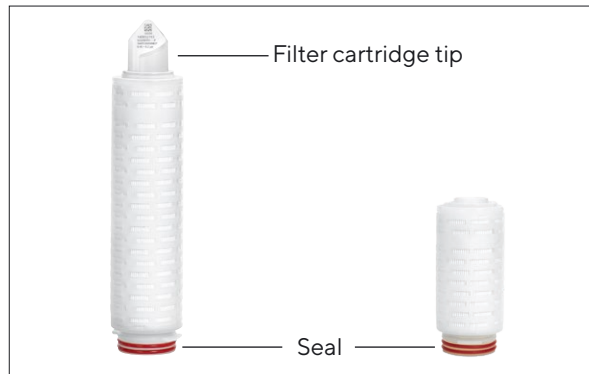




Instructions for Use

Standard and Mini Filter Cartridges



1. Validity

These instructions apply for the following product lines:

- Aerosart®
- Aquasart® Plus | Plus XL | PS
- Sartobev® PS
- Sartobran® P
- Sartoclean® CA | GF
- Sartocool® PS
- Sartofluor® GA | LG | HR
- Sartoguard GF | PES
- Sartolon®
- Sartopore® 2 | 2 XLG | 2 XLI | 2 XLM | Air | Platinum | Platinum HB
- Sartopure® GA | GF Plus | IND | PP3
- Sartovent®
- Vinosart® PS

2. Safety Information

There are no inherent dangers associated with Standard and Mini filter cartridges. However, specific application scenarios may pose risks in connection with the technical systems in which the filter cartridges are operated. The warning and safety instructions in the instructions for use for the system in which the standard and mini filter cartridges are used must therefore be observed. This document only applies in combination with the system's instructions for use.

3. Labeling

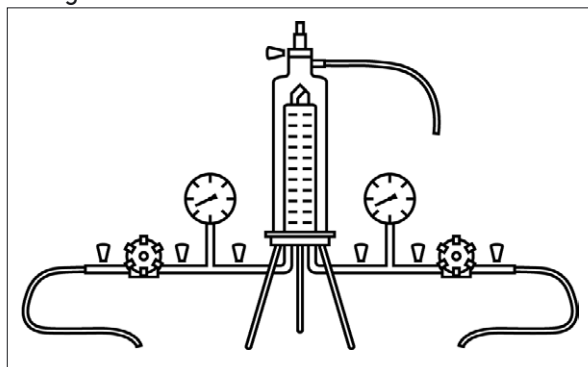
Information on filter cartridge tip on the label of the plastic bag and the outer packaging:

- Product designation
- Pore size or rejection rate
- Batch number
- Individual item number
- Order no.

Additional information on the label of the plastic bag and the outer packaging:

- Expiry date
- Batch number

4. Typical Filtration Setup with Stainless Steel Housing



5. Inserting Filter Cartridges into Housing

- Cut open the plastic bag at the bottom end on the seal side.
- Push the filter cartridge far enough out of the plastic bag so that the seals can be well moistened.
- Moisten the seals with water or the liquid to be filtered.
- Hold the filter cartridge firmly at the bottom end and insert into the underside of the housing by turning gently.
- Remove the plastic bag.
- Mount the housing dome on the base.

6. Moistening the Filter Unit

Filter units must be moistened before the integrity test.

Filter	Liquid for moistening
Hydrophilic filters	Aqueous solution
PTFE membrane filter	Liquid with surface tension of < 28 dyn/cm

- Close all valves.
- Open the vent valve until liquid comes out of it with no air bubbles.
- When the liquid emerges from the vent valve, stop filling.
- Close the vent valve.
- Set a differential pressure of 0.3 bar.

- Rinse for 3–5 minutes.
- To empty, open the vent valve and the discharge valve until no more liquid comes out of the housing.
- Close the valves.

7. Autoclaving the Filter Unit

Sterilization conditions: Up to 134 °C, 2 bar, 30 min.

- Place the filter unit in an autoclavable sterilization bag.
- Once the sterilization temperature has been reached, continue autoclaving the filter element for a further 30 minutes.
- After autoclaving, remove the filter unit from the sterilization bag.

8. Performing In-Line Steam Sterilization

Sterilization conditions: Up to 134 °C, 0.3 bar, 20 min.

Perform in-line steam sterilization of the filter cartridge in the filtration direction.

- Throughout the entire procedure, apply differential pressure of max 0.5 bar, 121 °C or max. 0.3 bar, 134 °C.
- Open the vent valve and the drain valve a little or use a steam separator.
- Let the steam flow in slowly, by opening the inlet valve slowly.
- If steam is escaping from all valves, leave at least one valve slightly open on the sterile side so that the steam can flow or use a steam separator. Close the other valves.

Error Prevention	Procedure
Preventing vacuum condensation	Blanket the filter system with compressed air on the inlet and outlet side following steam sterilization. The compressed air should be approx. 200 mbar higher than the previously applied sterilization pressure.
Cooling off filter cartridge	Flush system with hydrophilic filters with water or buffer until the system reaches ambient temperature. Hydrophobic filters can be dried with flowing air.

9. Performing Sanitization with Hot Water

- Open the vent valve and leave open during filling.
- Heat water to 85 °C.
- Completely fill the housing with water and allow to circulate for 30 minutes.
- Turn off the hot water supply.

10. Performing Integrity Tests

Requirement: Filter unit is moistened, sterilized and cooled to room temperature.

- Moisten the filter unit again.
- Perform the integrity test with an automatic test device, e.g., with Sartocheck®. Observe the Validation Guide and QAC for the IT values.

11. Performing Liquid Filtration

- Fully vent the housing. To do so, open the vent valve until some liquid escapes.
- Close the vent valve again.
- Set the filtration target pressure.
- Perform the filtration.

12. Returning Used Filter Elements

In the event of a complaint, the product can be returned to Sartorius. Returned products must be clean, decontaminated by sterilization, and packaged. Products contaminated with hazardous materials, e.g., biological or chemical substances that pose a risk to human health, will not be accepted for disposal.

- Contact your local Sartorius contact person for instructions on how to return parts (see www.sartorius.com).
- Pack the product for return.

13. Disposal

The product must be disposed of properly by disposal facilities. The product must be decontaminated by sterilization for this purpose

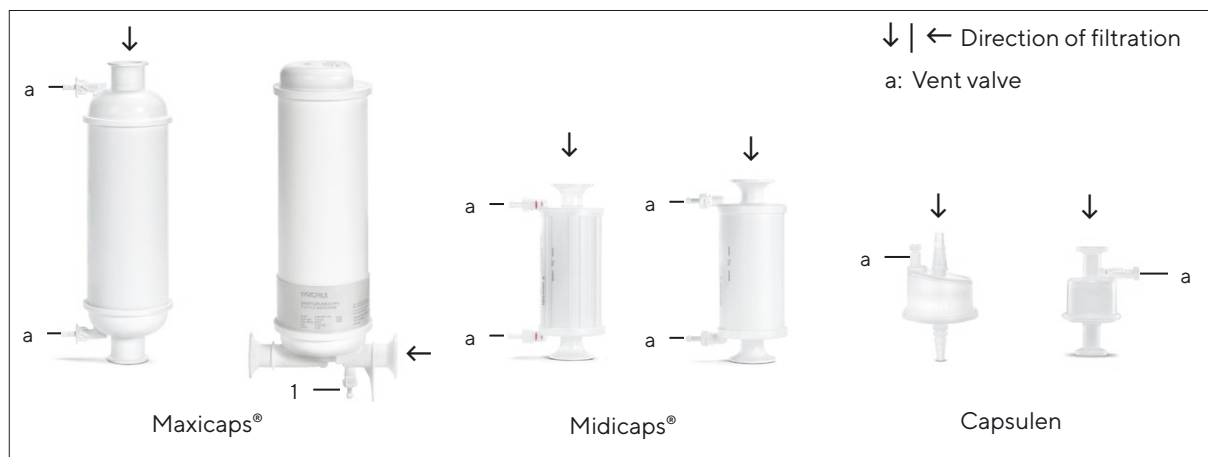
- Dispose of the product in accordance with local government regulations.
- Dispose of the packaging in accordance with local government regulations.

14. Application Support

If needed, you can request the corresponding documents with further technical data, information on how to perform product integrity tests, or specific information about additional applications from your local Sartorius contact person.

Instructions for Use

Maxicaps[®], Midicaps[®], and Capsules



1. Validity

These instructions apply for the following product lines:

- Aerosart[®]
- Aquasart[®] Plus | Plus XL | PS
- Sartobev[®] PS
- Sartobran[®] P
- Sartoclean[®] CA | GF
- Sartocool[®] PS
- Sartofluor[®] GA | LG | HR
- Sartoguard GF | PES
- Sartolon[®]
- Sartopore[®] 2 | 2 XLG | 2 XLI | 2 XLM | Air | Platinum | Platinum HB
- Sartopure[®] GA | GF Plus | IND | PP3
- Sartotent[®]
- Vinosart[®] PS

2. Safety Information

There are no inherent risks associated with Maxicaps[®], Midicaps[®], and capsules. However, specific application scenarios may pose risks in connection with the technical systems in which Maxicaps[®], Midicaps[®] or capsules are operated. The warning and safety instructions in the instructions for use for the system in which the Maxicaps[®], Midicaps[®], or capsules are used must therefore be observed. This document only applies in combination with the system's instructions for use.

3. Labeling

Information on the housing of the Maxicaps[®], Midicaps[®], and the capsules:

- Product designation
- Pore size or rejection rate
- Batch number
- Individual item number
- Order no.
- Operating parameters
- Direction of filtration
- Expiry date

Information on the label of the plastic bag | the outer packaging:

- Product designation
- Pore size or rejection rate
- Expiry date
- Batch number
- Order no.

4. Moistening the Filter Unit

Filter units must be moistened before the integrity test.

Filter	Liquid for moistening
Hydrophilic filters	Aqueous solution
PTFE membrane filter	Liquid with surface tension of < 28 dyn/cm

- Close all valves.
- Open the vent valve until liquid comes out of it with no air bubbles.
- When the liquid emerges from the vent valve, stop filling.
- Close the vent valve.
- Set a differential pressure of 0.3 bar.
- Rinse for 3–5 minutes.
- To empty, open the vent valve and the discharge valve until no more liquid comes out of the housing.
- Close the valves. Ensure that the valves of Maxicaps[®] and Midicaps[®] are not closed against pressure exceeding 2 bar.

5. Autoclaving | Gamma Irradiating the Filter Unit

Depending on the filter unit used, only one sterilization method can be used: gamma irradiation or autoclaving. Products cannot be autoclaved after gamma irradiation.

Autoclaving

Requirement: hydrophilic membrane filters must be moistened (exception is Sartopore[®] Platinum)
Sterilization conditions: Up to 134 °C, 2 bar, 30 min.

- Loosely connect the stainless steel adapter with the filter unit connection.
- Place the filter unit with the stainless steel adapter in an autoclavable sterilization bag.
- Once the sterilization temperature has been reached, continue autoclaving the filter element for a further 20 minutes.
- After autoclaving, remove the filter unit from the sterilization bag and tighten the stainless steel adapter by hand.

Gamma Irradiation

- Use a gamma-compatible capsule.
- Perform gamma irradiation of the capsule at max. 50 kGy.

6. Performing Integrity Tests

The filter unit has been moistened, sterilized, and cooled to room temperature.

- Perform the integrity test with an automatic test device, e.g., with Sartocheck[®]. Observe the Validation Guide and QAC for the IT values.

7. Performing Liquid Filtration

- Fully vent the housing.
- Open the vent valve until the liquid to be filtered escapes.
- Close the vent valve again.
- Set the filtration target pressure.
- Perform the filtration.

8. Returning Used Filter Elements

In the event of a complaint, the product can be returned to Sartorius. Returned products must be clean, decontaminated by sterilization, and packaged. Products contaminated with hazardous materials, e.g., biological or chemical substances that pose a risk to human health, will not be accepted for disposal.

- Contact your local Sartorius contact person for instructions on how to return parts (see www.sartorius.com).
- Pack the product for return.

9. Disposal

The product must be disposed of properly by disposal facilities. The product must be decontaminated by sterilization for this purpose

- Dispose of the product in accordance with local government regulations.
- Dispose of the packaging in accordance with local government regulations.

10. Application Support

If needed, you can request the corresponding documents with further technical data, information on how to perform product integrity tests, or specific information about additional applications from your local Sartorius contact person.

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