

0.1 µm STC-grade Small Filter Cartridge (L Model)

Description

The EverLUX® STC0.1 filter cartridge, or small flow element (SFE), features two serially layered PES membranes (one highly asymmetric and one asymmetric) designed for sterile filtration and 100% removal of mycoplasma. The coarser upstream layer is optimized for prefiltration. The filter 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.

Materials of Construction

All components of the filter are either animal component free (ACF) or in compliance with EMA/410/01 Rev. 3 (EDQM 5.2.807/2011:50208), 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:

Membranes: Polyethersulfone (PES) CFR Title 21, 177.2440 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 Polypropylene End caps: CFR Title 21, 177.1520

Sealing method: Thermal bonding

Pore Size 0.1 μm (sterilizing grade)

Effective Filtration Area 2.5" (7 cm): 1.2 ft² (0.11 m²)

5.0" (13 cm): 2.6 ft² (0.24 m²⁾

Maximum Diffusion Rate 1.2 ft2: 5.3 mL/min @ 40 psi (2.76 bar), water with air

2.6 ft2: 11 mL/min@ 40 psi (2.76 bar), water with air

Bacterial Retention >10⁷ per cm² removal of Brevundimonas diminuta per ASTM F838

>10⁷ per cm² removal of *Acholeplasma laidlawii* per modified ASTM F838

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 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, ≥ 3 cycles.

Water wet membrane first.

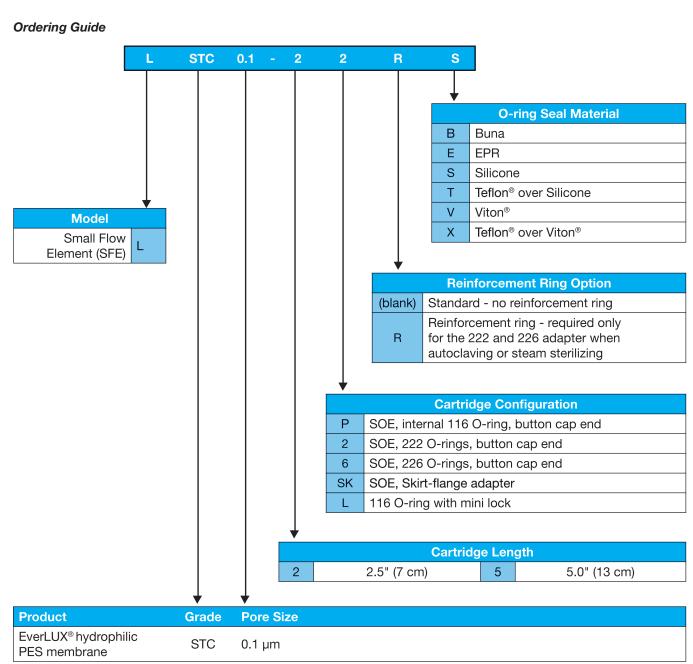
Biological Safety

EverLUX® filters meet the requirements as specified in USP 49 <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 Commission Regulation (EU) No. 10/2011.



Quality Assurance

EverLUX® STC0.1 filters are 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, lot number, and unique serial number. The serial number for all cartridge filters can be found on the product packaging.



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

