mdi
Membrane Technologies

Data Sheet

ClariSure® GS

Microglassfiber Cartridge Filters

mdi *ClariSure® GS* cartridge filters are multilayered, high throughput filters, specially designed for difficult to filter solutions.

It is a very high efficiency pre-filter combining the unique abilities of multilayered microglassfiber filter media to retain colloidal particles and heat calendered polypropylene filter media to ensure non media migration.

Applications

➢ Precipitate removal post viral inactivation

➢ Pre-filtration of serum and other viscous biologicals

➢ Pre-filtration of serum solutions

➢ Clarification of cell harvest supernatants

➢ Pre-filtration of large volume parenterals

➢ Pre-filtration of difficult to filter SVP

➢ Polishing of turbid solutions

Key Features

➢ High throughputs

➢ Long service life

➢ Non-toxic material of construction

➢ High flow rates

➢ Sterilizable by Autoclaving/Steaming in place (SIP)

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 cartridge filter lot 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.

Flow Rate

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

Pressure, Temperature Endurance

ClariSure® GS filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

Extractables

Extractables/leachables from *ClariSure® GS* filters, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

ClariSure® GS filters are validated to exhibit low extractables under harsh extraction conditions.

Total Traceability

ClariSure® GS filters come with completely traceable lot numbers to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

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

ClariSure® GS filters are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room 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
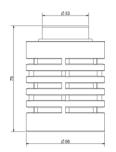
Adapters and Dimensions
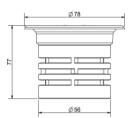
2.5" Mini Cartridge Filters

4463 Adapter (E0)

Total Length : 75 mm
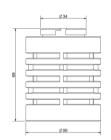Diameter : 56 mm

Seal-K Adapter (G0)

Total Length : 77 mm
Diameter : 56 mm

4463B Adapter (H0)

Total Length : 69 mm
Diameter : 56 mm

5" Mini Cartridge Filters

4463 Adapter (E0)

Total Length : 128 mm
Diameter : 56 mm

Seal-K Adapter (G0)

Total Length : 132 mm
Diameter : 56 mm

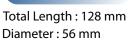### 4440 Adapter (U0)

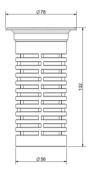Total Length : 118 mm
Diameter : 56 mm

Seal-O Adapter (F0)

Total Length : 117 mm
Diameter : 56 mm

4463B Adapter (H0)

Total Length : 123 mm
Diameter : 56 mm

Adapters and Dimensions

Standard Cartridge Filters

10" Cartridge Filter- 7P Adapter with Fin (A0)
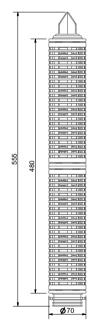
Total Length : 315 mm

Diameter : 70 mm

20" Cartridge Filter- 7P Adapter with Fin (A0)
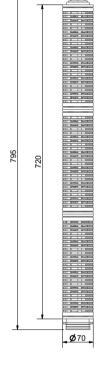
Total Length : 555 mm

Diameter : 70 mm

30" Cartridge Filter- 7P Adapter with Fin (A0)

Total Length : 795 mm

Diameter : 70 mm

Adapter and Elastomers Availability Chart

Mini Cartridge Filters		
Adapters	**2.5"**	**5"**
4463	√	√
4463B	√	√
4440	√	√
Seal-K	√	√
Seal-O	X	√
Seal-M	√	√

Mini Cartridge Filters	
	Elastomer
Adapters	**Silicone**
4463	√
4463B	√
4440	√
Seal-K	X
Seal-O	√
Seal-M	√

Standard Cartridge Filters				
Adapters	**5"**	**10"**	**20"**	**30"**
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	X	√	√	√
'O'	X	√	√	√

Standard Cartridge Filters				
Adapters	**Elastomers**			
	Silicone	**Viton**	**EPDM**	**FEP Encapsulated Viton**
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	√	√	√	X
'O'	√	√	√	X

Linear Upscaling
from Pilot Scale to Production Process

mdi offers a wide range of *ClariSure® 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 800 cm² to 10200 cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *ClariSure® GS* filters there by reducing the additional validation cost and time.enough documented evidence to justify specific filter use.

ClariSure® GS, 2.5"
EFA: 800 cm²

ClariSure® GS, 5"
EFA: 1200 cm²

ClariSure® GS, 5" Large
EFA: 1700 cm²

ClariSure® GS, 10"
EFA: 3400 cm²

ClariSure® GS, 20"
EFA: 6800 cm²

ClariSure® GS, 30"
EFA: 10200 cm²

*EFA: Effective Filtration Area

Specifications

Mini Cartridge Filters

Construction	
Filter Media	Microglassfiber
Plastic Parts	Polypropylene
O rings	Silicone

Size		
Size	2.5"	5"
Effective Filtration Area (Nominal)	800cm^2	1200cm^2

Operational	
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm^2)
Max. Differential Pressure	50 psi (3.5 Kg/cm^2) @ 25 °C
Sterilization	Autoclavable/Steam Sterilized at 121°C for 30 minute, 30 Cycles.

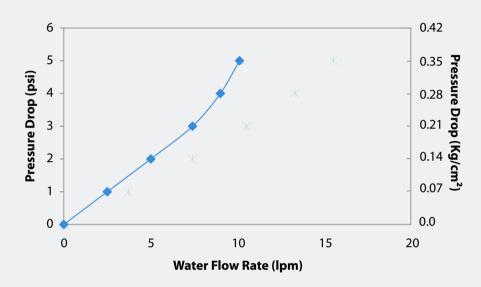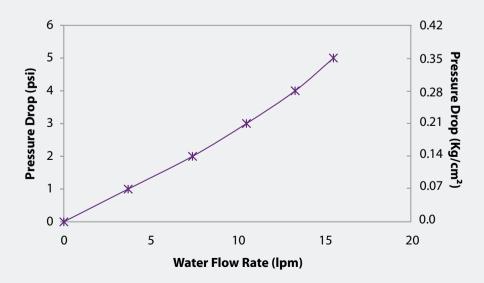| Assurance	
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
Extractables with WFI	Passes NVR test as per USP <661>
Indirect Food Additives	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications
Standard Cartridge Filters

Construction				
Filter Media	Microglassfiber			
Plastic Parts	Polypropylene			
O rings	Silicone			
	Viton			
	EPDM			
	FEP Encapsulated Viton			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	1700cm^2	3400cm^2	6800cm^2	10200cm^2
Operational				
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm^2)			
Max. Differential Pressure	50 psi (3.5 Kg/cm^2) @ 25 °C			
Sterilization	Autoclavable/Steam Sterilized at 121°C for 30 minute, 30 Cycles.			
Assurance				
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics			
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections			
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release			
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Indirect Food Additives	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520			
Oxidizable Substances	Passes test as per USP <1231>			
Quality Management System	ISO-9001 Certified			
USFDA	DMF No. 015554			

Typical Water Flow Rates
Mini Cartridge Filters

0.7μm *ClariSure® GS*, 2.5" Mini Cartridge Filters

0.7μm *ClariSure® GS*, 5" Mini Cartridge Filters

0.7µm *ClariSure® GS*, **5" Standard Cartridge Filters**

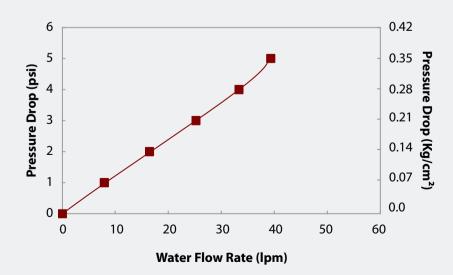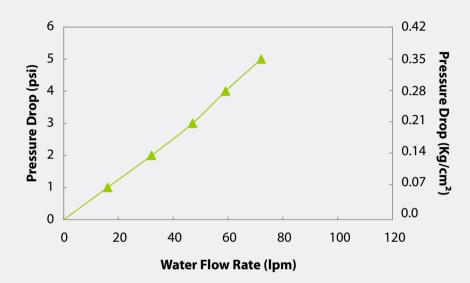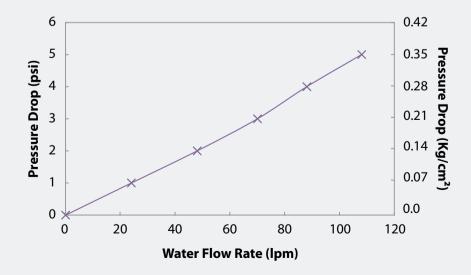**0.7µm** *ClariSure® GS*, **10" Standard Cartridge Filters**

Typical Water Flow Rates
Standard Cartridge Filters
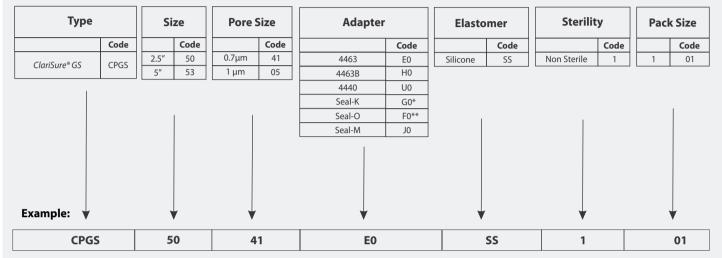
0.7μm *ClariSure® GS*, 20" Standard Cartridge Filters

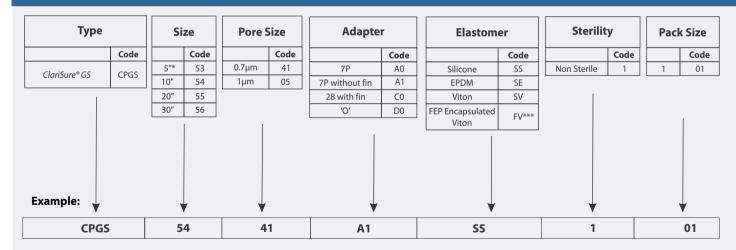**0.7μm *ClariSure® GS*, 30" Standard Cartridge Filters**

ClariSure® GS Microglassfiber Mini Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® GS	CPGS	2.5"	50	0.7μm	41	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	1 μm	05	4463B	H0						
						4440	U0						
						Seal-K	G0*						
						Seal-O	F0**						
						Seal-M	J0						

Example:

CPGS	50	41	E0	SS	1	01

*G0 adapter code is not available with any elastomer. Please mention XX in place of elastomer code while ordering

**Adapter code F0 is available only in 5" cartridge filters.

ClariSure® GS Microglassfiber Standard Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® GS	CPGS	5"*	53	0.7μm	41	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	1μm	05	7P without fin	A1	EPDM	SE				
		20"	55			28 with fin	C0	Viton	SV				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV***				

Example:

CPGS	54	41	A1	SS	1	01

*Size 5" is available in Adapter Code A0 (7P) and A1 (7P without fin) only

**FV is available in adapter code A0 (7P) and A1 (7P without fin) only