EverLUX®

0.2 µm STS-grade Large Capsule Filter UltraCap® H.D.

Description

The EverLUX® STS0.2 features two serially layered, asymmetric, hydrophilic PES membranes with the coarser, highly asymmetric upstream layer optimized for prefiltration and an asymmetric downstream layer. This advanced PES membrane filter provides high contaminant capacity, extended service life, and high flow rates when filtering a wide range of aqueous and biological liquids, and is ideal for sterilization and bioburden reduction in a range of low-to-high contaminant liquids, including pharmaceutical preparations, biopharmaceuticals, parenterals, vaccines, complex biologicals, serum, cell and tissue culture media, buffers, media additives, supernatants, process intermediate, ophthalmic and other dilute preservative solutions, UPW, chemicals, alcohols and sanitizing agents.

The EverLUX® STS0.2 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 EverLUX® filter capsule are either animal 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:

Membranes:	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
Capsule shell:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size (Absolute) 0.2 µm

Minimum Bubble Point 50 psi (3.45 bar), water
16.3 psi (1.12 bar), 60% IPA / 40% water
15.7 psi (1.08 bar), 70% IPA / 30% water

Maximum Diffusion Rate 28 mL/min per 10" (25 cm) @ 35 psi (2.41 bar), water

Bacterial Retention $>10^7$ 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: 140 °F @ 55 psig (60 °C @ 3.8 bar) liquid, @ 35 psig (2.4 bar) gas
Maximum operating pressure (liquid service): 90 psig @ 100 °F (6.2 bar @ 38 °C)
Maximum operating pressure (gas service): 60 psig @ 100 °F (4.1 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.
Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be steamed in place (SIP).

Biological Safety

EverLUX® 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 EverLUX® 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 EverLUX® filters. Filters comply with Commission Regulation (EU) No 10/2011.

MEISSNER FILTRATION PRODUCTS

Quality Assurance

Each EverLUX® STS0.2 is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. EverLUX® 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 EverLUX® filter is integrity tested during manufacture and is clearly marked with filter type, lot number and serial number.

Ordering Guide

CR	2	STS	0.2	–	1	T	00	4

Sterile Filter Option	
Standard; non-sterile	CR
Presterilized	GR

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

Vent/Drain Ports	
Inline Configuration	
0	No vents/ drains
2	Vent/drain at inlet and outlet
4	Vent/drain at outlet
T-style Configuration	
0	No vent; no drain
1	No vent; standard 1/4" drain plug
2	Std. vent valve; std. drain plug
3	Std. vent & drain plug; 3/4" TC gage port
4	Std. vent; no drain
5	Std. vent; no drain; gage port
6	No vent; no drain; gage port
A	No vent; sanitary drain valve
B	Std. vent; sanitary drain valve
C	Std. vent; san. drain valve; gage port

Inlet / Outlet Connections			
00	1" sanitary (TC) flange	77	3/4" sanitary flange
02	1" TC in & 3/8" hose barb out	88	3/4" hose barb
08	1" TC in & 3/4" hose barb out	99	9/16" hose barb
09	1" TC in & 9/16" hose barb out	AA	1/2" male Flaretek®
0C	1" TC in & 1/2" hose barb out	BB	3/4" male Flaretek®
0D	1" TC 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
EverLUX® PES membrane (hydrophilic)	STS	0.2

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

SSSTS05-02.A

MEISSNER FILTRATION PRODUCTS
1001 Flynn Road • Camarillo, CA 93012 • USA
+1.805.388.9911 • +1.805.388.5948 Fax
www.meissner.com