mdi
Membrane Technologies

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
- Fermentor exhaust
- 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

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 and cartridge 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 117 37-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Samples from each lot are subjected to LAL test before final lot release. The devices are tested as per USFDA CDER guidelines and exhibit <0.25 EU/ml endotoxin level.

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 polyethylene 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 fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, invivo, USP <88> for class VI Plastics

Easy Connect

Datasheet

Widest Range of End Connections

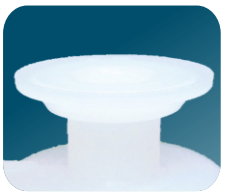
Biopharmaceutical processes involve transfer of high value fluids through multiple process steps. Making high quality, reliable, flexible and functionally convenient connectivity with filters is of utmost value to the bio-processors.

mdi *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

Some end connections available with *AseptiVent TF* Capsule Filters

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"Barb Hose

1½" Sanitary Flange to ¾" Sanitary Flange

***AseptiVent TF* with HighSecurity ½" hose barb connection**

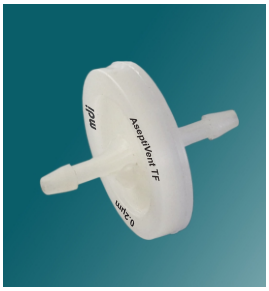
Linear Upscaling from R&D to Production Process

Datasheet

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 cm²

***AseptiVent* TF 37mm**
10 cm²

***AseptiVent* TF 50mm**
20 cm²

***AseptiVent* TF 1″**
250cm²

***AseptiVent* TF 2″**
500cm²

***AseptiVent* TF 5″**
1000cm²

Bioreactor Size	Filter Devices	EFA* (Nominal)
100 ml Shake Flasks	AseptiVent TF 25mm	5cm²
Up to 1 liter Shake Flasks	AseptiVent TF 37mm	10cm²
Up to 50 liter	AseptiVent TF 50mm	20cm²
Up to 100 liter	AseptiVent TF 1″	250cm²
Upto 300 liter	AseptiVent TF 2″	500cm²
Upto 1000 liter	AseptiVent TF 5″	1000cm²
> 1000 liter	AseptiVent TF 8″	2000cm²
> 5000 liter	AseptiVent TF10″	6000cm²

***AseptiVent* TF 8″**
2000cm²

***AseptiVent* TF 10″**
6000cm²

Specifications

Datasheet

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 (1.55 Kg/cm^2) with 70% IPA/Water Solution	≥ 15 psi (0.7 Kg/cm^2) with 70% IPA/Water Solution
Microbial Retention	LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm^2	LRV >7 for Serratia marcescens ATCC 14756) per cm^2

Size				
Size		25 mm	37 mm	50 mm
Effective Filtration Area (Nominal)		5 cm^2	10 cm^2	20 cm^2
Dimension (End to End)	Female Luer Lock Inlet/ MaleLuer Slip Outlet	23 mm	–	–
	¼" Stepped Hose Barb	–	64 mm	64.7 mm
	1/8" MNPT	–	–	55.84 mm
	¾" Sanitary Flange	–	–	51.4 mm
Operational Radius (with Vent/ Drain)		15 mm	22.5 mm	28 mm

Operational				
Max. Operating Temperature		60° C		
Max. Differential Pressure		42 psi (3 Kg/cm^2) @ 30 °C		
Burst Pressure		> 14 Kg/cm^2	> 8 Kg/cm^2	> 8 Kg/cm^2
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 838-05
Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test
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	Within limits as specified in USP
Particle Shedding	Passes USP test for particulates in injectables
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-9001:2008 Certified
USFDA	DMF No. 015554

Specifications

Datasheet

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

Size					
Size		1″	2″	5″	8″
Effective Filtration Area (Nominal)		250 cm^2	500 cm^2	1000 cm^2	2000 cm^2
Dimension (End to End)	¼″ SHB I/O	94 mm	122 mm	173 mm	231 mm
	¾″ Sanitary Flange Inlet I/O	91 mm	113 mm	155 mm	215 mm
	1½″ Sanitary Flange I/O	91 mm	110 mm	161 mm	211 mm
	½″ Hose Barb I/O	90 mm	112 mm	164 mm	215 mm
	½″ Single Step Hose Barb I/O	–	112 mm	164 mm	215 mm
Operational Radius (with Vent/ Drain)		30 mm	65 mm	65 mm	65 mm

Operational		
Max. Operating Temperature		80 °C @ < 30 psi (2 Kg/cm^2)
Max. Differential Pressure		< 60 psi (4 Kg/cm^2) @ 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 838-05
Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test
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	Within limits as specified in USP
Particle Shedding	Passes USP test for particulates in injectables
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-9001:2008 Certified
USFDA	DMF No. 015554

Specifications

AseptiVent TF- 10", 20", 30"

Datasheet

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^2)	≤ 45 ml/min @ 8 psi (0.56 Kg/cm^2)
Microbial Retention		LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm^2	LRV >7 for Serratia marcescens ATCC 14756) per cm^2
Size			
Size		10"	20"	30"
Effective Filtration Area (Nominal)		6000 cm^2	12000 cm^2	18000 cm^2
Dimension (End to End)	1½" Sanitary Flange	326 mm	587 mm	845 mm
	½" Single Step Hose Barb	332 mm	–	–
Operational Radius (with Vent/ Drain)		78 mm	78 mm	78 mm
Operational			
Max. Operating Temperature		80 °C @ < 30 psi (2 Kg/cm^2)	
Max. Differential Pressure		60 psi (4 Kg/cm^2) @ 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	

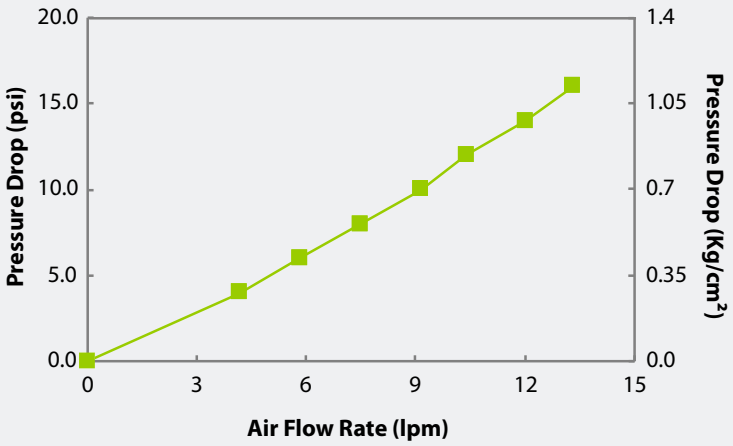
Assurance	
Microbial Bacterial Retention	Validated as per ASTM F 838-05
Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test
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	Within limits as specified in USP
Particle Shedding	Passes USP test for particulates in injectables
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-9001:2008 Certified
USFDA	DMF No. 015554

Air Flow Rates

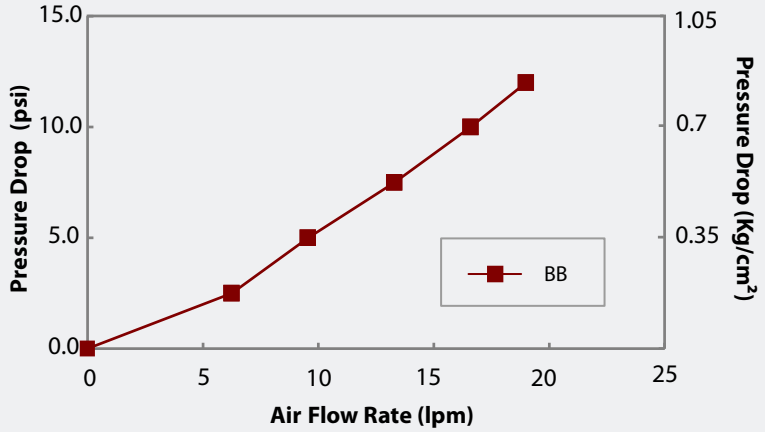
AseptiVent TF 25mm, 37mm, 50mm

Datasheet

0.2µm AseptiVent TF 25mm

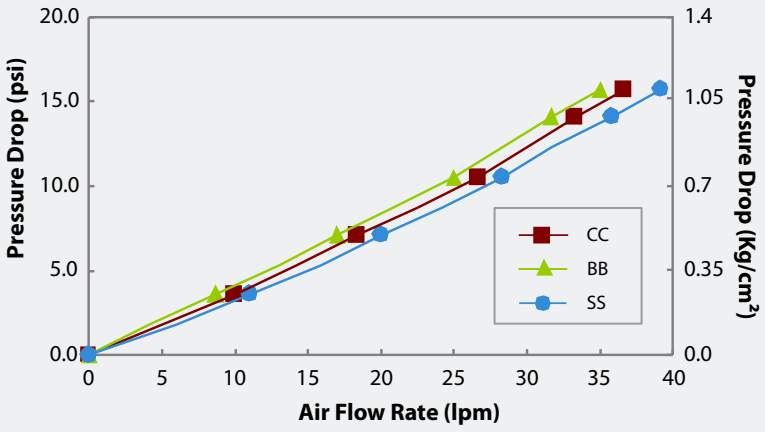


0.2µm AseptiVent TF 37mm



End Connection Type **B:** ¼" Stepped Hose Barb

0.2µm *AseptiVent TF* 50mm



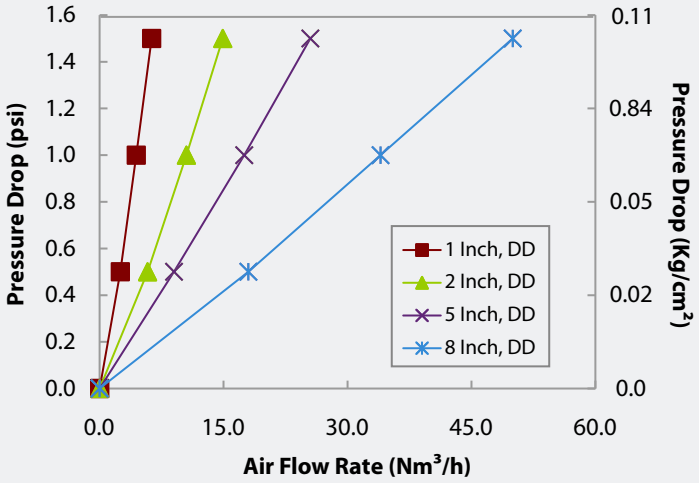
End Connection Type **B:** ¼" Stepped Hose Barb **C:** 1/8" MNPT **S:** ¾" Sanitary Flange

Air Flow Rates

AseptiVent TF

Datasheet

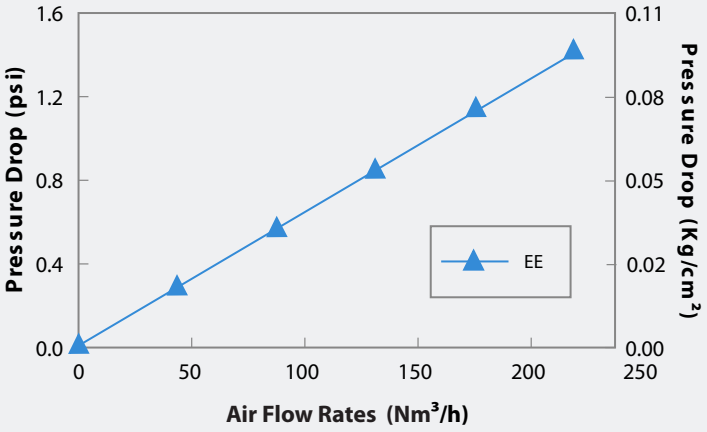
0.2µm *AseptiVent TF*-1", 2", 5", 8"



End Connection Type

D: ½" Hose Barb

0.2µm *AseptiVent TF*- 10"



End Connection Type

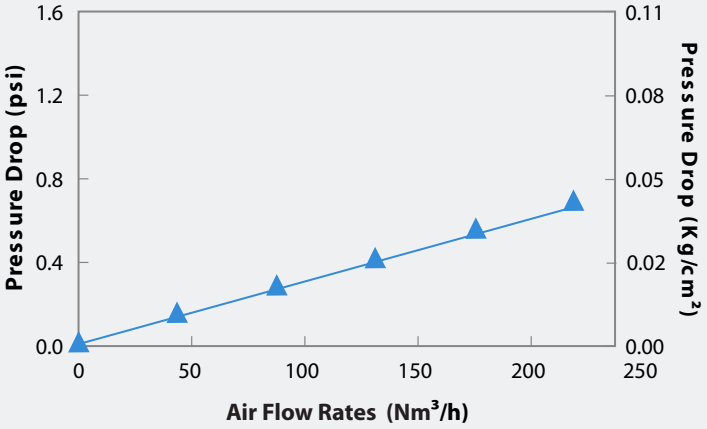
E: 1½" Sanitary Flange

Air Flow Rates

AseptiVent TF

Datasheet

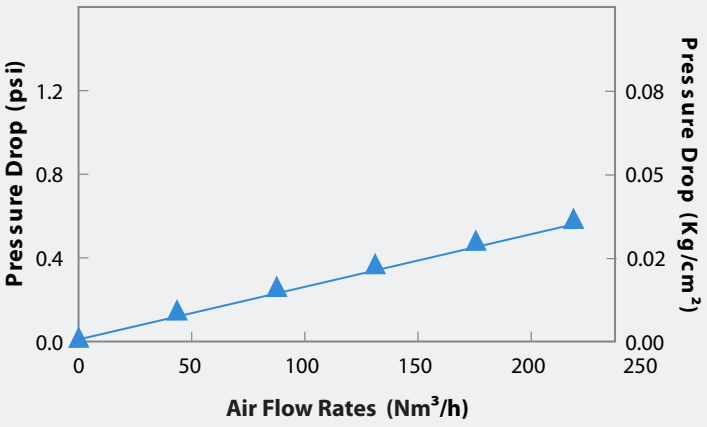
0.2µm *AseptiVent TF*- 20"



End Connection Type

E: 1½" Sanitary Flange

0.2µm *AseptiVent TF*- 30"



End Connection Type

E: 1½" Sanitary Flange

Ordering Information

Datasheet

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					

Example:

ITFX	06	01	MN	XX	1	04

Female Luer Lock is available as inlet only
Male Luer Slip is available as outlet only

AseptiVent TF-37mm

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	1/4" SHB	B			Non Sterile	1	20	09
				0.45µm	02					EO Sterile	2		

Example:

ITFX	08	01	BB	X	X	1	09

AseptiVent TF 50mm

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
AseptiVent TF	ITFX	50mm	10	0.2µm	01	⅛ " MNPT	C			Non Sterile	1	12	08
				0.45µm	02	¼" SHB	B			EO Sterile	2		
						¾" Sanitary Flange	S						

Example:

ITFX	10	01	SS	X	X	1	08

Ordering Information

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

Type	
	Code
AseptiVent TF	DTLX

Size	
	Code
1"	51
2"	52
5"	53
8"	57

Pore Size	
	Code
0.2µm	01
0.45µm	02

Inlet/Outlet	
	Code
¼" SHB	A
¼" MNPT	B
½" MNPT	C
½" Hose Barb	D
1½" Sanitary Flange	E
¾" Sanitary Flange	S
Quick Connector	J
Single Step ½" Hose Barb	Q

X

X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
1	01

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"Hose Barb	√	√	√	√
1½ " Sanitary Flange	√	√	√	√
¾" Sanitary Flange	X	√	√	√
Quick Connector	√	√	√	√
½" Single Step Hose Barb	X	√	√	√
1/4" MNPT	√	√	√	√
1/2" MNPT	X	√	√	√

Ordering Information

AseptiVent TF - 10", 20", 30"

Type	
	Code
AseptiVent TF	LTLX

Size	
	Code
10"	54
20"	55
30"	56

Pore Size	
	Code
0.2µm	01
0.45µm	02

Inlet/Outlet	
	Code
½" Single Step Hose Barb	Q
1½" Sanitary Flange	E

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		
	10"	20"	30"	10"	20"	30"
½" Single Step Hose Barb	√	√	√	X	X	X
1½" Sanitary Flange	√	√	√	√	√	√

Advanced Microdevices Pvt. Ltd.

20-21, Industrial Area, Ambala Cantt-133 006, INDIA
Tel : +91-171-2699290, 2699471 Fax : +91-171-2699221
E-mail : info@mdimembrane.com Internet : www.mdimembrane.com