



PROCESS FILTRATION
PRODUCT GUIDE

Company Profile



Advanced Microdevices (**mdi**) is a leader in innovative membrane technologies. Starting from a single person R&D operation in 1976, **mdi** has developed into a dedicated team of 600 plus with more than 15000 products.

The company's core competence is its ability to develop new membrane technologies and innovate existing ones to deliver advantages to the customer for high end purification and separation applications in a wide range of industries such as pharmaceuticals, biopharmaceuticals, biotechnology, food and beverage, hospitals, and immunodiagnostics.



As membranes end up being incorporated into user friendly devices, plastic design and moulding and sealing technologies become an integral part of the chain to deliver value to the customer. Realizing this, **mdi** has grown into a vertically integrated company that helps deliver prototypes rapidly for quicker conversion to products for the market.

mdi products are used for critical applications in pharmaceutical and biopharmaceutical industries, such as sterilization of injectable drugs, sterility testing, sample preparation of drugs that are tested with highly sophisticated instrumentation, and development of new drug entities and formulations. **mdi** also offers world class membranes for making reliable immunoassays for testing of diseases at patient bedside.

mdi products meet or exceed industry standards and many of these are recognized as the best available in the world.



These products are manufactured by highly trained manpower in modern GMP facilities with large ISO class 7 production areas under ISO 9001 certified quality management system and are backed by state of the art QC testing, microbiology, reliability and validation laboratories.

**World Class GMP Compliant
Multilocation Facilities (200,000 sq. ft.)**

A strong pipeline of new products is constantly being developed in its well equipped R&D labs.

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mdi offers customized solutions to enhance process efficiency, productivity, product quality, and consistency for wide range applications in biopharmaceuticals, pharmaceuticals, biotechnology, microelectronics, and immunodiagnostics.

Research and Development

A unique multidimensional research and development facility at **mdi**, involving teams specializing in critical areas of membrane technology, biotechnology, electronics, chemistry, and mechanical engineering, continuously strives with an integrated approach to develop advanced, innovative and customized products.

These filters have innovative design inputs to deliver unique performance advantages over competing products in terms of higher retention efficiencies, flow rates, throughputs, and lower filtration losses.

This unparalleled capability to develop custom products and solutions is a continuous source of pride and drives the **mdi** team to push the boundaries of technology and maximize value for the user.



mdi Microfiltration products are well designed with built-in quality assurance.

The careful selection of raw materials, validated production processes and Quality Management System certified by ISO 9001:2015 ensures consistently high quality products. **mdi** products meet 21 CFR, ASTM, compendia requirements and meet global regulatory expectations.

Facilities

mdi filters are produced and packaged in facilities meeting GMP requirements such as Clean Rooms with Class 10,000 and Class 100 areas for critical processes.

Deep Characterization and Certification

Apart from retention efficiency and other functional parameters such as flowrates, temperature/hydraulic stress etc., **mdi** filters are deeply characterized for critical areas of concern such as biosafety, bioburden levels, endotoxin levels and extractables.

Quality Control

The filters go through stringent in process and final product testing and quality is ensured by in place QMS.

Traceability

Each sterilizing grade cartridge and capsule filter has unique identification number and is accompanied with individual certificate of quality.



As per regulatory requirements, the pharmaceutical industry has to provide a high level of assurance that the sterile drug product, manufactured through aseptic processing, offers the identity, strength, quality, and purity it purports to have or is represented to possess (Ref. USFDA 21CFR 211.100(a).) Consequently it has become increasingly critical to establish/quantify the impact on the drug due to its interface with various process components under different process conditions.

Sterilizing grade filters are of critical importance in aseptic manufacturing, and it is the drug manufacturer's responsibility to show that the selected filter is able to sterilize the product under the process conditions and it does not affect the purity, quality and strength of the drug product.

Validation Services

mdi ascertain Filter validation services are designed to meet customer specific needs and help achieve regulatory compliance. These include the following:

- **Studies establishing filter integrity test values specific to drug product**
- **Filter fluid interaction studies**
 - Physico-Chemical compatibility studies
 - Extractable/Leachable studies
 - Adsorption studies
- **Microbial retention studies**
- **Throughput Studies**

All of these studies are executed as per pre-approved test methodologies to establish the test conditions and acceptance criteria.

mdi also offers post validation support for regulatory audits.

Validation Guides

mdi filters are validated as per global regulatory requirements. These filters, in compliance with the Regulation Title 21 Code of Federal Regulations (CFR) Part 314.420, have been registered at the U.S. Food and Drug Administration through Drug Master File #DMF 15554.

Detailed documentation on validation of **mdi** filters for sterilization of fluids (air/gases and liquids) in form of Validation Guides is also available.



mdi technology executives assist in problem solving and process upgradation through experience sharing and developing customized products and systems. Some of these customer support activities are:

» Customized Filtration Solutions

mdi offers customized solutions for complex filtration problems. **mdi** technology executives will help you in finding solutions to filter difficult to filter fluids & minimizing filtration losses.

» Filtration System Design

Designing an efficient filtration system is an integral part of process optimization for minimizing filtration costs, increasing yields and reducing process time. **mdi** offers technical support for selection of filter materials by performing throughput studies to optimize filter train and filter sizing.

» Installation and Operational Qualification

mdi provides well documented installation, operational and performance qualification guidelines for all the equipment and systems it offers.

» Regulatory Assistance

mdi provides complete regulatory assistance to its customers. **mdi** products and validation services meet global regulatory expectations.

» Technical Seminars

Technical seminars at customer's location are organized to help the users understand the performance characterization of product in use, differentiate between various options available in the market and select the best solutions to suit their requirements. These interactions help create optimized systems and also upgrade current processes in terms of performance and cost effectiveness.



Filter Selection and Sizing

Highly regulated process industries such as pharmaceuticals and biopharmaceuticals work with a very wide variety of process streams/fluids under different process conditions. They continuously face with the challenge of achieving their process objectives efficiently and cost effectively.

Microfiltration is a key process step to achieve critical process objectives that range from sterilization of process fluids to bioburden reduction, polishing and clarification.

These process streams can range from easy to filter water for injection to difficult to filter colloidal solutions, emulsions, liposomal drug delivery systems or large molecule high value therapeutic proteins and vaccine concentrates. Such a wide spectrum of process streams, coupled with different process objectives, is quite a challenge for the process owner.

Selection of the right filters and their sizing to meet various process needs is thus critical to successfully achieve the desired objectives.

For establishing filter type, the following important questions need to be answered with respect to the process:

1. What is the objective of filtration?
 - Sterilization
 - Bioburden reduction
 - Particle removal
 - Clarification
2. What is the fluid to be filtered?
 - Liquid or gases
 - What are the fluid properties such as pH, viscosity, temperature and surface tension
3. What will be the process conditions?
 - Will the filtration system be inline steam sterilized or autoclaved?
 - Will the system be sanitized with chemicals or hot water?
 - What are the sterilization/sanitization conditions?
 - Are the filters going to be used once or multiple times?
 - How many times the system will be sterilized /sanitized?
 - What is the maximum operating temperature?
 - What is the allowable maximum allowable differential pressure?
4. Is it going to be a continuous process or batch filtration?
5. What will be the batch volume for full scale process filtration?
6. What is the maximum allowable filtration time or the minimum desired flow rate?

Once the filter type with respect to MOC, pore size etc. has been established the next step is to establish the filter size.

Filter sizing, although to some extent is dependent on factors such as minimum desired flow rate, fluid viscosity as well as temperature, a critical parameter is the contamination profile of the fluid to be filtered. The nature and quantum of contaminants defines their interaction with the filter, which in turn defines the throughput one can achieve from a given filtration area for the fluid in question. An understanding of this behavior will help define not only the right sized filtration system but also the right combination of pre-filters and final filters to achieve desired/optimum throughput.

mdi offers filter sizing services to product development labs and process owners in full scale manufacturing. These involve small scale throughout studies to establish suitable and cost effective filtration system. Different lab scale filter and pre-filter combinations are used to maximize throughputs. The selected combination is, based on desired batch volumes or throughputs, linearly extrapolated to establish filter size.

For more information please contact our local technology executive or write to us at info@mdimembrane.com

Filter Sizing: Linear Upscaling from R&D to Production Process

Researchers in NDDS and formulation development are concerned about the impact of filter fluid interaction on stability, purity, strength etc. of the drug product. They take a keen interest in filter selection at the formulation development stage itself.

Although preliminary compatibility data support initial filter selection, for stability studies, detailed filter validations are required to provide enough documented evidence to justify specific filter use.

A critical requirement that needs to be addressed at this stage is of scalability from R&D to pilot scale to full scale production processes. Any change in filter MOC for full scale processes will require additional validation.

mdi offers a wide range of filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate filter size can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All materials of construction of core, sleeve, end caps, support layers and housing as well as manufacturing process is identical for all filter devices starting from 5 cm² to 18000 cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the filters thereby reducing the additional validation cost and time.



25 mm, 5 cm²



50 mm, 20 cm²



1", 250 cm²



2", 500 cm²



5", 1000 cm²



8", 2000 cm²



10", 6000 cm²

Easy Connect

Wide Range of End Connections

Pharmaceutical and 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.

mdi Capsule 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 conditions of extreme use.

Customized Connectivity

mdi Capsule filters can also be customized to offer different inlet-outlet combinations to meet the unique connectivity needs in process assemblies. 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.



3/4" Sanitary Flange



1 1/2" Sanitary Flange



1/2" HB



1/2" Single Stepped Hose Barb



1/4" SHB



Quick Connector



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



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



**High Security
1/2" Single Step
Hose Barb Connection**

Filters for Sterilization of Liquids: PES Membrane Filters

mdi produces a wide range of Gamma sterilizable and steam sterilizable PES membrane capsule and cartridge filters to meet filtration requirements of biopharmaceutical and pharmaceutical processing.

These filters meet key process requirements such as high retention efficiency, very high protein recoveries, extremely low extractables, high throughputs, wide chemical compatibility etc.

mdi PES filter devices are available as:

Filter Type	Single Layer	Multiple Layer
Gamma Sterilizable Capsule Filters	<i>AseptiCap KL-γ</i>	<i>AseptiCap KS -γ</i> <i>AseptiCap KSO -γ</i>
Autoclavable Capsule Filters	<i>AseptiCap KL</i> <i>AseptiCap KO</i>	<i>AseptiCap KS</i> <i>AseptiCap KSO</i>
Steam Sterilizable Cartridge Filters	–	<i>AseptiSure KS</i>
High Temperature Resistant Steam Sterilizable Cartridge Filters	–	<i>AseptiSure HS</i> <i>AseptiSure HSR</i>

Applications

Sterile Filtration of:

- Cell culture media
- Cell culture media containing serum
- Media additives
- Final product concentrates
- Buffers
- Adjuvants
- Small Volume Parenterals
- Large Volume Parenterals
- Water for Injection

Quality Assurance

These filter devices are manufactured in Class 10,000 clean rooms under ISO 9001 : 2015 certified quality management systems and are validated to meet compendia and regulatory requirements.

Assurance	
Toxicity	Passes Biological Reactivity Test, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity Test, In Vitro, USP <87> for Cytotoxicity
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1
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 211.72 for fiber release
Extractables with WFI	Passes test as per USP <661>
Oxidizable Substances	Passes test as per USP <1231>
Particle Shedding	Passes USP test for particulates in injections
TOC/Conductivity at 25 °C	Meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a specified volume of purified water flush
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

Filter Selection Chart

Application Area	Key Application Requirements	Gamma Sterilizable Capsule Filters	Steam Sterilizable		
			Capsule Filters	Cartridge Filters	
Biopharmaceuticals					
Media preparation	- Mycoplasma removal (in case of Mammalian Cell Culture)	AseptiCap KS -γ 0.1 μm PES Membrane Capsule Filter	AseptiCap KS 0.1 μm PES Membrane Capsule Filter	AseptiSure KS 0.1 μm PES Membrane Cartridge Filter	AseptiSure HS 0.1 μm High Temperature PES Membrane Cartridge Filter
	- Microbial retention (in case of Microbial Fermentation)	AseptiCap KS -γ 0.2 μm PES Membrane Capsule Filter	AseptiCap KS 0.2 μm PES Membrane Capsule Filter	AseptiSure KS 0.2 μm PES Membrane Cartridge Filter	AseptiSure HS 0.2 μm High Temperature PES Membrane Cartridge Filter
Sterile filtration of growth regulators	- Absolute retention - Low protein binding	AseptiCap KS -γ 0.2 μm PES Membrane Capsule Filter	AseptiCap KS 0.2 μm PES Membrane Capsule Filter	AseptiSure KS 0.2 μm PES Membrane Cartridge Filter	AseptiSure HS 0.2 μm High Temperature PES Membrane Cartridge Filter
Sterile filtration of alkaline/acidic solutions for pH control	- Absolute retention - Compatible with 1-14 pH	AseptiCap KSO-γ 0.2 μm PES Membrane Capsule Filter	AseptiCap KO/KSO 0.2 μm PES Membrane Capsule Filter	–	AseptiSure HSR 0.2 μm High Temperature PES Membrane Cartridge Filter
Cell Harvesting	- Bioburden reduction	AseptiCap KS -γ 0.2 μm or 0.45 μm PES Membrane Capsule Filter	AseptiCap KS 0.2 μm or 0.45 μm PES Membrane Capsule Filter	AseptiSure KS 0.2 μm or 0.45 μm PES Membrane Cartridge Filter	AseptiSure HS 0.2 μm or 0.45 μm High Temperature PES Membrane Cartridge Filter
Buffer filtration	- Bioburden reduction - Absolute retention	AseptiCap KS -γ 0.2 μm or 0.45 μm PES Membrane Capsule Filter	AseptiCap KS 0.2 μm or 0.45 μm PES Membrane Capsule Filter	AseptiSure KS 0.2 μm or 0.45 μm PES Membrane Cartridge Filter	AseptiSure HS 0.2 μm or 0.45 μm High Temperature PES Membrane Cartridge Filter
Sterile filtration of vaccines and therapeutic proteins	- Absolute retention - Low protein binding - Low holdup volume	AseptiCap KS -γ 0.2 μm PES Membrane Capsule Filter	AseptiCap KS 0.2 μm PES Membrane Capsule Filter	–	–
Pharmaceuticals					
Large Volume Parenterals	- Absolute retention - High throughputs	–	–	AseptiSure KS 0.2 μm PES Membrane Cartridge Filter	AseptiSure HS 0.2 μm High Temperature PES Membrane Cartridge Filter
Small Volume Parenterals	- Absolute retention - Low Protein Binding - Wide Chemical Compatibility	AseptiCap KS -γ 0.2 μm PES Membrane Capsule Filter	AseptiCap KS 0.2 μm PES Membrane Capsule Filter	AseptiSure KS 0.2 μm PES Membrane Cartridge Filter	AseptiSure HS 0.2 μm High Temperature PES Membrane Cartridge Filter
WFI	- Absolute retention	AseptiCap KS -γ 0.2 μm PES Membrane Capsule Filter	AseptiCap KS 0.2 μm PES Membrane Capsule Filter	AseptiSure KS 0.2 μm PES Membrane Cartridge Filter	AseptiSure HS 0.2 μm High Temperature PES Membrane Cartridge Filter

AseptiCap KL/KS 25 mm and 50 mm

Specially designed filters for process development and formulation development labs with identical materials of construction for easy scale up to large capsule and cartridge filters.

50mm is a specially vented device, for use with peristaltic pump, to ensure easy removal of entrapped air in the upstream.

Radiation Sterilizable: AseptiCap KL/KS-γ

Autoclavable: AseptiCap KL/KS



Microbiologically Validated
as per ASTM F 838-05

Complies with
USFDA 21 CFR 210.3 (b) (6)

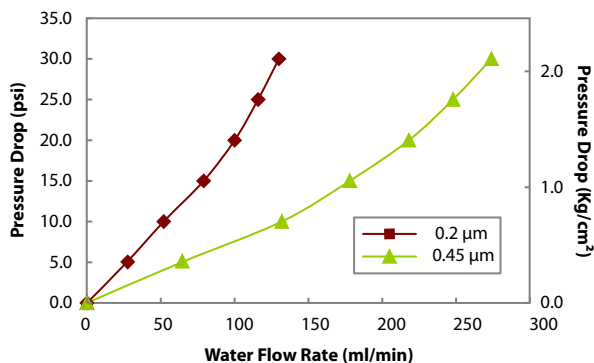
Meets and Exceeds
USFDA 21 CFR 177.1520

Specifications

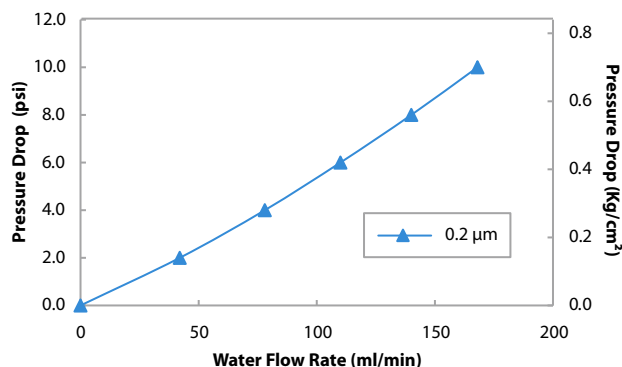
Construction			
Membrane		Hydrophilic PES	
Body and Core		Polypropylene	
Final Filter Pore Size	0.1 μm	0.2 μm	0.45 μm
Prefilter Pore Size (In case of <i>AseptiCap KS</i>)	0.2 μm, 0.45 μm	0.8 μm, 0.65 μm, 0.45 μm	0.8 μm, 0.65 μm
Integrity Testing/Retention			
Bubble Point	≥ 31 psi (2.18 Kg/cm ²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm ²) with Water	≥ 30 psi (2.11 Kg/cm ²) with Water
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²
Size			
Size	25 mm		50 mm
Effective Filtration Area (Nominal)	5 cm ²		20 cm ²
Operational			
Max. Operating Temperature	55 °C		60 °C
Max. Differential Pressure	75 Psi (5 Kg/cm ²) @ 25 °C		42 Psi (3 Kg/cm ²) @ 30 °C
Hold-up Volume(with air purge)	<50 μL		<300 μL
Burst Pressure	> 14 Kg/cm ²		> 8 Kg/cm ²
Sterilization	By Irradiation	<i>AseptiCap KL/KS</i> ~γ: Gamma Irradiatable up to 50 kGy	
	By Gas	<i>AseptiCap KL/KS</i> : Sterilizable by Ethylene Oxide	
	By Autoclave	<i>AseptiCap KL/KS</i> : Autoclavable at 125°C for 30 minutes, 25 cycles	
These cannot be In-line steam sterilized			
Shelf Life	2 years after gamma sterilization 3 years after Ethylene Oxide sterilization		
pH Compatibility	Compatible with pH range of 1-10		

Water Flow Rates

AseptiCap KL -γ 25 mm



AseptiCap KL -γ 50 mm



Ordering Information

AseptiCap KL/KS and AseptiCap KL/KS -γ, 25 mm

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code	Dia	Code		Code		Code		Code			Code		Code
AseptiCap KL	IKLX	25 mm	06			Female Luer Lock	M	Yes	R		Non Sterile	1	100	04
AseptiCap KS (0.2 μm Upstream)	IKS1			0.1 μm	36	Male Luer Slip	N	No	X		EO Sterile	2		
AseptiCap KS (0.45 μm Upstream)	IKSX			0.2 μm	01	1/8" Hose Barb	H				Gamma Sterile	3		
AseptiCap KS (0.65 μm Upstream)	IKS3			0.45 μm	02	1/4" Hose Barb	B							
AseptiCap KS (0.8 μm Upstream)	IKS5													

Example

IKLX	06	01	MN	R	X	1	04
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AseptiCap KL/KS and AseptiCap KL/KS -γ, 50 mm

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code	Dia	Code		Code		Code		Code			Code		Code
AseptiCap KL	VKLX	50 mm	10	0.1 μm	36	1/4" SHB	B	Yes	R		Non Sterile	1	10	02
AseptiCap KS (0.2 μm Upstream)	VKS1			0.2 μm	01	3/4" Sanitary Flange	S	No	X		EO Sterile	2		
AseptiCap KS (0.45 μm Upstream)	VKSX			0.45 μm	02						Gamma Sterile	3		
AseptiCap KS (0.65 μm Upstream)	VKS3													
AseptiCap KS (0.8 μm Upstream)	VKS5													

Example

VKSX	10	36	BS	X	X	1	02
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Note: Gamma Sterile filters cannot be Gamma Irradiated again

Example for Non Sterile: VKSX1036BBRX102

Example for Gamma Sterile: VKSX1036BBXX302

For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiCap KL/KS 1", 2", 5", 8"

Polyethersulfone membrane capsule filters are self contained, ready to use, disposable filtration devices that contain a mini cartridge filter element sealed inside a polypropylene housing. These offer highest packing density of the membrane resulting in a very compact capsule offering long service life.

Radiation Sterilizable: AseptiCap KL/KS- γ

Autoclavable: AseptiCap KL/KS

Microbially Validated
as per ASTM F 838-05

Complies with
USFDA 21 CFR 210.3 (b) (6)

Meets and Exceeds
USFDA 21 CFR 177.1520

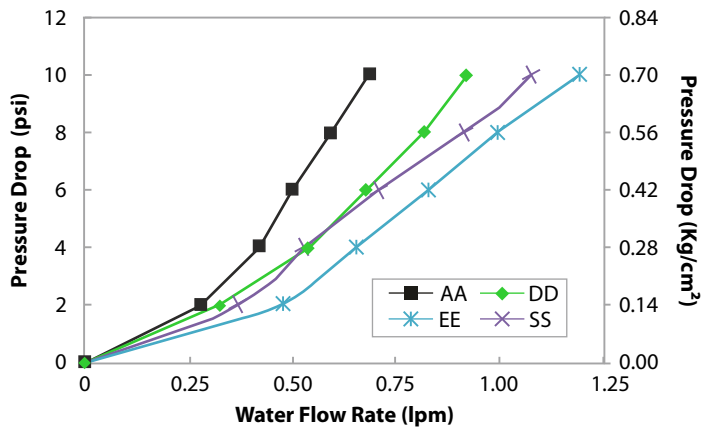


Specifications

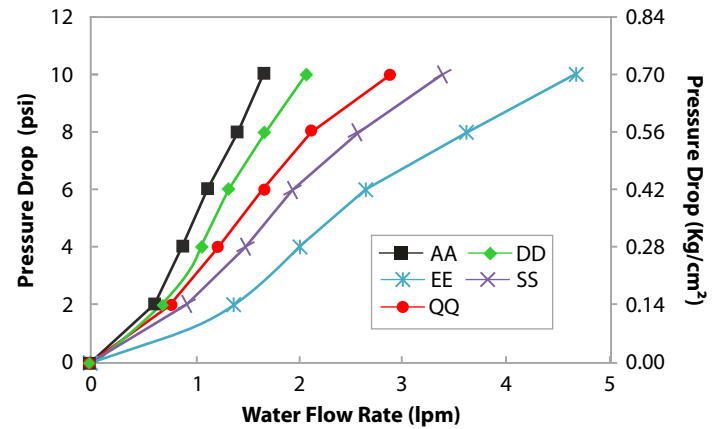
Construction				
Membrane		Hydrophilic PES		
Support Layers		Polyester		
Body and Core		Polypropylene		
Final Filter Pore Size	0.1 μm	0.2 μm	0.45 μm	
Prefilter Pore Size (In case of <i>AseptiCap KS</i>)	0.2 μm, 0.45 μm	0.8 μm, 0.65 μm, 0.45 μm		0.8 μm, 0.65 μm
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm ²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm ²) with Water	≥ 30 psi (2.11 Kg/cm ²) with Water	
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (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
Vent and Drain		¼ " Hose Barb with Platinum Cured 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 Irradiation	<i>AseptiCap KL/KS-γ</i> : Gamma Irradiatable up to 50 kGy		
	By Gas	<i>AseptiCap KL/KS</i> : Sterilizable by Ethylene Oxide		
	By Autoclave	<i>AseptiCap KL/KS</i> : Autoclavable at 125°C for 30 minutes, 25 cycles These cannot be In-line steam sterilized		
Shelf Life		2 years after gamma sterilization 3 years after Ethylene Oxide sterilization		
pH Compatibility		Compatible with pH range of 1-10		

Water Flow Rates

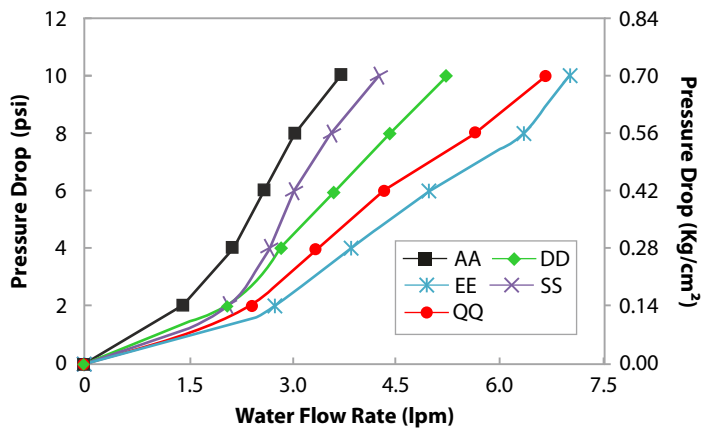
0.1µm AsepticCap KS-γ, 1" Capsule Filter



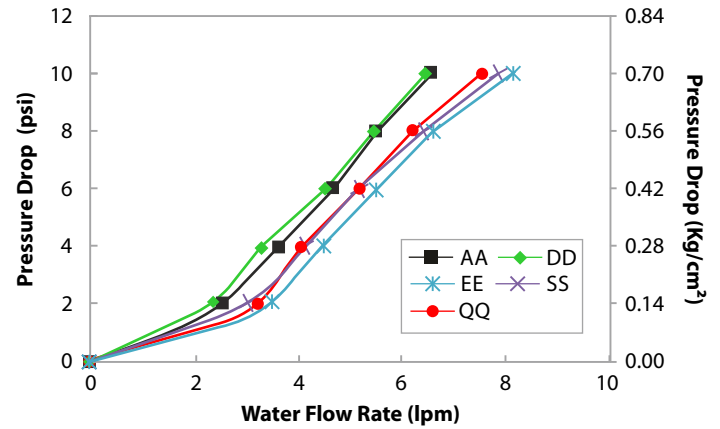
0.1µm AsepticCap KS-γ, 2" Capsule Filter



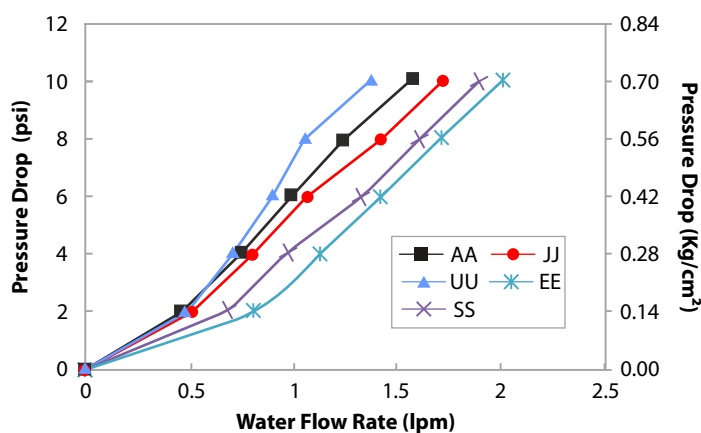
0.1µm AsepticCap KS-γ, 5" Capsule Filter



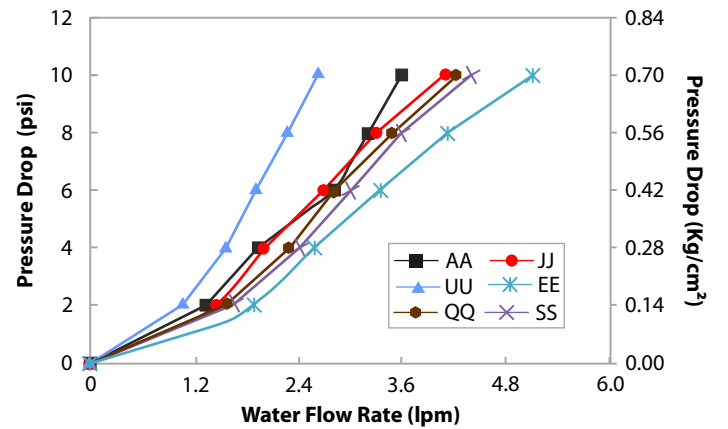
0.1µm AsepticCap KS-γ, 8" Capsule Filter



0.2µm AsepticCap KS-γ, 1" Capsule Filter



0.2µm AsepticCap KS-γ, 2" Capsule Filter

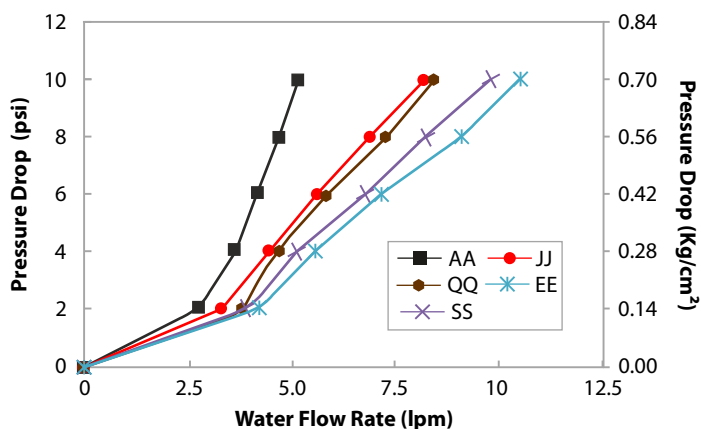


End Connection Type:

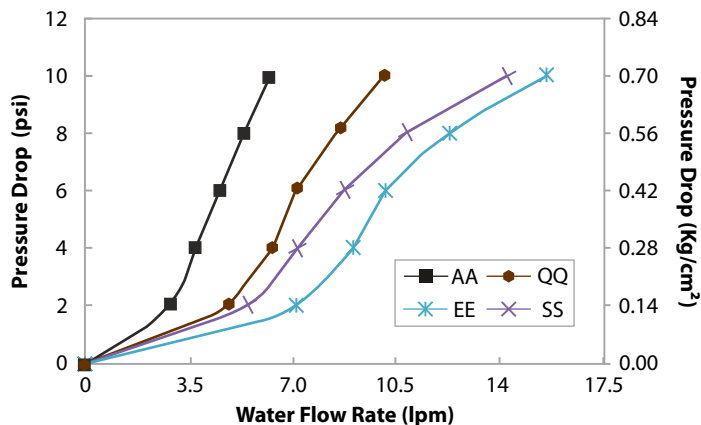
A: ¼" Stepped Hose Barb **Q:** Single Step ½" Hose Barb **E:** 1½" Sanitary Flange **J:** Quick Connector **S:** ¾" Sanitary Flange **U:** Female Luer Lock
J: Quick Connector **D:** ½" Hose Barb

Water Flow Rates

0.2µm AseptiCap KS-γ, 5" Capsule Filter



0.2µm AseptiCap KS-γ, 8" Capsule Filter



End Connection Type:

A: ¼" Stepped Hose Barb

Q: Single Step ½" Hose Barb

E: 1½" Sanitary Flange

J: Quick Connector

S: ¾" Sanitary Flange

J: Quick Connector

Ordering Information

AseptiCap KL/KS and AseptiCap KL/KS -γ

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Bell		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
AseptiCap KL (Single Layer)	DKLX	1"	51	0.1 µm	36	¼" SHB	A	Yes	R	Yes	B	Non Sterile	1	1	01
AseptiCap KS (0.2 µm Upstream)	DKS1	2"	52	0.2 µm	01	¼" MNPT	B	No	X	No Bell	X	EO Sterile	2		
AseptiCap KS (0.45 µm Upstream)	DKSX	5"	53	0.45 µm	02	½" MNPT	C					Gamma Sterile	3		
AseptiCap KS (0.65 µm Upstream)	DKS3	8"	57			½" Hose Barb	D								
AseptiCap KS (0.8 µm Upstream)	DKS5					1½" Sanitary Flange	E								
						¾" Sanitary Flange	S								
						Quick Connector	J								
						Single Step ½" Hose Barb	Q								
						Female Luer Lock	U								
						Male Luer Slip	W								
						¾" Hose Barb	N								
						¾" Hose Barb	I								

Example:

DKSX	57	36	DD	R	X	1	01
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Note: Gamma Sterile filters cannot be Gamma Irradiated again

Example for Non Sterile: DKSX5136DDR01

Example for Gamma Sterile: DKSX5136DDX01

For End Connection, bell availability and dimensions with different sizes refer Pages 85-86.

AseptiCap KS 5", 10", 20", 30"

These are large disposable Polyethersulfone membrane capsule filters for high value biopharma manufacturing processes, providing a unique combination of high throughputs and low hold up volumes. These capsule filters offer serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane and do away with the time and expense associated with assembling, cleaning and validating stainless steel housings.

Radiation Sterilizable: AseptiCap KS-γ

Autoclavable: AseptiCap KS



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

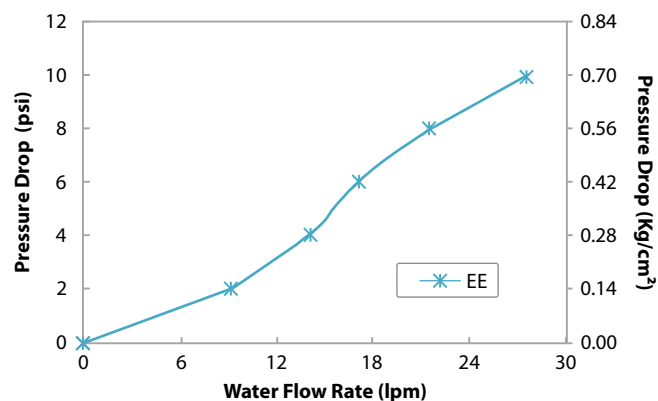
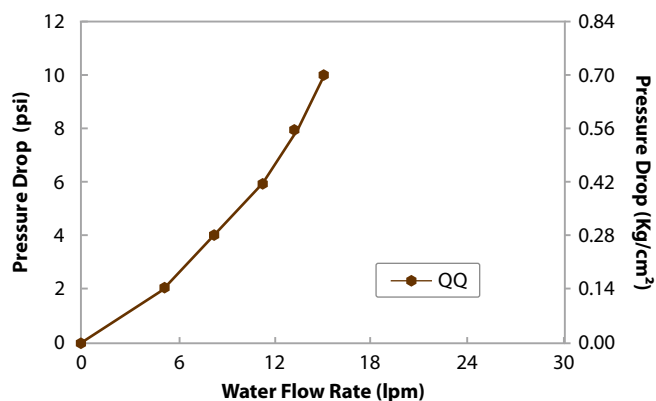
**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

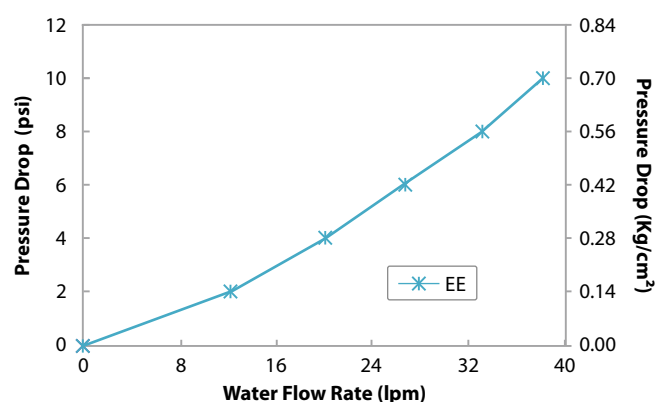
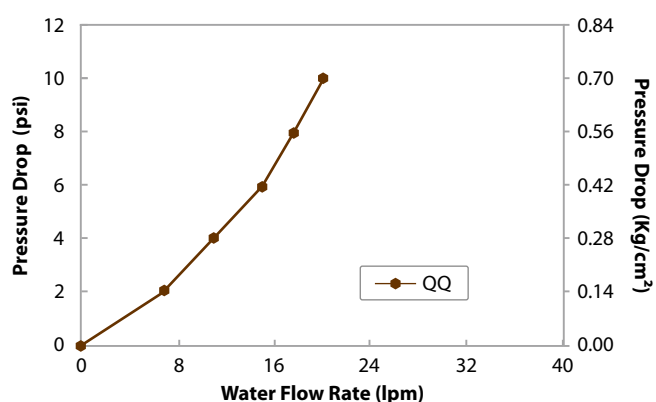
Construction				
Membrane		Hydrophilic PES		
Support Layers		Polyester		
Body and Core		Polypropylene		
Final Filter Pore Size	0.1 μm	0.2 μm	0.45 μm	
Prefilter Pore Size	0.2 μm, 0.45 μm	0.8 μm, 0.65 μm, 0.45 μm		0.8 μm, 0.65 μm
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm²) with Water	≥ 30 psi (2.11 Kg/cm²) with Water	
Max. Air Diffusion Flow for 10" Capsule Filters	≤ 29 ml/min @ 50 psi (3.52 Kg/cm²) with Water	≤ 30 ml/min @ 37 psi (2.6 Kg/cm²) with Water	≤ 35 ml/min @ 22 psi (1.54 Kg/cm²) with Water	
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm²	6000 cm²	12000 cm²	18000 cm²
Vent and Drain		¼" Hose Barb with platinum cured Silicone 'O' ring		
Operational				
Max. Operating Temperature		80 °C @ ≤ 30 psi (2 Kg/cm²)		
Max. Differential Pressure		60 psi (4 Kg/cm²) @ 30 °C		
Sterilization	By Irradiation	AseptiCap KL/KS -γ: Gamma Irradiatable up to 50 kGy		
	By Gas	AseptiCap KL/KS : Sterilizable by Ethylene Oxide		
	By Autoclave	AseptiCap KL/KS : Autoclavable at 125°C for 30 minutes, 25 cycles These cannot be In-line steam sterilized		
Shelf Life		2 years after gamma sterilization 3 years after Ethylene Oxide sterilization		
pH Compatibility		Compatible with pH range of 1-10		

Water Flow Rates

0.1 μm AseptiCap KS- γ , 10" Large Capsule Filters



0.2 μm AseptiCap KS- γ , 10" Large Capsule Filters



End Connection Type: Q: Single Step 1/2" Hose Barb E: 1 1/2" Sanitary Flange

Ordering Information

AseptiCap KS and AseptiCap KS- γ

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline / T-line		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
AseptiCap KS (0.2 μm Upstream)	LKS1	5"	53	0.1 μm	36	1 1/2" Sanitary Flange	E	Yes	R	Inline	X	Non Sterile	1	1	01
AseptiCap KS (0.45 μm Upstream)	LKSX	10"	54	0.2 μm	01	Single Step 1/2" Hose Barb	Q	No	X	T-line**	T	EO Sterile	2		
AseptiCap KS (0.65 μm Upstream)	LKS3	20"	55	0.45 μm	02	3/4" Sanitary Flange	S					Gamma Sterile	3		
AseptiCap KS (0.8 μm Upstream)	LKS5	30"	56			3/8" Hose Barb	I								
						1" Hose Barb	Z								

Example:

LKSX	54	02	EE	R	T	1	01
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* Size 5" is available in In-line Capsule Filters Only

** T-line Capsule Filters are available with 1 1/2" Sanitary Flange connections Only

Note: Gamma Sterile filters cannot be Gamma Irradiated again

Example for Non Sterile: LKSX5402EERX101

Example for Gamma Sterile: LKSX5402EEXX301

For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiCap KO 1", 2", 5", 8"

AseptiCap KO capsule filters incorporate a low protein binding PES membrane with polypropylene drainage layers to ensure pH compatibility from 1-14 making these ideal for alkaline fluid streams.



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

Construction				
Membrane		Hydrophilic PES		
Support Layers		Polypropylene		
Body and Core		Polypropylene		
Filter Pore Size	0.2 μm		0.45 μm	
Integrity Testing/Retention				
Bubble Point	≥ 50 psi (3.52 Kg/cm²) with Water		≥ 30 psi (2.11 Kg/cm²) with Water	
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²		LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm²	
Size				
Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	250 cm²	500 cm²	1000 cm²	2000 cm²
Vent and Drain	1/4" Hose Barb with platinum cured Silicone 'O' ring			
Operational				
Max. Operating Temperature		80 °C @ ≤ 30 psi (2 Kg/cm²)		
Max. Differential Pressure		60 psi (4 Kg/cm²) @ 30 °C		
Sterilization	By Gas	Sterilizable by Ethylene Oxide		
	By Autoclave	Autoclavable at 125 °C for 30 minutes, 25 cycles. Cannot be in-line steam sterilized		
Typical Water Flow Rates (0.2 μm, 8")		7.5 lpm @ 0.70 Kg/cm² @ 27 °C		
Shelf Life		3 years after Ethylene Oxide sterilization		
pH Compatibility		Compatible with pH range of 1-14		

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
AseptiCap KO	DKLO	1"	51	0.2 µm	01	1/4" SHB	A			Non Sterile	1	1	01
		2"	52	0.45 µm	02	1/2" Hose Barb	D			EO Sterile	2		
		5"	53			1 1/2" Sanitary Flange	E						
		8"	57			3/4" Sanitary Flange	S						
						Quick Connector	J						
						Single Step 1/2" Hose Barb	Q						
						Female Luer Lock	U						
						Male Luer Slip	W						
						3/16" Hose Barb	N						
						3/8" Hose Barb	I						

Example:

DKLO	57	01	DD	X	X	1	01
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For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiCap KSO 1", 2", 5", 8"

mdi AseptiCap KSO are Polyethersulfone membrane capsule filters offering wide pH (1-14) compatibility. These filters are specially designed for alkaline fluid streams in bio-pharma manufacturing processes, with added advantages of high throughputs and low hold up volumes.

These capsule filters offer serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughputs.

AseptiCap KSO are validated for use in pharmaceutical and biopharmaceutical applications.

Radiation Sterilizable: AseptiCap KSO- γ

Autoclavable: AseptiCap KSO



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

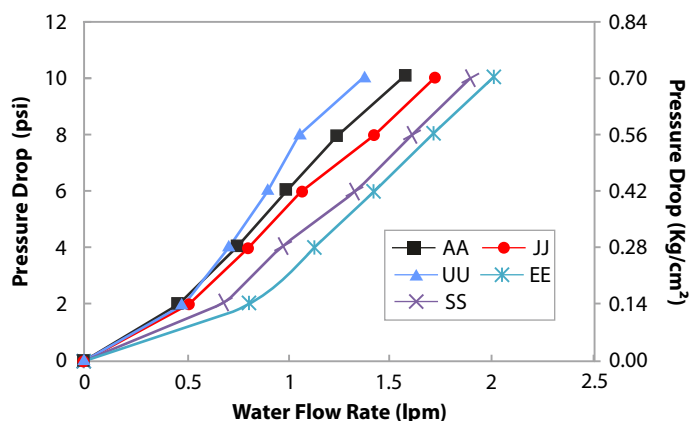
**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

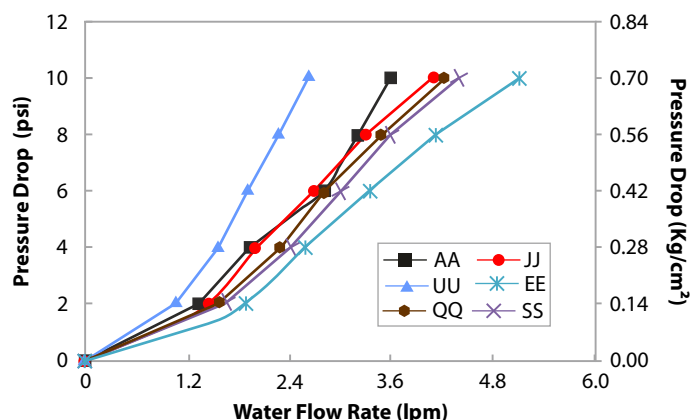
Construction				
Membrane		Hydrophilic PES		
Support Layers		Polypropylene		
Body and Core		Polypropylene		
Final Filter Pore Size	0.2 μm		0.45 μm	
Pre-filter Pore Size	0.8 μm, 0.45μm		0.8 μm	
Integrity Testing/Retention				
Bubble Point	≥ 50 psi (3.52 Kg/cm²) with Water		≥ 30 psi (2.11 Kg/cm²) with Water	
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²		LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm²	
Size				
Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	250 cm²	500 cm²	1000 cm²	2000 cm²
Vent and Drain	¼" Hose Barb with platinum cured Silicone 'O' ring			
Operational				
Max. Operating Temperature		80 °C @ ≤ 30 psi (2 Kg/cm²)		
Max. Differential Pressure		60 psi (4 Kg/cm²) @ 30 °C		
Sterilization	By Irradiation	<i>AseptiCap KSO</i> -γ: Gamma Irradiatable up to 50 kGy		
	By Gas	<i>AseptiCap KSO</i> : Sterilizable by Ethylene Oxide		
	By Autoclave	<i>AseptiCap KSO</i> : Autoclavable at 125°C for 30 minutes, 25 cycles		
	These cannot be In-line steam sterilized			
Shelf Life		2 years after Gamma Sterilization 3 years after Ethylene Oxide Sterilization		
pH Compatibility		Compatible with pH range of 1-14		

Water Flow Rates

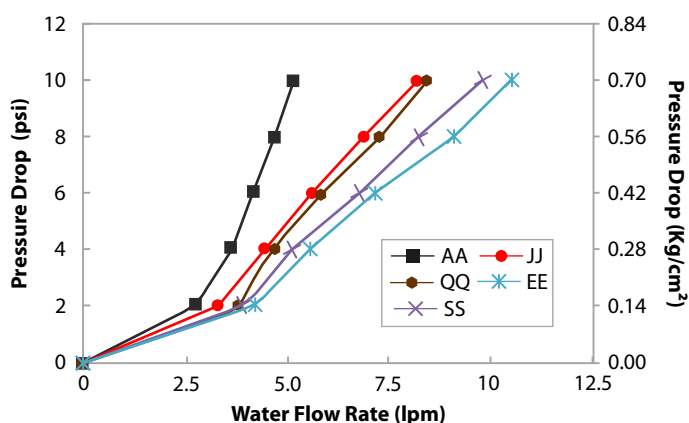
0.2µm AseptiCap KSO-γ, 1" Capsule Filter



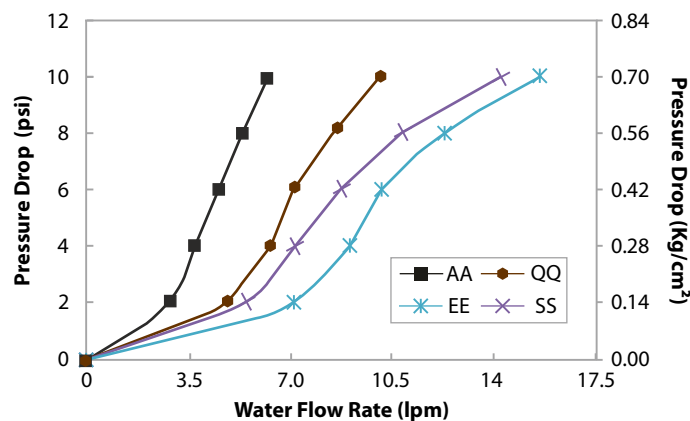
0.2µm AseptiCap KSO-γ, 2" Capsule Filter



0.2µm AseptiCap KSO-γ, 5" Capsule Filter



0.2µm AseptiCap KSO-γ, 8" Capsule Filter



End Connection Type:

A: ¼" Stepped Hose Barb **Q:** Single Step ½" Hose Barb **E:** 1½" Sanitary Flange **J:** Quick Connector **S:** ¾" Sanitary Flange **I:** Quick Connector

Ordering Information

AseptiCap KSO and AseptiCap KSO-γ

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
AseptiCap KSO (0.45 µm Upstream)	DKOX	1"	51	0.2 µm	01	¼" SHB	A	Yes	R		Non Sterile	1	1	01
AseptiCap KSO (0.8 µm Upstream)	DKO5	2"	52	0.45 µm	02	½" Hose Barb	D	No	X		EO Sterile	2		
		5"	53			1½" Sanitary Flange	E				Gamma Sterile	3		
		8"	57			¾" Sanitary Flange	S							
						Quick Connector	J							
						Single Step ½" Hose Barb	Q							
						Female Luer Lock	U							
						Male Luer Slip	W							
						¾" Hose Barb	N							
						¾" Hose Barb	I							

Example:

DKOX	52	02	EE	R	X	1	01
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Note: Gamma Sterile filters cannot be Gamma Irradiated again

Example for Non Sterile: DKOX5202EERX101

Example for Gamma Sterile: DKOX5202EEXX301

For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiCap KSO 5", 10", 20", 30"

mdi AseptiCap KSO are Polyethersulfone membrane capsule filters offering wide pH (1-14) compatibility. These filters are specially designed for alkaline fluid streams in biopharma manufacturing processes, with added advantages of high throughputs and low hold up volumes.

These capsule filters offer serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughputs.

AseptiCap KSO are validated for use in pharmaceutical and biopharmaceutical applications.

Radiation Sterilizable: AseptiCap KSO- γ

Autoclavable: AseptiCap KSO



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

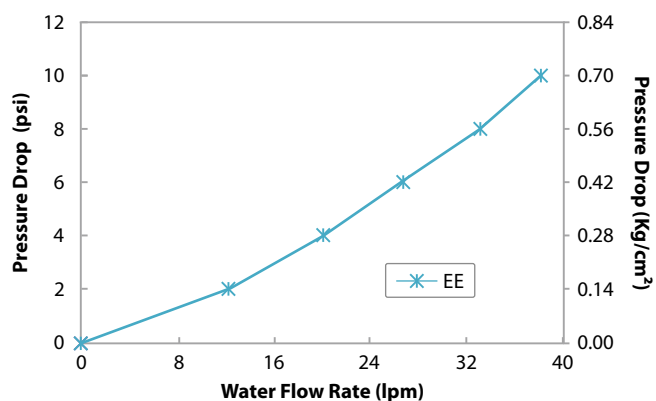
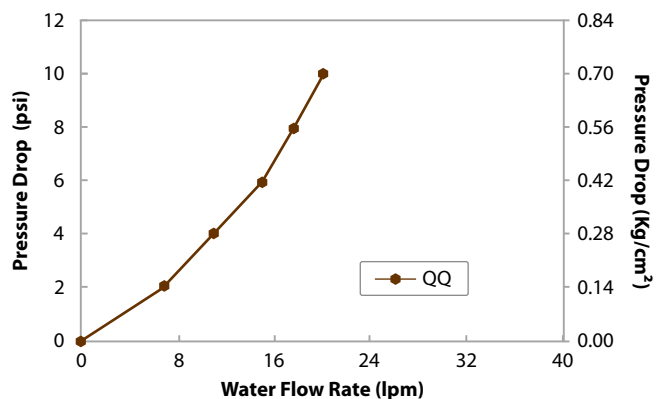
**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

Construction				
Membrane		Hydrophilic PES		
Support Layers		Polypropylene		
Body and Core		Polypropylene		
Final Filter Pore Size	0.2 μm		0.45 μm	
Pre-filter Pore Size	0.8 μm, 0.45μm		0.8 μm	
Integrity Testing/Retention				
Bubble Point	≥ 50 psi (3.52 Kg/cm²) with Water		≥ 30 psi (2.11 Kg/cm²) with Water	
Max. Air Diffusion Flows for 10" Capsule Filters	≤ 30 ml/min @ 37 psi (2.6 Kg/cm²) with Water		≤ 35 ml/min @ 22 psi (1.54 Kg/cm²) with Water	
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²		LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm²	6000 cm²	12000 cm²	18000 cm²
Vent and Drain	¼" Hose Barb with platinum cured Silicone 'O' ring			
Operational				
Max. Operating Temperature		80 °C @ ≤ 30 psi (2 Kg/cm²)		
Max. Differential Pressure		60 psi (4 Kg/cm²) @ 30 °C		
Sterilization	By Irradiation	<i>AseptiCap KSO</i> -γ: Gamma Irradiatable up to 50 kGy		
	By Gas	<i>AseptiCap KSO</i> : Sterilizable by Ethylene Oxide		
	By Autoclave	<i>AseptiCap KSO</i> : Autoclavable at 125°C for 30 minutes, 25 cycles		
		These cannot be In-line steam sterilized		
Shelf Life		2 years after Gamma Sterilization 3 years after Ethylene Oxide Sterilization		
pH Compatibility		Compatible with pH range of 1-14		

Water Flow Rates

0.2 µm AseptiCap KSO, 10" Large Capsule Filters



End Connection Type: Q: Single Step ½" Hose Barb E: 1½" Sanitary Flange

Ordering Information

AseptiCap KSO and AseptiCap KSO-γ

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline / T-line		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
AseptiCap KSO (0.45 µm Upstream)	LK0X	5"	53	0.2 µm	01	1½" Sanitary Flange	E	Yes	R	Inline	X	Non Sterile	1	1	01
AseptiCap KSO (0.8 µm Upstream)	LK05	10"	54	0.45 µm	02	Single Step ½" Hose Barb	Q	No	X	T-line	T	EO Sterile	2		
		20"	55			¾" Sanitary Flange	S					Gamma Sterile	3		
		30"	56			3/8" Hose Barb	I								
						1" Hose Barb	Z								

Example:

LK0X	54	02	EE	R	T	1	01
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* Size 5" is available in In-line Capsule Filters Only

Note: Gamma Sterile filters cannot be Gamma Irradiated again

Example for Non Sterile: LK0X5402EERX101

Example for Gamma Sterile: LK0X5402EEXX301

For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiSure HS Mini Cartridge filters

mdi Polyethersulfone (PES) membrane mini cartridge filters type *AseptiSure HS* are high temperature resistant filtration devices. These are designed to withstand high pressure steam sterilization upto 135°C.

AseptiSure HS mini cartridge filters with Polyethersulfone membrane serial layers offer enhanced throughputs, thus ensuring better economics.

These are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates.



Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 210.3 (b) (6)
Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

Construction			
Membrane	Hydrophilic PES		
Support Layers	Polyester		
Body and Core	Polypropylene		
Final Filter Pore Size	0.1 µm	0.2 µm	0.45 µm
Prefilter Pore Size	0.2 µm, 0.45 µm	0.8 µm, 0.65 µm, 0.45 µm	0.8 µm, 0.65 µm
Integrity Testing/Retention			
Bubble Point	> 31psi (2.18Kg/cm ²) with 50% IPA/Water Solution	> 50psi (3.52Kg/cm ²) with Water	> 30psi (2.11Kg/cm ²) with Water
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²
Size			
Size	2.5"		5"
Effective Filtration Area (Nominal)	1000 cm ²		2000 cm ²
Operational			
Water Flow Rate for 0.2µm @ 0.70kg/cm ² @27°C	9 lpm		15 lpm
Max. Operating Temperature	80 °C @ ≤ 2 Kg/cm ² (30 psi)		
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C		
Reverse Pressure	≤ 10 psi (0.7 Kg/cm ²) @ 80 °C		
Sterilization	In-line steam sterilizable upto 135 °C for 30 minutes at a maximum differential pressure of 5 psi (0.35 Kg/cm ²), 25 cycles		
pH Compatibility	Compatible with pH range of 1-10		

Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure HS (0.2 µm Upstream)	CPH1	2.5"	50	0.1 µm	36	4463	E0	Silicone	SS	Non Sterile	1	1	01
AseptiSure HS (0.45 µm Upstream)	CPHX	5"	53	0.2 µm	01	4463B	H0	*G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering					
AseptiSure HS (0.65 µm Upstream)	CPH3			0.45 µm	02	4440	U0						
AseptiSure HS (0.8 µm Upstream)	CPH5					Seal-K	G0*						
						Seal-O	F0						
						Seal-M	J0						

Example:

CPHX	50	01	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

AseptiSure HS

AseptiSure HS high temperature resistant, serial filtration Polyethersulfone cartridge filters are designed to withstand high pressure differential upto 0.3 Kg/cm² (5 psi) at high steam sterilization temperatures of upto 135 °C.



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

Construction				
Membrane	Hydrophilic PES			
Support Layers	Polyester			
Body and Core	Polypropylene			
Final Filter Pore Size	0.1 μm	0.2 μm	0.45 μm	
Prefilter Pore Size	0.2 μm, 0.45 μm	0.8 μm, 0.65 μm, 0.45 μm		0.8 μm, 0.65 μm
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm ²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm ²) with Water	≥ 30 psi (2.11 Kg/cm ²) with Water	
Air Diffusion Flow (10" Cartridge Filter)	≤ 29 ml/min @ 50 psi (3.52 Kg/cm ²) with Water	≤ 30 ml/min @ 37 psi (2.6 Kg/cm ²) with Water	≤ 35 ml/min @ 22 psi (1.54 Kg/cm ²) with Water	
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm ²	6000 cm ²	12000 cm ²	18000 cm ²
Operational				
Typical Water Flow Rates (for 0.2μm @ 0.70 Kg/cm ² @ 27 °C)	25 lpm	45 lpm	81 lpm	113 lpm
Max. Operating Temperature	80 °C @ ≤ 30psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			
Reverse Pressure	≤ 10 psi (0.7 Kg/cm ²) @ 25 °C			
Sterilization	In-line steam sterilizable upto 135 °C for 30 minutes at a maximum differential pressure of 5 psi (0.35 Kg/cm ²), 25 cycles			
pH Compatibility	Compatible with pH range of 1-10			

Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure HS (0.2 µm Upstream)	CPH1	5"	53	0.1 µm	36	7P	A0	Silicone	SS	Non Sterile	1	1	01
AseptiSure HS (0.45 µm Upstream)	CPHX	10"	54	0.2 µm	01	7P without fin	A1	Viton	SV				
AseptiSure HS (0.65 µm Upstream)	CPH3	20"	55	0.45 µm	02	28 with fin	C0	EPDM	SE				
AseptiSure HS (0.8 µm Upstream)	CPH5	30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CPHX	54	01	A0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

AseptiSure HSR Mini Cartridge Filter

mdi Polyethersulfone (PES) membrane mini cartridge filters type AseptiSure HSR are designed to withstand high pressure differential upto 0.3 Kg/cm² (5 psi) at high steam sterilization temperatures of upto 135 °C.

These filters with Polyethersulfone membrane and Polypropylene support layers offer pH compatibility from 1 to 14 , and are thus ideal for use with acidic as well as alkaline solutions.

mdi AseptiSure HSR Mini Cartridge filters are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates.



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

Construction			
Membrane	Hydrophilic PES		
Support Layers	Polypropylene		
Body and Core	Polypropylene		
Final Filter Pore Size	0.1 µm	0.2 µm	0.45 µm
Prefilter Pore Size	0.2 µm, 0.45 µm	0.8 µm, 0.65 µm, 0.45 µm	0.8 µm, 0.65 µm
Integrity Testing/Retention			
Bubble Point	≥ 31 psi (2.18 Kg/cm ²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm ²) with Water	≥ 30 psi (2.11 Kg/cm ²) with Water
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²
Size			
Size	2.5"	5"	
Effective Filtration Area (Nominal)	1000 cm ²	2000 cm ²	
Operational			
Typical Water Flow Rates (for 0.2µm @ 0.70 Kg/cm ² @ 27 °C)	9 lpm	15 lpm	
Max. Operating Temperature	80 °C @ ≤ 30psi (2 Kg/cm ²)		
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C		
Reverse Pressure	≤ 10 psi (0.7 Kg/cm ²) @ 25 °C		
Sterilization	In-line steam sterilizable upto 135 °C for 30 minutes at a maximum differential pressure of 5 psi (0.35 Kg/cm ²), 25 cycles		
pH Compatibility	Compatible with pH range of 1-14		

Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure HSR (0.2 µm Upstream)	CHR1	2.5"	50	0.1 µm	36	4463	E0	Silicone	SS	Non Sterile	1	1	01
AseptiSure HSR (0.45 µm Upstream)	CHRX	5"	53	0.2 µm	01	4463B	H0	*G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering					
AseptiSure HSR (0.65 µm Upstream)	CHR3			0.45 µm	02	4440	U0						
AseptiSure HSR (0.8 µm Upstream)	CHR5					Seal-K	G0*						
						Seal-O	F0						
						Seal-M	J0						

Example:

CHRX	53	01	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

AseptiSure HSR

mdi Polyethersulfone (PES) membrane cartridge filters type *AseptiSure HSR* are high temperature resistant filtration devices. These are designed to withstand high pressure differential at high steam sterilization temperature upto 135°C. These filters exhibit high mechanical stability, and wide chemical compatibility even with alkaline process fluids.

These filters come with Polyethersulfone membrane serial layers and Polypropylene support layers to offer 1-14 pH compatibility.

mdi *AseptiSure HSR* cartridge filters are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates.



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

Construction				
Membrane	Hydrophilic PES			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Final Filter Pore Size	0.1 μm	0.2 μm	0.45 μm	
Prefilter Pore Size	0.2 μm, 0.45 μm	0.8 μm, 0.65 μm, 0.45 μm		0.8 μm, 0.65 μm
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm ²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm ²) with Water	≥ 30 psi (2.11 Kg/cm ²) with Water	
Air Diffusion Flow (10" Cartridge Filter)	≤ 29 ml/min @ 50 psi (3.52 Kg/cm ²) with Water	≤ 30 ml/min @ 37 psi (2.6 Kg/cm ²) with Water	≤ 35 ml/min @ 22 psi (1.54 Kg/cm ²) with Water	
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm ²	6000 cm ²	12000 cm ²	18000 cm ²
Operational				
Typical Water Flow Rates (for 0.2μm @ 0.70 Kg/cm ² @ 27 °C)	25 lpm	45 lpm	81 lpm	113 lpm
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			
Reverse Pressure	≤ 10 psi (0.7 Kg/cm ²) @ 25 °C			
Sterilization	In-line steam sterilizable upto 135 °C for 30 minutes at a maximum differential pressure of 5 psi (0.35 Kg/cm ²), 25 cycles			
pH Compatibility	Compatible with pH range of 1-14			

Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure HSR (0.2 µm Upstream)	CHR1	5"	53	0.1 µm	36	7P	A0	Silicone	SS	Non Sterile	1	1	01
AseptiSure HSR (0.45 µm Upstream)	CHRX	10"	54	0.2 µm	01	7P without fin	A1	Viton	SV				
AseptiSure HSR (0.65 µm Upstream)	CHR3	20"	55	0.45 µm	02	28 with fin	C0	EPDM	SE				
AseptiSure HSR (0.8 µm Upstream)	CHR5	30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CHRX	54	01	A0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

AseptiSure KS Mini Cartridge filters

mdi Polyethersulfone (PES) membrane mini cartridge filters type *AseptiSure KS* are serial filtration devices with a larger pore size upstream PES membrane layer to protect the downstream final PES membrane layer from premature clogging and to give enhanced throughputs, thus resulting in better economics.

mdi *AseptiSure KS* filters are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates. These are available in a variety of pore sizes to suit specific microfiltration needs in critical and specialized process applications.



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

Construction			
Membrane	Hydrophilic PES		
Support Layers	Polyester		
Body and Core	Polypropylene		
Final Filter Pore Size	0.1 µm	0.2 µm	0.45 µm
Prefilter Pore Size	0.2 µm, 0.45 µm	0.8 µm, 0.65 µm, 0.45 µm	0.8 µm, 0.65 µm
Integrity Testing/Retention			
Bubble Point	> 31 psi (2.18Kg/cm ²) with 50% IPA/Water Solution	> 50 psi (3.52Kg/cm ²) with Water	> 30 psi (2.11Kg/cm ²) with Water
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²
Size			
Size	2.5"		5"
Effective Filtration Area (Nominal)	1000 cm ²		2000 cm ²
Operational			
Water Flow Rate for 0.2µm @ 0.70kg/cm ² @27°C	9 lpm		15 lpm
Max. Operating Temperature	80 °C @ ≤ 2 Kg/cm ² (30 psi)		
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C		
Reverse Pressure	≤ 10 psi (0.7 Kg/cm ²) @ 25 °C		
Sterilization	In-line steam sterilizable at 121°C for 30 minutes at a maximum differential pressure of 3 psi (0.21 kg/cm ²) , 25 cycles		
pH Compatibility	Compatible with pH range of 1-10		

Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
<i>AseptiSure KS</i> (0.2 µm Upstream)	CPK1	2.5"	50	0.1 µm	36	4463	E0	Silicone	SS	Non Sterile	1	1	01
<i>AseptiSure KS</i> (0.45 µm Upstream)	CPKX	5"	53	0.2 µm	01	4463B	H0	*G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering					
<i>AseptiSure KS</i> (0.65 µm Upstream)	CPK3			0.45 µm	02	4440	U0						
<i>AseptiSure KS</i> (0.8 µm Upstream)	CPK5					Seal-K	G0*						
						Seal-O	F0						
						Seal-M	J0						

Example:

CPKX	50	01	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

AseptiSure KS

AseptiSure KS serial filtration Polyethersulfone cartridge filters incorporate a large pore size upstream membrane layer to protect the downstream terminal filtration membrane layer.



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

Construction				
Membrane		Hydrophilic PES		
Support Layers		Polyester		
Body and Core		Polypropylene		
Final Filter Pore Size	0.1 μm	0.2 μm	0.45 μm	
Prefilter Pore Size	0.2 μm, 0.45 μm	0.8 μm, 0.65 μm, 0.45 μm		0.8 μm, 0.65 μm
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm ²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm ²) with Water	≥ 30 psi (2.11 Kg/cm ²) with Water	
Air Diffusion Flow (10" Cartridge Filter)	≤ 29 ml/min @ 50 psi (3.52 Kg/cm ²) with Water	≤ 30 ml/min @ 37 psi (2.6 Kg/cm ²) with Water	≤ 35 ml/min @ 22 psi (1.54 Kg/cm ²) with Water	
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm ²	6000 cm ²	12000 cm ²	18000 cm ²
Operational				
Typical Water Flow Rates (for 0.2μm @ 0.70 Kg/cm ² @ 27 °C)	25 lpm	45 lpm	81 lpm	113 lpm
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			
Reverse Pressure	≤ 10 psi (0.7 Kg/cm ²) @ 25 °C			
Sterilization	In-line steam sterilizable at 121 °C for 30 minutes at a maximum differential pressure of 3 psi (0.21 kg/cm ²) , 25 cycles			
pH Compatibility	Compatible with pH range of 1-10			

Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure KS (0.2 µm Upstream)	CPK1	5"	53	0.1 µm	36	7P	A0	Silicone	SS	Non Sterile	1	1	01
AseptiSure KS (0.45 µm Upstream)	CPKX	10"	54	0.2 µm	01	7P without fin	A1	Viton	SV				
AseptiSure KS (0.65 µm Upstream)	CPK3	20"	55	0.45 µm	02	28 with fin	C0	EPDM	SE				
AseptiSure KS (0.8 µm Upstream)	CPK5	30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CPKX	53	01	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

Filters for Sterilization of Liquids: PVDF Membrane Filters

mdi produces a wide range of Gamma sterilizable and steam sterilizable Hydrophilic PVDF membrane capsule and cartridge filters to meet filtration requirements of biopharmaceutical and pharmaceutical processing.

These filters meet key process requirements such as high retention efficiency, very high protein recoveries, extremely low extractables, high throughputs, wide chemical compatibility etc.

Quality Assurance

These filter devices are manufactured in Class 10,000 clean rooms under ISO 9001 : 2015 certified quality management systems and are validated to meet compendia and regulatory requirements.

Applications

Sterile Filtration of:

- Antibodies
- Protein Solutions
- Buffers
- Cell culture media
- Small volume parenterals
- Vaccine concentrates

Types Available

Gamma Sterilizable Capsule Filters	<i>AseptiCap WS -γ</i>
Autoclavable Capsule Filters	<i>AseptiCap WS</i>
High Temperature Resistant Steam Sterilizable Cartridge Filters	<i>AseptiSure WS</i>

Assurance	
Toxicity	Passes Biological Reactivity Test, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity Test, In Vitro, USP <87> for Cytotoxicity
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1
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 211.72 for fiber release
Extractables with WFI	Passes test as per USP <661>
Oxidizable Substances	Passes test as per USP <1231>
Particle Shedding	Passes USP test for particulates in injections <788>
TOC/Conductivity at 25 °C	Meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a specified volume of purified water flush
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

Filter Selection Chart

Application Area	Key Application Requirements	Gamma Sterilizable Capsule Filters	Steam Sterilizable	
			Capsule Filters	Cartridge Filters
Biopharmaceuticals				
Media preparation	- Mycoplasma removal (in case of mammalian Cell Culture)	<i>AseptiCap WS</i> -γ 0.1 μm PVDF Membrane Capsule Filter	<i>AseptiCap WS</i> 0.1 μm PVDF Membrane Capsule Filter	<i>AseptiSure WS</i> 0.1 μm High Temperature PVDF Membrane Cartridge Filter
	- Microbial retention (in case of microbial Fermentation)	<i>AseptiCap WS</i> -γ 0.2 μm PVDF Membrane Capsule Filter	<i>AseptiCap WS</i> 0.2 μm PVDF Membrane Capsule Filter	<i>AseptiSure WS</i> 0.2 μm High Temperature PVDF Membrane Cartridge Filter
Sterile filtration of vaccines and therapeutic proteins	- Absolute retention - Low protein binding - Low holdup volume	<i>AseptiCap WS</i> -γ 0.2 μm PVDF Membrane Capsule Filter	<i>AseptiCap WS</i> 0.2 μm PVDF Membrane Capsule Filter	–

AseptiCap WS 1", 2", 5", 8"

mdi AseptiCap WS are low protein binding hydrophilic PVDF membrane capsule filters offering serial filtration incorporating a larger pore size upstream membrane to protect the downstream membrane for enhanced throughput.

These capsule filters are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as absolute retention efficiency, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

Radiation Sterilizable : AseptiCap WS-γ

Autoclavable : AseptiCap WS

Microbially Validated
as per ASTM F 838-05

Complies with
USFDA 21 CFR 210.3 (b) (6)

Meets and Exceeds
USFDA 21 CFR 177.1520

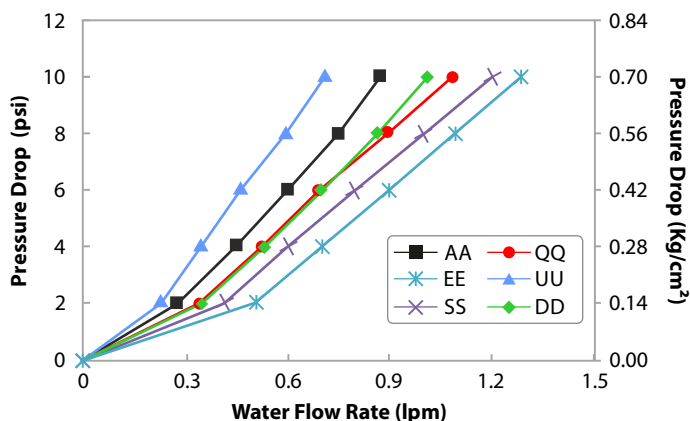


Specifications

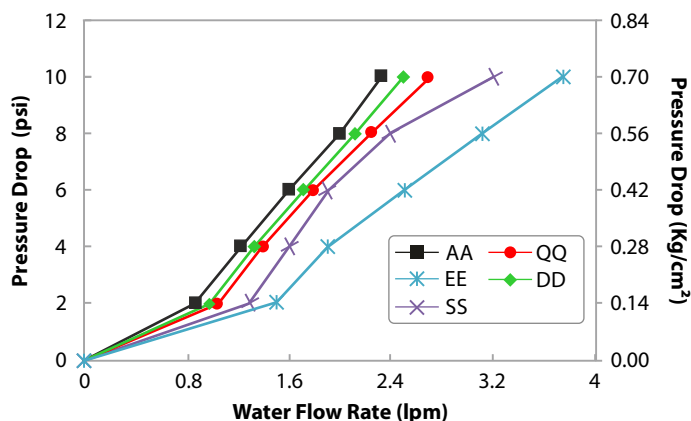
Construction				
Membrane		Hydrophilic PVDF		
Support Layers		Polyester		
Body and Core		Polypropylene		
Final Filter Pore Size	0.1 μm	0.2 μm	0.45 μm	
Prefilter Pore Size	0.2 μm, 0.45 μm	0.8 μm and 0.45 μm		0.8 μm
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm ²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm ²) with Water	≥ 30 psi (2.11 Kg/cm ²) with Water	
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (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
Vent and Drain		¼ " Hose Barb with Platinum Cured 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 Irradiation	AseptiCap WS -γ: Gamma Irradiatable up to 50 kGy		
	By Gas	AseptiCap WS : Sterilizable by Ethylene Oxide		
	By Autoclave	AseptiCap WS : Autoclavable at 125°C for 30 minutes, 2 cycles		
	These cannot be In-line steam sterilized			
Shelf Life		2 years after gamma sterilization 3 years after Ethylene Oxide sterilization		

Water Flow Rates

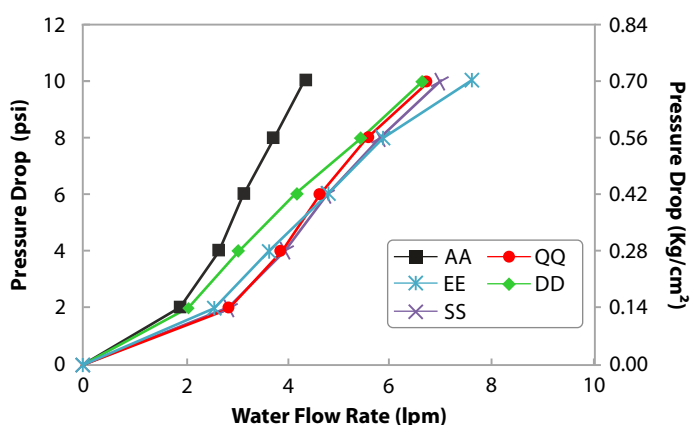
0.2 µm AseptiCap WS-γ, 1" Capsule Filters



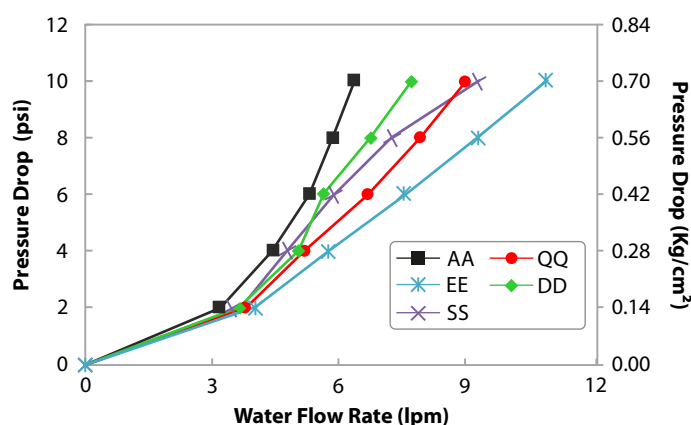
0.2 µm AseptiCap WS-γ, 2" Capsule Filters



0.2 µm AseptiCap WS-γ, 5" Capsule Filters



0.2 µm AseptiCap WS-γ, 8" Capsule Filters



End Connection Type:

A: ¼" Stepped Hose Barb **D:** ½" Hose Barb **E:** 1½" Sanitary Flange **J:** Quick Connector **U:** Female Luer Lock **Q:** Single Step ½" Hose Barb
S: ¾" Sanitary Flange

Ordering Information

AseptiCap WS and AseptiCap WS-γ

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Bell		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
AseptiCap WS (0.2 µm Upstream)	DWS1	1"	51	0.1 µm	36	¼" SHB	A	Yes	R	Yes	B	Non Sterile	1	1	01
AseptiCap WS (0.45 µm Upstream)	DWSX	2"	52	0.2 µm	01	¼" MNPT	B	No*	X	No Bell	X	EO Sterile	2		
AseptiCap WS (0.8 µm Upstream)	DWS5	5"	53	0.45 µm	02	½" MNPT	C					Gamma Sterile	3		
		8"	57			½" Hose Barb	D								
						1½" Sanitary Flange	E								
						¾" Sanitary Flange	S								
						Quick Connector	J								
						Single Step ½" Hose Barb	Q								
						Female Luer Lock	U								
						Male Luer Slip	W								
						⅜" Hose Barb	N								
						⅝" Hose Barb	I								

Example:

DWSX	57	36	DD	R	X	1	01
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*Gamma Sterile filters cannot be Gamma Irradiated again

Example for Non Sterile: DWSX5136DDRX101 Example for Gamma Sterile: DWSX5136DDXX301

For End Connection, bell availability and dimensions with different sizes refer Pages 85-86.

AseptiCap WS 5", 10", 20", 30"

mdi AseptiCap WS are low protein binding hydrophilic PVDF membrane capsule filters offering serial filtration incorporating a larger pore size upstream membrane to protect the downstream membrane for enhanced throughput.

These capsule filters are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as absolute retention efficiency, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

Radiation Sterilizable : AseptiCap WS-γ

Autoclavable : AseptiCap WS



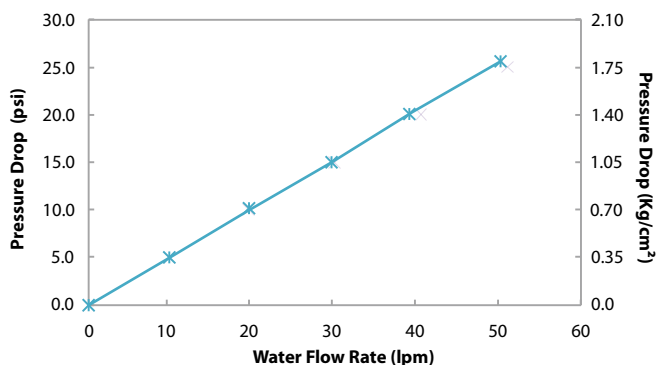
Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 210.3 (b) (6)
Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

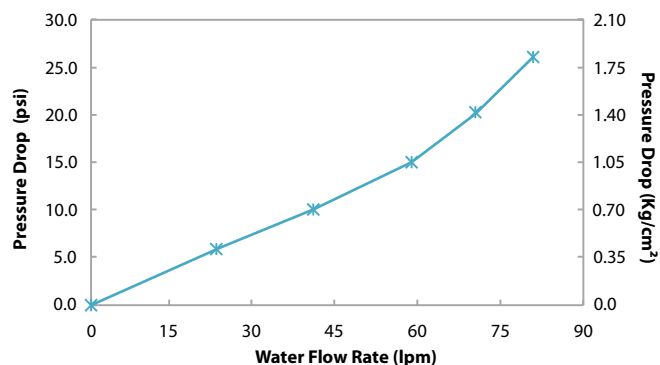
Construction				
Membrane		Hydrophilic PVDF		
Support Layers		Polyester		
Body and Core		Polypropylene		
Final Filter Pore Size	0.1 µm	0.2 µm	0.45 µm	
Prefilter Pore Size	0.2 µm, 0.45 µm	0.8 µm and 0.45 µm		0.8 µm
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm ²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm ²) with Water	≥ 30 psi (2.11 Kg/cm ²) with Water	
Max. Air Diffusion Flow for 10" Capsule Filters	≤ 30 ml/min @ 50 psi (3.52 Kg/cm ²) with Water	≤ 30 ml/min @ 37 psi (2.6 Kg/cm ²) with Water	≤ 30 ml/min @ 22 psi (1.54 Kg/cm ²) with Water	
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm ²	6000 cm ²	12000 cm ²	18000 cm ²
Vent and Drain		¼" Hose Barb with platinum cured 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 Irradiation	AseptiCap WS-γ : Gamma Irradiatable up to 50 kGy		
	By Gas	AseptiCap WS : Sterilizable by Ethylene Oxide		
	By Autoclave	AseptiCap WS : Autoclavable at 125°C for 30 minutes, 2 cycles These cannot be In-line steam sterilized		
Shelf Life		2 years after gamma sterilization 3 years after Ethylene Oxide sterilization		

Water Flow Rates

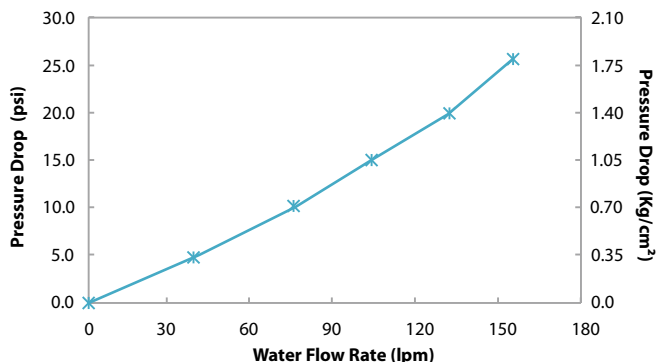
0.2 µm AseptiCap WS-γ, 5" Large Capsule Filters



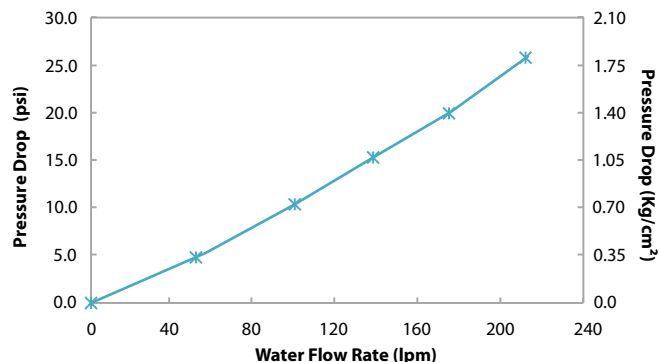
0.2 µm AseptiCap WS-γ, 10" Large Capsule Filters



0.2 µm AseptiCap WS-γ, 20" Large Capsule Filters



0.2 µm AseptiCap WS-γ, 30" Large Capsule Filters



End Connection Type: E: 1½" Sanitary Flange

Ordering Information

AseptiCap WS and AseptiCap WS-γ

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline / T-line		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
AseptiCap WS (0.2 µm Upstream)	LWS1	5"	53	0.1 µm	36	1½" Sanitary Flange	E	Yes	R	Inline	X	Non Sterile	1	1	01
AseptiCap WS (0.45 µm Upstream)	LWSX	10"	54	0.2 µm	01	Single Step ½" Hose Barb	Q	No	X	T-line**	T	EO Sterile	2		
AseptiCap WS (0.8 µm Upstream)	LWS5	20"	55	0.45 µm	02	¾" Sanitary Flange	S					Gamma Sterile	3		
		30"	56			3/8" Hose Barb	I								
						1" Hose Barb	Z								

Example:

LWSX	54	02	EE	R	T	1	01
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* Size 5" is available in In-line Capsule Filters Only

** T-line Capsule Filters are available with 1½" Sanitary Flange connections Only

Note: Gamma Sterile filters cannot be Gamma Irradiated again

Example for Non Sterile: LWSX5402EERX101

Example for Gamma Sterile: LWSX5402EEXX301

For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiSure WS Mini Cartridge filters

AseptiSure WS are low protein binding hydrophilic PVDF membrane mini cartridge filters offering serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

These cartridge filters are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as absolute retention efficiency, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.



Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 210.3 (b) (6)
Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

Construction			
Membrane	Hydrophilic PVDF		
Support Layers	Polyester		
Body and Core	Polypropylene		
Final Filter Pore Size	0.1 µm	0.2 µm	0.45 µm
Prefilter Pore Size	0.2 µm, 0.45 µm	0.8 µm and 0.45 µm	0.8 µm
Integrity Testing/Retention			
Bubble Point	> 31psi (2.18Kg/cm ²) with 50% IPA/Water Solution	> 50psi (3.52Kg/cm ²) with Water	> 30psi (2.11Kg/cm ²) with Water
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²
Size			
Size	2.5"	5"	
Effective Filtration Area (Nominal)	1000 cm ²	2000 cm ²	
Operational			
Typical Water Flow Rate for 0.2µm @ 0.70kg/cm ² @27°C	5.2 lpm	10.5 lpm	
Max. Operating Temperature	80 °C @ ≤ 2 Kg/cm ² (30 psi)		
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C		
Reverse Pressure	≤ 10 psi (0.7 Kg/cm ²) @ 25 °C		
Sterilization	In-line steam sterilizable upto 135 °C for 30 minutes at a maximum differential pressure of 5 psi (0.35 Kg/cm ²), 1 cycle		

Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure WS (0.2 µm Upstream)	CWH1	2.5"	50	0.1 µm	36	4463	E0	Silicone	SS	Non Sterile	1	1	01
AseptiSure WS (0.45 µm Upstream)	CWHX	5"	53	0.2 µm	01	4463B	H0						
AseptiSure WS (0.8 µm Upstream)	CWH5			0.45 µm	02	4440	U0						
						Seal-K	G0*	*G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering					
						Seal-O	F0						
						Seal-M	J0						

Example:

CWHX	50	01	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

AseptiSure WS

AseptiSure WS are low protein binding hydrophilic PVDF membrane cartridge filters offering serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

Construction				
Membrane	Hydrophilic PVDF			
Support Layers	Polyester			
Body and Core	Polypropylene			
Final Filter Pore Size	0.1 µm	0.2 µm	0.45 µm	
Prefilter Pore Size	0.2 µm, 0.45 µm	0.8 µm and 0.45 µm	0.8 µm	
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm ²) with 50% IPA/Water Solution	≥ 50 psi (3.52 Kg/cm ²) with Water	≥ 30 psi (2.11 Kg/cm ²) with Water	
Air Diffusion Flow (10" Cartridge Filter)	≤ 30 ml/min @ 50 psi (3.52 Kg/cm ²) with Water	≤ 30 ml/min @ 37 psi (2.6 Kg/cm ²) with Water	≤ 30 ml/min @ 22 psi (1.54 Kg/cm ²) with Water	
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ²	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm ²	6000 cm ²	12000 cm ²	18000 cm ²
Operational				
Typical Water Flow Rates (for 0.2µm @ 0.70 Kg/cm ² @ 27 °C)	18 lpm	33 lpm	60 lpm	84 lpm
Max. Operating Temperature	80 °C @ ≤ 30psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			
Reverse Pressure	≤ 10 psi (0.7 Kg/cm ²) @ 25 °C			
Sterilization	In-line steam sterilizable upto 135 °C for 30 minutes at a maximum differential pressure of 5 psi (0.35 Kg/cm ²), 1 cycle			

Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure WS (0.2 µm Upstream)	CWH1	5"	53	0.1 µm	36	7P	A0	Silicone	SS	Non Sterile	1	1	01
AseptiSure WS (0.45 µm Upstream)	CWHX	10"	54	0.2 µm	01	7P without fin	A1	Viton	SV				
AseptiSure WS (0.8 µm Upstream)	CWH5	20"	55	0.45 µm	02	28 with fin	C0	EPDM	SE				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CWHX	54	01	A0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

Filters for Sterilization of Liquids:

Nylon 66 Membrane Filters

mdi Nylon 66 membrane filters are sterilizing grade filters offering absolute retention and wide chemical compatibility.

mdi Nylon 66 filter devices are available as:

Filter Type	Single Layer	Multiple Layer
Capsule Filters	<i>AseptiCap NL</i>	<i>AseptiCap NS</i>
Cartridge Filters	–	<i>AseptiSure NS</i>
Membrane Disc Filters	–	NN

Applications

- Sterilization of compatible solvents and chemicals
- Sterilization of disinfectants in pharmaceutical process and lab areas
- Filtration of hospital disinfectants
- Filtration of rinse water for endoscopes and other hospital equipment and surfaces
- Sterilizing filtration in pharmaceutical for aqueous and non aqueous solutions

Quality Assurance

These filter devices are manufactured in Class 10,000 clean rooms under ISO 9001 : 2015 certified quality management systems and are validated to meet compendia and regulatory requirements.

Assurance	
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
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 211.72 for fiber release
Extractables with WFI	Passes test as per USP <661>
Oxidizable Substances	Within limits as specified in USP <1231>
Particle Shedding	Passes USP test for particulates in injectables
TOC/Conductivity at 25 °C	Meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a specified volume of purified water flush
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

Filter Selection Chart

Application Area	Key Application Requirements	Capsule Filters	Cartridge Filters	Disc Filters
Sterilization of compatible solvents and chemicals	<ul style="list-style-type: none"> - Absolute retention - Wide chemical compatibility 	AseptiCap NL/NS 0.2 µm Nylon 66 Membrane Capsule Filter	AseptiSure NS 0.2 µm Nylon 66 Membrane Cartridge Filter	0.2 µm Nylon 66 Membrane Disc Filters
Sterilization of disinfectants in pharmaceutical labs and process areas	<ul style="list-style-type: none"> - Absolute retention - Wide chemical compatibility 	AseptiCap NL/NS 0.2 µm Nylon 66 Membrane Capsule Filter	AseptiSure NS 0.2 µm Nylon 66 Membrane Cartridge Filter	0.2 µm Nylon 66 Membrane Disc Filters
Filtration of hospital disinfectants	<ul style="list-style-type: none"> - Absolute retention - Wide chemical compatibility 	AseptiCap NL/NS 0.2 µm Nylon 66 Membrane Capsule Filter	AseptiSure NS 0.2 µm Nylon 66 Membrane Cartridge Filter	0.2 µm Nylon 66 Membrane Disc Filters
Filtration of rinse water for endoscopes and other hospital equipments	<ul style="list-style-type: none"> - Absolute retention 	AseptiCap NL/NS 0.2 µm Nylon 66 Membrane Capsule Filter	AseptiSure NS 0.2 µm Nylon 66 Membrane Cartridge Filter	–
Sterilizing filtration of aqueous and non aqueous solutions	<ul style="list-style-type: none"> - Absolute retention - Wide chemical compatibility 	AseptiCap NL/NS 0.2 µm Nylon 66 Membrane Capsule Filter	AseptiSure NS 0.2 µm Nylon 66 Membrane Cartridge Filter	0.2 µm Nylon 66 Membrane Disc Filters

AseptiCap NL/NS 1", 2", 5", 8"

**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

AseptiCap NL/NS Nylon 66 membranes capsule filters are sterilizing grade filters offering absolute retention, wide chemical compatibility, and very low hold up volumes.

Single Layered: AseptiCap NL

Multiple Layered: AseptiCap NS

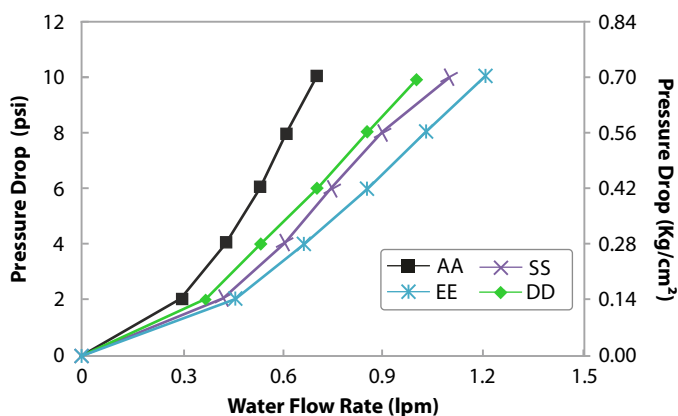


Specifications

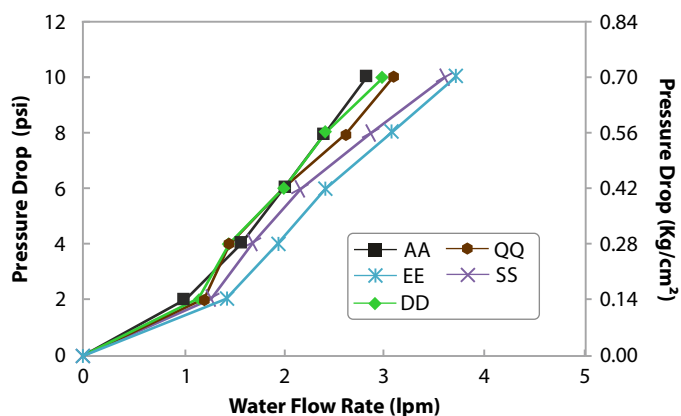
Construction					
Membrane		Nylon 66			
Support Layers		Polyester			
Body and Core		Polypropylene			
Final Filter Pore Size		0.2 µm		0.45 µm	
Prefilter Pore Size (In case of <i>AseptiCap NS</i>)		0.8 µm, 0.45 µm		0.8 µm	
Integrity Testing/Retention					
Bubble Point (with water)		≥ 50 psi (3.52 Kg/cm ²)		≥ 30 psi (2.1 Kg/cm ²)	
Microbial Retention (LRV >7 for)		<i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²		<i>Serratia marcescens</i> (ATCC 14756) per cm ²	
Size					
Size		1"	2"	5"	8"
Effective Filtration Area (Nominal)	<i>AseptiCap NL</i>	250 cm ²	900 cm ²	1800 cm ²	2700 cm ²
	<i>AseptiCap NS</i>	200 cm ²	700 cm ²	1400 cm ²	2100 cm ²
Vent and Drain			¼" Hose Barb with Silicone 'O' ring		
Operational					
Max. Operating Temperature			80 °C @ ≤ 2 Kg/cm ² (30 psi)		
Max. Differential Pressure			4 Kg/cm ² (60 psi) @ 30 °C		
Sterilization	By Gas	Sterilizable by Ethylene Oxide			
	By Autoclave	Autoclavable at 125 °C for 30 minutes. Cannot be In-line steam sterilized			

Water Flow Rates

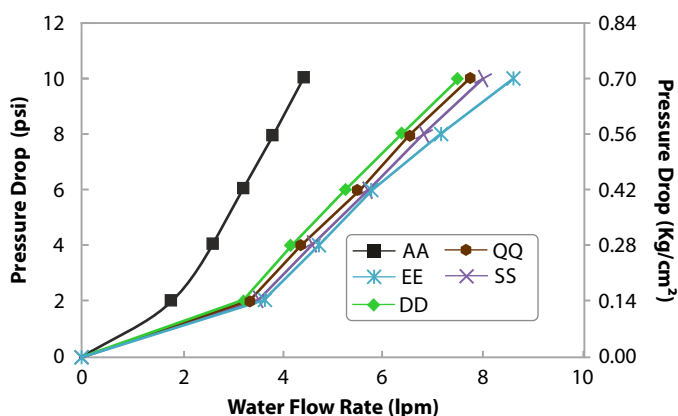
0.2µm AseptiCap NS, 1" Capsule Filter



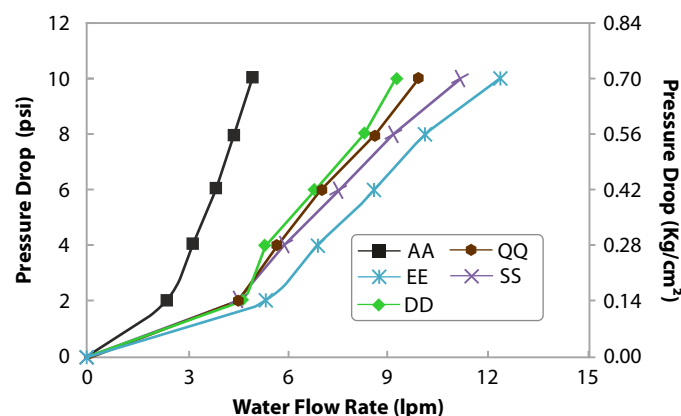
0.2µm AseptiCap NS, 2" Capsule Filter



0.2µm AseptiCap NS, 5" Capsule Filter



0.2µm AseptiCap NS, 8" Capsule Filter



End Connection Type:

A: ¼" Stepped Hose Barb **Q:** Single Step ½" Hose Barb **E:** 1½" Sanitary Flange **S:** ¾" Sanitary Flange **D:** ½" Hose Barb

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		X	Bell		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
AseptiCap NL	DNLX	1"	51	0.2 µm	01	¼" SHB	A		Yes	B	Non Sterile	1	1	01
AseptiCap NS (0.45 µm Upstream)	DNSX	2"	52	0.45 µm	02	¼" MNPT	B		No Bell	X	EO Sterile	2		
AseptiCap NS (0.8 µm Upstream)	DNS5	5"	53			½" MNPT	C							
		8"	57			½" Hose Barb	D							
						1½" Sanitary Flange	E							
						¾" Sanitary Flange	S							
						Quick Connector	J							
						Single Step ½" Hose Barb	Q							
						Female Luer Lock	U							
						Male Luer Slip	W							
						⅜" Hose Barb	N							
						⅝" Hose Barb	I							

Example:

DNSX	52	01	DD	X	X	1	01
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For End Connection, bell availability and dimensions with different sizes refer Pages 85-86.

AseptiCap NS 5", 10", 20", 30"

AseptiCap NS Nylon 66 large membranes capsule filters are double layered sterilizing grade filters offering absolute retention, wide chemical compatibility, and serial filtration for enhanced throughputs.



**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

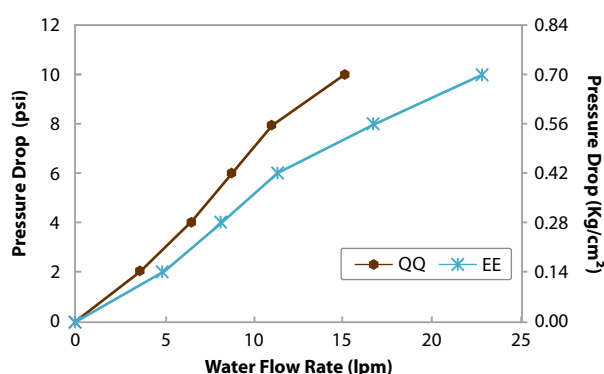
**Meets and Exceeds
USFDA 21 CFR 177.1520**

Specifications

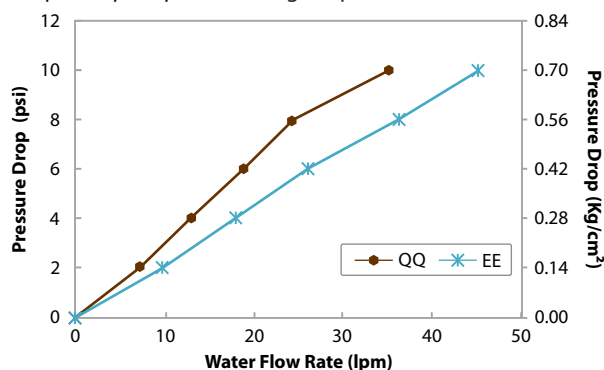
Construction				
Membrane	Nylon 66			
Support Layers	Polyester			
Body and Core	Polypropylene			
Final Filter Pore Size	0.2 µm		0.45 µm	
Prefilter Pore Size	0.8 µm, 0.45 µm		0.8 µm	
Integrity Testing/Retention				
Air Diffusion Flow for 10" Capsule Filters (with water)	≤ 30 ml/min @ 37 psi (2.60 kg/cm²)		≤ 35 ml/min @ 22 psi (1.54 kg/cm²)	
Microbial Retention (LRV >7 for)	Brevundimonas diminuta (ATCC 19146) per cm²		Serratia marcescens (ATCC 14756) per cm²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm²	6000 cm²	12000 cm²	18000 cm²
Vent and Drain	¼" Hose Barb with Silicone 'O' ring			
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm²)			
Max. Differential Pressure	60 psi (4 Kg/cm²) @ 30 °C			
Sterilization	By Gas	Sterilizable by Ethylene Oxide		
	By Autoclave	Autoclavable at 125 °C for 30 minutes. Cannot be In-line steam sterilized		

Water Flow Rates

0.2 µm AseptiCap NS, 5" Large Capsule Filters



0.2 µm AseptiCap NS, 10" Large Capsule Filters



End Connection Type: Q: Single Step ½" Hose Barb
E: 1½" Sanitary Flange

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		X	Inline / T-line		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
AseptiCap NS (0.45 µm Upstream)	LNSX	5"	53	0.2 µm	01	1½" Sanitary Flange	E		Inline	X	Non Sterile	1	1	01
AseptiCap NS (0.8 µm Upstream)	LNS5	10"	54	0.45 µm	02	Single Step ½" Hose Barb	Q		T-line	T	EO Sterile	2		
		20"	55			¾" Sanitary Flange	S							
		30"	56			¾" Hose Barb	I							
						1" Hose Barb	Z							

Example:

LNSX	54	01	QQ	X	T	1	01
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* Size 5" is available in In-line Capsule Filters Only

For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiSure NS Mini Cartridge filters

mdi AseptiSure NS Nylon 66 membrane mini cartridge filters are sterilizing grade filters offering absolute retention and wide chemical compatibility. These filters offer serial filtration for enhanced throughput. The upstream layer is of larger pore size to protect the downstream final filtration layer.

**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

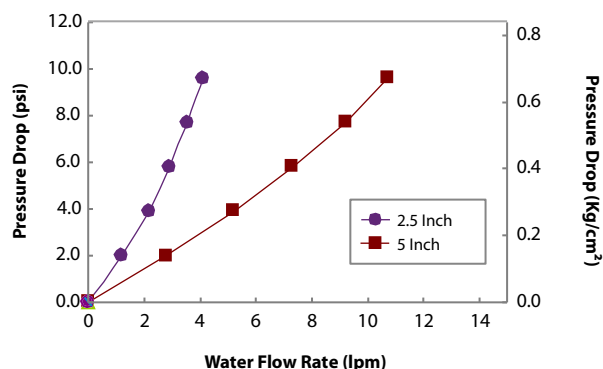
Specifications

Construction		
Membrane	Nylon 66	
Support Layers	Polyester	
Body and Core	Polypropylene	
Final Filter Pore Size	0.2 µm	0.45 µm
Prefilter Pore Size	0.8 µm, 0.45 µm	0.8 µm
Integrity Testing/Retention		
Bubble Point (with water)	≥ 50 psi (3.52 Kg/cm ²)	≥ 30 psi (2.1 Kg/cm ²)
Microbial Retention (LRV >7 for)	<i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	<i>Serratia marcescens</i> (ATCC 14756) per cm ²
Size		
Size	2.5"	5"
Effective Filtration Area (Nominal)	1000 cm ²	2000 cm ²
Operational		
Max. Operating Temperature	80 °C @ ≤ 2 Kg/cm ² (30 psi)	
Max. Differential Pressure	< 3.5Kg/cm ² (50 psi) @ 25°C	
Reverse Pressure	< 0.7 Kg/cm ² (10 psi) @ 25 °C	
Sterilization	Autoclavable/In-line Steam Sterilizable at 121 °C for 30 minutes @ a maximum differential pressure of 3psi (0.21 kg/cm ²)	



Water Flow Rates

0.2µm AseptiSure NS Mini Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure NS (0.45 µm Upstream)	CPNX	2.5"	50	0.2 µm	01	4463	E0	Silicone	SS	Non Sterile	1	1	01
AseptiSure NS (0.8 µm Upstream)	CPN5	5"	53	0.45 µm	02	4463B	H0						
						4440	U0						
						Seal-K	G0*						
						Seal-O	F0						
						Seal-M	J0						

Example:

CPNX	50	01	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

***G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering**

AseptiSure NS

AseptiSure NS Nylon 66 membrane cartridge filters are sterilizing grade filters offering absolute retention and wide chemical compatibility. These filters offer serial filtration for enhanced throughput. The upstream layer is of larger pore size to protect the downstream final filtration layer.

Microbially Validated
as per ASTM F 838-05

Complies with
USFDA 21 CFR 210.3 (b) (6)

Meets and Exceeds
USFDA 21 CFR 177.1520

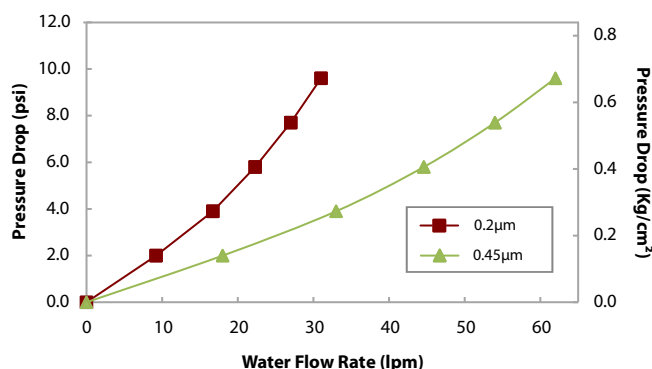
Specifications

Construction				
Membrane	Nylon 66			
Support Layers	Polyester			
Body and Core	Polypropylene			
Final Filter Pore Size	0.2 µm		0.45 µm	
Prefilter Pore Size	0.8 µm, 0.45 µm		0.8 µm	
Integrity Testing/Retention				
Air Diffusion Flow (with water wetted) (10" Cartridge Filter)	≤ 30 ml/min @ 37 psi (2.60 kg/cm²)		≤ 35 ml/min @ 22 psi (1.54 kg/cm²)	
Microbial Retention (LRV >7 for)	Brevundimonas diminuta (ATCC 19146) per cm²		Serratia marcescens (ATCC 14756) per cm²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm²	6000 cm²	12000 cm²	18000 cm²
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm²)			
Max. Differential Pressure	50 psi (3.5Kg/cm²) @ 25°C			
Reverse Pressure	< 10 psi (0.7 Kg/cm²) @ 25 °C			
Sterilization	Autoclavable/In-line Steam Sterilizable at 121 °C for 30 minutes @ a maximum differential pressure of 3psi (0.21 kg/cm²)			



Water Flow Rates

AseptiSure NS, 10" Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure NS (0.45 µm Upstream)	CPNX	5"	53	0.2 µm	01	7P	A0	Silicone	SS	Non Sterile	1	1	01
AseptiSure NS (0.8 µm Upstream)	CPN5	10"	54	0.45 µm	02	7P without fin	A1	Viton	SV				
		20"	55			28 with Fin	C0	EPDM	SE				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CPNX	54	01	A0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

Nylon 66 Membrane Disc Filters - Type NN

Microbially Validated
as per ASTM F 838-05

Complies with
USFDA 21 CFR 210.3 (b) (6)

NN membrane disc filters are double layered, hydrophilic, non-media migrating, biologically inert, plain white absolute membrane filters offering wide chemical compatibility.



Specifications

Construction				
Membrane		Nylon 66		
Pore Size		0.2 μm, 0.45 μm, 0.8 μm, 1.2 μm		
Size		90 mm, 142 mm, 293 mm		
Integrity Testing/Retention				
Bubble Point (with Water)	0.2 μm	≥ 50 psi (3.51 Kg/cm ²) with water		
	0.45 μm	≥ 32 psi (2.25 Kg/cm ²) with water		
Microbial Retention	0.2 μm	LRV> 7 for <i>Brevundimonas diminuta</i> as per ASTM F 838-05		
	0.45 μm	LRV> 7 for <i>Serratia marcescens</i> as per ASTM F 838-05		
Operational				
Max. Operating Temperature		80 °C continuous		
Max. Differential Pressure		5 Kg/cm ²		
Water Flow Rates (27 °C @ 0.70 Kg/cm ²)	0.2 μm	0.45 μm	0.8 μm	1.2 μm
	14 ml/min/cm ²	37 ml/min/cm ²	120 ml/min/cm ²	180 ml/min/cm ²
Sterilization		Autoclavable at 121 °C for 30 minutes		

Ordering Information

Type	Size	Pore Size	XX	XX	Sterility	Pack Size
Code	Code	Code			Code	Code
NN	90 mm 142 mm 293 mm	0.2 µm 0.45 µm 0.8 µm 1.2 µm			Non Sterile	50
NNXX	14 16 19	01 02 03 10			1	03
Example:						
NNXX	14	01	XX	XX	1	03

Filters for Sterilization of Air/Gases

Single Use PVDF Membrane Filter Devices

mdi Gamma Sterilizable *AseptiVent VF-γ* are hydrophobic PVDF membrane single use capsule filters with a wide range of end connections and different sizes for linear scalability to use with disposable single use assemblies for biopharmaceutical processes.

These filters are validated for microbial retention with liquid bacterial challenge test as per ASTM F838-05 to ensure reliable performance under worst case conditions.

Multiple Use PTFE Membrane Filter Devices

mdi produces a wide range of PTFE membrane capsule and cartridge 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 such as bioreactor/fermentor venting etc. As they offer wide chemical compatibility with organic solvents, these are ideal for manufacture of sterile API.

Quality Assurance

These filter devices are manufactured in Class 10,000 clean rooms under ISO 9001: 2015 certified quality management systems and are validated to meet compendia and regulatory requirements.

Filter Type	Single Use	Multiple Use
Gamma Sterilizable Capsule Filters	<i>AseptiVent VF-γ</i>	–
Autoclavable Capsule Filters	–	<i>AseptiVent TF</i>
Steam Sterilizable Cartridge Filters	–	<i>AseptiSure TF</i>
High Temperature Resistant Steam Sterilizable Cartridge Filters	–	<i>AseptiSure TH</i>

Applications

- 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
- Sterile filtration of API and solvents
- Dry powder injectable filling
- Sterile air for dryers and micronizers

Assurance	
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
Bacterial Endotoxin	Aqueous extracts exhibit < 0.5 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 210.3 (b)(6) for fiber release
Oxidizable Substances	Within limits as specified in USP <1231>
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

Filter Selection Chart

Application Area	Key Application Requirements	Gamma Sterilizable Capsule Filters	Steam Sterilizable	
			Capsule Filters	Cartridge Filters
Sterile venting for fermentors and bioreactors	<ul style="list-style-type: none"> - Absolute retention - High hydrophobicity - High flow rates 	AseptiVent VF-γ 0.2 μm PVDF Membrane Capsule Filters	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter
Sterile air sparging in fermentors and bioreactors	<ul style="list-style-type: none"> - Absolute retention - High hydrophobicity - High flow rates 	AseptiVent VF-γ 0.2 μm PVDF Membrane Capsule Filters	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter
Sterile air for cell factories	<ul style="list-style-type: none"> - Absolute retention - High hydrophobicity 	AseptiVent VF-γ 0.2μm PVDF Membrane Capsule Filters	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	–
Venting of small bioreactors	<ul style="list-style-type: none"> - Absolute retention - High hydrophobicity 	AseptiVent VF-γ 0.2 μm PVDF Membrane Capsule Filters	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	–
Fermentor exhaust	<ul style="list-style-type: none"> - Absolute retention - High hydrophobicity - High flow rates 	–	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter
Venting of sterile collection vessels	<ul style="list-style-type: none"> - Absolute retention - High hydrophobicity - High flow rates 	AseptiVent VF-γ 0.2 μm PVDF Membrane Capsule Filters	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter
Nitrogen blanketing in sterile API	<ul style="list-style-type: none"> - Absolute retention - High flow rates 	–	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter
Cleaning sterile surfaces	<ul style="list-style-type: none"> - Absolute retention - High flow rates 	–	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter
Dry powder injectable filling	<ul style="list-style-type: none"> - Absolute retention - High flow rates 	–	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter
WFI tank venting	<ul style="list-style-type: none"> - Absolute retention - High hydrophobicity - High flow rates 	–	–	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter
Sterile filtration of API/Solvents	<ul style="list-style-type: none"> - Absolute retention - High flow rates 	–	–	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter
Sterile air for dryers and micronizers	<ul style="list-style-type: none"> - Absolute retention - High flow rates 	–	AseptiVent TF 0.2 μm PTFE Membrane Capsule Filter	AseptiSure TF/TH 0.2 μm PTFE Membrane Cartridge Filter

AseptiVent VF-γ 25mm, 37mm, 50mm

0.2 µm **AseptiVent VF-γ**, Gamma Sterilizable PVDF membrane vent 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 such as small bioreactors, sterile tank venting, bottle venting, barrier filter for vacuum pump etc.

Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 210.3 (b) (6)
Meets and Exceeds USFDA 21 CFR 177.1520

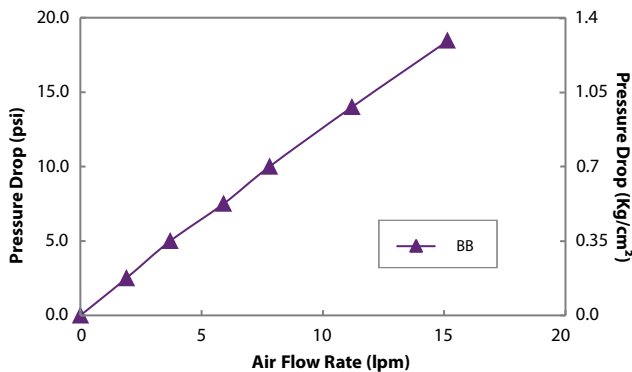


Specifications

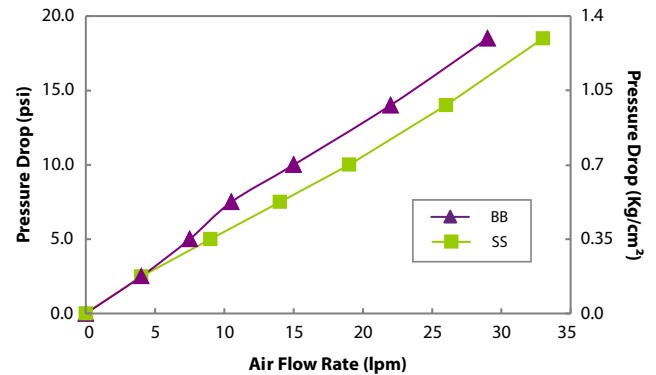
Construction			
Final Filter Pore Size		0.2 µm	
Membrane		Hydrophobic PVDF	
Support Layers		Polyester	
Body and Core		Polypropylene	
Integrity Testing/Retention			
Bubble Point		≥ 18 psi (1.27 Kg/cm²) with 50% IPA/ Water Solution	
Microbial Retention		LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²	
Size			
Size	25 mm	37 mm	50 mm
Effective Filtration Area (Nominal)	5 cm²	10 cm²	20 cm²
Operational			
Max. Operating Temperature		60 °C	
Max. Differential Pressure		1.5 Kg/cm² (21 psi) @ 30° C	
Burst Pressure		> 14 Kg/cm²	> 8 Kg/cm²
Sterilization	By Irradiation	Gamma Irradiatable up to 50 kGy	
	By Autoclave	Autoclavable at 125 °C for 30 minutes, 1 cycle after Gamma Irradiation. Cannot be In-line steam sterilized	
Shelf Life		2 years after Gamma Sterilization	

Air Flow Rates

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

Ordering Information

AseptiVent VF-γ, 25 mm

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
AseptiVent VF	IVFX	25 mm	06	0.2 µm	01	Female Luer Lock	M	Yes	R		Non Sterile	1	100	04
						Male Luer Slip	N	No*	X		Gamma Sterile	3		
						½" Hose Barb	H							
						¼" Hose Barb	B							
Example:														
IVFX		06		01		MN		R		X	1		04	

*Gamma Sterile filters cannot be Gamma Irradiated again

AseptiVent VF-γ, 37 mm and 50 mm

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
AseptiVent VF	IVFX	37 mm	08	0.2 µm	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		08		01		BB		R		X	1		02	

*¾" Sanitary Flange connection is available only in 50 mm filter

**Gamma Sterile filters cannot be Gamma Irradiated again

AseptiVent VF-γ 1", 2", 5", 8"

AseptiVent VF-γ PVDF membrane vent capsule 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.

**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

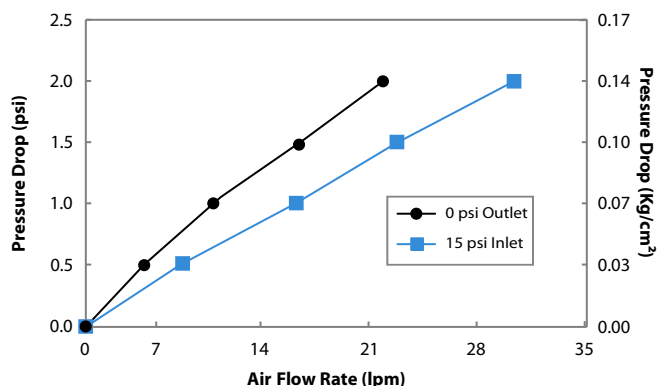


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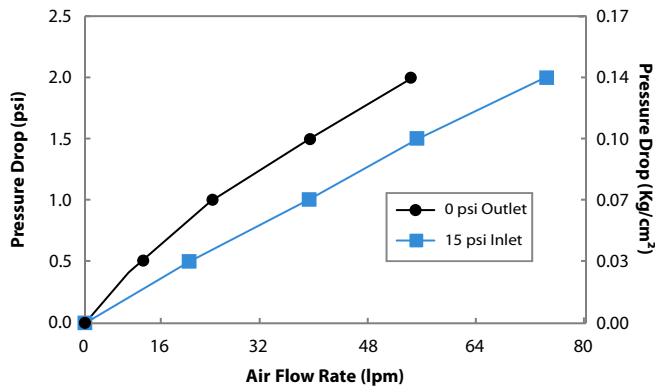
Construction				
Pore Size	0.2 μm			
Membrane	Hydrophobic PVDF			
Support Layers	Polyester			
Body and Core	Polypropylene			
Integrity Testing/Retention				
Bubble Point	≥ 18 psi (1.26 Kg/cm ²) with 50% IPA/Water Solution			
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²			
Size				
Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	250 cm ²	500 cm ²	1000 cm ²	2000 cm ²
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 Irradiation	Gamma Irradiatable up to 50 kGy			
Shelf Life	2 years after Gamma Sterilization			

Air Flow Rates

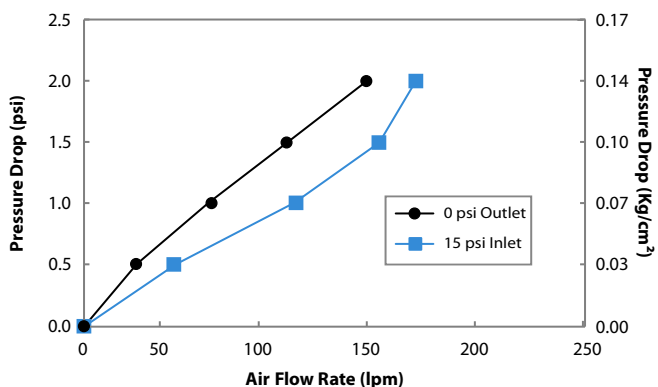
0.2 µm AseptiVent VF-γ, 1" Capsule Filters, EE Connection



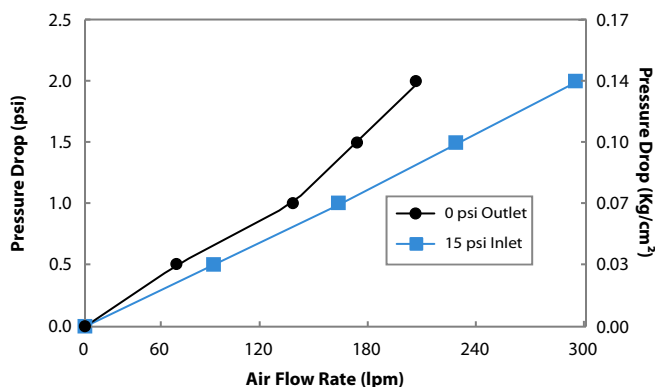
0.2 µm AseptiVent VF-γ, 2" Capsule Filters, EE Connection



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



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



End Connection Type E: 1½" Sanitary Flange

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
AseptiVent VF	DVLX	1"	51	0.2 μm	01	¼" SHB	A	Yes	R		Non Sterile	1	1	01
		2"	52			½" Hose Barb	D	No*	X		Gamma Sterile	3		
		5"	53			1½" Sanitary Flange	E							
		8"	57			¾" Sanitary Flange	S							
						Quick Connector	J							
						Single Step ½" Hose Barb	Q							
						Female Luer Lock	U							
						Male Luer Slip	W							
						⅜" Hose Barb	N							
						⅝" Hose Barb	I							

Example:

DVLX	57	01	EE	R	X	1	01
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* Gamma Sterile filters cannot be Gamma Irradiated again

For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiVent VF-γ 5", 10", 20", 30"

AseptiVent VF-γ PVDF membrane vent 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.



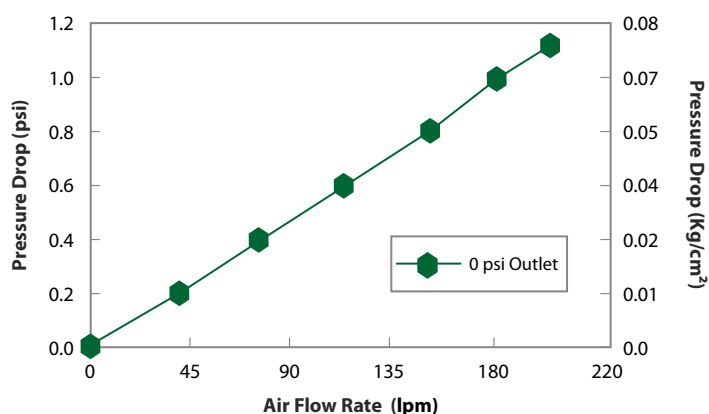
Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 210.3 (b) (6)
Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

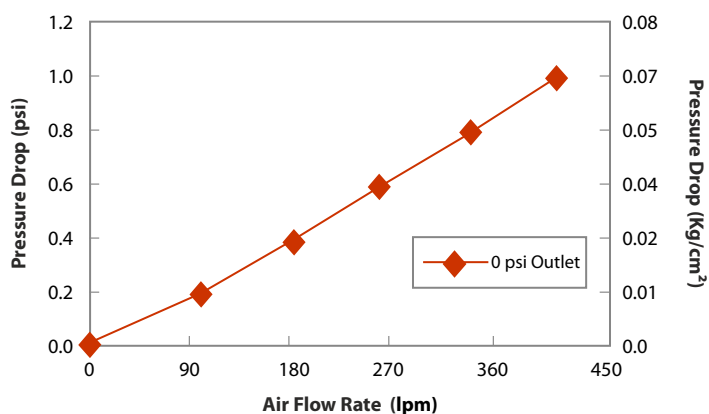
Construction				
Pore Size		0.2 μm		
Membrane		Hydrophobic PVDF		
Support Layers		Polyester		
Integrity Testing/Retention				
Air Diffusion Flow (50% IPA/ Water) (10" Capsule Filter)		≤ 30 ml/min @ 16 psi (1.12 Kg/cm²)		
Microbial Retention		LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²		
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm²	6000 cm²	12000 cm²	18000 cm²
Vent and Drain		¼" Hose Barb with Silicone 'O' ring		
Operational				
Typical Air Flow Rate		67 Nm³/h @ ΔP = 2 psi (15 psi inlet)		
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		

Air Flow Rates

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



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



End Connection Type: E: 1½" Sanitary Flange

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline / T-line		Sterility		Pack Size	
	Code		Code		Code				Code		Code		Code		Code
AseptiVent VF	LVLX	5"	53	0.2 µm	01	1½" Sanitary Flange	E	Yes	R	Inline	X	Non Sterile	1	1	01
		10"	54			Single Step ½" Hose Barb	Q	No*	X	T-line	T	Gamma Sterile	3		
		20"	55			¾" Sanitary Flange	S								
		30"	56			¾" Hose Barb	I								
						1" Hose Barb	Z								

Example:

LVLX	54	01	EE	R	X	1	01
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* Gamma Sterile filters cannot be Gamma Irradiated again

**Size 5" is available in In-line Capsule Filters Only

For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiVent TF 25 mm, 37 mm, 50 mm

AseptiVent TF Disposable Inline PTFE gas filters are convenient pre-fabricated devices used for sterilization of gases and as a bacterial air vent in various pharmaceutical and biopharmaceutical processes.

Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 210.3 (b) (6)
Meets and Exceeds USFDA 21 CFR 177.1520

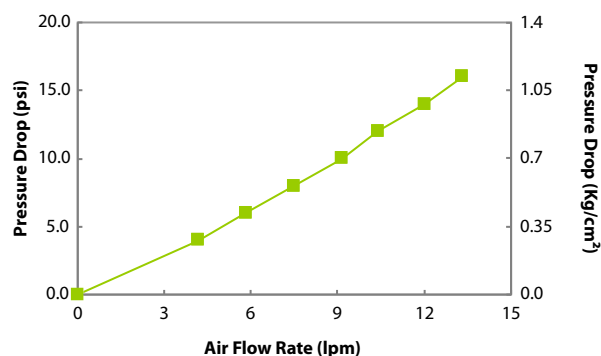


Specifications

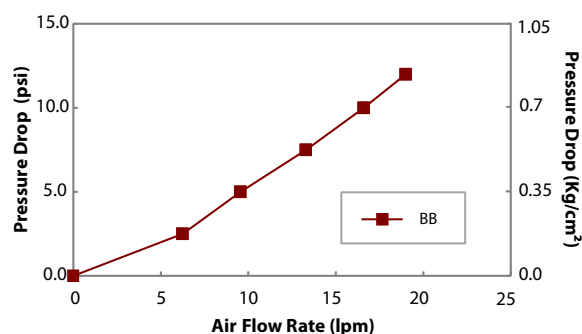
Construction			
Membrane	Hydrophobic PTFE		
Support Layers	Polypropylene		
Body and Core	Polypropylene		
Final Filter Pore Size	0.2 μm	0.45 μm	
Integrity Testing/Retention			
Bubble Point	≥ 22 psi (1.54 Kg/cm²) with 70% IPA/Water Solution	≥ 10 psi (0.7 Kg/cm²) with 70% IPA/Water Solution	
Microbial Bacterial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²	LRV >7 for <i>Serratia marcescens</i> ATCC 14756) per cm²	
Size			
Size	25 mm	37 mm	50 mm
Effective Filtration Area (Nominal)	5 cm²	10 cm²	20 cm²
Operational			
Max. Operating Temperature	60 °C		
Max. Differential Pressure	42 psi (3 Kg/cm²) @ 30 °C		
Burst Pressure	> 14 Kg/cm²	> 8 Kg/cm²	> 8 Kg/cm²
Sterilization	By Gas	Sterilizable by Ethylene Oxide	
	By Autoclave	Autoclavable at 125 °C for 30 minutes, 30 cycles. Cannot be In-line steam sterilized	
Shelf Life	3 years after Ethylene Oxide Sterilization		

Air Flow Rates

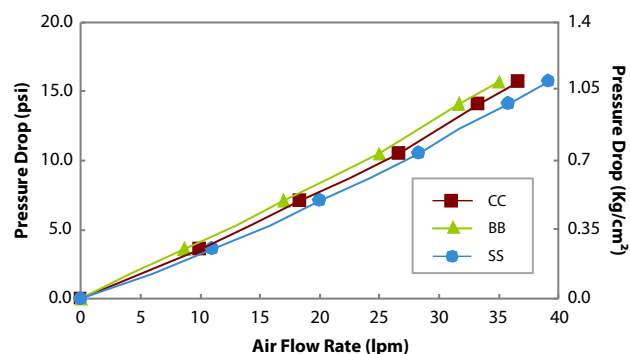
0.2 µm AseptiVent TF, 25 mm Capsule Filters



0.2 µm AseptiVent TF, 37 mm Capsule Filters



0.2 µm AseptiVent TF, 50 mm Capsule Filters



End Connection Type:

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

Ordering Information

AseptiVent TF- 25 mm

Type	Size	Pore Size	Inlet/Outlet	XX	Sterility	Pack Size
Code	Code	Code	Code		Code	Code
AseptiVent TF	25 mm	0.2 µm	Female Luer Lock		Non Sterile	100
ITFX	06	01	M		1	04
		0.45 µm	Male Luer Slip		EO Sterile	
		02	N		2	
			⅛" Hose Barb			
			H			
			¼" Hose Barb			
			B			
Example:						
ITFX	06	01	MN	XX	1	04

AseptiVent TF- 37 mm, 50 mm

Type	Size	Pore Size	Inlet/Outlet	XX	Sterility	Pack Size
Code	Code	Code	Code		Code	Code
AseptiVent TF	37 mm*	0.2 µm	¼" SHB		Non Sterile	10
ITFX	08	01	B		1	02
	50 mm	0.45 µm	⅛" MNPT		EO Sterile	
		02	C		2	
			¾" Sanitary Flange			
			S			
Example:						
ITFX	08	01	BB	XX	1	02

* Note: AseptiVent TF- 37 mm is available with BB connection only

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

AseptiVent TF capsule filters employ hydrophobic PTFE membrane offering absolute retention and very wide chemical compatibility making these useful for sterile filtration of air/gases as well as aggressive solvents.

**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

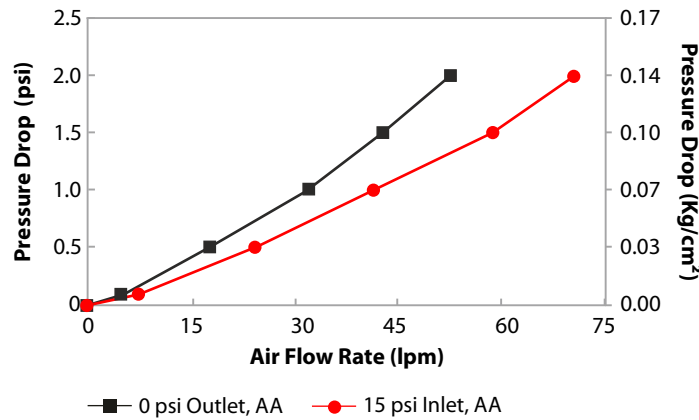


Specifications

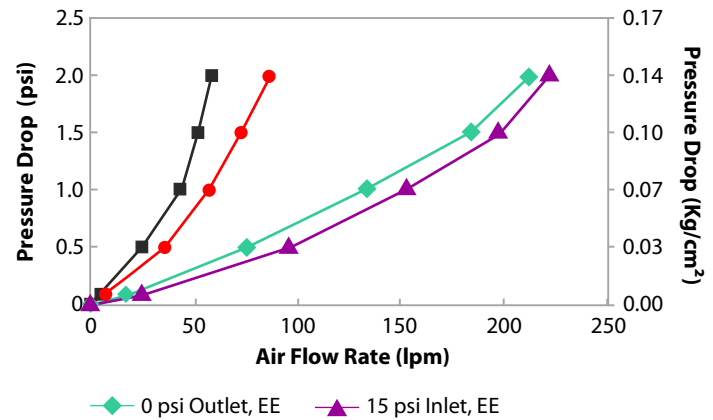
Construction				
Membrane		Hydrophobic PTFE		
Support Layers		Polypropylene		
Body and Core		Polypropylene		
Final Filter Pore Size		0.2 μm		0.45 μm
Integrity Testing/Retention				
Bubble Point (with 70% IPA Wetted)		≥ 22 psi (1.55 Kg/cm ²)		≥ 10 psi (0.7 Kg/cm ²)
Microbial Retention (LRV >7 for)		<i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²		<i>Serratia marcescens</i> (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
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 Gas	Sterilizable by Ethylene Oxide		
	By Autoclave	Autoclavable at 125 °C for 30 minutes, 50 cycles. Cannot be In-line steam sterilized		
Shelf Life		3 years after Ethylene Oxide sterilization		

Air Flow Rates

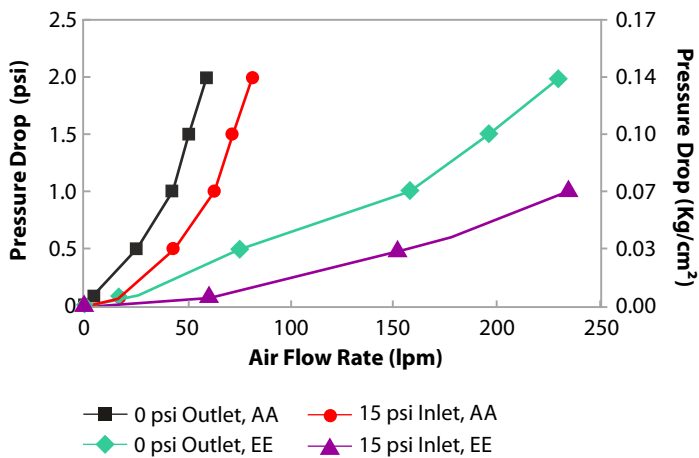
0.2µm AseptiVent TF, 1" Capsule Filter



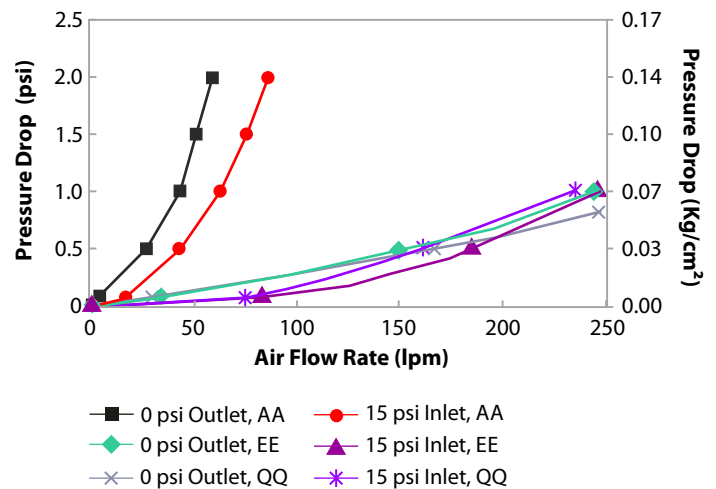
0.2µm AseptiVent TF, 2" Capsule Filter



0.2µm AseptiVent TF, 5" Capsule Filter



0.2µm AseptiVent TF, 8" Capsule Filter



End Connection Type

A: ¼" Stepped Hose Barb

E: 1½" Sanitary Flange

Q: Single Step ½" Hose Barb

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
AseptiVent TF	DTLX	1"	51	0.2 µm	01	¼" SHB	A			Non Sterile	1	1	01
		2"	52	0.45 µm	02	¼" MNPT	B			EO Sterile	2		
		5"	53			½" MNPT	C						
		8"	57			½" Hose Barb	D						
						1½" Sanitary Flange	E						
						¾" Sanitary Flange	S						
						Quick Connector	J						
						Single Step ½" Hose Barb	Q						
						Female Luer Lock	U						
						Male Luer Slip	W						
						¾" Hose Barb	N						
						¾" Hose Barb	I						

Example:

DTLX	53	01	DD	X	X	1	01
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For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiVent TF 5", 10", 20", 30"

AseptiVent TF PTFE large capsule filters offer absolute retention and wide chemical compatibility for sterile filtration of air/gases as well as aggressive solvents in large volume.

Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 210.3 (b) (6)
Meets and Exceeds USFDA 21 CFR 177.1520

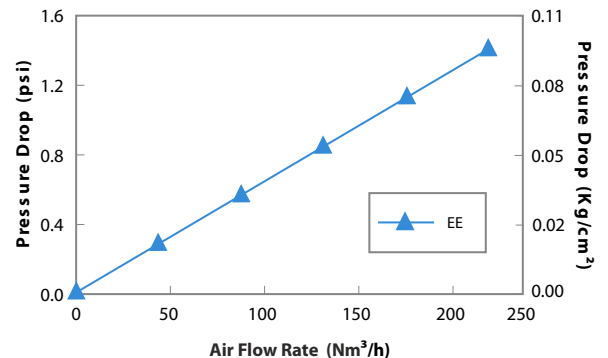
Specifications

Construction				
Membrane	Hydrophobic PTFE			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Pore Size	0.2 μm		0.45 μm	
Integrity Testing/Retention				
Air Diffusion Flow (70% IPA Wetted) (10" Capsule Filter)	≤ 45 ml/min @ 16 psi (1.12 Kg/cm²)		≤ 45 ml/min @ 8 psi (0.56 Kg/cm²)	
Microbial Retention (LRV >7 for)	<i>Brevundimonas diminuta</i> (ATCC 19146) per cm²		<i>Serratia marcescens</i> (ATCC 14756) per cm²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm²	6000 cm²	12000 cm²	18000 cm²
Vent and Drain	¼" Hose Barb with Silicone 'O' ring			
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm²)			
Max. Differential Pressure	60 psi (4 Kg/cm²) @ 30 °C			
Sterilization	By Gas	Sterilizable by Ethylene Oxide		
	By Autoclave	Autoclavable at 125 °C for 30 minutes, 30 cycles. Cannot be In-line steam sterilized		
Shelf Life	3 years after Ethylene Oxide sterilization			



Air Flow Rates

0.2 µm AseptiVent TF, 10" Large Capsule Filters



End Connection Type

E: 1½" Sanitary Flange

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		X	Inline / T-line		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
AseptiVent TF	LTLX	5"	53	0.2 µm	01	1½" Sanitary Flange	E		Inline	X	Non Sterile	1	1	01
		10"	54	0.45 µm	02	Single Step ½" Hose Barb	Q		T-line	T	EO Sterile	2		
		20"	55			¾" Sanitary Flange	S							
		30"	56			¾" Hose Barb	I							
						1" Hose Barb	Z							

Example:

LTLX	54	01	EE	X	X	1	01
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* Size 5" is available in In-line Capsule Filters Only

For End Connection availability and dimensions with different sizes refer Pages 85-86.

AseptiSure TH Mini Cartridge filters

mdi AseptiSure TH PTFE mini cartridge filters are specially designed high temperature resistant PTFE filters which are steam sterilizable at upto 135°C. These filters are validated with liquid microbial challenge test as per ASTM F 838-05 to offer absolute retention even under high moisture conditions.

These are also validated for other key performance parameters such as chemical compatibility, extractables, heat stability, flow rates, blow through and ability to withstand accidental reverse pressure. These are available in a variety of pore sizes to suit specific microfiltration needs in critical and specialized process applications for air as well as liquid.

Specifications

Construction			
Pore Size		0.2 µm	0.45 µm
Membrane		Hydrophobic PTFE	
Support Layers		Polypropylene	
Body and Core		Polypropylene	
Integrity Testing/Retention			
Bubble Point (70% IPA/Water)		22psi (1.54 kg/cm ²)	10psi (0.7 kg/cm ²)
Water Intrusion Rate	2.5"	≤ 0.3 ml/min @ 2.0kg/cm ²	–
	5"	≤ 0.6 ml/min @ 2.0kg/cm ²	–
Microbial Bacterial Retention (LRV >7 for)		<i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	<i>Serratia marcescens</i> (ATCC 14756) per cm ²
Size			
Size		2.5"	5"
Effective Filtration Area (Nominal)		1000 cm ²	2000 cm ²
Operational			
Max. Operating Temperature		95 °C @ ≤ 2 Kg/cm ² (30 psi)	
Max. Differential Pressure		3.5 Kg/cm ² (50 psi) @ 25 °C	
Reverse Pressure		≤ 0.7 Kg/cm ² (10 psi) @ 25 °C	
Sterilization		Autoclavable/In-line steam sterilizable at 135 °C @ maximum differential pressure of 5 psi (0.35 kg/cm ²) for 30 minutes, 80 cycles	

**Microbially Validated
as per ASTM F 838-05**

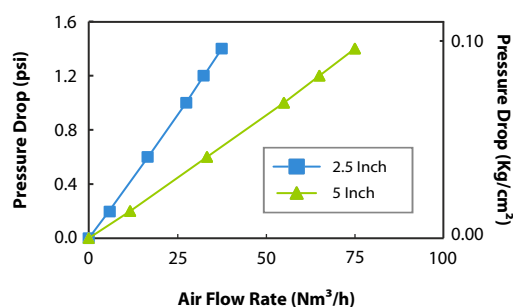
**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**



Air Flow Rates

0.2 µm AseptiSure TH Mini Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure TH	CPH	2.5"	50	0.2 µm	01	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	0.45 µm	02	4463B	H0						
						4440	U0						
						Seal-K	G0*						
						Seal-O	F0						
						Seal-M	J0						

*G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering

Example:

CPH	50	01	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

AseptiSure TH

AseptiSure TH cartridge filters are high temperature resistant PTFE filters which are steam sterilizable at 135°C. These filters are validated with liquid microbial challenge test as per ASTM F 838-05 to offer absolute retention even under high moisture conditions.

**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

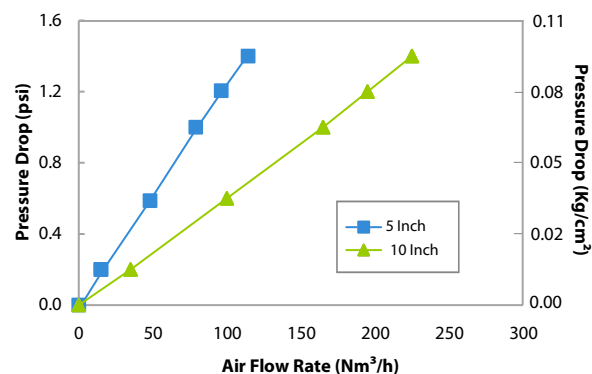
Specifications

Construction				
Final Filter Pore Size	0.2 µm		0.45 µm	
Membrane	Hydrophobic PTFE			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Integrity Testing/Retention				
Air Diffusion Flow (with 70% IPA Wetted) (10" Cartridge Filter)	≤ 45 ml/min @ 16 psi (1.12 Kg/cm²)		≤ 45 ml/min @ 8 psi (0.56 Kg/cm²)	
Microbial Retention (LRV >7 for)	Brevundimonas diminuta (ATCC 19146) per cm²		Serratia marcescens (ATCC 14756) per cm²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm²	6000 cm²	12000 cm²	18000 cm²
Operational				
Max. Operating Temperature	95 °C @ ≤ 30 psi (2 Kg/cm²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm²) @ 25 °C			
Reverse Pressure	≤ 10 psi (0.7 Kg/cm²) @ 25 °C			
Sterilization	Autoclavable/In-line steam sterilizable at 135 °C @ maximum differential pressure of 5 psi (0.35 Kg/cm²) for 30minutes, 80 cycles .			



Air Flow Rates

0.2 µm AseptiSure TH Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure TH	CPH	5"	53	0.2 µm	01	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	0.45 µm	02	7P without fin	A1	Viton	SV				
		20"	55			28 with fin	C0	EPDM	SE				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CPH	56	01	A0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

AseptiSure TF Mini Cartridge filters

mdi AseptiSure TF PTFE membrane mini cartridge filters are hydrophobic filters offering absolute retention. These filters are designed for sterilizing filtration of gases. The high quality of membrane and design of cartridge assures long life and ability to withstand adverse process conditions experienced during use.

mdi AseptiSure TF filters are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability, flow rates and blow through.

**Microbially Validated
as per ASTM F 838-05**

**Complies with
USFDA 21 CFR 210.3 (b) (6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

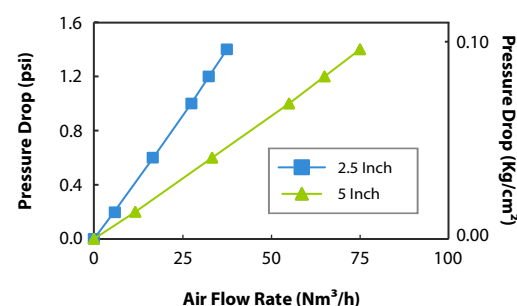
Specifications

Construction			
Final Filter Pore Size		0.2 µm	0.45 µm
Membrane		Hydrophobic PTFE	
Support Layers		Polypropylene	
Body and Core		Polypropylene	
Integrity Testing/Retention			
Bubble Point		22psi (1.52 Bar) with 70% IPA/Water Solution	10psi (0.69 Bar) with 70% IPA/Water Solution
Water Intrusion Rate	2.5"	≤ 0.3 ml/min @ 2.0kg/cm ²	–
	5"	≤ 0.6 ml/min @ 2.0kg/cm ²	–
Microbial Bacterial Retention (LRV >7 for)		<i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	<i>Serratia marcescens</i> (ATCC 14756) per cm ²
Size			
Size		2.5"	5"
Effective Filtration Area (Nominal)		1000 cm ²	2000 cm ²
Operational			
Max. Operating Temperature		80 °C @ ≤ 2 Kg/cm ² (30 psi)	
Max. Differential Pressure		3.5 Kg/cm ² (50 psi) @ 25 °C	
Reverse Pressure		≤ 0.7 Kg/cm ² (10 psi) @ 25 °C	
Sterilization		Autoclavable/In-line steam sterilizable at 121°C @maximum differential pressure of 3 psi (0.21 kg/cm ²) for 30 minutes, 100 cycles	



Air Flow Rates

0.2 µm AseptiSure TF Mini Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure TF	CPTF	2.5"	50	0.2 µm	01	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	0.45 µm	02	4463B	H0						
						4440	U0						
						Seal-K	G0*						
						Seal-O	F0						
						Seal-M	J0						

*G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering

Example:

CPTF	50	01	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

AseptiSure TF

AseptiSure TF cartridge filters employ hydrophobic PTFE membrane offering absolute retention, wide chemical compatibility, and are validated with liquid bacterial challenge test.

Microbially Validated
as per ASTM F 838-05

Complies with
USFDA 21 CFR 210.3 (b) (6)

Meets and Exceeds
USFDA 21 CFR 177.1520

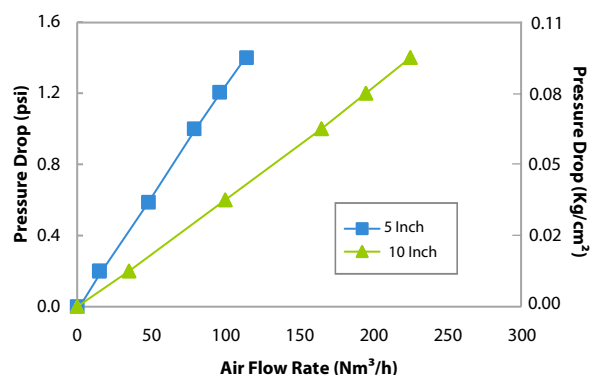
Specifications

Construction				
Final Filter Pore Size	0.2 μm		0.45 μm	
Membrane	Hydrophobic PTFE			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Integrity Testing/Retention				
Air Diffusion Flow (with 70% IPA Wetted) (10" Cartridge Filter)	≤ 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		Serratia marcescens (ATCC 14756) per cm ²	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm ²	6000 cm ²	12000 cm ²	18000 cm ²
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			
Reverse Pressure	≤ 10 psi (0.7 Kg/cm ²) @ 25 °C			
Sterilization	Autoclavable/In-line steam sterilizable at 121°C @maximum differential pressure of 3 psi (0.21 kg/cm ²) for 30 minutes, 100 cycles			



Air Flow Rates

0.2 µm AseptiSure TF Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure TF	CPTF	5"	53	0.2 µm	01	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	0.45 µm	02	7P without fin	A1	Viton	SV				
		20"	55			28 with fin	C0	EPDM	SE				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CPTF	54	01	A0	FV	1	01
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For Adapters and Elastomers availability refer Page 87.

Filters for Clarification and Pre-filtration

mdi offers a range of pre-filters designed to protect the terminal sterilizing grade membrane filters and maximize throughputs.

These are biologically inert filters with wide chemical compatibility, offering very high retention efficiency and are available in cartridge filter and capsule filter formats, in different sizes, pore sizes and end connections to suit different needs.

These filter devices are available as:

Filter Type	Product Name
Polyethersulfone Membrane Capsule Filters with Microglassfiber Upstream	<i>ClariPro GK</i>
Polyethersulfone Membrane Cartridge Filters with Microglassfiber Upstream	<i>ClariSure GK</i>
Microglassfiber Capsule Filter	<i>ClariCap GS</i>
Microglassfiber Cartridge Filters	<i>ClariSure GS</i>
	<i>ClariSure GP</i>
Polypropylene Capsule Filters	<i>ClariCap PP</i>
Polypropylene Cartridge Filters	<i>ClariSure PA</i>

Applications

- Precipitate removal post viral inactivation
- Pre-filtration of cell culture media
- Pre-filtration of serum and other viscous biologicals
- Pre-filtration of serum solutions
- Clarification of cell harvest supernatant
- Pre-filtration of protein solutions
- Pre-filtration of high value difficult to filter drug solutions
- Pre-filtration of large volume parenterals
- Pre-filtration of difficult to filter SVP
- Polishing of turbid solutions
- Pre-filtration of fermentor air

Quality Assurance

These filter devices are manufactured in Class 10,000 clean rooms under ISO 9001:2015 certified quality management systems and are deeply validated to meet compendia and regulatory requirements.

Assurance	
Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3 (b)(6) for fiber release
Extractables with WFI	Passes test as per USP <661>
Oxidizable Substances	Within limits as specified in USP <1231>
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

Filter Selection Chart

Application Area	Key Application Requirements	Capsule Filters		Cartridge Filters	
Biopharmaceuticals					
Precipitate removal post viral inactivation	<ul style="list-style-type: none">- High retention efficiency- High throughput	ClariPro GK PES Membrane Capsule Filters with Microglassfiber upstream	ClariCap GS Microglassfiber Capsule Filters	ClariSure GK PES Membrane Cartridge Filters with Microglassfiber upstream	ClariSure GS Microglassfiber Cartridge Filters
Pre-filtration of cell culture media	<ul style="list-style-type: none">- High retention efficiency- High throughput	ClariPro GK PES Membrane Capsule Filters with Microglassfiber upstream	ClariCap GS Microglassfiber Capsule Filters	ClariSure GK PES Membrane Cartridge Filters with Microglassfiber upstream	ClariSure GS Microglassfiber Cartridge Filters
Prefiltration of serum and other viscous biologicals	<ul style="list-style-type: none">- High retention efficiency- High throughput	ClariPro GK PES Membrane Capsule Filters with Microglassfiber upstream	ClariCap GS Microglassfiber Capsule Filters	ClariSure GK PES Membrane Cartridge Filters with Microglassfiber upstream	ClariSure GS Microglassfiber Cartridge Filters
Pre-filtration of serum solutions	<ul style="list-style-type: none">- High retention efficiency- High throughput	ClariPro GK PES Membrane Capsule Filters with Microglassfiber upstream	ClariCap GS Microglassfiber Capsule Filters	ClariSure GK PES Membrane Cartridge Filters with Microglassfiber upstream	ClariSure GS Microglassfiber Cartridge Filters
Clarification of cell harvest supernatants	<ul style="list-style-type: none">- High retention efficiency- High throughput	ClariPro GK PES Membrane Capsule Filters with Microglassfiber upstream	ClariCap GS Microglassfiber Capsule Filters	ClariSure GK PES Membrane Cartridge Filters with Microglassfiber upstream	ClariSure GS Microglassfiber Cartridge Filters
Pre-filtration of fermentor air	<ul style="list-style-type: none">- High retention efficiency	–	ClariCap PP Polypropylene Capaule Filters	ClariSure PA Pleated Polypropylene Cartridge Filters	–
Pre-filtration of proteinaceous liquids	<ul style="list-style-type: none">- Low hold up volume- High throughput	ClariPro GK PES Membrane Capsule Filters with Microglassfiber upstream	ClariCap PP Polypropylene Capaule Filters	–	–
Pharmaceuticals					
Pre-filtration of high value difficult to filter drug solutions	<ul style="list-style-type: none">- High retention efficiency- High throughput	ClariPro GK PES Membrane Capsule Filters with Microglassfiber upstream	ClariCap GS Microglassfiber Capsule Filters	ClariSure GK PES Membrane Cartridge Filters with Microglassfiber upstream	ClariSure GS Microglassfiber Cartridge Filters
Pre-filtration of large volume parenterals	<ul style="list-style-type: none">- High retention efficiency- High throughput	–	–	ClariSure PA Pleated Polypropylene Cartridge Filters	ClariSure GP Microglassfiber Cartridge Filters
Pre-filtration of difficult to filter SVP like Oxytetracycline	<ul style="list-style-type: none">- High retention efficiency- High throughput	–	–	ClariSure GK PES Membrane Cartridge Filters with Microglassfiber upstream	ClariSure GP Microglassfiber Cartridge Filters
Polishing of turbid solutions	<ul style="list-style-type: none">- Very high retention efficiency for colloidal particles- High throughput	ClariPro GK PES Membrane Capsule Filters with Microglassfiber upstream	ClariCap GS Microglassfiber Capsule Filters	ClariSure GK PES Membrane Cartridge Filters with Microglassfiber upstream	ClariSure GS Microglassfiber Cartridge Filters

ClariPro GK 1", 2", 5", 8"

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariPro GK hydrophilic PES membrane capsule filters are ready to use, disposable filtration devices. These filters are specially designed filters incorporating a microglassfiber upstream layer and a downstream PES membrane layer and are used as pre-filters in biopharmaceuticals process development as well as manufacturing processes for difficult to filter solutions.

Radiation Sterilizable: ClariPro GK-γ

Autoclavable: ClariPro GK

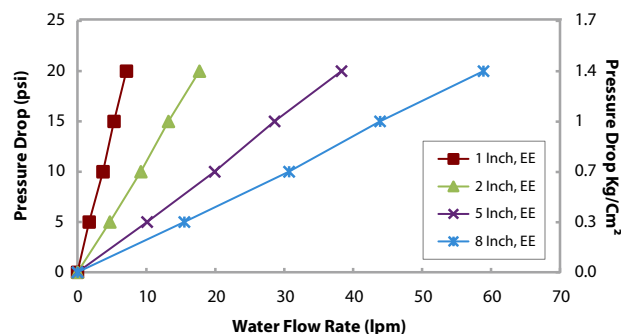
Specifications

Construction				
Pore Size	0.1 μm, 0.2 μm, 0.5μm			
Membrane	Hydrophilic PES			
Pre-filter	Microglassfiber			
Support Layers	Polyester			
Body and Core	Polypropylene			
Size				
Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	150 cm ²	500 cm ²	1000 cm ²	1500 cm ²
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 Irradiation	ClariPro GK-γ : Gamma Irradiatable up to 50 kGy		
	By Gas	ClariPro GK : Sterilizable by Ethylene Oxide		
	By Autoclave	ClariPro GK : Autoclavable at 125 °C for 30 minutes, 25 cycle.		
These cannot be In-line steam sterilized				



Water Flow Rates

0.5 μm ClariPro GK Capsule Filters



E: 1½" Sanitary Flange Connections

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
ClariPro GK	DGKX	1"	51	0.1 μm	36	¼" SHB	A	Yes	R		Non Sterile	1	1	01
		2"	52	0.2 μm	01	½" Hose Barb	D	No*	X		EO Sterile	2		
		5"	53	0.5 μm	04	1½" Sanitary Flange	E				Gamma Sterile	3		
		8"	57			¾" Sanitary Flange	S							
						Quick Connector	J							
						Single Step ½" Hose Barb	Q							
						Female Luer Lock	U							
						Male Luer Slip	W							
						⅜" Hose Barb	N							
						⅝" Hose Barb	I							

Example:

DGKX	57	04	DD	R	X	2	01
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*Gamma Sterile capsule filters cannot be Gamma Irradiated again

For End Connection availability and dimensions with different sizes refer Pages 85-86.

ClariPro GK 5", 10", 20", 30"

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariPro GK hydrophilic PES membrane large capsule filters are ready to use, disposable filtration devices with a microglassfiber upstream layer and a downstream PES membrane final layer.

The microglassfiber layer offers high dirt holding capacity and efficient retention of colloidal particles to give clear downstream in case of difficult to filter turbid solutions. The downstream PES membrane offers absolute retention and low protein binding along with high flow rates.

Radiation Sterilizable: ClariPro GK-γ

Autoclavable: ClariPro GK

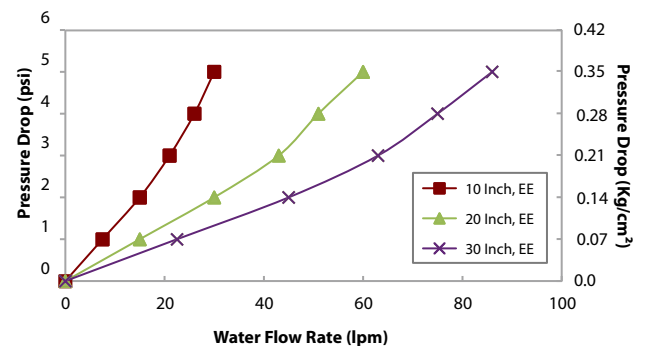
Specifications

Construction				
Pore Size	0.1 μm, 0.2 μm, 0.5 μm			
Membrane	Hydrophilic PES			
Pre-filter	Microglassfiber			
Support Layers	Polyester			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500 cm ²	5000 cm ²	10000 cm ²	15000 cm ²
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 Irradiation	ClariPro GK -γ : Gamma Irradiatable up to 50 kGy		
	By Gas	ClariPro GK : Sterilizable by Ethylene Oxide		
	By Autoclave	ClariPro GK : Autoclavable at 125 °C for 30 minutes 25 cycles		
These cannot be In-line steam sterilized				



Water Flow Rates

0.5 μm ClariPro GK Large Capsule Filters



E: 1½" Sanitary Flange Connections

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline / T-line		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
ClariProGK	LGKX	5"***	53	0.1 μm	36	1½" Sanitary Flange	E	Yes	R	Inline	X	Non Sterile	1	1	01
		10"	54	0.2 μm	01	Single Step ½" Hose Barb	Q	No*	X	T-line	T	EO Sterile	2		
		20"	55	0.5 μm	04	¾" Sanitary Flange	S					Gamma Sterile	3		
		30"	56			¾" Hose Barb	I								
						1" Hose Barb	Z								

Example:

LGKX	54	01	EE	R	T	1	01
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* Gamma Sterile capsule filters cannot be Gamma Irradiated again

** Size 5" is available in In-line Capsule Filters Only

For End Connection availability and dimensions with different sizes refer Pages 81-82.

ClariSure GK Mini Cartridge Filters

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariSure GK hydrophilic PES membrane mini cartridge filters offer a microglassfiber upstream layer with a PES membrane final filter to combine high dirt holding capacities with efficient retention of colloidal particles to give clear downstream in case of difficult to filter turbid solutions.

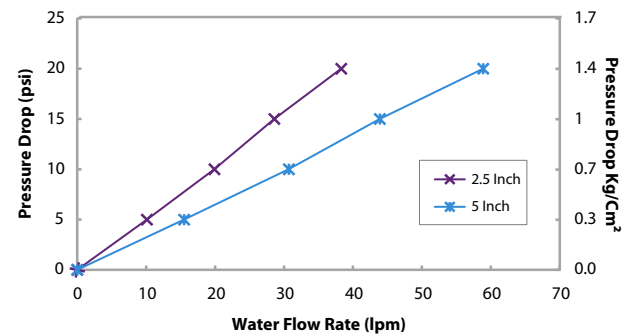
Specifications

Construction		
Pore Size	0.1 μm, 0.2 μm, 0.5 μm	
Membrane	Hydrophilic PES	
Pre-filter	Microglassfiber	
Support Layers	Polyester	
Body and Core	Polypropylene	
Size		
Size	2.5"	5"
Effective Filtration Area (Nominal)	1000 cm ²	1500 cm ²
Operational		
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)	
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C	
Sterilization	Autoclavable/In-line steam sterilizable at 121°C for 30 minutes, 25 cycles	



Water Flow Rates

0.5 µm ClariSure GK Mini Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure GK	CGKX	2.5"	50	0.1 µm	36	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	0.2 µm	01	4463B	H0						
				0.5 µm	04	4440	U0						
						Seal-K	G0*						
						Seal-O	F0						
						Seal-M	J0						

*G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering

Example:

CGKX	50	04	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

ClariSure GK hydrophilic PES membrane cartridge filters offer a microglassfiber upstream layer with a PES membrane final filter to combine high dirt holding capacities with efficient retention of colloidal particles to give clear downstream in case of difficult to filter turbid solutions.

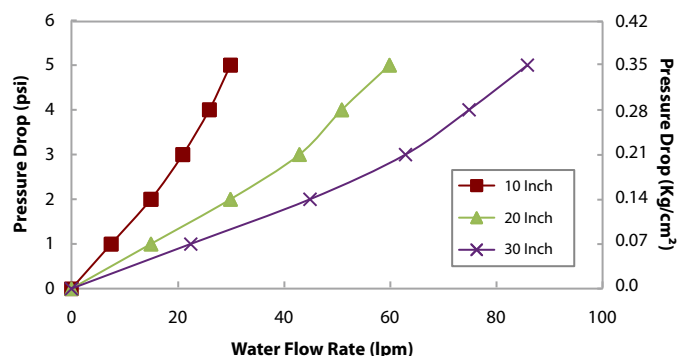
Specifications

Construction				
Pore Size	0.1 μm, 0.2 μm, 0.5 μm			
Membrane	Hydrophilic PES			
Pre-filter	Microglassfiber			
Support Layers	Polyester			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500 cm ²	5000 cm ²	10000 cm ²	15000 cm ²
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			
Sterilization	Autoclavable/In-line steam sterilizable at 121°C for 30 minutes, 25 cycles			



Water Flow Rates

0.5 µm ClariSure GK Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure GK	CGKX	5"	53	0.1 µm	36	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	0.2 µm	01	7P without fin	A1	Viton	SV				
		20"	55	0.5 µm	04	28 with fin	C0	EPDM	SE				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CGKX	56	36	A0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

ClariCap GS 1", 2", 5", 8"

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariCap GS capsule filters employ microglassfiber filter media for efficient retention of colloidal particles to give clear downstream in case of difficult to filter turbid solutions. These specially designed filtration devices are non media migrating with a heat calendered polypropylene layer in the downstream.

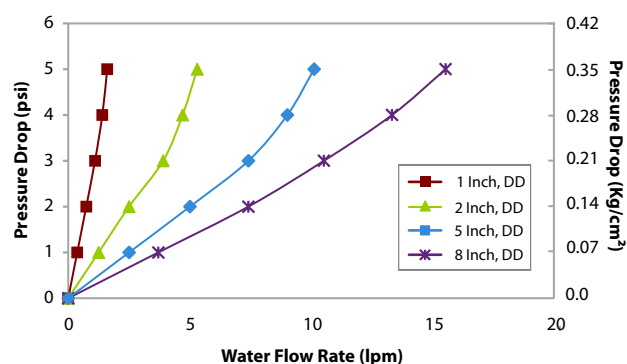
Specifications

Construction				
Pore Size	0.7 μm, 1 μm, 1.5 μm, 2 μm			
Filter Media	Microglassfiber			
Body and Core	Polypropylene			
Size				
Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	150 cm ²	400 cm ²	800 cm ²	1200 cm ²
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	Autoclavable at 125 °C for 30 minutes, 30 cycles. Cannot be In-line steam sterilized			



Water Flow Rates

0.7 µm ClariCap GS Capsule Filters



D: ½" Hose Barb

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		X	Bell		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
ClariCap GS	DGSX	1"	51	0.7 µm	41	¼" SHB	A				Yes	B	1	01
		2"	52	1 µm	05	½" Hose Barb	D				No Bell	X		
		5"	53	1.5 µm	14	1½" Sanitary Flange	E							
		8"	57	2 µm	15	¾" Sanitary Flange	S							
						Quick Connector	J							
						Single Step ½" Hose Barb	Q							
						Female Luer Lock	U							
						Male Luer Slip	W							
						¾" Hose Barb	N							
						⅜" Hose Barb	I							

Example:

DGSX	57	05	DD	X	X	1	01
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For End Connection availability, Bell and dimensions with different sizes refer Pages 85-86.

ClariCap GS 5", 10", 20", 30"

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariCap GS large capsule filters are multilayered, high throughput filters, specially designed for difficult to filter solutions.

These are high efficiency pre-filters combining the unique abilities of microglassfiber filter media to retain colloidal particles and heat calendered polypropylene filter media to ensure non media migration.

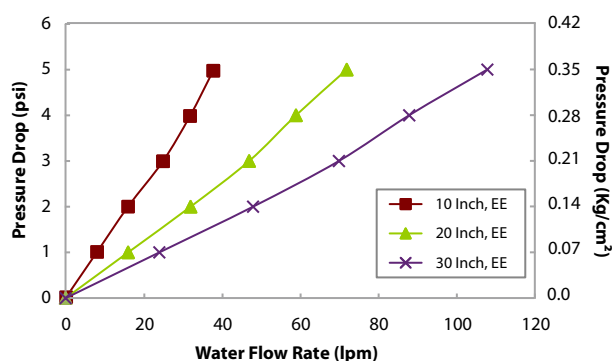
Specifications

Construction				
Pore Size	0.7 μm, 1 μm, 1.5 μm, 2 μm			
Filter Media	Microglassfiber			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	1700 cm ²	3400 cm ²	6800 cm ²	10200 cm ²
Vent and Drain	¼" Hose Barb with Silicon '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	Autoclavable at 125 °C for 30 minutes, 30 cycles. Cannot be In-line steam sterilized			



Water Flow Rates

0.7µm ClariCap GS Large Capsule Filters



E: 1½" Sanitary Flange Connections

Ordering Information

Type		Size		Pore Size		Inlet/Outlet		X	Inline / T-line		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
ClariCap GS	LGSX	5"*	53	0.7 µm	41	1½" Sanitary Flange	E			X	Non Sterile	1	1	01
		10"	54	1 µm	05	Single Step ½" Hose Barb	Q							
		20"	55	1.5 µm	14	¾" Sanitary Flange	S							
		30"	56	2 µm	15	3/8" Hose Barb	I							
						1" Hose Barb	Z							

Example:

LGSX	54	41	EE	X	T	1	01
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*Size 5" is available in Inline capsule filters only

For End Connection availability and dimensions with different sizes refer Page 85-86.

ClariSure GS Mini Cartridge Filters

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariSure GS mini cartridge filters are multilayered, high throughput filters, specially designed for difficult to filter solutions.

It is a very high efficiency pre-filter combining the unique abilities of microglassfiber filter media to retain colloidal particles and heat calendered polypropylene filter media to ensure non media migration.

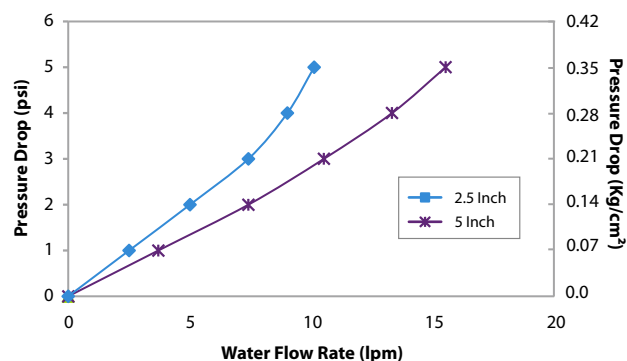
Specifications

Construction		
Pore Size	0.7 μm, 1 μm	
Filter Media	Microglassfiber	
Support Layers	Polyester	
Body and Core	Polypropylene	
Size		
Size	2.5"	5"
Effective Filtration Area (Nominal)	800 cm ²	1200 cm ²
Operational		
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)	
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C	
Sterilization	Autoclavable/In-line steam sterilizable at 121°C for 30 minutes, 30 cycles	



Water Flow Rates

0.7 µm ClariSure GS Mini Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure GS	CPGS	2.5"	50	0.7 µm	41	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	1 µm	05	4463B	H0						
						4440	U0						
						Seal-K	G0*						
						Seal-O	F0						
						Seal-M	J0						

*G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering

Example:

CPGS	50	41	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

ClariSure GS

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariSure GS cartridge filters are multilayered, high throughput filters, specially designed for difficult to filter solutions.

It is a very high efficiency pre-filter combining the unique abilities of microglassfiber filter media to retain colloidal particles and heat calendered polypropylene filter media to ensure non media migration.

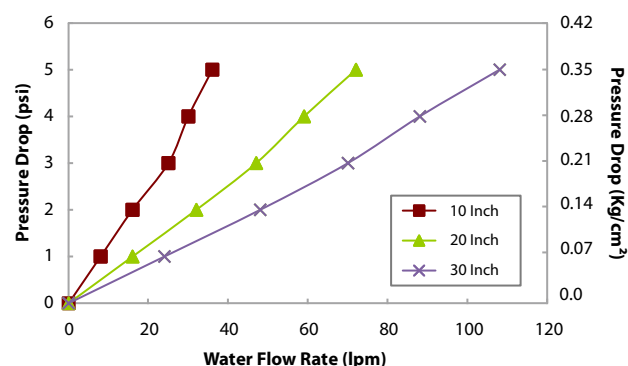
Specifications

Construction				
Pore Size	0.7 μm, 1 μm			
Filter Media	Microglassfiber			
Support Layers	Polyester			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	1700 cm ²	3400 cm ²	6800 cm ²	10200 cm ²
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 30 °C			
Sterilization	Autoclavable/In-line steam sterilizable at 121 °C for 30 minutes, 30 cycles			



Water Flow Rates

0.7 μm ClariSure GS Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure GS	CPGS	5"	53	0.7 μm	41	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	1 μm	05	7P without fin	A1	Viton	SV				
		20"	55			28 with fin	C0	EPDM	SE				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CPGS	55	41	A0	SV	1	01
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For Adapters and Elastomers availability refer Page 87.

ClariSure GP Mini Cartridge Filters

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariSure GP mini cartridge filters are specially designed multilayered precision filtration devices. These cartridge filters act as throughput enhancers, specially in case of difficult to filter solutions.

A microglassfiber upstream layer retains very fine colloidal particles and a downstream polypropylene layer checks any kind of media migration.

Specifications

Construction		
Pore Size	0.5 μm, 1 μm, 2 μm	
Filter Media	Microglassfiber	
Support Layers	Polypropylene	
Body and Core	Polypropylene	
Size		
Size	2.5"	5"
Effective Filtration Area (Nominal)	800 cm ²	1600 cm ²
Operational		
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)	
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C	
Sterilization	Autoclavable/In-line steam sterilizable at 121°C for 30 minutes, 30 cycles	



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure GP	CPGP	2.5"	50	0.5 µm	04	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	1 µm	05	4463B	H0						
				2 µm	15	4440	U0						
						Seal-K	G0*						
						Seal-O	F0						
						Seal-M	J0						

*G0 adapter is not available with elastomer. Please mention XX in place of elastomer code while ordering

Example:

CPGP	50	05	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

ClariSure GP

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariSure GP cartridge filters are specially designed multilayered precision filtration devices. These cartridge filters act as throughput enhancers, specially in case of difficult to filter solutions.

A microglassfiber upstream layer retains very fine colloidal particles and a downstream polypropylene layer checks any kind of media migration.

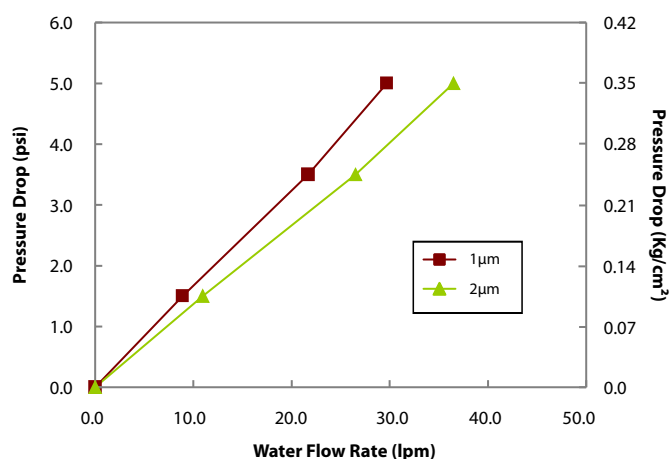
Specifications

Construction				
Pore Size	0.5 μm, 1 μm, 2 μm			
Filter Media	Microglassfiber			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500 cm ²	5000 cm ²	10000 cm ²	15000 cm ²
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			
Sterilization	Autoclavable/In-line steam sterilizable at 121°C for 30 minutes, 30 cycles			



Water Flow Rates

ClariSure GP, 10" Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure GP	CPGP	5"	53	0.5 µm	04	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	1 µm	05	7P without fin	A1	Viton	SV				
		20"	55	2 µm	15	28 with fin	C0	EPDM	SE				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV				

Example:

CPGP	55	04	A0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

ClariCap PP 1", 2", 5", 8"

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariCap PP capsule filters employ high retention efficiency polypropylene filter media with wide chemical compatibility for pre-filtration and polishing applications.

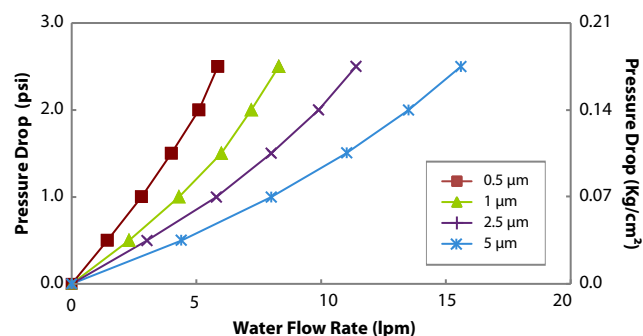
Specifications

Construction				
Pore Size	0.5 μm, 1 μm, 2.5 μm, 5 μm, 10 μm, 20 μm			
Filter Media	Polypropylene			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Size				
Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	250 cm ²	500 cm ²	800 cm ²	1600 cm ²
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	Autoclavable at 125 °C for 30 minutes, 30 cycles. Cannot be In-line steam sterilized			



Water Flow Rates

ClariCap PP, 5" Capsule Filters



Ordering Information

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
ClariCap PP	DOLX	1"	51	0.5 µm	04	¼" SHB	A			Non Sterile	1	1	01
		2"	52	1 µm	05	¼" MNPT	B						
		5"	53	2.5 µm	06	½" MNPT	C						
		8"	57	5 µm	07	½" Hose Barb	D						
				10 µm	08	1½" Sanitary Flange	E						
				20 µm	11	¾" Sanitary Flange	S						
						Quick Connector	J						
						Single Step ½" Hose Barb	Q						
						Female Luer Lock	U						
						Male Luer Slip	W						
						⅜" Hose Barb	N						
						⅝" Hose Barb	I						

Example:

DOLX	53	05	CC	X	X	1	01
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For End Connection availability, Bell and dimensions with different sizes refer Pages 85-86.

ClariCap PP 5", 10", 20", 30"

ClariCap PP large capsule filters employ high retention efficiency Polypropylene filter media for wide chemical compatibility, efficient pre-filtration for clarification and polishing applications.

Specifications

Construction				
Pore Size	0.5 µm, 1 µm, 2.5 µm, 5 µm, 10 µm, 20 µm			
Filter Media	Polypropylene			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500 cm ²	5000 cm ²	10000 cm ²	15000 cm ²
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	Autoclavable at 125 °C for 30 minutes, 30 cycles. Cannot be In-line steam sterilized			

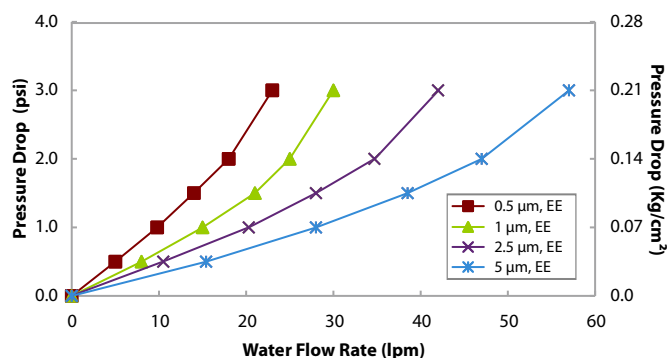
Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520



Water Flow Rates

ClariCap PP 10", Large Capsule Filters



End Connection Type:

E: 1½" Sanitary Flange

Ordering Information

Type	Size	Pore Size	Inlet/Outlet	X	Inline / T-line	Sterility	Pack Size
	Code		Code		Code	Code	Code
ClariCap PP	LOLX						
	5"*	53	0.5 µm	04			
	10"	54	1 µm	05			
	20"	55	2.5 µm	06			
	30"	56	5 µm	07			
			10 µm	08			
			20 µm	11			
			1½" Sanitary Flange	E			
			Single Step ½" Hose Barb	Q			
			¾" Sanitary Flange	S			
			¾" Hose Barb	I			
			1" Hose Barb	Z			
					Inline	X	
					T-line	T	
						Non Sterile	1
							1
							01

Example:

LOLX	54	06	QQ	X	T	1	01
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* Size 5" is available in In-line Capsule Filters Only

For End Connection availability and dimensions with different sizes refer Pages 85-86.

ClariSure PA Mini Cartridge Filters

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

mdi ClariSure PA mini cartridge filters are 100% polypropylene, very high retention efficiency pleated cartridge filters offering large filtration area.

These filters have heat stable construction and are used as pre-filters to sterilizing membrane cartridge filters.

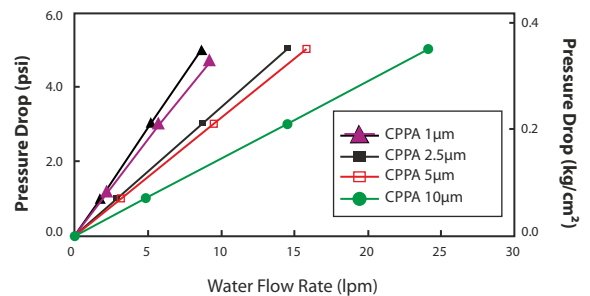


Specifications

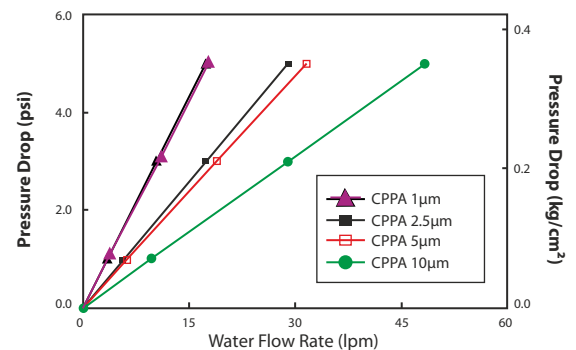
Construction		
Pore Size	0.5 μm, 1 μm, 1.2 μm, 2.5 μm, 5 μm, 8 μm, 10 μm	
Filter Media	Polypropylene	
Support Layers	Polypropylene	
Body and Core	Polypropylene	
Size		
Size	2.5"	5"
Effective Filtration Area (Nominal)	800 cm ²	1600 cm ²
Operational		
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)	
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C	
Sterilization	Autoclavable/In-line steam sterilizable at 121°C for 30 minutes, 100 cycles	

Water Flow Rates

ClariSure PA, 2.5" Mini Cartridge Filters



ClariSure PA, 5" Mini Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure PA	CPPA	2.5"	50	0.5 µm	04	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	1 µm	05	4463B	H0						
				1.2 µm	10	4440	U0						
				2.5 µm	06	Seal-K	G0*						
				5 µm	07	Seal-O	F0						
				8 µm	17	Seal-M	J0						
				10 µm	08								

*G0 adapter does not come with elastomer. Please mention XX in place of elastomer while ordering

Example:

CPPA	50	05	E0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

ClariSure PA

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariSure PA cartridge filters are 100% polypropylene, very high retention efficiency pleated cartridge filters offering large filtration area.

These filters have heat stable construction and are used as pre-filters to sterilizing membrane cartridge filters.

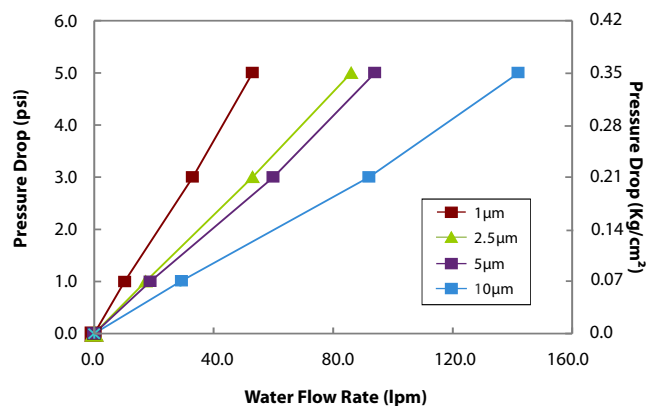
Specifications

Construction				
Pore Size	0.5 µm, 1 µm, 1.2 µm, 2.5 µm, 5 µm, 8 µm, 10 µm			
Filter Media	Polypropylene			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500 cm ²	5000 cm ²	10000 cm ²	15000 cm ²
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			
Sterilization	Autoclavable/In-line steam sterilizable at 121 °C for 30 minutes, 100 cycles			



Water Flow Rates

ClariSure PA, 10" Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure PA	CPPA	5"	53	0.5 µm	04	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	1 µm	05	7P without fin	A1	Viton	SV				
		20"	55	1.2 µm	10	28 with fin	C0	EPDM	SE				
		30"	56	2.5 µm	06	'O'	D0	FEP Encapsulated Viton	FV				
				5 µm	07								
				8 µm	17								
				10 µm	08								

Example:

CPPA	56	05	A0	SS	1	01
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For Adapters and Elastomers availability refer Page 87.

Microglassfiber Disc Filters

Microglassfiber Disc Filters Type - GF2

GF2 filters are high dirt holding microglassfiber disc filters specially designed for pre-filtration of solutions with high dirt load.

Pore Size: 1.5 μm

Special Features

- High flow rates
- High dirt holding capacity

Fine Microglassfiber Disc Filters - Type GFS

GFS filters are high retention efficiency fine microglassfiber disc filters.

Pore Size: 2 μm

Special Features

- High retention efficiency

Positively Charged Microglassfiber Disc Filters- Type GFSZ

GFSZ filters are positively charged high retention efficiency microglassfiber disc filters.

Pore Size: 2 μm

Special Features

- Very high retention efficiency for negatively charged particles

Ordering Information

Type		Size		Pore Size		XX	XX	Sterility		Pack Size	
	Code		Code		Code				Code		Code
GF2	GF2X	127 mm	15	1.5 µm	14	↓	↓	Non Sterile	1	50	03
GFS	GFSX	142 mm	16	2 µm	15						
GFSZ	GFSZ	257 mm	17								
		279 mm	18								
		293 mm	19								

Example:

GFSX	18	15	XX	XX	1	03
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Filters for Polishing and Clarification

mdi offers a range of cartridge filters for polishing and clarification applications requiring absolute removal of particulate contaminants.

These are non media migrating, biologically and chemically inert, large area filter cartridges, offering very high (99.999%) to moderate high (99.9%) retention efficiencies to suit different applications.

Types Available

>> **ClariSure PP**- Pleated Polypropylene cartridge filters

>> **ClariSure PL**- Pleated Profile cartridge filters

>> **ClariSure DP**- Pleated Depth cartridge filters

Applications

- Filtration of organic solvents in non sterile API
- Polishing filtration of Non Sterile API
- Filtration of precipitating agents
- Filtration of wash solvents for final non sterile API
- Filtration of air to dryers and micronizers
- Final wash water for Ampoule/Vial washing and Bung washing
- Bottle washing in oral formulations
- Filtration of feed water for RO plants

Quality Assurance

These filter devices are manufactured in Class 10,000 clean rooms under ISO 9001:2015 certified quality management systems and are validated to meet compendia and regulatory requirements.

Assurance	
Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3 (b)(6) for fiber release
Extractables with WFI	Passes test as per USP <661>
Oxidizable Substances	Within limits as specified in USP <1231>
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

Filter Selection Chart

Application Area	Key Application Requirements	Cartridge Filters		
Filtration of organic solvents in non sterile API	<ul style="list-style-type: none"> - High retention efficiency - Wide chemical compatibility 	ClariSure PP Pleated Polypropylene Cartridge Filters	ClariSure PL Pleated Profile Cartridge Filters	ClariSure DP Pleated Depth Cartridge Filters
Polishing filtration of non sterile API	<ul style="list-style-type: none"> - Very high retention efficiency - Wide chemical compatibility 	ClariSure PP Pleated Polypropylene Cartridge Filters	ClariSure PL Pleated Profile Cartridge Filters	-
Filtration of precipitating agents	<ul style="list-style-type: none"> - Very high retention efficiency - Wide chemical compatibility 	ClariSure PP Pleated Polypropylene Cartridge Filters	ClariSure PL Pleated Profile Cartridge Filters	-
Filtration of wash solvents for final non sterile API	<ul style="list-style-type: none"> - Very high retention efficiency - Wide chemical compatibility 	ClariSure PP Pleated Polypropylene Cartridge Filters	ClariSure PL Pleated Profile Cartridge Filters	-
Filtration of air to dryers and micronizers	<ul style="list-style-type: none"> - Very high retention efficiency 	ClariSure PP Pleated Polypropylene Cartridge Filters	ClariSure PL Pleated Profile Cartridge Filters	-
Final wash water for ampoule/vial washing and bung washing	<ul style="list-style-type: none"> - Very high retention efficiency - Wide chemical compatibility 	ClariSure PP Pleated Polypropylene Cartridge Filters	ClariSure PL Pleated Profile Cartridge Filters	-
Bottle washing in oral formulations	<ul style="list-style-type: none"> - Very high retention efficiency - Wide chemical compatibility 	ClariSure PP Pleated Polypropylene Cartridge Filters	ClariSure PL Pleated Profile Cartridge Filters	-
Filtration of feed water for RO plants	<ul style="list-style-type: none"> - High dirt holding capacity 	-	-	ClariSure DP Pleated Depth Cartridge Filters

ClariSure PP

Complies with
USFDA 21 CFR 210.3 (b)(6)

Meets and Exceeds
USFDA 21 CFR 177.1520

ClariSure PP cartridge filters are 100% polypropylene construction precision filtration devices. These are very high retention efficiency (99.999%) pleated cartridge filters offering large filtration area.

These filters are used as terminal filters in applications requiring highly efficient particulate removal.

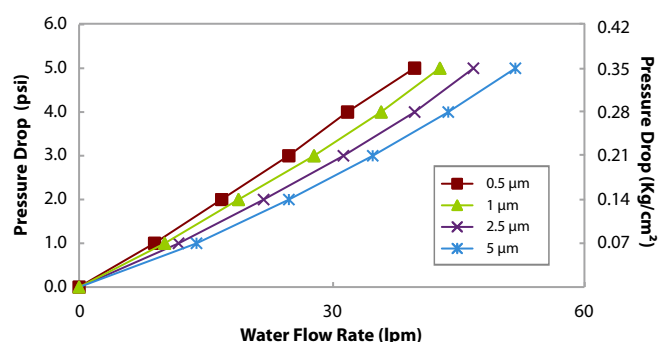


Specifications

Construction				
Pore Size	0.5 µm, 1µm, 1.2 µm, 2 µm, 2.5 µm, 5 µm 10 µm, 20 µm, 30 µm			
Filter Media	Polypropylene			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500 cm ²	5000 cm ²	10000 cm ²	15000 cm ²
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			

Water Flow Rates

ClariSure PP, 10" Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure PP	CPPP	5"	53	0.5 µm	04	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	1 µm	05	7P without fin	A1	Viton	SV				
		20"	55	1.2 µm	10	28 with fin	C0	EPDM	SE				
		30"	56	2 µm	15	BEO	B0	PTFE	ST*				
				2.5 µm	06	'O'	D0	FEP Encapsulated Viton	FV				
				5 µm	07								
				10 µm	08								
				20 µm	11								
				30 µm	19								

Example:

CPPP	55	04	A0	FV	1	01
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*PTFE (ST) gasket seals are available with Adapter Code B0 only

For Adapters and Elastomers availability refer Page 83.

ClariSure PL

**Complies with
USFDA 21 CFR 210.3 (b)(6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

ClariSure PL cartridge filters are all polypropylene high retention efficiency (**99.99%**) pleated cartridge filters offering large filtration area.

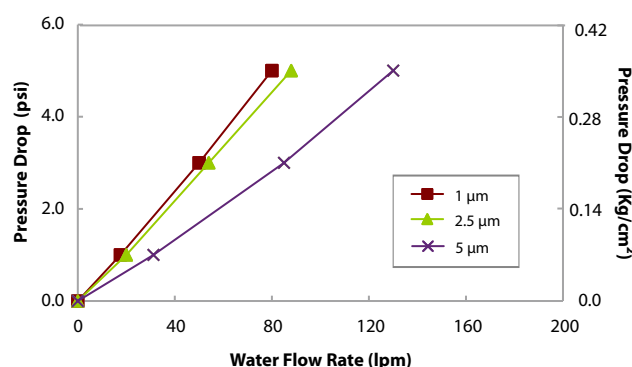


Specifications

Construction				
Pore Size	1 μm, 2.5 μm, 5 μm, 10 μm			
Filter Media	Polypropylene			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500 cm ²	5000 cm ²	10000 cm ²	15000 cm ²
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			

Water Flow Rates

ClariSure PL, 10" Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure PL	CPPL	5"	53	1 µm	05	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	2.5 µm	06	7P without fin	A1	Viton	SV				
		20"	55	5 µm	07	28 with fin	C0	EPDM	SE				
		30"	56	10 µm	08	BEO	B0	PTFE	ST*				
						'O'	D0	FEP Encapsulated Viton	FV				

Example:

CPPL	54	07	B0	SV	1	01
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*PTFE (ST) gasket seals are available with Adapter Code B0 only

For Adapters and Elastomers availability refer Page 83.

ClariSure DP

**Complies with
USFDA 21 CFR 210.3 (b)(6)**

**Meets and Exceeds
USFDA 21 CFR 177.1520**

ClariSure DP cartridge filters are specially designed medium retention efficiency, multilayered, all polypropylene depth cartridge filters offering high dirt holding capacity as well as high flow rates due to their pleated configuration.

These filters are primarily used as pre-filters but can also be used as terminal filters for non-critical applications.

Specifications

Construction				
Pore Size	1 μm, 1.5 μm, 3 μm, 5 μm, 10 μm, 20 μm 30 μm, 40 μm			
Filter Media	Polypropylene			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2000 cm ²	4000 cm ²	8000 cm ²	12000 cm ²
Operational				
Max. Operating Temperature	80 °C @ ≤ 30 psi (2 Kg/cm ²)			
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C			



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure DP	CPDP	5"	53	1 µm	05	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	1.5 µm	14	7P without fin	A1	Viton	SV				
		20"	55	3 µm	16	28 with fin	C0	EPDM	SE				
		30"	56	5 µm	07	BEO	B0	PTFE	ST*				
				10 µm	08	'O'	D0	FEP Encapsulated Viton	FV				
				20 µm	11								
				30 µm	19								
				40 µm	20								

Example:

CPDP	56	14	A0	SS	1	01
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*PTFE (ST) gasket seals are available with Adapter Code B0 only

For Adapters and Elastomers availability refer Page 83.

Chemical Compatibility

Table below shows the chemical compatibility of various process filtration products with some commonly used solvents. All products were exposed to specified chemicals for 72 hours at 25 °C. Chemical compatibility data with specific reagents is available on request.

Reagents	AseptiSure Cartridge Filters					ClariSure Cartridge Filters								'O' Rings/Gasket Seals			
	HS/KS	HSR	WS	NS	TH/TF	GK	GS	GP	PA	PP	PL	DP	Silicone	Viton	EP	FEP Encapsulated Viton	
Solvents																	
Acetone	N	N	G	G	G	N	G	G	G	G	G	G	N	N	G	G	
Acetonitrile	G	G	G	G	G	G	G	G	G	G	G	G	G	N	G	G	
Benzene	G	G	N	G	G	F	F	F	F	F	F	F	N	G	N	G	
Benzyl Alcohol	N	N	N	G	G	N	G	G	G	G	G	G	G	G	G	G	
Benzyl Alcohol 2%	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	
Diethyl Ether	G	G	G	G	G	N	N	N	N	N	N	N	N	N	N	G	
Dimethylformamide	N	N	G	G	G	N	G	G	G	G	G	G	G	N	N	G	
Ethyl Acetate	G	G	G	G	G	G	G	G	G	G	G	G	N	N	G	G	
Ethylene Glycol	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	
Hexane	F	F	N	F	F	F	F	F	F	F	F	F	N	G	N	G	
Iso Propyl Alcohol	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	
Methanol	G	G	G	G	G	G	G	G	G	G	G	G	G	N	G	G	
Methylene Chloride	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	G	
n-Butanol	G	G	G	G	G	G	G	G	G	G	G	G	N	G	G	G	
Peanut oil	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	G	
Tetrahydrofuran/Water (50:50)	N	N	N	N	G	N	N	N	N	N	N	N	N	N	N	G	
Toluene	G	G	N	G	G	G	G	G	G	G	G	G	N	G	N	G	
Trichloroethylene	N	N	N	N	N	N	N	N	N	N	N	N	N	G	N	G	
Acids																	
Hydrochloric Acid 37%	G	G	G	N	G	G	G	G	G	G	G	G	N	G	N	G	
Hydrofluoric Acid 10%	G	G	NT	F	G	N	N	N	G	G	G	G	N	G	F	G	
Nitric Acid 67%	N	N	N	N	G	N	G	G	G	G	G	G	N	G	N	G	
Nitric Acid 7%	G	G	G	N	G	G	G	G	G	G	G	G	G	G	G	G	
Sulphuric Acid 10%	G	G	G	F	G	G	G	G	G	G	G	G	G	G	G	G	
Bases																	
Ammonium Hydroxide 25%	N	G	N	N	G	N	N	G	G	G	G	G	G	G	G	G	
Sodium Hydroxide 32%	N	G	N	N	G	N	N	G	G	G	G	G	G	G	G	G	
Potassium Hydroxide 32%	N	G	N	N	G	N	N	G	G	G	G	G	G	G	G	G	

G: Good F: Fair N: Not recommended NT : Not Tested

Chemical Compatibility

Table below shows the chemical compatibility of various process filtration products with some commonly used solvents. All products were exposed to specified chemicals for 72 hours at 25 °C. Chemical compatibility data with specific reagents is available on request.

Reagents	AseptiCap Capsule Filters				AseptiVent Capsule Filters	ClariCap Capsule Filters			Membrane Disc Filters	Microglassfiber Pre-filter Discs
	KL/ KS	KO/ KSO	NL/ NS	WS	TF	GK	GS	PP	NN	GF
Solvents										
Acetone	N	N	G	G	G	N	G	G	G	G
Acetonitrile	G	G	G	G	G	G	G	G	G	G
Benzene	G	G	G	N	G	F	F	F	G	G
Benzyl Alcohol	N	N	G	N	G	N	G	G	G	G
Benzyl Alcohol 2%	G	G	G	G	G	G	G	G	G	G
Diethyl Ether	G	G	G	G	G	N	N	N	G	G
Dimethylformamide	N	N	G	G	G	N	G	G	G	G
Ethyl Acetate	G	G	G	G	G	G	G	G	G	G
Ethylene Glycol	G	G	G	G	G	G	G	G	G	G
Hexane	N	N	N	N	N	N	N	N	G	G
Iso Propyl Alcohol	G	G	G	G	G	G	G	G	G	G
Methanol	G	G	G	G	G	G	G	G	G	G
Methylene Chloride	N	N	N	N	N	N	N	N	G	G
n-Butanol	G	G	G	G	G	G	G	G	G	G
Peanut oil	G	G	G	G	G	G	G	G	G	G
Tetrahydrofuran/Water (50:50)	N	N	N	N	G	N	N	N	G	G
Toluene	N	N	N	N	N	N	N	N	G	G
Trichloroethylene	N	N	N	N	N	N	N	N	G	G
Acids										
Hydrochloric Acid 37%	G	G	N	G	G	G	G	G	N	G
Hydrofluoric Acid 10%	G	G	G	NT	G	N	N	G	G	N
Nitric Acid 67%	N	N	N	N	G	N	G	G	N	G
Nitric Acid 7%	G	G	G	G	G	G	G	G	G	G
Sulphuric Acid 10%	G	G	G	G	G	G	G	G	G	G
Bases										
Ammonium Hydroxide 25%	N	G	N	N	G	N	G	G	G	G
Sodium Hydroxide 32%	N	G	N	N	G	N	G	G	G	F
Potassium Hydroxide 32%	N	G	N	N	G	N	G	G	N	G

G: Good F: Fair N: Not recommended NT : Not Tested

End Connection Availability Chart for Capsule Filters

Connections Available			
Inlet/ Outlet	25mm	37mm	50mm
¼" SHB I/O	X	√	√
¾" Sanitary Flange I/O	X	X	Outlet Only
Female Luer Lock	Inlet Only	X	X
Male Luer Slip	Outlet Only	X	X
1/8" Hose Barb I/O	√	X	X

	Small Capsule Filters			
End Connections	1"	2"	5"	8"
½" Hose Barb	√	√	√	√
Single Step ½" Hose Barb	X	√	√	√
¼" Stepped Hose Barb	√	√	√	√
1½" Sanitary Flange	√	√	√	√
¾" Sanitary Flange	√	√	√	√
½" MNPT	X	√	√	√
¼" MNPT	√	√	√	√
Quick Connector	√	√	√	√
Female Luer Lock	√	√	√	√
Male Luer Slip	Outlet Only	X	X	X
¾" Hose Barb	√	√	Outlet Only	X
⅝" Hose Barb	X	√	√	√

Bell is available with ¼" SHB outlet in 1" Capsule Filters only

Bell is available with ½" Hose Barb outlet in 1", 2", 5" and 8" Capsule Filters

	Large Capsule Filters						
	Inline				T-line		
End Connections	5"	10"	20"	30"	10"	20"	30"
Single Step ½" Hose Barb	√	√	√	√	X	X	X
1½" Sanitary Flange	√	√	√	√	√	√	√
¾" Sanitary Flange	√	√	X	X	X	X	X
⅝" Hose Barb	√	√	√	√	X	X	X
1" Hose Barb	X	√	√	√	X	X	X

Dimensions: Capsule Filters

	Inline Capsule Filters		
Inlet/ Outlet	25mm	37mm	50mm
¼" - ⅜" Stepped Hose Barb I/O	-	64 mm	79 mm
¼" Single Step Hose Barb I/O	38 mm	-	-
¾" Sanitary Flange I/O	-	-	51 mm
Female Luer Lock Inlet/ Male Luer Slip Outlet	23 mm	-	-
1/8" Hose Barb I/O	36 mm	-	-
Operational Radius	15 mm	23 mm	28 mm

	Small Capsule Filters			
End Connections	1"	2"	5"	8"
¼" SHB I/O	94 mm	122 mm	172 mm	223 mm
¾" Sanitary Flange Inlet I/O	91 mm	103 mm	155 mm	205 mm
Quick Connector	100 mm	111 mm	163 mm	212 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	-	115 mm	165 mm	217 mm
1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	-	111 mm	162 mm	212 mm
⅜" Hose Barb I/O	-	115 mm	165 mm	217 mm
Operational Radius	30 mm	65 mm	65 mm	65 mm

	Inline Capsule Filters				T-line Capsule Filters		
End Connections	5"	10"	20"	30"	10"	20"	30"
1½" Sanitary Flange I/O	207 mm	326 mm	605 mm	865 mm	338 mm	588 mm	848 mm
¾" Sanitary Flange I/O	212 mm	345 mm	x	x	x	x	x
½" Single Step Hose Barb I/O	217 mm	332 mm	628 mm	888 mm	x	x	x
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	203 mm	332 mm	618 mm	878 mm	x	x	x
⅜" Hose Barb I/O	211 mm	330 mm	618 mm	878 mm	x	x	x
1" Hose Barb I/O	x	405 mm	635 mm	895 mm	x	x	x
Operational Radius	78 mm	78 mm	78 mm	78 mm	78 mm	78 mm	78 mm

Adapter and Elastomers Availability Chart for Cartridge Filters

Mini Cartridge Filters		
Adapters	2.5"	5"
4463	√	√
4463B	√	√
4440	√	√
Seal-K	√	√
Seal-O	X	√
Seal-M	√	√

Mini Cartridge Filters	
Adapters	Elastomer
	Silicone
4463	√
4463B	√
4440	√
Seal-K	X
Seal-O	√
Seal-M	√

Standard Cartridge Filters				
Adapters	5"	10"	20"	30"
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	X	√	√	√
'O'	X	√	√	√

Standard Cartridge Filters				
Adapters	Elastomers			
	Silicone	Viton	EPDM	FEP Encapsulated Viton
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	√	√	√	X
'O'	√	√	√	X

Notes

Quality Policy

Quality is built into **mdi** products and services by not only adhering to well designed quality systems to consistently produce high quality, internationally acceptable products but also by striving to incorporate superior performance parameters into all our products and services and provide our customers with a unique performance advantage in their application. Our quality policy provides a glimpse of our commitment:

mdi strives to provide to its customers products and services of highest standards possible, consistently superior, and more satisfying than what is available anywhere else."

Stride Towards Excellence

At **mdi**, our mission is to constantly strive to achieve excellence in all our endeavors by establishing systems to create excellent products and services to fulfil the needs of our customers. To achieve this we

- ♦ Frequently compare our products with competing brands
- ♦ Simulate tests for functional use
- ♦ Develop easy-to-use innovative products

We are constantly working on improvements and welcome suggestions from our customers.

Guarantee

All **mdi** products are guaranteed and are backed by our

- ♦ Technical expertise and experience of over 35 years
- ♦ Validated **mdi** process' for consistency and repeatability
- ♦ Strict quality control and quality assurance regimen
- ♦ Certificate of Analysis accompanying all shipments

We have an unconditional replacement policy in case of any defects.



Exclusive distributor for process filters
for pharma and bio-pharma applications
in Germany, Austria and Switzerland.

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