

PGD Cartridge Filters

Pleated Fiberglass Depth Media



PGD Depth Filter Cartridges are designed to meet FDA requirements. Our pharmaceutical grade fiberglass depth media cartridges are composite media cartridges containing a final downstream layer of polypropylene media to ensure fiber free effluent. These cartridges have been rinsed with high purity water to remove manufacturing debris from the product. They are rated at 99% retention at the rated pore size. The cartridge offers the benefits of high contaminant holding as well as excellent retention. These high capacity cartridges are used in pre-filter applications as well as final filter applications where the goal is bioburden reduction and not sterile product.

Construction Materials

Filtration Media	Pleated Fiberglass and Polypropylene Composite Depth Media
Media Support	Polyester
End Caps	Polypropylene
Support Components	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)

Total Performance

CriticalProcessFiltration, 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.

Applications

- ◆ Diagnostics
- ◆ LVPs and SVPs
- ◆ Water
- ◆ Ophthalmics
- ◆ Biologicals
- ◆ Medications
- ◆ Bulk Pharmaceutical Chemicals
- ◆ Buffers and Other Media

Dimensions

Length	5 to 40 in. (12.7 to 101.6 cm) nominal
Outside Diameter	2.75 in. (7.0 cm) nominal
Filtration Area	5.8 ft ² (0.54 m ²) per 10 in. length (Average - area varies with media thickness and porosity)

Integrity Test Information

All filter cartridges are factory tested for integrity before shipment. Field duplication of these tests is not practical because of the absence of commercial portable testing equipment.

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.

USP Biosafety and FDA Compliance

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

Extractables

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

Flow Rate

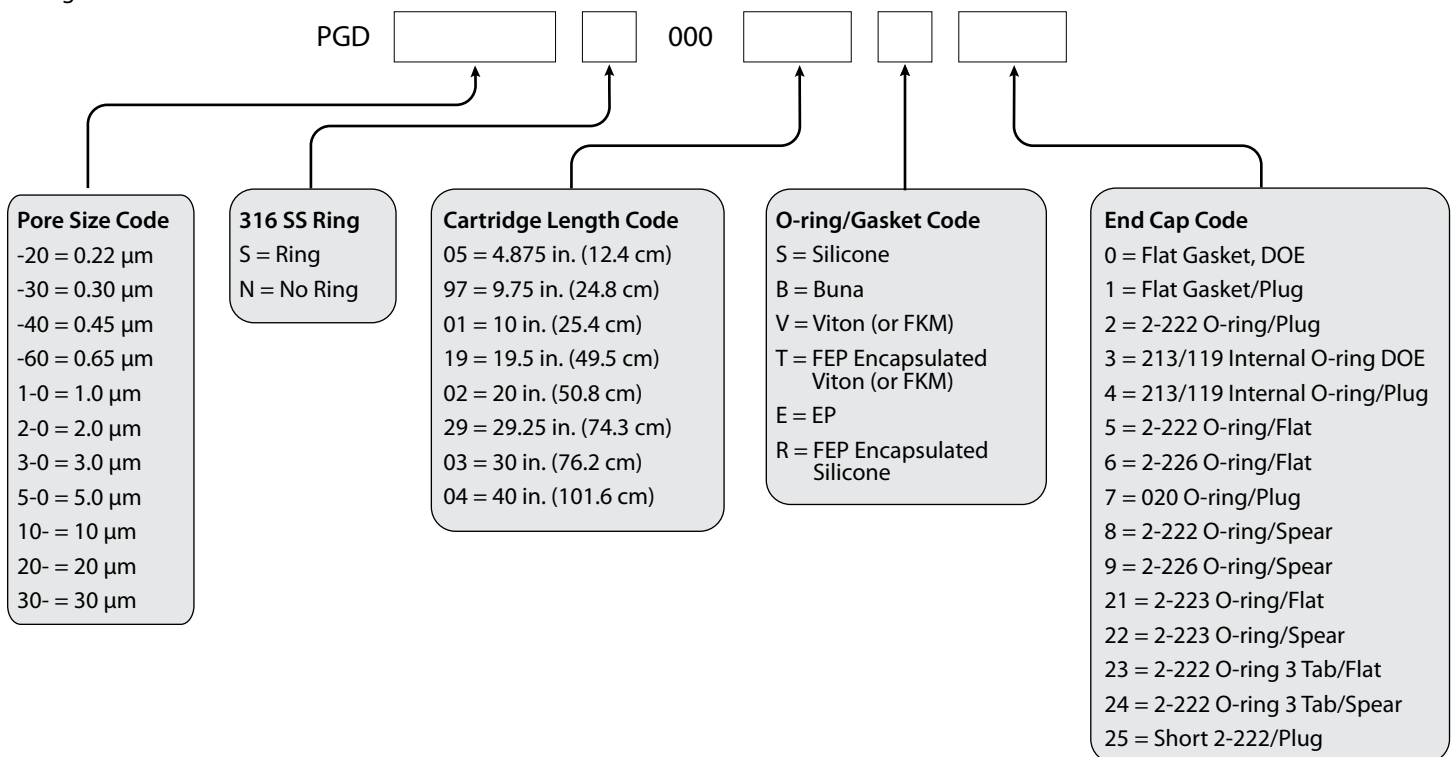
The Typical Flow Rate table represents typical water flow rates through a single 10-inch cartridge at 1 psid (69 mbard) pressure differential. These values are approximations because of the differences in pressure drop encountered in housings and piping systems. Extrapolation to multiple length cartridges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

Typical Flow Rates

Pore Size	0.22 µm	0.30 µm	0.45 µm	0.65 µm	1.0 µm	2.0 µm	3.0 µm	5.0 µm	10 µm	20 µm	30 µm
GPM	2.6	3.0	5.0	6.0	8.0	10	12	14	> 15	> 15	> 15
LPM	9.84	11.35	18.92	22.71	30.28	37.85	45.42	52.99	> 56.78	> 56.78	> 56.78

Ordering Information

Cartridge order numbers have several variables from pore size to end cap type. For example, Pharmaceutical Grade Pleated Fiberglass/ Polypropylene Composite Depth Media, 1.0 Micron Rating, With SS Support Ring, 20" Length, Silicone O-Rings, 2-226 O-Ring/Spear End Cap Configuration = PGD1-0S00002S9.



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. 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.

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