Van Borselen FILTERS

BorsoPTFE – M Filter Cartridges

BorsoPTFE-M

- Unique filter media arrangement, that minimises resistance to flow versus competitors' products
- Superb chemical and thermal compability
- USP VI and ISO10993 compliant materials
- Membrane is fully validated to retain bacteria in a liquid challenge (as per PDA TR40 guidlines for sterile gas filtration)
- Meets latest EC food contact guidelines
- Available in a range of sizes and pore ratings
- Manufactured with a range of seals and adaptors and in capsule format

Van Borselen Fitlers BorsoPTFE-M, filter cartridges are manufactured with a zPTFE membrane that increases flow. The cartridges are manufactured with custom made processing equipment that allows Van Borselen to meet the challenge of developing a filter using novel materials. A high temperature resin is used to ensure resistance to multiple steam sterilisation cycles. Mutiple configurations allow for applications from scale-up to small-scale processes. The majority of current adaptor configurations for junior/mini filters are available. The reduction in non-PTFE degradable polymer also results in fewer extractables in solvent-based filtration processes. The application of the zPTFE membrane is of particular benefit in applications where pressure drop can have a significant impact on energy costs.

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BorsoPTFE-M filter cartridges are manufactured with a unique structure incorporating a PTFE membrane with a reduced resistance to flow (zPTFE), that allows a high flow with minimal pressure drop while ensuring full retention of contaminant bacteria. A high-temperature resin is used for constructing the hardware to ensure that the filter can withstand high temperature steaming without distortion or damage.

BorsoPTFE-M filter cartridges can easily be integrity tested in-situ by solvent-free water intrusion testing (WIT); filling and testing can take place with a single automated instrument. Testing by diffusive flow and bubblepoint can be carried out with with solvent-based wetting.

Features and Benefits

- Robust construction of shell and core to withstand high pressure drops and chemical and thermal stress
- Simplified and rapid integrity testing
- Minimal adsorption of product
- High flow with a low pressure drop
- True sterile filtration at each micron rating
- Variety of connections to retrofit major competitors
- Also available in single-use capsule format

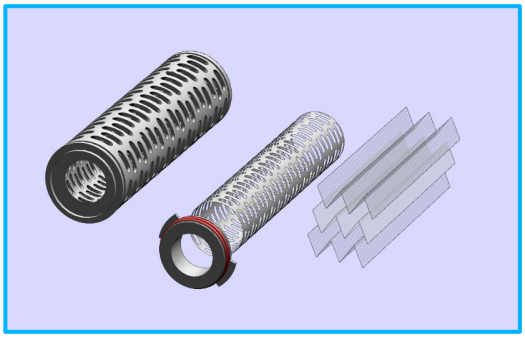
Material of Construction

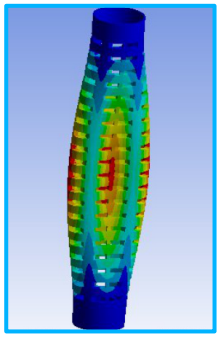
All materials are FDA CFR Title 21 approved for food use.

1. Polypropylene core, adaptor and cage
2. 316 Stainless steel adaptor insert option for hot air and steam applications
3. FDA and USP VI approved seal materials
4. Polypropylene support and drainage layers with PTFE membrane
5. zPTFE membrane for superior flow

Traceability and Integrity

1. Test parameters correlate with retention of bacteria at each grade
2. Each individual module of every cartridge is tested to ensure that there is no risk of 'masking' of defective modules within a cartridge.
3. Each cartridge is marked with a batch and unique number that allows full traceability.





Finite Element Analysis optimised polypropylene cage

Stainless steel reinforced adaptor for multiple steam cycles

FEA optimised high-temperature resistant polypropylene core

Various sealmaterials available

Polypropylene drainage and support layers

zPTFE membrane

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Applications

Sterile Compressed Air/Gases

The zPTFE membrane used for BorsoPTFE-M cartridges is uniquely incorporated into cartridges. The lower pressure drop, in comparison to cartridges constructed using standard PTFE, results in lower energy costs during the lifetime of the cartridge.

Sterile Vessel Ventilation

BorsoPTFE-M cartridges are designed to offer rapid drying times to reduce offline time and the risk of vacuum formation. The high temperature resin used, results in resistance to oxidation and distortion in Water-for-Injection applications.

Biopharmaceuticals

BorsoPTFE-M cartridges are designed to withstand repeated steam sterilisation cycles. A high temperature polypropylene resin is used to ensure that the cartridges do not deform at high temperatures. They are ideal for sterile filtration of process gases.

Solvent Filtration e.g. API production

BorsoPTFE-M cartridges are suited to Active Pharmaceutical Ingredient (API) applications where solvent recovery is a key part of an economical and environmentally-safe process. BorsoPTFE-M cartridges are flushed with low conductivity water and can be used in electronics applications where compatibility is a key requirement. The structure of the zPTFE membrane results in reduced extractables in comparison to standard PTFE.

Regulatory Compliance

- All materials of construction are compliant with FDA CFR Title 21 and USP VI/ISO10993
- Animal Ingredients where present meet requirements to ensure that they are free of BSE / TSE transmissible agents
- The materials of construction are free of melamine, bisphenol A and cyanuric acid
- The cartridges meet Specific and Overall Migration Limits for both acidic and alcohol products in accordance with EC 10/2011
- ISO class 8 cleanroom production
- Cartridges are flushed with purified water prior to packaging

Maximum and recommended operating pressures

Recommended max. differential pressure 2.1 bar
Maximum differential pressure 6.5 bar at 50°C
Max. reverse differential pressure 2 bar at 50°C

Steam sterilisation, autoclave and hot water sanitisation

- Forward flow at 142°C for 50 X 1 hour cycles
- Reverse flow at 142°C for 50 X 1 hour cycles
- Autoclave at 135°C for 50 X 30 min cycles

Nominal lengths for BorsoPTFE-M type cartridge

10 in (244mm), 20in (491mm), 30 in (738mm)

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Microbiological Security with Pharmaceutical GradeTesting	
Pore Size	**Microbial retention at ≥ log 7**
0.2 µm 0.45 µm 1.0 µm	Brevundimonas diminuta Serratia marcescens ISO fine dust at ≥ 99.9 % in a single pass challenge test

Pore Size	Diffusive flow per 10 in module (at pressure)	Water Intrusion (at pressure) in 10 min
0.2 µm	10 ml/min (800 mbar)	3714µl (2500mbar)
0.45 µm	10 ml/min (400 mbar)	3714µl (1200mbar)

Pore Size	Minimum Bubble Point in isopropanol / water 60/40
0.2 µm	966 mbar
0.45 µm	610 mbar

Media		Length		Connection		O-ring		Micron Rating	
BPFM	Polytetrafluoroethylene	1	10"	0	DOE	EP	EPDM	002	0.2 µm
		2	20"	2	226 / flat	SP	Silicone	004	0.45 µm
		3	30"	3	222 + fin	VP	Viton	006	0.65 µm
				7	226 / fin	FP	FEP	01	1.0 µm
				8	222 + fin				

BPFM — 1 — 7 — SP — 002

BPFM17SP002

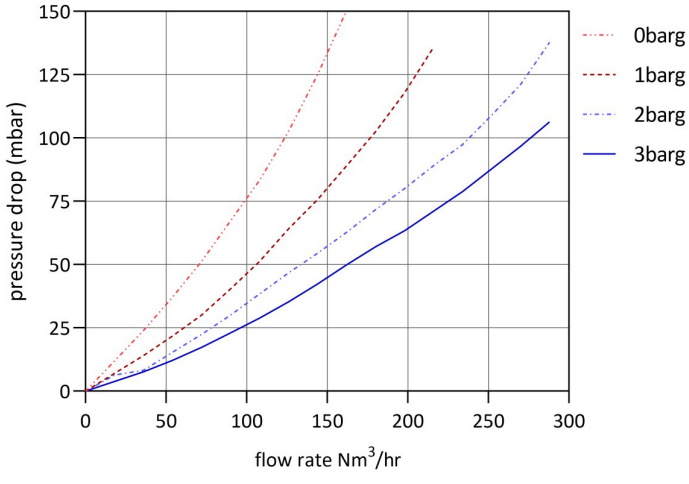
PTFE membrane cartridge filter: 0.2µm pore size BS226 O-rings with a location fin (code 7), 10 inches in length (6800 cm2 filter area) with silicone O-rings

222

Double Open End

Fin

Code-7



Air flow vs pressure drop at various pressures for a 10 inch BPFM, 0.2 µm zPTFE membrane filter cartridge

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