

Sartopore® Platinum

Sterilizing-Grade Filter Elements



Product Information

- Highest product yield due to lowest adsorption
- Excellent wettability ensures to low flushing volumes and high reliability of integrity testing
- High filtration capacity enables use of less filter elements or smaller filter sizes
- Smaller dimensions of single-use assemblies necessary – smaller bags, less tubing

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.

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.

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.

Reliable Integrity Testing

Imperfect wetting is the most frequent reason for failed integrity tests. Especially for single-use processes the re-wetting possibility is limited.

The extraordinary wetting behavior of Sartopore® Platinum thus helps to eliminate this important risk factor. Using Sartopore® Platinum leads to highly reliable integrity tests.

Applications

- Production of high-value biologicals like monoclonal antibodies
- Final conjugated bulk
- Point of fill filtration
- Especially beneficial for single-use filtration processes
- Blood and plasma processes
- Ophthalmics

Services

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

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 m² 10.8 ft²	25	3.5 51
Size 2	2.0 m² 21.5 ft²	50	3.5 51
Size 3	3.0 m² 32.3 ft²	75	3.5 51
Midicaps® Gamma Midicaps®			
Size 7	0.065 m² 0.7 ft²	4	3.5 51
Size 8	0.13 m² 1.4 ft²	5	3.5 51
Size 9	0.26 m² 2.8 ft²	7	3.5 51
Size 0	0.52 m² 5.6 ft²	14	3.5 51
Capsules Gamma Capsules			
Size 4	0.021 m² 0.22 ft²	1.1	3.5 51

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

Materials

Prefilter Membrane

Modified polyethersulfone, asymmetric

Endfilter Membrane

Modified polyethersulfone, asymmetric

Support Fleece

Polypropylene (In-line steam sterilizable and autoclavable)

Polyester (γ-irradiatable or γ-irradiatable | autoclavable)

Core

Polypropylene

End Caps

Polypropylene

Capsule Housing

Polypropylene

O-Ring

Silicone

(other materials on request)

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

- For release, 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)
Max. 134 °C, 0.3 bar, 20 min
Min. 25 Sterilization Cycles

or

Autoclaving

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

Midicaps® and Capsules

Autoclaving

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

Gamma Midicaps® and Gamma Capsules

Gamma Irradiation
≤ 50 kGy
1 Sterilization Cycle

T-Style Maxicaps® and Maxicaps®

Autoclaving

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

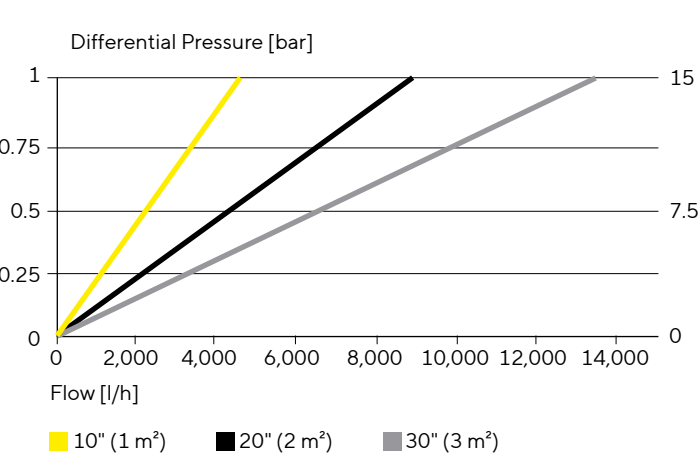
or

Gamma Irradiation

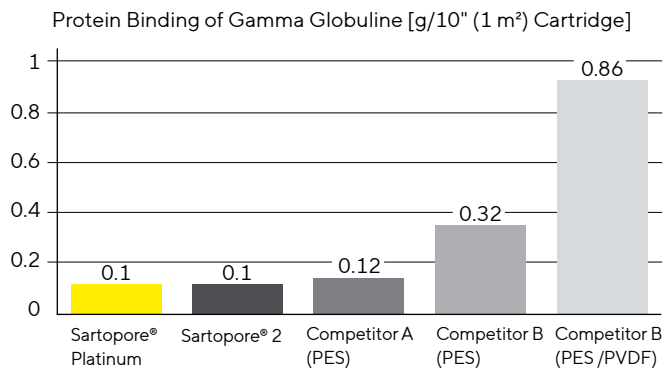
≤ 50 kGy
1 Sterilization Cycle

Performance

Water Flow Rates 10", 20", 30"



Unspecific Protein Binding



Technical References

Validation Guide 2665259
Extractables Guide 2650008

Ordering Information



Cartridge

549 25 07 H ■

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")

(Standard with silicone o-ring optional with EPDM or Fluoroelastomer o-ring).



T-Style Maxicaps®

549 83 07 H ■ G- ■ ■

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
Y: 1" single stepped
hose barb

Connector Outlet

- S: 1½" tri-clamp 50.5 mm
O: ½" single stepped
hose barb
Y: 1" single stepped
hose barb



Maxicaps®

549 73 07 H ■ G- ■ ■

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
F: ¾" tri-clamp 25 mm

Connector Outlet

- S: 1½" tri-clamp 50.5 mm
O: ½" single stepped
hose barb
F: ¾" tri-clamp 25 mm

(Optional with vent valve design for connection of integrity tester. Example: 5497307H1G-SOIT)



Midicaps® | Gamma Midicaps®

549 53 07 H ■ ■ ■ ■ -- ■

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
F: ¾" tri-clamp 25 mm
H: ¼" multiple stepped
hose barb (only size 7
with filling bell)

Connector Outlet

- S: 1½" tri-clamp 50.5 mm
O: ½" single stepped
hose barb
F: ¾" tri-clamp 25 mm
H: ¼" multiple stepped
hose barb (only size 7
with filling bell)

Packing Size

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



Capsules | Gamma Capsules

549 13 07 H 4 ■ ■ ■ -- 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