



Introduction

A range of microbially rated Microfilters from Microfiltrex, featuring the latest developments in membrane technology, Biofil PES cartridges are based on a naturally hydrophilic polyethersulphone membrane with a mirrored asymmetric pore structure. When combined with quality all-polypropylene cartridge components and high integrity manufacturing techniques common to all Microfiltrex microfilters, polyethersulphone membrane provides a high strength, long life cartridge of consistently precise particle retention across a wide range of particle sizes.

Biofil cartridges exploit the narrow pore size distribution and high void volume of the media to provide a choice of cartridges capable of meeting the requirements of most applications. Careful media selection ensures that Biofil PES cartridges are also very suited to critical particle control down to 0.04 micron ratings. Biofil PES cartridges offer high flux rates and low differential pressures, a feature common to polyethersulphone membranes.

Biofil PES cartridges benefit from the low non-specific protein binding characteristics of polyethersulphone membranes, by ensuring that most proteins present in the feed are retained within the filtrate. They are also highly resistant to integrity failure caused by steam sterilisation and have excellent chemical compatibility characteristics. Furthermore, since they will not hydrolyse, Biofil PES cartridges are ideal for use in ultra pure water supply systems (18M Ω .cm).

As a consequence Biofil PES cartridges provide a combination of features and benefits not hitherto available from cartridges based on PVDF, nylon, mixed esters of cellulose or polysulphone membranes. They are suitable for applications ranging from sterile filtration, bioburden reduction and the clarification of a wide range of process liquids and end products.



Biofil PES Polyethersulphone Membrane Cartridge Filters

Cartridge Construction

Biofil PES cartridges are manufactured from a multi-layer combination of irrigation mesh, filter membrane, membrane support and drainage material, precision pleated and thermally seam-bonded to maximise the available filtration area and ensure an efficient flow throughout the cartridges. Final assembly is by thermal fusion bonding the cartridge components, including the filter media to the end fittings. This patented method of fusion bonding helps to guarantee cartridge integrity, eliminating the risk of by-passing or extractables derived from bonding agents.

Manufactured as standard with injection moulded polypropylene inner and outer supports, Biofil PES cartridges are designed with the strength necessary to withstand the high differential pressures encountered during steam sterilisation and from hydraulic shock. They can be steam sterilised and will retain total integrity following steaming at 135°C (275°F). However, due to possible distortion and integrity loss, the steaming of double open-ended cartridges is not recommended.

As all polypropylene constructions with a polyethersulphone filter media, Biofil PES cartridges have excellent chemical capability characteristics (see 'Chemical Compatibility'). They can therefore be chemically sanitised and are chemically and biologically stable in a wide range of beverage, pharmaceutical and chemical applications. Furthermore, Biofil PES cartridges will not hydrolyse or degrade during long term exposure to ultra-pure water.

Quality Assurance

Biofil PES cartridges are manufactured in class 5000 clean rooms 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, Microfiltrex procedures are subject to high standards of quality assurance.

Material Conformity and Validation

The bio-safety of all materials in the manufacture of Biofil PES cartridges is assured by FDA approval and the polypropylene cartridge materials conform to USP Class VI.

Biofil PES cartridges have been tested and shown to be 100% retentive in line with HIMA guidelines for *Brevundimonas diminuta* challenge (0.2 micron) and with yeast (0.65 micron). To guarantee the uniform performance of every cartridge, a correlation has been made between the bacterial challenge and integrity tests. A comprehensive validation guide for Biofil PES cartridges is available on request.

Range

Suitable for use in Microfiltrex filter housings and as direct replacements for existing cartridges, Biofil PES 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, and in a choice of six microbial ratings: 0.04, 0.10, 0.20, 0.45, 0.65 and 1.2 micron. Each cartridge is supplied with all necessary seals or O-rings, chemically compatible with the application.

Chemical Compatibility

Care must be taken to ensure that the cartridge and seals selected are chemically compatible with the application. Susceptibility to chemical attack varies considerably between solutions and is greatest at the extremes of the pH scale. It also varies according to the duration of exposure and operating temperature. All data provided for Biofil PES cartridges is based on 48 hours exposure at 25°C (77°F). Since operating conditions vary considerably between applications, verification by users for particular processes is recommended.

Applications

Biofil PES cartridges are suitable for the sub-micronic filtration of a wide range of process liquids, in applications where the characteristics of a naturally hydrophilic membrane are required.

Typical applications include:

- **Biopharmaceuticals** - for the sub-micronic filtration of ingredients, intermediates, make-up waters and final products, including sterilisation, clarification and the reduction of bioburden.
- **Electronics and Semiconductors** - for the sub-micronic filtration of process water and chemicals, including solvents, developers and photoresists. Applications typically include central water plant treatment and critical 'wet bench' point of use filtration.
- **Fine Chemicals** - for the clarification and sterilisation of a wide range of process chemicals.
- **Beverages** - for the clarification and sterilisation of various beverages, including the removal of yeast and spoilage organisms.
- **Pure water supply** - for use in de-mineralised and de-ionised water treatment systems, as either a resin trap sterilisation filter, or for bioburden reduction.

Specifications

Materials of Manufacture

Filter Membrane	Polyethersulphone
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 (short)	125mm	(5")
1 Module	250mm	(10")
2 Modules	510mm	(20")
3 Modules	860mm	(30")
4 Modules	1020mm	(40")

Effective Filtration Area

<i>Absolute</i>	<i>EFA</i>
<i>Microbial Rating</i>	<i>(Each 250mm Module)</i>
0.04, 0.10, 0.20, 0.45, 0.65, 0.8 and 1.2 micron	0.6m ² (6.5 ft ²)

Cartridge Treatment

Standard	Cleaned and flushed, without further treatment
Rinsed	Ultra-clean, pulse flushed to give a system resistivity of 18M Ω .cm

Gaskets and O-Rings

Ethylene Propylene, PTFE Encapsulated, Silicone, Viton or Nitrile

Maximum Differential Pressure

Normal Flow Direction at:

20°C (68°F)	6.0 bar (87lb/in ²)
80°C (176°F)	4.0 bar (57lb/in ²)
100°C (212°F)	3.0 bar (43lb/in ²)
120°C (248°F)	2.0 bar (29lb/in ²)

Reverse Flow Direction (Excluding 'Net Sleeve' types) at:

20°C (68°F)	2.1 bar (30lb/in ²)
80°C (176°F)	1.0 bar (15lb/in ²)
100°C (212°F)	0.5 bar (7lb/in ²)

Operating Temperature

Maximum continuous	60°C (140°F)
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Sterilisation

Chemical, Autoclave or In-line Steam up to 135°C (277°F) ('N' Suffix Types - Not suitable for steaming, since they do not have stainless steel reinforcing rings)

Extractables

Minimum total extractables

Integrity Testing

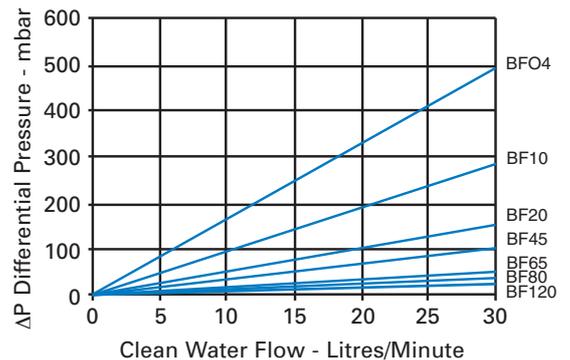
All cartridges are integrity tested prior to despatch and may be subsequently repeatedly tested

Test Conditions

Typical Clean Water Flow Rate - Based on a 250mm (10") single module housing exhibiting the differential pressure characteristics indicated above, for solutions with a viscosity of 1 centipoise.

Other Solutions - For solutions with a viscosity greater than 1 centipoise, divide the indicated flow rate by the viscosity in centipoise.

Clean Water Flow Rates - Biofil PES Cartridges BF04 - BF65



Features and Benefits

Biofil PES cartridges - Careful media selection means that Biofil PES cartridges are available to suit a wide range of process critical and general purpose applications.

Guaranteed Microbial Ratings - Biofil PES cartridges are validated for bacterial removal according to HIMA guidelines, with a log reduction value in excess of 7. They are therefore suitable for applications requiring sterilising grade filtration.

Low Protein Binding - Biofil PES cartridges have excellent low protein binding characteristics, typically 10 times lower than Nylon, 2 times lower than Polysulfone and similar to PVDF. Since they do not strip-out proteins carried in liquids, they have low colour stripping characteristics and particularly long life when used with liquids such as beverages.

Will Not Hydrolyse - Compared with other membranes such as nylon, the polyethersulphone membrane used in Biofil PES cartridges is extremely resistant to hydrolysis. Capable of exposure in excess of 2 years, they are ideal for HOT DI-water applications.

Excellent Chemical Compatibility - Resistant to many process chemicals Biofil PES cartridges are suitable for use in a wide range of process applications.

Resistant to 'Grow Through' - When compared with symmetrical membranes, the mirrored asymmetric structure of a polyethersulphone membrane substantially extends the time following sanitisation or sterilisation required for bacteria to grow through the membrane. The natural path of growth for bacteria with a mirrored asymmetric media is backwards towards the upstream side. However, it should be noted that sanitisation or sterilisation is necessary with all membrane filters.

High Cartridge Integrity and Low TOC Levels - All Biofil PES cartridges are integrity tested and supplied clean, having been flushed with pure water. When required they can be pulse flushed with 18MW.cm pyrogen free ultra-clean water.

Suitable for Steam Sterilising - Unless otherwise indicated (with an 'N' suffix), Biofil PES cartridges can be subjected to steam sterilisation at 135°C (275°F) without loss of integrity.

Full Traceability - All Biofil PES cartridges are individually and batch identified with a unique serial number. This allows for the subsequent recall of the full manufacturing process.

Controlled Manufacturing Environment - Biofil PES cartridges are manufactured and packed in clean environmental conditions by fully gowned staff, minimising the risk of contamination.

Available Housings



Sanitary Grade Housing



Industrial Grade Housing



Polypropylene Housing



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The company reserves the right to change specifications without notice.
Freedom from patent restrictions must not be assumed.



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