mdi
Membrane Technologies

Data Sheet

ClariCap® GS

Microglassfiber Capsule Filters

Pre-filtration is an important process requirement which helps protects sterilizing membrane filters, specially while filtering difficult to filter solutions.

Process owners are continuously looking for high efficiency filters, which not only help enhance the life of final membrane filters, but also can be used as final filters for clarification and polishing applications.

mdi *ClariCap® GS* Microglassfiber Capsule Filters are multilayered, high throughput filters, specially designed for turbid and difficult to filter solutions. The microglassfiber medium is designed to retain colloidal particles and for removal of deformable and non-deformable particles and microorganisms from liquids.

The high dirt holding capacity, biochemical inertness, adsorption and high wet strength of the filtration medium makes it suitable for clarification and prefiltration of wide range of aqueous, non-aqueous and biologicals solutions.

ClariCap® GS

Datasheet

ClariCap® GS microglassfiber capsule filters use **mdi** microglasssfiber filter media 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. *ClariCap® GS* are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities. Packaging is done in double polybags for convenience of taking *ClariCap®* in clean areas for making disposable assemblies for subsequent sterilization.

Applications

- Pre-filtration of high value difficult to filter drug solutions
- Precipitate removal in protein processing and plasma fractions
- Removal of un-dissolved buffer salts and cell culture media
- Prefiltration of serum and other viscous biologicals
- Polishing of turbid solution
- Chemical Processing
- Beverage clarification

Key Features

- Very high particulate retention efficiency
- High throughput
- High heat resistance
- Wide chemical compatibility
- No media migrating
- Biologically inert
- Easy installation
- 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
- 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 lot of capsule filter is accompanied by Certificate of Quality to ensure traceable documentation at user's end.

It certifies the product compliance to various regulatory as well as user requirements.

Flow Rate

Each lot is tested for clean water flow rates to ensure that flow rates are within the specifications.

Pressure, Temperature Endurance

ClariCap® GS 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.

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

ClariCap® GS 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 lots.

These unique lot 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

ClariCap® GS 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

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 *ClariCap® GS* 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 *ClariCap® GS* 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

***ClariCap® GS* with HighSecurity ½" hose barb connection**

Linear Upscaling from R&D to Production Process

Datasheet

mdi offers a wide range of *ClariCap® GS* 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 10200 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 *ClariCap® GS* filters there by reducing the additional validation cost and time.

ClariCap® GS
25mm, 5cm^2

ClariCap® GS
50mm, 20cm^2

ClariCap® GS
1", 150cm^2

ClariCap® GS
2", 400cm^2

ClariCap® GS
5", 800cm^2

ClariCap® GS
8", 1200cm^2

ClariCap® GS
10", 3400cm^2

ClariCap® GS
20", 6800cm^2

ClariCap® GS
10", 10200cm^2

Filter Devices	EFA* (Nominal)	Hold up Volume
ClariCap® GS 25 mm	5cm^2	< 50µl
ClariCap® GS 50 mm	20cm^2	< 200µl
ClariCap® GS 1"	150cm^2	< 5ml
ClariCap® GS 2"	400cm^2	< 25ml
ClariCap® GS 5"	800cm^2	< 45ml
ClariCap® GS 8"	1200cm^2	< 60ml
ClariCap® GS 5"	1700cm^2	< 80ml
ClariCap® GS 10"	3400cm^2	< 150ml
ClariCap® GS 20"	6800cm^2	< 250ml
ClariCap® GS 30"	10200cm^2	< 350ml

***EFA: Effective Filtration Area**

Specifications

Construction			
Filter Media		Multilayered Microglassfiber	
Plastic Parts		Polypropylene	
Size			
Size		25 mm	50 mm
EFA (Effective Filtration Area)		5 cm^2	20 cm^2
Operational Radius		15 mm	28 mm
Operational			
Max. Operating Temperature		60 °C	
Max. Differential Pressure		42 psi (3 Kg/cm^2) @ 30 °C	
Sterilization	**By Autoclave**	Autoclavable at 125 °C for 30 minutes, 30 cycles and it cannot be inline 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	
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	
Extractables with WFI		Passes NVR test as per USP <661>	
Indirect Food Additives		Comply with USFDA 21 CFR Part 177.1520	
Oxidizable Substances		Within limits as specified in USP <1231>	
Quality Management System		ISO-9001 Certified	
USFDA		DMF No. 015554	

Specifications
Small Capsule Filters

Datasheet

Construction					
Filter Media		Multilayered Microglassfiber			
Plastic Parts		Polypropylene			
Size					
Size		1″	2″	5″	8″
EFA (Effective Filtration Area)		150 cm^2	400 cm^2	800 cm^2	1200 cm^2
Operational Radius		40 mm	65 mm	65 mm	65 mm
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 minutes, 30 cycles and it cannot be inline 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			
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			
Extractables with WFI		Passes NVR test as per USP <661>			
Indirect Food Additives		Comply with USFDA 21 CFR Part 177.1520			
Oxidizable Substances		Within limits as specified in USP <1231>			
Quality Management System		ISO-9001 Certified			
USFDA		DMF No. 015554			

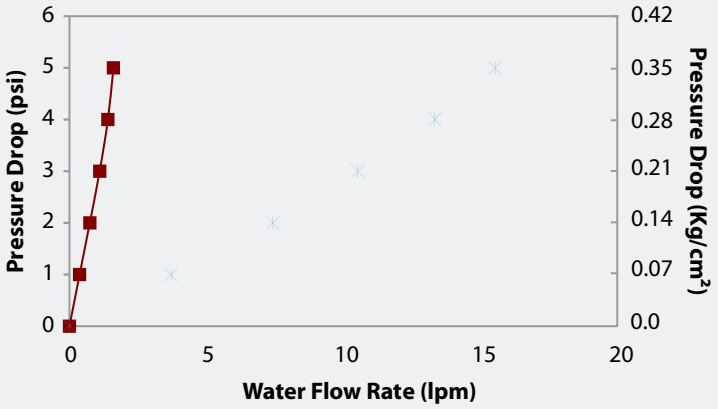
Specifications
Large Capsule Filters

Datasheet

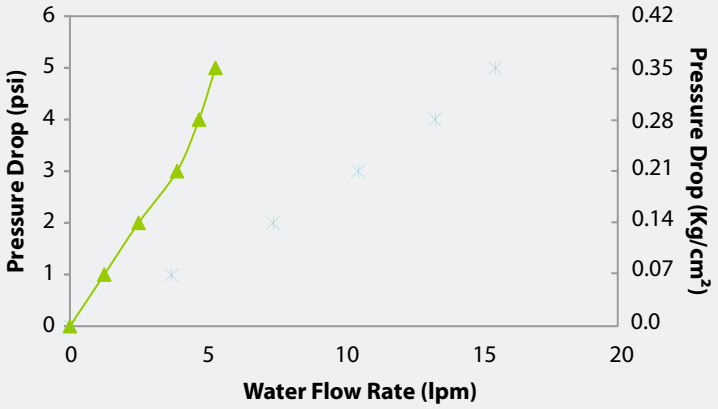
Construction					
Filter Media		Multilayered Microglassfiber			
Plastic Parts		Polypropylene			
Size					
Size		5″	10″	20″	30″
EFA (Effective Filtration Area)		1700 cm^2	3400 cm^2	6800 cm^2	10200 cm^2
Operational Radius		80 mm	80 mm	80 mm	80 mm
Operational					
Max. Operating Temperature		80 °C @ < 30 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 minutes, 30 cycles and it cannot be inline 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			
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			
Extractables with WFI		Passes NVR test as per USP <661>			
Indirect Food Additives		Comply with USFDA 21 CFR Part 177.1520			
Oxidizable Substances		Within limits as specified in USP <1231>			
Quality Management System		ISO-9001 Certified			
USFDA		DMF No. 015554			

Typical Water Flow Rates

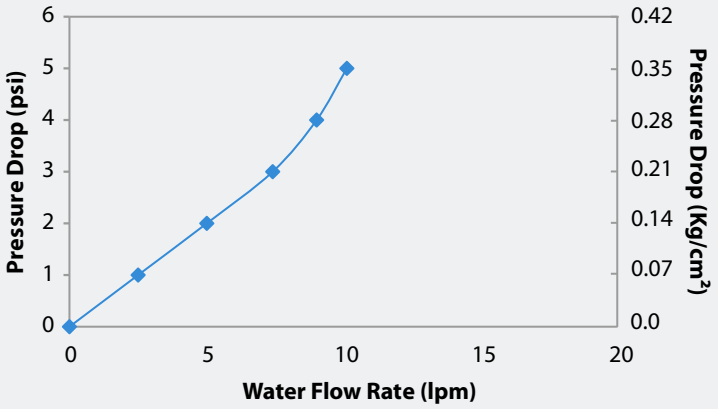
0.7 µm *ClariCap*® *GS*, 1" Capsule Filter



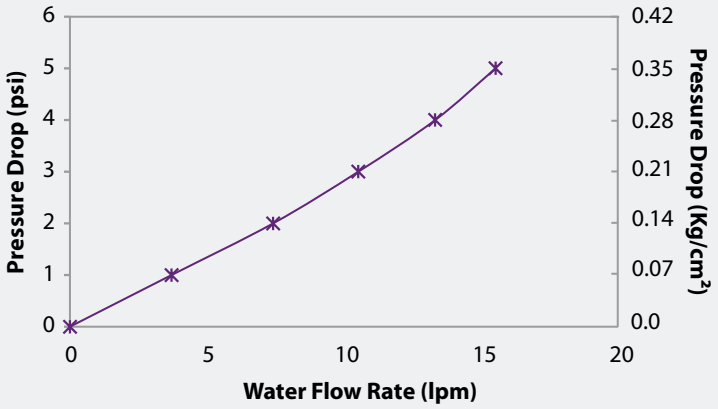
0.7 µm *ClariCap*® *GS*, 2" Capsule Filter

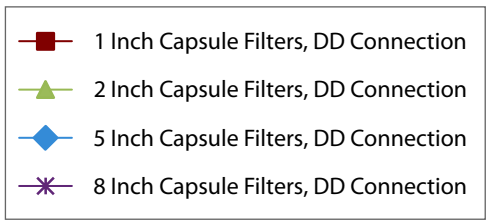


0.7 µm *ClariCap*® *GS*, 5" Capsule Filter



0.7 µm *ClariCap*® *GS*, 8" Capsule Filter



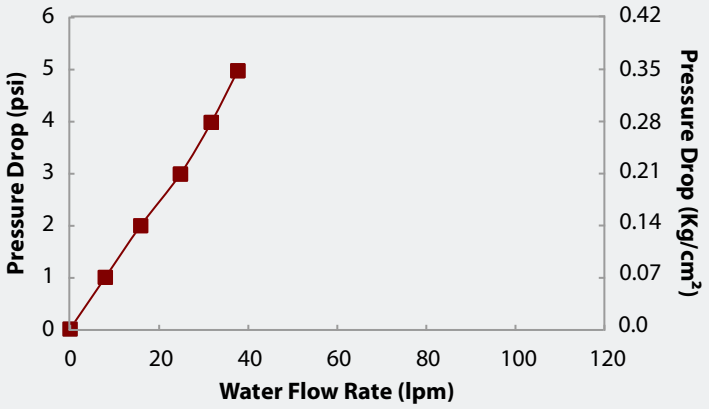


End Connection Type:

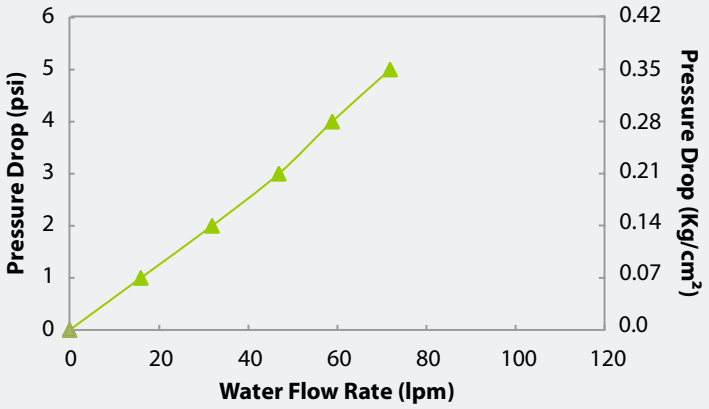
D: ½" Hose Barb

Typical Water Flow Rates

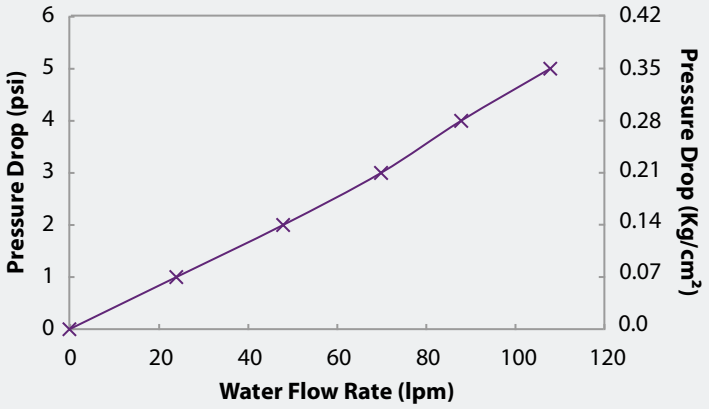
0.7 µm *ClariCap*® *GS*, 10" Capsule Filter

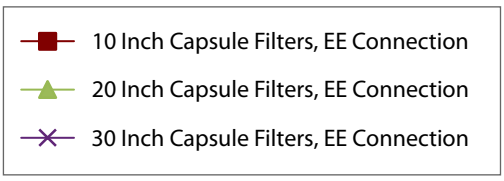


0.7 µm *ClariCap*® *GS*, 20" Capsule Filter



0.7 µm *ClariCap*® *GS*, 30" Capsule Filter





End Connection Type:

E: 1½" Sanitary Flange Connections

Ordering Information

ClariCap® GS 25mm Inline Capsule filter

Type	
	Code
ClariCap® GS	IGSX

Size	
	Code
25mm	06

Pore Size	
	Code
0.7µm	41
1µm	05
1.5µm	14
2µm	15

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

X

X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
100	04

Example:

IGSX	06	41	MN	X	X	1	04

Example for Non Sterile: IGSX0641MNXX104

Example for EO Sterile: IGSX0641MNXX204

ClariCap® GS 50mm Inline Capsule filter

Type	
	Code
ClariCap® GS (without Vent)	IGSX
ClariCap® GS (with Vent)	VGSX

Size	
	Code
50mm	10

Pore Size	
	Code
0.7µm	41
1µm	05
1.5µm	14
2µm	15

Inlet/Outlet	
	Code
¼" SHB	B
¾" Sanitary Flange	S
Female Luer Lock	M
¼" Single Step Hose Barb	A

X

X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
10	02

Example:

VGSX	10	41	BB	X	X	1	02

Example for Non Sterile: VGSX1041BBXX102

Example for EO Sterile: VGSX1041BBXX202

Inlet/Outlet Connections Available

Inlet/Outlet	25mm	50mm	
		with Vent	without Vent
¼" - ¾" Stepped Hose Barb	X	√	X
¾" Sanitary Flange	X	√	X
Female Luer Lock	Inlet Only	X	√
Male Luer Slip	Outlet Only	X	X
⅛" Hose Barb	√	X	X
Male Luer Lock	Outlet Only	X	X
¼" Hose Barb	√	X	X
¼" Single Step Hose Barb	X	X	√

Dimension (Length) (in mm)

Inlet/ Outlet	25mm	50mm
¼" - ⅜" Stepped Hose Barb I/O	-	79
¼" Hose Barb I/O	38	-
¼" Single Step Hose Barb I/O	-	62
¾" Sanitary Flange I/O	-	51
Female Luer Lock Inlet/ Male Luer Slip Outlet	23	-
⅛" Hose Barb I/O	36	-

Operational Radius	15	28

Ordering Information

ClariCap® GS Small Capsule filter

Type		Size		Pore Size		Inlet/Outlet		X	Bell		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
ClariCap® GS	DGSX	1″	51	0.7µm	41	¼″ SHB	A		Yes*	B	Non Sterile	1	1	01
		2″	52	1µm	05	¼″ MNPT (18 TPI)	B		No Bell	X	EO Sterile	2		
		5″	53	1.5µm	14	¼″ BSP (19 TPI)	M		Bell with cover	C				
		8″	57	2µm	15	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:

DGSX	57	41	DD	X	X	1	01

Example for Non Sterile: DGSX5141QQXX101 **Example for EO Sterile: DGSX5141QQXX201**

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

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

ClariCap® GS Large Capsule filter

Type	
	Code
ClariCap® GS	LGSX

Size	
	Code
5″	53
10″	54
20″	55
30″	56

Pore Size	
	Code
0.7µm	41
1µm	05
1.5µm	14
2µm	15

Inlet/Outlet	
	Code
½″ Single Step Hose Barb	Q
1½″ Sanitary Flange	E
¾″ Sanitary Flange	S
⅜″ Hose Barb	I
1″ Hose Barb	Z

X

Inline/ T-Line	
	Code
Inline	X
T-Line*	T

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
1	01

Example:

LGSX	54	41	EE	X	T	1	01

Example for Non Sterile: LGSX5341QQXX101 **Example for EO Sterile: LGSX5341QQXX201**

***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

Dimensions (in mm)	Inline Capsule Filters				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	x	x	x	x	x
½″ Single Step Hose Barb I/O	218	336	630	890	x	x	x
1½″ Sanitary Flange Inlet ½″ Hose Barb Outlet	212	334	620	870	x	x	x
⅜″ 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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