



ClariPro[®] *GK-γ* Radiation Sterilizable Polyethersulfone Membrane Capsule Filters Data Sheet

Intermediate process fluids in Biopharmaceutical manufacturing are difficult to filter as these have a varying contamination profile. Processes owners are continuously looking for efficient microfiltration solutions:

- Offering absolute retentions for colloidal particles, lipids, cell organelles and microprecipitates
- High throughputs to achieve process economy
- Choice of filter end connections for easy and reliable quick connection

mdi *ClariPro* GK- γ hydrophilic PES membrane capsule filters are ready to use, disposable filtration devices. These are specially designed filters incorporating multilayered

microglassfiber upstream and a downstream PES membrane final layer and are used as pre-filters in biopharmaceuticals process development as well as manufacturing process for difficult to filter solutions.

The microglassfiber upstream offers high dirt holding capacity and efficient retention of colloidal particles to give clear downstream in case of difficult to filter turbid solutions. The downstream PES membrane offers absolute retention, and low protein binding along with high flow rates.

ClariPro[®] GK- γ 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 and specially recommended for single use systems. ClariPro[®] GK- 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 ClariPro[®] in clean areas for making disposable assemblies for subsequent sterilization.

Applications

- Precipitate removal post viral inactivation
- Pre-filtration of serum solutions
- Clarification of cell harvest supernatants
- Polishing of turbid solution

Key Features

- High throughput
- 100% integrity tested
- Low protein binding
- High flow rates
- Biologically Inert
- Easy Installation
- 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

Quality Assurance

mdi 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.

100% Integrity Tested

Each *ClariPro*[®] *GK-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.

Pressure, Temperature Endurance

ClariPro[®] *GK-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 filters, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

ClariPro[®] *GK-γ* 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

Total Traceability

ClariPro[®] *GK-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

ClariPro[®] *GK-γ* filters are fitted with vent caps and are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room assembly or process areas.

Other Regulatory Compliance

- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics

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 ClariPro® GK-γ filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

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



1/2" HB



1/2" Single Stepped
Hose Barb



1/4" MNPT



1/4" SHB



Quick Connector



Male Luer Slip



3/8" Hose Barb



Female Luer Lock



1 1/2" Sanitary Flange



3/4" Sanitary Flange



1/2" MNPT



1" Hose Barb

Variety of end connections

Customized Connectivity

mdi ClariPro® GK-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.



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



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



ClariPro® with HighSecurity
1/2" hose barb connection

Linear Upscaling from R&D to Production Process

Datasheet

mdi offers a wide range of *ClariPro*[®] GK-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 15000 cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *ClariPro*[®] GK-γ filters there by reducing the additional validation cost and time.



ClariPro[®] GK-γ
25mm, 5cm²



ClariPro[®] GK-γ
50mm, 20cm²



ClariPro[®] GK-γ
1", 150cm²



ClariPro[®] GK-γ
2", 500cm²



ClariPro[®] GK-γ
5", 1000cm²



ClariPro[®] GK-γ
8", 1500cm²



ClariPro[®] GK-γ
10", 5000cm²



ClariPro[®] GK-γ
20", 10000cm²



ClariPro[®] GK-γ
30", 15000cm²

Filter Devices	EFA* (Nominal)	Hold up Volume
<i>ClariPro</i> [®] GK-γ 25 mm	5cm ²	< 50µl
<i>ClariPro</i> [®] GK-γ 50 mm	20cm ²	< 200µl
<i>ClariPro</i> [®] GK-γ 1"	150cm ²	< 5ml
<i>ClariPro</i> [®] GK-γ 2"	500cm ²	< 25ml
<i>ClariPro</i> [®] GK-γ 5"	1000cm ²	< 45ml
<i>ClariPro</i> [®] GK-γ 8"	1500cm ²	< 60ml
<i>ClariPro</i> [®] GK-γ 5"	2500cm ²	< 80ml
<i>ClariPro</i> [®] GK-γ 10"	5000cm ²	< 150ml
<i>ClariPro</i> [®] GK-γ 20"	10000cm ²	< 250ml
<i>ClariPro</i> [®] GK-γ 30"	15000cm ²	< 350ml

*EFA: Effective Filtration Area

Specifications

Inline Capsule Filters

Datasheet

Construction

Membrane	Hydrophilic PES
Pre-filter	Microglassfiber
Support layers	Polyester
Plastic Parts	Polypropylene

Integrity Testing/ Retention

Microbial Retention	0.1µm: LRV >6 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ² 0.2µm: LRV >5 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²
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Size

Size	25 mm	50 mm
Effective Filtration Area (Nominal)	5 cm ²	20 cm ²
Operational Radius (with Vent/ Drain)	15 mm	25 mm

Operational

Max. Operating Temperature	60 °C
Max. Differential Pressure	42 psi (3 Kg/cm ²) @ 30 °C
Sterilization by Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters must not be autoclaved or in-line steam sterilized.
Shelf Life	2 years after Gamma Sterilization

Assurance

Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
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
Extractables with WFI	Passes NVR test as per USP <661>
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications Small Capsule Filters

Datasheet

Construction

Membrane	Hydrophilic PES
Pre-filter	Microglassfiber
Support layers	Polyester
Plastic Parts	Polypropylene

Integrity Testing/ Retention

Microbial Retention	<p>0.1µm: LRV >6 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²</p> <p>0.2µm: LRV >5 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²</p>
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Size

Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	150cm ²	500cm ²	1000cm ²	1500 cm ²
Operational Radius (with Vent/ Drain)	40 mm	65 mm	65 mm	65 mm
Vent and Drain	¼" Hose Barb with Silicone "O" rings			

Operational

Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm ²)
Max. Differential Pressure	60 psi (4 Kg/cm ²) @ 30 °C
Sterilization by Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters must not be autoclaved or in-line steam sterilized.
Shelf Life	2 years after Gamma Sterilization

Assurance

Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
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
Extractables with WFI	Passes NVR test as per USP <661>
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications

Large Capsule Filters

Datasheet

Construction

Membrane	Hydrophilic PES
Pre-filter	Microglassfiber
Support layers	Polyester
Plastic Parts	Polypropylene

Integrity Testing/ Retention

Microbial Retention	<p>0.1µm: LRV >6 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²</p> <p>0.2µm: LRV >5 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm²</p>
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Size

Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500cm ²	5000cm ²	10000cm ²	15000 cm ²
Operational Radius (with Vent/ Drain)	80 mm	80 mm	80 mm	80 mm
Vent and Drain	¼" Hose Barb with Silicone "O" rings			

Operational

Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm ²)
Max. Differential Pressure	60 psi (4 Kg/cm ²) @ 30 °C
Sterilization by Gamma Irradiation	Gamma Irradiatable up to 50 kGy. These filters must not be autoclaved or in-line steam sterilized.
Shelf Life	2 years after Gamma Sterilization

Assurance

Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
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Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Dimensions

Inline 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)	150	500	1000	1500
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	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
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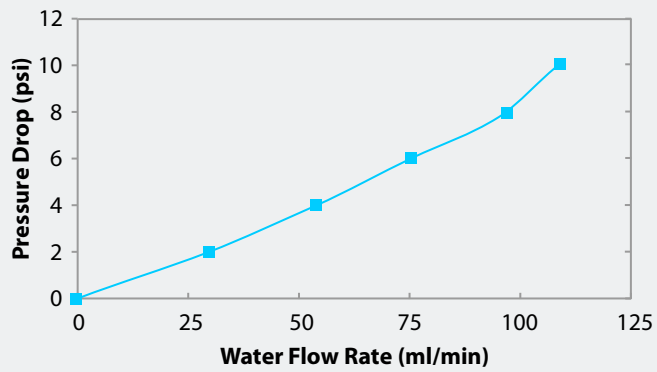
Large Capsule Filters

Size	5"	10"	20"	30"
Effective Filtration Area (cm²)	2500	5000	10000	15000
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	212 mm	332 mm	618 mm	878 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

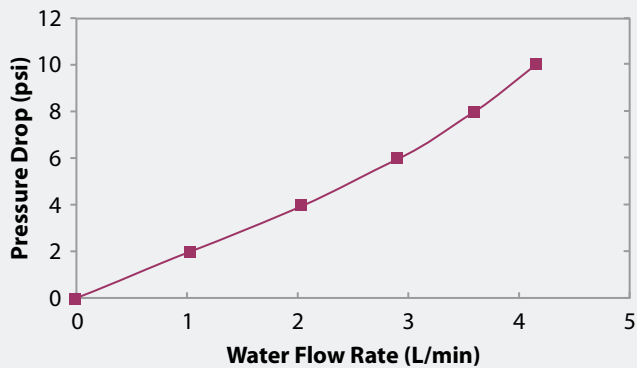
Operational Radius	78 mm	78 mm	78 mm	78 mm
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Typical Water Flow Rates

0.5µm ClariPro® GK-γ, 25 mm Capsule Filter



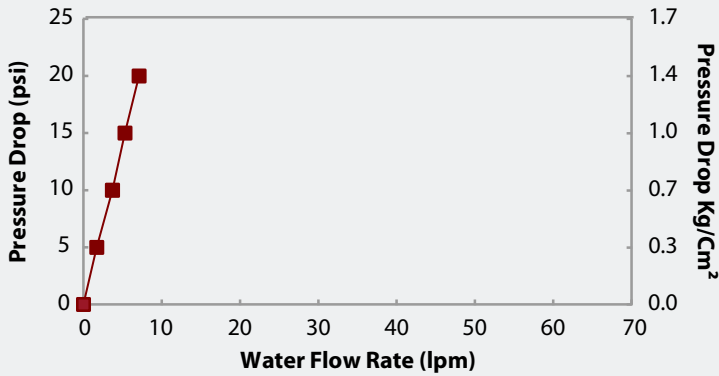
0.5µm ClariPro® GK-γ, 50 mm Capsule Filter



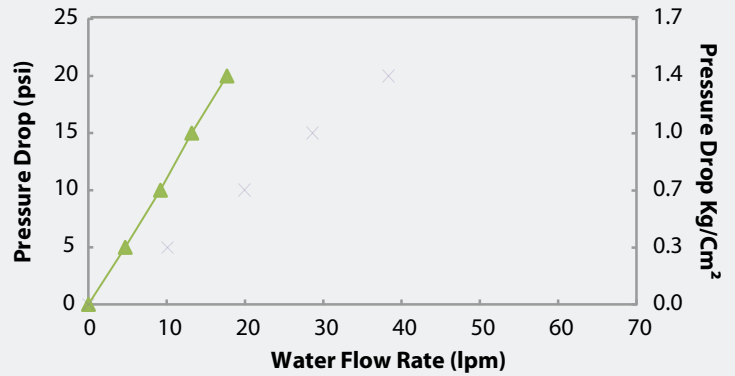
- 25 mm Capsule Filters
- 50 mm Capsule Filters

Typical Water Flow Rates

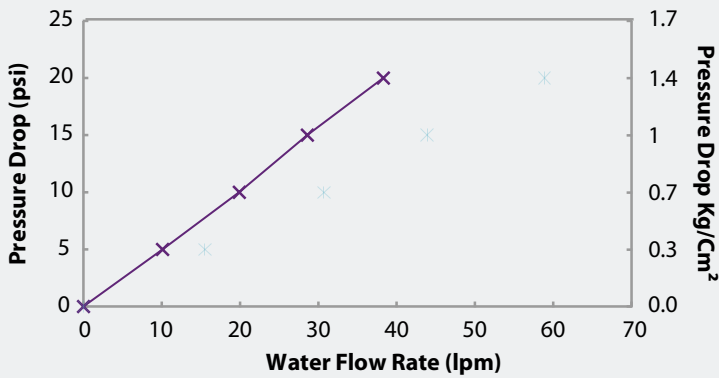
0.5µm ClariPro® GK-γ, 1" Capsule Filter



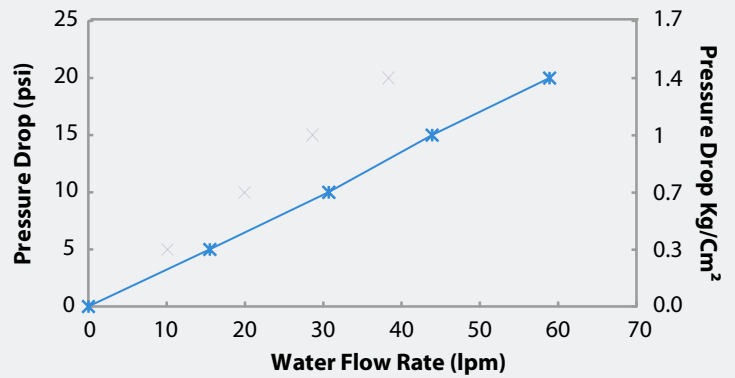
0.5µm ClariPro® GK-γ, 2" Capsule Filter



0.5µm ClariPro® GK-γ, 5" Capsule Filter



0.5µm ClariPro® GK-γ, 8" Capsule Filter



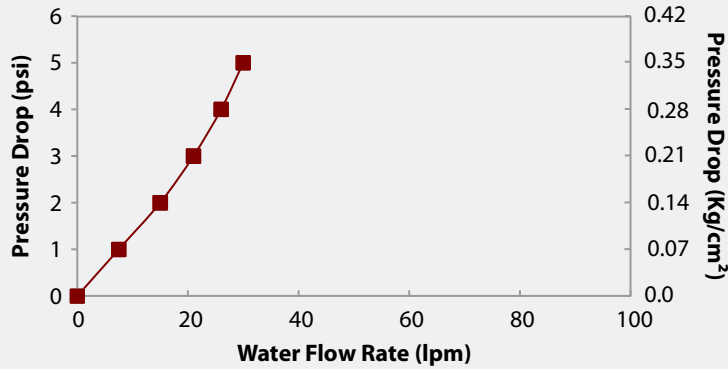
- 1 Inch Capsule Filters, EE Connection
- ▲ 2 Inch Capsule Filters, EE Connection
- × 5 Inch Capsule Filters, EE Connection
- ✱ 8 Inch Capsule Filters, EE Connection

End Connection Type:

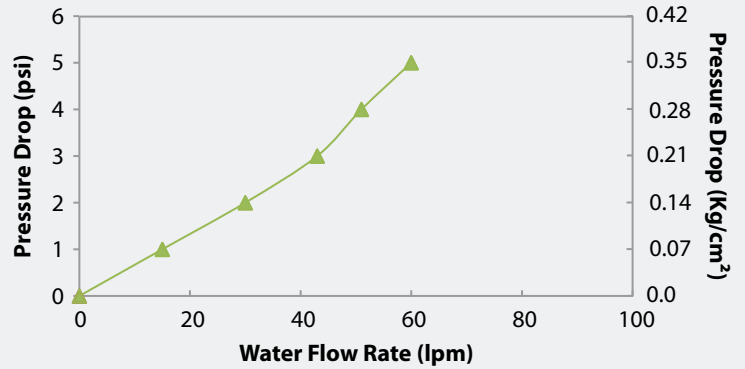
E: 1½" Sanitary Flange Connections

Typical Water Flow Rates

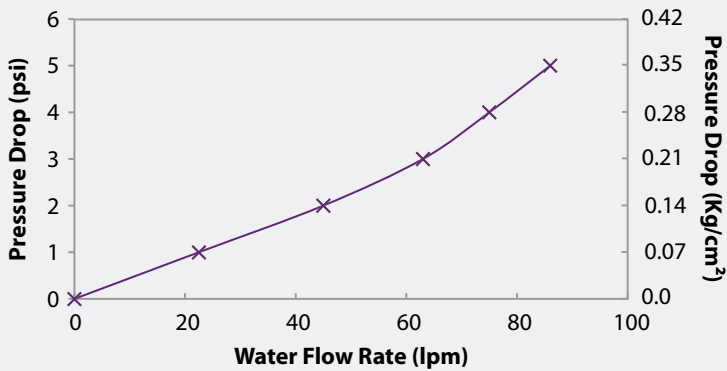
0.5µm ClariPro® GK-γ, 10" Capsule Filter



0.5µm ClariPro® GK-γ, 20" Capsule Filter



0.5µm ClariPro® GK-γ, 30" Capsule Filter



- 10 Inch Capsule Filters, EE Connection
- ▲ 20 Inch Capsule Filters, EE Connection
- ✕ 30 Inch Capsule Filters, EE Connection

End Connection Type:

E: 1½" Sanitary Flange Connections

Ordering Information

Datasheet

ClariPro® GK-γ 25mm PES Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code	Yes	Code			Code		Code
ClariPro® GK-γ	IGKX	25mm	06	0.1µm	36	Female Luer Lock	M	Yes	R		Non Sterile	1	100	04
				0.2µm	01	Male Luer Slip	N	No*	X		Gamma Sterile	3		
				0.5µm	04	1/8" Hose Barb	H							
						1/4" Hose Barb	B							

Example:

IGKX	06	01	MN	R	X	1	04
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*Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: IGKX0601MNRX104

Example for gamma Sterile: IGKX0601MNXX304

ClariPro® GK-γ 50mm PES Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code	Yes	Code			Code		Code
ClariPro® GK-γ (without Vent)	IGKX	50mm	10	0.1µm	36	1/4" SHB	B	Yes	R		Non Sterile	1	10	02
ClariPro® GK-γ (with Vent)	VGKX			0.2µm	01	3/4" Sanitary Flange	S	No*	X		Gamma Sterile	3		
				0.5µm	04	Female Luer Lock	M							

Example:

VGKX	10	01	BB	R	X	1	02
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*Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: VGKX1001BBRX102

Example for gamma Sterile: VGKX1001BBXX302

Inlet/Outlet Connections Available

Inlet/Outlet	25mm	50mm	
		with Vent	without Vent
1/4" - 3/4" Stepped Hose Barb	X	√	X
3/4" Sanitary Flange	X	√	X
Female Luer Lock	Inlet Only	X	√
Male Luer Slip	Outlet Only	X	X
1/8" Hose Barb	√	X	X
Male Luer Lock	Outlet Only	X	X
1/4" Hose Barb	√	X	X

Ordering Information

Datasheet

ClariPro® GK-γ PES Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Bell		Sterility		Pack Size		
	Code		Code		Code		Code	Yes	R	Yes**	B	Non Sterile	Code	1	Code	
ClariPro® GK-γ	DGKX	1"	51	0.1µm	36	¼" SHB	A	Yes	R	Yes**	B	Non Sterile	1	1	01	
		2"	52	0.2µm	01	¼" MNPT (18 TPI)	B	No*	X	No Bell	X	Gamma Sterile	3			
		5"	53	0.5µm	04	¼" BSP (19 TPI)	M			Bell with cover	C					
		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									
						⅜" Hose Barb	N									
						⅝" Hose Barb	I									

Example:

DGKX	57	01	DD	R	X	1	01
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* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: DGKX5101QQRX101

Example for gamma Sterile: DGKX5101QQXX301

** Bell is available with

½" Hose Barb outlet connections in 1", 2", 5" and 8" capsule filters

¼" SHB outlet connection in 1" capsule filters only

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

Inlet/Outlet	Size/Length				Bell at outlet Available with (Size/outlet)
	1"	2"	5"	8"	
¼" Stepped Hose Barb	√	√	√	√	1" / ¼" SHB
½" Single Step Hose Barb	X	√	√	√	1", 2", 5", 8" / ½" HB
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	
⅜" Hose Barb	√	√	Outlet Only	X	
⅝" Hose Barb	X	√	√	√	

Ordering Information

Datasheet

ClariPro® GK-γ PES Membrane Large Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Inline/T-Line		Sterility		Pack Size		
	Code		Code		Code		Code		Code		Code		Code		Code	
ClariPro® GK-γ	LGKX	5"	53	0.1µm	36	½" Single Step Hose Barb	Q	Yes	R	Inline	X	Non Sterile	1	1	01	
		10"	54	0.2µm	01	1½" Sanitary Flange	E	No*	X	T-Line**	T	Gamma Sterile	3			
		20"	55	0.5µm	04	¾" Sanitary Flange	S									
		30"	56			⅝" Hose Barb	I									
						1" Hose Barb	Z									

Example:

LGKX	54	01	EE	R	T	1	01
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* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: LGKX5301QQRX101

Example for gamma Sterile: LGKX5301QQXX301

**T-line is not available in 5" Capsule filter

**T-line Capsule Filter are available with 1½" Sanitary Flange I/O Connections Only

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	√	√	√	√	√	√	√
¾" Sanitary Flange	√	√	X	X	X	X	X
⅝" Hose Barb	√	√	√	√	X	X	X
1" Hose Barb	X	√	√	√	X	X	X

Advanced Microdevices Pvt. Ltd.

20-21, Industrial Area, Ambala Cantt-133 006, INDIA

Tel : +91-171-2699290, 2699471

E-mail : info@mdimembrane.com

Website : www.mdimembrane.com