Membrane Technologies

BioPro® KS

Polyethersulfone Membrane Bioburden Reduction Capsule Filters

Data Sheet

Biopharmaceutical processing requires microfiltration at multiple stages to meet specific process requirements.

Processes managers are continuously looking for fast and efficient microfiltration solutions for buffer filtration, a key requirement for downstream chromatography applications. Some key concerns are:

- Absolute retentions of particulate matter and bioburden reduction to protect high cost downstream process steps such as.
- Minimizing protein losses due to adsorption to improve over all product yields
- High throughputs to achieve process economy
- Choice of filter end connections for easy and reliable quick connections

mdi *BioPro® KS* capsule filters are designed for protecting your critical and high value downstream systems such as TFF, ion chromatography, elution chromatography and affinity chromatography.

These help in significant reduction of bioburden and complete removal of particulate contamination and are ideal for applications which do not require sterilization but where reduction in bio load in the process fluid is the objective.

These improve the process efficiency by reducing filter sizing and prolonging life of expensive sterilizing filters.

These filter devices are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as high retention efficiency, very high protein recoveries, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

BioPro® KS

Bioburden Reduction Capsule Filters

Datasheet

BioPro® KS 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. *BioPro® KS-γ* are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities. Packaging is done in double polybags for convenience of taking *BioPro®* in clean areas for making disposable assemblies for subsequent sterilization.

Applications

- Clarification of cell harvest
- Buffer filtration
- In process protein filtration
- Prefiltration to sterile filtration
- Prefiltration to virus filtration

Key Features

- Validated for high bioburden
- High throughput
- 100% integrity tested
- Low protein binding
- High flow rates
- No media migrating
- 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 autoclaving or Ethylene Oxide

Quality Assurance

Datasheet

mdi 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.

100% Integrity Tested

Each *BioPro® KS* 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

BioPro® KS 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.

BioPro® KS 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

BioPro® KS 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

BioPro® KS 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
- Complete filter devices tested for cytotoxicity as per Biological Reactivity Tests, In-vitro, USP <87>

Easy Connect

Datasheet

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 *BioPro® KS* 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 EO sterilization and Autoclaving.

½" HB

½" Single Stepped Hose Barb

1/4" MNPT

¼" SHB

Quick Connector

Male Luer Slip

3/8" Hose Barb

Female Luer Lock

1½" Sanitary Flange

¾" Sanitary Flange

½" MNPT

1" Hose Barb

Variety of end connections

Customized Connectivity

mdi *BioPro® KS* 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

***BioPro®* with HighSecurity ½" hose barb connection**

Linear Upscaling fro Process Development to Production

Datasheet

mdi offers a wide range of *BioPro® KS* 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 250 cm^2 to 18000 cm^2 hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *BioPro® KS* filters there by reducing the additional validation cost and time.

BioPro® KS
1", 250cm^2

BioPro® KS
2", 500cm^2

BioPro® KS
5", 1000cm^2

BioPro® KS
8", 2000cm^2

BioPro® KS
10", 6000cm^2

BioPro® KS
20", 12000cm^2

BioPro® KS
30", 18000cm^2

Filter Devices	EFA* (Nominal)	Hold up Volume
BioPro® KS 1"	250cm^2	< 5ml
BioPro® KS 2"	500cm^2	< 25ml
BioPro® KS 5"	1000cm^2	< 45ml
BioPro® KS 8"	2000cm^2	< 60ml
BioPro® KS 5"	3000cm^2	< 80ml
BioPro® KS 10"	6000cm^2	< 150ml
BioPro® KS 20"	12000cm^2	< 250ml
BioPro® KS 30"	18000cm^2	< 350ml

***EFA: Effective Filtration Area**

Specifications
Small Capsule Filters

Datasheet

Construction					
Membrane		Hydrophilic PES			
Support Layers		Polyester			
Plastic parts		Polypropylene			
Integrity Testing/ Retention					
Bubble Point		**0.1µm:** ≥ 40 psi (2.8 Kg/cm^2) with Water **0.2µm:** ≥ 30 psi (2.1 Kg/cm^2) with Water			
Microbial Retention		**0.1µm:** LRV >6 for *Brevundimonas diminuta* (ATCC 19146) per cm^2 **0.2µm:** LRV >5 for *Brevundimonas diminuta* (ATCC 19146) per cm^2			
Size					
Size		1″	2″	5″	8″
Effective Filtration Area (Nominal)		250cm^2	500cm^2	1000cm^2	2000 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 Autoclave**	Autoclavable at 125°C for 30 minute, 25 cycle and it cannot be In-line steam sterilized			
	By Gas	Sterilizable by Ethylene Oxide			
Shelf Life		3 years after EO sterilization			
Assurance					
Toxicity		Passes Biological Reactivity Tests, 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 liters of WFI 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 aas per USP <1231>			
Quality Management System		ISO-9001 Certified			
USFDA		DMF No. 015554			

Specifications
Large Capsule Filters

Datasheet

Construction					
Membrane		Hydrophilic PES			
Support Layers		Polyester			
Plastic parts		Polypropylene			
Integrity Testing/ Retention					
Bubble Point		**0.1µm:** ≥ 40 psi (2.8 Kg/cm^2) with Water **0.2µm:** ≥ 30 psi (2.1 Kg/cm^2) with Water			
Microbial Retention		**0.1µm:** LRV >6 for *Brevundimonas diminuta* (ATCC 19146) per cm^2 **0.2µm:** LRV >5 for *Brevundimonas diminuta* (ATCC 19146) per cm^2			
Size					
Size		5"	10"	20"	30"
Effective Filtration Area (Nominal)		3000 cm^2	6000 cm^2	10000 cm^2	18000 cm^2
Operational Radius (with Vent/Drain)		78 mm	78 mm	78 mm	78 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 Autoclave**	Autoclavable at 125°C for 30 minute, 25 cycle and it cannot be In-line steam sterilized			
	By Gas	Sterilizable by Ethylene Oxide			
Shelf Life		3 years after EO sterilization			
Assurance					
Toxicity		Passes Biological Reactivity Tests, 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 liters of WFI 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 aas per USP <1231>			
Quality Management System		ISO-9001 Certified			
USFDA		DMF No. 015554			

Dimensions

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	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
¼″ Single Step Hose Barb I/O	90 mm	106 mm	160 mm	212 mm

Operational Radius	40 mm	65 mm	65 mm	65 mm

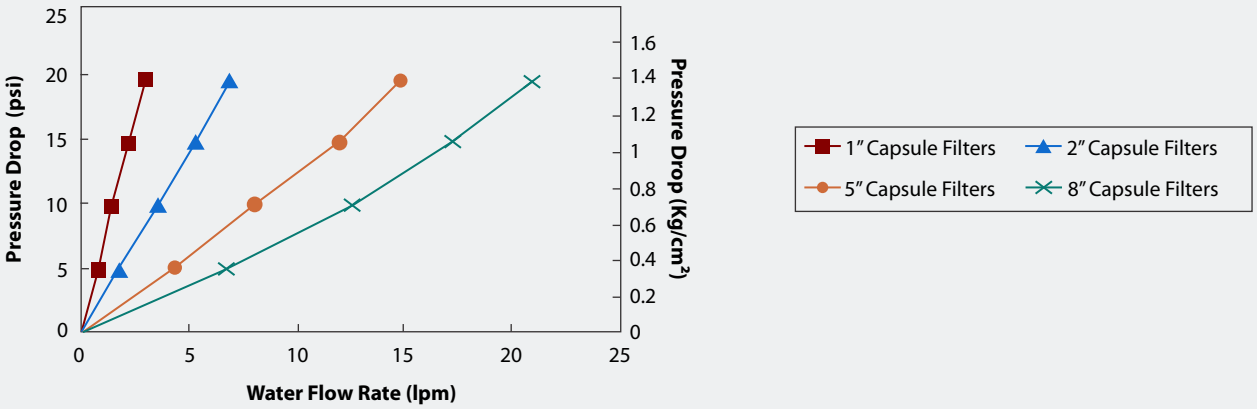
Large Capsule Filters

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	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

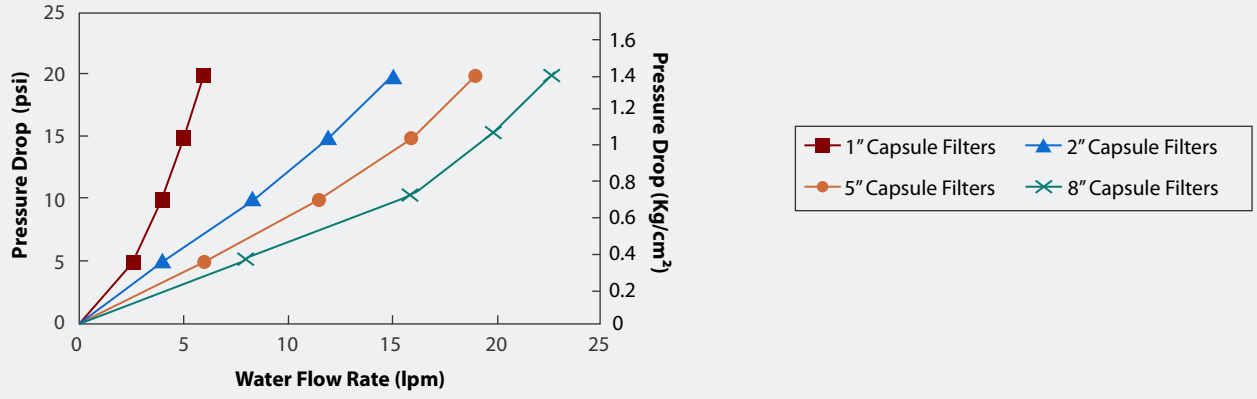
Operational Radius	78 mm	78 mm	78 mm	78 mm

Typical Water Flow Rates

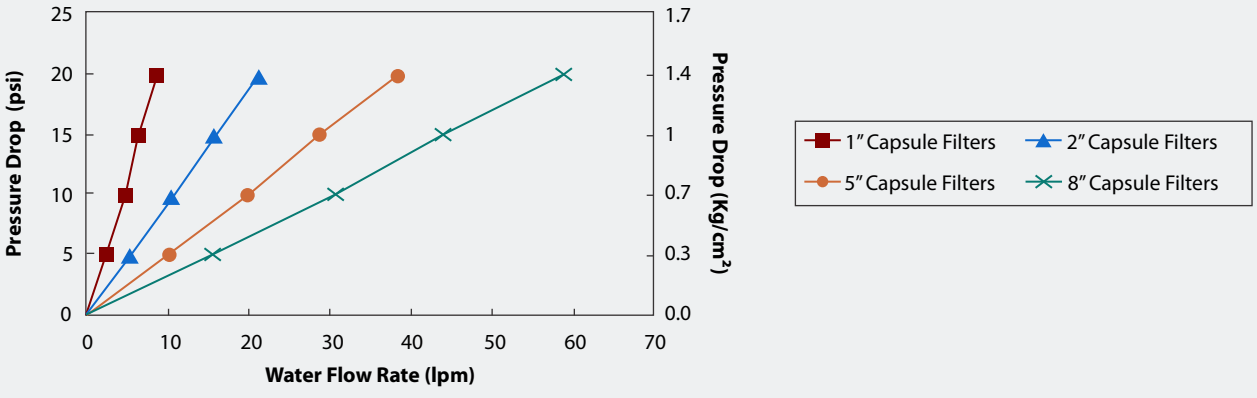
0.1µm *BioPro®KS*, Small Capsule Filter



0.2µm *BioPro®KS*, Small Capsule Filter

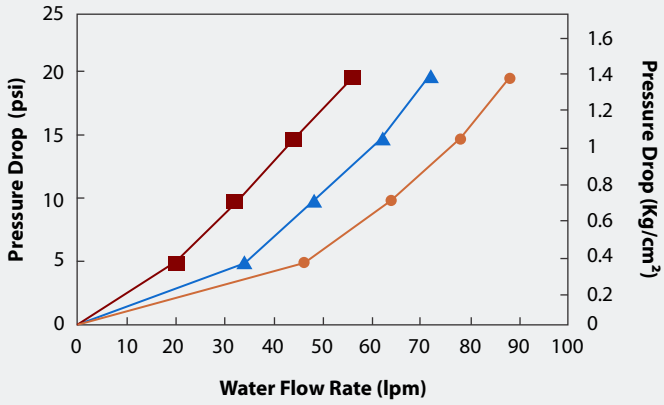


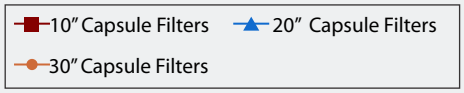
0.45µm *BioPro®KS*, Small Capsule Filter



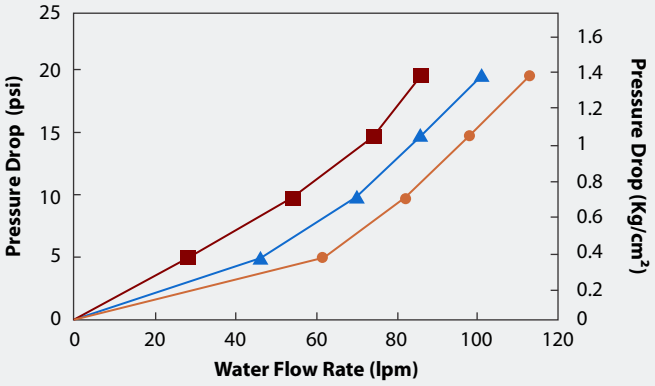
Typical Water Flow Rates

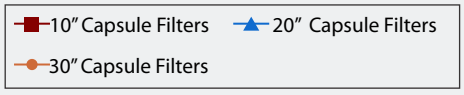
0.1µm *BioPro®KS*, Large Capsule Filter



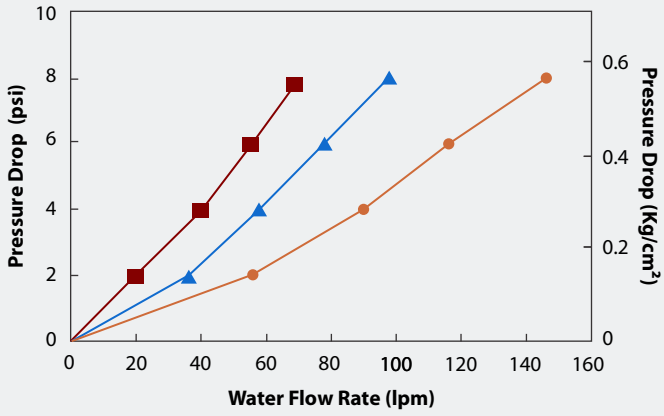


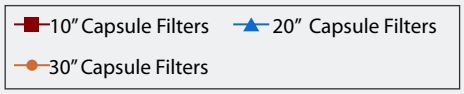
0.2µm *BioPro®KS*, Large Capsule Filter





0.45µm *BioPro®KS*, Large Capsule Filter





Ordering Information
Small Capsule Filters

Datasheet

BioPro KS PES Membrane Capsule filter

Type		Size		Pore Size		Inlet/Outlet		X	Bell		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
BioPro KS	DBKS	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	0.45µm	02	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							
						3⁄16″ Hose Barb	N							
						3⁄8″ Hose Barb	I							
						¼″ Single Step Hose Barb	R							

Example:

DBKS	57	01	DD	X	X	1	01

*** 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			
	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	√	√	√	√
¼″ Single Step Hose Barb	√	√	√	√

Bell at outlet Available with (Size/outlet)
1″/ ¼″ SHB
1″, 2″, 5″, 8″/ ½″ HB

Ordering Information
Large Capsule Filters

Datasheet

BioPro KS PES Membrane Large Capsule filter

Type		Size		Pore Size		Inlet/Outlet		X	Inline/ T-Line		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
BioPro KS	LBKS	5″	53	0.1µm	36	½″ Single Step Hose Barb	Q		Inline	X	Non Sterile	1	1	01
		10″	54	0.2µm	01	1½″ Sanitary Flange	E		T-Line*	T	EO Sterile	2		
		20″	55	0.45µm	02	¾″ Sanitary Flange	S							
		30″	56			⅜″ Hose Barb	I							
						1″ Hose Barb	Z							

Example:

LBKS	54	01	EE	X	T	1	01

***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
⅜″ Hose Barb	√	√	√	√	X	X	X
1″ Hose Barb	X	√	√	√	X	X	X

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