Sartopore® 2 XLG

Sterilizing-Grade Filter Elements

Product Information

- Outstanding capacity and flow performance
- Lowest filter consumption for filtration of cell culture media
- Highly economic sizing for intermediate steps in downstream processing
- Optimization of conventional and single-use processes

Reducing 50 – 90% of Filtration Costs

Sartopore® 2 XLG uses a coarser pre-filter layer (0.8 μm) in front of the sterilizing-grade rated final membrane (0.2 μm). The coarser pre-filter layer avoids early blocking in many biological liquids. The enhanced filtration capacity can reduce filtration costs by 50 – 90% for many processes.
Scalability

Sartopore® 2 XLG 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 economic filter sizing.

Applications

- Filtration of cell culture media such as:
  - Plant peptone or yeast supplemented cell culture media
  - Serum containing cell culture media
  - Other cell culture media used in biotech manufacturing
  - Post cell harvest filtration
  - Downstream intermediates
    (before and after UF | DF and chromatography steps)

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 m² | 8.6 ft² | 23 | 3.2 | 46 |
| Size 2          | 1.6 m² | 17.2 ft² | 46 | 3.2 | 46 |
| Size 3          | 2.4 m² | 25.8 ft² | 69 | 3.2 | 46 |
| **Midicaps® | Gamma Midicaps®** | | | |
| Size 7          | 0.065 m² | 0.7 ft² | 5 | 3.2 | 46 |
| Size 8          | 0.13 m² | 1.4 ft² | 6 | 3.2 | 46 |
| Size 9          | 0.26 m² | 2.8 ft² | 9 | 3.2 | 46 |
| Size 0          | 0.52 m² | 5.6 ft² | 18 | 3.2 | 46 |
| **Capsules | Gamma Capsules** | | | |
| Size 4          | 0.021 m² | 0.22 ft² | 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)

Pore Size Combination

0.8 μm + 0.2 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 (Y-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® & Maxicaps®)
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

**Soy Peptone Supplemented Cell Culture Media**

![Graph showing total throughput per 10" filter element (L)]

- Sartopore® 2 XLG
  - 0.8 | 0.2 PES
- Competitor A
  - 0.5 | 0.2 PES
- Competitor B
  - 0.45 | 0.2 PES

**Monoclonal Antibody Pool**

![Graph showing total throughput per 10" filter element (L)]

- Sartopore® 2 XLG
  - 0.8 | 0.2 PES
- Competitor A
  - 0.5 | 0.2 PES
- Competitor B
  - 0.45 | 0.2 PES

*Antibody Concentration: 47.5 mg/ml

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Technical References

- Validation Guide: 2665242
- Extractables Guide: SPK5775-e
Ordering Information

**Cartridge**

<table>
<thead>
<tr>
<th>Code</th>
<th>Filter Size</th>
<th>Adapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>544 25 07 G</td>
<td>1: 0.8 m²</td>
<td>8.6 ft² (10&quot;)&lt;br&gt;2: 1.6 m²</td>
</tr>
</tbody>
</table>

**T-Style Maxicaps®**

<table>
<thead>
<tr>
<th>Code</th>
<th>Filter Size</th>
<th>Sterilization</th>
<th>Connector Inlet</th>
<th>Connector Outlet</th>
</tr>
</thead>
<tbody>
<tr>
<td>544 83 07 G</td>
<td>1: 0.8 m²</td>
<td>8.6 ft² (10&quot;)&lt;br&gt;2: 1.6 m²</td>
<td>17.2 ft² (20&quot;)&lt;br&gt;3: 2.4 m²</td>
<td>25.8 ft² (30&quot;)&lt;br&gt;γ-irradiatable and autoclavable</td>
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**Maxicaps® | Gamma Maxicaps®**

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**Midicaps® | Gamma Midicaps®**

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<th>Packing Size</th>
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</thead>
<tbody>
<tr>
<td>544 53 07 G</td>
<td>1: 0.065 m²</td>
<td>0.7 ft²&lt;br&gt;8: 0.13 m²</td>
<td>1.4 ft²&lt;br&gt;9: 0.26 m²</td>
<td>2.8 ft²&lt;br&gt;0: 0.52 m²</td>
<td>5.6 ft²&lt;br&gt;γ-irradiatable and autoclavable</td>
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**Capsules | Gamma Capsules**

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<th>Connector Outlet</th>
<th>Packing Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>544 13 07 G</td>
<td>4: 0.021 m²</td>
<td>0.22 ft²&lt;br&gt;γ-irradiatable and autoclavable</td>
<td>γ-irradiatable</td>
<td>γ-irradiatable</td>
<td>γ-irradiatable</td>
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**Adapter**

25: 2 flange bayonet adapter<br>with 226 double o-ring

(Standard with silicone o-ring optional with EPDM or Fluoroelastomer o-ring).