

## Data Sheet

### ClariSure® GP

#### Microglassfiber Cartridge Filters

**mdi** ClariSure® GP cartridge filters are specially designed multilayered precision filtration devices. These cartridge filters act as throughput enhancers, specially in case of difficult to filter solutions.

A microglassfiber upstream layer retains very fine colloidal particles and a downstream polypropylene layer checks any kind of media migration.

#### Applications

- Pre-filtration of difficult to filter solutions
- Pre-filtration of difficult to filter SVP like Oxytetracycline

#### Key Features

- High throughputs
- Long service life
- Non-toxic material of construction
- Sterilizable by Autoclaving/Steaming in place (SIP)



## 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 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*<sup>®</sup> GP filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

### Extractables

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

*ClariSure*<sup>®</sup> GP filters are validated to exhibit low extractables under harsh extraction conditions.

### Total Traceability

*ClariSure*<sup>®</sup> GP 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*<sup>®</sup> GP 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.

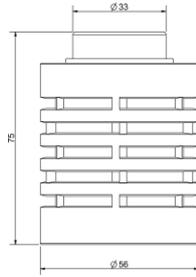
### Other Regulatory Compliance

- 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

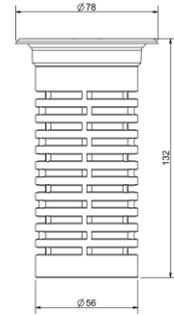
### 2.5" Mini Cartridge Filters

#### 4463 Adapter (E0)



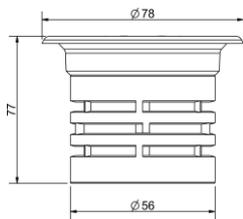
Total Length : 75 mm  
Diameter : 56 mm

#### Seal-K Adapter (G0)



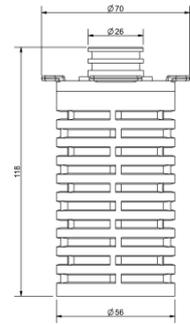
Total Length : 132 mm  
Diameter : 56 mm

#### Seal-K Adapter (G0)



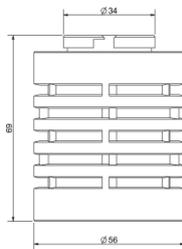
Total Length : 77 mm  
Diameter : 56 mm

#### 4440 Adapter (U0)



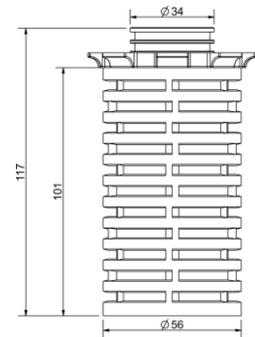
Total Length : 118 mm  
Diameter : 56 mm

#### 4463B Adapter (H0)



Total Length : 69 mm  
Diameter : 56 mm

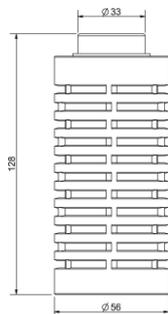
#### Seal-O Adapter (F0)



Total Length : 117 mm  
Diameter : 56 mm

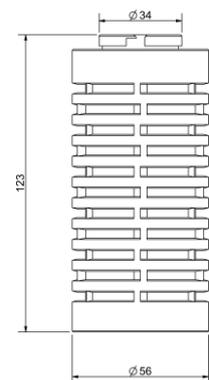
### 5" Mini Cartridge Filters

#### 4463 Adapter (E0)



Total Length : 128 mm  
Diameter : 56 mm

#### 4463B Adapter (H0)

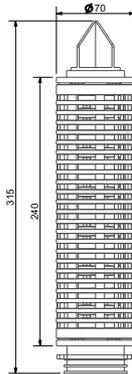


Total Length : 123 mm  
Diameter : 56 mm

## Adapters and Dimensions

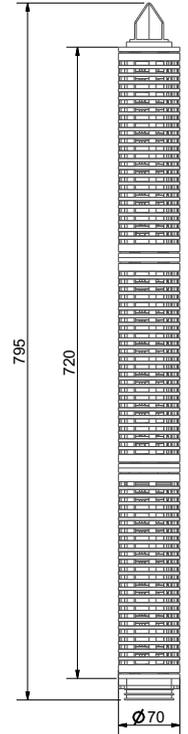
### Standard Cartridge Filters

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



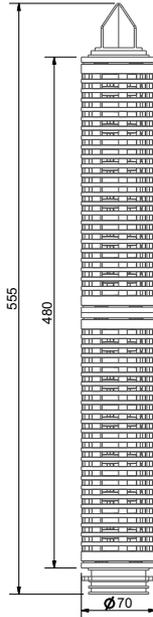
Total Length : 315 mm  
Diameter : 70 mm

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



Total Length : 795 mm  
Diameter : 70 mm

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



Total Length : 555 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	
Adapters	Elastomer
	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*<sup>®</sup> GP 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 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 *ClariSure*<sup>®</sup> GP filters there by reducing the additional validation cost and time.



***ClariSure*<sup>®</sup> GP, 2.5"**  
EFA: 800 cm<sup>2</sup>



***ClariSure*<sup>®</sup> GP, 5"**  
EFA: 1600 cm<sup>2</sup>



***ClariSure*<sup>®</sup> GP, 5" Large**  
EFA: 2500 cm<sup>2</sup>



***ClariSure*<sup>®</sup> GP, 10"**  
EFA: 5000 cm<sup>2</sup>



***ClariSure*<sup>®</sup> GP, 20"**  
EFA: 10000 cm<sup>2</sup>



***ClariSure*<sup>®</sup> GP, 30"**  
EFA: 15000 cm<sup>2</sup>

\*EFA: Effective Filtration Area

# Specifications

## Mini Cartridge Filters

### Construction

Filter Media	Microglassfiber
Support Layers	Polypropylene
Plastic Parts	Polypropylene
O rings	Silicone

### Size

Size	2.5"	5"
Effective Filtration Area (Nominal)	800cm <sup>2</sup>	1600cm <sup>2</sup>

### Operational

Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm <sup>2</sup> )
Max. Differential Pressure	50 psi (3.5 Kg/cm <sup>2</sup> ) @ 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
Support Layers	Polypropylene
Plastic Parts	Polypropylene
O rings	Silicone
	Viton
	EPDM
	FEP Encapsulated Viton

### Size

Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500cm <sup>2</sup>	5000cm <sup>2</sup>	10000cm <sup>2</sup>	15000cm <sup>2</sup>

### Operational

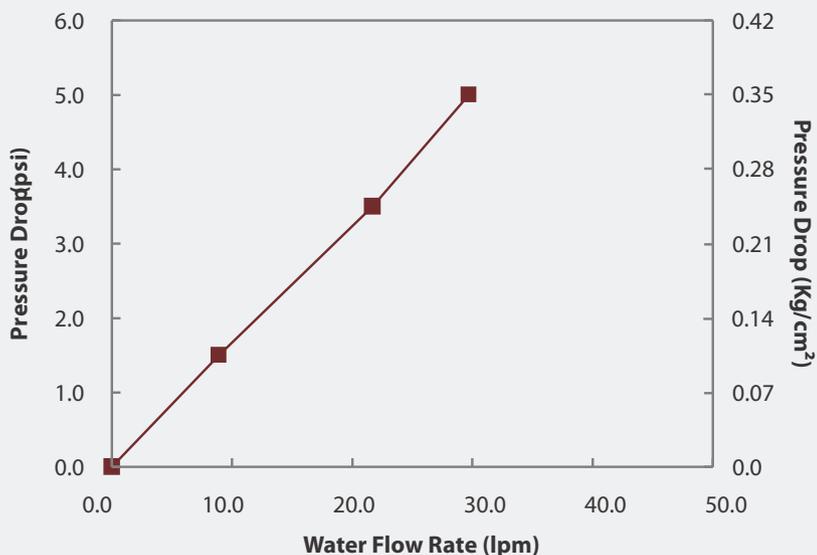
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm <sup>2</sup> )
Max. Differential Pressure	50 psi (3.5 Kg/cm <sup>2</sup> ) @ 25 °C
Sterilization	Autoclavable/Steam Sterilized at 121°C for 30 minute, 30 Cycles.

### Assurance

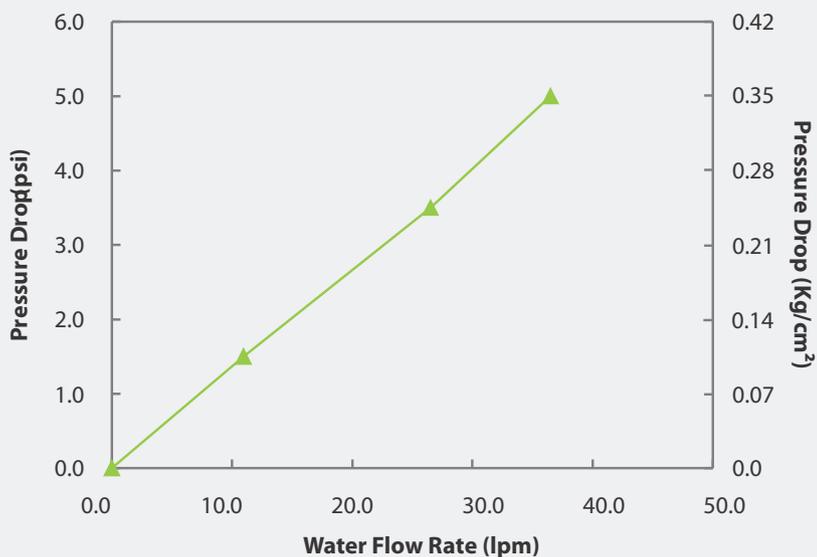
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics
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# Typical Water Flow Rates Standard Cartridge Filters

### 1 $\mu\text{m}$ ClariSure GP, 10" Cartridge Filters



### 2 $\mu\text{m}$ ClariSure GP, 10" Cartridge Filters



# Ordering Information

## ClariSure® GP Microglassfiber Mini Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® GP	CPGP	2.5"	50	0.5µm	04	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	1 µm	05	4463B	H0						
				2 µm	15	4440	U0						
						Seal-K	G0*						
						Seal-O	F0**						
						Seal-M	J0						

Example:

CPGP	50	04	E0	SS	1	01
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\*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® GP Microglassfiber Standard Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® GP	CPGP	5"*	53	0.5µm	04	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	1 µm	05	7P without fin	A1	EPDM	SE				
		20"	55	2 µm	15	28 with fin	C0	Viton	SV				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV***				

Example:

CPGP	54	01	A1	SS	1	01
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\*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

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