

Data Sheet

0.2μm *AseptiCap*[®] *KL/KS-*γ

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.

Management of A

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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

Gamma Compatible PES Membrane Devices

Datasheet

for Biopharmaceuticals

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

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 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 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- 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>

Performance Data

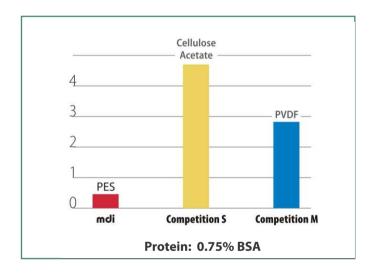
Datasheet

Low Protein Binding

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

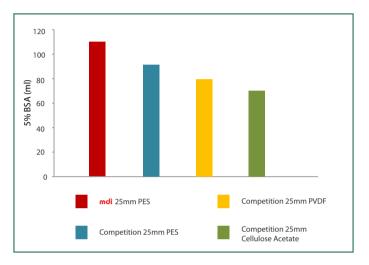
The low protein binding results in increased overall product yield and higher throughputs with biological streams.

Protein Binding (µg/cm²)



0.2 μm <i>AseptiCap®</i> Filters	Protein Binding
25 mm, 5 cm ²	1.45 µg
50 mm, 20 cm ²	6.3 µg
1″, 250 cm²	80.5 µg
2", 500 cm ²	175 µg
10″, 6000 cm²	1925 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
<i>AseptiCap®KL/KS-</i> γ 25mm	5cm ²	< 50µl
<i>AseptiCap®KL/KS-</i> γ 50mm	20cm ²	< 200µl
AseptiCap [®] KL/KS-γ 1"	250cm ²	< 5ml
AseptiCap® KL/KS-γ 2″	500cm ²	< 25ml
AseptiCap®KL/KS-γ 5″	1000cm ²	< 45ml
AseptiCap [®] KL/KS-γ 8″	2000cm ²	< 60ml



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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.

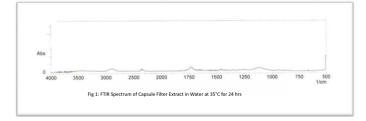
Low extractables mean less addition to impurity profile of the biological product from the filters.

Preconditioning: Gamma Irradiated at 50 kGy

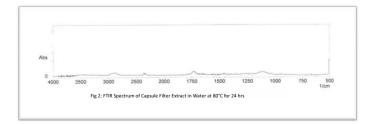
Extraction Time: 24 hours

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

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

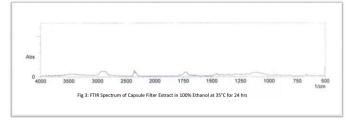


FTIR Analysis of Extractables From AseptiCap* KS- γ 1" Capsule Filter with Water @ 80 °C

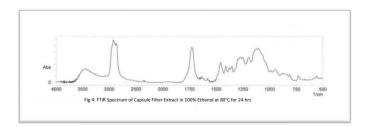


	Non Volatile Residue					
Model Solvent	AseptiCap® KS-γ 1″ (250 cm²)	AseptiCap® KS-γ 10" (6000 cm²)				
100% Ethanol @ 35 °C	13.4 mg	320.43 mg				

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 100% Ethanol @ 80 °C



The Spectrum of extracts from $AseptiCap^{\circ}KS-\gamma$ 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- γ filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

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



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



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



1/2" HB





3/8" Hose Barb



3/4" Sanitary Flange



¹/₂" Single Stepped Hose Barb



Quick Connector



Female Luer Lock



1" Hose Barb

Variety of end connections

1/2" MNPT

Male Luer Slip

1/4" MNPT



1¹/₂" Sanitary Flange





1¹/₂" 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*[®] *KL/KS-* γ filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to 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*^{\circ} *KL/KS*- γ filters there by reducing the additional validation cost and time.



AseptiCap[®] KL/KS-γ 25mm, 5cm²



AseptiCap[®] KL/KS-γ 50mm, 20cm²



AseptiCap[®] KL/KS-γ 1″, 250cm²



AseptiCap® KL/KS-γ 2", 500cm²



AseptiCap[®]*KL/KS-γ* 5″, 1000cm²



AseptiCap[®] *KL/KS*-γ 8″, 2000cm²

Filter Devices	EFA* (Nominal)	Hold up Volume
<i>AseptiCap®KL/KS-</i> γ 25 mm	5cm ²	< 50µl
<i>AseptiCap®KL/KS-</i> γ 50 mm	20cm ²	< 200µl
AseptiCap® KL/KS-ү 1″	250cm ²	< 5ml
AseptiCap® KL/KS-γ 2″	500cm ²	< 25ml
AseptiCap®KL/KS-γ 5″	1000cm ²	< 45ml
AseptiCap®KL/KS-γ 8″	2000cm ²	< 60ml
AseptiCap [®] KS-γ 5″	3000cm ²	< 80ml
AseptiCap [®] KS-γ 10"	6000cm ²	< 150ml
AseptiCap [®] KS-γ 20″	12000cm ²	< 250ml
AseptiCap [®] KS-γ 30″	18000cm ²	< 350ml



AseptiCap[®]*KL/KS*-γ 10″, 6000cm²

Specifications 0.2 μm *AseptiCap*[®] KL/KS-γ

Datasheet

	Construction						
Membrane	0.2 μm Hydrop	ohilic PES					
Upstream Membrane (in case of <i>AseptiCap® KS-</i> γ)	0.8 μm, 0.65μm or 0.45 μm Hydrophilic PES						
Plastic Parts	Parts Gamma Stable Polypropylene						
	Integrity Testing / Retention						
Bubble Point	\geq 50 psi (3.52 Kg/cm ²) with Water						
Microbial Retention	LRV >7 for Brevundimonas diminuta (ATCC 191	146) per cm ²					
	Size						
Size	25 mm	50 mm					
EFA (Effective Filtration Area)	5 cm ²	20 cm ²					
Operational Radius	15 mm	28 mm					
	Operational						
Max. Operating Temperature	55 °C	60 °C					
Max. Differential Pressure	75 psi (5 Kg/cm²) @ 25 °C	42 psi (3 Kg/cm²) @ 30 °C					
Sterilization By Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters should not be autoclaved or in-line	e steam sterilized.					
Shelf Life	2 years after gamma sterilization						
	Assurance						
Toxicity	Passes Biological Reactivity tests, In Vivo, as per	r USP <88> for Class VI plastics					
Cytotoxicity	Passes Biological Reactivity tests, In Vitro, USP	<87> for cytotoxicity					
Bacterial Retention	LRV> 7 for <i>B. diminuta</i> (ATCC 19146) per cm ² of	filter area as per ASTM F 838					
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as estab as per USP <85>	olished by Limulus Amebocyte Lysate (LAL) Test					
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 <6	43> 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						

Specifications 0.2 μm *AseptiCap*[®] KL/KS-γ

Datasheet

	Cor	nstruction				
Membrane		0.2 µm Hydrop	hilic PES			
Upstream Membrane (in case of <i>AseptiCap®KS-</i> γ)	0.8 μm, 0.65μm or 0.45 μm Hydrophilic PES					
Support Layers		Polyest	er			
Plastic Parts		Gamma Stable Po	lypropylene			
	Integrity Te	esting / Retention				
Bubble Point	<u>></u> 50psi (3.52Kg/cm²) w	vith Water				
Microbial Retention	LRV >7 for Brevundime	onas diminuta (ATCC 1914	16) per cm²			
		Size				
Size	1″	2″	5″	8″		
Effective Filtration Area (Nominal)	250cm ²	500cm ²	1000cm ²	2000cm ²		
Operational Radius (with Vent/ Drain)	40 mm	65 mm	65 mm	65 mm		
Vent and Drain	¹ ⁄4" Hose Barb with Silic	one "O" ring				
	0	perational				
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/o	cm²)				
Max. Differential Pressure	60 psi (4 Kg/cm²) @ 30	°C				
Sterilization By Gamma Irradiation	Gamma Irradiatable up These filters should no	to 50 kGy. t be autoclaved or in-line	steam sterilized.			
Shelf Life	2 years after gamma st	erilization				
	A	ssurance				
Toxicity	Passes Biological React	ivity tests, In Vivo, as per	USP <88> for Class VI pla	stics		
Cytotoxicity	Passes Biological React	ivity tests, In Vitro, USP <	87> for cytotoxicity			
Bacterial Retention	LRV> 7 for <i>B. diminuta</i> ((ATCC 19146) per cm ² of f	ilter area as per ASTM F 8	38		
Bacterial Endotoxin	Aqueous extracts exhib as per USP <85>	oit < 0.25 EU/ml as establ	ished by Limulus Amebo	cyte Lysate (LAL) Test		
Non Fiber Releasing	Passes test as per USP a	and comply with USFDA	21 CFR Part 210.3(b)(6) fo	r fiber release		
TOC and Conductivity	Meets the WFI requiren	nents of USP for TOC <64	3> and Conductivity <64	5> after a 3 liter flush		
pH Compatibility	Compatible with pH ra	nge 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					

Specifications 0.2 μm *AseptiCap*[®] KL/KS-γ

Datasheet

	Cons	truction						
Membrane		0.2 μm Hydroj	ohilic PES					
Upstream Membrane (in case of <i>AseptiCap® KS-</i> γ)		0.8 μm, 0.65μm or 0.45 μm Hydrophilic PES						
Support Layers		Polyest	er					
Plastic Parts		Gamma Stable Po	olypropylene					
	Integrity Tes	sting/Retention						
Bubble Point \geq 50psi (3.52Kg/cm ²) with Water								
Max. Air Diffusion Flows per 10" Capsule Filter	<u>≤</u> 30 ml/min @ 37 psi (2	.6 Kg/cm ²) with water						
Microbial Retention	LRV >7 for Brevundimor	nas diminuta (ATCC 1914	6) 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 Radius (with Vent/ Drain)	80 mm	80 mm	80 mm	80 mm				
Vent and Drain	¹ ⁄4" Hose Barb with Silico	one "O" ring						
	Ор	erational						
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/c	m²)						
Max. Differential Pressure	60 psi (4 Kg/cm ²) @ 30 °	°C						
Sterilization By Gamma Irradiation	Gamma Irradiatable up These filters should not	to 50 kGy. be autoclaved or in-line s	steam sterilized.					
Shelf Life	2 years after gamma ste	rilization						
	As	surance						
Toxicity	Passes Biological Reactiv	vity tests, In Vivo, as per l	JSP <88> for Class VI pla	astics				
Cytotoxicity	Passes Biological Reactive	vity tests, In Vitro, USP <8	37> for cytotoxicity					
Bacterial Retention	LRV> 7 for <i>B. diminuta</i> (<i>I</i>	ATCC 19146) per cm ² of fi	lter area as per ASTM F	838				
Bacterial Endotoxin	Aqueous extracts exhib as per USP <85>	it < 0.25 EU/ml as establi	shed by Limulus Amebo	ocyte Lysate (LAL) Test				
Non Fiber Releasing	Passes test as per USP a	nd comply with USFDA 2	1 CFR Part 210.3(b)(6) fo	or fiber release				
TOC and Conductivity		ents of USP for TOC <643 20 liter flush for 10″ caps		45> after a 10 liter flush				
pH Compatibility	Compatible with pH rar	nge of 1 - 10						
Extractables with WFI	Passes NVR test as per U	ISP <661>						
Indirect Food Additives	Comply with USFDA 21	CFR Part 177.1520						
Oxidizable Substances	Within limits as specifie	d in USP <1231>						
Quality Management System	ISO-9001 Certified							
USFDA	DMF No. 015554							

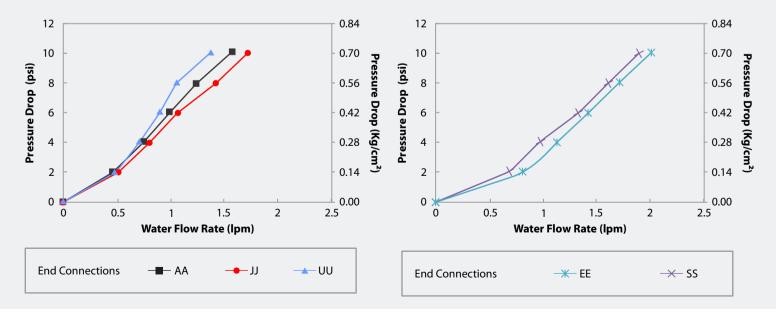
Typical Water Flow RatesDatasheet0.2 μm AseptiCap® KL/KS-γ (with Prefilter)

50mm Capsule Filters 25mm Capsule Filters 12.0 12.0 0.8 0.8 10.0 10.0 (isd) Press Pressure Drop (psi) 0.6 8.0 8.0 Pressure Drop ure Drop 6.0 6.0 0.4 4.0 4.0 (Kg/cm 0.2 2.0 2.0 0.0 0.0 0.0 0.0 0 200 50 100 150 20 40 0 60 80 100 Water Flow Rate (ml/min) Water Flow Rate (ml/min) End Connections: BB End Connections: MN

End Connection Type:

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

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



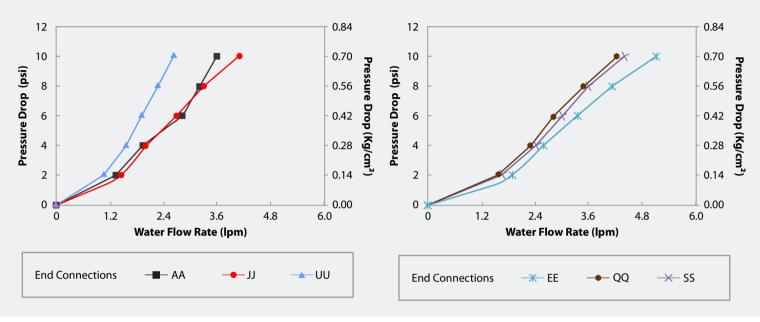
1"Capsule Filters

End Connection Type:

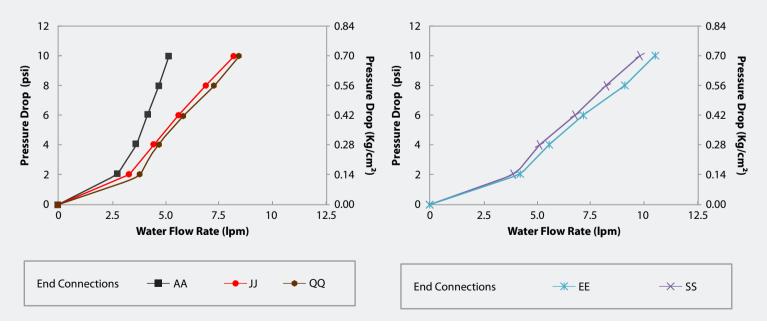
A: ¼" Stepped Hose Barb E: 1½" Sanitary Flange J: Quick Connector S: ¾" Sanitary Flange U: Female Luer Lock

Typical Water Flow RatesDatasheet0.2 μm AseptiCap® KL/KS-γ (with Prefilter)





5" Capsule Filters



End Connection Type:

A: ¹/₄" Stepped Hose Barb Q: ¹/₂" Sing U: Female Luer Lock

Q: 1/2" Single Step Hose Barb

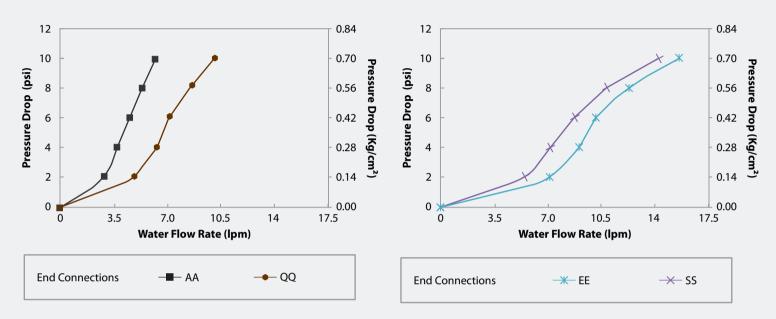
E: 1¹/₂" Sanitary Flange

J: Quick Connector

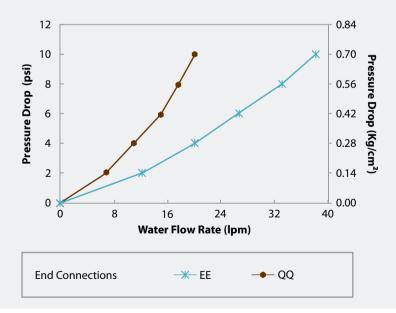
S: 34" Sanitary Flange

Typical Water Flow RatesDatasheet0.2 μm AseptiCap® KL/KS-γ (with Prefilter)

8" Capsule Filters



10" Capsule Filters



End Connection Type:

A: ¼" Stepped Hose Barb

Q: ½" Single Step Hose Barb

E: 1¹/₂" Sanitary Flange

J: Quick Connector

S: 34" Sanitary Flange

Ordering Information

Datasheet

0.2 μm *AseptiCap*[®] *KL/KS*-γ 25mm PES Membrane Capsule filter

Туре		Size		Pore Size		Inlet/Outlet		Inlet/Outlet		Inlet/Outlet		Radia Sterili		X	Sterilit	у	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					Male Luer Slip	N	No*	Х		Gamma Sterile	3						
IKS						1/8" Hose Barb	Н											
(0.8 µm Upstream)	IKS5					1/4" Hose Barb	В											
IKS (0.65 μm Upstream)	IKS3				·													
IKS (0.45 μm Upstream)	IKSX																	
Example:																		
IKSX		0	б	(01	MN		F	2	Х	1		04	4				

*Gamma irradiated filters can not be gamma sterilized again

0.2 μm *AseptiCap*[®] *KL/KS*-γ 50mm PES Membrane Capsule filter

Туре		Si	ze	Pore	Size	Inlet/Out	tlet	Radiation Ste	erilizable	X	Sterilit	у	Pack	Size
	Code		Code		Code		Code		Code			Code		Code
IKL (without Vent)		50mm	10	0.2µm	01	1⁄4″ SHB	В	Yes	R		Non Sterile	1	10	02
(Single Layer)	IKLX					³ ⁄ ₄ " Sanitary	S	No*	Х		Gamma Sterile	3		
IKS (without Vent) (0.8 μm Upstream)	IKS5					Flange Female								
IKS (without Vent) (0.65 µm Upstream)	IKS3					Luer Lock	М							
IKS (without Vent) (0.45 µm Upstream)	IKSX					¼" Single Step Hose Barb	A							
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	х	1	02

*Gamma irradiated filters can not be gamma sterilized again

Inlet/Outlet Connections Available

		501	mm
Inlet/Outlet	25mm	with Vent	without Vent
¹ / ₄ " - ³ / ₄ " Stepped Hose Barb	x	\checkmark	х
¾" Sanitary Flange	x	\checkmark	х
Female Luer Lock	Inlet Only	х	
Male Luer Slip	Outlet Only	х	х
1/8" Hose Barb	\checkmark	х	х
Male Luer Lock	Outlet Only	х	х
¼" Hose Barb	√	х	х
¼" Single Step Hose Barb	х	х	\checkmark

Dimension (Length) (in mm)

Inlet/ Outlet	25mm	50mm			
¼″ - ¾″ Stepped Hose Barb I/O	-	79			
¼" Hose Barb I/O	38	-			
¹ ⁄4" Single Step Hose Barb I/O	-	62			
¾" 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			
Operational Radius	15	28			

Ordering Information

Datasheet

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

Туре		Size Por		Pore Size		Inlet/Outlet		Radiation Sterilizable		t/Outlet Bell Sterility		Bell		Sterility		Pacl	k Size
	Code		Code		Code		Code	Code		Code			Code		Code		
DKL	DKLX	1″	51	0.2µm	01	1⁄4″ SHB	A	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)	0100	8″	57			¼" BSP (19 TPI) with O-ring	Р			cover							
DKS	DKS3					1⁄4″ BSP	F										
(0.65 µm Upstream)						1/2" MNPT	С										
DKS (0.45 μm Upstream)	DKSX					½" Hose Barb	D										
(0.45 µm Opstream)						1½" Sanitary Flange	E										
						³ 4" Sanitary Flange	S										
						Quick Connector	J										
						1/2" Single Step Hose Barb	Q										
						Female Luer Lock	U										
						Male Luer Slip	W										
						¾6″ Hose Barb	N										
						³⁄₀″ Hose Barb	I										
Example:						¼" Single Step Hose Barb	R										
DKSX			57	(01	DD		F	{	X	ζ	1		0	1		

* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: DKLX5101QQRX101

Example for gamma Sterile: DKLX5101QQXX301

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

Inlet/Outlet		Size/	Length		Bell at outlet Available with			
met/Outlet	1″	2″			(Size/outlet)			
/4" Stepped Hose Barb	√				1"/ ¼" SHB			
½" Single Step Hose Barb	x	√		√	1", 2", 5", 8"/ ½" HB			
⁄2"Hose Barb	√				Dimensions (in mm)		Small Ca	q
1½" Sanitary Flange	√				,		1	
¼" Sanitary Flange	√	√			End Connections	1″	2″	
Quick Connector	√		\checkmark		1/4" SHB I/O	94	122	
" MNPT	х		\checkmark		³ 4" Sanitary Flange Inlet I/O	85	104	
4″ MNPT (18TPI)	1		\checkmark		Quick Connector	100	113	
" BSP (19 TPI)	Inlet Only	Х	х	Х	1½" Sanitary Flange I/O	92	112	
4″ BSP (19 TPI) with O-ring	Inlet Only	х	х	х	¹ / ₂ " Hose Barb I/O	90	112	
4″BSP	Inlet Only					90	112	
emale Luer Lock	√				½" Single Step Hose Barb I/O	-	115	
Male Luer Slip	Outlet Only	x	x	X	1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	-	112	
‰" Hose Barb	\checkmark		Outlet Only	Х	3/8" Hose Barb I/O	-	115	
á" Hose Barb			\checkmark		¹ /4" Single Step Hose Barb I/O	90	106	
" Single Step Hose Barb	\checkmark		\checkmark	\checkmark	Operational Radius	40	65	

Ordering Information

Datasheet

0.2 μm *AseptiCap*[®] KS-γ PES Membrane Large Capsule filter

Туре		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline/ T-Line		Sterility		Pack	c 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)		10″	54			1½" Sanitary Flange	E	No*	Х	T-Line**	Т	Gamma Sterile	3		
LKS	LKS3	20″	55			³ ⁄ ₄ " Sanitary Flange	S								
(0.65 µm Upstream)		30″	56			¾" Hose Barb	Ι								
LKS (0.45 μm Upstream)	LKSX					1" Hose Barb	Z								

Example:

LKSX	54	01	EE	R	т	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 11/2" Sanitary Flange I/O Connections Only

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

Inline		ne		T-Line			Dimensions (in mm)	Inline Capsule Filters			ers	T-line Capsule Filters			
Inlet/Outlet		End Connections	5″	10″	20″	30″	10″	20″	30″						
1/ " Single Step Lless Barb	1	1	1	1	x	v	x	1½" Sanitary Flange I/O	205	330	600	855	340	580	840
¹ / ₂ " Single Step Hose Barb	V	N	N	N	×	X		³ ⁄ ₄ " Sanitary Flange I/O	214	335	х	х	х	х	x
1½" Sanitary Flange	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	½" Single Step Hose Barb I/O	218	336	630	890	x	х	x
³ 4" Sanitary Flange		\checkmark	х	х	х	х	х	1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334	620	870	x	х	x
³∕a″ Hose Barb					х	x	х	¾″ Hose Barb I/O	211	332	634	885	x	х	х
								1" Hose Barb I/O	х	405	635	895	х	х	х
1" Hose Barb	Х	\checkmark		\checkmark	Х	X X	Operational Radius	80	80	80	80	80	80	80	

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