EverLUX®

0.1 µm STC-grade 25 mm Syringe Filter (CA2 Model)

Description

The EverLUX® STC0.1 capsule filter features two serially layered PES membranes, one highly asymmetric and one asymmetric, designed for 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 animal component free (ACF). These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Membrane	Polyethersulfone (PES)	CFR Title 21, 177.2440
Downstream support	Polypropylene	CFR Title 21, 177.1520
Capsule housing	Polypropylene	CFR Title 21, 177.1520
Sealing method	Thermal Bonding	

Pore Size	0.1 µm
Effective Filtration Area	3.6 cm^2
Minimum Bubble Point	36 psi (2.48 bar) in 60% IPA/40% water, with air or nitrogen 35 psi (2.41 bar) in 70% IPA/30% water, with air or nitrogen
Bacterial Retention	>10^7 cfu per cm^2 removal of *Brevundimonas diminuta* per ASTM F838 >10^7 per cm^2 removal of *Acholeplasma laidlawii* per modified ASTM F838

Operating Characteristics

Operating temperature range:	32 ºF to 100 ºF (0 °C to 38 °C)
Maximum temperature rating:	160 ºF @ 35 psig (71 °C @ 2.4 bar)
Maximum operating pressure:	80 psig @ 100 ºF (5.5 bar @ 38 ºC)
Maximum reverse pressure:	15 psig @ 100 °F (1.0 bar @ 38 ºC)

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.
Water wet membrane prior to autoclaving.
Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be in-line steam sterilized.

Biological Safety

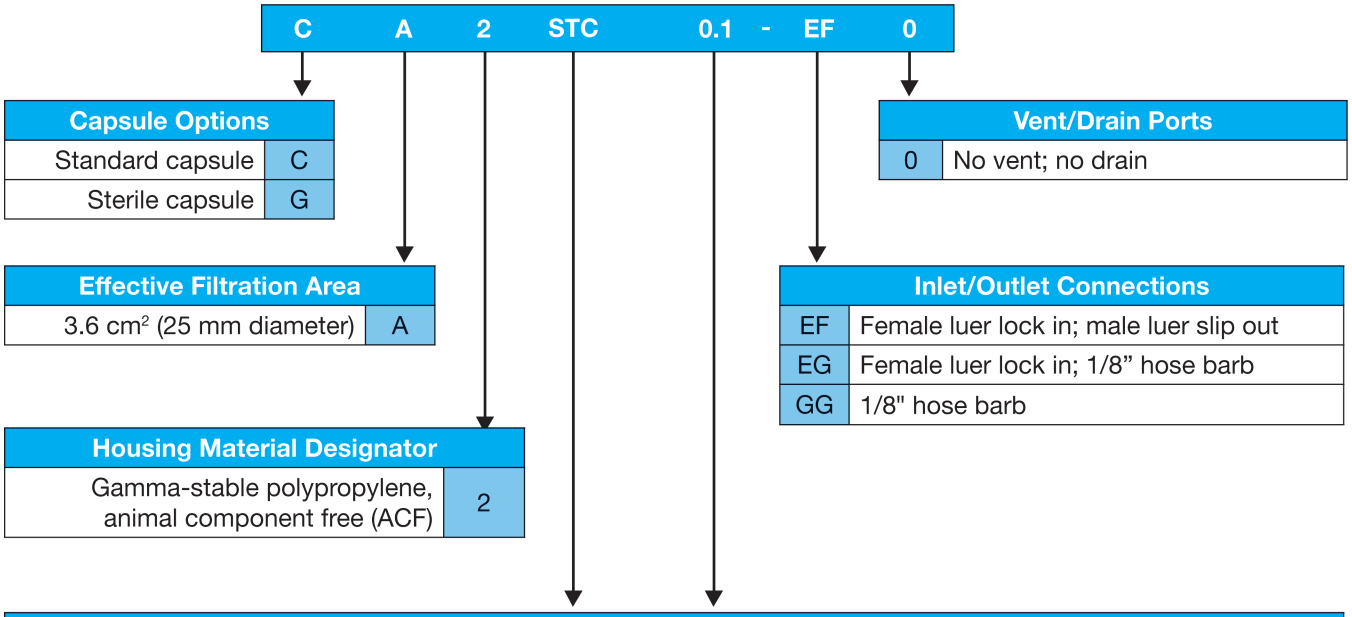
EverLUX® filters meet the requirements as specified in USP 49 <88> Class VI plastics, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of EverLUX® filters are less than 0.5 EU/mL, as determined 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. The 25 mm capsules are TSE/BSE/animal component free (ACF).

Quality Assurance

A Certificate of Quality is supplied for EverLUX® STC0.1 filters 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 serial number.

MEISSNER

Ordering Guide



Product	Grade	Pore Size
EverLUX® hydrophilic PES membrane	STC	0.1 µm

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

SSSTC06-01.A

MEISSNER
1001 Flynn Road • Camarillo, CA 93012 • USA
+1.805.388.9911 • +1.805.388.5948 Fax
www.meissner.com