STyLUX®

MEISSNER FILTRATION PRODUCTS

STyLUX® Filter Cartridge

The STyLUX® filter cartridge is an absolute rated, pleated polyethersulfone (PES) 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.

For applications requiring *Mycoplasma* removal, Meissner offers the STyLUX® SC0.1 filter. This sterilizing grade filter provides 100% retention of *Mycoplasma* per modified ASTM F838 Challenge, while delivering the highest reliability and security for the sterilization of serum, culture media and other biological fluids.

All components of the STyLUX® filter cartridge comply with FDA regulations for food contact use. A unique state-of-the-art process thermally bonds the membrane and polypropylene support components 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 PES and PP 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 and cold sterilization of beverages, including:

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

The wide chemical resistance of PES and PP makes the STyLUX® filter perfectly suited for the purification of chemicals such as:

- Acids & bases
- Aldehydes
- Alcohols

STyLUX® is designed for the removal of particulates, colloids and microorganisms from a broad variety of pharmaceutical and biological solutions, including:

- Serum & blood-based products
- Diagnostics
- Tissue culture media
- Protein solutions
- Microbiological growth media
- Antibiotics
- Ophthalmics
- Vaccine preparations
- Oral and topical medications

Materials of Construction

Filter Media:	Polyethersulfone (PES)
Upstream Support:	Polypropylene (PP)
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, Teflon® over Viton®

All materials of construction listed above 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 Commission Regulation (EU) no 10/2011.

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):
SM, ST, SL	0.04, 0.1, 0.2, 0.4, 0.6
SP	0.04, 0.1, 0.2, 0.4
SC	0.1

Integrity Testing

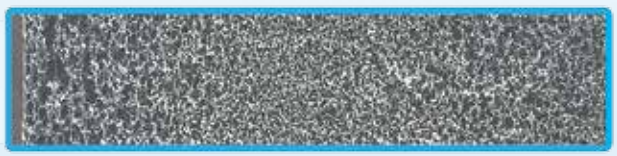
Minimum Bubble Point, Water

SM/ST		
0.04 µm	115 psi	(7,9 bar)
0.1 µm	80 psi	(5,5 bar)
0.2 µm	44 psi	(3,0 bar)
0.4 µm	32 psi	(2,2 bar)
0.6 µm	18 psi	(1,2 bar)

SC		
0.1 µm	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 µm, 0.1 µm, 0.2 µm > 10^7 cfu/cm² *Brevundimonas diminuta* and meet the FDA definition of a sterilizing grade filter.
0.04 µm > 10^7 cfu/cm² *Acholeplasma laidlawii*
0.1 µm ≥ 10^4 cfu/cm² *Acholeplasma laidlawii*
0.4 µm > 10^7 cfu/cm² *Serratia marcescens*
0.6 µm > 10^7 cfu/cm² *Saccharomyces cerevisiae*

SC

0.1 µm > 10^7 cfu/cm² *Brevundimonas diminuta* and meets the FDA definition of a sterilizing grade filter.
0.1 µm > 10^7 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. (Membrane must be wet prior to steam sterilization. Reference “Green Docs” online for more information.)

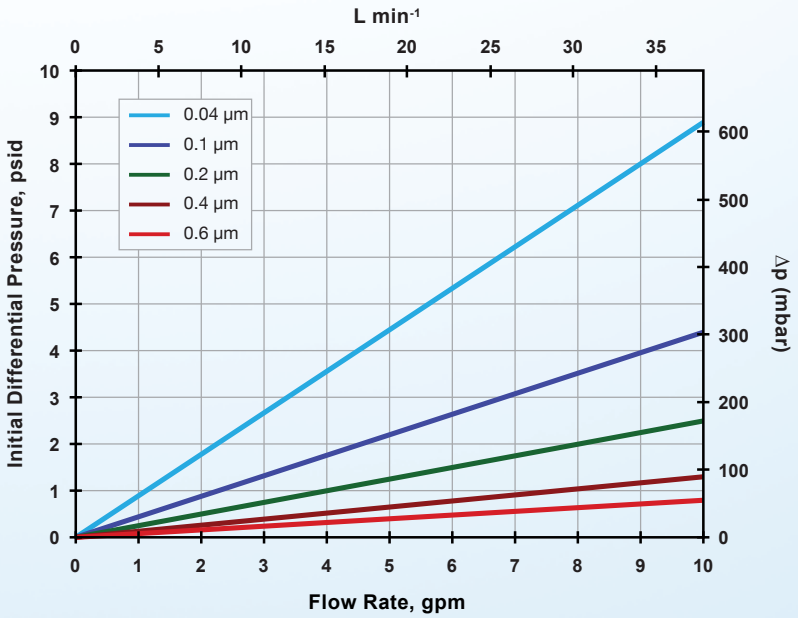
Maximum Operating Temperatures and Pressures

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)

Typical Water Flow Rates per 10" Cartridge



End Cap Configuration

-226 O-ring

External -226 O-rings with locking tabs; open end for C6 and F6 SOE configurations

-222 O-ring

External -222 O-rings; open end for C2 and F2 SOE configurations

-226 nO-Ring®

External -226 nO-Ring® with locking tabs; open end for C5 and F5 SOE configurations

-222 nO-Ring®

External -222 nO-Ring®, open end for C1 and F1 SOE configurations

Flat Gasket

Flat Gasket; open end for GS and GL DOE configurations

Internal O-ring

Internal O-ring; open end for DN and DA DOE or RN and RA SOE configurations

Button Cap

Button Cap; closed end for C1, C2, C5 and C6 SOE configurations

Alignment Fin

Alignment Fin; closed end for F1, F2, F5 and F6 SOE configurations

Recessed Cap

Recessed Cap; closed end for RN and RA SOE configurations

DOE = Double Open End
SOE = Single Open End

Ordering Information

Filter Grade	Absolute Rating (µm)	—	Cartridge Length	End Cap Configuration	Reinforcement Ring Option	Seal Material (O-ring or Gasket)
SM	*0.2*		*3*	*F2*	*R*	*S*

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**

1 = 10" (25 cm)
2 = 20" (50 cm)
3 = 30" (75 cm)
4 = 40" (100 cm)

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

(Blank) = Standard - no reinforcement ring

R = Reinforcement ring; required for autoclave/ SIP applications

O-ring Seal
B = Buna
E = EPR
S = Silicone
T = Teflon® over silicone
V = Viton®
X = Teflon® over Viton®

Gasket Seal
B = Buna
E = EPR
P = 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 sterilizing grade, absolute 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.

SC0.1 = 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 comes with a Certificate of Quality that gives precise information on the quality, integrity and acceptance criteria of the filter.

SL = This 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.

MEISSNER FILTRATION PRODUCTS

SM 3.2

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