

# SteriLUX<sup>®</sup>



 **MEISSNER**  
FILTRATION PRODUCTS, INC.

# Meissner Filtration Products, Inc.

Meissner offers the leading solutions for today's most critical pharmaceutical filtration applications. Our sophisticated material tracking and automated manufacturing processes provide unmatched quality control and traceability, guaranteeing the highest level of product performance and reliability. Our products are delivered on-time and error-free. Meissner Technical Services (MTS) provides customer support for selecting, sizing, installing and operating filtration systems, as well as complete validation testing services and documentation. From membrane filters and housings to integrity test equipment and support services, Meissner works closely with clients to specify filtration products that maximize efficiency and optimize applications.



## SteriLUX<sup>®</sup> Filter

The SteriLUX<sup>®</sup> 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<sup>®</sup> also provides high performance filtration of bulk pharmaceutical chemicals, cosmetics and toiletries, diagnostics, solvents and solvent/product mixtures, reagents and high purity water.



The SteriLUX<sup>®</sup> 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, it offers the highest assurance of product integrity and filtration performance.

## Sterilizing Grade

Based on ASTM F838-83 liquid bacterial challenge testing, SteriLUX<sup>®</sup> 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. SteriLUX<sup>®</sup> filters can withstand multiple steam sterilizations. Each SteriLUX<sup>®</sup> filter cartridge is integrity tested and flushed with deionized water during manufacture. SteriLUX<sup>®</sup> filters are certified as non-fiber-releasing. Biologically inert and non-toxic, SteriLUX<sup>®</sup> meets FDA requirements for food contact use and passes USP Class VI Plastics biological reactivity tests.



## 0.1 µm, 0.2 µm, 0.45 µm, 0.6 µm

The SteriLUX® filter is offered with absolute ratings of 0.1 µm, 0.2 µm, 0.45 µm and 0.6 µm. Filter configurations include discs, capsules and mini-cartridges for small filtration volumes, and cartridges and ultra-capacity UltraCap® capsules for large filtration volumes. SteriLUX® can be used to filter aqueous solutions and many high surface tension chemicals and solvents.

## 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, Viton® or Teflon® |

All materials of construction are FDA approved for food contact use per CFR Title 21,177.

## Meissner Technical Services

Meissner Technical Services offers the comprehensive technical and validation support that is essential to our pharmaceutical clients. With a technical staff that helped write the current guidelines on sterilizing filtration of liquids, MTS understands the needs of the pharmaceutical industry.

MTS provides a wide range of analytical and testing services in our laboratories and at customer facilities. We assist our clients through all phases of development, installation, scale-up, system optimization, validation and compliance. We evaluate, trouble-shoot and engineer filtration solutions to maximize system efficiency, economics and safety. MTS validation support includes validation guides, bacterial challenge testing, compatibility studies, extractables testing, test protocols, and complete validation documentation to ensure compliance with regulatory requirements.

### Cartridge Dimensions (nominal)

Diameter: 2.75" (7 cm)  
Lengths: 10", 20", 30", 40"  
(25, 50, 75, 100 cm)

### Integrity Testing:

|                            |                  |
|----------------------------|------------------|
| Minimum Water Bubble Point |                  |
| 0.1 µm                     | 70 psi (4,8 bar) |
| 0.2 µm                     | 50 psi (3,4 bar) |
| 0.45 µm                    | 28 psi (1,9 bar) |
| 0.6 µm                     | 14 psi (1,0 bar) |

Maximum Operating Temperatures & Pressures  
100 °F @ 80 psid  
(38 °C @ Δp 5,5 bar)

150 °F @ 60 psid  
(66 °C @ Δp 4,1 bar)

180 °F @ 30 psid  
(82 °C @ Δp 2,1 bar)

### Quantitative Bacterial Retention

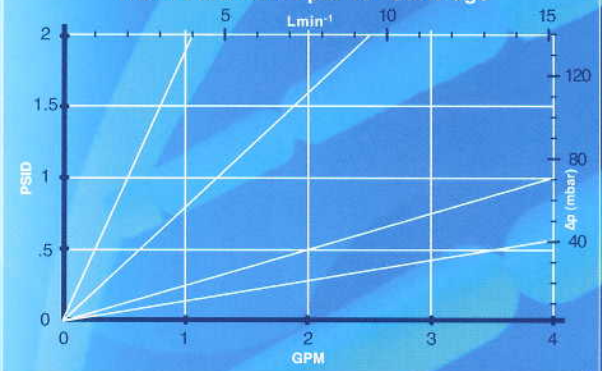
HIMA/ASTM Challenge  
0.1 µm, 0.2 µm >10<sup>7</sup> LRV/cm<sup>2</sup>  
*Brevundimonas diminuta*  
0.1 µm and 0.2 µm meet the FDA definition of a sterilizing grade filter.  
0.45 µm >10<sup>7</sup> LRV/cm<sup>2</sup>  
*Serratia marcescens*

### Sterilization

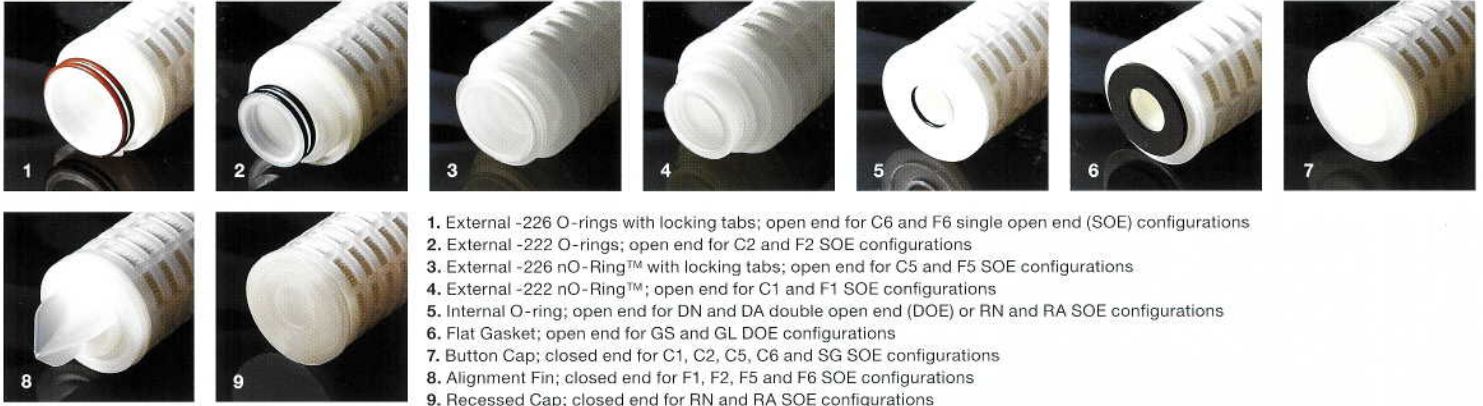
Inline Steam: 121-135 °C, 30-60 minutes  
Autoclave: 121-125 °C, 30-60 minutes

SteriLUX® cartridges can withstand repeated sterilization cycles without loss of integrity. For applications requiring autoclave/SIP, a reinforcement ring must be ordered. See "Reinforcement Ring Option" in "Ordering Information."

Water Flow Rates per 10" Cartridge



# End Cap Configurations



1. External -226 O-rings with locking tabs; open end for C6 and F6 single open end (SOE) configurations
2. External -222 O-rings; open end for C2 and F2 SOE configurations
3. External -226 nO-Ring™ with locking tabs; open end for C5 and F5 SOE configurations
4. External -222 nO-Ring™; open end for C1 and F1 SOE configurations
5. Internal O-ring; open end for DN and DA double open end (DOE) or RN and RA SOE configurations
6. Flat Gasket; open end for GS and GL DOE configurations
7. Button Cap; closed end for C1, C2, C5, C6 and SG SOE configurations
8. Alignment Fin; closed end for F1, F2, F5 and F6 SOE configurations
9. Recessed Cap; closed end for RN and RA SOE configurations

## Ordering Information

| Filter Grade   | Absolute Rating (µm) | Cartridge Length | End Cap Configuration   | Reinforcement Ring Option  | Gasket or O-ring Material             |
|--|----------------------|------------------|---|--|---------------------------------------|
| <b>VMH</b>   | 0.2                  | – 3              | <b>F2</b>   | <b>R</b>   | <b>S</b>                              |
| <p><b>VTH = Certified, fully traceable PVDF membrane</b></p> <p>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.</p> | 0.1                  | 1 = 10"          | <p><b>GS</b> = DOE; flat gaskets (9.75", 18.5", 29.25", 39" length filters)</p> | <p><b>(Blank)</b> = Standard-no reinforcement ring</p>                                 | <b>B</b> = Buna                       |
|  | 0.2                  | 2 = 20"          | <p><b>GL</b> = DOE; flat gaskets (20", 30", 40" length filters)</p>             | <p><b>R</b> = Optional reinforcement ring; required for autoclave/SIP applications</p> | <b>E</b> = EPR                        |
|  | 0.4                  | 3 = 30"          | <p><b>C1</b> = SOE; -222 nO-Ring™, button cap end</p>                           |  | <b>P</b> = Polyethylene (gasket only) |
|  | 0.6                  | 4 = 40"          | <p><b>F1</b> = SOE; -222 nO-Ring™, fin end</p>                                  |  | <b>S</b> = Silicone                   |
|  |                      |                  | <p><b>C2</b> = SOE; -222 O-rings, button cap end</p>                            |  | <b>T</b> = Teflon®                    |
|  |                      |                  | <p><b>F2</b> = SOE; -222 O-rings, fin end</p>                                   |  | <b>V</b> = Viton®                     |
|  |                      |                  | <p><b>C5</b> = SOE; -226 nO-Ring™, button cap end</p>                           |  |                                       |
|  |                      |                  | <p><b>F5</b> = SOE; -226 nO-Ring™, fin end</p>                                  |  |                                       |
|  |                      |                  | <p><b>C6</b> = SOE; -226 O-rings, button cap end</p>                            |  |                                       |
|  |                      |                  | <p><b>F6</b> = SOE; -226 O-rings, fin end</p>                                   |  |                                       |
|  |                      |                  | <p><b>SG</b> = SOE; smooth internal -020, button cap end</p>                    |  |                                       |
|  |                      |                  | <p><b>DN</b> = DOE; internal -120 O-rings</p>                                   |  |                                       |
|  |                      |                  | <p><b>RN</b> = SOE; internal -120 O-ring, recessed cap end</p>                  |  |                                       |
|  |                      |                  | <p><b>DA</b> = DOE; internal -213 O-rings</p>                                   |  |                                       |
|  |                      |                  | <p><b>RA</b> = SOE; internal -213 O-ring, recessed cap end</p>                  |  |                                       |
| <p><b>VMH = Standard PVDF membrane</b></p> <p>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.</p>  |                      |                  |   |  |                                       |
| <p><b>VLH = PVDF membrane prefilter</b></p> <p>This VMH grade 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 is not required.</p>  |                      |                  |   |  |                                       |



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