

BorsoPes Biological+

Double Layer Polyethersulphone Membrane Cartridge Filters

VAN BORSELEN FILTERS



The Van Borselen Filters BorsoPes Biological+ microbial rated cartridge has been developed and manufactured for the filtration of liquids in the pharmaceutical, biotechnology and other critical applications. BorsoPes Biological+ utilises a naturally hydrophilic polyethersulphone (PES) membrane with a mirrored asymmetric pore structure. The cartridge's unique built in prefiltration membrane layer provides longer life and higher throughput.

When combined with quality all-polypropylene components and high integrity manufacturing techniques, the BorsoPes Biological+ filter cartridge is ideally suited to the most demanding process conditions.

Van Borselen Filters BorsoPes Biological+ cartridges are constructed in a clean room under tightly controlled conditions using advanced, highly specialised machinery. Quality and consistency of product is assured by the quality control and manufacturing procedures, which are in place throughout all stages of manufacture.

BorsoPes Biological+ membrane cartridges are 100% integrity tested during manufacture by the forward flow diffusion test method.

Applications

BorsoPes Biological+ 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 sterilisation of biological fluids, cell culture media, sera and blood fractionations.

- **Fermentation**

For providing sterile feed stock for the production of antibiotics and enzymes

- **Ophthalmic solutions**

Shelf life assured through the low adsorption of preservatives, such as Benzalkonium Chloride (BAK).

- **API's**

For the clarification and sterilisation of a wide range of active pharmaceutical ingredients.

- **LVP's**

For final filtration of Total Nutritional Fluids, dextrose, amino acids and saline solutions

- **Beverages**

For the clarification and sterilisation of various beverages, including the removal of yeast and spoilage organisms. Low colour removal is an additional advantage.

- **Pure water supply**

For use in ultrapure water treatment systems (including Water-For-Injection).



Features and Benefits

• BorsoPes Biological+ cartridges

BorsoPes Biological+ cartridges contain an optimised, validated prefiltration membrane upstream of the final micron rated membrane. This results in long life and higher throughput.

• Guaranteed microbial ratings

BorsoPes Biological+ cartridges are validated for bacterial removal according to HIMA guidelines and ASTM F838-05, with a log reduction value >7. They are therefore suitable for applications requiring sterilising grade filtration.

• Low protein binding

BorsoPes Biological+ cartridges have excellent low protein binding characteristics, typically 10 times lower than nylon, 2 times lower than polysulphone and similar to PVDF.

• Will not hydrolyse

Compared with other membranes such as nylon, the polyethersulphone membrane used in BorsoPes Biological+ cartridges is extremely resistant to hydrolysis. Capable of exposure in excess of 2 years, they are ideal for hot deionised water applications.

• Excellent chemical compatibility

Resistant to many process chemicals, BorsoPes Biological+ cartridges are suitable for use in a wide range of process applications.

• Cartridge integrity and low TOC levels

Each BorsoPes Biological+ module of every cartridge is individually integrity tested. Each complete filter cartridge is flushed with pure water which is inspected daily for pyrogens using the standard LAL test. When required, they can be pulse flushed with 18MQ.cm pyrogen-free ultra-clean water.

• Suitable for steam sterilising

BorsoPes Biological+ cartridges incorporating a stainless steel support ring can be subjected to steam sterilisation at 125°C (257°F) without loss of integrity.

• Full traceability

All BorsoPes Biological+ cartridges are individually and batch identified with a unique serial number. Each BorsoPes Biological+ cartridge is supplied with a Certificate of Quality and an operating instruction leaflet

• Controlled manufacturing environment

BorsoPes Biological+ cartridges are manufactured in an ISO Cleanroom environment by fully gownned staff, minimising the risk of contamination.

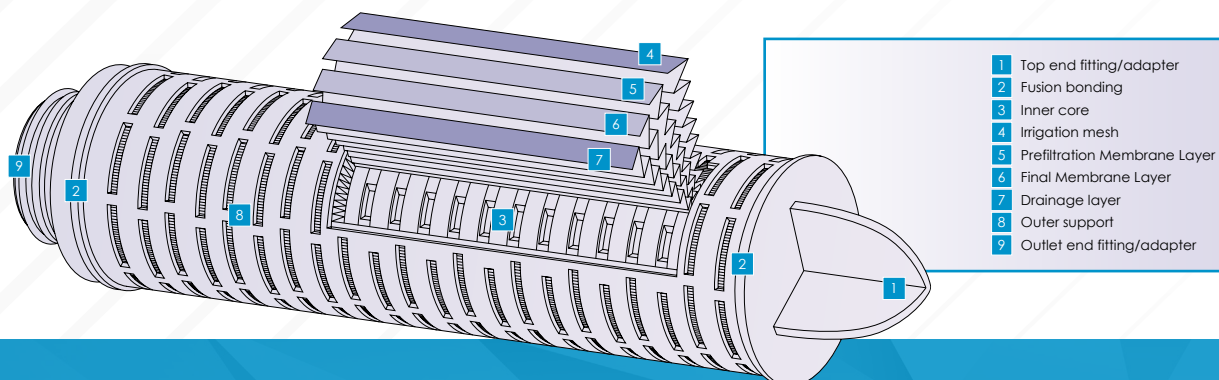
Cartridge Construction

BorsoPes Biological+ cartridges are manufactured from a multi-layer combination of irrigation mesh, prefiltration membrane, final membrane, membrane support and drainage material. BorsoPes Biological+ 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, BorsoPes Biological+ 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 125°C (257°F).

All components used in the construction of BorsoPes Biological+ cartridges are FDA approved to 21CFR and meet or exceed the latest EC Directives for Food Contact.



Specification

Materials of Manufacture

Prefilter membrane	: Polyethersulphone
Filter membrane	: Polyethersulphone
Membrane support	: Polypropylene
Irrigation mesh (support)	: Polypropylene
Drainage layer:	: Polypropylene
Inner core	: Polypropylene
Outer support	: Polypropylene
End fittings	: Polypropylene
Support ring	: Stainless Steel

Cartridge Dimensions (Nominal)

Diameter	: 70mm (2.8")
Length	: 1 module : 127mm (5")
	1 module : 254mm (10"),
	2 modules : 508mm (20")
	3 modules : 762mm (30"),
	4 modules : 1016mm (40")

Effective Filtration Area

Absolute Microbial Rating	Effective Filtration Area (each 254mm (10") module)
0.2, 0.45 and 0.65µm	0.48m ² (5.2ft ²)

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

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)
100°C (212°F)	: 3.0bar (44psi)
120°C (248°F)	: 2.0bar (29psi)

Reverse flow direction at :

20°C (68°F)	: 2.1bar (30psi)
80°C (176°F)	: 1.0bar (15psi)
100°C (212°F)	: 0.5bar (7psi)

Operating Temperature

Maximum continuous	: 85-90°C (185-194°F)
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Sterilisation

In situ steam 80 x 20 minute cycles at 125°C (257°F).
Hot water 100 x 20 minute cycles at 85-90°C (185-194°F).

Extractables

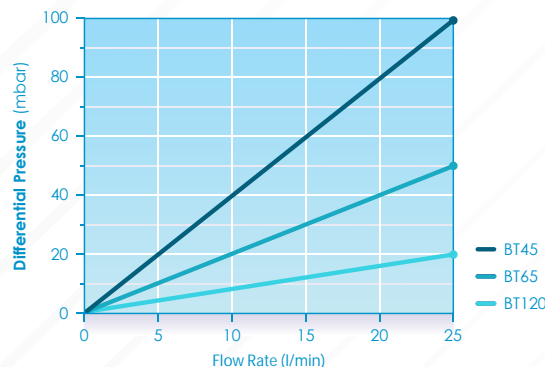
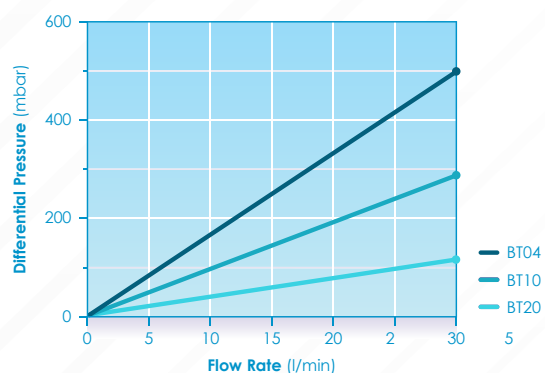
Minimum total extractables. Please refer to the BorsoPes Biological+ Validation Guide.

Integrity Testing

Each BorsoPes Biological+ 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 Pressure Hold, Diffusive Flow and Bubble Point, can be performed by customers. Procedural details are available from Van Borselen Filters.

Clean Water Flow Rates

- Typical clean water flow rate:
A 254mm (10") BorsoPes Biological+ 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.



Range

Suitable for use in Van Borselen Filters and as direct replacements for existing cartridges, BorsoPes Biological+ 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 three microbial ratings: 0.20, 0.45 and 0.65 micron. BorsoPes Biological+ Junior versions are also available. Each cartridge is supplied with all necessary seals or O-rings to ensure chemical compatibility.

Quality Assurance

BorsoPes Biological+ 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, Van Borselen Filters 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 BorsoPes Biological+ cartridges is assured by FDA approval, USP Class VI and meets or exceeds the latest EC Directives for Food Contact.

BorsoPes Biological+ cartridges have been tested and shown to be 100% retentive in line with HIMA and ASTM F838-05 guidelines for *Brevundimonas diminuta* challenge (0.2 micron), *Serratia marcescens* (0.45 micron) and with *Saccharomyces cerevisiae* (0.65 micron). To guarantee the bacterial retention performance of every cartridge, a correlation has been made between the bacterial challenge & integrity tests. A comprehensive validation guide for BorsoPes Biological+ cartridges is available on request.

Chemical Compatibility

The BorsoPes Biological+ materials of construction are compatible with a wide range of chemicals and solvents, 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.

Filter Housings

Please contact a **Van Borselen Filters** representative for further information on our range of filter housings.

Van Borselen Filters

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