STyLUX®

0.4 µm ST-grade Standard Capsule Filter — CS(2), CL(2), CJ2 Model

Description

The STyLUX® ST0.4 capsule 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 for sterile filtration and bioburden reduction of a broad range of pharmaceutical preparations, antibiotics, vaccines, protein solutions, virus suspensions, enzymes, buffers, ophthalmic solutions, reagents, salt solutions, nutrients, serum and blood-based products, and biologicals. The filter's asymmetrical 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 and is compatible with most cleaning chemicals, sanitizers, and biocides.

The 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 filter are either animal component free 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:

Membrane:	Polyethersulfone	CFR Title 21, 177.2440
Upstream support:	Polypropylene	CFR Title 21, 177.1520
Downstream support:	Polypropylene	CFR Title 21, 177.1520
Outer guard:	Polypropylene	CFR Title 21, 177.1520
Core:	Polypropylene	CFR Title 21, 177.1520
End caps:	Polypropylene	CFR Title 21, 177.1520
Capsule housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.4 µm

Minimum Bubble Point
32 psi (2.2 bar) in water, with air or nitrogen
10 psi (0.69 bar) in 60% IPA/40% water, with air or nitrogen
9 psi (0.62 bar) in 70% IPA/30% water, with air or nitrogen

Maximum Diffusion Rate
CS: 5.5 mL/min @ 25 psi (1.72 bar), water, with air
CL: 11.3 mL/min @ 25 psi (1.72 bar), water, with air
CJ: 17 mL/min @ 25 psi (1.72 bar), water, with air

Typical Water Flow Rate
CS: 1.04 gpm @ 1 psid (0.571 L min^{-1} at Δp 10 mbar)
CL: 1.46 gpm @ 1 psid (0.801 L min^{-1} at Δp 10 mbar)
CJ: 1.92 gpm @ 1 psid (1.05 L min^{-1} at Δp 10 mbar)
Capsule inlet/outlet selection may affect pressure drop and flow rate

Bacterial Retention >10^7 per cm^2 removal of *Serratia marcescens* per modified 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 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.

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Biological Safety

STyLUX® filters meet the requirements as specified in the current USP <88> Class VI plastics, <87> cytotoxicity, pyrogenicity, and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of STyLUX® 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 STyLUX® filters. Filters comply with Commission Regulation (EU) No. 10/2011.

Quality Assurance

STyLUX® ST0.4 filters are supplied with a Certificate of Quality verifying the high standards and superior performance of the product. 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

C	S	2	ST	0.4 - 00	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

Effective Filtration Area	
1.6 ft² (0.15 m²)	S
3.3 ft² (0.31 m²)	L
5.2 ft² (0.48 m²)	J

Inlet/Outlet Connections			
00	1" sanitary flange	2B	3/8" hose barb with filling bell
02	1" sanitary flange in; 3/8" hose barb out	72**	¾" sanitary flange in; 3/8" hose barb out
09	1" sanitary flange in; ½" hose barb out (flexible tubing)	77**	¾" sanitary flange
LL	1" sanitary flange, long neck	88	¾" hose barb
22	3/8" hose barb	99	½" hose barb

Housing Material Designator	
Standard polypropylene	(blank)
Gamma-stable polypropylene, animal component free (ACF)	2*

Product	Grade	Pore Size
STyLUX® hydrophilic PES membrane	ST	0.4 µm

**CJ2 filters are animal component free (ACF) and only available with a gamma-stable polypropylene housing.*
***3/4 sanitary flange fitting option is only available for CS2, CL2, and CJ2 capsules.*
Additional information about this filter product is available in the STyLUX® Green Docs document at www.meissner.com/green-docs.

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