

0.2 µm STS-grade 25 mm Syringe Filter (CA2 Model)

Description

The EverLUX® STS0.2 capsule filter 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 animal component free (ACF). These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

MembranePolyethersulfone (PES)CFR Title 21, 177.2440Downstream supportPolypropyleneCFR Title 21, 177.1520Capsule housingPolypropyleneCFR Title 21, 177.1520

Sealing method Thermal Bonding

 Pore Size
 0.2 μm

 Effective Filtration Area
 3.6 cm²

Minimum Bubble Point 50 psi (3.45 bar) in water with, air or nitrogen

16.3 psi (1.12 bar) in 60% IPA/40% water, with air or nitrogen 15.7 psi (1.08 bar) in 70% IPA/30% water, with air or nitrogen

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

Operating Characteristics

Operating temperature range: 32 °F to 100 °F (0 °C to 38 °C)

Maximum temperature rating: 160 °F @ 35 psig (71 °C @ 2.4 bar)

Maximum operating pressure: 80 psig @ 100 °F (5.5 bar @ 38 °C)

Maximum reverse pressure: 15 psig @ 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, \geq 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

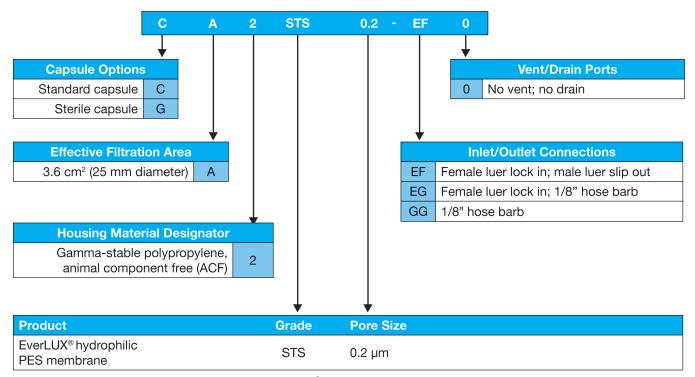
EverLUX® filters meet the requirements as specified in USP 49 <88> Class VI plastics, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of EverLUX® filters are less than 0.5 EU/mL, as determined 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 50 mm capsules are TSE/BSE/ animal component free (ACF).

Quality Assurance

A Certificate of Quality is supplied for EverLUX® STS0.2 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.



Ordering Guide



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