porvair filtration group

PFG708

Fluorofil™ Plus

High Flow Sterile Gas Filter with ePTFE Membrane

Fluorofil™ Plus 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™ Plus cartridges are recommended for sterile gas filtration and venting applications. The hydrophobic characteristics of the ePTFE membrane makes the Fluorofil™ Plus filter cartridge particularly suitable for wet gas sterilising applications, such as fermenter air feed.

The construction of the Fluorofil™ Plus cartridge has design features that allow higher membrane surface area, lower pressure drops and incorporates a stainless steel core for greater mechanical strength when operated at higher temperatures.

Applications

Fluorofil™ Plus ePTFE membrane cartridges meet the demanding filtration requirements of pharmaceutical, biotechnology, food and beverage industries. They are suitable for high flow sterile venting and gas filtration applications, including the filtration of wet gases.

Typical applications include:

- **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.
- **Biotechnology**
  The sterile filtration of exhaust gases from biological fermenters.
- **Powder handling and tabletting**
  The removal of ultrafine powder particles from compounding environments.

World Class Filtration Solutions

Features and Benefits

- **Fluorofil™ Plus cartridges**
  The ePTFE membrane is recognised as the world leading gas sterilising hydrophobic membrane. It is the membrane of choice in all **Porvair** Fluorofil™ Plus filter cartridges.
- **Guaranteed microbial ratings**
  Fluorofil™ Plus cartridges are validated for bacterial removal according to HIMA guidelines and ASTM F838-05, with a log reduction value >7.
- **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.
- **High Flow ΔP characteristics**
  The unique characteristics of the ePTFE membrane, having higher surface area, combined with the construction of the Fluorofil™ Plus 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.
- **Mechanical strength**
  Fluorofil™ Plus cartridges incorporate a stainless steel central core which provides greater mechanical strength. This allows the filter to be used at higher gas flow rates with low pressure differentials.
- **Steam sterilisation**
  Fluorofil™ Plus cartridges have been designed and validated to be repeatedly steam sterilised in-situ at temperatures of up to 142°C (286°F). 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™ Plus cartridges are integrity tested and supplied clean, having been flushed with pure water.
- **Full traceability**
  All Fluorofil™ Plus cartridges are individually and batch identified with a unique serial number. Each Fluorofil™ Plus cartridge is supplied with a Certificate of Quality and an operating instruction leaflet.
- **Controlled manufacturing environment**
  Fluorofil™ Plus cartridges are manufactured in an ISO Cleanroom environment by fully gowned staff, minimising the risk of contamination.

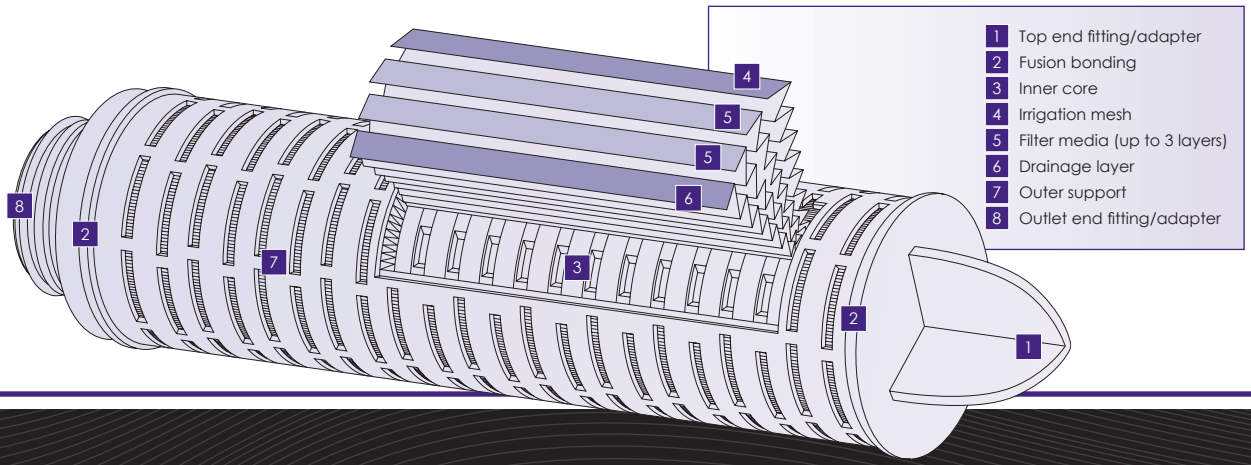
Cartridge Construction

Fluorofil™ Plus cartridges are manufactured from a multi-layer combination of irrigation mesh, filter membrane, membrane support and drainage material. Fluorofil™ Plus cartridges have increased surface area and a wide diameter inner core with optimal pleat geometry 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 outer cage and stainless steel core, Fluorofil™ Plus 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 142°C (286°F).

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



Materials of Manufacture

Filter membrane:	ePTFE
Membrane support:	Polypropylene
Irrigation mesh (support):	Polypropylene
Drainage layer:	Polypropylene
Inner core:	316L Stainless Steel
Outer support:	Polypropylene
End fittings:	Polypropylene
Sealing:	Fusion bonding

Cartridge Dimensions (Nominal)

Diameter:	70mm (2.8")	
Length:	1 module:	127mm (5")
	1 module:	254mm (10")
	2 modules:	508mm (20")
	3 modules:	762mm (30")
	4 modules:	1016mm (40")

Effective Filtration Area

Absolute Microbial Rating	Effective Filtration Area (each 254mm (10") module)
0.2µm	0.8m² (8.6ft²)

Cartridge Treatment

Standard: Cleaned and flushed, without further treatment.

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 500 x 30 minute cycles at 135°C (275°F).
In situ steam cycles for 200 hours at 142°C (286°F).

Extractables

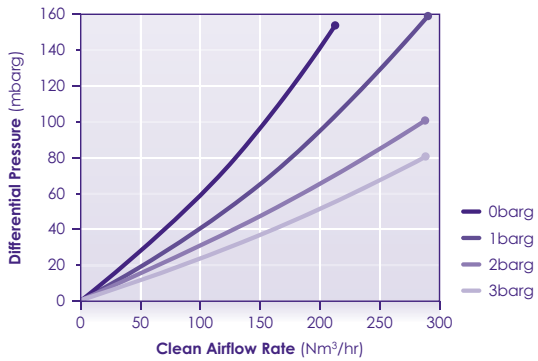
Minimum total extractables. Please refer to the Fluorofil™ Plus Validation Guide.

Integrity Testing

Each Fluorofil™ Plus 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™ Plus single cartridge exhibits the flow-**Δ**P characteristics indicated below.



Range

Suitable for use in **Porvair** filter housings and as direct replacements for existing cartridges, Fluorofil™ Plus 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 microbial rating of 0.2 micron.

Quality Assurance

Fluorofil™ Plus 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. 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™ Plus cartridges is assured by FDA approval, USP Class VI and meets or exceeds the latest EC Directives for Food Contact.

Fluorofil™ Plus 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 astrophaeus* 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™ Plus cartridges is available on request.

Chemical Compatibility

The Fluorofil™ Plus 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.

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