## Nylon membrane cartridge





- Easy integrity testable in situ
- Repeatedly steamable in situ and in autoclave
- Thermowelded construction
- EC-listed materials for Food contact
- FDA-listed materials per 21 CFR
- Bio-Safety per USP-Plastics
- Low filter extractables even with solvents
- Validation Guide available on request

STERINYL filter element is designed and manufactured to satisfy and assure high quality and consistent performances in critical applications.

STERINYL cartridge includes Nylon 6,6 membrane at controlled porosity and provides high efficiency in bacteria retention.

The membrane is pleated with support and drainage layers in polyester which give high endurance versus thermal sterilization and hydraulic pulsation stress. The intrinsically water wettability of nylon and polyester allows easy integrity testability. Manufacturing is completed in a controlled environment; each filter is integrity tested.

STERINYL filter element 0.1 micron and 0.2 micron are available with single and double membrane layer.



#### **MATERIALS OF CONSTRUCTION**

Filter media	nylon 6,6
Upstream supports	polyester
Downstream supports	polyester
Internal Core	polypropylene
External Cage	polypropylene
End caps / Adapters	polyester

#### **FOOD-SAFETY**

STERINYL filter element materials meet (EU) regulation 10/2011 and its amendments, regulations (EC) 1935/2004 and 1895/2005.

#### **BIO-SAFETY**

Filter media and components pass USP CLASS VI Biological Reactivity

and Chemical-Physical tests for USP plastics.

Specific for "PH" and "PHH" grade: the filter meets USP "Water for injection" requirements for particle release and the effluent is Non-Pyrogenic per USP Bacterial Endotoxins (< 0,25 EU/ml).

## **QUALITY STANDARDS**

Produced under a certified Quality System to guarantee traceability of manufacturing records and integrity testing results.

### **OPERATING CONDITIONS**

- max. continuous temperature	80 °C
- max. cumulative time of steam sterilization	5 hours at 140°C / 13 hours at 125°C / 20 hours at 121 °C
- sanitization with hot water	80 °C max
- sanitization with chemicals	Can be sanitized by standard chemical agents
- max. differential pressure	5,0 bar at 25 °C—2,5 bar 80 °C—0,3 bar 135 °C
- recommended change out differential pressure	2,0 bar at 25 °C
- recommended rinse up volume	3 liters/cartridge 10"

CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION OF MICRO-ORGANISM >10 <sup>10</sup> CFU/ 10" CARTRIDGE*	ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST WITH WATER FOR 10" CARTRIDGE (ml/min)
CX**	0,1 μm	Hydrogenophaga pseudoflava	≤ 15 @ 2,8 bar
CXX**	0,1 μm double layer	Hydrogenophaga pseudoflava	≤ 15 @ 2,8 bar
CY	0,2 μm	Brevundimonas diminuta	≤ 16 @ 2,1 bar
CYY	0,2 μm double layer	Brevundimonas diminuta	≤ 16 @ 2,1 bar
СТ	0,45 μm	Serratia marcescens	≤ 16 @ 1,5 bar
CK	0,65 μm	Leuconostoc oenos	≤ 18 @ 0,9 bar

\*as per ASTM F838

bacterical retention with Acholeplasma laidlawii ≥ 10<sup>8</sup>









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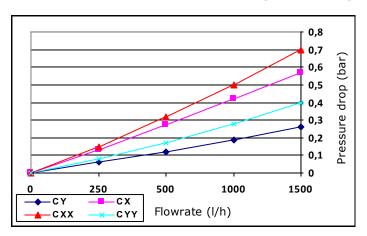






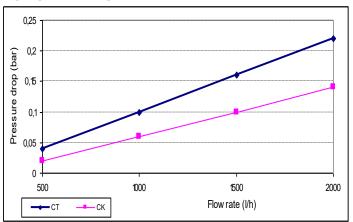


## WATER FLOW RATE FOR 10" CARTRIDGE



**207** 

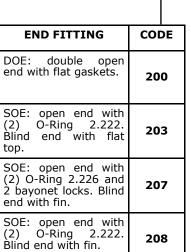
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# STERINYL KLE ORDERING INFORMATION

<u>PH</u> - <u>SB</u>

<u>CY</u> -



KLE -

SOE: open end with (2) O-Ring 2.222 and 3 bayonet locks. Blind end with fin. 212

top.

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ABSOLUTE FILTRATION RATING micron	CODE
0,1	СХ
0,1	СХХ
0,2	CY
0,2	CYY
0,45	СТ
0,65	СК

CODE	NOMINAL LENGTH
1	10"
2	20"
3	30"
4	40″
05	5"

CODE	GASKETS	
No code	Standard	Silicone
E	On request	EPDM
V	On request	VITON
F	On request	FEP

CODE	PACKING TYPE
SB	Single box

CODE	PRODUCT GRADE	
BQ	Biological Grade; tested and prefluxed. Quality Certification in the box.	
РН	Biological Grade; tested and prefluxed with non-pyrogenic water. Quality Certification in the box.	
РНН	Biological Grade; tested and prefluxed with non-pyrogenic water. Quality Certification, with serial number, in the box.	









