

mdi Polyethersulfone (PES) Membrane Cartridge filters Type AseptiSure KS are serial filtration devices with upstream nominal PES membrane layer to protect the downstream final PES membrane layer from Premature clogging and to give enhanced throughputs, thus resulting in better economics.

mdi AseptiSure KS filters are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates. These are available in a variety of pore sizes to suit specific microfiltration needs in critical and specialized process applications.



Special Features

- Large filtration area
- High throughputs
- Long service life
- Pre-flushed to minimize particulate release after installation
- Non-toxic material of construction
- Multiple autoclavable/SIP
- Heat sealed, no glues or adhesives
- Low protein binding

Specifications

Applications

- Sterile liquid filtration
- Filtration of proteinaceous liquid where minimum protein loss is desired, such as sera, culture soups and recombinant proteins, antibodies etc.
- Filtration of media, buffers etc.
- Water filtration

Microbially Validated as per ASTM F 838-05

Complies with USDFA 21 CFR 210.3(b)(6)

Meets and Exceeds USDFA 21 CFR 177.1520

Construction

Final Filter Pore Size	0.2µm	0.45µm
Prefilter Pore Size	0.8 µm, 0.65 µm, 0.45 µm	0.65 µm, 0.8 µm
Membrane	Hydrophilic PES	
Support Layers	Polyester	
Body and Core	Polypropylene	

Integrity Testing / Retention

Bubble Point	> 50psi (3.52Kg/cm ²) with Water	> 30psi (2.11Kg/cm ²) with Water
Air Diffusion Flow (10")	< 30ml/min @ 37 psi (2.6Kg/cm ²) with Water	< 35ml/min @ 22 psi (1.54Kg/cm ²) with Water
Microbial Retention	LRV >7 for Brevundimonas diminuta (ATCC 19146) per cm ²	LRV >7 for Serratia marcescens (ATCC 14756) per cm ²

Size

Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000cm ²	6000cm ²	12000cm ²	18000cm ²

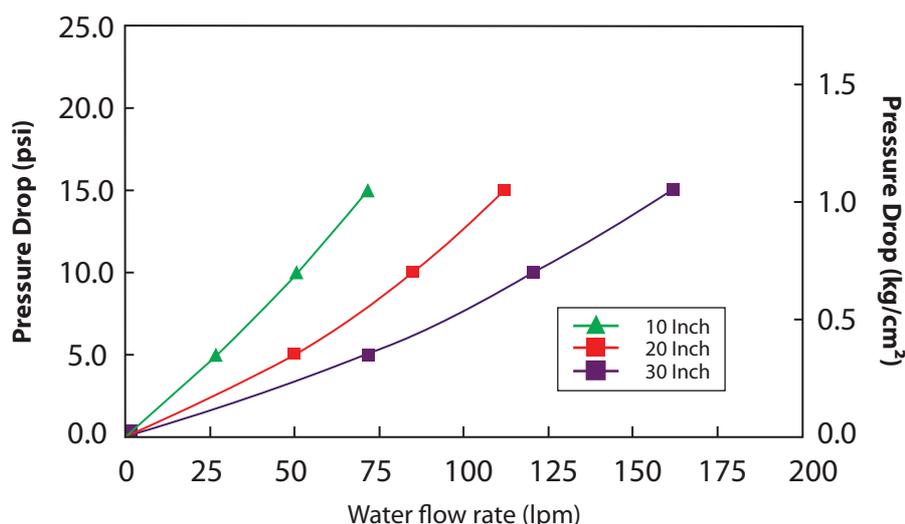
Operational

Max. Operating Temperature	80 °C @ < 2 Kg/cm ² (30 psi)		
Max. Differential Pressure	3.5 Kg/cm ² (50 psi) @ 25 °C		
Reverse Pressure	< 0.7 Kg/cm ² (10 psi) @ 25 °C		
Typical Water Flow Rates (10")	40 lpm @ 0.70 Kg/cm ² @ 27 °C	55 lpm @ 0.70 Kg/cm ² @ 27 °C	
Sterilization	Autoclavable/In-line steam sterilizable at 121 °C for 30 minutes, 25 cycles		

Assurance	
Toxicity	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
Cytotoxicity	Passes Biological Reactivity Tests, In Vitro, USP <87> for cytotoxicity
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
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
pH Compatibility	Compatible with pH range of 1 - 10
Extractables with WFI	Passes NVR test as per USP <661>
Oxidizable Substances	Passes test as per USP <1231>
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
TOC/Conductivity at 25 °C	Meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a specified volume of purified water flush
Indirect Food Additive	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Good Manufacturing Practice	These products are manufactured in a facility which adheres to Good Manufacturing Practices.
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Water Flow Rates

0.2 µm AseptiSure KS Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adaptor		Elastomer		Sterility		Pack Size	
	Code	Length and filtration Area	Code		Code		Code		Code		Code		Code
CPPKS (0.8 µm) Upstream Layer	CPK5	5" (3000 cm ²)**	53	0.2 µm	01	7P	A0	Silicone	SS	Non Sterile	1	1	01
CPPKS (0.65 µm) Upstream Layer	CPK3	10" (6000 cm ²)	54	0.45 µm**	02	7P without fin	A1	EPDM	SE				
CPPKS (0.45 µm) Upstream Layer	CPKX	20" (12000 cm ²)	55			28 with fin	C0	Viton	SV				
		30" (18000 cm ²)	56			'0'	D0	FEP Encapsulated Viton	FV***				

* FV is available in Adapter Code A0 (7P) only

** 0.45µm pore size is not available with 0.45µm upstream layer

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

Example

CPKX	56	01	A0	SS	1	01
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