

3M Purification Inc.

LifeASSURE™ PFC Series Filters

Sterilizing Grade Air & Gas Filters with ECTFE Membrane



**Innovative
Filtration**

Performance. Quality. Service.



LifeASSURE™ PFC Series Filters

LifeASSURE™ PFC Series filters represent a new generation in sterilizing grade gas filtration. Featuring a novel ethylene chlorotrifluoroethylene (ECTFE) microporous membrane developed by 3M, LifeASSURE PFC series filters are ideally suited for large scale fermentation air inlet and exhaust systems, as well as tank venting applications.

The single layer, hydrophobic ECTFE membrane is contained in a single open end (SOE) filter cartridge construction optimized for long service life with multiple exposures to steam sterilization.

LifeASSURE PFC series filters have been validated for complete retention of *Brevundimonas diminuta* bacteria in liquid and demonstrated complete retention of ΦX-174 virus in aerosol. A complete Validation Guide for the LifeASSURE PFC series filter is available.

Each filter is 100% integrity tested in manufacturing before release and is supplied with a Certificate of Quality. All filter materials are fully traceable in 3M Purification Inc.'s ISO 9001:2008 certified quality system.

LifeASSURE PFC series filters feature a flow enhanced construction that can allow use of smaller, more efficient systems.

LifeASSURE PFC Series Filters

LifeASSURE PFC series filters combine excellent air flow with a demonstrated aerosolized virus retentive and validated liquid bacteria retentive hydrophobic bacteria retentive, hydrophobic ECTFE microporous membrane. Filter structural components are polypropylene and optimized for long on-stream air service.

Features & Benefits

Flow enhancing layer construction

- High air flow for fermenter aeration and small, economical vent filter assemblies

Liquid and aerosol 0.2 µm validation

- Documented, reliable sterilizing performance

Hydrophobic ECTFE membrane

- Membrane will not become blocked with moisture

Withstands multiple autoclave and steam cycles

- Excellent thermal resistance

100% integrity tested in manufacturing

- Provides conformance to Validation Guide

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

- Eases validation and regulatory submissions



Applications

LifeASSURE™ PFC series filters can be used in a wide variety of applications, including:

- Sterilizing filtration of fermentation inlet and exhaust air
- 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

The most important characteristics for a sterilizing grade air filter include:

Validated ECTFE Membrane

LifeASSURE™ PFC Series filters are validated by liquid bacteria challenge for complete retention. Liquid bacteria challenge represents a stringent test of filter performance and provides a high level of assurance for sterilizing performance. In addition, LifeASSURE PFC series filters have demonstrated complete aerosol retention of the bacteriophage ΦX-174. For complete details, request the LifeASSURE PFC series Validation Guide (70020313048). The Scanning Electron Micrograph (SEM) (Photo 1.) shows the structure of the ECTFE membrane with a tortuous pore pathway of flow channels.

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, a hydrophobic ECTFE membrane is used which prevents wetting with water or moisture.

Excellent Air Flow

Efficient performance requires high air flow at minimum pressure drop. LifeASSURE PFC series filters are constructed to achieve excellent air flow and pressure drop performance. This 3M development involves the use of specially designed polypropylene flow enhancing layers contribute to the excellent performance. Photo 2. shows how each layer is positioned within the filters.

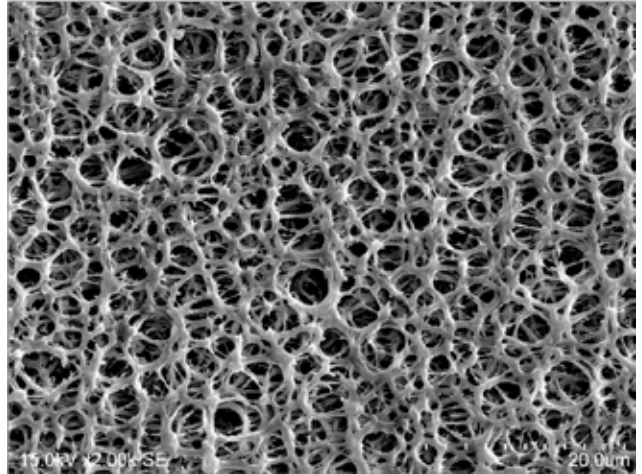


Photo 1. SEM of LifeASSURE™ PFC Series ECTFE Filter membrane.

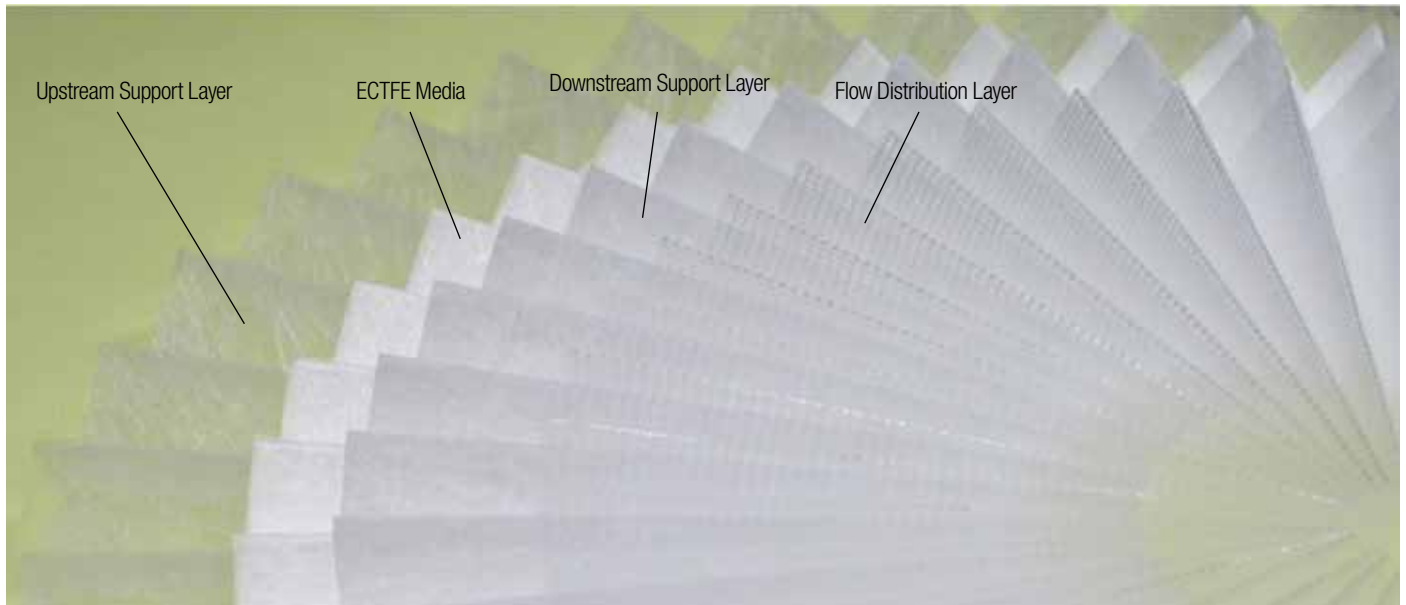


Photo 2. LifeASSURE™ PFC series filter construction

Regulatory Compliance

LifeASSURE™ PFC Series filters are manufactured in accordance with a Quality Management System audited and approved by an accrediting body to an ISO 9001:2008 Quality System Standard. The polymers and manufacturing aids used to prepare the LifeASSURE PFC series filters comply fully with the Federal Pure Food, Drug and Cosmetic Act and applicable food additives regulations. All materials of construction incorporated into LifeASSURE PFC Series filters meet the requirements of the USP <88> Biological Reactivity Test: Plastics Class VI — 121 °C. Each filter is 100% integrity tested in manufacturing and is shipped with a Certificate of Quality. A comprehensive Validation Guide is available for compliance with regulatory needs.

Reliable Microorganism Retention Performance

LifeASSURE PFC series filters are validated for sterilizing performance using a liquid bacteria (*Brevundimonas diminuta*) challenge test method. Liquid bacteria retention testing is a stringent test of sterilizing filter performance and provides the user with confidence that appropriate protection against contamination has been provided to critical product or fermentation broth. In addition to demonstrating sterilizing performance in liquid, LifeASSURE PFC series filters were tested for complete bacteriophage retention using aerosol challenge test methods. Aerosol retention performance provides reliable air and gas sterilization. Aerosol challenge testing was performed using ΦX-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 LifeASSURE PFC Series Validation Guide (70020313048).

Table 1. LifeASSURE™ PFC series filter retention performance.

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

Excellent Flow Rates at Low Pressure Differentials

LifeASSURE PFC series filters were designed to provide excellent air flow rates with low differential pressures (Figures 1, 2 and 3). LifeASSURE PFC series filters are available in a range of cartridge lengths to meet any process requirement. Shown in (Figures 1, 2 and 3) 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 technical services for sizing program assistance.

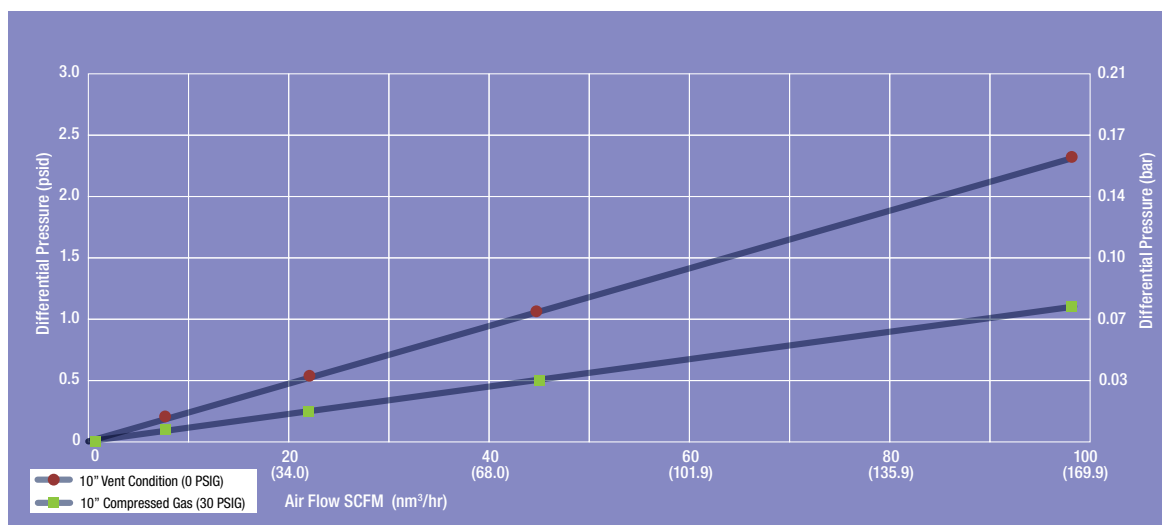


Figure 1. LifeASSURE™ PFC series 10" Cartridge.

LifeASSURE™ PFC Series Filters

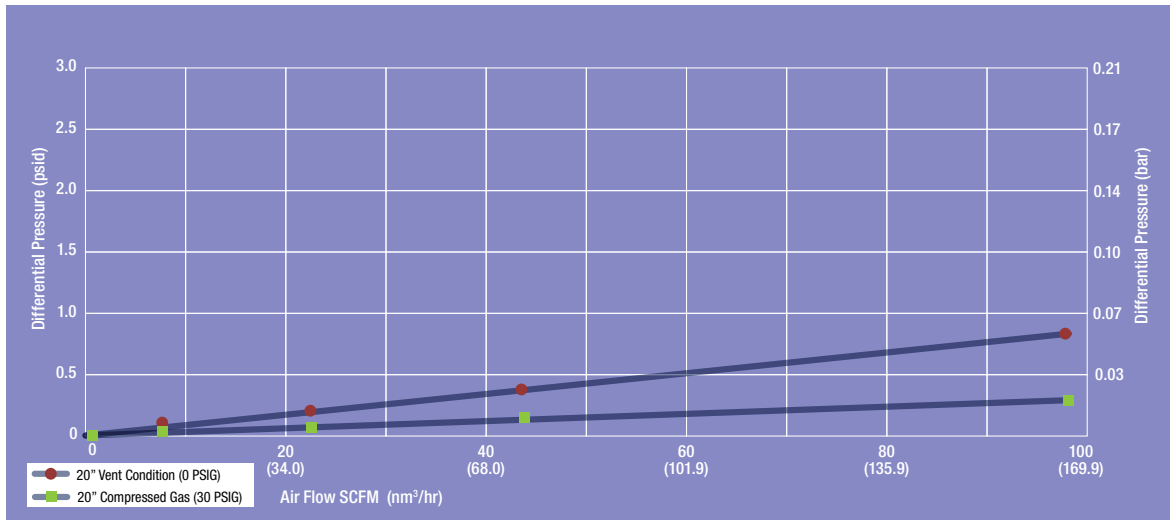


Figure 2. LifeASSURE™ PFC series 20" Cartridge.

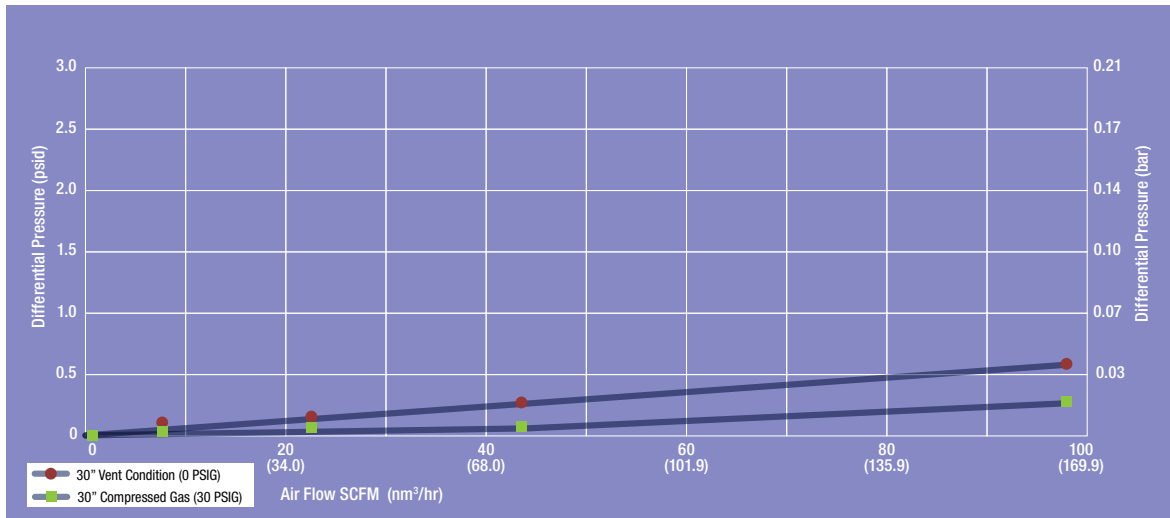


Figure 3. LifeASSURE™ PFC series 30" Cartridge.

Steam Sterilization

LifeASSURE™ PFC Series filters were designed to perform in demanding process conditions. Materials of construction and cartridge design provide an extremely durable filter that can be *in-situ* steam sterilized (or autoclaved) repeatedly without loss of integrity. LifeASSURE PFC series filters maintained integrity and complete *B. diminuta* retention following 200 steam sterilization cycles of 30 minutes each at 145 °C.

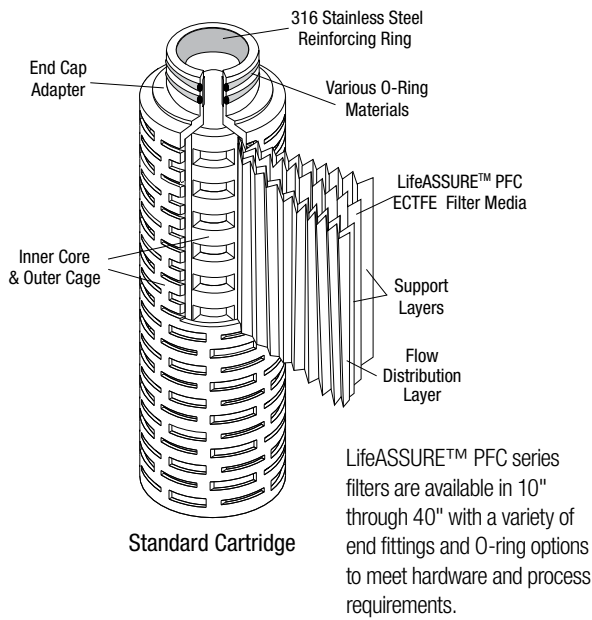
Low Gravimetric Water Soluble Extractables

LifeASSURE™ PFC series 10" filters from multiple production lots were tested for total nonvolatile gravimetric extractables (TNVGE). Sample filters were autoclaved and soaked in distilled water for 4 hours with agitation. The extract water was then brought to dryness and the resulting total, nonvolatile gravimetric extractables were weighed. In all samples the results were below the quantification limit of 10 mg/10" filter.

Table 2. LifeASSURE™ PFC series filter Total Nonvolatile Gravimetric Extractables (TNVGE)

10" Filter Element	Total Nonvolatile Gravimetric Extractables (TNVGE)
LifeASSURE™ PFC series filter	<10 mg/filter*

* below limit of quantification



Quality & Reliability

LifeASSURE™ PFC series 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 compliant with the United States Food & Drug Administration Code of Federal Regulations, Title 21. All filter components have been tested in accordance with United States Pharmacopoeia (USP <88>) Class VI Biological Reactivity. All LifeASSURE PFC series filters are shipped with a Certificate of Quality affirming compliance with rigid manufacturing quality specifications. Supporting Drug Master File (DMF 27687) documentation is on file with the United States Food and Drug Administration (FDA).

A complete LifeASSURE PFC series Validation Guide (70020313048) is available upon request.

Operating Parameters and Specifications

Filter Rating	0.2 µm
Materials of Construction	
Membrane	ECTFE
Membrane Support Layer	Polypropylene
Inner core, outer cage, end cap adapters, and adapters	Polypropylene
Adapter Reinforcing Ring	316 Stainless Steel
Filtration Surface Area: ft ² (m ²)	10.6 (0.98) per 10" module
Maximum Differential Pressure	
Forward Pressure	80 psid (5.5 bar) @ 77 °F (25 °C) 25 psid (1.7 bar) @ 176 °F (80 °C) 3 psid (0.2 bar) @ 293 °F (145 °C)
Reverse Pressure	3 psid (0.2 bar) @ 293 °F (145 °C)
Maximum Short Term Operating Temperature	176 °F (80 °C)
Maximum Continuous Operating Temperature	140 °F (60 °C)
Integrity Test Parameters - Forward Flow Test - @ 14 psig (0.96 bar)*	
25%/75% (v/v) TBA/Water @ 20 °C and 1 atm: cc/min.	≤ 6.3*
60%/40% (v/v) IPA/Water @ 25 °C and 1 atm: cc/min.	≤ 14.5*
Minimum Bubble Point: psig (bar)**	16 (1.1)
Autoclave Conditions:	Up to 259 °F (126 °C)
<i>In situ</i> Steam Conditions:	Up to 293 °F (145 °C)

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

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

Quality Management & ISO Standards

3M Purification has maintained its leadership in liquid purification and filtration by continually providing superior products and technical support. 3M Purification filtration systems are designed and manufactured to the most stringent industry standards to provide the reliability of 3M Purification 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.

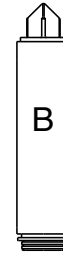
Scientific Applications Support Services (SASS)

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

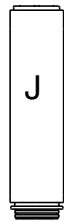


LifeASSURE™ PFC Series Filter Ordering Guide

Description	US Part Number	3M Global ID Number
10" filter with 226 connector, spear top and silicone O-rings	PFC020A01BA	70-0202-8964-4
10" filter with 226 connector, spear top and nitrile O-rings	PFC020A01BD	70-0202-8967-7
10" filter with 226 connector, flat top and silicone O-rings	PFC020A01JA	70-0202-8984-2
10" filter with 226 connector, flat top and nitrile O-rings	PFC020A01JD	70-0202-8985-9
20" filter with 226 connector, spear top and silicone O-rings	PFC020A02BA	70-0202-8968-5
20" filter with 226 connector, spear top and nitrile O-rings	PFC020A02BD	70-0202-8969-3
20" filter with 226 connector, flat top and silicone O-rings	PFC020A02JA	70-0202-8986-7
20" filter with 226 connector, flat top and nitrile O-rings	PFC020A02JD	70-0202-8987-5
30" filter with 226 connector, spear top and silicone O-rings	PFC020A03BA	70-0202-8970-1
30" filter with 226 connector, spear top and nitrile O-rings	PFC020A03BD	70-0202-8973-5
30" filter with 226 connector, flat top and silicone O-rings	PFC020A03JA	70-0202-8988-3
30" filter with 226 connector, flat top and nitrile O-rings	PFC020A03JD	70-0202-8989-1



226 connector
with spear top



226 connector
with flat cap

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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