

## Data Sheet

### 0.2 $\mu$ m *AseptiCap*<sup>®</sup> KL/KS- $\gamma$

#### Gamma Irradiatable Sterilization Grade Hydrophilic Polyethersulfone (PES) Membrane Devices for Liquid Streams in Biopharmaceuticals

Biopharmaceutical processing requires sterilizing grade microfiltration at multiple stages to meet specific process requirements.

Process managers are continuously looking for microfiltration solutions to upstream, downstream, intermediate processes and final biological preparations. Since bio manufacturing is a multi stage process and bio molecules by nature are extremely sensitive, they are looking for:

- Minimizing protein losses due to adsorption to improve overall product yields
- Minimizing filter extracts which add up due to multiple points of use in a process
- High throughputs to achieve process economy
- Choice of filter end connections for easy and reliable quick connections
- Absolute retentions for higher sterility assurance

**mdi** produces a wide range of Gamma compatible Sterilizing grade PES membrane devices to meet filtration requirements of biopharmaceutical processing. These filter devices are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as high retention efficiency, very high protein recoveries, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

With the advantages of pre filtration layer built into the device for higher throughputs, linear scalability of filter area for smooth transitions from lab scale to pilot to process scale and widest range of end connections for quick and reliable connections to the existing fittings, **mdi AseptiCap**<sup>®</sup> KL/KS- $\gamma$  filters are a universal solution for process filtration.

# AseptiCap® KL/KS-γ

## Gamma Compatible PES Membrane Devices for Biopharmaceuticals

# Datasheet

AseptiCap® KL/KS-γ 0.2 micron capsule filters use **mdi** PES membrane in Gamma compatible Polypropylene housing. No adhesives or glue are used in the manufacturing process and all bonding is done by heat welding.

The products are deeply validated for use in Biopharmaceutical applications and specially recommended for single use systems. AseptiCap® KL/KS-γ are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities. Packaging is done in double polybags for direct irradiation by gamma or for convenience of taking AseptiCap® in clean areas for making disposable assemblies for subsequent sterilization.

### Types Available

- AseptiCap®KS-γ: Double Layer (with Prefilter)
- AseptiCap®KL-γ: Single Layer (without Prefilter)

### Applications

#### Sterile Filtration of

- Cell culture media
- Cell culture media containing serum
- Media additives
- pH adjusters
- Final product concentrates

#### Bioburden Reduction/ Particulate Removal

- Buffers
- Centrifuge supernatants
- Clarified cell lysates

### Key Features

- Absolute retention
- 100% integrity tested
- Low protein binding
- Very low hold up volume in filters
- High flow rates
- Serial construction with prefilter for higher throughput with fouling streams
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Widest range of end connections
- Products available for total scalability from a few ml to thousands of liters
- Total traceability through unique serial number for each filter
- Individual certificate of quality for each device
- Sterilizable by Gamma irradiation or autoclaving

### Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the 'Sterilizing Filter' with drug product under simulated worst-case conditions of use.

**mdi** provides validation services supported by customized validation protocols and world class test facilities to assist you in filter validations with your specific drug product.

## Quality Assurance

**mdi's** quality management system emphasizes on quality by design rather than by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

### Certificate of Quality

Each capsule filter is accompanied by individual certificate of quality to ensure traceable documentation at user's end.

It certifies the product compliance to various regulatory as well as user requirements.

### Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention with *B.diminuta* (ATCC 19146) as per ASTM F838 to establish acceptable integrity test values.

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

### 100% Integrity Tested

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

### Flow Rate

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

### Adsorption

*AseptiCap*® KL/KS-γ filters are validated for low protein binding to ensure minimal active ingredient losses when used for filtration of high value proteins.

### Pressure, Temperature Endurance

*AseptiCap*® KL/KS-γ filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

These filters are also validated for high burst pressure to ensure user safety in case of inadvertent pressure build-up.

### Extractables

Extractables/leachables from sterilizing filters, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

*AseptiCap*® KL/KS-γ filters are validated to exhibit low extractables under harsh extraction conditions.

### Bioburden Testing

Device bioburden is tested as per ISO 11737-1 and assured to be <1000 cfu/device.

### Endotoxin Testing

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test

### Total Traceability

*AseptiCap*® KL/KS-γ filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

### Packaging Integrity

*AseptiCap*® KL/KS-γ filters are fitted with vent caps and are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room assembly or process areas.

### Other Regulatory Compliance

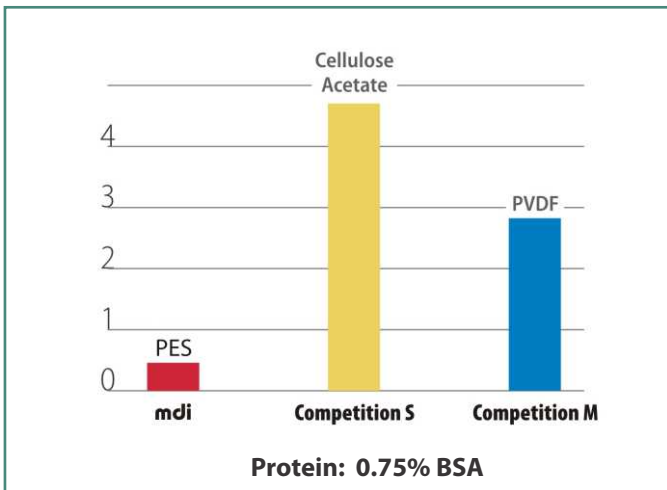
- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics
- Complete filter devices tested for cytotoxicity as per Biological Reactivity Tests, In-vitro, USP <87>

## Low Protein Binding

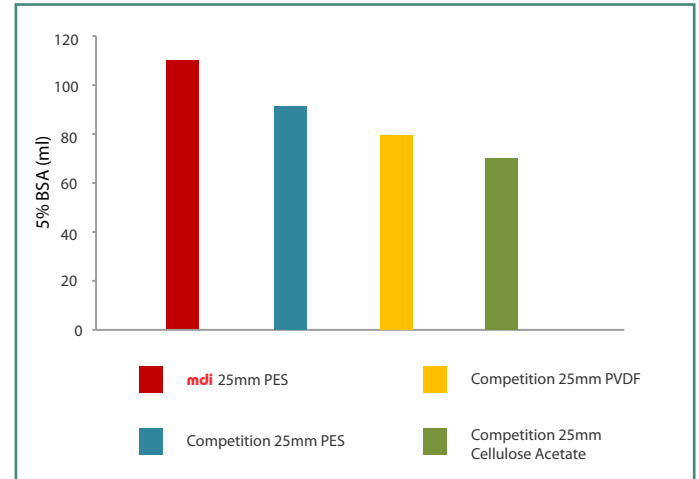
A comparative study on **mdi** PES membrane exhibits much lower protein adsorption than other competing membranes of Cellulose Acetate and PVDF.

The low protein binding results in increased overall product yield and higher throughputs with biological streams.

### Protein Binding ( $\mu\text{g}/\text{cm}^2$ )



## High Throughputs



**mdi** PES membrane exhibits higher throughput than either Cellulose Acetate or PVDF membranes.

The high throughput translates to lower filtration costs, less number of filter changes and overall economy of operations.

## Very Low Hold-Up Volumes

**mdi** PES membrane capsule filters are designed to offer very low hold-up volumes to minimize filtration losses and maximize product recovery.

0.2 $\mu\text{m}$ AseptiCap® Filters	Protein Binding
25 mm, 5 cm <sup>2</sup>	1.45 $\mu\text{g}$
50 mm, 20 cm <sup>2</sup>	6.3 $\mu\text{g}$
1", 250 cm <sup>2</sup>	80.5 $\mu\text{g}$
2", 500 cm <sup>2</sup>	175 $\mu\text{g}$
10", 6000 cm <sup>2</sup>	1925 $\mu\text{g}$

Filter Devices	EFA* (Nominal)	Hold up Volume
AseptiCap® KL/KS- $\gamma$ 25mm	5cm <sup>2</sup>	< 50 $\mu\text{l}$
AseptiCap® KL/KS- $\gamma$ 50mm	20cm <sup>2</sup>	< 200 $\mu\text{l}$
AseptiCap® KL/KS- $\gamma$ 1"	250cm <sup>2</sup>	< 5ml
AseptiCap® KL/KS- $\gamma$ 2"	500cm <sup>2</sup>	< 25ml
AseptiCap® KL/KS- $\gamma$ 5"	1000cm <sup>2</sup>	< 45ml
AseptiCap® KL/KS- $\gamma$ 8"	2000cm <sup>2</sup>	< 60ml

## Extractables

It is useful to evaluate extractables that may be leached out of the filter and enter the process stream. **mdi** filters give low extractables under harsh preconditioning and extraction conditions.

**Low extractables mean less addition to impurity profile of the biological product from the filters.**

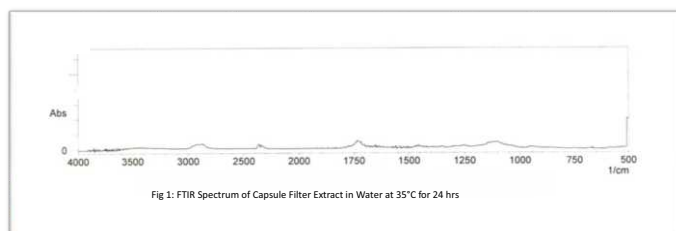
**Preconditioning:** Gamma Irradiated at 50 kGy

**Extraction Time:** 24 hours

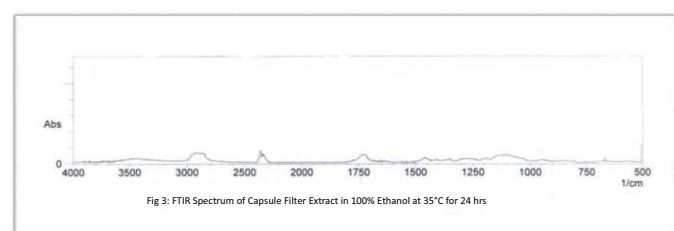
Model Solvent	Non Volatile Residue	
	AseptiCap® KS-γ 1" (250 cm <sup>2</sup> )	AseptiCap® KS-γ 10" (6000 cm <sup>2</sup> )
Water @ 35 °C	1.6 mg	38.26 mg
Water @ 80 °C	1.8 mg	43.04 mg

Model Solvent	Non Volatile Residue	
	AseptiCap® KS-γ 1" (250 cm <sup>2</sup> )	AseptiCap® KS-γ 10" (6000 cm <sup>2</sup> )
100% Ethanol @ 35 °C	13.4 mg	320.43 mg

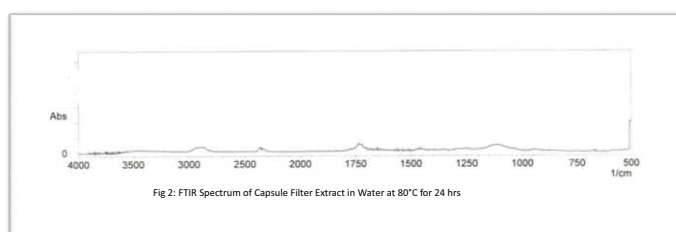
### FTIR Analysis of Extractables From AseptiCap® KS-γ 1" Capsule Filter with Water @ 35 °C



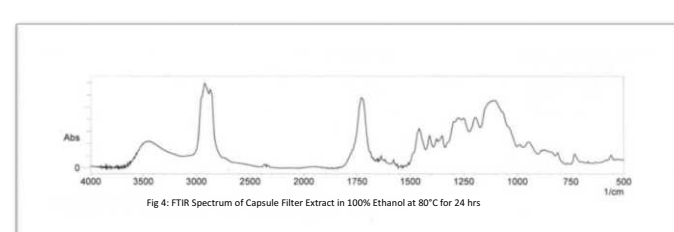
### FTIR Analysis of Extractables From AseptiCap® KS-γ 1" Capsule Filter with 100% Ethanol @ 35 °C



### FTIR Analysis of Extractables From AseptiCap® KS-γ 1" Capsule Filter with Water @ 80 °C



### FTIR Analysis of Extractables From AseptiCap® KS-γ 1" Capsule Filter with 100% Ethanol @ 80 °C



The Spectrum of extracts from AseptiCap® KS-γ capsule filters with 100% ethanol under extreme extraction conditions show presence of various components used in the manufacture of **mdi** PES membrane capsule filters.

## Easy Connect

### Widest Range of End Connections

Biopharmaceutical processes involve transfer of high value fluids through multiple process steps. Making high quality, reliable, flexible and functionally convenient connectivity with filters is of utmost value to the bio-processors.

**mdi** *AseptiCap*® KL/KS- $\gamma$  filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

### Validated for Performance

These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand prevalent sterilization methods including gamma irradiation, EO sterilization and autoclaving.



1/2" HB



1/2" Single Stepped  
Hose Barb



1/4" MNPT



1/4" SHB



Quick Connector



Male Luer Slip



3/8" Hose Barb



Female Luer Lock



1 1/2" Sanitary Flange



3/4" Sanitary Flange



1/2" MNPT



1" Hose Barb

Variety of end connections

### Customized Connectivity

**mdi** *AseptiCap*® KL/KS- $\gamma$  filters are available in a wide range of end connections and are also customized to offer different inlet-outlet combinations to meet the unique connectivity needs in biopharmaceutical process assemblies where, for example, stainless steel components with sanitary flange connections are sometimes required to be connected to single use disposable systems through quick-connectors or hose barb connections.



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



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



*AseptiCap*® with HighSecurity  
1/2" hose barb connection

# Linear Upscaling from R&D to Production Process

## Datasheet

Scientists 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.

**mdi** offers a wide range of *AseptiCap*<sup>®</sup> KL/KS- $\gamma$  filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process are identical for all filter devices starting from 5 cm<sup>2</sup> to 19500cm<sup>2</sup> hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *AseptiCap*<sup>®</sup> KL/KS- $\gamma$  filters there by reducing the additional validation cost and time.



*AseptiCap*<sup>®</sup> KL/KS- $\gamma$   
25mm, 5cm<sup>2</sup>



*AseptiCap*<sup>®</sup> KL/KS- $\gamma$   
50mm, 20cm<sup>2</sup>



*AseptiCap*<sup>®</sup> KL/KS- $\gamma$   
1", 250cm<sup>2</sup>



*AseptiCap*<sup>®</sup> KL/KS- $\gamma$   
2", 500cm<sup>2</sup>



*AseptiCap*<sup>®</sup> KL/KS- $\gamma$   
5", 1000cm<sup>2</sup>



*AseptiCap*<sup>®</sup> KL/KS- $\gamma$   
8", 2000cm<sup>2</sup>

Filter Devices	EFA* (Nominal)	Hold up Volume
<i>AseptiCap</i> <sup>®</sup> KL/KS- $\gamma$ 25 mm	5cm <sup>2</sup>	< 50 $\mu$ l
<i>AseptiCap</i> <sup>®</sup> KL/KS- $\gamma$ 50 mm	20cm <sup>2</sup>	< 200 $\mu$ l
<i>AseptiCap</i> <sup>®</sup> KL/KS- $\gamma$ 1"	250cm <sup>2</sup>	< 5ml
<i>AseptiCap</i> <sup>®</sup> KL/KS- $\gamma$ 2"	500cm <sup>2</sup>	< 25ml
<i>AseptiCap</i> <sup>®</sup> KL/KS- $\gamma$ 5"	1000cm <sup>2</sup>	< 45ml
<i>AseptiCap</i> <sup>®</sup> KL/KS- $\gamma$ 8"	2000cm <sup>2</sup>	< 60ml
<i>AseptiCap</i> <sup>®</sup> KS- $\gamma$ 5"	3000cm <sup>2</sup>	< 80ml
<i>AseptiCap</i> <sup>®</sup> KS- $\gamma$ 10"	6000cm <sup>2</sup>	< 150ml
<i>AseptiCap</i> <sup>®</sup> KS- $\gamma$ 20"	12000cm <sup>2</sup>	< 250ml
<i>AseptiCap</i> <sup>®</sup> KS- $\gamma$ 30"	18000cm <sup>2</sup>	< 350ml



*AseptiCap*<sup>®</sup> KL/KS- $\gamma$   
10", 6000cm<sup>2</sup>

## 0.2 µm AseptiCap® KL/KS-γ

Construction		
Membrane	0.2 µm Hydrophilic PES	
Upstream Membrane (in case of AseptiCap® KS-γ)	0.8 µm, 0.65µm or 0.45 µm Hydrophilic PES	
Plastic Parts	Gamma Stable Polypropylene	
Integrity Testing / Retention		
Bubble Point	≥ 50 psi (3.52 Kg/cm <sup>2</sup> ) with Water	
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm <sup>2</sup>	
Size		
Size	25 mm	50 mm
EFA (Effective Filtration Area)	5 cm <sup>2</sup>	20 cm <sup>2</sup>
Operational Radius	15 mm	28 mm
Operational		
Max. Operating Temperature	55 °C	60 °C
Max. Differential Pressure	75 psi (5 Kg/cm <sup>2</sup> ) @ 25 °C	42 psi (3 Kg/cm <sup>2</sup> ) @ 30 °C
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters should not be autoclaved or in-line steam sterilized.	
Shelf Life	2 years after gamma sterilization	
Assurance		
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics	
Cytotoxicity	Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity	
Bacterial Retention	LRV > 7 for <i>B. diminuta</i> (ATCC 19146) per cm <sup>2</sup> of filter area as per ASTM F 838-05	
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>	
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release	
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 500 ml flush	
pH Compatibility	Compatible with pH range of 1 - 10	
Extractables with WFI	Passes NVR test as per USP <661>	
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520	
Oxidizable Substances	Within limits as specified in USP <1231>	
Quality Management System	ISO-9001 Certified	
USFDA	DMF No. 015554	



## 0.2 $\mu\text{m}$ AseptiCap<sup>®</sup> KL/KS- $\gamma$

### Construction

Membrane	0.2 $\mu\text{m}$ Hydrophilic PES
Upstream Membrane (in case of AseptiCap <sup>®</sup> KS- $\gamma$ )	0.8 $\mu\text{m}$ , 0.65 $\mu\text{m}$ or 0.45 $\mu\text{m}$ Hydrophilic PES
Support Layers	Polyester
Plastic Parts	Gamma Stable Polypropylene

### Integrity Testing / Retention

Bubble Point	$\geq 50$ psi (3.52Kg/cm <sup>2</sup> ) with Water
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm <sup>2</sup>

### Size

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

### Operational

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

### Assurance

Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity
Bacterial Retention	LRV > 7 for <i>B. diminuta</i> (ATCC 19146) per cm <sup>2</sup> of filter area as per ASTM F 838-05
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 3 liter flush
pH Compatibility	Compatible with pH range of 1 - 10
Extractables with WFI	Passes NVR test as per USP <661>
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

## 0.2 $\mu\text{m}$ AseptiCap<sup>®</sup> KL/KS- $\gamma$

### Construction

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Upstream Membrane (in case of AseptiCap <sup>®</sup> KS- $\gamma$ )	0.8 $\mu\text{m}$ , 0.65 $\mu\text{m}$ or 0.45 $\mu\text{m}$ Hydrophilic PES
Support Layers	Polyester
Plastic Parts	Gamma Stable Polypropylene

### Integrity Testing/Retention

Bubble Point	$\geq 50\text{psi}$ (3.52Kg/cm <sup>2</sup> ) with Water
Max. Air Diffusion Flows per 10" Capsule Filter	$\leq 30\text{ ml/min}$ @ 37 psi (2.6 Kg/cm <sup>2</sup> ) with water
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm <sup>2</sup>

### Size

Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000 cm <sup>2</sup>	6000 cm <sup>2</sup>	12000 cm <sup>2</sup>	18000 cm <sup>2</sup>
Operational Radius (with Vent/ Drain)	80 mm	80 mm	80 mm	80 mm
Vent and Drain	1/4" Hose Barb with Silicone "O" ring			

### Operational

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

### Assurance

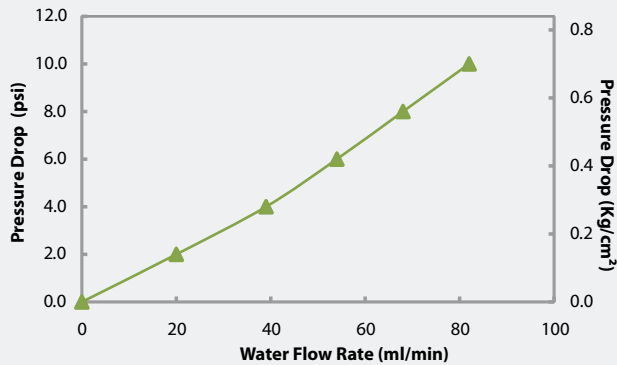
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity
Bacterial Retention	LRV > 7 for <i>B. diminuta</i> (ATCC 19146) per cm <sup>2</sup> of filter area as per ASTM F 838-05
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 10 liter flush for 5" capsule filters and 20 liter flush for 10" capsule filters
pH Compatibility	Compatible with pH range of 1 - 10
Extractables with WFI	Passes NVR test as per USP <661>
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Within limits as specified in USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

# Typical Water Flow Rates

# Datasheet

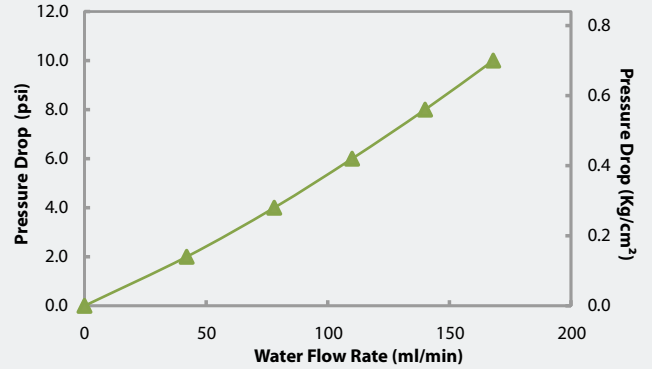
## 0.2 $\mu\text{m}$ AseptiCap<sup>®</sup> KL/KS- $\gamma$ (with Prefilter)

### 25mm Capsule Filters



End Connections: MN

### 50mm Capsule Filters



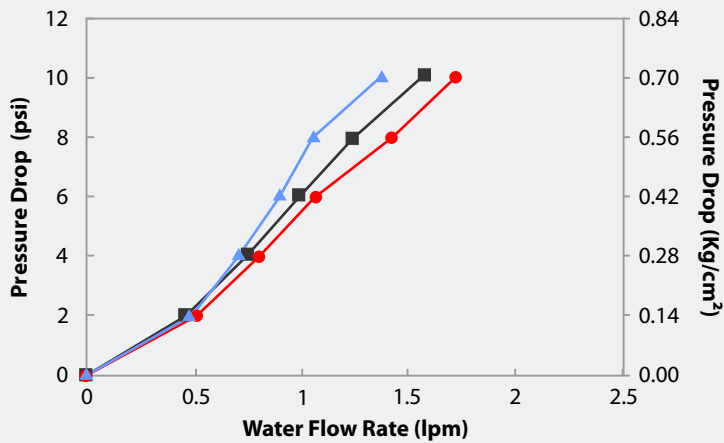
End Connections: BB

### End Connection Type:

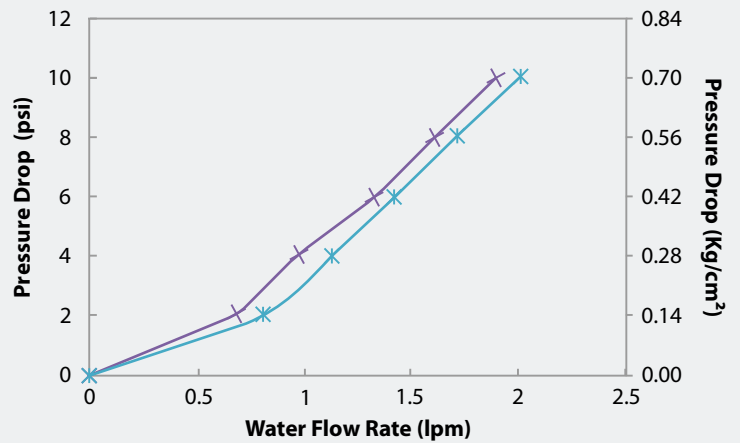
B: 1/4" Stepped Hose Barb (for 50mm only)

MN: End Connections: Female Luer Lock Inlet/Male Luer Slip Out let

### 1" Capsule Filters



End Connections: AA (black square), JJ (red circle), UU (blue triangle)



End Connections: EE (cyan asterisk), SS (purple cross)

### End Connection Type:

A: 1/4" Stepped Hose Barb

E: 1/2" Sanitary Flange

J: Quick Connector

S: 3/4" Sanitary Flange

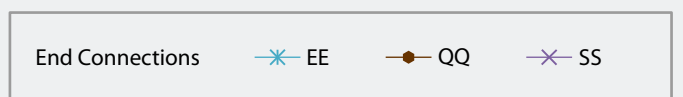
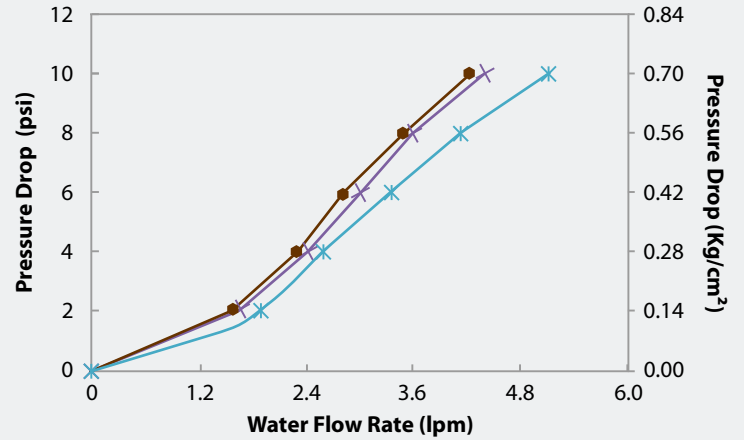
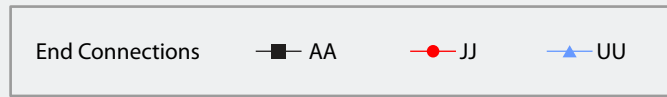
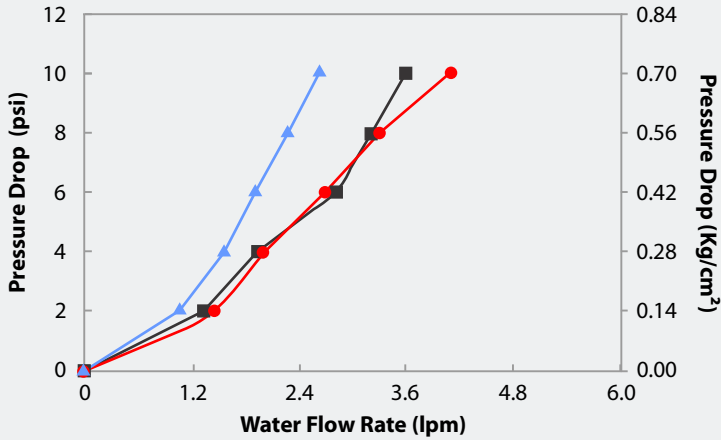
U: Female Luer Lock

# Typical Water Flow Rates

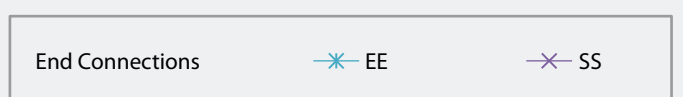
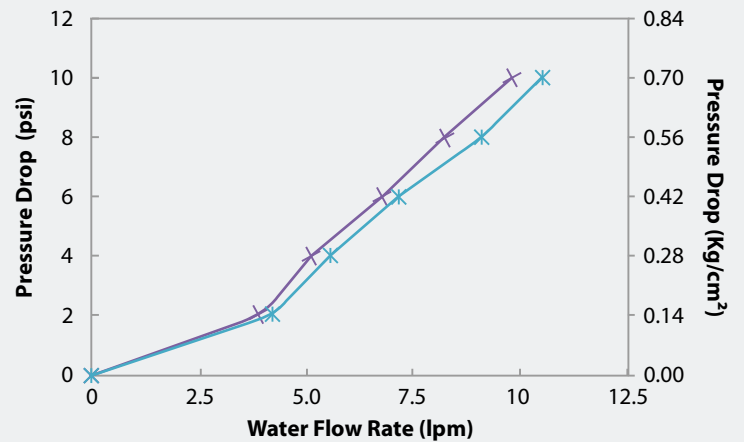
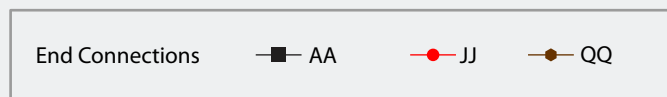
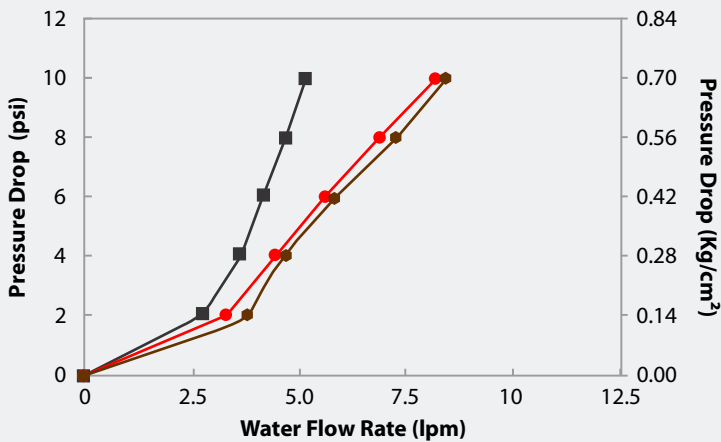
# Datasheet

## 0.2 $\mu\text{m}$ AseptiCap<sup>®</sup> KL/KS- $\gamma$ (with Prefilter)

### 2" Capsule Filters



### 5" Capsule Filters



### End Connection Type:

A: 1/4" Stepped Hose Barb  
U: Female Luer Lock

Q: 1/2" Single Step Hose Barb

E: 1 1/2" Sanitary Flange

J: Quick Connector

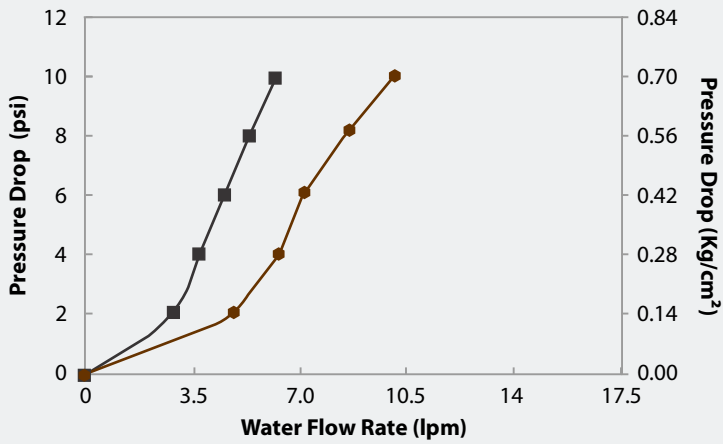
S: 3/4" Sanitary Flange

# Typical Water Flow Rates

# Datasheet

## 0.2 $\mu\text{m}$ AseptiCap<sup>®</sup> KL/KS- $\gamma$ (with Prefilter)

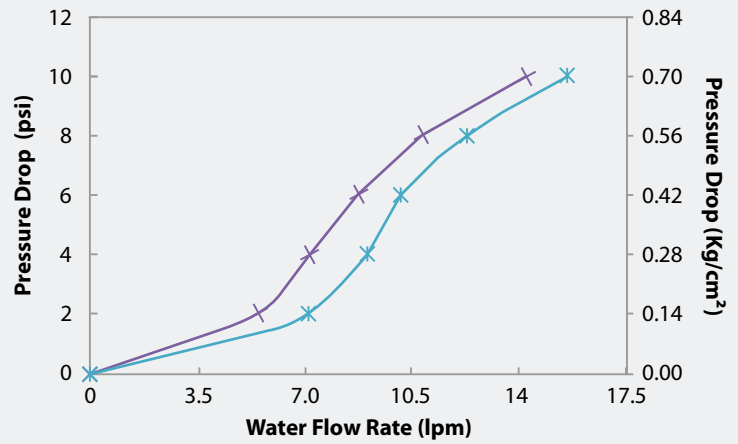
### 8" Capsule Filters



End Connections

■ AA

● QQ

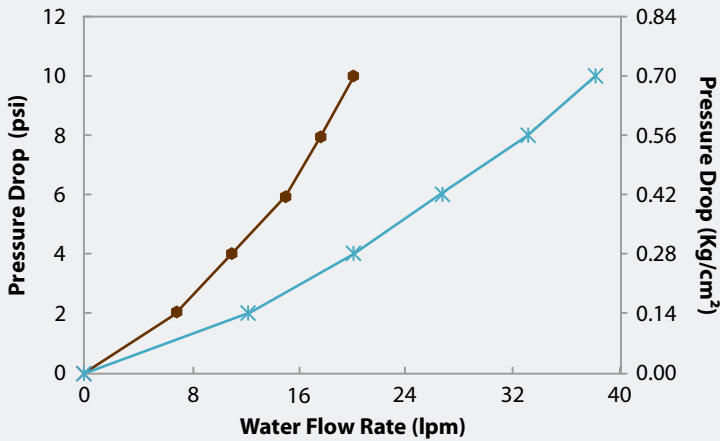


End Connections

\* EE

\* SS

### 10" Capsule Filters



End Connections

\* EE

● QQ

### End Connection Type:

A: 1/4" Stepped Hose Barb

Q: 1/2" Single Step Hose Barb

E: 1 1/2" Sanitary Flange

J: Quick Connector

S: 3/4" Sanitary Flange

# Ordering Information

# Datasheet

## 0.2 µm AseptiCap® KL/KS-γ 25mm PES Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
IKL (Single Layer)	IKLX	25mm	06	0.2µm	01	Female Luer Lock	M	Yes	R		Non Sterile	1	100	04
IKS (0.8 µm Upstream)	IKS5					Male Luer Slip	N	No*	X		Gamma Sterile	3		
IKS (0.65 µm Upstream)	IKS3					1/8" Hose Barb	H							
IKS (0.45 µm Upstream)	IKSX					1/4" Hose Barb	B							

### Example:

IKSX	06	01	MN	R	X	1	04
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\*Gamma irradiated filters can not be gamma sterilized again

## 0.2 µm AseptiCap® KL/KS-γ 50mm PES Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
IKL (without Vent) (Single Layer)	IKLX	50mm	10	0.2µm	01	1/4" SHB	B	Yes	R		Non Sterile	1	10	02
IKS (without Vent) (0.8 µm Upstream)	IKS5					3/4" Sanitary Flange	S	No*	X		Gamma Sterile	3		
IKS (without Vent) (0.65 µm Upstream)	IKS3					Female Luer Lock	M							
IKS (without Vent) (0.45 µm Upstream)	IKSX													
VKL (with Vent) (Single Layer)	VKLX													
VKS (with Vent) (0.8 µm Upstream)	VKS5													
VKS (with Vent) (0.65 µm Upstream)	VKS3													
VKS (withou Vent) (0.45 µm Upstream)	VKSX													

### Example:

VKSX	10	01	BB	R	X	1	02
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\*Gamma irradiated filters can not be gamma sterilized again

### Inlet/Outlet Connections Available

Inlet/Outlet	25mm	50mm	
		with Vent	without Vent
1/4" - 3/4" Stepped Hose Barb	X	√	X
3/4" Sanitary Flange	X	√	X
Female Luer Lock	Inlet Only	X	√
Male Luer Slip	Outlet Only	X	X
1/8" Hose Barb	√	X	X
Male Luer Lock	Outlet Only	X	X
1/4" Hose Barb	√	X	X

### Dimension (Length) (in mm)

Inlet/Outlet	25mm	50mm
1/4" - 3/8" Stepped Hose Barb I/O	-	79
1/4" Single Step Hose Barb I/O	38	-
3/4" Sanitary Flange I/O	-	51
Female Luer Lock Inlet/ Male Luer Slip Outlet	23	-
1/8" Hose Barb I/O	36	-
Operational Radius	15	28

## 0.2 µm AseptiCap® KL/KS-γ PES Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Bell		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
DKL (Single Layer)	DKLX	1"	51	0.2µm	01	¼" SHB	A	Yes	R	Yes**	B	Non Sterile	1	1	01
		2"	52			¼" MNPT (18 TPI)	B	No*	X	No Bell	X	Gamma Sterile	3		
DKS (0.8 µm Upstream)	DKS5	5"	53			¼" BSP (19 TPI)	M				Bell with cover				
		8"	57			¼" BSP (19 TPI) with O-ring	P								
						¼" BSP	F								
DKS (0.65 µm Upstream)	DKS3					½" MNPT	C								
DKS (0.45 µm Upstream)	DKSX					½" Hose Barb	D								
						1½" Sanitary Flange	E								
						¾" Sanitary Flange	S								
						Quick Connector	J								
						½" Single Step Hose Barb	Q								
						Female Luer Lock	U								
						Male Luer Slip	W								
						⅜" Hose Barb	N								
						⅝" Hose Barb	I								

**Example:**

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

Example for Non Sterile: DKLX5101QQRX101

Example for gamma Sterile: DKLX5101QQXX301

\*\* Bell is available with

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

¼" SHB outlet connection in 1" capsule filters only

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

Inlet/Outlet	Size/Length			
	1"	2"	5"	8"
¼" Stepped Hose Barb	√	√	√	√
½" Single Step Hose Barb	X	√	√	√
½" Hose Barb	√	√	√	√
1½" Sanitary Flange	√	√	√	√
¾" Sanitary Flange	√	√	√	√
Quick Connector	√	√	√	√
½" MNPT	X	√	√	√
¼" MNPT (18TPI)	√	√	√	√
¼" BSP (19 TPI)	Inlet Only	X	X	X
¼" BSP (19 TPI) with O-ring	Inlet Only	X	X	X
¼" BSP	Inlet Only	√	√	√
Female Luer Lock	√	√	√	√
Male Luer Slip	Outlet Only	X	X	X
⅜" Hose Barb	√	√	Outlet Only	X
⅝" Hose Barb	X	√	√	√

Bell at outlet Available with (Size/outlet)
1" / ¼" SHB
1", 2", 5", 8" / ½" HB

Dimensions (in mm)	Small Capsule Filters			
End Connections	1"	2"	5"	8"
¼" SHB I/O	94	122	172	223
¾" Sanitary Flange Inlet I/O	85	104	155	206
Quick Connector	100	113	164	218
1½" Sanitary Flange I/O	92	112	164	216
½" Hose Barb I/O	90	112	162	214
½" Single Step Hose Barb I/O	-	115	165	218
1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	-	112	165	216
3/8" Hose Barb I/O	-	115	167	217
Operational Radius	40	65	65	65

## 0.2 µm AseptiCap® KS-γ PES Membrane Large Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline/T-Line		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
LKS (0.8 µm Upstream)	LKS5	5"	53	0.2µm	01	½" Single Step Hose Barb	Q	Yes	R	Inline	X	Non Sterile	1	1	01
		10"	54			1½" Sanitary Flange	E	No*	X	T-Line**	T	Gamma Sterile	3		
LKS (0.65 µm Upstream)	LKS3	20"	55			¾" Sanitary Flange	S								
		30"	56			⅝" Hose Barb	I								
LKS (0.45 µm Upstream)	LKSX					1" Hose Barb	Z								

### Example:

LKSX	54	01	EE	R	T	1	01
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\* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: LKS55301QQRX101

Example for gamma Sterile: LKS55301QQXX301

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

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

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

Inlet/Outlet	Inline				T-Line			Dimensions (in mm)	Inline Capsule Filters				T-line Capsule Filters		
	5"	10"	20"	30"	10"	20"	30"		5"	10"	20"	30"	10"	20"	30"
½" Single Step Hose Barb	√	√	√	√	X	X	X	<b>End Connections</b>	5"	10"	20"	30"	10"	20"	30"
1½" Sanitary Flange	√	√	√	√	√	√	√	1½" Sanitary Flange I/O	205	330	600	855	340	580	840
¾" Sanitary Flange	√	√	X	X	X	X	X	¾" Sanitary Flange I/O	214	335	x	x	x	x	x
⅝" Hose Barb	√	√	√	√	X	X	X	½" Single Step Hose Barb I/O	218	336	630	890	x	x	x
1" Hose Barb	X	√	√	√	X	X	X	1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334	620	870	x	x	x
								⅝" Hose Barb I/O	211	332	634	885	x	x	x
								1" Hose Barb I/O	x	405	635	895	x	x	x
								Operational Radius	80	80	80	80	80	80	80

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