

Sartopore[®] Platinum HB

Sterilizing Grade Filter Elements



Product Information

- Increased BP (> 4.1 bar) for the sterilizing-grade filtration of especially challenging solutions
- Including Twinpleat technology for higher EFA and thus smaller filters
- Highly hydrophilic due to unique surface modification
- Ideal Single-Use solution

Enhanced Safety for Challenging Processes and Solutions

Every sterilizing grade filter has to pass Bacterial Challenge Tests according to current ASTM F-838 guideline. However it is known that specific product formulations and also process conditions may increase the risk of bacterial penetration of standard 0.2 µm rated filters. Especially to meet these stricter requirements Sartorius developed 0.2 µm sterilizing-grade filters with slightly tighter membranes. These filters are characterized by elevated bubble point values. Due to the tighter pore structure of the membranes these filters resist also most challenging filtration conditions.

Unique Surface Modification

A patented membrane hydrophilization process is used to permanently modify the membrane surface. This technology provides those membrane surface properties that are responsible for the outstanding wettability and low protein binding character of the Sartopore® Platinum membrane, even after extreme thermal and chemical stress, without affecting wettability and integrity testing.

Maximum Yield for High-Value Products

Besides high filtration capacity the surface modification leads to lowest protein adsorption of any PES membrane in the market by which product yield can be maximized.

Perfect Solution for Single-Use Processes

The perfect wettability of the PES membrane leads to drastic reduction of the required flushing volumes (up to 95% less water needed) which is highly beneficial especially for single-use processes. Due to the low flushing volume the required waste bags can be significantly downsized by which costs are reduced and handling is optimized.

Applications

- Production of high-value biologicals like monoclonal antibodies
- Final conjugated bulk
- Point of fill filtration
- Processes with long filtration periods
- Processes with frequent start-stop
- Extremely challenging media (surfactant-containing | liposomal | lipid & lipid-like | protein-based)

Technical Specifications

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar 36 psi [ml/min]	Min. Bubble Point [bar psi]
Cartridges, T-Style Maxicaps®, Maxicaps®			
Size 1	1.0 m ² 10.8 ft ²	25	4.1 59.5
Size 2	2.0 m ² 21.5 ft ²	50	4.1 59.5
Size 3	3.0 m ² 32.3 ft ²	75	4.1 59.5
Midicaps® Gamma Midicaps®			
Size 7	0.065 m ² 0.7 ft ²	4	4.1 59.5
Size 8	0.13 m ² 1.4 ft ²	5	4.1 59.5
Size 9	0.26 m ² 2.8 ft ²	7	4.1 59.5
Size 0	0.52 m ² 5.6 ft ²	14	4.1 59.5
Capsules Gamma Capsules			
Size 4	0.021 m ² 0.22 ft ²	1.1	4.1 59.5

Max. Allowable Differential Pressure

Cartridges

5 bar | 72.5 psi at 20 °C
2 bar | 29 psi at 80 °C

T-Style Maxicaps®, Maxicaps®, Midicaps® | Gamma Midicaps®

5 bar | 72.5 psi at 20 °C
3 bar | 43.5 psi at 50 °C

Capsules | Gamma Capsules Size 4

4 bar | 58 psi at 20 °C
2 bar | 29 psi at 50 °C

Important Information: Due to limited pressure resistance of single-use filter housings, the recommended integrity test method (pre- and post-use) at customers' site is a Diffusion test. If a Bubble Point test is required, then the max. test pressure of the integrity tester must be limited according to the maximum allowable operating pressure of the respective single-use housing.

Materials

Prefilter Membrane

Polyethersulfone,
asymmetric

Core

Polypropylene

Endfilter Membrane

Polyethersulfone,
asymmetric

End Caps

Polypropylene

Support Fleece

Polypropylene
(In-Line Steam sterilizable
& autoclavable)
Polyester
(γ -irradiatable or
 γ -irradiatable | autoclavable)

Capsule Housing

Polypropylene

O-Ring

Silicone
(optional EPDM or
Fluoroelastomer)

Max. Allowable Back Pressure

2 bar | 29 psi at 20 °C
(for all elements)

Pore Size Combination

0.45 μm + 0.2 μm

Regulatory Compliance

- Each individual element is tested for integrity by Bubble Point and Diffusion test
- Fully validated as sterilizing grade filters according to ASTM current F-838 guidelines
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System
- Meet or exceed the requirements for WFI quality standards set by the current USP
- Non pyrogenic according to USP Bacterial Endotoxins
- USP Plastic Class VI Test
- Non fiber releasing according to 21 CFR



Sterilization

Cartridges

In-Line Steam Sterilization (dry or wet steaming)
134 °C, 0.3 bar, 20 min.
Min. 25 Sterilization Cycles

or

Autoclaving
134 °C, 2 bar, 30 min
Min. 25 Sterilization Cycles

Midicaps® & Capsules

Autoclaving
134 °C, 2 bar, 30 min
Min. 25 Sterilization Cycles (Midicaps®)
Min. 5 Sterilization Cycles (Capsules)

Gamma Midicaps® & Gamma Capsules

Gamma Irradiation
≤ 50 kGy
1 Sterilization Cycle

T-Style Maxicaps® & Maxicaps®

Autoclaving
134 °C, 2 bar, 30 min
Min. 5 Sterilization Cycles

or

Gamma Irradiation
≤ 50 kGy
1 Sterilization Cycle

Technical References

Validation Guide
Extractables Guide

DIR no.:2665259
DIR no.:2650008

Services

Sartorius Confidence® Validation Services is the perfect complement to *Sartopore® Platinum HB filters.

Our services provide:

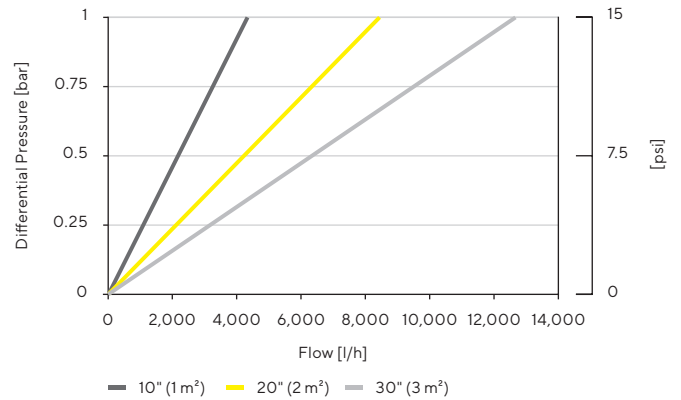
- Extractables and leachables services
- Microbiological testing
- Physicochemical testing

in compliance with regulatory requirements.

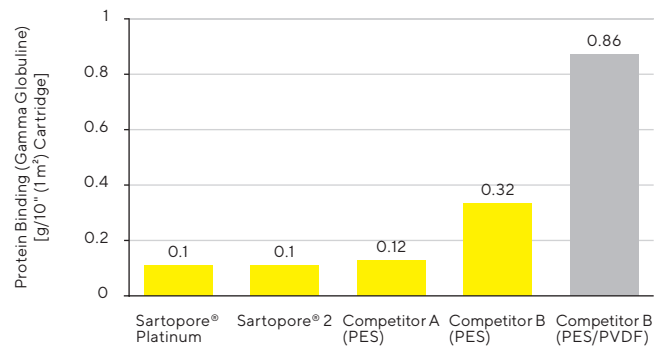
Our local teams of validation experts support you with our tailored and consultative approach to determine the most cost-effective solution and give you the confidence you need to succeed.

Performance

Water Flow Rates 10", 20", 30"



Unspecific Protein Binding



Ordering Information



Cartridge

549 25 07 H ■ -- - - HB

Adapter

25: 2 Flange Bayonet adapter with 226 double o-ring

Filter Size

- 1: 1.0 m²|10.8 ft² (10")
- 2: 2.0 m²|21.5 ft² (20")
- 3: 3.0 m²|32.3 ft² (30")



T-Style Maxicaps®

549 83 07 H ■ G- ■ ■ HB

Filter Size

- 1: 1.0 m²|10.8 ft² (10")
- 2: 2.0 m²|21.5 ft² (20")
- 3: 3.0 m²|32.3 ft² (30")

Sterilization

G-: γ-irradiatable and autoclavable

Connector Inlet

S: 1½" Tri-Clamp 50.5 mm
O: ½" single stepped hose barb

Connector Outlet

S: 1½" Tri-Clamp 50.5 mm
O: ½" single stepped hose barb



Maxicaps®

549 73 07 H ■ G- ■ ■ HB

Filter Size

- 1: 1.0 m²|10.8 ft² (10")
- 2: 2.0 m²|21.5 ft² (20")
- 3: 3.0 m²|32.3 ft² (30")

Sterilization

G-: γ-irradiatable and autoclavable

Connector Inlet

S: 1½" Tri-Clamp 50.5 mm
O: ½" single stepped hose barb

Connector Outlet

S: 1½" Tri-Clamp 50.5 mm
O: ½" single stepped hose barb



Midicaps® | Gamma Midicaps®

549 53 07 H ■ ■ ■ ■ HB ■

Filter Size

- 7: 0.065 m²|0.7 ft²
- 8: 0.13 m²|1.4 ft²
- 9: 0.26 m²|2.8 ft²
- 0: 0.52 m²|5.6 ft²

Sterilization

G-: γ-irradiatable
--: autoclavable

Connector Inlet

S: 1½" Tri-Clamp 50.5 mm
O: ½" single stepped hose barb

Connector Outlet

S: 1½" Tri-Clamp 50.5 mm
O: ½" single stepped hose barb

Packing Size

A: box of 4 (size 7,8,9)
V: box of 2 (size 0)



Capsules | Gamma Capsules

549 13 07 H 4 ■ ■ ■ HB B

Filter Size

4: 0.021 m²|0.22 ft²

Sterilization

G-: γ-irradiatable
--: autoclavable

Connector Inlet

S: ¾" Tri-Clamp 25 mm
O: ¼" multiple stepped hose barb

Connector Outlet

S: ¾" Tri-Clamp 25 mm
O: ¼" multiple stepped hose barb

Packing Size


B: box of 5

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