

# 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



Broad Chemical

Compatibility

Autoclavable



Scalable

Asymmetric



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 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 $\mu m$ 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) |  |            |                       |                |  |  |  |
|------------------------|--|------------|-----------------------|----------------|--|--|--|
| Size                   | Outside Diameter Body Length Without Fitting |            | Filtration Area (cm²) |                |  |  |  |
| 512e                   | (mm)   | (mm)       | 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            |  |  |
| 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   |
| Dhyaia ahamiaal     | 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   |
| 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   |
| REACH               | REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Article 57,                  |
| KEACH               | 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 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

**Disc Capsules** 

Saint-Gobain Life Sciences – Bioprocess Solutions



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

| Filter<br>Size | Body<br>Diameter<br>(mm) | Body Length<br>Without Fittings<br>(mm) | Filtration<br>Area<br>(cm²) | Typical Flow Performance*             |
|----------------|--------------------------|---|-----------------------------|---------------------------------------|
| D13Z           | 16                       | 3.7                                     | 0.8                         | D13ZS0201H1H - 10 psid at 20 mL/min   |
| D25Z           | 33                       | 5.45                                    | 4.6                         | D25ZS0201H1H - 13 psid at 100 mL/min  |
| D40Z           | 45.5                     | 8                                       | 10.5                        | D40ZS0202H2H - 4.2 psid at 100 mL/min |
| D50Z           | 54                       | 8                                       | 15.9                        | D50ZS0201H1H - 4.5 psid at 100 mL/min |
| D65Z           | 72                       | 10                                      | 26                          | D65ZS0202H2H - 1.6 psid at 100 mL/min |
| D90Z           | 99                       | 10                                      | 60                          | D90ZS0202H2H - 0.9 psid at 100 mL/min |

## **Ordering Guide**

PART NUMBER:

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

[1] Filter Size [2] 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

**90** XS020 = ZenFlo<sup>®</sup> 0.65/0.2 μm

OH = 1/16" hose barb
AH = 3/32" hose barb
1H = 1/8" hose barb
2H = 1/4" hose barb

[3] Inlet and [4] Outlet Fitting

**3H** = 3/8" hose barb

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

# \_\_\_\_\_SAINT-GOBAIN

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## PLEASE NOTE:

Not all fittings are available for all filter sizes. Please refer to the next page of the brochure for a standard list of fitting available for each filter size.

[5] Optional

-[6] Optional

-FC = Filling Bell

(2H or 3H only)

-1 = Individually

bagged

## PureFlo® Z Series Disc Capsule Ordering Guide (continued)

3/8" hose barb with filling bell (outlet only)

Table A. Inlet and outlet fitting option availability

1/2" hose barb

5/8" hose barb

Male luer lock

Male luer slip

1/2" tri-clamp

11/2" tri-clamp

Female luer lock

| Inlet/Outlet Fitting | Description                                   | D13Z | D25Z | D40Z | D50Z | D65Z | D90Z |
|----------------------|---|------|------|------|------|------|------|
| ОН                   | 1/16" hose barb                               | •    | ^    | ^    |      |      |      |
| AH                   | 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) |      |      | •    | -    |      |      |
| 3H                   | 3/8" hose barb                                |      | ^    | ^    |      | ^    | ^    |

| Table B. Vent | fitting availabili | ity (located nea | r inlet of capsu | les when prese | nt)  |
|---------------|--------------------|------------------|------------------|----------------|------|
| D13Z          | D25Z               | D40Z             | D50Z             | D65Z           | D90Z |
|               |                    |                  |                  | _              | _    |

<sup>• =</sup> fitting is available (if it is a hose barb, it is straight)



3H-FC

4H

5H

LF

LM

LS

MT

TC

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\* 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.

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

# PureFlo® Z Series PES **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 Area (cm²) |                   | — Typical Flow                   |
|------------------|--------------------------|-----------------------|-------------------|----------------------------------|
| Diameter<br>(mm) | Without Fittings<br>(mm) | Single Layer<br>(S)   | ZenFlo<br>(ZS/XS) | — Typical Flow Performance*      |
| 41               | 41                       | 260                   | 170               | JZPS0203H3H - 2 psid<br>at 1 LPM |

1 bar = 14.5038 psi

### **Ordering Guide**

PART NUMBER:

Z Γ21 **[11**] Г31 Г41 Γ51 [4] Optional [2] Inlet and [3] Outlet Fitting **1H** = 1/8" hose barb [11] Filter Membrane  $SO10 = 0.1 \mu m (single-layer)$ 2H = 1/4" hose barb [5] Optional  $S020 = 0.2 \mu m (single-layer)$ 3H = 3/8" hose barb

**ZS010** = ZenFlo<sup>®</sup> 0.2/0.1 μm **LF** = Female luer lock **ZS020** = ZenFlo<sup>®</sup> 0.45/0.2 μm LM = Male luer lock **XS010** = ZenFlo<sup>®</sup> 0.45/0.1 μm

MT = 1/2" tri-clamp

**-FC** = Filling Bell (2H or 3H only)

> -NO = No vent near inlet

> > -NI = No vent near outlet



**XS020** = ZenFlo<sup>®</sup> 0.65/0.2 μm

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# PureFlo® Z Series PES Mini Capsules

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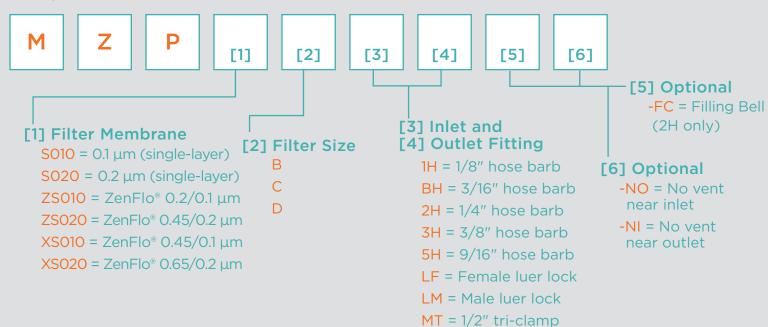
PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

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

1 bar = 14.5038 psi

# Ordering Guide







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# PureFlo® Z Series PES Mid Size Capsules

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

|      | Body<br>Diameter<br>(mm) | Body Length<br>Without Fittings<br>(mm) | Filtration Area (cm²) |                   | - Typical Flow                       |
|------|--------------------------|---|-----------------------|-------------------|--------------------------------------|
| Size |                          |   | Single Layer (S)      | ZenFlo<br>(ZS/XS) | Performance*                         |
| Н    | 71.5                     | 56                                      | 730                   | 650               | SZVS020HTCTC -<br>5.8 psid at 5 LPM  |
| S    | 71.5                     | 84                                      | 1400                  | 1200              | SZVS020STCTC -<br>5.5 psid at 10 LPM |
| L    | 71.5                     | 141                                     | 2600                  | 2300              | SZVS020LTCTC -<br>3.1 psid at 10 LPM |
| E    | 71.5                     | 206                                     | 4000                  | 3500              | SZVS020ETCTC -<br>4.9 psid at 20 LPM |
| K    | 71.5                     | 260                                     | 5100                  | 4500              | SZVS020KTCTC -<br>3.3 psid at 20 LPM |

1 bar = 14.5038 psi

## **Ordering Guide**

PART NUMBER:





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# PureFlo® Z Series PES ZenCap® Full Size Capsules

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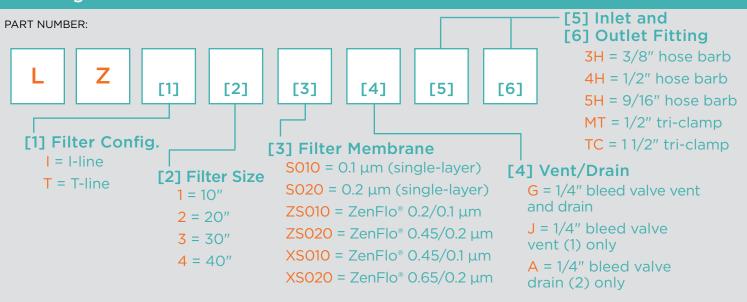


PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

| Size | Body<br>Diameter<br>(mm) | I-line Body<br>Length Without<br>Fittings (mm) | Filtration Area (m²) |                   | — Typical Flow      |
|------|--------------------------|--|----------------------|-------------------|---------------------|
|      |                          |  | Single Layer (S)     | ZenFlo<br>(ZS/XS) | Performance*        |
| 1    | 90                       | 279  | 0.64                 | 0.57              | LZI1S020GTCTC -     |
|      |                          |  |                      |                   | 2 psid at 20 LPM    |
| 2    | 90                       | 522  | 1.4                  | 1.2               | LZI2SO2OGTCTC -     |
|      |                          |  |                      |                   | 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



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(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 Don't see what you're looking for?



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(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.

# PureFlo® Z Series PES Capsules

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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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