

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 μ 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	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	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> (USP Class VI Plastics) Biological Reactivity Tests, In Vivo USP 21 CFR 177 FDA Indirect Food Additive
Bacterial Retention	Quantitative retention of 10 ⁷ CFU/cm ² Brevundimonas diminuta per ASTM methodology
Animal-derived Components	EMA/410/01 Rev. 3
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® 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
OSP Dacterial Endotoxins	contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.

FLS5349-082021-BPS ©2021 Saint-Gobain Life Sciences

PureFlo® PE Junior Capsules

Saint-Gobain Life Sciences -Bioprocess Solutions



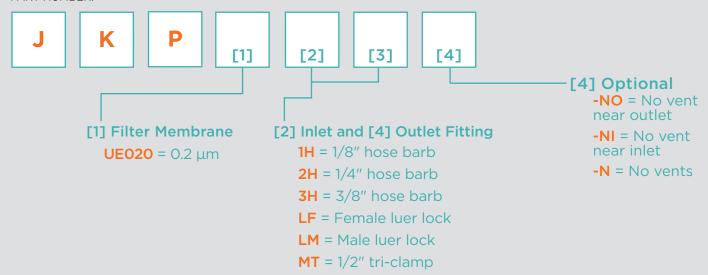
PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

Body	Body Length	Filtration	Typical Flow Performance*
Diameter	Without Fittings	Area	
(mm)	(mm)	(cm²)	

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.

PureFlo® PE Mini Capsules

Saint-Gobain Life Sciences -Bioprocess Solutions



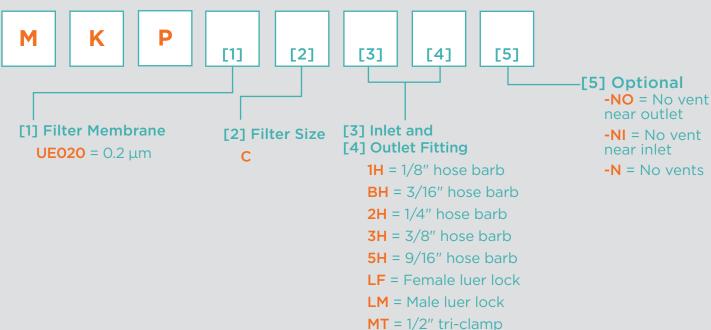
PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

Size	Body Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (cm²)	Typical Flow Performance*
	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

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

PureFlo® PE Mini Capsules

Saint-Gobain Life Sciences -Bioprocess Solutions



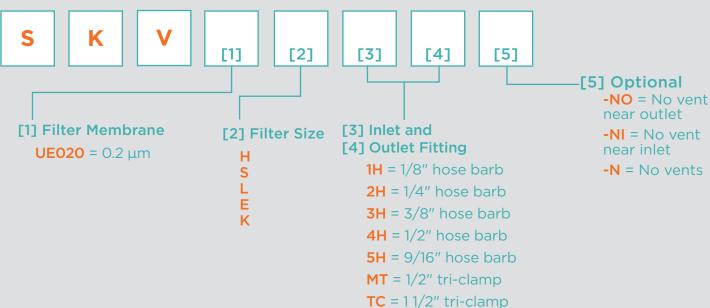
PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

Size	Body Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (cm²)
Н	71.5	56	550
S	71.5	84	990
L	71.5	141	1900
E	71.5	206	2900
K	71.5	260	3800

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.

PureFlo® PE ZenCap® Full Size Capsules

Saint-Gobain Life Sciences -Bioprocess Solutions

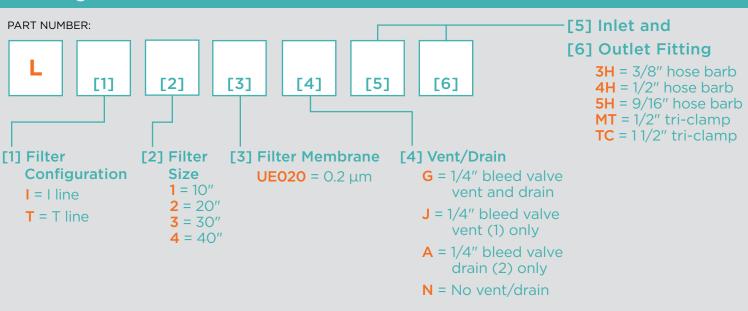


PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

Size	Body Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (m²)
1	90	279	0.53
2	90	522	1.1
3	90	765	1.6
4	90	1007	2.1

1 bar =14.5038 psi

Ordering Guide



(1) For I-line capsules, this is the valve closest to the inlet. For T-line capsules, this is the valve at the 'top' of the capsule and farthest from the inlet, outlet fittings.

(2) For T-line capsules, this is the valve closest to the outlet. For T-line capsules this is the valve closest to the inlet/outlet fittings and is at the 'bottom' of the capsule)



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.



PureFlo®, ZenCap®, and ZenFlo® are registered trademarks of Saint-Gobain Life Sciences

Uncontrolled Document - for the controlled version of this document please visit www.biopharm.saint-gobain.com

<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 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.



Customer Service

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