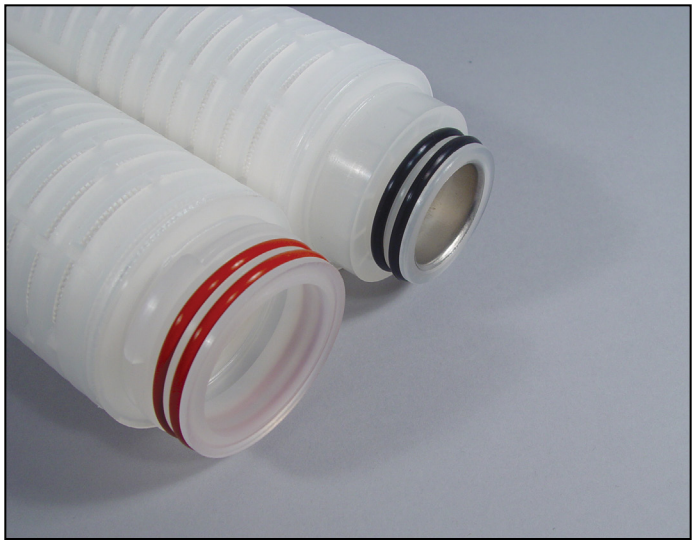
BTM Cartridge Filters

PTFE Membrane

CRITICAL PROCESS FILTRATION, INC.



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 fermentation air, compressed gas filtration and tank vent filtration to protect the integrity of stored liquids.

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

Filtration Media	PTFE Membrane
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)

Applications

- Fermentation Air
- Solvent Filtration
- Non-Aqueous Solutions
- Compressed Air Filtration
- Tank Vents
- 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)

Maximum Operating Parameters

Differential Pressure • **Forward**	50 psid (3.4 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

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

Chemical Sanitization

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

Total Performance

Critical Process Filtration, Inc. is a vertically integrated manufacturer of filtration products to industries in which filtration is considered a critical part of the manufacturing process. We supply a complete line of products and services to help you cost effectively satisfy all your filtration requirements from a single source.

Biopharmaceutical Grade

Quality Assurance and Standards

Critical Process Filtration 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, and 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 biopharmaceutical 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 cartridge filters are below current USP limits as specified for water for injection.

Extractables

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

Validation

Biopharmaceutical grade TM cartridges are validated using test procedures based on ASTM Method F838-05 and HIMA protocols. The challenge level is 10^7 organisms per cm^2 of filter media:
0.22 µm challenged with Brevundimonas diminuta;
0.45 µm challenged with Serratia marcescens;

Critical Process Filtration can provide validation assistance.

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
Liquid Flow Rates (gpm)	1.8	2.8	5.7	9.0
Air/Gas Flow Rates (scfm)	26	42	68	85

Ordering Information

Cartridge order numbers have several variables from pore size to end cap type. For example, Biopharmaceutical Grade PTFE Membrane, 0.22 Micron Rating, With SS Support Ring, 20" Length, Silicone O-Rings, 2-226/Spear End Cap Configuration = BTM-20S00002S9.

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Pore Size Code
-10 = 0.10 µm
-20 = 0.22 µm
-40 = 0.45 µm
1-0 = 1.0 µm

316 SS Ring
S = Ring
N = No Ring

Cartridge Length Code
05 = 4.875 in. (12.4 cm)
97 = 9.75 in. (24.8 cm)
01 = 10 in. (25.4 cm)
19 = 19.5 in. (49.5 cm)
02 = 20 in. (50.8 cm)
29 = 29.25 in. (74.3 cm)
03 = 30 in. (76.2 cm)
04 = 40 in. (101.6 cm)

O-ring/Gasket Code
S = Silicone
B = Buna
V = Viton (or FKM)
T = FEP Encapsulated Viton (or FKM)
E = EP
R = Teflon Encapsulated Silicone

End Cap Code
0 = Flat Gasket, DOE
1 = Flat Gasket/Plug
2 = 2-222 O-ring/Plug
3 = 213/119 Internal O-ring DOE
4 = 213/119 Internal O-ring/Plug
5 = 2-222 O-ring/Flat
6 = 2-226 O-ring/Flat
7 = 020 O-ring/Plug
8 = 2-222 O-ring/Spear
9 = 2-226 O-ring/Spear
21 = 2-223 O-ring/Flat
22 = 2-223 O-ring/Spear
23 = 2-222 O-ring 3 Tab/Flat
24 = 2-222 O-ring 3 Tab/Spear
25 = Short 2-222/Plug

Request a **QUOTE** from your area representative

CRITICAL PROCESS FILTRATION, INC.

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