

STERINYL

High performance nylon 6,6

- 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

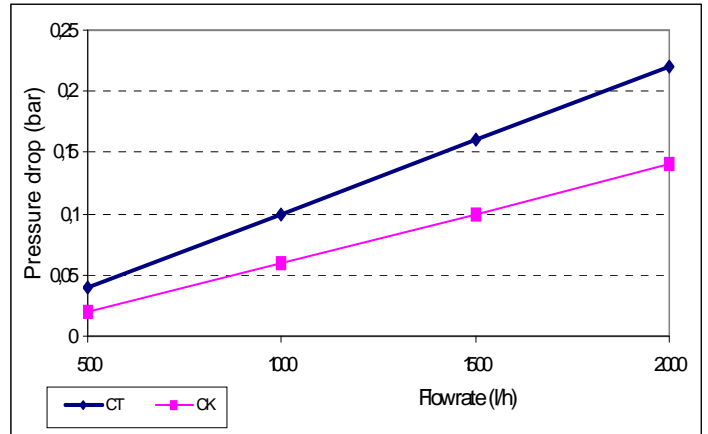
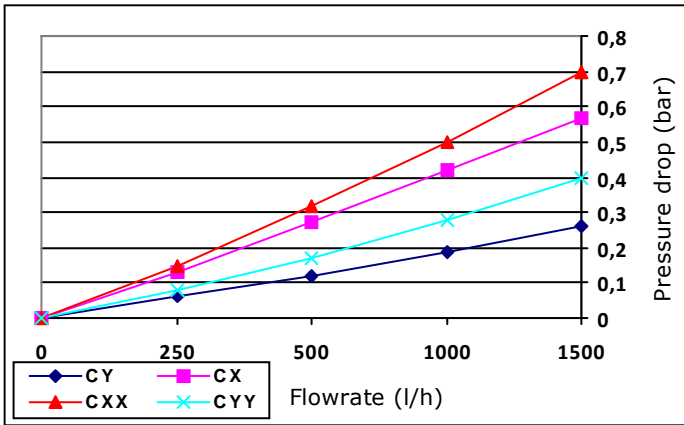
- max. continuous temperature	80 °C
- max. cumulative time of steam sterilization	13 hours at 125 °C with cycles of 60 minutes /20 hours at 121 °C
- sanitization with hot water	80 °C max
- sanitization with chemicals	Can be sanitized by standard chemical agents
- max. differential pressure	5,0 bar at 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 ¹⁰ 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
CT	0,45 µm	Serratia marcescens	≤ 16 @ 1,5 bar
CK	0,65 µm	Leuconostoc oenos	≤ 18 @ 0,9 bar

*as per ASTM F838-05

** bacterial retention with Acholeplasma laidlawii ≥ 10⁸

WATER FLOW RATE FOR 10" CARTRIDGE



STERINYL KLE ORDERING INFORMATION

KLE - 207 1 - CY - PH - SB -

END FITTING	CODE
DOE: double open end with flat gaskets.	200
SOE: open end with (2) O-Ring 2.222. Blind end with flat top.	203
SOE: open end with (2) O-Ring 2.226 and 2 bayonet locks. Blind end with fin.	207
SOE: open end with (2) O-Ring 2.222. Blind end with fin.	208
SOE: open end with (2) O-Ring 2.222 and 3 bayonet locks. Blind end with fin.	212

ABSOLUTE FILTRATION RATING micron	CODE
0,1	CX
0,1	CXX
0,2	CY
0,2	CYY
0,45	CT
0,65	CK

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

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

DS-KLE-560-UK-15-A

Data contained in this bulletin are informative and subject to change without notice. User is responsible for determining whether the product is fit for particular purpose and suitable for User's method of application.



Bea Technologies Spa Via Newton, 4 - 20016 Pero (Milano) ITALY
 Tel +39 02 339271 FAX +39 02 3390713 e-mail: info@bea-italy.com
 web: www.bea-italy.com