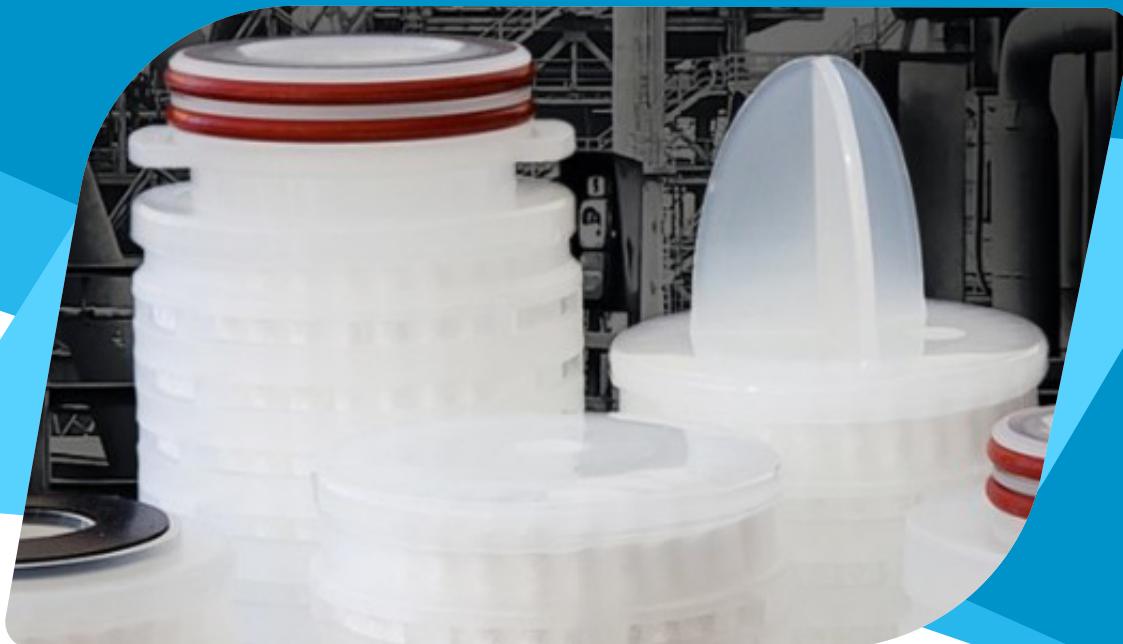


Van Borselen Junior Filter Cartridges



BorsoPTFE-JM PTFE membrane Mini-Filter Cartridges

- 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 guidelines 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 Filters BorsoPTFE-JM, PTFE mini 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. Multiple 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.



BorsoPTFE-JM junior cartridges are manufactured with a zPTFE membrane with a reduced resistance to flow while fully retaining bacteria. The cartridges are highly resistant to thermal stress during steam sterilization. A multitude of adaptor options are available for easy retrofitting into existing housings.

BorsoPTFE-JM junior 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 solvent-based wetting.

Features and Benefits

- Robust construction 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



Materials of Construction

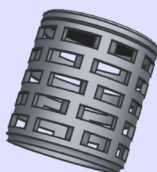
All materials are FDA CFR Title 21 and USP VI approved.

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

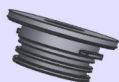
Traceability and Integrity

- Test parameters correlate with retention of bacteria at each grade
- Each individual cartridge is tested
- Each module is marked with a batch number that allows full traceability.

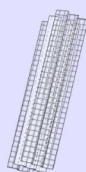
Finite Element Analysis optimised polypropylene cage and core ⁽¹⁾



Stainless steel reinforced adaptor for multiple steam cycles ⁽²⁾



Various seal ⁽³⁾ materials available



zPTFE membrane with polypropylene support and drainage layers ⁽⁴⁾



Applications

Sterile Compressed Air/Gases

The zPTFE membrane used for BorsoPTFE-JM junior 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

The junior cartridges are designed with a number of convenient fittings to allow for a range of applications. The high temperature resin used, results in resistance to oxidation and distortion in Water-for-Injection applications.

Biopharmaceuticals

The cartridges are designed to withstand repeated steam sterilisation cycles at the maximum recommended temperatures. Reliable and validated retention of bacteria and integrity testing options help to meet quality requirements.

Solvent Filtration e.g. API production

BorsoPTFE-JM junior cartridges are suited to the filtration of small batches and scale-down studies. Van Borselen sizing options deliver exceptional flexibility

Food and beverages

The cartridges are suitable for small-scale venting and the protection of sensitive equipment in production lines.

Regulatory Compliance

Materials approvals

- 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

Customer Support

Onsite and laboratory-based qualification procedures (IQ, OQ and PQ) for integrity testing can be carried by Van Borselen Filters to meet regulatory requirements. Process based qualification in accordance with PDA TR26 for bacterial retention, compatibility and extractables is available with independent FDA accredited laboratories. Van Borselen Filters are able to manufacture the full range of housings for each type of BorsoPTFE-JM junior cartridge.

Maximum and recommended operating pressures

Recommended max. differential pressure 2.1 bar
(based on ASTM-F838 bacterial retention)
Maximum differential pressure 5.0 bar at 50°C
Max. reverse differential pressure 1 bar at 50°C

Steam sterilisation, autoclave and hot water sanitisation

Forward /reverse flow at 143°C for 30 X 30 min cycles
Forward flow at 125°C for 50 X 1 hour cycles
Autoclave at 135°C for 25 X 30 min cycles

Nominal lengths for BorsoPTFE-JM junior type cartridge

1.5 in , 2.5 in, 4 in (CM and M1 code), 4.5 in (CM and M1 code), 5 in

Microbiological Security with Pharmaceutical Grade Testing	
Pore	Microbial retention at $\geq \log 7$
0.2 μm	Brevundimonas diminuta
0.45 μm	Serratia marcescens
1.0 μm	ISO fine dust at $\geq 99.9\%$

Pore Size	Diffusive flow per 10 in module (pressure), IPA/ Water 60/40 we1ed)	Water Intrusion (pressure) in 10 min
0.2 μm	4 ml/min (800 mbar)	1000 μl (2500mbar)
0.45 μm	4ml/min (400 mbar)	1000 μl (1200mbar)

Media
BPFJM



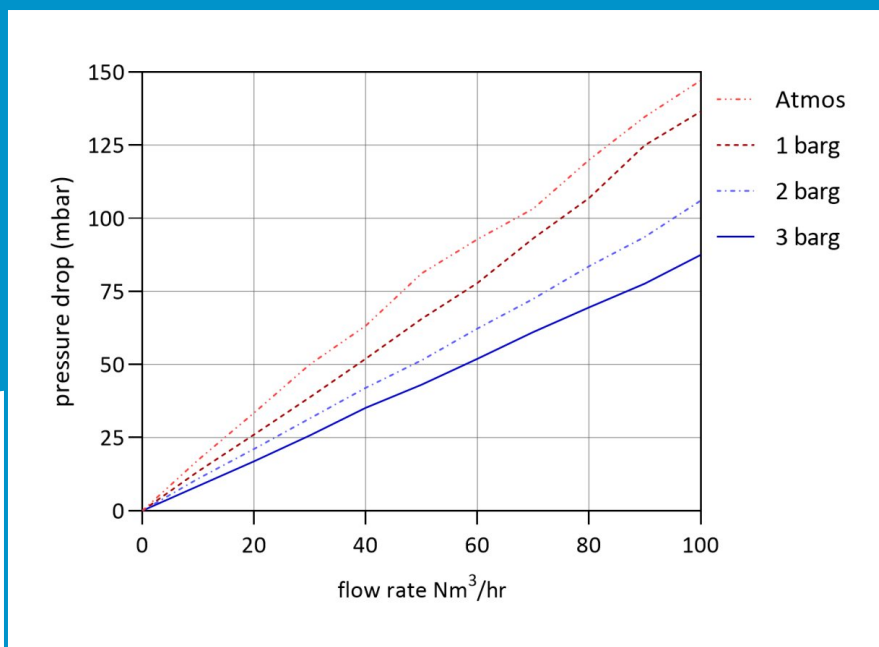
Length
015 = 1.5"
025 = 2.5"
040 = 4"
045 = 4.5"
050 = 5"

Adapter style	
IR	BS116 internal
IRS	BS116 slot
SLV	BS118 Outer
SLVL	SLV 4 long-lug
SLVLS	SLV 4 short-lug
B7	Baby Code 7
CM	Code M
M1	Code M120
SK	SLK

O-rings
EP = EPDM
SP = Silicone
VP = Viton
FEP = FEP

Micron Rating
001 = 0.1 μm
002 = 0.2 μm
045 = 0.45 μm
01 = 1.0 μm

IR	IRS	SLV	SLVL/S	B7	CM	M1	SK



Air flow vs pressure drop at various pressures for a 5 inch BorsoPTFE-JM, 0.2 μm zPTFE membrane junior cartridge

