

Midisart® BV

Gamma-Irradiatable
Sterile Venting Filter for
Single-Use Applications



Applications

Midisart® BV sterilizing grade air and gas filter elements are ideal for use with single-use assemblies that need to be sterilized by gamma radiation. The possibility of sterilizing the whole assembly without disconnecting individual parts provides maximum handling ease. During integrity testing Midisart® BV filters can be used as a sterile barrier.

Product Information

The gamma-irradiatable Midisart® BV disposable venting filters, manufactured with reinforced hydrophobic PTFE membranes, are especially designed for sterile venting on disposable bag manifolds and tubing systems. The possibility to choose between autoclaving or gamma irradiation provides flexibility regarding sterilization. 100% factory integrity testing ensures inherent quality in every filter prior to use.

Stability

The hydrophobic PTFE membrane, reinforced by a polyester fleece, assures full mechanical stability of the PTFE membrane for specified applications after gamma sterilization. Validated by a liquid BCT (Bacterial Challenge Test), using the ASTM® F838-05 (2005) challenge methodology, Midisart® BV filters ensure sterile filtration. Midisart® BV is integrity testable by the bubble point test.

Quality Control

Each Midisart® BV is integrity tested prior to release. This 100% test has been defined as the final release criteria. Lot number and individual unit number are lasered on the top part of each Midisart® BV housing to ensure complete traceability.

Documentation

Midisart® BV filter elements are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide (SPK 5778-e) is available for compliance with regulatory requirements.

Biosafety

Materials pass current UPS Plastics, class VI
Non fiber releasing according to 21 CFR

Technical Data

Specifications

Materials	
Membrane	PTFE
Support Fleece	Polyester
Housing	Polypropylene
Pore Size	
0.2 µm	
Article Codes	
17805-----BVE (12 per box)	
17805-----BVN (100 per box)	
17805-----BVQ (500 per box)	

Connectors

Multiple stepped hosebarb (in- and outlet)
Other connectors on request
(Hose Barb, 1/8" NPT, Triclamp, small Hose Barb)

Filtration Area

20 cm² | 3 square inch

Housing Diameter

64 mm | 2.5"

Sterilization

- Gamma Irradiation:
- 25 kGy (recommended)
 - 50 kGy (max.)
- or
- Autoclaving:
- Max. 20 cycles at temperature 134 °C for 30 min.

Max. Differential Pressure

In direction of filtration 1.5 bar | 22 psi

In reverse direction of filtration 0.5 bar | 7.25 psi

Typical Air Flow Rates [L/min]

	Prior irradiation	After irradiation (50 kGy)
$\Delta p = 0.02 \text{ bar}$	2.06	2.06
$\Delta p = 0.05 \text{ bar}$	4.27	4.29
$\Delta p = 0.1 \text{ bar}$	8.00	8.09

1 bar = 100 kPA = 14.5 psi


* Average values: 30 samples of 3 different lots

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