

# Saint-Gobain Life Sciences – Bioprocess Solutions



# PureFlo® PTFE Capsules

PureFlo® PTFE capsules are easy-to-use filtration units, ideally suited for single-use applications in the pharmaceutical industry. The hydrophobic polytetrafluoroethylene (PTFE) membrane is chemically resistant and demonstrates exceptional thermal strength and flow performance in venting and compressed gas applications. The filter capsules are available in a complete spectrum of sizes to simplify scale-up throughout each stage of the drug development process.

#### **Superior Flow Performance**

PureFlo $^{\circ}$  PTFE capsules incorporate a sterilizing grade 0.2  $\mu$ m membrane that exhibits a lower pressure drop compared to other hydrophobic membranes such as PVDF. The superior flow performance results in a light-weight, compact filter designed to promote optimal process efficiency.

#### **Engineered Filtration Solutions**

To meet the needs of an innovative and rapidly growing industry, and in addition to the standard product offering, Saint-Gobain offers a collaborative service with a dedicated team of engineers and subject matter experts to develop specialized filtration solutions that are tailored to achieve optimal performance. Please contact us for more information.

#### Features / Benefits



Inherently Hydrophobic



Autoclavable



High Flow Rate



Animal-Derived Component Free





100% Integrity Tested

#### **Typical Applications**

- Bioreactor Vent
- Moisture Barrier
- Compressed Gas
- Fermentation Tank Vent
- Bottle or Carboy Vent
- Autoclave Vent



# **Technical Summary**

Materials	
Membrane	PTFE
Support Material	Polypropylene
Molded Components (cage, core, shell, end caps)	Polypropylene
O-rings (when present)	Silicone

Membrane Configurations						
Membrane	Membrane Description Minimum Bubble Point (at 22 °C)					
F020	0.2 μm	1.2 bar   17.4 psi (in 60% isopropyl alcohol, 40% water)				

Measurements (nominal)					
Size	Outside Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (cm²)		
Disc (D)	16 - 99	3.7 - 10	0.8 - 60		
Junior (JKP)	41	41	230		
Mini (MKP)	59	60	450		
Mid (SKV)	71.5	52 - 257	730 - 5200		
Full (L)	90	279 - 1007	7300 - 26000		

Vented Connections (when present)						
	Disc (D)	Junior (JKP)	Mini (MKP)	Mid (SKV)	Full (L)	
Category	Luer lock w/ cap	Luer lock w/ cap	Luer lock w/ cap	Bleed valve	Bleed valve	
Connection Type	Female Luer Lock	Female Luer Lock	Female Luer Lock	1/8" hose barb	1/4" hose barb	

Recommended Operating Conditions (for untreated/non-sterile product)						
	Disc (D)	Junior (JKP)	Mini (MKP)	Mid (SKV)	Full (L)	
Maximum Temperature	80 °C					
Maximum Inlet Pressure (at 22 °C)	5.5 bar   80 psi					
Maximum Forward Differential Pressure (at 22 °C)	4.1 bar   60 psi	5 bar   72.5 psi				
Maximum Reverse Differential Pressure (at 22 °C)	2.1 bar   30 psi	2.1 bar   30 psi	2.1 bar   30 psi	3 bar   43.5 psi	3 bar   43.5 psi	

Sterilization	
Autoclave	Disc: Up to 10 cycles at 125 °C for 30 minutes
	Junior, Mini, Mid, Full Size: Up to 20 cycles at 125 °C for 30 minutes
Ethylene Oxide	The materials of construction are generally regarded as compatible but testing is recommended.

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#### **Shelf Life**

Non-sterile products have a shelf life of 3 years after the date of manufacture.

## **Traceability**

For traceability and easy identification:

- A Certificate of Conformance is provided in each box.
- Each filter bag and box are labeled with the product part number, lot number, and identifying characteristics.
- Each Junior, Mini, Mid, and Full size capsule is engraved and labeled with the product part number, lot number, and identifying characteristics.
- Each 25 mm, 40 mm, 50 mm. 65 mm and 90 mm disc capsule is engraved with the product lot number and identifying characteristics.

## **Regulatory & Stewardship**

Saint-Gobain's PureFlo® PTFE Capsules were designed, manufactured, and qualified with an ISO 13485 certified Quality Management System. For more information, please refer to the product <u>Validation Guide and Regulatory Information Overview (RIO)</u>.

Category	Standard or Reference Test
Cleanliness	USP <85> Bacterial Endotoxin Test
Biocompatibility	USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5
Food Contact	USP 21 CFR 177 FDA Indirect Food Additive
Bacterial Retention	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> Brevundimonas diminuta per ASTM methodology
Animal-derived Components	No animal-derived material is intentionally added or used during the manufacture of PureFlo® PTFE Capsules.
RoHS	Restriction of Hazardous Substances (RoHS 3) Directive 2015/863
REACH	REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Article 57, Regulation No. 1907/2006)

#### Lot Release Criteria

Each PureFlo® PTFE Disc, Junior, Mini, Mid and Full Size Capsules product lot is sampled and tested for conformity to the following criteria:

Criteria	Description
Integrity (membrane)	Each filter (100%) in a lot is integrity tested during the manufacturing process.
Integrity (housing)	A representative sample of the lot is tested to meet published burst pressure values.
USP Bacterial Endotoxins	A representative sample from the lot is tested to confirm that an aqueous extraction of the product contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.

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# PureFlo® PTFE **Disc Capsules**

Saint-Gobain Life Sciences -**Bioprocess Solutions** 



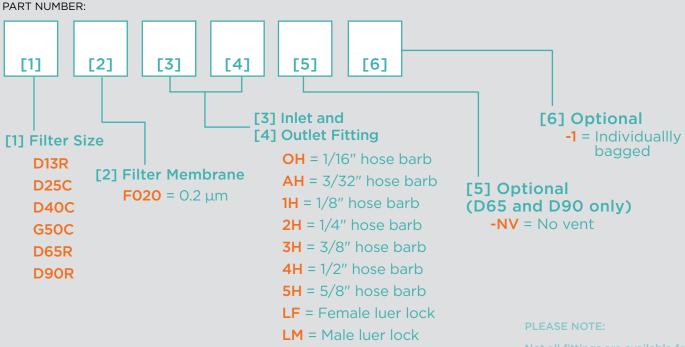
PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

Size	Body Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (cm²)	Typical Flow Performance* (22 °C, vent condition)
D13R	16	3.7	0.8	D13RF0201H1H - 5.7 psid at 1 L/min
D25C	33	5.45	4.6	D25CF0201H1H - 5.6 psid at 5 L/min
D40C	45.5	8	10.5	D40CF0202H2H - 2.4 psid at 5 L/min
G50C	54	8	15.9	G50CF0201H1H - 5.8 psid at 10 L/min
D65R	72	10	26	D65RF0202H2H - 1.5 psid at 10 L/min
D90R	99	10	60	D90RF0202H2H - 1.6 psid at 20 L/min

1 bar =14.5038 psi

## **Ordering Guide**







#### **Customer Service**

50 W. Watkins Mill Rd. Gaithersburg, MD 20878 Tel: (301) 407-2720 Fax: (240) 566-5774 Email: info.ft@saint-gobain.com

www.biopharm.saint-gobain.com

Don't see what you're looking for? Please let us know! We're here to help.

MT = 1/2" tri-clamp

TC = 11/2" tri-clamp

#### \* IMPORTANT:

The flow performance of a filter capsule is dependent on several variables including the process fluid characteristics, operating conditions, filter surface area, pore size and fittings. The above values are approximate for example part numbers and provided for reference only. Actual values may vary. For application guidance and flow performance information for a specific part number please contact your local Saint-Gobain representative.

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sizes. Please refer to the next page of

the brochure for a standard list of fitting

# **PureFlo® PTFE Series Disc Capsule Ordering Guide continued)**

Table A. Inlet and outlet fitting option availability							
Inlet/Outlet Fitting	Description	D13R	D25C	D40C	G50C	D65R	D90R
ОН	1/16" hose barb	•	^	^			
AH	3/32" hose barb	•	^				
1H	1/8" hose barb	•	•	^	•	•	
2H	1/4" hose barb		^	^	^	^	•
3H	3/8" hose barb		^	^		^	•
4H	1/2" hose barb					•	•
5H	5/8" hose barb					•	•
LF	Female luer lock	•	•	•	•	•	•
LM	Male luer lock	•	•	•	•	•	•
MT	1/2" tri-clamp						•
TC	1 1/2" tri-clamp						

ble B. Vent fitting availability (located near inlet of capsules when present)					
D13R	D13R D25C D40C G50C D65R				
				•	•

<sup>• =</sup> fitting is available (if it is a hose barb, it is straight)



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<sup>^ =</sup> fitting is available (if it is a hose barb, it is stepped or tapered)



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# For registered access to Saint-Gobain Product Validation Summaries, <u>CLICK HERE</u>

IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Life Sciences products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain Life Sciences 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.

WARRANTY: For a period of 12 months from the date of first sale, Saint-Gobain Life Sciences warrants this product to be free of defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price there of.

SAINT-GOBAIN LIFE SCIENCES DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.



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