



0.2μm AseptiCap WL/WS-γ Gamma Irradiatable Sterilization Grade Hydrophilic PVDF Membrane Capsule Filters for Liquid Streams in Biopharmaceuticals Data Sheet

Biopharmaceutical processing requires sterilizing grade microfiltration at multiple stages to meet specific process requirements.

Processes managers are continuously looking for microfiltration solutions to upstream, downstream, intermediate processes and final biological preparations. Since bio manufacturing is a multi stage process and bio molecules by nature are extremely sensitive, they are looking for:

- Minimizing protein losses due to adsorption to improve over all product yields
- Minimizing filter extracts which add up due to multiple points of use in a process
- > High throughputs to achieve process economy
- Choice of filter end connections for easy and reliable quick connections
- > Absolute retentions for higher sterility assurance

mdi AseptiCap WL/WS-γ are low protein binding hydrophilic PVDF gamma sterilizable membrane capsule filters. AseptiCap WS-γ offers serial filtration incorporating a larger pore size upstream membrane to protect the downstream membrane for enhanced throughput. These filter devices are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as high retention efficiency, very high protein recoveries, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

With the advantages of pre filtration layer built into the *AseptiCap WS*- γ for higher throughputs, linear scalability of filter area for smooth transitions from lab scale to pilot to process scale and widest range of end connections for quick and reliable connections to the existing fittings,

mdi AseptiCap WL/WS- γ filters are a universal solution for process filtration.

AseptiCap WL/WS-γ

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Gamma Sterilizable PVDF Membrane Devices for Biopharmaceuticals

Asepticap WL/WS- γ 0.2 μ m capsule filters use **mdi** hydrophilic PVDF membrane in gamma stable polypropylene housing. No adhesives or glue are used in the manufacturing process and all bonding is done by heat welding.

The products are deeply validated for use in biopharmaceutical applications and specially recommended for single use systems. Asepticap WL/WS- γ are manufactured in class 10,000 clean rooms and ISO 9001:2015 certified facilities.

Packaging is done in double polybags for direct irradiation by gamma or for convenience of taking *Asepticap* in clean areas for making disposable assemblies for subsequent sterilization.

Types Available

AseptiCap WS-γ: Double Layer (with Prefilter)

AseptiCap WL-γ: Single Layer (without Prefilter)

Applications

Sterile Filtration of

- Antibodies
- Protein Solutions
- Buffers
- Vaccine concentrates
- Small Volume Parenterals

Key Features

- Absolute retention
- > 100% integrity tested
- Low protein binding
- > Very low hold up volume in filters
- > High flow rates
- Serial construction with prefilter for higher throughput with fouling streams
- ➤ Bioburden maintained below 1000 cfu/device
- ➤ Endotoxin level certified to be < 0.25 EU/ml
- Wide range of end connections
- Products available for total scalability from a few ml to thousands of liters
- Total traceability through unique serial number for each filter
- > Individual certificate of quality for each device
- > Sterilizable by Gamma irradiation

Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the 'Sterilizing Filter' with drug product under simulated worst-case conditions of use.

mdi provides validation services supported by customized validation protocols and world class test facilities to assist you in filter validations with your specific drug product.

Quality Assurance

Datasheet

mdi's quality management system emphasizes on quality by design rather by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

Certificate of Quality

Each capsule filter is accompanied by individual certificate of quality to ensure traceable documentation at user's end.

It certifies the product compliance to various regulatory as well as user requirements.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention with *B.diminuta* (ATCC 19146) as per ASTM F838 to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each *AseptiCap WL/WS*- γ is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Flow Rate

Each lot is tested for clean water flow rates to ensure that flow rates are within the specifications.

Adsorption

AseptiCap WL/WS- γ filters are validated for low protein binding to ensure minimal active ingredient losses when used for filtration of high value proteins.

Pressure, Temperature Endurance

AseptiCap WL/WS- γ filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

These filters are also validated for high burst pressure to ensure user safety in case of inadvertent pressure build-up.

Extractables

Extractables/leachables from sterilizing filters, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

AseptiCap $WL/WS-\gamma$ filters are validated to exhibit low extractables under harsh extraction conditions.

Bioburden Testing

Device bioburden is tested as per ISO 117 37-1 and assured to be <1000 cfu/device.

Endotoxin Testing

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

Total Traceability

AseptiCap $WL/WS-\gamma$ filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

Packaging Integrity

AseptiCap WL/WS- γ filters are fitted with vent caps and are packed in double polybags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room assembly or process areas.

Other Regulatory Compliance

- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for indirect food additives
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics
- Complete filter devices tested for cytotoxicity as per Biological Reactivity Tests, In-vitro, USP <87>

Performance Data

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Very Low Hold-Up Volumes

mdi PVDF membrane capsule filters are designed to offer very low hold-up volumes to minimize filtration losses and maximize product recovery.

Filter Devices	EFA (Nominal)	Hold up Volume
AseptiCap WL/WS-γ, 25 mm	5cm²	< 50μl
AseptiCap WL/WS-γ, 50 mm	20cm²	< 200µl
AseptiCap WL/WS-γ, 1"	250cm ²	< 5ml
AseptiCap WL/WS-γ, 2"	500cm²	< 25ml
AseptiCap WL/WS-γ, 5"	1000cm ²	< 45ml
AseptiCap WL/WS-γ, 8"	2000cm ²	< 60ml
AseptiCap WL/WS-γ, 5"	3000cm ²	< 80ml
AseptiCap WL/WS-γ, 10″	6000cm ²	< 150ml
AseptiCap WL/WS-γ, 20″	12000cm ²	< 250ml
AseptiCap WL/WS-γ, 30"	18000cm²	< 350ml

Solvent	Non Volatile Residue
	mg/10" Capsule Filters
	60.8 mg
Water	64.8 mg
	57.6 mg
	237.6 mg
Ethanol	317.7 mg
	244.8 mg

mdi 0.2 μ m *AseptiCap WL/WS-\gamma* hydrophilic PVDF membrane capsule filters exhibit very low non volatile residue (NVR) with Water and Ethanol.

Extractables

mdi filters give low extractables under harsh preconditioning and extraction conditions.

Low extractables mean less addition to impurity profile of the biological product from the filters.

Easy Connect

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Widest Range of End Connections

Biopharmaceutical processes involve transfer of high value fluids through multiple process steps. Making high quality, reliable, flexible and functionally convenient connectivity with filters is of utmost value to the bio-processors.

mdi AseptiCap WL/WS-y filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand prevalent sterilization methods including gamma irradiation.



1/2" HB



1/4" SHB



3/8" Hose Barb



34" Sanitary Flange



1/2" Single Stepped **Hose Barb**



Quick Connector



Female Luer Lock





11/2" Sanitary Flange

1/4" MNPT

Male Luer Slip

Variety of end connections

Customized Connectivity

mdi AseptiCap WL/WS-γ filters are available in a wide range of end connections and are also customized to offer different inlet-outlet combinations to meet the unique connectivity needs in biopharmaceutical process assemblies where, for example, stainless steel components with sanitary flange connections are sometimes required to be connected to single use disposable systems through quick-connectors or hose barb connections.



11/2" Sanitary Flange to 1/2"Barb Hose







AseptiCap with HighSecurity 1/2" hose barb connection

Linear Upscaling from R&D to Production Process

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Scientists are concerned about filter fluid interaction impacting the stability, purity, strength etc. of the drug product, and they take a keen interest in filter selection at the formulation development stage itself. Although preliminary compatibility data support initial filter selection, for stability studies detailed filter validations are required to provide enough documented evidence to justify specific filter use.

A critical requirement that needs to be addressed at this stage is of scalability from R&D to pilot scale to full scale production processes.

mdi offers a wide range of *AseptiCap WL/WS-\gamma* filters to provide linear scale up from lab scale to production process.

While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process are identical for all filter devices starting from 5 cm² to 18000cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions.

mdi provides complete documentation for each of the *AseptiCap WL/WS-γ* filters there by reducing the additional validation cost and time.



AseptiCap WL/WS-γ 25mm, 5cm²



AseptiCap WL/WS-γ
50mm, 20cm²



AseptiCap WL/WS-γ 1", 250cm²



AseptiCap WL/WS-γ 2", 500cm²



AseptiCap WL/WS-γ 5", 1000cm²



AseptiCap WL/WS-γ 8", 2000cm²



AseptiCap WL/WS-γ 5", 3000cm²



AseptiCap WL/WS-γ
10", 6000cm²



AseptiCap WL/WS-γ
20". 12000cm²



AseptiCap WL/WS-γ
30", 18000cm²

Specifications 0.2 μm *AseptiCap WL/WS*-γ

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		Construction						
Membrane	0.2 μm Hydrophilic PVDF							
Pre-filter Membrane	0.8 μm or 0.45 μm Hydroph	nilic PVDF						
Support Layers	ort Layers Polyester (Small and Large Capsule Filters only)							
Plastic Parts	Gamma Stable Polypropyle	ene						
Vent and Drain	1/4" Hose Barb with Silicone	"O" ring						
	Integri	ty Testing / Retention						
Bubble Point	≥ 50 psi (3.52 Kg/cm²) with	n Water						
Microbial Retention	LRV >7 for Brevundimonas	<i>diminuta</i> (ATCC 19146) per cm²	2					
Max. Air Diffusion Flows per 10" Capsule Filter	≤ 30 ml/min @ 37 psi (2.6 K	(g/cm²) with water						
		Operational						
Size	25 mm Inline Capsule Filters	50 mm Inline Capsule Filters	1", 2", 5", 8" Small Capsule Filters	5", 10", 20", 30 Large Capsule Filters				
Max. Operating Temperature	55 °C	60 °C	80 °C @ < 30	psi (2 Kg/cm²)				
Max. Differential Pressure	75 psi (5 Kg/cm²) @ 25 °C	42 psi (3 Kg/cm²) @ 30 °C	60 psi (4 Kg/	′cm²) @ 30 °C				
Sterilization	By Irradiation: Gamma Irra These filters must not be a	adiatiable up to 50 kGy. utoclaved or in-line steam steri	ilized.					
Shelf Life	2 years after Gamma Sterili	zation						
		Assurance						
Toxicity	Passes Bioreactivity test, In	Vivo, as per USP <88> for Class	s VI plastics					
Cytotoxicity	Passes Biological Reactivity	Tests, In vitro, USP <87> for Cy	ytotoxicity					
Bacterial Endotoxin	Aqueous extracts exhibit <	0.25 EU/ml as established by I	imulus Amebocyte Lysate (L	AL) Test as per USP <85>				
Non Fiber Releasing	Passes test as per USP and	comply with USFDA 21 CFR Pa	rt 210.3(b)(6) for fiber release					
TOC and Conductivity		ts of USP for TOC <643> and Co le filters ,10 liter flush for 5" ca						
Extractables with WFI	Passes NVR test as per USP	<661>						
Indirect Food Additives	All Polypropylene compon	ents meet the FDA Indirect Foo	od Additive requirements cite	ed in 21 CFR Part 177.1520				
Oxidizable Substances	Passes test as per USP <123	31>						
Quality Management System	ISO-9001:2015 Certified							
USFDA	DMF No. 015554							

Specifications 0.2 μm *AseptiCap WL/WS*-γ

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Inline Capsule Filters

Typical Dimension (in mm)	Inline Cap	sule Filters		
Inlet/ Outlet	25mm	50mm		
1/4" - 3%" Stepped Hose Barb I/O	-	79		
1/4" Single Step Hose Barb I/O	38	-		
¾" Sanitary Flange I/O	-	51		
Female Luer Lock Inlet/ Male Luer Slip Outlet	23	-		
1/8" Hose Barb I/O	36	-		
Operational Radius	15	28		
Effective Filtration Area (EFA) (cm²)	5 cm ²	20 cm ²		

Small Capsule Filters

Typical Dimensions (in mm)		Small Cap	sule Filter	s
End Connections	1"	2"	5″	8″
1/4" SHB I/O	94	122	172	223
¾" Sanitary Flange Inlet I/O	85	104	155	206
Quick Connector	100	113	164	218
1½" Sanitary Flange I/O	92	112	164	216
½" Hose Barb I/O	90	112	162	214
½" Single Step Hose Barb I/O	-	115	165	218
1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	-	112	165	216
3/8" Hose Barb I/O	-	115	167	217
Operational Radius	40	65	65	65
Effective Filtration Area (EFA)	100	500	1000	2000
(cm²)	250	300	1000	2000

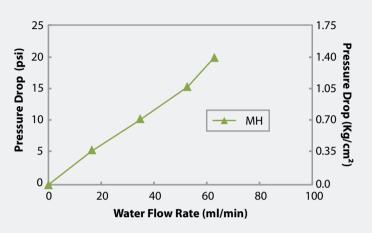
Large Capsule Filters

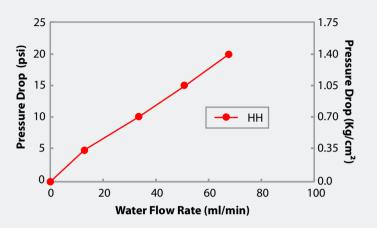
Typical Dimensions (in mm)	Inl	ine Cap	sule Filt	T-line Capsule Filters			
End Connections	5"	10"	20"	30"	10"	20"	30"
1½" Sanitary Flange I/O	205	330	600	855	340	580	840
3⁄4" Sanitary Flange I/O	214	335	х	х	х	х	х
½" Single Step Hose Barb I/O	218	336	630	890	х	х	х
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334	620	870	х	х	х
%" Hose Barb I/O	211	332	634	878	х	х	х
1" Hose Barb I/O	х	405	635	895	х	х	х
Operational Radius	80	80	80	80	80	80	80
Effective Filtration Area (EFA) (cm²)	3000	6000	12000	18000	6000	12000	18000

Typical Water Flow Rates 0.2 μm *AseptiCap WL/WS-*γ

Datasheet

25mm Inline Capsule Filters



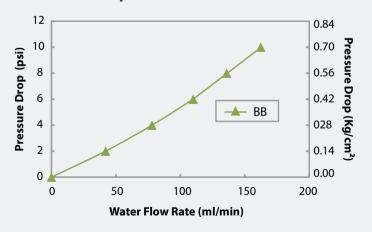


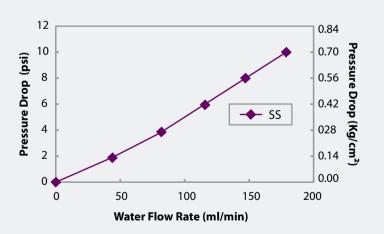
End Connection Type:

M: Female Luer Lock

H: 1/8" Hose Barb

50mm Inline Capsule Filters





End Connection Type:

B: 1/4" - 3/8" Stepped Hose Barb

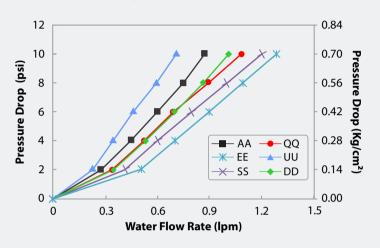
S: ¾" Sanitary Flange

Typical Water Flow Rates 0.2 μm *AseptiCap WL/WS-*γ

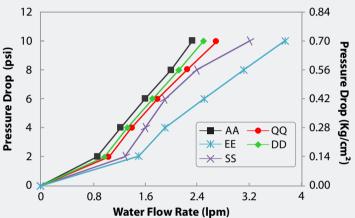
Datasheet

Small Capsule Filters

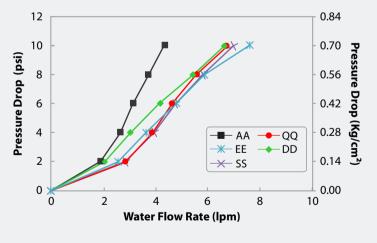
0.2μm AseptiCap WS-γ, 1" Capsule Filter



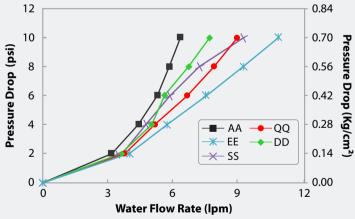
0.2μm AseptiCap WS-γ, 2" Capsule Filter



0.2μm AseptiCap WS-γ, 5" Capsule Filter



0.2μm AseptiCap WS-γ, 8" Capsule Filter



End Connection Type:

A: ¼"Stepped Hose Barb E: 1½"Sanitary Flange

S: ¾" Sanitary Flange

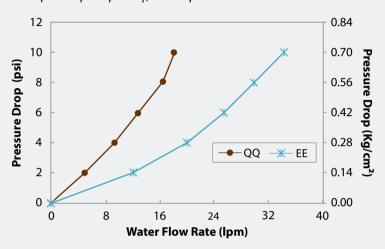
- Q: 1/2" Single Step Hose Barb
- U: Female Luer Lock
- D: 1/2" Hose Barb

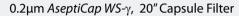
Typical Water Flow Rates 0.2 μm *AseptiCap WL/WS-*γ

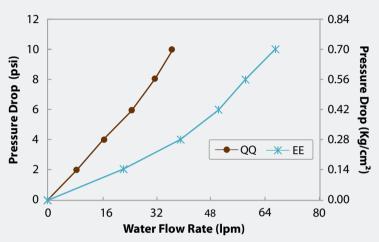
Datasheet

Large Capsule Filters

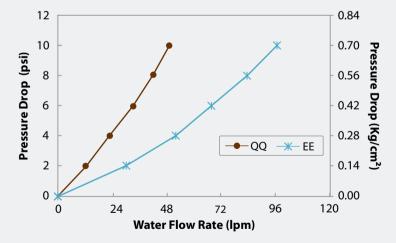
0.2μm AseptiCap WS-γ, 10" Capsule Filter







0.2μm AseptiCap WS-γ, 30" Capsule Filter



End Connection Type:

E: 11/2" Sanitary Flange

Q: 1/2" Single Step Hose Barb

Ordering Information

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0.2 μm AseptiCap WL/WS-γ 25mm Hydrophilic PVDF Membrane Capsule filter

Туре		Si	ze	Pore	Size	Inlet/Outlet		Radia Sterili		Х	Sterilit	у	Pack	Size
	Code		Code		Code		Code		Code			Code		Code
IWL		25mm	06	0.2μm	01	Female Luer Lock	М	Yes	R		Non Sterile	1	100	04
(Single Layer)	IWLX					Male Luer Slip	N	No*	Х] ,	Gamma Sterile	3		
IWS	11465					1/8" Hose Barb	Н							
(0.8 µm Upstream)	IWS5					1⁄4" Hose Barb	В				1			
IWS (0.45 μm Upstream)	IWSX													
Example:		,	1		1	\			1					1
IWSX		0	б		01	MN		ı	R	Х	1		0	4

^{*}Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: IWLX0601MNRX104

Example for gamma Sterile: IWLX0601MNXX304

0.2 μm AseptiCap WL/WS-γ 50mm Hydrophilic PVDF Membrane Capsule filter

Туре		Si	ze	Pore	Size	Inlet/Outl	et	Radiation Sterilizable		Radiation Sterilizable		Х	Sterilit	у	Pack S	Size
	Code		Code		Code		Code		Code			Code		Code		
VWL		50mm	10	0.2μm	01	1/4" - 3/8" Stepped	В	Yes	R		Non Sterile	1	10	02		
(Single Layer)	VWLX					Hose Barb		No*	Х		Gamma Sterile	3				
VWS (0.8 µm Upstream)	VWS5					¾" Sanitary Flange	S				1					
VWS (0.45 μm Upstream)	VWSX															
Example:		•	1		1			•			1					
vwsx		10)	0	1	ВВ		R		Х	1		02	2		

^{*}Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: VWSX1001BBRX102

Example for gamma Sterile: VWSX1001BBXX302

Note: Inlet/Outlet Connections and Dimensions available with different diameter filters as follows:

Connections Available										
Inlet/Outlet	25mm	50mm								
¼" - ¾" Stepped Hose Barb	х	√								
¾" Sanitary Flange	х	√								
Female Luer Lock	Inlet Only	Х								
Male Luer Slip	Outlet Only	Х								
1/8" Hose Barb	√	Х								
Male Luer Lock	Outlet Only	Х								
1/4" Hose Barb	√	Х								

Datasheet

Ordering Information

0.2 μm AseptiCap WL/WS-γ Hydrophilic PVDF Membrane Capsule filter

Туре		Si	ize	Pore	Size	Inlet/Outlet		Radia Sterili		Ве	H	Sterility		Pac	k Size
	Code		Code		Code		Code		Code		Code		Code		Code
DWL	DWLX	1"	31	0.2µm	01	1/4" SHB	Α	Yes	R	Yes**	В	Non Sterile	1	1	01
(Single Layer)	DWLX	'	51		-	1/4" MNPT (18 TPI)	В	No*	Х	No Bell	Χ	Gamma Sterile	3		
DWS	DWS5	2"	52			1/4" BSP (19 TPI)	М			Bell with	С				
(0.8 μm Upstream)	DWSS	5"	53			1/4" BSP (19 TPI) with O-ring	Р		I	cover	_	I			
DWS	DWSX	8"	57			1/4" BSP	F								
(0.45 μm Upstream)	J 115/1		İ			½" MNPT	С			1					
						½" Hose Barb	D								
						1½" Sanitary Flange	Е								
						¾" Sanitary Flange	S								
						Quick Connector	J								
						½" Single Step Hose Barb	Q								
						Female Luer Lock	U								
						Male Luer Slip	W								
						¾6" Hose Barb	N								
						3%" Hose Barb	I								
Example:		,		,	•	+	,			\	,	\			\downarrow
DWS	(57	(01	DD		F	?	Х	(1		0	1

^{*} Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: DWLX5201QQRX101

Example for gamma Sterile: DWLX5201QQXX301

1/2" Hose Barb outlet connections in 1", 2", 5" and 8" capsule filters

1/4" SHB outlet connection in 1" capsule filters only

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Inlet/Outlet	Size/Length									
illet/Odtlet	1"	2"	5"	8″						
1/4" Stepped Hose Barb		$\sqrt{}$	√	$\sqrt{}$						
½" Single Step Hose Barb	Х	√	√	$\sqrt{}$						
½"Hose Barb	√	√	√	√						
1½" Sanitary Flange	√	√	√	√						
¾"Sanitary Flange	√	√	√	√						
Quick Connector	√	√	√	√						
½"MNPT	Х	√	√	√						
1/4" MNPT (18TPI)	√	√	√	√						
1/4" BSP (19 TPI)	Inlet Only	Х	х	х						
1/4" BSP (19 TPI) with O-ring	Inlet Only	Х	Х	Х						
1/4" BSP	Inlet Only	√	√	√						
Female Luer Lock	√	√	√	√						
Male Luer Slip	Outlet Only	Х	Х	х						
3//6" Hose Barb	√	√	Outlet Only	х						
%" Hose Barb	х	V	√	V						

Bell at outlet Available with (Size/outlet)
1"/ ¼" SHB
1", 2", 5", 8"/ ½" HB

^{**} Bell is available with

Ordering Information

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0.2 μm AseptiCap WS-γ Hydrophilic PVDF Membrane Large Capsule filter

Туре		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline/ T-Line		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
LWL (Single Layer)	LWLX	5"	53	0.2μm	01	1/2" Single Step Hose Barb	Q	Yes	R	Inline	Х	Non Sterile	1	1	01
		10"	54			1½" Sanitary Flange	Е	No*	Х	T-Line**	Т	Gamma Sterile	3		
LWS (0.8 µm Upstream)	LWS5	20"	55			¾" Sanitary Flange	S								
	LVV33	30"	56			3%" Hose Barb	I								
LWS (0.45 µm Upstream)	LWSX					1" Hose Barb	Z								
Example: 🔻						↓ ·		•		•		\		,	↓
LWSX		54		01		EE		R		Т		1		01	

^{*} Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: LWS55301QQRX101

Example for gamma Sterile: LWS55301QQXX301

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Index/Outlet		Inli	ne	T-Line			
Inlet/Outlet	5″	10"	20"	30"	10"	20"	30"
1/2" Single Step Hose Barb	√	√	√	√	Х	х	Х
1½" Sanitary Flange	√	√	√	√	√	√	√
¾" Sanitary Flange	√	√	х	х	х	х	Х
%" Hose Barb	√	√	√	√	Х	х	Х
1" Hose Barb	Х	√	√	√	Х	Х	Х

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^{**}T-line is not available in 5" Capsule filter

^{**}T-line Capsule Filter are available with 11/2" Sanitary Flange I/O Connections Only