

Saint-Gobain Life Sciences – Bioprocess Solutions



PureFlo® Z Series PES Cartridges

PureFlo® Z Series PES cartridges are validated sterilizing grade filters with a robust design capable of withstanding multiple steam-in-place cycles. 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.

Membrane Configurations

PureFlo $^{\circ}$ Z Series PES capsules incorporate a final sterilizing grade 0.1 or 0.2 μ 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.

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



Hydrophilic



100% Integrity Tested



Optimal Flow



Autoclavable



Asymmetric



Broad Chemical Compatibility



Scalable



Steam Sterilizable

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	Silicone
Adapter Insert (when present)	Stainless Steel (overmolded)

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	$0.2~\mu m$ PES membrane with built-in $0.45~\mu m$ 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)	Filtration Area (cm²)	Filtration Area (cm²)		
		Single Layer (S)	ZenFlo (ZS/XS)		
Mini (MMZ)	56	730 - 2,600	650 - 2,300		
Full (MZ)	70	6,400 - 27,000	5,700 - 23,000		

Operating Conditions				
	Mid (SZV)	Full (LZ)		
Maximum Temperature	80°C	80°C		
Maximum Forward Differential Pressure (at 22°C)	3.1 bar 45 psi	5 bar 72.5 psi		

Sterilization	Sterilization			
Steam-in-Place (SIP)	Up to 10 cycles at 135°C for 30 minutes (filters with stainless steel inserts only)			
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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Regulatory & Stewardship

Saint-Gobain Life Sciences' PureFlo® Z Series 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	
	USP Oxidizable Substances	
Physiochemical	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)	
Diagonaratibility	ASTM F756-17 Hemolysis	
Biocompatibility	USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5	
Bacterial Retention	Quantitative Retention of 10 ⁷ CFU/cm ² Brevundimonas Diminuta per ASTM methodology	
Shelf Life	Non-sterile products have a shelf life of 3 years after the date of manufacture.	
	For traceability and easy identification:	
	 A Certificate of Conformance is provided with each cartridge. 	
Tracoability	• Each filter bag and box are labeled with the product part number, lot number, and identifying	
Traceability	characteristics.	
	• Each cartridge is engraved and labeled with the product part number, lot number, and	
	identifying characteristics.	

Lot Release Criteria

Each PureFlo® Z Series PES 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.	

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PureFlo® Z Series PES **Mini Cartridges**

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

Filter Size	Diameter (mm)	Filtration Area (cm²)	Filtration Area (cm²)	Typical Flow Performance*
		Single Layer (S)	ZenFlo® (ZS/XS)	
1.5"	56	730	650	MMZS020AH3P - 5.8 psid at 5 L/min
2.5"	56	1,400	1,200	MMZSO2OAS3P - 5.3 psid at 10 L/min
5"	56	2,600	2,300	MMZS020AL2P - 2.7 psid at 10 L/min

Ordering Guide

PART NUMBER:























[3] Length H = 1.5''

S = 2.5''

L = 5''





[1] Filter Membrane

 $S010 = 0.1 \, \mu m (single-layer)$

 $S020 = 0.2 \mu m (single-layer)$

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

[2] End Modification

0 = 2-222 O-rings, Flat

6 = 2-226 O-rings, Flat

A = 116 Inner O-ring

E = 118 O-rings

M = 123 O-rings with Tabs

S = 116 Inner O-ring with Locking Groove

T = 126 O-rings with Tabs

[5] Optional

-5 = Stainless Steel Insert for steam-inplace (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® Z Series PES **Full Size Cartidges**

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



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

Filter Size	Body Diameter (mm)	Filtration Area (m²)	Filtration Area (m²)
		Single Layer (S)	ZenFlo® (ZS/XS)
5"	70	0.32	0.29
10"	70	0.64	0.57
20"	70	1.28	1.14
30"	70	1.92	1.71
40"	70	2.56	2.28

Typical pressure drop in water (22 °C) at 20 LPM is approximately 2 psid per 10" cartridge*

Ordering Guide

PART NUMBER:

[4] Optional **[11] [21 [31 [41** -5 = Stainless Steel Insert [2] End Modification 0 = 2-222 O-rings, Flat [1] Filter Membrane $S10 = 0.1 \mu m (single-layer)$ **5** = 2-222 O-rings, Spear $S20 = 0.2 \mu m (single-layer)$ **6** = 2-226 O-rings with Tabs

7 = 2-226 O-rings with Tabs, Spear **ZS10** = ZenFlo 0.2/0.1 μm **ZS20** = ZenFlo $0.45/0.2 \mu m$ F = DOE, Flat gasket

 $XS10 = ZenFlo 0.45/0.1 \mu m$

[3] Length **5** = 5" **1** = 10" **2** = 20" **3** = 30"

4 = 40"

for steam-in-place (0, 5, 6, and 7

adaptors only)

 $XS20 = ZenFlo 0.65/0.2 \mu m$

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PureFlo® Z Series PES Cartidges

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PureFlo® is a registered trademark of Saint-Gobain Life Sciences

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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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