



Instructions for Use

Sartopore Air Midisart®

Sartopore Air Midisart® 0.2 µm, non sterile

Sartopore Air Midisart® are ready-to-connect filtration units that are supplied non-sterile. They are designed for particulate removal and sterilization of gases in single-use applications. The hydrophobic PES membrane allows sterilizing the filtration units with gamma irradiation.

1. Labeling

Each Sartopore Air Midisart® filtration unit is labeled with filter type, lot number, individual unit number and use before date. For simplyfied data integration into Sartocheck® integrity testing devices these information are also available in form of a Data Matrix code according to ISO | IEC 16022 applied to the units by laser along with the direction of filtration.

2. Applications

Sartopore Air Midisart® filtration units have been designed for single-use venting applications like venting of single-use bioreactors and single-use assemblies that need to be gamma-irradiated.

3. Installation

- Remove a Sartopore Air Midisart® from the box
- Fit the connector of e.g. your tubing system to the Sartopore Air Midisart® hose barb without touching it
- Available conncetions (inlet and outlet):
 - standard stepped hose barbs for hoses with an inner diameter of 6 – 12 mm
- small stepped hose barbs for hoses with an inner diameter of 4–12 mm

NOTE Please check the label on the housing of the Sartopore Air Midisart® filtration unit to be sure that you have connected it in the right direction. The direction of filtration is governed by the application and must always be checked before starting filtration.

4. Sterilization

Sartopore Air Midisart® filtration units can be sterilized by gamma irradiation or autoclaving.

Gamma irradiation:

Recommended dose 25 kGy, max. dose 50 kGy

IMPORTANT Gamma irradiation may only be performed once.

Autoclaving:

Max. temperature 134 $^{\circ}\text{C}$ for 30 min. (max. 20 cycles)

▲ WARNING Repeated gamma sterilization will result in damage to the product. Once a Sartopore Air Midisart® was irradiated, further autoclaving steps are prohibited, and vice versa.

5. Integrity test data

Integrity testing can be performed by using a Sartocheck® integrity test device, which records the corresponding integrity test data.

For detailed information on how to perform an automatic integrity test, please see our Operating Instructions for Sartocheck® integrity test devices.

Bubble Point Limit with 60% IPA | Water:

■ ≥950 mbar

∧ NOTE Bubble Point measuring only IN direction
of filtration

6. Maximum allowable differential pressure In direction of filtration:

- Air: 2 bar
- Liquid: 2 bar

In reversed direction of filtration:

- Air: 1 bar
- Liquid: 1 bar

7. Specifications

Filter material	Hydrophobic PES
Housing material	Polypropylene
Filtration Area	20 cm ²
Housing diameter	64 mm
Priming volume	3 mL
Hold-up volume	approx. 1 mL before, 0.5 mL after bubble point
Max. operating pressure	200 kPa (2 bar)

8. Return of used filtration units

If you wish to return used filtration units for testing at Sartorius in Germany, make sure that you sterilize or decontaminate the filter units before packing them for shipment. You must enclose a completed Return Shipment Form in every shipment. This form is available from your local Sartorius representative. Any return shipment not accompanied by this completed form must be rejected under the German Regulations for Workplace Safety.

9. Liability

Sartorius shall not assume any liability for defects or damage resulting from improper handling of Sartopore Air Midisart® filtration units. In particular, if the user does not follow these Instructions for Use, the filtration units will be considered to have been improperly handled. In the interest of further development of Sartorius products, we reserve the right to make changes to the specifications of these products without notice.

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List of Sartorius material numbers applying to EPA-FIFRA

17805——-Al1
17805———AIE
17805——-AIM
17805——AIN
17805——AIQ
17805AQN
17877——AIM
17877———AIN