BTM/HT-PTFE Membrane

SEALING SYSTEMS
Engineering Equipment for Sanitary Applications

BTM Filter Cartridges are manufactured with inherently hydrophobic polytetrafluoroethylene (PTFE) membrane. These cartridges are designed for use in the filtration of gases and non-aqueous liquids. Applications include bioburden control in frmentation air, compressed gas filtration to protect the integrity of stored liquids. Each cartridge module is individually teted 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

Filtration Media	PTFE Membrane (absolute rated)
Media Support	High Temperature Polypropylene
End Caps	High Temperature Polypropylene
Center Core	High Temperature Polypropylene
Outer Support Cage	High Temperature 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	105°C (221 °F)
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

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.

Applications

- Compressed Air Filtration
- Fermentation Air
- Solvent Filtration
- Non-Aqueous Solutions
- Tank Ventilation
- Process Gas

Dimensions

Length	5 to 40 in. (12.7 to 101.6 cm) nominal
Outside Diameter	2.75 in. (7.0 cm) nominal
Filtration Area	7.0 ft^2 (0.65 m^2) per 10 in. length

Integrity Test Specifications

60/40 IPA/water wetted membrane

Pore Size (liquid)	Bubble Point
0.10 µm	21 psig (1.45 barg)
0.22 µm	15 psig (1.0 barg)
0.45 µm	9 psig (621 mbarg)
1.0 µm	6 psig (414 mbarg)
3.0 µm	2 psig (138 mbarg)
5.0 µm	1 psig (69 mbarg)

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 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, allowing quick and easy analysis driving constant improvements in quality.

USP Biosafety and FDA Compliance

The materials used to construct pharmaceutical grade TM cartridge 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. BTM 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 biopharmaceutical grade filters are below current USP limits as specified for water for injection.

Extractables

Biopharmaceutical grade filters typically exhibit low levels of non-volatile residues. The levels of bacterial endotoxins in aqueous extracts from pharmaceutical grade filters are below current USP limits as specified for water for injection.

Validation

PTM/HT 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 challenge level is 10^7 organisms per cm^2 of filter media: 0.22 µm challenged with Brvundimonas diminuta.

Flow Rate

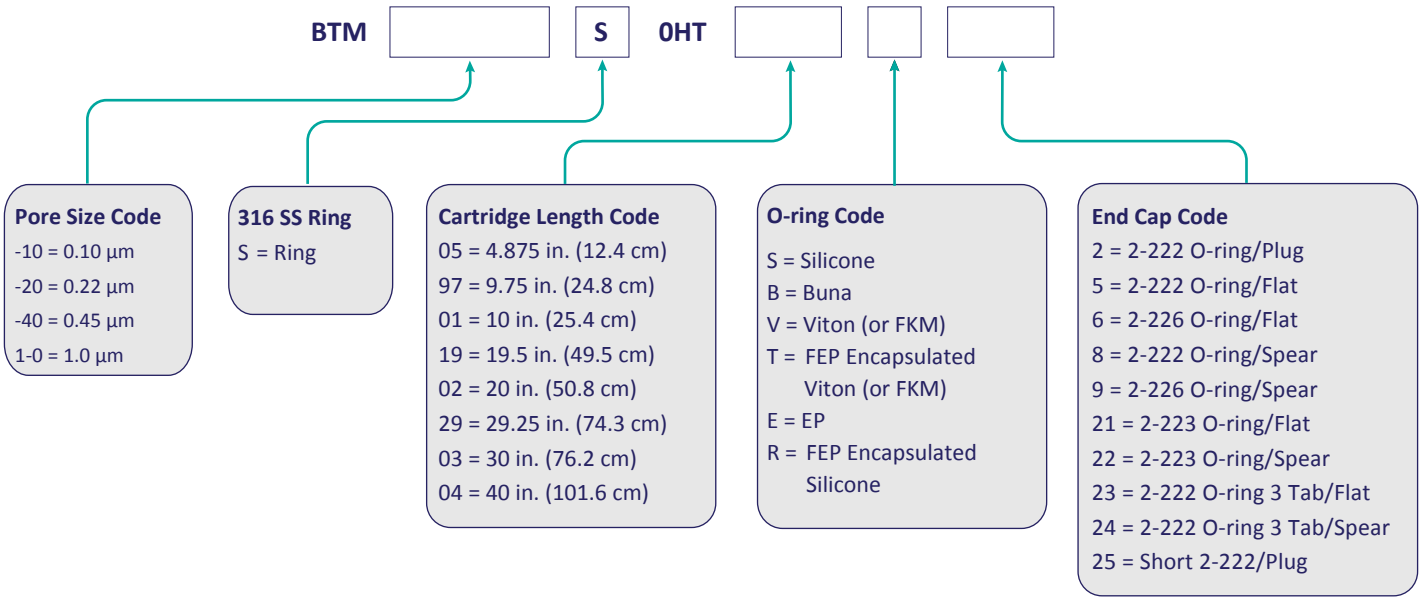
The Typical Flow Rates table represents typical water and air flows at ambient temperature and a 1 psid (69 mbard) pressure differential across a single 10 in. cartridge element. Extrapolation for housings with multiple elements and higher pressure drops is acceptable, but as flows increase the pressure drop of the housing becomes more apparent.

Typical Flow Rates

Pore Size	0.1 µm	0.22 µm	0.45 µm	1.0 µm	3.0 µm	5.0 µm
Liquid Flow Rates (gpm)	1.8	2.8	5.7	9.0	10.0	11.0
Air/Gas Flow Rates (scfm)	26	42	68	85	>95	>95

Ordering Information

Catridge 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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