

**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



## Integrity Test Specifications

### Bubble Point Test (70% IPA)

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

### Air Diffusion Flow Test (70% IPA)

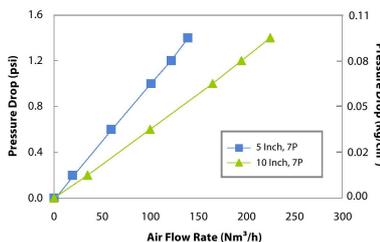
Pore Size	Air Diffusion Flow / 10" Cartridge Filter
0.2µm	≤ 45ml/min @ 16psi (1.12 Kg/cm <sup>2</sup> )
0.45µm	≤ 45 ml/min @ 8 psi (0.56 Kg/cm <sup>2</sup> )

### Water Intrusion Test

Pore Size	Water Intrusion Rate (ml/min) @30 psi	
0.2µm	5"	10"
	0.75	1.3

## Air Flow Rates

0.2 µm AseptiSure TH Cartridge Filters



Microbiologically Validated as per ASTM F 838-05
Complies with USFDA 21 CFR Part 210.3 (b) (6)
Meets and Exceeds USFDA 21 CFR Part 177.1520

## Specifications

### Membrane

PTFE

### Pore Size

0.2µm, 0.45µm

### Maximum Differential Pressure

3.5 Kg/cm<sup>2</sup> @ 25 ° C

### Maximum Operating Temperature

95 ° C @ < 2 Kg/cm<sup>2</sup>

### Service Life in Air

For 12 months @100°C (In continuous mode)

### Sterilization

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

### Retention Efficiency (0.2 µm)

LRV>7 for *B.diminuta* (ATCC 19146) per cm<sup>2</sup> 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

Passes NVR test as per USP <661>

### 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 <1231>

Type	Size		Pore Size		Adaptor		Elastomer		Sterility		Pack Size	
	Code	Length Code	Code	Code	Code	Code	Code	Code	Code	Qty	Code	
AseptiSure TH	CPTH	5" (3000cm <sup>2</sup> )	53	0.2µm	01	7P	A0	Silicone	SS	Non Sterile	1	1 01
		10" (6000cm <sup>2</sup> )	54	0.45µm	02	7P without fin	A1	Viton	SV	*Size 5" is available in Code A0(7P) and A1 (7P without fin) only **FV is available in adaptor code A0(7P) and A1 (7P without fin) only		
		20" (12000cm <sup>2</sup> )	55			'O'	D0	EPDM	SE			
		30" (18000cm <sup>2</sup> )	56			28 with Fin	C0	FEP Encapsulated Viton	FV**			
Example:	CPTH	54		01		A0		SS				

DST CPTHXX1207L