

STyLUX®

ST0.1 Mini Capsule

Description

The sterilizing grade STyLUX® ST0.1 PES hydrophilic asymmetric mini filter capsule, is manufactured with an animal free gamma stable polypropylene, and provides the added benefit of certification that meets the critical demands of the pharmaceutical, biotechnology and related industries.

Materials of Construction

All components of the STyLUX® mini capsule are animal free. These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Membrane:	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 housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.1 µm

Minimum Bubble Point 30 psi (2,1 bar), 60% IPA / 40% water
27 psi (1,9 bar), 70% IPA / 30% water

Bacterial Retention >10⁷ per cm² removal of *Brevundimonas diminuta* per ASTM F838
Typically 10⁵ per cm² removal of *Acholeplasma laidlawii* per modified ASTM F838

Operating Characteristics

Operating temperature range: 32 °F to 122 °F (0 °C to 50 °C)
Maximum operating pressure: 100 psig (6,9 bar)

Sterilization

Autoclave: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 3 cycles.
Gamma irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be steamed in place (SIP).

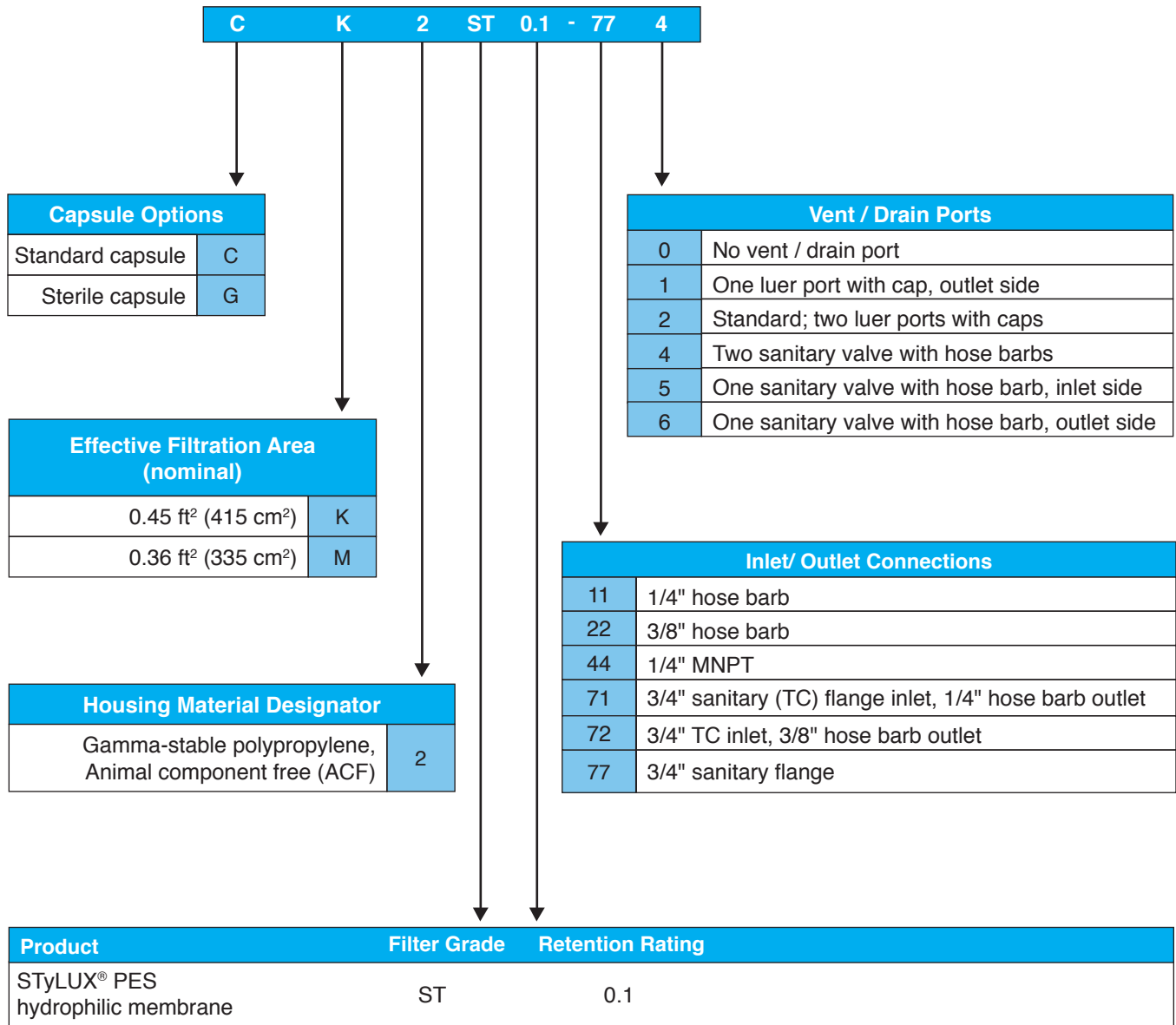
Biological Safety

STyLUX® 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 STyLUX® filters are less than 0.5 EU/mL, as determined using the *Limulus* amoebocyte 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 free.

Quality Assurance

Each STyLUX® ST0.1 is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. 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



Additional information about STyLUX[®] filter products is available in the Green Docs document which is viewable at <https://www.meissner.com/downloads/stylux-gd001.pdf>

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