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

mdi 0.1µm *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 large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

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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

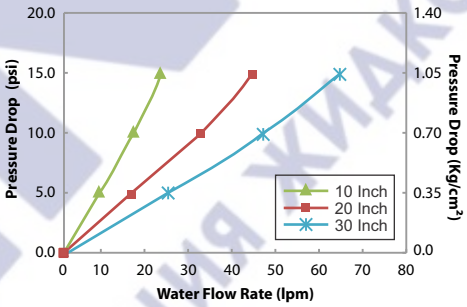
Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 210.3(b)(6)
Meets and Exceeds USFDA 21 CFR 177.1520

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 cm^2

Maximum Operating Temperature

80 °C @ ≤ 30 psi (2 Kg/cm^2)

Maximum Differential Pressure

60 psi (4 Kg/cm^2) @ 30 °C

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

Extractables with WFI

Passes NVR test as per USP <661>

Oxidizable Substances

Passes test as per USP <1231>

Ordering Information

Type		Size		Pore Size		Inlet /Outlet		Radiation Sterilizable		Inline/T-Line		Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code		Code		Code		Code		Code
AseptiCap WS (0.2µm upstream)	LWS1	5" (3000 cm^2)	53	0.1µm	36	1½" Triclover	E	Yes	R	Inline	X	Non-Sterile	1	1	01
		10" (6000 cm^2)	54			Single Step ½" Hose Barb	Q	No**	X	T-Line***	T	Gamma Sterile	3		
AseptiCap WS (0.45µm upstream)	LWSX	20" (12000 cm^2)	55			3/8" Hose Barb	I								
		30" (18000 cm^2)	56			1" Hose Barb*	Z								

*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

EFA: Effective Filtration Area

Example

LWS1	54	36	QQ	R	X	1	01

For Non-Sterile: LWS15436QQRX101 **For Gamma Sterile: LWS15436QQXX301**

DATA SHEET

Advanced Microdevices Pvt. Ltd., 20-21, Industrial Area, Ambala Cantt - 133006, INDIA
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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

Specifications

Materials of Construction

Membrane	Hydrophilic PVDF
Plastic Components	Polypropylene

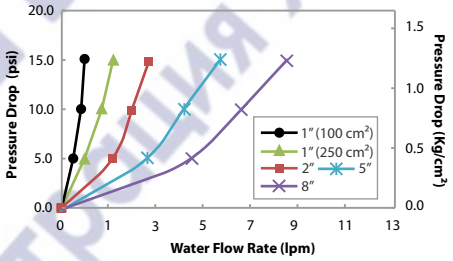
Microbial Retention
LRV >7 for *Acholeplasma laidlawii* (ATCC 23206) per cm^2

Bubble Point with 50% IPA/Water
≥ 31 psi

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

Maximum Differential Pressure
60 psi (4 Kg/cm^2) @ 30 °C

Typical Water Flow Rates



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

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code		Code			Code		Code
AseptiCap WS (with 0.45µm Upstream)	DWSX	1" (100 cm^2)	31	0.1µm	36	¼" SHB	A	Yes	R		Non-Sterile	1	1	01
		1" (250 cm^2)	51			½" Hose Barb	D	No****	X		Gamma Sterile	3		
AseptiCap WS (with 0.2µm Upstream)	DWS1	2" (500 cm^2)	52			1½" Sanitary Flange	E							
		5" (1000 cm^2)	53			¾" Sanitary Flange	S							
		8" (2000 cm^2)	57			Quick Connector	J							
						Single Step ½" Hose Barb*	Q							
						Female Luer Lock	U							
						Male Luer Slip**	W							
						3/16" Hose Barb***	N							
						3/8" Hose Barb*	I							

* Single step ½" hose barb and 3/8" hose barb end connections are not available in 1" Capsule filter
**Male luer slip end connection is available as outlet only in 1" capsule filters
***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

EFA: Effective Filtration Area

Example

DWSX	53	36	QQ	R	X	1	01

For Non-Sterile: DWSX5336QQRX101 **For Gamma Sterile: DWSX5336QQXX301**

DATA SHEET

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mdi Membrane Technologies

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 Components		Polypropylene	
Size			
Size		25 mm	50 mm
Effective Filtration Area (Nominal)		5 cm^2	20 cm^2
Integrity Testing/Retention			
Bubble Point		≥ 31psi (2.18Kg/cm^2) with 50% IPA/Water Solution	
Microbial Retention		LRV>7 for *Acholeplasma laidlawii* (ATCC 23206) per cm^2	
Operational			
Max. Operating Temperature		55 °C	60 °C
Max. Differential Pressure		75 psi (5 Kg/cm^2 @25°C)	42 psi (3 Kg/cm^2) @ 30 °C
Sterilization	By Gas	Sterilization by Ethylene Oxide	
	By Autoclave	Autoclavable at 125°C for 30 minutes, 2 cycles. Cannot be in-line steam sterilized	
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, *In Vivo*, as per USP <88> for Class VI plastics	

DATA SHEET

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

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code		Code				Code		Code
AseptiCap WS (0.45µm Upstream)	IWSX	25mm	06	0.1 µm	36	⅛" Hose Barb	H	⅛" Hose Barb	H			Non Sterile	1	100	04
AseptiCap WS (0.2µm Upstream)	IWS1					¼" Hose Barb	B	¼" Hose Barb	B			EO Sterile	2		
						Female Luer Lock	M	Male Luer Slip	N						
								Male Luer Lock	L						

Example:

IWSX	06	36	M	N	X	X	1	04

50 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code		Code				Code		Code
AseptiCap WS (0.45 µm Upstream)	IWSX	50 mm	10	0.1 µm	36	¼" SHB	B	¼" SHB	B			Non Sterile	1	10	02
AseptiCap WS (0.2 µm Upstream)	IWS1					¾" Sanitary Flange	S	¾" Sanitary Flange*	S			EO Sterile	2	100	04
Vented *AseptiCap WS* (0.45 µm Upstream)	VWSX														
Vented *AseptiCap WS* (0.2 µm Upstream)	VWS1														

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

Example:

IWSX	10	36	S	S	X	X	1	04

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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

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 cm^2

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

Maximum Differential Pressure
60 psi (4 Kg/cm^2) @ 30 °C

Bubble Point
≥31psi (2.18 Kg/cm^2) 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 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

Type		Size		Pore Size		Inlet /Outlet		X	Inline/T-Line		Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code			Code		Code		Code
AseptiCap WS (0.2 µm upstream)	LWS1	5" (3000 cm^2)	53	0.1 µm	36	1½" Sanitary Flange	E		Inline	X	Non-Sterile	1	1	01
		10" (6000 cm^2)	54			Single Step ½" Hose Barb	Q		T-Line*	T	EO Sterile	2		
AseptiCap WS (0.45 µm upstream)	LWSX	20" (12000 cm^2)	55			3/8" Hose Barb	I							
		30" (18000 cm^2)	56			1" Hose Barb	Z							

*T-line Capsule Filter are available with 1½"Sanitary Flange I/O Connections only
Size 5" is available in Inline Capsule filters only

EFA: Effective Filtration Area

Example

LWS1	56	36	QQ	X	X	1	01

DATA SHEET

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DATA SHEET

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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 cm^2

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

Maximum Differential Pressure
60 psi (4 Kg/cm^2) @ 30 °C

Bubble Point
≥ 31psi (2.18Kg/cm^2) 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

Type		Size		Pore Size		Inlet /Outlet		X	X	Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code				Code		Code
AseptiCap WS (0.2 µm Upstream)	DWS1	1" (250 cm^2)	51	0.1 µm	36	¼" SHB	A			Non-Sterile	1	1	01
		2" (500 cm^2)	52			½" Hose Barb	D			EO Sterile	2		
AseptiCap WS (0.45 µm Upstream)	DWSX	5" (1000 cm^2)	53			1½" Sanitary Flange	E						
		8" (2000 cm^2)	57			¾" Sanitary Flange	S						
						Quick Connector	J						
						Single Step ½" Hose Barb*	Q						
						Female Luer Lock	U						
						Male Luer Slip**	W						
						3/16" Hose Barb***	N						
						3/8" Hose Barb*	I						

*Single step ½" hose barb and 3/8" Hose Barb end connections are not available in 1" capsule filter

**Male luer slip end connection is available as outlet only in 1" capsule filters

***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

Example

DWSX	53	36	EE	X	X	1	01

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mdi
Membrane Technologies

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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 Components		Polypropylene	
Size			
Size		25 mm	50 mm
Microbial Retention		LRV>7 for *Acholeplasma laidlawii* (ATCC 23206) per cm^2	
Integrity Testing/Retention			
Bubble Point (with 50% IPA/Water)		≥ 31psi (2.18Kg/cm^2)	
Effective Filtration Area (Nominal)		5 cm^2	20 cm^2
Operational			
Max. Operating Temperature		55 °C	60 °C
Max. Differential Pressure		75 psi (5 Kg/cm^2 @25°C)	42 psi (3 Kg/cm^2) @ 30 °C
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	
Assurance			
Bacterial Endotoxin		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	

DATA SHEET

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

Type		Size		Pore Size		Inlet		Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code			Code		Code
AseptiCap WS (0.45µm Upstream)	IWSX	25mm	06	0.1 µm	36	⅛" Hose Barb	H	⅛" Hose Barb	H	Yes	R		Non Sterile	1	100	04
AseptiCap WS (0.2µm Upstream)	IWS1					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	36	M	N	X	X	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

Type		Size		Pore Size		Inlet		Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code			Code		Code
AseptiCap WS (0.45 µm Upstream)	IWSX	50 mm	10	0.1 µm	36	¼" SHB	B	¼" SHB	B	Yes	R		Non Sterile	1	10	02
AseptiCap WS (0.2 µm Upstream)	IWS1					¾" Sanitary Flange	S	¾" Sanitary Flange*	S	No	X		Gamma Sterile	3	100	04
Vented *AseptiCap WS* (0.45 µm Upstream)	VWSX															
Vented *AseptiCap WS* (0.2 µm Upstream)	VWS1															

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

Example:

IWSX	10	36	SS	SS	R	X	1	04

Note: Gamma Sterile filters can not be sterilized again

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

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Hydrophilic PVDF Membrane Large Capsule Filters

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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

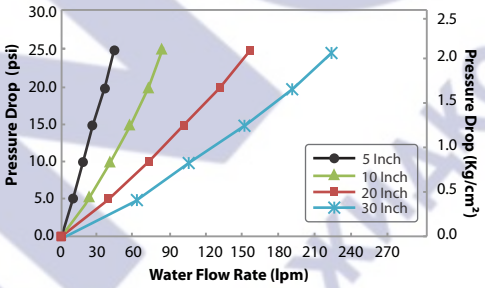
Specifications

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
0.2µm: LRV >7 for *B. diminuta* (ATCC 19146) per cm^2
0.45µm: LRV >7 for *Serratia marcescens* (ATCC 14756) per cm^2

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

Maximum Differential Pressure
60 psi (4 Kg/cm^2) @ 30 °C

Bubble Point
0.2 µm: > 50psi (3.51Kg/cm^2) with Water
0.45 µm: > 30 psi (2.11 Kg/cm^2) 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>

Ordering Information

DATA SHEET

Type	Code	Size	Code	Pore Size	Code	Inlet /Outlet	Code	Radiation Sterilizable	Code	Inline/T-Line	Code	Sterility	Code	Pack Size	Code
AseptiCap WS (0.45 µm upstream)	LWSX	5" (3000 cm^2)	53	0.2µm	01	1½" Triclover	E	Yes	R	Inline	X	Non-Sterile	1	1	01
		10" (6000 cm^2)	54	0.45µm	02	Single Step ½" Hose Barb	Q	No**	X	T-Line***	T	Gamma Sterile	3		
		20" (12000 cm^2)	55			3/8" Hose Barb	I								
AseptiCap WS (0.8 µm upstream)*	LWS5	30" (18000 cm^2)	56			1" Hose Barb	Z								

EFA: Effective Filtration Area

**0.45 µm capsule filters are available with 0.8 µm upstream only
**Gamma sterile capsule filters cannot be gamma irradiated again
***T-line Capsule Filters are available with 1½"Sanitary Flange I/O Connections only
Size 5" is available in Inline Capsule filters only

Example

LWSX	56	01	QQ	R	X	1	01

For Non-Sterile: LWSX5601QQRX101 **For Gamma Sterile: LWSX5601QQXX301**

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mdi Membrane Technologies

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.

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

Applications

Sterile Filtration of

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

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 Components		Polypropylene	
Size			
Size		25 mm	50 mm
Effective Filtration Area (Nominal)		5 cm^2	20 cm^2
Integrity Testing/Retention			
Bubble Point		≥ 50psi (3.52 Kg/cm^2) with Water	
Microbial Retention		LRV>7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2	
Operational			
Max. Operating Temperature		55 °C	60 °C
Max. Differential Pressure		75 psi (5 Kg/cm^2 @25°C)	42 psi (3 Kg/cm^2) @ 30 °C
Sterilization	By Gas	Sterilization by Ethylene Oxide	
	By Autoclave	Autoclavable at 125°C for 30 minutes, 2 cycles. Cannot be in-line steam sterilized	
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, *In Vivo*, as per USP <88> for Class VI plastics	

DATA SHEET

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

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code		Code				Code		Code
AseptiCap WS (0.45µm Upstream)	IWSX	25mm	06	0.2 µm	01	⅛" Hose Barb	H	⅛" Hose Barb	H			Non Sterile	1	100	04
						¼" Hose Barb	B	¼" Hose Barb	B			EO Sterile	2		
						Female Luer Lock	M	Male Luer Slip	N						
								Male Luer Lock	L						

Example:

IWSX	06	01	M	N	X	X	1	04

50 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code		Code				Code		Code
AseptiCap WS (0.45 µm Upstream)	IWSX	50 mm	10	0.2 µm	01	¼" SHB	B	¼" SHB	B			Non Sterile	1	10	02
Vented *AseptiCap WS* (0.45 µm Upstream)	VWSX					¾" Sanitary Flange	S	¾" Sanitary Flange*	S			EO Sterile	2	100	04

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

Example:

IWSX	10	01	S	S	X	X	1	04

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AseptiCap WS-γ
Hydrophilic PVDF Membrane Capsule Filters

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
- 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

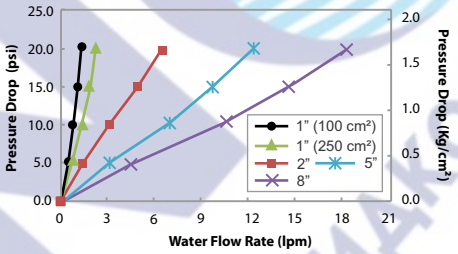
Specifications

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 cm^2
0.45µm: LRV >7 for *Serratia marcescens* (ATCC 14756) per cm^2

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

Maximum Differential Pressure
60 psi (4 Kg/cm^2) @ 30 °C

Bubble Point (with water)
0.2 µm: ≥ 50psi (3.51Kg/cm^2)
0.45 µm: ≥ 30 psi (2.11 Kg/cm^2)

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>

Ordering Information

Type		Size		Pore Size		Inlet /Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code	Length and EFA	Code		Code		Code		Code			Code		Code
AseptiCap WS (with 0.45µm Upstream)	DWSX	1" (100 cm^2)	31	0.2µm	01	¼" SHB	A	Yes	R		Non-Sterile	1	1	01
		1" (250 cm^2)	51	0.45µm	02	½" Hose Barb	D	No*****	X		Gamma Sterile	3		
		2" (500 cm^2)	52			1½" Triclover	E							
*AseptiCap WS (with 0.8µm Upstream)**	DWS5	5" (1000 cm^2)	53			¾" Sanitary Flange	S							
		8" (2000 cm^2)	57			Quick Connector	J							
						Single Step ½" Hose Barb**	Q							
						Female Luer Lock	U							
						Male Luer Slip***	W							
						3/16" Hose Barb****	N							
						3/8" Hose Barb**	I							

*0.8 µm upstream is available with 0.45µm capsule filters only
**Single step ½" hose barb and 3/8" Hose Barb end connections are not available in 1" capsule filter
***Male luer slip end connection is available as outlet only in 1" capsule filters
****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

EFA: Effective Filtration Area

Example

DWSX	53	01	QQ	R	X	1	01

For Non-Sterile: DWSX5301QQRX101 **For Gamma Sterile:** DWSX5301QQXX301

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AseptiCap WS
Hydrophilic PVDF Membrane Capsule Filters

DATA SHEET

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
- 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

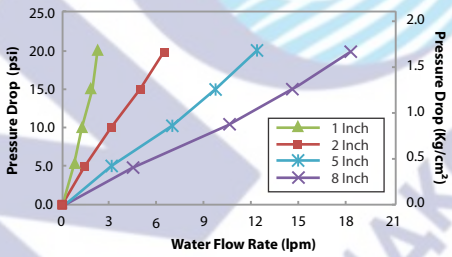
Specifications

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 µm: LRV >7 for *B. diminuta* (ATCC 19146) per cm^2
0.45 µm: LRV >7 for *S. marcescens* (ATCC 14756) per cm^2

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

Maximum Differential Pressure
60 psi (4 Kg/cm^2) @ 30 °C

Bubble Point (with water)
0.2 µm: ≥ 50psi (3.51Kg/cm^2)
0.45 µm: ≥ 30 psi (2.11 Kg/cm^2)

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

Type		Size		Pore Size		Inlet /Outlet		X	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	¼" SHB	A			Non-Sterile	1	1	01
		2" (500 cm^2)	52	0.45 µm	02	½" Hose Barb	D			EO Sterile	2		
AseptiCap WS (0.8 µm Upstream)*	DWS5	5" (1000 cm^2)	53			1½" Sanitary Flange	E						
		8" (2000 cm^2)	57			¾" Sanitary Flange	S						
						Quick Connector	J						
						Single Step ½" Hose Barb**	Q						
						Female Luer Lock	U						
						Male Luer Slip***	W						
						3/16" Hose Barb****	N						
						3/8" Hose Barb**	I						

*0.8 µm upstream is available with 0.45µm capsule filters only
**Single step ½" hose barb and 3/8" Hose Barb end connections are not available in 1" capsule filter
***Male luer slip end connection is available as outlet only in 1" capsule filters
****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

Example

DWSX	53	01	EE	X	X	1	01

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