SPS Filters provide a wide selection of validated, single layer Polyethersulfone (PES) cartridge and capsule filters used for the sterilizing of aqueous liquids. Pore sizes range from 0.03 to 1.2 µm and the filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

The hydrophilic SPS filters have low binding characteristics that are ideal for filtering products with preservatives and high protein solutions that can adsorb to media. SPS filters deliver high flow and throughput with compatibility across a wide pH range.

SPS filters are flushed to remove manufacturing debris and reduce extractables. Products are 100% integrity tested. SPS capsules are available pre-sterilized.

Critical Process provides unrivaled delivery times, technical consulting before purchasing, and very competitively priced high-performance products. Our comprehensive testing & analysis and validation services support your team whenever they need it. Your process experts partnering with our filtration experts is how we deliver your company’s solution right the first time.

Applications
- SVPs & LVPs
- Diagnostics
- Buffers
- WFI, Water Purification
- Vaccines
- Biologicals

Non-Sterilizing Use
Prefilter fluids with the identical materials at larger pore sizes.
0.45 µm / 0.65 µm / 0.80 µm / 1.0 µm / 1.2 µm

SPS Filters provide a wide selection of validated, single layer Polyethersulfone (PES) cartridge and capsule filters used for the sterilizing of aqueous liquids. Pore sizes range from 0.03 to 1.2 µm and the filter sizes scale from laboratory to full production using identical materials to ensure consistent results.

CARTRIDGES – Nominal Dimensions
Length: 5 to 40 in. (12.7 to 101.6 cm)
Outside Diameter: 2.75 in. (7.0 cm)

CAPSULES – Nominal Dimensions
Length: 2 to 30 in. (5.1 to 76.2 cm)
Outside Diameter: 3.50 in. (8.9 cm)
**Maximum Operating Parameters**

<table>
<thead>
<tr>
<th></th>
<th>CARTRIDGES</th>
<th>CAPSULES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Liquid Operational Pressure</strong></td>
<td>N/A</td>
<td>80 psi at 68 °F (5.52 bar at 20 °C)</td>
</tr>
<tr>
<td><strong>Gases Operational Pressure</strong></td>
<td>N/A</td>
<td>60 psi at 68 °F (4.14 bar at 20 °C)</td>
</tr>
<tr>
<td><strong>Operating Temperature (water)</strong></td>
<td>180 °F at 30 psid (82 °C at 2.07 bard)</td>
<td>110 °F at 30 psid (43 °C at 2.07 bard)</td>
</tr>
<tr>
<td><strong>Forward Differential Pressure</strong></td>
<td>80 psid at 68 °F (5.52 bard at 20 °C) (Liquid and Gas)</td>
<td>Liquid - 80 psid at 68 °F (5.52 bard at 20 °C) Gas - 60 psi at 68 °F (4.14 bar at 20 °C)</td>
</tr>
<tr>
<td><strong>Reverse Differential Pressure</strong></td>
<td>50 psid at 68 °F (3.45 bard at 20 °C)</td>
<td>50 psid at 68 °F (3.45 bard at 20 °C)</td>
</tr>
<tr>
<td><strong>Recommended Changeout Pressure</strong></td>
<td>35 psid (2.41 bard)</td>
<td>35 psid (2.41 bard)</td>
</tr>
</tbody>
</table>

**Sanitization & Sterilization**

<table>
<thead>
<tr>
<th></th>
<th>CARTRIDGES</th>
<th>CAPSULES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Filtered Hot Water</strong></td>
<td>N/A</td>
<td>90 °C (194 °F), 30 minutes, multiple cycles, max 3 psid forward flow</td>
</tr>
<tr>
<td><strong>Inline Steam</strong></td>
<td>N/A</td>
<td>275 °F (135 °C), 30 min, 25+ cycles</td>
</tr>
<tr>
<td><strong>Autoclave</strong></td>
<td>N/A</td>
<td>250 °F (121 °C), 30 min, 25+ cycles</td>
</tr>
</tbody>
</table>

**Chemical Sanitization**

Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.

*Cartridge Filters – For all elevated temperature procedures above, a stainless-steel support ring is required.

**Filtration Area (Nominal)**

<table>
<thead>
<tr>
<th>Length</th>
<th>CAPSULES</th>
<th>CARTRIDGES AND CAPSULES</th>
<th>CARTRIDGES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2”</td>
<td>5”</td>
<td>10”</td>
</tr>
<tr>
<td></td>
<td>5.08cm</td>
<td>12.7cm</td>
<td>25.4cm</td>
</tr>
<tr>
<td></td>
<td>1.2 ft²</td>
<td>3.4 ft²</td>
<td>7.3 ft²</td>
</tr>
<tr>
<td></td>
<td>0.11 m²</td>
<td>0.32 m²</td>
<td>0.68 m²</td>
</tr>
<tr>
<td></td>
<td>5”</td>
<td>10”</td>
<td>20”</td>
</tr>
<tr>
<td></td>
<td>12.7cm</td>
<td>25.4cm</td>
<td>50.8cm</td>
</tr>
<tr>
<td></td>
<td>3.4 ft²</td>
<td>7.3 ft²</td>
<td>14.6 ft²</td>
</tr>
<tr>
<td></td>
<td>0.32 m²</td>
<td>0.68 m²</td>
<td>1.36 m²</td>
</tr>
<tr>
<td></td>
<td>10”</td>
<td>20”</td>
<td>30”</td>
</tr>
<tr>
<td></td>
<td>25.4cm</td>
<td>50.8cm</td>
<td>76.2cm</td>
</tr>
<tr>
<td></td>
<td>7.3 ft²</td>
<td>14.6 ft²</td>
<td>21.9 ft²</td>
</tr>
<tr>
<td></td>
<td>0.68 m²</td>
<td>1.36 m²</td>
<td>2.04 m²</td>
</tr>
<tr>
<td></td>
<td>30”</td>
<td>40”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>76.2cm</td>
<td>101.6cm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>21.9 ft²</td>
<td>29.2 ft²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.04 m²</td>
<td>2.72 m²</td>
<td></td>
</tr>
</tbody>
</table>

**Integrity Testing**

<table>
<thead>
<tr>
<th>PORE SIZE</th>
<th>DIFFUSION TEST PRESSURE*</th>
<th>BUBBLE POINT MINIMUM*</th>
</tr>
</thead>
<tbody>
<tr>
<td>µm</td>
<td>PSIG</td>
<td>BARG</td>
</tr>
<tr>
<td>0.03</td>
<td>60</td>
<td>4.14</td>
</tr>
<tr>
<td>0.10</td>
<td>48</td>
<td>3.31</td>
</tr>
<tr>
<td>0.22</td>
<td>35</td>
<td>2.41</td>
</tr>
<tr>
<td>0.45</td>
<td>20</td>
<td>1.38</td>
</tr>
<tr>
<td>0.65</td>
<td>15</td>
<td>1.03</td>
</tr>
<tr>
<td>0.80</td>
<td>12</td>
<td>0.83</td>
</tr>
<tr>
<td>1.0</td>
<td>8</td>
<td>0.55</td>
</tr>
<tr>
<td>1.2</td>
<td>7</td>
<td>0.48</td>
</tr>
</tbody>
</table>

**DIFFUSION SPECIFICATIONS **

<table>
<thead>
<tr>
<th>Length</th>
<th>2”</th>
<th>5”</th>
<th>10”</th>
<th>20”</th>
<th>30”</th>
<th>40”</th>
</tr>
</thead>
<tbody>
<tr>
<td>mL/min</td>
<td>≤ 2.9</td>
<td>≤ 8.6</td>
<td>≤ 20</td>
<td>≤ 40</td>
<td>≤ 60</td>
<td>≤ 80</td>
</tr>
</tbody>
</table>

* For water wetted membrane

** Test pressure exceeds operational limits of capsule filters. Use the Diffusion Test method.
Critical Process Filtration, Inc.

Validation

SPS filters are validated using test procedures that comply with ASTM F 838-15(ae1) protocols for the determination of bacterial retention in filters used for liquid filtration. The challenge level is a minimum of $10^7$ organisms per cm² of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.03 μm, 0.10 μm and 0.22 μm meet the FDA definition of sterilizing grade filters).

- 0.03 μm: *Acholeplasma laidlawii*
- 0.10 μm: *Brevundimonas diminuta*
- 0.22 μm: *Brevundimonas diminuta*
- 0.45 μm: *Serratia marcescens*
- 0.65 μm: *Saccharomyces cerevisiae*

Validation Guides available upon request.

Endotoxins

The levels of bacterial endotoxins in aqueous extracts from SPS filters are below current USP limits as specified for water for injection.

Extractables

SPS filters typically exhibit low levels of non-volatile residues.

TOC and Conductivity

SPS filters conform with TOC standards of USP <643> and the water conductivity standards of USP <645> after an appropriate flush with purified water.

Toxicity Compliance

Materials used to construct SPS filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the requirements for Biological Reactivity Tests in the current version of the United States Pharmacopeia (USP) for Class VI - 121 °C Plastics.

Non-Fiber Releasing

The SPS filters comply with Title 21 CFR sections 210.3(b)(6) and 211.72, for non-fiber releasing filters.

FDA Compliance

Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

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**Construction Materials**

<table>
<thead>
<tr>
<th>Filtration Media</th>
<th>Single Layered Polyethersulfone (PES) Membrane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Media Support</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>End Caps, Center Core, Outer Support Cage, Capsule Housing</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Sealing Method</td>
<td>Thermal Bonding</td>
</tr>
<tr>
<td>O-Rings/Gaskets Cartridges only</td>
<td>Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)</td>
</tr>
</tbody>
</table>
Flow Rates for SPS Cartridges by Pore Size

Flow rates for Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.

Flow Rates for SPS Capsules by Pore Size

Flow rates for Capsule filters are tested using a 2” capsule filter with 1” sanitary inlet and outlet ports. The test fluid is water at ambient temperature. Flow rates for larger capsules will scale with filtration area. Rates will vary based on end configuration of the capsule.
SPS Filters Ordering Information

Fill in the corresponding codes in the boxes below to build your Part Number.

To consult with one of our technical team members, request a quote or place an order: call (603) 880-4420 or contact us here.

---

Cartridge Filters

- **Pore Size Code**
  - -03 = 0.03 μm
  - -10 = 0.10 μm
  - -20 = 0.22 μm
  - -40 = 0.45 μm
  - -60 = 0.65 μm
  - -80 = 0.80 μm
  - 1-0 = 1.0 μm
  - 1-2 = 1.2 μm

- **SS Ring**
  - S = Ring
  - N = No Ring

- **Length**
  - 05 = 5 in. (12.7 cm)
  - 97 = 9.75 in. (24.8 cm)
  - 01 = 10 in. (25.4 cm)
  - 02 = 20 in. (50.8 cm)
  - 03 = 30 in. (76.2 cm)
  - 04 = 40 in. (101.6 cm)

- **O-Ring/Gasket Code**
  - S = Silicone
  - B = Buna
  - V = Viton (or FKM)
  - T = FEP Encapsulated Viton (or FKM)
  - R = FEP Encapsulated Silicone

- **End Cap Code**
  - 0 = Flat Gasket, DOE
  - 1 = Flat Gasket/Plug
  - 2 = 2-222 O-ring/Plug
  - 3 = 213/119 Internal O-ring DOE
  - 4 = 213/119 Internal O-ring/Plug
  - 5 = 2-222 O-ring/Flat
  - 6 = 2-226 O-ring/Flat
  - 7 = 020 O-ring/Plug
  - 8 = 2-222 O-ring/Spear
  - 9 = 2-226 O-ring/Spear
  - 21 = 2-223 O-ring/Flat
  - 22 = 2-223 O-ring/Spear
  - 23 = 2-222 O-ring 3 Tab/Flat
  - 24 = 2-222 O-ring 3 Tab/Spear
  - 25 = Short 2-222/Plug

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Capsule Filters

- **Pore Size Code**
  - -03 = 0.03 μm
  - -10 = 0.10 μm
  - -20 = 0.22 μm
  - -40 = 0.45 μm
  - -60 = 0.65 μm
  - -80 = 0.80 μm
  - 1-0 = 1.0 μm
  - 1-2 = 1.2 μm

- **Pre-Sterilized or Not**
  - S = Pre-Sterilized
  - G = Gamma Stable
  - N = Not Sterilized

- **Length**
  - A = 2”
  - B = 5”
  - C = 10”
  - D = 20”
  - E = 30”

- **Inlet**
  - A = 1/4” Female NPT
  - B = 1/4” Male NPT
  - C = 3/8” Female NPT
  - D = 1/2” Male NPT
  - E = 1/2” Male NPT
  - F = 1” Sanitary
  - G = Hose Barb*
  - H = 1 ½” Sanitary with side vent
  - I = ½” Single Stepped Barb with side vent

- **Outlet**
  - A = 1/4” Female NPT
  - B = 1/4” Male NPT
  - C = 3/8” Female NPT
  - D = 1/2” Female NPT
  - E = 1/2” Male NPT
  - F = 1” Sanitary
  - G = Hose Barb*
  - H = 1 ½” Sanitary with side vent
  - I = ½” Single Stepped Barb with side vent
  - IB = ½” Single Stepped Barb with filling bell and side vent

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* Additional end configurations available

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One Chestnut Street
Nashua, NH 03060
603.880.4420
FAX: 603.880.4536
CriticalProcess.com

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