STyLUX®



The STyLUX® filter cartridge is an absolute rated, pleated polyethersulfone membrane filter designed to provide greater bacteria and particle removal at high flow rates and extremely low pressure drops. It offers the greatest assurance of filtration performance, stability and service life for controlling contaminants in demanding environments.

The exceptional performance of STyLUX® is derived from its unique filtration media.

The filter media is made by a patented process which produces an asymmetric polyethersulfone membrane that is inherently hydrophilic. The membrane is a highly porous structure whose pore size decreases progressively through its depth. This highly durable structure maintains consistent porosity and contaminant retention throughout its operational life without

shedding or unloading particles. This results in a filter that provides absolute retention and superior flow rates, cleanliness and throughputs, even in severe process conditions.

All components of the STyLUX® filter cartridge comply with FDA regulations for food contact use. By a unique state-of-the-art process, the membrane and polypropylene support components are thermally bonded to the cartridge end caps. This provides an integral filter cartridge that has excellent chemical compatibility and extremely low extractables in a wide range of fluids and applications.

Features and Benefits

- Durable polyethersulfone and polypropylene components
- Absolute ratings of 0.04, 0.1, 0.2, 0.4 and 0.6 µm
- · Highly porous asymmetric membrane
- Extremely high flow rates at low pressure drops
- · Permanently hydrophilic membrane
- Integrity testable in water
- Contains no binders, adhesives or other extraneous materials
- · High thermal and hydrolytic stability
- Resistant to oxidizing agents
- · Rugged, thermally bonded construction
- Biologically inert and non-toxic
- · High protein transmission
- 100% integrity tested during manufacture

Typical Applications

STyLUX® meets the critical demand for contamination control in the chemical, microelectronics, aerospace, food and beverage, biologicals, veterinary, pharmaceutical and other industries. STyLUX® may be used as either a prefilter or final filter. It offers the greatest security for bulk and point-of-use filtration.

STyLUX® provides high quality filtration for a variety of ultrapure water requirements, including:

- Deionized water
- High temperature water
- · Chemically treated water

STyLUX® is ideal for the clarification/cold sterilization of beverages, including:

- Mineral water
- · Soft drinks
- Wine and wine coolers
- Draft beer

and polypropylene makes the STyLUX® filter perfectly suited for the purification of chemicals such as:

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- · Microbiological growth media
- Diagnostics
- Protein solutions
- Antibiotics
- Vaccine preparations

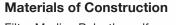
The wide chemical resistance of polyethersulfone

- Acids & bases Alcohols Aldehydes

The wide chemical resistance of polyethersulfone

- · Serum & blood-based products
- Tissue culture media

- Ophthalmics
- Oral and topical medications



Filter Media: Polyethersulfone 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, Viton®, Teflon® over Viton®

All materials of construction 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.

STyLUX® filters are manufactured in conformance to cGMP. 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* amebocyte lysate (LAL) test. No binders, adhesives or surfactants are used in the construction of STyLUX® filters. STyLUX® filters are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72.

Filtration Ratings

Filter Grade: Absolute Ratings (µm): 0.04, 0.1, 0.2, 0.4, 0.6 SM, ST, SL SP 0.04, 0.1, 0.2, 0.4

SC 0.1

Integrity Testing

Minimum Bubble Point, Water

SM/ST

115 psi	(7,9 bar)
80 psi	(5,5 bar)
44 psi	(3,0 bar)
32 psi	(2,2 bar)
18 psi	(1,2 bar)
	80 psi 44 psi 32 psi

SC

0.1 um 110 psi (7.6 bar)

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:

SM/ST

 $0.04 \mu m$, $0.1 \mu m$, $0.2 \mu m > 10^7 \text{ cfu/cm}^2$ Brevundimonas diminuta and meet the FDA definition of a sterilizing grade filter.

0.04 μm > 10⁷ cfu/cm² Acholeplasma laidlawii 0.1 µm 10⁴ cfu/cm² Acholeplasma laidlawii 0.4 μm > 10⁷ cfu/cm² Serratia marcescens

0.6 μm > 10⁷ cfu/cm² Saccharomyces cerevisiae

0.1 μm > 10⁷ cfu/cm² Acholeplasma laidlawii

Sterilization

Steam-in-place (SIP):

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

Autoclave: 121-135 °C, 30-60 minutes

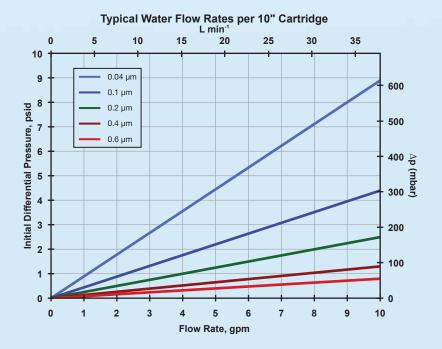
STyLUX® cartridges are capable of repeated sterilization cycles without loss of integrity. For applications requiring autoclave/SIP, a stainless steel reinforcement ring must be ordered. See "Reinforcement Ring Option" on back page.

Maximum Operating Temperatures & Pressures

Δp 80 psi @ 32°F to 100°F (Δp 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)





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

Ord	lering	Informat	ion

Filter Grade	Absolute Rating (µm)
SM	0.04, 0.1, 0.2, 0.4, 0.6
ST	0.04, 0.1, 0.2, 0.4, 0.6
sc	0.1
SL	0.04, 0.1, 0.2, 0.4, 0.6
SP	0.04, 0.1, 0.2, 0.4

	ength
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Cartridge

1 = 10" (25 cm) 20" (50 cm) 3 = 30"

(75 cm) 4 = 40" (100 cm)

End Cap Configuration

GS = DOE; flat gaskets (9.75", 19.5", 29.25", 39" length filters)

GL = DOE; flat gaskets (20", 30", 40" length filters)

C1 = SOE; -222 nO-Ring®, button cap end C2 = SOE; -222 O-rings, button cap end

F1 = SOE; -222 nO-Ring®, fin end F2 = SOE; -222 O-rings, fin end

C5 = SOE; -226 nO-Ring®, button cap end C6 = SOE; -226 O-rings, button cap end

F5 = SOE; -226 nO-Ring[®], fin end

F6 = SOE; -226 O-rings, fin end DN = DOE; internal -120 O-rings

RN = SOE; internal -120 O-rings, recessed cap end

DA = DOE; internal -213 O-rings RA = SOE; internal -213 O-rings,

recessed cap end

Reinforcement **Ring Option**

(Blank) = Standard; no reinforcement ring

R = Reinforcement ring; required for autoclave/SIP applications

Seal Material (O-ring or Gasket)

DOE = Double Open End SOE = Single Open End

O-ring Seal

 $\mathbf{B} = \mathbf{B}\mathbf{u}\mathbf{n}\mathbf{a}$

 $\mathbf{E} = \mathbf{EPR}$

S = Silicone T = Teflon® over Silicone

V = Viton®

X = Teflon® over Viton®

Gasket Seal

 $\mathbf{B} = \mathbf{B} \mathbf{u} \mathbf{n} \mathbf{a}$

 $\mathbf{E} = \mathbf{EPR}$

= Polyethylene

S = Silicone

T = Teflon®

V = Viton®

Grade Descriptions

SM = This sterilizing grade filter is absolute, microbially rated and 100% integrity tested and flushed with DI water during manufacture. It is suited for critical applications when regulatory documentation requirements are minimal. A Certificate of Conformance is provided.

ST = This absolute sterilizing-grade, microbially rated filter meets full traceability requirements for the pharmaceutical industry. It is 100% integrity tested and flushed with DI water during manufacture. Each ST grade filter is shipped with a Certificate of Quality that gives precise information on the quality, integrity and acceptance criteria of the filter. This is a validatable product to meet the stringent requirements of the pharmaceutical industry.

SC = This is a sterilizing grade filter designed specifically for the 100% removal of Mycoplasma. It is 100% integrity tested and DI flushed during manufacture and it has the added benefit of certification that meets the critical needs of the pharmaceutical, biotechnology and related industries. Each SC0.1 filter includes a Certificate of Quality that gives precise information on the quality, integrity and acceptance criteria of the filter.

SL = This SM grade filter is not 100% integrity tested or flushed with DI water during manufacture. It is offered as an economical prefilter or final filter when sterility assurance and validation are not required. A Certificate of Conformance is provided.

SP = This is an absolute, particulate rated filter. It is 100% integrity tested and DI flushed during manufacture. A Certificate of Conformance is provided



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