

Sartopore® 2 0.45 µm

Bioburden & Particle Retentive Filter Elements

Product Information

- Extremely high flow rates and total throughputs
- Number one choice for bioburden reduction & particle removal
- Broad compatibility and easy scalability
- Outstanding filtration performance of aqueous solutions that are highly viscous & difficult to filter



No. 1 Choice for Bioburden Reduction and Particle Removal

Due to the “built-in prefiltration” by a 0.8 µm membrane, Sartopore® 2 0.45 µm rated filters are ideally suited for bioburden reduction and particle removal of highly viscous and difficult to filter pharmaceutical solutions. Due to its hydrophilic Polyethersulfone membrane Sartopore® 2 0.45 µm filter elements offer outstanding total throughputs and flow rate performances. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Broad Compatibility and Highest Reliability

The unique Polyethersulfone membrane gives Sartopore® 2 0.45 µm broad chemical compatibility, including a pH-range from pH 1 to pH 14, and a high thermal resistance, making it suitable for a broad range of filtration liquids. To assure absolute reliability, each individual Sartopore® 2 0.45 µm filter element is integrity tested by Diffusion Point and Bubble Point Test prior to release.

Scalability

Sartopore® 2 0.45 µm filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale. The wide range of membrane areas from 300 cm² to 1.8 m² per filter element guarantees greatest flexibility and most economic filter sizing.

Applications

- Therapeutics
- Buffers
- Injectables
- Ophthalmics
- Large volume parenterals
- Antibiotics
- Biological Fluids
- Tissue Culture Media
- Bulk pharmaceutical products
- Acetic and basic solutions

Services

Sartorius Confidence® Validation Services is the perfect complement to Sartopore® 2 0.45 µm 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® Gamma Maxicaps®			
Size 0.5 (Only Cartridge)	0.3 m ² 3.2 ft ²	7	2.2 32
Size 1	0.6 m ² 6.5 ft ²	12	2.2 32
Size 2	1.2 m ² 12.9 ft ²	24	2.2 32
Size 3	1.8 m ² 19.4 ft ²	36	2.2 32
Mini Cartridges, Midicaps® Gamma Midicaps®			
Size 7	0.05 m ² 0.5 ft ²	3	2.2 32
Size 8	0.1 m ² 1.1 ft ²	4	2.2 32
Size 9	0.2 m ² 2.2 ft ²	6	2.2 32
Size 0 (Only Midicaps®)	0.45 m ² 4.8 ft ²	12	2.2 32
Capsules Gamma Capsules			
Size 5	0.03 m ² 0.32 ft ²	2	2.2 32

Max. Allowable Differential Pressure

Cartridges | Mini Cartridges

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

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

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

Midicaps® | Gamma Midicaps®

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

Capsules | Gamma Capsules Size 5

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

Core

Polypropylene

End Caps

Polypropylene

Capsule Housing

Polypropylene

O-Ring

Silicone (other materials on request)

Filling Bell

Polycarbonate

Max. Allowable Back Pressure

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

Pore Size Combination

0.8 μm + 0.45 μm

Regulatory Compliance

- Each individual element is tested for integrity by bubble point and diffusion test
- 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, Mini Cartridges

In-Line Steam Sterilization
 134 °C, 0.5 bar, 20 min.
 Min. 25 Sterilization Cycles

or

Autoclaving

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

Maxicaps®, Midicaps® & Capsules

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

Gamma Maxicaps®, Gamma Midicaps® &

Gamma Capsules

Gamma Irradiation

≤ 50 kGy

1 Sterilization Cycles

T-Style Maxicaps®

Autoclaving

134 °C, 2 bar, 30 min

Min. 5 Sterilization Cycles

or

Gamma Irradiation

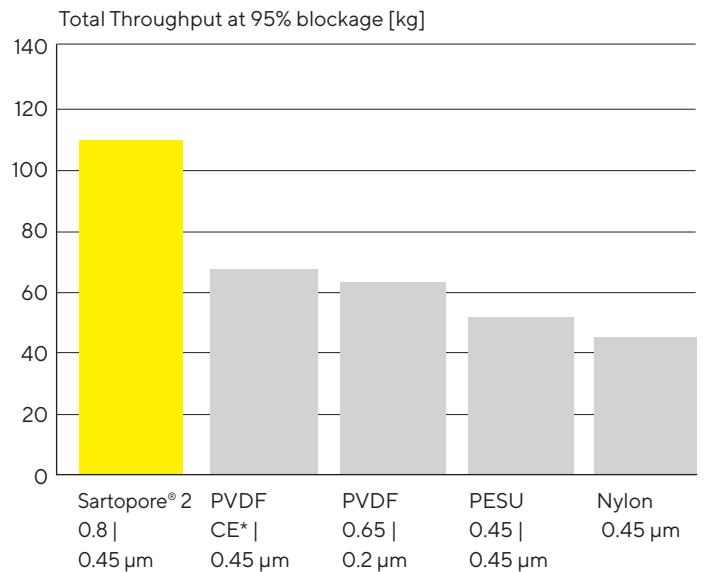
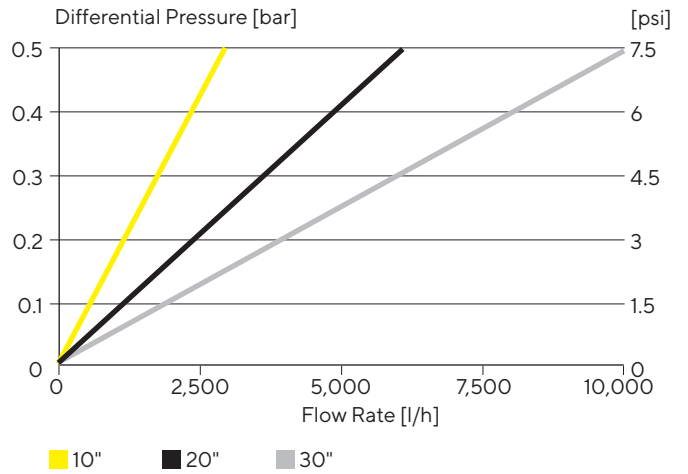
≤ 50 kGy

1 Sterilization Cycle

Technical References

Validation Guide 2665239

Extractables Guide 2396283



Ordering Information



Mini Cartridge

544 ■ 06 G ■ -- - - -- -- B

Adapter

15: Bayonet adapter with o-ring
18: Plug Adapter with double o-ring

Filter Size

7: 0.05 m² | 0.5 ft²
8: 0.1 m² | 1.1 ft²
9: 0.2 m² | 2.2 ft²

Packing Size

B: box of 5

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



Cartridge

544 25 06 G ■

Adapter

21: double open end with flat gaskets
25: 2 flange bayonet adapter with 226 double o-ring
27: Bayonet adapter with 222 double o-ring
28: 3 Flange bayonet adapter with 222 double o-ring

Filter Size

0: 0.3 m² | 3.2 ft² (5")
1: 0.6 m² | 6.5 ft² (10")
2: 1.2 m² | 12.9 ft² (20")
3: 1.8 m² | 19.4 ft² (30")

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



T-Style Maxicaps®

544 83 06 G ■ G- ■ ■

Filter Size

1: 0.6 m² | 6.5 ft² (10")
2: 1.2 m² | 12.9 ft² (20")
3: 1.8 m² | 19.4 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® | Gamma Maxicaps®

544 73 06 G ■ ■ ■ ■

Filter Size

1: 0.6 m² | 6.5 ft² (10")
2: 1.2 m² | 12.9 ft² (20")
3: 1.8 m² | 19.4 ft² (30")

Sterilization

--: autoclavable
G-: γ-irradiatable

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: 5447307H1--SSIT)



Midicaps® | Gamma Midicaps®

544	53	06	G	■	■	■	■	--	■
Filter Size 7: 0.05 m ² 0.5 ft ² 8: 0.1 m ² 1.1 ft ² 9: 0.2 m ² 2.2 ft ² 0: 0.45 m ² 4.8 ft ²		Sterilization --: autoclavable G-: γ-irradiatable		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

544	13	06	G	■	■	■	■	--	B
Filter Size 5: 0.03 m ² 0.32 ft ²		Sterilization --: 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