

Data Sheet

AseptiVent® VF- γ

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

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</p>
- > 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

1

Quality Assurance

mdi 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.

Bioburden Testing

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

Endotoxin Testing

Aqeous extracts exhibit <0.25 EU/ml as established by Lumulus Amebocyte Lysate (LAL) test.

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

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.



³⁄₄" Sanitary Flange



1⁄2″ HB



1/4" SHB



Male Luer Slip Outlet for 25 mm

1/2" Single Stepped HB

1¹/₂" Sanitary Flange



Quick Connector



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.



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

1¹/₂" Sanitary Flange to ³/₄" Sanitary Flange





HighSecurity ¹/₂" 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	<i>AseptiVent®VF-</i> γ 25 mm	5 cm ²
Up to 1 liter Cell Factories	<i>AseptiVent®VF-</i> γ 37 mm	10 cm ²
Up to 5 liter	<i>AseptiVent®VF-</i> γ 50 mm	20 cm ²
Up to 50 liter	AseptiVent [®] VF-γ 1″	250 cm ²
Upto 100 liter	AseptiVent [®] VF-γ 2″	500 cm ²
Upto 300 liter	AseptiVent [®] VF-γ 5″	1000 cm ²
Upto 1000 liter	AseptiVent® VF-γ 8″	2000 cm ²
Upto 5000 liter	AseptiVent®VF-γ 10″	6000 cm ²

*Effective Filtration Area



AseptiVent[®]*VF*-γ 10", 6000cm²

Specifications 0.2μm *AseptiVent*[®] VF-γ

	Constr	uction					
Size	25 mm	37 mm	50 mm				
Effective Filtration Area (Nominal)	5 cm²	10 cm ²	20 cm ²				
Membrane	0.2 μm Hydr	ophobic PVDF					
Support Layers	Poly	ester					
Plastic Parts	Gamma Stable	Polypropylene					
Operational Radius	15 mm	15 mm 23 mm 28 mm					
	Oper	ational					
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	≥ 1.27 Kg/cm² (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 de	vice as per ISO 11737-1					
Bacterial Retention	LRV> 7 for <i>B. diminuta</i> per cm ² of filter	area as per ASTM F 838					
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/m as per USP <85>	l as established by Limulus Amebocyt	e Lysate (LAL) Test				
Non Fiber Releasing	Passes test as per USP and comply wit	h USFDA 21 CFR Part 210.3(b)(6) for fil	ber release				
Particle Shedding	The filtrate complies with USP <788>	test for particulate matter in injection	S				
Oxidizable Substances	Passes test as per USP <1231>						
Indirect Food Additive	All Polypropylene components meet	the FDA Indirect Food Additive require	ements cited in 21 CFR 177.1520				
Good Manufacturing Practice	These products are manufactured in a	a facility which adheres to Good Manu	facturing Practices				
Quality Management System	ISO-9001 Certified						
USFDA	DMF No. 015554						

Specifications 0.2μm *AseptiVent*[®] VF-γ (1", 2", 5", 8")

DMF No. 015554

Construction 1″ 2″ Size 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 **Operational Radius** 30 mm 65 mm 65 mm 65 mm (with Vent/ Drain) Vent and Drain 1/4" Hose Barb with Silicone "O" ring Operational 80° C @ 2 Kg/cm² (30psi) Max. Operating Temperature 4Kg/cm² (60psi) @ 30° C Max. Differential Pressure Minimum Acceptable \geq 1.27 Kg/cm² (18 psi) Bubble Point with 50% IPA 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 LRV> 7 for *B. diminuta* per cm² of filter area as per ASTM F 838 **Bacterial Retention** Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test **Bacterial Endotoxin** 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 The filtrate complies with USP <788> test for particulate matter in injections Particle Shedding 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 These products are manufactured in a facility which adheres to Good Manufacturing Practices Good Manufacturing Practice **Quality Management System** ISO-9001 Certified

USFDA

Specifications 0.2μm *AseptiVent*[®] VF-γ 5", 10", 20", 30"

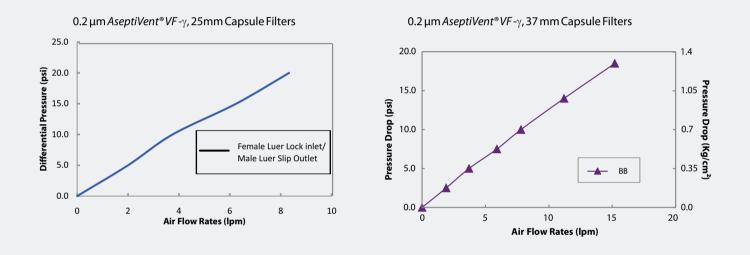
Construction 5″ 10″ Size 20″ 30″ Effective Filtration Area (Nominal) 3000cm² 6000cm² 12000cm² 18000 cm² Membrane 0.2 µm Hydrophobic PVDF Support Layers Polyester Body and Core Gamma Stable Polypropylene **Operational Radius** 78 mm 78 mm 78 mm 78 mm (with Vent/ Drain) Vent and Drain 1/4" Hose Barb with Silicone "O" ring Operational Max. Operating Temperature 80° C @ 2Kg/cm² (30psi) 4Kg/cm² (60psi) @ 30° C Max. Differential Pressure Minimum Acceptable \geq 1.27 Kg/cm² (18 psi) Bubble Point with 50% IPA 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 LRV> 7 for *B. diminuta* per cm² of filter area as per ASTM F 838 **Bacterial Retention 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 DMF No. 015554 USFDA

Typical Air Flow Rates

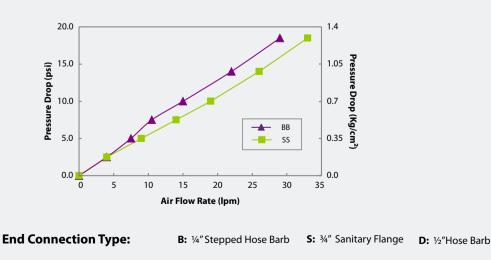
Datasheet

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.



 $0.2 \,\mu m \, A septi Vent^{\circ} VF$ - γ , 50 mm Capsule Filters

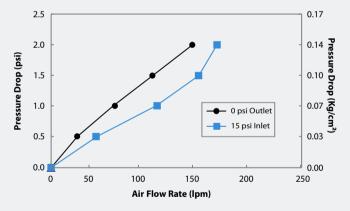


Typical Air Flow Rates

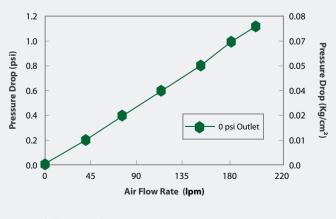
2.5 0.17 0.14 **Pressure Drop (Kg/cm²)** 0.07 0.07 2.0 Pressure Drop (psi) 1.5 1.0 0 psi Outlet 15 psi Inlet 0.03 0.5 0.0 0.00 21 35 0 7 14 28 Air Flow Rate (Ipm)

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

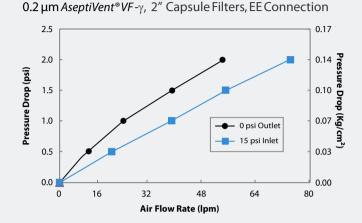
0.2 μm AseptiVent[®]VF-γ, 5" Capsule Filters, EE Connection



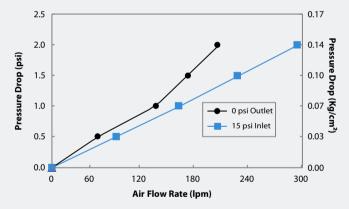
0.2 μm AseptiVent[®] VF -γ, 5" Large Capsule Filters, EE Connection



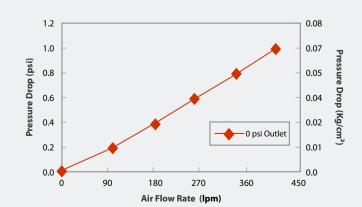
End Connection Type: E: 1½" Sanitary Flange



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



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



DST DVLV01X1423L

Ordering Information

Datasheet

0.2 μm AseptiVent[®] VF-γ 25mm PVDF Membrane Capsule filter

Туре		Size		Pore Size Inlet/Outlet		Inlet/Outlet		Radiat Steriliz		X	Sterility		Pack S	ize
Co	ode		Code		Code		Code		Code			Code		Code
AseptiVent [®] VF-γ IV	/FX	25 mm	06	0.2µm	01	1/8" Hose Barb	Н	Yes	R		Non Sterile	1	100	04
						Female Luer Lock	М	No*	Х		Gamma Sterile	3		
						Male Luer Slip	N							
						Male Luer Lock	L							
						1/4" Hose Barb	В							
Example:						L								
IVFX		06		01		MN		R		Х	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

Туре		Size		Pore S	ize	Inlet/Outlet		Inlet/Outlet		Radiati Steriliza		x	Sterility	,	Pack	Size
	Code		Code		Code		Code		Code			Code		Code		
AseptiVent [®] VF-γ	IVFX	37 mm	08	0.2µm	01	1⁄4″ SHB	В	Yes	R		Non Sterile	1	10	02		
		50 mm	10			³ ⁄ ₄ " Sanitary Flange	S	No*	Х		Gamma Sterile	3				

Example:

IVFX 10 01	BB	R	Х	1	02
------------	----	---	---	---	----

* Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: IVFX0801BBRX102

Example for gamma Sterile: IVFX0801BBXX302

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

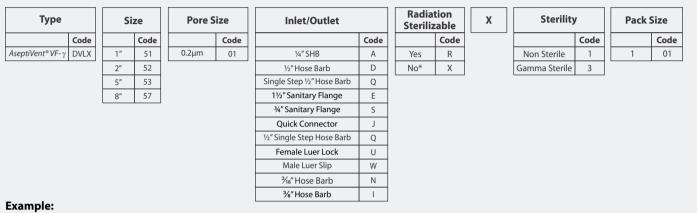
Connections Available								
Inlet/Outlet	37mm	50mm						
¹ ⁄ ₄ " - ³ ⁄ ₄ " Stepped Hose Barb	Х	\checkmark	\checkmark					
¾" Sanitary Flange	Х	x	\checkmark					
Female Luer Lock	Inlet Only	х	х					
Male Luer Slip	Outlet Only	х	х					
1⁄8" Hose Barb		х	х					
Male Luer Lock	Outlet Only	Х	Х					
¼" Hose Barb		Х	Х					

Dimension (in mm)	Inline Capsule Filters						
Inlet/ Outlet	25mm	37mm	50mm				
1/4" - 3/8" Stepped Hose Barb I/O	-	64	79				
¼" 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				

Ordering Information

Datasheet

0.2 μm AseptiVent[®] VF-γ PVDF Membrane Capsule filter



DVLX 57	01 EE	R	х	1	01
---------	-------	---	---	---	----

* Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: DVLX5301QQRX101 Example for gamma Sterile: DVLX5301QQXX301

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Inlet/Outlet	Size/Length								
	1″	2″	5″	8″					
1/4" Stepped Hose Barb	\checkmark	\checkmark	\checkmark						
½"Hose Barb		\checkmark	\checkmark						
1½ ″ Sanitary Flange		\checkmark	\checkmark						
¾" Sanitary Flange	\checkmark	\checkmark	\checkmark						
Quick Connector		\checkmark	\checkmark						
1/2" Single Step Hose Barb	х	\checkmark	\checkmark	\checkmark					
Female Luer Lock	\checkmark	\checkmark	\checkmark	\checkmark					
Male Luer Slip	Outlet Only	х	х	х					
¾₅" Hose Barb	\checkmark	\checkmark	Outlet Only	х					
¾" Hose Barb	х								

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				
1⁄2" Hose Barb I/O	90	112	162	214				
½" Single Step Hose Barb I/O	-	115	165	218				
1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	-	112	165	216				
3/8" Hose Barb I/O	-	115	167	217				
Operational Radius	40	65	65	65				

Ordering Information

Datasheet

0.2 μm AseptiVent[®] VF-γ PVDF Membrane Capsule filter

Type Size		Size		Pore Size		Inlet/Outlet	Inlet/Outlet		Inlet/Outlet Radiation Sterilizable			Inline/T	-1
	Code		Code		Code		Code		Code		Γ		
AseptiVent [®] VF-γ	LVLX	5″	53	0.2µm	01	1/2" Single Step Hose Barb	Q	Yes	R	Inline	T		
		10″	54			1½" Sanitary Flange	E	No*	Х	T-line**	T		
		20″	55			³ 4" Sanitary Flange	S	-					
		30″	56			³‰" Hose Barb	I						
						1" Hose Barb	Z						

Inline/T	Line	Sterilit	Sterility		
	Code		Code		Code
Inline	Х	Non Sterile	1	1	01
T-line**	Т	Gamma Sterile	3		

Example:

LVLX 54 01	EE R	X 1 01	
------------	------	--------	--

* Gamma irradiated filters cannot be gamma sterilized again

Example for Non Sterile: LVLX5401QQRX101 Example for gamma Sterile: LVLX5401QQXX301

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

** T-line Capsule Filter are available with 11/2" Sanitary Flange I/O Connections Only

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Inlet/Outlet	Inline			T-Line		Dimensions (in mm)	Inline Capsule Filters			ers	T-line Capsule Filters				
	5″	10″	20″	30″	10″	20″	30″	End Connections	5″	10″	20″	30″	10″	20″	30″
1/" Single Step Lless Barb	1	1	1	1	x	<u> </u>	v	1½" Sanitary Flange I/O	205	330	600	855	340	580	840
¹ / ₂ " Single Step Hose Barb	Hose Barb $\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{$	X	X	³ ⁄₄" Sanitary Flange I/O	214	335	х	х	х	х	x				
1½" Sanitary Flange	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	1/2" Single Step Hose Barb I/O	218	336	630	890	x	х	х
¾" Sanitary Flange			х	х	х	х	х	1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334	620	870	x	x	x
¾″ Hose Barb					х	x	х	¾″ Hose Barb I/O	211	332	634	878	х	x	х
			1" Hose Barb I/O	х	405	635	895	х	х	х					
1" Hose Barb	Х			\checkmark	Х	Х	Х	Operational Radius	80	80	80	80	80	80	80

Advanced Microdevices Pvt. Ltd.

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