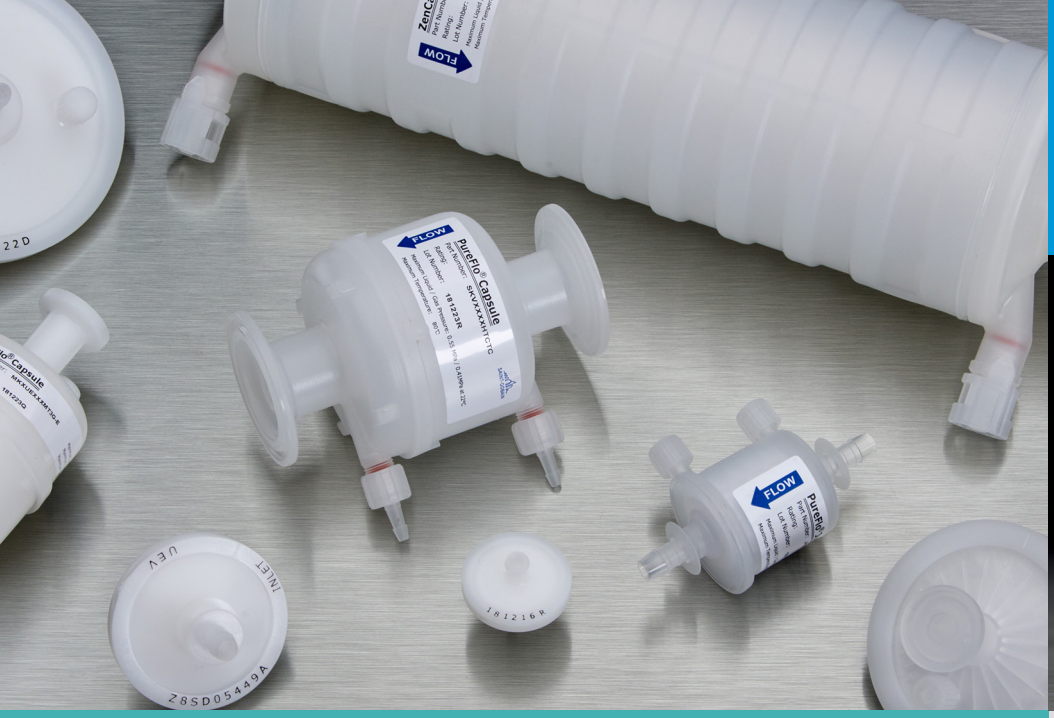
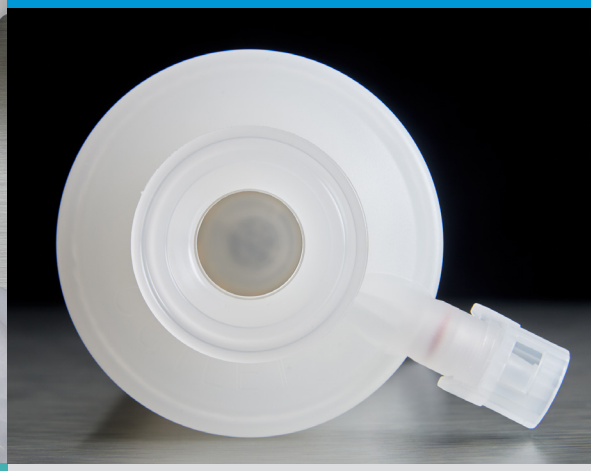


Saint-Gobain
Life Sciences –
Bioprocess Solutions



PureFlo® Z Series PES
Capsules

PureFlo® Z Series PES capsules are gamma-irradiatable, easy-to-use filtration units, ideally suited for integration into single-use sterile assemblies. The hydrophilic, asymmetric polyethersulfone (PES) membrane demonstrates exceptional throughput capacity and flow performance in liquid applications. The materials and design were carefully selected to ensure quick and reliable pre- and post-use integrity testing in critical biopharmaceutical applications. The filter capsules are available in a complete spectrum of sizes to simplify scale-up throughout each stage of the drug development process.

Membrane Configurations

PureFlo® Z Series PES capsules incorporate a final sterilizing grade 0.1 or 0.2 µm membrane as well as an optional built-in ZenFlo® highly asymmetric prefilter tailored to enhance filter performance and efficiency in a variety of biopharmaceutical processes.

Connectivity

Saint-Gobain offers the broadest portfolio of standard and custom filter inlet and outlet fittings, simplifying system design by reducing the number of unnecessary connections thereby decreasing the associated risk and cost of adapters. Please refer to the Ordering Information section for a complete list of standard fittings that are available.

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

- Hydrophilic
- Gamma-Irradiatable
- Optimal Flow
- Autoclavable
- Asymmetric
- Broad Chemical Compatibility
- Scalable
- Animal-Derived Component Free

Typical Applications

- Buffer
- Cell Culture Media
- Serum
- Opthalmics
- Reagents
- Biologics
- Final Drug Product

SAINT-GOBAIN

Technical Summary

Materials	
Membrane	Polyethersulfone (PES)
Support Material	Polyester (PET)
Molded Components (cage, core, shell, end caps)	Polypropylene (PP) and Nylon*
O-rings (when present)	Silicone

*Except disc filters. Disc filters have polypropylene molded components only.

Membrane Configurations

Membrane	Description	Minimum Bubble Point (at 22 °C)
S010	0.1 µm	1.6 bar | 23 psi (in 60% isopropyl alcohol, 40% water)
S020	0.2 µm	3.5 bar | 50 psi (in water)
ZS010	0.1 µm PES membrane with built-in 0.2 µm ZenFlo PES prefilter	1.6 bar | 23 psi (in 60% isopropyl alcohol, 40% water)
ZS020	0.2 µm PES membrane with built-in 0.45 µm ZenFlo PES prefilter	3.5 bar | 50 psi (in water)
XS010	0.1 µm PES membrane with built-in 0.45 µm ZenFlo PES prefilter	1.6 bar | 23 psi (in 60% isopropyl alcohol, 40% water)
XS020	0.2 µm PES membrane with built-in 0.65 µm ZenFlo PES prefilter	3.5 bar | 50 psi (in water)

Measurements (nominal)

Size	Outside Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (cm^2)	
			Single Layer (S)	ZenFlo (ZS/XS)
Disc (D)	16 - 97	3.7 - 10	0.8 - 60	0.8 - 60
Junior (JZP)	41	41	260	170
Mini (MZP)	59	60	390 - 530	360 - 500
Mid (SZV/SZL)	71.5	52 - 257	730 - 5100	650 - 4500
Full (LZ)	90	279 - 1007	6400 - 27000	5700 - 23000

Vent Connections (when present)

	Disc (D)	Junior (JZP)	Mini (MZP)	Mid (SZV)	Full (LZ)
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

Operating Conditions (for untreated/non-sterile product)

	Disc (D)	Junior (JZP)	Mini (MZP)	Mid (SZV)	Full (LZ)
Maximum Temperature	80 °C	80 °C	80 °C	80 °C	80 °C
Maximum Inlet Pressure (at 22 °C)	3.1 bar | 45 psi	5.5 bar | 78 psi	5.5 bar | 78 psi	5.5 bar | 78 psi	5.5 bar | 78 psi
Maximum Forward Differential Pressure (at 22 °C)	3.1 bar | 45 psi	5 bar | 72.5 psi	5 bar | 72.5 psi	5 bar | 72.5 psi	5 bar | 72.5 psi

Sterilization

Gamma	Up to 50 kGy
Autoclave	Up to 10 cycles at 125 °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 with each capsule.
- 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, 65 mm, and 90 mm disc capsule is engraved with the product lot number

Regulatory & Stewardship

Saint-Gobains' PureFlo® Z Series 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
Physiochemical	USP Oxidizable Substances USP <645> Conductivity USP <643> Non-Volatile Residue Total Organic Carbon (TOC) Analysis
Cleanliness	USP <85> Bacterial Endotoxin Test USP <788> Particulate Matter 21 CFR sections 211.72 and 210.3 (b) (6)
Biocompatibility	ASTM F756-17 Hemolysis USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5
Sterility	Pre-sterilized products have a sterility assurance level (SAL) of 10^{-6} in accordance with ANSI/AAMI/ISO 11137 for fluid path only.
Food Contact	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	No animal-derived material is intentionally added or used during the manufacture of PureFlo® Z Series PES Capsules.
RoHS	Restriction of Hazardous Substances (RoHS 3) Directive 2015/863

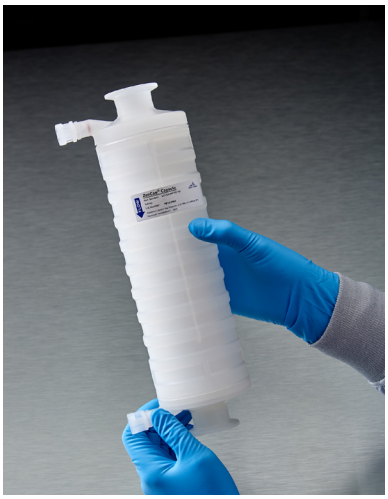
Lot Release Criteria

Each PureFlo® Z Series PES capsule 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 to meet published integrity test values.
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.

PureFlo® Z Series PES
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)	I-line Body Length Without Fittings (mm)	Filtration Area (m^2)		Typical Flow Performance*
			Single Layer (S)	ZenFlo (ZS/XS)	
1	90	279	0.64	0.57	LZI1S020GTCTC - 2 psid at 20 LPM
2	90	522	1.4	1.2	LZI2S020GTCTC - 1 psid at 20 LPM
3	90	765	2.0	1.7	LZI3S020GTCTC - 0.5 psid at 20 LPM
4	90	1007	2.7	2.3	LZI4S020GTCTC - 0.25 psid at 20 LPM

1 bar = 14.5038 psi

Ordering Guide

PART NUMBER:

L	Z	[1]	[2]	[3]	[4]	[5]	[6]

[1] Filter Config.
I = I-line
T = T-line

[2] Filter Size
1 = 10″
2 = 20″
3 = 30″
4 = 40″

[3] Filter Membrane
S010 = 0.1 µm (single-layer)
S020 = 0.2 µm (single-layer)
ZS010 = ZenFlo® 0.2/0.1 µm
ZS020 = ZenFlo® 0.45/0.2 µm
XS010 = ZenFlo® 0.45/0.1 µm
XS020 = ZenFlo® 0.65/0.2 µm

[4] Vent/Drain
G = 1/4″ bleed valve vent and drain
J = 1/4″ bleed valve vent (1) only
A = 1/4″ bleed valve drain (2) only

[5] Inlet and [6] Outlet Fitting
3H = 3/8″ hose barb
4H = 1/2″ hose barb
5H = 9/16″ hose barb
MT = 1/2″ tri-clamp
TC = 1 1/2″ tri-clamp

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

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

SAINT-GOBAIN

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

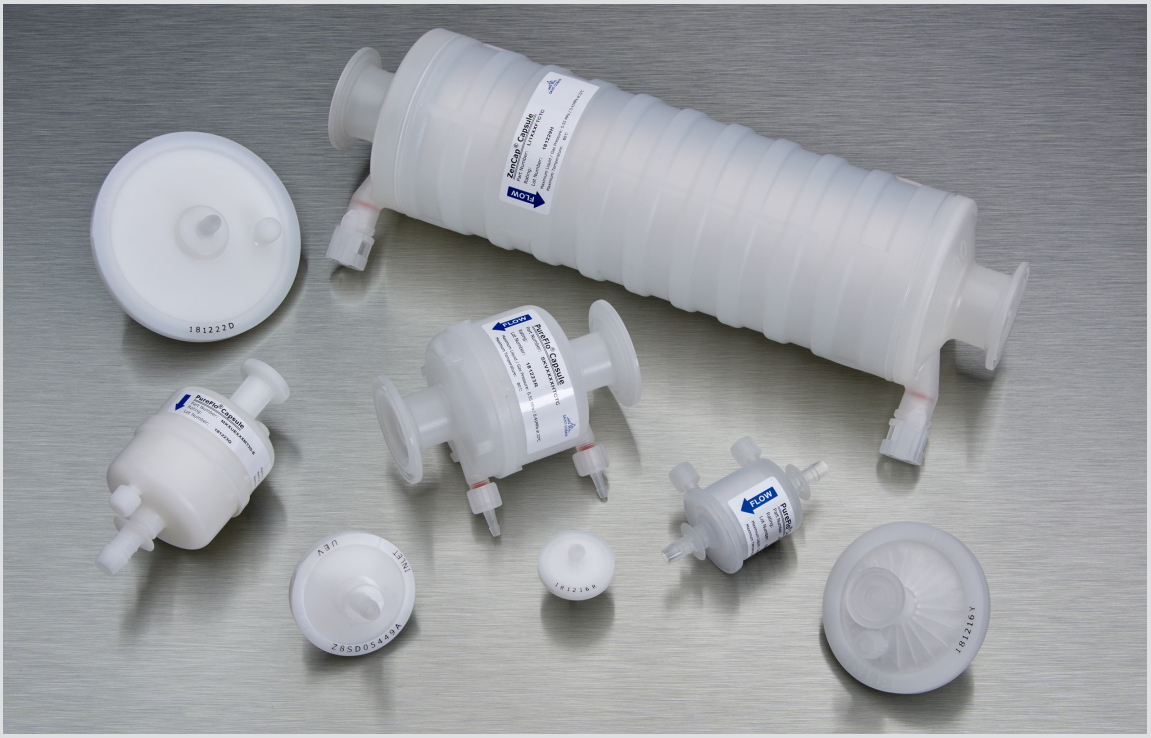
www.biopharm.saint-gobain.com

* 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.

FLS5328C-1104024-BPS

PureFlo® Z Series PES
Capsules

Saint-Gobain
Life Sciences –
Bioprocess Solutions



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

Contact us today for:
Consultations • Samples • Quotes • Orders

For registered access to Saint-Gobain Product Validation Summaries, CLICK HERE

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.

SAINT-GOBAIN

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

FLS5328C-1104024-BPS