

## AseptiPrime<sup>®</sup> KS

### Taking Throughput to the next level Sterile filtration with upto 3x smaller filter area

DATASHEET

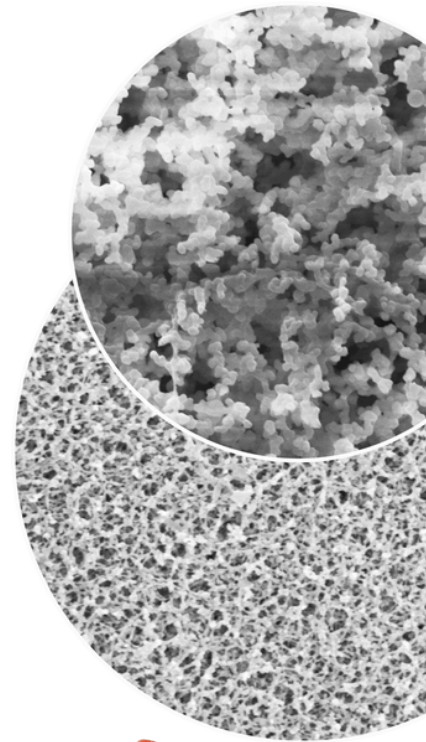
Bio-pharmaceutical manufacturing is a complex, multistep process which involves a very wide variety of process streams under different process conditions at different steps. These process streams include cell culture media, media additives, growth regulators in the upstream and post centrifuge cell harvest supernatants, post viral inactivation intermediates, buffers, and high value product concentrates in the downstream. Filtration and purification of such a wide spectrum of fluid streams, to achieve varied objectives at each step, is quite a challenge for the process owner.

Microfiltration accounts for a very high (approximately 25%) of the filtration and purification costs. Sterilizing filters are a huge component of this cost as these are critical for multiple applications across the entire biopharmaceutical process. Some of these are :

- Sterile filtration of culture media and product concentrates
- Protection of expensive virus filters and chromatography columns
- Control of microbial load throughout the process chain

There is therefore a continuous need to enhance the throughput obtained from 0.2µm/0.1µm filters with various process streams.

DST DKXLKXX2325F



AseptiPrime<sup>®</sup> KS is designed to fulfil the above need. These low protein binding filters, incorporate a very high porosity optimized pre-filter PES membrane with unique pore structure that ensures high loading capacity for suspended contaminants and high volume handling. This results in much higher throughput when compared with other available sterilizing filters.

The robust, highly retentive final membrane layer ensures that AseptiPrime<sup>®</sup> KS filters meet international regulatory requirements for microbial retention and deliver sterile filtrate.

AseptiPrime<sup>®</sup> KS capsule filters offer additional advantages of 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 connectivity to the existing fittings.

AseptiPrime<sup>®</sup> KS capsule filters use MDI PES membrane in 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. AseptiPrime<sup>®</sup> KS are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities. Packaging is done in double polybags for convenience of taking AseptiPrime<sup>®</sup> KS in clean areas for making disposable assemblies for subsequent sterilization.

## 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

- Very high throughput
- Absolute retention
- 100% integrity tested
- Low protein binding
- Very low hold up volume in filters
- High flow rates
- 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 Autoclaving or Ethylene Oxide

## 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.

# Performance Data

## High Throughputs

MDI *AseptiPrime*<sup>®</sup> KS filter consistently outperformed other available sterilizing filters by exhibiting much higher throughput with a wide variety of fluid streams.

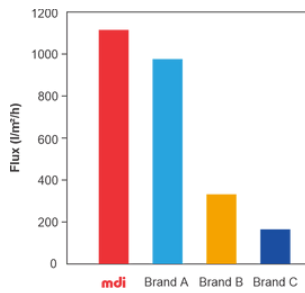
The large throughput difference allows use of filters with much smaller filter area and enhance process economy.

Also, optimized filter sizes do away with the possibilities of mid batch change out of filters or having to isolate a complete batch because it could not be processed.

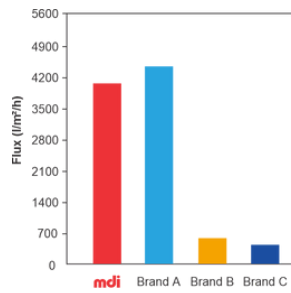
## Protein Adsorption

*AseptiPrime*<sup>®</sup> KS filters are validated for low protein binding to ensure minimal active ingredient losses when used for filtration of high value proteins.

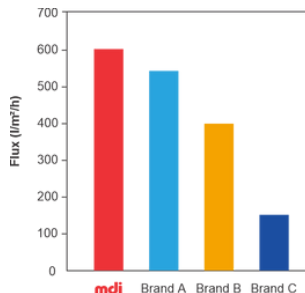
0.2 μm <i>AseptiPrime</i> <sup>®</sup> Filters	Protein Binding (0.75% BSA)
25 mm, 5 cm <sup>2</sup>	1.45 μg
50 mm, 20 cm <sup>2</sup>	6.3 μg
1", 250 cm <sup>2</sup>	80.5 μg
2", 500 cm <sup>2</sup>	175 μg
10", 6000 cm <sup>2</sup>	1925 μg



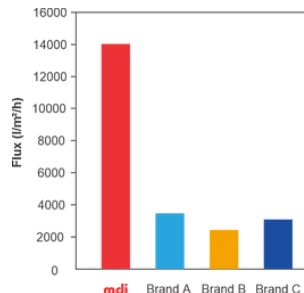
Soy Media



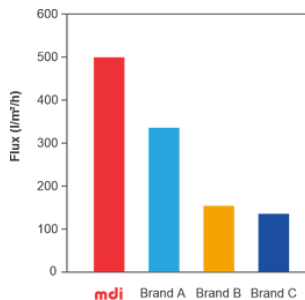
RPMI



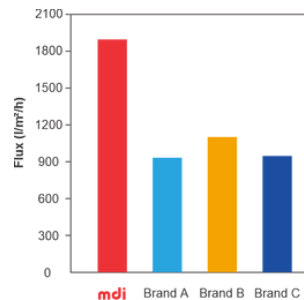
Yeast Peptone Dextrose



Luria Bertani



6M Urea



6M Guanidine HCl

# 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.

## Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention with *Acholeplasma laidlawii* (ATCC 23206) and 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 *AseptiPrime*<sup>®</sup> KS is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

## 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 as per USP <85>.

## 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.

## Flow Rate

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

## Pressure, Temperature Endurance

*AseptiPrime*<sup>®</sup> KS 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. *AseptiPrime*<sup>®</sup> KS filters are validated to exhibit low extractables under harsh extraction conditions.

## Total Traceability

*AseptiPrime*<sup>®</sup> KS 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

*AseptiPrime*<sup>®</sup> KS 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 indirect food additives
- 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>

# Linear Upscaling from R&D to Production Process

DATASHEET

DST DKXLKXX2325F

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 *AseptiPrime*<sup>®</sup> KS 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 18000 cm<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 *AseptiPrime*<sup>®</sup> KS filters there by reducing the additional validation cost and time.



*AseptiPrime*<sup>®</sup> KS  
25mm, 5 cm<sup>2</sup>



*AseptiPrime*<sup>®</sup> KS  
50mm, 20 cm<sup>2</sup>



*AseptiPrime*<sup>®</sup> KS  
1", 250 cm<sup>2</sup>



*AseptiPrime*<sup>®</sup> KS  
2", 500 cm<sup>2</sup>



*AseptiPrime*<sup>®</sup> KS  
5", 1000 cm<sup>2</sup>



*AseptiPrime*<sup>®</sup> KS  
8", 2000 cm<sup>2</sup>



*AseptiPrime*<sup>®</sup> KS  
10", 6000 cm<sup>2</sup>



*AseptiPrime*<sup>®</sup> KS  
20", 12000 cm<sup>2</sup>



*AseptiPrime*<sup>®</sup> KS  
30", 18000 cm<sup>2</sup>

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

\*EFA: Effective Filtration Area

# 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 *AseptiPrime*<sup>®</sup> KS 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 dimensional 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 EO sterilization and autoclaving.

## Customized Connectivity

MDI *AseptiPrime*<sup>®</sup> KS 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.



1/2" HB



1/2" Single Stepped  
Hose Barb



1/4" SHB



Quick Connector



3/4" Sanitary  
Flange



1 1/2" Sanitary  
Flange

Variety of end connections



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



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



*AseptiPrime*<sup>®</sup> with HighSecurity  
1/2" hose barb connection

# Specifications

Construction				
Membrane	0.1µm/0.2µm Hydrophilic PES			
Pre-filter Membrane	<b>0.1µm:</b> 0.3µm or 0.5µm PES <b>0.2µm:</b> 0.5µm PES			
Support Layers	Polyester			
Plastic Parts	Polypropylene			
Integrity Testing/ Retention				
Bubble Point	<b>0.1µm:</b> ≥ 26 psi (1.82 Kg/cm <sup>2</sup> ) with 50% IPA ≥ 65 psi (4.56 Kg/cm <sup>2</sup> ) with Water <b>0.2µm:</b> ≥ 50 psi (3.52 Kg/cm <sup>2</sup> ) with Water			
Max. Air Diffusion Flows per 10" Capsule Filter	<b>0.1µm:</b> ≤ 29 ml/min @ 50 psi (3.52 Kg/cm <sup>2</sup> ) with water <b>0.2µm:</b> ≤ 30 ml/min @ 37 psi (2.6 Kg/cm <sup>2</sup> ) with water			
Microbial Retention	<b>for 0.1µm:</b> LRV > 7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm <sup>2</sup> <b>for 0.2µm:</b> LRV > 7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm <sup>2</sup>			
Operational				
Sterilization	<b>By Autoclave:</b> Autoclavable at 125°C for 30 minutes, 3 cycles and it cannot be in-line steam sterilized <b>By Gas:</b> Sterilizable by Ethylene Oxide			
Shelf Life	3 years after EO Sterilization			
Size	25 mm	50 mm	1", 2", 5", 8"	5", 10", 20", 30"
Max. Operating Temperature	55 °C	60 °C	80 °C @ < 30 psi (2 Kg/cm <sup>2</sup> )	
Max. Differential Pressure	75 psi (5 Kg/cm <sup>2</sup> ) @ 25 °C	42 psi (3 Kg/cm <sup>2</sup> ) @ 30 °C	60 psi (4 Kg/cm <sup>2</sup> ) @ 30 °C	
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 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 5 liter flush for 5" capsule filters and 10 liter 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	Passes test as per USP <1231>			
Quality Management System	ISO-9001 Certified			
USFDA	DMF No. 015554			

# Dimensions

## Disc Capsule Filters

Size	25mm	50mm
Effective Filtration Area (cm <sup>2</sup> )	5	20
End Connections	End to End Length	
1/4" SHB I/O	-	79 mm
3/4" Sanitary Flange I/O	-	51 mm
Female Luer Lock Inlet/ Male Luer Slip Outlet	23 mm	-
1/8" Hose Barb I/O	36 mm	-
Operational Radius	15 mm	28 mm

## Small Capsule Filters

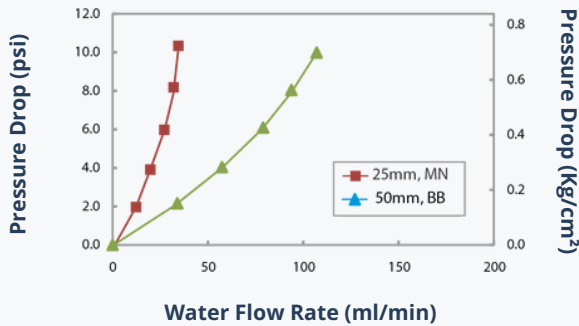
Size	1"	2"	5"	8"
Effective Filtration Area(cm <sup>2</sup> )	250	500	1000	2000
End Connections	End to End Length			
1/4" SHB I/O	94 mm	122 mm	172 mm	223 mm
3/4" Sanitary Flange Inlet I/O	85 mm	104 mm	155 mm	206 mm
1½" Sanitary Flange I/O	92 mm	112 mm	165 mm	216 mm
½" Hose Barb I/O	90 mm	112 mm	162 mm	214 mm
½" Single Step Hose Barb I/O	-	115 mm	165 mm	218 mm
1½" Sanitary Flange Inlet 1/2" Hose Barb Outlet	-	112 mm	165 mm	216 mm
Operational Radius	40 mm	65 mm	65 mm	65 mm

## Large Capsule Filters

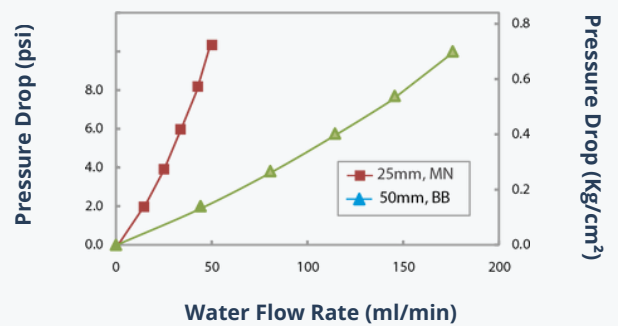
Size	5"	10"	20"	30"
Effective Filtration Area (cm <sup>2</sup> )	3000	6000	12000	18000
End Connections	End to End Length			
1½" Sanitary Flange I/O	205 mm	326 mm	605 mm	865 mm
½" Single Step Hose Barb I/O	218 mm	332 mm	628 mm	888 mm
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212mm	332 mm	618 mm	878 mm
3/8" Hose Barb I/O	211mm	332 mm	634 mm	885 mm
¾" Sanitary Flange I/O	214 mm	335 mm	x	x
Operational Radius	78 mm	78 mm	78 mm	78 mm

# Typical Water Flow Rates

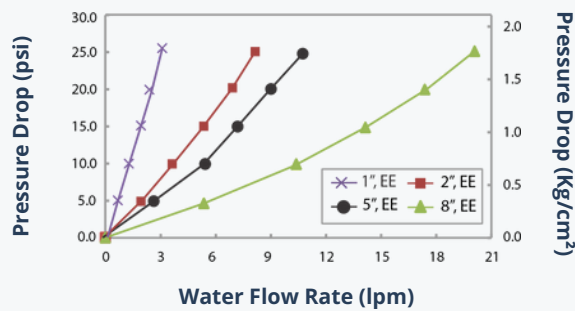
**0.1µm AseptiPrime® KS**  
25mm and 50 mm capsule filter



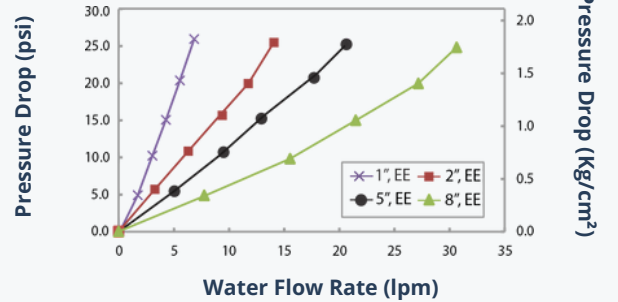
**0.2µm AseptiPrime® KS**  
25mm and 50 mm capsule filter



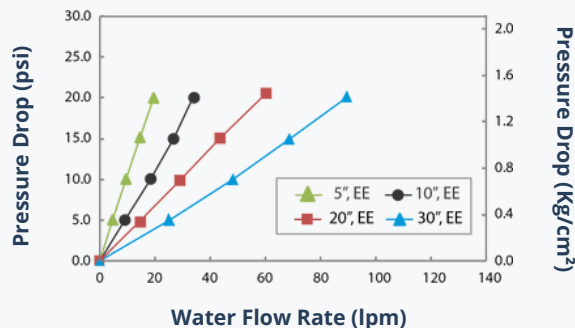
**0.1µm AseptiPrime® KS**  
1", 2", 5" and 8" Capsule Filters



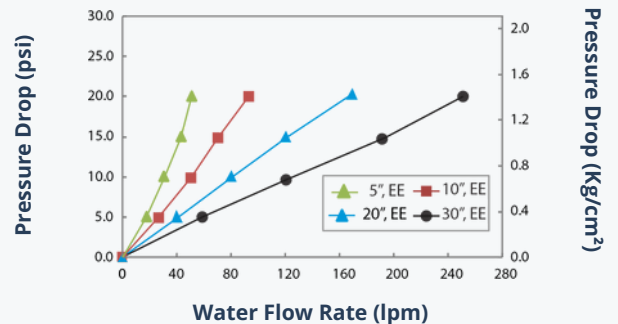
**0.2µm AseptiPrime® KS**  
1", 2", 5" and 8" Capsule Filters



**0.1µm AseptiPrime® KS**  
5", 10", 20" and 30" Capsule Filters



**0.2µm AseptiPrime® KS**  
5", 10", 20" and 30" Capsule Filters



**End Connection Type:**

**E:** 1½" Sanitary Flange **B:** ¼" Stepped Hose Barb (for 50mm only)

**MN:** Female Luer Lock Inlet/Male Luer Slip Outlet

# Ordering Information

## AseptiPrime® KS 25mm PES Membrane Inline Capsule Filters

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack size	
	Code		Code		Code		Code				Code		Code
AseptiPrime® KS (0.3µm optimized pre-filter)	IKX9	25 mm	06	0.1 µm	36	Female Luer Lock	M			Non Sterile	1	100	04
AseptiPrime® KS (0.5µm optimized pre-filter)	IKX7			0.2 µm*	01	Male Luer Slip	N			EO Sterile	2		
						1/8" Hose Barb	H						
						1/4" Hose Barb	B						

**Example:**

IKX7	06	01	MN	X	X	1	04
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\* 0.2µm capsule filters are available with 0.5µm pre-filter only

Example for Non Sterile: IKX70601MNXX104

Example for EO Sterile: IKX70601MNXX204

## AseptiPrime® KS 50mm PES Membrane Inline Capsule Filters

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
AseptiPrime® KS (0.3µm optimized pre-filter)	VKX9	50 mm	10	0.1 µm	36	1/4" SHB	B			Non Sterile	1	10	02
AseptiPrime® KS (0.5µm optimized pre-filter)	VKX7			0.2 µm*	01	3/4" Sanitary Flange	S			EO Sterile	2		
						Female Luer Lock	M						

**Example:**

VKX7	10	01	BB	X	X	1	02
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\* 0.2µm capsule filters are available with 0.5µm pre-filter only

Example for Non Sterile: VKX71001BBXX102

Example for EO Sterile: VKX71001BBXX202

**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	X	✓
3/4" Sanitary Flange	X	✓
Female Luer Lock	Inlet Only	✓
Male Luer Slip	Outlet Only	X
1/8" Hose Barb	✓	X
Male Luer Lock	Outlet Only	X
¼" Hose Barb	✓	X

Pack Size Available		
Pack Size	25 mm	50 mm
10/Pack	X	✓
100/Pack	✓	X

# Ordering Information

## AseptiPrime® KS PES Membrane Small Capsule Filters

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
AseptiPrime® KS (0.3µm optimized pre-filter)	DKX9	1"	51	0.1µm	36	¼" SHB	A			Non Sterile	1	1	01
		2"	52	0.2 µm*	01	¼" MNPT (18 TPI)	B			EO Sterile	2		
		5"	53			¼" BSP (19 TPI)	M						
		8"	57			¼" BSP (19 TPI) with O-ring	P						
¼" BSP	F												
AseptiPrime® KS (0.5µm optimized pre-filter)	DKX7					½" MNPT	C						
						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						
						3/16" Hose Barb	N						
						¾" Hose Barb	I						
				¼" Single Step Hose Barb	R								

**Example:**

DKX7	57	01	DD	X	X	1	01
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Example for Non Sterile: DKX75101QQXX101

Example for EO Sterile: DKX75101QQXX201

\* 0.2µm capsule filters are available with 0.5µm pre-filter only

**Inlet/Outlet Connections Available**

Inlet/Outlet	Size/Length			
	1"	2"	5"	8"
1/4" 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
3/16" Hose Barb	✓	✓	Outlet Only	X
3/8" Hose Barb	✓	✓	✓	✓
¼" Single Step Hose Barb	✓	✓	✓	✓

# Ordering Information

## AseptiPrime® KS PES Membrane Large Capsule Filters

Type		Size		Pore Size		Inlet/Outlet		X	Inline/ T-Line		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
AseptiPrime® KS (0.3µm optimized pre-filter)	LKX9	5"	53	0.1µm	36	½" Single Step Hose Barb	Q		X		Non Sterile	1	1	01
		10"	54	0.2 µm*	01						EO Sterile	2		
		20"	55											
AseptiPrime® KS (0.5µm optimized pre-filter)	LKX7	30"	56			1½" Sanitary Flange	E							
						¾" Sanitary Flange	S							
						⅝" Hose Barb	I							
						1" Hose Barb	Z							

### Example:

LKX7	54	01	EE	X	T	1	01
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Example for Non Sterile: LKX75301QQXX101

Example for EO Sterile: LKX75301QQXX201

\* 0.2µm capsule filters are available with 0.5µm pre-filter only

### Inlet/Outlet Connections Available

Inlet/Outlet	Inline				T-Line		
	5"	10"	20"	30"	10"	20"	30"
½" Single Step Hose Barb	✓	✓	✓	✓	X	X	X
1½" Sanitary Flange	✓	✓	✓	✓	✓	✓	✓
¾" Sanitary Flange	✓	✓	X	X	X	X	X
⅝" Hose Barb	✓	✓	✓	✓	X	X	X
1" Hose Barb	X	✓	✓	✓	X	X	X



### CORPORATE OFFICE

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