STyLUX®

SM0.2 Cartridge

Description

The STyLUX® SM0.2 hydrophilic filter capsule is manufactured using high quality components that are nontoxic and biologically inert.

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:

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
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: 30 mL/min per 10" @ 35 psi, water (30 mL min^{-1} per 25 cm @ 2,4 bar, water)

Typical Water Flow Rate: 0.25 psid/gpm per 10" (2,2 L min^{-1} at Δp 10 mbar per 25 cm)

Operating Characteristics

100°F @ 80 psid	150°F @ 60 psid	180°F @ 30 psid
(38°C @ Δp 5,5 bar)	(66°C @ Δp 4,1 bar)	(82°C @ Δp 2,1 bar)

Bacterial Retention

>10^7 per cm^2 removal of *Brevundimonas diminuta* per ASTM F838-05

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.
Steam in place: 121 to 135°C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 3 cycles, water wet membrane first.

Biological Safety

STyLUX® filters meet the requirements as specified in the current USP Class VI plastics, physicochemical, oxidizable substances, and 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. 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 and lot number.

MEISSNER FILTRATION PRODUCTS

Ordering Guide

SM	0.2	-	1	C2	R	S

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 for autoclave/SIP applications

Cartridge Configuration	
C2	SOE, 222 O-rings, button cap end
C6	SOE, 226 O-rings, button cap end
F2	SOE, 222 O-rings, fin end
F6	SOE, 226 O-rings, fin end

Cartridge Length							
1	10"	2	20"	3	30"	4	40"

Filter Code	Retention Rating
SM	0.2

Additional information about STyLUX® filter products is available in the Green Docs document which is viewable at
http://www.meissner.com/downloads/stylux-gd001-2.0.pdf

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