

STyLUX®

0.04 µm ST-grade Large Capsule Filter (UltraCap® H.D. Model)

Description

The STyLUX® 0.04 µm 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, buffers, ophthalmic solutions, reagents, salt solutions, nutrients, 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, and is compatible with most cleaning chemicals, sanitizers, and biocides. The ST-grade filter provides the added benefit of certification that meets the critical demands of the pharmaceutical, biotechnology and related industries.

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, outer guard, end caps:	Polypropylene	CFR Title 21, 177.1520
Capsule shell:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.04 µm

Minimum Bubble Point 38 psi (2.62 bar), 60% IPA/40% water; 37 psi (2.55 bar), 70% IPA/30% water

Maximum Diffusion Rate 30 mL/min per 10" (25 cm) @ 45 psi (3.10 bar), water

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

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 temperature rating:	140 °F @ 35 psig (2.1 bar), gas service
Maximum operating pressure:	90 psig @ 100 °F (6.2 bar @ 38 °C), liquid service
Maximum operating pressure:	60 psig @ 100 °F (4.1 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 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* amoebocyte 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

CR 2 ST 0.04 - 1 T 00 4

Sterile Filter Option	
Standard capsule	CR
Sterile capsule	GR

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

Vent/Drain Ports	
Inline Configuration	
0	No vent/drain valves
2	Vent/drain valves at inlet and outlet
4	Vent/drain valve at outlet
T-style Configuration	
0	No vent; no drain
1	No vent; standard drain plug
2	Standard vent valve; standard drain plug
3	Standard vent valve & drain plug; 3/4" sanitary flange gauge port
4	Standard vent valve; no drain
5	Standard vent valve; no drain; 3/4" sanitary flange gauge port
6	No vent; no drain; 3/4" sanitary flange gauge port
A	No vent; sanitary drain valve
B	Standard vent valve; sanitary drain valve
C	Standard vent valve; sanitary drain valve; 3/4" sanitary flange gauge port

Inlet/Outlet Connections			
00	1" sanitary flange	77	3/4" sanitary flange
02	1" sanitary flange in & 3/8" hose barb out	88	3/4" hose barb
08	1" sanitary flange in & 3/4" hose barb out	99	9/16" hose barb
09	1" sanitary flange in & 9/16" hose barb out	AA	1/2" male Flaretek®
0C	1" sanitary flange in & 1/2" hose barb out	BB	3/4" male Flaretek®
0D	1" sanitary flange in & 1" hose barb out	CC	1/2" hose barb
22	3/8" hose barb	DD	1" hose barb

Body Style	
N	Inline configuration
T	T-style configuration

Filter Length									
1	10"	2	20"	3	30"	4	40"	5	50"

Product	Filter Grade	Retention Rating
STyLUX® hydrophilic PES membrane	ST	0.04 µm

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

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