STyLUX®

0.1 µm ST-grade 50 mm Filter (CB2 Model)

Description

STyLUX® ST0.1 critical small scale filter is a hydrophilic PES membrane filter compatible with a wide range of liquids. It withstands a wide pH range (1-14) and can be used to remove contaminants from a broad range of pharmaceutical preparations, antibiotics, vaccines, protein solutions, virus suspensions, enzymes, serum and blood-based products, and biologicals. The filter's asymmetric structure provides bacteria and particle removal at high flow rates and low pressure drops. STyLUX® has very low binding characteristics for preservatives commonly used in the pharmaceutical industry.

The STyLUX® ST0.1 critical small scale filter is 100% integrity tested during manufacture and has the added benefit of quality certification that meets the critical demands of the pharmaceutical, biotechnology and related industries.

Materials of Construction

All components of the encapsulated discs are animal component free. 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	19.6 cm^2
Minimum Bubble Point	30 psi (2.07 bar), 60% IPA/40% water 27 psi (1.86 bar), 70% IPA/30% water
Bacterial Retention	>10^7 cfu per cm^2 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)

Sterilization

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

Biological Safety

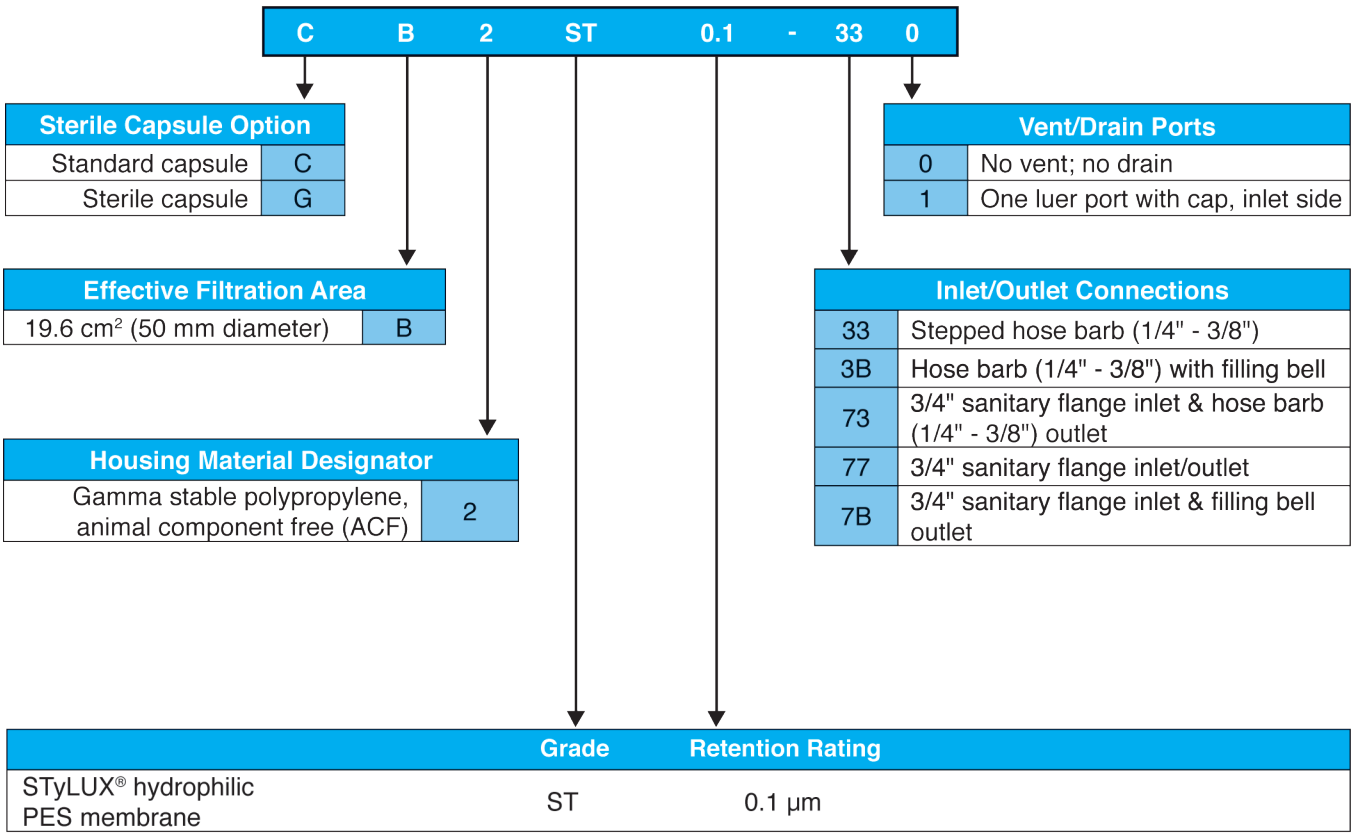
STyLUX® filters meet the requirements as specified in the current USP <88> Class VI plastics, physicochemical, oxidizable substances, and USP <87> cytotoxicity tests. Bacterial endotoxin levels in aqueous extracts of STyLUX® filters are less than 0.5 EU/mL as determined using the *Limulus* amebocyte lysate (LAL) test USP <85>. No binders, adhesives or surfactants are used in the construction of the filters. Filters comply with European Commission Regulation No 10/2011. The 50 mm capsules are TSE/BSE/animal component free (ACF).

Quality Assurance

A Certificate of Quality is supplied for STyLUX® ST0.1 filters verifying the high standards and superior performance of the product. 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 STyLUX® filter is integrity tested during manufacture and is clearly marked with filter type, lot number and serial number.

MEISSNER FILTRATION PRODUCTS

Ordering Guide



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

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