



# International Filter Products

*Revolutionary systems for your industry*

## MCS Series PES 0.8 µm/0.2µm – Dual Layer Filter Cartridge

The MCS Series Pharmaceutical Grade Cartridges are designed for product sterility. The all-polypropylene construction provides excellent chemical compatibility and superior flow per unit area as compared to other membrane cartridges. MCS 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. 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 and free from animal-derived components raw materials can be traced by Lot Number and strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.

### Application

- Buffers and Media
- LVP (Large Volume Parenteral)
- Vaccines
- Scale up processing
- Product Sterilization
- Bio Bags Compatible
- Biologics
- Ultrapure Water
- Fermentation Broths
- Pharmaceuticals
- Antibiotics
- Serums

### MCS Series Filter Cartridge Filters with Code 7: 226 O-Ring with Spear



[Nominal 10-inch]



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## Technical Data Sheet

### Micron Rating:

**Final Membrane:** 0.2  $\mu\text{m}$  PES [Sterilizing Grade Membrane]

**Pre-Filter:** 0.8  $\mu\text{m}$  PES

### Effective Filtration Area:

**5"** ; 3.6  $\text{ft}^2$ , (0.33  $\text{m}^2$ )

**10"** ; 7  $\text{ft}^2$ , (0.65  $\text{m}^2$ )

**20"** ; 14  $\text{ft}^2$ , (1.3  $\text{m}^2$ )

**30"** ; 28  $\text{ft}^2$ , (2.6  $\text{m}^2$ )

**40"** ; 56  $\text{ft}^2$ , (5.2  $\text{m}^2$ )

### Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

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

Shell, Cage, Core, End Caps: Polypropylene

Sealing: Thermally Bonded

O-Ring Material: Silicone [Standard]

### Operating Conditions:

Maximum Forward Differential Pressure: **Liquid:** 5.5 bar (80psi) at 77°F/25°C

**Gas:** 4.1 bar (60psi) at 77°F/25°C

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

Maximum Reverse Differential Pressure: 3.0 bar (44psi) at 68°F/20°C

Maximum Operating Temperature: 176°F/80°C

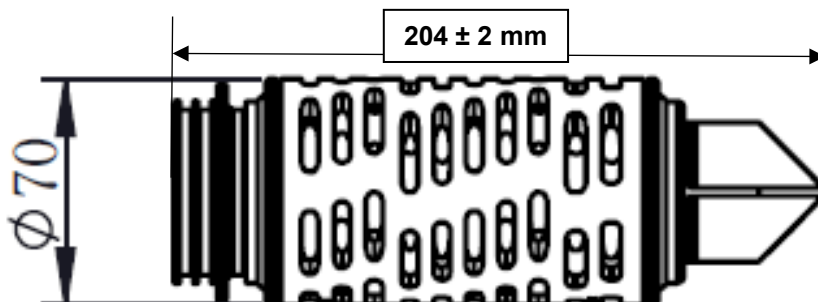




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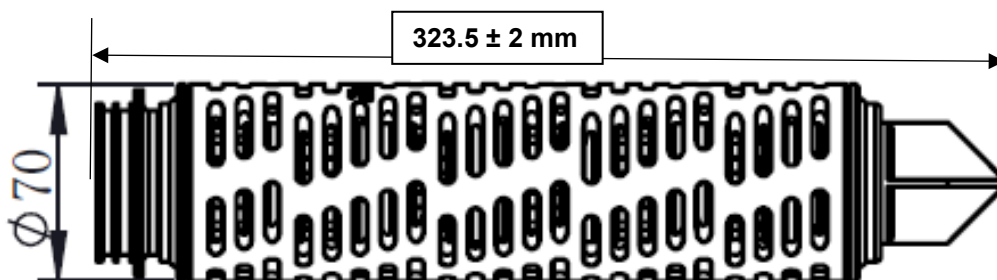
Nominal Dimension:



**MCS – 5 inches**

Part Number	Internal Filter Length (inches)	End Modification	Gasket Material
MCS2075S	5"	Code 7: 226 O-Ring with Spear	Silicone

- ❖ Find the complete list of available standard inlet and outlet fittings in page 5.
- ❖ ETO- Sterilization is available for all 5-inch cartridges. Add “-ETO” with the original Part Number



**MCS – 10 inches**

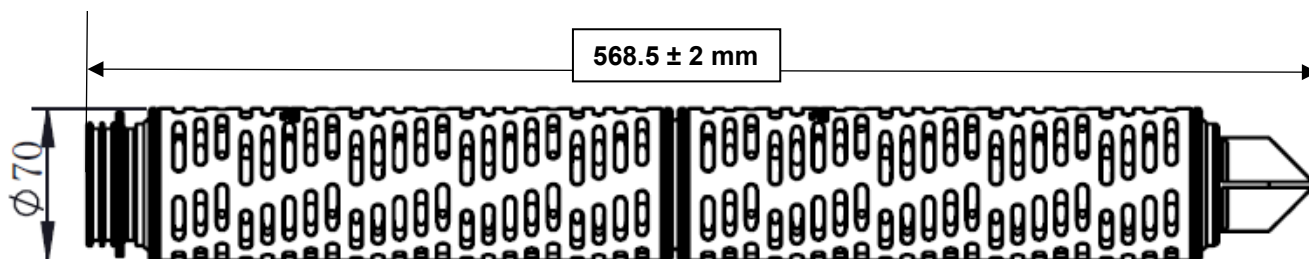
Part Number	Internal Filter Length (inches)	End Modification	Gasket Material
MCS2071S	10"	Code 7: 226 O-Ring with Spear	Silicone

- ❖ Find the complete list of available standard inlet and outlet fittings in page 5.
- ❖ ETO- Sterilization is available for all 10-inch cartridges. Add “-ETO” with the original Part Number



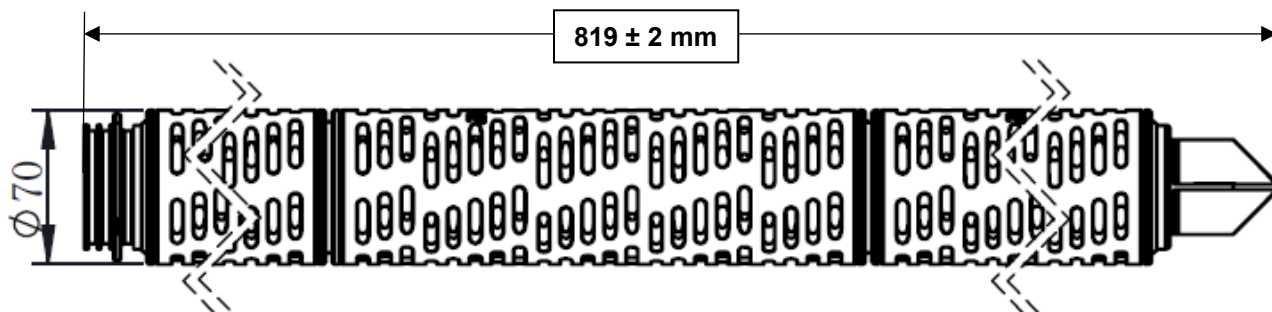
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**MCS – 20 inches**

Part Number	Internal Filter Length (inches)	End Modification	Gasket Material
MCS2072S	20"	Code 7: 226 O-Ring with Spear	Silicone
❖ Find the complete list of available standard inlet and outlet fittings in page 5.			



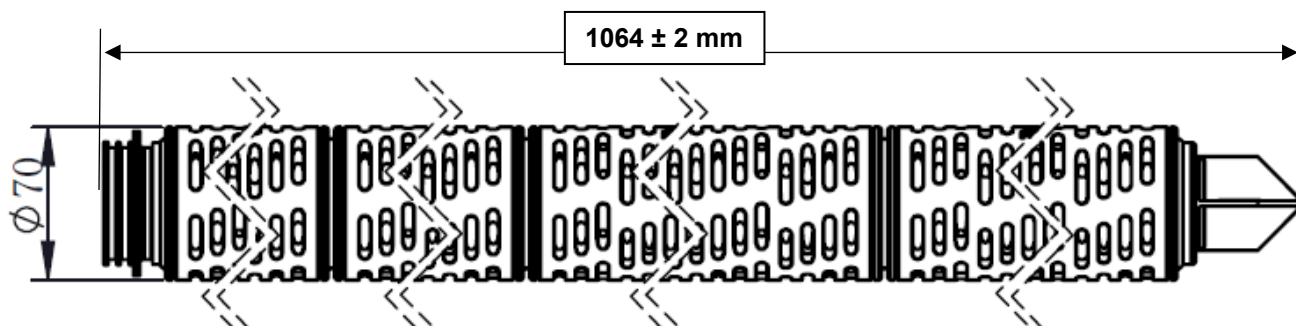
**MCS – 30 inches**

Part Number	Internal Filter Length (inches)	End Modification	Gasket Material
MCS2073S	30"	Code 7: 226 O-Ring with Spear	Silicone
❖ Find the complete list of available standard inlet and outlet fittings in page 5.			



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MCS – 40 inches

Part Number	Internal Filter Length (inches)	End Modification	Gasket Material
MCS2074S	40"	Code 7: 226 O-Ring with Spear	Silicone
❖ Find the complete list of available standard inlet and outlet fittings in page 5.			

## Typical Filtered Volume:

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

## Filter Integrity:

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



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## **Sterilization:**

**Autoclave:** The filters can be sterilized by autoclaving for up to 50 cycles at 125 °C (257 °F) for 30 minutes.

**Steam-In-Place:** The filters can also be sterilized by steam-in-place procedure up to 30 cycles at 135 °C (275 °F) for 30 minutes at less than 0.3 bar differential pressure.

**Sanitization:** The filters can also be sanitized by hot water or common chemicals that are compatible with filter components.

## **Regulatory Compliance 21CFR Part 177 & USP <88>:**

The filters are constructed with polypropylene resins and filtration media in compliance with 21CFR Part 177 of the US Code of Federal Regulations and USP Class VI Biological USP <88> Test for Plastic.

## **USP <85> Bacterial Endotoxins:**

The filters were tested to confirm that an aqueous extraction of this product contains <0.25 EU/ml as determined by the Limulus Amebocyte Lysate (LAL) Test

## **USP <645> Conductivity USP:**

Effluent is tested during the manufacturing process and shown to meet the requirements for USP Sterile Water for Injection for conductivity.

## **Bacterial Retention ASTM F838-05:**

The filters are quantitatively retentive towards *Brevundimonas diminuta* (ATCC #19146) at a minimum challenge level of  $10^7$  CFU per  $cm^2$  of filtration area, consistent with ASTM F838-05

## **USP <87> / ISO 10993-5 Cytotoxicity:**

Extract from this product is non-Cytotoxic

## **Hemolysis ASTM F756-17:**

Extract from this product is non-Hemolytic

## **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.

## **Animal-Derived Components & TSE/BSE Risk:**

No animal-derived material is intentionally added or used during the manufacture of this product.

## **Shelf Life:**

The MCS capsules have a shelf life of 3 years from the date of sterilization.

Ethylene Oxide (ETO) Sterilized product packaging provides adequate protection to maintain a sterile barrier throughout the distribution, handling, and 3-year shelf life of the product.



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## MCS - Series PES Cartridge

(Pharmaceutical Grade)

### Ordering Guide



[1]	[2]	[3]	[4]	[5]	[6]	[7]
Micron Rating	End Modification	Length	O-Ring/Gasket Material	Optional	Pre-Filter	Sterilization
<ul style="list-style-type: none"> <li>04 : 0.04 µm</li> <li>10 : 0.10 µm</li> <li>20 : 0.20 µm</li> <li>50 : 0.45 µm</li> <li>65 : 0.65 µm</li> <li>80 : 0.80 µm</li> <li>1X : 1.20 µm</li> </ul> <p>Note: All final membranes are sterilizing grade.</p>	<ul style="list-style-type: none"> <li>0 : 222 O-Ring Flat</li> <li>5 : 222 O-Ring Spear</li> <li>6 : 226 O-Ring Flat</li> <li>7 : 226 O-Ring Spear</li> <li>F : DOE Flat Gasket</li> <li>S : SOE Flat Gasket</li> </ul>	<ul style="list-style-type: none"> <li>1 : 10-Inch</li> <li>2 : 20-Inch</li> <li>3 : 30-Inch</li> <li>4 : 40-Inch</li> <li>5 : 5-Inch</li> </ul>	<ul style="list-style-type: none"> <li>S : Silicone</li> <li>E : EPDM</li> <li>N : Buna-N</li> <li>P : Peroxide Cured EPDM</li> <li>Q : Platinum Cured Silicon</li> <li>T : TEV or FEP Gasket</li> <li>V : Viton</li> </ul>	<ul style="list-style-type: none"> <li>-5 : SS Insert</li> <li>-RI : RFID Chip</li> </ul>	<ul style="list-style-type: none"> <li>DS065 : Highly Asymmetric 0.65µm</li> <li>DS045 : Highly Asymmetric 0.45µm</li> <li>S080 : 0.8µm</li> </ul>	<ul style="list-style-type: none"> <li>-ETO: Ethylene Oxide Sterilization</li> </ul> <p>Note: Only available for 5-in &amp; 10-in Cartridges</p>

#### Example:

**MCS2071S-S080-PH-ETO**

PureFlo MCS Series Cartridge, Dual Layer PES 0.8µm / 0.2µm PES membrane (Sterilizing Grade), 10.0-inch Long, Filtration Area 0.65 m<sup>2</sup>, 226 O-Rings with Spear, Silicone Double O-Rings, ETO Sterilized (Factory Sterilized)

Part Number

Description





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## Special Configuration:

### Layer Option:

- Single Layer
- Dual Layer

### Micron Rating Option:

- 0.04 Micron
- 0.1 Micron
- 0.2 Micron
- 0.45 Micron
- 0.65 Micron
- 0.8 Micron
- 1.2 Micron

### 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

