

Sartopore[®] 2 XLI

Sterilizing-Grade Filter Elements



Product Information

- Lowest filter consumption for filtration of chemically defined process fluids
- Outstanding capacity and flow performance
- Highly economic sizing for intermediate steps in downstream processing
- Ideal solution for conventional and single-use processes

30% Enlarged Effective Filtration Area

The combination of the built-in 0.35 µm pre-filter in front of a 0.2 µm final filter together with the 30% enlarged effective filtration area per filter element provide an outstanding total throughput and flow rate performance in the target applications. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Scalability

Sartopore® 2 XLI filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to commercial process scale. The wide range of membrane areas from 210 cm² to 2.4 m² per filter element guarantees greatest flexibility and most economic filter sizing.

Applications

- Ophthalmic solutions
- Chemically defined cell culture media
- High viscous large volume parenterals
- Any fully chemically defined media

Services

Sartorius Confidence® Validation Services is the perfect complement to Sartopore® 2 XLI 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 1	0.8 m ² 8.6 ft ²	21	3.2 46
Size 2	1.6 m ² 17.2 ft ²	42	3.2 46
Size 3	2.4 m ² 25.8 ft ²	63	3.2 46
Midicaps® Gamma Midicaps®			
Size 7	0.065 m ² 0.7 ft ²	4.5	3.2 46
Size 8	0.13 m ² 1.4 ft ²	5.5	3.2 46
Size 9	0.26 m ² 2.8 ft ²	8	3.2 46
Size 0	0.52 m ² 5.6 ft ²	16	3.2 46
Capsules Gamma Capsules			
Size 4	0.021 m ² 0.22 ft ²	1.1	3.2 46

Max. Allowable Differential Pressure

Cartridges

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

T-Style Maxicaps®, Maxicaps® | Gamma 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 & autoclavable)
Polyester (Y-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

0.35 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

134 °C, 0.3 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®)

Min. 5 Sterilization Cycles (Capsules)

Gamma Maxicaps®, Gamma Midicaps® & Gamma Capsules

Gamma Irradiation

≤ 50 kGy

1 Sterilization Cycle

T-Style Maxicaps®

Autoclaving

134°C, 2 bar, 30 min

Min. 5 Sterilization Cycles

or

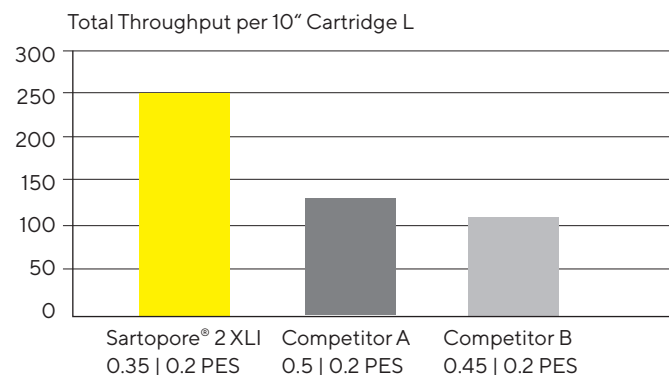
Gamma Irradiation

≤ 50 kGy

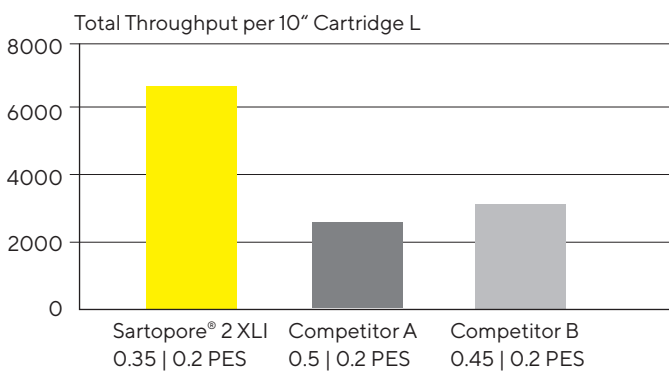
1 Sterilization Cycle

Performance

Chemically Defined Cell Culture Media



Ophthalmic Solution



Technical References

Validation Guide	2665243
Extractables Guide	SPK5776-e

Ordering Information



Cartridge

544 25 07 I ■

Adapter
25: 2 flange bayonet adapter with 226 double o-ring

Filter Size
1: 0.8 m² | 8.6 ft² (10")
2: 1.6 m² | 17.2 ft² (20")
3: 2.4 m² | 25.8 ft² (30")



T-Style Maxicaps®

544 83 07 I ■ G- ■ ■

Filter Size
1: 0.8 m² | 8.6 ft² (10")
2: 1.6 m² | 17.2 ft² (20")
3: 2.4 m² | 25.8 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 07 I ■ ■ ■ ■

Filter Size
1: 0.8 m² | 8.6 ft² (10")
2: 1.6 m² | 17.2 ft² (20")
3: 2.4 m² | 25.8 ft² (30")

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

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



Midicaps® | Gamma Midicaps®

544 53 07 I ■ ■ ■ ■ -- ■

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

544 13 07 I 4 ■ ■ ■ -- B

Filter Size
4: 0.021 m² | 0.22 ft²

Sterilization
G-: γ-irradiatable
--: autoclavable

Connector Inlet
S: 1½" tri-clamp 25 mm
O: ½" single stepped hose barb

Connector Outlet
S: 1½" tri-clamp 25 mm
O: ½" single stepped hose barb

Packing Size
B: box of 5

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