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MZS Series PES 0.65µm/0.2µm – Dual Layer Filter Capsules

The MZS Series Pharmaceutical Grade Cartridges are designed for product sterility, provide excellent chemical compatibility and superior flow per unit area as compared to other membrane cartridges. MZS Series Pharmaceutical Grade Cartridges have been designed for final filtration in biopharmaceutical applications. The hydrophilic PES membrane does not require pre-wetting agents, thereby eliminating a potential source of contamination. Also, the PES membrane has low protein binding characteristics to maximize yields. No adhesives, binders, or surfactants are used in the manufacturing process. All cartridges are rinsed with pyrogen-free water to reduce extractables and downtime. All filter cartridges are 100% integrity tested to ensure filter performance and quality. MZS Series Pharmaceutical Grade Cartridges are well-suited for critical applications where superior flow and bacterial retention are required. The filters are manufactured in accordance with GMP and comply with <USP 797> guidelines. The filters are flushed with pharmaceutical-grade purified pyrogens-free water, and 100% integrity tested prior to dispatch. Our filters are free from animal-derived components. The raw materials can be traced by Lot Number and strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.

Application

	Buffers and Media		Product Sterilization		Fermentation Broths
	LVP (Large Volume Parenteral)		Fine Chemicals		Pharmaceuticals
	Vaccines		Biologics		Antibiotics
≻	Scale up processing	≻	Ultrapure Water	\triangleright	Serums

MZS Series Filter Cartridges with 226 O-Rings with Fin End Connection





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Tel: (818) 504-8115 -Tel: (818) 917-9538 -



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Technical Data Sheet

Micron Rating:

Final Membrane: 0.2 µm PES [Sterilizing Grade Membrane]

Pre-Filter: Highly Asymmetric 0.65 µm PES

Effective Filtration Area:

5 – inch: 3.6 ft^2 , (0.33 m^2)

10 – inch: 7 ft^2 , (0.65 m^2)

20 – inch: 14 ft^2 , (1.3 m^2)

30 – inch: $28ft^2$, (2.6 m^2)

40 – inch: 56 ft^2 , (5.2 m^2)

Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

Membrane Feature: Hydrophilic, Low Protein Binding, High Flow Rate

Media Supports: Polyester (PET)

Shell, Cage, Core: Gamma Stable Polypropylene

End Caps: Nylon

O-Rings: Silicone (Standard)

Sealing: Thermally Bonded

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Operating Conditions:

Maximum Forward Differential Pressure:

5.0 bar (72.5psi) at 72°F/22°C

2.0 bar (29psi) at 176°F/80°C

Minimum Burst Pressure: 8.3 bar (120psi) at 77°F/25°C

Maximum Reverse Differential Pressure: 3.0 bar (43.5psi) at 72°F/22°C

1.0 bar (14.5psi) at 176°F/80°C

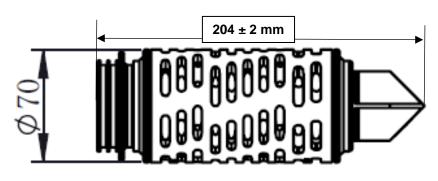
Maximum Operating Temperature: 176°F/80°C

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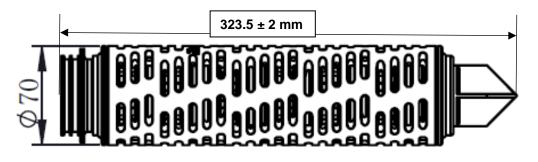


Nominal Dimension:



MZS – 5 inches

Part Number	Internal Filter Length (inches)	End Modification	Gasket Material			
MZXS2075S	5"	Code 7: 226 O-Ring with Spear	Silicone			
 Find the complete list of available standard inlet and outlet fittings on page 8. ETO- Sterilization is available for all 5-inch cartridges. Add "-ETO" with the original Part Number 						



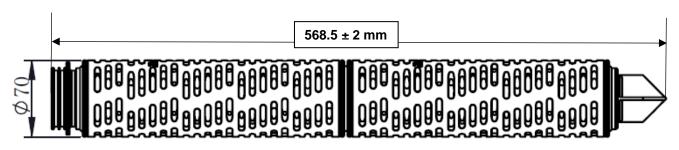
MZS – 10 inches

Part Number	Internal Filter Length (inches)	End Modification	Gasket Material			
MZXS2071S	10"	Code 7: 226 O-Ring with Spear	Silicone			
 Find the complete list of available standard inlet and outlet fittings on page 8. ETO- Sterilization is available for all 10-inch cartridges. Add "-ETO" with the original 						

Part Number

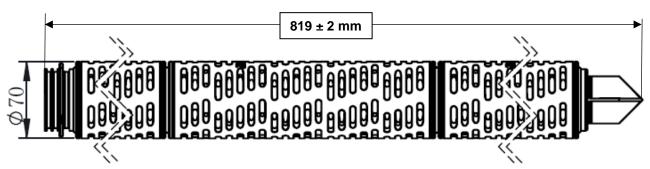


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MZS – 20 inches

Part Number	Internal Filter Length (inches)	End Modification	Gasket Material		
MZXS2072S	20"	Code 7: 226 O-Ring with Spear	Silicone		
Find the complete list of available standard inlet and outlet fittings on page 8.					

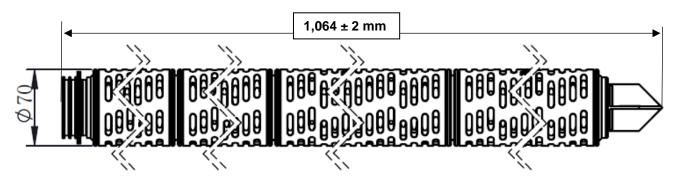


MZS – 30 inches

Part Number	Internal Filter Length (inches)	End Modification	Gasket Material			
MZXS2073S	30"	Code 7: 226 O-Ring with Spear	Silicone			
Find the complete list of available standard inlet and outlet fittings on page 8.						







MZS – 40 inches

Part Number	Internal Filter Length	End Modification	Gasket Material		
	(inches)				
MZXS2074S	40"	Code 7: 226 O-Ring with Spear	Silicone		
Find the complete list of available standard inlet and outlet fittings on page 8.					

Typical Filtered Volume:

Filter Size	Filter Area	Volume to be Filtered (Thru-Put in Liters)	
5"	$0.33 m^2$	60-240	
10"	$0.65 m^2$	120-480	
20" 1.3 <i>m</i> ²		240-960	
30" 2.6 m ²		480-1,920	
40" 5.2 m ²		960-3,840	

*Volume Filtered is an estimated range for Sterile compounding, Pharmaceutical & Biological applications. The Filtration Volume is significantly influenced by your solution's viscosity, active ingredients, etc., properties. The best way to determine the exact filtration volume per filter is to try it with your solution.



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Regulatory Compliance

Bacterial Retention:

Quantitative retention of 107 CFU/cm2 Brevundimonas diminuta per ASTM methodology

Filter Integrity:

The finished product was sampled and shown to exhibit a minimum bubble point of \geq 18 psi (1.2 bar) in 60%IPA / 40% water and \geq 50 psi (3.5 bar) in DI Water (at 22°C).

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 210.72 and 2010.3 (b) (6) Fiber Shedding

Biocompatibility:

- ASTM F756-17 Hemolysis
- USP <88> (USP Class VI Plastics) Biological Reactivity Tests, In Vivo
- USP <87> / ISO 10993-5, In Vitro Cytotoxicity
- 21 CFR 177 FDA Indirect Food Additive

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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Sterilization:

- Gamma Irradiation: The filters can be Gamma Sterilized up to 50kGy.
- Autoclave: The filters can be autoclaved for up to 50 cycles at 125°C (257°F) for 30 minutes.
- **<u>Steam-in-place</u>**: The filters can be sterilized by steam-in-place procedure up to 30 cycles at

 $135^\circ C~(275^\circ F)$ for 30 minutes at less than 0.3 bar differential pressure.

• <u>Sanitization</u>: The filters can be sanitized by hot water or common chemicals that are compatible with filter components.

Animal-derived Components:

No animal-derived material is intentionally added or used during the manufacture of PureFlo Z Series PES Capsules.

Human and Veterinarian Use:

The product is safe for Human and Veterinarian use. CGMP CFR part 210 & 211, additional requirement of 21 CFR part 600 and 21 CFR part 680 are applicable to the aseptic manufacturing process.

RoHS:

Restriction of Hazardous Substances (RoHS 3) Directive 2015/863

REACH:

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) Article 57, Regulation No. 1907/2006)

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 capsule is engraved and labeled with the product part number, lot number, and identifying characteristics.

Shelf Life:

The MZS cartridges have a shelf life of 3 years from the date of manufacture.



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MZS - Series PES Cartridge

(Pharmaceutical Grade)

Ordering Guide

M Z [1] [2] [3] [4] 1 [5]					
[1]	[2]	[3]	[4]	[5]	
Micron Rating [Pre-Filter/Final Filter]	End Modification	Length	O-Ring/Gasket Material	Optional	
 S10 : 0.1 μm S20 : 0.2 μm ZS10 : 0.2/0.1 μm ZS20 : 0.45/0.2 μm XS10 : 0.45/0.1 μm XS20 : 0.65/0.2 μm 	 0: 222 O-Ring Flat 5: 222 O-Ring Spear 6: 226 O-Ring Flat 7: 226 O-Ring Spear 	 1:10-Inch 2:20-Inch 3:30-Inch 4:40-Inch 5:5-Inch 	 S: Silicone E: EPDM N: Buna-N P: Peroxide Cured EPDM Q: Platinum Cured Silicon T: TEV or FEP Gasket V: Viton 	• -5 : SS Insert	

Example:

MZXS2072S1-5

PureFlo MZS Series Cartridge, Highly Asymmetric Dual Layer PES 0.65µm / 0.2µm PES membrane (Sterilizing Grade), 20.0-inch Long, Filtration Area 1.3 m2, 226 O-Rings with Spear, Silicone Double O-Rings, Stainless Steel Insert

Part Number

Description



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Special Configuration:

Layer Option:

- Single Layer
- Dual Layer

Micron Rating Option:

- **S10** : 0.1 µm
- S20 : 0.2 μm
- ZS10 : 0.2/0.1 μm
- ZS20 : 0.45/0.2 μm
- XS10 : 0.45/0.1 μm
- XS20 : 0.65/0.2 μm

End Modification Option:

- 0:222 O-Ring Flat
- 3: 222 O-Ring w /tabs Spear
- 5:222 O-Ring Spear
- 6:226 O-Ring Flat
- 7:226 O-Ring Spear
- 8: 223 O-Ring Flat
- F : DOE Flat Gasket
- S : SOE Flat Gasket

O-Ring/Gasket Material Option:

- S : Silicone
- E : EPDM
- N : Buna-N
- P : Peroxide Cured EPDM
- Q : Platinum Cured Silicon
- T : TEV or FEP Gasket
- V : Viton

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