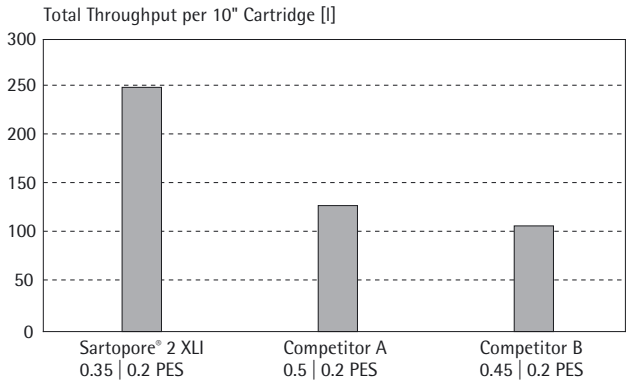
Scalability
Sartopore® 2 XLI filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

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



▷ 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 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 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

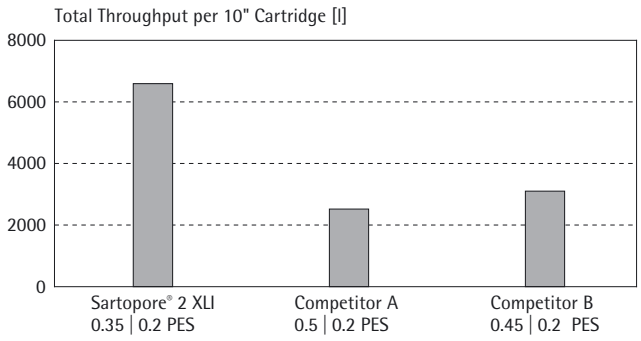
Technical References
Validation Guide:
SPK5768-e

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



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.

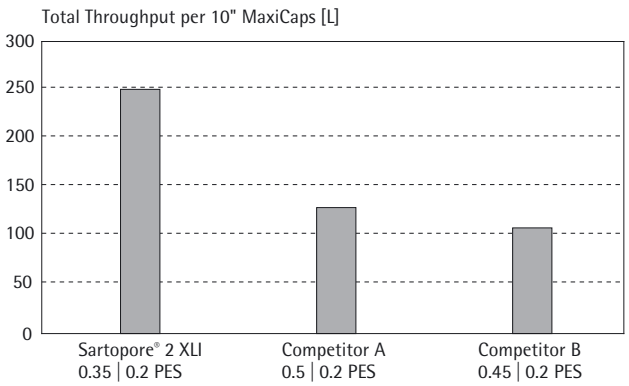
Cost Saving
The use of the capsule design concept avoids investment in stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

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.

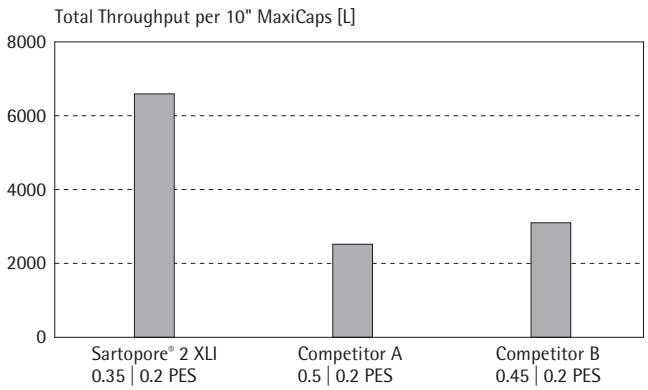
Quality Control
Each individual element is tested for integrity by B.P. and Diffusion-Test prior to being released assuring absolute reliability.

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



Ophthalmic Solution



▷ 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 m^2 | 0.22 ft^2

MidiCaps

Size 7	0.065 m^2 | 0.7 ft^2
Size 8	0.13 m^2 | 1.4 ft^2
Size 9	0.26 m^2 | 2.8 ft^2
Size 0	0.52 m^2 | 5.6 ft^2

MaxiCaps

Size 1	0.8 m^2 | 8.6 ft^2
Size 2	1.6 m^2 | 17.2 ft^2
Size 3	2.4 m^2 | 25.8 ft^2

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.

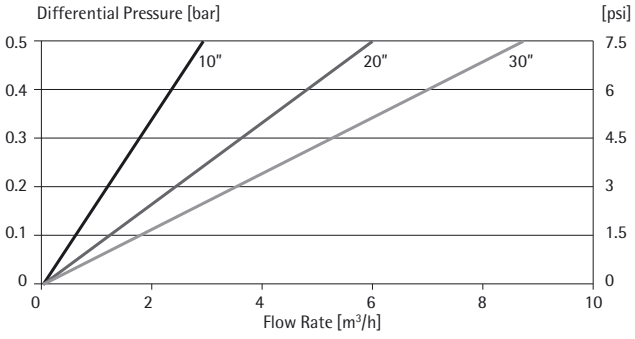
Wettability
Sartopore® 2 HF cartridges can be easily wetted out for integrity testing even after drying cycles with 80°C for 12 hours.

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.

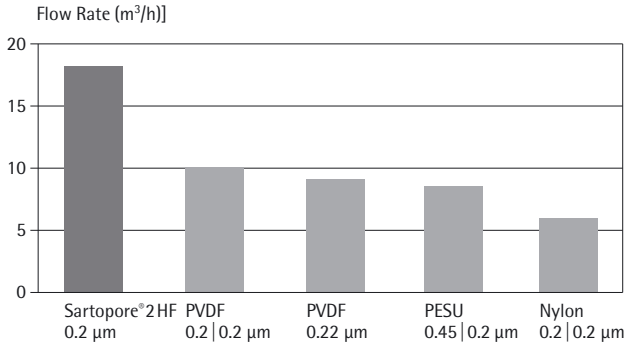
Documentation
Sartopore® 2 HF cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and an Extractables Guide are available for compliance with regulatory requirements.

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 m^2 | 7 ft^2
Size 2	20"	1.4 m^2 | 14 ft^2
Size 3	30"	2.1 m^2 | 21 ft^2

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.

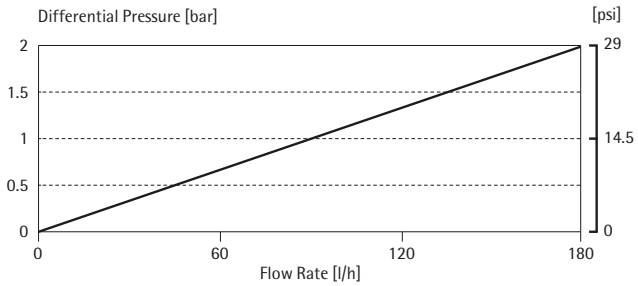
Scalability
Featuring the same materials and type of construction as any other Sartopore® 2 filter element, Sartopore® 2 150 and 300 are ideally suited for R&D Labs in pharmaceutical development. Filtration trials can be performed using extremely small volumes of high-value products.

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°C

▷ 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

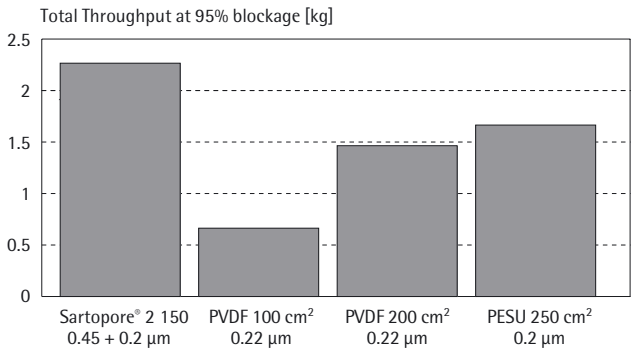
No in-line steam-sterilization

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



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 polyethersulfone 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.

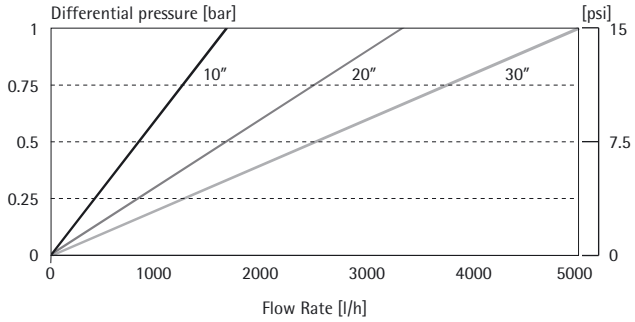
Wettability
Sartopore® 2 cartridges can be easily wetted out for integrity testing even after drying at 80°C for 12 hours

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 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 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

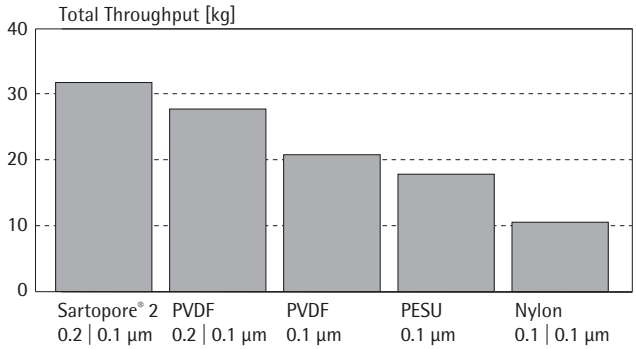
Technical References

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.

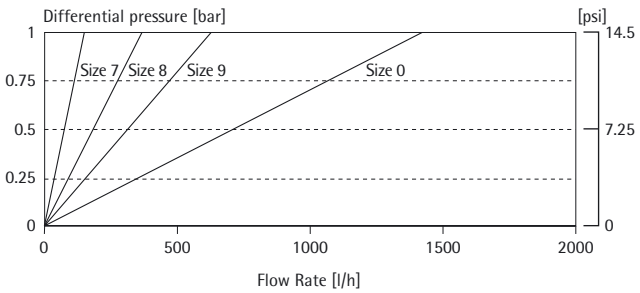
Cost Saving
The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

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.

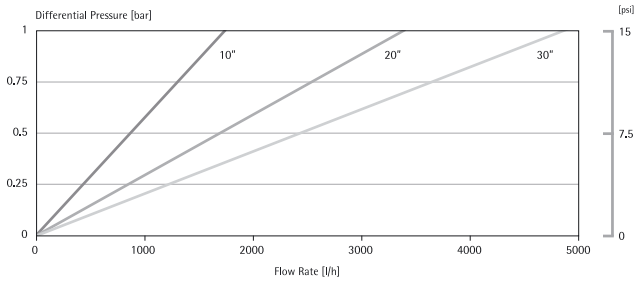
Quality Control
Each individual element is tested for integrity by Diffusion-Test prior to be released assuring absolute reliability.

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 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 & 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.

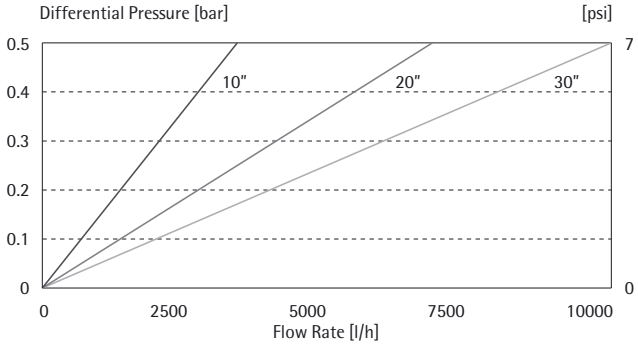
Wettability
Sartopore® 2 cartridges can be easily wetted out for integrity testing even after drying at 80°C for 12 hours.

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 m^2 | 6.5 ft^2
Size 2	20"	1.2 m^2 | 12.9 ft^2
Size 3	30"	1.8 m^2 | 19.4 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 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 0.45 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°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

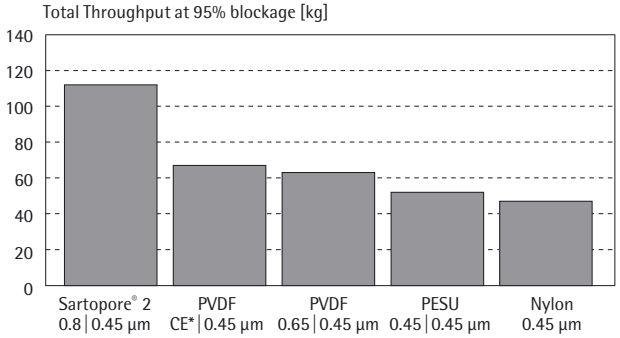
Technical References

Validation Guide	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



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 cm^2 | 0.5 ft^2 up to 1.8 m^2 | 18 ft^2 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.

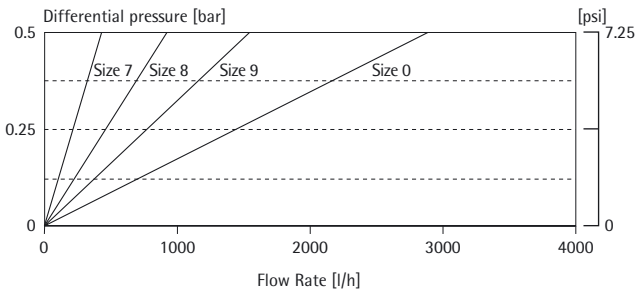
Cost Saving
The use of the disposalbe capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

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.

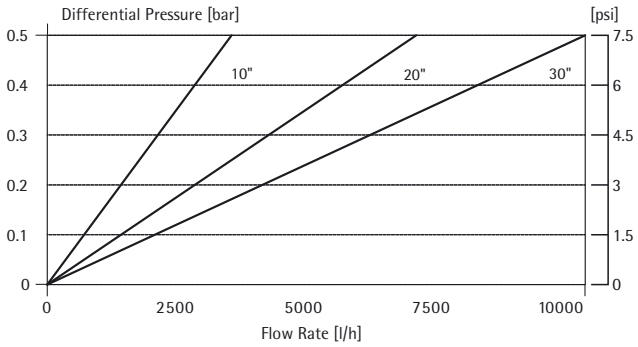
Quality Control
Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

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 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
0.8 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 throughputs and excellent flow rates.

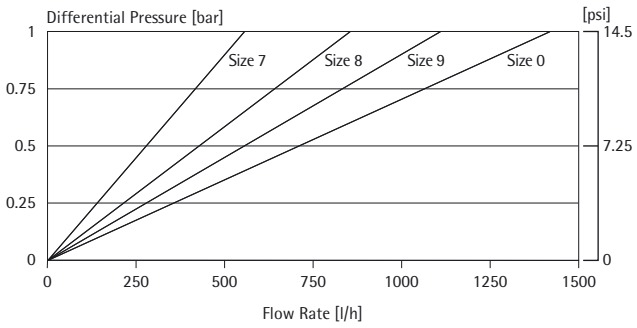
Flexibility
Sartopore® 2-γ-MidiCaps are available with various filtration areas from 500 cm^2 | 0.5 ft^2 up to 0.45 m^2 | 4.8 ft^2 and a broad range of different connector styles to allow an easy integration into any bag-container system.

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.

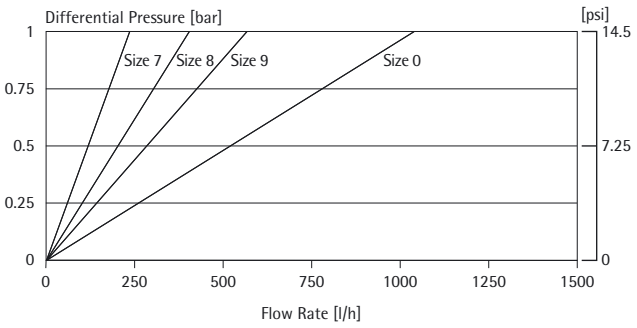
Quality Control
Each individual element is tested for integrity by B.-P. (0.2 µm only) and Diffusion-Test prior to be released assuring absolute reliability.

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 throughputs and excellent flow rates.

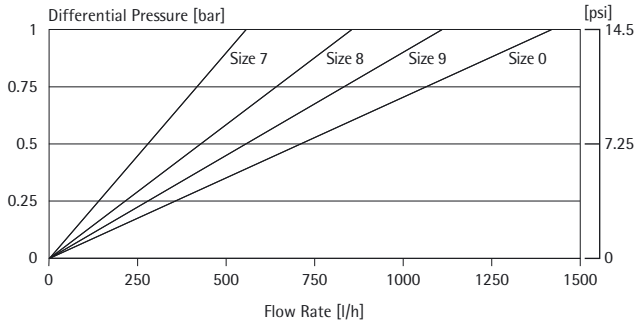
Flexibility
Sartopore® 2-γ-MidiCaps & MaxiCaps are available with filtration areas from 0.015 m^2 | 0.15 ft^2 up to 0.45 m^2 | 5 ft^2 for easy use in any bag filtration process, independent of the batch size.

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



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 m^2 | 0.15 ft^2
Size 5	0.03 m^2 | 0.3 ft^2
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, 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

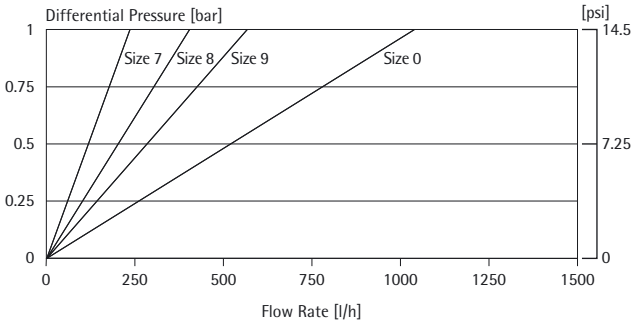
Technical References

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

Single-Use Technology

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.

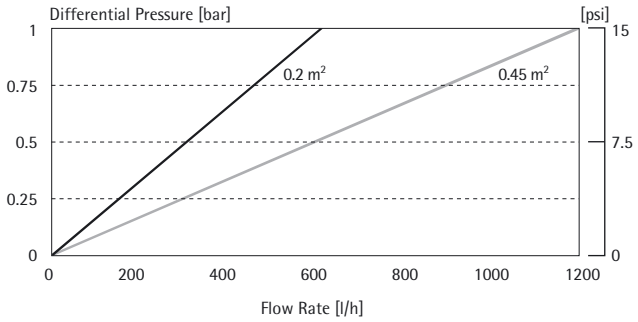
Flexibility
Sartopore® 2-γ-MidiCaps & MaxiCaps are available with filtration areas from 0.03 m^2 | 0.3 ft^2 up to 0.45 m^2 | 5 ft^2 for easy adaption to any bag-filtration process, independent of the batch size.

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 m^2 and 0.45 m^2 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 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, 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

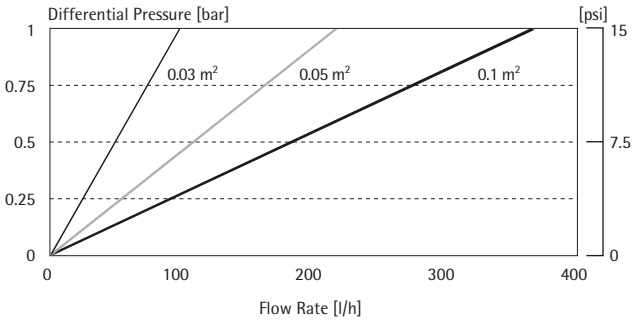
Validation Guide	SPK5734-e
Extractables Guide	SPK5740-e

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 m^2, 0.05 m^2 and 0.1 m^2 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 processing of biotech applications. They provide consistently high total throughput performance 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 Polyethersulfone 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.

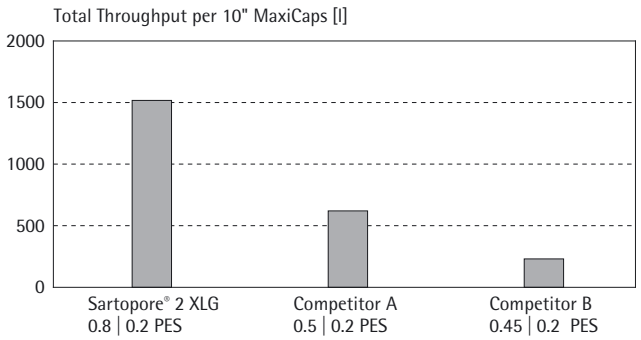
Flexibility
Sartopore® 2-XLG-γ-MaxiCaps® are ideally suited to be used in large scale filtration applications in combination with flexible bag containers due to their superior effective filtration area of up to 2.4 m^2 | 25.8 ft^2 per 30" element.

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.

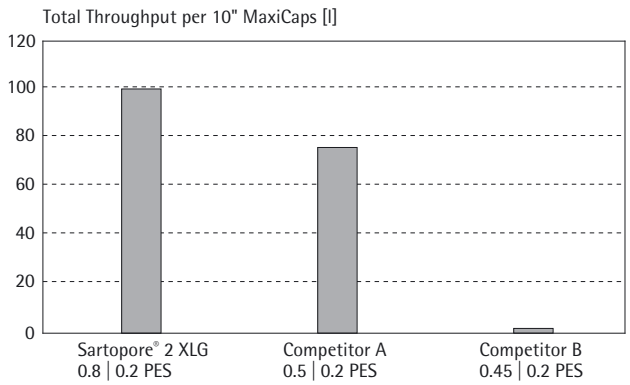
Quality Control
Each individual element is tested for integrity by B.-P. (0.2 µm only) and Diffusion-Test prior to be released assuring absolute reliability.

Documentation
Sartopore® 2-XLG-γ-MaxiCaps® are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Soy Peptone Supplemented Cell Culture Media



Monoclonal Antibody Pool



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 m^2 | 8.6 ft^2
Size 2	1.6 m^2 | 17.2 ft^2
Size 3	2.4 m^2 | 25.8 ft^2

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.

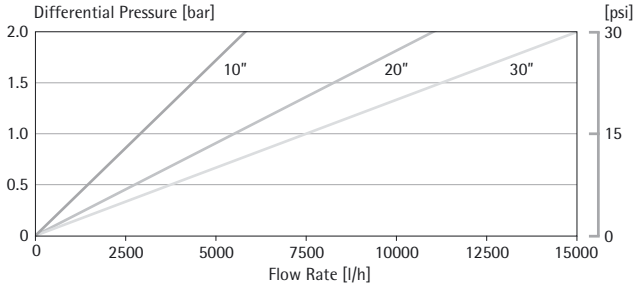
Performance
Sartolon® filter elements offer higher total throughputs than any other sterilizing grade nylon filter element on the market. The heterogeneous double-layer construction provides higher total throughputs than homogeneous double-layer types due to the "built-in prefiltration."

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 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 | MidiCaps

Size 9	0.2 m^2 | 2 ft^2

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

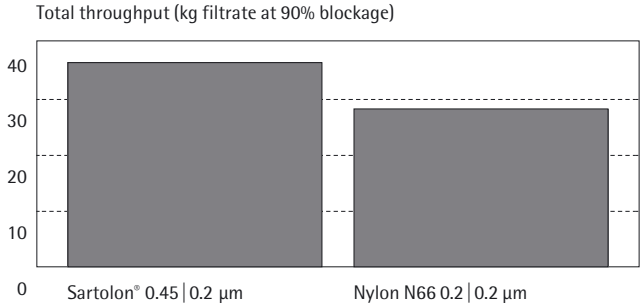
Technical References

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



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.

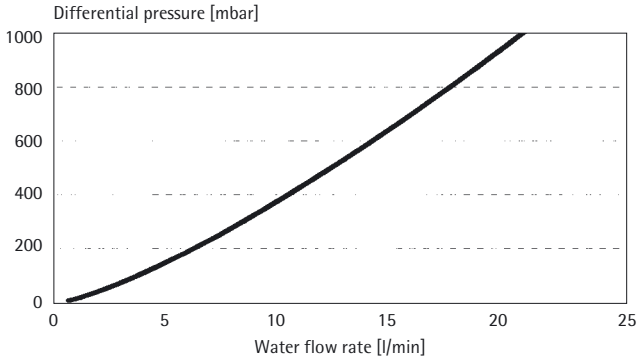
Speed of Operation
MaxiCaps are ready-to-use, saving time and money. No more backup filtration rigs to prepare. MaxiCaps can be easily replaced, should any operational difficulties occur.

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 m^2 | 5.4 ft^2
Size 2	20"	1.0 m^2 | 10.8 ft^2
Size 3	30"	1.5 m^2 | 16.1 ft^2

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 sterilizing and polishing filtration processes. A large emphasis has been placed on the integrity of construction of the filter cartridges. However, 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. 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 the housing surface.

Finally, electropolishing 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.

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.

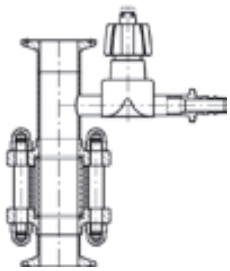
Ease in Cleaning
Jumbo P Filter Housings are designed to allow for a more thorough cleaning. Sprayball assembly is available for all Jumbo P housings. CIP caps are also available.

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.

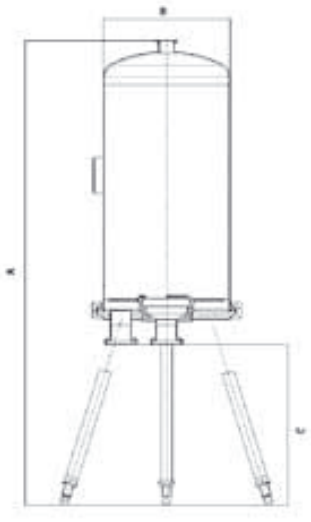
Quality Control and Documentation
Premium document package as standard includes as-built drawing(s), BOM, MTRs, elastomer certs., hydrotest certs., surface finish certs., EP|passivation certs.,weld log, etc. Each Filter Housing is also labled with a matching serial number on the base and bell for complete 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.

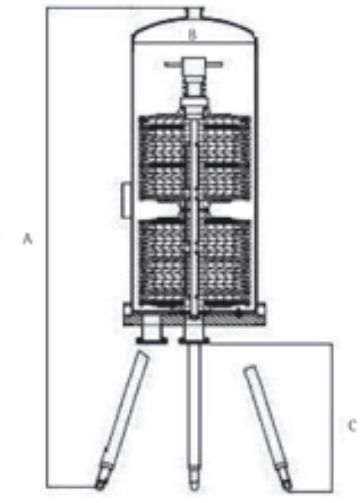
Ease in Cleaning
Sartoclear® P Filter Housings are designed to allow for a more thorough cleaning. The secure center post assembly conceals small grooves and threads from the process fluid making cleaning easier. While some of the internal components must be washed separately, riboflavin testing utilizing 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"
018 = 1.8 m^2
036 = 3.6 m^2
054 = 5.4 m^2
072 = 7.2 m^2

Filtration Area, 16"
036 = 3.6 m^2
072 = 7.2 m^2
108 = 10.8 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.

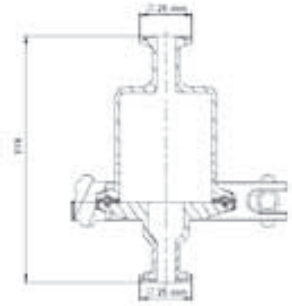
Ease in Cleaning
Sartorius Stedim Biotech utilizes a unique plugin adapter design that is conducive to a thorough cleaning. The plug-in adapter design eliminates small grooves and tight spaces that might be difficult to validate for cleaning, while still allowing complete drainage of the housing.

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

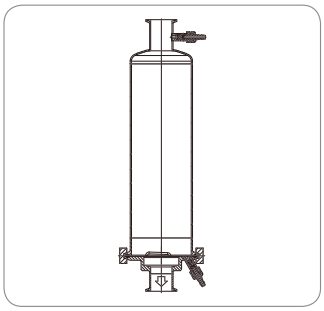
Ordercode

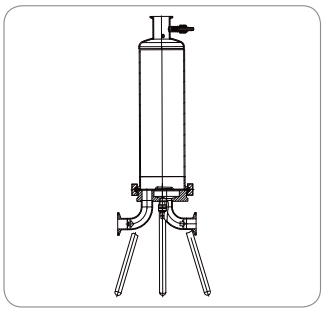
7U17LEN00002	½" Pipe diameter 12.70 × 1.65 mm
7U17LEN00003	¾" Pipe diameter 19.05 × 1.65 mm
In– and outlet	Sanitary TC Flange 25 mm diameter

North America Version

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

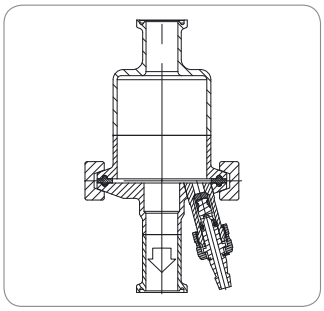
1	2	3	4	5	6	7	8	9	10	11	12
x	x	x	x	x	x	x	x	x	x	x	x

- Product Family — "7"
- Cartridge type \| number of filter cartridges — "Sx" = Standard 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))

North America Version

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

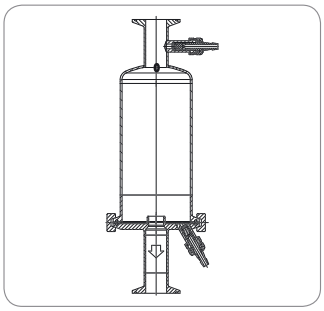
1	2	3	4	5	6	7	8	9	10	11	12
x	x	x	x	x	x	x	x	x	x	x	x

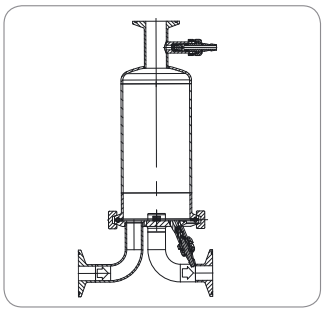
- Product Family — "7"
- Cartridge type \| number of filter cartridges — "U1" = Junior cartridges
- Height — 7 = Size 7 (2")
- Material — 316L
- Seal Material — S = Silicone; V = Viton; E = EPDM; W = PTFE enveloped Viton
- Certification — U = North America
- Consecutive ID number (Depends on the 1st – 3rd position(s))

North America Version

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 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
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

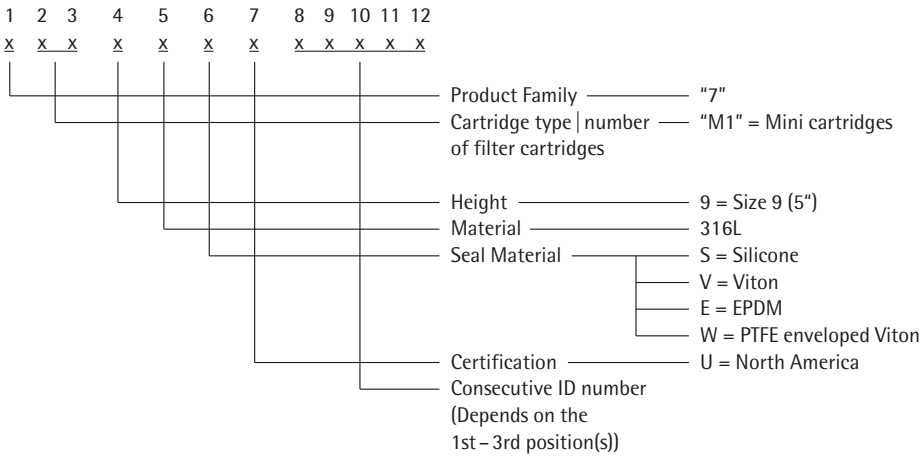
7M19LSUS0584	1 × 9 Mini T-type, Pharma valve vent | drain, 1.5" TC (Pipe 3/4")
7M19LSUS0148	1 × 9 Mini I-type, Pharma valve vent | drain, 1" TC
7M19LEUS0567	1 × 9 Mini T-type | C-line base (Pressure Gas), Pharma valve vent | drain, 1.5" TC (Pipe 3/4")

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



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.

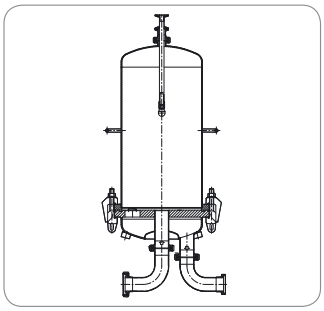
Heater Specifications

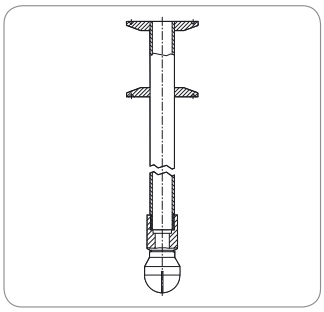
Pre-Set Temperature Points	95°C (203°F)
Exterior Range Temperature	Ambient to 43°C (109°F) based on 95°C set point
Foam Thickness	0.5 in. (12.7 mm)
Connectors	Bulgin Mini Buccaneer
Weight Range	1 to 5 lbs (0.45 to 2.27 kg)
Product Safety	UL®/C-UL Listed, CE, Semi S2, NEMA 4X

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.

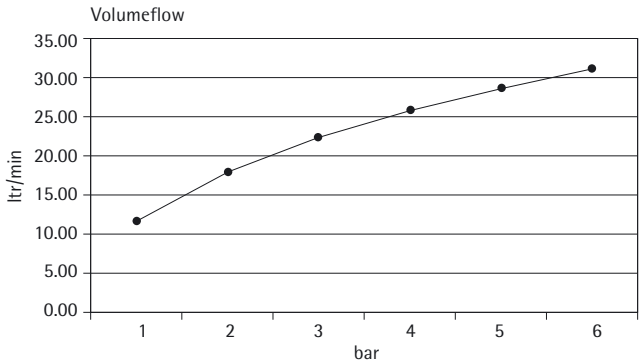
Operating Principle
The axial system works on the basis of spectral distribution. Using the operating pressure of the cleaning agent, the spray head rotates and thus reaches all areas within the housing bell over 360°.

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.



▷ 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	9000 ml
– with external ref. Vessel	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 equivalent 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.

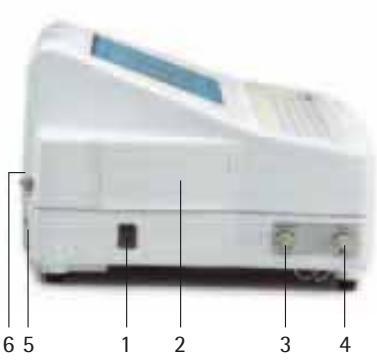
▷ Specifications

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°C to +35°C
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

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 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°C
Relative humidity	10 – 80%
Max distance between SC4 and multiunit (RS485)	100 m

Order Information

Order number	16288---TU

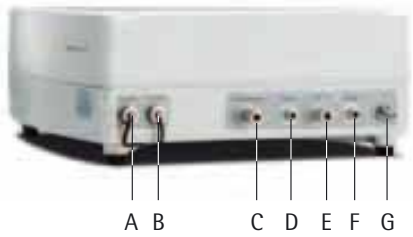
Equipment Supplied

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