



## 0.2μm *AseptiCap KL/KS-*γ

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

### **Data Sheet**

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

Processes 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 over all 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 KL/KS-γ filters are a universal solution for process filtration.

## AseptiCap KL/KS-γ

### **Datasheet**

### Gamma Compatible PES Membrane Devices

### for Biopharmaceuticals

Asepticap  $KL/KS-\gamma$  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-* $\gamma$  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**

## **Datasheet**

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

#### **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 F838-05 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- $\gamma$  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  $KL/KS-\gamma$  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- $\gamma$  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 117 37-1 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- $\gamma$  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>

### **Datasheet**

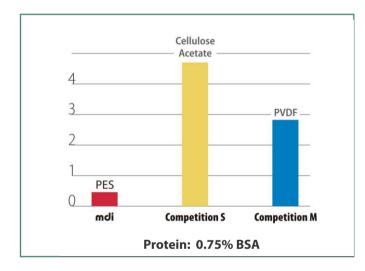
## Performance Data

#### **Low Protein Binding**

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

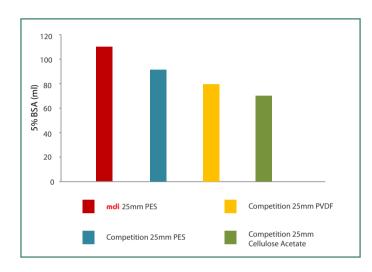
The low protein binding results in increased overall product yield and higher throughputs with biological streams.

#### Protein Binding (µg/cm²)



0.2 μm <i>AseptiCap</i> Filters	Protein Binding
25 mm, 5 cm <sup>2</sup>	1.45 μg
50 mm, 20 cm <sup>2</sup>	6.3 µg
1″, 250 cm²	80.5 μg
2", 500 cm <sup>2</sup>	175 μg
10", 6000 cm <sup>2</sup>	1925 μg
10,0000 CIII	1923 μg

#### **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.

Filter Devices	EFA* (Nominal)	Hold up Volume
AseptiCap KL/KS-γ 25mm	5cm²	< 50μl
AseptiCap KL/KS-γ 50mm	20cm²	< 200µl
AseptiCap KL/KS-γ 1″	250cm <sup>2</sup>	< 5ml
AseptiCap KL/KS-γ 2"	500cm²	< 25ml
AseptiCap KL/KS-γ 5″	1000cm²	< 45ml
AseptiCap KL/KS-γ 8″	2000cm <sup>2</sup>	< 60ml

## Performance Data

### **Datasheet**

#### **Extractables**

It is useful to evaluate extractables that may be leeched 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.

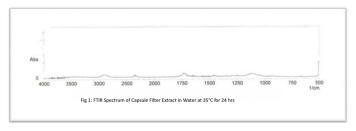
**Preconditioning:** Gamma Irradiated at 50 kGy

**Extraction Time:** 24 hours

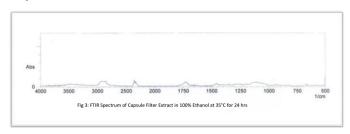
	Non Volatile Residue							
Model Solvent	AseptiCap KS-γ 1″ (250 cm²)	AseptiCap KS-γ 10" (6000 cm²)						
Water @ 35 ℃	1.6 mg	38.26 mg						
Water @ 80 °C	1.8 mg	43.04 mg						

# Model Solvent AseptiCap KS- $\gamma$ 1" (250 cm²) AseptiCap KS- $\gamma$ 10" (6000 cm²) 100% Ethanol @ 35 °C 13.4 mg 320.43 mg

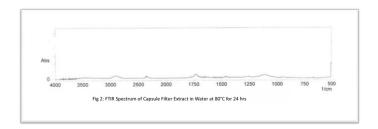
## FTIR Analysis of Extractables From AseptiCap KS- $\gamma$ 1" Capsule Filter with Water @ 35 °C



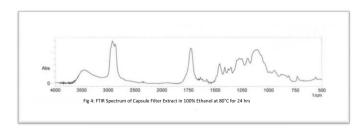
## FTIR Analysis of Extractables From AseptiCap KS-γ 1" Capsule Filter with 100% Ethanol @ 35 °C



## FTIR Analysis of Extractables From AseptiCap KS- $\gamma$ 1" Capsule Filter with Water @ 80 °C



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



The Spectrum of extracts from *AseptiCap KS*- $\gamma$  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**

### **Datasheet**

#### **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.



34" Sanitary Flange



1/2" HB



1/4" SHB



11/2" Sanitary Flange



1/2" Single Stepped HB



**Quick Connector** 

Some end connections available with AseptiCap

#### **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.



1½" Sanitary Flange to ½"Barb Hose





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 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 cm² to 19500cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *AseptiCap KL/KS-γ* filters there by reducing the additional validation cost and time.



AseptiCap KL/KS-γ
25mm, 5cm<sup>2</sup>



AseptiCap KL/KS-γ
50mm, 20cm<sup>2</sup>



AseptiCap KL/KS-γ
1", 250cm<sup>2</sup>



AseptiCap KL/KS-γ
2", 500cm<sup>2</sup>



**AseptiCap KL/KS-**γ **5".** 1000cm<sup>2</sup>



**AseptiCap KL/KS**-γ
8", 2000cm<sup>2</sup>

Filter Devices	EFA* (Nominal)	Hold up Volume
AseptiCap KL/KS-γ 25 mm	5cm²	< 50μl
AseptiCap KL/KS-γ 50 mm	20cm²	< 200µl
AseptiCap KL/KS-γ 1"	250cm <sup>2</sup>	< 5ml
AseptiCap KL/KS-γ 2"	500cm <sup>2</sup>	< 25ml
AseptiCap KL/KS-γ 5"	1000cm <sup>2</sup>	< 45ml
AseptiCap KL/KS-γ 8"	2000cm <sup>2</sup>	< 60ml
AseptiCap KL/KS-γ 10″	6000cm <sup>2</sup>	-
AseptiCap KL/KS-γ 20"	12000cm²	-
AseptiCap KL/KS-γ 30"	18000cm²	_



AseptiCap KL/KS-γ
10", 6000cm<sup>2</sup>

## Specifications 0.2 μm *AseptiCap KL/KS*-γ

## **Datasheet**

		Construction						
Membrane		0.2 μm Hydrophilic PES						
Upstream Mei (in case of <i>Ase</i>		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/cm²) with Water						
Microbial Rete	ention	LRV >7 for Brevundimonas diminuta (ATCC 19	146) per cm²					
		Size						
Size		25 mm	50 mm					
EFA (Effective	Filtration Area)	5 cm²	20 cm²					
	1⁄4" SHB I/O	-	79 mm					
Dimensions (End to End)	3⁄4" Sanitary Flange Inlet I/O	-	51 mm					
	Female Luer Lock Inlet/ Male Luer Slip Outlet	23 mm	-					
Operational	Radius	15 mm	28 mm					
		Operational						
Max. Operatir	ng Temperature	55 ℃	60 °C					
Max. Differen	tial Pressure	75 psi (5 Kg/cm²) @ 25 °C	42 psi (3 Kg/cm²) @ 30 °C					
Charittee stan	By Irradiation	Gamma Irradiatable up to 50 kGy						
Sterilization	By Autoclave	Autoclavable at 125 °C for 30minutes, 1 Cycle. Can not be in-line steam sterilized						
Shelf Life		2 years after gamma sterilization						
		Assurance						
Toxicity		Passes Biological Reactivity tests, In Vivo, as pe	r USP <88> for Class VI plastics					
Cytotoxicity		Passes Biological Reactivity tests, In Vitro, USP	<87> for cytotoxicity					
Bacterial Rete	ntion	LRV> 7 for <i>B. diminuta</i> (ATCC 19146) per cm <sup>2</sup> of	f filter area as per ASTM F 838-05					
Bacterial Endo	otoxin	Aqueous extracts exhibit < 0.25 EU/ml as estables as per USP <85>	olished by Limulus Amebocyte Lysate (LAL) Test					
Non Fiber Rele	easing	Passes test as per USP and comply with USFDA	A 21 CFR Part 210.3(b)(6) for fiber release					
TOC and Conc	luctivity	Meets the WFI requirements of USP for TOC <6 minimal flush	643> and Conductivity <645> after a specified					
pH Compatibi	lity	Compatible with pH range of 1 - 10						
Extractables w	vith WFI	Passes NVR test as per USP <661>						
Indirect Food	Additives	Comply with USFDA 21 CFR Part 177.1520						
Oxidizable Sul	bstances	Within limits as specified in USP <1231>						
Quality Manag	gement System	ISO-9001 Certified						
USFDA		DMF No. 015554						

## Specifications 0.2 μm *AseptiCap KL/KS*-γ

## **Datasheet**

		Con	struction							
Membrane			0.2 μm Hydrop	hilic PES						
Upstream Me		0	0.8 μm, 0.65μm or 0.45 μm Hydrophilic PES							
Support Laye	rs	Polyester								
Plastic Parts			Gamma Stable Po	lypropylene						
		Integrity Testing / Retention								
Bubble Point		≥ 50psi (3.52Kg/cm²) with Water								
Microbial Ret	ention	LRV >7 for Brevundimor	nas diminuta (ATCC 191	46) per cm²						
			Size							
Size		1"	2"	5″	8"					
Effective Filtr	ation Area (Nominal)	250cm <sup>2</sup>	500cm <sup>2</sup>	1000cm <sup>2</sup>	2000cm <sup>2</sup>					
	1½" Sanitary Flange I/O	91 mm	110 mm	161 mm	211 mm					
	½" Hose Barb I/O	90 mm	112 mm	164 mm	215 mm					
(End to End)	1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	-	111 mm	162 mm	212 mm					
	¾" Sanitary Flange I/O	91 mm	103 mm	155 mm	205 mm					
Operational I	Radius (with Vent/ Drain)	30 mm 65 mm 65 mm 65 mm								
Vent and Dra	in	¼" Hose Barb with Silico	ne "O" ring							
		Oį	perational							
	ting Temperature	80 °C @ < 30 psi (2 Kg/cm²)								
Max. Differe	ntial Pressure	60 psi (4 Kg/cm²) @ 30 ℃								
Sterilization	By Irradiation	Gamma Irradiatable up								
	By Autoclave	Autoclavable at 125 °C Can not be in-line stean		fter gamma irradiation.						
Shelf Life		2 years after gamma ste	rilization							
		A:	ssurance							
Toxicity		Passes Biological Reacti	vity tests, In Vivo, as per	USP <88> for Class VI plass	tics					
Cytotoxicity		Passes Biological Reacti	vity tests, In Vitro, USP <	87> for cytotoxicity						
Bacterial Rete	ention		· · · · · · · · · · · · · · · · · · ·	filter area as per ASTM F 83						
Bacterial End	otoxin	Aqueous extracts exhib as per USP <85>	it < 0.25 EU/ml as estab	lished by Limulus Ameboc	yte Lysate (LAL) Test					
Non Fiber Re	_	Passes test as per USP a	nd comply with USFDA	21 CFR Part 210.3(b)(6) for	fiber release					
TOC and Con	ductivity	Meets the WFI requirem	ents of USP for TOC <64	3> and Conductivity <645	> after a 3 liter flush					
pH Compatib	,	Compatible with pH ran	ige of 1 - 10							
Extractables	with WFI	Passes NVR test as per U	ISP <661>							
Indirect Food	l Additives	Comply with USFDA 21 CFR Part 177.1520								
Oxidizable Su	ubstances	Passes test as per USP <1231>								
Quality Mana	gement System	ISO-9001 Certified								
USFDA		DMF No. 015554								

## Specifications 0.2 μm *AseptiCap KL/KS*-γ

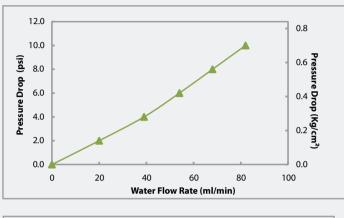
## **Datasheet**

		Con	struction									
Membrane			0.2 μm Hydr	ophilic PES								
Upstream Mer (in case of Asep			0.8 μm, 0.65μm or 0.45	μm Hydrophilic PES								
Support Layer	S	Polyester										
Plastic Parts			Gamma Stable I	Polypropylene								
		Integrity Te	esting/Retention									
Bubble Point		≥ 50psi (3.52Kg/cm²) v	≥ 50psi (3.52Kg/cm²) with Water									
Max. Air Diffus per 10" Capsul		≤ 30 ml/min @ 37 psi (2	2.6 Kg/cm²) with water									
Microbial Rete	ntion	LRV >7 for Brevundimo	onas diminuta (ATCC 191	46) per cm <sup>2</sup>								
			Size									
Size		5″	10"	20"	30"							
Effective Filtra	tion Area (Nominal)	3000 cm <sup>2</sup>	6000 cm <sup>2</sup>	12000 cm <sup>2</sup>	18000 cm <sup>2</sup>							
Dimensions	½" Single Step Hose Barb I/O	217 mm	332 mm	607 mm	882 mm							
(End to End) Inline Capsule Filters	1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	203 mm	332 mm	607 mm	882 mm							
	1½" Sanitary Flange I/O	207 mm	326 mm	601 mm	876 mm							
Operational Ra	adius (with Vent/ Drain)	78 mm 78 mm 78 mm										
Vent and Draii	า	¼" Hose Barb with Silicone "O" ring										
		O	perational									
Max. Operati	ng Temperature	80 °C @ < 30 psi (2 Kg/o	cm²)									
Max. Differen	itial Pressure	60 psi (4 Kg/cm²) @ 30	°C									
Charillandian	By Irradiation	AseptiCap KL/KS- γ: Ga	mma Irradiatiable up to	50 kGy								
Sterilization	By Autoclave	Autoclavable at 125 °C for 30minutes, 1 Cycle after gamma irradiation. Can not be in-line steam sterilized										
Shelf Life		2 years after gamma sterilization										
		A:	ssurance									
Toxicity		Passes Biological React	tivity tests, In Vivo, as per	USP <88> for Class VI pla	astics							
Cytotoxicity			tivity tests, In Vitro, USP <	<u> </u>								
Bacterial Reter	ntion	LRV> 7 for <i>B. diminuta</i>	(ATCC 19146) per cm <sup>2</sup> of	filter area as per ASTM F	838-05							
Bacterial Endo	toxin	Aqueous extracts exhil as per USP <85>	bit < 0.25 EU/ml as estab	olished by Limulus Amebo	ocyte Lysate (LAL) Test							
Non Fiber Rele	easing	Passes test as per USP a	and comply with USFDA	21 CFR Part 210.3(b)(6) fo	or fiber release							
TOC and Cond	luctivity	Meets the WFI requirer	ments of USP for TOC <6	43> and Conductivity <64	45> after a 3 liter flush							
pH Compatibi	lity	Compatible with pH range of 1 - 10										
Extractables w	rith WFI	Passes NVR test as per USP <661>										
Indirect Food	Additives	Comply with USFDA 21 CFR Part 177.1520										
Oxidizable Sul	ostances	Within limits as specific	ed in USP <1231>									
Quality Manag	gement System	ISO-9001 Certified										
		DMF No. 015554										

## Typical Water Flow Rates 0.2 μm *AseptiCap KL/KS-*γ (with Prefilter)

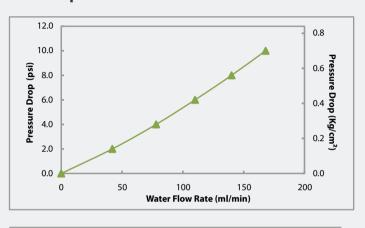
## **Datasheet**

#### 25mm Capsule Filters



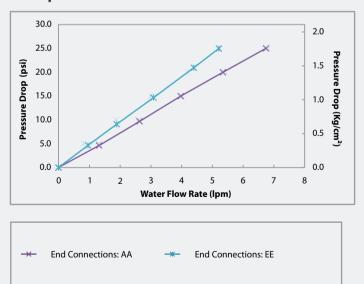


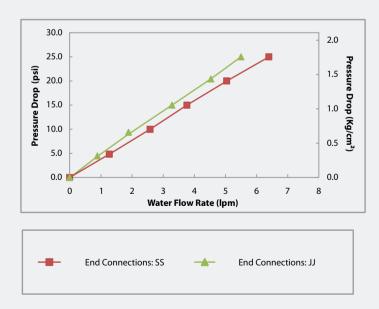
#### **50mm Capsule Filters**





#### 1"Capsule Filters





#### **End Connection Type:**

A: ¼" Stepped Hose Barb

E: 11/2" Sanitary Flange

J: Quick Connector

S: ¾" Sanitary Flange

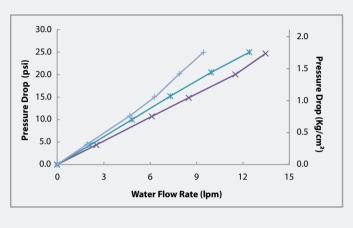
B: 1/4" Stepped Hose Barb (for 50mm only)

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

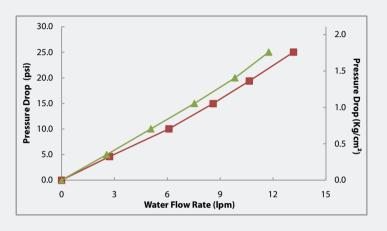
## Typical Water Flow Rates 0.2 μm *AseptiCap KL/KS-*γ (with Prefilter)

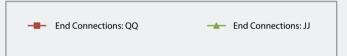
## **Datasheet**

#### 2"Capsule Filters

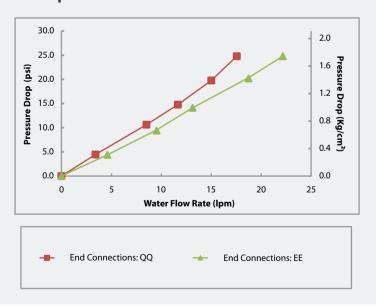


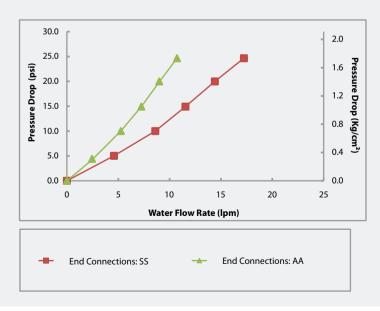






#### 5"Capsule Filters





#### **End Connection Type:**

A: ¼" Stepped Hose Barb

Q: 1/2" Single Step Hose Barb

E: 1½" Sanitary Flange

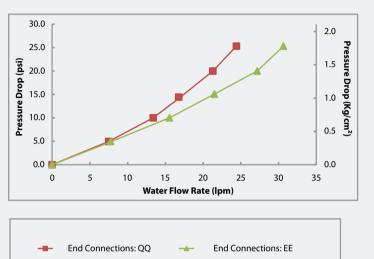
J: Quick Connector

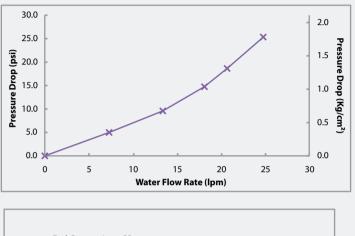
S: ¾" Sanitary Flange

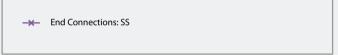
## Typical Water Flow Rates 0.2 μm *AseptiCap KL/KS*-γ (with Prefilter)

## **Datasheet**

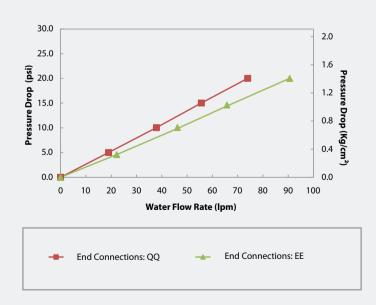
#### 8" Capsule Filters



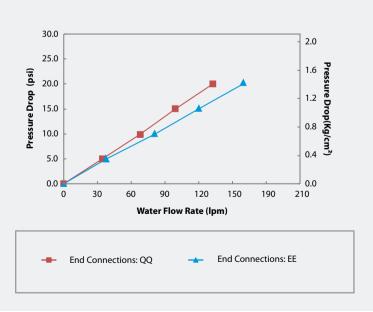




#### 10" Capsule Filters



#### 20" Capsule Filters



#### **End Connection Type:**

A: ¼" Stepped Hose Barb Q: ½" Single Step Hose Barb

E: 1½" Sanitary Flange

J: Quick Connector

S: ¾" Sanitary Flange

## **Datasheet**

## **Ordering Information**

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

Туре		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Х	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
IKL		25mm	06	0.2μm	01	Female Luer Lock	М	Yes	R		Non Sterile	1	100	04
( Single Layer )	IKLX			1		Male Luer Slip	N	No*	Х	]	Gamma Sterile	3		
IKS						1/8" Hose Barb	Н							
( 0.8 μm Upstream )	IKS5					1/4" Hose Barb B					1			
IKS (0.65 μm Upstream)	IKS3													
IKS (0.45 μm Upstream)	IKSX													
Example:		,	1		,	<b>\</b>			1	<b>\</b>	•			,
IKSX		0	6		01	MN		F	2	Х	1		0	4

<sup>\*</sup>Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: IKLX0601MNRX104

**Example for gamma Sterile: IKLX0601MNXX304** 

#### 0.2 $\mu$ m AseptiCap KL/KS- $\gamma$ 50mm PES Membrane Capsule filter

Type		Si	Size Pore Size		Size	Inlet/Outlet		Radiation Ste	rilizable	Х	Sterilit	у	Pack	Size
	Code		Code		Code		Code		Code			Code		Code
VKL		50mm	10	0.2µm	01	1/4" SHB	В	Yes	R	1 [	Non Sterile	1	10	02
( Single Layer )	VKLX				1	3/4" Sanitary Flange	S	No*	Х		Gamma Sterile	3		
VKS ( 0.8 μm Upstream )	VKS5										1			
VKS (0.65 μm Upstream)	VKS3													
VKS (0.45 μm Upstream)	VKSX													
Example:	<b>\</b>	•	,	•	1	<u></u>		<b>V</b>		<b>—</b>	<b>+</b>			1
VKSX		10	0	0	1	ВВ		R		х	1		0	2

<sup>\*</sup>Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: VKSX1001BBRX102 Example for gamma Sterile: VKSX1001BBXX302

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

Connections Available											
Inlet/Outlet	25mm	50mm									
1/4" - 3/4" Stepped Hose Barb	х	√									
3/4" Sanitary Flange	Х	√									
Female Luer Lock	Inlet Only	Х									
Male Luer Slip	Outlet Only	Х									
1/8" Hose Barb	√	Х									
Male Luer Lock	Outlet Only	Х									
1/4" Hose Barb	$\sqrt{}$	Х									

Pack Size Available										
Pack Size	25mm	50mm								
10/Pack	Х	$\sqrt{}$								
100/Pack	√	Х								

## **Datasheet**

## **Ordering Information**

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

Туре		Si	ze	Pore Size		Inlet/Outlet		Radiation Sterilizable		Ве	ell	II Sterility		Pack	k Size
	Code		Code		Code		Code		Code		Code		Code		Code
DKL	DKLX	1"	51	0.2μm	01	1⁄4" SHB	Α	Yes	R	Yes**	В	Non Sterile	1	1	01
( Single Layer )	DILLA	2"	52			1/4" MNPT (18 TPI)	В	No*	Х	No Bell	Х	Gamma Sterile	3		
DKS	DKS5	5″	53			1/4" BSP (19 TPI)	М			Bell with	С				
( 0.8 μm Upstream )	DIGG	8"	57			1/4" BSP (19 TPI) with O-ring	Р		I	cover		ı			
DKS	DKS3					1/4" BSP	F								
(0.65 µm Upstream)						½" MNPT	С								
DKS	DKSX					½" Hose Barb	D								
(0.45 μm Upstream)						1½" Sanitary Flange	Е								
I						¾" Sanitary Flange	S								
						Quick Connector	J								
						½" Single Step Hose Barb	Q								
						Female Luer Lock	U								
						Male Luer Slip	W								
						3/16" Hose Barb	N								
						3/8" Hose Barb	ı								
Example:		1		•	•	<b>+</b>		•		<b>\</b>	,	<b>\</b>		,	<b>\</b>
DKSX		!	57	(	<b>D1</b>	DD		F	3	Х	(	1		0	1

<sup>\*</sup> Gamma irradiated filters can not be gamma sterilized again

**Example for Non Sterile: DKLX5101QQRX101** 

Example for gamma Sterile: DKLX5101QQXX301

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

1/4" SHB outlet connection in 1" capsule filters only

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

Inlet/Outlet
1/4" Stepped Hose Barb
½" Single Step Hose Barb
½"Hose Barb
1½" Sanitary Flange
¾" Sanitary Flange
Quick Connector
½"MNPT
¼" MNPT (18TPI)
¼" BSP (19 TPI)
1/4" BSP (19 TPI) with O-ring
1/4" BSP
Female Luer Lock
Male Luer Slip
3/16" Hose Barb
3/8" Hose Barb

Size/Length								
1"	2"		5"	8″				
√	<b>√</b>		√	√				
х	<b>√</b>		√	√				
√	√		√	√				
√	<b>√</b>		√	$\sqrt{}$				
√	<b>√</b>		√	$\sqrt{}$				
√	√		√	√				
Х	<b>√</b>		√	√				
√	<b>√</b>		√	√				
Inlet Only	х		х	Х				
Inlet Only	х		Х	Х				
Inlet Only	<b>√</b>		√	$\sqrt{}$				
√	√		√	√				
Outlet Only	х		х	Х				
√	<b>V</b>		Outlet Only	Х				
Х	V		√	√				

Bell at outlet Available with (Size/outlet)						
1"/ 1/4" SHB						
1", 2", 5", 8"/ ½" HB						

<sup>\*\*</sup> Bell is available with

## **Ordering Information**

#### **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	LKS5	5″	53	0.2μm	01	1/2" Single Step Hose Barb	Q	Yes	R	Inline	Х	Non Sterile	1	1	01
( 0.8 μm Upstream )	LKSS	10"	54			1½" Sanitary Flange	E	No*	Х	T-Line**	Т	Gamma Sterile	3		
LKS	LKS3	20"	55	1		3/8" Hose Barb	3/8" Hose Barb		-		-				
(0.65 µm Upstream)	2.133	30"	56			1" Hose Barb	Z								
LKS	LKSX					1									
(0.45 μm Upstream)															
Example:															
	$\downarrow$	1	<b>V</b>	<b>\</b>		<b>\</b>		<b>\</b>		1	1	<b>\</b>			₩
	1											<u> </u>			
LKSX		5	54	0	1	EE		R			Т	1		0	1

<sup>\*</sup> Gamma irradiated filters can not be gamma sterilized again

**Example for Non Sterile: LKS55301QQRX101** 

Example for gamma Sterile: LKS55301QQXX301

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

Inlet/Outlet	
½" Single Step Hose Barb	
1½" Sanitary Flange	
3/8" Hose Barb	
1" Hose Barb	

	Inl	ine	T-Line				
5"	10"	20"	30"	10"	20"	30"	
√	$\sqrt{}$	√	$\sqrt{}$	х	х	х	
√	√	√	√	√	√	√	
√	√	√	$\sqrt{}$	х	х	х	
Х	√	√	√	х	х	х	

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<sup>\*\*</sup>T-line is not available in 5" Capsule filter

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