

The Hydrophobic PTFE Membrane Cartridge Filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## **AseptiSure TH Hydrophobic PTFE Membrane Cartridge Filters**

Catalog No. : CPTH5401A0FV101  
 Type : CPTH  
 Pore Size : 0.2 µm  
 Lot Number : CT8557G      SI.No. 008

### SPECIFICATION

<b>Length</b>	10"
<b>Filter Media</b>	Hydrophobic PTFE Membrane
<b>Drainage Layers</b>	Polypropylene
<b>Plastic Components</b>	Polypropylene
<b>Differential Pressure</b>	< 3.5 Kg/cm <sup>2</sup> at 25°C
<b>Maximum operating Temperature</b>	95 °C at < 2 Kg/cm <sup>2</sup>
<b>Reverse Pressure</b>	< 0.7 Kg/cm <sup>2</sup> at 25°C
<b>Sterilization</b>	By Autoclaving or Steam-in-place (SIP)

### LOT RELEASE CRITERIA

- 100% Integrity Tested** : The cartridge filters have been tested for integrity by Air Diffusion flow test and Bubble point test using 70% IPA/Water solution.  
 Diffusion flow was: ≤ 45 ml/min at 1.12 Kg/cm<sup>2</sup>  
 Bubble point was: ≥ 22 psi (1.52 Bars)
  - Water Intrusion Rate** : ≤ 13 ml /10 min at 2.0 kg/cm<sup>2</sup>
  - Air Flow Rate** : ≥ 200 Nm<sup>3</sup>/Hr @ 0.10 Kg/cm<sup>2</sup>
  - Microbial Challenge Test** : Retains ≥ 10<sup>7</sup> organisms/cm<sup>2</sup> of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.
  - Bacterial Endotoxin Levels** : Aqueous extracts exhibit < 0.5 EU/ml as established by Limulus Amoebocyte Lysate (LAL) test.
- VALIDATED FOR**
- Heat Stability** : Maintains integrity after 80 Steam sterilization cycles at 135 °C for 30 minutes each.
  - Biosafety** : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.
  - Indirect Food Additives** : Passes as per FDA 21CFR 177.1520(a)1(i).
  - Particle Release** : Passes test as per USP <788>, "Particulate matter in Injections".
  - Fiber Release** : Complies with FDA 21CFR 210.3(b)(6).

### CUSTOMER SUPPORT

**mdi** offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.



Head of Quality Assurance

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**An ISO 9001 Company**