mdi
Membrane Technologies

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 300 plus, manufacturing 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.

Existing Facility (100,000 sq. ft.)

New GMP Facility (100,000 sq. ft.)

mdi is a vertically integrated company with inter disciplinary expertise that helps deliver an ever increasing portfolio of innovative products with unique performance advantages.

mdi products are used in highly regulated industries for critical applications such as sterile filtration of pharmaceutical and biopharmaceutical process fluids, sterility testing of aseptic drug products, analytical sample preparation, new drug development, and making reliable immunoassays for testing of diseases at patient bedside.

mdi's modern GMP facilities with large ISO 7 Clean Areas more than meets the required standards. The products are manufactured in ISO 9001:2008 certified facility with the help of trained manpower meeting or exceeding industry standards. Many **mdi** products are recognized as the best available in the world.

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mdi Membrane Technologies

mdi offers customized solutions to enhance process efficiency, productivity, product quality, and consistency in wide ranging 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 Quality Assurance

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 9001:2008 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 testing 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.

mdi Validation Services

As per regulatory requirement, 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 posses (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 asertain 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**

All of these studies are executed as per pre-approved test methodologies establishing 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 Customer Support

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, performing throughput studies to optimize filter train and filter sizing.

Installation and Operation Qualification

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

Regulatory Assistance

mdi provides complete regulatory assistance to it's 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 are working with a very wide variety of process streams/fluids under different process conditions. They are continuously faced 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 .

This would require the following important questions 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/sanitizations 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 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 desired minimum 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 in the contamination profile of the fluid to be filtered. The nature and quantum of contaminants defines their interaction with the filter, which in term defines the throughput one can achieve from a given filter 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 to achieve desired/optimum throughputs.

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 support@mdimembrane.com

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

Researchers in NDDS and formulation development are concerned about filter fluid interaction impacting the stability, purity, strength etc. of the drug product, and 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 cm^2 to 18000 cm^2 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 cm^2

50 mm, 20 cm^2

1", 250 cm^2

2", 500 cm^2

5", 1000 cm^2

8", 2000 cm^2

10", 6000 cm^2

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 extreme use and sterilization conditions.

Customized Connectivity

mdi Capsule filters can also be customized to offer different inlet-outlet combinations to meet the unique connectivity needs in process assemblies where, for example, stainless steel components with sanitary flange connections are sometimes required to be connected to single use disposable systems through quick-connectors or hose barb connections.

¾" Sanitary Flange

1½" Sanitary Flange

½" HB

Single Stepped Hose Barb

¼" SHB

Quick Connector

1½" Sanitary Flange to ½" Barb Hose

1½" Sanitary Flange to ¾" Sanitary Flange

***AseptiCap* with HighSecurity ½" 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	*AseptiCap KL-*	*AseptiCap KS -*
Autoclavable Capsule Filters	*AseptiCap KL* / *AseptiCap KO*	*AseptiCap KS*
Steam Sterilizable Cartridge Filters	*AseptiSure KR*	*AseptiSure KS*
High Temperature Resistant Steam Sterilizable Cartridge Filters	–	*AseptiSure HS*

Quality Assurance

These filter devices are manufactured in class 10,000 clean rooms under ISO 9001 : 2008 certified quality management systems and are validated to meet compendia and regulatory requirements.

Applications

Sterile Filtration of:

- Cell culture media
- Cell culture media containing serum
- Media additives
- Final product concentrates
- Bioburden reduction from cell harvest supernatants
- Filtration of equilibrating, washing and elution buffers for chromatography steps
- Sterilization of biopharmaceuticals such as vaccines and therapeutic proteins
- Sterilization of buffers
- Sterilization of adjuvants
- Manufacture of high value SVP like Oncology drugs, hormones and therapeutic proteins
- Manufacture of Large Volume Parenterals
- Manufacture of Water for Injection
- Manufacture of Small Volume Parenterals

Assurance	
Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity Tests, In Vitro, USP <87> for cytotoxicity
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 211.72 for fiber release
Extractables with WFI	Passes test as per USP
Oxidizable Substances	Within limits as specified in USP
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	Gamma Sterilizable Capsule Filters	Steam Sterilizable	
			Capsule Filters	Cartridge Filters
Biopharmaceuticals				
Media preparation	- Mycoplasma removal (in case of Mammalian Cell Culture)	***AseptiCap KS*** - 0.1 µm PES Membrane Capsule Filter	***AseptiCap KS*** 0.1 µm PES Membrane Capsule Filter	***AseptSure*** **KS** 0.1 µm PES Membrane Cartridge Filter	***AseptSure*** **HS** 0.1 µm High Temperature PES Membrane Cartridge Filter
	- Microbial retention (in case of Microbial Fermentation)	***AseptiCap KS*** - 0.2 µm PES Membrane Capsule Filter	***AseptiCap KS*** 0.2 µm PES Membrane Capsule Filter	***AseptSure*** **KS** 0.2 µm PES Membrane Cartridge Filter	***AseptSure*** **HS** 0.2 µm High Temperature PES Membrane Cartridge Filter
Sterile filtration of growth regulators	- Absolute retention - Low protein binding	***AseptiCap KS*** - 0.2 µm PES Membrane Capsule Filter	***AseptiCap KS*** 0.2 µm PES Membrane Capsule Filter	***AseptSure*** **KS** 0.2 µm PES Membrane Cartridge Filter	***AseptSure*** **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 KO*** 0.2 µm PES Membrane Capsule Filter	***AseptiSure*** **KR** 0.2 µm PES Membrane Cartridge Filter	–
Cell Harvesting	- Bioburden reduction	***AseptiCap KS*** - 0.2 µm or 0.45 µm PES Membrane Capsule Filter	***AseptiCap*** **KS** 0.2 µm or 0.45 µm PES Membrane Capsule Filter	***AseptSure*** **KS** 0.2 µm or 0.45 µm PES Membrane Cartridge Filter	***AseptSure*** **HS** 0.2 µm or 0.45 µm High Temperature PES Membrane Cartridge Filter
Buffer filtration	- Bioburden reduction - Absolute retention	***AseptiCap KS*** - 0.2 µm or 0.45 µm PES Membrane Capsule Filter	***AseptiCap*** **KS** 0.2 µm or 0.45 µm PES Membrane Capsule Filter	***AseptSure*** **KS** 0.2 µm or 0.45 µm PES Membrane Cartridge Filter	***AseptSure*** **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*** - 0.2 µm PES Membrane Capsule Filter	***AseptiCap*** **KS** 0.2 µm PES Membrane Capsule Filter	–	–
Pharmaceuticals					
Large Volume Parenterals	- Absolute retention - High throughputs	–	–	***AseptSure*** **KS** 0.2 µm PES Membrane Cartridge Filter	***AseptSure*** **HS** 0.2 µm High Temperature PES Membrane Cartridge Filter
Small Volume Parenterals	- Absolute retention - Low Protein Binding - Wide Chemical Compatiblity	***AseptiCap KS*** - 0.2 µm PES Membrane Capsule Filter	***AseptiCap*** **KS** 0.2 µm PES Membrane Capsule Filter	***AseptSure*** **KS** 0.2 µm PES Membrane Cartridge Filter	***AseptSure*** **HS** 0.2 µm High Temperature PES Membrane Cartridge Filter
WFI	- Absolute retention	***AseptiCap KS*** - 0.2 µm PES Membrane Capsule Filter	***AseptiCap*** **KS** 0.2 µm PES Membrane Capsule Filter	***AseptSure*** **KS** 0.2 µm PES Membrane Cartridge Filter	***AseptSure*** **HS** 0.2 µm High Temperature PES Membrane Cartridge Filter

AseptiCap KL/KS- 25 mm and 50 mm

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

Specially designed filters for process development and formulation development labs with identical materials of construction for easy scale up to larger capsule filters 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 -*

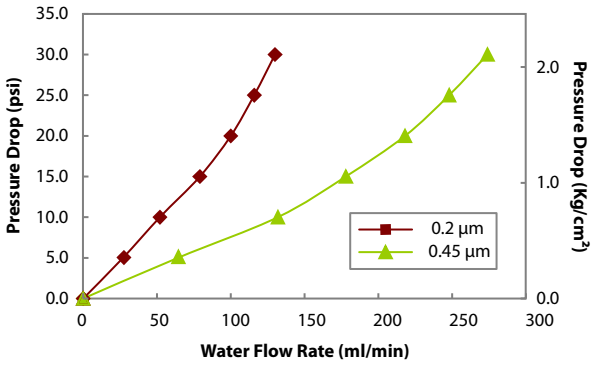
Autoclavable: *AseptiCap KL/KS*

Specifications

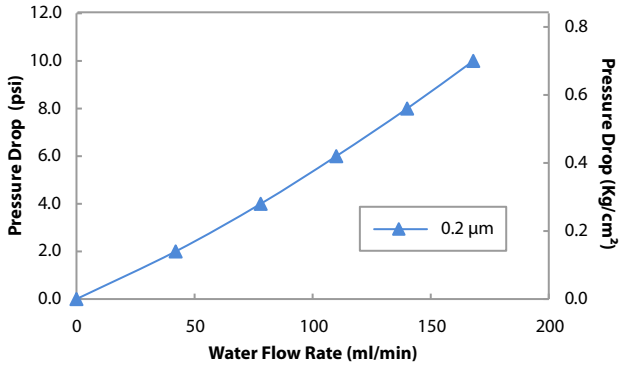
Construction			
Final Filter Pore Size	0.1 µm	0.2 µm	0.45 µm
Prefilter Pore Size (in case of *AseptiCap KS)*	0.45 µm	0.8 µm, 0.65 µm, 0.45 µm	0.8 µm, 0.65 µm
Membrane	Hydrophilic PES		
Support Layers	Polyester		
Body and Core	Polypropylene		
Integrity Testing/Retention			
Bubble Point	≥ 31 psi (2.18 Kg/cm^2) with 50% IPA/Water Solution	≥ 50 psi (3.51 Kg/cm^2) with Water	≥ 30 psi (2.11 Kg/cm^2) with Water
Microbial Retention	LRV >7 for Acholeplasma laidlawii (ATCC 23206) per cm^2	LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm^2	LRV >7 for Serratia marcescens (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	***AseptiCap KL/KS -*** Gamma Irradiatiable up to 50 kGy		
Sterilization – By Gas	***AseptiCap KL/KS***: Sterilizable by Ethylene Oxide		
Sterilization – By Autoclave	***AseptiCap KL/KS -*** : Autoclavable at 121°C for 30 minutes, 1 cycle after gamma irradiation ***AseptiCap KL/KS***: Autoclavable at 121°C for 30 minutes, 25 cycles **These cannot be inline 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 - 25 mm



AseptiCap KL - 50 mm



Ordering Information

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

Type	
	Code
AseptiCap KL	IKLX
AseptiCap KS (0.45 µm Upstream)	IKSX
AseptiCap KS (0.65 µm Upstream)	IKS3
AseptiCap KS (0.8 µm Upstream)	IKS5

Size	
Dia	Code
25 mm	06

Pore Size	
	Code
0.1 µm*	36
0.2 µm	01
0.45 µm	02

Inlet/Outlet	
	Code
Female Luer Lock	M
Male Luer Slip	N

Radiation Sterilizable	
	Code
Yes	R
No	X

X

Sterility	
	Code
Non Sterile	1
EO Sterile	2
Gamma Sterile	3

Pack Size	
	Code
100	04

Example

IKLX	06	01	MN	R	X	1	04

AseptiCap KL/KS and *AseptiCap KL/KS* - , 50 mm

Type	
	Code
AseptiCap KL	VKLX
AseptiCap KS (0.45 µm Upstream)	VKSX
AseptiCap KS (0.65 µm Upstream)	VKS3
AseptiCap KS (0.8 µm Upstream)	VKS5

Size	
Dia	Code
50 mm	10

Pore Size	
	Code
0.1 µm*	36
0.2 µm	01
0.45 µm	02

Inlet/Outlet	
	Code
¼" SHB	B
¾" Sanitary Flange	S

Radiation Sterilizable	
	Code
Yes	R
No	X

Bell	
	Code
Yes	B
No	X

Sterility	
	Code
Non Sterile	1
EO Sterile	2
Gamma Sterile	3

Pack Size	
	Code
12	08

Example

VKSX	10	36	SS	X	X	1	08

*** Note: 0.1 µm is available in *AseptiCap KS and AseptiCap KS* - only with 0.45 µm upstream**

For End Connection availability and dimensions with different sizes refer Page no. 59.

Note: Gamma Sterile filters can not be gamma irradiated again

Example for Non Sterile: VKSX1036SSRX104 **Example for gamma Sterile:** VKSX1036SSXX304

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

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

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* -

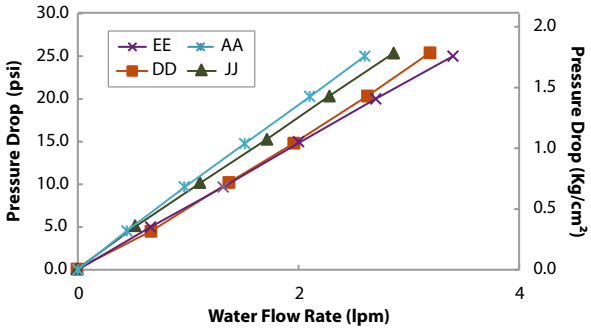
Autoclavable: *AseptiCap KL/KS*

Specifications

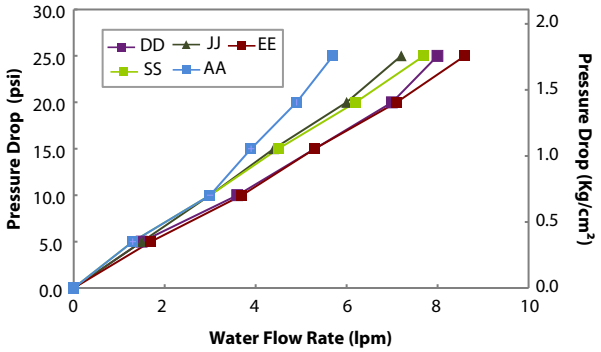
Construction					
Final Filter Pore Size		0.1 µm	0.2 µm		0.45 µm
Prefilter Pore Size (in case of *AseptiCap KS)*		0.45 µm	0.8 µm, 0.65 µm, 0.45 µm		0.8 µm, 0.65 µm
Membrane		Hydrophilic PES			
Support Layers		Polyester			
Body and Core		Polypropylene			
Integrity Testing/Retention					
Bubble Point		≥ 31 psi (2.18 Kg/cm²) with 50% IPA/Water Solution	≥ 50 psi (3.51 Kg/cm²) with Water		≥ 30 psi (2.11 Kg/cm²) with Water
Microbial Retention		LRV >7 for Acholeplasma laidlawii (ATCC 23206) per cm²	LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm²		LRV >7 for Serratia marcescens (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 double platinum cured Silicone 'O' rings for 2", 5" and 8"			
Operational					
Max. Operating Temperature	0.1 µm	80 °C @ ≤ 15 psi (1.0 Kg/cm²)			
	0.2 µm	80 °C @ ≤ 30 psi (2 Kg/cm²)			
Max. Differential Pressure		60 psi (4 Kg/cm²) @ 30 °C			
Sterilization	By Irradiation	***AseptiCap KL/KS* -** Gamma Irradiatiable up to 50 kGy			
	By Gas	***AseptiCap KL/KS***: Sterilizable by Ethylene Oxide			
	By Autoclave	***AseptiCap KL/KS* -** : Autoclavable at 121°C for 30 minutes, 1 cycle after gamma irradiation ***AseptiCap KL/KS***: Autoclavable at 121°C for 30 minutes, 25 cycles **These cannot be inline 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

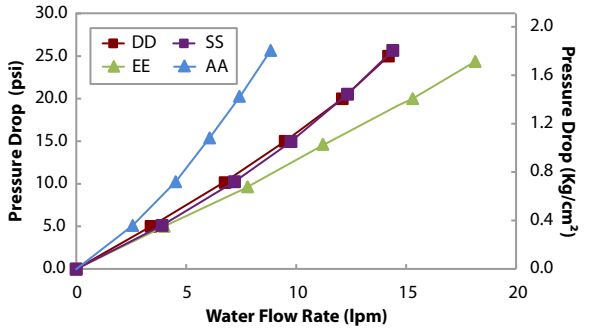
0.2 µm *AseptiCap KS* - , 1″ Capsule Filters



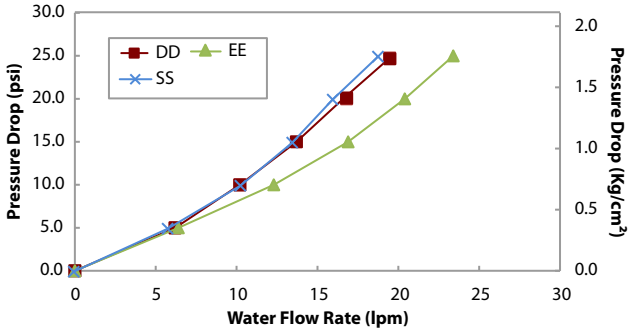
0.2 µm *AseptiCap KS* - , 2″ Capsule Filters



0.2 µm *AseptiCap KS* - , 5″Capsule Filters



0.2 µm *AseptiCap KS* - , 8″Capsule Filters



End Connection Type:

A: ¼″ Stepped Hose Barb **D:** ½″Hose Barb **E:** 1½″ Sanitary Flange **J:** Quick Connector **S:** ¾″ Sanitary Flange

Ordering Information

AseptiCap KL/KS and *AseptiCap KL/KS* -

Type	Code
AseptiCap KL (Single Layer)	DKLX
AseptiCap KS (0.45 µm Upstream)	DKSX
AseptiCap KS (0.65 µm Upstream)	DKS3
AseptiCap KS (0.8 µm Upstream)	DKS5

Size	Code
1″	51
2″	52
5″	53
8″	57

Pore Size	Code
0.1 µm*	36
0.2 µm	01
0.45 µm	02

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

Radiation Sterilizable	Code
Yes	R
No	X

Bell	Code
Yes	B
No Bell	X

Sterility	Code
Non Sterile	1
EO Sterile	2
Gamma Sterile	3

Pack Size	Code
1	01

Example:

DKSX	57	36	DD	R	X	1	01

*** Note: 0.1 µm is available in *AseptiCap KS and AseptiCap KS* - only with 0.45 µm upstream**

For End Connection, bell availability and dimensions with different sizes refer Page no. 59.

Note: Gamma Sterile filters can not be gamma irradiated again

Example for Non Sterile: DKSX5136DDRX104 **Example for gamma Sterile:** DKSX5136DDXX304

AseptiCap KS- 10", 20", 30"

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

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* -

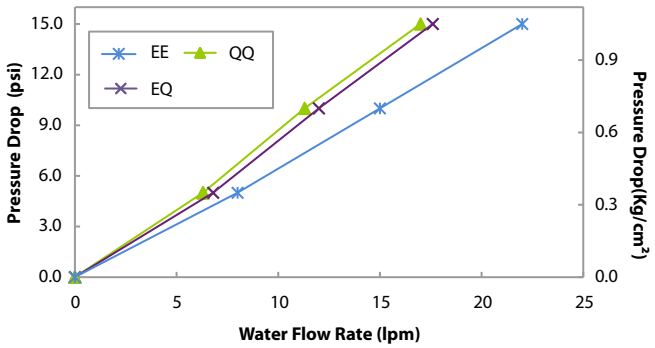
Autoclalvable: *AseptiCap KS*

Specifications

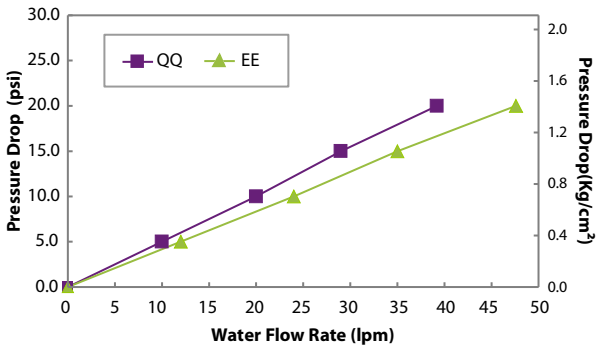
Construction				
Final Filter Pore Size		0.1 µm	0.2 µm	0.45 µm
Prefilter Pore Size		0.45 µm	0.8 µm, 0.65 µm, 0.45 µm	0.8 µm, 0.65 µm
Membrane		Hydrophilic PES		
Support Layers		Polyester		
Body and Core		Polypropylene		
Integrity Testing/Retention				
Bubble Point		≥ 31 psi (2.18 Kg/cm^2) with 50% IPA/Water Solution	≥ 50 psi (3.51 Kg/cm^2) with Water	≥ 30 psi (2.11 Kg/cm^2) with Water
Max. Air Diffusion Flows for 10" Capsule Filters		≤ 29 ml/min @ 50 psi (3.51 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 Acholeplasma laidlawii (ATCC 23206) per cm^2	LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm^2	LRV >7 for Serratia marcescens (ATCC 14756) per cm^2
Size				
Size		10"	20"	30"
Effective Filtration Area (Nominal)		6000 cm^2	12000 cm^2	18000 cm^2
Vent and Drain		1/4" Hose Barb with double platinum cured Silicone 'O' rings		
Operational				
Max. Operating Temperature	0.1 µm	80 °C @ ≤ 15 psi (1.0 Kg/cm^2)		
	0.2 µm	80 °C @ ≤ 30 psi (2 Kg/cm^2)		
Max. Differential Pressure		60 psi (4 Kg/cm^2) @ 30 °C		
Sterilization	By Irradiation	***AseptiCap KL/KS -*** Gamma Irradiatiable up to 50 kGy		
	By Gas	***AseptiCap KL/KS***: Sterilizable by Ethylene Oxide		
	By Autoclave	***AseptiCap KL/KS -*** : Autoclavable at 121°C for 30 minutes, 1 cycle after gamma irradiation ***AseptiCap KL/KS***: Autoclavable at 121°C for 30 minutes, 25 cycles **These cannot be inline 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

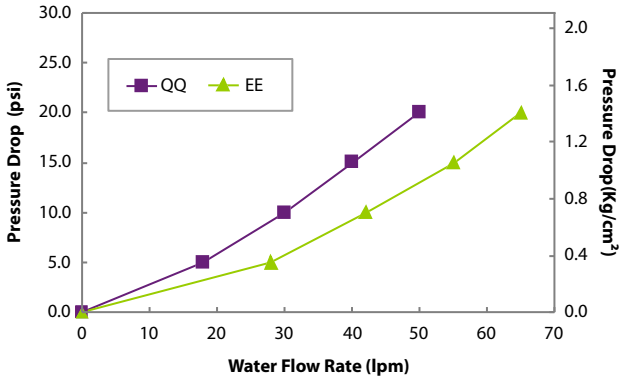
0.1 µm *AseptiCap KS* - , 10" Large Capsule Filters



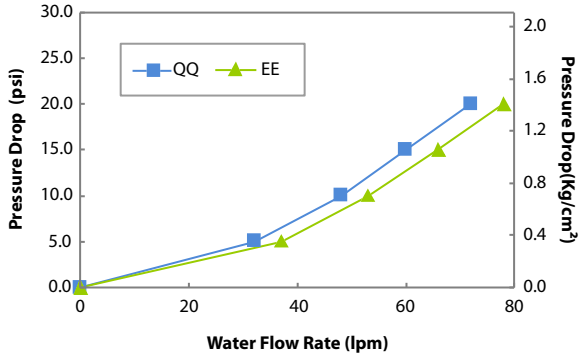
0.2 µm *AseptiCap KS* - , 10" Large Capsule Filters



0.2 µm *AseptiCap KS* - , 20" Large Capsule Filters



0.2 µm *AseptiCapKS* - , 30" Large Capsule Filters



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

Ordering Information

AseptiCap KS and *AseptiCap KS-*

Type	
	Code
AseptiCap KS (0.45 µm Upstream)	LKSX
AseptiCap KS (0.65 µm Upstream)	LKS3
AseptiCap KS (0.8 µm Upstream)	LKS5

Size	
	Code
10"	54
20"	55
30"	56

Pore Size	
	Code
0.1 µm*	36
0.2 µm	01
0.45 µm	02

Inlet/Outlet	
	Code
1½" Sanitary Flange	E
Single Step ½" Hose Barb	Q

Radiation Sterilizable	
	Code
Yes	R
No	X

Inline / T-line	
	Code
Inline	X
T-line	T

Sterility	
	Code
Non Sterile	1
EO Sterile	2
Gamma Sterile	3

Pack Size	
	Code
1	01

Example:

LKSX	54	02	EE	R	T	1	01

*** Note: 0.1 µm is available in *AseptiCap KS and AseptiCap KS* - only with 0.45 µm upstream**

For End Connection availability and dimensions with different sizes refer Page no. 59.

Note: Gamma Sterile filters can not be gamma irradiated again

Example for Non Sterile: LKSX5402EERX104 **Example for gamma Sterile:** LKSX5402EEXX304

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 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

Construction				
Final Filter Pore Size	0.2 µm		0.45 µm	
Membrane	Hydrophilic PES			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Integrity Testing/Retention				
Bubble Point	≥ 50 psi (3.51 Kg/cm^2) with Water		≥ 30 psi (2.11 Kg/cm^2) with Water	
Microbial Retention	LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm^2		LRV >7 for Serratia marcescens (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	1/4″ Hose Barb with double Silicone 'O' rings			
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			
Sterilization – By Autoclave	Autoclavable at 121 °C for 30 minutes, 25 cycles. Can not be in-line steam sterilized			
Typical Water Flow Rates (0.2 µm, 8″)	7.5 lpm @ 0.70 Kg/cm^2 @ 27 °C			
Shelf Life	3 years after Ethylene Oxide sterilization			
pH Compatibility	Compatible with pH range of 1-14			

Ordering Information

Type	
	Code
AseptiCap KO	DKLO

Size	
	Code
1″	51
2″	52
5″	53
8″	57

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

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

X	X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
1	01

Example:

DKLO	57	01	DD	X	X	1	01

For End Connection availability and dimensions with different sizes refer Page no. 59.

AseptiSure HS

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

AseptiSure HS high temperature resistant, serial filtration Polyethersulfone cartridge filters designed to withstand high pressure differential up to 0.3 Kg/cm^2 (5 psi) at high steam sterilization temperatures of up to 135 °C.

Specifications

Construction				
Final Filter Pore Size	0.1 µm	0.2 µm		0.45 µm
Prefilter Pore Size	0.45 µm	0.8 µm, 0.65 µm, 0.45 µm		0.8 µm, 0.65 µm
Membrane	Hydrophilic PES			
Support Layers	Polyester			
Body and Core	Polypropylene			
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm^2) with 50% IPA/Water Solution	≥ 50 psi (3.51 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 (3.51 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 Acholeplasma laidlawii (ATCC 23206) per cm^2	LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm^2		LRV >7 for 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 @ ≤ 30psi (2 Kg/cm^2)			
Max. Differential Pressure	50psi (3.5 Kg/cm^2) @ 25 °C			
Reverse Pressure	≤ 10 psi (0.7 Kg/cm^2) @ 25 °C			
Sterilization	Inline steam sterilizable upto 135 °C for 30 minutes at a maximum differential pressure of 5 psi (0.3 Kg/cm^2), 25 cycles			
Typical Water Flow Rates (10″ Cartridge filters)	15 lpm @ 0.70 Kg/cm^2 @ 27 °C	24 lpm @ 0.70 Kg/cm^2 @ 27 °C		32 lpm @ 0.70 Kg/cm^2 @ 27 °C

Ordering Information

Type	
	Code
AseptiSure HS (0.45 µm Upstream)	CPHX
AseptiSure HS (0.65 µm Upstream)	CPH3
AseptiSure HS (0.8 µm Upstream)	CPH5

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

Pore Size	
	Code
0.1 µm	36
0.2 µm	01
0.45 µm	02

Adapter	
	Code
7P	A0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPHX	53	01	E0	SS	1	01

***FV is available in Adapter Code A0 (7P) only**

AseptiSure KS

AseptiSure KS are 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 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

Construction				
Final Filter Pore Size	0.1 µm	0.2 µm	0.45 µm	
Prefilter Pore Size	0.45 µm	0.8 µm, 0.65 µm, 0.45 µm	0.8 µm, 0.65 µm	
Membrane	Hydrophilic PES			
Support Layers	Polyester			
Body and Core	Polypropylene			
Integrity Testing/Retention				
Bubble Point	≥ 31 psi (2.18 Kg/cm^2) with 50% IPA/Water Solution	≥ 50 psi (3.51 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 (3.51 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 Acholeplasma laidlawii (ATCC 23206) per cm^2	LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm^2	LRV >7 for 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 for 30 minutes, 25 cycles			
Typical Water Flow Rates (10″ Cartridge filters)	15 lpm @ 0.70 Kg/cm^2 @ 27 °C	24 lpm @ 0.70 Kg/cm^2 @ 27 °C	32 lpm @ 0.70 Kg/cm^2 @ 27 °C	

Ordering Information

Type	
	Code
AseptiSure KS (0.45 µm Upstream)	CPKX
AseptiSure KS (0.65 µm Upstream)	CPK3
AseptiSure KS (0.8 µm Upstream)	CPK5

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

Pore Size	
	Code
0.1 µm	36
0.2 µm	01
0.45 µm	02

Adapter	
	Code
7P	A0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPKX	53	01	E0	SS	1	01

***FV is available in Adapter Code A0 (7P) only**

AseptiSure KR

AseptiSure KR cartridge 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 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

Construction				
Pore Size	0.2 µm		0.45 µm	
Membrane	Hydrophilic PES			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Integrity Testing/Retention				
Bubble Point (with Water)	≥ 50 psi (3.51 Kg/cm²)		≥ 30 psi (2.11 Kg/cm²)	
Air Diffusion Flow (10″ Cartridge Filter)	≤ 40 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 Brevundimonas diminuta (ATCC 19146) per cm²		LRV >7 for 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 @ ≤ 2 Kg/cm² (30 psi)			
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 121 ° C for 30 minutes, 25 cycles			
Typical Water Flow Rates (10″ Cartridge filters)	24 lpm @ 0.70 Kg/cm² @ 27 °C		32 lpm @ 0.70 Kg/cm² @ 27 °C	

Ordering Information

Type	
	Code
AseptiSure KR	CPKR

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

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Adapter	
	Code
7P	A0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPKR	53	01	E0	SS	1	01

***FV is available in Adapter Code A0 (7P) only**

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 filter devices are available as:

Filter Type	Single Layer	Multiple Layer
Capsule Filters	*AseptiCap NL*	*AseptiCap NS*
Cartridge Filters	–	*AseptiSure NS*
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 of pharmaceutical, aqueous and non aqueous solutions

Quality Assurance

These filter devices are manufactured in class 10,000 clean rooms under ISO 9001 : 2008 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 : 1995
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 211.72 for fiber release
Extractables with WFI	Passes test as per USP
Oxidizable Substances	Within limits as specified in USP
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	- Absolute retention - Wide chemical compatibility	***AseptiCap NL/NS*** 0.2 µm Nylon- 66 Membrane Capsule Filter	***AseptSure NS*** 0.2 µm Nylon- 66 Membrane Cartridge Filter	0.2 µm Nylon- 66 Membrane Disc Filters **Type- NN**
Sterilization of disinfectants in pharmaceutical labs and process areas	- Absolute retention - Wide chemical compatibility	***AseptiCap NL/NS*** 0.2 µm Nylon- 66 Membrane Capsule Filter	***AseptSure NS*** 0.2 µm Nylon-66 Membrane Cartridge Filter	0.2 µm Nylon- 66 Membrane Disc Filters **Type- NN**
Filtration of hospital disinfectants	- Absolute retention - Wide chemical compatibility	***AseptiCap NL/NS*** 0.2 µm Nylon- 66 Membrane Capsule Filter	***AseptSure NS*** 0.2 µm Nylon- 66 Membrane Cartridge Filter	0.2 µm Nylon- 66 Membrane Disc Filters **Type- NN**
Filtration of rinse water for endoscopes and other hospital equipments	- Absolute retention	***AseptiCap NL/NS*** 0.2 µm Nylon- 66 Membrane Capsule Filter	***AseptSure NS*** 0.2 µm Nylon- 66 Membrane Cartridge Filter	–
Sterilizing filtration of pharmaceutical, aqueous and non aqueous solutions	- Absolute retention - Wide chemical compatibility	***AseptiCap NL/NS*** 0.2 µm Nylon- 66 Membrane Capsule Filter	***AseptSure NS*** 0.2 µm Nylon- 66 Membrane Cartridge Filter	0.2 µm Nylon- 66 Membrane Disc Filters **Type- NN**

AseptiCap NL/NS- 1″, 2″, 5″, 8″

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

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.

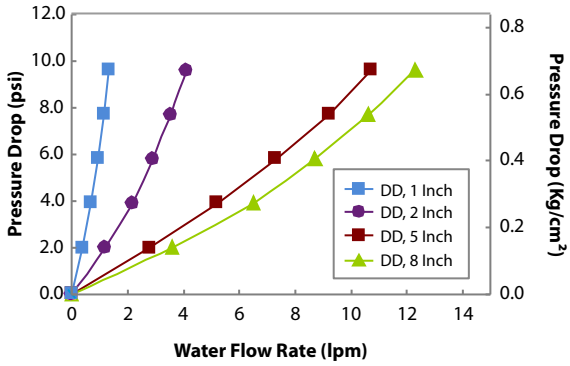
Single Layered: *AseptiCap NL*
Multiple Layered: *AseptiCap NS*

Specifications

Construction					
Final Filter Pore Size		0.2 µm		0.45 µm	
Prefilter Pore Size (In case of *AseptiCap NS)*		0.8 µm, 0.45 µm		0.8 µm	
Membrane		Nylon- 66			
Support Layers		Polyester			
Body and Core		Polypropylene			
Integrity Testing/Retention					
Bubble Point (with 50% IPA)		≥ 17 psi (1.19 Kg/cm²)		≥ 11 psi (0.77 Kg/cm²)	
Microbial Retention (LRV >7 for)		Brevundimonas diminuta (ATCC 19146) per cm²		Serratia marcescens (ATCC 14756) per cm²	
Size					
Size		1″	2″	5″	8″
Effective Filtration Area (Nominal)	*AseptiCap NL*	250 cm²	900 cm²	1800 cm²	2700 cm²
	AseptiCap NS	200 cm²	700 cm²	1400 cm²	2100 cm²
Vent and Drain		1/4″ Hose Barb with double Silicone 'O' rings			
Operational					
Max. Operating Temperature		80 °C @ ≤ 2 Kg/cm² (30 psi)			
Max. Differential Pressure		4 Kg/cm² (60 psi) @ 30 °C			
Sterilization	By Gas	Sterilizable by Ethylene Oxide			
	By Autoclave	Autoclavable at 121 °C for 30 minutes. Can not be in-line steam sterilized			

Water Flow Rates

0.2 µm *AseptiCap NL* Capsule Filters



End Connection Type

D: ½″Hose Barb

Ordering Information

Type	
	Code
AseptiCap NL	DNLX
AseptiCap NS (0.45 µm Upstream)	DNSX
AseptiCap NS (0.8 µm Upstream)	DNS5

Size	
	Code
1″	51
2″	52
5″	53
8″	57

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

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

X

Bell	
	Code
Yes	B
No Bell	X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
1	01

Example:

DNSX	52	01	DD	X	X	1	01

For End Connection, bell availability and dimensions with different sizes refer Page no. 59.

AseptiCap NS- 10", 20", 30"

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

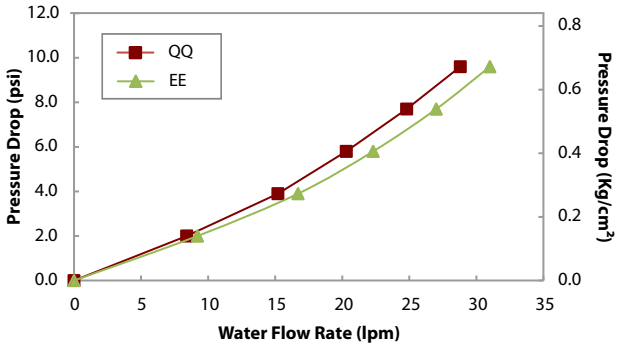
AseptiCap NS- Nylon- 66 membrane large capsule filters are double layered sterilizing grade filters offering absolute retention, wide chemical compatibility, and serial filtration for enhanced throughputs.

Specifications

Construction			
Final Filter Pore Size		0.2 µm	0.45 µm
Prefilter Pore Size		0.8 µm, 0.45 µm	0.8 µm
Membrane		Nylon- 66	
Support Layers		Polyester	
Body and Core		Polypropylene	
Integrity Testing/Retention			
Air Diffusion Flow for 10" Capsule Filters (with 50% IPA)		< 25 ml/min @ 16 psi (1.12 Kg/cm^2)	< 25 ml/min @ 10 psi (0.7 Kg/cm^2)
Microbial Retention (LRV >7 for)		Brevundimonas diminuta (ATCC 19146) per cm^2	Serratia marcescens (ATCC 14756) per cm^2
Size			
Size		10"	20" 30"
Effective Filtration Area (Nominal)		6000 cm^2	12000 cm^2 18000 cm^2
Vent and Drain		1/4" Hose Barb with double Silicone 'O' rings	
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 121 °C for 30 minutes. Can not be in-line steam sterilized	

Water Flow Rates

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	
	Code
AseptiCap NS (0.45 µm Upstream)	LNSX
AseptiCap NS (0.8 µm Upstream)	LNS5

Size	
	Code
10"	54
20"	55
30"	56

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Inlet/Outlet	
	Code
1½" Sanitary Flange	E
Single Step ½" Hose Barb	Q

X

Inline / T-line	
	Code
Inline	X
T-line	T

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
1	01

Example:

LNSX	54	01	QQ	X	T	1	01

For End Connection availability and dimensions with different sizes refer Page no. 59.

AseptiSure NS

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

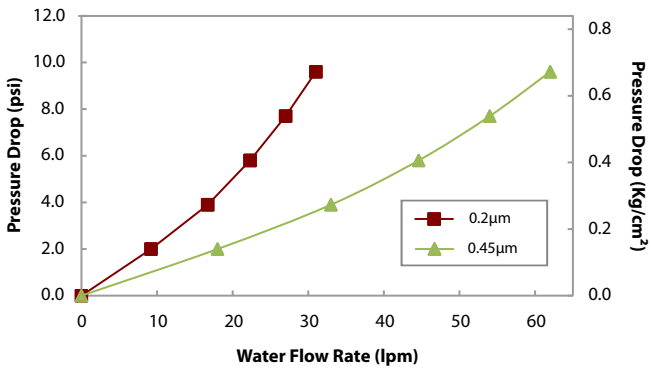
AseptiSure NS- Nylon- 66 membrane cartridge filters are sterilizing grade filters offering absolute retention and wide chemical compatibility. These filters offer serial filtration for enhanced throughput. The upstream layer is of larger pore size to protect the downstream final filtration layer.

Specifications

Construction				
Final Filter Pore Size	0.2 µm		0.45 µm	
Prefilter Pore Size	0.8 µm, 0.45 µm		0.8 µm	
Membrane	Nylon- 66			
Support Layers	Polyester			
Body and Core	Polypropylene			
Integrity Testing/Retention				
Air Diffusion Flow (with 50% IPA Wetted) (10″ Cartridge Filter)	< 25 ml/min @ 16 psi (1.12 Kg/cm²)		<25 ml/min @ 10 psi (0.7 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			

Water Flow Rates

AseptiSure NS, 10″ Cartridge Filters



Ordering Information

Type	
	Code
AseptiSure NS (0.45 µm Upstream)	CPNX
AseptiSure NS (0.8 µm Upstream)	CPN5

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

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Adapter	
	Code
7P	A0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPNX	54	01	A0	SS	1	01

***FV is available in Adapter Code A0 (7P) only**

Nylon-66 Membrane Disc Filters - Type NN

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

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

Specifications

Construction					
Pore Size		0.2 µm, 0.45 µm, 0.8 µm, 1.2 µm			
Membrane		Nylon- 66 polymer			
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 Brevundimonas diminuta as per ASTM F 838-05			
	0.45 µm	LRV> 7 for Serratia marcescens 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	
	Code
NN	NNXX

Size	
	Code
90 mm	14
142 mm	16
293 mm	19

Pore Size	
	Code
0.2 µm	01
0.45 µm	02
0.8 µm	03
1.2 µm	10

XX	XX

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
50	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 -* are hydrophobic PVDF membrane single use capsule filters with a wide range of end connections and different sizes for linear scalability for use with disposable single use assemblies for biopharmaceutical processes.

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

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.

Filter Type	Single Use	Multiple Use
Gamma Sterilizable Capsule Filters	*AseptiVent VF -*	–
Autoclavable Capsule Filters	–	*AseptiVent TF*
Steam Sterilizable Cartridge Filters	–	*AseptiSure TF*
High Temperature Resistant Steam Sterilizable Cartridge Filters	–	*AseptiSure TH*

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

Quality Assurance

These filter devices are manufactured in class 10,000 clean rooms under ISO 9001 : 2008 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 : 1995
Bacterial Endotoxin	Aqueous extracts exhibit < 0.5 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 211.72 and 210.3 (b)(6) for fiber release
Oxidizable Substances	Within limits as specified in USP
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	- 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*** 0.2 µm PTFE Membrane Cartridge Filter
Sterile air sparging in fermentors and bioreactors	- 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*** 0.2 µm PTFE Membrane Cartridge Filter
Sterile air for cell factories	- 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	- 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	- Absolute retention - High hydrophobicity - High flow rates	–	***AseptiVent TF*** 0.2 µm PTFE Membrane Capsule Filter	***AseptiSure TF*** 0.2 µm PTFE Membrane Cartridge Filter
Venting of sterile collection vessels	- 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*** 0.2 µm PTFE Membrane Cartridge Filter
Nitrogen blanketing in sterile API	- Absolute retention - High flow rates	–	***AseptiVent TF*** 0.2 µm PTFE Membrane Capsule Filter	***AseptiSure TF*** 0.2 µm PTFE Membrane Cartridge Filter
Cleaning sterile surfaces	- Absolute retention - High flow rates	–	***AseptiVent TF*** 0.2 µm PTFE Membrane Capsule Filter	***AseptiSure TF*** 0.2 µm PTFE Membrane Cartridge Filter
Dry powder injectable filling	- Absolute retention - High flow rates	–	***AseptiVent TF*** 0.2 µm PTFE Membrane Capsule Filter	***AseptiSure TF*** 0.2 µm PTFE Membrane Cartridge Filter
WFI tank venting	- Absolute retention - High hydrophobicity - High flow rates	–	–	***AseptiSure TF*** 0.2 µm PTFE Membrane Cartridge Filter
Sterile filtration of API/Solvents	- Absolute retention - High flow rates	–	–	***AseptiSure TF*** 0.2 µm PTFE Membrane Cartridge Filter
Sterile air for dryers and micronizers	- Absolute retention - High flow rates	–	***AseptiVent TF*** 0.2 µm PTFE Membrane Capsule Filter	***AseptiSure TF*** 0.2 µm PTFE Membrane Cartridge Filter

AseptiVent VF - , 25mm, 37mm, 50mm

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

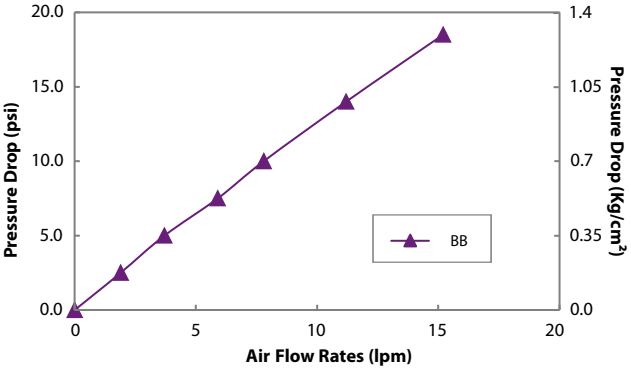
0.2 µm ***AseptiVent VF -γ,*** gamma sterilizable PVDF membrane vent filters are validated for microbial retention with liquid bacterial challenge test as per ASTM F838-05 to provide a high degree of sterility assurance for critical applications such as small bioreactors, sterile tank venting, bottle venting, barrier filter for vacuum pump etc

Specifications

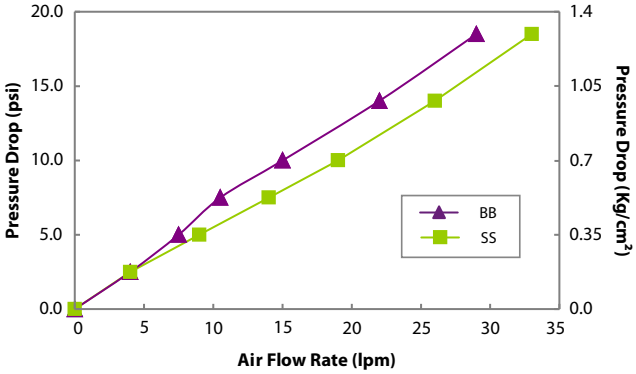
Construction				
Final Filter Pore Size		0.2 µm		
Membrane		Hydrophobic PVDF		
Support Layers		Polyester		
Body and Core		Polypropylene		
Integrity Testing/Retention				
Bubble Point		≥ 18 psi (1.27 Kg/cm^2) with 50% IPA/ Water Solution		
Microbial Retention		LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm^2		
Size				
Size		25 mm	37 mm	50 mm
Effective Filtration Area (Nominal)		5 cm^2	10 cm^2	20 cm^2
Operational				
Max. Operating Temperature		60 °C		
Max. Differential Pressure		1.5 Kg/cm^2 (21 psi) @ 30° C		
Burst Pressure		> 14 Kg/cm^2	> 8 Kg/cm^2	> 8 Kg/cm^2
Sterilization	By Irradiation	Gamma Irradiatiable up to 50 kGy		
	By Gas	Sterilizable by Ethylene Oxide		
	By Autoclave	Autoclavable at 121 °C for 30 minutes, 1 cycle after gamma irradiation. Can not be in-line steam sterilized		
Shelf Life		2 years after gamma sterilization 3 years after Ethylene Oxide sterilization		

Air Flow Rates

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



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



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

Ordering Information

AseptiVent VF - , 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				EO Sterile	2		
											Gamma Sterile	3		

Example:

IVFX	06	01	MN	R	X	1	04

AseptiVent VF - , 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	12	08
		50 mm	10			¾" Sanitary Flange*	S				EO Sterile	2	20	09
											Gamma Sterile	3		

Example:

IVFX	08	01	BB	R	X	1	09

*** Available only in 50 mm**

AseptiVent VF - , 1″, 2″, 5″, 8″

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

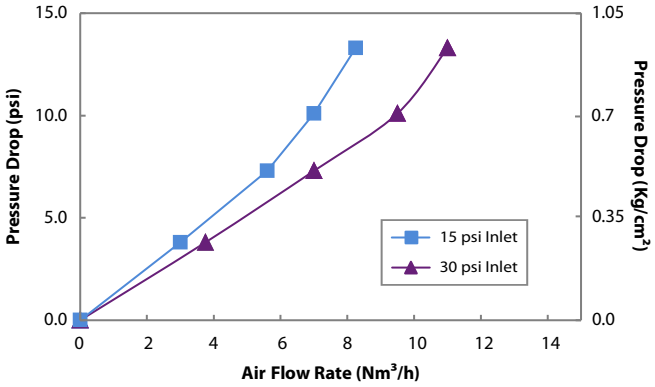
AseptiVent VF -γ PVDF membrane vent filters are validated for microbial retention with liquid bacterial challenge test as per ASTM F838-05 to provide a high degree of sterility assurance for critical applications.

Specifications

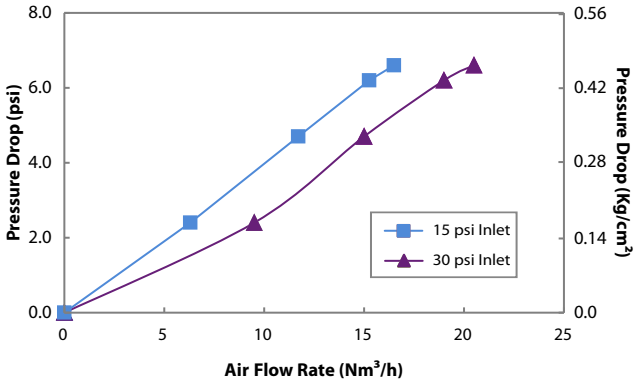
Construction					
Pore Size		0.2 µm			
Membrane		Hydrophobic PVDF			
Support Layers		Polyester			
Body and Core		Polypropylene			
Integrity Testing/Retention					
Bubble Point		≥ 18 psi (1.26 Kg/cm^2) with 50% IPA/Water Solution			
Microbial Retention		LRV >7 for Brevundimonas diminuta (ATCC 19146) per 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		1/4″ Hose Barb with double Silicone 'O' rings for 2″, 5″ and 8″ capsule filters			
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 Irradiatiable up to 50 kGy			
	By Gas	Sterilizable by Ethylene Oxide			
	By Autoclave	Autoclavable at 121°C for 30 minutes, 1 cycle after gamma irradiation. Can not be in-line steam sterilized			
Shelf Life		2 years after gamma sterilization 3 years after Ethylene Oxide sterilization			

Air Flow Rates

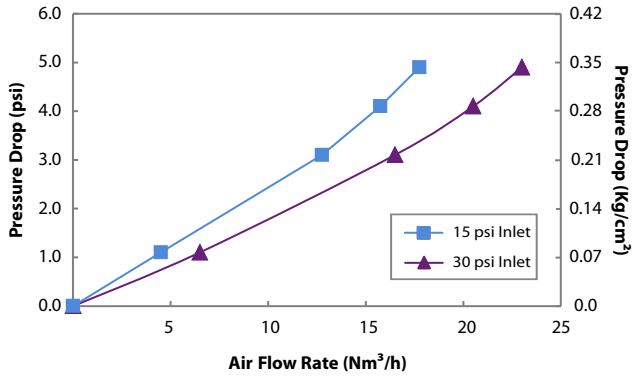
0.2 µm *AseptiVent VF-* , 1″ Capsule Filters, DD



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



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



End Connection Type

D: ½″Hose Barb

Ordering Information

Type	
	Code
AseptiVent VF	DVLX

Size	
	Code
1″	51
2″	52
5″	53
8″	57

Pore Size	
	Code
0.2 µm	01

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

Radiation Sterilizable	
	Code
Yes	R

X

Sterility	
	Code
Non Sterile	1
EO Sterile	2
Gamma Sterile	3

Pack Size	
	Code
1	01

Example:

DVLX	57	01	EE	R	X	1	01

For End Connection availability and dimensions with different sizes refer Page no. 59.

AseptiVent TF- 25 mm, 37 mm, 50 mm

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

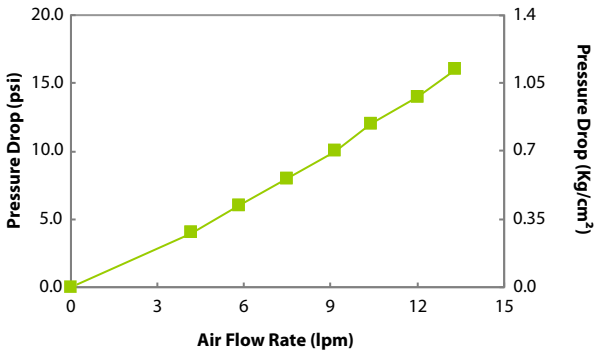
AseptiVent TF Disposable inline PTFE gas filters are convenient pre-fabricated devices used for sterilization of gases and as a bacterial air vent in various pharmaceutical and biopharmaceutical processes.

Specifications

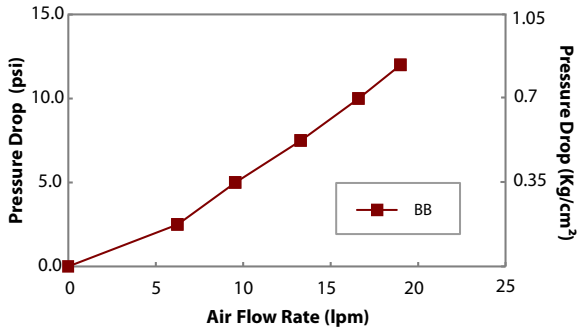
Construction				
Final Filter Pore Size		0.2 µm		0.45 µm
Membrane		Hydrophobic PTFE		
Support Layers		Polypropylene		
Body and Core		Polypropylene		
Integrity Testing/Retention				
Bubble Point		≥ 22 psi (1.54 Kg/cm²) with 70% IPA/Water Solution		≥ 10 psi (0.7 Kg/cm²) with 70% IPA/Water Solution
Microbial Bacterial Retention		LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm²		LRV >7 for Serratia marcescens 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 121 °C for 30 minutes, 30 cycles. Can not be in-line steam sterilized		
Shelf Life		3 years after Ethylene Oxide sterilization		

Air Flow Rates

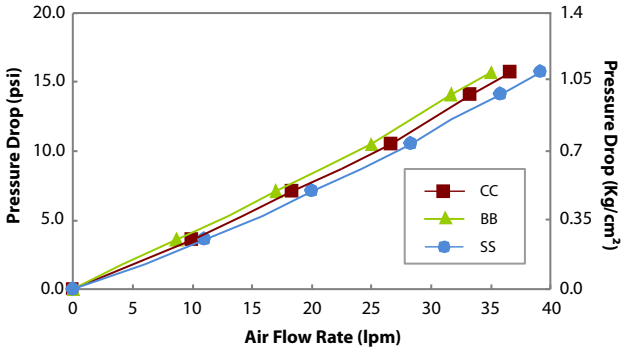
0.2 µm *AseptiVent TF*, 25 mm Capsule Filters



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	ITFX	25 mm	06	0.2 µm	01	Female Luer Lock	M		Non Sterile	1	100	04
				0.45 µm	02	Male Luer Slip	N		EO Sterile	2		

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	ITFX	37 mm	08	0.2 µm	01	*¼" SHB	B		Non Sterile	1	12	08
		50 mm	10	0.45 µm	02	1/8" MNPT	C		EO Sterile	2	20	09
						¾" Sanitary Flange*	S					

Example:

ITFX	08	01	BB	XX	1	09

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

AseptiVent TF- 1″, 2″, 5″, 8″

Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR 211.72
Meets and Exceeds USFDA 21 CFR 177.1520

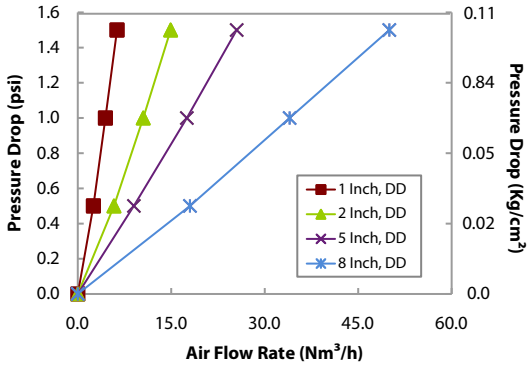
AseptiVent TF capsule filters employ hydrophobic PTFE membrane offering absolute retention and very wide chemical compatibility making these useful for sterile filtration of air/gases as well as aggressive solvents.

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 (with 70% IPA Wetted)	≥ 22 psi (1.55 Kg/cm²)		≥ 10 psi (0.7 Kg/cm²)	
Microbial Retention (LRV >7 for)	Brevundimonas diminuta (ATCC 19146) per cm²		Serratia marcescens (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 double Silicone 'O' rings for 2″, 5″ and 8″ capsule filters			
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			
Sterilization – By Autoclave	Autoclavable at 121 °C for 30 minutes, 50 cycles. Can not be in-line steam sterilized			
Shelf Life	3 years after Ethylene Oxide sterilization			

Air Flow Rates

0.2 µm *AseptiVent TF* Capsule Filters



End Connection Type

D: ½″ Hose Barb

Ordering Information

Type	
	Code
AseptiVent TF	DTLX

Size	
	Code
1″	51
2″	52
5″	53
8″	57

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

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

X

X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
1	01

Example:

DTLX	53	01	DD	X	X	1	01

For End Connection availability and dimensions with different sizes refer Page no. 59.

AseptiVent TF- 10", 20", 30"

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

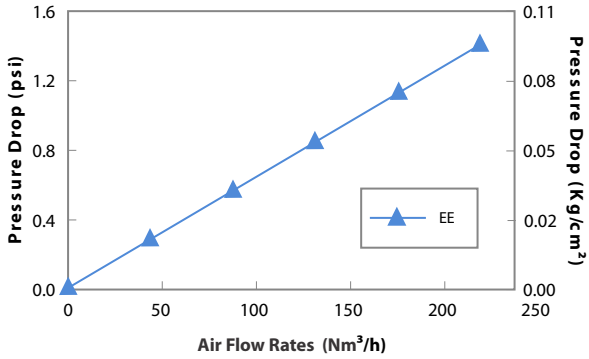
AseptiVent TF PTFE large capsule filters offer absolute retention and wide chemical compatibility for sterile filtration of air/gases as well as aggressive solvents in large volume.

Specifications

Construction			
Pore Size		0.2 µm	0.45 µm
Membrane		Hydrophobic PTFE	
Support Layers		Polypropylene	
Body and Core		Polypropylene	
Integrity Testing/Retention			
Air Diffusion Flow (70% IPA Wetted) (10" Capasule 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		10"	20" 30"
Effective Filtration Area (Nominal)		6000 cm²	12000 cm² 18000 cm²
Vent and Drain		1/4" Hose Barb with double Silicone 'O' rings	
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 121 °C for 30 minutes, 30 cycles. Can not 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	
	Code
AseptiVent TF	LTLX

Size	
	Code
10"	54
20"	55
30"	56

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Inlet/Outlet	
	Code
1½" Sanitary Flange	E
Single Step ½" Hose Barb	Q

X

Inline / T-line	
	Code
Inline	X
T-line	T

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
1	01

Example:

LTLX	54	01	EE	X	X	1	01

For End Connection availability and dimensions with different sizes refer Page no. 59.

AseptiSure TH

Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 211.72

Meets and Exceeds USFDA 21 CFR 177.1520

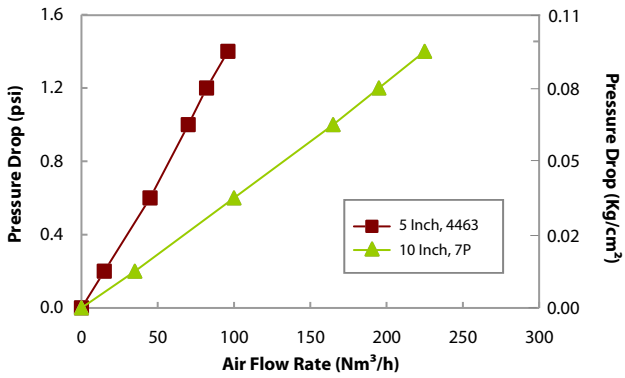
AseptiSure TH cartridge filters are high temperature resistant PTFE filters which are steam sterilizable at upto 135°C. These filters are validated with liquid microbial challenge test as per ASTM F 838-05 to offer absolute retention even under high moisture conditions.

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	1200 cm²	18000 cm²
Operational				
Max. Operating Temperature	80 °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 upto 135 °C, 80 cycles @ maximum differential pressure of 5 psi (0.3 Kg/cm²) for 30minutes.			

Air Flow Rates

0.2 µm *AseptiSure TH* Cartridge Filters



Ordering Information

Type	
	Code
AseptiSure TH	CPTH

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

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Adapter	
	Code
7P	A0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPTH	56	01	A0	SS	1	01

***FV is available in Adapter Code A0 (7P) only**

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 211.72

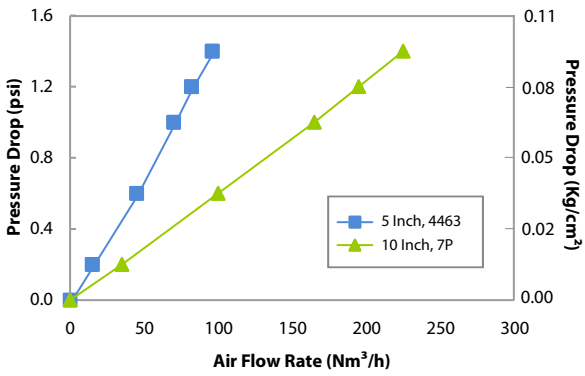
Meets and Exceeds USFDA 21 CFR 177.1520

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	80 °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 121 °C for 30 minutes, 100 cycles			

Air Flow Rates

0.2 µm *AseptiSure TF* Cartridge Filters



Ordering Information

Type	
	Code
AseptiSure TF	CPTF

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

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Adapter	
	Code
7P	A0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPTF	54	01	A0	FV	1	01

***FV is available in Adapter Code A0 (7P) only**

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 and chemically inert filters 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	*ClariPro GK*- 1", 2", 5", 8"
	ClariPro GK- 10", 20", 30"
Polyethersulfone Membrane Cartridge Filters with Microglassfiber Upstream	*ClariSure GK*
Microglassfiber Capsule Filters	*ClariCap GS*- 1", 2", 5", 8"
	ClariCap GS- 10", 20", 30"
Microglassfiber Cartridge Filters	*ClariSure GS*
	ClariSure GP
Polypropylene Capsule Filters	*ClariCap PP*-1", 2", 5", 8"
	ClariCap PP-10", 20", 30"
Polypropylene Cartridge Filters	*ClariSure PA*

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 : 2008 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
Oxidizable Substances	Within limits as specified in USP
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	- 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	- 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	- 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	- 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	- 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	- High retention efficiency	–	***ClariCap PP*** Polypropylene Capaule Filters	***ClariSure PA*** Pleated Polypropylene Cartridge Filters	–
Pre-filtration of proteinaceous liquids	- 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	- 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	- 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	- High retention efficiency - High throughput	–	–	***ClariSure GK*** PES Membrane Cartridge Filters with Microglassfiber upstream	***ClariSure GP*** Microglassfiber Cartridge Filters
Polishing of turbid solutions	- 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 0.5µm 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-*

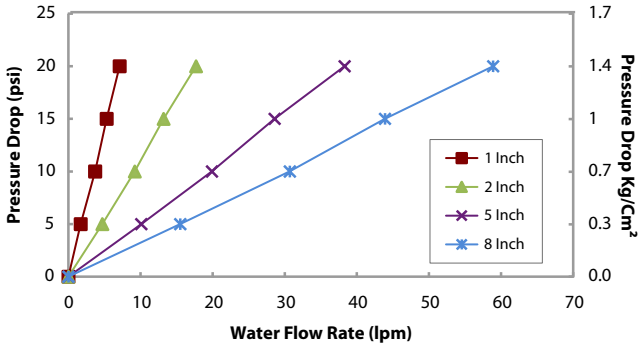
Autoclavable: *ClariPro GK*

Specifications

Construction				
Pore Size	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	1/4″ Hose Barb with double Silicone 'O' rings			
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 Irradiatiable up to 50 kGy			
Sterilization – By Gas	Sterilizable by Ethylene Oxide			
Sterilization – By Autoclave	Autoclavable at 121 °C for 30 minutes, 1 cycle after gamma irradiation. Can not be in-line steam sterilized			

Water Flow Rates

0.5 µm *ClariPro GK* Capsule Filters



Ordering Information

Type	
	Code
ClariPro GK	DGKX

Size	
	Code
1″	51
2″	52
5″	53
8″	57

Pore Size	
	Code
0.5 µm	04

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

Radiation Sterilizable	
	Code
Yes	R

X

Sterility	
	Code
Non Sterile	1
EO Sterile	2
Gamma Sterile	3

Pack Size	
	Code
1	01

Example:

DGKX	57	04	DD	R	X	2	01

For End Connection availability and dimensions with different sizes refer Page no. 59.

ClariPro GK- 10″, 20″, 30″

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

Meets and Exceeds USFDA 21 CFR 177.1520

ClariPro GK 0.5 µm 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-*

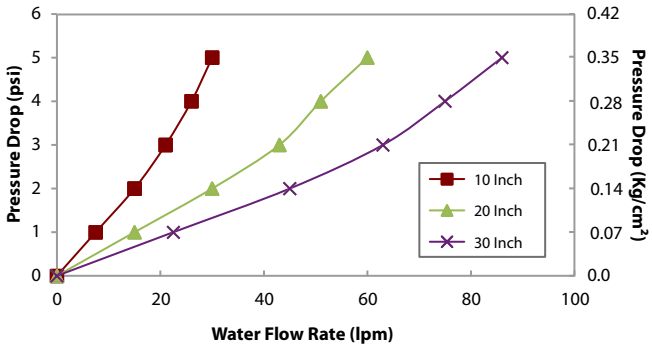
Autoclavable: *ClariPro GK*

Specifications

Construction			
Pore Size	0.5 µm		
Membrane	Hydrophilic PES		
Pre-filter	Microglassfiber		
Support Layers	Polyester		
Body and Core	Polypropylene		
Size			
Size	10″	20″	30″
Effective Filtration Area (Nominal)	5000 cm^2	10000 cm^2	15000 cm^2
Vent and Drain	1/4″ Hose Barb with double Silicone 'O' rings		
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 Irradiatiable up to 50 kGy		
Sterilization – By Gas	Sterilizable by Ethylene Oxide		
Sterilization – By Autoclave	Autoclavable at 121 °C for 30 minutes, 1 cycle after gamma irradiation. Can not be in-line steam sterilized		

Water Flow Rates

0.5 µm *ClariPro GK* Large Capsule Filters



Ordering Information

Type	
	Code
ClariProGK	LGKX

Size	
	Code
10″	54
20″	55
30″	56

Pore Size	
	Code
0.5 µm	04

Inlet/Outlet	
	Code
1½″ Sanitary Flange	E
Single Step ½″ Hose Barb	Q

Radiation Sterilizable	
	Code
Yes	R

X
X

Inline / T-line	
	Code
Inline	X
T-line	T

Sterility	
	Code
Non Sterile	1
EO Sterile	2
Gamma Sterile	3

Pack Size	
	Code
1	01

Example:

LGKX	54	04	EE	R	X	T	1	01

For End Connection availability and dimensions with different sizes refer Page no. 59.

ClariSure GK

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

Meets and Exceeds USFDA 21 CFR 177.1520

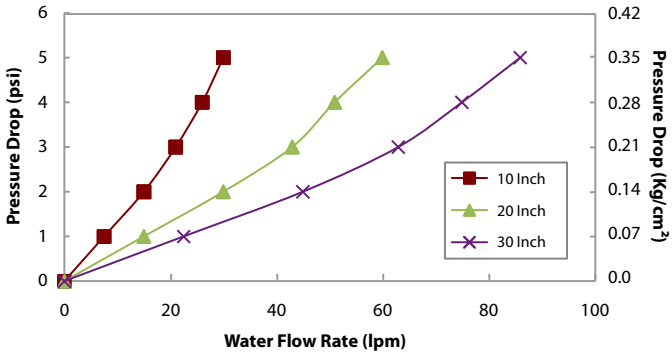
ClariSure GK 0.5 µm hydrophilic PES membrane cartridge filters offer a microglassfiber upstream layer with a PES membrane final filter to combine high dirt holding capacities with efficient retention of colloidal particles to give clear downstream in case of difficult to filter turbid solutions.

Specifications

Construction				
Pore Size	0.5 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	
	Code
ClariSure GK	CGKX

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

Pore Size	
	Code
0.5 µm	04

Adapter	
	Code
7P	A0
BEO	B0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CGKX	56	04	A0	SS	1	01

***FV is available in Adapter Code A0 (7P) only**

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

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

Meets and Exceeds USFDA 21 CFR 177.1520

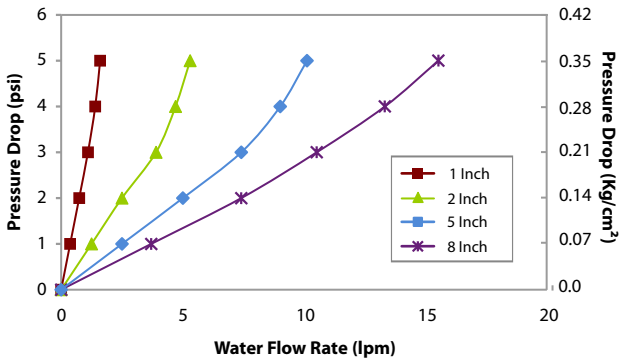
ClariCap GS Capsule filters employ microglassfiber filter media for efficient retention of colliodal particles to give clear downstream in case of difficult to filter turbid solutions. These specially designed filtration devices are non media migrating with a heat calendered polypropylene layer in the 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	500 cm^2	1000 cm^2	2000 cm^2
Vent and Drain	1/4" Hose Barb with double Silicone 'O' rings			
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 121 °C for 30 minutes, 30 cycles. Can not be inline steam sterilized			

Water Flow Rates

0.7 µm *ClariCap GS* Capsule Filters



Ordering Information

Type	
	Code
ClariCap GS	DGSX

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

Pore Size	
	Code
0.7 µm	41
1 µm	05
1.5 µm	14
2 µm	15

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

X

Bell	
	Code
Yes	B
No Bell	X

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

DGSX	57	05	DD	X	X	1	01

For End Connection availability, Bell and dimensions with different sizes refer Page no. 59.

ClariCap GS- 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.

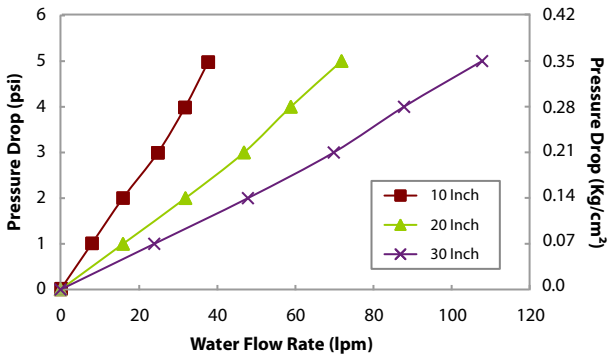
These are high efficiency pre-filters combining the unique abilities of microglassfiber filter media to retain colloidal particles and heat calendered polypropylene filter media to ensure non media migration.

Specifications

Construction			
Pore Size	0.7 µm, 1 µm, 1.5 µm, 2 µm		
Filter Media	Microglassfiber		
Body and Core	Polypropylene		
Size			
Size	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm^2	6000 cm^2	9000 cm^2
Vent and Drain	1/4" Hose Barb with double Silicone 'O' rings		
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 121 °C for 30 minutes, 30 cycles. Can not be inline steam sterilized		

Water Flow Rates

0.7µm *ClariCap GS* Large Capsule Filters



Ordering Information

Type	
	Code
ClariCap GS	LGSX

Size	
	Code
10"	54
20"	55
30"	56

Pore Size	
	Code
0.7 µm	41
1 µm	05
1.5 µm	14
2 µm	15

Inlet/Outlet	
	Code
1½" Sanitary Flange	E
Single Step ½" Hose Barb	Q

X

Inline / T-line	
	Code
Inline	X
T-line	T

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

LGSX	54	41	EE	X	T	1	01

For End Connection availability and dimensions with different sizes refer Page no. 59.

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.

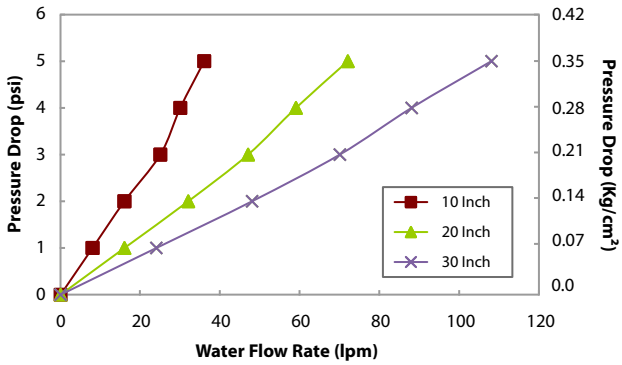
It is a very high efficiency pre-filter combining the unique abilities of microglassfiber filter media to retain colloidal particles and heat calendered polypropylene filter media to ensure non media migration.

Specifications

Construction				
Pore Size	0.7 µm			
Filter Media	Microglassfiber			
Support Layers	Polyester			
Body and Core	Polypropylene			
Size				
Size	5″	10″	20″	30″
Effective Filtration Area (Nominal)	1500 cm^2	3000 cm^2	6000 cm^2	9000 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	
	Code
ClariSure GS	CPGS

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

Pore Size	
	Code
0.7 µm	41

Adapter	
	Code
7P	A0
BEO	B0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPGS	55	41	A0	SV	1	01

*** FV is available in Adapter Code A0 (7P) only**

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.

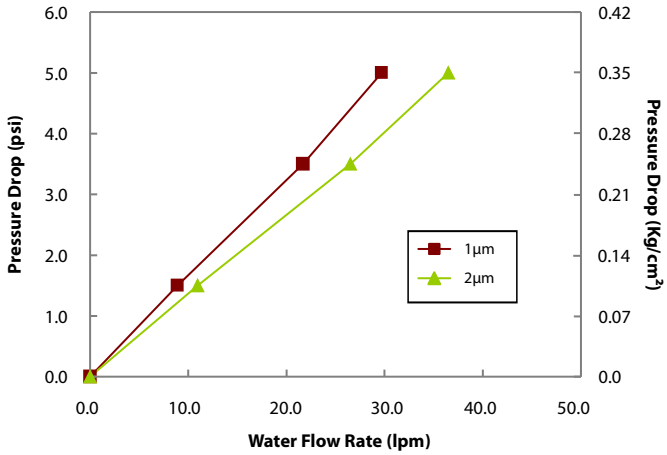
A microglassfiber upstream layer retains very fine colloidal particles and a downstream polypropylene layer checks any kind of media migration.

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	1000 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	
	Code
ClariSure GP	CPGP

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

Pore Size	
	Code
0.5 µm	04
1 µm	05
2 µm	15

Adapter	
	Code
7P	A0
BEO	B0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPGP	55	04	A0	SS	1	01

*** FV is available in Adapter Code A0 (7P) only**

ClariCap PP- 1″, 2″, 5″, 8″

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

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

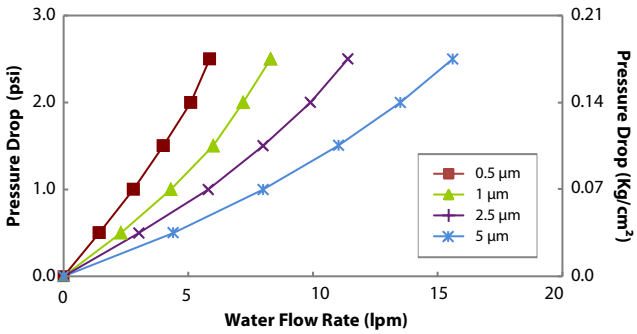
Meets and Exceeds USFDA 21 CFR 177.1520

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	1000 cm^2	2000 cm^2
Vent and Drain	1/4″ Hose Barb with double Silicone 'O' rings			
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 121 °C for 30 minutes, 30 cycles. Can not be inline steam sterilized			

Water Flow Rates

ClariCap PP, 5″ Capsule Filters



Ordering Information

Type	
	Code
ClariCap PP	DOLX

Size	
	Code
1″	51
2″	52
5″	53
8″	57

Pore Size	
	Code
0.5 µm	04
1 µm	05
2.5 µm	06
5 µm	07
10 µm	08
20 µm	11

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

X

Bell	
	Code
Yes	B
No Bell	X

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

DOLX	53	05	CC	X	X	1	01

For End Connection availability, Bell and dimensions with different sizes refer Page no. 59.

ClariCap PP- 10", 20", 30"

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

Meets and Exceeds USFDA 21 CFR 177.1520

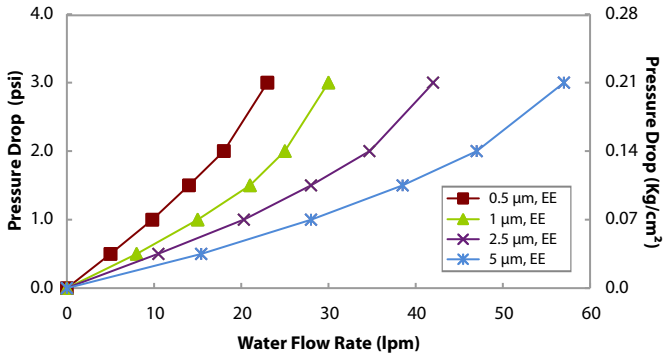
ClariCap PP large capsule filters employ high retention efficiency Polypropylene filter media for wide chemical compatibility, efficient pre-filtration, with clarification and polishing applications.

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	10"	20"	30"
Effective Filtration Area (Nominal)	5000 cm^2	10000 cm^2	15000 cm^2
Vent and Drain	1/4" Hose Barb with double Silicone 'O' rings		
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 121 °C for 30 minutes, 30 cycles. Can not be inline steam sterilized		

Water Flow Rates

ClariCap PP 10", Large Capsule Filters



End Connection Type:

E: 1½" Sanitary Flange

Ordering Information

Type	
	Code
ClariCap PP	LOLX

Size	
	Code
10"	54
20"	55
30"	56

Pore Size	
	Code
0.5 µm	04
1 µm	05
2.5 µm	06
5 µm	07
10 µm	08
20 µm	11

Inlet/Outlet	
	Code
1½" Sanitary Flange	E
Single Step ½" Hose Barb	Q

X

Inline / T-line	
	Code
Inline	X
T-line	T

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

LOLX	54	06	QQ	X	T	1	01

For End Connection availability and dimensions with different sizes refer Page no. 59.

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.

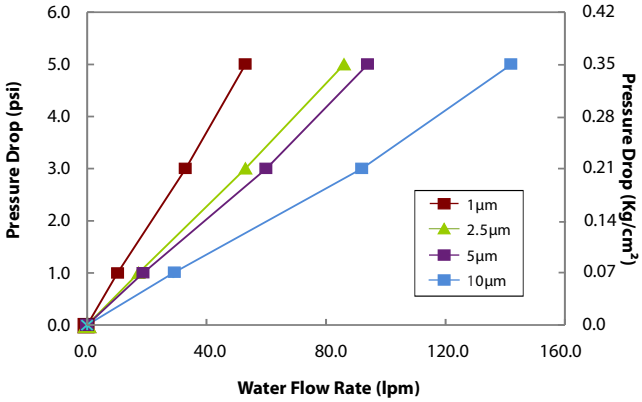
These filters have heat stable construction and are used as pre-filters to sterilizing membrane cartridge filters.

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	
	Code
ClariSure PA	CPPA

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

Pore Size	
	Code
0.5 µm	04
1 µm	05
1.2 µm	10
2.5 µm	06
5 µm	07
8 µm	17
10 µm	08

Adapter	
	Code
7P	A0
BEO	B0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPPA	56	05	A0	SS	1	01

***FV is available in Adapter Code A0 (7P) only**

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.

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.

Special Features

- High retention efficiency

Positively Charged Microglassfiber Disc Filters-
Type GFSZ

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

Special Features

- Very high retention efficiency for negatively charged particles

Ordering Information

Type	
	Code
GF2	GF2X
GFS	GFSX
GFSZ	GFSZ

Size	
	Code
127 mm	15
142 mm	16
257 mm	17
279 mm	18
293 mm	19

Pore Size	
	Code
1.5 µm	14
2 µm	15

XX	XX

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
50	03

Example:

GFSX	18	15	XX	XX	1	03

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 : 2008 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
Oxidizable Substances	Within limits as specified in USP
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	- 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	- Very high retention efficiency - Wide chemical compatibility	***ClariSure PP*** Pleated Polypropylene Cartridge Filters	***ClariSure PL*** Pleated Profile Cartridge Filters	–
Filtration of precipitating agents	- 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	- 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	- 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	- Very high retention efficiency - Wide chemical compatibility	***ClariSure PP*** Pleated Polypropylene Cartridge Filters	***ClariSure PL*** Pleated Profile Cartridge Filters	–
Bottle washing in oral formulations	- 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	- 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.

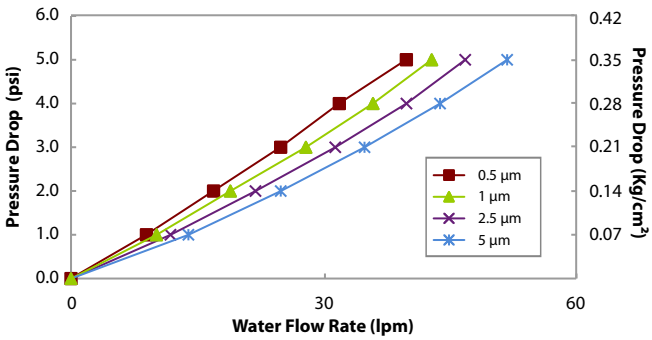
These filters are used as terminal filters in applications requiring highly efficient particulate removal.

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	
	Code
ClariSure PP	CPPP

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

Pore Size	
	Code
0.5 µm	04
1 µm	05
1.2 µm	10
2 µm	15
2.5 µm	06
5 µm	07
10 µm	08
20 µm	11
30 µm	19

Adapter	
	Code
7P	A0
BEO	B0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
PTFE	ST
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPPP	55	04	A0	FV	1	01

*** FV is available in Adapter Code A0 (7P) only**

ClariSure PL

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

Meets and Exceeds USFDA 21 CFR 177.1520

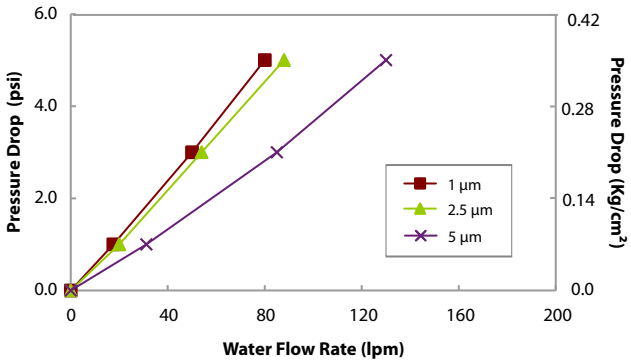
ClariSure PL cartridge filters are all polypropylene high retention efficiency **(99.99%)** pleated cartridge filters offering large filtration area.

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	
	Code
ClariSure PL	CPPL

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

Pore Size	
	Code
1 µm	05
2.5 µm	06
5 µm	07
10 µm	08

Adapter	
	Code
7P	A0
BEO	B0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
PTFE	ST
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPPL	54	07	B0	SV	1	01

***FV is available in Adapter Code A0 (7P) only**

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	
	Code
ClariSure DP	CPDP

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

Pore Size	
	Code
1 µm	05
1.5 µm	14
3 µm	16
5 µm	07
10 µm	08
20 µm	11
30 µm	19
40 µm	20

Adapter	
	Code
7P	A0
BEO	B0
28	C0
'O'	D0
4463	E0
4463B	H0

Elastomer	
	Code
Silicone	SS
Viton	SV
EPDM	SE
PTFE	ST
FEP Encapsulated Viton	FV*

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CPDP	56	14	A0	SS	1	01

***FV is available in Adapter Code A0 (7P) only**

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 on specific reagents is available on request.

Reagents	*AseptiSure* Cartridge Filters				*ClariSure* Cartridge Filters						'O' Rings/Gasket Seals			
	HS/KS	KR	NS	TH/TF	GS	GP	PA	PP	PL	DP	Silicone	Viton	EP	FEP Encapsulated Viton
Solvents														
Acetone	N	N	G	G	G	G	G	G	G	G	N	N	G	G
Acetonitrile	G	G	G	G	G	G	G	G	G	G	G	N	G	G
Benzene	G	G	G	G	F	F	F	F	F	F	N	G	N	G
Benzyl Alcohol	N	N	G	G	G	G	G	G	G	G	G	G	G	G
Benzyl Alcohol 4%	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Diethyl Ether	G	G	G	G	N	N	N	N	N	N	N	N	N	G
Dimethylformamide	N	N	G	G	G	G	G	G	G	G	G	N	N	G
Ethyl Acetate	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
Hexane	G	G	G	G	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
Methanol	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	G
n-Butanol	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
Tetrahydrafuran/Water (50:50)	N	N	N	G	N	N	N	N	N	N	N	N	N	G
Toluene	G	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	G	N	G
Acids														
Hydrochloric Acid 37%	G	G	N	G	G	G	G	G	G	G	N	G	N	G
Hydrofluoric Acid 10%	G	G	F	G	N	N	G	G	G	G	N	G	F	G
Nitric Acid 67%	N	N	N	G	G	G	G	G	G	G	N	G	N	G
Nitric Acid 7%	G	G	N	G	G	G	G	G	G	G	G	G	G	G
Sulphuric Acid 10%	G	G	F	G	G	G	G	G	G	G	G	G	G	G
Bases														
Ammonium Hydroxide 25%	N	G	N	G	G	G	G	G	G	G	G	G	G	G
Sodium Hydroxide 32%	N	G	N	G	G	G	G	G	G	G	G	G	G	G
Potassium Hydroxide 32%	N	G	N	G	G	G	G	G	G	G	G	G	G	G

G: Good F: Fair N: Not recommended

Chemical Compatibility

Reagents	*AseptiCap* Capsule Filters			*AseptiVent* Capsule Filters	*ClariCap* Capsule Filters		Membrane Disc Filters	Microglassfiber Pre-filter Discs
	KL/KS	KO	NL/NS	TF	GS	PP	NN	GF
Solvents								
Acetone	N	N	G	G	G	G	G	G
Acetonitrile	G	G	G	G	G	G	G	G
Benzene	G	G	G	G	F	F	G	G
Benzyl Alcohol	N	N	G	G	G	G	G	G
Benzyl Alcohol 4%	G	G	G	G	G	G	G	G
Diethyl Ether	G	G	G	G	N	N	G	G
Dimethylformamide	N	N	G	G	G	G	G	G
Ethyl Acetate	G	G	G	G	G	G	G	G
Ethylene Glycol	G	G	G	G	G	G	G	G
Hexane	G	G	G	G	F	F	G	G
Iso Propyl Alcohol	G	G	G	G	G	G	G	G
Methanol	G	G	G	G	G	G	G	G
Methylene Chloride	N	N	N	N	N	N	G	G
n-Butanol	G	G	G	G	G	G	G	G
Peanut oil	G	G	G	G	G	G	G	G
Tetrahydrafuran/Water (50:50)	N	N	N	G	N	N	G	G
Toluene	G	G	G	G	G	G	G	G
Trichloroethylene	N	N	N	N	N	N	G	G
Acids								
Hydrochloric Acid 37%	G	G	N	G	G	G	N	G
Hydrofluoric Acid 10%	G	G	G	G	N	G	G	N
Nitric Acid 67%	N	N	N	G	G	G	N	G
Nitric Acid 7%	G	G	G	G	G	G	G	G
Sulphuric Acid 10%	G	G	G	G	G	G	G	G
Bases								
Ammonium Hydroxide 25%	N	G	N	G	G	G	G	G
Sodium Hydroxide 32%	N	G	N	G	G	G	G	F
Potassium Hydroxide 32%	N	G	N	G	G	G	N	G

G: Good F: Fair N: Not recommended

End Connections Availability Chart for Capsule Filters

End Connections	Small Capsule Filters						LargeCapsule Filters					
							Inline			T-line		
	37mm	50mm	1"	2"	5"	8"	10"	20"	30"	10"	20"	30"
½" Hose Barb	X	X	√	√	√	√	X	X	X	X	X	X
Single Step ½" Hose Barb	X	X	X	√	√	√	√	√	√	X	X	X
¼" Stepped Hose Barb	√	√	√	√	√	√	X	X	X	X	X	X
1½" Sanitary Flange	X	X	√	√	√	√	√	√	√	√	√	√
¾" Sanitary Flange	X	√	X	√	√	√	X	X	X	X	X	X
½" MNPT	X	X	X	√	√	√	X	X	X	X	X	X
¼" MNPT	X	X	√	√	√	√	X	X	X	X	X	X
1/8" MNPT	X	√	X	X	X	X	X	X	X	X	X	X
Quick Connector	X	X	√	√	√	√	X	X	X	X	X	X

Bell at Outlet is available with only 1" Capsule Filter with ¼" SHB End Connection

Dimensions: Capsule Filters

End Connections	Capsule Filter Size							
	25mm	37mm	50mm	1"	2"	5"	8"	10"
¼" SHB I/O	-	64 mm	64.7 mm	94 mm	121 mm	173 mm	231 mm	-
¾" Sanitary Flange Inlet I/O	-	–	51.4 mm	91 mm	113 mm	164 mm	215 mm	-
Female Luer Lock Inlet/ Male Luer Slip Out let	23 mm	-	-	-	-	-	-	-
1½" Sanitary Flange I/O	-	-	-	93 mm	111 mm	161 mm	213 mm	332mm
½" Hose Barb I/O	-	-	-	91 mm	113 mm	164 mm	215 mm	-
½" Single Step Hose Barb I/O	-	-	-	91 mm	113 mm	164 mm	215 mm	337 mm
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	-	-	-	96 mm	118 mm	175 mm	228 mm	332 mm
Operational Radius	15mm	22.5mm	28mm	30 mm	65 mm	65 mm	65 mm	78 mm

Ordering Information

Shipment details for customers outside India

Through Federal Express, UPS, or DHL courier (specify complete street address).

By air freight for large quantities (specify airport of discharge).

Goods usually reach destination within 5-10 days from date of shipment.

Membrane products are light weight and air freight charges usually vary between 3% to 10% of the value. Any duties/taxes in the country of destination are the responsibility of the consignee.

Shipment details for customers in India

The consignments can be sent through courier. Courier charges will be borne by the customer. Please specify the preferred courier and provide any form and instructions for octroi etc. that may be required for shipment.

How to order

Orders may be placed by phone/fax/email/mail directly to Sales.

Advanced Microdevices Pvt. Ltd.

20-21, Industrial Area, Ambala Cantt - 133 006, INDIA
Tel: +91-171-2699290, 2699471
Fax: +91-171-2699221, 2699008
Email: orders@mdimembrane.com
support@mdimembrane.com

mdi Quality

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 competing products and complying with quality management systems."

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 30 years
- 'Special **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.

WORLD WIDE EXPORTS

MUMBAI
Tel/ Fax : 022-28654435
022-40214436
Mobile : 09323801794

Delhi
Mobile : 08295618833

AHMEDABAD
Mobile : 09328257987

BANGALORE
Mobile : 09972587761

CHENNAI
Mobile : 09972587761

HYDERABAD
Mobile : 09391935423

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