

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

These are also validated for other key performance parameters such as chemical compatibility, extractable, heat stability, flow rates, blow through and ability to withstand accidental reverse pressure. These are available in a variety of pore sizes to suit specific microfiltration needs in critical and specialized process applications for air as well as liquid.



Special Features

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

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

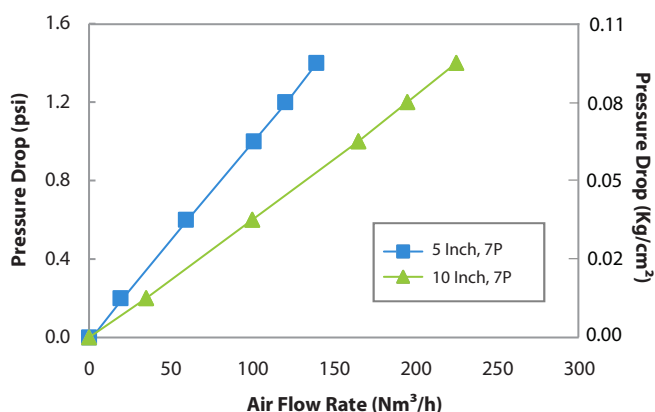
Specifications

Construction				
Final Filter Pore Size	0.2µm		0.45µm	
Membrane	Hydrophobic PTFE			
Support Layers	Polypropylene			
Body and Core	Polypropylene			
Integrity Testing / Retention				
Air Diffusion Flow (with 70% IPA Wetted)	< 45ml/min @ 16 psi (1.12Kg/cm ²)		< 45ml/min @ 8 psi (0.56Kg/cm ²)	
Microbial Bacterial Retention (LRV >7 for)	Brevundimonas diminuta (ATCC 19146) per cm ²		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			
Sterilization	Autoclavable/In-line steam sterilizable at 121 °C for 30 minutes, 100 cycles			

Assurance	
Toxicity	Passes Bioreactivity 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-9001:2008 Certified
USFDA	DMF No. 015554

Air Flow Rates

0.2 µm AseptiSure TF Cartridge Filters



Ordering Information

Type		Size		Pore Size		Adaptor		Elastomer		Sterility		Pack Size	
	Code	Length and filtration Area	Code		Code		Code		Code		Code		Code
AseptiSure TF	CPTF	5***	53	0.2 µm	01	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	0.45 µm	02	7P without Fin	A1	EPDM	SE				
		20"	55			28 with Fin	C0	Viton	SV				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV*				

Example

CPTF	56	01	A0	SS	1	01
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* FV is available in Adaptor Code A0 (7P) and A1 (7P without fin) only

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

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