SteriLUX® Filter Cartridge

The SteriLUX® hydrophilic PVDF membrane filter is ideal for sterile filtration, prefiltration and clarification of pharmaceutical and biological solutions. It has been optimized to sterile filter pharmaceutical preparations, active ingredients, biopharmaceuticals, vaccines, serum and blood products, parenterals, ophthalmics, orals, topicals, protein solutions, salts, buffers, diluents, growth media, cell and tissue culture media and media additives. SteriLUX® also provides high performance filtration of bulk pharmaceutical chemicals, cosmetics and toiletries, diagnostics, solvents and solvent/product mixtures, reagents and high purity water. SteriLUX® filters can also be used for particulate removal and bioburden reduction in aqueous liquid streams.

The SteriLUX® membrane is surface-modified to provide immediate and permanent water-wettability. It also provides high flow rates and long service life. It features extremely low binding of proteins and preservatives. Integrity testable, SteriLUX® offers the highest assurance of product integrity and filtration performance.

Based on ASTM F838-05 liquid bacterial challenge testing, SteriLUX® is a sterilizing grade filter. Its inert PVDF membrane and polypropylene components provide wide chemical compatibility and thermal stability, enabling effective use in a broad range of fluids and applications. The SteriLUX® filter is offered with absolute ratings of 0.1 μm, 0.2 μm, 0.4 μm and 0.6 μm. SteriLUX® can be used to filter aqueous solutions and many high surface tension chemicals and solvents.

**Design Features**
- Modified PVDF membrane for inherent water wettability
- Extremely low protein and preservative binding for maximum product recovery
- Extremely low extractables
- Highest flow rate of any PVDF membrane filter

**Typical Applications**
SteriLUX® has been optimized for the sterile filtration of critical fluids used in pharmaceutical and biopharmaceutical manufacturing, including:
- Parenterals
- Antibiotics
- Vaccines
- Diagnostics
- Buffers
- Diluents
- Reagents
- Serum
- Tissue culture media
- Media additives

SteriLUX® can be used for the clarification and purification of:
- Deionized water
- Aqueous solvents
- Acids
- Bases
- Plating solutions

Within the food and beverage industry, SteriLUX® can be used for clarification and stabilization of fluids, such as:
- Beer
- Wine
- Bottled water
Product Specifications

**Materials of Construction**
- **Filter Media:** Polyvinylidene fluoride (PVDF)
- **Upstream Support:** Polypropylene
- **Downstream Support:** Polypropylene
- **Core/Outer Guard:** Polypropylene
- **End Caps:** Polypropylene
- **Sealing Method:** Thermal bonding
- **Gaskets/O-rings:** Buna, EPR, polyethylene, silicone, Teflon®, Teflon® over silicone, Teflon® over Viton®


SteriLUX® filters are manufactured in conformance to cGMP. SteriLUX® filters meet the requirements as specified in the current USP Class VI plastics, physicochemical, oxidizable substances, and cytotoxicity tests. Bacterial endotoxin levels in aqueous extracts of SteriLUX® filters are less than 0.5 EU/mL, as determined using the Limulus amebocyte lysate (LAL) test. No binders, adhesives or surfactants are used in the construction of SteriLUX® filters. SteriLUX® filters are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72

**Filtration Ratings**
- **Absolute Ratings (µm)**
  - 0.1 µm, 0.2 µm, 0.4 µm and 0.6 µm

**Integrity Testing**
- **Minimum Bubble Point, Water**
  - 0.1 µm: 70 psi (4.8 bar)
  - 0.2 µm: 50 psi (3.4 bar)
  - 0.4 µm: 28 psi (1.9 bar)
  - 0.6 µm: 14 psi (1.0 bar)

**Cartridge Dimensions (nominal)**
- **Diameter:** 2.75” (7 cm)
- **Lengths:** 10”, 20”, 30”, 40” (25 cm, 50 cm, 75 cm, 100 cm)

**Bacterial Retention**
- **ASTM F838-05 Challenge:**
  - VTH/VMH: 0.1 µm, 0.2 µm > 10^7 cfu/cm^2 *Brevundimonas diminuta* and meet the FDA definition of a sterilizing grade filter.
  - 0.1 µm ≥ 10^4 cfu/cm^2 *Acholeplasma laidlawii*
  - 0.4 µm > 10^7 cfu/cm^2 *Serratia marcescens*
  - 0.6 µm > 10^7 cfu/cm^2 *Saccharomyces cerevisiae*

**Sterilization**
- **Steam-in-place (SIP):**
  - Saturated steam @ 121-135 °C, 30-60 minutes
  - [15 psi (1 bar) to 30 psi (2 bar), 30-60 minutes]
- **Autoclave:** 121-135 °C, 30-60 minutes

SteriLUX® cartridges are capable of repeated sterilization cycles without loss of integrity. For applications requiring autoclave/SIP, a stainless steel reinforcement ring must be ordered. See “Reinforcement Ring Option” within the Ordering Information.

**Maximum Operating Temperatures & Pressures**
- **Δp 80 psi @ 32 °F to 100 °F**
  - (Δp 5,5 bar @ 0 °C to 38 °C)
- **Δp 60 psi @ 150 °F**
  - (Δp 4,1 bar @ 66 °C)
- **Δp 30 psi @ 180 °F**
  - (Δp 2,1 bar @ 82 °C)

![Typical Water Flow Rates per 10" Cartridge](chart.png)
## End Cap Configuration

<table>
<thead>
<tr>
<th>End Cap Configuration</th>
<th>Image</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>-226 O-ring</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td>External -226 O-rings with locking tabs; open end for C6 and F6 SOE configurations</td>
</tr>
<tr>
<td>-222 O-ring</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td>External -222 O-rings; open end for C2 and F2 SOE configurations</td>
</tr>
<tr>
<td>-226 nO-Ring®</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td>External -226 nO-Ring® with locking tabs; open end for C5 and F5 SOE configurations</td>
</tr>
<tr>
<td>-222 nO-Ring®</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td>External -222 nO-Ring®, open end for C1 and F1 SOE configurations</td>
</tr>
<tr>
<td>Flat Gasket</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td>Flat Gasket; open end for GS and GL DOE configurations</td>
</tr>
<tr>
<td>Internal O-ring</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td>Internal O-ring; open end for DN and DA DOE or RN and RA SOE configurations</td>
</tr>
<tr>
<td>Button Cap</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td>Button Cap; closed end for C1, C2, C5 and C6 SOE configurations</td>
</tr>
<tr>
<td>Alignment Fin</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td>Alignment Fin; closed end for F1, F2, F5 and F6 SOE configurations</td>
</tr>
<tr>
<td>Recessed Cap</td>
<td><img src="https://via.placeholder.com/150" alt="Image" /></td>
<td>Recessed Cap; closed end for RN and RA SOE configurations</td>
</tr>
</tbody>
</table>

## Ordering Information

<table>
<thead>
<tr>
<th>Filter Grade</th>
<th>Absolute Rating (μm)</th>
<th>Cartridge Length</th>
<th>End Cap Configuration</th>
<th>Reinforcement Ring Option</th>
<th>Seal Material (O-ring or Gasket)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VMH = Standard</td>
<td>0.1</td>
<td>1 = 10&quot; (25 cm)</td>
<td>DOE; flat gaskets (9.75&quot;, 19.5&quot;, 29.25&quot;, 39&quot; length filters)</td>
<td>(Blank) = Standard - no reinforcement ring</td>
<td>O-ring Seal</td>
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<tr>
<td>0.2</td>
<td>2 = 20&quot; (50 cm)</td>
<td>DOE; flat gaskets (20&quot;, 30&quot;, 40&quot; length filters)</td>
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<tr>
<td>0.4</td>
<td>3 = 30&quot; (75 cm)</td>
<td>SOE; -226 nO-Ring®, button cap end</td>
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<tr>
<td>0.6</td>
<td>4 = 40&quot; (100 cm)</td>
<td>SOE; -226 O-rings, button cap end</td>
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<tr>
<td>VLH = PVDF membrane; not integrity tested or flushed</td>
<td>GS = DOE; flat gaskets (9.75&quot;, 19.5&quot;, 29.25&quot;, 39&quot; length filters)</td>
<td>C1 = SOE; -222 nO-Ring®, button cap end</td>
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<td></td>
<td>GL = DOE; flat gaskets (20&quot;, 30&quot;, 40&quot; length filters)</td>
<td>C2 = SOE; -222 O-rings, button cap end</td>
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<td></td>
<td></td>
<td>C1 = SOE; -222 nO-Ring®, fin end</td>
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<td>C2 = SOE; -222 O-rings, fin end</td>
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<td>C5 = SOE; -226 nO-Ring®, button cap end</td>
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<td>C6 = SOE; -226 O-rings, button cap end</td>
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<td></td>
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<td>F1 = SOE; -226 nO-Ring®, fin end</td>
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<td></td>
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<td>F2 = SOE; -226 O-rings, fin end</td>
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<td>C5 = SOE; -226 nO-Ring®, button cap end</td>
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<td></td>
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<td>C6 = SOE; -226 O-rings, button cap end</td>
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<td>F5 = SOE; -226 nO-Ring®, fin end</td>
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<td>F6 = SOE; -226 O-rings, fin end</td>
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<td>DN = DOE; internal -120 O-rings</td>
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<td>RN = SOE; internal -120 O-ring, recessed cap end</td>
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<td>DA = DOE; internal -213 O-rings</td>
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<td></td>
<td></td>
<td>RA = SOE; internal -213 O-ring, recessed cap end</td>
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### Filter Grade Descriptions

**VTH** = This absolute, microbially rated filter meets full traceability requirements for the pharmaceutical industry. It is 100% integrity tested and flushed with DI water during manufacture. Each VTH grade filter is shipped with a Certificate of Quality stating exact quality control criteria and test performance results. This is a validatable product to meet the stringent requirements of the pharmaceutical industry.

**VMH** = This sterilizing grade filter is absolute, microbially rated and 100% integrity tested and flushed with DI water during manufacture. It is suited for critical applications when regulatory documentation requirements are minimal. A Certificate of Conformance is available on a lot basis.

**VLH** = This filter is not 100% integrity tested or flushed with DI water during manufacture. It is offered as an economical prefilter or final filter when sterility assurance and validation are not required.

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