

## Saint-Gobain Life Sciences – Bioprocess Solutions



# PureFlo® PE Capsules

PureFlo® PE capsules are gamma-irradiatable, easy-to-use filtration units, ideally suited for integration into single-use sterile assemblies. The hydrophobic polyethylene (PE) membrane demonstrates exceptional flow performance in venting and compressed gas applications.

#### **Superior Flow Performance**

PureFlo $^{\circ}$  PE 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 Hydrophibic



Gamma-Irradiatable



High Flow Rate



EMA/410/01 Rev. 3 Compliant



Sterilizing Grade



100% Integrity Tested

#### **Typical Applications**

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



## **Technical Summary**

Materials		
Membrane	Polyethylene (PE)	
Support Material	Polyethylene (PE)	
Molded Components (shell)	Polyethylene (PE)	
O-rings (when present)	Silicone	

Membrane Configurations			
Membrane	ne Description Minimum Bubble Point (at 22 °C)		
UE020	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)	
Junior (JKP)	41	4.1	130	
Mini (MKP)	59	60	400	
Mid (SKV)	71.5	52 - 257	550 - 3800	
Full (L)	90	279 - 1007	5300 - 21000	

Recommended Operating Conditions (for untreated/non-sterile product)			
Maximum Temperature	60 °C		
Maximum Inlet Pressure (at 22 °C)	4.1 bar   59.5 psi		
Maximum Forward Differential Pressure (at 22 °C)	5 bar   72.5 psi		
Maximum Reverse Differential Pressure (at 22 °C)	2.1 bar   30.45 psi		

Sterilization		
Gamma	Up to 50 kGy	
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 Junior, Mini, Mid, and Full size capsule is engraved and labeled with the product part number, lot number, and identifying characteristics.

## **Regulatory & Stewardship**

Saint-Gobain's PureFlo® PE Junior, Mini, Mid and Full Size Capsules 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	
Biocompatibility	USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5 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	EMA/410/01 Rev. 3	
RoHS	HS Restriction of Hazardous Substances (RoHS 3) Directive 2015/863	
REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Article 5 Regulation No. 1907/2006)		

### Lot Release Criteria

Each PureFlo® PE 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® PE Mini Capsules

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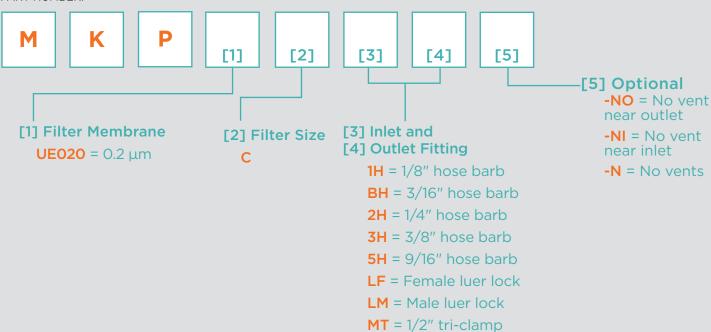
**PRODUCT TECH SNAPSHOT:** (Values are nominal. Please see Technical Summary for additional information)

Size	Body Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (cm²)	Typical Flow Performance*
С	59	60	400	MKPUE020C3H3H -0.1 psid at 7 LPM

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.

\* 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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## 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.

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#### **Customer Service**

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