

3M Purification Inc.

LifeASSURE™ PFS Series PTFE Filters





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LifeASSURE™ PFS series PTFE filters offer the ultimate in microorganism retention for air and gas streams while providing superior air flow capacity.

- 3M Purification Inc.'s LifeASSURE PFS series PTFE filters with flow enhanced construction allow use of smaller, more economical air filter assemblies compared to competitive air filters.
- LifeASSURE PFS series PTFE filters provide absolute retention based on liquid bacteria challenge and aerosol bacteriophage challenge.
- LifeASSURE PFS series PTFE filters are available in a wide range of cartridge and capsule configurations to provide the most economical solution to air, gas and aggressive liquid filtration applications.

Cartridge & Capsule Configurations to Meet Any Process Requirement

LifeASSURE PFS series PTFE filters are available in 5" through 40" cartridges, 2.5" and 5" Mini Cartridges and 2.5", 5", 10", 20" and 30" capsules. With the exceptionally high flow rates, smaller and more economical assemblies can provide the same air flow as larger, more costly competitive PTFE filters.

Features & Benefits

Flow enhancing layer construction

Higher air flow for fermenter aeration and smaller, more economical vent filter assemblies

Liquid validation of *B. diminuta* retention

Reliable sterilizing performance in wet or dry conditions

Hydrophobic PTFE membrane

Membrane will not become blocked with moisture

21 CFR Materials of Construction, USP Biological Safety Test, Validation Guide and Drug Master File Listing

Eases validation and regulatory submissions



LifeASSURE™ PFS Series PTFE Filter Applications

LifeASSURE™ PFS series PTFE filters are optimized for applications requiring sterilization of air, gas or aggressive solvents and chemicals. The hydrophobic PTFE filter membrane prevents wetting with aqueous liquids or moisture that can block free air flow. Some applications, however, may require filtration of aggressive fluids such as acids or bases. Depending on compatibility, LifeASSURE PFS series PTFE filters can be used to provide sterile filtration of these fluids by prewetting the membrane with a low surface tension fluid such as alcohol.

A list of LifeASSURE PFS series PTFE filter applications includes:

- Sterile venting of process tanks
- Sterile filtration of process air and aseptic filling lines
- Sterile venting of lyophilizers
- Sterile venting of autoclaves
- Sterile air filtration on blow, fill, and seal machines
- Sterilizing filtration of fermentation inlet and exhaust air
- Sterile filtration of aggressive liquids

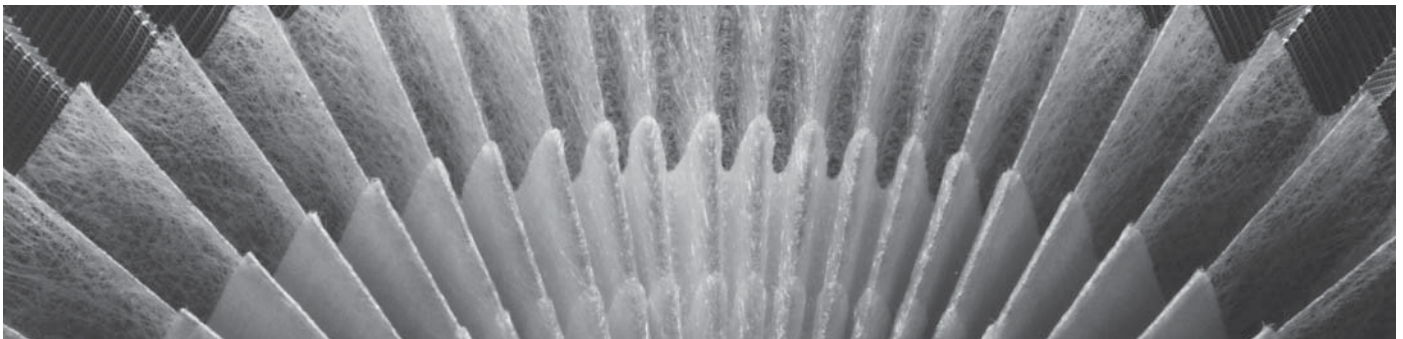
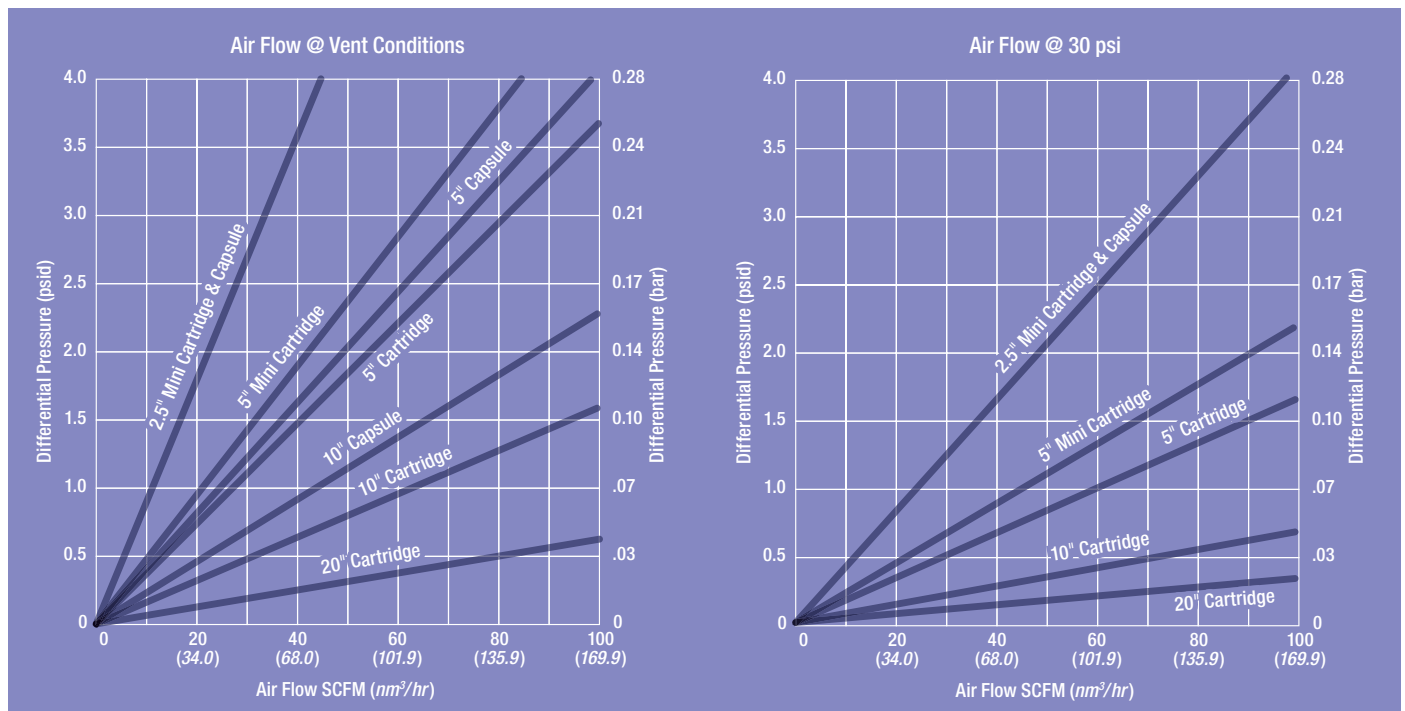


Photo 1. LifeASSURE™ PFS series PTFE filter detail.

LifeASSURE PFS series PTFE filters were designed to provide exceptionally high flow rates with low differential pressures (Figure 1). LifeASSURE PFS series PTFE filters are available in a range of cartridge and capsule filter configurations to meet any process requirement. Shown in Figure 1 are flow curves for filter assemblies at atmospheric (vent) and compressed air conditions. For details of sizing vent and compressed air assemblies, please ask for 3M Purification automated sizing program assistance.

Figure 1. LifeASSURE PFS series PTFE filter air flow vs. differential pressure*



* Cartridge airflow values with housing pressure loss subtracted (excluding capsules).

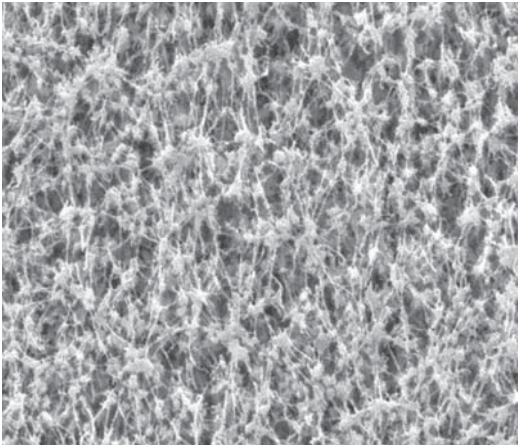


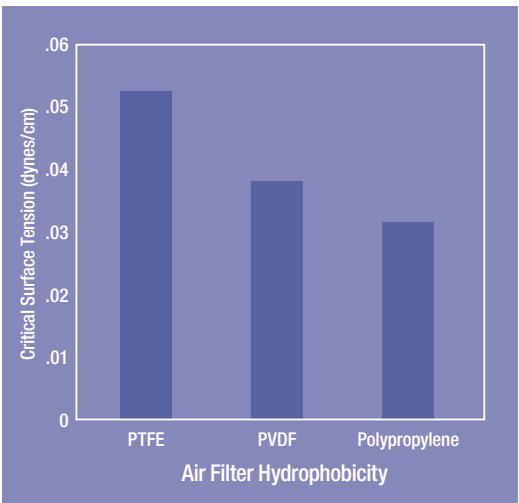
Photo 2. SEM of LifeASSURE™ PFS series PTFE filter membrane.

The LifeASSURE™ PFS Series PTFE Filter Advantage

LifeASSURE™ PFS series PTFE filters combine high flow with a liquid validated, bacteria retentive, hydrophobic PTFE filter membrane. Filter structural components are polypropylene, optimized for long on-stream air service. The most important characteristics for a sterilizing grade air filter include:

Validated PTFE Membrane

LifeASSURE PFS series PTFE filters are validated by liquid bacteria challenge for complete retention. Liquid bacteria challenge represents the most severe test of filter performance and provides the highest assurance level of reliable sterilizing performance. In addition, LifeASSURE PFS series PTFE filters have demonstrated complete aerosol retention of the bacteriophage ΦX-174. For complete details, request the LifeASSURE PFS series Validation Guide (70-0201-8843-2). The Scanning Electron Micrograph (SEM) (Photo 2) shows the structure of the PTFE membrane with a tortuous pore pathway of flow channels.



Graph 1. Comparative hydrophobicity.

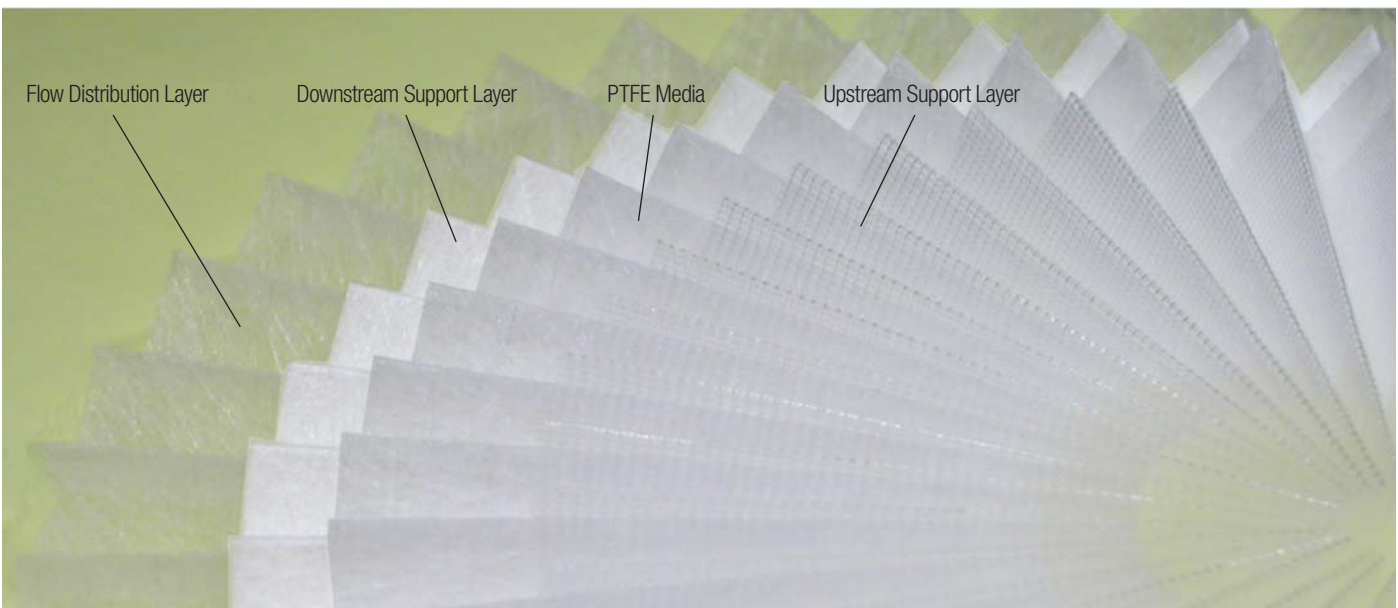
Hydrophobicity

Free air flow with little resistance requires that the filter membrane not wet with water or moisture. Membrane wetting can result in filter pore blockage, which in turn prevents free air flow and can cause filter failure. In order to prevent pore blockage, an extremely hydrophobic PTFE membrane is used which prevents wetting with water or moisture. Graph 1 shows the relative hydrophobicity of filter media used in air filters. As can be seen, PTFE offers the highest level of hydrophobicity ensuring optimum air flow service.

High Air Flow

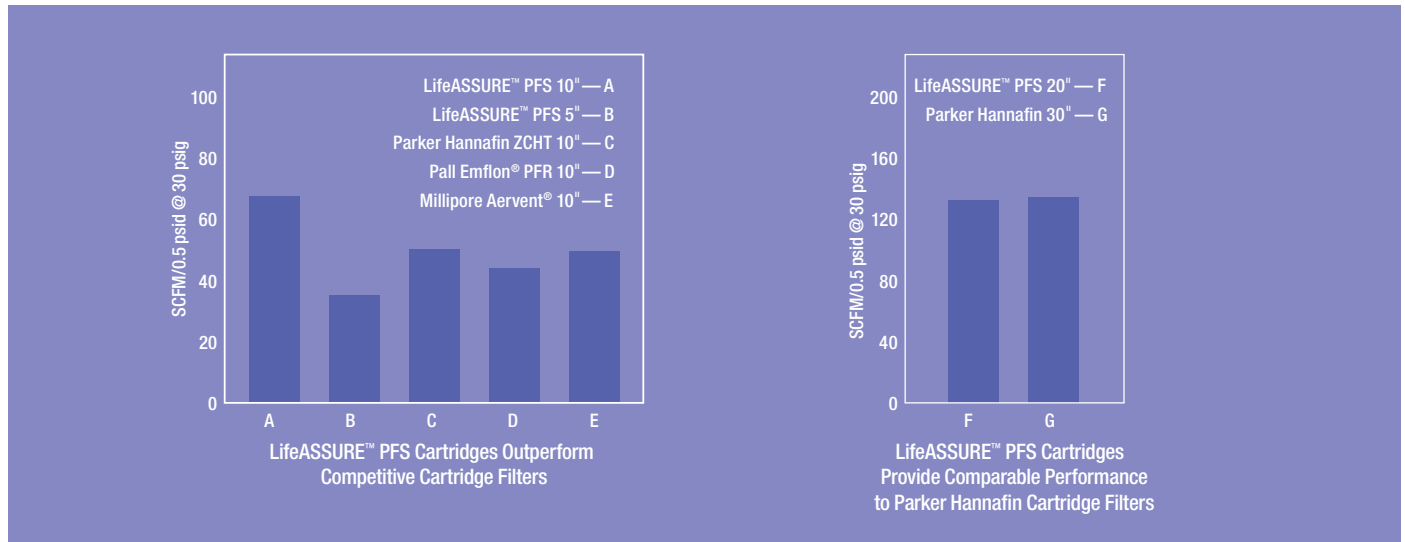
Efficient performance requires maximum air flow at minimum pressure drop. LifeASSURE PFS series PTFE air filters are constructed to achieve higher air flow vs. pressure drop compared to competitive air filters. This 3M Purification development involves the use of specially designed PTFE filter membrane and polypropylene flow enhancing layers. This construction is applied to LifeASSURE PFS series PTFE filters. Photo 3 shows how each layer is positioned within the filters.

Photo 3. LifeASSURE™ PFS series PTFE filter construction.



Superior Flow Rate Performance

LifeASSURE™ PFS series PTFE filters offer outstanding flow rate performance at low differential pressures. Whether used for tank venting, lyophilizer or autoclave vacuum breaking, blow, fill, seal machines or fermentation air sterilization, filter flow rate is a critical parameter. Using the design enhancements described, LifeASSURE PFS series PTFE filters provide maximum flow performance. Graph 2 presents the comparison of LifeASSURE PFS series PTFE filter performance to competitive air filters.



Graph 2. Air flow rate comparisons.

Reliable Microorganism Retention Performance

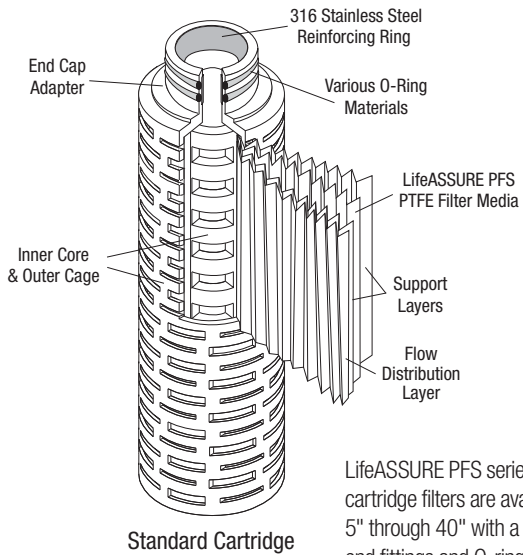
LifeASSURE PFS series PTFE filters are validated for sterilizing performance using a liquid bacteria (*B. diminuta*) challenge test method. Liquid bacteria retention testing is the most critical test of sterilizing filter performance and provides the user with the utmost assurance that critical product or fermentation broth will be protected from contamination. In addition to demonstrating sterilizing performance in liquid, LifeASSURE PFS series PTFE filters were tested for complete bacteriophage retention using aerosol challenge test methods. Aerosol retention performance provides users that LifeASSURE PFS series PTFE filters will provide reliable air and gas sterilization. Aerosol challenge testing was performed using Φ X-174 bacteriophage which are small organisms that infect bacteria cells and can ruin bacteria fermentation processes. Complete retention of bacteriophage was observed as shown in Table 1. For complete details request the 3M LifeASSURE PFS Series Validation Guide (70-0201-8843-2).

Table 1. LifeASSURE PFS series PTFE filter retention performance.

| Test Method | Test Organism | Test Result |
|---------------------------|----------------------------|------------------------|
| Liquid Bacteria Challenge | <i>B. diminuta</i> | Sterile |
| Aerosol Virus Test | Φ X-174 Bacteriophage | 0 Plaque Forming Units |

Scientific Applications Support Services (SASS)

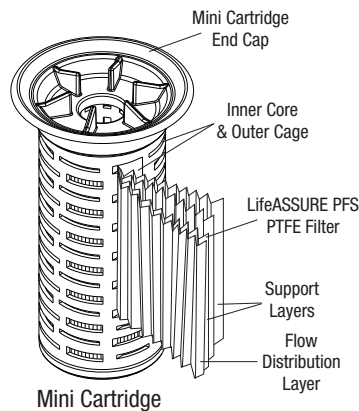
3M Purification Inc.'s years of experience are synonymous with quality, performance and high-level technical support. The cornerstone of 3M Purification's philosophy is service to customers, not only in product quality and prompt delivery, but also in validation assistance, applications support and in the sharing of scientific information. 3M Purification's Scientific Applications Support Services (SASS) group works closely with customers to solve difficult separations problems and to recommend the most economical and efficient filter system. SASS Specialists are skilled in performing on-site testing and relating test results to full-scale manufacturing operations.



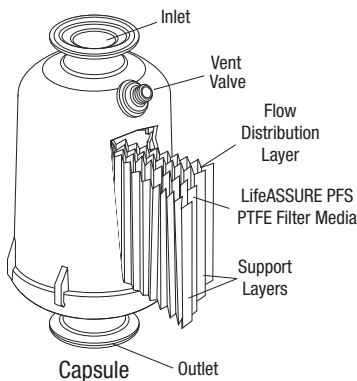
Standard Cartridge

LifeASSURE PFS series PTFE cartridge filters are available in 5" through 40" with a variety of end fittings and O-ring options to meet hardware and process requirements.

3M Purification 2.5" and 5" LifeASSURE PFS series PTFE mini cartridges can be installed in existing Pall Sealkleen™ housings or 3M Purification mini cartridge housing (70-0201-8886-1).



Mini Cartridge



Capsule

LifeASSURE PFS series PTFE capsule filters are available in 2.5", 5", 10", 20" and 30" configurations. Capsule filters may be autoclave sterilized and offer a convenient, easy to use format for air sterilization. As with LifeASSURE PFS series PTFE cartridge filters, the capsule filters have been specially designed to provide optimum air flow. Capsules are not recommended for continuous compressed gas service.

Quality & Reliability

LifeASSURE™ PFS series PTFE filters are manufactured within an ISO 9001:2008 registered quality system and are 100% diffusion flow tested prior to shipment. All materials of construction are 21 CFR listed and filter components have been tested in accordance with United States Pharmacopoeia (USP) Class VI Biological Safety. All LifeASSURE PFS series PTFE filters are shipped with a Certificate of Quality affirming compliance with rigid manufacturing quality specifications. Supporting Drug Master File (DMF) documentation is on file with the United States Food and Drug Administration (FDA). A complete LifeASSURE PFS series Validation Guide (70-0201-8843-2) is available upon request.

Integrity Testing

LifeASSURE PFS series PTFE filters can be easily and automatically tested to verify filter integrity pre and post use using the CUNOCheck™ 2 integrity test instrument. Filters can be tested using diffusive flow, pressure hold, bubble point or water intrusion test (WIT) methods. Refer to 3M Purification publication (70-0201-8804-4) — Integrity Testing LifeASSURE PFS Series PTFE filters.



Quality Management & ISO Standards

3M Purification has maintained its leadership in fluid purification and filtration by continually providing superior products and technical support. 3M Purification Inc. filtration systems are designed and manufactured to the most stringent industry standards to provide the reliability of 3M Purification Inc. systems that our customers have come to expect.

3M Purification has established a global quality management program which encompasses all facets of its operations. An essential part of the program is the creation of multi-function teams whose combined expertise is devoted to continuous improvement of processes, procedures and quality systems. In addition, the system has the active support and participation of senior management. 3M Purification Inc. is fully committed to the tenets of the quality management program and provides a support system for the quality process. The majority of 3M Purification Inc. manufacturing plants are ISO 9001:2008 registered. At 3M Purification Inc., quality is defined by the never-ending pursuit for continuous improvement in products, services, and personnel.

LifeASSURE™ PFS Series PTFE Filters

Operating Parameters and Specifications

| Filter Configuration | Cartridge | Mini Cartridge | | Capsule** | | | | |
|--|---|----------------|------------|------------------------------------|------------|-----------|-----------|-----------|
| | 5" to 40" | 2.5" | 5" | 2.5" | 5" | 10" | 20" | 30" |
| Filter Rating | 0.2 µm | | | | | | | |
| Materials of Construction | | | | | | | | |
| Membrane | PTFE | | | | | | | |
| Membrane Support Layer | Polypropylene | | | | | | | |
| Inner core, outer cage, end cap adapters, and adapters | Polypropylene | | | | | | | |
| Adapter Reinforcing Ring | Stainless Steel | NA | | | | | | |
| Filtration Surface Area: ft ² (m ²) | 11 (1.02)* | 1.8 (0.17) | 3.7 (0.34) | 2.8 (0.26) | 5.5 (0.51) | 11 (1.02) | 22 (2.04) | 33 (3.07) |
| Maximum Differential Pressure | | | | | | | | |
| Forward Pressure | 80 psid (5.5 bar) @ 77 °F (25 °C) 25 psid (1.7 bar) @ 176 °F (80 °C) | | | 75 psid (5.2 bar) @ 104 °F (40 °C) | | | | |
| Reverse Pressure | 65 psid (4.5 bar) @ 77 °F (25 °C) | | | 65 psid (4.5 bar) @ 77 °F (25 °C) | | | | |
| Maximum Operating Temperature | 176 °F (80 °C) | | | 104 °F (40 °C) | | | | |
| Integrity Test Parameters - Forward Flow Test - @ 16 psig (1.1 bar)*** | | | | | | | | |
| 25%/75% (v/v) TBA/Water @ 20 °C and 1 atm: cc/min. | ≤ 8.7 * | ≤ 1.4 | ≤ 2.9 | ≤ 2.2 | ≤ 4.4 | ≤ 8.7 | ≤ 17.4 | ≤ 26.1 |
| 60%/40% (v/v) IPA/Water @ 25 °C and 1 atm: cc/min. | ≤ 35.5* | ≤ 5.8 | ≤ 11.9 | ≤ 9.0 | ≤ 17.8 | ≤ 35.5 | ≤ 71.0 | ≤ 106.5 |
| 70%/30% (v/v) IPA/Water @ 25 °C and 1 atm: cc/min. | ≤ 54.0* | ≤ 8.8 | ≤ 18.2 | ≤ 13.7 | ≤ 27.0 | ≤ 54.0 | ≤ 108.0 | ≤ 162.0 |
| Minimum Bubble Point: psig (bar)**** | 16 (1.1) | | | | | | | |
| Water Intrusion Test — Maximum Allowable Flow at 40 psig (2.76 bar) @ 20 °C and 1 atm: cc/min. | 0.59 | 0.10 | 0.20 | 0.15 | 0.30 | 0.59 | 1.18 | 1.77 |
| Autoclave Conditions: | Up to 259 °F (126 °C) | | | | | | | |
| <i>In situ</i> Steam Conditions: | Up to 293 °F (145 °C) | | | Do not <i>in situ</i> steam | | | | |

* per 10" element

** not for continuous compressed gas service.

*** NOTE: Wetting fluid should be maintained within +/- 2% v/v concentration and +/- 2 °C temperature.

**** Wet with 25%/75% (v/v) TBA/Water, 60%/40% (v/v) IPA/Water, or 70%/30% (v/v) IPA/Water.

3M Purification Inc. Filter Housings

A complete line of sanitary design, stainless steel filter housings is available for LifeASSURE™ PFS series PTFE cartridge filters. Options are available for heat traced (electrical and steam jacketed) housings where condensate is a concern. Specialized configurations and housing designs are also available for high flow, fermentation air filtration applications.

| Housing Model | Mini ZMS | ZMS | ZWB | ZVS | Mini Cartridge Housing | | |
|-------------------------------------|------------------------------------|--------------------------------------|-----------------------------------|------------------------------------|------------------------------------|------------------------------------|-------------|
| Basic Part #/ Cartridge Capacity | For 5" Cartridge | For 10", 20", 30" and 40" cartridges | | | For 2.5" Mini Cartridges | For 5" Mini Cartridges | |
| | 70236 / 1 | 70628-01 | 70612 / 3 | | 70627-01 | 7023502 / 1 | 7023501 / 1 |
| | | 70628-02 | 70614 / 5 | | 70627-02 | | |
| | | 70628-03 | 70616 / 8 | | 70627-03 | | |
| | | 70628-04 | 70626 / 12 | | 70627-04 | | |
| Housing Style | T-line Sanitary type connection | | | Sanitary type in-line | | | |
| Equivalent Cartridge Lengths | 5" | 10", 20", 30" and 40" | | | 2.5" | 5" | |
| Materials of Construction | 316L Stainless Steel | | | | | | |
| Pressure & Temperature Ratings | 150 psi (10 bar) @ 212 °F (100 °C) | 150 psi (10 bar) @ 212 °F (100 °C) | 150 psi (10 bar) @ 200 °F (90 °C) | 150 psi (10 bar) @ 212 °F (100 °C) | 150 psi (10 bar) @ 300 °F (149 °C) | 150 psi (10 bar) @ 300 °F (149 °C) | |
| Literature # | 70-0201-8887-9 | 70-0201-8883-8 | 70-0201-8884-6 | 70-0201-8883-8 | 70-0201-8886-1 | | |

LifeASSURE™ PFS Series PTFE Filter Ordering Guide

Cartridges

| Grade Designation | Configuration | Height (Inches) | End Modification | O-ring Material |
|-------------------|---------------|--|--|--|
| PFS020 | A | 01 - 10 02 - 20 03 - 30 04 - 40 50 - 5 | B - 226 O-ring & spear C - 222 O-ring & spear F - 222 O-ring & flat cap J - 226 O-ring & flat cap | A - Silicone B - Fluorocarbon C - EPR D - Nitrile K - PTFE Encapsulated fluorocarbon |

Mini Cartridges

| Grade Designation | Configuration | Height (Inches) | End Modification | Package Quantity |
|-------------------|---------------|--------------------|------------------|------------------|
| PFS020 | R | 01 - 2.5 02 - 5 | AN | 06 - 6 pack |

Capsules

| Grade Designation | Configuration | Height (Inches) | End Modification | Vent O-ring Material | Package Quantity |
|-------------------|---------------|---|----------------------|---|------------------|
| PFS020 | J | 01 - 10 02 - 20 03 - 30 25 - 2.5 50 - 5 | A - Sanitary fitting | A - Silicone B - Fluorocarbon C - EPR | 01 - 1 pack |

Important Notice

The information described in this literature is accurate to the best of our knowledge. A variety of factors, however, can affect the performance of the Product(s) in a particular application, some of which are uniquely within your knowledge and control. **INFORMATION IS SUPPLIED UPON THE CONDITION THAT THE PERSONS RECEIVING THE SAME WILL MAKE THEIR OWN DETERMINATION AS TO ITS SUITABILITY FOR THEIR USE. IN NO EVENT WILL 3M PURIFICATION INC. BE RESPONSIBLE FOR DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM THE USE OF OR RELIANCE UPON INFORMATION.**

It is your responsibility to determine if additional testing or information is required and if this product is fit for a particular purpose and suitable in your specific application.

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