

#### 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 $^{\circ}$  Z Series PES capsules incorporate a final sterilizing grade 0.1 or 0.2  $\mu$ m membrane as well as an optional built-in ZenFlo $^{\circ}$  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. <u>Please contact us for more information</u>.

#### 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



### **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

<sup>\*</sup>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 $\mu m$ PES membrane with built-in 0.2 $\mu m$ ZenFlo PES prefilter	1.6 bar   23 psi (in 60% isopropyl alcohol, 40% water)			
ZS020	0.2 $\mu$ m PES membrane with built-in 0.45 $\mu$ m ZenFlo PES prefilter	3.5 bar   50 psi (in water)			
XS010	0.1 $\mu m$ PES membrane with built-in 0.45 $\mu m$ 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)					
Outside Diameter	Body Length Without Fittings	Filtration Area (cm²)			
(mm)	(mm)	Single Layer (S)	ZenFlo (ZS/XS)		
16 - 97	3.7 - 10	0.8 - 60	0.8 - 60		
41	41	260	170		
59	60	390 - 530	360 - 500		
71.5	52 - 257	730 - 5100	650 - 4500		
90	279 - 1007	6400 - 27000	5700 - 23000		
	Outside Diameter (mm)  16 - 97  41  59  71.5	Outside Diameter (mm)         Body Length Without Fittings (mm)           16 - 97         3.7 - 10           41         41           59         60           71.5         52 - 257	Outside Diameter (mm)         Body Length Without Fittings (mm)         Filtration Area (cm²)           16 - 97         3.7 - 10         0.8 - 60           41         41         260           59         60         390 - 530           71.5         52 - 257         730 - 5100		

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				
Maximum Inlet Pressure (at 22 °C)	3.1 bar   45 psi	5.5 bar   78 psi			
Maximum Forward Differential Pressure (at 22 °C)	3.1 bar   45 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.

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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 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
	USP Oxidizable Substances
Dhysiochemical	USP <645> Conductivity
Physiochemical	USP <643> Non-Volatile Residue
	Total Organic Carbon (TOC) Analysis
	USP <85> Bacterial Endotoxin Test
Cleanliness	USP <788> Particulate Matter
	21 CFR sections 211.72 and 210.3 (b) (6)
Dia a a mana a bila iliba a	ASTM F756-17 Hemolysis
Biocompatibility	USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5
Chaullin.	Pre-sterilized products have a sterility assurance level (SAL) of 10 <sup>-6</sup> in accordance with ANSI/AAMI/
Sterility	ISO 11137 for fluid path only.
Food Contact	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 No animal-derived material is intentionally added or used during the manufacture of	
Components 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.

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## PureFlo® Z Series PES Mini Capsules

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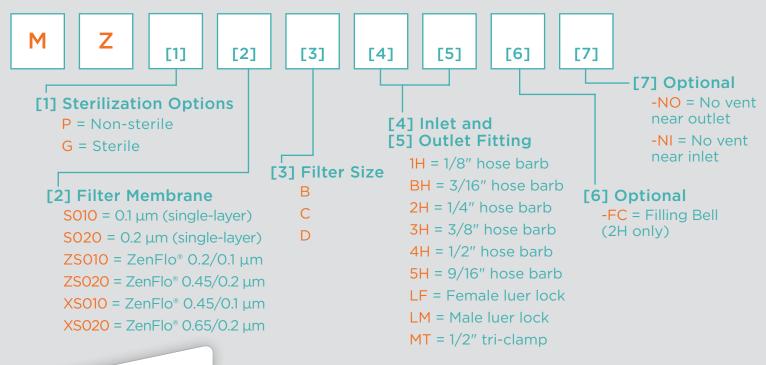
PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

	Body	Body Length	Filtration Area (cm²)		– Typical Flow
Size	Diameter (mm)	Without Fittings (mm)	Single Layer (S)	ZenFlo (ZS/XS)	Performance*
В	59	60	390	360	MZPS020B2H2H - 11 psid at 3 LPM
С	59	60	440	420	MZPS020C2H2H - 9 psid at 3 LPM
D	59	60	530	500	MZPS020D2H2H - 7 psid at 3 LPM

1 bar = 14.5038 psi

#### **Ordering Guide**

PART NUMBER:





#### **Customer Service**

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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.

## PureFlo® Z Series PES Capsules

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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.



#### **Customer Service**

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