

# Biofil™ 3 Plus

Sterilising-Grade  
Polyethersulfone  
Membrane Cartridge  
Filters



**Biofil™ 3 Plus 0.2micron are sterilising grade filters designed for filtration of a broad range of liquids in pharmaceutical, biotechnology and other critical applications.**

Biofil™ 3 Plus cartridges feature a unique hydrophilic and highly asymmetric double layer polyethersulfone membrane with broad chemical compatibility, high thermal resistance, fast flow rates, enhanced wettability and reliable sterilising filtration performance. When combined with quality all-polypropylene components and high integrity manufacturing techniques, the Biofil™ 3 Plus filter cartridge is ideally suited to the most demanding process conditions.

## Typical Applications

- Final 0.2µm sterilising filtration
- Biopharmaceuticals
- Fermentation
- Ophthalmic solutions
- Vaccines
- Parenteral drugs (SVP, LVP)
- High purity DI water and WFI systems

## Ordering Information

| Product Code: 1 2 3 4 5 6 7 |                       |                |                     |               |                           |                     |
|-----------------------------|-----------------------|----------------|---------------------|---------------|---------------------------|---------------------|
| 1: Membrane                 |                       | 2: Pore rating |                     | 3: Version    |                           | 4: Length (Nominal) |
| BWP                         | Biofil™ 3 Plus        | 20             | 0.2µm               | R             | Rinsed                    | 1 10" (254mm)       |
|                             |                       |                |                     | S             | Standard                  | 2 20" (508mm)       |
|                             |                       |                |                     |               |                           | 3 30" (762mm)       |
|                             |                       |                |                     |               |                           | 4 40" (1016mm)      |
|                             |                       |                |                     |               |                           | 5 5" (125mm)        |
| 5: End Fitting              |                       | 6: Seals       |                     | 7: Additional |                           |                     |
| A                           | Code 3                | A              | Ethylene Propylene  | A             | N+U                       |                     |
| B                           | Code 7                | B              | Silicone            | N             | Non-steamable (no insert) |                     |
| C                           | Code 8                | C              | Viton®              | P             | Pharma Grade              |                     |
| F                           | N SOE                 | D              | Nitrile             | U             | Unbranded                 |                     |
| G                           | G DOE (short)         | E              | FEP Encap. Viton®   |               |                           |                     |
| H                           | G SOE                 | G              | FEP Encap. Silicone |               |                           |                     |
| J                           | 216 (218), fin        | J              | DOE PTFE            |               |                           |                     |
| K                           | Code 2                |                |                     |               |                           |                     |
| L                           | 223, fin (no lugs)    |                |                     |               |                           |                     |
| M                           | DOE                   |                |                     |               |                           |                     |
| S                           | Code 28, fin (3 lugs) |                |                     |               |                           |                     |
| T                           | 223, flat (no lugs)   |                |                     |               |                           |                     |
| U                           | 224, fin              |                |                     |               |                           |                     |
| V                           | 226, fin              |                |                     |               |                           |                     |
| Y                           | BS832, flat           |                |                     |               |                           |                     |

## Features and Benefits

- Validated 0.2µm absolute-rated membrane
- Reliable sterilising filtration
- Hydrophilic asymmetric polyethersulfone membrane
- Low protein binding
- Excellent hydrolysis resistance
- Excellent chemical compatibility
- Suitable for steam sterilising
- Full traceability
- Controlled manufacturing environment

## Specifications

### Materials of Manufacture

|                         |                                      |
|-------------------------|--------------------------------------|
| Filter membrane:        | Dual-layer Polyethersulfone Membrane |
| Support/Drainage layer: | Polypropylene/<br>Polypropylene      |
| Inner core:             | Polypropylene                        |
| Shroud:                 | Polypropylene                        |
| End fittings:           | Polypropylene                        |
| Support ring:           | Stainless steel                      |

All polymeric materials used in the manufacture of Biofil™ 3 Plus are USP Class VI-121°C, FDA CFR 21 & EU 10/2011 compliant. The finished device has also been tested and proven to show compliance with USP Class VI-121°C plastics.

### Cartridge Dimensions (Nominal)

|                            |  |
|----------------------------|--|
| Effective Filtration Area: | 0.53m <sup>2</sup> (5.7ft <sup>2</sup> )<br>(per 10" module)   |
| Diameter:                  | 70mm (2.8")  |
| Length:                    | 1 module: 254mm (10")<br>2 modules: 508mm (20")<br>3 modules: 762mm (30")<br>4 modules: 1016mm (40") |

### Cartridge Treatment

|           |  |
|-----------|--|
| Standard: | Cleaned and flushed with pyrogen-free water                        |
| Rinsed:   | Ultra-clean, pulse flushed to give a system resistivity of 18MΩ.cm |

### Gaskets and O-Rings

FDA approved 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) |
| Reverse flow direction at: |                |
| 20°C (68°F):               | 2.1bar (30psi) |
| 80°C (176°F):              | 1.0bar (15psi) |

### Operating Temperature

Maximum continuous: 80°C (176°F)

### Sterilisation

*In situ* steam 40 x 30 minute cycles at 135°C (275°F)  
Hot water 100 x 30 minute cycles at 90°C (194°F)

### Extractables

Minimum total extractables. Please refer to the Biofil™ 3 Plus Validation Guide.

### Integrity Testing

Each Biofil™ 3 Plus module of every cartridge is individually integrity tested using the Diffusive Flow Test, which correlates to the HIMA and ASTM F838-20 bacterial challenge tests. Non-destructive integrity tests, such as Pressure Hold, Diffusive Flow and Bubble Point, can be performed by customers. Please contact us for procedural detail.

### Filtrate Quality

Cartridges have been validated to give high levels of effluent cleanliness, in accordance with USP guidance for:

- Extractables
- TOC & Conductivity
- Particulates & Non-Fibre Release
- Bacterial Endotoxins

Please refer to the Biofil™ 3 Plus Validation Guide for full supporting data.

### Clean Water Flow Rates

- Typical clean water flow rate:  
A 254mm (10") Biofil™ Plus single cartridge 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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