

mdi 0.1µm AseptiCap WS-y are low protein binding hydrophilic PVDF membrane capsule filters, validated to retain mycoplasma, a critical requirement for sterilization of mammalian cell culture media.

These capsules offer serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

0.1μm AseptiCap WS-γ 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.

Key features

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

Applications

Sterile Filtration of

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

Ordering Information



Microbially Validated as per ASTM F 838-05 Complies with USFDA 21 CFR 210.3(b)(6)

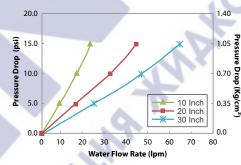
Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

Materials of Construction

Membrane	Hydrophilic PVDF
Support Layer	Polyester
Plastic Components	Polypropylene

Typical Water Flow Rates



Microbial Retention

LRV >7 for Acholeplasma laidlawii (ATCC

23206) per cm²

Maximum Operating Temperature $80 \,^{\circ}C @ \leq 30 \, \text{psi} (2 \, \text{Kg/cm}^2)$

Maximum Differential Pressure 60 psi (4 Kg/cm²) @ 30 °C

0.1µm AseptiCap WS-y

Large Capsule Filters

Hydrophilic PVDF Membrane

Bubble Point with 50% IPA > 31 psi

Sterilization

By Irradiation: Gamma irradiatiable up to 50 kGy

By Autoclave: Autoclavable at 125°C for 30 minutes, 1 cycle after gamma irradiation. Can not be in-line steam sterilized

Toxicity

Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics

Cytotoxicity

Passes Biological Reactivity Tests, *In Vitro*, USP <87> for cytotoxicity

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

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

DST LWSX36R1630B

Extractables with WFI

Passes NVR test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

Туре		Size		Pore	Size	Inlet /Outlet		Radiation Sterili	zable	Inline/T-L	.ine	Sterility		Pack	Size
	Code	Length and EFA	Code		Code		Code		Code		Code		Code		Cod
AseptiCap WS	LWS1	5" (3000 cm ²)	53	0.1µm	36	1 ¹ / ₂ " Triclover	E	Yes	R	Inline	Х	Non-Sterile	1	1	01
(0.2µm upstream)	LVVSI	10" (6000 cm ²)	54			Single Step 1/2" Hose Barb	Q	No**	Х	T-Line***	Т	Gamma Sterile	3		
AseptiCap WS	LWSX	20" (12000 cm ²)	55	1		3/8" Hose Barb	I								
(0.45µm upstream)	LVVSA	30" (18000 cm ²)	56	1		1" Hose Barb*	Z								
EFA: Effective Filtration Area *1"Hose Barb is not available in 5" capsule filters **Gamma sterile capsule filters cannot be gamma irradiated again ****T-line Capsule Filter are available with 1½"Sanitary Flange I/O Connections only Note: Size 5" is available in Inline Capsule filters only															
LWS1		54		36	3	QQ		R		Х		1		0	1



mdi 0.1 μm *AseptiCap WS-γ* are low protein binding hydrophilic PVDF membrane capsule filters, validated to retain mycoplasma, a critical requirement for sterilization of mammalian cell culture media.

These capsules offer serial filtration incorporating a larger pore size upstream membrane to protect the downstream membrane for enhanced throughput.

0.1 μm AseptiCap WS-γ 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.

Key features

- Absolute retention
- > 100% integrity tested
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- Low extractables
- > Very low hold up volume in filters

Applications

Sterile Filtration of

- Cell culture media
- Growth regulators
- Small Volume Parenterals

Ordering Information



Specifications

Materials of Construction

Membrane	Hydrophilic PVDF
Plastic Components	Polypropylene

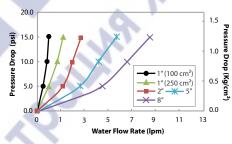
Microbial Retention LRV >7 for *Acholeplasma laidlawii* (ATCC 23206) per cm²

Bubble Point with 50% IPA/Water ≥31psi

Maximum Operating Temperature $80 \degree C @ \le 30 \text{ psi} (2 \text{ Kg/cm}^2)$

Maximum Differential Pressure 60 psi (4 Kg/cm²) @ 30 °C

Typical Water Flow Rates



0.1µm AseptiCap WS-γ Hydrophilic PVDF Membrane Capsule Filters

Sterilization

By Irradiation: Gamma irradiatiable up to 50 kGy

By Autoclave: Autoclavable at 125°C for 30 minutes, 1 cycle after gamma irradiaton. Can not be in-line steam sterilized

Toxicity

Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics

Cytotoxicity

Passes Biological Reactivity Tests, *In Vitro*, USP <87> for cytotoxicity

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

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 a 3 liter flush

Extractables with WFI Passes NVR test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

Complies with USFDA 21 CFR 210.3(b)(6)
Meets and Exceeds USFDA 21 CFR 177.1520

DST DWSX36R1620C

Туре		Size		Pore	Size	Inlet/Outlet		Radiation St	erilizable	X	Sterility	/	Pack	k Size		
	Code	Length and EFA	Code	- ·	Code		Code		Code			Code		Code		
AseptiCap WS	DWSX	1" (100 cm ²)	31	0.1µm	36	1⁄4″ SHB	A	Yes	R		Non-Sterile	1	1	01		
(with 0.45µm Upstream)	DWSK	1" (250 cm ²)	51			1⁄2" Hose Barb	D	No****	Х		Gamma Sterile	3				
AseptiCap WS	DIALCT	2" (500 cm ²)	52			1½" Sanitary Flange	E			,			•			
(with 0.2µm Upstream)	DWS1	5" (1000 cm ²)	53]		¾" Sanitary Flange	S	* Single sten ½"	hose harh ar	nd 3/8" l	8" hose barb end connections are not					
	8" (2000 cm ²) 57						J	in 1" Capsule filter								
				,		Single Step ½"Hose Barb*	Q	**Male luer slip end connection is available as outlet only in 1" capsule filters								
						Female Luer Lock	U		***3/16" hose barb end connection is available in: 1" and 2" capsule filters as inlet and outlet 5" as outlet only ****Gamma sterile capsule filters cannot be gamma irradiated again							
						Male Luer Slip**	w									
EFA: Effective Filtra	tion Are	ea				3/16" Hose Barb***	N									
Example						3/8" Hose Barb*	1									
DWSX		53		30	5	QQ		R		Х	1		0	1		
For Non-Sterile: DWS	X53360	ORX101	For	Gamma	Sterile	: DWSX533600XX301		•								

ATA SHEET



0.1µm AseptiCap WS Hydrophilic PVDF Membrane Inline Capsule Filters

mdi AseptiCap WS are low protein binding hydrophilic PVDF 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 PVDF								
Plastic Compor	nents	Polypropylene								
		Size								
Size		25 mm	50 mm							
Effective Filtrati	on Area (Nominal)	5 cm ²	20 cm ²							
		Integrity Testing/Retention								
Bubble Point		≥ 31psi (2.18Kg/cm²) w	vith 50% IPA/Water Solution							
Microbial Reten	tion	LRV>7 for Acholeplasma	<i>laidlawii</i> (ATCC 23206) per cm ²							
		Operational								
Max. Operating	Temperature	55 °C	60 °C							
Max. Differenti	al Pressure	75 psi (5 Kg/cm² @25°C)	42 psi (3 Kg/cm²) @ 30 °C							
	By Gas	Sterilization by Ethylene Oxide								
Sterilization By Autoclave		Autoclavable at 125°C for 30 minutes, 2 cycles. Cannot	be in-line steam sterilized							
		Assurance								
Bacterial Endot	oxin	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 <8	8> for Class VI plastics							

	Assurance									
Cytotoxicity	Passes Biological Reactivity Tests, In Vitro, USP <87> for cytotoxicity									
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

	•														
Туре		Size Pore Size		Inlet		Outlet	Outlet		x	Sterility		Pack Size			
	Code		Code		Code		Code		Code	1			Code		Code
AseptiCap WS	IWSX	25mm	06	0.1 µm	36	1/8" Hose Barb	Н	1⁄8" Hose Barb	Н			Non Sterile	1	100	04
(0.45µm Upstream)						1/4" Hose Barb	В	¼" Hose Barb	В			EO Sterile	2	1	
AseptiCap WS (0.2µm Upstream)	IWS1					Female Luer Lock	м	Male Luer Slip	N				5		
		1						Male Luer Lock	L						
Example:												1			
IWSX		0	6	30	5	М	6.	N	1	Х	X	1			04

50 mm Inline Capsule Filters

			/												
Туре		Siz	:e	Pore	Size	Inlet		Outlet		x	х	Sterility	,	Pack	k Size
	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			Non Sterile	1	10	02
(0.45 µm Upstream) AseptiCap WS						³ ⁄ ₄ " Sanitary Flange	S	³ ⁄ ₄ " Sanitary Flange*	S			EO Sterile	2	100	04
(0.2 μm Úpstream)	IWS1							N	•						
Vented AseptiCap WS (0.45 µm Upstream)															
(0.45 μm Upstream) Vented AseptiCap WS Vented AseptiCap WS * In vented AseptiCap WS ¾" Sanitary Flange is available as outlet only (0.2 μm Upstream) VWS1												only			
Example:							1	T							
IWSX		10)	30	6	S	1	S		Х	Х	1			04
			~	21	14	290									



mdi AseptiCap WS are low protein binding hydrophilic PVDF membrane capsule filters offering serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

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.

Key features

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

Applications

- > 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

Large Capsule Filters

By Autoclave: Autoclavable at 125°C for 30 minutes, 2 cycles. Can not be in-line steam sterilized

0.1µm AseptiCap WS

Hydrophilic PVDF Membrane

By Gas: Sterilization by Ethylene Oxide

Toxicity

Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics

Cytotoxicity

Passes Biological Reactivity Tests, *In Vitro*, USP <87> for cytotoxicity

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL)Test as per USP <85>

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

DST LWSX36X1600B

Extractables with WFI

Passes test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

Ordering Information

Туре		Size		Pore Size		Inlet /Outlet		Х	Inline/T-Line		Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code			Code		Code		Code
AseptiCap WS	LWS1	5" (3000 cm ²)	53	0.1 µm	36	1½" Sanitary Flange	E		Inline	Х	Non-Sterile	1	1	01
(0.2 µm upstream)	LVVSI	10" (6000 cm ²)	54			Single Step ½" Hose Barb	Q		T-Line*	Т	EO Sterile	2		
AseptiCap WS	LWSX	20" (12000 cm ²)	55			3/8" Hose Barb	Ι	*** !!	Control In Fil			1/ // 6		
(0.45 µm upstream)	LWSX	30" (18000 cm ²)	56]		1" Hose Barb	Z		ctions only	ter are	available with 1	¹ /2"Sanita	ary Fian	ige I/O
		EFA: Effectiv	e Filtrat	ion Area					,	Inline Ca	apsule filters only			
Example														



Hydrophilic PVDF

Polypropylene

Polyester

Maximum Operating Temperature 80 °C @ ≤ 30 psi (2 Kg/cm²)

 cm^2

Maximum Differential Pressure 60 psi (4 Kg/cm²) @ 30 °C

Bubble Point

Specifications

Materials of Construction

Pore Size

Membrane

Support Layer

Plastic Components

Microbial Retention

 \geq 31psi (2.18 Kg/cm²) with 50% IPA/ water solution

LRV >7 for A. laidlawii (ATCC 23206) per



0.1 µm AseptiCap WS Hydrophilic PVDF Membrane Capsule Filters

mdi AseptiCap WS are low protein binding hydrophilic PVDF membrane capsule filters offering serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

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.

Key features

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

Applications

Sterile Filtration of

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

Complies with USFDA 21 CFR 210.3(b)(6) Meets and Exceeds USFDA 21 CFR 177.1520



Specifications

Pore Size 0.1 μm

Materials of Construction

Membrane	Hydrophilic PVDF
Support Layer	Polyester
Plastic Components	Polypropylene

Microbial Retention

LRV>7 for *A.laidlawii* (ATCC 23206) per cm²

Maximum Operating Temperature $80 \degree C @ \le 30 \text{ psi} (2 \text{ Kg/cm}^2)$

Maximum Differential Pressure 60 psi (4 Kg/cm²) @ 30 °C

Bubble Point ≥ 31psi (2.18Kg/cm²) with 50% IPA/water Solution

Sterilization

By Autoclave: Autoclavable at 125°C for 30 minutes, 2 Cycles. Can not be in-line steam sterilized

By Gas: Sterilization by Ethylene Oxide

Toxicity

Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics

Cytotoxicity

Passes Biological Reactivity Tests, *In Vitro*, USP <87> for cytotoxicity

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

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 a 3 liter flush

Extractables with WFI

Passes NVR test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

Ordering Information

Туре		Size		Pore	Size	Inlet /Outlet		х	x	Sterilit	у	Pack	Size			
	Code	Length and EFA	Code		Code		Code				Code		Code			
AseptiCap WS	DWS1	1" (250 cm ²)	51	0.1 µm	36	1⁄4″ SHB	A	1		Non-Sterile	1	1	01			
(0.2 µm Upstream)	00031	2" (500 cm ²)	52	×		1⁄2" Hose Barb	D			EO Sterile	2					
AseptiCap WS	DWSX	5" (1000 cm ²)	53			1½" Sanitary Flange	E	1								
(0.45 µm Upstream)	DWSA	8" (2000 cm ²)	57			³ 4" Sanitary Flange	S	*Single step 1/2" hose barb and 3/8" Hose Barb end connections are available in 1" capsule filter								
	· · · · · · · · · · · · · · · · · · ·						J	**Male luer slip end connection is available as outlet only in 1" capsul								
						Single Step ½" Hose Barb*	Q	filters								
						Female Luer Lock	U		***3/16" hose barb end connection is available in: - 1" and 2" capsule filters as inlet and outlet							
						Male Luer Slip**	W	- 1" and 2 - 5" as out								
EFA: Effective Filtra	ation A	rea				3/16" Hose Barb***	N		,							
Example						3/8" Hose Barb*	I									
	ampie															
DWSX 53 36				5	EE		Х	Х	1		0	1				

DST DWSX36X1630C



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

mdi AseptiCap WS- γ 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

Key features

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

Complies with USFDA 21 CFR 210.3(b)(6) Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

		Construction							
Pore Size		0.1µ	ım						
Membrane		Hydrophil	Hydrophilic PVDF						
Plastic Compone	ents	Polyprop	pylene						
		Size							
Size		25 mm	50 mm						
Microbial Retenti	ion	LRV>7 for Acholeplasma laidlawii (ATCC 23206) per cm ²							
		Integrity Testing/Reter	ntion						
Bubble Point (wi	ith 50% IPA/Water)		≥ 31psi (2.18Kg/cm²)						
Effective Filtratio	on Area (Nominal)	5 cm ²	20 cm ²						
		Operational							
Max. Operating	Temperature	55 ℃	60 °C						
Max. Differential	l Pressure	75 psi (5 Kg/cm² @25°C)	42 psi (3 Kg/cm²) @ 30 °C						
	By Irradiation	Gamma Irradiatiable up to 50 kGy							
Sterilization	By Autoclave	Autoclavable at 125°C for 30 minutes, 1 cycle af	fter gamma irradiation. Cannot be in-line steam sterilized						
		Assurance							
Bacterial Endoto	oxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test							
Toxicity		Passes Biological reactivity Test, In Vivo, as per USP <88> for Class VI plastics							
Cytotoxicity		Passes Biological Reactivity Tests, In Vitro, 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
Oxidizable Substances	Within limits as specified in USP

Ordering Information

25 mm Inline Capsule Filters

Туре		Size		Pore	Size	Inlet		Outlet		Outlet		Outlet		Outlet			Radiation Sterilizable X Sterility		terility Pack		k Size
	Code		Code		Code		Code		Code		Code			Code		Code					
AseptiCap WS	IWSX	25mm	06	0.1 µm	36	1/8" Hose Barb	Н	1⁄8" Hose Barb	Н	Yes	R		Non Sterile	1	100	04					
(0.45µm Upstream)	1113/					1⁄4" Hose Barb	В	¹ ⁄ ₄ ″ Hose Barb	В	No	Х		Gamma Sterile	3							
AseptiCap WS (0.2µm Upstream)	IWS1					Female Luer Lock	М	Male Luer Slip	N												
						2/	17	Male Luer Lock	L												
Example:																					
IWSX		06	5	36	5	М		N	A	X		Х	1		(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		Siz	:e	Pore	Size	Inlet		Outlet		Outlet		Outlet		Outlet				Radiation 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)						³ / ₄ " Sanitary Flange	S	³ / ₄ " Sanitary Flange*	S	No	Х		Gamma Sterile	3	100	04								
<i>AseptiCap WS</i> (0.2 μm Upstream)	IWS1								7			I				1								
Vented <i>AseptiCap WS</i> (0.45 µm Upstream)								* In vented	d Asepti	Cap WS 🗄	4″ Sanita	ary Flar	nge is available a	s outlet	only									
Vented AseptiCap WS (0.2 µm Upstream)	VWS1																							
Example:								¢.'																
IWSX		1()	36	5	SS		SS		F	1	Х	1			04								

Note: Gamma Sterile filters can not be sterilized again

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

MAD



mdi AseptiCap WS- γ are low protein binding hydrophilic PVDF gamma sterilizable membrane capsule filters offering serial filtration incorporating a larger pore size upstream membrane to protect the downstream membrane for enhanced throughput.

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.

Key features

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

Applications

Sterile Filtration of

- Antibodies
- > Protein Solutions
- Buffers
- 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

Ordering Information

AseptiCap WS-γ Hydrophilic PVDF Membrane Large Capsule Filters



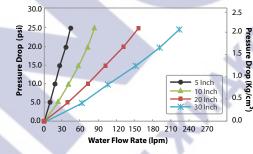
Specifications

Pore Size 0.2 μm and 0.45 μm

Materials of Construction

Membrane	Hydrophilic PVDF
Plastic Components	Polypropylene

Typical Water Flow Rates, 0.2µm Filters



Microbial Retention

0.2\mum: LRV >7 for *B. diminuta* (ATCC 19146) per cm²

0.45μm:LRV >7 for *Serratia marcescens* (ATCC 14756) per cm²

Maximum Operating Temperature $80 \degree C @ \le 30 \text{ psi} (2 \text{ Kg/cm}^2)$

Maximum Differential Pressure 60 psi (4 Kg/cm²) @ 30 °C

Bubble Point

0.2 μm: > 50psi (3.51Kg/cm²) with Water **0.45 μm:** > 30 psi (2.11 Kg/cm²) with water

Sterilization

By Irradiation: Gamma irradiatiable up to 50 kGy

By Autoclave: Autoclavable at 125°C for 30 minutes, 1 cycle after gamma irradiation. Cannot be in-line steam sterilized

Toxicity

Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics

Cytotoxicity

Passes Biological Reactivity Tests, In Vitro, USP <87> for cytotoxicity

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL)Test as per USP <85>

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

Within limits as specified in USP <1231>

Туре		Size		Pore	Size	Inlet /Outlet		Radiation Steril	izable	Inline/T-Line		Inline/T-Line		Inline/T-Line		Sterility		Pacl	k Size
	Code	Length and EFA	Code	~	Code		Code		Code		Code		Code		Code				
AseptiCap WS		5" (3000 cm ²)	53	0.2µm	01	1 ¹ / ₂ "Triclover	Е	Yes	R	Inline	Х	Non-Sterile	1	1	01				
(0.45 µm	LWSX	10" (6000 cm ²)	54	0.45µm	02	Single Step ½" Hose Barb	Q	No**	X T-Line***			Gamma Sterile	3						
upstream)		20" (12000 cm ²)	55	55 3/8" Hose Barb I **0.45 μm capsule filters are available with 0.8 μm upstream only							nly								
AseptiCap WS		30" (18000 cm ²)	56	1		1" Hose Barb	Z												
(0.8 µm upstream)*	LWS5	EFA: Effective Fil	tration	Area									nection	sonly					
Example																			
Example																			

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DST LWSXRXX1600B



0.2µm AseptiCap WS Hydrophilic PVDF Membrane Inline Capsule Filters

mdi AseptiCap WS are low protein binding hydrophilic PVDF 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			0.2μm						
Membrane		Hydrophilic PVDF							
Plastic Compo	nents	Polypropylene							
		Size							
Size		25 mm	50 mm						
Effective Filtrat	ion Area (Nominal)	5 cm ²	20 cm ²						
		Integrity Testing/Retention							
Bubble Point		<u>≥</u> 50psi (3.52	Kg/cm ²) with Water						
Microbial Reter	ntion	LRV>7 for Brevundimona	s diminuta (ATCC 19146) per cm ²						
		Operational							
Max. Operating	gTemperature	55 ℃	60 °C						
Max. Differenti	al Pressure	75 psi (5 Kg/cm² @25°C)	42 psi (3 Kg/cm²) @ 30 °C						
	By Gas	Sterilization by Ethylene Oxide							
Sterilization	By Autoclave	Autoclavable at 125°C for 30 minutes, 2 cycles. Cannot	t be in-line steam sterilized						
		Assurance							
Bacterial Endo	coxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>							
Toxicity		Passes Biological reactivity Test, In Vivo, as per USP <88> for Class VI plastics							

	Assurance
Cytotoxicity	Passes Biological Reactivity Tests, In Vitro, USP <87> for cytotoxicity
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

	-													_											
Туре		Siz	Size		Size	Inlet		Outlet	Outlet		Outlet		Outlet		Outlet		Outlet		Outlet		x	Sterility		Pac	k Size
	Code		Code		Code		Code		Code	1			Code		Code										
AseptiCap WS	IWSX	25mm	06	0.2 µm	01	1/8" Hose Barb	н	1/8" Hose Barb	Н			Non Sterile	1	100	04										
(0.45µm Upstream)						¹ ⁄4" Hose Barb	В	1⁄4" Hose Barb	В			EO Sterile	2	/											
						Female Luer Lock	M	Male Luer Slip	N		-		5												
								Male Luer Lock	L			. \													
Example:									- 2			1.													
IWSX		0	6	0		М	6.	N	1	Х	Х	1			04										

50 mm Inline Capsule Filters

Туре		Siz	ze	Pore	Size	Inlet		Outlet		Х	х	Sterility	,	Pac	k Size
	Code		Code		Code		Code		Code				Code		Code
AseptiCap WS	IWSX	50 mm	10	0.2 μm	01	1⁄4″ SHB	В	1⁄4″ SHB	В			Non Sterile	1	10	02
(0.45 µm Upstream)						³ / ₄ " Sanitary Flange	S	³ / ₄ " Sanitary Flange*	S			EO Sterile	2	100	04
Vented AseptiCap WS	VWSY					, ,			5	I					·]

(0.45 µm Upstream)

* In vented AseptiCap WS 34" Sanitary Flange is available as outlet only

Example:		N.					
IWSX 10	01	S	S	Х	X	1	04
	8 MM	.001×					

DST IVWSX011710B



AseptiCap WS-γ Hydrophilic PVDF Membrane Capsule Filters

mdi AseptiCap WS-y are low protein binding hydrophilic PVDF gamma sterilizable membrane capsule filters offering serial filtration incorporating a larger pore size upstream membrane to protect the downstream membrane for enhanced throughput.

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.

Key features

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

Applications

Sterile Filtration of

- Antibodies
- Protein Solutions
- Buffers
- 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

Ordering Information



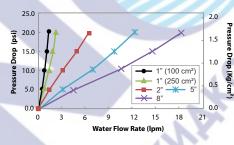
Specifications

Pore Size 0.2 μm

Materials of Construction

Membrane	Hydrophilic PVDF
Plastic Components	Polypropylene

Typical Water Flow Rates, 0.2µm



Microbial Retention

0.2 μm: LRV >7 for *B. diminuta* (ATCC 19146) per cm²
0.45μm: LRV >7 for *Serratia marcescens* (ATCC 14756) per cm²

Maximum Operating Temperature $80^{\circ}C @ \le 30 \text{ psi} (2 \text{ Kg/cm}^2)$

Maximum Differential Pressure 60 psi (4 Kg/cm²) @ 30 °C

Bubble Point (with water)

0.2 μm: ≥ 50psi (3.51Kg/cm²) **0.45 μm:** ≥ 30 psi (2.11 Kg/cm²)

Sterilization

By Irradiation: Gamma irradiatiable up to 50 kGy

By Autoclave: Autoclavable at 125°C for 30 minutes, 1 Cycle after gamma irradiation. Cannot be in-line steam sterilized

Toxicity

Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics

Cytotoxicity

Passes Biological Reactivity Tests, *In Vitro*, USP <87> for cytotoxicity

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

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 NVR test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

Туре		Size		Pore Size		Inlet /Outlet		Radiation Sterilizable		х	Sterility		Pack Size		
	Code	Length and EFA	Code		Code		Code		Code			Code		Code	
AseptiCap WS		1" (100 cm ²)	31	0.2µm	01	1⁄4″ SHB	Α	Yes	R		Non-Sterile	1	1	01	
1 · · · · ·	DWSX	1" (250 cm ²)	51	0.45µm	02	1/2" Hose Barb	D	No*****	Х	1	Gamma Sterile	3			
Upstream)		2" (500 cm ²)	52			1½"Triclover	E	*0.8 µm unstre	am is avai	m is available with 0.45µm capsule filters only					
AseptiCap WS (with 0.8µm	DWS5	5" (1000 cm ²)	53			34" Sanitary Flange	S	**Single step ½" hose barb and 3/8" Hose Barb end connections are not available							
Upstream)*		8" (2000 cm ²)	57			Quick Connector	J	in 1" capsule filter							
Single Step ½"Hose Barb						Single Step ½" Hose Barb**	Q	***Male luer slip end connection is available as outlet only in 1" capsule filters ****3/16" hose barb end connection is available in:							
Female L					Female Luer Lock	U	- 1" and 2" capsule filters as inlet and outlet								
EFA: Effective Filtration Area Male Luer Slip***				W	- 5" as outlet only										
3/16″ Hose B					3/16" Hose Barb****	N	 *****Gamma sterile capsule filters cannot be gamma irradiated again 								
Example 3/8" Hose Barb**							I								
DWSX		53		01		QQ		R		Х	1		0)1	
For Non-Sterile: DWSX5301OORX101 For Gamma Ste					erile: DWSX5301QQXX301										



AseptiCap WS Hydrophilic PVDF Membrane Capsule Filters

mdi AseptiCap WS are low protein binding hydrophilic PVDF membrane capsule filters offering serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

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.

Key features

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

Applications

Sterile Filtration of

- Antibodies
- Protein Solutions
- Buffers
- > Vaccine concentrates

Ordering Information

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

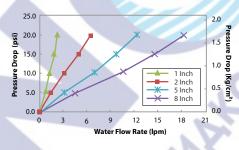
Specifications

Pore Size 0.2 μm and 0.45 μm

Materials of Construction

Membrane	Hydrophilic PVDF
Support Layer	Polyester
Plastic Components	Polypropylene

Typical Water Flow Rates, 0.2 μm



Microbial Retention

0.2 \mum: LRV >7 for *B. diminuta* (ATCC 19146) per cm²

0.45 μm: LRV >7 for *S. marcescens* (ATCC 14756) per cm²

Maximum Operating Temperature $80 \degree C @ \le 30 \text{ psi} (2 \text{ Kg/cm}^2)$

Maximum Differential Pressure 60 psi (4 Kg/cm²) @ 30 °C

Bubble Point (with water) 0.2 μm: ≥ 50psi (3.51Kg/cm²) **0.45 μm**: ≥ 30 psi (2.11 Kg/cm²)

Sterilization

By Autoclave: Autoclavable at 125°C for 30 minutes, 2 Cycles. Can not be in-line steam sterilized

By Gas: Sterilization by Ethylene Oxide

Toxicity

Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics

Cytotoxicity

Passes Biological Reactivity Tests, *In Vitro*, USP <87> for cytotoxicity

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

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 a 3 liter flush

Extractables with WFI

Passes NVR test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

Туре		Size		Pore Size		Inlet /Outlet		Х	X	Sterility		Pack Size		
	Code	Length and EFA	Code		Code		Code				Code		Code	
AseptiCap WS (0.45 µm Upstream)	DWSX	1" (250 cm ²)	51	0.2 µm	01	1⁄4″ SHB	A			Non-Sterile	1	1	01	
	DWSX	2" (500 cm ²)	52	0.45 μm	02	1⁄2" Hose Barb	D			EO Sterile	2			
AseptiCap WS		5" (1000 cm ²)	53			1½" Sanitary Flange	E					-		
(0.8 µm Upstream)*	DWS5	8" (2000 cm ²)	57			34" Sanitary Flange	S			ole with 0.45µm cap				
						Quick Connector	J	**Single step ½" hose barb and 3/8" Hose Barb end connections are not available in 1" capsule filter						
						Single Step ½" Hose Barb**	Q		***Male luer slip end connection is available as outlet only in 1" capsule					
						Female Luer Lock	U	filters	shp chu con		us outlet	only in	i cupsu	
-						Male Luer Slip***	w	****3/16" hose barb end connection is available in: - 1" and 2" capsule filters as inlet and outlet - 5" as outlet only						
EFA: Effective Filtration Area					3/16" Hose Barb****	N								
zample						3/8" Hose Barb**	I							
DWSX 53 01						EE		X X 1 01						

DST DWSX01X1630C