

16254

Directions for Use
Stainless Steel In-Line Filter Holder



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The major applications for stainless steel in-line filter holder 16254 are particulate removal from or sterilization of gases – with PTFE membrane filters in place. They are also used for the clarification or sterilization of liquids; and in-line sampling for routine quality control. In liquid filtration, the valve in the top part of the holder allows the holder to be vented, and in air or gas filtration, it permits occasional run-off of condensed water. The stainless steel nipples for 10 mm tubing that are part of the standard equipment supplied can be exchanged for connectors with a G 3/4" threaded nut, a G 3/8" male thread or a G 3/8" threaded nut (see "Recommended Accessories").

1. Specifications

Material:	AISI 316 stainless steel (German standard: 1.4401)
O-rings:	Silicone (standard); EPDM, Fluoroe-lastomer and PTFE optionally available (CFR 21, 177.2600)
Connectors on the holder:	Inlet and outlet: M 12 x 1 female thread
Fittings supplied with the holder:	Inlet and outlet: stainless steel nipples for 10 mm hose (spare part no. 6980801). Other matching connectors are listed under "Accessories."

Appropriate filter diameter:	
Membrane filter:	47 mm
Prefilter:	40 mm
Filtration area:	13 cm²
Weight:	490 g
Max. operating pressure:	2,000 kPa (20 bar)
Sterilization:	Autoclave up to 134 °C – 30 min. Sterilize with dry heat up to 180 °C – 2 1/2 hours

2. Unpacking the Filter Holder and Equipment Supplied

Remove the filter holder from the box and check the list below to make sure you have all parts available:

Equipment supplied	Shown in Fig. 1 as
2 Hose nipples	No. 1
1 Vent valve	No. 2
1 Locking ring	No. 3
1 Top part of holder	No. 4
1 Back pressure screen, PTFE-coated	No. 5
1 Silicone O-ring	No. 6
1 Filter support screen, PTFE-coated	No. 7
1 Underdrain screen, PTFE-coated	No. 8
1 Base of filter holder	No. 9

3. Cleaning and Care of the Filter Holder

To ensure a long in-service life and proper functioning, it is necessary to clean the filter holder prior to initial use and after every filtration run.

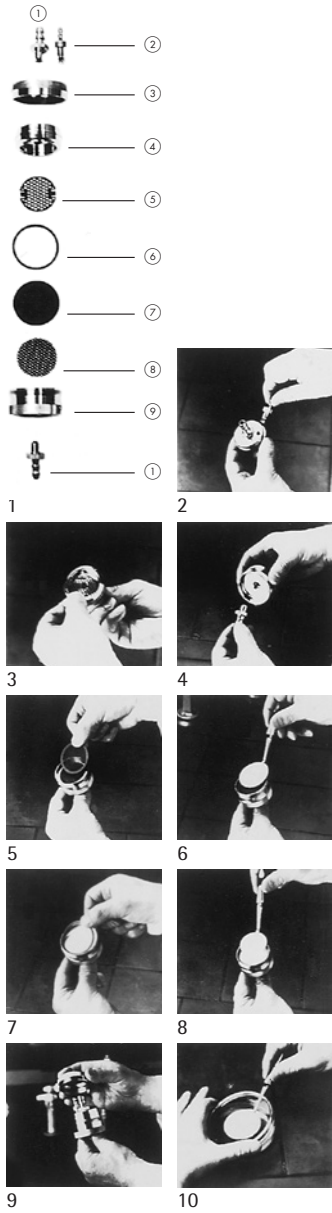
Proceed as follows:

- 3.1 Completely disassemble the filter holder as indicated in the list of the parts supplied.
- 3.2 Use soft brushes, warm water, and a gentle, commercially available laboratory detergent (for metal, glass and plastic) to clean all parts.
- 3.3 Rinse all parts with hot water and then with distilled water.
- 3.4 Dry the parts with compressed air or let them drip-dry. Please do not use cloth or towels to dry because they may leave lint on the filter holder.

4. How to Assemble the Filter Holder and Insert a Membrane Filter

- 4.1 Screw one hose nipple and the vent valve onto the top part of the filter holder. (Fig. 2). Tighten the hose nipple using an open-end wrench (17–19 mm).
- 4.2 Invert the top part of the filter holder and insert the back pressure screen so that the tabs point downwards and are engaged in the recesses. Fasten the back pressure screen by turning it approx. 2 cm to the right so that the tabs are lowered (Fig. 3).
- 4.3 Screw the other hose nipple onto the base of the filter holder, and tighten it using an open-end wrench (Fig. 4).
- 4.4 Now install the underdrain screen and the support screen in the base of the filter holder. First place the underdrain screen with the smoother surface face-up in the recess provided in the base, and then position the filter support screen on top of the underdrain screen. (Fig. 5)
- 4.5 Remove a membrane filter from the tray and moisten it with distilled water, if necessary, (see note in step 5.1) and center it on the support screen. (Fig. 6)

- 4.6 Place the silicone O-ring on the membrane filter. (Fig. 7). If you need to use a prefilter, center it on the top of the membrane filter (within the silicone O-ring). (Fig. 8). The diameter of the prefilter may not be larger than 40 mm. Make sure that the prefilter is not positioned underneath the silicone O-ring, otherwise leakage may occur.
- 4.7 Position the top part of the holder on the base with the membrane filter and silicone O-ring (including the prefilter, if required) in place and assemble both parts by tightening the locking ring. (Fig. 9)



5. Sterilization of the Filter Holder

5.1 Assemble the filter holder and insert a membrane filter as described in section 4.

Important Note:

Wet cellulose nitrate filters before placing them in wet filter holders; place dry cellulose nitrate filters in dry filter holders. Always make it a point to wet cellulose acetate and nylon (Sartolon) filters before placing them in a filter holder. PTFE filters must be dry when they are installed in a filter holder.

5.2 Open the valve (half a turn) and wrap the filter holder in aluminum foil or kraft paper.

Note:

Steam must be able to permeate the fittings and the valve!

5.3 Autoclave the filter holder at 121 °C and 1 bar for 30 minutes (this is possible with all appropriate Sartorius membrane filters). After sterilizing and allowing for the filter holder to cool off, close the valve.

5.4 Steam sterilize the filter holder inline. In the process, keep the valve slightly open, otherwise steam will not be able to penetrate the membrane filter (condensed water blocks the passage of steam). Cellulose acetate membranes 111.. and PTFE filters 118.. (including glass fiber filters 134..) can be alternatively sterilized in a filter holder with dry heat at 180 °C for 2 ½ hours or at 160° C for 3 hours (do not wet the filters before placing them in the filter holders). It is also possible to sterilize them with ETO (ethylene oxide).

6. IntegrityTesting

The integrity and the proper working condition of a ready-to-use filtration system are checked by the bubble point test. The bubble point is the pressure in bar (or psi) that is required to force air through a completely wetted membrane filter. The characteristic bubble points given in the catalog for Sartorius membrane filters apply to water (except for PTFE filters – they are wetted with isopropanol). For liquids with a different surface tension, please allow for variations in the bubble points listed. The GMP guidelines recommend that you perform an integrity test before and after sterile filtration.

Procedure:

6.1 To perform a bubble point test, it is necessary to connect a tube attached to the filter holder inlet to a pressure source and to attach tubing to the filter holder outlet. Immerse the other end of the tubing in about 1 cm of alcohol or water.

6.2 After the membrane filter is completely wetted, increase the pressure to 70–80% of the expected minimum bubble point (e.g., for 0.2 µm membrane filters of the type 11107–2.5 bar or 36 psi). Maintain this pressure for 2–5 minutes.

Afterwards, increase the pressure every 5 seconds by approx. 0.1 bar (1.45 psi) and observe the end of the tubing immersed in water or alcohol. Individual bubbles that exit from the tubing originate in the system and are not significant for determining the bubble point. The bubble point is not attained until continuous bubbling occurs. This value must be equivalent to the bubble point specified for the type of filter you are using.

Note:
Depending on the type of filter material, the bubble point may be somewhat lower or higher after the filter in the holder has been autoclaved or sterilized with dry heat.

7. Filtration of Liquids

7.1 Assemble the filter holder and insert the membrane filter as described in section 4.

7.2 To perform a sterile filtration run, sterilize the filter holder as described in section 5.

7.3 To integrity test the holder and membrane filter, follow the directions given in section 6.

7.4 You can install the filter holder inline in plumbing, integrate it into a machine or use it in conjunction with a pressure tank. Please make sure that the side with the vent valve is used as the filter holder inlet.

7.5 At the beginning of filtration, open the valve on the top part of the filter holder to vent it. As soon as liquid exits, close the valve again. Slightly tilting the filter holder (valve uppermost) aids venting.

7.6 Upon completion of the filtration run, shut off the pressure supply line and repeat the integrity test, if necessary, as described in section 6. Afterwards, clean the filter holder as directed in section 3.

Note:
It is recommended to work at a relatively low pressure (0.5–1.0 bar = 7.3–14.5 psi) in order to increase the overall volume of the liquid that can be recovered by filtration. In any case, the operating pressure should be below the bubble point of the filter used in order to avoid air passage upon completion of the filtration run.

8. Air and Gas Filtration with Hydrophobic PTFE Membrane Filters
For particulate removal from and sterile filtration of gases, the upstream valve (inlet side of the filter holder) is used for occasional run-off of condensed water. Therefore, it is practical to install the filter holder vertically and upside-down (valve on the bottom).

9. Microbiological Testing

9.1 For microbiological testing, sterilize the filter holder and perform a filtration run (under sterile conditions) as described in sections 5 and 6.

9.2 Upon completion of the filtration run, remove the membrane filter from the filter holder and incubate it under sterile conditions in liquid culture medium, on agar or on a Sartorius Nutrient Pad. (Fig. 10)

10. Recommended Accessories

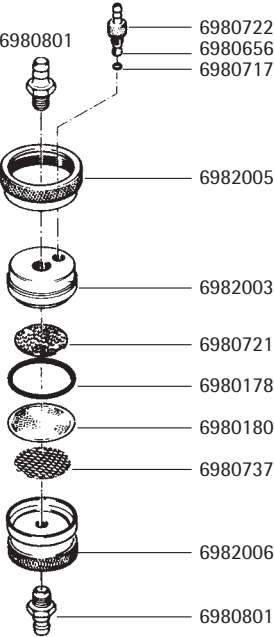
- O-rings of other materials:
- | | |
|---------|---------------------------------|
| 179 | Fluoroelastomer O-ring, 42×3 mm |
| 17038 | PTFE O-ring, 42×3 mm |
| 6982083 | EPDM O-ring, 42×3 mm |
| 6985183 | Silicone O-ring, 3×1.5 mm |
| 6985184 | EPDM O-ring, 3×1.5 mm |
- Connectors:
- | | |
|-------|---|
| 17068 | M 12×1 male thread G ¾" threaded nut for direct connection to a water tap with a G ¾" male thread |
| 17069 | M 12×1 male thread G ⅝" threaded nut |
| 17089 | M 12×1 male thread G ⅝" male thread |

- Pressure hoses and connectors:
- | | |
|-------|---|
| 16999 | PTFE pressure hose, 1.5 m G ⅝" threaded nut on each end |
| 16803 | Connector, G ⅝" male thread G ¼" threaded out |

- Pumps:
- | | |
|-------|---|
| 16617 | Pressure pump, diaphragm type, G ⅝" male thread, 220 V, 50 Hz |
| 16662 | Pressure pump, diaphragm type, G ⅝" male thread, 110 V, 60 Hz |
| 16650 | Peristaltic pump, 220 V, 50 Hz |
| 16655 | Peristaltic pump, 110 V, 60 Hz |
| 16651 | Silicone tubing, 6×2 mm, (2 m) |

- Other accessories:
- | | |
|-------|--|
| 17530 | Stainless steel pressure tank, 5 l, G ⅝" male thread |
| 16625 | Stainless steel forceps for membrane filters |

11. Spare Parts
- | | |
|---------|---------------------------------------|
| 6982003 | Top part of filter holder |
| 6982006 | Base of filter holder |
| 6980178 | Silicone O-ring, 42×3 mm |
| 6980801 | Stainless steel nipple for 10 mm hose |
| 6980721 | Back pressure screen, PTFE-coated |
| 6980180 | Filter support screen, PTFE-coated |
| 6980737 | Underdrain screen, PTFE-coated |
| 6980722 | Vent valve |
| 6980656 | PTFE disc (for vent valve) |
| 6980717 | Fluoroelastomer O-ring 3×1.5 mm |
| 6982005 | Locking ring |



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