



Hydrophilic Durapore® CBR 0.1 µm Bioburden Reduction Filters

- ▶ *Removes particles, microorganisms and mycoplasma from tissue culture media and serum*
- ▶ *Superior membrane for filtration processes requiring high throughputs and flow rates*
- ▶ *Controlled low bioburden for lower overall filtration costs and improved process economics*
- ▶ *Very low extractables — ideal for media prefiltration*

Superior filters for controlled low bioburden in tissue culture media and serum

Hydrophilic Durapore CBR 0.1 µm filters are ideal for clean processes due to low extractables, broad chemical compatibility and its non-fiber releasing properties. Hydrophilic Durapore CBR 0.1 µm Bioburden Reduction polyvinylidene fluoride (PVDF) membrane is recommended for applications requiring mycoplasma reduction and small particle and microorganism removal. Typical applications include the filtration of serum, tissue culture media and media additives. Hydrophilic Durapore CBR 0.1 µm filters are ideally suited to applications where bioburden should be maintained at very low levels.

High Throughput Flow Rates

Hydrophilic Durapore CBR 0.1 µm cartridge filters provide high throughput and flow rates with minimal differential pressure. Cartridges are robust, strong, resilient and are designed to withstand multiple steam-in-place

cycles. Each Durapore CBR cartridge filter is integrity tested during the manufacturing process.

Code 7, Code 5 and Code 0 connections are available to suit your application and housing needs.

Membrane Type

- Hydrophilic Durapore CBR 0.1 µm PVDF

Filter Format

- Cartridge filters

Recommended Applications

- Tissue culture media
- Serum
- Media additives

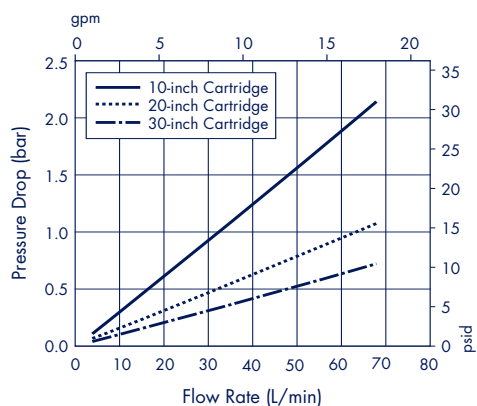
Specifications

	Cartridges (per 10-inch element)
Nominal Dimensions <i>Outside diameter:</i>	6.9 cm (2.7 in.)
Filtration Area	0.69 m ² (7.4 ft ²)
Materials of Construction <i>Filter membrane:</i> <i>Film edge:</i> <i>Supports:</i> <i>Structural components*:</i> <i>O-rings:</i>	Hydrophilic PVDF Polypropylene Polypropylene Polypropylene Fluorocarbon rubber or silicone
Maximum Differential Pressure <i>Forward:</i> <i>Reverse:</i>	5.5 bar (80 psid) at 25 °C, 1.75 bar (25 psid) at 80 °C, 345 mbar (5 psid) at 135 °C 3.4 bar (50 psid) at 25 °C, intermittent
Bubble Point at 23 °C	≥ 4830 mbar (70.0 psig) air with water
Air Diffusion	Through a water wet membrane at ambient temperature: ≤ 20 cc/min at 3860 mbar (56 psi) per 10-inch cartridge
Bacterial Retention	Samples of the Durapore membrane used in these cartridges are tested for bacterial retention and meet the criteria for sterilizing grade performance as defined by the ASTM® test method using <i>Brevundimonas diminuta</i> at a minimum challenge concentration of 1 x 10 ⁷ CFU/cm ² .
Extractables	After 24 hour soak in 1 liter 18 megohm/cm water at controlled room temperature: ≤ 25 mg per 10-inch cartridge
Downstream Cleanliness/ Effluent Particle Level	After a 50 gallon flush at 2 gpm: ≤ 10 particles per liter (particle diameter ≥ 1.0 µm) per 10-inch cartridge
Resistivity Recovery	Effluent quality after a 15 gallon flush with > 16.5 megohm/cm water at 25 °C and at 1 gpm per 10-inch cartridge: ≥ 15 megohm/cm
Good Manufacturing Practices	These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.
Non-Fiber Releasing	Durapore membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).
Component Material Toxicity	Component materials were tested and meet the criteria for the USP <88> Reactivity Tests for Class VI Plastics. This filter meets the requirements of the USP <88> Safety Test utilizing a 0.9% sodium chloride extraction.
Indirect Food Additive	The Durapore membrane used in these filters meets the FDA Indirect Food Additive requirements cited in 21 CFR 177.2910. All other component materials also meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.

*Outer sleeve, core and end caps

Typical Clean Water Flow Rates

Cartridge Filters — 0.1 µm Hydrophilic Durapore (CVI)

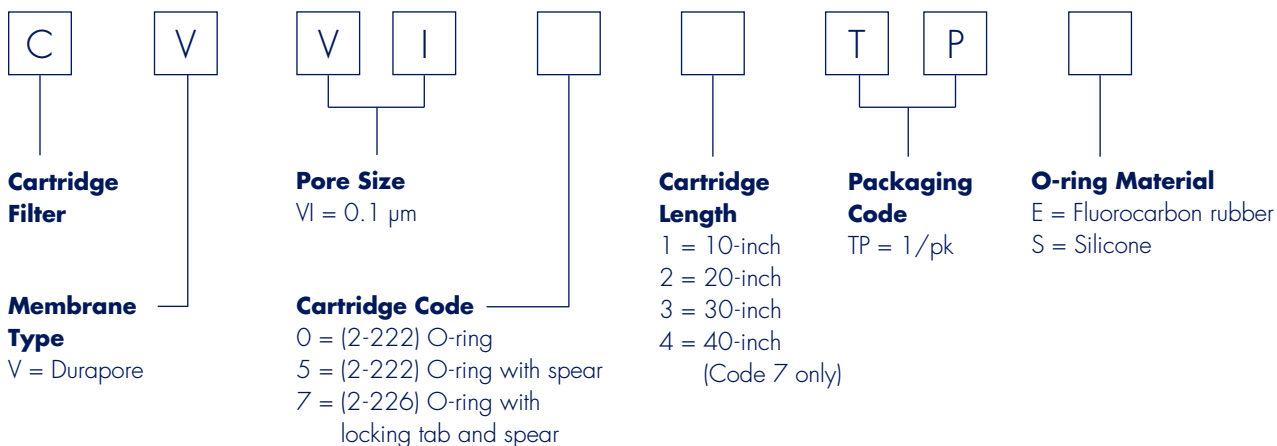


Regulatory Compliance

Filters with hydrophilic Durapore membrane are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO® 9000 Quality Systems Standard. A detailed Certificate of Quality is available on request. Each cartridge filter is integrity tested during manufacturing and is supported by a Validation Guide. For traceability and easy identification, each filter is labeled with the product name and identifying characteristics.

Ordering Information

Cartridge Filters



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In every application, every step and every scale, count on Millipore to be everywhere for you — from monoclonals to vaccines, from clinical through pilot to full-scale manufacturing. Our technologies are used by most of the world's major biopharmaceutical companies. But we deliver more than advanced separation, purification, sterilization and quality control products. With Millipore, you get services to optimize and validate your processes, comprehensive resources to streamline and enhance your operation, unmatched know how forged from more than 50 years' experience — and solutions that integrate it all. For higher yields, improved process economics and faster speed to market, discover the more in Millipore.

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Durapore-CBR-01-Bioburden-Reduction-Filters

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