Sartopore® 2
0.2 µm
Sterilizing-Grade Filter Elements

Product Information

- Industry standard of high-performance liquid sterile filters
- Unique hydrophilic heterogeneous double layer Polyethersulfone membrane
- Exceptionally high throughput and excellent flow rates at low pressure drops
- High thermal resistance and broad chemical compatibility

High-Performance and broad compatibility

Sartopore® 2 filter elements feature a unique hydrophilic heterogeneous double layer design of a 0.45 µm pre-filter and 0.2 µm final filter membrane with an exceptionally high throughput and flow rate. In addition to its outstanding performance, the Polyethersulfone membrane gives Sartopore® 2 0.2 µm broad chemical compatibility, including a pH-range from pH 1 to pH 14, and a high thermal resistance.
Industry standard for sterile-grade liquid filters

Sartopore® 2 0.2 μm filters are fully validated as sterilizing grade filter elements according to current ASTM F-838 guidelines. Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability. Sartopore® 2 filter elements are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. The Validation and Extractables Guide are available for compliance with regulatory requirements.

Scalability

Sartopore® 2 0.2 μm 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 150 cm$^2$ to 1.8 m$^2$ per filter element guarantees greatest flexibility and most economic filter sizing.

Applications

- Therapeutics
- Biological Fluids
- Ophthalmic solutions
- Injectables
- Media
- SVPs, LVPs
- Antibiotics
- WFI
- Buffers
- Chemicals
- Cleaning and sanitizing agents
- Bulk pharmaceutical products

Services

Sartorius Confidence® Validation Services is the perfect complement to Sartopore® 2 0.2 μm 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.
<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></td>
<td></td>
<td>[36 psi]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>[ml/min]</td>
<td></td>
</tr>
<tr>
<td>**Cartridges, T-Style Maxicaps®, Maxicaps®</td>
<td>Gamma Maxicaps®**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Size 0.5 (Only Cartridge)</td>
<td>0.3 m²</td>
<td>3.2 ft²</td>
<td>10</td>
</tr>
<tr>
<td>Size 1</td>
<td>0.6 m²</td>
<td>6.5 ft²</td>
<td>18</td>
</tr>
<tr>
<td>Size 2</td>
<td>1.2 m²</td>
<td>12.9 ft²</td>
<td>36</td>
</tr>
<tr>
<td>Size 3</td>
<td>1.8 m²</td>
<td>19.4 ft²</td>
<td>54</td>
</tr>
<tr>
<td>**Mini Cartridges, Midicaps®</td>
<td>Gamma Midicaps®**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Size 7</td>
<td>0.05 m²</td>
<td>0.5 ft²</td>
<td>4</td>
</tr>
<tr>
<td>Size 8</td>
<td>0.1 m²</td>
<td>1.1 ft²</td>
<td>5</td>
</tr>
<tr>
<td>Size 9</td>
<td>0.2 m²</td>
<td>2.2 ft²</td>
<td>7</td>
</tr>
<tr>
<td>Size 0 (Only Midicaps® &amp; Gamma Midicaps®)</td>
<td>0.45 m²</td>
<td>4.8 ft²</td>
<td>14</td>
</tr>
<tr>
<td>**Capsules</td>
<td>Gamma Capsules**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Size 4</td>
<td>0.015 m²</td>
<td>0.16 ft²</td>
<td>1</td>
</tr>
<tr>
<td>Size 5</td>
<td>0.03 m²</td>
<td>0.32 ft²</td>
<td>2</td>
</tr>
</tbody>
</table>
Max. Allowable Differential Pressure

**Mini Cartridges | 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**
- 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

0.45 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 (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

**Mini Cartridges, 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

Technical References

Validation Guide 2665239
Extractables Guide 2396283

Performance

**Total Throughput Comparison**

<table>
<thead>
<tr>
<th>Cartridges format</th>
<th>Total Throughput at 95% blockage [kg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>10&quot;</td>
<td></td>
</tr>
<tr>
<td>100</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td></td>
</tr>
<tr>
<td>60</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

10" Cartridges format

**Water Flow Rates for Standard Cartridges**

![Water Flow Rates for Standard Cartridges](chart1)

<table>
<thead>
<tr>
<th>Differential Pressure [bar]</th>
<th>Flow Rate [l/h]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>0.75</td>
<td>7.5</td>
</tr>
<tr>
<td>0.5</td>
<td>4</td>
</tr>
<tr>
<td>0.25</td>
<td>2</td>
</tr>
<tr>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

10" 20" 30"

**Water Flow Rates for T-Style Maxicaps®**

![Water Flow Rates for T-Style Maxicaps®](chart2)

<table>
<thead>
<tr>
<th>Differential Pressure [bar]</th>
<th>Flow Rate [l/h]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>14.5</td>
</tr>
<tr>
<td>0.75</td>
<td>7.25</td>
</tr>
<tr>
<td>0.5</td>
<td>4</td>
</tr>
<tr>
<td>0.25</td>
<td>2</td>
</tr>
<tr>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

10" OO, SO 20" OO, SO 30" OO, SO
10" SS, SY, YY 20" SS, SY, YY 30" OSS, SY, YY
Ordering Information

**Mini Cartridge**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Adapter</th>
<th>Filter Size</th>
<th>Packing Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>544 15 07 H</td>
<td>15: Bayonet adapter with o-ring</td>
<td>7: 0.05 m²</td>
<td>0.5 ft²</td>
</tr>
<tr>
<td></td>
<td>18: Plug Adapter with double o-ring</td>
<td>8: 0.1 m²</td>
<td>1.1 ft²</td>
</tr>
<tr>
<td></td>
<td>9: 0.2 m²</td>
<td>2.2 ft²</td>
<td></td>
</tr>
</tbody>
</table>

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

**Cartridge**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Adapter</th>
<th>Filter Size</th>
<th>Packing Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>544 25 07 H</td>
<td>21: double open end with flat gaskets</td>
<td>0: 0.3 m²</td>
<td>3.2 ft² (5”)</td>
</tr>
<tr>
<td></td>
<td>25: 2 flange bayonet adapter with 226 double o-ring</td>
<td>1: 0.6 m²</td>
<td>6.5 ft² (10”)</td>
</tr>
<tr>
<td></td>
<td>27: Bayonet adapter with 222 double o-ring</td>
<td>2: 1.2 m²</td>
<td>12.9 ft² (20”)</td>
</tr>
<tr>
<td></td>
<td>28: 3 Flange bayonet adapter with 222 double o-ring</td>
<td>3: 1.8 m²</td>
<td>19.4 ft² (30”)</td>
</tr>
</tbody>
</table>

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

**T-Style Maxicaps®**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Adapter</th>
<th>Filter Size</th>
<th>Sterilization</th>
<th>Connector Inlet</th>
<th>Connector Outlet</th>
</tr>
</thead>
<tbody>
<tr>
<td>544 83 07 H</td>
<td>21: double open end with flat gaskets</td>
<td>1: 0.6 m²</td>
<td>6.5 ft² (10”)</td>
<td>S: 1½” tri-clamp 50.5 mm</td>
<td>O: ½” single stepped hose barb</td>
</tr>
<tr>
<td></td>
<td>25: 2 flange bayonet adapter with 226 double o-ring</td>
<td>2: 1.2 m²</td>
<td>12.9 ft² (20”)</td>
<td>Y: 1” single stepped hose barb</td>
<td></td>
</tr>
<tr>
<td></td>
<td>27: Bayonet adapter with 222 double o-ring</td>
<td>3: 1.8 m²</td>
<td>19.4 ft² (30”)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>28: 3 Flange bayonet adapter with 222 double o-ring</td>
<td>G-: γ-irradiatable and autoclavable</td>
<td>F: ¾” tri-clamp 25 mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Maxicaps® | Gamma Maxicaps®**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Adapter</th>
<th>Filter Size</th>
<th>Sterilization</th>
<th>Connector Inlet</th>
<th>Connector Outlet</th>
</tr>
</thead>
<tbody>
<tr>
<td>544 73 07 H</td>
<td>21: double open end with flat gaskets</td>
<td>1: 0.6 m²</td>
<td>6.5 ft² (10”)</td>
<td>S: 1½” tri-clamp 50.5 mm</td>
<td>O: ½” single stepped hose barb</td>
</tr>
<tr>
<td></td>
<td>25: 2 flange bayonet adapter with 226 double o-ring</td>
<td>2: 1.2 m²</td>
<td>12.9 ft² (20”)</td>
<td>F: ¾” tri-clamp 25 mm</td>
<td></td>
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<tr>
<td></td>
<td>27: Bayonet adapter with 222 double o-ring</td>
<td>3: 1.8 m²</td>
<td>19.4 ft² (30”)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>28: 3 Flange bayonet adapter with 222 double o-ring</td>
<td>G-: γ-irradiatable and autoclavable</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Optional with vent valve design for connection of integrity tester. Example: 5447307H1--SSIT)
Midicaps® | Gamma Midicaps®

Filter Size
7: 0.05 m² | 0.5 ft²
8: 0.1 m² | 1.1 ft²
9: 0.2 m² | 2.2 ft²
O: 0.45 m² | 4.8 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

Filter Size
4: 0.015 m² | 0.16 ft²
5: 0.03 m² | 0.32 ft²

Sterilization
G: γ-irradiatable
--: autoclavable

Connector Inlet
S: 1¼" tri-clamp 50.5 mm
O: ¾" multiple stepped hose barb

Connector Outlet
S: 1¼" tri-clamp 50.5 mm
O: ¾" single stepped hose barb

Packing Size
B: box of 5