



Data Sheet

0.2µm *AseptiCap*[®] VK-γ

Gamma Irradiatable Hydrophilic Polyethersulfone (PES) and Hydrophobic PVDF Membrane Capsule Filters

mdi *AseptiCap*[®] VK-γ capsule filters incorporate a specially designed combination of validated sterilizing grade hydrophobic PVDF as well as hydrophilic Polyethersulfone (PES) membrane to facilitate and provide unique performance advantages in pre-use integrity testing of aseptic filtration systems.

AseptiCap[®] VK-γ capsule filters help carry out critical functions such as filter wetting and integrity testing while maintaining sterility of the aseptic filtration system.

mdi produces a wide range of Gamma compatible Sterilizing grade *AseptiCap*[®] VK-γ devices to meet filtration requirements of biopharmaceutical processing. These filter devices are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as absolute retention, high flow rates and throughputs.

With the advantages linear scalability of filter area for smooth transitions from lab scale to pilot to process scale and widest range of end connections for quick and reliable connections to the existing fittings, **mdi** *AseptiCap*[®] VK-γ filters offer a universal solution for process filtration.

Advantages

- Allows unlimited water for injection (WFI) flushing of sterilizing grade product filter for easy wetting
- Allows fast drying of the filtration system necessary for processes involving oily solutions
- Acts as a sterile barrier against inadvertent ingress of environmental air

AseptiCap® VK-γ 0.2 micron capsule filters use **mdj** hydrophilic PES membrane and hydrophobic PVDF membrane in Gamma compatible Polypropylene housing. No adhesives or glue are used in the manufacturing process and all bonding is done by heat welding.

Key Features

- Absolute retention
- 100% integrity tested
- Very low hold up volume in filters
- High flow rates
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Widest range of end connections
- Products available for total scalability
- Total traceability through unique serial number for each filter
- Sterilizable by Gamma irradiation

Quality Assurance

mdi 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.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention to establish acceptable integrity test values.

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

100% Integrity Tested

Each *AseptiCap*® VK- γ is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Flow Rate

Each lot is tested for water and air flow rates to ensure that flow rates are within the specifications.

Pressure, Temperature Endurance

AseptiCap® VK- γ 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.

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 Limulus Amebocyte Lysate (LAL) Test as per USP <85>.

Total Traceability

AseptiCap® VK- γ 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.

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, In-vivo, USP <88> for class VI Plastics
- Complies with Biological Reactivity Tests, In-vitro, USP <87> for Cytotoxicity

Easy Connect

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 AseptiCap® VK-γ 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 gamma irradiation.



1/2" HB



1/2" Single Stepped
Hose Barb



1/4" MNPT



1/4" SHB



Quick Connector



Male Luer Slip



3/8" Hose Barb



Female Luer Lock



1 1/2" Sanitary Flange



3/4" Sanitary Flange



1/2" MNPT



1" Hose Barb

Variety of end connections

Customized Connectivity

mdi AseptiCap® VK-γ 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.



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



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



AseptiCap® with HighSecurity
1/2" hose barb connection

Linear Upscaling from R&D to Production Process

mdi offers a wide range of *AseptiCap*[®] VK-γ filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to required flush volumes.



***AseptiCap*[®] VK-γ**
1", 250cm²



***AseptiCap*[®] VK-γ**
2", 500cm²



***AseptiCap*[®] VK-γ**
5", 1000cm²



***AseptiCap*[®] VK-γ**
8", 2000cm²



***AseptiCap*[®] VK-γ**
5", 3000cm²



***AseptiCap*[®] VK-γ**
10", 6000cm²

Filter Devices	EFA* (Nominal)	Hold up Volume
<i>AseptiCap</i> [®] VK-γ 1"	250cm ²	< 5ml
<i>AseptiCap</i> [®] VK-γ 2"	500cm ²	< 25ml
<i>AseptiCap</i> [®] VK-γ 5"	1000cm ²	< 45ml
<i>AseptiCap</i> [®] VK-γ 8"	2000cm ²	< 60ml
<i>AseptiCap</i> [®] VK-γ 5" Large	3000cm ²	< 80ml
<i>AseptiCap</i> [®] VK-γ 10"	6000cm ²	< 150ml

***EFA: Effective Filtration Area**

Specifications

Small Capsule Filters

Datasheet

Construction

Membrane	Hydrophobic PVDF and Hydrophilic PES
Support Layers	Polyester
Plastic Parts	Gamma Stable Polypropylene

Integrity Testing / Retention

Bubble Point	≥ 18 psi (1.26 Kg/cm ²) with 50% IPA/water solution
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²

Size

Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	250cm ²	500cm ²	1000cm ²	2000cm ²
Operational Radius (with Vent/ Drain)	40 mm	65 mm	65 mm	65 mm
Vent and Drain	¼" Hose Barb with Silicone "O" ring			

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 Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters should not be autoclaved or in-line steam sterilized.
Shelf Life	2 years after gamma sterilization

Assurance

Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity
Bacterial Retention	LRV > 7 for <i>B. diminuta</i> (ATCC 19146) 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
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications

Large Capsule Filters

Construction

Membrane	Hydrophobic PVDF and Hydrophilic PES
Support Layers	Polyester
Plastic Parts	Gamma Stable Polypropylene

Integrity Testing / Retention

Bubble Point	≥ 18 psi (1.26 Kg/cm ²) with 50% IPA/water solution
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²

Size

Size	5"	10"
Effective Filtration Area (Nominal)	3000 cm ²	6000 cm ²
Operational Radius (with Vent/ Drain)	80 mm	80 mm
Vent and Drain	¼" Hose Barb with Silicone "O" ring	

Operational

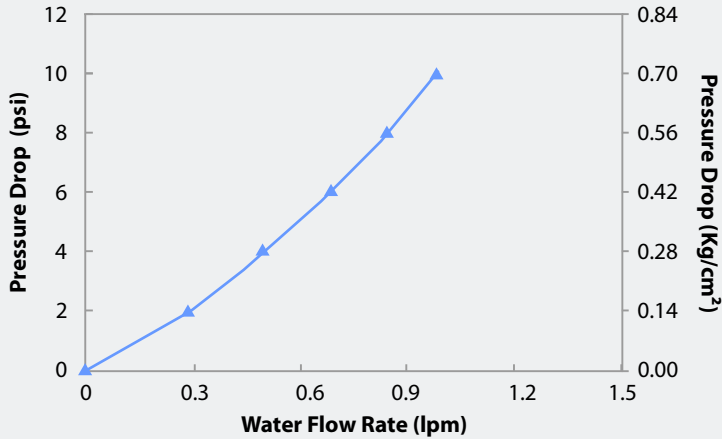
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm ²)
Max. Differential Pressure	60 psi (4 Kg/cm ²) @ 30 °C
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters should not be autoclaved or in-line steam sterilized.
Shelf Life	2 years after gamma sterilization

Assurance

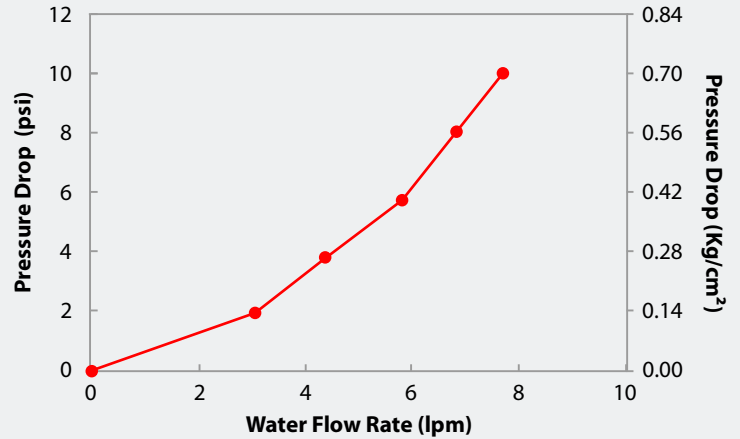
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity
Bacterial Retention	LRV > 7 for <i>B. diminuta</i> (ATCC 19146) per cm ² of filter area as per ASTM F 838
Bacterial Endotoxin	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
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Typical Water Flow Rates

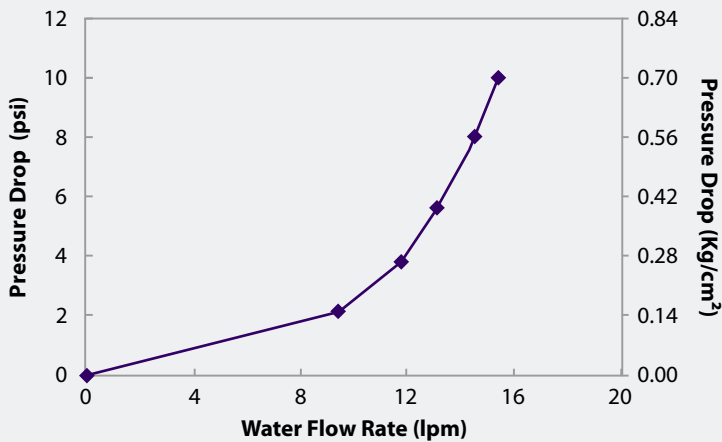
1" Capsule Filters, DD Connection



5" Capsule Filters, DD Connection



10" Capsule Filters, QQ Connection



End Connection Type:

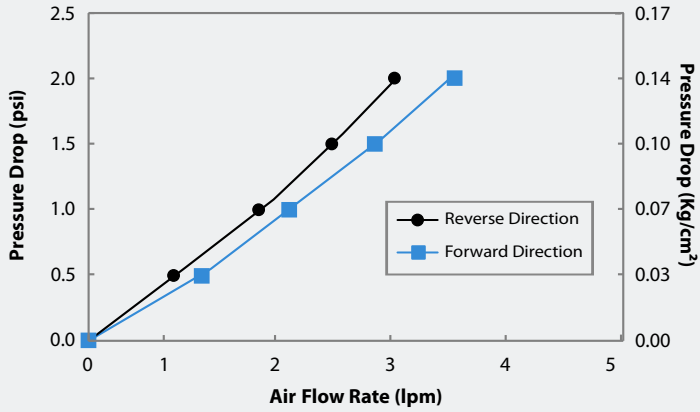
DD: ½" Hose Barb

QQ: ½" Single Step Hose Barb

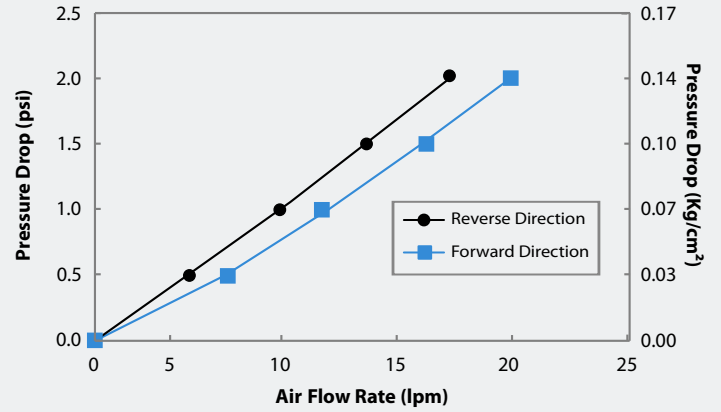
Typical Air Flow Rates in Wet Condition

Datasheet

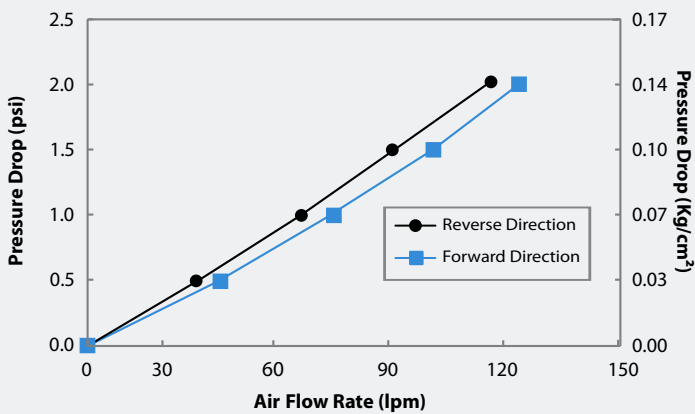
1" Capsule Filters, DD Connection



5" Capsule Filters, DD Connection



10" Capsule Filters, QQ Connection



End Connection Type:

DD: 1/2" Hose Barb

QQ: 1/2" Single Step Hose Barb

0.2 µm AseptiCap® VK-γ Small Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Bell		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
AseptiCap VK-γ	DVKX	1"	51	0.2µm	01	¼" SHB	A	Yes	R	Yes**	B	Non Sterile	1	1	01
		2"	52			1½" Sanitary Flange	E	No*	X	No Bell	X	Gamma Sterile	3		
		5"	53			½" Hose Barb	D			Bell with cover	C				
		8"	57			¾" Sanitary Flange	S								
						Quick Connector	J								
						½" Single Step Hose Barb	Q								
						⅜" Hose Barb	N								
						⅝" Hose Barb	I								

Example:

DVKX	57	01	DD	R	X	1	01
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* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: DVKX5101QQRX101

Example for gamma Sterile: DVKX5101QQXX301

** Bell is available with

½" Hose Barb outlet connections in 1", 2", 5" and 8" capsule filters

¼" SHB outlet connection in 1" capsule filters only

Inlet/Outlet Connections

Inlet/Outlet	Size/Length			
	1"	2"	5"	8"
¼" Stepped Hose Barb	√	√	√	√
½" Single Step Hose Barb	X	√	√	√
½" Hose Barb	√	√	√	√
1½" Sanitary Flange	√	√	√	√
¾" Sanitary Flange	√	√	√	√
Quick Connector	√	√	√	√
⅜" Hose Barb	√	√	Outlet Only	X
⅝" Hose Barb	X	√	√	√

Dimensions (in mm)

End Connections	1"	2"	5"	8"
¼" SHB I/O	94	122	172	223
¾" 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 ½" Single Step Hose Barb Outlet	-	112	165	216
3/8" Hose Barb I/O	-	115	167	217
Operational Radius	40	65	65	65

0.2 µm AseptiCap® VK-γ Large Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
AseptiCap VK-γ	LVKX	5"	53	0.2µm	01	½" Single Step Hose Barb	Q	Yes	R		Non Sterile	1	1	01
		10"	54			1½" Sanitary Flange	E	No*	X		Gamma Sterile	3		
						¾" Sanitary Flange	S							
						⅜" Hose Barb	I							
						1" Hose Barb	Z							

Example:

LVKX	54	01	EE	R	X	1	01
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* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: LVKX5301QQRX101

Example for gamma Sterile: LVKX5301QQXX301

Inlet/Outlet Connections

Inlet/Outlet	Inline	
	5"	10"
½" Single Step Hose Barb	√	√
1½" Sanitary Flange	√	√
¾" Sanitary Flange	√	√
⅜" Hose Barb	√	√
1" Hose Barb	x	√

Dimensions (in mm)

Dimensions (in mm)	Inline Capsule Filters	
End Connections	5"	10"
1½" Sanitary Flange I/O	205	330
¾" Sanitary Flange I/O	214	335
½" Single Step Hose Barb I/O	218	336
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334
⅜" Hose Barb I/O	211	332
1" Hose Barb I/O	x	405
Operational Radius	80	80

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