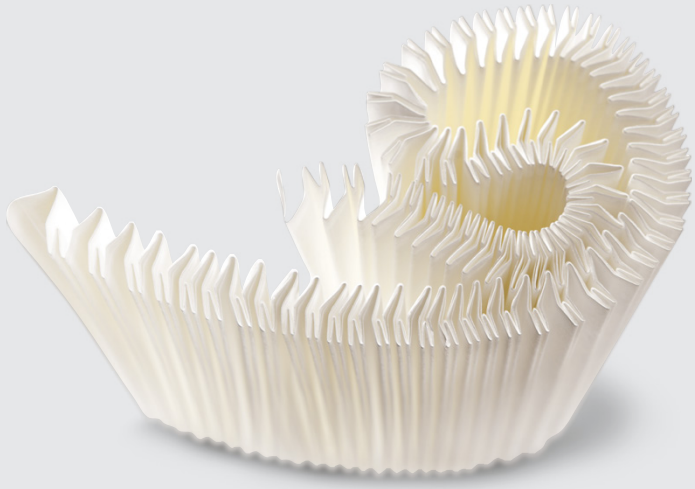
SARTORIUS

Product Datasheet

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 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
Polyethersulfone, asymmetric

Endfilter Membrane
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

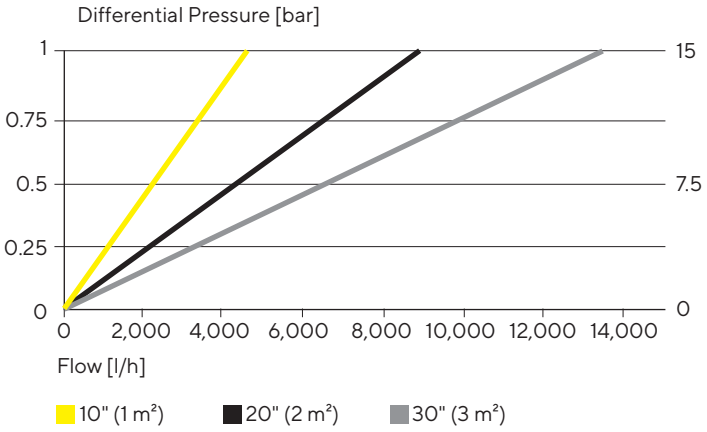
T-Style Maxicaps® and Maxicaps®
Autoclaving
Max. 134 °C, 2 bar, 30 min
Min. 5 Sterilization Cycles

or

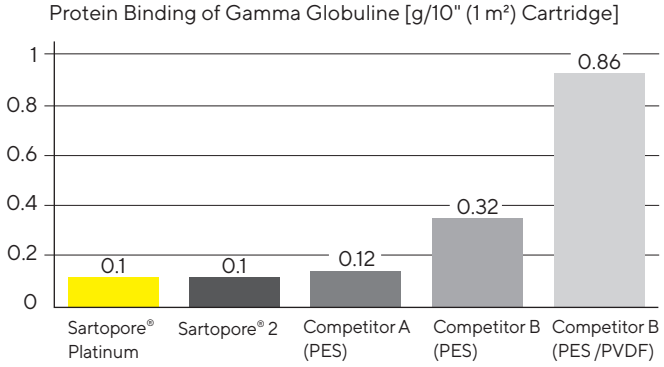
Gamma Irradiation
≤ 50 kGy
1 Sterilization Cycle

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

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For more information, visit
www.sartorius.com

Publication No.:SPK2157-e | Status: 08 | 01 | 2022