

Sartopore® 2 XLI 0.2 µm

Sterilizing Grade Filter Elements

Product Information

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

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 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

Technical Data

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

Max. Allowable Back Pressure

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

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

Polycarboate

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

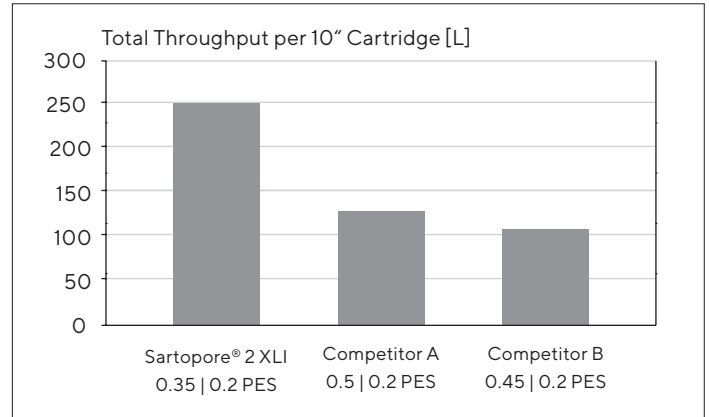
or

Gamma Irradiation

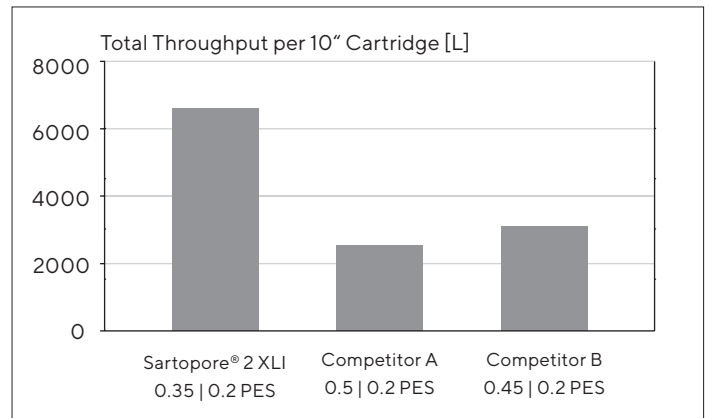
≤ 50 kGy
1 Sterilization Cycle

Performance

Chemically Defined Cell Culture Media



Ophthalmic Solution



Technical References

Validation Guide SPK5811-e
Extractables Guide SPK5776-e

Ordering Information



Cartridge



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")

(Standard with silicone o-ring optional with EPDM o-ring. Example: 544250711-E)



T-Style Maxicaps®

544	83	07	I		G-		
Filter Size		Sterilization		Connector Inlet		Connector Outlet	
1: 1.0 m ² 10.8 ft ² (10") 2: 2.0 m ² 21.5 ft ² (20") 3: 3.0 m ² 32.3 ft ² (30")		G-: γ-irradiatable and autoclavable		S: 1½" Tri-Clamp 50.5 mm O: ½" single stepped hose barb Y: 1" single stepped hose barb		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	H		G-		
Filter Size		Sterilization		Connector Inlet		Connector Outlet	
1: 0.8 m ² 8.6 ft ² (10") 2: 1.6 m ² 17.2 ft ² (20") 3: 2.4 m ² 25.8 ft ² (30")		G-: γ-irradiatable --: autoclavable		S: 1½" Tri-Clamp 50.5 mm O: ½" single stepped hose barb F: ¾" Tri-Clamp 25 mm		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: 544730711-SSIT)



Midicaps® | Gamma Midicaps®

544	53	07	I					--	
Filter Size		Sterilization		Connector Inlet		Connector Outlet		Packing Size	
7: 0.065 m ² 0.7 ft ² 8: 0.13 m ² 1.4 ft ² 9: 0.26 m ² 2.8 ft ² O: 0.52 m ² 5.6 ft ²		G-: γ-irradiatable --: autoclavable		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)		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)		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		Sterilization		Connector Inlet		Connector Outlet		Packing Size	
4: 0.021 m ² 0.22 ft ²		G-: γ-irradiatable --: autoclavable		S: ¾" Tri-Clamp 25 mm O: ¼" multiple stepped hose barb		S: ¾" Tri-Clamp 25 mm O: ¼" multiple stepped hose barb		B: box of 5	

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