



LIFE SCIENCES

# INSTRUCTIONS FOR USE

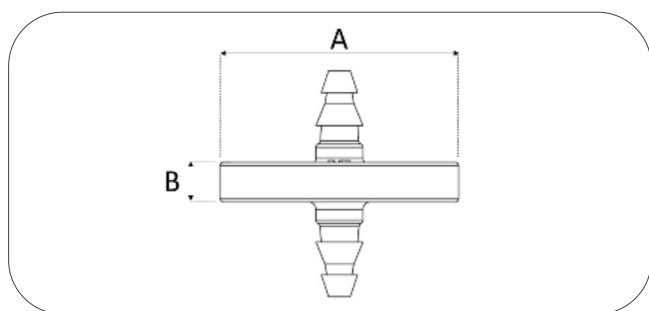
## PRODUCT

PureFlo® PE Disc Capsule Filters with part number prefix D13R, D25C, D40C, and G50A as defined in Datasheet Doc. #FLS5346-072021-BPS

## INTRODUCTION

The following document outlines the recommended procedures for use of the PureFlo® PE Disc Capsules including installation, operation, sterilization, wetting, and integrity testing.

## NOMINAL DIMENSIONS



	Outside Diameter [A]	Body Length Without Fittings [B]	Filtration Area
D13R	16 mm	3.7 mm	0.8 cm <sup>2</sup>
D25C	33 mm	5.45 mm	4.6 cm <sup>2</sup>
D40C	45.5 mm	8 mm	10.5 cm <sup>2</sup>
G50A	54 mm	8 mm	15.9 cm <sup>2</sup>

## OPERATING CONDITIONS

Maximum Temperature	55°C
Maximum Inlet Pressure (at 22°C)	D13, D25, D40: 2.1 bar (30 psi) G50: 4.1 bar (59.5 psi)
Maximum Forward Differential Pressure (at 22°C)	2.1 bar (30 psi)
Maximum Reverse Differential Pressure (at 22°C)	1 bar (14.5 psi)

## STERILIZATION

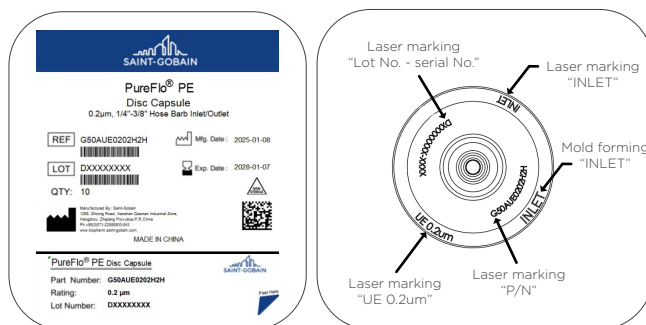
PureFlo® PE Disc Capsule filters may be gamma-irradiated up to 50 kGy.

**!** PureFlo® PE Disc Capsule filters should NOT be autoclaved or in-line steam sterilized.

## INSTALLATION

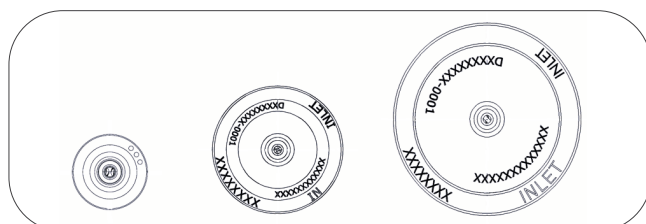
Upon receipt, the filter should be visually inspected to ensure that damage has not occurred during shipping and handling.

Before use, check that the correct filter is being installed by looking at the part number, membrane material, and micron size. This information can be found on the box, on the filter bag, as well as on the capsule itself. See examples below.



The inlet and outlet of the filter may be installed within a system via connection types that are compatible with the inlet and outlet fittings. When installing the capsule, orient it such that the direction of flow is from the inlet to the outlet of the filter.


The inlet fitting of the filter is on the side of the filter which has one of the following markings: "INLET", "IN", or three raised dots. Markings indicating the location of the inlet side of the filter.



# INTEGRITY TEST SPECIFICATION

The minimum bubble point specification of Saint-Gobain Life Sciences' PureFlo® PE filters which incorporate a sterilizing grade, 0.2 µm hydrophobic polyethylene (PE) membrane is outlined in the following table according to the type of wetting fluid used.

Wetting Fluid	Minimum Bubble Point Specification using air at 22 °C
60% isopropanol and 40% water	1.2 bar (17.4 psi)
70% isopropanol and 30% water	1.2 bar (17.4 psi)

 *Variability in wetting fluid concentration, temperature, and environmental conditions may impact the bubble point test results.*

## WETTING PROCEDURES

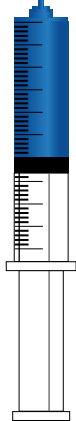
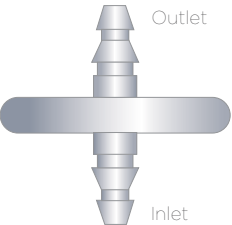
Complete wetting is essential to ensure accurate and repeatable integrity test results. There are many acceptable methods that can be used to ensure that a filter membrane is completely wetted, each one requiring that the chosen wetting fluid is compatible with, and capable of wetting (i.e. spontaneously filling the pores of) the filter membrane. The following procedures outline one such method that involves using a syringe filled with 60 - 70% isopropyl alcohol (IPA).


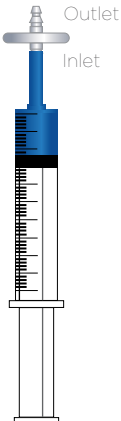
1. Fill the syringe with enough IPA to fill and flush the filter.

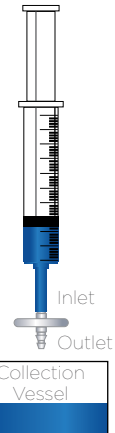
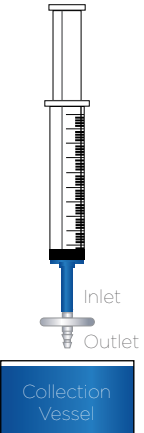
Filter Size	Recommended Min. Flush Volume
D13R	10 mL
D25C	20 mL
D40C	40 mL
G50A	70 mL

2. Orient the disc capsule such that the outlet is facing upwards.
3. Connect the syringe to the disc filter inlet via a compatible, leak-free connection. (Optional: Attach a piece of tubing to the outlet of the filter to direct the flow of liquid out of the filter capsule and into a collection vessel.)
4. Slowly press the plunger of the syringe inward to begin filling the inverted disc capsule with the 60 - 70% IPA solution until the inlet side of the disc is filled with liquid and the liquid begins flowing into the outlet of the filter.
5. Reorient the disc such that the outlet is facing down and into a collection vessel.
6. Continue to press the plunger of the syringe inward until the specified minimum flush volume has been reached.

## SUMMARY OF PUREFLO® PE DISC CAPSULE WETTING PROCEDURES

STEP 1	STEP 2
Fill the syringe	Orient the filter
	

STEP 3	STEP 4
Connect the syringe to the filter	Fill the filter
	

STEP 5	STEP 6
Direct flow into a collection vessel	Flush the filter
	

## INTEGRITY TEST PROCEDURES

1. Once the filter membrane has been thoroughly wetted, disconnect the inlet of the filter from the syringe.
2. Connect the inlet of the filter to an automated integrity tester via a compatible, leak-free connection.
3. Ensure the outlet of the filter is open and the flow path is free of obstruction.
4. Follow the instructions as outlined by the manufacturer of the automated integrity tester.

## POST-INTEGRITY TEST BLOW DOWN PROCEDURES

Saint-Gobain's PureFlo® PE Disc Capsules are provided dry and ready to use. If you decide to integrity test the filter prior to use, the membrane inside the filter capsule will be wet. To dry the filter, which is necessary to restore the air flow performance, the filter should be blown down with clean air or nitrogen using the following recommended procedures.

1. Connect a regulated pressurized gas source to the inlet of the filter.
2. With the inlet valve (V1) closed, slowly increase the pressure (P1) to 30 psi (2.1 bar).
3. Open V1 very slowly to allow the nitrogen or air to flow through the filter for a minimum of 30 minutes.
4. After 30 minutes, slowly close V1 to stop the flow of compressed air or nitrogen to the filter and depressurize the system.

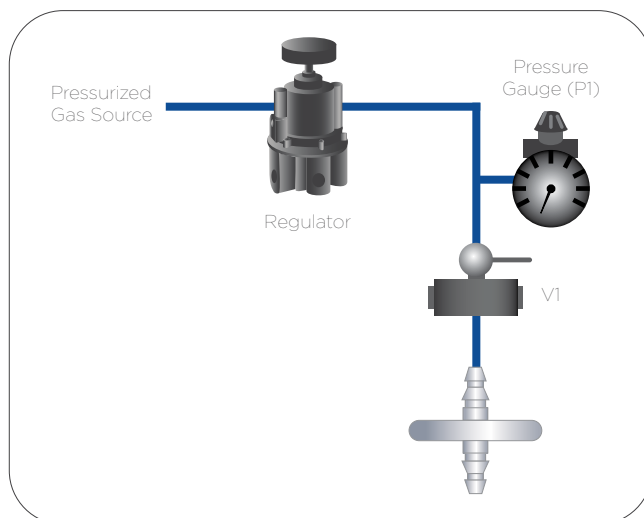


*All materials and equipment should be rated to meet the pressure requirements of the intended use.*

For more information, please contact technical support [ft-ae.request@saint-gobain.com](mailto:ft-ae.request@saint-gobain.com)

PureFlo® is a registered trademark of Saint-Gobain Life Sciences.

## EXAMPLE OF POST-INTEGRITY TEST BLOW DOWN APPARATUS



**IMPORTANT:** It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain Performance Plastics assumes no responsibility for any product failures that occur due to misuse of the materials it provides arising out of the design, fabrication, or application of the products into which the materials are incorporated.