SteriLUX®

MEISSNER
FILTRATION PRODUCTS

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.

Meissner Technical Services (MTS) offers the comprehensive technical and validation support that is essential to our pharmaceutical clients.

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:

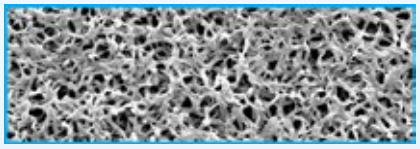
- Parenterals
- Antibiotics
- Vaccines
- Diagnostics
- Buffers
- Diluents
- Reagents
- Serum
- Tissue culture media
- Media additives

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



SteriLUX® SEM

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®

All materials of construction listed above are FDA approved for food contact use per 21 CFR 177. Filters comply with European Commission Directive 2002/72/EC and subsequent amendments up to Commission Regulation (EU) no 10/2011.

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)

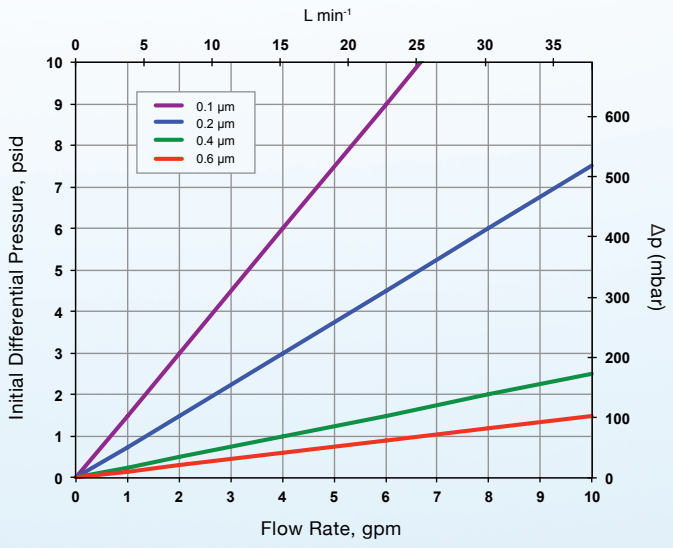
Δp 60 psi @ 150 °F

(Δp 4,1 bar @ 66 °C)

Δp 30 psi @ 180 °F

(Δp 2,1 bar @ 82 °C)

Typical Water Flow Rates per 10" Cartridge



End Cap Configuration

-226 O-ring

External -226 O-rings with locking tabs; open end for C6 and F6 SOE configurations

-222 O-ring

External -222 O-rings; open end for C2 and F2 SOE configurations

-226 nO-Ring®

External -226 nO-Ring® with locking tabs; open end for C5 and F5 SOE configurations

-222 nO-Ring®

External -222 nO-Ring®, open end for C1 and F1 SOE configurations

Flat Gasket

Flat Gasket; open end for GS and GL DOE configurations

Internal O-ring

Internal O-ring; open end for DN and DA DOE or RN and RA SOE configurations

Button Cap

Button Cap; closed end for C1, C2, C5 and C6 SOE configurations

Alignment Fin

Alignment Fin; closed end for F1, F2, F5 and F6 SOE configurations

Recessed Cap

Recessed Cap; closed end for RN and RA SOE configurations

DOE = Double Open End
SOE = Single Open End

Ordering Information

Filter Grade	Absolute Rating (µm)		Cartridge Length	End Cap Configuration	Reinforcement Ring Option	Seal Material (O-ring or Gasket)
VMH	*0.2*	—	*3*	*F2*	*R*	*S*

VTH = Certificated; fully traceable PVDF membrane

VMH = Standard PVDF membrane

VLH = PVDF membrane; not integrity tested or flushed

0.1

0.2

0.4

0.6

1 = 10" (25 cm)
2 = 20" (50 cm)
3 = 30" (75 cm)
4 = 40" (100 cm)

GS = DOE; flat gaskets (9.75", 19.5", 29.25", 39" length filters)
GL = DOE; flat gaskets (20", 30", 40" length filters)
C1 = SOE; -222 nO-Ring®, button cap end
C2 = SOE; -222 O-rings, button cap end
F1 = SOE; -222 nO-Ring®, fin end
F2 = SOE; -222 O-rings, fin end
C5 = SOE; -226 nO-Ring®, button cap end
C6 = SOE; -226 O-rings, button cap end
F5 = SOE; -226 nO-Ring®, fin end
F6 = SOE; -226 O-rings, fin end
DN = DOE; internal -120 O-rings
RN = SOE; internal -120 O-ring, recessed cap end
DA = DOE; internal -213 O-rings
RA = SOE; internal -213 O-ring, recessed cap end

(Blank) = Standard - no reinforcement ring

R = Reinforcement ring; required for autoclave/ SIP applications

O-ring Seal

B = Buna
E = EPR
S = Silicone
T = Teflon® over silicone
V = Viton®
X = Teflon® over Viton®

Gasket Seal

B = Buna
E = EPR
P = Polyethylene
S = Silicone
T = Teflon®
V = Viton®

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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