

0.2 μm SM-grade Large Capsule Filter (UltraCap® H.D. Model)

Description

The STyLUX® SM-grade 0.2 µm is a hydrophilic PES membrane filter compatible with a wide range of liquids. It withstands a wide pH range (1-14) and is recommended for sterilizing filtration and bioburden reduction of pharmaceutical preparations, active ingredients, biopharmaceuticals, parenterals, vaccines, biologicals including dilute protein solutions, cell and tissue culture media, media additives, ophthalmic and other dilute preservative solutions, UPW, chemicals, and alcohols. The filter's asymmetric membrane provides absolute retention, while also providing superior flow rates and contaminant capacity.

Materials of Construction

All components of the STyLUX® filter capsule are either animal component free or in compliance with EMEA/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:

Filter Membrane: Polyethersulfone CFR Title 21, 177.2440
Up/Downstream support: Polypropylene CFR Title 21, 177.1520
Core, guard, end caps: Polypropylene CFR Title 21, 177.1520
Capsule shell: Polypropylene CFR Title 21, 177.1520

Sealing Method: Thermal Bonding

Pore Size 0.2 μm

Minimum Bubble Point 44 psi (3.03 bar), water

16 psi (1.10 bar), 60% IPA/40% water 15 psi (1.03 bar), 70% IPA/30% water

Maximum Diffusion Rate 30 mL/min per 10" (25 cm) @ 35 psi (2.41 bar), water

Typical Water Flow Rate 0.3 psid/gpm per 10" (1.8 L/min @ Δp 10 mbar per 25 cm), with 1" (25 mm) inlet/outlet

Capsule body style and I/O selection may affect pressure drop and flow rate.

Operating Characteristics

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

Maximum temperature rating: 140 °F @ 55 psig (60 °C @ 3.8 bar), liquid service Maximum operating pressure: 90 psig @ 100 °F (6.2 bar @ 38 °C), liquid service

Maximum reverse pressure: 15 psig @ 100 °F (1.0 bar @ 38 °C)

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

Sterilization

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

Biological Safety

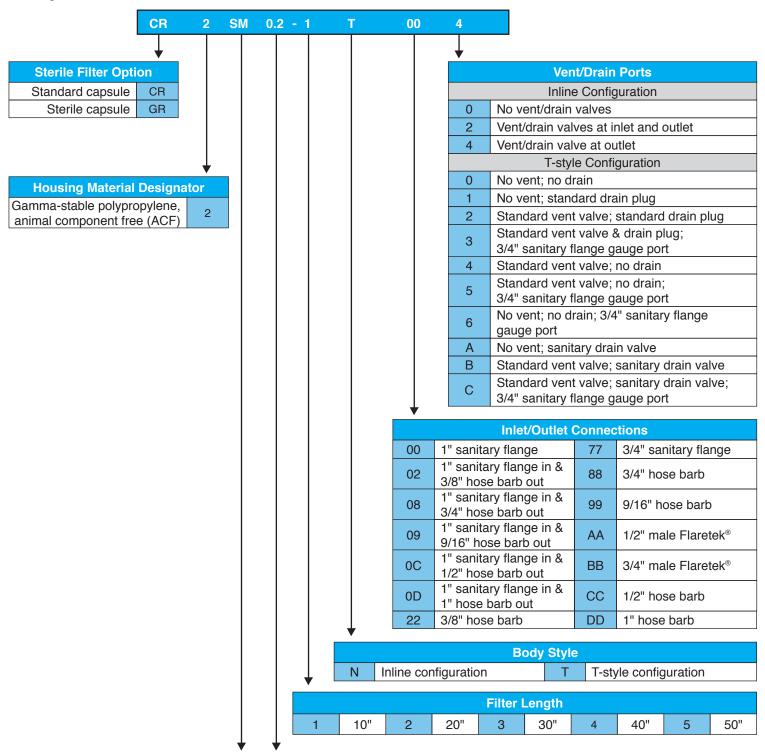
STyLUX® filters meet the requirements as specified in the current USP <88> Class VI plastics, physicochemical, oxidizable substances, and USP <87> cytotoxicity tests. Bacterial endotoxin levels in aqueous extracts of STyLUX® filters are less than 0.5 EU/mL, as determined using the Limulus amebocyte lysate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

Quality Assurance

STyLUX® 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.



Ordering Guide



Product	Filter Grade	Retention Rating	Effective Filtration Area
STyLUX® hydrophilic PES membrane	SM	0.2 μm	7.3 ft² (0.68 m²) per 10" (25 cm)

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

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