



## **HarvestPro™-γ** **Radiation Sterilizable** **Polyethersulfone Membrane Capsule Filters**

### **Data Sheet**

CART-cell therapy for treating malignant tumors (cancer) involves production of viral vectors which are used for cell modification through genetic engineering so as to express a specific Chimeric Antigen Receptor (CAR). This CAR targets a specific antigen expressed only on a tumor and not on healthy cells. After CART-cells are infused into the patient, they act as a "living drug" against cancer cells.

Viral vectors are cultured in mammalian cells such as HEK 293 and clarification of the virus culture is a challenge for the process owner. Whole cells and cell debris which includes colloidal particles, lipids and cell fragments are difficult to remove and pose a risk to downstream processes such as Tangential flow Filtration (TFF), Ion exchange Chromatography and Size Exclusion Chromatography.

**mdi** HarvestPro™-γ Capsule filters are highly efficient multilayered filtration devices specially designed to retain all the submicron cell debris constituents and provide a clear downstream to protect high cost downstream processing steps, making these ideal for virus culture filtration in cell and gene therapy processes.

These filters are available for complete scale up from 25 mm (5 cm<sup>2</sup>) to 30" (15000 cm<sup>2</sup>) capsule filters with a wide range of end connections to suit different process requirements.

HarvestPro™-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 Biopharmaceutical applications and comply with various regulatory requirement. HarvestPro™-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 HarvestPro™ in clean areas for making disposable assemblies for subsequent sterilization.

### Applications

- Virus culture harvest for cell and gene therapy processes

### 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 lab to process development to manufacturing
- Total traceability through unique serial number for each filter
- Individual certificate of quality for each device
- Sterilizable by Gamma irradiation

**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 *HarvestPro*<sup>™</sup>- $\gamma$  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

*HarvestPro*<sup>™</sup>- $\gamma$  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.

*HarvestPro*<sup>™</sup>- $\gamma$  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

*HarvestPro*<sup>™</sup>- $\gamma$  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

*HarvestPro*<sup>™</sup>- $\gamma$  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

## 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** HarvestPro™-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** HarvestPro™-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



HarvestPro™ with HighSecurity  
1/2" hose barb connection

# Linear Upscaling from R&D to Production Process

**mdi** offers a wide range of *HarvestPro*<sup>TM-γ</sup> 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 15000 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 *HarvestPro*<sup>TM-γ</sup> filters there by reducing the additional validation cost and time.



*HarvestPro*<sup>TM-γ</sup>  
25mm, 5cm<sup>2</sup>



*HarvestPro*<sup>TM-γ</sup>  
50mm, 20cm<sup>2</sup>



*HarvestPro*<sup>TM-γ</sup>  
1", 150cm<sup>2</sup>



*HarvestPro*<sup>TM-γ</sup>  
2", 500cm<sup>2</sup>



*HarvestPro*<sup>TM-γ</sup>  
5", 1000cm<sup>2</sup>



*HarvestPro*<sup>TM-γ</sup>  
8", 1500cm<sup>2</sup>



*HarvestPro*<sup>TM-γ</sup>  
10", 5000cm<sup>2</sup>



*HarvestPro*<sup>TM-γ</sup>  
20", 10000cm<sup>2</sup>



*HarvestPro*<sup>TM-γ</sup>  
30", 15000cm<sup>2</sup>

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

\*EFA: Effective Filtration Area

# Specifications

## Inline Capsule Filters

# Datasheet

### Construction

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

### Size

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

### Operational

Max. Operating Temperature	60 °C
Max. Differential Pressure	42 psi (3 Kg/cm <sup>2</sup> ) @ 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

### Size

Size	1"	2"	5"	8"
Effective Filtration Area (Nominal)	150cm <sup>2</sup>	500cm <sup>2</sup>	1000cm <sup>2</sup>	1500 cm <sup>2</sup>
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 <sup>2</sup> )
Max. Differential Pressure	60 psi (4 Kg/cm <sup>2</sup> ) @ 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
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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

### Size

Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500cm <sup>2</sup>	5000cm <sup>2</sup>	10000cm <sup>2</sup>	15000 cm <sup>2</sup>
Operational Radius (with Vent/ Drain)	80 mm	80 mm	80 mm	80 mm
Vent and Drain	1/4" Hose Barb with Silicone "O" rings			

### Operational

Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm <sup>2</sup> )
Max. Differential Pressure	60 psi (4 Kg/cm <sup>2</sup> ) @ 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

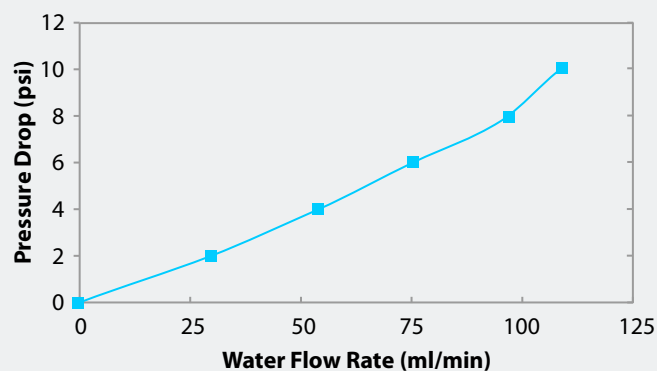
Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
Non Fiber Releasing	Passes test and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
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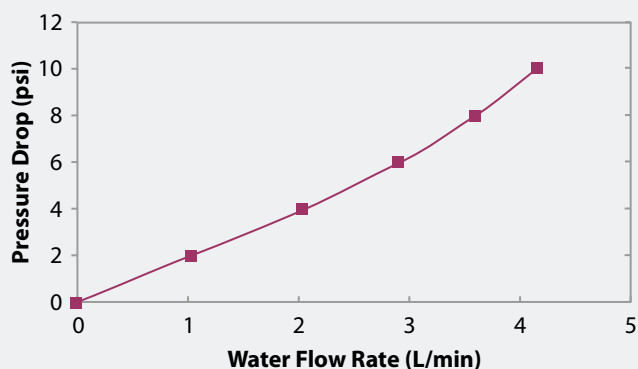
# Typical Water Flow Rates

## Datasheet

### 0.5µm HarvestPro™-γ, 25 mm Capsule Filter



### 0.5µm HarvestPro™-γ, 50 mm Capsule Filter

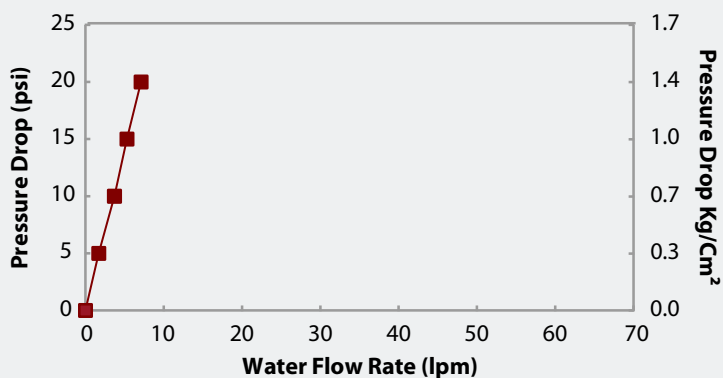


- 25 mm Capsule Filters
- 50 mm Capsule Filters

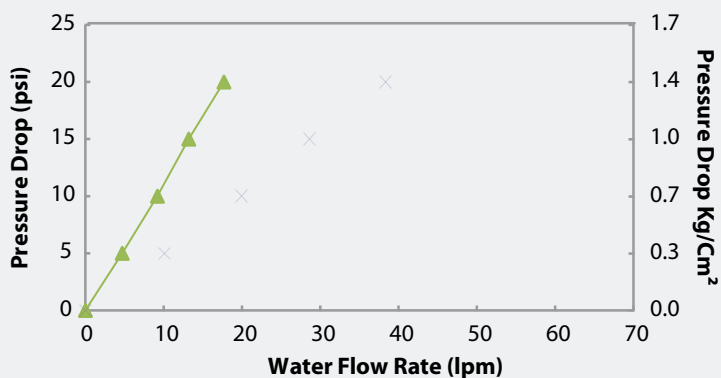
# Typical Water Flow Rates

## Datasheet

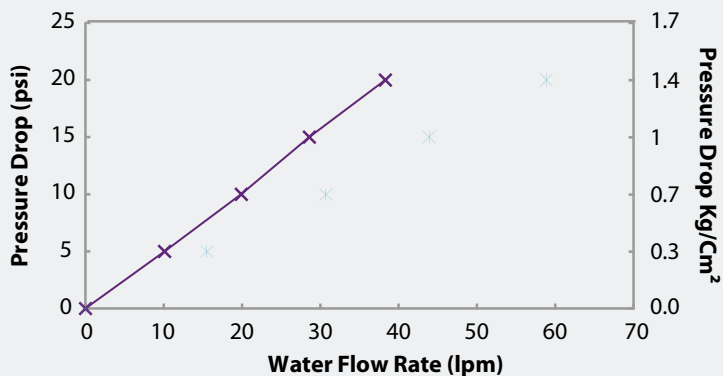
**0.5µm HarvestPro™-γ, 1" Capsule Filter**



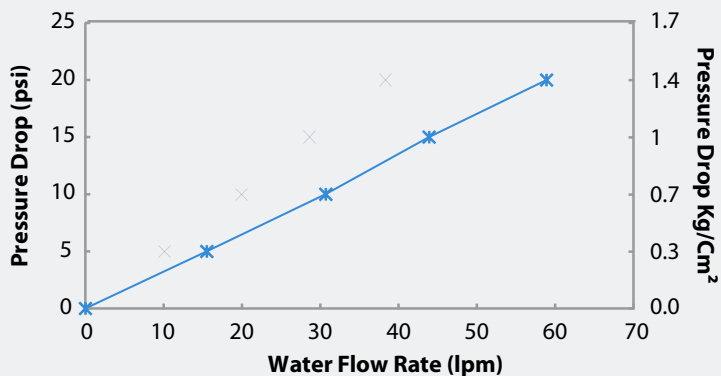
**0.5µm HarvestPro™-γ, 2" Capsule Filter**



**0.5µm HarvestPro™-γ, 5" Capsule Filter**



**0.5µm HarvestPro™-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

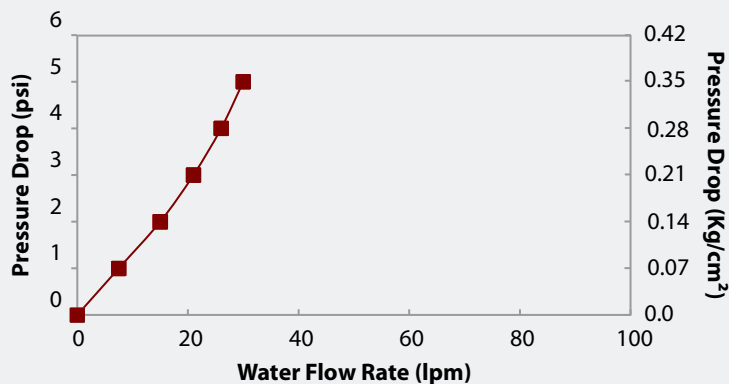
**End Connection Type:**

**E:** 1½" Sanitary Flange Connections

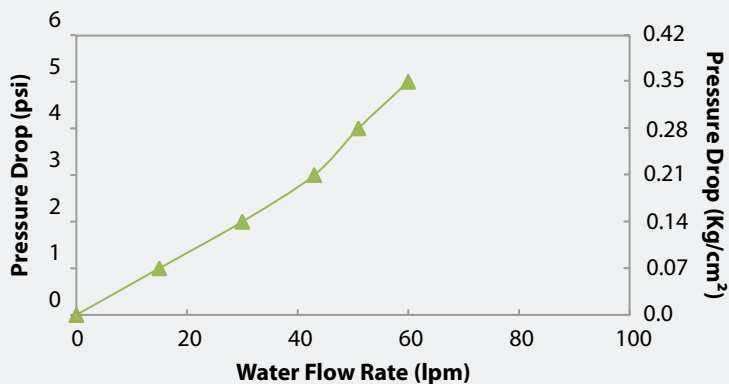
# Typical Water Flow Rates

## Datasheet

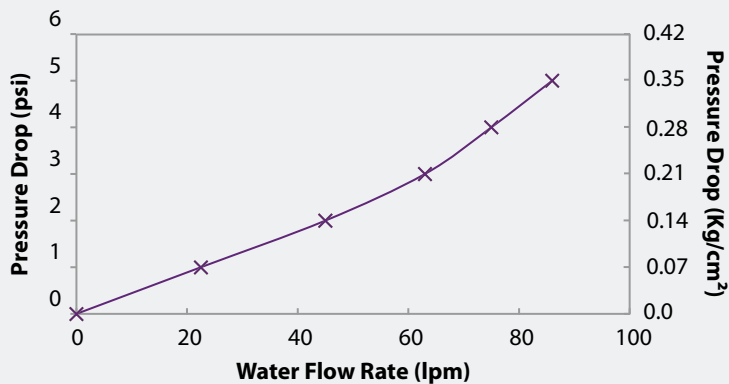
0.5µm HarvestPro™-γ, 10" Capsule Filter



0.5µm HarvestPro™-γ, 20" Capsule Filter



0.5µm HarvestPro™-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

## HarvestPro™-γ 25mm PES Membrane Inline Capsule filter

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

### Example:

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

Example for Non Sterile: IKGX0604MNRX104

Example for gamma Sterile: IKGX0604MNXX304

## HarvestPro™-γ 50mm PES Membrane Inline Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code		Code
HarvestPro™-γ (without Vent)	IKGX	50mm	10	0.5μm	04	1/4" SHB	B	Yes	R		Non Sterile	1	10	02
HarvestPro™-γ (with Vent)	VKGX					3/4" Sanitary Flange	S	No*	X		Gamma Sterile	3		
						Female Luer Lock	M							
						1/4" Single Step Hose Barb	A							

### Example:

VKGX	10	04	BB	R	X	1	02
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\*Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: VKGX1004BBRX102

Example for gamma Sterile: VKGX1004BBXX302

### 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
1/4" Single Step Hose Barb	X	X	√

### Dimension (Length) (in mm)

Inlet/ Outlet	25mm	50mm
1/4" - 3/8" Stepped Hose Barb I/O	-	79
1/4" Hose Barb I/O	38	-
1/4" Single Step Hose Barb I/O	-	62
3/4" 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

# Ordering Information

# Datasheet

## HarvestPro™-γ PES Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		Radiation Sterilizable		Bell		Sterility		Pack Size				
	Code		Code		Code		Code		Code		Code		Code		Code			
HarvestPro™-γ	DKGX	1"	51	0.5μm	04	¼" SHB	A	Yes	R	Yes**	B	Non Sterile	1	1	01			
		2"	52			¼" MNPT (18 TPI)	B	No*	X	No Bell	X	Gamma Sterile	3					
		5"	53			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						
								¼" Single Step Hose Barb				R						

**Example:**

DKGX	57	04	DD	R	X	1	01
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\* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: DKGX5104QQRX101

Example for gamma Sterile: DKGX5104QQXX301

**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	√	√	√	√	
¼" Single Step Hose Barb	√	√	√	√	

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
¼" Single Step Hose Barb I/O	90	106	160	212
Operational Radius	40	65	65	65

# Ordering Information

# Datasheet

## HarvestPro™-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
HarvestPro™-γ	LKGX	5"	53	0.5µm	04	½" Single Step Hose Barb	Q	Yes	R	Inline	X	Non Sterile	1	1	01
		10"	54			1½" Sanitary Flange	E	No*	X	T-Line**	T	Gamma Sterile	3		
		20"	55			¾" Sanitary Flange	S								
		30"	56			¾" Hose Barb	I								
						1" Hose Barb	Z								

### Example:

LKGX	54	04	EE	R	T	1	01
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\* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: LKGX5304QQRX101

Example for gamma Sterile: LKGX5304QQXX301

\*\*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			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	¾" 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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