Fluorofil™
ePTFE Membrane
Cartridge Filters

Fluorofil™ cartridges are manufactured using a highly hydrophobic ePTFE membrane. The enhanced ePTFE membrane offers exceptionally high gas flow rates at low pressure differentials (see graph). Fluorofil™ cartridges are recommended for sterile gas filtration and venting applications. The hydrophobic characteristics of the ePTFE membrane makes the Fluorofil™ filter cartridge particularly suitable for wet gas sterilising applications, such as fermenter air feed.

For solvent and aggressive chemical filtration applications, Fluorofil™ cartridges offer a wide range of chemical compatibility with high thermal stability. Suitable for the most demanding microfiltration applications, the cartridges can be used for the filtration of aggressive chemical solutions including acids, alkalis, solvents and etchants.

Applications

Fluorofil™ ePTFE membrane cartridges meet the demanding filtration requirements of pharmaceutical, semiconductor and fine chemical manufacturers. They are suitable for a wide range of sterile venting and gas filtration applications, including the filtration of wet gases. They can also be used for the fine filtration of aggressive chemical solutions including acids, alkalis, solvents and etchants.

• Sterile process gases
  The supply of sterile gas for critical applications in the pharmaceutical, biotechnology, food and beverage markets.

• Sterile vents
  The safe sterile venting of processing vessels in pharmaceutical, fermentation, and food and beverage processes.

• Fine chemicals and solvents
  The removal of submicronic particles from processing chemicals and solvents.

• Photoresists and developers
  The microfiltration of photoresists and developer solvents, susceptible to contamination and precipitation during manufacture, storage and processing.

• Pure water supply systems
  For use in de-mineralised and de-ionised water systems, for the supply of ultra-pure water, for example in the semiconductor industry.
Features and Benefits

- **Fluorofil\textsuperscript{TM} cartridges**
  The ePTFE membrane is recognised as the world leading gas sterilising hydrophobic membrane. It is the membrane of choice in all *Porvair* Fluorofil\textsuperscript{TM} filter cartridges.

- **Guaranteed microbial ratings in a liquid challenge**
  Fluorofil\textsuperscript{TM} cartridges are validated for bacterial removal in liquids in accordance with PDA, HIMA guidelines and ASTM F838-05, with a log reduction value >7. This test is stringent in comparison to an airborne particulate challenge test.

- **Bacterial spores and viruses**
  The retention of bacterial spores and viruses carried in aerosols over extended time periods has been independently validated in tests carried out by the UK Health Protection Agency.

- **Flow ΔP characteristics**
  The unique characteristics of the ePTFE membrane, combined with the construction of the Fluorofil\textsuperscript{TM} filter cartridge, results in exceptionally high gas flow rates at low pressure differentials. These features result in lower energy consumption and fewer filter cartridges per system.

- **Steam sterilisation**
  Fluorofil\textsuperscript{TM} cartridges have been designed and validated to be repeatedly steam sterilised in-situ at temperatures of up to 135°C (275°F) for 100 cycles at 20 minutes per cycle. Steam sterilisation in the reverse direction for in excess of 70 cycles in a venting application, without loss of integrity, has been independently validated by customers.

- **Cartridge integrity and low TOC levels**
  All Fluorofil\textsuperscript{TM} cartridges are integrity tested and supplied clean, having been flushed with pure water. When required they can be pulse flushed with 18MΩ.cm pyrogen-free ultra-clean water.

- **Solvents and aggressive chemicals**
  The exceptional chemical resistance of ePTFE allows Fluorofil\textsuperscript{TM} filter cartridges to be compatible with aggressive chemical solutions, including strong acids, alkalis, solvents and etchants.

- **Full traceability**
  All Fluorofil\textsuperscript{TM} cartridges are individually and batch identified with a unique serial number. Each Fluorofil\textsuperscript{TM} cartridge is supplied with a Certificate of Quality and an operating instruction leaflet.

- **Controlled manufacturing environment**
  Fluorofil\textsuperscript{TM} cartridges are manufactured in an ISO Cleanroom environment by fully gowned staff, minimising the risk of contamination.

**Cartridge Construction**

Fluorofil\textsuperscript{TM} cartridges are manufactured from a multi-layer combination of irrigation mesh, filter membrane, membrane support and drainage material. Fluorofil\textsuperscript{TM} cartridges have optimal pleat geometry to maximise the available filtration area and to ensure an efficient flow through the cartridges.

An all thermal fusion bonded assembly process eliminates the use of resins and binders.

Manufactured as standard with injection moulded polypropylene inner and outer supports, Fluorofil\textsuperscript{TM} cartridges are designed with the strength necessary to withstand thermal stresses encountered during steam sterilisation and subsequent cooling. They can be steam sterilised and will retain total integrity following steaming at 135°C (275°F).

All components used in the construction of Fluorofil\textsuperscript{TM} cartridges are FDA approved to 21CFR and meet or exceed the latest EC Directives for Food Contact.
Specifications

Materials of Manufacture
Filter membrane: ePTFE
Membrane support: Polypropylene
Irrigation mesh (support): Polypropylene
Drainage layer: Polypropylene
Inner core: Polypropylene
Outer support: Polypropylene
End fittings: Polypropylene
Sealing: Fusion bonding

Cartridge Dimensions (Nominal)
Diameter: 70mm (2.8”)
Length: 1 module: Fluorofil™ Junior
1 module: 254mm (10”)
2 modules: 508mm (20”)
3 modules: 762mm (30”)
4 modules: 1016mm (40”)

Effective Filtration Area

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<tr>
<th>Absolute Microbial Rating (in liquids)</th>
<th>Effective Filtration Area (each 254mm (10”) module)</th>
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<tr>
<td>0.02, 0.1, 0.2 and 0.45µm</td>
<td>0.73m² (7.8 ft²)</td>
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Cartridge Treatment
Standard: Cleaned and flushed, without further treatment.
Rinsed: Ultra-clean, pulse flushed to give a system resistivity of 18MΩ.cm.

Gaskets and O-Rings
Ethylene Propylene, FEP encapsulated, Silicone, Viton® or Nitrile.

Maximum Differential Pressure
Normal flow direction at:
20°C (68°F): 6.0bar (87psi)
80°C (176°F): 4.0bar (58psi)
100°C (212°F): 3.0bar (44psi)
120°C (248°F): 2.0bar (29psi)
125°C (257°F): 1.5bar (22psi)
Reverse flow direction at:
20°C (68°F): 2.1bar (30psi)
80°C (176°F): 1.0bar (15psi)
100°C (212°F): 0.5bar (7psi)

Operating Temperature
Maximum continuous: 80°C (176°F)

Sterilisation
In situ steam 100 x 20 minute cycles at 135°C (275°F) to 150 x 20 minute cycles at 125°C (257°F).

Extractables
Minimum total extractables. Please refer to the Fluorofil™ Validation Guide.

Integrity Testing
Each Fluorofil™ module of every cartridge is individually integrity tested using the Diffusive Flow Test, which correlates to the HIMA and ASTM F838-05 bacterial challenge tests. Non-destructive integrity tests, such as Diffusive Flow, Water Intrusion, Pressure Hold and Bubble Point, can be performed by customers. Procedural details are available from Porvair.

Gas Flow Rates

- Typical clean air flow rate:
  A 254mm (10”) Fluorofil™ single cartridge exhibits the flow-Δp characteristics indicated below.

Clean Water Flow Rates

- Typical clean water flow rate:
  A 254mm (10”) Fluorofil™ single cartridge with 0.2µm microbial rating exhibits the flow-Δp characteristics indicated below, for solutions with a viscosity of 1 centipoise.

- Other solutions:
  For solutions with a viscosity of greater than 1 centipoise, multiply the indicated differential pressure by the viscosity in centipoise.
Range
Suitable for use in Porvair filter housings and as direct replacements for existing cartridges, Fluorofil™ cartridges can be supplied with end fittings to suit most hardware installations without modification. They are available in single or multiple module units of 5, 10, 20, 30 and 40 inches, with a choice of four microbial ratings: 0.02, 0.1, 0.2 and 0.45 micron. Fluorofil™ Junior versions are also available.

Quality Assurance
Fluorofil™ cartridges are manufactured in an ISO Cleanroom environment by staff fully gowned to minimise any risk of contamination during production. All cartridges are integrity tested and, if required, pulse flushed with 18MΩ.cm pyrogen-free ultra-pure water to give rapid resistivity recovery rates and low TOC levels. As a further safeguard, every cartridge is individually and batch identified with a unique serial number, allowing users to maintain their own process records.

Registered to ISO 9001, Porvair Filtration Group procedures are subject to high standards of quality assurance as demonstrated through its Drug Master File status.

Material Conformity and Validation
The bio-safety of all materials in the manufacture of Fluorofil™ cartridges is assured by FDA approval, USP Class VI and meets or exceeds the latest EC Directives for Food Contact.

Fluorofil™ cartridges have been tested and shown to be 100% retentive in liquids in accordance with HIMA and ASTM F838-05 guidelines for the Brevundimonas diminuta challenge. The retention of Bacillus atrophaeus bacterial spores and MS-2 Coliphage viruses carried in aerosols over extended time periods has been independently validated in tests carried out by the UK Health Protection Agency. To guarantee the bacterial retention performance of every cartridge, a correlation has been made between the bacterial challenge and integrity tests. A comprehensive validation guide for Fluorofil™ cartridges is available on request.

Chemical Compatibility
The Fluorofil™ materials of construction are compatible with a wide range of aggressive solvents and chemicals, however care must be taken to select the appropriate seal material. A comprehensive chemical compatibility guide is available. Since operating conditions vary considerably between applications, verification by the end user is recommended.

Filter Housings
Please contact a Porvair Filtration Group representative for further information on our range of filter housings.