STyLUX®

0.6 µm SM-grade Mini Capsule Filter (CM2/CK2 Model)

Description

The STyLUX® SM0.6 mini capsule filter is a hydrophilic PES membrane filter compatible with a wide range of liquids. It withstands a wide pH range (1-14) and is suited for removal of microorganisms and particulates in high-purity liquids and aqueous chemicals. The filter's asymmetric membrane provides absolute retention and also superior flow rates and contaminant capacity. The STyLUX® filter delivers reliable and consistent high-quality performance and is ideal for prefiltration or final filtration when sterility assurance is not required.

Materials of Construction

All components of the STyLUX® mini capsule are animal component free. 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 housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.6 µm

Minimum Bubble Point 18 psi (1.2 bar), water
6 psi (0.4 bar) 70% IPA/30% water

Bacterial Retention >10^7 cfu per cm^2 removal of *Saccharomyces cerevisiae* per modified ASTM F838

Operating Characteristics

Operating temperature range:	32 ºF to 122 ºF (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 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 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

STyLUX® 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 STyLUX® 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 STyLUX® filters. Filters comply with Commission Regulation (EU) No 10/2011. STyLUX® CM2/CK2 capsules are TSE/BSE animal component free (ACF).

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, lot number, and serial number.

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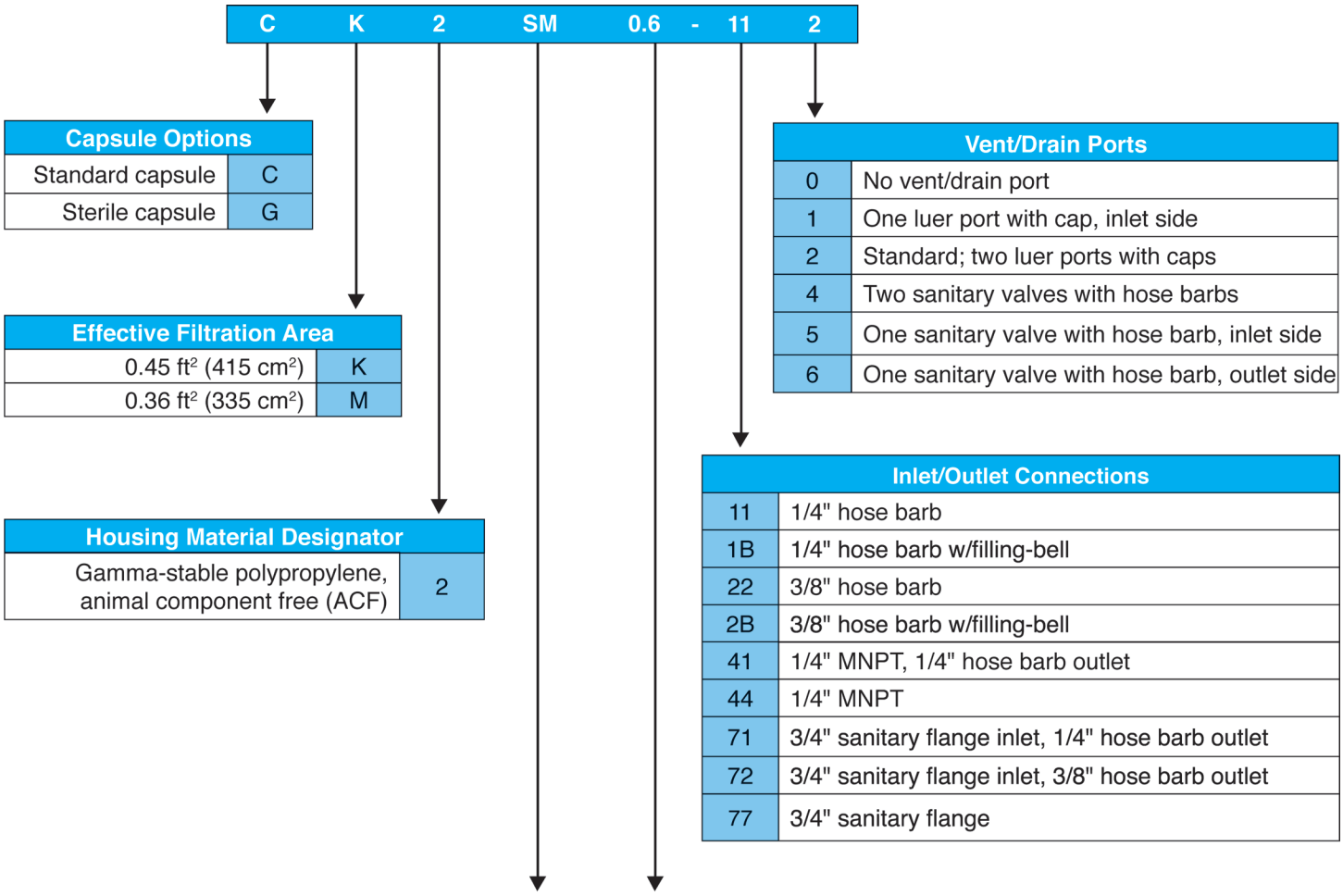
Ordering Guide



Capsule Options	
Standard capsule	C
Sterile capsule	G

Effective Filtration Area	
0.45 ft² (415 cm²)	K
0.36 ft² (335 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, inlet 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 w/filling-bell
22	3/8" hose barb
2B	3/8" hose barb w/filling-bell
41	1/4" MNPT, 1/4" hose barb outlet
44	1/4" MNPT
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	Retention Rating
STyLUX® hydrophilic PES membrane	SM	0.6 µm

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

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