EverLUX®

0.2 µm STS-grade Filter Cartridge

Description

The EverLUX[®] STS0.2 filter cartridge is an advanced PES membrane filter that features a highly asymmetric PES membrane layered over an asymmetric PES membrane for an optimized pre- and final filtration combination. The filter is 100% integrity tested during manufacture and has the added benefit of certification that meets the critical needs of the pharmaceutical, biotechnology, and related industries.

Materials of Construction

All components of the filter are either animal 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:

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Membrane: Upstream support: Downstream support: Outer guard: Core: End caps: Adapters: Sealing method:	Polyethersulfone (PES) Polypropylene Polypropylene Polypropylene Polypropylene Polypropylene Thermal bonding	CFR Title 21, 177.2440 CFR Title 21, 177.1520 CFR Title 21, 177.1520
Pore Size	0.2 µm	
Minimum Bubble Point	50 psi (3.45 bar), water 16.3 psi (1.12 bar), 60% IPA/40% water 15.7 psi (1.08 bar), 70% IPA/30% water	
Maximum Diffusion Rate	28 mL/min @ 35 psi (2.41 bar), water	
Typical Water Flow Rate	0.42 psid/gpm per 10" (1.31 L/min at Δp 10 mbar per 25 cm)	
Bacterial Retention	>10 ⁷ per cm ² removal of <i>Brevundimonas diminuta</i> per ASTM F838	
Operating Characteristics Operating temperature range: Maximum temperature rating: Maximum operating pressure:	32 °F to 100 °F (0 °C to 38 °C) 180 °F @ 30 psid (82 °C @ 2.1 bar) 80 psid @ 100 °F (5.5 bar @ 38 °C)	

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 min., \geq 3 cycles. Water wet membrane prior to autoclaving. Steam in place (SIP): 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, \geq 3 cycles. Water wet membrane first.

Biological Safety

Maximum reverse pressure:

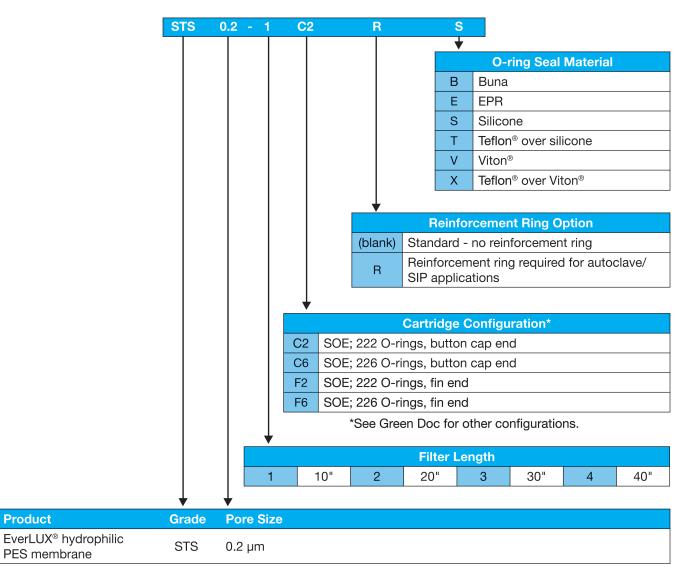
EverLUX[®] filters meet the requirements as specified in the current USP <88> Class VI plastics, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of EverLUX[®] filters are less than 0.5 EU/mL,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

Quality Assurance

The EverLUX[®] STS0.2 filter is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. EverLUX[®] 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 EverLUX[®] filter is integrity tested during manufacture and is clearly marked with filter type, and lot number.



Ordering Guide



Additional information about this filter product is available in the EverLUX® Green Docs document at www.meissner.com/green-docs.

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