

**mdi** AseptiCap WS- $\gamma$  are low protein binding hydrophilic PVDF gamma sterilizable membrane inline capsule filters, designed for sterile filtration of very small fluid volumes in formulation and process development labs.

These capsule filters are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as absolute retention efficiency, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

## Applications

### Sterile Filtration of

- Antibodies
- Protein Solutions
- Buffers
- Heat labile additives
- Vaccine concentrates
- Small Volume Parenterals



Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 210.3(b)(6)

Meets and Exceeds USFDA 21 CFR 177.1520

## Key features

- Absolute retention
- 100% integrity tested
- Low protein binding
- Low extractables
- Very low hold up volume

## Specifications

### Construction

Pore Size	0.2 $\mu\text{m}$	
Membrane	Hydrophilic PVDF	
Plastic Components	Polypropylene	

### Size

Size	25 mm	50 mm
Effective Filtration Area (Nominal)	5 cm <sup>2</sup>	20 cm <sup>2</sup>

### Integrity Testing/Retention

Bubble Point ( with Water)	$\geq$ 50psi (3.52 Kg/cm <sup>2</sup> )	
Microbial Retention	LRV>7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm <sup>2</sup>	

### Operational

Max. Operating Temperature	55 °C	60 °C
Max. Differential Pressure	75 psi (5 Kg/cm <sup>2</sup> @25°C)	42 psi (3 Kg/cm <sup>2</sup> ) @ 30 °C
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy	

### Assurance

Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>	
Toxicity	Passes Biological reactivity Test, <i>In Vivo</i> , as per USP <88> for Class VI plastics	
Cytotoxicity	Passes Biological Reactivity Tests, <i>In Vitro</i> , USP <87> for cytotoxicity	

## Assurance

Fiber Release	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
Particle Release	The filtrate complies with USP <788> test for particulate matter in injections
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after flushing with a specified volume of WFI
Extractables with WFI	Passes test as per USP <661>
Oxidizable Substances	Passes test as per USP <1231>

## Ordering Information

### 25 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code			Code		Code
<i>AseptiCap WS</i> (0.45µm Upstream)	IWSX	25mm	06	0.2 µm	01	½" Hose Barb	H	½" Hose Barb	H	Yes	R	X	Non Sterile	1	100	04
						¼" Hose Barb	B	¼" Hose Barb	B	No	X		Gamma Sterile	3		
						Female Luer Lock	M	Male Luer Slip	N							
								Male Luer Lock	L							

Example:

IWSX	06	01	M	N	X	X	1	04
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**Note: Gamma Sterile filters can not be sterilized again**

Example for Non Sterile: IWSX0601MNRX104

Example for Gamma Sterile: IWSX0601MNXX304

### 50 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code			Code		Code
<i>AseptiCap WS</i> (0.45 µm Upstream)	IWSX	50 mm	10	0.2 µm	01	¼" SHB	B	¼" SHB	B	Yes	R	X	Non Sterile	1	10	02
						¾" Sanitary Flange	S	¾" Sanitary Flange*	S	No	X		Gamma Sterile	3		
<i>Vented AseptiCap WS</i> (0.45 µm Upstream)	VWSX															

\* In vented *AseptiCap WS* ¾" Sanitary Flange is available as outlet only

Example:

IWSX	10	01	SS	SS	R	X	1	04
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**Note: Gamma Sterile filters can not be sterilized again**

Example for Non Sterile: IWSX1001SSRX104

Example for Gamma Sterile: IWSX1001SSXX304