mdi
Membrane Technologies

Data Sheet

0.2µm *AseptiCap® WL/WS*

Sterilization Grade Hydrophilic PVDF Membrane Capsule Filters

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* are low protein binding hydrophilic PVDF membrane capsule filters. *AseptiCap® WS* 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* 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* filters are a universal solution for process filtration.

AseptiCap® WL/WS

PVDF Membrane Devices for Biopharmaceuticals

Datasheet

AseptiCap® WL/WS 0.2µm 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 bio-pharmaceutical applications and specially recommended for single use systems. *AseptiCap® WL/WS* 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*: Double Layer (with Prefilter)
- *AseptiCap® WL*: 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 Autoclave or Ethylene Oxide

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* 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 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 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 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 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 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

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, 25 mm	5cm²	< 50µl
AseptiCap® WL/WS, 50 mm	20cm²	< 200µl
AseptiCap® WL/WS, 1"	250cm²	< 5ml
AseptiCap® WL/WS, 2"	500cm²	< 25ml
AseptiCap® WL/WS, 5"	1000cm²	< 45ml
AseptiCap® WL/WS, 8"	2000cm²	< 60ml
AseptiCap® WL/WS, 5"	3000cm²	< 80ml
AseptiCap® WL/WS, 10"	6000cm²	< 150ml
AseptiCap® WL/WS, 20"	12000cm²	< 250ml
AseptiCap® WL/WS, 30"	18000cm²	< 350ml

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.

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

mdi 0.2 µm *AseptiCap® WL/WS* hydrophilic PVDF membrane capsule filters exhibit very low non volatile residue (NVR) with Water and Ethanol.

Easy Connect

Datasheet

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* 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.

½" HB

½" Single Stepped Hose Barb

1/4" MNPT

¼" SHB

Quick Connector

Male Luer Slip

3/8" Hose Barb

Female Luer Lock

1½" Sanitary Flange

¾" Sanitary Flange

½" MNPT

1" Hose Barb

Variety of end connections

Customized Connectivity

mdi *AseptiCap® WL/WS* 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.

1½" Sanitary Flange to ½"Barb Hose

1½" Sanitary Flange to ¾" Sanitary Flange

AseptiCap® with HighSecurity ½" hose barb connection

Linear Upscaling from R&D to Production Process

Datasheet

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* 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 cm^2 to 18000cm^2 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* filters there by reducing the additional validation cost and time.

AseptiCap® WL/WS
25mm, 5cm^2

AseptiCap® WL/WS
50mm, 20cm^2

AseptiCap® WL/WS
1", 250cm^2

AseptiCap® WL/WS
2", 500cm^2

AseptiCap® WL/WS
5", 1000cm^2

AseptiCap® WL/WS
8", 2000cm^2

AseptiCap® WL/WS
5", 3000cm^2

AseptiCap® WL/WS
10", 6000cm^2

AseptiCap® WL/WS
20", 12000cm^2

AseptiCap® WL/WS
30", 18000cm^2

Specifications

Datasheet

0.2 µm *AseptiCap® WL/WS*

Construction				
Membrane	0.2 µm Hydrophilic PVDF			
Pre-filter Membrane	0.8 µm or 0.45 µm Hydrophilic PVDF			
Support Layers	Polyester (Small and Large Capsule Filters only)			
Plastic Parts	Polypropylene			
Vent and Drain	¼" Hose Barb with Silicone "O" ring			
Integrity Testing / Retention				
Bubble Point	≥ 50 psi (3.52 Kg/cm^2) with Water			
Microbial Retention	LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2			
Max. Air Diffusion Flows per 10" Capsule Filter	≤ 30 ml/min @ 37 psi (2.6 Kg/cm^2) 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/cm^2)	
Max. Differential Pressure	75 psi (5 Kg/cm^2) @ 25 °C	42 psi (3 Kg/cm^2) @ 30 °C	60 psi (4 Kg/cm^2) @ 30 °C	
Sterilization by Autoclaving	Autoclavable at 125°C for 30 minutes, 2 cycles and it cannot be in-line steam sterilized			
Sterilization by EO	Sterilization by Ethylene Oxide			
Shelf Life	3 years after EO sterilization			
Assurance				
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>			
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release			
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 500ml flush for inline filters, 3 liter flush for small capsule filters ,10 liter flush for 5" capsule filters and 20 liter flush for 10" capsule filters			
Extractables with WFI	Passes NVR test as per USP <661>			
Indirect Food Additives	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR Part 177.1520			
Oxidizable Substances	Passes test as per USP <1231>			
Quality Management System	ISO-9001:2015 Certified			
USFDA	DMF No. 015554			

Specifications

Datasheet

0.2 µm *AseptiCap® WL/WS*

Dimensions (mm): Inline Capsule Filters

Inlet/ Outlet	25mm	50mm
¼" - ⅜" Stepped Hose Barb I/O	-	79
¼" Hose Barb I/O	38	-
¼" Single Step Hose Barb I/O	-	62
¾" Sanitary Flange I/O	-	51
Female Luer Lock Inlet/ Male Luer Slip Outlet	23	-
⅛" Hose Barb I/O	36	-
Operational Radius	15	28
Effective Filtration Area (EFA) (cm^2)	**5 cm^2**	**20 cm^2**

Small Capsule Filters

Typical Dimensions (in mm)	Small Capsule Filters			
End Connections	**1"**	**2"**	**5"**	**8"**
¼" 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
¼" Single Step Hose Barb I/O	90	106	160	212
Operational Radius	40	65	65	65
Effective Filtration Area (EFA) (cm^2)	**100** / **250**	**500**	**1000**	**2000**

Large Capsule Filters

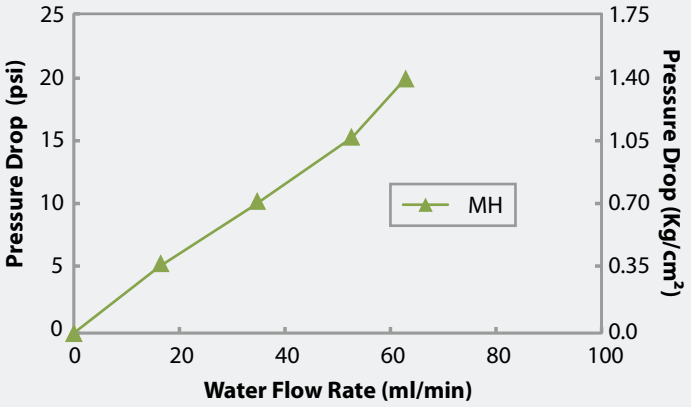
Typical Dimensions (in mm)	Inline Capsule Filters				T-line Capsule Filters		
End Connections	**5"**	**10"**	**20"**	**30"**	**10"**	**20"**	**30"**
1½" Sanitary Flange I/O	205	330	600	855	340	580	840
¾" Sanitary Flange I/O	214	335	x	x	x	x	x
½" Single Step Hose Barb I/O	218	336	630	890	x	x	x
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334	620	870	x	x	x
⅜" Hose Barb I/O	211	332	634	878	x	x	x
1" Hose Barb I/O	x	405	635	895	x	x	x
Operational Radius	80	80	80	80	80	80	80
Effective Filtration Area (EFA) (cm^2)	**3000**	**6000**	**12000**	**18000**	**6000**	**12000**	**18000**

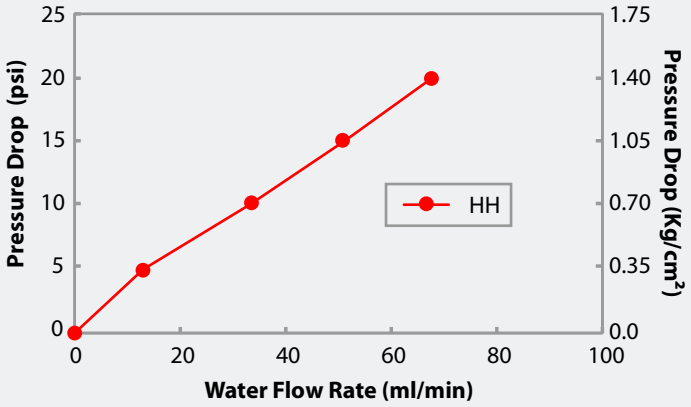
Typical Water Flow Rates

0.2 µm *AseptiCap® WL/WS*

Datasheet

25mm Inline Capsule Filters



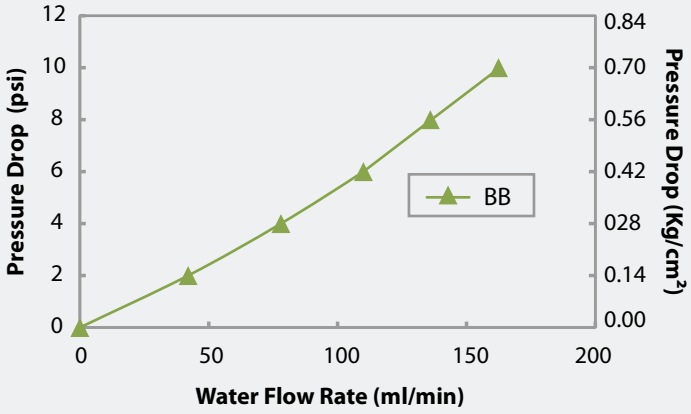


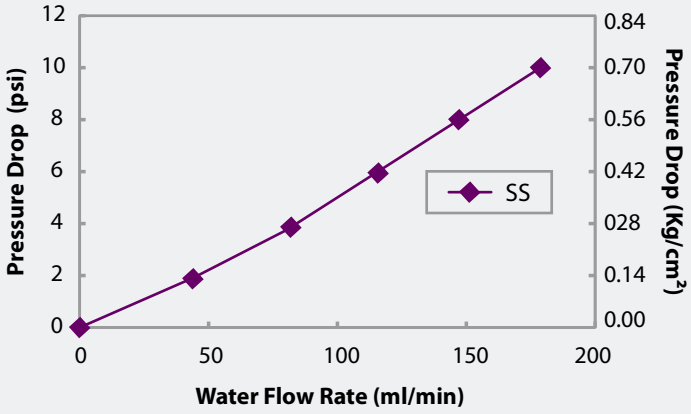
End Connection Type:

M: Female Luer Lock

H: ⅛" Hose Barb

50mm Inline Capsule Filters





End Connection Type:

B: ¼" - ⅜" Stepped Hose Barb

S: ¾" Sanitary Flange

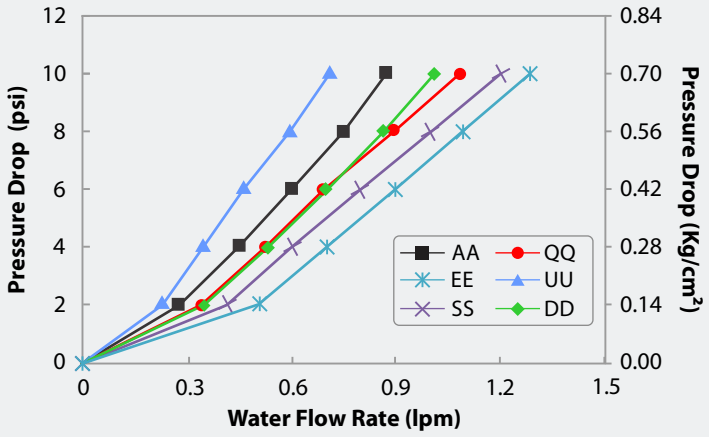
Typical Water Flow Rates

0.2 µm *AseptiCap® WL/WS*

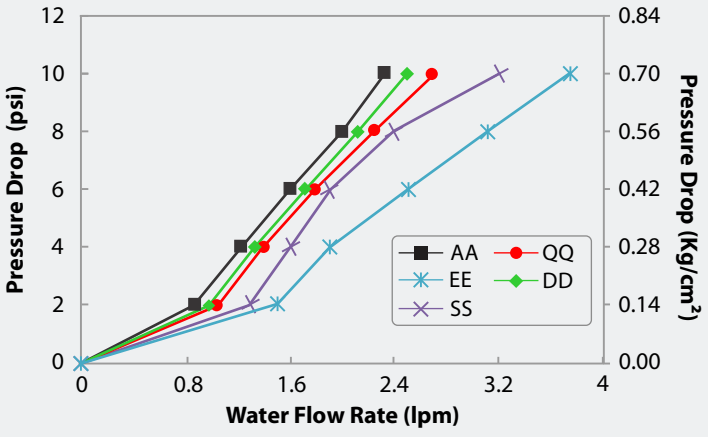
Datasheet

Small Capsule Filters

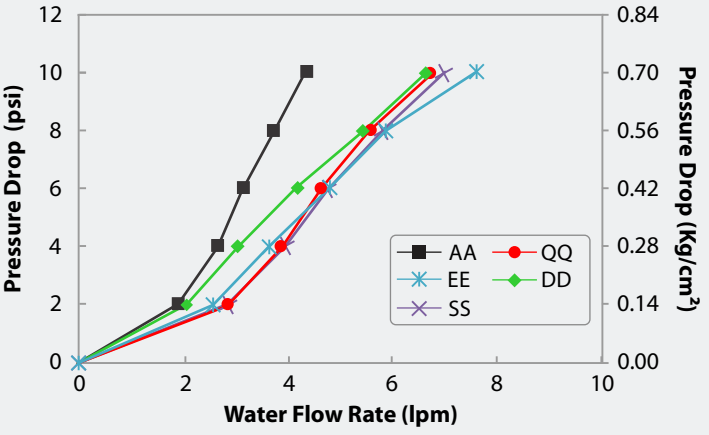
0.2µm *AseptiCap® WS*, 1" Capsule Filter



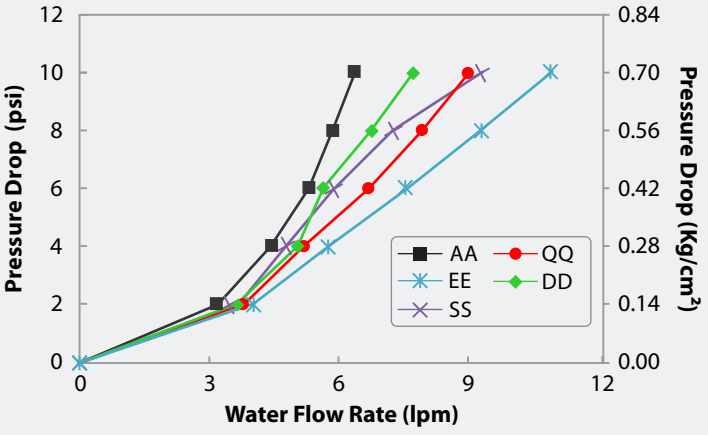
0.2µm *AseptiCap® WS*, 2" Capsule Filter



0.2µm *AseptiCap® WS*, 5" Capsule Filter



0.2µm *AseptiCap® WS*, 8" Capsule Filter



End Connection Type:

A : ¼" Stepped Hose Barb
E: 1½" Sanitary Flange
S: ¾" Sanitary Flange
Q: ½" Single Step Hose Barb
U: Female Luer Lock
D: ½" Hose Barb

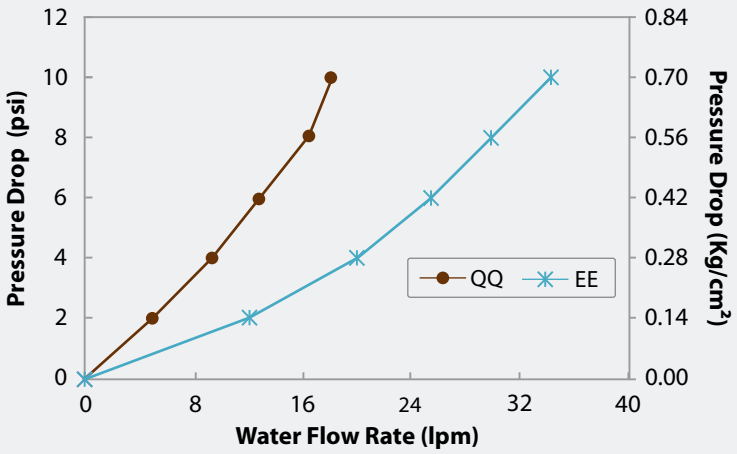
Typical Water Flow Rates

0.2 µm *AseptiCap® WL/WS*

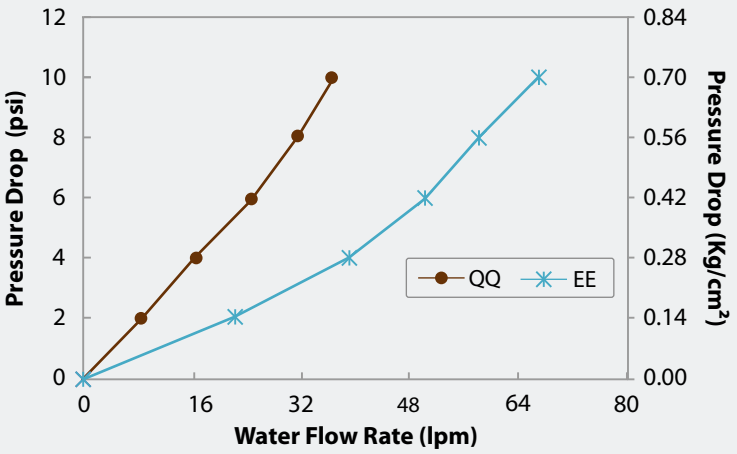
Datasheet

Large Capsule Filters

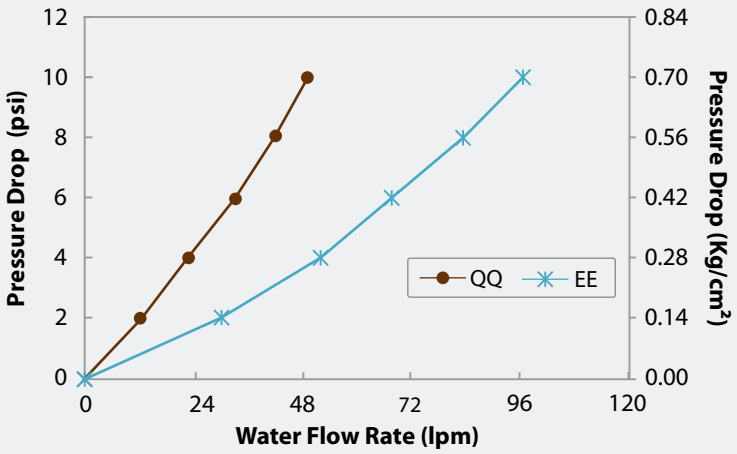
0.2µm *AseptiCap® WS*, 10" Capsule Filter



0.2µm *AseptiCap® WS*, 20" Capsule Filter



0.2µm *AseptiCap® WS*, 30" Capsule Filter



End Connection Type:

E: 1½" Sanitary Flange

Q: ½" Single Step Hose Barb

Ordering Information

0.2 µm *AseptiCap® WL/WS* 25mm Hydrophilic PVDF Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
IWL (Single Layer)	IWLX	25mm	06	0.2µm	01	Female Luer Lock	M			Non Sterile	1	100	04
IWS (0.8 µm Upstream)	IWS5					Male Luer Slip	N			EO Sterile	2		
IWS (0.45 µm Upstream)	IWSX					⅛" Hose Barb	H						
						¼" Hose Barb	B						

Example:

IWSX	06	01	MN	X	X	1	04

0.2 µm *AseptiCap® WL/WS* 50mm Hydrophilic PVDF Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
IWL(without Vent) (Single Layer)	IWLX	50mm	10	0.2µm	01	¼" - ⅜" Stepped Hose Barb	B			Non Sterile	1	10	02
IWS (without Vent) (0.8 µm Upstream)	IWS5					¾" Sanitary Flange	S			EO Sterile	2		
IWS (without Vent) (0.45 µm Upstream)	IWSX					Female Luer Lock	M						
VWL (with Vent) (Single Layer)	VWLX					¼" Single Step Hose Barb	A						
VWS (with Vent) (0.8 µm Upstream)	VWS5												
VWS (with Vent) (0.45 µm Upstream)	VWSX												

Example:

VWSX	10	01	BB	X	X	1	02

Inlet/Outlet Connections Available

Inlet/Outlet	25mm	50mm	
		with Vent	without Vent
¼" - ¾" Stepped Hose Barb	X	√	X
¾" Sanitary Flange	X	√	X
Female Luer Lock	Inlet Only	X	√
Male Luer Slip	Outlet Only	X	X
⅛" Hose Barb	√	X	X
Male Luer Lock	Outlet Only	X	X
¼" Hose Barb	√	X	X
¼" Single Step Hose Barb	X	X	√

Ordering Information

0.2 µm *AseptiCap® WL/WS* Hydrophilic PVDF Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		X	Bell		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
DWL (Single Layer)	DWLX	1"	31	0.2µm	01	¼" SHB	A		Yes	B	Non Sterile	1	1	01
			51			¼" MNPT (18 TPI)	B		No Bell	X	EO Sterile	2		
DWS (0.8 µm Upstream)	DWS5	2"	52			¼" BSP (19 TPI)	M		Bell with cover	C				
DWS (0.45 µm Upstream)	DWSX	5"	53			¼" BSP (19 TPI) with O-ring	P							
		8"	57			¼" BSP	F							
						½" MNPT	C							
						½" Hose Barb	D							
						1½" Sanitary Flange	E							
						¾" Sanitary Flange	S							
						Quick Connector	J							
						½" Single Step Hose Barb	Q							
						Female Luer Lock	U							
						Male Luer Slip	W							
						3/16" Hose Barb	N							
						3/8" Hose Barb	I							
						¼" Single Step Hose Barb	R							

Example:

DWSX	57	01	DD	X	X	1	01

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

Inlet/Outlet	Size/Length			
	1"	2"	5"	8"
¼" Stepped Hose Barb	√	√	√	√
½" Single Step Hose Barb	X	√	√	√
½"Hose Barb	√	√	√	√
1½" Sanitary Flange	√	√	√	√
¾" Sanitary Flange	√	√	√	√
Quick Connector	√	√	√	√
½" MNPT	X	√	√	√
¼" MNPT (18TPI)	√	√	√	√
¼" BSP (19 TPI)	Inlet Only	X	X	X
¼" BSP (19 TPI) with O-ring	Inlet Only	X	X	X
¼" BSP	Inlet Only	√	√	√
Female Luer Lock	√	√	√	√
Male Luer Slip	Outlet Only	X	X	X
3/16" Hose Barb	√	√	Outlet Only	X
3/8" Hose Barb	√	√	√	√
¼" Single Step Hose Barb	√	√	√	√

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

Ordering Information

0.2 µm *AseptiCap® WL/WS* Hydrophilic PVDF Membrane Large Capsule filter

Type		Size		Pore Size		Inlet/Outlet		X	Inline/ T-Line		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
LWL (Single Layer)	LWLX	5″	53	0.2µm	01	½″ Single Step Hose Barb	Q		Inline	X	Non Sterile	1	1	01
LWS (0.8 µm Upstream)	LWS5	10″	54			1½″ Sanitary Flange	E		T-Line	T	EO Sterile	2		
LWS (0.45 µm Upstream)	LWSX	20″	55			¾″ Sanitary Flange	S							
		30″	56			⅜″ Hose Barb	I							
						1″ Hose Barb	Z							

Example:

LWSX	54	01	EE	X	T	1	01

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

Inlet/Outlet	Inline				T-Line		
	5″	10″	20″	30″	10″	20″	30″
½″ Single Step Hose Barb	√	√	√	√	X	X	X
1½″ Sanitary Flange	√	√	√	√	√	√	√
¾″ Sanitary Flange	√	√	X	X	X	X	X
⅜″ Hose Barb	√	√	√	√	X	X	X
1″ Hose Barb	X	√	√	√	X	X	X

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