

Poliflo PTFE

POLIFLO PTFE Membrane Cartridge Filters

Introduction

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

Cartridge Construction

POLIFLO PTFE cartridges are manufactured from a multi layer combination of irrigation mesh, filter membrane, membrane support and drainage material. POLIFLO PTFE 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. POLIFLO PTFE 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 POLIFLO PTFE cartridges are FDA approved to 21CFR and meet or exceed the latest EC Directives for Food Contact.

Material Conformity and Validation

The bio-safety of all materials in the manufacture of POLIFLO PTFE cartridges is assured by FDA approval. USP Class VI and meet or exceeds the latest EC Directives for Food Contact. POLIFLO PTFE 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 spares and MS-2 Coliphage viruses carried in aerosols over estended time periods has been independently validated in tests carried out by the UK Health Protection Agency. To guarantee the bacterial rention performance of every cartridge, a correlation has been made between the bacterial challenge and integrity tests. A comprehensive validation guide for POLIFLO PTFE cartridges is available on request.



Quality Assurance

POLIFLO PTFE cartridges are manufactured in a 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 $18M\Omega$.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. Registred to ISO 9001. Envirogen Group procedures are subject to high standards of quality assurance.

Steam Sterilisation

POLIFLO PTFE 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 off integrity, has been independently validated by customers



Range

Suitable for use in Envirogen Group filter housings and as direct replacements for existing cartridges, POLIFLO PTFE-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. POLIFLO PTFE Junior version are also available.

Chemical Compatibility

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

Filter Housings

Please contact a Envirogen Group representative for further information on our range of filter housings.

Applications

POLIFLO PTFE 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

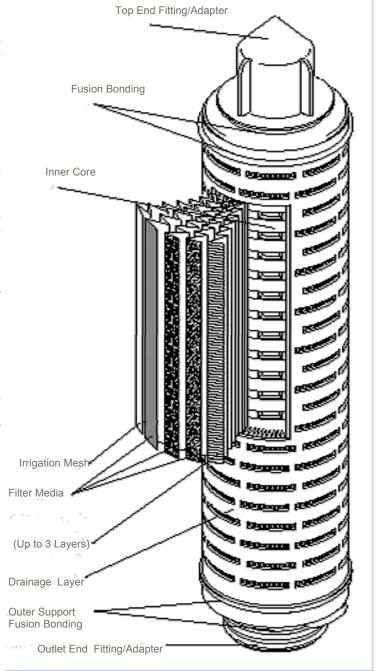
The removal of submicronic particles from processing chemicals and solvents.

> 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.





Specifications

Materials of Manufacture

Filter Membrane Gore ePTFE Membrane Support Polypropylene Polypropylene Irrigation Mesh (Support) Drainage Layer Polypropylene Polypropylene Inner Core Outer Support Polypropylene **End Fittings** Polypropylene Sealing Fusion bonding

Cartridge Dimensions (Nominal)

Diameter:	•	70mm	(2.8")
Length:	1 Module (short)	125mm	(5")
	1 Module	254mm	(10")
	2 Modules	508mm	(20")
	3 Modules	762mm	(30")
	4 Modules	1016mm	(40")

Effective Filtration Area

Cartridge Treatment

Standard Cleaned and flushed, without

further treatment.

Rinsed Ultra-clean, pulse flushed to give

a system resistivity of $18M\Omega$.cm.

Gaskets and O-Rings

Ethylene Propylene, PTFE encapsulated, Silicone, Viton or Nitrile

Maximum Differential Pressure

Normal Flow Direction at:

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20°C (68°F)	6.0 bar (87lb/in ²)
80°C (176°F)	4.0 bar (58lb/in ²)
100°C (212°F)	3.0 bar (43lb/in ²)
120°C (248°F)	2.0 bar (29lb/in ²)
125°C (257°F)	1.5 bar (22lb/in ²)

Reverse Flow Direction at:

20°C (68°F) 2.1 bar (30lb/in²) 80°C (176°F) 1.0 bar (15lb/in²) 100°C (212°F) 0.5 bar (7lb/in²)

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 POLIFLO PTFE Validation Guide

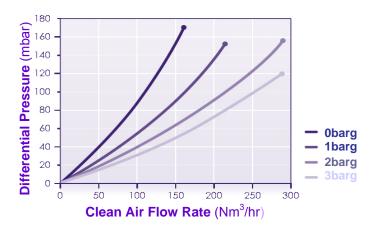
Integrity Testing

Each POLIFLO PTFE 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 Envirogen Group.

Gas Flow Rates

> Typical clean oir flow rate:

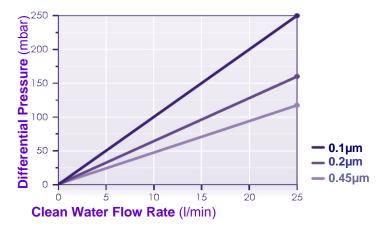
A 254mm (10") POLIFLO PTFE single cartridge exhibits the flow-ΔP characteristics indicated below.



Clean Water Flow Rates

- Typical clean water flow rate: A 254mm (10") POLIFLO PTFE single cartridge with 0.2μm microbial rating exhibit the flow-ΔP characteristics indicated below, for solutions with a viscosity of 1 centipoises.
- > Other Solutions:

For solutions with a viscosity greater than 1 centipoise, multiply the indicated differential pressure by the viscosity in centipoise.





Features and Benefits

POLIFLO PTFE cartridges - The Gore™ ePTFE membrane is recognised as the word leading gas sterilising hydrophobic membrane. It is the membrane of choice in all Envirogen Group POLIFLO PTFE filter cartridges.

Guaranteed Microbial Ratings - POLIFLO PTFE 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 period has been independently validated in tests carried out by the UK Health Protection Agency.

Flow ΔP characteristics - The unique characteristics of the Gore™ ePTFE membrane, combined with the construction of the POLIFLO PTFE 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 - POLIFLO PTFE 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 POLIFLO PTFE cartridge are integrity tested and

supplied clean, having been flushed with pure water. When required, they can be pulse flushed with $18M\Omega$.cm pyrogen-free ultra-clean water.

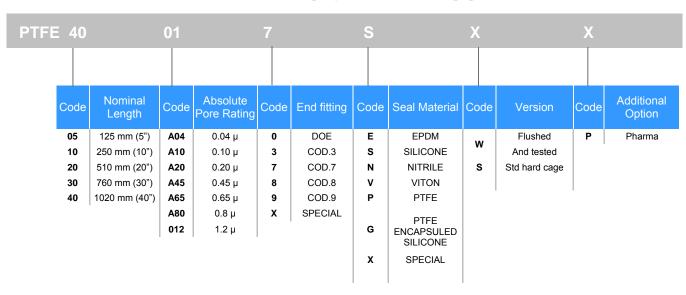
Solvents and aggressive chemicals - The exceptional chemical resistance of ePTFE allows POLIFLO PTFE filter cartridges to be compatible with aggressive chemical solutions, including strong acids, alkalis, solvents and atchants.

Full Traceability - All POLIFLO PTFE cartridges are individually and batch identified with a unique serial number. Each POLIFLO PTFE cartridge is supplied with a Certificate of Quality and an operating instruction leaflet.

Controlled Manufacturing Environment –

POLIFLO PTFE cartridges are manufactured in an ISO Cleanroom environment by fully gowned staff, minimising the risk of contamination.

Cartridge part numbering guide



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