

Sartopore® Air Midisart®

Gamma-Irradiatable
or Autoclavable
Single-Use Venting Filter
for Critical Applications

Product Information

The Sartopore® Air Midisart® with its revolutionary hydrophobic 0.2 µm PES membrane completely addresses the rigorous demands of small-scale, single-use, venting applications. Sartopore® Air Midisart® ensures sterilizing-grade venting performance in either direction. Sartopore® Air Midisart® delivers a high level of performance and process security.



Introduction

This filter sets the standards when it comes to requirements needed for critical applications. Particle retention, particle release limits, phage retention and of course bacteria retention in air and liquids (bi-directional) are specifications that prove the quality of Sartopore® Air Midisart®.

100% factory integrity testing ensures inherent quality in every filter prior to use. Superior and steady flow rates over long duration imply highly efficient processes. The absence of fleeces guarantees no particle release. Tubing kinking is no issue due to the proven light-weight construction.

Applications

- Single-use assemblies
- Small bioreactors
- Carboys
- Filling and transfer vessels
- Holding and storage tanks | bags
- Fill & finish applications
- Bags | Bottles | Tubing assemblies
- Mixers
- Cell Culture Chambers

Inherent Quality Provides Full Confidence

The 0.2 µm single-layer hydrophobic polyethersulfone (PES) membrane is self-dewetting and therefore provides high air flow rates even at very low differential pressures over an extended process time. All components were developed and are produced under full control of Sartorius. Furthermore the following indispensable requirements are fulfilled:

- **Particulate release in quantities** well within the requirements established for Grade A classification of cleanrooms under EU Annex1 in forward and reverse direction
- **Bi-directional sterility** proven by worst case liquid Bacterial Challenge Test in forward and reverse direction
- **Retention of $\geq 10^7$ *Brev. diminuta/cm^2*** in aerosol and liquid
- **Retention of $\geq 10^7$ Bacteriophage MS2/cm²** in aerosol
- **Retention of particles** sizes 0.005 µm | 0.3 µm
- **100% integrity tested** prior to release
- **Clear labeling** with Lot number, individual unit number and "IN" as an indicator for direction of flow. All information lasered on the top part of each filter housing. No use of ink or glue labels.

Technical Data

Filtration Area

20 cm² | 3 in²

Integrity Testing

Min. Bubble Point \geq 950 mbar | 13.8 psi
Wetting agent: IPA/Water (60 | 40)

Sartopore® Air Midisart® guarantees intact filters released by a 100% pre-use test. For critical applications, we recommend the use of a filter tandem, as a pre-use test cannot fully cover the loading of the filter units in customer applications. A filter tandem greatly reduces the risk of a failed post-use integrity test if safety or other concerns arise.

Max. Differential Pressure

In direction of filtration:

- Air: 2 bar
- Liquid: 2 bar

In reversed direction of filtration:

- Air: 1 bar
- Liquid: 1 bar

Pore Size

0.2 µm

Materials

Membrane

Hydrophobic polyethersulfone (PES)

Housing

Polypropylene (PP)

Connectors

Multiple stepped hose barb (in- and outlet)

Other connectors on request (Hose Barb, 1/8" NPT, Tri-clamp, small Hose Barb)

Sterilization

Gamma Irradiation

max. 50 kGy

Autoclaving

max. 134°C temperature for 30 min. (max. 20 cycles)

Note: Multiple sterilization cycles by gamma-irradiation are not allowed. Once a Sartopore® Air Midisart® was irradiated, further autoclaving steps are prohibited.

Housing Diameter

64 mm | 2.5"

Regulatory Compliance

- Each individual element is tested for integrity in direction of filtration
- Fully validated as sterilizing grade filters according to ASTM current F-838 guidelines
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System
- USP Plastic Class VI Test
- Non fiber releasing according to 21 CFR
- This product meets the requirements established for Grade A classification of cleanrooms under the most current version of EU Annex1: Manufacture of Sterile Medicinal Products.
- Oxidizable Substances: The filtrate of these filter elements shows a negative reaction when tested according to the current USP.

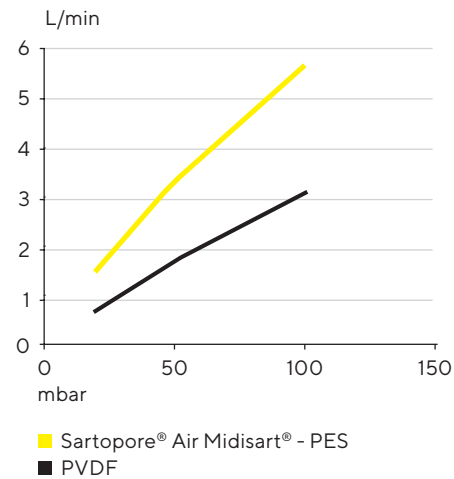
Technical Reference

A Validation Guide is available under DIR No. 2920913.

Performance

Superior Air Flow Rates

The Sartopore® Air Midisart® PES membrane filters outperform any PVDF filters easily. Resulting flow rates at low differential pressures are illustrated in the diagram.



Ordering Information



17805 ----- AI ■


Packing Size
E: 12 per box
N: 100 per box
Q: 500 per box

Germany

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