EverLUX®



ESSNER
FILTRATION PRODUCTS, INC.

EverLUX® Filter Cartridge

The EverLUX® polyethersulfone (PES) filter is designed for very high contaminant capacity, extended service life and high flow with low pressure drop in a wide range of biological fluids.

Optimized for sterile filtration, prefiltration and clarification applications, the permanently hydrophilic EverLUX® filter offers up to 2.5 times higher flow rates than other PES membranes. It also offers exceptional capacity, low protein binding and absolute bacteria retention when filtering moderate to high contaminant liquids.

The EverLUX® filter incorporates the most technologically advanced PES membrane manufactured today. It is produced by a state-of-the art process, which creates a unique, highly asymmetric structure with the highest contaminant capacity of any PES filter.

The membrane's asymmetric structure extends its capacity and service life by withstanding higher particle loads and protein concentrations. Increased membrane thickness allows the EverLUX® to retain its sterilizing properties, while its tapered pore structure allows more contaminant capacity than even conventional PES membranes.

The fast-flowing, high-throughput, low-binding and bacteria-retentive properties of the EverLUX® PES membrane make it a very reliable, cost-effective and time-saving filter.



Design Features and Benefits

- Unique, patented PES membrane offers very high flow rates and exceptional service life
- · Chemical compatibility across pH 1-14
- Low adsorption, high transmission of proteins, active ingredients and preservatives
- Superior throughput in high contaminant fluids, including growth media, serum and protein-containing solutions
- Lower filtration costs through increased service life and contaminant-holding capacity
- · Permanently hydrophilic membrane
- · Contains no binders, adhesives or other extraneous materials
- 100% integrity tested during manufacture
- Biologically inert and non-toxic, the filter meets FDA requirements for food contact use and passes USP Class VI Plastics biological reactivity tests
- Filters comply with European Commission Directive 2002/72/EC and subsequent amendments up to 2008/39/EC

Typical Applications

EverLUX® filters are ideal for use in a range of low to high contaminant liquids, including:

- · Blood products
- · Complex biologicals
- Serum
- · Cell and tissue culture media
- · Process intermediates
- Supernatants
- Vaccines
- · Ophthalmics
- Buffers



Materials of Construction

Filter Membrane: Polyethersulfone (PES) Upstream Support: Polypropylene Downstream Support: Polypropylene Core/Outer Guard: Polypropylene

End Caps: Polypropylene

Sealing Method: Thermal bonding

O-ring/Gasket Seal: Buna, EPR, polyethylene, silicone,

Teflon® over silicone, Teflon® over Viton®

All materials of construction listed above are FDA approved for food contact use per 21 CFR 177. Filters comply with European Commission Directive 2002/72/EC and subsequent amendments up to 2008/39/EC.

EverLUX® filters are manufactured in conformance to cGMP. 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. EverLUX® filters are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72.

Filtration Ratings

Filter Grade: Absolute Ratings (µm):

SMH 0.2, 0.4, 0.6

STW 0.2

SLH 0.2, 0.4, 0.6

SLW 0.2

SPH 0.1, 0.2, 0.4

Integrity Testing

Minimum Bubble Point, Water

SMH

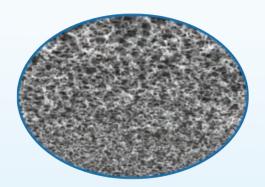
0.2 μm 62 psi (4,3 bar) 0.4 μm 40 psi (2,8 bar) 0.6 μm 22 psi (1,5 bar)

Maximum Diffusion Rate, Water

STW

0.2 μm 30 mL/min per 10" @ 30 psi

(30 mL min⁻¹ per 25 cm @ 2,07 bar)



EverLUX® SEM

Cartridge Dimensions (nominal)

Diameter: 2.75" (7 cm) Lengths: 10", 20", 30", 40" (25 cm, 50 cm, 75 cm, 100 cm)

Bacterial Retention

ASTM F838-05 Challenge

SMF

0.4 μm > 10⁷ cfu/cm² Serratia marcescens 0.6 μm > 10⁷ cfu/cm² Saccharomyces cerevisiae

STW

 $0.2 \ \mu m > 10^7 \ cfu/cm^2 \ Brevundimonas \ diminuta$ and meets the FDA definition of a sterilizing grade filter.

Sterilization

Steam-in-place (SIP):

saturated steam @ 121-135 °C, 30-60 minutes [15 psi (1bar) to 30 psi (2 bar), 30-60 minutes]

Autoclave: 121-135 °C, 30-60 minutes

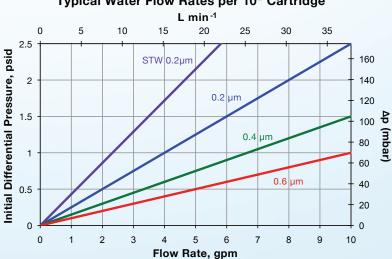
EverLUX® cartridges are capable of repeated sterilization cycles without loss of integrity. For applications requiring autoclave/SIP, a stainless steel reinforcement ring must be ordered. See "Reinforcement Ring Option" within Ordering Information.

Maximum Operating Temperatures and Pressures

 Δ p 80 psi @ 32 °F to 100 °F (Δ p 5,5 bar @ 0 °C to 38 °C)

Δp 60 psi @ 150 °F (Δp 4,1 bar @ 66 °C) Δp 30 psi @ 180 °F (Δp 2,1 bar @ 82 °C)

Typical Water Flow Rates per 10" Cartridge



End Cap Configuration



External -226 O-rings with locking tabs; open end for C6 and F6 SOE configurations



External -222 O-rings; open end for C2 and F2 SOE configurations



External -226 nO-Ring® with locking tabs; open end for C5 and F5 SOE configurations



External -222 nO-Ring®, open end for C1 and F1 SOE configurations



Flat Gasket; open end for GS and GL DOE configurations



Internal O-ring; open end for DN and DA DOE or RN and RA SOE configurations



Button Cap; closed end for C1, C2, C5 and C6 SOE configurations



Alignment Fin; closed end for F1, F2, F5 and F6 SOE configurations



Recessed Cap; closed end for RN and RA SOE configurations

DOE = Double Open End SOE = Single Open End

Ordering Information

Filter Grade	Absolute Rating (µm)	Cartridge Length	End Cap Configuration	Reinforcement Ring Option	Seal Material (O-ring or Gasket)
SMH	0.2 –	- 3	F2	R	S
SMH	0.2, 0.4, 0.6	1 = 10" (25 cm)	GS = DOE; flat gaskets (9.75", 19.5", 29.25", 39" length filters)	(Blank) = Standard - no reinforcement ring	O-ring Seal B = Buna
STW	0.2	2 = 20" (50 cm)	GL = DOE; flat gaskets (20", 30", 40" length filters)	R = Reinforcement ring;	E = EPR S = Silicone
SLH	0.2, 0.4, 0.6	3 = 30" (75 cm)	C1 = SOE; -222 nO-Ring®, button cap end C2 = SOE; -222 O-rings, button cap end	required for autoclave/ SIP applications	T = Teflon® over silicone V = Viton®
SLW	0.2	4 = 40" (100 cm)	F1 = SOE; -222 nO-Ring®, fin end F2 = SOE; -222 O-rings, fin end		X = Teflon® over Viton®
SPH	0.1, 0.2, 0.4		C5 = SOE; -226 nO-Ring®, button cap endC6 = SOE; -226 O-rings, button cap end		Gasket Seal B = Buna
			F5 = SOE; -226 nO-Ring®, fin end		E = EPR
			F6 = SOE; -226 O-rings, fin end		P = Polyethylene
			DN = DOE; internal -120 O-rings		S = Silicone
			RN = SOE; internal -120 O-rings,		T = Teflon®
			recessed cap end		V = Viton®
			DA = DOE; internal -213 O-rings		
			RA = SOE; internal -213 O-rings,		

Grade Descriptions

SMH = This standard, single layer PES membrane features a highly asymmetric pore structure. It is 100% integrity tested and flushed during manufacture. It is suited for critical applications when regulatory documentation requirements are minimal.

recessed cap end

STW = This pharmaceutical validated, sterilizing grade filter features two serially layered, highly asymmetric PES membranes with the coarser upstream layer optimized for prefiltration. This filter meets full traceability requirements for the pharmaceutical industry. Each STW filter is shipped with a Certificate of Quality stating exact quality control criteria and test performance results. SLH = This single layer PES membrane features a highly asymmetric pore structure, but is not 100% integrity tested or flushed during

manufacture. It is offered as an economical pre-filter or final filer when sterility assurance is not required.

SLW = This filter features two serially layered, highly asymmetric PES membranes with the coarser upstream layer optimized for prefiltration. This filter is not 100% integrity tested or flushed during manufacture. It is offered as an economical pre-filter or final

filter that provides longer life in biological solutions.

SPH = This is an absolute, particulate rated filter. It is 100% integrity tested and DI flushed during manufacture.

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