Fluorofil™ Junior ePTFE Membrane Cartridge Filters for Small-Scale Applications

Fluorofil™ Junior cartridges are manufactured using a highly hydrophobic ePTFE membrane and are designed for retrofitting into existing Junior-style housings. The enhanced ePTFE membrane offers exceptionally high gas flow rates at low pressure differentials (see graph).

The Junior range are available in two formats: J-style, a single open-ended element with a single internal o-ring seal on the downstream end cap and S-style, a single open-ended element incorporating an integral flange on the downstream end cap.

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

For small-scale solvent and aggressive chemical filtration applications, Fluorofil™ Junior 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 small-scale filtration of aggressive chemical solutions including acids, alkalis, solvents and etchants.

Fluorofil™ Juniors can be used in scale-up bench-top experiments and pilot plant evaluations to confirm suitability in new process applications.

Available in J-style with internal O-ring, S-style with moulded flange seal and L-style with 4-lug locking end cap with double external O-rings.

Applications

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

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

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

• **Small-scale fine chemicals and solvents**
  The removal of submicronic particles from processing chemicals and solvents.

• **Small-scale photoresists and developers**
  The microfiltration of photoresists and developer solvents, susceptible to contamination and precipitation during manufacture, storage and processing.
Features and Benefits

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

- **Guaranteed microbial ratings in a liquid challenge**
  Fluorofil™ 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™ Junior 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™ Junior cartridges have been designed and validated to be repeatedly steam sterilised in-situ at temperatures of up to 135°C (275°F) for 70 cycles at 25 minutes per cycle.

- **Cartridge integrity and low TOC levels**
  All Fluorofil™ Junior 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™ Junior filter cartridges to be compatible with aggressive chemical solutions, including strong acids, alkalis, solvents and etchants.

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

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

**Cartridge Construction**

Fluorofil™ Junior cartridges are manufactured from a multi-layer combination of irrigation mesh, filter membrane, membrane support and drainage material. Fluorofil™ Junior 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™ Junior 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™ Junior 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
Internal adaptor support ring: Stainless Steel

Cartridge Dimensions (Nominal)
Diameter: 56mm (2.2")
Lengths: 77.5mm (2.5")
136mm (5")

Effective Filtration Area

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<th>Absolute Microbial Rating (in liquids)</th>
<th>Effective Filtration Area (for 5&quot; cartridge)</th>
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<tr>
<td>0.2μm</td>
<td>0.19m² (2.05ft²)</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
J-style: Silicone (other materials are available on request).
S-style: Not supplied.
L-style: Silicone (other materials are available on request).

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)

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

Sterilisation
Autoclave 70 x 25 minute cycles at 135°C (275°F).

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

Integrity Testing
Each Fluorofil™ Junior cartridge is individually integrity tested using the Diffusive Flow Test, which correlates to the HIMA and ASTM FB38-05 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 136mm (5”) Fluorofil™ Junior cartridge exhibits the flow-ΔP characteristics indicated below.

Clean Water Flow Rates
- Typical clean water flow rate:
  A 136mm (5”) Fluorofil™ Junior cartridge (J-style) 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.
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Range
Fluorofil™ Junior cartridges are designed for retrofitting into existing Junior-style housings as direct replacements for existing cartridges. Available in two formats of 2.5 and 5 inch lengths, with a validated microbial rating for gases and liquids of 0.2 micron:

- J-style, a single open-ended element with a single internal o-ring seal on the downstream end cap.
- S-style, a single open-ended element incorporating an integral flange on the downstream end cap.
- L-style, a single open ended element with 4 locating lugs and double external ‘o’-rings.

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.