

## Data Sheet

### 0.1 $\mu\text{m}$ AseptiSure® KS

#### Hydrophilic Polyethersulfone (PES) Membrane Cartridge Filters

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

Processes managers are continuously looking for microfiltration solutions to upstream, downstream, intermediate processes and final biological preparations. Since bio manufacturing is a multi stage process and bio molecules by nature are extremely sensitive, they are looking for:

- Minimizing protein losses due to adsorption to improve overall product yields
- Minimizing filter extracts which add up due to multiple points of use in a process
- High throughputs to achieve process economy
- Absolute retentions for higher sterility assurance

**mdi** 0.1  $\mu\text{m}$  AseptiSure® KS double layer PES membrane cartridge filters are validated for mycoplasma removal and are used for sterile media filtration in mammalian cell culture.

The upstream PES membrane layer protects the downstream side PES membrane layer from premature clogging. The membrane pore structure is specially designed to give high throughputs, thus resulting in better economics

**mdi** 0.1  $\mu\text{m}$  AseptiSure® KS filters are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates.



# 0.1 µm AseptiSure® KS

## PES Membrane Cartridge Filters

# Datasheet

**mdi** 0.1 µm AseptiSure® KS cartridge filters are deeply validated for use in Biopharmaceutical applications. These filters are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities.

Packaging is done in polybags for convenience of taking AseptiSure® KS in clean areas for making disposable assemblies for subsequent sterilization.

### Key Features

- Low protein binding
- High throughputs
- Long service life
- Pre-flushed to minimize particulate release after installation
- Non-toxic material of construction
- Multiple autoclavable/SIP
- Absolute retention
- 100% integrity tested
- High flow rates
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Unique identification number is laser etched on each filter
- Individual certificate of quality for each device
- Sterilizable by Autoclaving/Steaming in place (SIP)

### Applications

- Sterile liquid of culture media for mammalian cell culture

### Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the filter with drug product under simulated worst-case conditions of use.

**mdi** provides validation services supported by customized validation protocols and world class test facilities to assist you in filter validations with your specific drug product.

**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 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.

## Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention with *Acholeplasma laidlawii* (ATCC 23206) to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

## 100% Integrity Tested

Each 0.1µm *AseptiSure*® *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.

## Adsorption

0.1µm *AseptiSure*® *KS* filters are validated for low protein binding to ensure minimal active ingredient losses when used for filtration of high value proteins.

## Pressure, Temperature Endurance

0.1µm *AseptiSure*® *KS* filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

## Extractables

Extractables/leachables from 0.1µm *AseptiSure*® *KS* filters, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

0.1µm *AseptiSure*® *KS* filters are validated to exhibit low extractables under harsh extraction conditions.

## Bioburden Testing

0.1µm *AseptiSure*® *KS* bioburden is tested as per ISO 11737-1 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

0.1µm *AseptiSure*® *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

0.1µm *AseptiSure*® *KS* filters 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.

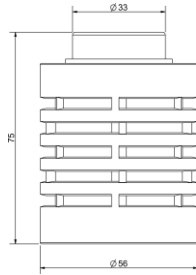
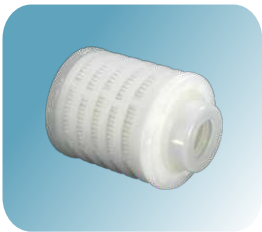
## Other Regulatory Compliance

- 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>

## Adapters and Dimensions

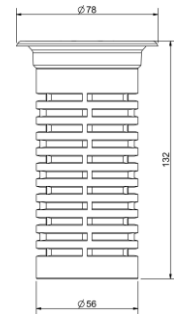
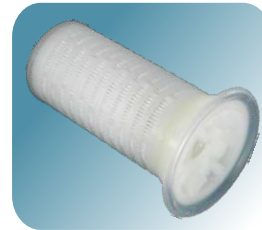
### 2.5" Mini Cartridge Filters

#### 4463 Adapter (E0)



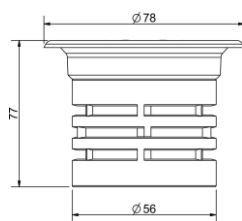
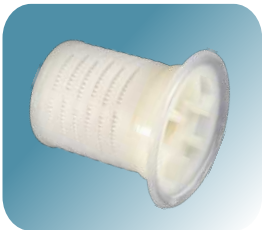
Total Length : 75 mm  
Diameter : 56 mm

#### Seal-K Adapter (G0)



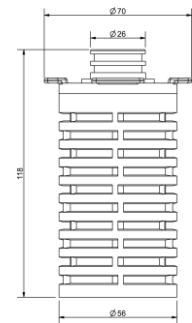
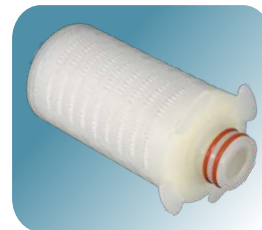
Total Length : 132 mm  
Diameter : 56 mm

#### Seal-K Adapter (G0)



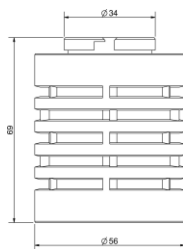
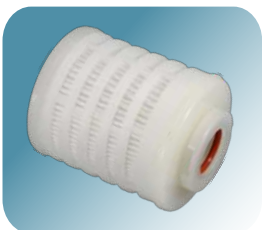
Total Length : 77 mm  
Diameter : 56 mm

#### 4440 Adapter (U0)



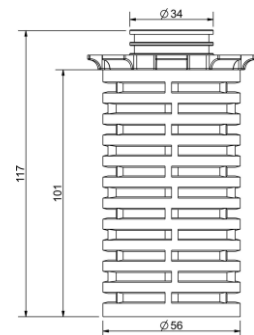
Total Length : 118 mm  
Diameter : 56 mm

#### 4463B Adapter (H0)



Total Length : 69 mm  
Diameter : 56 mm

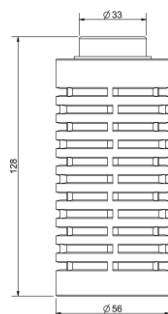
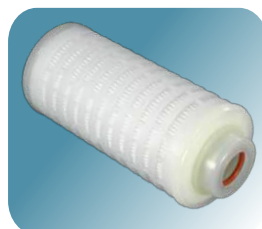
#### Seal-O Adapter (F0)



Total Length : 117 mm  
Diameter : 56 mm

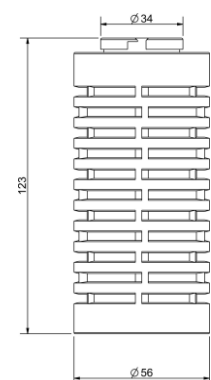
### 5" Mini Cartridge Filters

#### 4463 Adapter (E0)



Total Length : 128 mm  
Diameter : 56 mm

#### 4463B Adapter (H0)

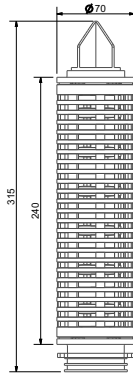


Total Length : 123 mm  
Diameter : 56 mm

## Adapters and Dimensions

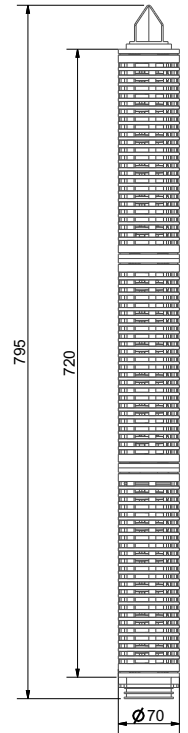
### Standard Cartridge Filters

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



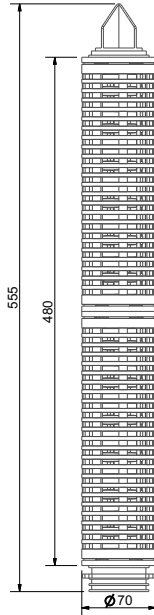
Total Length : 315 mm  
Diameter : 70 mm

#### 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

Scientists are concerned about filter fluid interaction impacting the stability, purity, strength etc. of the drug product, and they take a keen interest in filter selection at the formulation development stage itself. Although preliminary compatibility data support initial filter selection, for stability studies detailed filter validations are required to provide enough documented evidence to justify specific filter use.

A critical requirement that needs to be addressed at this stage is of scalability from pilot scale to full scale production processes.

**mdi** offers a wide range of 0.1µm *AseptiSure*® *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 1000 cm<sup>2</sup> to 18000cm<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 0.1µm *AseptiSure*® *KS* filters there by reducing the additional validation cost and time.



0.1µm *AseptiSure*® *KS*, 2.5"  
EFA: 1000 cm<sup>2</sup>



0.1µm *AseptiSure*® *KS*, 5"  
EFA: 2000 cm<sup>2</sup>



0.1µm *AseptiSure*® *KS*, 5" Large  
EFA: 3000 cm<sup>2</sup>



0.1µm *AseptiSure*® *KS*, 10"  
EFA: 6000 cm<sup>2</sup>



0.1µm *AseptiSure*® *KS*, 20"  
EFA: 12000 cm<sup>2</sup>



0.1µm *AseptiSure*® *KS*, 30"  
EFA: 18000 cm<sup>2</sup>

\*EFA: Effective Filtration Area

# Specifications

## Mini Cartridge Filters

# Datasheet

### Construction

Membrane	Hydrophilic PES
Support Layers	Polyester
Plastic Parts	Polypropylene
O rings	Silicone
Final Filter Pore Size	0.1µm
Pre-Filter Pore Size	0.2µm and 0.45µm

### Integrity Testing / Retention

Bubble Point	≥ 31psi (2.18 Kg/cm <sup>2</sup> ) with 50% IPA/Water Solution
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23026) per cm <sup>2</sup>

### Size

Size	2.5"	5"
Effective Filtration Area (Nominal)	1000cm <sup>2</sup>	2000cm <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
Reverse Pressure	< 0.7 Kg/cm <sup>2</sup> (10 psi) @ 25 °C
Sterilization	Autoclavable/In-line steam sterilizable at 121 °C for 30 minutes, 25 cycles

### 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>
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1
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
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 3 liter WFI flush
pH Compatibility	Compatible with pH range of 1 - 10
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

Membrane	Hydrophilic PES
Support Layers	Polyester
Plastic Parts	Polypropylene
O rings	Silicone
	Viton
	EPDM
	FEP Encapsulated Viton
Final Filter Pore Size	0.1µm
Pre-Filter Pore Size	0.2µm and 0.45µm

### Integrity Testing / Retention

Bubble Point	≥ 31psi (2.18 Kg/cm <sup>2</sup> ) with 50% IPA/Water Solution
Air Diffusion Flow (10" Filter)	≤ 29 ml/min @ 50 psi (3.52 Kg/cm <sup>2</sup> ) with Water
Microbial Retention	LRV >7 for <i>Acholeplasma laidlawii</i> (ATCC 23026) per cm <sup>2</sup>

### Size

Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000cm <sup>2</sup>	6000cm <sup>2</sup>	12000cm <sup>2</sup>	18000cm <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
Reverse Pressure	< 0.7 Kg/cm <sup>2</sup> (10 psi) @ 25 °C
Sterilization	Autoclavable/In-line steam sterilizable at 121 ° C for 30 minutes, 25 cycles

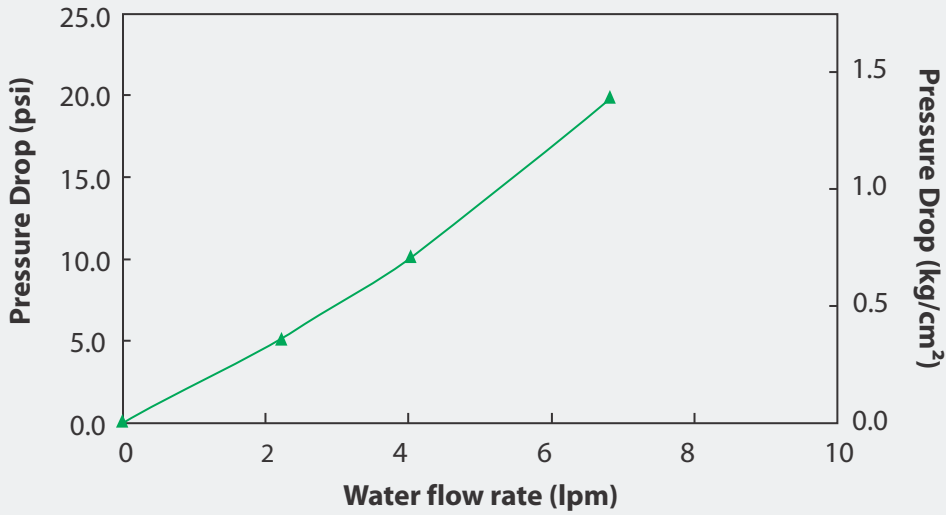
### Assurance

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USFDA	DMF No. 015554

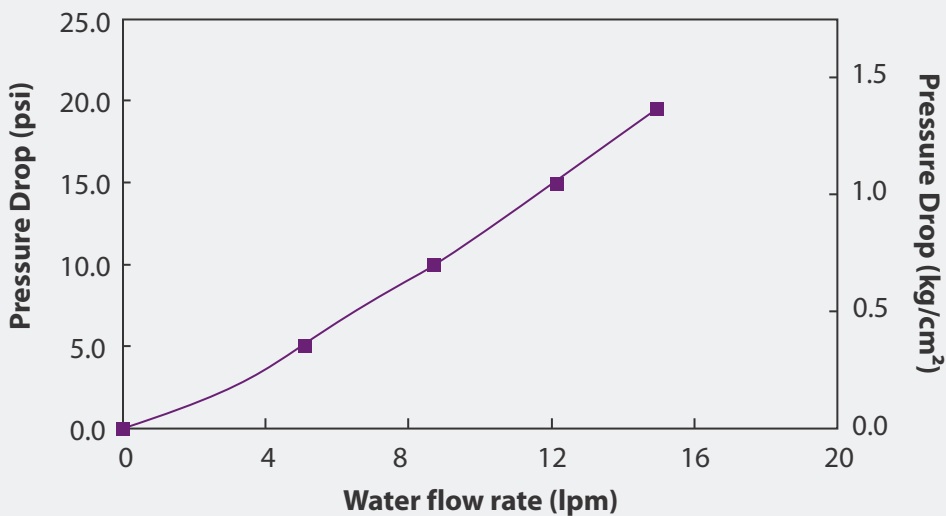
# Typical Water Flow Rates

## Mini Cartridge Filters

### AseptiSure® KS, 2.5" Mini Cartridge Filters



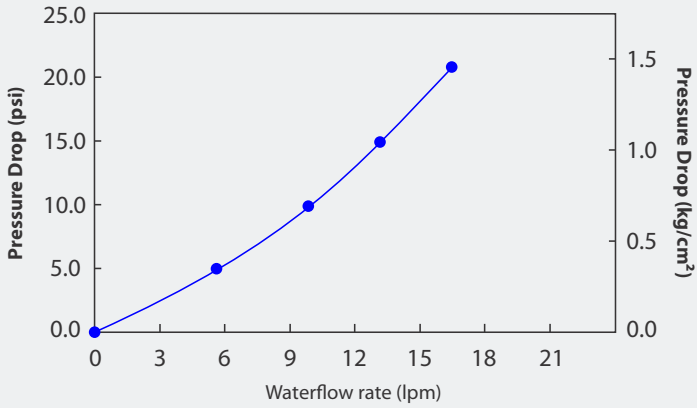
### AseptiSure® KS, 5" Mini Cartridge Filters



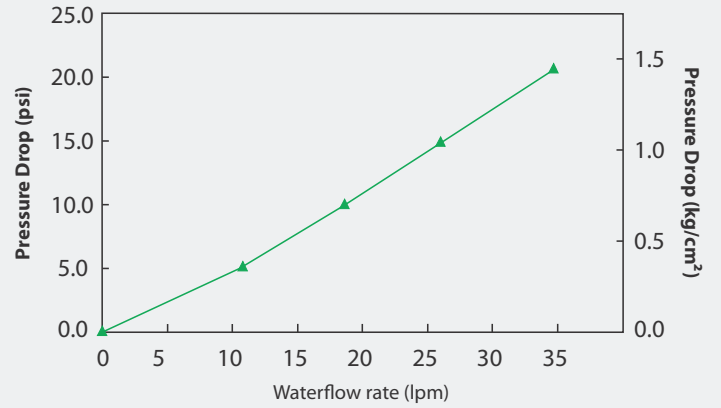
# Typical Water Flow Rates Standard Cartridge Filters

# Datasheet

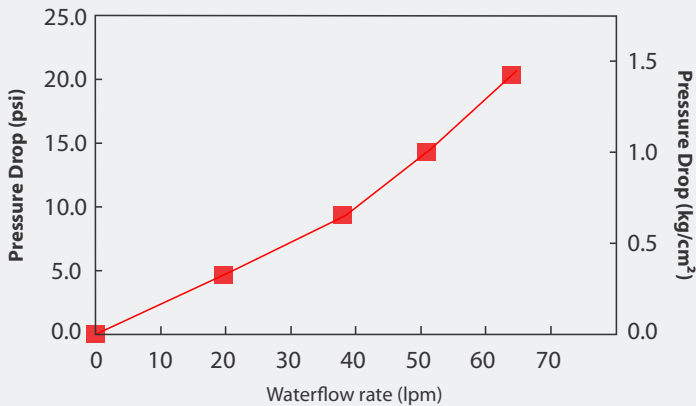
### AseptiSure® KS, 5" Standard Cartridge Filters



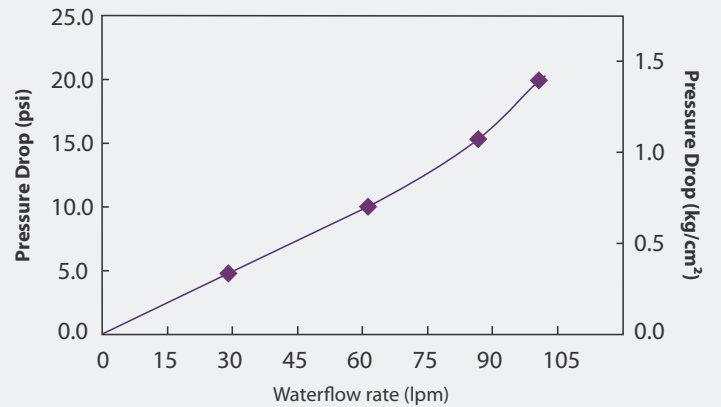
### AseptiSure® KS, 10" Standard Cartridge Filters



### AseptiSure® KS, 20" Standard Cartridge Filters



### AseptiSure® KS, 30" Standard Cartridge Filters



## 0.1µm AseptiSure® KS PES Membrane Mini Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure® KS (0.2µm Upstream)	CPK1	2.5"	50	0.1µm	36	4463	E0	Silicone	SS	Non Sterile	1	1	01
AseptiSure® KS (0.45µm Upstream)	CPKX	5"	53			4463B	H0						
						Seal-K	G0*						
						Seal-O	F0**						
						Seal-M	J0						

Example:

<b>CPKX</b>	<b>50</b>	<b>36</b>	<b>E0</b>	<b>SS</b>	<b>1</b>	<b>01</b>
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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.

## 0.1µm AseptiSure® KS PES Membrane Standard Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure® KS (0.2µm Upstream)	CPK1	5"	53	0.1µm	36	7P	A0	Silicone	SS	Non Sterile	1	1	01
AseptiSure® KS (0.45µm Upstream)	CPKX	10"	54			7P without fin	A1						
		20"	55			28 with fin	C0	Viton	SV				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV**				

Example:

<b>CPKX</b>	<b>54</b>	<b>36</b>	<b>A1</b>	<b>SS</b>	<b>1</b>	<b>01</b>
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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

## Advanced Microdevices Pvt. Ltd.

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Website : www.mdimembrane.com