

EverLUX[®]

0.6 µm SMH-grade Large Capsule Filter (UltraCap[®] H.D. Model)

Description

The EverLUX[®] is an advanced PES membrane filter that provides high contaminant capacity, extended service life, and flow rates when filtering a wide range of aqueous and biological liquids. This hydrophilic filter is ideal for 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 additives, supernatants, process intermediate, ophthalmic and other dilute preservative solutions, UPW, chemicals, alcohols and sanitizing agents.

Materials of Construction

All components of the EverLUX[®] 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:

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

Pore Size 0.6 µm

Minimum Bubble Point 22 psi (1.5 bar), water

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

EverLUX[®] 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 EverLUX[®] 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 EverLUX[®] filters. Filters comply with European Commission Regulation No 10/2011.

Quality Assurance

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 SMH 0.6 - 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
EverLUX® hydrophilic PES membrane	SMH	0.6 µm

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

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