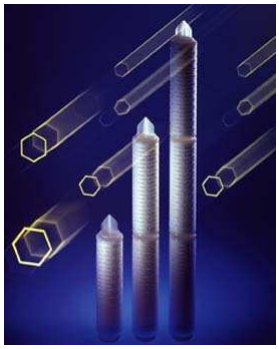
STERYULTRA

Mycoplasma retentive PES membrane filter element



- High effective filtering area
- Repeatedly steamable in situ or in autoclave
- Thermowelded construction
- EC-listed materials for Food contact
- FDA-listed materials per CFR21
- Bio-Safety per USP—Plastics
- Validation Guide available on request

STERYULTRA is designed to be the final sterilizing filter in the biotechnological industry; preflushed with non-pyrogenic water is utilized in critical applications as processing of serum, vaccines, tissue culture media, biological fluids, etc.
The polyetersulfone membrane (PES) offers the highest retention performances in ultrafine particles and microorganisms and provides extensive service life with high flow rate.
Steryultra cartridges are available with liquid absolute filtration ratings from 0,04 micron to 0,45 micron. Manufacturing is completed in a controlled environment; each cartridge is integrity tested and the limits of acceptability are monitored on regular basis by bacteria challenge test.

MATERIALS OF CONSTRUCTION

Filter media	**Asymmetric PES membrane**
Upstream supports	polypropylene
Downstream supports	polypropylene
Internal Core	polypropylene
External Cage	polypropylene
End caps / Adapters	polypropylene

FOOD-SAFETY

STERYULTRA filter elements meet Directive 2002/72/EC and its subsequent amendments and regulations EC 1935/2004 and 1895/2005.

BIO-SAFETY

Filter media and components pass USP Biological Reactivity and Chemical-Physical tests for CLASS VI plastics.
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

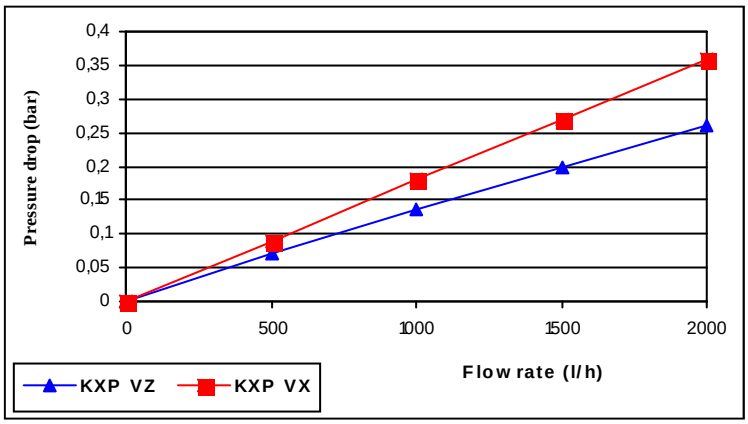
RECOMMENDED OPERATING CONDITIONS

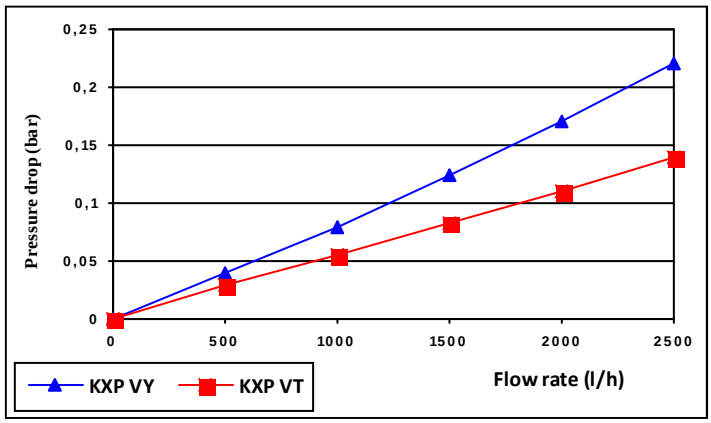
- max. continuous temperature	65 °C
- max. cumulative time of steam sterilization	10 hours at 135 °C with cycles of 30 minutes
- sanitization with hot water	80 °C max
- sanitization with chemicals	can be sanitized by ordinary chemical agents
- max. differential pressure	5,0 bar at 25 °C - 1,7 bar at 80 °C
- recommended change out differential pressure	2,0 bar at 25 °C
- recommended rinse up volume	3 liters / 10" cartridge

CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION CFU/cm^2	ACCEPTABLE LIMIT FOR INTEGRITY TEST 10" CARTRIDGE (ml/min)
VX	0,04 µm	> 10^7 Acholeplasma laidlawii	≤ 29 @ 1,7 bar
VZ**	0,1 µm	> 10^7 Hydrogenophaga pseudoflava	≤ 27 @ 1,4 bar
VY	0,2 µm	> 10^7 Brevundimonas diminuta	≤ 18 @ 0,9 bar
VT	0,45 µm	> 10^7 Serratia marcenscens	≤ 15 @ 0,6 bar

Note:
The integrity is verified by DIFFUSION TEST using an aqueous solution of isopropylic alcohol (IPA 60/40 V/V) as wetting liquid.
** Retention with ≥ 10^7 /Acholeplasma laidlawii, 10" cartridges.

WATER FLOW RATE FOR 10" CARTRIDGE





STERYULTRA ORDERING INFORMATION

KXP - 207 1 - VX - PH - ☐

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 bayo-net 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 bayo-net locks. Blind end with fin.	**212**

ABSOLUTE FILTRATION RATING micron	CODE
0.04	**VX**
0.1	**VZ**
0,2	**VY**
0,45	**VT**

CODE	GASKETS	
No code	Standard	Silicone

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

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

DS-KXP-571-UK-15

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