



BorsoVent

ePTFE Membrane Cartridge Filters for Autoclave Venting

BorsoVent cartridges are manufactured using a highly hydrophobic ePTFE membrane and are designed for autoclave venting. The enhanced ePTFE membrane offers exceptionally high gas flow rates at low pressure differentials (see graph).

BorsoVent cartridges are designed with a ½" BSP male thread for autoclave and small tank venting applications. The hydrophobic characteristics of the ePTFE membrane makes the BorsoVent filter cartridge particularly suitable for rapid vacuum break in autoclaves

Applications

BorsoVent ePTFE membrane cartridges meet the demanding filtration requirements of pharmaceutical, laboratory and sterile production environments. They are suitable for a wide range of small-scale sterile venting applications.

- **Autoclave vents**

The safe sterile venting of autoclaves in pharmaceutical and laboratory processes.

- **Sterile product storage vessels**

The venting of sterile air to reduce the risk of vacuum formation in pharmaceutical, laboratory and small-scale processes.



Features and Benefits

- **BorsoVent cartridges**

The ePTFE membrane is recognised as the world leading gas sterilising hydrophobic membrane. The membrane of choice is also used in all Van Borselen Filters BorsoVent filter cartridges.

- **Guaranteed microbial ratings in a liquid challenge**

BorsoVent cartridges are validated for bacterial removal in liquids in accordance with PDA, HIMA guidelines and ASTM F838-05, with a log reduction value >7. This test is stringent in comparison to an airborne particulate challenge test.

- **Bacterial spores and viruses**

The retention of bacterial spores and viruses carried in aerosols over extended time periods has been independently validated in tests carried out by the UK Health Protection Agency.

- **Flow ΔP characteristics**

The unique characteristics of the ePTFE membrane, combined with the construction of the BorsoVent filter cartridge, results in exceptionally high gas flow rates at low pressure differentials. This allows rapid vacuum-break conditions to be reached.

- **Steam sterilisation**

BorsoVent cartridges have been designed and validated to be repeatedly steam sterilised in-situ at temperatures of up to 135°C (275°F) for 100 cycles at 20 minutes per cycle. Steam sterilisation in the reverse direction for in excess of 70 cycles in a venting application, without loss of integrity, has been independently validated by customers.

- **Cartridge integrity and low TOC levels**

All BorsoVent cartridges are integrity tested and supplied clean, having been flushed with pure water. When required they can be pulse flushed with 18M Ω.cm pyrogen-free ultra-clean water.

- **Full traceability**

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

- **Controlled manufacturing environment**

BorsoVent cartridges are manufactured in an ISO Cleanroom environment by fully gowned staff, minimising the risk of contamination.

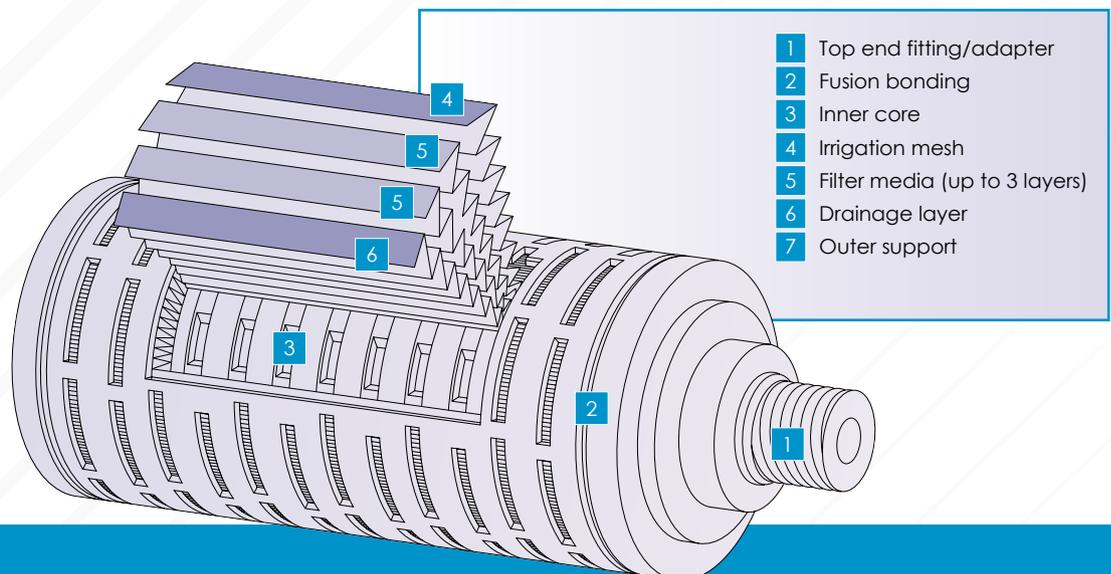
Cartridge Construction

BorsoVent cartridges are manufactured from a multi-layer combination of irrigation mesh, filter membrane, membrane support and drainage material. BorsoVent 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, BorsoVent 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 135°C (275°F).

All components used in the construction of BorsoVent cartridges are FDA approved to 21CFR



- 1 Top end fitting/adaptor
- 2 Fusion bonding
- 3 Inner core
- 4 Irrigation mesh
- 5 Filter media (up to 3 layers)
- 6 Drainage layer
- 7 Outer support

Specification

Materials of Manufacture

Filter membrane	: ePTFE
Membrane support	: Polypropylene
Irrigation mesh (support)	: Polypropylene
Drainage layer	: Polypropylene
Inner core	: Polypropylene
Outer support	: Polypropylene
End fittings	: Stainless Steel
Sealing	

Cartridge Dimensions (Nominal)

Diameter	: 56mm (2.2")
Length	: 77.5mm (2.5") 136mm (5")

Effective Filtration Area

Absolute Microbial Rating (in liquids)	Effective Filtration Area (for 5" cartridge)
0.2µm	0.37m ² (4.0ft ²)

Cartridge Treatment

Standard	: Cleaned and flushed, without further treatment.
Flushed	Ultra-clean, pulse flushed to give a system resistivity of 18MΩ.cm.

Adaptor and O-Ring

Silicone (other materials are available on request).
½" BSP male thread.

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)
125°C (257°F)	: 1.5bar (22psi)

Sterilisation

In situ steam 70 x 25 minute cycles at 135°C (275°F).

Extractables

Minimum total extractables. Please refer to the BorsoVent Validation Guide.

Integrity Testing

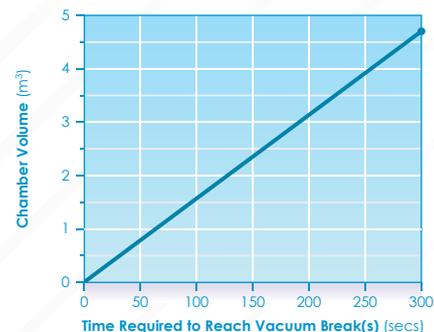
Each BorsoVent cartridge is individually integrity tested using the Diffusive Flow Test, which correlates to the HIMA and ASTM F838-05 bacterial challenge tests. Non-destructive integrity tests, such as Diffusive Flow, Water Intrusion, Pressure Hold and Bubble Point, can be performed by customers. Procedural details are available from **Van Borselen Filters**.

Clean Air Flow Rates

- Typical clean air flow rate:
A 136mm (5") BorsoVent cartridge exhibits the flow-ΔP characteristics indicated below



- Vacuum break application:
If the initial vacuum is at -980 mbarg, the time required before the vacuum break conditions required to safely open the autoclave door (at -20mbarg) are achieved, is indicated below.



Range

BorsoVent cartridges are designed for autoclave and small-scale tank vent applications. Available in a 5 inch length, with a validated microbial rating of 0.2 micron in liquids.

Quality Assurance

BorsoVent 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 BorsoVent cartridges is assured by FDA approval and USP Class VI.

BorsoVent cartridges have been tested and shown to be 100% retentive in liquids in accordance with PDA, HIMA and ASTM F838-05 guidelines for the Brevundimonas diminutachallenge. The retention of Bacillus astrophaeus bacterial spores and MS-2 Coliphage viruses carried in aerosols over extended time periods has been independently validated in tests carried out by the UK Health Protection Agency. To guarantee the bacterial retention performance of every cartridge, a correlation has been made between the bacterial challenge and integrity tests. A comprehensive validation guide for BorsoVent cartridges is available on request.

Van Borselen Filters

Tel: +31 (0)79-3412314

Fax: 079-3412892

PO Box: 3 - 2700 AA Zoetermeer

E-mail: info@vanborselen.nl

KVK nr.: Register Haaglanden 27103715

BTW/VAT-Nr.: NL005625452B01

Argonstraat 66, Zoetermeer

www.vanborselen.nl

VAN BORSELEN FILTERS

