

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.

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)						
U	224, fin						
V	226, fin						
Y	BS832, flat						



Typical Applications

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

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/ 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 ² (5.7ft ²) (per 10" module)
Diameter:	70mm (2.8")
Length:	1 module: 254mm (10") 2 modules: 508mm (20") 3 modules: 762mm (30") 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.

