

## PTM/HT-PTFE Membrane

PTM/HT Membrane Filter Cartridges are sterilizing grade filters manufactured with inherently hydrophobic polytetrafluoroethylene (PTFE) membrane. These cartridges are designed for use in elevated temperature applications for 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, filter 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

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

### Maximum Operating Parameters

<b>Differential Pressure</b>	
• Forward	50 psid (3.54 barg) at 20 °C (68 °F)
• Reverse	40 psid (2.7 barg) at 20 °C (68 °F)
<b>Operating Temperature</b>	105°C (221 °F)

**Recommended maximum service life 1 year**

### Sanitization/Sterilization

<b>Autoclave</b>	121 °C (250 °F), 30 min, multiple cycles
<b>In-line Steam</b>	135 °C (275 °F), 30 min, multiple cycles

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.

## SEALING SYSTEMS

Engineering Equipment for Sanitary Applications



### Applications

- ② Compressed Air
- ② Pressurized Gases
- ② Fermentation Air
- ② Tank Ventilation
- ② Solvents

### Dimensions

<b>Length</b>	5 to 40 in. (12.7 to 101.6 cm) nominal
<b>Outside Diameter</b>	2.75 in. (7.0 cm) nominal
<b>Filtration Area</b>	8.2 ft <sup>2</sup> (0.76 m <sup>2</sup> ) 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	21 psig (1.5 barg)	10 cc/10 minutes @ 35 psi (2.4 bar)
0.22 µm	18 psig (1.2 barg)	13 cc/10 minutes @ 35 psi (2.4 bar)
0.45 µm	9 psig (0.62 barg)	N/A
1.0 µm	6 psig (0.41 barg)	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 9001:2008 standards. Each operation from assembly and test to cleaning, drying, and packaging is done in appropriately rated clean rooms. Each filter is assigned a lot code 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/HT 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. PTM/HT 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/HT cartridge 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 challenge level is 10<sup>7</sup> organisms per cm<sup>2</sup> of filter media: 0.22 µm challenged with Brvundimonas diminuta.

## Flow Rate

The Typical Flow Rates table represents typical water and air flow rates. These values are approximations because of the differences in pressure drop encountered in housings and piping systems. Extrapolation to multiple length cartridges in multi-round 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
Liquid Flow Rates (gpm)	> 1.25	> 2.0	> 5.0	> 8.0
Air/Gas Flow Rates (scfm)	> 25	> 40	> 60	> 75

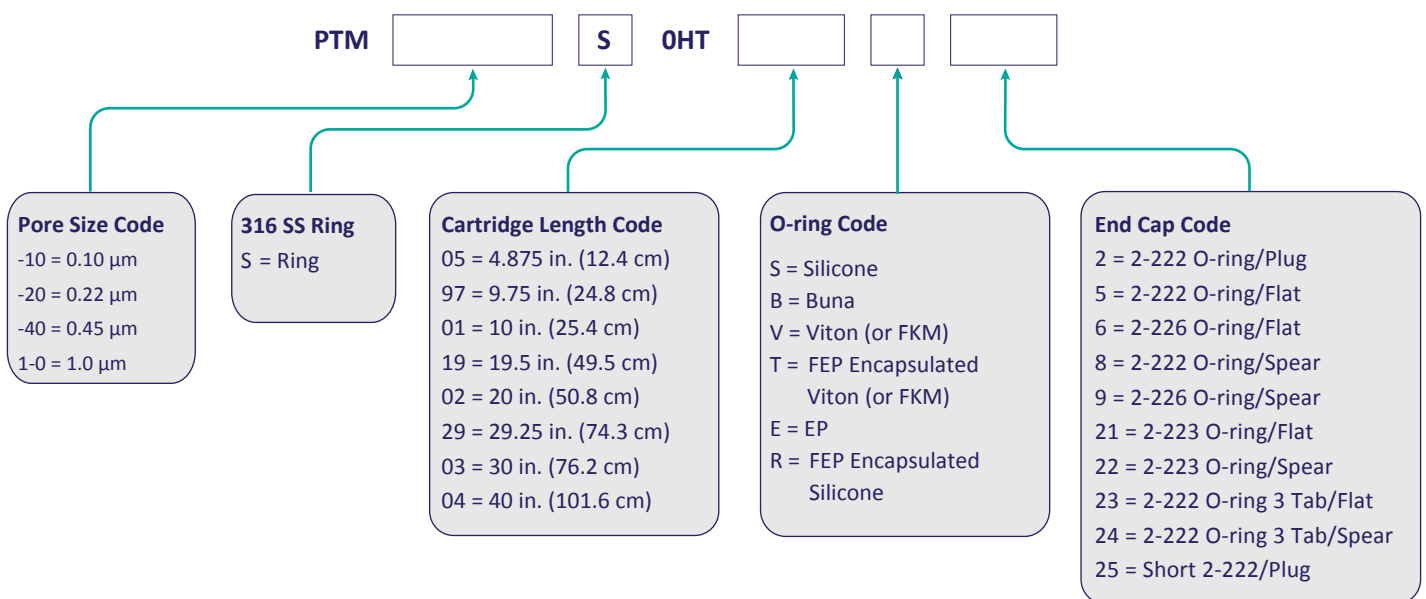
## Ordering Information

Cartridge order numbers have several variables from pore size to end cap type.

For example, Pharmaceutical Grade, PTFE Membrane, 0.22 Micron Rating (liquid),

With SS Support Ring, High Temperature 20" Length, Silicone O-Rings, 2-226/

Spear End Cap Configuration= PPS-20S00002S9.



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