Pharmsteri™ PES Disposable Filters

Installation and use manual

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1. INTRODUCTION

Please follow the instructions when using Pharmsteri™ disposable filters. It is very important to strictly operate according to this manual. It is proposed that the instructions in this manual are included in users' standard operation manual. If any step is not applicable in actual operation, please contact Entegris.

Entegris assumes no responsibility if any harm or loss occurs due to operations without following this manual.

1.1 MATERIALS OF CONSTRUCTION

Pharmsteri PES disposable filters are designed to provide smart, disposable, safe filtration for pharmaceutical applications. Constructed of polypropylene (PP) components and a hydrophilic polyethersulfone (PES) membrane, these disposable filters can help eliminate cleaning problems and extra validation costs.

COMPONENT	MATERIAL
Membrane	Polyethersulfone (PES)
Support	Polypropylene (PP)
Core, cage, caps	Polypropylene (PP)
O-rings	Silicone

1.2 NET CONTENT AND PRODUCT WEIGHT

Each 10" filter is double pouched with a Certificate of Qualty (COQ) in an inner box, then put into an outer carton before delivery.

Disposable filter length	Standard package	Volume	Weight, KG
5"	16 pieces/ carton	1026 × 401 × 241 mm	10.4 kg (23 lb)
10"	8 pieces/ carton	1026 × 401 × 241 mm	11.4 kg (25 lb)

Note: Two pieces of 5" disposable filters are double pouched separately then put into one inner box.

2. ACCEPTANCE

Please check product's specifications and product number after receiving. Besides product number, each product has its own tracking number as shown in Figure 1.

The tracking number can be found on the cage body.

Annotation for tracking number

G	Year	Month	SAP lot number
G: Hangzhou	1: 2021 2: 2022 3: 2023 4: 2024 5: 2025 6: 2026 7: 2027 8: 2028 9: 2029	A: January B: February C: March D: April E: May H: June J: July K: August M: September N: October P: November S: December	Last 6 numbers of the lot

Example: *Lot number G2A471270 was manufactured at Entegris Hangzhou China in January 2022, under work order ending in 471270.*

Figure 1. Annotation for lot number.

3. STORAGE

1. Store the filters in a cool dry area away from the sun, rain, or heat.
2. To keep disposable filters in good condition, do not store them with toxic, corrosive, volatile, or smelly materials.
3. Handle filters gently during shipment and unpack only when ready to use.

4. INSTALLATION

Disposable filters may be used for aseptic filtration if you follow the Flushing and Wetting, Integrity Test, and Sterilization procedures on pages 4, 5, and 6 respectively.

4.1 STRUCTURE SPECIFICATION

A disposable filter is usually composed of an inner core, a shell, an inlet, an outlet, an exhaust, and a drain. Refer to the schematic diagram for your product specifics.

4.2 INSTALLATION PROCEDURE

Please follow these steps when installing the filters:

1. Prior to installation, ensure the disposable filter and the accessories (if any) are intact.
2. The installation location of disposable filters should be a sufficient distance from other equipment and walls to ensure adequate space for proper filter installation and replacement.
3. Make sure the pipeline can connect the matching interface with the disposable filter.
4. Place the disposable filter with quick-opening interface in the desired location then place the sealing gasket on the quick-opening interface and carefully install the filter into the piping system.

   IMPORTANT! During installation, make sure the sealing gasket is placed correctly and the fluid flow through the disposable filter is in the direction indicated by the arrow on the housing.

5. It is recommended to install pressure gauges in the piping system upstream and downstream of the filter so operation can be determined by the pressure drop of the filter.

4.3 INSTRUCTIONS FOR USE

1. Open the disposable filter vent valve.
2. Open the inlet valve slightly so the liquid can slowly influx the housing; close the exhaust valve until the liquids overflow from the exhaust valve at the top of the housing.
3. Slowly open the outlet valve until fully open.
4. Slowly open the inlet valve, gradually increase the flow rate or pressure to the expected value to avoid excessive flow. Do not exceed the maximum operating pressure specified in the product specifications. If there is no leakage, begin filtering.

⚠ **WARNING: improper use may cause leakage, shell rupture, and other dangerous events. A system designer with sufficient knowledge and experience is required to determine the appropriate selection of components and must pay attention to the following:**

1. **Maximum forward differential pressure for liquids: 3.5 bar @ 25° (77°F), 3.0 bar @ 60° (140°F).**
2. **Filtering fluids: chemical compatibility between the filtering fluids and the disposable filter shell, core, filter media, and seal should be determined before filtration. Filtering incompatible fluids is not recommended.**
3. **Operational environment: do not use disposable filters in corrosive environments. Do not press, vibrate, or shock the disposable filter while using.**

ATTENTION: to protect the disposable filter and ensure filtration performance and workability of maintenance inspection, please observe the following precautions:

1. Installation space

   Before installation, ensure there is enough space for installing, replacing, and maintaining the disposable filters, and place all valves and fittings in a convenient place for operation and maintenance.

2. Remove foreign bodies in the distribution tubes

   Before first use, fully blow or clean the distribution tubes to ensure normal operation of the disposable filters.

3. Pipeline connection

   When connecting pipelines, piping should be fitted after the inlet/outlet of the disposable filter is confirmed. To avoid pipeline rupture and excessive differential pressure as well as inlet/outlet connection integrity, ensure pipelines and fittings meet the pressure resistance and diameter in accordance with the design requirements.

ATTENTION: to ensure the safety of operators as well as the filter system, please comply with the following:

1. Always use safety precautions during filter operation and maintenance. For example, a protective cover should be installed outside the disposable filter to prevent personal injury if the filter bursts under improper operating conditions.
2. During operation, pressure impacting shall be prevented and reverse pressure shall be prohibited.
3. Under pressure conditions, filter disconnection is prohibited. Fluids will spurt out under pressure and may cause harm.
4. Before any operation of the disposable filter including but not limited to installation, replacement and drainage, keep the device in a pressure-free state. All gas and liquid sources should be turned off and only turned on when needed for operations such as exhaust.
5. If the seal in the disposable filter is aged or damaged, please replace it with the same type of seal.
6. If any part of the disposable filter is deformed or damaged, stop using it immediately.

5. FLUSHING AND WETTING

5.1 PURPOSE

1. Flushing can fully wet a disposable filter more easily and the integrity test results will be more accurate with a fully wetted disposable filter.
2. Flushing can also clean disposable filters.

5.2 METHODS

5.2.1 Parameters for PES Disposable Filters

1. Prepare components: filter housing, pressure gauges, combined connectors, clean gas source, pump, tank, pipes, etc, Figure 2.
2. Set up a flushing and wetting system.
3. Close V1, V3, and the drain valve.
4. Open V2, V4, and the vent valve.
5. Turn on the pump and regulate V4.
6. Close the vent valve when the wetting fluid flows from the vent valve.
7. Start flushing and wetting.
8. Fully open V4, flush for 5 – 10 seconds.
9. Then adjust V4 until the pressure gauge shows the pressure is P1 = 3±0.2 bar.
10. Keep flushing for 10 to 15 minutes at the flow rate that is higher than 2 to 3 L/min per 5" filter, and 5 – 7 L/min per 10" filter..

    NOTE: Purified water or water for injection (WFI) is recommended to flush hydrophilic membrane disposable filters.

6. INTEGRITY TEST

6.1 OVERVIEW

Integrity tests should be performed when the disposable filter is designed to remove bacteria.

1. Perform integrity tests on the sterilized disposable filters following methods approved by pharmacopoeia or pharmaceutical production validation guidelines before sterilization, after sterilization, and after use.
2. The integrity test before sterilization verifies filter integrity, pore size, and installation.
3. The integrity test after sterilization can tell if the disposable filter is integral or not. The downstream of the filter should keep sterile in performing integrity test after sterilization.
4. The integrity test after use can tell if the disposable filter is damaged during operation.

Filter components are shown in Figure 2.

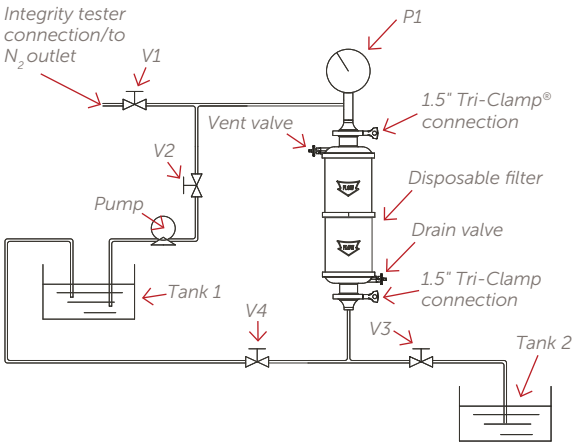

Figure 2. Flushing and wetting system.

6.2 BUBBLE POINT TEST

6.2.1 Using Automation Equipment

1. Turn off the pump.
2. Close V2 and V3. Open V4.
3. Connect equipment gas tube to N_2 outlet.
4. Open V1.
5. Conduct bubble point test with the full-automatic integrity tester.
6. Print the test results when the test is completed.
7. Opening the V3 and drain valves completely drains the water in the filter shell.

6.2.2 Using Manual Equipment

1. Turn off the pump. Close V2.
2. Connect equipment gas tube to N_2 outlet.
3. Regulate V1 and increase the pressure P1 evenly within 1.5 minutes to a set value.
4. The set value is 80% of standard bubble point pressure.
5. Close V4 and open V3.
6. Increase the pressure P1 at a rate of 1 bar/min until continuous bubbles appear in tank 2.
7. Now, P1 pressure is the real bubble point pressure. After measurement, close V1 and slowly open the vent valve.
8. Close the vent valve after the gas is exhausted.
9. End test with recording data.

A fully wetted filter is necessary. If the integrity test result does not meet the requirement, please rewet the filter according to instruction 5.2, and then repeat the integrity test.

1. Maintain the temperature at 23° – 25°C (73° – 77°F) during bubble point testing.
2. In the bubble point test, if P1 reaches 4 bar before bubbles continuously appear in tank 2, stop the test to prevent damaging the filter. And the bubble point test should be regarded as passed.
3. The bubble point test result may be lower if pressure increases too rapidly as gas flow will impact and damage liquid film on membrane.
4. It is not necessary to keep increasing pressure after bubbles continuously show in tank 2. Continuing to increase pressure may damage membrane or filter structure.
5. If lots of bubbles continuously show soon after pressurizing, two causes should be considered. First, the filter may not be fully wetted and not be sealed properly at the adapter. Rewetting and reinstalling after checking the seal material may help. Second, the filter's structure is damaged after use and the filter should be discarded.

7. STERILIZATION

Unless marked on the label, all Entegris disposable filters and membrane components are non-aseptic.

Filters can be autoclaved for 5 cycles for 30 minutes at 127° (261°F). They cannot be steam sterilized in-line.

7.1 AUTOCLAVE GUIDELINES

1. Vent

   Open filter vents and make sure that they remain open throughout the entire sterilization cycle. (The vents provide proper air displacement and condensate removal only when open and unobstructed.)

2. Inlet and Outlet Fitting

   Ensure that the filter inlet and outlet openings are open and unobstructed to allow maximum air displacement and steam flow. Ensure that all open

inlets and open outlets are covered with suitable barrier paper. Alternatively, place the filter in an autoclave bag. Any protection for inlet and outlet openings must ensure proper steam penetration and air displacement.

If you attached stainless steel parts, please separate the filters and stainless steel parts.

NOTE: The weight of unsupported attachments coupled with the loss of the fitting's rigidity at the autoclave temperatures can deform and damage the filter.

3. Tubing

   Ensure that any tubing attached to the filter is open and unobstructed to provide for adequate steam flow.

4. Orientation

   Place the filter into the autoclave as follows:

   The ideal filter orientation is in the upright or normal operating position (direction of flow) with the core (outlet) facing downward. If the filter is oriented horizontally or upside down, condensate accumulates in the core.

   NOTE: Ensure that the openings are covered with suitable barrier paper or place the entire filter in an autoclave bag.

   During autoclave sterilization, do not load the filters, which may deform and damage the filter.

8. REPLACEMENT

Pharmaceutical manufacturers should follow GMP requirements for replacing disposable filters.

Entegris recommends replacing a disposable filter once any of the following situation occurs:

1. The filter fails integrity test.
2. The differential pressure in normal operation is above 2 bar.
3. The flow rate cannot meet production requirements.
4. The disposable filter is beyond its verified lifetime.

9. DISPOSAL

Adhere to local regulations when disposing of used, disposable filters.

10. FIRST AID

1. Ingestion: These devices are not likely to be hazardous by ingestion. Consult a physician if necessary.
2. Eyes: Because of the size and solid nature of these devices they are not expected to present an eye injury hazard.
3. Inhalation: These devices do not present an inhalation hazard because of the non-volatile nature of the polymeric component materials.
4. Skin: These devices are not likely to be hazardous by skin contact but cleansing the skin is advisable.

11. HAZARD IDENTIFICATION

1. Appearance: Porous white membrane encased in a solid polymer (plastic) housing with silicon O-rings on end cap subassembly.
2. Health Hazard: Under normal operating temperature and pressure conditions, these devices do not present a health hazard.
3. Physical Hazard: Under normal operating temperature and pressure conditions, these devices do not present a physical hazard. If removed from its housing, the membrane and nonwoven fabric are considered a combustible solid.

12. WARNING

To reduce the risk associated with choking, do not allow children under three years of age to have access to small parts during the installation of this product.

13. WARRANTY AND CLAIMS

Entegris warrants that all products are manufactured in accordance with their specifications and quality standards. A certificate of quality will also be issued by quality upon lot release and attached to product package. Date of manufacture of all products is indicated on label and the shelf-life claim validated.

To ensure the capsule filter is not damaged during transportation, carefully check that the product packaging corrugated cartons are not damaged.

14. EPA INFORMATION

PRODUCED BY:

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EPA Est. No.: 97725-CHN-002

Hangzhou Anow Filtration and Materials Co., Ltd. is a subsidiary of Entegris, Inc.

15. SERVICES

Entegris provides a variety of technical services including filter selection, system design, process verification, and more. Contact us or visit our website www.entegris.com to learn more.

LIMITED WARRANTY

Entegris' products are subject to the Entegris, Inc. General Limited Warranty. To view and print this information, visit entegris.com and select the Legal & Trademark Notices link in the footer. Entegris does not warrant any failure in the case of customers using unapproved foreign components.

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