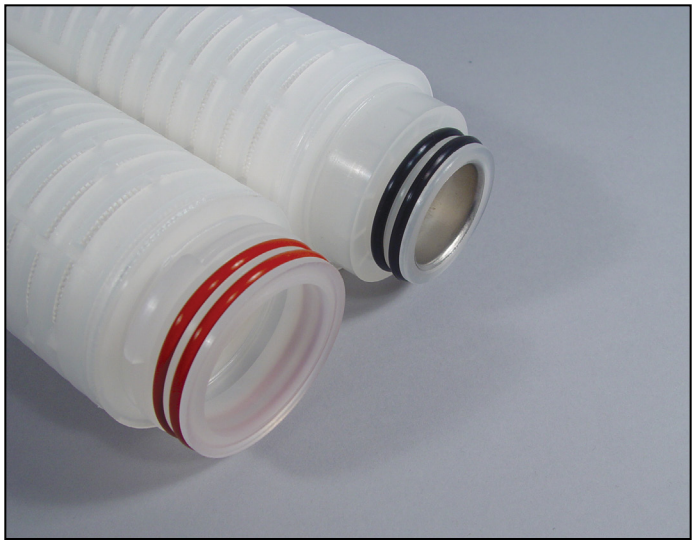
BPVWL Cartridge Filters

High Capacity PVDF Membrane

CRITICAL PROCESS FILTRATION, INC.



Biopharmaceutical Grade

Biopharmaceutical grade PVWL filters are made using hydrophilic polyvinylidene fluoride (PVDF) membrane. The proprietary membrane casting process creates a thick membrane with excellent retention characteristics and flow rates and low protein binding. BPVWL cartridges are used for a wide range of critical applications in the biopharmaceutical production.

Applications include bioburden reduction in buffers and media, water for injection (WFI), solvents, alcohols and other liquids. Our filters provide high efficiency, validatable performance protecting sterilizing grade filters.

PVDF is particularly suited for the filtration of products containing elements that can adsorb to the media, such as preservatives and proteins. The very low binding nature of PVDF makes it a good choice for filtration of valuable protein solutions such as vaccines, plasma products, MAb products, other biopharmaceuticals as well as products that contain low amounts of preservatives.

Construction Materials

Filtration Media	High Capacity Polyvinylidene Fluoride (PVDF) 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

- Buffers and Feedstocks
- WFI Water
- Serum
- Plasma Products
- SVPs
- LVPs
- Vaccines

Dimensions

Length	5 to 40 in. (12.7 to 101.6 cm) nominal
Outside Diameter	2.75 in. (7.0 cm) nominal

Integrity Test Information

Representative samples from each manufacturing lot are tested for integrity to ensure consistent performance.

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) in water
Recommended Changeout Pressure	35 psid (2.4 bard)

Sanitization/Sterilization

Filtered Hot Water	90 °C (194 °F), 30 minutes, multiple cycles, max 3 psid forward flow
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.

USP Biosafety and FDA Compliance

The materials used to construct biopharmaceutical grade 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. BPVWL 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

BPVWL filters are rinsed with high purity water to remove manufacturing debris and extractable substances. Biopharmaceutical grade filters typically exhibit low levels of non-volatile residues.

Ordering Information

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

Quality Assurance and Standards

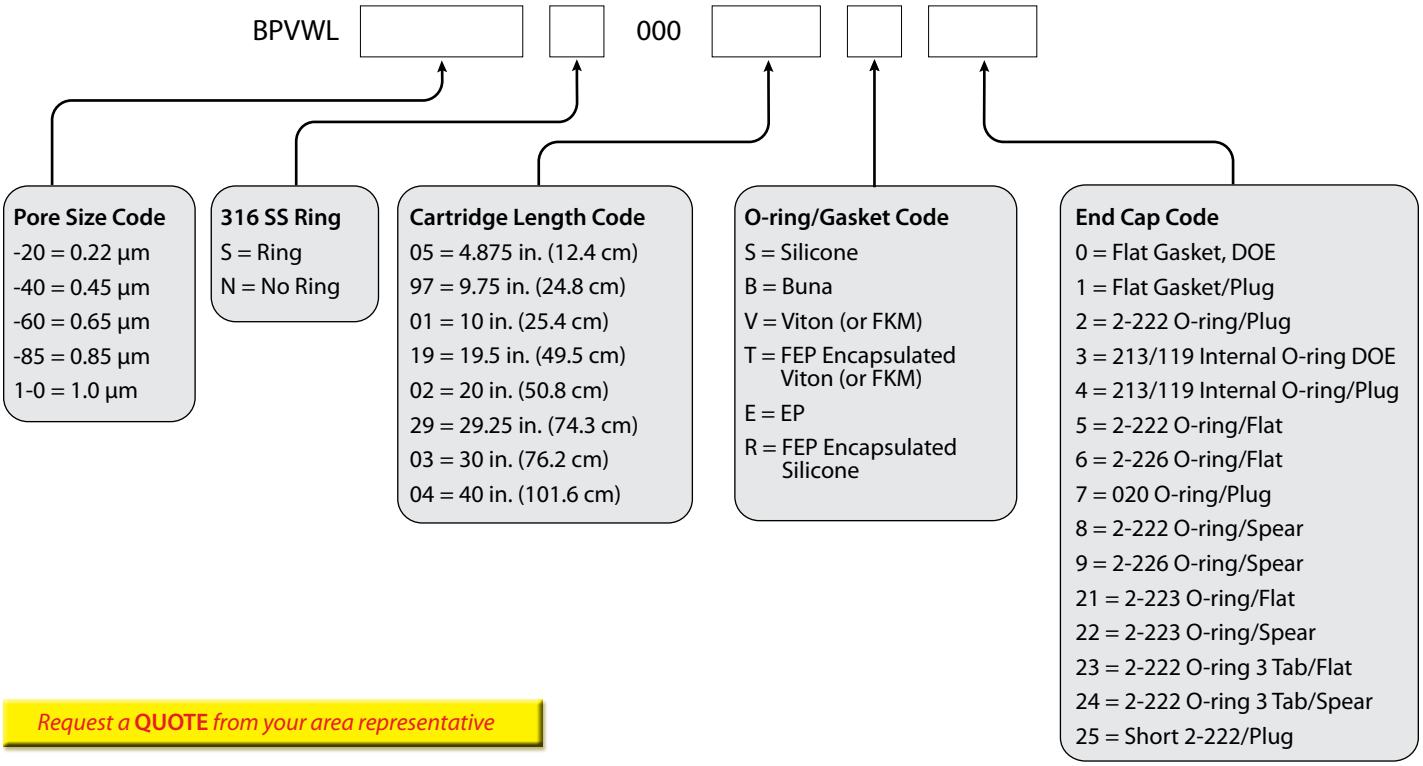
Our goal is to ensure our customers the greatest possible value for their filtration dollar. Our state of the art manufacturing facility and quality management system both meet ISO 9001:2008 standards. Each operation from assembly and test to cleaning, drying, and packaging is done in appropriately rated clean rooms. 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.

Flow Rate

The Typical Flow Rates table represents typical water flow at a 1 psid (69 mbard) pressure differential across a single 10 in. cartridge element. The test fluid is water at ambient temperature. 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	0.22 µm	0.45 µm	0.65 µm	0.85 µm	1.0 µm
GPM	1.1	1.4	2.5	4.0	7.0
LPM	4.16	5.30	9.46	15.14	26.50



Request a **QUOTE** *from your area representative*

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