

mdi AseptiSure TF PTFE Membrane mini cartridge filters are hydrophobic filters offering absolute retention. These filters are designed for sterilizing filtration of gases. The high quality of membrane and design of cartridge assures long life and ability to withstand adverse process conditions experienced during use.

mdi AseptiSure TF filters are validated for key performance parameters such as retention efficiency, chemical compatibility, extractable, heat stability, flow rates and blow through.



Special Features

- Absolute retention
- High heat stability
- Wide chemical compatibility
- Heat sealed
- No leaching
- 100% Integrity tested
- Each filter comes with an individual certificate of quality
- Total traceability:
Unique identification number is laser etched on each filter

Applications

- Fermentors venting and aeration
- Sterile filtration of API and injectables
- Sterile compressed air for pharma machineries
- Sterile air for dry powder injectables filling

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

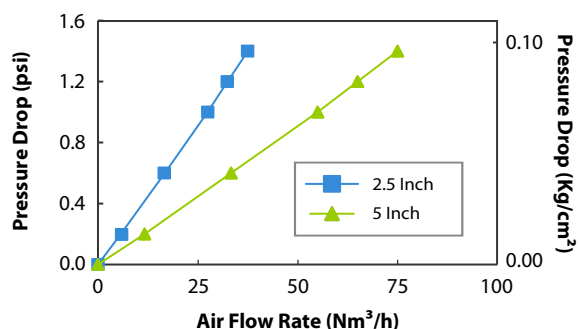
Specifications

Construction		
Final Filter Pore Size	0.2µm	0.45µm
Membrane	Hydrophobic PTFE	
Support Layers	Polypropylene	
Body and Core	Polypropylene	
Integrity Testing / Retention		
Bubble Point	22psi (1.52 Bar) with 70% IPA/Water Solution	10psi (0.69 Bar) with 70% IPA/Water Solution
Water Intrusion Rate	2.5"	≤ 0.3 ml/min @ 2.0kg/cm ²
	5"	≤ 0.6 ml/min @ 2.0kg/cm ²
Microbial Bacterial Retention (LRV >7 for)	<i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	<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, 100 cycles	

Assurance	
Toxicity	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
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>
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
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

Air Flow Rates

0.2 µm AseptiSure TF Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code	Length and filtration Area	Code		Code		Code		Code		Code		Code
Aseptisure TF	CPTF	2.5" (1000 cm²)	50	0.2 µm	01	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5" (2000 cm²)	53	0.45 µm	02	4463B	H0						
						4440	U0						
						½" MNPT	K0*						
						Seal-K	G0*						
						Seal-O	F0**						
						Seal-M	J0						

*K0 and G0 adapter codes are 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

CPTF	50	01	E0	SS	1	01
------	----	----	----	----	---	----

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