

mdi AseptiSure TH PTFE cartridge filters are specially designed high temperature resistant PTFE filters which are steam sterilizable at upto 135°C. These filters are validated with liquid microbial challenge test as per ASTM F 838-05 to offer absolute retention even under high moisture conditions.

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
- Essentially hydrophobic
- High heat stability
- Wide chemical compatibility
- Heat sealed
- No leaching
- 100% Integrity tested
- **Total traceability:** Unique marking 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
- ◆ High temperature WFI tank venting

Ordering Information

Type	Size		Pore Size		Adaptor		Elastomer		Sterility		Pack Size	
	Code	Length Code	Code	Code	Code	Code	Code	Code	Code	Code	Qty	Code
AseptiSure TH	CPTH	5" (3000cm ²)	53	0.2µm	01	7P	A0	Silicone	SS	Non Sterile	1	01
		10" (6000cm ²)	54	0.45µm	02	7P without fin	A1	Viton	SV	*FV is available in Code A0(7P) and A1 (7P without fin) only Size 5" are available in Code A0(7P) and A1 (7P without fin) only		
		20" (12000cm ²)	55			'O'	D0	EPDM	SE			
		30" (18000cm ²)	56					FEP Encapsulated Viton	FV*			
Example:												
CPTH		54		01		A0		SS		1		01



Microbially Validated as per ASTM F 838-05

Complies with
USFDA 21 CFR 211.72
Meets and Exceeds
USFDA 21 CFR 177.1520

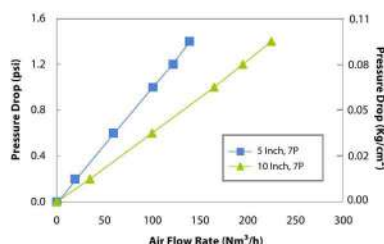
Integrity Test Data (70% IPA)

Pore Size	Bubble Point
0.2µm	≥ 22psi (≥ 1.54 Kg/cm ²)
0.45µm	≥ 10psi (0.7 Kg/cm ²)

Pore Size	Air Diffusion Flow / 10" Cartridge Filter
0.2µm	≤ 45ml/min @ 16psi (1.12 Kg/cm ²)
0.45µm	≤ 45 ml/min @ 8 psi (0.56 Kg/cm ²)

Air Flow Rates

0.2 µm AseptiSure TH Cartridge Filters



Specifications

Membrane
PTFE

Pore Size
0.2µm, 0.45µm

Maximum Differential Pressure
3.5 Kg/cm² @ 25 °C

Maximum Operating Temperature
80° C @ < 2 Kg/cm²

Sterilization
80 autoclave/steam sterilization cycles at 135° C for 30 minutes each

Retention Efficiency
LRV>7 for *B.diminuta* (ATCC 19146) per cm² of filter area as per ASTM F 838-05

Biosafety
Passes the Biological Reactivity Tests, *In Vivo* for Class VI plastics as described in USP <88>

Extractables with Water
Does not affect the quality of Water for Injection as specified by USP

Fiber Release
Complies with USFDA CFR Title 21, 210.3 (b) (6), after 10 liter flush

Particle Release
The filtrate complies with USP <788> test for particulate matter in injections

Oxidizable Matter
Passes test as per USP