Product information

STERYFLUS 0.1 micron

0.1 micron for MYCOPLASMA RETENTION

STERYFLUS TSE filter element is final sterilizing filter for general application in pharmaceutical and biological applications. In critical applications is recommended PH grade, which is preflushed with non-pyrogenic water and provided with a certification of quality reporting the serial number.
Steryflus cartridges is available with single and double membrane layers and have a liquid absolute filtration rating of 0,1 micron.
Manufacturing is completed in a clean room; each cartridge is integrity tested and the Bacteria retention listed in the VALIDATION GUIDE is monitored on regular basis by bacteria challenge test.

MATERIALS OF CONSTRUCTION

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

FOOD-SAFETY AND FDA

STERYFLUS TSE filter elements are made from materials listed for food contact use per Title 21 of CFR.

BIO-SAFETY

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

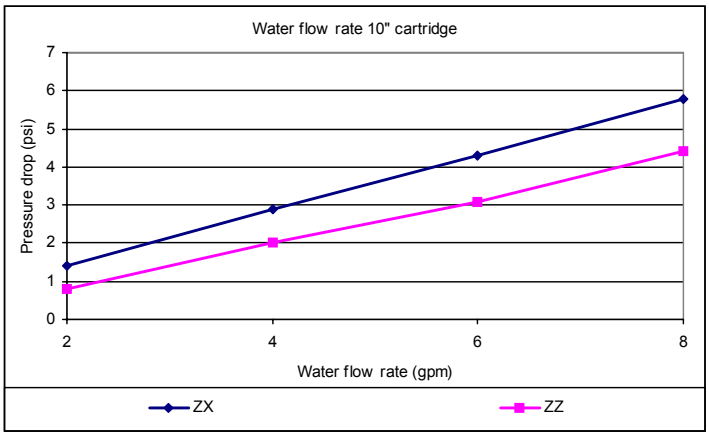
QUALITY STANDARDS

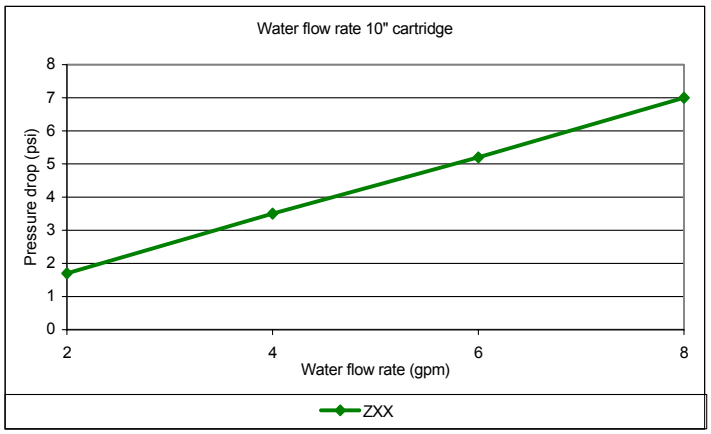
Produced under a certified ISO 9001 Quality System to guarantee traceability of manufacturing records and integrity testing results.

OPERATING CONDITIONS

- max. continuous temperature	149°F (65°C)
- max. cumulative time of steam sterilization	13 hours at 257°F (125°C) with cycles of 30 minutes
- sanitization with hot water	176°F (80°C max)
- sanitization with chemicals	can be sanitized by standard chemical agents
- max. differential pressure	73 psi at 77°F (5,0 bar at 25°C)
- recommended change out differential pressure	29 psi at 77°F (2,0 bar at 25°C)
- recommended rinse up volume	1 gallon/10"module (4 liters/10" cartridge)

CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION $>10^{10}$ CFU/10" CARTRIDGE*	ACCEPTABLE LIMIT FOR DIFFUSION TEST WITH WATER FOR 10" CARTRIDGE (ml/min)
ZZ	0,1 µm single membrane high flow rate	Brevundimonas diminuta	≤ 30 @ 51 psi (or 3,5 bar)
ZX	0,1 µm single membrane	Acholeplasma laidlawii	≤ 18 @ 51 psi (or 3,5 bar)
ZXX	0,1 µm double membrane	Acholeplasma laidlawii	≤ 20 @ 51 psi (or 3,5 bar)
*as per ASTM F838-83 edition 1993			





STERYFLUS TSE ORDERING INFORMATION

TSE - 207 1 - ZZ - [ ] - PH - [ ]

END FITTING	CODE
SOE: open end with (2) O-Ring 2.226 and 2 bayonet locks. Blind end with fin.	**207**

ABSOLUTE FILTRATION RATING micron	CODE
0.1 single membrane high flow rate	**ZZ**

CODE	NOMINAL LENGTH
1	**10”**

CODE	GASKETS	
No code	Standard	Silicone

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

CODE	PACKING TYPE
No code	Single box

PI-001-TSE-UK-07-1

Data contained 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