

Saint-Gobain Life Sciences – Bioprocess Solutions



# PureFlo® Z Series PES Prefiltration Capsules

PureFlo® Z Series PES Prefiltration Capsules are economical, easy-to-use filtration units, designed for effective bioburden and particulate removal in a broad range of applications. The hydrophilic, asymmetric polyethersulfone (PES) membrane demonstrates exceptional throughput capacity and flow performance in aqueous and viscous solutions. The filter capsules are available in a complete spectrum of sizes to simplify scale-up throughout each stage of the development process.

#### **Membrane Configurations**

PureFlo<sup>®</sup> Z Series PES Prefiltration Capsules incorporate a 0.45 or 0.65 μm membrane as well as an optional built-in ZenFlo<sup>®</sup> 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



#### **Typical Applications**

- Buffer
- Cell Culture Media
- Serum
- Opthalmics
- Reagents
- Biologics



## **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, in water)				
S045	0.45 μm	2.4 bar   35 psi				
S065	0.65 μm	1.6 bar   23 psi				
ZS045	0.45 $\mu m$ PES membrane with built-in 0.65 $\mu m$ ZenFlo PES prefilter	2.4 bar   35 psi				

Measurements (nominal)							
Size	Outside Diameter	Body Length Without Fittings	Filtration Area (cm²)				
5120	(mm)	(mm)	Single Layer (S)	ZenFlo (ZS)			
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)	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						
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.

## 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<sup>®</sup> 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
Dhysiashamisal	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)
	ASTM F756-17 Hemolysis
Biocompatibility	USP <88> (USP Class VI Plastics) Biological Reactivity Tests, In Vivo
	USP <87> / ISO 10993-5, In Vitro Cytotoxicity
Food Contact	21 CFR 177 FDA Indirect Food Additive
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
REACH	REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Article 57,
	Regulation No. 1907/2006)

### 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.
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** Disc Prefiltration Capsules

Filter Size

D13Z

D25Z

D40Z

D50Z

D65Z

D90Z

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**Filtration Area** 

(cm<sup>2</sup>)

0.8

4.6

10.5

15.9

26

60

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

(mm)

3.7

5.45

8

8

10

10

Body Length Without Fittings

**Body Diameter** 

(mm)

16

33

45.5

54

72

99



## Ordering Guide

PART NUMBER: Ζ D **[21 [51** [6] [1] **[31 [4]** [5] Optional -FC = Filling Bell [3] Inlet and [4] Outlet Fitting (2H or 3H only) [1] Filter Size [2] Filter Membrane OH = 1/16'' hose barb  $SO45 = 0.45 \mu m$  (single-layer) 13 -[6] Optional AH = 3/32'' hose barb -1 = Individually  $SO65 = 0.65 \mu m$  (single-layer) 25 1H = 1/8'' hose barb bagged **ZSO45** = ZenFlo<sup>®</sup> 0.65/0.45 μm 40 2H = 1/4'' hose barb 50 3H = 3/8'' hose barb 65 4H = 1/2'' hose barb 90 5H = 5/8'' hose barb LF = Female luer lock LM = Male luer lock LS = Male luer slip MT = 1/2'' tri-clamp TC = 11/2'' tri-clamp **PLEASE NOTE:** Not all fittings are available for all filter sizes. Please refer to SAINT-GOBAIN the next page of the brochure for a standard list of fitting **Customer Service** available for each filter size. 50 W. Watkins Mill Rd. Gaithersburg, MD 20878 Tel: (301) 407-2720 Fax: (240) 566-5774 Email: info.ft@saint-gobain.com

## PureFlo<sup>®</sup> Z Series Disc Capsule Ordering Guide (continued)

#### Table A. Inlet and outlet fitting option availability

Inlet/Outlet Fitting	Description	D13Z	D25Z	D40Z	D50Z	D65Z	D90Z
ОН	1/16" hose barb	•	^	^			
АН	3/32" hose barb	•	^				
1H	1/8" hose barb	•	^	^	•	•	
2H	1/4" hose barb		^	^	^	^	^
2H-FC	1/4" hoe barb with filling bell (outlet only)	4" hoe barb with filling bell (outlet only)				•	
3H	3/8" hose barb		^	^		^	^
3H-FC	3/8" hose barb with filling bell (outlet only)						•
4H	1/2" hose barb					•	•
5H	5/8″ hose barb						•
LF	Female luer lock	•	•	•	•	•	•
LM	Male luer lock	•	•	•	•	•	•
LS	Male luer slip	•	•	•	•		
MT	1/2" tri-clamp					•	•
TC	11/2" tri-clamp						•

Table B. Vent fitting availability (located near inlet of capsules when present)								
D13Z	D25Z	D40Z	D50Z	D65Z	D90Z			
				•	•			

• = fitting is available (if it is a hose barb, it is straight)

^ = fitting is available (if it is a hose barb, it is stepped or tapered)



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

## PureFlo<sup>®</sup> Z Series PES Junior Prefiltration Capsules

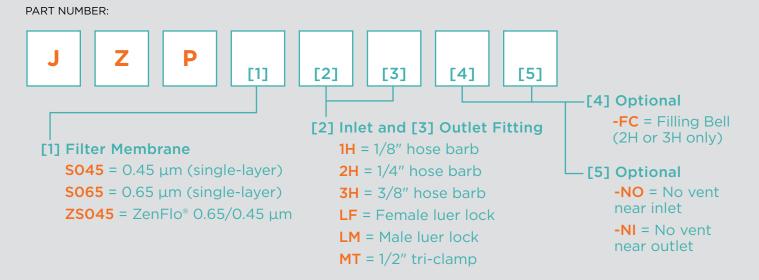
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PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

Body Diameter (mm)	Body Length	Filtration Area (cm <sup>2</sup>	Filtration Area (cm²)		
	Without Fittings (mm)	Single Layer (S)	ZenFlo (ZS)		
41	41	260	170		

## **Ordering Guide**





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## PureFlo<sup>®</sup> Z Series PES Mini Prefiltration Capsules

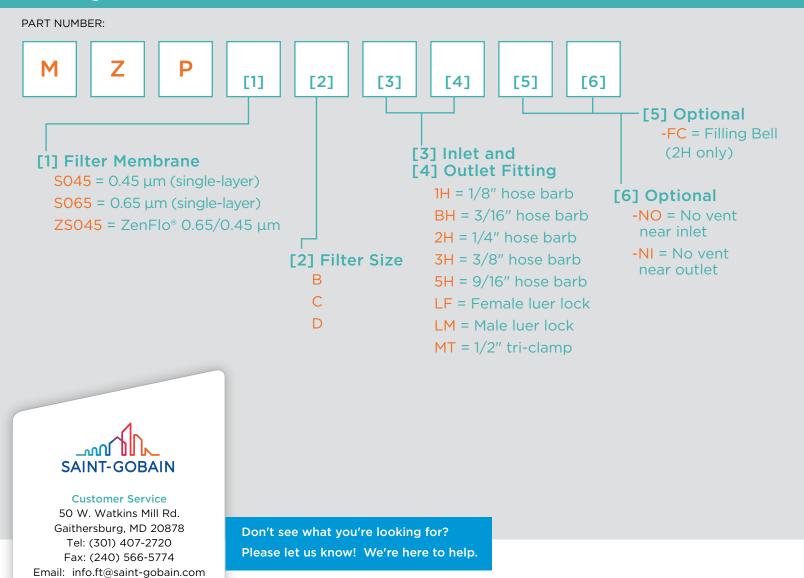
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PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

		Body Diameter	Body Length	Filtration Area (cm <sup>2</sup> )	
Si	ze	(mm)	Without Fittings (mm)	Single Layer (S)	ZenFlo (ZS)
В		59	60	390	360
С		59	60	440	420
D		59	60	530	500

#### **Ordering Guide**



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## PureFlo<sup>®</sup> Z Series PES Mid Size Prefiltration Capsules

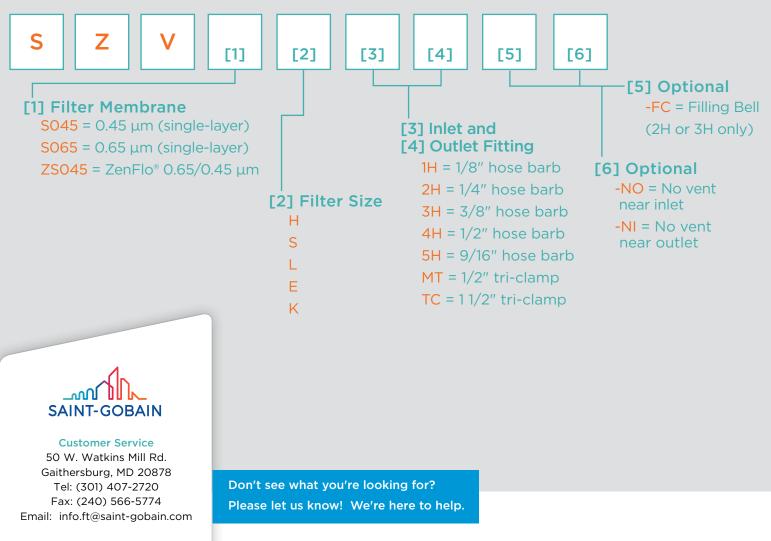
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Size	Body Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (cm <sup>2</sup> )	
			Single Layer (S)	ZenFlo (ZS)
н	71.5	56	730	650
S	71.5	84	1400	1200
L	71.5	141	2600	2300
E	71.5	206	4000	3500
к	71.5	260	5100	4500

### **Ordering Guide**



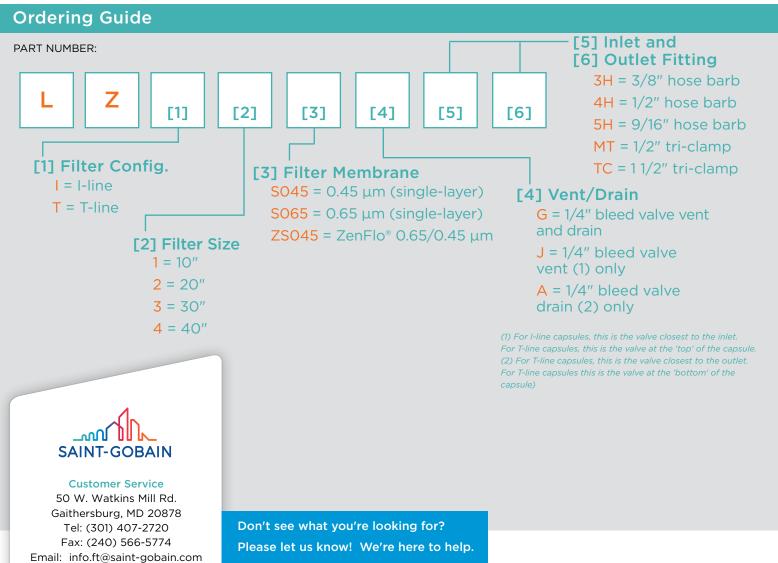


## **PureFlo® Z Series PES** ZenCap® Full Size Prefiltration Capsules

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Size	Body Diameter (mm)	I-line Body Length Without Fittings (mm)	Filtration Area (m <sup>2</sup> )	
			Single Layer (S)	ZenFlo (ZS)
1	90	279	0.64	0.57
2	90	522	1.4	1.2
3	90	765	2.0	1.7
4	90	1007	2.7	2.3



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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 Performance Plastics products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain Performance Plastics 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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