

owner.

AseptiPrime® KSO-γ

Taking Throughput to the next level

Sterile filtration with upto 3x smaller filter area

AseptiPrime® KSO-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 $AseptiPrime^*KSO-\gamma$ filters meet international regulatory requirements for microbial retention and deliver sterile filtrate.

AseptiPrime® KSO- 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.

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

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 $0.2\mu m/0.1\mu m$ filters with various process streams.



AseptiPrime® KSO-γ

High Throughput Sterilizing Filters

AseptiPrime® KSO- 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® KSO- 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® KSO- 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

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.

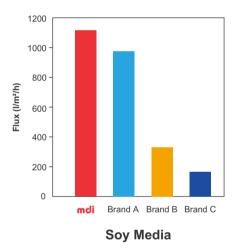
Performance Data

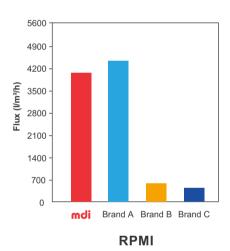
High Throughputs

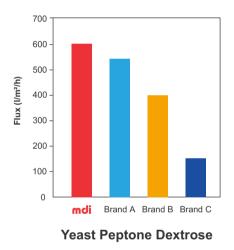
mdi AseptiPrime® KSO- γ filter consistently outperformed other available sterilizing filters by exhibiting much higher throughput with a wide variety of fluid streams .

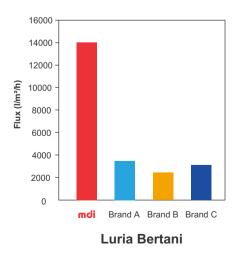
The large throughput difference allows use of filters with much smaller filter area and enhance process economy.

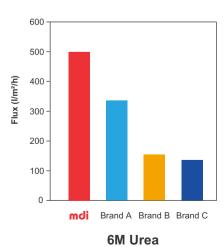
Also, optimized filter sizes do away with the possibilities of mid batch change out of filters or having to isolate a complete batch because it could not be processed.

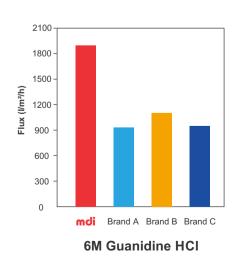












Quality Assurance

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® $KSO-\gamma$ 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- 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 <i>AseptiPrime</i> ® Filters	Protein Binding (0.75% BSA)
25 mm, 5 cm ²	1.45 μg
50 mm, 20 cm²	6.3 µg
1″, 250 cm²	80.5 μg
2", 500 cm ²	175 μg
10", 6000 cm²	1925 μg

Pressure, Temperature Endurance

AseptiPrime® KSO- 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® KSO- 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® KSO-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® KSO- 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 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- 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 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 $^{\circ}$ KSO- γ filters there by reducing the additional validation cost and time.



AseptiPrime® KSO-y 25mm, 5cm²



AseptiPrime® KSO-γ AseptiPrime® 50mm, 20cm²



1", 250cm²



2", 500cm²



5", 1000cm²



8", 2000cm²



AseptiPrime® KSO-y 10", 6000cm²



AseptiPrime® KSO-y 20", 12000cm²



AseptiPrime® KSO-y 30", 18000cm²

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

*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-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.



34" Sanitary Flange



11/2" 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-y

Customized Connectivity

mdi AseptiPrime® KSO- 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 1/2" hose barb connection

Specifications

Construction

0.1μm/0.2 μm Hydrophilic PES Membrane Pre-filter Membrane **0.1μm:** 0.3μm or 0.5μm PES

0.2μm: 0.5μm PES

Support Layers Polypropylene

Plastic Parts Gamma Stable Polypropylene

Integrity Testing / Retention

Bubble Point 0.1μm: > 31 psi (2.18Kg/cm²) with 50% IPA/Water Solution

0.2\mum: ≥ 50 psi (3.52 Kg/cm²) with Water

Max. Air Diffusion Flows per 10" Capsule Filter

0.1µm: ≤ 29 ml/min @ 50 psi (3.52 Kg/cm²) with water **0.2µm:** ≤ 30 ml/min @ 37 psi (2.6 Kg/cm²) with water

for 0.1 µm: LRV >7 for Acholeplasma laidlawii (ATCC 23206) per cm² Microbial Retention

for 0.2μm: LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm²

Operational

By Irradiation: Gamma Irradiatiable up to 50 kGy. Sterilization

These filters must not be autoclaved or in-line steam sterilized.

Shelf Life 2 years after Gamma Sterilization

	Inline Cap	sule 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/cm²)			
Max. Differential Pressure	75 psi (5 Kg/cm²) @ 25 °C	42 psi (3 Kg/cm²) @ 30 °C	60 psi (4 Kg/cm²) @ 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

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85> **Bacterial Endotoxin**

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 liter flush

pH Compatibility Compatible with pH range of 1-14 Passes NVR test as per USP <661>

Comply with USFDA 21 CFR Part 177.1520 Indirect Food Additives

Passes test as per USP <1231> Oxidizable Substances

Quality Management System ISO-9001 Certified **USFDA** DMF No. 015554

Extractables with WFI

Dimensions

Disc Capsule Filters

Size	25mm	50mm		
Effective Filtration Area (cm²)	5	20		
End Connections	End to Er	nd 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 (cm²)	250	500	1000	2000				
End Connections	End to End Length							
1⁄4" 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	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 ½" Hose Barb Outlet	-	112 mm	165 mm	216 mm				
Operational Radius	40 mm	65 mm	65 mm	65 mm				

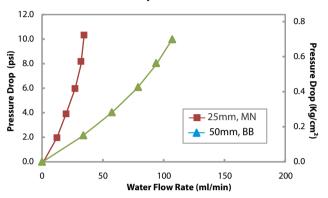
Large Capsule Filters

Size	5″	10"	20"	30"				
Effective Filtration Area (cm²)	3000	6000	12000	18000				
End Connections	End to End Length							
1½" Sanitary Flange I/O	205 mm	326 mm	605 mm	865 mm				
1/2" Single Step Hose Barb I/O	218 mm	332 mm	628 mm	888 mm				
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212 mm	332 mm	618 mm	878 mm				
3/8" Hose Barb I/O	211 mm	332 mm	634 mm	885 mm				
³ ⁄ ₄ " Sanitary Flange I/O	214 mm	335 mm	Х	х				
Operational Radius	78 mm	78 mm	78 mm	78 mm				

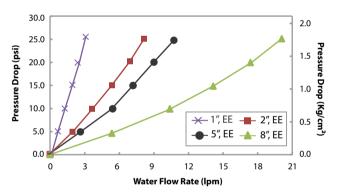
Typical Water Flow Rates

0.1μm AseptiPrime® KSO-γ

25mm and 50 mm Inline Capsule Filter

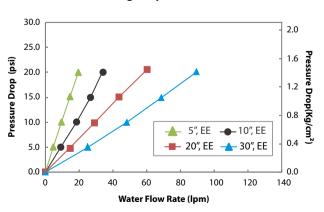


0.1μm *AseptiPrime* **KSO*-γ 1", 2", 5" and 8" Small Capsule Filters



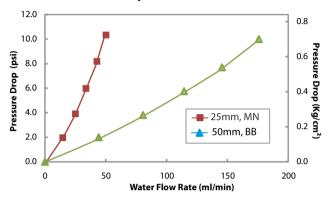
0.1µm AseptiPrime® KSO-y

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

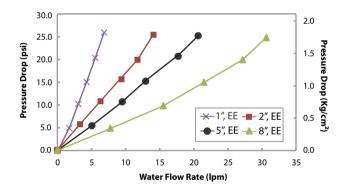


0.2μm AseptiPrime® KSO-γ

25mm and 50 mm Inline Capsule Filter

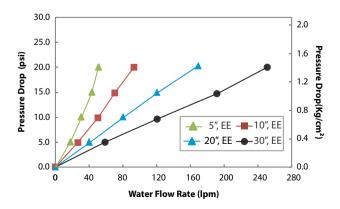


0.2μm *AseptiPrime* **KSO*-γ 1", 2", 5" and 8" Small Capsule Filters



0.2μm AseptiPrime® KSO-γ

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



End Connection Type:

E: 11/2" Sanitary Flange

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

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

Ordering Information

AseptiPrime® KSO-γ 25mm PES Membrane Inline Capsule filters

Туре		Si	ze	Pore S	iize	Inlet/Outle	t	Radia Sterili:		х	Sterilit	у	Pack	Size
	Code		Code		Code		Code		Code			Code		Code
AseptiPrime® KSO-γ		25mm	06	0.1µm	36	Female Luer Lock	М	Yes	R		Non Sterile	1	100	04
(0.3µm optimized	IKO9			0.2μm*	01	Male Luer Slip	N	No**	Х		Gamma Sterile	3		
pre-filter)						1/8" Hose Barb	Н							
AseptiPrime® KSO-γ (0.5μm optimized	IKO7					1⁄4" Hose Barb	В							
pre-filter) Example:	ļ,		\		\	\		\		*	4	7	,	•
IKO7		0	6	01	l	MN		R		Х	1	l	04	4

^{* 0.2} μ m capsule filters are available with 0.5 μ m pre-filter only

Example for Non Sterile: IKO70601MNRX104

Example for gamma Sterile: IKO70601MNXX304

AseptiPrime® KSO-γ 50mm PES Membrane Inline Capsule filters

Туре		Si	ze	Pore S	iize	Inlet/Ou	tlet	Radia Sterili		X	Sterilit	у	Pack S	Size
	Code		Code		Code		Code		Code			Code		Code
AseptiPrime® KSO-γ		50mm	10	0.1µm	36	1⁄4" SHB	В	Yes	R		Non Sterile	1	10	02
(0.3μm optimized pre-filter)	VKO9			0.2μm*	01	¾" Sanitary Flange	S	No**	Х		Gamma Sterile	3		
AseptiPrime® KSO-γ (0.5μm optimized pre-filter)	VKO7					Female Luer Lock	М							
Example:	,		\		\	4	1		\	\		1	4	1
VKO7		1	10	()1	BI	В		R	х	1	l	02	2

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

Example for Non Sterile: VKO71001BBRX102

Example for gamma Sterile: VKO71001BBXX302

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

Connections Available										
Inlet/Outlet	25mm	50mm								
1/4" - 3/4" Stepped Hose Barb	Х	√								
3/4" Sanitary Flange	Х	Outlet Only								
Female Luer Lock	Inlet Only	√								
Male Luer Slip	Outlet Only	Х								
1/8" Hose Barb	√	Х								
Male Luer Lock	Outlet Only	Х								
1/4" Hose Barb	V	Х								

Dimension (in mm)	Inline Capsule Filters					
Inlet/ Outlet	25mm	50mm				
1/4" - 3/8" Stepped Hose Barb I/O	-	79				
1/4" Single Step Hose Barb I/O	38	-				
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				

^{**}Gamma irradiated filters can not be gamma sterilized again

^{**}Gamma irradiated filters can not be gamma sterilized again

Ordering Information

AseptiPrime® KSO-γ PES Membrane Small Capsule filters

Туре	Туре		ize	Pore	Size	Inlet/Outlet		Radia Sterili		Х	Sterilit	у	Pacl	k Size
	Code		Code		Code		Code		Code			Code		Code
AseptiPrime® KSO-γ	DKO9	1"	51	0.1µm	36	1/4" SHB	Α	Yes	R		Non Sterile	1	1	01
(0.3µm optimized	DIO	2"	52	0.2μm*	01	1/4" MNPT (18 TPI)	В	No**	Х		Gamma Sterile	3		
pre-filter)		5″	53			1/4" BSP (19 TPI)	М							
AseptiPrime® KSO-γ (0.5μm optimized	DKO7	8"	57			1/4" BSP (19 TPI) with O-ring	Р			1				
pre-filter)	DKO7					1/4" BSP	F	1						
1 ,						½"MNPT	С				1			
			ı			½"Hose Barb	D							
						1½" Sanitary Flange	Е							
						¾" Sanitary Flange	S							
						Quick Connector	J							
						1/2" Single Step Hose Barb	Q							
						Female Luer Lock	U							
						Male Luer Slip	W							
						3/8" Hose Barb	I							
Example:		,	•	\	,			\downarrow		\downarrow	\downarrow		\	,
DKO	7		57	0	1	DD		R		Х	1		01	

Example for Non Sterile: DKO75301QQRX101

Example for gamma Sterile: DKO75301QQXX301

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

Inlet/Outlet		Size/Length							
illet/Outlet	1"	2"		5″	8"				
1/4" Stepped Hose Barb		√		√	√				
½" Single Step Hose Barb	Х	√		√	√				
½"Hose Barb	√	√		√	√				
1½" Sanitary Flange	√	√		√	√				
¾" Sanitary Flange	√	√		√	√				
Quick Connector	√	√		√	√				
1/2" MNPT	Х	√		√	√				
1/4" MNPT (18TPI)	√	√		√	√				
1/4" BSP (19 TPI)	Inlet Only	х		х	х				
1/4" BSP (19 TPI) with O-ring	Inlet Only	х		х	х				
1/4" BSP	Inlet Only	√		√	√				
Female Luer Lock	√	√		√	√				
Male Luer Slip	Outlet Only	х		х	х				
3/8" Hose Barb	Х	√		√	√				

Dimensions (in mm)	Small Capsule Filters					
End Connections	1"	2″	5″	8"		
1/4" 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		

 $^{*0.2 \}mu m$ capsule filters are available with $0.5 \mu m$ pre-filter only

 $^{**} Gamma\ sterile\ capsule\ filters\ cannot\ be\ gamma\ irradiated\ again$

Ordering Information

AseptiPrime® KSO-γ PES Membrane Large Capsule filters

Туре		Si	ze	Pore S	Size	Inlet/Outlet		Radiation Sterilizable		Inline/ T-Line		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code		Code
AseptiPrime® KSO-γ		5"	53	0.1µm	36	1/2" Single Step Hose Barb	Q	Yes	R	Inline	Х	Non Sterile	1	1	01
(0.3µm optimized	LKO9	10"	54	0.2μm*	01	1½" Sanitary Flange	E	No**	Х	T-Line	Т	Gamma Sterile	3		
pre-filter)		20"	55			¾" Sanitary Flange	S								
AseptiPrime® KSO-γ (0.5μm optimized	LKO7	30"	56			3/8" Hose Barb	- 1			1					
pre-filter)	LKO/					1" Hose Barb	Z								
Example:	•		•					•			,	•		•	
LKO7			54	0	1	EE		R		-	г	1		01	I

Example for Non Sterile: LKO75301QQRX101

Example for gamma Sterile: LKO75301QQXX301

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

11.40.41.4		Inli	ne	T-Line			
Inlet/Outlet	5″	10"	20"	30"	10"	20"	30"
1/2" Single Step Hose Barb	√	√	√	√	Х	х	х
1½" Sanitary Flange	√	√	√	√	√	√	√
¾" Sanitary Flange	√	√	х	х	х	х	х
¾" Hose Barb	√	√	√	√	х	х	х
1" Hose Barb	Х	√	√	√	Х	Х	Х

Dimensions (in mm)	Inl	ine Cap	sule Filt	T-line Capsule Filters			
End Connections	5″	10"	20"	30"	10"	20"	30"
1½" Sanitary Flange I/O	205	330	600	855	340	580	840
¾" Sanitary Flange I/O	214	335	х	х	х	х	х
½" Single Step Hose Barb I/O	218	336	630	890	х	х	х
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334	620	870	х	х	х
¾″ Hose Barb I/O	211	332	634	885	х	х	х
1" Hose Barb I/O	х	405	635	895	х	х	х
Operational Radius	80	80	80	80	80	80	80

ADVANCED MICRODEVICES PVT. LTD.

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

^{**} Gamma irradiated filters can not be gamma sterilized again