mdi
Membrane Technologies

AseptiVent VF-γ

Gamma Irradiatable PVDF Capsule Filters

for Sterile Filtration of Air/Gases in Biopharmaceuticals

Data Sheet

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-γ* 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 <0.5 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 or autoclaving

Quality Assurance

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 F838-05 to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each PVDF capsule filter is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Pressure, Temperature Endurance

PVDF 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.

Bioburden Testing

Device bioburden is tested as per ISO 117 37-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Samples are subjected to LAL test before final lot release. The devices are tested as per USFDA CDER guidelines and exhibit <0.5 EU/ml endotoxin level.

Gamma Sterilizability

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

Total Traceability

PVDF 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

PVDF 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 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

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.

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.

¾" Sanitary Flange

1½" Sanitary Flange

½" HB

1/2" Single Stepped HB

¼" SHB

Quick Connector

Male Luer Slip Outlet for 25 mm

Female Luer Lock Inlet for 25 mm

Some end connections available with *AseptiVent VF-γ*

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"Barb Hose

1½" Sanitary Flange to ¾" Sanitary Flange

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 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.

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

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

AseptiVent VF-γ
10", 6000cm²

Specifications

Datasheet

0.2µm *AseptiVent* VF-γ

Construction				
Size		25 mm	37 mm	50 mm
Effective Filtration Area (Nominal)		5 cm²	10 cm²	20 cm²
Membrane		0.2 µm Hydrophobic PVDF		
Support Layers		Polyester		
Body and Core		Gamma Stable Polypropylene		
Dimension (End to End)	¼" SHB I/O	–	64 mm	79 mm
	3/4" Sanitary Flange I/O	–	–	51 mm
	Female Luer Lock Inlet / Male Luer Slip Outlet	23 mm	–	–
Operational Radius		15 mm	23 mm	28 mm

Operational		
Max. Operating Temperature		80° C @ ≤ 0.5 Kg/cm² (7psi)
Max. Differential Pressure		1.5 Kg/cm² (22 psi) @ 30° C
Minimum Acceptable Bubble Point with 50% IPA/Water		≥ 1.26 Kg/cm² (18 psi)
Sterilization	By Irradiation	Gamma Irradiatable up to 50 kGy
	By Autoclave	Autoclavable at 125 °C for 30minutes, 1 Cycle after gamma irradiation. Can not be in line steam sterilized

Assurance	
Toxicity	Passes Bioreactivity test, In Vivo, as per USP for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
Bacterial Retention	LRV> 7 for B. diminuta per cm² of filter area as per ASTM F 838-05 against liquid bacterial challenge
Bacterial Endotoxin	Aqueous extracts exhibit < 0.5 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 210.3(b)(6) for fiber release
Particle Shedding	Passes USP test for particulates in injections
Fractional Dissolution	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Within limits as specified in USP
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

Datasheet

0.2µm *AseptiVent* VF-γ (1″, 2″, 5″, 8″)

Construction					
Size		1″	2″	5″	8″
Effective Filtration Area (Nominal)		250cm²	500cm²	1000cm²	2000 cm²
Membrane		0.2 µm Hydrophobic PVDF			
Support Layers		Polyester			
Body and Core		Gamma Stable Polypropylene			
Dimension (End to End)	1½″ Sanitary Flange I/O	91 mm	110 mm	161 mm	211 mm
	½″ HB I/O	90 mm	112 mm	164 mm	215 mm
	Quick Connector	100 mm	111 mm	163 mm	212 mm
	¼″ SHB I/O	94 mm	122 mm	172 mm	223 mm
	¾″ Sanitary Flange	91 mm	103 mm	155 mm	205 mm
Operational Radius (with Vent/ Drain)		30 mm	65 mm	65 mm	65 mm
Vent and Drain		-	¼″ Hose Barb with Silicone "O" ring in 2″, 5″ and 8″ capsule filters		

Operational		
Max. Operating Temperature		80° C @ 2Kg/cm² (30psi)
Max. Differential Pressure		4Kg/cm² (60psi) @ 30° C
Minimum Acceptable Bubble Point with 50% IPA		≥ 1.26 Kg/cm² (18 psi)
Sterilization	By Irradiation	Gamma Irradiatable up to 50 kGy
	By Autoclave	Autoclavable at 125 °C for 30minute, 1 Cycle after gamma irradiation. Can not be in line steam sterilized

Assurance	
Toxicity	Passes Bioreactivity test, In Vivo, as per USP for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
Bacterial Retention	LRV> 7 for B. diminuta per cm² of filter area as per ASTM F 838-05 (liquid bacterial challenge)
Bacterial Endotoxin	Aqueous extracts exhibit < 0.5 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 210.3(b)(6) for fiber release
Particle Shedding	Passes USP test for particulates in injections
Fractional Dissolution	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Within limits as specified in USP
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

Datasheet

0.2µm *AseptiVent* VF-γ 5", 10", 20", 30"

Construction					
Size		5"	10"	20"	30"
Effective Filtration Area (Nominal)		3000cm²	6000cm²	12000cm²	18000 cm²
Membrane		0.2 µm Hydrophobic PVDF			
Support Layers		Polyester			
Body and Core		Gamma Stable Polypropylene			
Dimension (End to End)	1½" Sanitary Flange	207 mm	326 mm	601 mm	876 mm
	½" Single Step Hose Barb	217 mm	332 mm	607 mm	882 mm
Operational Radius (with Vent/ Drain)		78 mm	78 mm	78 mm	78 mm
Vent and Drain		1/4" Hose Barb with Silicone "O" ring			

Operational		
Max. Operating Temperature		80° C @ 2Kg/cm² (30psi)
Max. Differential Pressure		4Kg/cm² (60psi) @ 30° C
Minimum Acceptable Bubble Point with 50% IPA		≥ 1.26 Kg/cm² (18 psi)
Sterilization	By Irradiation	Gamma Irradiatable up to 50 kGy
	By Autoclave	Autoclavable at 125 °C for 30minute, 1 Cycle after gamma irradiation. Can not be in line steam sterilized

Assurance	
Toxicity	Passes Bioreactivity test, In Vivo, as per USP for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
Bacterial Retention	LRV> 7 for B. diminuta per cm² of filter area as per ASTM F 838-05 (liquid bacterial challenge)
Bacterial Endotoxin	Aqueous extracts exhibit < 0.5 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 210.3(b)(6) for fiber release
Particle Shedding	Passes USP test for particulates in injections
Fractional Dissolution	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Within limits as specified in USP
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

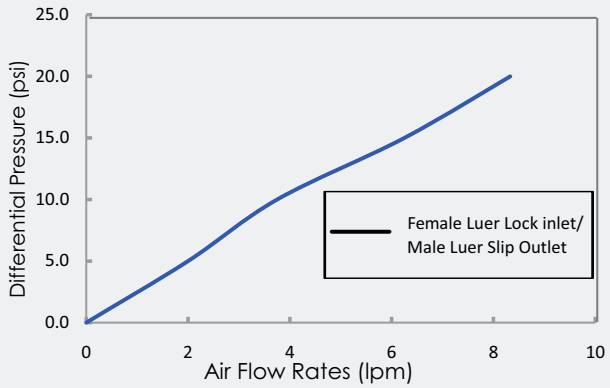
Air Flow Rates

Datasheet

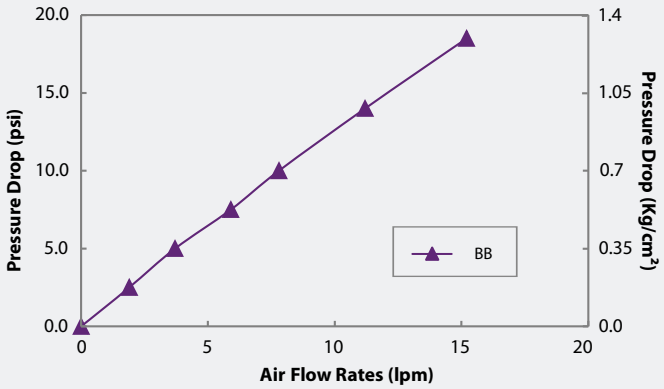
AseptiVent VF-γ is produced using a high hydrophobicity PVDF membrane. This ensures good flow rates even with high moisture content in the inlet air.

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

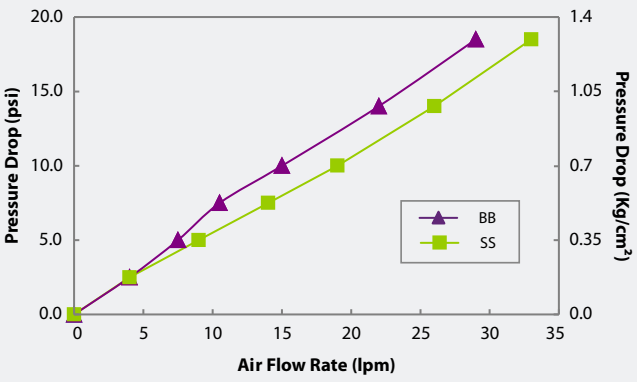
0.2 µm *AseptiVent VF-γ*, 25mm Capsule Filters



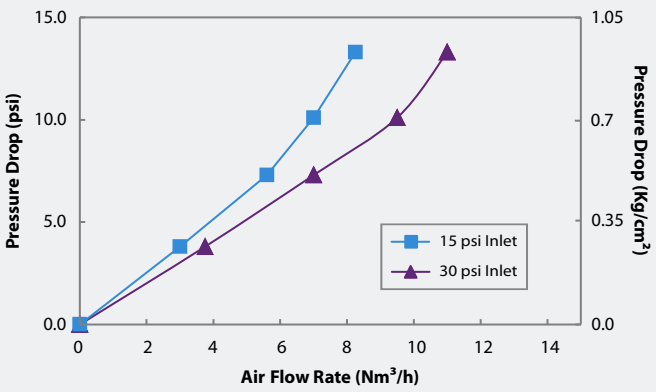
0.2 µm *AseptiVent VF-γ*, 37 mm Capsule Filters



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



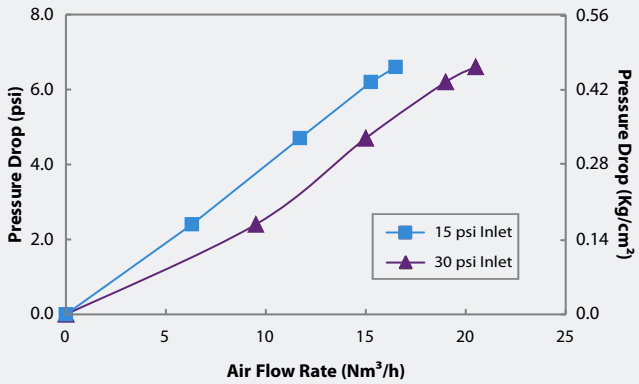
0.2 µm *AseptiVent VF-γ*, 1" Capsule Filters, DD Connection



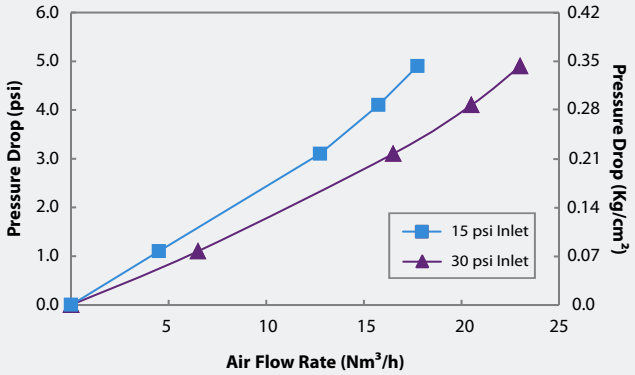
End Connection Type: **B:** ¼" Stepped Hose Barb **S:** ¾" Sanitary Flange **D:** ½"Hose Barb

Air Flow Rates

0.2 µm *AseptiVent VF-γ*, 2″ Capsule Filters, DD Connection



0.2 µm *AseptiVent VF-γ*, 5″ Capsule Filters, DD Connection



End Connection Type: **D:** ½″Hose Barb

Ordering Information

0.2 µm *AseptiVent* VF-γ 25mm PVDF Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
AseptiVent VF-γ	IVFX	25 mm	06	0.2µm	01	1/8" Hose Barb	H	Yes	R		Non Sterile	1	100	04
						Female Luer Lock	M	No*	X		Gamma Sterile	3		
						Male Luer Slip	N							
						Male Luer Lock	L							

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-γ 37mm, 50mm PVDF Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
AseptiVent VF-γ	IVFX	37 mm	08	0.2µm	01	¼" SHB	B	Yes	R		Non Sterile	1	10	02
		50 mm	10			¾" Sanitary Flange	S	No*	X		Gamma Sterile	3		

Example:

IVFX	10	01	BB	R	X	1	02

*** Gamma irradiated filters cannot be gamma sterilized again**

Example for Non Sterile: IVFX0801BBRX104 **Example for gamma Sterile: IVFX0801BBXX304**

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	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

Pack Size Available			
Pack Size	**25mm**	**37mm**	**50mm**
10/Pack	X	√	√
100/Pack	√	X	X

Ordering Information

0.2 µm *AseptiVent* VF-γ PVDF Membrane Capsule filter

Type	
	Code
AseptiVent VF-γ	DVLX

Size	
	Code
1″	51
2″	52
5″	53
8″	57

Pore Size	
	Code
0.2µm	01

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

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: DVLX5301QQRX104 **Example for gamma Sterile: DVLX5301QQXX304**

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	√	√	√	√
Quick Connector	√	√	√	√
½″ Single Step Hose Barb	X	√	√	√
Female Luer Lock	√	X	X	X
Male Luer Slip	Outlet Only	X	X	X

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

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**

Example for Non Sterile: LVLX5401QQRX104 **Example for gamma Sterile: LVLX5401QQXX304**

**** T-line is not available in 5" Capsule filter**

**** T-line Capsule Filter are available with 1½" Sanitary Flange I/O Connections Only**

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	√	√	√	√	√	√	√

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