STyLUX® Filter Cartridge

The STyLUX® filter cartridge is an absolute rated, pleated polyethersulfone (PES) membrane filter designed to provide greater bacteria and particle removal at high flow rates and extremely low pressure drops. It offers the greatest assurance of filtration performance, stability and service life for controlling contaminants in demanding environments.

The exceptional performance of STyLUX® is derived from its unique filtration media. The filter media is made by a patented process which produces an asymmetric polyethersulfone membrane that is inherently hydrophilic. The membrane is a highly porous structure whose pore size decreases progressively through its depth. This highly durable structure maintains consistent porosity and contaminant retention throughout its operational life without shedding or unloading particles. This results in a filter that provides absolute retention and superior flow rates, cleanliness and throughputs, even in severe process conditions.

For applications requiring Mycoplasma removal, Meissner offers the STyLUX® SC0.1 filter. This sterilizing grade filter provides 100% retention of Mycoplasma per modified ASTM F838 Challenge, while delivering the highest reliability and security for the sterilization of serum, culture media and other biological fluids.

All components of the STyLUX® filter cartridge comply with FDA regulations for food contact use. A unique state-of-the-art process thermally bonds the membrane and polypropylene support components to the cartridge end caps. This provides an integral filter cartridge that has excellent chemical compatibility and extremely low extractables in a wide range of fluids and applications.

Features and Benefits

• Durable PES and PP components
• Absolute ratings of 0.04, 0.1, 0.2, 0.4 and 0.6 μm
• Highly porous asymmetric membrane
• Extremely high flow rates at low pressure drops
• Permanently hydrophilic membrane
• Integrity testable in water
• Contains no binders, adhesives or other extraneous materials
• High thermal and hydrolytic stability
• Resistant to oxidizing agents
• Rugged, thermally bonded construction
• Biologically inert and non-toxic
• High protein transmission
• 100% integrity tested during manufacture

STyLUX® is ideal for the clarification and cold sterilization of beverages, including:

• Mineral water
• Wine and wine coolers
• Draft beer

The wide chemical resistance of PES and PP makes the STyLUX® filter perfectly suited for the purification of chemicals such as:

• Acids & bases
• Alcohols
• Aldehydes

STyLUX® is designed for the removal of particulates, colloids and microorganisms from a broad variety of pharmaceutical and biological solutions, including:

• Serum & blood-based products
• Tissue culture media
• Microbiological growth media
• Ophthalmics
• Oral and topical medications
• Diagnostics
• Protein solutions
• Antibiotics
• Vaccine preparations

Typical Applications

STyLUX® meets the critical demand for contamination control in the chemical, microelectronics, aerospace, food and beverage, biologicals, veterinary, pharmaceutical and other industries. STyLUX® may be used as either a prefilter or final filter. It offers the greatest security for bulk and point-of-use filtration.

STyLUX® provides high quality filtration for a variety of ultrapure water requirements, including:

• Deionized water
• High temperature water
• Chemically treated water
**Materials of Construction**

Filter Media: Polyethersulfone (PES)
Upstream Support: Polypropylene (PP)
Downstream Support: Polypropylene
Core/Outer Guard: Polypropylene
End Caps: Polypropylene
Sealing Method: Thermal Bonding

O-ring/Gasket Seal: Buna, EPR, polyethylene, silicone, Teflon over silicone, Teflon® over Viton®


STyLUX® filters are manufactured in conformance to cGMP. STyLUX® 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 STyLUX® 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 STyLUX® filters. STyLUX® filters are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72.

**Filtration Ratings**

<table>
<thead>
<tr>
<th>Filter Grade</th>
<th>Absolute Ratings (µm):</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM, ST, SL</td>
<td>0.04, 0.1, 0.2, 0.4, 0.6</td>
</tr>
<tr>
<td>SP</td>
<td>0.04, 0.1, 0.2, 0.4</td>
</tr>
<tr>
<td>SC</td>
<td>0.1</td>
</tr>
</tbody>
</table>

**Integrity Testing**

Minimum Bubble Point, Water

<table>
<thead>
<tr>
<th>SM/ST</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0.04 µm</td>
<td>115 psi (7.9 bar)</td>
</tr>
<tr>
<td>0.1 µm</td>
<td>80 psi (5.5 bar)</td>
</tr>
<tr>
<td>0.2 µm</td>
<td>44 psi (3.0 bar)</td>
</tr>
<tr>
<td>0.4 µm</td>
<td>32 psi (2.2 bar)</td>
</tr>
<tr>
<td>0.6 µm</td>
<td>18 psi (1.2 bar)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SC</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 µm</td>
<td>110 psi (7.6 bar)</td>
</tr>
</tbody>
</table>

**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:

**SM/ST**

0.04 µm, 0.1 µm, 0.2 µm > 10^7 cfu/cm² *Brevundimonas diminuta* and meet the FDA definition of a sterilizing grade filter.

0.04 µm > 10^7 cfu/cm² *Acholeplasma laidlawii*

0.1 µm ≥ 10^4 cfu/cm² *Acholeplasma laidlawii*

0.4 µm > 10^7 cfu/cm² *Serratia marcescens*

0.6 µm > 10^7 cfu/cm² *Saccharomyces cerevisiae*

**SC**

0.1 µm > 10^7 cfu/cm² *Brevundimonas diminuta* and meets the FDA definition of a sterilizing grade filter.

0.1 µm > 10^7 cfu/cm² *Acholeplasma laidlawii*

**Sterilization**

Steam-in-place (SIP):

saturated steam @ 121-135 ºC, 30-60 minutes

[15 psi (1 bar) to 30 psi (2 bar), 30-60 minutes]

Autoclave: 121-135 ºC, 30-60 minutes

STyLUX® 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” on back page. (Membrane must be wet prior to steam sterilization. Reference “Green Docs” online for more information.)

**Maximum Operating Temperatures and Pressures**

<table>
<thead>
<tr>
<th>Initial Differential Pressure, psid</th>
<th>Minimum Water Flow Rates per 10” Cartridge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Δp 80 psi @ 32 °F to 100 °F</td>
<td>0.04 µm</td>
</tr>
<tr>
<td>(Δp 5.5 bar @ 0 °C to 38 °C)</td>
<td>(Δp 2,1 bar @ 82 °C)</td>
</tr>
<tr>
<td>Δp 60 psi @ 150 °F</td>
<td>0.1 µm</td>
</tr>
<tr>
<td>(Δp 4.1 bar @ 66 °C)</td>
<td>(Δp 2,1 bar @ 82 °C)</td>
</tr>
<tr>
<td>Δp 30 psi @ 180 °F</td>
<td>0.2 µm</td>
</tr>
<tr>
<td>(Δp 2,1 bar @ 82 °C)</td>
<td>(Δp 2,1 bar @ 82 °C)</td>
</tr>
<tr>
<td>(Δp 2,1 bar @ 82 °C)</td>
<td>0.4 µm</td>
</tr>
<tr>
<td>(Δp 2,1 bar @ 82 °C)</td>
<td>(Δp 2,1 bar @ 82 °C)</td>
</tr>
<tr>
<td>(Δp 2,1 bar @ 82 °C)</td>
<td>0.6 µm</td>
</tr>
<tr>
<td>(Δp 2,1 bar @ 82 °C)</td>
<td>(Δp 2,1 bar @ 82 °C)</td>
</tr>
</tbody>
</table>
A Certificate of Conformance is provided.

**SP** = This is an absolute, particulate rated filter. It is 100% integrity tested and DI flushed during manufacture.

**SL** = This filter is not 100% integrity tested or flushed with DI water during manufacture. It is offered as an economical alternative to SP filters.

**SM** 0.2 = 3.2 μm and 2.3 μm cartridge correspond to the 0.2 micron filtration performance. It is 100% integrity tested and has the added benefit of certification that meets the critical needs of the pharmaceutical, biotechnology and related industries.

**SC** 0.1 = This is a sterilizing grade filter designed specifically for the 100% removal of Mycoplasma. It is 100% integrity tested and DI flushed during manufacture and it has the added benefit of certification that meets the critical needs of the pharmaceutical, biotechnology and related industries. Each SC0.1 filter comes with a Certificate of Quality that gives precise information on the quality, integrity and acceptance criteria of the filter.

**ST** = This sterilizing grade, 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 ST grade filter is shipped with a Certificate of Quality that gives precise information on the quality, integrity and acceptance criteria of the filter.

**SM** = 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 provided.

**SC** = This filter is not 100% integrity tested or flushed with DI water during manufacture. It is offered as an economical alternative to SM filters.

**SP** = This is an absolute, particulate rated filter. It is 100% integrity tested and DI flushed during manufacture. A Certificate of Conformance is provided.

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SM 3.2

End Cap Configuration

<table>
<thead>
<tr>
<th>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>SM</td>
<td>0.04, 0.1, 0.2, 0.4, 0.6</td>
<td>1 = 10&quot; (25 cm)</td>
<td>GS = DOE: flat gaskets</td>
<td>R = Reinforcement ring required for autoclave / SIP applications</td>
<td>O-ring Seal</td>
</tr>
<tr>
<td>ST</td>
<td>0.04, 0.1, 0.2, 0.4, 0.6</td>
<td>2 = 20&quot; (50 cm)</td>
<td>GL = DOE: flat gaskets</td>
<td>S = Standard - no reinforcement ring</td>
<td>B = Buna</td>
</tr>
<tr>
<td>SC</td>
<td>0.1</td>
<td>3 = 30&quot; (75 cm)</td>
<td>C1 = SOE; -222 nO-Ring®, button cap end</td>
<td>S = Standard - no reinforcement ring</td>
<td>E = EPR</td>
</tr>
<tr>
<td>SL</td>
<td>0.04, 0.1, 0.2, 0.4, 0.6</td>
<td>4 = 40&quot; (100 cm)</td>
<td>C2 = SOE; -222 O-rings, button cap end</td>
<td>S = Standard - no reinforcement ring</td>
<td>S = Silicone</td>
</tr>
<tr>
<td>SP</td>
<td>0.04, 0.1, 0.2, 0.4, 0.6</td>
<td></td>
<td>C5 = SOE; -226 nO-Ring®, button cap end</td>
<td>S = Standard - no reinforcement ring</td>
<td>T = Teflon® over silicone</td>
</tr>
</tbody>
</table>

Grade Descriptions:
- **SM** = 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 provided.
- **ST** = This sterilizing grade, 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 ST grade filter is shipped with a Certificate of Quality that gives precise information on the quality, integrity and acceptance criteria of the filter. This is a valuable product to meet the stringent requirements of the pharmaceutical industry.
- **SC0.1** = This is a sterilizing grade filter designed specifically for the 100% removal of Mycoplasma. It is 100% integrity tested and DI flushed during manufacture and it has the added benefit of certification that meets the critical needs of the pharmaceutical, biotechnology and related industries. Each SC0.1 filter comes with a Certificate of Quality that gives precise information on the quality, integrity and acceptance criteria of the filter.
- **SL** = This filter is not 100% integrity tested or flushed with DI water during manufacture. It is offered as an economical alternative to SM filters.
- **SP** = This is an absolute, particulate rated filter. It is 100% integrity tested and DI flushed during manufacture. A Certificate of Conformance is provided.