

## Data Sheet

### ClariSure® PA

#### Polypropylene Media Cartridge Filters

**mdi** ClariSure® PA polypropylene media cartridge filters are 100% polypropylene, very high retention efficiency pleated cartridge filters offering large filtration area.

These filters have heat stable construction and are used as pre-filters to sterilizing membrane cartridge filters.

#### Applications

- Pre-filtration of fermentor air
- Pre-filtration of small volume parenterals

#### Key Features

- Very high retention efficiency (99.99%)
- Heat stable construction
- No media migrating
- Wide chemical compatibility
- Biologically inert
- 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 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*® PA filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

### Extractables

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

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

### Total Traceability

*ClariSure*® PA 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*® PA 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.

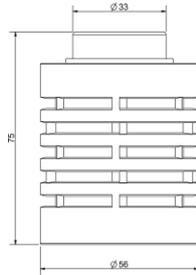
### Other Regulatory Compliance

- 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

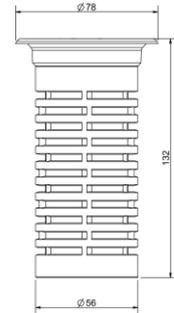
### 2.5" Mini Cartridge Filters

#### 4463 Adapter (E0)



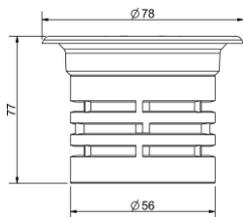
Total Length : 75 mm  
Diameter : 56 mm

#### Seal-K Adapter (G0)



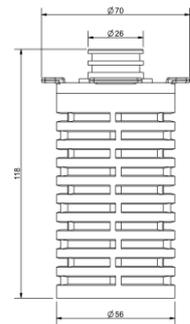
Total Length : 132 mm  
Diameter : 56 mm

#### Seal-K Adapter (G0)



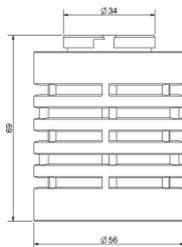
Total Length : 77 mm  
Diameter : 56 mm

#### 4440 Adapter (U0)



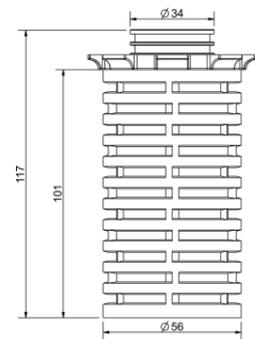
Total Length : 118 mm  
Diameter : 56 mm

#### 4463B Adapter (H0)



Total Length : 69 mm  
Diameter : 56 mm

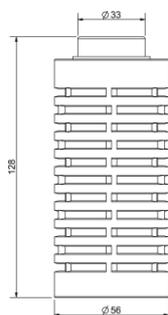
#### Seal-O Adapter (F0)



Total Length : 117 mm  
Diameter : 56 mm

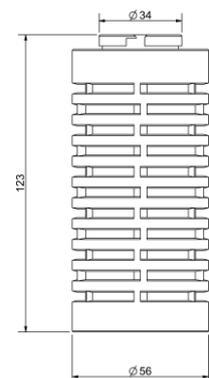
### 5" Mini Cartridge Filters

#### 4463 Adapter (E0)



Total Length : 128 mm  
Diameter : 56 mm

#### 4463B Adapter (H0)

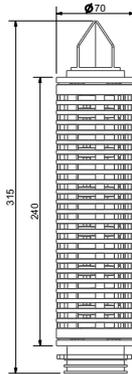


Total Length : 123 mm  
Diameter : 56 mm

## Adapters and Dimensions

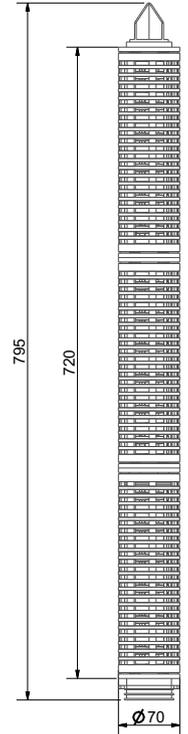
### Standard Cartridge Filters

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



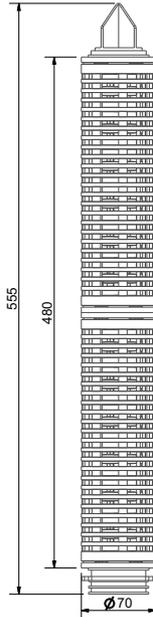
Total Length : 315 mm  
Diameter : 70 mm

#### 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*® PA 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*® PA filters there by reducing the additional validation cost and time.



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



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



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



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



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



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

\*EFA: Effective Filtration Area

# Specifications

## Mini Cartridge Filters

### Construction

Filter Media	Polypropylene	
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/In-line steam sterilizable at 121 °C for 30 minutes, 100 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	Polypropylene		
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

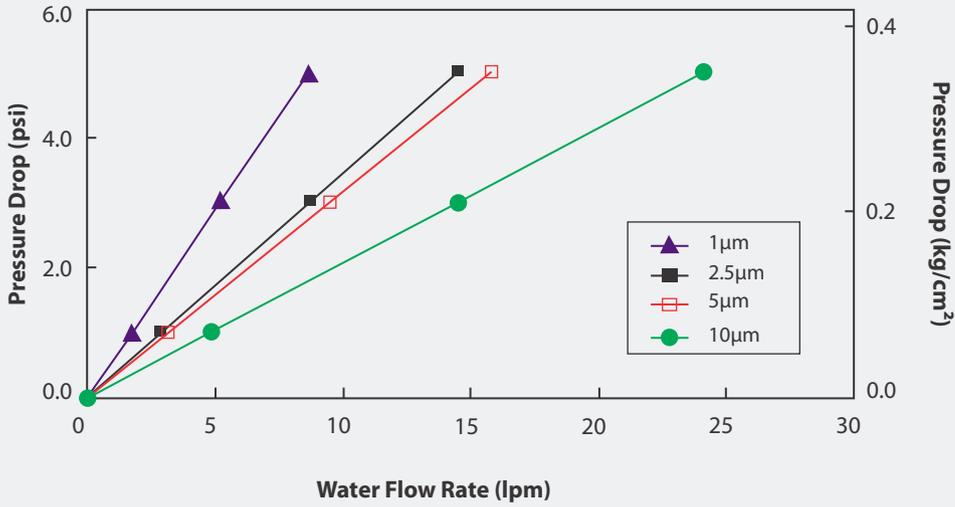
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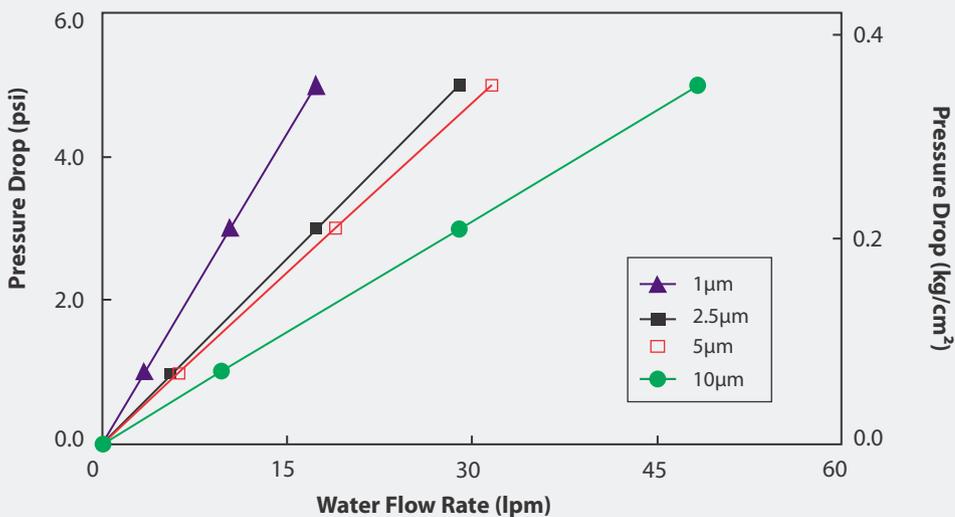
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# Typical Water Flow Rates Mini Cartridge Filters

### ClariSure® PA, 2.5" Mini Cartridge Filters

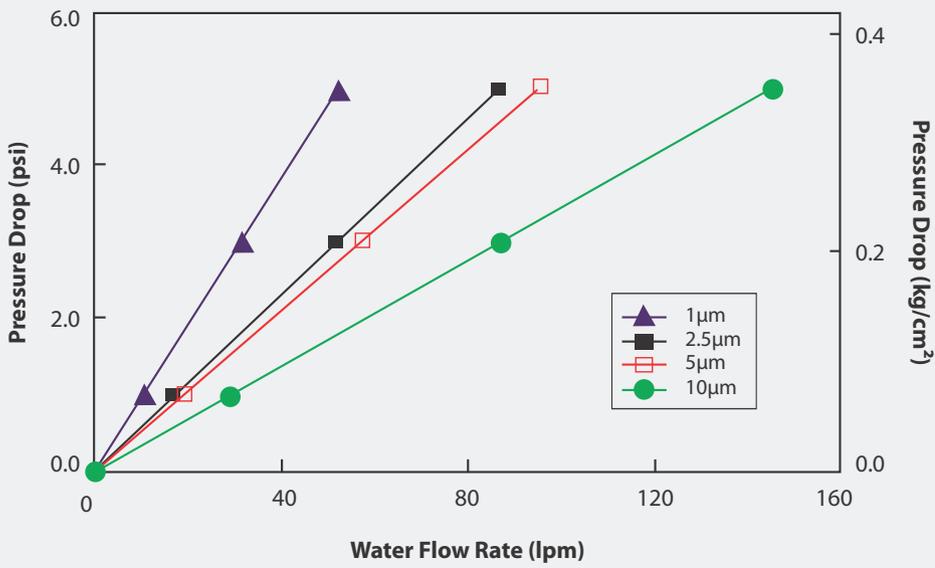


### ClariSure® PA, 5" Mini Cartridge Filters



# Typical Water Flow Rates Standard Cartridge Filters

### ClariSure® PA, 10" Standard Cartridge Filters



## ClariSure® PA Mini Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® PA	CPPA	2.5"	50	0.2 µm	01	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	0.5 µm	04	4463B	H0						
				0.65 µm	09	4440	U0						
				1 µm	05	Seal-K	G0*						
				1.2 µm	10	Seal-O	F0**						
				2.5 µm	06	Seal-M	J0						
				5 µm	07								
				8 µm	17								
				10 µm	08								
				20 µm	11								
				30 µm	19								
				40 µm	20								

**Example:**

CPPA	50	01	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® PA Standard Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® PA	CPPA	5"	53	0.2 µm	01	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	0.5 µm	04	7P without fin	A1	EPDM	SE				
		20"	55	0.65 µm	09	28 with fin	C0	Viton	SV				
		30"	56	1 µm	05	'O'	D0	FEP Encapsulated Viton	FV***				
				1.2 µm	10								
				2.5 µm	06								
				5 µm	07								
				8 µm	17								
				10 µm	08								
				20 µm	11								
				30 µm	19								
				40 µm	20								

**Example:**

CPPA	54	04	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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