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

Technical Specifications

<table>
<thead>
<tr>
<th>Available Sizes</th>
<th>Filtration Area</th>
<th>Max. Diffusion at 2.5 bar</th>
<th>Min. Bubble Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>**Cartridges, T-Style Maxicaps®, Maxicaps®</td>
<td>Gamma Maxicaps®**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Size 1</td>
<td>0.8 m²</td>
<td>8.6 ft²</td>
<td>21</td>
</tr>
<tr>
<td>Size 2</td>
<td>1.6 m²</td>
<td>17.2 ft²</td>
<td>42</td>
</tr>
<tr>
<td>Size 3</td>
<td>2.4 m²</td>
<td>25.8 ft²</td>
<td>63</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>**Midicaps®</th>
<th>Gamma Midicaps®**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size 7</td>
<td>0.065 m²</td>
</tr>
<tr>
<td>Size 8</td>
<td>0.13 m²</td>
</tr>
<tr>
<td>Size 9</td>
<td>0.26 m²</td>
</tr>
<tr>
<td>Size 0</td>
<td>0.52 m²</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>**Capsules</th>
<th>Gamma Capsules**</th>
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<tbody>
<tr>
<td>Size 4</td>
<td>0.021 m²</td>
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</table>

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.
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)

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

Materials

**Prefilter Membrane**
Polyethersulfone, asymmetric

**Endfilter Membrane**
Polyethersulfone, asymmetric

**Support Fleece**
Polypropylene (In-line steam sterilizable & autoclavable)
Polyester (β-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
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**

<table>
<thead>
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<th>Total Throughput per 10&quot; Cartridge L</th>
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<td>Sartopore® 2 XLI 0.35</td>
</tr>
<tr>
<td>Competitor A 0.5</td>
</tr>
<tr>
<td>Competitor B 0.45</td>
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**Ophthalmic Solution**

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Technical References

Validation Guide 2665243
Extractables Guide SPK5776-e