

# 0.1 μm *AseptiCap WS-γ* Hydrophilic PVDF Membrane Inline Capsule Filters

**mdi** AseptiCap WS-y 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**

- Cell culture media
- Growth regulators
- > Small Volume Parenterals

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		0.1μm							
Membrane		Hydrophilic PVD	F						
Plastic Compo	nents	Polypropylene							
		Size							
Size		25 mm	50 mm						
Microbial Rete	ntion	LRV>7 for <i>Acholeplasma</i>	a laidlawii (ATCC 23206) per cm²						
		Integrity Testing/Retention							
Bubble Point (	with 50% IPA/Water)	≥ 31psi (2.18Kg/cm²)							
Effective Filtrat	ion Area (Nominal)	5 cm²	20 cm²						
		Operational							
Max. Operating	g Temperature	55 °C	60 ℃						
Max. Different	ial Pressure	75 psi (5 Kg/cm² @25°C) 42 psi (3 Kg/cm²) @ 30							
	By Irradiation	Gamma Irradiatiable up to 50 kGy							
Sterilization	By Autoclave	Autoclavable at 125°C for 30 minutes, 1 cycle after gamma irradiation. Cannot be in-line steam sterilized							
		Assurance							
Bacterial Endo	toxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test							
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	or 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									
Oxidizable Substances	Within limits as specified in USP									

# **Ordering Information**

## 25 mm Inline Capsule Filters

Туре		Size		Size	Inlet		Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
Code		Code		Code		Code		Code		Code			Code		Code
WSX	25mm	06	0.1 μm	36	1/8" Hose Barb	Н	1/8" Hose Barb	Н	Yes	R		Non Sterile	1	100	04
					1/4" Hose Barb	В	1/4" Hose Barb	В	No	Χ		Gamma Sterile	3		
IWS1					Female Luer Lock	М	Male Luer Slip	N							
							Male Luer Lock	L							
	WSX	Code 25mm	Code Code WSX 25mm 06	Code   Code   25mm   06   0.1 μm	Code         Code         Code         Code           WSX         25mm         06         0.1 μm         36	Code         Code         Code           WSX         25mm         06         0.1 μm         36         ½" Hose Barb           ½" Hose Barb         ½" Hose Bar	Code   Code   Code   Code   Usy   Code   Usy   Code   Usy   Usy   Code   Usy   C	Code   Code   Code   Code	Code   Code   Code   Code   (Code   (D.1 μm   36)   (D.1 μm	Size   Pore Size   Inlet   Outlet   Steriliz	Size   Pore Size   Inlet   Outlet   Sterilizable	Size   Pore Size   Inlet   Outlet   Sterilizable   X	Size   Pore Size   Inlet   Outlet   Sterilizable   X   Sterilizable	Size   Pore Size   Inlet   Outlet   Sterilizable   X   Sterilizable	Size

Example:

**Example:** 

IWSX	06	36	M	N	X	X	1	04
IVVSX	- 00		IVI	14			•	04

Note: Gamma Sterile filters can not be sterilized again

Example for Non Sterile: IWSX0636MNRX104

Example for Gamma Sterile: IWSX0636MNXX304

## 50 mm Inline Capsule Filters

Туре		Size		Pore Size		Inlet		Outlet		Sterilizable		Х	Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code			Code		Code
AseptiCap WS	IWSX	50 mm	10	0.1 μm	36	1⁄4" SHB	В	1⁄4" SHB	В	Yes	R		Non Sterile	1	10	02
(0.45 µm Upstream)						¾" Sanitary Flange	S	34" Sanitary Flange*	S	No	Χ		Gamma Sterile	3	100	04
AseptiCap WS (0.2 μm Upstream)	IWS1					, ,						l				
Vented AseptiCap WS (0.45 μm Upstream)	VWSX							* In vented	d Asepti	Cap WS 3	¼" Sanita	ary Flar	nge is available a	s outlet	only	
Vented AseptiCap WS (0.2 μm Upstream)	VWS1															

SS

Χ

SS

Note: Gamma Sterile filters can not be sterilized again

**Example for Gamma Sterile:** IWSX1036SSXX304 **Example for Non Sterile:** IWSX1036SSRX104