# **Ultradyne**<sup>®</sup> 0.2 µm TM-grade Filter Cartridge

### Description

The Ultradyne<sup>®</sup> TM0.2 filter cartridge is a hydrophobic PTFE membrane filter offering maximum chemical compatibility with minimal extractables in a wide range of fluids and applications. This filter provides reliable removal of particles and microorganisms from aggressive liquids, including strong acids and bases, and organic solvents. Ultradyne<sup>®</sup> is optimized for applications requiring complete removal of contaminant bacteria and viruses from air and gas streams, such as fermenter inlet air and exhaust, sterile process air, and sterile venting of tanks, lyophilizers, and autoclaves. The Ultradyne<sup>®</sup> filter provides sterility assurance, high flow rates and throughput under demanding conditions.

#### Materials of Construction

All components of the filter are either animal component free or in compliance with EMA/410/01 Rev. 3 (EDQM 5.2.807/2011:50208), and US Code of Federal Regulations 9 CFR 94.18 and 21 CFR 189.5 These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Membrane: Upstream support: Downstream support: Outer guard: Core: End caps: O-rings: Sealing method:	Polytetrafluoroethylene (PTFE) Polypropylene Polypropylene Polypropylene Polypropylene Polypropylene Typically Silicone Thermal bonding	CFR Title 21, 177.1550 CFR Title 21, 177.1520 CFR Title 21, 177.2600
Pore Size	0.2 μm	
Effective Filtration Area	6.0 ft² (0.56 m²)	
Minimum Bubble Point	14 psi (0.97 bar) in 60% IPA/40% water, with air or nitrogen 14 psi (0.97 bar) in 70% IPA/30% water, with air or nitrogen	
Maximum Diffusion Rate	10 mL/min per 10" (25 cm)@ 9 psig (0.6 bar), 60% IPA with air	
Maximum Water Intrusion Rate	0.6 mL/min water per 10" (25 cm) after 10 minutes @ 32 psi (2.2 bar) Specification can vary by instrumentation; consult Meissner.	
Typical Water Flow Rate	0.4 psid/gpm per 10" (1.4 L/min per $\Delta p$ 10 mbar per 25 cm)	
Typical Air Flow Rate	50 scfm/psid per 10" (62 Nm <sup>3</sup> /hr per $\Delta p$ 50 mbar per 25 cm)	
<b>Operating Characteristics</b> Operating temperature range: Maximum temperature rating: Maximum operating pressure: Maximum reverse pressure:	32 °F to 100 °F (0 °C to 38 °C) 180 °F @ 30 psid (82 °C @ 2.1 bar) 80 psid @ 100 °F (5.5 bar @ 38 °C) 15 psid @ 100 °F (1.0 bar @ 38 °C)	

#### Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min,  $\geq$  3 cycles. Steam in place (SIP): 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min,  $\geq$  3 cycles. Irradiation not recommended.

#### **Biological Safety**

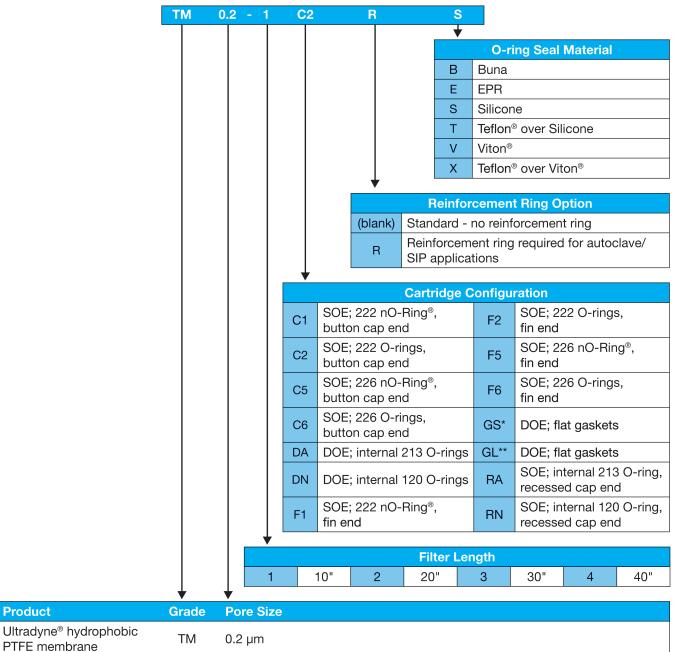
Ultradyne<sup>®</sup> filters meet the requirements as specified in USP 49 <88> Class VI plastics, <87> cytotoxicity and pyrogenicity tests. No binders, adhesives, or surfactants are used in its construction. Filters comply with Commission Regulation (EU) No. 10/2011.

#### **Quality Assurance**

Ultradyne<sup>®</sup> filters comply with the Food and Drug Administration Code of Federal Regulations, Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA Good Manufacturing Practice Standards. To ensure product reliability, Meissner's Quality Assurance staff continually audits the manufacturing process for conformance to its Quality Management System. Each Ultradyne<sup>®</sup> filter is clearly marked with filter type, lot number, and unique serial number. The serial number for all cartridge filters can be found on the product packaging.



## **Ordering Guide**



\*GS option is only available for 9.75", 19.5", 29.25", and 39" length filters. \*\*GL option is only available for 20", 30", and 40" length filters.

Product

Additional information about this filter product is available in the Ultradyne® Green Docs document at www.meissner.com/green-docs.

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