

mdi AseptiSure TH PTFE mini 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
- 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
- High temperature WFI tank venting

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

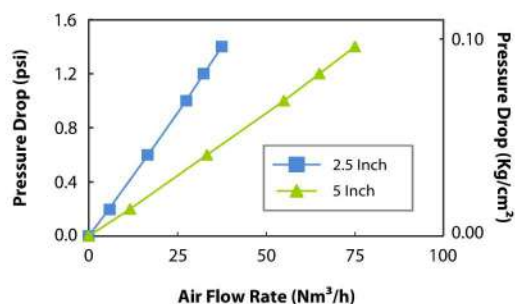
Specifications

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)		Brevundimonas diminuta (ATCC 19146) per cm ²	Serratia marcescens (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 135 °C for 30 minutes, P = 0.3kg/cm ² (5psi), 80 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
Extractables with WFI	Passes test as per USP
Oxidizable Substances	Within limits as specified in USP
Particle Shedding	Passes USP test for particulates in injectables.
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 TH 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 TH	CPTH	2.5" (1000cm ²)	50	0.2 µm	01	½" MNPT	K0	Silicone	SS	Non Sterile	1	1	01
		5" (2000cm ²)	53	0.45 µm	02	4463	E0						
						4463B	H0						
						4440	U0						

Example

CPTH	50	01	E0	SS	1	01
------	----	----	----	----	---	----



Gesfilter, S.L.

Distribuidor Oficial España

Avenida Cerdanyola, 92-94 Local B4

08173 - Sant Cugat del Vallès - Barcelona

Tel: 935921554 - Email: comercial@gesfilter.com

www.gesfilter.com

Advanced Microdevices Pvt. Ltd.

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

Tel : +91-171-2699290, 2699471 Fax : +91-171-2699221

E-mail : info@mdimembrane.com Internet : www.mdimembrane.com