Product Information

- Lowest filter consumption by high filtration capacity
- Lowest risk of Mycoplasma contamination for your fermentation process
- High performance 0.1 µm Mycoplasma retentive filter
- 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 sterilizing-grade filters, Sartorius specifically developed the Sartopore® 2 XLM with finer filter membranes (0.1 µm) for the successful retention of Mycoplasma.
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.

Services

Sartorius Confidence® Validation Services is the perfect complement to Sartopore® 2 XLM 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.

Exceptional Performance

The 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 leads to remarkable throughput performance and Mycoplasma retention. This reduces the filtration costs per liter, the filtration time as well as the 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 cm² to 2.4 m² per filter element guarantees greatest flexibility and most economic filter sizing.

Fully Validated - Reliable Bacterial Retention

- Fully validated as sterilizing-grade filter (LRV>7/cm² filter area for Brevundimonas diminuta according to current ASTM F-838 guideline)
- Validated for retaining Acholeplasma laidlawii with an LRV7/cm² 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 licerasiae (LRV<7/cm²)
## Technical Specifications

<table>
<thead>
<tr>
<th>Available Sizes</th>
<th>Filtration Area</th>
<th>Max. Diffusion at 4.0 bar</th>
<th>58 psi [ml/min]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartridges, T-Style Maxicaps®, Maxicaps®</td>
<td>Gamma Maxicaps®</td>
<td>Size 0.5</td>
<td>0.4 m²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Size 1</td>
<td>0.8 m²</td>
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<tr>
<td></td>
<td></td>
<td>Size 2</td>
<td>1.6 m²</td>
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<tr>
<td></td>
<td></td>
<td>Size 3</td>
<td>2.4 m²</td>
</tr>
<tr>
<td>Midicaps®</td>
<td>Gamma Midicaps®</td>
<td>Size 7</td>
<td>0.065 m²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Size 8</td>
<td>0.13 m²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Size 9</td>
<td>0.26 m²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Size 0</td>
<td>0.52 m²</td>
</tr>
<tr>
<td>Capsules</td>
<td>Gamma Capsules</td>
<td>Size 4</td>
<td>0.021 m²</td>
</tr>
</tbody>
</table>
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®**
- 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
- 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)

Pore Size Combination

0.2 μm + 0.1 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

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
Sterilization

**Cartridges**
In-Line Steam Sterilization
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

**Maxicaps®, Midicaps® & Capsules**
Autoclaving
Max. 134°C, 2 bar, 30 min
Min. 25 Sterilization Cycles (Midicaps®)
Min. 5 Sterilization Cycles (Capsules)

**Gamma Maxicaps®, Gamma Midicaps® & Gamma Capsules**
Gamma Irradiation
≤ 50 kGy
1 Sterilization Cycle

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

or

**Gamma Irradiation**
≤ 50 kGy
1 Sterilization Cycle

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Performance

**Plant Peptone Supplemented Cell Culture Media**

![Graph showing total throughput per 10" cartridge for different media](#)

**Soy Supplemented Cell Culture Media**

![Graph showing total throughput per 10" cartridge for different media](#)

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Technical References

Validation Guide 2665248
Extractables Guide SPK5823-e
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 or Fluoroelastomer o-ring).

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**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 mm
- O: ¼” single stepped hose barb
- Y: ⅜” single stepped hose barb

**Connector Outlet**

- S: 1½” tri-clamp 50 mm
- O: ¼” single stepped hose barb

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**Maxicaps® | Gamma 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 --: autoclavable

**Connector Inlet**

- S: 1½” tri-clamp 50.5 mm
- O: ½” single stepped hose barb
- Y: ⅜” single stepped hose barb

**Connector Outlet**

- S: 1½” tri-clamp 50.5 mm
- O: ½” single stepped hose barb

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**Midicaps® | Gamma Midicaps®**

| 544 | 53 | 58 | M | G– |

**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: ¼” single stepped hose barb
- F: ¼” tri-clamp 25 mm

**Connector Outlet**

- S: 1½” tri-clamp 50.5 mm
- O: ¼” single stepped hose barb
- F: ¼” tri-clamp 25 mm

**Packing Size**

- A: box of 4 (size 7, 8, 9)
- V: box of 2 (size 0)

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**Capsules | Gamma Capsules**

| 544 | 13 | 58 | M | 4 | G– |

**Filter Size**

- 4: 0.021 m² | 0.22 ft²

**Sterilization**

G–: γ-irradiatable --: autoclavable

**Connector Inlet**

- S: 1¼” tri-clamp 25 mm
- O: ¼” multiple stepped hose barb

**Connector Outlet**

- S: 1¼” tri-clamp 25 mm
- O: ¼” single stepped hose barb

**Packing Size**

- B: box of 5