PTM-PTFE Membrane

PTM Membrane Filter Cartridges are sterilizing grade filters msnufsctured with inherently hydrophobic polytetrafluoroethylene (PTFE) membrane. These cartridges are designed for use in the filtration of aggressive solvents and as compressed gas and vent filters. Each cartridge module is individually tested using the water intrusion method before it is released from manufacture. The cartridge surface area, filtr core design, pleat configuration, and pleat packing density have been optimized to provide increased cartridge life and lower filtration operating costs. Rugged construction ensures repeatable steaming and testing.

Construction Materials

Filtration Media	Polytetrafluoroethylene (PTFE) (absolute rated)			
Media Support	Polypropylene			
End Caps	Polypropylene			
Center Core	Polypropylene			
Outer Support Cage	Polypropylene			
Sealing Method	Thermal Bonding			
O-rings	Buna, Viton® (or FKM), EP, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)			

Maximum Operating Parameters

Differential Pressure				
• Forward	50 psid (3.54 bard) at 20 °C (68 °F)			
• Reverse	40 psid (2.7 bard) at 20 °C (68 °F)			
Operating Temperature	82 °C (180 °F) at 10 psid (0.69 bard)			
Recommended Changeout Pressure	35 psid (2.4 bard)			

Sanitization/Sterilization

Autoclave	121 °C (250 °F), 30 min, multiple cycles		
In-line Steam	135 °C (275 °F), 30 min, multiple cycles		
or all elevated temperature procedures above, a stainless steel			

For all elevated temperature procedures above, a stainless steel support ring is required.

Chemical Sanitization

Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.



Engineering Equipment for Sanitary Applications



Applications

Compressed Air
Pressurized Gases

Fermentation AirTank Ventilation

2 Solvents

Dimensions

Length	5 to 40 in. (12.7 to 101.6 cm) nominal
Outside Diameter	2.75 in. (7.0 cm) nominal
Filtration Area	8.2 ft ² (0.76 m ²) per 10 in. length

Integrity Test Specifications

Per 10-in. length

Pore Size (liquid)	Bubble Point 60/40 IPA/water wetted	Water Intrusion	
0.10 μm	22 psig (1.52 barg)	10 cc/10 minutes @ 35 psi (2.4 bar)	
0.22 μm	18 psig (1.24 barg)	13 cc/10 minutes @ 35 psi (2.4 bar)	
0.45 μm	9 psig (621 mbarg)	N/A	
1.0 μm	6 psig (414 mbarg)	N/A	
3.0 μm	2 psig (138 mbarg)	N/A	
5.0 μm	1 psig (69 mbarg)	N/A	



Quality Assurance and Standards

Filters are designed for use in cGMP-compliant processes. Our state of the art manufacturing facility and quality management system both meet ISO 9001 standards. Each operation from assembly and test to cleaning, drying, and packaging is done in appropriately rated clean rooms. Each catridge filter is marked with a lot code and serial number to ensure the traceability of manufacturing data and materials. A sophisticated MRP system collects and processes real time data from manufacturing centers and inspection points. This allows variable and attribute data to be quickly and easily analyzed driving constant improvements in both quality and cost.

USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical grade TM filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the requirements for Biological Reactivity Tests in the current version of the United States Pharmacopeia (USP) for Class VI-121° C Plastics. In addition, the materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as appropriate. PPS filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters. The levels of bacterial endotoxins in aqueous extracts from pharmaceutical grade filters are below current USP limits as specified for water for injection.

Extractables

Pharmaceutical grade filters typically exhibit low levels of non-volatile residues.

Validation

PTM catridge are validated using test procedures that comply with the intent of both ASTM F 838-05 and HIMA protocols for the determination of bacterial retention in filters used for liquid filtration. The filters are validated to remove 10^7 organisms per cm^2 of filter media: $0.10~\mu\text{m}$ membrance is challenged with Acholeplasma laidlawii $0.22~\mu\text{m}$ challenged with Brevundimonas diminuta $0.45~\mu\text{m}$ challenged with Serratia marcescens.

Flow Rate

The Typical Flow Rates table represents typical water flow at a 1 psid (69 mbard) pressure differential across a single 10 in. catridge element. These values are approximations because of the differences in pressure drop encountered in housings and piping systems. Extrapolation to multiple length cartridges in multiround housings can be done for sizing purposes. Exact flow rates will be installation dependent.

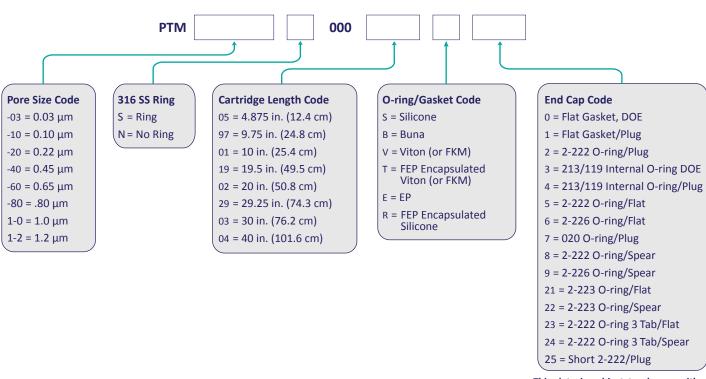
Typical Flow Rates

Pore Size	0.10 μm	0.22 μm	0.45 μm	1.0 μm	3.0 μm	5.0 μm
Liquid Flow Rates (gpm)	> 1.25	> 2.0	> 5.0	> 8.0	> 10.0	> 11.0
Air/Gas Flow Rates (scfm)	> 25	> 40	> 60	> 75	> 85	> 85



Ordering Information

Catridge order numbers have several variables from pore size to end cap type. For example, Pharmaceutical Grade, Double Layered Asymmetric PES Membrane, 0.22 Micron Rating, With SS Support Ring, 20" Length, Silicone O-Rings, 2-226/ Spear End Cap Configuration= PPS-20S00002S9.



This data is subject to change without notice.

