



## *AseptiVent* TF

# Hydrophobic PTFE Membrane Devices for Sterile Filtration of Air/Gases

## Data Sheet

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

**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 F838-05 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.

## 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.

## Bioburden Testing

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

## Endotoxin Testing

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

## 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 pouch 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

## 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

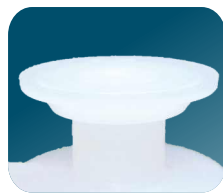
These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand prevalent sterilization methods including EO sterilization and autoclaving.

## 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.



**3/4" Sanitary Flange**



**1 1/2" Sanitary Flange**



**1/2" HB**



**Single Stepped Hose Barb**



**1/4" SHB**



**Quick Connector**

Some end connections available with *AseptiVent TF* Capsule Filters



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

**1 1/2" Sanitary Flange to 3/4" Sanitary Flange**



***AseptiVent TF* with HighSecurity 1/2" hose barb connection**

# Linear Upscaling from R&D to Production Process

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 25mm**  
5 cm<sup>2</sup>



**AseptiVent TF 37mm**  
10 cm<sup>2</sup>



**AseptiVent TF 50mm**  
20 cm<sup>2</sup>



**AseptiVent TF 1"**  
250cm<sup>2</sup>



**AseptiVent TF 2"**  
500cm<sup>2</sup>



**AseptiVent TF 5"**  
1000cm<sup>2</sup>



**AseptiVent TF 8"**  
2000cm<sup>2</sup>



**AseptiVent TF 10"**  
6000cm<sup>2</sup>

Bioreactor Size	Filter Devices	EFA* (Nominal)
100 ml Shake Flasks	<i>AseptiVent TF 25mm</i>	5cm <sup>2</sup>
Up to 1 liter Shake Flasks	<i>AseptiVent TF 37mm</i>	10cm <sup>2</sup>
Up to 50 liter	<i>AseptiVent TF 50mm</i>	20cm <sup>2</sup>
Up to 100 liter	<i>AseptiVent TF 1"</i>	250cm <sup>2</sup>
Up to 300 liter	<i>AseptiVent TF 2"</i>	500cm <sup>2</sup>
Up to 1000 liter	<i>AseptiVent TF 5"</i>	1000cm <sup>2</sup>
up to 5000 liter	<i>AseptiVent TF 8"</i>	2000cm <sup>2</sup>
more than 5000 liter	<i>AseptiVent TF 10"</i>	6000cm <sup>2</sup>

\*Effective Filtration Area

## AseptiVent TF- 25mm, 37mm, 50mm

### 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/cm <sup>2</sup> ) with 70% IPA/Water Solution	≥ 10 psi (0.7 Kg/cm <sup>2</sup> ) with 70% IPA/Water Solution
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm <sup>2</sup>	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm <sup>2</sup>

### Size

Size	25 mm	37 mm	50 mm
Effective Filtration Area (Nominal)	5 cm <sup>2</sup>	10 cm <sup>2</sup>	20 cm <sup>2</sup>
Operational Radius (with Vent/ Drain)	15 mm	23 mm	28 mm

### Operational

Max. Operating Temperature	60° C		
Max. Differential Pressure	42 psi (3 Kg/cm <sup>2</sup> ) @ 30 °C		
Burst Pressure	> 14 Kg/cm <sup>2</sup>	> 8 Kg/cm <sup>2</sup>	> 8 Kg/cm <sup>2</sup>
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

<b>Microbial Bacterial Retention</b>	Validated as per ASTM F 838-05
<b>Cytotoxicity</b>	Passes Biological reactivity test, In Vitro, as per USP <87> for cytotoxicity
<b>Toxicity</b>	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
<b>Bioburden</b>	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1
<b>Bacterial Endotoxin</b>	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
<b>Non Fiber Releasing</b>	Passes test as per USP and comply with USFDA 21 CFR Part 211.72 and 210.3 (b)(6) for fiber release
<b>Oxidizable Substances</b>	Passes test as per USP <1231>
<b>Particle Shedding</b>	The filtrate complies with USP <788> test for particulate matter in injections
<b>Indirect Food Additive</b>	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
<b>Good Manufacturing Practice</b>	These products are manufactured in a facility which adheres to Good Manufacturing Practices
<b>Quality Management System</b>	ISO-9001 Certified
<b>USFDA</b>	DMF No. 015554

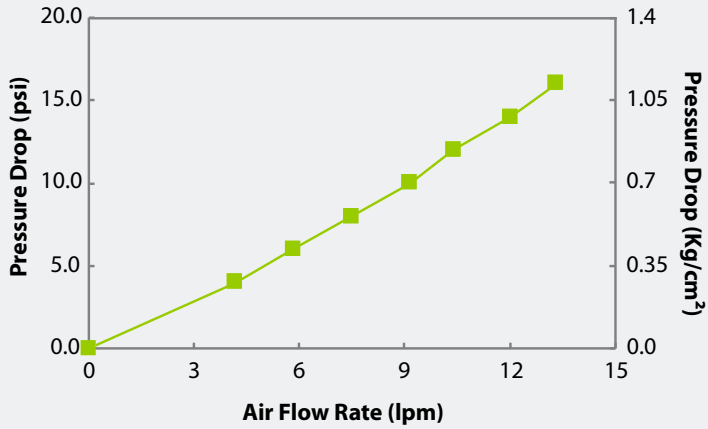
## AseptiVent TF- 1", 2", 5", 8"

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/cm <sup>2</sup> ) with 70% IPA/Water Solution		≥ 10 psi (0.7 Kg/cm <sup>2</sup> ) with 70% IPA/Water Solution	
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm <sup>2</sup>		LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm <sup>2</sup>	
Size				
Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	250 cm <sup>2</sup>	500 cm <sup>2</sup>	1000 cm <sup>2</sup>	2000 cm <sup>2</sup>
Operational Radius (with Vent/ Drain)	30 mm	65 mm	65 mm	65 mm
Operational				
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm <sup>2</sup> )			
Max. Differential Pressure	< 60 psi (4 Kg/cm <sup>2</sup> ) @ 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				
<b>Microbial Bacterial Retention</b>	Validated as per ASTM F 838-05			
<b>Cytotoxicity</b>	Passes Biological reactivity test, In Vitro, as per USP <87> for cytotoxicity			
<b>Toxicity</b>	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics			
<b>Bioburden</b>	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1			
<b>Bacterial Endotoxin</b>	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>			
<b>Non Fiber Releasing</b>	Passes test as per USP and comply with USFDA 21 CFR Part 211.72 and 210.3 (b)(6) for fiber release			
<b>Oxidizable Substances</b>	Passes test as per USP <1231>			
<b>Particle Shedding</b>	The filtrate complies with USP <788> test for particulate matter in injections			
<b>Indirect Food Additive</b>	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520			
<b>Good Manufacturing Practice</b>	These products are manufactured in a facility which adheres to Good Manufacturing Practices			
<b>Quality Management System</b>	ISO-9001 Certified			
<b>USFDA</b>	DMF No. 015554			

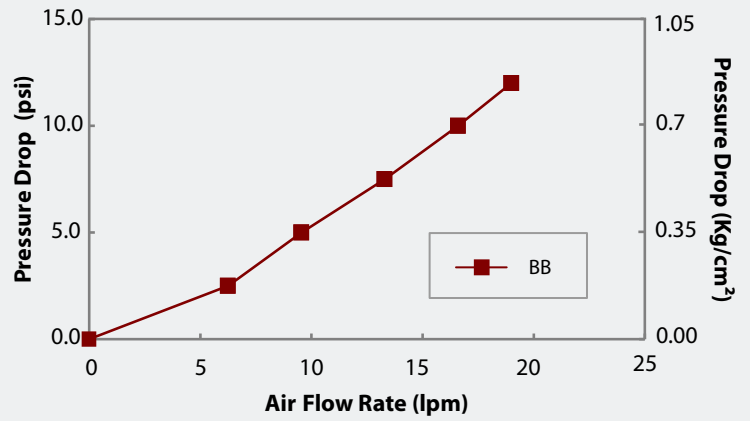
## AseptiVent TF- 5", 10", 20", 30"

Construction				
Pore Size	0.2 µm		0.45 µm	
Membrane	Hydrophobic PTFE			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Integrity Testing/Retention				
Air Diffusion Flow (70% IPA Wetted)	≤ 45 ml/min @ 16 psi (1.12 Kg/cm <sup>2</sup> )		≤ 45 ml/min @ 8 psi (0.56 Kg/cm <sup>2</sup> )	
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm <sup>2</sup>		LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm <sup>2</sup>	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm <sup>2</sup>	6000 cm <sup>2</sup>	12000 cm <sup>2</sup>	18000 cm <sup>2</sup>
Operational Radius (with Vent/ Drain)	78 mm	78 mm	78 mm	78 mm
Operational				
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm <sup>2</sup> )			
Max. Differential Pressure	60 psi (4 Kg/cm <sup>2</sup> ) @ 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				
<b>Microbial Bacterial Retention</b>	Validated as per ASTM F 838-05			
<b>Cytotoxicity</b>	Passes Biological reactivity test, In Vitro, as per USP <87> for cytotoxicity			
<b>Toxicity</b>	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics			
<b>Bioburden</b>	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1			
<b>Bacterial Endotoxin</b>	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>			
<b>Non Fiber Releasing</b>	Passes test as per USP and comply with USFDA 21 CFR Part 211.72 and 210.3 (b)(6) for fiber release			
<b>Oxidizable Substances</b>	Passes test as per USP <1231>			
<b>Particle Shedding</b>	The filtrate complies with USP <788> test for particulate matter in injections			
<b>Indirect Food Additive</b>	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520			
<b>Good Manufacturing Practice</b>	These products are manufactured in a facility which adheres to Good Manufacturing Practices			
<b>Quality Management System</b>	ISO-9001 Certified			
<b>USFDA</b>	DMF No. 015554			

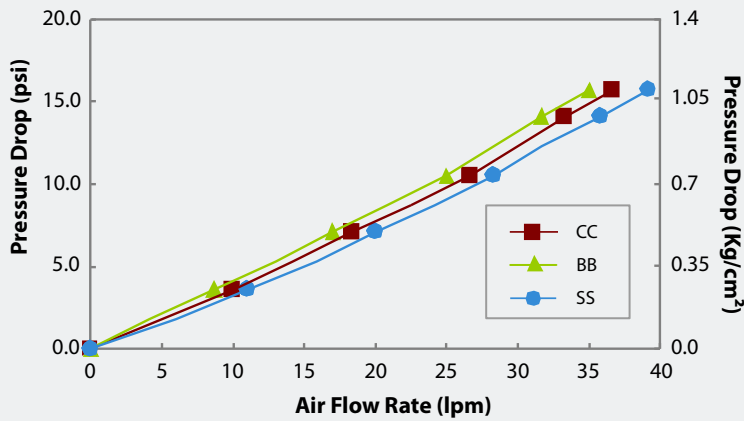
0.2µm AseptiVent TF 25mm



0.2µm AseptiVent TF 37mm



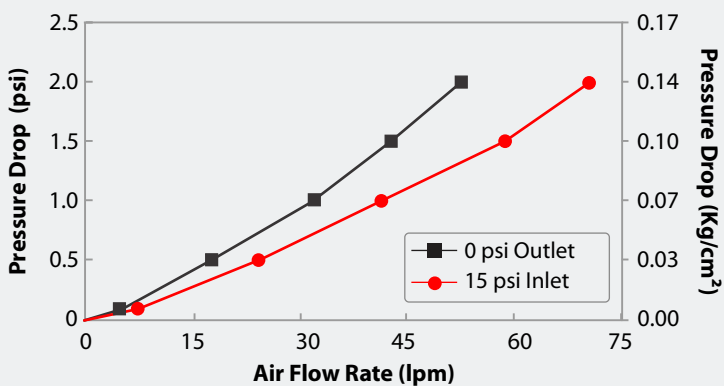
0.2µm AseptiVent TF 50mm



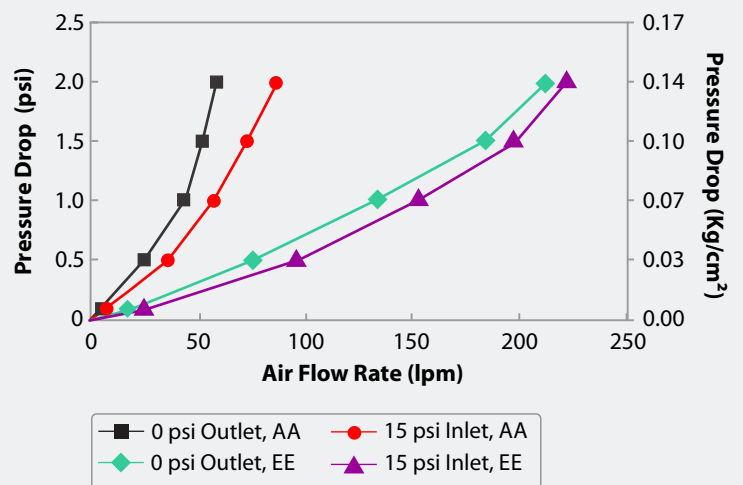
**End Connection Type**

- B:** 1/4" Stepped Hose Barb
- C:** 1/8" MNPT
- S:** 3/4" Sanitary Flange

0.2µm AseptiVent TF, 1" Capsule Filter



0.2µm AseptiVent TF, 2" Capsule Filter

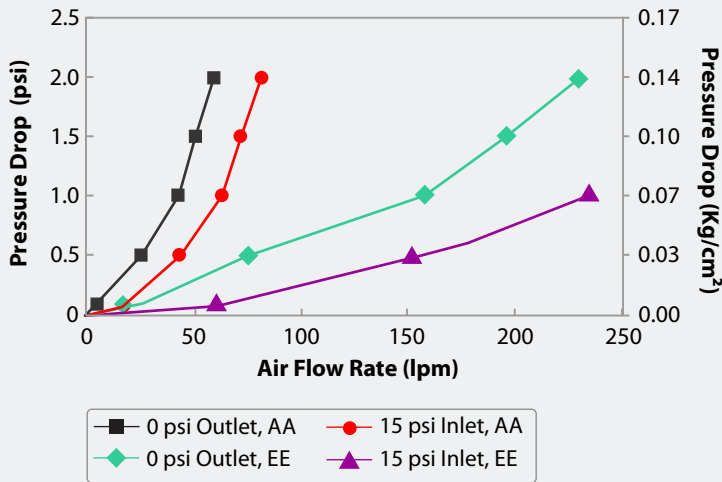




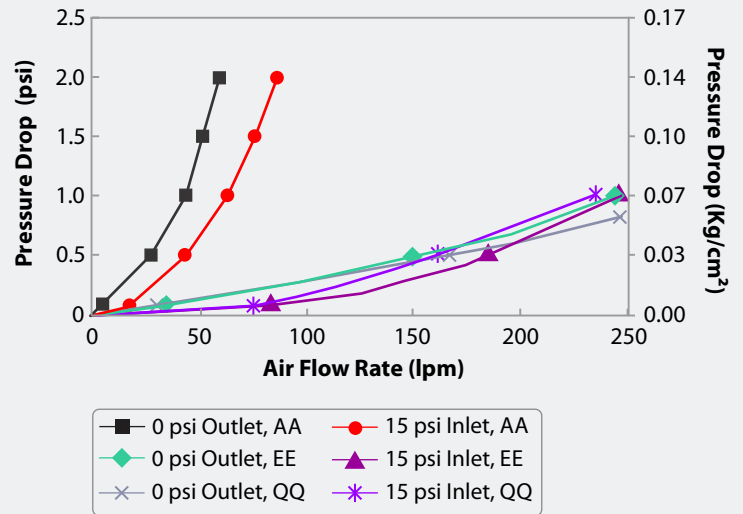
# Air Flow Rates

## AseptiVent TF

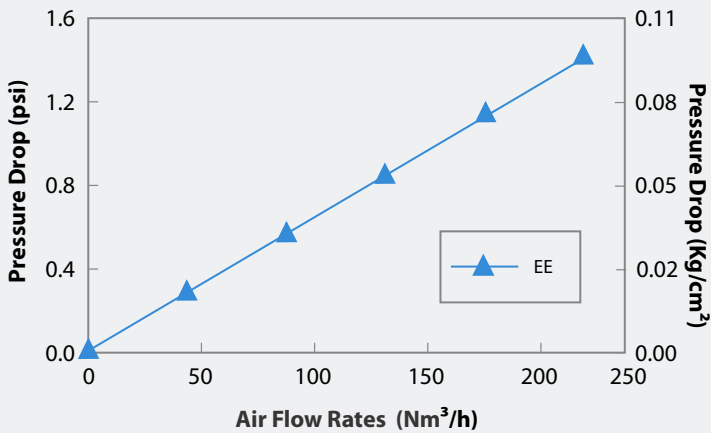
0.2µm AseptiVent TF, 5" Capsule Filter



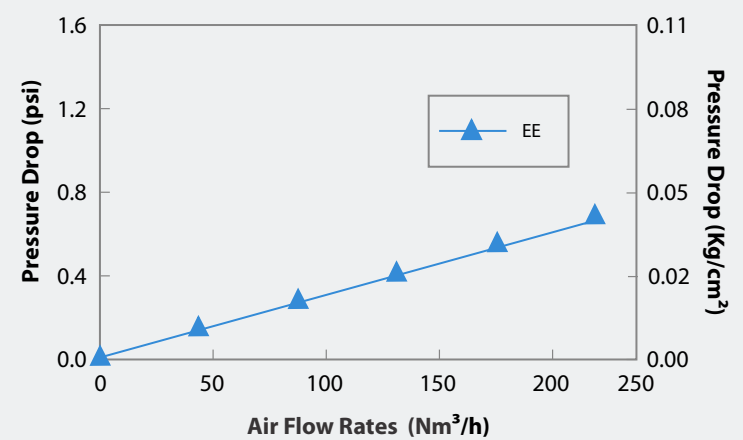
0.2µm AseptiVent TF, 8" Capsule Filter



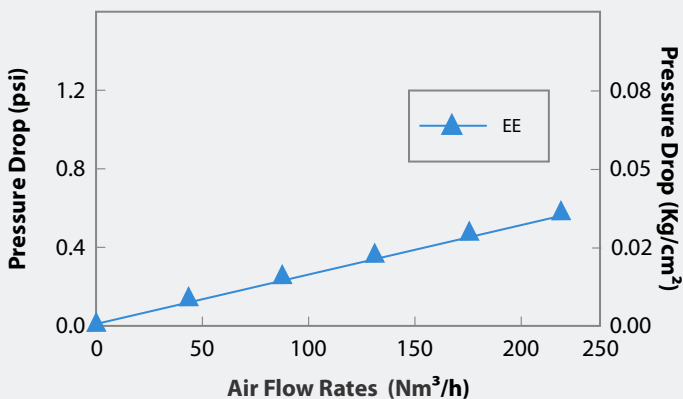
0.2µm AseptiVent TF, 10" Capsule Filter



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

## AseptiVent TF-25mm

Type		Size		Pore Size		Inlet/Outlet		XX	Sterility		Pack Size		
	Code		Code		Code		Code			Code		Code	
AseptiVent TF	ITFX	25mm	06	0.2µm	01	Female Luer Lock	M		Non Sterile	1	100	04	
				0.45µm	02	Male Luer Slip	N		EO Sterile	2			
						1/8" Hose Barb	H						
						1/4" Hose Barb	B						

**Example:**

ITFX	06	01	MN	XX	1	04
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Female Luer Lock is available as inlet only  
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	37mm	08	0.2µm	01	1/8" MNPT	C			Non Sterile	1	20 (37 mm)	09	
		50mm	10	0.45µm	02	1/4" SHB	B			EO Sterile	2	10 (50 mm)	02	
						3/4" Sanitary Flange	S							

**Example:**

ITFX	10	01	SS	X	X	1	02
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**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
1/4" Hose Barb	√	X	X

Dimension (in mm)	Inline Capsule Filters			
	Inlet/ Outlet	25mm	37mm	50mm
1/4" - 3/8" Stepped Hose Barb I/O		-	64	79
1/4" Single Step Hose Barb I/O		38	-	-
3/4" Sanitary Flange I/O		-	-	51
Female Luer Lock Inlet/ Male Luer Slip Outlet		23	-	-
1/8" Hose Barb I/O		36	-	-
Operational Radius		15	23	28

## 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	0.2µm	01	¼" Stepped Hose Barb	A	↓	↓	Non Sterile	1	↓	1	01
		2"	52	0.45µm	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" Hose Barb	Q							
						Female Luer Lock	U							
						Male Luer Slip	W							
						⅜" Hose Barb	N							
						⅝" Hose Barb	I							

**Example:**

DTLX	53	01	DD	X	X	1	01
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**Note: Inlet/Outlet Connections available with different Sizes/Length as follows:**

Inlet/Outlet	Size/Length			
	1"	2"	5"	8"
1/4" Stepped Hose Barb	√	√	√	√
1/2" Hose Barb	√	√	√	√
1 1/2" Sanitary Flange	√	√	√	√
3/4" Sanitary Flange	X	√	√	√
Quick Connector	√	√	√	√
1/2" Single Step Hose Barb	X	√	√	√
1/4" MNPT	√	√	√	√
1/2" MNPT	X	√	√	√
Female Luer Lock	√	√	√	√
Male Luer Slip	Outlet Only	X	X	X
3/16" Hose Barb	√	√	Outlet Only	X
3/8" Hose Barb	X	√	√	√

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	91	103	155	205
Quick Connector	100	111	163	212
1 1/2" Sanitary Flange I/O	91	110	161	211
1/2" Hose Barb I/O	90	112	164	215
1/2" Single Step Hose Barb I/O	-	115	165	217
1 1/2" Sanitary Flange Inlet 1/2" Single Step Hose Barb Outlet	-	111	162	212
3/8" Hose Barb I/O	-	115	165	217
Operational Radius	30	65	65	65

## AseptiVent TF Large Capsule Filters

Type		Size		Pore Size		Inlet/Outlet		X	Inline/T-Line		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
AseptiVent TF	LTLX	5"	53	0.2µm	01	½" Single Step Hose Barb	Q		Inline	X	Non Sterile	1	1	01
		10"	54	0.45µm	02	1½" Sanitary Flange	E		T-Line	T	EO Sterile	2		
		20"	55			¾" Sanitary Flange	S							
		30"	56			⅜" Hose Barb	I							
						1" Hose Barb	Z							

**Example:**

LTLX	54	01	EE	X	T	1	01
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**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	207	326	605	865	338	588	848
¾" Sanitary Flange I/O	212	345	x	x	x	x	x
½" Single Step Hose Barb I/O	217	332	628	888	x	x	x
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	203	332	618	878	x	x	x
⅜" Hose Barb I/O	211	330	618	878	x	x	x
1" Hose Barb I/O	x	405	635	895	x	x	x
Operational Radius	78	78	78	78	78	78	78

## Advanced Microdevices Pvt. Ltd.

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