EverLUX®

0.2 µm STS-grade Mini Capsule Filter (CM2, CK2 Model)

Description

The EverLUX® STS0.2 capusle filter is an advanced PES membrane filter that features a highly asymmetric PES membrane layered over an asymmetric PES membrane for an optimized pre- and final filtration combination. The filter is 100% integrity tested during manufacture and has the added benefit of certification that meets the critical needs of the pharmaceutical, biotechnology, and related industries.

Materials of Construction

All components of the filter are animal component free (ACF). 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
Capsule shell:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 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 CM: 0.28 ft^2: 1.2 mL/min @ 35 psi (2.41 bar), water
CK: 0.35 ft^2: 1.4 mL/min @ 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 122 °F (0 °C to 50 °C)
Maximum temperature rating:	160 °F @ 35 psig (72 °C @ 2.4 bar)
Maximum operating pressure:	100 psig @ 122 °F (6.9 bar @ 50 °C)
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.
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, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of EverLUX® filters are less than 0.5 EU/mL, as determined using the current USP <85> *Limulus* amebocyte lysate (LAL) test. No binders, adhesives, or surfactants are used in the construction of EverLUX® filters. Filters comply with European Commission Regulation (EU) No. 10/2011.

Quality Assurance

The EverLUX® STS0.2 filter 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.

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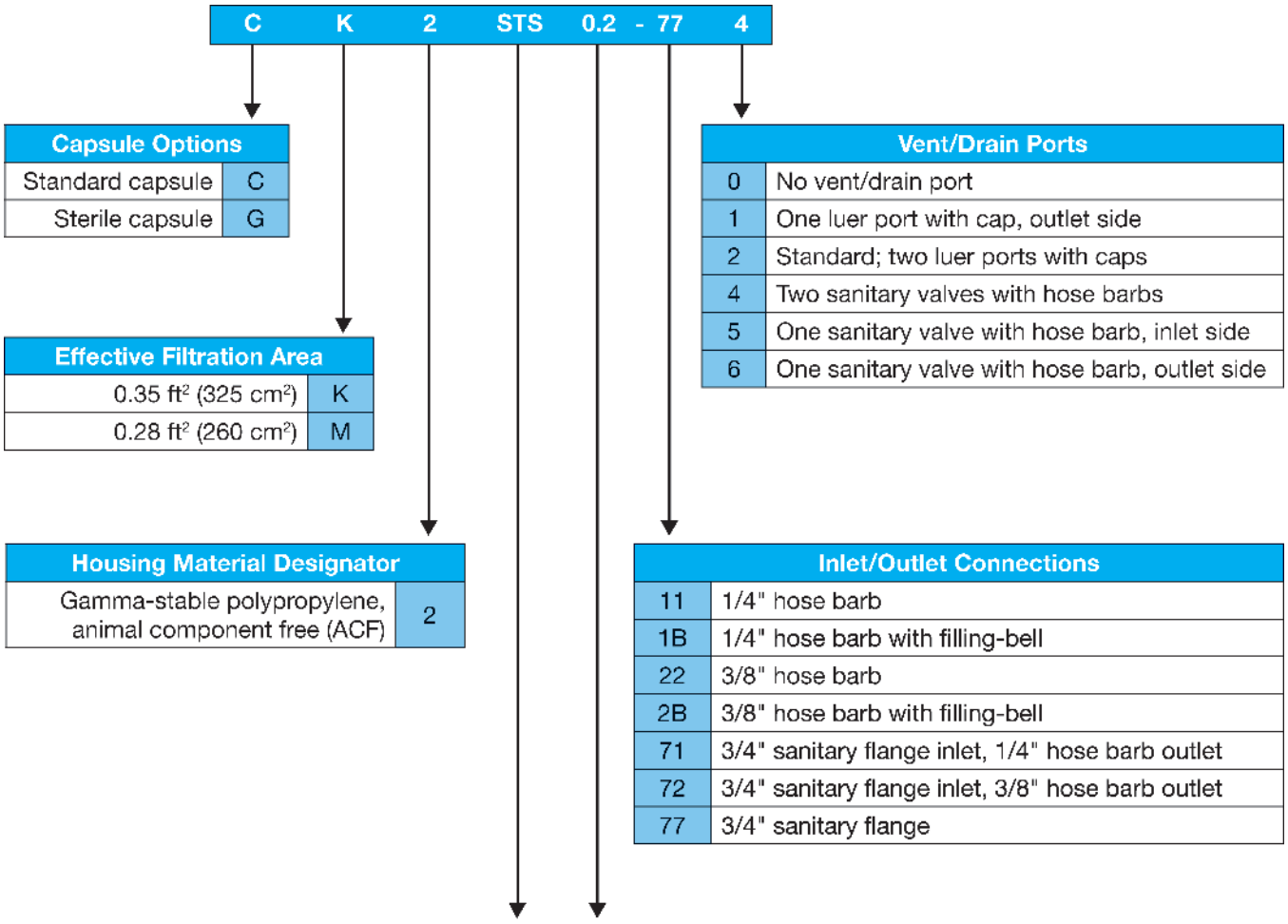
Ordering Guide



Capsule Options	
Standard capsule	C
Sterile capsule	G

Effective Filtration Area	
0.35 ft² (325 cm²)	K
0.28 ft² (260 cm²)	M

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

Vent/Drain Ports	
0	No vent/drain port
1	One luer port with cap, outlet side
2	Standard; two luer ports with caps
4	Two sanitary valves with hose barbs
5	One sanitary valve with hose barb, inlet side
6	One sanitary valve with hose barb, outlet side

Inlet/Outlet Connections	
11	1/4" hose barb
1B	1/4" hose barb with filling-bell
22	3/8" hose barb
2B	3/8" hose barb with filling-bell
71	3/4" sanitary flange inlet, 1/4" hose barb outlet
72	3/4" sanitary flange inlet, 3/8" hose barb outlet
77	3/4" sanitary flange

Product	Grade	Pore Size
EverLUX® hydrophilic PES membrane	STS	0.2 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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