AseptiVent® VF-y

Gamma Irradiatable PVDF Capsule Filters for Sterile Filtration of Air/Gases in Biopharmaceuticals

DATASHEET

Biopharmaceutical manufacturing involves sterile filtration of air and gases for a multitude of critical processes such as air sparging, bioreactor venting, fermentor exhaust etc. The critical nature of biopharmaceutical 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.

In order to do away with validation, energy and cleaning costs associated with reusable process assemblies and bioreactors, biopharma industry is moving towards single use disposable systems. Gamma sterilizable hydrophobic membrane filter devices offering high quality and reliability have become a necessity.

MDI gamma sterilizable *AseptiVent*® VF-y hydrophobic PVDF membrane capsule filters with a wide range of end connections and different sizes for linear scalability are specially designed for use with disposable single use assemblies for biopharmaceutical processes.

These filters are validated for microbial retention with liquid bacterial challenge test to ensure reliable performance under worst case conditions.

Applications

- Sterile air sparging
- Sterile venting
- Fermentor exhaust

Key Features

- Absolute retention
- 100% integrity tested
- High hydrophobicity
- High air flow rates
- Low Bioburden, <1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Widest range of end connections
- Products available for total scalability from seed reactors to process scale bioreactors/fermentors
- Total traceability (unique serial number for each filter)
- Individual certificate of quality for each device
- Sterilizable by Gamma irradiation

DST DVLV01X1435E

Quality Assurance

DATASHEET

DST DVLV01X1435E

MDI's quality management system emphasizes on quality by design rather than 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 *AseptiVent*® VF-γ 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

Even though *AseptiVent*® VF-γ is used for air/gas filtration, it is validated by liquid bacterial challenge test to subject the filter to most stringent conditions for higher degree of assurance. Integrity test data have been correlated to actual microbial retention with *Brevundimonas 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*® VF-γ capsule filter is tested for integrity to comply with validated acceptable Integrity Test Specifications.

Pressure, Temperature Endurance

AseptiVent® VF-γ capsule filters are validated to endure high operating pressure and temperature conditions which may be encountered during use. These filters are also validated to meet pre-determined burst pressure specifications to ensure user safety in case of inadvertent pressure build-up.

Endotoxin Testing

Aqeous 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.

Gamma Sterilizability

AseptiVent® *VF-γ* are gamma sterilizable with up to 50 kGy of gamma irradiation.

Total Traceability

AseptiVent® VF-γ capsule 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® VF-γ capsule filters are fitted with vent caps and are packed in double 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 indirect food additives
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In vivo, USP <88> for class VI Plastics

Easy Connect

DATASHEET

DST DVLV01X1435E

Widest Range of End Connections

Critical nature of biopharmaceutical processes involving steps such as sterile venting, air sparging, fermentor exhaust etc requires high quality, reliable, flexible and functionally convenient connectivity with filters.

MDI filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

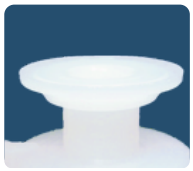
½" HB

½" Single Stepped Hose Barb

¼" SHB

Quick Connector

¾" Sanitary Flange



1½" Sanitary Flange

Male Luer Slip Outlet for 25 mm

Female Luer Lock Inlet for 25 mm

Variety of end connections

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 and autoclaving.

Customized Connectivity

MDI 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*® with High Security ½" hose barb connection**

Linear Upscaling from R&D to Production Process

DATASHEET

DST DVLV01X1435E

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*® VF-γ Hydrophobic PVDF 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.

Bioreactor Size	Filter Devices	EFA* (Nominal)
200 ml Cell Factories	*AseptiVent*® VF-γ 25 mm	5 cm²
Up to 1 liter Cell Factories	*AseptiVent*® VF-γ 37 mm	10 cm²
Up to 5 liter	*AseptiVent*® VF-γ 50 mm	20 cm²
Up to 50 liter	*AseptiVent*® VF-γ, 1"	250 cm²
Upto 100 liter	*AseptiVent*® VF-γ, 2"	500 cm²
Upto 300 liter	*AseptiVent*® VF-γ, 5"	1000 cm²
Upto 1000 liter	*AseptiVent*® VF-γ, 8"	2000 cm²
Upto 5000 liter	*AseptiVent*® VF-γ, 10"	6000 cm²

*EFA: Effective Filtration Area

AseptiVent® *VF-γ*
25 mm, 5 cm²

AseptiVent® *VF-γ*
50 mm, 20cm²

AseptiVent® *VF-γ*
1", 250cm²

AseptiVent® *VF-γ*
2", 500cm²

AseptiVent® *VF-γ*
5", 1000cm²

AseptiVent® *VF-γ*
8", 2000cm²

AseptiVent® *VF-γ*
10", 6000 cm²

Specifications
Inline Capsule Filters

DATASHEET

DST DVLV01X1435E

Construction			
Size	25 mm	37 mm	50 mm
Effective Filtration Area (Nominal)	5 cm^2	10 cm^2	20 cm^2
Membrane	0.2 µm Hydrophobic PVDF		
Support Layers	Polyester		
Plastic Parts	Gamma Stable Polypropylene		
Operational Radius	15 mm	23 mm	28 mm

Operational	
Max. Operating Temperature	80° C @ $\leq$ 0.5 Kg/cm^2 (7psi)
Max. Differential Pressure	1.5 Kg/cm^2 (22 psi) @ 30° C
Minimum Acceptable Bubble Point with 50% IPA	$\geq$ 1.27 Kg/cm^2 (18 psi)
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters must not be autoclaved or in-line steam sterilized.

Assurance	
Toxicity	Passes biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1
Bacterial Retention	LRV> 7 for *B. diminuta* per cm^2 of filter area as per ASTM F 838
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
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
Oxidizable Substances	Passes test as per USP <1231>
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
Small Capsule Filters

DATASHEET

DST DVLV01X1435E

Construction				
Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	250 cm^2	500 cm^2	1000 cm^2	2000 cm^2
Membrane	0.2 µm Hydrophobic PVDF			
Support Layers	Polyester			
Plastic Parts	Gamma Stable Polypropylene			
Operational Radius (with Vent/ Drain)	30 mm	65 mm	65 mm	65 mm
Vent and Drain	¼" Hose Barb with Silicone "O" ring			

Operational	
Max. Operating Temperature	80° C @ 2 Kg/cm^2 (30psi)
Max. Differential Pressure	4Kg/cm^2 (60psi) @ 30° C
Minimum Acceptable Bubble Point with 50% IPA	≥ 1.27 Kg/cm^2 (18 psi)
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters must not be autoclaved or in-line steam sterilized.

Assurance	
Toxicity	Passes biological Reactivity Test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1
Bacterial Retention	LRV> 7 for *B.diminuta* per cm^2 of filter area as per ASTM F 838
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
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
Oxidizable Substances	Passes test as per USP <1231>
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
Large Capsule Filters

DATASHEET

DST DVLV01X1435E

Construction				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm^2	6000 cm^2	12000 cm^2	18000 cm^2
Membrane	0.2 µm Hydrophobic PVDF			
Support Layers	Polyester			
Plastic Parts	Gamma Stable Polypropylene			
Operational Radius (with Vent/ Drain)	78 mm	78 mm	78 mm	78 mm
Vent and Drain	¼" Hose Barb with Silicone "O" ring			

Operational	
Max. Operating Temperature	80° C @ 2 Kg/cm^2 (30psi)
Max. Differential Pressure	4Kg/cm^2 (60psi) @ 30° C
Minimum Acceptable Bubble Point with 50% IPA	$\geq$ 1.27 Kg/cm^2 (18 psi)
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters must not be autoclaved or in-line steam sterilized.

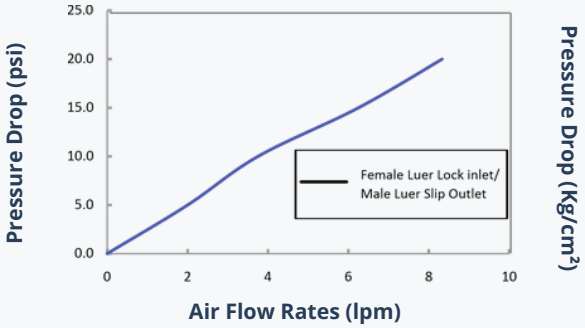
Assurance	
Toxicity	Passes biological Reactivity Test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1
Bacterial Retention	LRV> 7 for *B.diminuta* per cm^2 of filter area as per ASTM F 838
Bacterial Endotoxin	Aqueous extracts exhibit < 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
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
Oxidizable Substances	Passes test as per USP <1231>
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

Typical Air Flow Rates

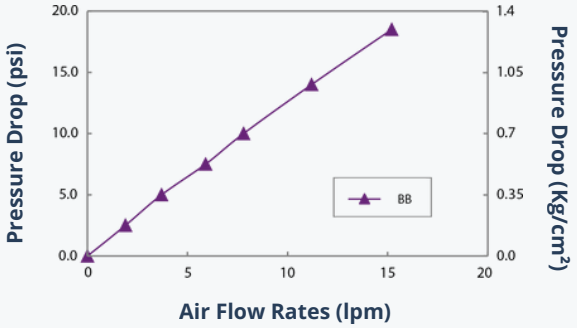
AseptiVent® VF-γ is produced using a high hydrophobicity PVDF membrane. This ensures good flow rates even with high moisture content in the inlet air.

AseptiVent® VF-γ capsule filters are designed to offer high air/gas flow rates at low differential pressures.

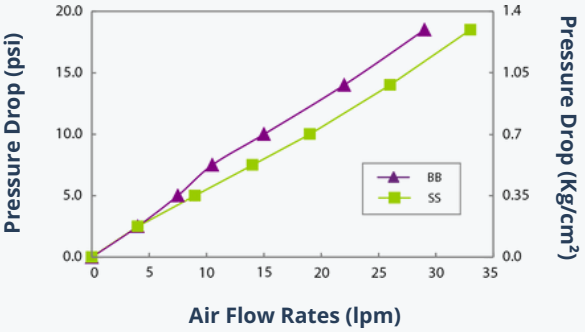
0.2 µm *AseptiVent*® VF-γ, 25mm Capsule Filters



0.2 µm *AseptiVent*® VF-γ, 37 mm Capsule Filters



0.2 µm *AseptiVent*® VF-γ, 50 mm Capsule Filters

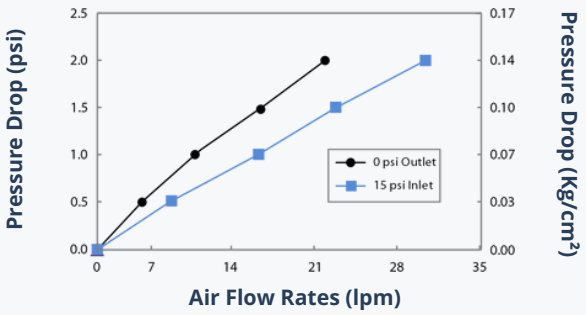


End Connection Type:

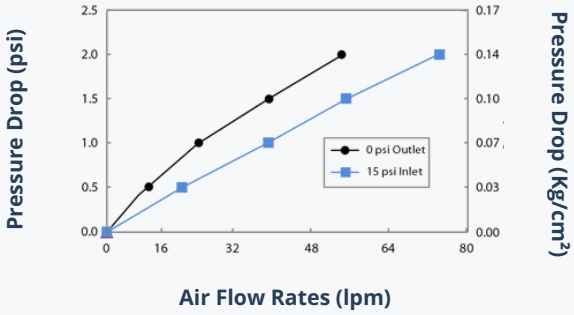
B: ¼" Stepped Hose Barb
S: ¾" Sanitary Flange
D: ½"Hose Barb

Typical Air Flow Rates

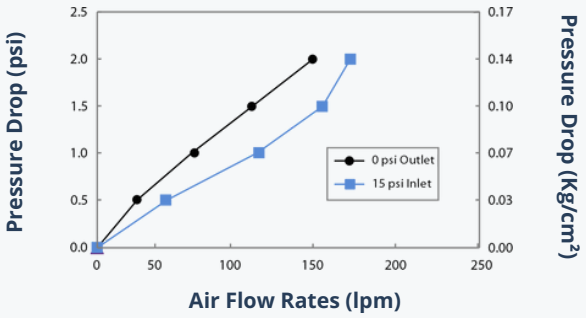
0.2 µm *AseptiVent*® VF-γ, 1" Capsule Filters, EE Connection



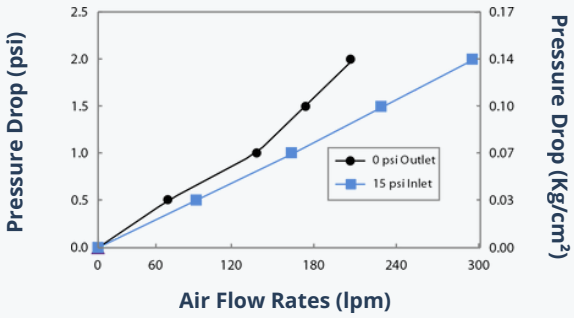
0.2 µm *AseptiVent*® VF-γ, 2" Capsule Filters, EE Connection



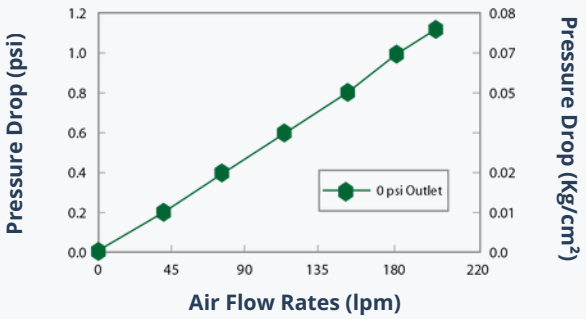
0.2 µm *AseptiVent*® VF-γ, 5" Capsule Filters, EE Connection



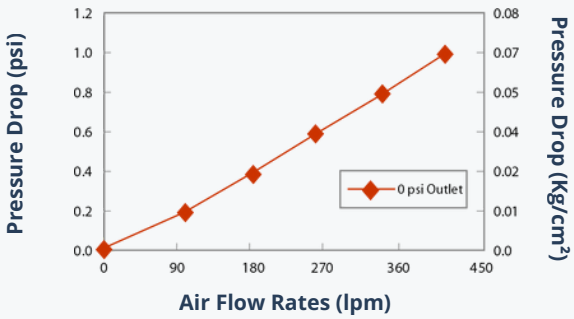
0.2 µm *AseptiVent*® VF-γ, 8" Capsule Filters, EE Connection



0.2 µm *AseptiVent*® VF-γ, 5" Large Capsule Filters, EE Connection



0.2 µm *AseptiVent*® VF-γ, 10" Capsule Filters, EE Connection



End Connection Type:
E: 1½" Sanitary Flange

Ordering Information

0.2 µm *AseptiVent*® VF-y 25mm PVDF Membrane Capsule Filter

Type	
	Code
AseptiVent® VF-y	IVFX

Size	
	Code
25 mm	06

Pore Size	
	Code
0.2 µm	01

Inlet/Outlet	
	Code
1/8" Hose Barb	H
Female Luer Lock	M
Male Luer Slip	N
Male Luer Lock	L
1/4" Hose Barb	B

Radiation Sterilizable	
	Code
Yes	R
No*	X

X

Sterility	
	Code
Non Sterile	1
Gamma Sterile	3

Pack Size	
	Code
100	04

Example:

IVFX	06	01	MN	R	X	1	04

*Gamma irradiated filters cannot be gamma sterilized again
Example for Non Sterile: IVFX0601MNRX104

Example for gamma Sterile: IVFX0601MNXX304

0.2 µm *AseptiVent*® VF-y 37mm, 50mm PVDF Membrane Capsule Filter

Type	
	Code
AseptiVent® VF-y	IVFX

Size	
	Code
37 mm	08
50 mm	10

Pore Size	
	Code
0.2 µm	01

Inlet/Outlet	
	Code
1/4" Single Step Hose Barb	A
1/4" SHB	B
3/4" Sanitary Flange	S

Radiation Sterilizable	
	Code
Yes	R
No*	X

X

Sterility	
	Code
Non Sterile	1
Gamma Sterile	3

Pack Size	
	Code
10	02

Example:

IVFX	10	01	BB	R	X	1	02

*Gamma irradiated filters cannot be gamma sterilized again
Example for Non Sterile: IVFX0801BBRX102

Example for gamma Sterile: IVFX0801BBXX302

Inlet/Outlet 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 (Length) (in mm)

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

0.2 µm *AseptiVent*® VF-y PVDF Membrane Capsule Filter

Type	
	Code
AseptiVent® VF-y	DVLX

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

Pore Size	
	Code
0.2 µm	01

Inlet/Outlet	
	Code
¼" SHB	A
½" Hose Barb	D
½" Single Step Hose Barb	Q
1½" Sanitary Flange	E
¾" Sanitary Flange	S
Quick Connector	J
Female luer lock	U
Male luer slip	W
3/16" Hose Barb	N
3/8 " Hose Barb	I
¼" Single Step Hose Barb	R

Radiation Sterilizable	
	Code
Yes	R
No*	X

X

Sterility	
	Code
Non Sterile	1
Gamma Sterile	3

Pack Size	
	Code
1	01

Example:

DVLX	57	01	EE	R	X	1	01

*Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: DVLX5301QQRX101

Example for gamma Sterile: DVLX5301QQXX301

Inlet/Outlet Connections Available

Inlet/Outlet	Size/Length			
	1"	2"	5"	8"
1/4" Stepped Hose Barb	✓	✓	✓	✓
¼" Single Step Hose Barb	✓	✓	✓	✓
½"Hose Barb	✓	✓	✓	✓
1½" Sanitary Flange	✓	✓	✓	✓
3/4" Sanitary Flange	✓	✓	✓	✓
Quick Connector	✓	✓	✓	✓
½" Single Step Hose Barb	X	✓	✓	✓
Female Luer Lock	✓	✓	✓	✓
Male Luer Slip	Outlet Only	X	X	X
3/16" Hose Barb	✓	✓	Outlet Only	X
3/8" Hose Barb	X	✓	✓	✓

Dimension (Length) (in mm)

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

0.2 µm *AseptiVent*® VF-γ PVDF Membrane Capsule Filter

Type	
	Code
AseptiVent® VF-γ	LVLX

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

Pore Size	
	Code
0.2µm	01

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

Radiation Sterilizable	
	Code
Yes	R
No*	X

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

Sterility	
	Code
Non Sterile	1
Gamma Sterile	3

Pack Size	
	Code
1	01

Example:

LVLX	54	01	EE	R	X	1	01

*Gamma irradiated filters cannot be gamma sterilized again
** T-line is not available in 5" Capsule filter
** T-line Capsule Filter are available with 1½" Sanitary Flange I/O Connections Only

Example for Non Sterile: LVLX5401QQRX101

Example for gamma Sterile: LVLX5401QQXX301

Inlet/Outlet Connections Available

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

Dimension (Length) (in mm)

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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