SteriLUX®

0.2 µm VPH-grade Filter Cartridge

Description

The SteriLUX® VPH0.2 filter cartridge is a hydrophilic PVDF membrane filter with high flow rates, high throughputs, low protein binding properties and broad chemical compatibility. It is recommended for bioburden reduction of pharmaceutical preparations, active ingredients, biopharmaceuticals, parenterals, vaccines, biologicals including dilute protein solutions, cell and tissue culture media, media additives, ophthalmic and other dilute preservative solutions, UPW, chemicals, alcohols, and sanitizing agents.

Materials of Construction

All components of the filter are either animal component free (ACF) or in compliance with EMA/410/01 Rev. 3 (EDQM 5.2.8 07/2011:50208), and US Code of Federal Regulations 9 CFR 94.18 and 21 CFR 189.5. These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Membrane:	Polyvinylidene fluoride (PVDF)	CFR Title 21, 177.2510
Upstream support:	Polypropylene	CFR Title 21, 177.1520
Downstream support:	Polypropylene	CFR Title 21, 177.1520
Outer guard:	Polypropylene	CFR Title 21, 177.1520
Core:	Polypropylene	CFR Title 21, 177.1520
End caps:	Polypropylene	CFR Title 21, 177.1520
O-rings/gasket:	Typically silicone	CFR Title 21, 177.2600
Sealing method:	Thermal bonding	

Pore Size	0.2 µm
Effective Filtration Area	7.9 ft^2 (0.73 m^2) per 10" (25 cm)
Minimum Bubble Point	28 psi (1.93 bar) in water, with air or nitrogen 10 psi (0.69 bar) in 60% IPA/40% water, with air or nitrogen
Maximum Diffusion Rate	15 mL/min per 10" (25 cm) @ 22 psi (1.51 bar), water with air
Typical Water Flow Rate	0.25 psid/gpm per 10" (2.2 L/min at Δp 10 mbar per 25 cm)

Operating Characteristics

Operating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum temperature rating:	180 °F @ 30 psid (82 °C @ 2.1 bar)
Maximum operating pressure:	80 psid @ 100 °F (5.5 bar @ 38 °C)
Maximum reverse pressure:	15 psid @ 100 °F (1.0 bar @ 38 °C)

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.
Steam-In-Place (SIP): 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.

Biological Safety

SteriLUX® meet the requirements as specified in USP 43 <88> Class VI plastics, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of SteriLUX® filters are less than 0.5 EU/mL, as determined using the current USP <85> *Limulus* amebocyte lysate (LAL) test. No binders, adhesives, or surfactants are used in the construction of SteriLUX® filters. Filters comply with European Commission Regulation (EU) No. 10/2011.

Quality Assurance

SteriLUX® filters comply with the Food and Drug Administration Code of Federal Regulations, Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA Good Manufacturing Practice Standards. To ensure product reliability, Meissner's Quality Assurance staff continually audits the manufacturing process for conformance to its Quality Management System. Each SteriLUX® filter is integrity tested during manufacture and labeled with filter type, lot number, and unique serial number. The serial number for all cartridge filters can be found on the product packaging.

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Ordering Guide

VPH 0.2 - 1 C2 R S

O-ring Seal Material	
B	Buna
E	EPR
S	Silicone
T	Teflon® over Silicone
V	Viton®
X	Teflon® over Viton®

Reinforcement Ring Option	
(blank)	Standard - no reinforcement ring
R	Reinforcement ring required for autoclave/ SIP applications

Cartridge Configuration			
C1	SOE; 222 nO-Ring®, button cap end	F2	SOE; 222 O-rings, fin end
C2	SOE; 222 O-rings, button cap end	F5	SOE; 226 nO-Ring®, fin end
C5	SOE; 226 nO-Ring®, button cap end	F6	SOE; 226 O-rings, fin end
C6	SOE; 226 O-rings, button cap end	GS*	DOE; flat gaskets
DA	DOE; internal 213 O-rings	GL**	DOE; flat gaskets
DN	DOE; internal 120 O-rings	RA	SOE; internal 213 O-ring, recessed cap end
F1	SOE; 222 nO-Ring®, fin end	RN	SOE; internal 120 O-ring, recessed cap end

Filter Length							
1	10"	2	20"	3	30"	4	40"

Product	Grade	Pore Size
SteriLUX® hydrophilic PVDF membrane	VPH	0.2 µm

**GS option is only available for 9.75", 19.5", 29.25", and 39" length filters.*
***GL option is only available for 20", 30", and 40" length filters.*
Additional information about this filter product is available in the SteriLUX® Green Docs document at www.meissner.com/green-docs.

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