

Ultradyne®

TTM0.2 Cartridge

Description

The hydrophobic, liquid-rated sterilizing grade Ultradyne® TTM0.2 PTFE filter cartridge includes an upstream prefiltration layer of PP and provides the added benefit of certification that meets the critical demands of the pharmaceutical, biotechnology and related industries.

Materials of Construction

All components of the Ultradyne® filter cartridge are either animal free or in compliance with EMEA/410/01 Rev. 3 (EDQM 5.2.8 07/2011:50208), 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:

Prefilter media:	Polypropylene	CFR Title 21, 177.1520
Membrane:	Polytetrafluoroethylene	CFR Title 21, 177.1550
Upstream support:	Polypropylene	CFR Title 21, 177.1520
Downstream support:	Polypropylene	CFR Title 21, 177.1520
Outer guard:	Polypropylene	CFR Title 21, 177.1520
Core:	Polypropylene	CFR Title 21, 177.1520
End caps:	Polypropylene	CFR Title 21, 177.1520
O-rings:	Typically Silicone	CFR Title 21, 177.2600
Sealing method:	Thermal bonding	

Pore Size 0.2 µm

Minimum Bubble Point 16 psi (1,1 bar), 60% IPA / 40% water, air
16 psi (1,1 bar), 70% IPA / 30% water, nitrogen

Maximum Diffusion Rate 10 mL/min at 10 psig (0,7 bar), 60% IPA, per 10" (25 cm)

Operating Characteristics

100 °F @ 80 psid (38 °C @ Δp 5,5 bar)	150 °F @ 60 psid (66 °C @ Δp 4,1 bar)	180 °F @ 30 psid (82 °C @ Δp 2,1 bar)
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Bacterial Retention >10⁷ per cm² removal of *Brevundimonas diminuta* per ASTM F838-05

Sterilization

Autoclave: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 3 cycles
Steam in place: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 3 cycles

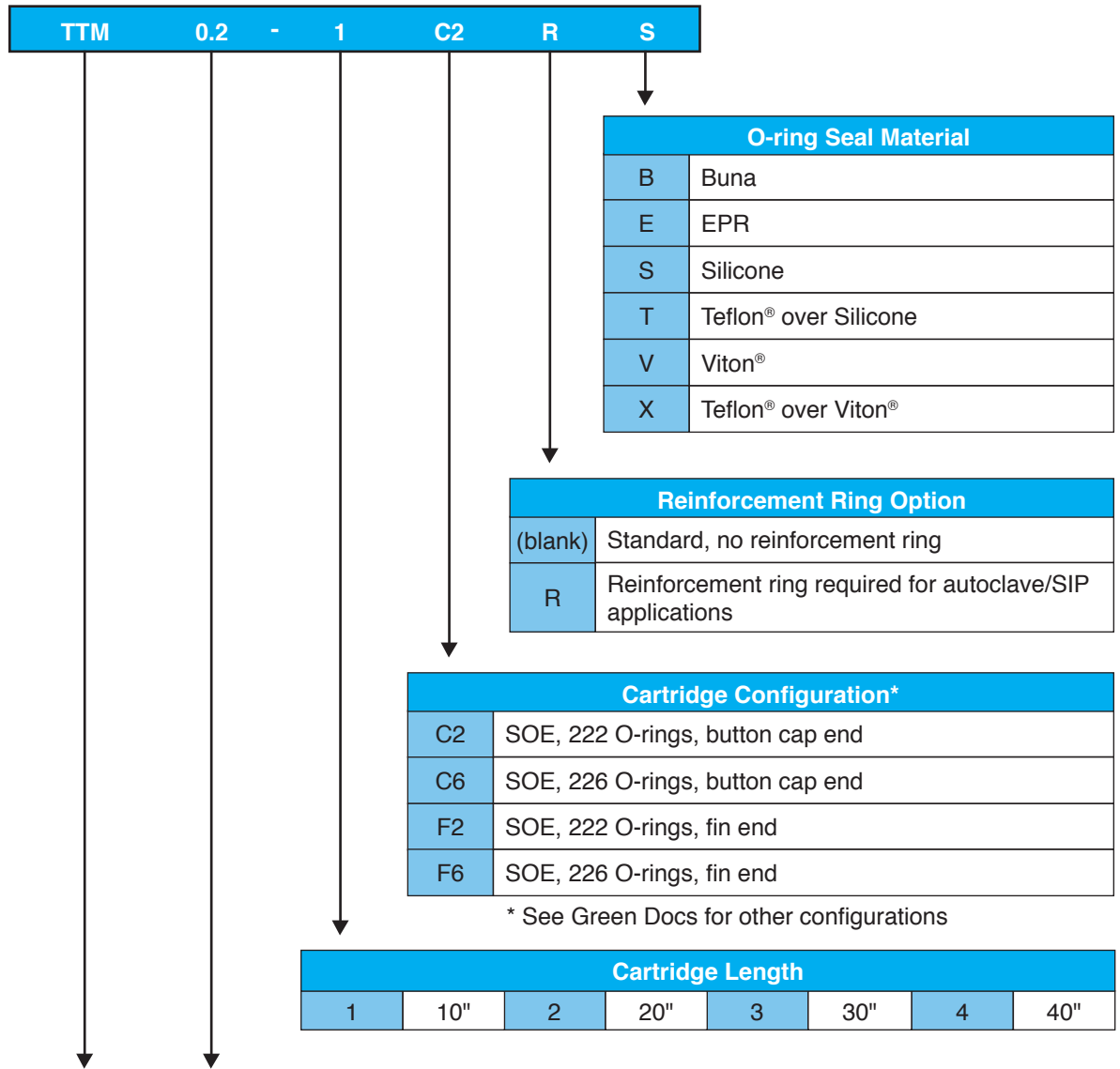
Biological Safety

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

Quality Assurance

Each Ultradyne® TTM0.2 filter is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. Ultradyne® 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® filter is integrity tested during manufacture and is clearly marked with filter type and lot number.

Ordering Guide



Product	Filter Grade	Retention Rating
Ultradyne® hydrophobic PTFE membrane	TTM	0.2

Additional information about Ultradyne® filter products is available in the Green Docs document which is viewable at <https://www.meissner.com/downloads/ultradyne-gd006-2.1.pdf>

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