

# Ultradyne®

## TM0.05 Cartridge

### Description

The hydrophobic, TM grade Ultradyne® TM0.05 PTFE filter cartridge is manufactured using high quality components that are nontoxic and biologically inert.

### 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:

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** 0.05 µm

**Minimum Bubble Point** 45 psi (3,1 bar), 60% IPA / 40% water, air

**Typical Water Flow Rate** 1.4 psid/gpm per 10" (0,39 L min<sup>-1</sup> @ Δp 10 mbar per 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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### 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

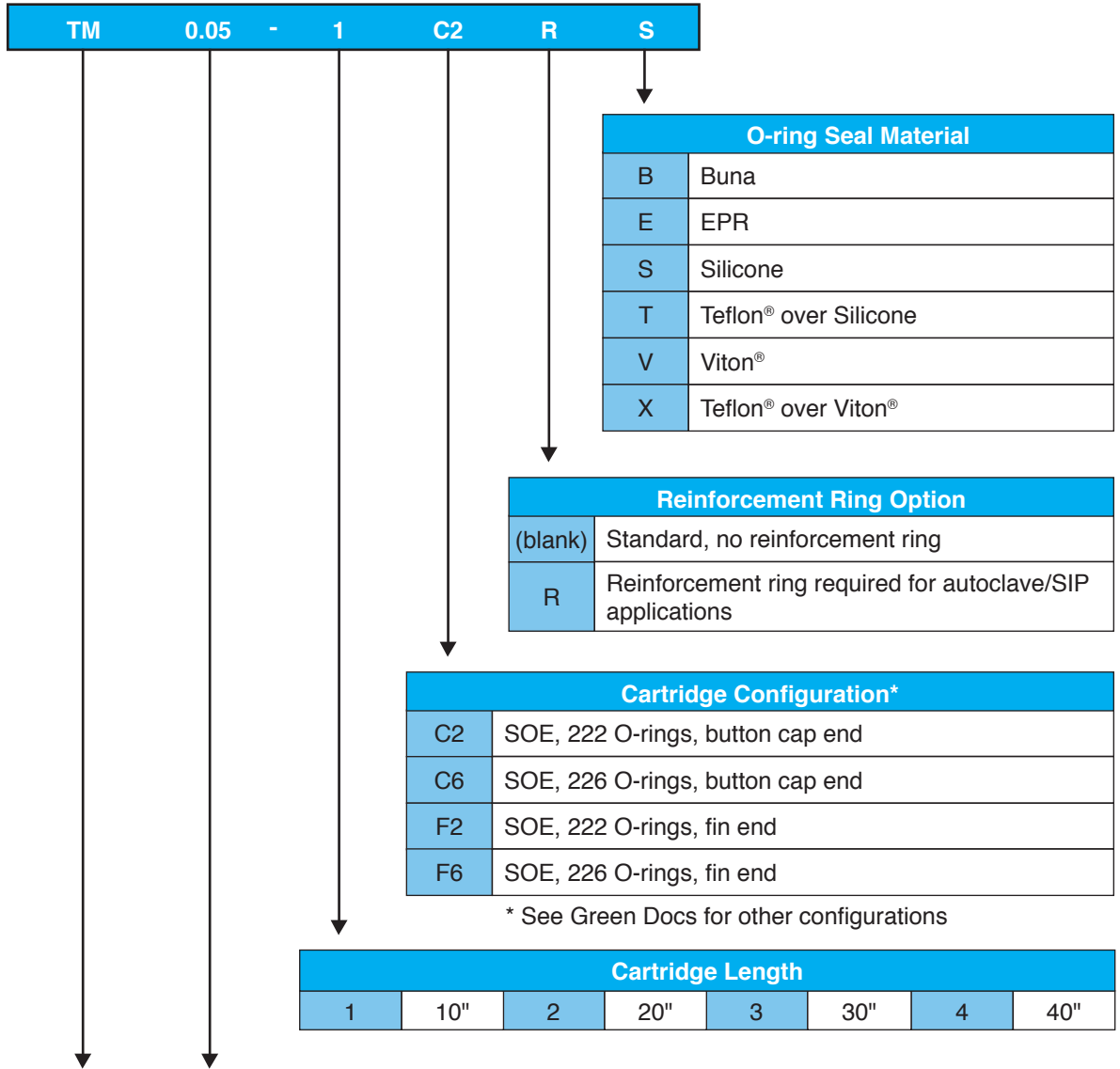
### Biological Safety

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

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	TM	0.05

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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