

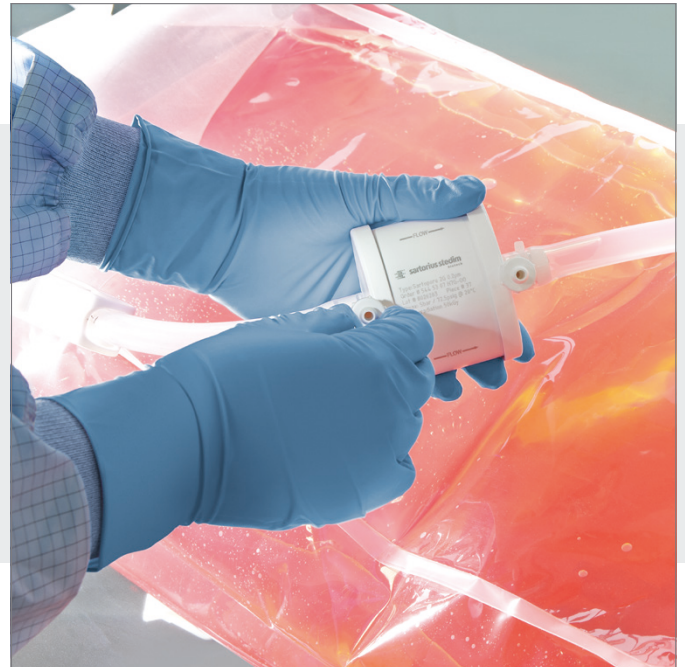


Sartopore[®] 2 XLM 0.1 μm

Sterilizing Grade & Mycoplasma Retentive Filter Elements

Product Information

- Lowest filter consumption by high filtration capacity
- Lowest risk of Mycoplasma contamination for your fermentation process
- Unmet combination of highest safety and performance for any 0.1 μm Mycoplasma retentive filter in the market
- Fully validated as sterilizing grade filter (according to current ASTM F-838 guideline)



Background Information

It is well known that Mycoplasma can be present in commercially available cell culture media. Because Mycoplasma are able to penetrate 0.2 μm rated sterile filters, Sartorius Stedim Biotech specifically developed Sartopore[®] 2 XLM with finer filter membranes (0.1 μm) for the successful retention of Mycoplasma.

Over 50% More Performance

The build in 0.2 μm prefilter layer is specifically designed to protect the final 0.1 μm membrane layer in cell culture media filtration applications. The optimized membrane combination together with the exceptionally high effective filtration area per filter element allows for > 50% more performance compared to existing 0.1 μm rated filter elements, thus ensuring lowest filtration costs per liter, minimized filtration times and smallest footprint of the filtration system.

Scalability

Sartopore[®] 2 XLM 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 cm^2 to 2.4 m^2 per filter element guarantees greatest flexibility and most economic filter sizing.

Highest Safety – Best Bacterial Retention

- Fully validated as sterilizing-grade filter (LRV>7/ cm^2 filter area for *Brevundimonas diminuta* according to current ASTM F-838 guideline)
- Validated for retaining *Acholeplasma laidlawii* with an LRV7/ cm^2 filter area using the filtration method published by the PDA Mycoplasma Task Force (PDA J Pharm Sci and Tech 2014, 68 281–296)
- This filter has also successfully been tested for *Mycoplasma orale* and *Mycoplasma fermentans*
- Sartopore[®] 2 XLM also retains *Leptospira icerasiae* (LRV<7/ cm^2)

Applications

Sterilizing grade filtration and Mycoplasma removal from:

- Plant peptone or yeast supplemented cell culture media
- Chemically defined cell culture media
- Cell culture media components such as serum (e. g. Fetal Calf Serum)
- All other cell culture media used in biotech manufacturing

Any other application requiring below 0.2 μm filtration for enhanced sterility assurance.

Technical Data

Available Sizes	Filtration Area	Max. Diffusion at 4.0 bar 58 psi [ml/min]
Cartridges, T-Style MaxiCaps®, MaxiCaps®		
Size 0.5	0.4 m ² 4.3 ft ²	19
Size 1	0.8 m ² 8.6 ft ²	39
Size 2	1.6 m ² 17.2 ft ²	78
Size 3	2.4 m ² 25.8 ft ²	117
MidiCaps® Gamma MidiCaps®		
Size 7	0.065 m ² 0.7 ft ²	5
Size 8	0.13 m ² 1.4 ft ²	7
Size 9	0.26 m ² 2.8 ft ²	12
Size 0	0.52 m ² 5.6 ft ²	24
Capsules Gamma Capsules		
Size 4	0.021 m ² 0.22 ft ²	1.5

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

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

Polycarbonate

Pore Size Combination

0.2 μm + 0.1 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

MidiCaps® & Capsules

Autoclaving

134°C, 2 bar, 30 min

Min. 25 Sterilization Cycles (MidiCaps®)

Min. 5 Sterilization Cycles (Capsules)

Gamma MidiCaps® & Gamma Capsules

Gamma Irradiation

≤ 50 kGy

1 Sterilization Cycle

T-Style MaxiCaps® & MaxiCaps®

Autoclaving

134°C, 2 bar, 30 min

Min. 5 Sterilization Cycles

or

Gamma Irradiation

≤ 50 kGy

1 Sterilization Cycle

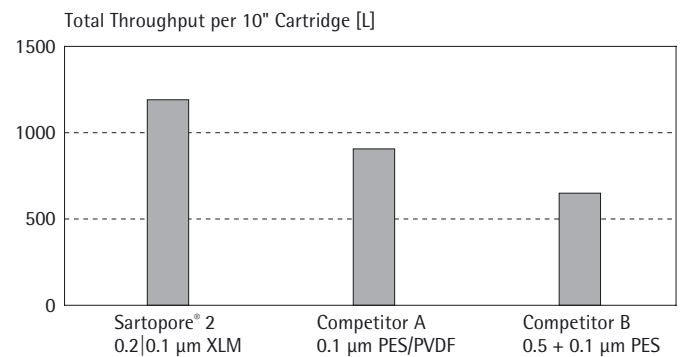
Technical References

Validation Guide

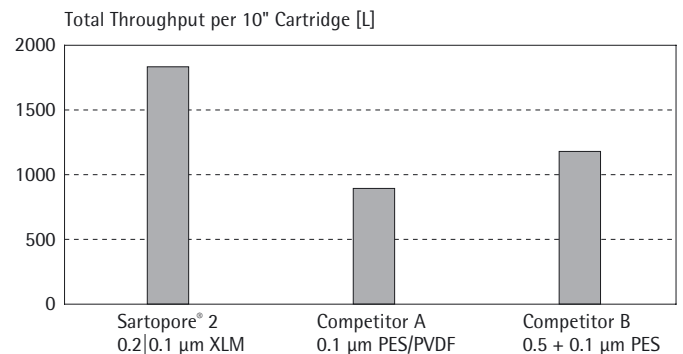
SPK5809-e

Performance

Plant Peptone Supplemented Cell Culture Media



Soy Supplemented Cell Culture Media



Ordering Information



Cartridge

544 25 58 M

Adapter

25: 2 Flange Bayonet adapter with 226 double o-ring

Filter Size

0: 0.4 m² | 4.3 ft² (5")
 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: 5442558M1---E)



T-Style MaxiCaps®

544 83 58 M 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®

544 73 58 M 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
 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: 5447358M1G-SOIT)



MidiCaps® | Gamma MidiCaps®

544 53 58 M --

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 58 M 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

Check the availability of your desired configuration with your Sartorius sales representative or online at www.sartorius-stedim.com

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