AseptiVent® TF

Hydrophobic PTFE Membrane Devices for Sterile Filtration of Air/Gases

DATASHEET

Pharmaceutical and Biopharmaceutical manufacturing involves sterile filtration of air/gases for a multitude of critical processes such as air sparging, bioreactor venting, fermentor exhaust, dry powder filling, WFI tank venting etc. The critical nature of these processes and associated high costs require the highest degree of reliability for the filter device with regard to its retention efficiency, flow rates, service life and mechanical and thermal stability.

MDI produces a wide range of PTFE membrane capsule filters to meet filtration requirements of biopharmaceutical and pharmaceutical processing.

These filters are validated for microbial retention with liquid bacterial challenge test as per ASTM F838-05 to provide a high degree of sterility assurance for critical applications involving sterilization of air/gases.

Applications

- Fermentor exhaust
- Sterile air sparging in fermentors and bioreactors
- Sterile venting of cell factories, bioreactors and fermentors
- Sterilization of environmental air in isolators
- Venting of sterile collection vessels
- Cleaning sterile surfaces
- WFI tank venting
- Nitrogen blanketing
- Dry powder injectable filling
- Sterile air for dryers and micronizers

Key Features

- Absolute retention
- Hydrophobic
- High heat stability
- Wide chemical compatibility
- Heat sealed to ensure 'no leaching'
- 100% Integrity tested
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Widest range of end connections
- Total traceability through unique serial number for each filter
- Individual certificate of quality for each device
- Sterilizable by EO gas or autoclaving

DST DTLLTLX1435E

Quality Assurance

DATASHEET

DST DTLLTLX1435E

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 *AseptiVent*® TF is tested for integrity to comply with validated acceptable Integrity Test Specifications.

Flow Rate

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

Pressure, Temperature Endurance

AseptiVent® TF 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.

Endotoxin Testing

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

Bioburden Testing

Device bioburden is tested as per ISO 11737-1 and assured to be <1000 cfu/device.

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.

AseptiVent® TF filters are validated to exhibit low extractables under harsh extraction conditions.

Total Traceability

AseptiVent® TF 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

AseptiVent® TF filters are fitted with vent caps and are packed in bags 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 vitro, USP <87> for cytotoxicity and In vivo, USP <88> for class VI Plastics

Easy Connect

Widest Range of End Connections

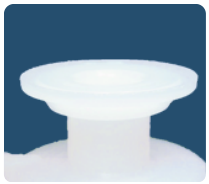
Biopharmaceutical processes involve transfer of high value fluids through multiple process steps. Making high quality, reliable, flexible and functionally convenient connectivity with filters is of utmost value to the bio-processors.

MDI *AseptiVent*® TF 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 EO sterilization and autoclaving.

¾" Sanitary Flange



1½" Sanitary Flange

½" HB

Single Stepped Hose Barb

¼" SHB

Quick Connector

Variety of end connections

Customized Connectivity

MDI *AseptiVent*® TF 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" Hose Barb

1½"Sanitary Flange to ¾"Sanitary Flange

***AseptiVent*® TF with High Security ½" hose barb connection**

Linear Upscaling from R&D to Production Process

DATASHEET

DST DTLLTLX1435E

Scientists in process development labs working with cell factories or small bioreactors require small area hydrophobic filters for air/gas filtration or sterile venting.

A scale up of these processes for larger productions requires larger area devices.

MDI offers a wide range of *AseptiVent*® TF Hydrophobic PTFE capsule filters to provide linear scale up from lab scale to pilot scale to full scale biopharmaceutical manufacturing processes. The appropriate size filter can be selected on the basis of the bioreactor size and required flow rates.

AseptiVent® TF 25 mm
5 cm²

AseptiVent® TF 37 mm
10 cm²

AseptiVent® TF 50 mm
20 cm²

AseptiVent® TF 1"
250 cm²

AseptiVent® TF 2"
500 cm²

AseptiVent® TF 5"
1000 cm²

AseptiVent® TF 8"
2000 cm²

AseptiVent® TF 10"
6000 cm²

Bioreactor Size	Filter Devices	EFA* (Nominal)
100 ml Shake Flasks	*AseptiVent*® TF 25mm	5 cm²
Up to 1 liter Shake Flasks	*AseptiVent*® TF 37mm	10 cm²
Up to 50 liter	*AseptiVent*® TF 50mm	20 cm²
Up to 100 liter	*AseptiVent*® TF 1"	250 cm²
Upto 300 liter	*AseptiVent*® TF 2"	500 cm²
Upto 1000 liter	*AseptiVent*® TF 5"	1000 cm²
Upto 5000 liter	*AseptiVent*® TF 8"	2000 cm²
more than 5000 liter	*AseptiVent*® TF 10"	6000 cm²

*EFA: Effective Filtration Area

Specifications

AseptiVent® TF- 25mm, 37mm, 50mm

DATASHEET

DST DTLLTLX1435E

Construction		
Pore Size	0.2 µm	0.45 µm
Membrane	Hydrophobic PTFE	
Support Layers	Polypropylene	
Body and Core	Polypropylene	

Integrity Testing / Retention		
Bubble Point	≥ 22 psi (1.54 Kg/cm²) with 70% IPA/Water Solution	≥ 10 psi (0.7 Kg/cm²) with 70% IPA/Water Solution
Microbial Retention	LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm²	LRV >7 for *Serratia marcescens* (ATCC 14756) per cm²

Size			
Size	25 mm	37 mm	50 mm
Effective Filtration Area (Nominal)	5 cm²	10 cm²	20 cm²
Operational Radius (with Vent/ Drain)	15 mm	23 mm	28 mm

Operational			
Max. Operating Temperature	60° C		
Max. Differential Pressure	42 psi (3 Kg/cm²) @ 30 °C		
Burst Pressure	> 14 Kg/cm²	> 8 Kg/cm²	> 8 Kg/cm²
Sterilization	**By Gas:** Sterilizable by Ethylene Oxide **By Autoclave:** Autoclavable at 125°C for 30 minutes, 30 cycles. Can not be in-line steam sterilized.		
Shelf Life	3 years after Ethylene Oxide sterilization		

Assurance	
Microbial Bacterial Retention	Validated as per ASTM F 838
Cytotoxicity	Passes Biological Reactivity Tests, In Vitro, as per USP <87> for cytotoxicity
Toxicity	Passes Biological Reactivity Tests, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1
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 211.72 and 210.3 (b)(6) for fiber release
Oxidizable Substances	Passes test as per USP <1231>
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
Indirect Food Additive	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Good Manufacturing Practice	These products are manufactured in a facility which adheres to Good Manufacturing Practices
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications

AseptiVent® TF- 1", 2", 5", 8"

DATASHEET

DST DTLLTLX1435E

Construction				
Pore Size	0.2 µm		0.45 µm	
Membrane	Hydrophobic PTFE			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Integrity Testing / Retention				
Bubble Point	≥ 22 psi (1.55 Kg/cm²) with 70% IPA/Water Solution		≥ 10 psi (0.7 Kg/cm²) with 70% IPA/Water Solution	
Microbial Retention	LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm²		LRV >7 for *Serratia marcescens* (ATCC 14756) per cm²	
Size				
Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	250 cm²	500 cm²	1000 cm²	2000 cm²
Operational Radius (with Vent/ Drain)	30 mm	65 mm	65 mm	65 mm
Operational				
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm²)			
Max. Differential Pressure	< 60 psi (4 Kg/cm²) @ 30 °C			
Sterilization	**By Gas:** Sterilizable by Ethylene Oxide **By Autoclave:** Autoclavable at 125°C for 30 minutes, 50 cycles. Can not be in-line steam sterilized.			
Shelf Life	3 years after Ethylene Oxide sterilization			
Assurance				
Microbial Bacterial Retention	Validated as per ASTM F 838			
Cytotoxicity	Passes Biological Reactivity Tests, In Vitro, as per USP <87> for cytotoxicity			
Toxicity	Passes Biological Reactivity Tests, In Vivo, as per USP <88> for Class VI plastics			
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1			
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 211.72 and 210.3 (b)(6) for fiber release			
Oxidizable Substances	Passes test as per USP <1231>			
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections			
Indirect Food Additive	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520			
Good Manufacturing Practice	These products are manufactured in a facility which adheres to Good Manufacturing Practices			
Quality Management System	ISO-9001 Certified			
USFDA	DMF No. 015554			

Specifications

AseptiVent® TF- 5”, 10”, 20”, 30”

DATASHEET

DST DTLLTLX1435E

Construction		
Pore Size	0.2 µm	0.45 µm
Membrane	Hydrophobic PTFE	
Support Layer	Polypropylene	
Body and Core	Polypropylene	

Integrity Testing / Retention		
Air Diffusion Flow (70% IPA Wetted) (10” Capsule Filter)	≤ 45 ml/min @ 16 psi (1.12 Kg/cm²)	≤ 45 ml/min @ 8 psi (0.56 Kg/cm²)
Microbial Retention	LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm²	LRV >7 for *Serratia marcescens* (ATCC 14756) per cm²

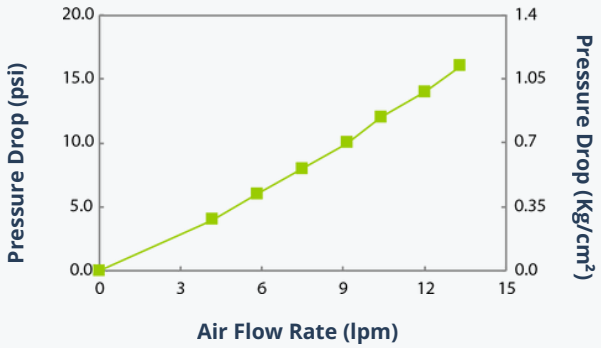
Size				
Size	5”	10”	20”	30”
Effective Filtration Area (Nominal)	3000 cm²	6000 cm²	12000 cm²	18000 cm²
Operational Radius (with Vent/ Drain)	78 mm	78 mm	78 mm	78 mm

Operational	
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm²)
Max. Differential Pressure	60 psi (4 Kg/cm²) @ 30 °C
Sterilization	**By Gas:** Sterilizable by Ethylene Oxide **By Autoclave:** Autoclavable at 125°C for 30 minutes, 30 cycles. Can not be in-line steam sterilized
Shelf Life	3 years after Ethylene Oxide sterilization

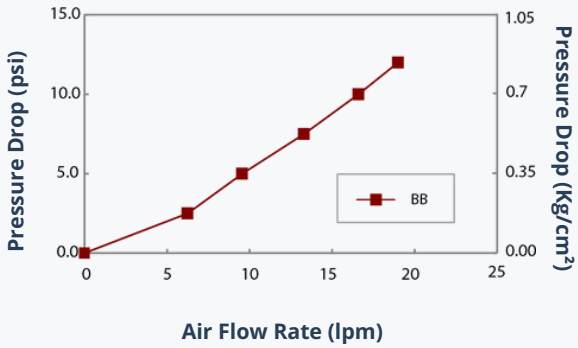
Assurance	
Microbial Bacterial Retention	Validated as per ASTM F 838
Cytotoxicity	Passes Biological Reactivity Tests, In Vitro, as per USP <87> for cytotoxicity
Toxicity	Passes Biological Reactivity Tests, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1
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 211.72 and 210.3 (b)(6) for fiber release
Oxidizable Substances	Passes test as per USP <1231>
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
Indirect Food Additive	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Good Manufacturing Practice	These products are manufactured in a facility which adheres to Good Manufacturing Practices
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Air Flow Rates

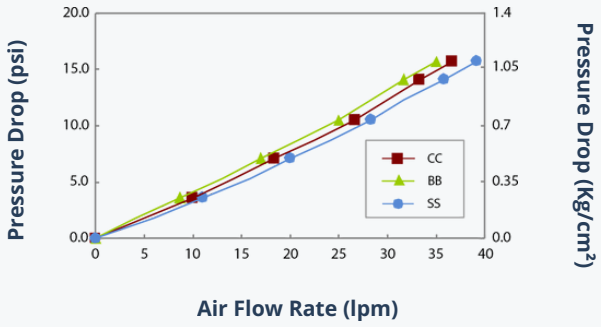
0.2µm *AseptiVent*® TF 25mm



0.2µm *AseptiVent*® TF 37mm



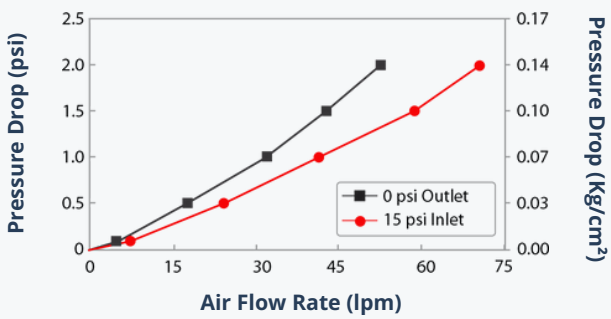
0.2µm AseptiVent® TF 50mm



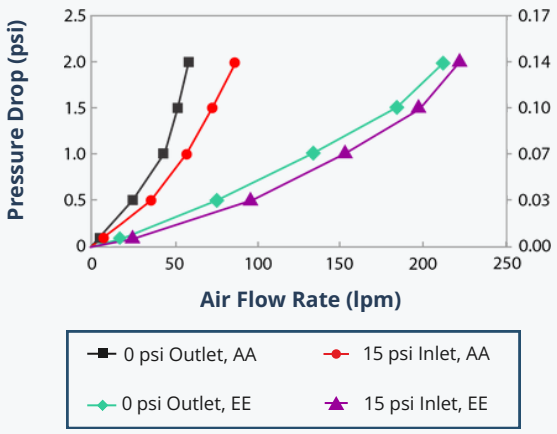
End Connection Type:

B: ¼" Stepped Hose Barb
C: 1/8" MNPT
S: ¾" Sanitary Flange

0.2µm AseptiVent® TF, 1" Capsule Filter

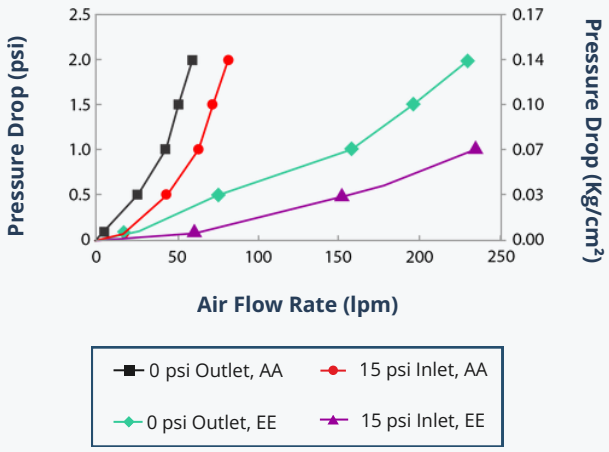


0.2µm *AseptiVent*® TF, 2" Capsule Filte

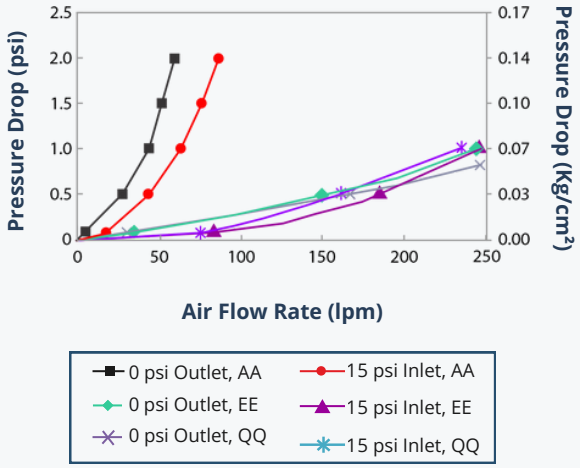


Air Flow Rates

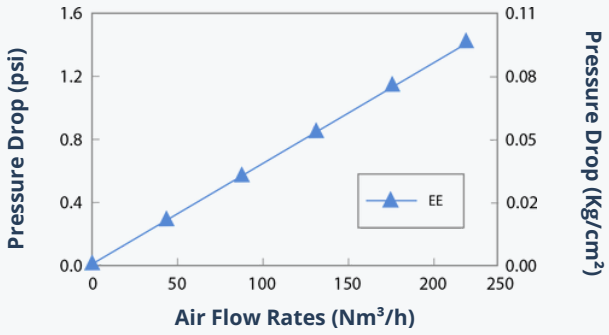
0.2µm *AseptiVent*® TF, 5" Capsule Filter



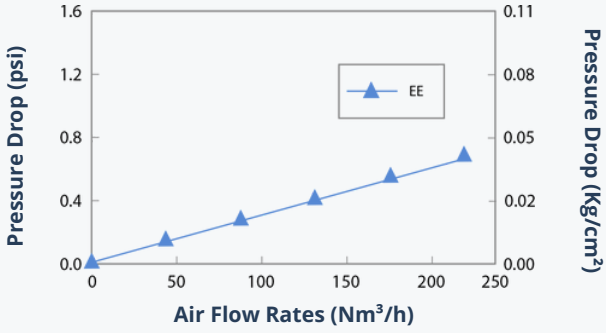
0.2µm *AseptiVent*® TF, 8" Capsule Filter



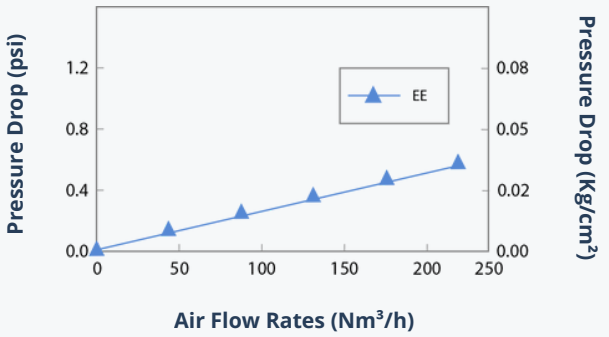
0.2µm *AseptiVent*® TF, 10"Capsule Filter



0.2µm *AseptiVent*® TF, 20"Capsule Filter



0.2µm *AseptiVent*® TF, 30"Capsule Filter



End Connection Type

A: ¼" Stepped Hose Barb
E: 1½" Sanitary Flange
Q: Single step ½" Hose Barb

Ordering Information

AseptiVent® TF-25mm

Type		Size		Pore Size		Inlet/Outlet		XX	Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code
AseptiVent® TF	ITFX	25 mm	06	0.2 µm	01	Female Luer Lock	M		Non Sterile	1	100	04
				0.45 µm	02	Male Luer Slip	N		EO Sterile	2		
						⅛" Hose Barb	H					
						¼" Hose Barb	B					

Example:

ITFX	06	01	MN	XX	01	04

Note: Female Luer Lock is available as inlet only and Male Luer Slip is available as outlet only

AseptiVent® TF-37mm/50mm

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
AseptiVent® TF	ITFX	37 mm	08	0.2 µm	01	MNPT	C			Non Sterile	1	20 (37 mm)	09
		50 mm	10	0.45 µm	02	¼" SHB	B			EO Sterile	2	10 (50 mm)	02
						¾" Sanitary Flange	S						
						¼" Single Step Hose Barb	A						

Example:

ITFX	10	01	SS	X	X	1	02

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

Connections Available			
Inlet/Outlet	**25mm**	**37mm**	**50mm**
1/4" - 3/4" Stepped Hose Barb	X	✓	✓
3/4" Sanitary Flange	X	X	✓
Female Luer Lock	Inlet Only	X	X
Male Luer Slip	Outlet Only	X	X
1/8" Hose Barb	✓	X	X
Male Luer Lock	Outlet Only	X	X
¼" Hose Barb	✓	X	X
¼" Single Step Hose Barb	X	X	✓

Dimension (in mm)	Inline Capsule Filters		
Inlet/Outlet	**25mm**	**37mm**	**50mm**
¼"- ⅜" Stepped Hose Barb I/O	-	64	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	23	28

Ordering Information

AseptiVent® TF Small Capsule Filters

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
AseptiVent® TF	DTLX	1"	51	0.2 µm	01	¼" SHB	A			Non Sterile	1	1	01
		2"	52	0.45 µm	02	¼" MNPT	B			EO Sterile	2		
		5"	53			½" MNPT	C						
		8"	57			½" Hose Barb	D						
						1½" Sanitary Flange	E						
						¾" Sanitary Flange	S						
						Quick Connector	J						
						Single Step ½"HB	Q						
						Female Luer Lock	U						
						Male Luer Slip	W						
						3/16" Hose Barb	N						
						⅜" Hose Barb	I						
						¼" Single Step Hose Barb	R						

Example:

DTLX	53	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"
1/4" Stepped Hose Barb	✓	✓	✓	✓
½" Single Step Hose Barb	X	✓	✓	✓
½"Hose Barb	✓	✓	✓	✓
1½" Sanitary Flange	✓	✓	✓	✓
3/4" Sanitary Flange	X	✓	✓	✓
Quick Connector	✓	✓	✓	✓
½" MNPT	X	✓	✓	✓
¼" MNPT (18TPI)	✓	✓	✓	✓
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	✓	✓	✓	✓

Dimensions (in mm)	Small Capsule Filters			
End Connections	1"	2"	5"	8"
1/4" SHB I/O	94	122	172	223
3/4" 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 1/2" 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

Ordering Information

AseptiVent® TF Large Capsule Filters

Type	
	Code
AseptiVent® TF	LTLX

Size	
	Code
5"	53
10"	54
20"	55
30"	56

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Inlet/Outlet	
	Code
½" Single Step Hose Barb	Q
1½" Sanitary Flange	E
¾" Sanitary Flange	S
⅜" Hose Barb	I
1" Hose Barb	Z

X

Inline/ T-Line	
	Code
Inline	X
T-Line	T

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
1	01

Example:

LTLX	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

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

mdi Membrane Technologies

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