

#### Saint-Gobain Life Sciences – Bioprocess Solutions



# PureFlo® PTFE Cartridges

PureFlo® PTFE cartridges are validated sterilizing grade air filters with a robust design capable of withstanding multiple steam-in-place cycles. The hydrophobic, polytetrafluoroethylene (PTFE) membrane demonstrates exceptional flow performance in compressed air and venting applications in the biopharmaceutical industry.

#### **Membrane Configurations**

PureFlo® PTFE capsules incorporate a final sterilizing grade 0.2 µm membrane.

#### **Engineered Filtration Solutions**

To meet the needs of an innovative and rapidly growing industry, and in addition to the standard product offering, Saint-Gobain Life Sciences 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 Hydrophibic



100% Integrity Tested



Optimal Flow



Autoclavable



Steam Sterilizable



Broad Chemical Compatibility

#### **Typical Applications**

- Bioreactor Vent
- Moisture Barrier
- Compressed Gas
- Fermentation Tank Vent
- Autoclavable Vent



#### **Technical Summary**

| Materials                                       |                                |
|---|--------------------------------|
| Membrane  | Polytetrafluoroethylene (PTFE) |
| Support Material                                | Polypropylene (PP)             |
| Molded Components (cage, core, shell, end caps) | Polypropylene (PP)             |
| O-rings   | Silicone                       |
| Adapter Insert (when present)                   | Stainless Steel (overmolded)   |

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

| Measurements (nominal) |                       |                       |
|------------------------|-----------------------|-----------------------|
| Size                   | Outside Diameter (mm) | Filtration Area (cm²) |
| Mini (MM)              | 56                    | 730 - 2600            |
| Full (M)               | 70                    | 3650 - 26000          |

| Operating Conditions                            |                    |                  |  |
|---|--------------------|------------------|--|
|   | Mid (MM)           | Full (MC)        |  |
| Maximum Temperature                             | 80°C               | 80°C             |  |
| Maximum Forward Differential Pressure (at 22°C) | 4.1 bar   59.5 psi | 5 bar   72.5 psi |  |

| Sterilization        |  |  |
|----------------------|--|--|
| Steam-in-Place (SIP) | Mini (MM): Up to 10 cycles at 135°C for 30 minutes |  |
|                      | Full (MC): Up to 50 cycles at 135°C for 30 minutes |  |
| A. the electe        | Mini (MM): Up to 25 cycles at 135°C for 30 minutes |  |
| Autoclave            | Full (MC): Up to 50 cycles at 135°C for 30 minutes |  |
| Ethylene Oxide       | Testing is recommended                             |  |

#### **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 cartridge is engraved and labeled with the product part number, lot number, and identifying characteristics.

#### **Regulatory & Stewardship**

Saint-Gobain Life Sciences' PureFlo® PTFE Cartridges were designed, manufactured, and qualified with an ISO 13485 certified Quality Management System. For more information, please refer to the Product Validation Guide and Regulatory Information Overview (RIO).

| Category  | Standard or Reference Test                             |
|---|--|
| Cleanliness   | USP <85> Bacterial Endotoxin Test                      |
| Clediliness   | 21 CFR sections 211.72 and 210.3 (b) (6)               |
| Diagonamatikility   | ASTM F756-17 Hemolysis                                 |
| Biocompatibility  | USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5 |
| Bacterial Retention Quantitative Retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> Brevundimonas Diminuta per ASTM methodology |  |

#### Lot Release Criteria

Each PureFlo® PTFE cartridge 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.  |
| 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. |

FLS-5365A-10212024-BPS ©2024 Saint-Gobain Life Sciences

## PureFlo® PTFE **Mini Cartridges**

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

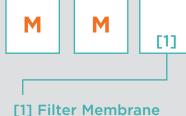


PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information).

| Filter<br>Size | Diameter<br>(mm) | Filtration Area<br>(cm²) | Typical Flow Performance in Air (22 °C)* |
|----------------|------------------|--------------------------|--|
| 1.5"           | 56               | 730                      | MMF020AH3P - 1.4 psid at 200 L/min       |
| 2.5"           | 56               | 1,400                    | MMF020AS3P - 0.65 psid at 200 L/min      |
| 5"             | 56               | 2,600                    | MMF020AL2P - 0.33 psid at 200 L/min      |

#### **Ordering Guide**





 $F020 = 0.2 \mu m$ 

[5] **[21 [31 [41** 

[3] Length

H = 1.5''

S = 2.5''

L = 5''

#### **[21 End Modification**

0 = 2-222 O-rings, Flat

6 = 2-226 O-rings, Flat

A = 116 Inner O-ring

B = 1.5" Tri-clamp, Flat

**E** = 118 O-rings

F = Flange (compatible with Pall Sealkleen<sup>™</sup> housing)

M = 123 O-rings with Tabs

S = 116 Inner O-ring with **Locking Groove** 

#### [5] Optional

**-5** = Stainless Steel Insert for steamin-place (0 and 6 adaptors only)

#### [4] Package Quantity

2P = 2 pcs/pack(5" only)

3P = 3 pcs/pack(1.5" and 2.5" only)



#### **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.

\*IMPORTANT: The flow performance of a filter 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 Life Sciences representative.

## PureFlo® PTFE Full Size

Saint-Gobain Life Sciences – Bioprocess Solutions



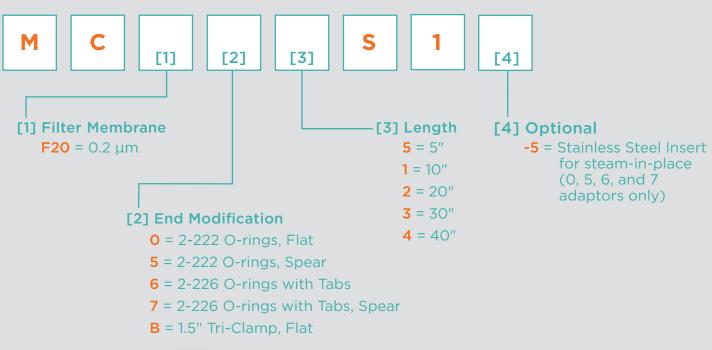
PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information).

| Filter<br>Size | Body Diameter<br>(mm) | Filtration Area<br>(m²) |  |
|----------------|-----------------------|-------------------------|--|
| 5"             | 70                    | 0.365                   |  |
| 10"            | 70                    | 0.73                    |  |
| 20"            | 70                    | 1.5                     |  |
| 30"            | 70                    | 1.9                     |  |
| 40"            | 70                    | 2.6                     |  |

Typical pressure drop in air (22 °C) at 200 LPM is approximately 0.12 psid per 10" cartridge with code 7 adapter\*

#### **Ordering Guide**

PART NUMBER:





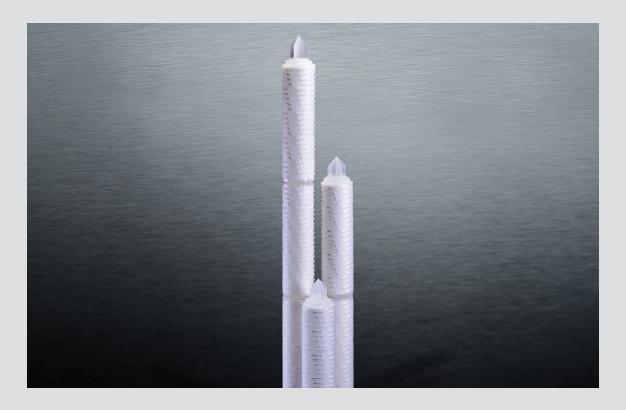
#### **Customer Service**

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.

\*IMPORTANT: The flow performance of a filter 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 Life Sciences representative.



PureFlo® is a registered trademark of Saint-Gobain Performance Plastics

Uncontrolled Document - for the controlled version of this document please visit <a href="https://www.biopharm.saint-gobain.com">www.biopharm.saint-gobain.com</a>

<u>Contact us today for:</u> <u>Consultations • Samples • Quotes • Orders</u>

### 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 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.

WARRANTY: For a period of 12 months from the date of first sale, Saint-Gobain Performance Plastics 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 PERFORMANCE PLASTICS DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.



#### **Customer Service**

50 West 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