

# Ultradyne

## 0.1 µm TM-grade Standard Capsule Filter — CS(2), CL(2), CJ2 Model

### Description

The Ultradyne® TM0.1 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® 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® filter provides sterility assurance, high flow rates and throughput under demanding conditions.

### Materials of Construction

All components of the filter are either animal free or in compliance with EMA/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 (PTFE)	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
Capsule housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

**Pore Size** 0.1 µm

**Minimum Bubble Point** 20 psi (1.38 bar) in 60% IPA/40% water, with air or nitrogen  
19 psi (1.31 bar) in 70% IPA/30% water, with air or nitrogen

**Maximum Diffusion Rate** CS: 3.0 mL/min @ 15 psi (1.03 bar), 60% IPA/40% water, with air  
CL: 6.5 mL/min @ 15 psi (1.03 bar), 60% IPA/40% water, with air  
CJ: 13 mL/min @ 15 psi (1.03 bar), 60% IPA/40% water, with air

**Typical Air Flow Rate** CS: 4.81 scfm @ 1 psid (5.93 Nm³/hr @ Δp 50 mbar)  
CL: 6.45 scfm @ 1 psid (7.95 Nm³/hr @ Δp 50 mbar)

**Bacterial Retention** >10<sup>7</sup> per cm² removal of *Brevundimonas diminuta* per ASTM F838

### Operating Characteristics

Operating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum operating temperature:	160 °F @ 35 psig (71 °C @ 2.4 bar)
Maximum operating pressure:	75 psig @ 100 °F (5.2 bar @ 38 °C), liquid service
Maximum operating pressure:	50 psig @ 100 °F (3.4 bar @ 38 °C), gas service
Maximum reverse pressure:	15 psig @ 100 °F (1.1 bar @ 38 °C)

### Sterilization

Autoclave: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.  
Capsules must not be in-line steam sterilized. Irradiation is not recommended.

### Biological Safety

Ultradyne® filters meet the requirements as specified in USP 43 <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® 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 clearly marked with filter type, lot number, and unique serial number.

## Ordering Guide

C S 2 TM 0.1 - 00 2							
<b>Capsule Options</b>						<b>Vent/Drain Ports</b>	
Standard capsule	C					0	No vent/drain port
Sterile capsule	G					1	One luer port with cap, outlet side
Opaque shell	O					2	Standard; two luer ports with caps
						4	Two sanitary valves with hose barbs
						5	One sanitary valve with hose barb, outlet side
						6	One sanitary valve with hose barb, inlet side
<b>Effective Filtration Area</b>						<b>Inlet/Outlet Connections</b>	
1.2 ft <sup>2</sup> (0.11 m <sup>2</sup> )	S					00	1" sanitary flange 44 1/4" MNPT
2.5 ft <sup>2</sup> (0.23 m <sup>2</sup> )	L					02	1" sanitary flange in; 3/8" hose barb out 55 3/8" FNPT
5.3 ft <sup>2</sup> (0.49 m <sup>2</sup> )	J					09	1" sanitary flange in; 1/2" hose barb out (flexible tubing) 66 3/8" MNPT
<b>Housing Material Designator</b>						CC	1/2" hose barb (rigid tubing) 72** 3/4" sanitary flange; 3/8" hose barb out
Standard polypropylene	(blank)					LL	1" sanitary flange, long neck 77** 3/4" sanitary flange
Animal component free (ACF) polypropylene	2*					22	3/8" hose barb 88 3/4" hose barb
						2B	3/8" hose barb with filling bell 99 1/2" hose barb
<b>Product</b>		<b>Grade</b>		<b>Pore Size</b>			
Ultradyn <sup>®</sup> hydrophobic PTFE membrane		TM		0.1 µm			

\*CJ2 filters are only available with an animal component free (ACF) polypropylene housing.

\*\*3/4 sanitary flange fitting option is only available for CS2, CL2, and CJ2 capsules.

Additional information about this filter product is available in the Ultradyn<sup>®</sup> Green Docs document at [www.meissner.com/green-docs](http://www.meissner.com/green-docs).