STyLUX®

0.2 µm ST-grade Small Filter Cartridge (L model)

Description

The STyLUX® ST0.2 is a hydrophilic polyethersulfone (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, biologicals, wine, and beverages. 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 STyLUX® ST0.2 small filter cartridge, or small flow element (SFE), 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 STyLUX® filter 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:

Membrane:	Polyethersulfone (PES)	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
O-rings:	Typically Silicone	CFR Title 21, 177.2600
Sealing method:	Thermal bonding	

Pore Size 0.2 µm

Minimum Bubble Point 44 psi (3.0 bar), water

Maximum Diffusion Rate 2" (0.15 m^2): 7 mL/min @ 35 psi (2.41 bar), water
5" (0.31 m^2): 14 mL/min @ 35 psi (2.41 bar), 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:	180 °F @ 30 psid (82 °C @ 2.1 bar)
Maximum operating pressure:	80 psid @ 100 °F (5.5 bar @ 38 °C)
Maximum reverse pressure:	15 psid @ 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 minutes, ≥ 3 cycles. Water wet membrane prior to autoclaving.
Steam-in-place (SIP): 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles. Water wet membrane first.

Biological Safety

STyLUX® filters meet the requirements as specified in the current USP <88> Class VI plastics, physiocochemical, 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.

MEISSNER FILTRATION PRODUCTS

Quality Assurance

Each STyLUX® ST0.2 is supplied with a Certificate of Quality 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 and lot number.

Ordering Guide

L	ST	0.2	-	5	2	R	S

Model	
Small Flow Element (SFE)	L

O-ring Seal Material	
B	Buna
E	EPR
S	Silicone
T	Teflon® over Silicone
V	Viton®
X	Teflon® over Viton®

Reinforcement Ring Option	
(blank)	Standard - no reinforcement ring
R	Reinforcement ring - required only for the 222 and 226 adapter when autoclaving or steam sterilizing

Cartridge Configuration	
P	SOE, internal 116 O-ring, button cap end
2	SOE, 222 O-rings, button cap end
6	SOE, 226 O-rings, button cap end
SK	SOE, Skirt-flange adapter (reinforcement or O-ring not required)
L	116 O-ring with Mini Lock

Cartridge Length			
2	2.5" (7 cm)	5	5.0" (13 cm)

Product	Grade	Pore Size
STyLUX® hydrophilic PES membrane	ST	0.2 µm

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

SSST05-05.A

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