

# STyLUX®

## 0.2 µm SM-grade Large Capsule Filter (UltraCap® H.D. Model)

### Description

The STyLUX® SM-grade 0.2 µm is a hydrophilic PES membrane filter compatible with a wide range of liquids. It withstands a wide pH range (1-14) and is recommended for sterilizing filtration and bioburden reduction of pharmaceutical preparations, active ingredients, biopharmaceuticals, parenterals, vaccines, biologicals including dilute protein solutions, cell and tissue culture media, media additives, ophthalmic and other dilute preservative solutions, UPW, chemicals, and alcohols. The filter's asymmetric membrane provides absolute retention, while also providing superior flow rates and contaminant capacity.

### Materials of Construction

All components of the STyLUX® 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:

Filter Membrane:	Polyethersulfone	CFR Title 21, 177.2440
Up/Downstream support:	Polypropylene	CFR Title 21, 177.1520
Core, guard, 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**  
44 psi (3.03 bar), water  
16 psi (1.10 bar), 60% IPA/40% water  
15 psi (1.03 bar), 70% IPA/30% water

**Maximum Diffusion Rate** 30 mL/min per 10" (25 cm) @ 35 psi (2.41 bar), water

**Typical Water Flow Rate** 0.3 psid/gpm per 10" (1.8 L/min @ Δp 10 mbar per 25 cm), with 1" (25 mm) inlet/outlet  
*Capsule body style and I/O selection may affect pressure drop and flow rate.*

### 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 operating pressure: 90 psig @ 100 °F (6.2 bar @ 38 °C), liquid service  
Maximum reverse pressure: 15 psig @ 100 °F (1.0 bar @ 38 °C)

**Bacterial Retention** >10<sup>7</sup> per cm<sup>2</sup> removal of *Brevundimonas diminuta* per ASTM F838

### 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

STyLUX® 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 STyLUX® 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 STyLUX® filters. Filters comply with European Commission Regulation No 10/2011.

### 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.

**Ordering Guide**

**CR 2 SM 0.2 - 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	Effective Filtration Area
STyLUX® hydrophilic PES membrane	SM	0.2 µm	7.3 ft <sup>2</sup> (0.68 m <sup>2</sup> ) per 10" (25 cm)

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

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