



0.2 µm SM-grade Medium Capsule Filter (CF/CF2 Model)

Description

The STyLUX® SM0.2 capsule filter 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, antibiotics, vaccines, protein solutions, virus suspensions, enzymes, buffers, ophthalmic solutions, reagents, salt solutions, nutrients, serum and blood-based products, biologicals, and wine and beverages. The filter's asymmetric membrane provides absolute retention, superior flow rates and contaminant capacity.

Materials of Construction

All components of the filter are either animal component free (ACF) or in compliance with EMA/410/01 Rev. 3 (EDQM 5.2.8 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 (PES)	CFR Title 21, 177.2440
Up/downstream support:	Polypropylene	CFR Title 21, 177.1520
Core, outer 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) in water, with air or nitrogen
16 psi (1.10 bar) in 60% IPA/40% water, with air or nitrogen
15 psi (1.03 bar) in 70% IPA/30% water, with air or nitrogen

Maximum Diffusion Rate 3 mL/min @ 35 psi (2.41 bar), water with air

Typical Water Flow Rate 1.2 psid @ 1 L/min (0.12 L/min @ Δp 10 mbar)

Bacterial Retention >10⁷ 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:	75 psig @ 100 °F (5.2 bar @ 38 °C), liquid service
Maximum operating pressure:	50 psig @ 100 °F (3.4 bar @ 38 °C), gas service
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 min, ≥ 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

STyLUX® filters meet the requirements as specified in USP 43 <88> Class VI plastics, <87> cytotoxicity, physicochemical, and USP 43 oxidizable substances tests. Bacterial endotoxin levels in aqueous extracts of STyLUX® filters are less than 0.5 EU/mL, as determined using the current USP <85> *Limulus* amoebocyte lysate (LAL) test. No binders, adhesives, or surfactants are used in the construction of STyLUX® filters. Filters comply with Commission Regulation (EU) 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 unique serial number.

Ordering Guide

C F 2 SM 0.2 - 33 B 2			
Capsule Options Standard capsule C Sterile capsule G		Vent/Drain Ports 0 No vent/drain port 1 One luer port with cap, outlet side 2 Standard; two luer ports with caps 4 Two sanitary valves with hose barbs 5 One sanitary valve with hose barb, outlet side 6 One sanitary valve with hose barb, inlet side	
Housing Material Designator Standard polypropylene (blank) Gamma-stable polypropylene, animal component free (ACF) 2		Effective Filtration Area B 0.70 ft ² (650 cm ²)	
		Inlet/Outlet Connections 33 Stepped barb (1/4" - 3/8") 44 1/4" MNPT 3B Stepped barb (1/4" - 3/8") in; with filling-bell out 73* 3/4" sanitary flange in; stepped barb outlet 41 1/4" MNPT inlet, 1/4" hose barb outlet 77* 3/4" sanitary flange	
Product		Grade	Pore Size
STyLUX® hydrophilic PES membrane		SM	0.2 µm

*3/4" sanitary flange fitting option is only available for CF2 Capsules.

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