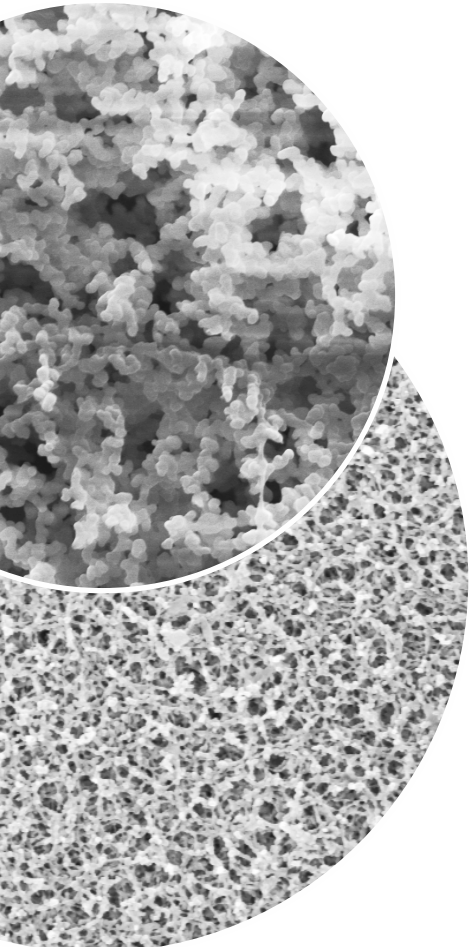


AseptiPrime® KSO

Taking Throughput to the next level

Sterile filtration with upto 3x smaller filter area



AseptiPrime® KSO 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® KSO filters meet international regulatory requirements for microbial retention and deliver sterile filtrate.

AseptiPrime® KSO 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.

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.



mdi
Membrane Technologies

AseptiPrime® KSO

High Throughput Sterilizing Filters

AseptiPrime® KSO 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® KSO are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities.

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 EO 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.

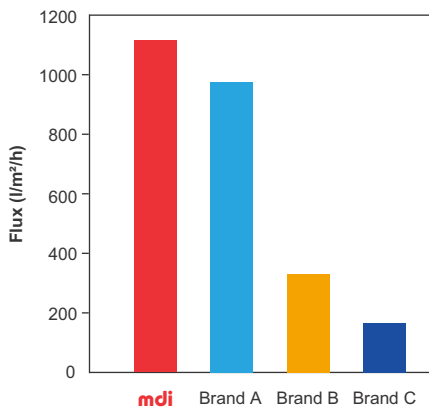
Performance Data

High Throughputs

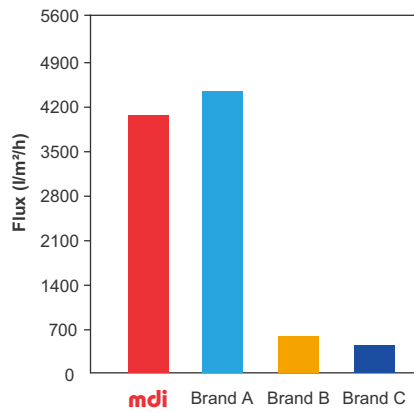
mdi AseptiPrime® KSO filter consistently outperformed other available sterilizing filters by exhibiting much higher throughput with a wide variety of fluid streams.

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

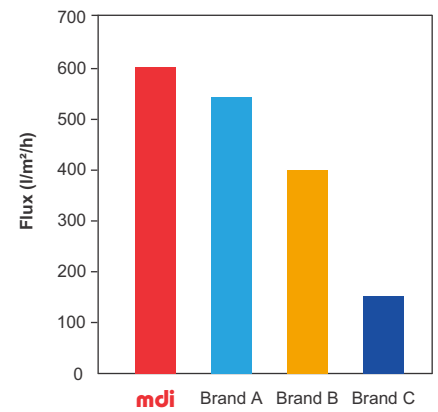
Also, optimized filter sizes do away with the possibilities of mid batch change out of filters or having to isolate a complete batch because it could not be processed.



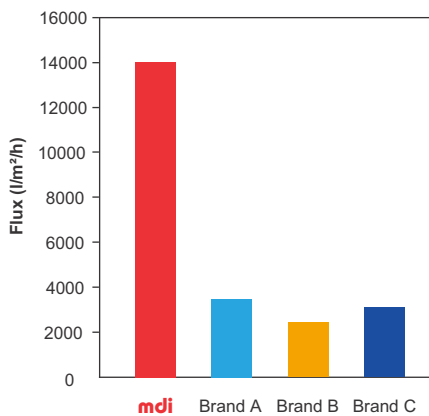
Soy Media



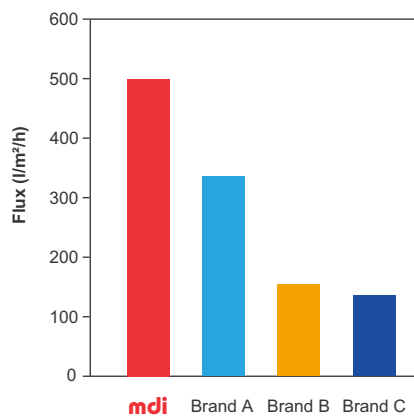
RPMI



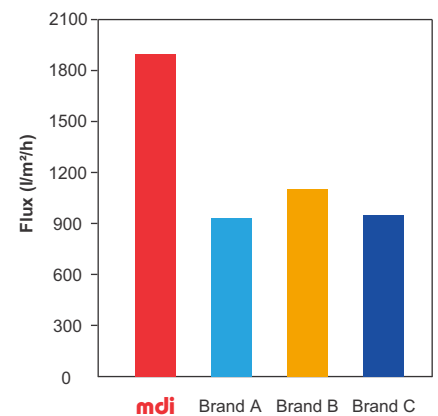
Yeast Peptone Dextrose



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.

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 *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*® KSO filter 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.

Protein Adsorption

AseptiPrime® KSO 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> ® Filters	Protein Binding (0.75% BSA)
25 mm, 5 cm ²	1.45 µg
50 mm, 20 cm ²	6.3 µg
1', 250 cm ²	80.5 µg
2', 500 cm ²	175 µg
10', 6000 cm ²	1925 µg

Pressure, Temperature Endurance

AseptiPrime® KSO 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® KSO 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 as per USP <85>

Total Traceability

AseptiPrime® KSO 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® KSO 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 and Biological Reactivity Tests, In-vitro, USP <87> for cytotoxicity**

Linear Upscaling from R&D to Production Process

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*[®] KSO 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 18000cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *AseptiPrime*[®] KSO filters there by reducing the additional validation cost and time.



AseptiPrime[®] KSO
25mm, 5cm²



AseptiPrime[®] KSO
50mm, 20cm²



AseptiPrime[®] KSO
1", 250cm²



AseptiPrime[®] KSO
2", 500cm²



AseptiPrime[®] KSO
5", 1000cm²



AseptiPrime[®] KSO
8", 2000cm²



AseptiPrime[®] KSO
10", 6000cm²



AseptiPrime[®] KSO
20", 12000cm²



AseptiPrime[®] KSO
30", 18000cm²

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

*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*® KSO 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 gamma irradiation, EO sterilization and autoclaving.



3/4" Sanitary Flange



1 1/2" Sanitary Flange



1/2" Hose Barb



1/2" Single Stepped Hose Barb



1/4" Stepped Hose Barb



Quick Connector

Some end connections available with *AseptiPrime* KSO

Customized Connectivity

mdi *AseptiPrime*® KSO 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**



***AseptiPrime* with High Security
1/2" hose barb connection**

Specifications

Construction

Membrane	0.1µm/0.2 µm Hydrophilic PES
Pre-filter Membrane	0.1µm: 0.3µm or 0.5µm PES 0.2µm: 0.5µm PES
Support Layers	Polypropylene
Plastic Parts	Polypropylene

Integrity Testing / Retention

Bubble Point	0.1µm: ≥ 31 psi (2.18Kg/cm ²) with 50% IPA/Water Solution 0.2µm: ≥ 50 psi (3.52 Kg/cm ²) with Water
Max. Air Diffusion Flows per 10" Capsule Filter	0.1µm: ≤ 29 ml/min @ 50 psi (3.52 Kg/cm ²) with water 0.2µm: ≤ 30 ml/min @ 37 psi (2.6 Kg/cm ²) with water
Microbial Retention	for 0.1µm: LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per cm ² for 0.2µm: LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²

Operational

Sterilization	By Gas: Sterilization by Ethylene Oxide Autoclave: Autoclavable at 125°C for 30 minutes, 3 cycles. Can not be in-line steam sterilized
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	Inline Capsule Filters		Small Capsule Filters	Large Capsule Filters
	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 ²)	
Max. Differential Pressure	75 psi (5 Kg/cm ²) @ 25 °C	42 psi (3 Kg/cm ²) @ 30 °C	60 psi (4 Kg/cm ²) @ 30 °C	

Assurance

Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity Tests, In vitro, USP <87> for Cytotoxicity
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 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 specified WFI flush
pH Compatibility	Compatible with pH range of 1-14
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 (cm²)	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
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Small Capsule Filters

Size	1"	2"	5"	8"
Effective Filtration Area (cm²)	250	500	1000	2000
End Connections	End to End Length			
¼" SHB I/O	94 mm	122 mm	172 mm	223 mm
¾" Sanitary Flange Inlet I/O	85 mm	104 mm	155 mm	206 mm
1½" Sanitary Flange I/O	92 mm	112 mm	164 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 ½" Hose Barb Outlet	-	112 mm	165 mm	216 mm

Operational Radius	40 mm	65 mm	65 mm	65 mm
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Large Capsule Filters

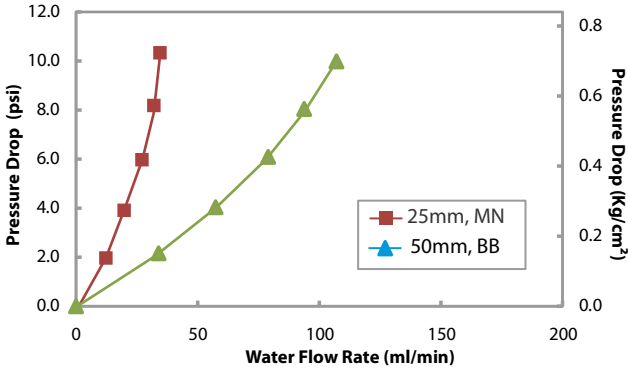
Size	5"	10"	20"	30"
Effective Filtration Area (cm²)	3000	6000	12000	18000
End Connections	End to End Length			
1½" Sanitary Flange I/O	205 mm	330 mm	600 mm	855 mm
½" Single Step Hose Barb I/O	218 mm	336 mm	630 mm	890 mm
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212 mm	334 mm	620 mm	870 mm
3/8" Hose Barb I/O	211 mm	332 mm	634 mm	885 mm
¾" Sanitary Flange I/O	214 mm	335 mm	x	x

Operational Radius	80 mm	80 mm	80 mm	80 mm
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Typical Water Flow Rates

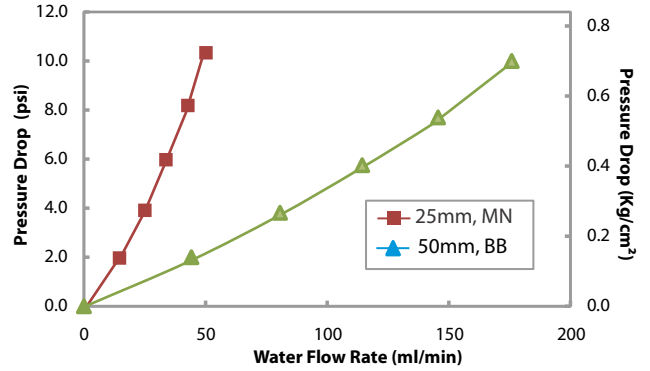
0.1µm AseptiPrime® KSO

25mm and 50mm Inline Capsule Filter



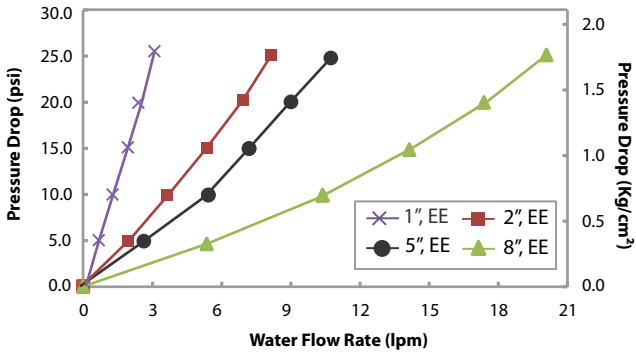
0.2µm AseptiPrime® KSO

25mm and 50mm Inline Capsule Filter



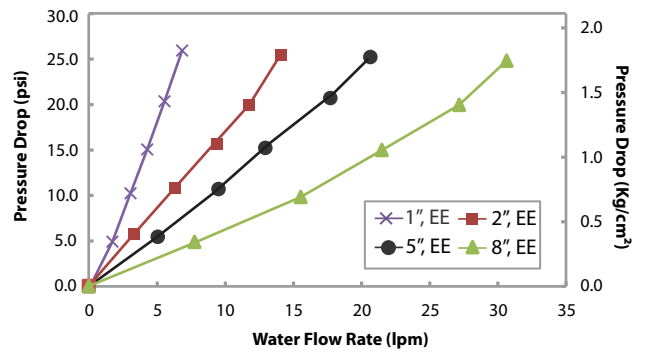
0.1µm AseptiPrime® KSO

1", 2", 5" and 8" Small Capsule Filters



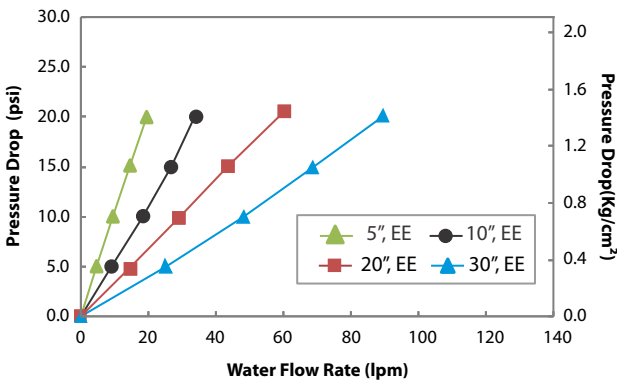
0.2µm AseptiPrime® KSO

1", 2", 5" and 8" Small Capsule Filters



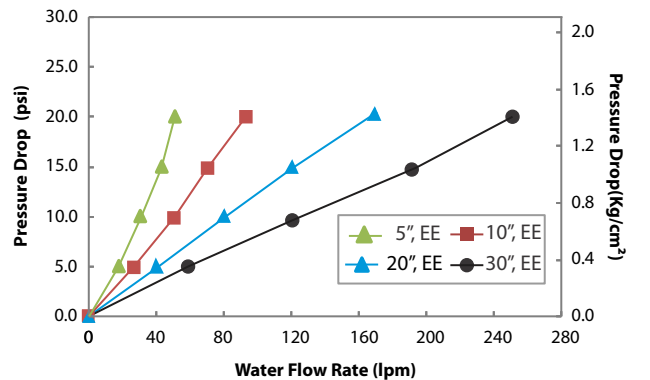
0.1µm AseptiPrime® KSO

5", 10", 20" and 30" Large Capsule Filters



0.2µm AseptiPrime® KSO

5", 10", 20" and 30" Large Capsule Filters



End Connection Type:

E: 1½" Sanitary Flange

B: ¼" Stepped Hose Barb (for 50mm only)

MN: End Connections: Female Luer Lock Inlet/Male Luer Slip Outlet

Ordering Information

AseptiPrime® KSO 25mm PES Membrane Inline Capsule filters

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
AseptiPrime® KSO (0.3µm optimized pre-filter)	IKO9	25mm	06	0.1µm	36	Female Luer Lock	M			Non Sterile	1	100	04
AseptiPrime® KSO (0.5µm optimized pre-filter)	IKO7			0.2µm*	01	Male Luer Slip	N			EO Sterile	2		
						1/8" Hose Barb	H						
						1/4" Hose Barb	B						

Example:

IKO7	06	01	MN	X	X	1	04
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*0.2µm capsule filters are available with 0.5µm pre-filter only

AseptiPrime® KSO 50mm PES Membrane Inline Capsule filters

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
AseptiPrime® KSO (0.3µm optimized pre-filter)	VKO9	50mm	10	0.1µm	36	1/4" SHB	B			Non Sterile	1	10	02
AseptiPrime® KSO (0.5µm optimized pre-filter)	VKO7			0.2µm*	01	3/4" Sanitary Flange	S			EO Sterile	2		
						Female Luer Lock	M						

Example:

VKO7	10	01	BB	X	X	1	02
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*0.2µm capsule filters are available with 0.5µm pre-filter only

Note: Inlet/Outlet Connections and Dimensions as follows:

Connections Available	Dimension (in mm)		Inline Capsule Filters		
	Inlet/Outlet	25mm	50mm	25mm	50mm
1/4" - 3/4" Stepped Hose Barb		X	√	-	79
3/4" Sanitary Flange		X	Outlet Only	38	-
Female Luer Lock	Inlet Only		√	-	51
Male Luer Slip	Outlet Only		X	23	-
1/8" Hose Barb		√	X	36	-
Male Luer Lock	Outlet Only		X		
1/4" Hose Barb		√	X	15	28

Ordering Information

AseptiPrime® KSO PES Membrane Small Capsule filters

Type		Size		Pore Size		Inlet/Outlet		X	Bell		Sterility		Pack Size			
	Code		Code		Code		Code			Code		Code		Code		
AseptiPrime® KSO (0.3µm optimized pre-filter)	DKO9	1"	51	0.1µm	36	¼" SHB	A		Yes	B	Non Sterile	1	1	01		
		2"	52	0.2µm*	01	¼" MNPT (18 TPI)	B		No Bell	X	EO Sterile	2				
		5"	53			¼" BSP (19 TPI)	M		Bell with cover	C						
AseptiPrime® KSO (0.5µm optimized pre-filter)	DKO7	8"	57			¼" BSP (19 TPI) with O-ring	P									
						¼" BSP	F									
						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									
						3/8" Hose Barb	I									

Example: DKO7 57 01 DD X X 1 01

* 0.2µm capsule filters are available with 0.5µm pre-filter 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
3/8" 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

Ordering Information

AseptiPrime® KSO 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® KSO (0.3µm optimized pre-filter)	LKO9	5"	53	0.1µm	36	½" Single Step Hose Barb	Q	X	Inline	X	Non Sterile	1	1	01
		10"	54	0.2µm*	01	1½" Sanitary Flange	E		T-Line	T	EO Sterile	2		
		20"	55			¾" Sanitary Flange	S							
AseptiPrime® KSO (0.5µm optimized pre-filter)	LKO7	30"	56			3/8" Hose Barb	I							
						1" Hose Barb	Z							

Example:

LKO7	54	01	EE	X	T	1	01
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* 0.2µm capsule filters are available with 0.5µm pre-filter 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"	End Connections	5"	10"	20"	30"	10"	20"	30"	
½" Single Step Hose Barb	√	√	√	√	X	X	X	1½" Sanitary Flange I/O	205	330	600	855	340	580	840	
1½" Sanitary Flange	√	√	√	√	√	√	√	¾" Sanitary Flange I/O	214	335	x	x	x	x	x	
¾" Sanitary Flange	√	√	X	X	X	X	X	½" Single Step Hose Barb I/O	218	336	630	890	x	x	x	
¾" Hose Barb	√	√	√	√	X	X	X	1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334	620	870	x	x	x	
1" Hose Barb	X	√	√	√	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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