

mdi Polyethersulfone (PES) Membrane mini Cartridge filters Type *AseptiSure KS* are serial filtration devices with a larger pore size upstream 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

- Low protein binding
- 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
- Each filter comes with an individual Certificate of quality
- Total traceability:
Unique identification number is laser etched on each filter

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

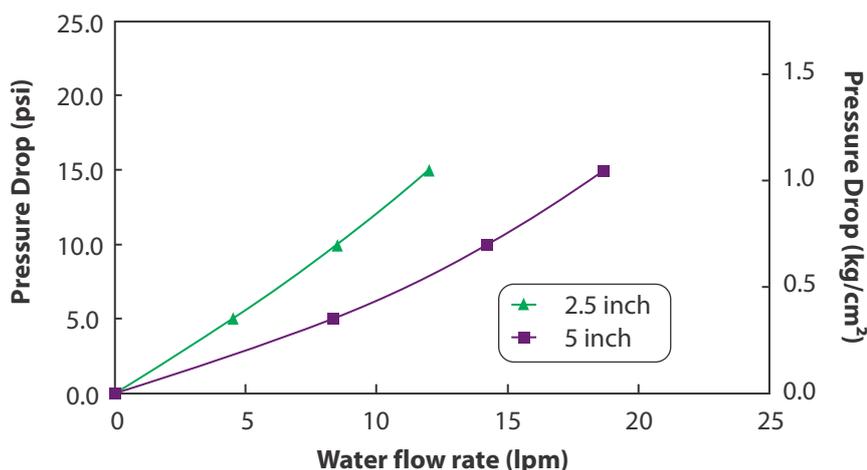
Specifications

Construction		
Final Filter Pore Size	0.2µm	0.45µm
Pre-filter 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
Microbial Retention	LRV >7 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >7 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²
Size		
Size	2.5"	5"
Effective Filtration Area (Nominal)	1000cm ²	2000cm 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	
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		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
AseptiSure KS (0.8 µm Upstream)	CPK5	2.5"	50	0.2 µm	01	4463	E0	Silicone	SS	Non Sterile	1	1	01
AseptiSure KS (0.65µm Upstream)	CPK3	5"	53	*0.45 µm	02	4463B	H0						
AseptiSure KS (0.45 µm Upstream)	CPKX					4440	U0						
						Seal-K	G0**						
						Seal-O	F0***						
						Seal-M	J0						

* 0.45µm cartridge filter are available with 0.65µm or 0.8µm upstream layer only
 **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

Example

CPKX	50	01	E0	SS	1	01
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Advanced Microdevices Pvt. Ltd.

20-21, Industrial Area, Ambala Cantt-133 006, INDIA

Tel : +91-171-2699290, 2699471

E-mail : info@mdimembrane.com

Website : www.mdimembrane.com