

# 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]
<b>Cartridges, T-Style Maxicaps®, Maxicaps®</b>			
Size 1	1.0 m <sup>2</sup>   10.8 ft <sup>2</sup>	25	3.5   51
Size 2	2.0 m <sup>2</sup>   21.5 ft <sup>2</sup>	50	3.5   51
Size 3	3.0 m <sup>2</sup>   32.3 ft <sup>2</sup>	75	3.5   51
<b>Midicaps®   Gamma Midicaps®</b>			
Size 7	0.065 m <sup>2</sup>   0.7 ft <sup>2</sup>	4	3.5   51
Size 8	0.13 m <sup>2</sup>   1.4 ft <sup>2</sup>	5	3.5   51
Size 9	0.26 m <sup>2</sup>   2.8 ft <sup>2</sup>	7	3.5   51
Size 0	0.52 m <sup>2</sup>   5.6 ft <sup>2</sup>	14	3.5   51
<b>Capsules   Gamma Capsules</b>			
Size 4	0.021 m <sup>2</sup>   0.22 ft <sup>2</sup>	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 ( $\gamma$ -irradiatable or  $\gamma$ -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  $\mu\text{m}$  + 0.2  $\mu\text{m}$

## 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

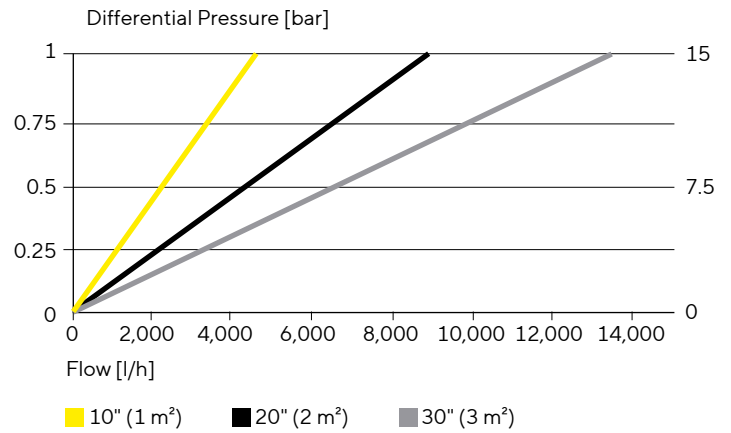
or

### Gamma Irradiation

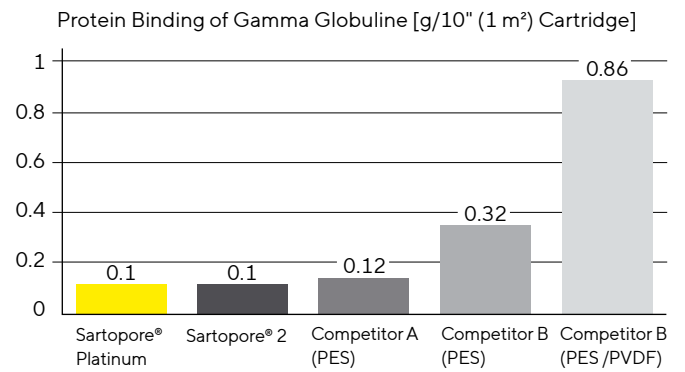
≤ 50 kGy  
 1 Sterilization Cycle

## 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 m<sup>2</sup> | 10.8 ft<sup>2</sup> (10")  
 2: 2.0 m<sup>2</sup> | 21.5 ft<sup>2</sup> (20")  
 3: 3.0 m<sup>2</sup> | 32.3 ft<sup>2</sup> (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 m<sup>2</sup> | 10.8 ft<sup>2</sup> (10")  
 2: 2.0 m<sup>2</sup> | 21.5 ft<sup>2</sup> (20")  
 3: 3.0 m<sup>2</sup> | 32.3 ft<sup>2</sup> (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 m<sup>2</sup> | 10.8 ft<sup>2</sup> (10")  
 2: 2.0 m<sup>2</sup> | 21.5 ft<sup>2</sup> (20")  
 3: 3.0 m<sup>2</sup> | 32.3 ft<sup>2</sup> (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 m<sup>2</sup> | 0.7 ft<sup>2</sup>  
 8: 0.13 m<sup>2</sup> | 1.4 ft<sup>2</sup>  
 9: 0.26 m<sup>2</sup> | 2.8 ft<sup>2</sup>  
 0: 0.52 m<sup>2</sup> | 5.6 ft<sup>2</sup>

### 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 m<sup>2</sup> | 0.22 ft<sup>2</sup>

### 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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