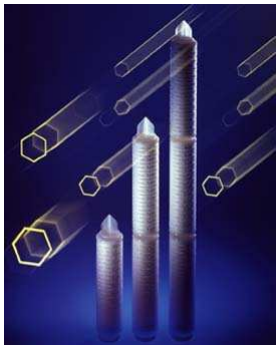
STERYFLUS TSE—PH



- Easy integrity testable in situ
- Repeatedly steamable in situ or in autoclave
- Sanitizable
- Thermowelded construction
- EC-listed materials for Food contact
- FDA-listed materials per CFR21
- Bio-Safety per USP—Plastics
- Validation Guide available on request

STERYFLUS TSE-PH cartridge is final sterilizing filter for general application in pharmaceutical industries; prefluxed with non-pyrogenic water and with certification of quality reporting the serial number, it is utilized in critical applications.
Steryflus cartridges have liquid absolute filtration ratings from 0,1 micron to 0,45 micron; 0,1 micron and 0,2 micron are available with single and double membrane layers.
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	polyester
Downstream supports	polyester
Internal Core	polypropylene
External Cage	polypropylene
End caps / Adapters	polyester

FOOD-SAFETY

STERYFLUS TSE filter elements meet (EU) regulation 10/2011 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

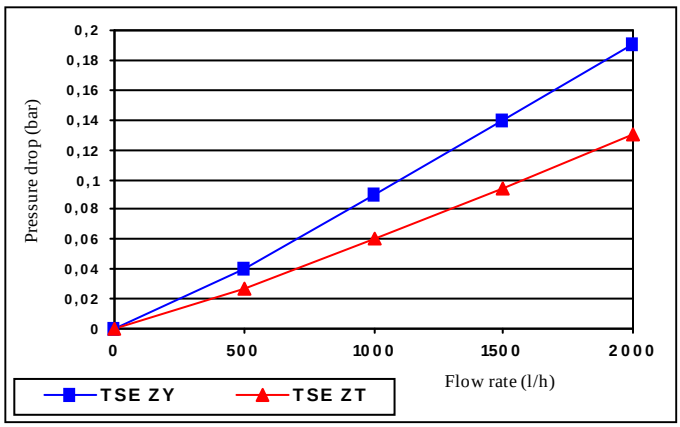
Produced under a certified Quality System to guarantee traceability of manufacturing records and integrity testing results.

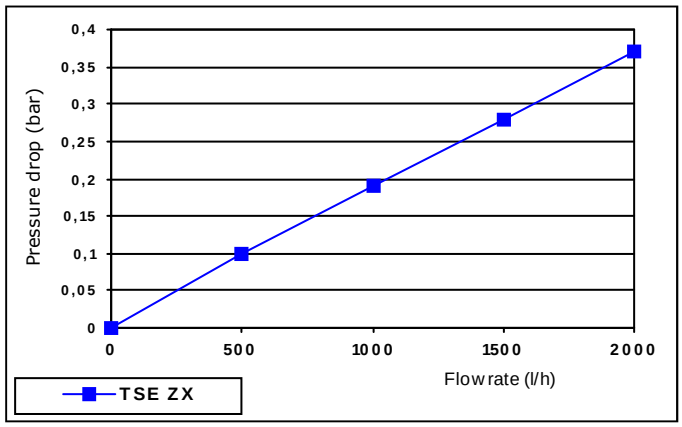
RECOMMENDED OPERATING CONDITIONS

- max. continuous temperature	65 °C
- max. cumulative time of steam sterilization	13 hours at 125 °C with cycles of 30 minutes
- 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 - 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 $>10^7$ CFU/cm^2 *	ACCEPTABLE LIMIT FOR DIFFUSION TEST WITH WATER FOR 10" CARTRIDGE (ml/min)
ZXX	0,1 µm double membrane	Acholeplasma laidlawii	≤ 20 @ 3,5 bar
ZX	0,1 µm	Acholeplasma laidlawii	≤ 20 @ 3,5 bar
ZYY	0,2 µm double membrane	Brevundimonas diminuta	≤ 16.5 @ 2,8 bar
ZY	0,2 µm	Brevundimonas diminuta	≤ 16.5 @ 2,8 bar
ZT	0,45 µm	Serratia marcescens	≤ 13 @ 1,7 bar
* as per ASTM F838			

WATER FLOW RATE FOR 10" CARTRIDGE





STERYFLUS TSE ORDERING INFORMATION

TSE - 207 1 - ZY - [ ] - PH

END FITTING	CODE
DOE: double open end with flat gaskets.	**200**
SOE: open end with (1) O-Ring 2.20. Blind end with flat top.	**202**
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**

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

ABSOLUTE FILTRATION RATING micron	CODE
0.1 double membrane	**ZXX**
0.1	**ZX**
0,2 double membrane	**ZYY**
0,2	**ZY**
0,45	**ZT**

CODE	GASKETS	
No code	Standard	Silicone

CODE	PRODUCT GRADE
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-TSE-565-UK-17

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