

# Porex<sup>®</sup> Capsule Filters

## Capsule Sterilization Guidelines

- If capsule is already gamma sterilized, do not autoclave or steam sterilize.
- Differences in filter configurations may affect sterilization process. The sterilization process needs to be validated by the end user.

## Autoclaving of Filter Capsules

- We recommend autoclave sterilization for a maximum of 20 cycles at 60 minutes per cycle at 125 °C.
- PES membrane filters must be flushed with water before autoclaving and should be autoclaved wet. Drain excess water before autoclaving.
- A wetted membrane filter will transmit steam slowly. To minimize risk of damage to the membrane, we recommend using a slow exhaust cycle and ensuring tubing clamps in the filter assembly are open.
- Ideally, sterilizing-grade hydrophobic vent filters should be included in the filter assembly on both sides of the filter. Alternatively, vent and drain valves should be opened.
- Autoclave wrap should be used to protect any open vents or valves. Autoclave wrap should be loose to permit air purging and steam penetration. Alternatively, filter assembly can be placed in a steam permeable autoclave bag or pouch.
- Vent and drain valves should be closed when the filter assembly has cooled to ambient temperature.

## Gamma Irradiation Guidelines

- Capsule can be gamma irradiated between the dosage of 27.5 kGy to 45.0 kGy.
- Capsule should be gamma irradiated only one time.

## Capsule Installation

- Capsule should be installed based on your capsule connector/fitting configuration.
- Capsule configurations with hose barbs should have connections between tubing and capsule secured using tightened cable ties or hose clamps.

## Filter Wetting Procedure

- Open the upstream vent valve to allow air inside the capsule to escape freely.
- Ensure outlet valve is closed. Fill the capsule with clean, filtered water at 15°-25 °C until it flows out from the vent valve; at which time the vent may be closed.
- Open outlet valve and rinse at a flow of 7.6-11.4 LPM per 10-inch capsule (or 12.2-20.3 LPM/m<sup>2</sup> of filter surface area) for 10-15 minutes.
- Below is table for recommended flush conditions:

Filter Size	Flush Volume (L)	Flow Rate (LPM)	Time (min)
10"	76 to 170	7.6 to 11.4	10 to 15
5"	34 to 86	3.4 to 5.7	10 to 15
Mini 2SFT	21 to 53	2.1 to 3.5	10 to 15
Mini 1SFT	12 to 29	1.2 to 1.9	10 to 15

## Integrity Testing

We recommend an integrity test before each process run to ensure the integrity and function of the filter capsules. Capsules and water must be at ambient temperature to perform the integrity test.

## Bubble Point Testing

- Wet capsule using filter wetting procedure.
- Open the outlet valve and using 3-4 psi/0.25 bar clean, oil and moisture-free, compressed air, apply pressure to the filter capsule housing in the direction of filtration flow for 1 minute. This will allow residual water to drain.
- Connect the capsule outlet to a tube extending into an open-top container partially filled with water, ensuring the tube end is held below the surface of the water.
- Slowly increase the inlet pressure while watching for air bubbles in the open top container.
- The bubble point is the pressure at which a surge of bubbles escapes from the tube in the open top container.
- The minimum bubble point values are listed below.

Table 1: Minimum bubble point values for filter capsules

Filter Cartridge	Minimum Bubble Point (psi/bar)
SRC (Double Layer 0.2/0.2um)	49/3.4
SCW (Double Layer 0.45/0.2um)	49/3.4
BHS (Single Layer 0.2um)	49/3.4
BTG (Single Layer 0.45um)	38/2.6
BRH (Single Layer 0.8um)	16/1.1

- In the event you are unable to reach the minimum bubble point as indicated in Table 1, repeat filter wetting procedure and bubble point test, as most bubble point failures are due to incomplete wetting of the filters.

## Diffusive Flow Test

- Wet capsules using filter wetting procedure.
- Open the outlet valve and using 3-4 psi/0.25 bar clean, oil and moisture-free, compressed air, apply pressure to the filter capsule housing in the direction of filtration flow for 1 minute. This will allow residual water to drain.
- Connect suitable air flow measuring device to the filter capsule outlet.
- Slowly increase pressure to the filter capsule up to the appropriate test pressure as listed in table 2.

- Upon reaching test pressure, wait 2 minutes for system to stabilize, ensuring pressure is maintained at the pressure listed in table 2.
- After 2 minutes, verify air diffusion flow rate (mL/min) for the system meets the acceptable limits as listed in Table 2.
- If the air diffusion flow exceeds the prescribed value, repeat wetting and test procedure. Most failures are due to incomplete wetting of the filters.
- If the air diffusion flow fails the second time, the filter capsule may be defective and should not be used.

Table 2: Maximum air diffusion rate for filter capsules

Filter Capsule	Size	Max Air Diffusion Rate
SRC (Double Layer 0.2/0.2um)	10" 5" Mini 2SFT Mini 1SFT	16 mL/min @ 40psig 7.15 mL/min @ 40psig 5.0 mL/min @ 40psig 2.8 mL/min @ 40psig
SCW (Double Layer 0.45/0.2um)	10" 5" Mini 2SFT Mini 1SFT	26 mL/min @ 40psig 11.6 mL/min @ 40psig 7.0 mL/min @ 40psig 4.0 mL/min @ 40psig
BHS (Single Layer 0.2um)	10" 5" Mini 2SFT Mini 1SFT	100 mL/min @ 40psig 45 mL/min @ 40psig 33 mL/min @ 40psig 18 mL/min @ 40psig
BTG (Single Layer 0.45um)	10" 5" Mini 2SFT Mini 1SFT	100 mL/min @ 30psig 45 mL/min @ 30psig 33 mL/min @ 30psig 18 mL/min @ 30psig



For technical information including performance guide, instructions for use, and certificate of quality, please visit our website.