# PPS-Double Layered PES Membrane

SEALING SYSTEMS
Engineering Equipment for Sanitary Applications

Pharmaceutical grade polyethersulfone PPS Filter Cartridges are sterilizing grade cartridges. The polyethersulfone (PES) membrane used in these cartridges is optimized for retention and is double layered for extra security. Polyethersulfone cartridges see broad service in sterile fill applications in SVPs and biological proucts. Polyethersulfone is particularly suited for the filtration of products whose constituents, such as preservatives and proteins, can adsorb to the media. The low binding characteristics of polyethersulfone make it a good choice for filtration of ophthalmics and valuable protein solutions such as vaccines and other biologicals. PPS Membrane Filter Cartridges are flushed to remove manufacturing debris and reduce extractables and are 100% integrity tested.

## Construction Materials

| | |
|---|---|
| **Filtration Media** | Double Layered Asymmetric Polyethersulfone (PES) Membrane (absolute rated) |
| **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) |

## We Do It Right the First Time

We solve filtration challenges where filters are a critical part of your manufacturing process. Our Technical Team works with you to enginner filtration solutions that fit your needs. Then we manufacture the filters in our ISO 9001 certified facility and deliver them fast, so you have the right filters when you need them.

## Maximum Operating Parameters

| | |
|---|---|
| **Differential Pressure** | |
| • **Forward** | 80 psid (5.5 bard) at 20 °C (68 °F) |
| • **Reverse** | 50 psid (3.5 bard) at 20 °C (68 °F) |
| **Operating Temperature** | 82 °C (180 °F) at 30 psid (2.1 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, 25+ cycles |
| **In-line Steam** | 135 °C (275 °F), 30 min, 25+ 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

- Diagnostics
- LVPs and SVPs
- Water for Injection
- Vaccines
- Biologicals
- Ophthalmics

## Dimensions

| | |
|---|---|
| **Length** | 5 to 40 in. (12.7 to 101.6 cm) nominal |
| **Outside Diameter** | 2.75 in. (7.0 cm) nominal |
| **Filtration Area** | 6.1 $ft^2$ (0.57 $m^2$) per 10 in. length |

## Integrity Test Specifications

Per 10-in. length, water wetted membrane

| Pore Size | Air Diffusion Rate |
|---|---|
| **0.03 µm** | < 15 cc/min at 60 psig (4.1 barg) |
| **0.10 µm** | < 15 cc/min at 48 psig (3.3 barg) |
| **0.22 µm** | < 15 cc/min at 35 psig (2.4 barg) |
| **0.45 µm** | < 15 cc/min at 20 psig (1.4 barg) |
| **0.65 µm** | < 15 cc/min at 15 psig (1.0 barg) |
| **0.80 µm** | < 15 cc/min at 12 psig (0.8 barg) |
| **1.0 µm** | < 15 cc/min at 8 psig (552 mbarg) |
| **1.2 µm** | < 15 cc/min at 7 psig (483 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 catridge filter is marked with a lot code and serial number 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 PS 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. PPS filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

## Extractables

Pharmaceutical 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 limitsas specified for water for injection.

## Validation

PPS 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 filters are validated to remove $10^7$ organisms per $cm^2$ of filter media: 0.10 µm membrance is challenged with Acholeplasma laidlawii 0.22 µm challenged with Brevundimonas diminuta 0.45 µm challenged with Serratia marcescens 0.65 µm challenged with Saccharomyces cerevisiae.

## Flow Rate

The Typical Flow Rates table represents typical water flow at a 1 psid (69 mbard) pressure differential across a single 10 in. catridge 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 | 0.03 µm | 0.10 µm | 0.22 µm | 0.45 µm | 0.65 µm | 0.8 µm | 1.0 µm | 1.2 µm |
|---|---|---|---|---|---|---|---|---|
| GPM | 0.6 | 1.0 | 1.6 | 3.2 | 4.0 | 5.4 | 8.0 | 10.0 |
| LPM | 2.27 | 3.79 | 6.06 | 12.11 | 15.14 | 20.44 | 30.28 | 37.85 |

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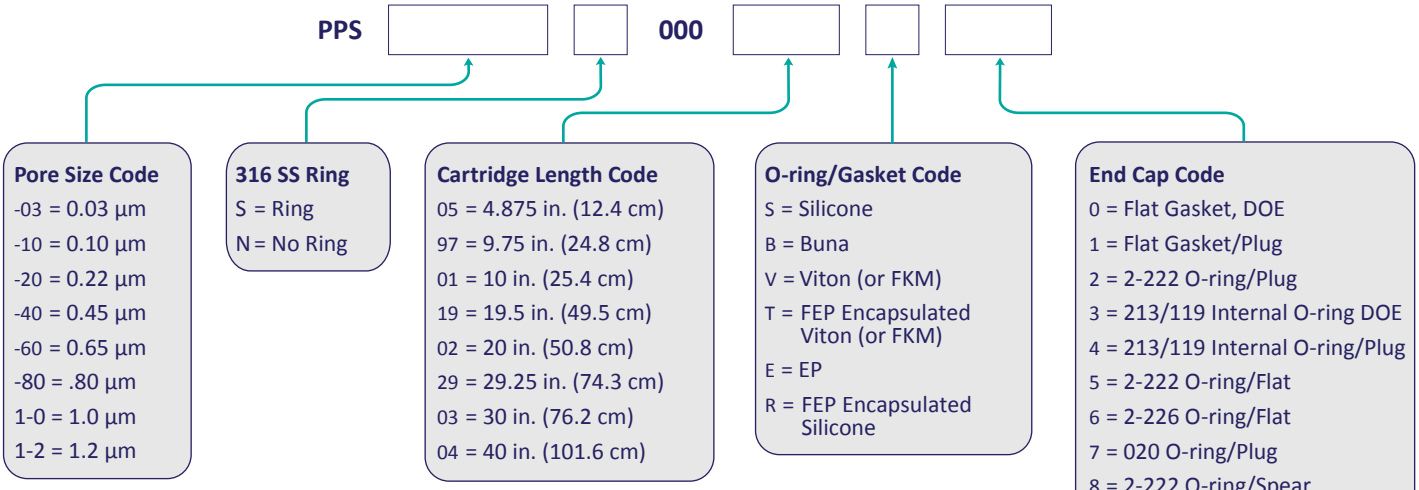
## Ordering Information

Catridge order numbers have several variables from pore size to end cap type.
For example, Pharmaceutical Grade, Double Layered Asymmetric PES Membrane, 0.22 Micron Rating, With SS Support Ring, 20" Length, Silicone O-Rings, 2-226/ Spear End Cap Configuration= PPS-20S00002S9.




**This data is subject to change without notice.**


Sealing Systems

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