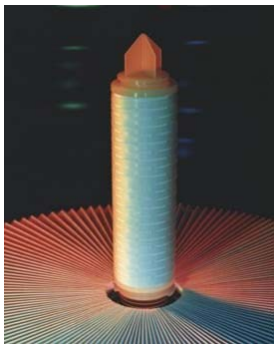
STERYFLON Plus



- Intrinsecally Hydrophobic PTFE membrane
- High permeability versus gas
- Thermic cycles resistant
- Repeatedly steamable in situ or in autoclave
- Thermowelded construction
- FDA-listed materials per CFR21
- Bio-Safety per USP-Plastics
- Validation Guide available on request

STERYFLON Plus is a filter element designed, manufactured and submitted to severe controls for applications in processes where the effluent is required to be free from particellar and biological contaminants.
The expanded PTFE membrane, intrinsically hydrophobic, allows superior performances both in gas filtration and non-acqueos liquid filtration. Bio-tech pharmaceutical, electronic, food & beverage industries can roly on a product with high standard of quality suitable to solve contamination issues on critical applications.
STERYFLON is manufactured within a controlled environment and each cartridge is integrity tested and is validated for bacterial retention correlated with microbiological challenge test.
The retention is checked on regular sampling.

MATERIALS OF CONSTRUCTION

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

FOOD-SAFETY

STERYFLON Plus filter elements meet regulation (EC) 1935/2004 for indirect food contact.

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.

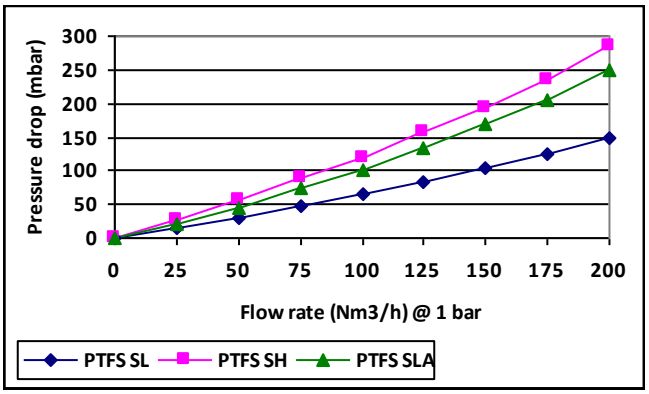
OPERATING CONDITIONS

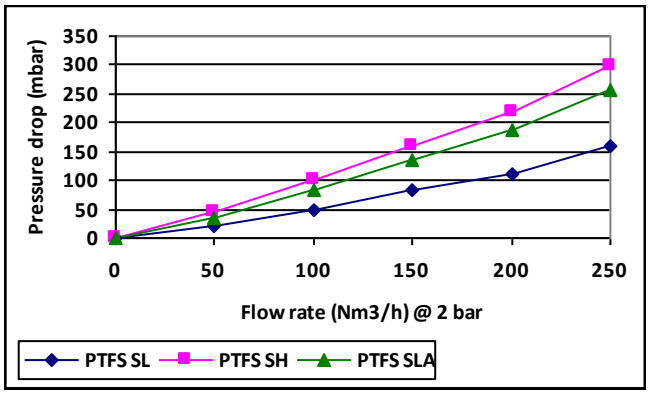
- max. continuous temperature of fermentation inlet and exhaust air	70 °C
- max. continuous temperature for vent filter in recirculation loop	83 °C
- max. cumulative time of steam sterilization	150 hours at 140 °C with cycles of 30 minutes
- sanitization with chemicals	can be sanitized by standard chemical agents
- max. differential pressure	5,0 bar at 25 °C
- recommended change out differential pressure	2,0 bar at 25 °C

CODE	**ABSOLUTE FILTRATION RATING**		**3) BACTERIAL RETENTION >10^7 CFU/cm^2**	**ACCEPTABLE LIMIT FOR INTEGRITY TEST FOR 10" CARTRIDGE**
	IN LIQUID	**IN DRY GAS**		
SH	0,1 µm	< 0,01 µm	Acheleoplasma laidlawii in liquid	1) ≤ 25 ml/min @ 1,0 bar
SL	0,2 µm	< 0,01 µm	B. Diminuta in liquid / Batteriofago T1 in aerosol	1) ≤ 12 ml/min @ 0,8 bar
SLA	0,2 µm	< 0,01 µm	Brevundimonas diminuta in liquid	2) ≤ 16 Nml/10min @ 2,5 bar

Note:
1– The integrity is verified by DIFFUSION TEST using an aqueous solution of isopropyl alcohol (IPA 60/40 V/V) as wetting liquid.
2– The integrity is verified by WATER FLOW INTRUSION TEST.
3– Cartridges are validated for retention of the microorganism reported in the table according to ASTM F838.

AIR FLOW RATE FOR 10" CARTRIDGE





STERYFLON Plus ORDERING INFORMATION

PTFS - 207 1 - SL - [ ] - 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 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	**SH ***
0,2	**SL ***
0,2	**SLA ****

* Integrity by IPA diffusion test
** Integrity by water intrusion test

CODE	PRODUCT GRADE
No code	Biological Grade
PH	Non-pyrogenic Grade. Quality Certification in the box
PHH	Non-pyrogenic Grade. Quality Certification, with serial number, in the box

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

CODE	GASKETS		END FITTING
No code	Standard	EPDM	200
T	On request	Teflon	
No code	Standard	Silicone	All the others
V	On request	Viton	
E	On request	EPDM	
F	On request	FEP	207

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