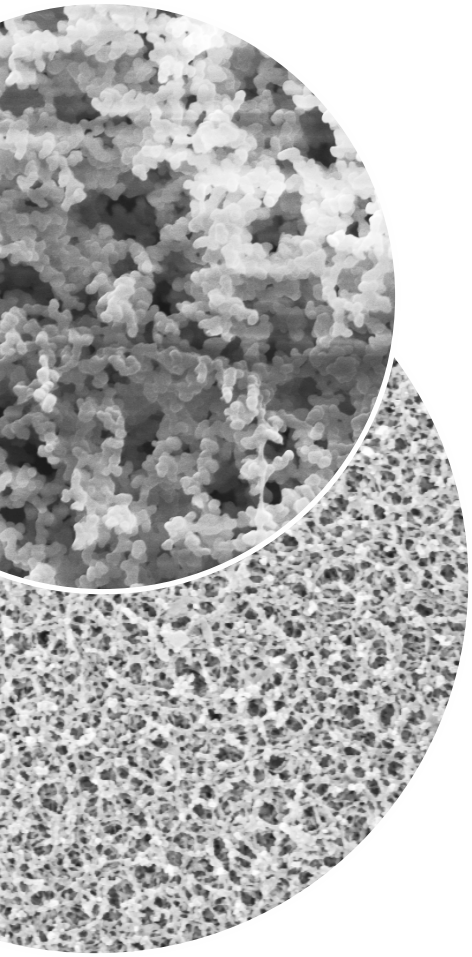


AseptiPrime KS-γ

Taking Throughput to the next level

Sterile filtration with upto 3x smaller filter area

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.

AseptiPrime KS-γ is designed to fulfil the above need. These gamma sterilizable 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 KS-γ* filters meet international regulatory requirements for microbial retention and deliver sterile filtrate.

AseptiPrime KS-γ 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.

mdi
Membrane Technologies

AseptiPrime KS-γ

High Throughput Sterilizing Filters

AseptiPrime KS-γ 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. *AseptiPrime 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 *AseptiPrime KS-γ* 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 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.

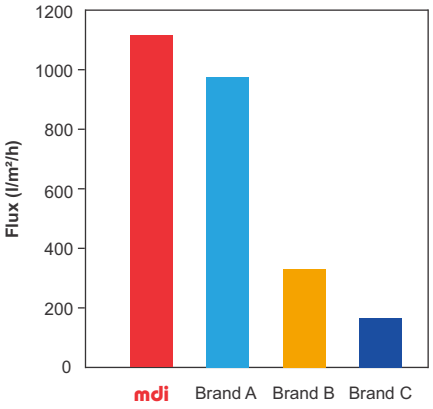
Performance Data

High Throughputs

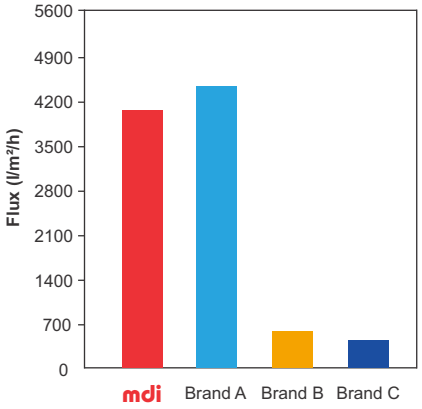
mdi *AseptiPrime KS-γ* filter consistently outperformed other available sterilizing filters by exhibiting much higher throughput with a wide variety of fluid streams .

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

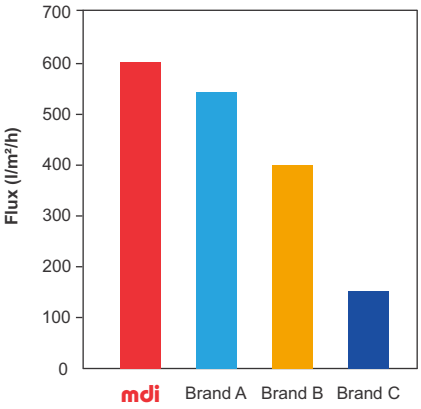
Also, optimized filter sizes do away with the possibilities of mid batch change out of filters or having to isolate a complete batch because it could not be processed.



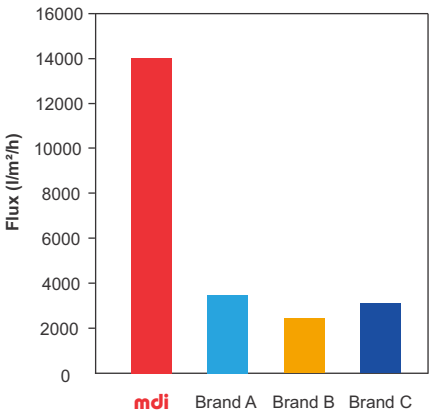
Soy Media



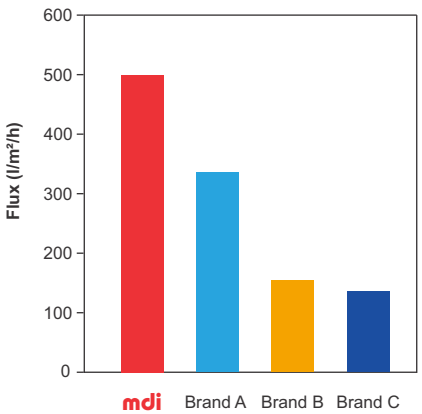
RPMI



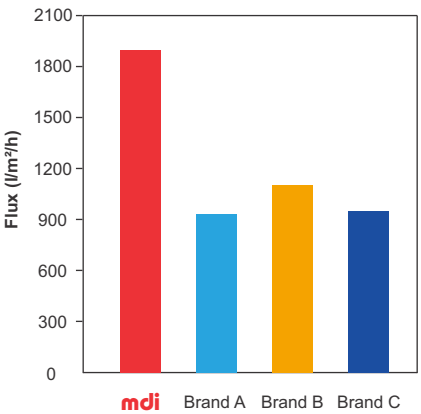
Yeast Peptone Dextrose



Luria Bertani



6M Urea



6M Guanidine HCl

Quality Assurance

mdi's quality management system emphasizes on quality by design rather 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 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.

Protein Adsorption

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

0.2 µm *AseptiPrime* 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 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.

AseptiPrime 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 as per USP <85>

Total Traceability

AseptiPrime 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

AseptiPrime 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 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

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 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 cm^2 to 18000cm^2 hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *AseptiPrime KS-γ* filters there by reducing the additional validation cost and time.

AseptiPrime KS-γ **25mm, 5cm^2**

AseptiPrime KS-γ **50mm, 20cm^2**

AseptiPrime KS-γ **1", 250cm^2**

AseptiPrime KS-γ **2", 500cm^2**

AseptiPrime KS-γ **5", 1000cm^2**

AseptiPrime KS-γ **8", 2000cm^2**

AseptiPrime KS-γ **10", 6000cm^2**

AseptiPrime KS-γ **20", 12000cm^2**

AseptiPrime KS-γ **30", 18000cm^2**

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

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 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 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.

¾" Sanitary Flange

1½" Sanitary Flange

½" Hose Barb

½" Single Stepped Hose Barb

¼" Stepped Hose Barb

Quick Connector

Some end connections available with *AseptiPrime KS-γ*

Customized Connectivity

mdi *AseptiPrime 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.

1½" Sanitary Flange to ½"Barb Hose

1½" Sanitary Flange to ¾" Sanitary Flange

***AseptiPrime* with HighSecurity ½" 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	Polyester
Plastic Parts	Gamma Stable 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 *Acholeplasma laidlawii* (ATCC 23206) per cm^2 **for 0.2µm:** LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2

Operational

Sterilization	**By Irradiation:** Gamma Irradiatiable up to 50 kGy **By Autoclave:** Autoclavable at 125 °C for 30 minutes, 1 cycle after Gamma irradiation Cannot be In-line steam sterilized
Shelf Life	2 years after Gamma Sterilization

	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 as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 3 liter flush
pH Compatibility	Compatible with pH range of 1-10
Extractables with WFI	Passes NVR test as per USP <661>
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Dimensions

Disc Capsule Filters

Size	25mm	50mm
Effective Filtration Area (cm^2)	**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^2)	**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	91 mm	103 mm	155 mm	205 mm
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
½″ Single Step Hose Barb I/O	-	115 mm	165 mm	217 mm
1½″ Sanitary Flange Inlet ½″ Hose Barb Outlet	-	111 mm	162 mm	212 mm
Operational Radius	30 mm	65 mm	65 mm	65 mm

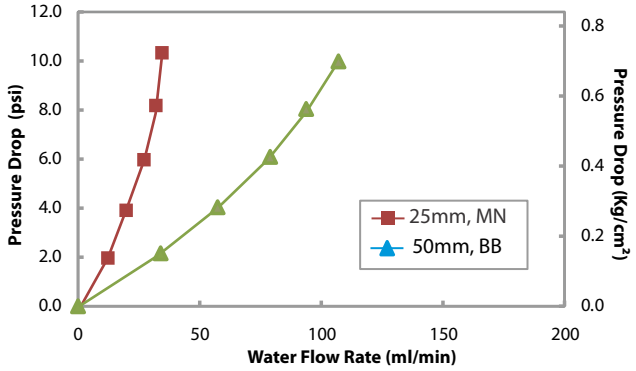
Large Capsule Filters

Size	5″	10″	20″	30″
Effective Filtration Area (cm^2)	**3000**	**6000**	**12000**	**18000**
End Connections	**End to End Length**			
1½″ Sanitary Flange I/O	207 mm	326 mm	601 mm	876 mm
½″ Single Step Hose Barb I/O	217 mm	332 mm	607 mm	882 mm
1½″ Sanitary Flange Inlet ½″ Hose Barb Outlet	203 mm	332 mm	607 mm	882 mm
Operational Radius	78 mm	78 mm	78 mm	78 mm

Typical Water Flow Rates

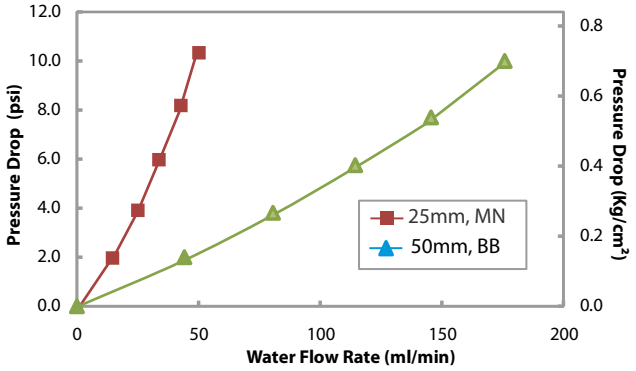
0.1µm *AseptiPrime KS-γ*

25mm and 50 mm capsule filter



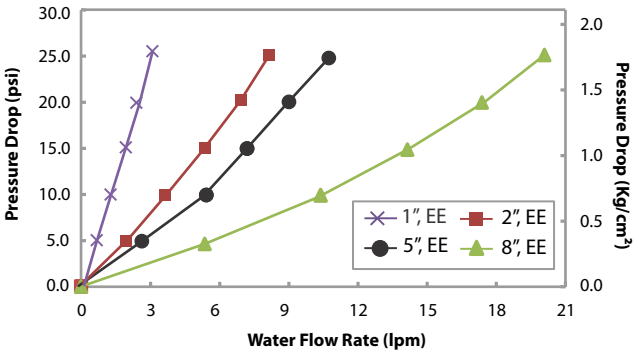
0.2µm *AseptiPrime KS-γ*

25mm and 50 mm capsule filter



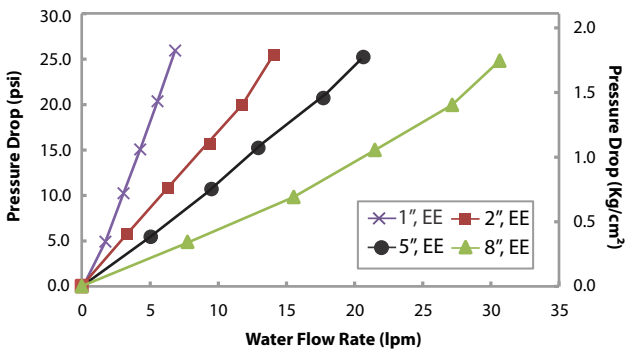
0.1µm *AseptiPrime KS-γ*

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



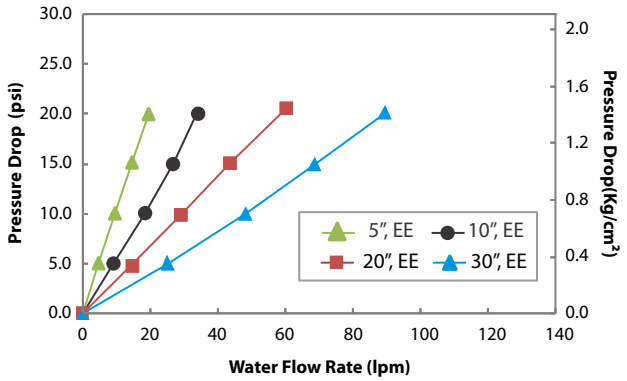
0.2µm *AseptiPrime KS-γ*

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



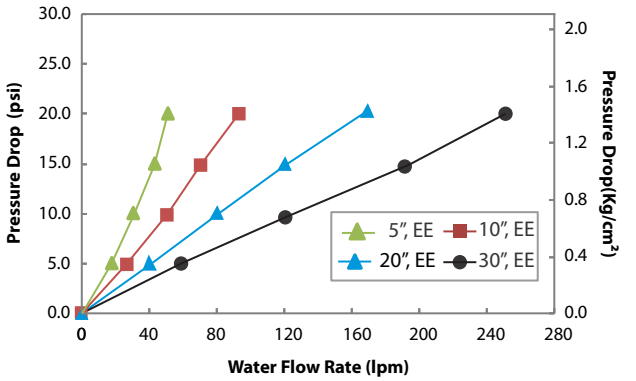
0.1µm *AseptiPrime KS-γ*

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



0.2µm *AseptiPrime KS-γ*

5", 10", 20" and 30" 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 KS-γ 25mm PES Membrane Capsule filters

Type	Code
AseptiPrime KS (0.3µm optimized pre-filter)	IKX9
AseptiPrime KS (0.5µm optimized pre-filter)	IKX7

Size	Code
25mm	06

Pore Size	Code
0.1µm	36
0.2µm**	01

Inlet/Outlet	Code
Female Luer Lock	M
Male Luer Slip	N
⅛" Hose Barb	H
¼" Hose Barb	B

Radiation Sterilizable	Code
Yes	R
No*	X

X

Sterility	Code
Non Sterile	1
Gamma Sterile	3

Pack Size	Code
100	04

Example:

IKX7	06	01	MN	R	X	1	04

***Gamma irradiated filters can not be gamma sterilized again**

Example for Non Sterile: IKX70601MNRX104 **Example for gamma Sterile: IKX70601MNXX304**

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

AseptiPrime KS-γ 50mm PES Membrane Capsule filters

Type	Code
AseptiPrime KS (0.3µm optimized pre-filter)	VKX9
AseptiPrime KS (0.5µm optimized pre-filter)	VKX7

Size	Code
50mm	10

Pore Size	Code
0.1µm	36
0.2µm**	01

Inlet/Outlet	Code
¼" SHB	B
¾" Sanitary Flange	S
Female Luer Lock	M

Radiation Sterilizable	Code
Yes	R
No*	X

X

Sterility	Code
Non Sterile	1
Gamma Sterile	3

Pack Size	Code
10	02

Example:

VKX7	10	01	BB	R	X	1	02

*** Gamma irradiated filters can not be gamma sterilized again**

Example for Non Sterile: VKX71001BBRX102 **Example for gamma Sterile: VKX71001BBXX302**

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

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	**25mm**	**50mm**
10/Pack	X	√
100/Pack	√	X

Ordering Information

AseptiPrime KS-γ PES Membrane Small Capsule filters

Type	Code
AseptiPrime KS (0.3µm optimized pre-filter)	DKX9
AseptiPrime KS (0.5µm optimized pre-filter)	DKX7

Size	Code
1″	51
2″	52
5″	53
8″	57

Pore Size	Code
0.1µm	36
0.2µm*	01

Inlet/Outlet	Code
¼″ SHB	A
¼″ MNPT (18 TPI)	B
¼″ BSP (19 TPI)	M
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
3/16″ Hose Barb	N
3/8″ Hose Barb	I

Radiation Sterilizable	Code
Yes	R
No**	X

X

Sterility	Code
Non Sterile	1
Gamma Sterile	3

Pack Size	Code
1	01

Example:

DKX7	57	01	DD	R	X	1	01

Example for Non Sterile: DKX75101QQRX101 **Example for gamma Sterile: DKX75101QQXX301**

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

**** Gamma sterile capsule filters cannot be gamma irradiated again**

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
3/16″ Hose Barb	√	√	Outlet Only	X
3/8″ Hose Barb	X	√	√	√

Ordering Information

AseptiPrime KS-γ PES Membrane Large Capsule filters

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline/ T-Line		Sterility		Pack Size	
	Code		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	Yes	R	Inline	X	Non Sterile	1	1	01
AseptiPrime KS (0.5µm optimized pre-filter)	LKX7	10″	54	0.2µm*	01	1½″ Sanitary Flange	E	No**	X	T-Line	T	Gamma Sterile	3		
		20″	55			3/8″ Hose Barb	I								
		30″	56			1″ Hose Barb	Z								

Example:

LKX7	54	01	EE	R	T	1	01

Example for Non Sterile: LKX75301QQRX101 **Example for gamma Sterile: LKX75301QQXX301**

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

**** Gamma irradiated filters can not be gamma sterilized again**

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

Inlet/Outlet	Inline				T-Line		
	5″	10″	20″	30″	10″	20″	30″
½″ Single Step Hose Barb	√	√	√	√	X	X	X
1½″ Sanitary Flange	√	√	√	√	√	√	√
3/8″ Hose Barb	√	√	√	√	X	X	X
1″ Hose Barb	X	√	√	√	X	X	X

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