



## Durapore® CBR 0.2 µm Bioburden Reduction Filters

### **Superior filters for controlled low bioburden levels in biopharmaceutical fluids**

- ▶ For fine filtration of deionized water, in vitro diagnostics, oral suspensions, bulk pharmaceutical solutions, and for media prefiltration
- ▶ Superior membrane for filtration processes requiring high throughputs and flow rates
- ▶ Controlled low bioburden for lower overall filtration costs and improved process economics
- ▶ Ideal for LVP bulk pharmaceutical product filtration

A trusted name in the industry for over 25 years, hydrophilic Durapore 0.2 µm polyvinylidene fluoride (PVDF) membrane offers consistent and reliable performance for bioburden reduction and particle removal. Hydrophilic Durapore CBR devices are ideal for clean processes due to low extractables, broad chemical compatibility and its non-fiber releasing properties.

Hydrophilic Durapore CBR 0.2 µm Bioburden Reduction filters are recommended for applications requiring bioburden reduction and small particle removal across a wide range of pharmaceutical and biological liquids and intermediate bulk pharmaceutical products. Typical applications for the Durapore CBR 0.2 µm filters include the filtration of diagnostics, diluents, bulk pharmaceutical products, serum, tissue culture media and media additives.

#### **High Throughput Flow Rates**

Durapore CBR 0.2 µm hydrophilic 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 and Code 0 connections are available to suit your application and housing needs.

#### **Membrane Type**

- Durapore 0.2 µm hydrophilic

#### **Filter Format**

- Cartridge filters

#### **Recommended Applications**

- Cell culture media
- Large volume parenterals (LVP's)
- Pharmaceutical bulk chemical solutions
- Bioprocessed protein solutions
- Biologicals
- Diagnostics
- Purified water
- Blood and serum fractions

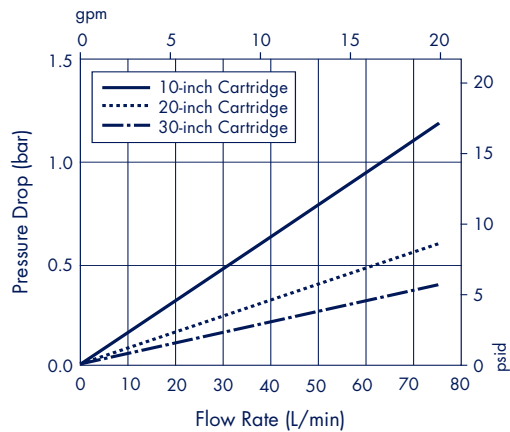
## Specifications

	Cartridges (per 10-inch element)
<b>Nominal Dimensions</b> <i>Outside diameter:</i>	6.9 cm (2.7 in.)
<b>Filtration Area</b>	0.69 m <sup>2</sup> (7.4 ft <sup>2</sup> )
<b>Materials of Construction</b> <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
<b>Maximum Differential Pressure</b> <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
<b>Bubble Point at 23 °C</b>	≥ 3100 mbar (45.0 psig) air with water
<b>Air Diffusion</b>	Through a water wet membrane at ambient temperature, at 2.8 bar (40 psig): ≤ 13.3 cc/min per 10-inch cartridge
<b>Bacterial Retention</b>	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 <sup>7</sup> CFU/cm <sup>2</sup> .
<b>Extractables</b>	After 24 hour soak in 1 liter 18 megohm/cm water at controlled room temperature: ≤ 25 mg per 10-inch cartridge
<b>Downstream Cleanliness/ Effluent Particle Level</b>	After a 50 gallon flush at 2 gpm: ≤ 10 particles per liter (particle diameter ≥ 1.0 µm) per 10-inch cartridge
<b>Resistivity Recovery</b>	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
<b>Good Manufacturing Practices</b>	These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.
<b>Non-Fiber Releasing</b>	Durapore membrane meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6).
<b>Component Material Toxicity</b>	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.
<b>Indirect Food Additive</b>	The Durapore membrane used in these products 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

### 0.2 µm Hydrophilic Durapore (CVDI) Cartridge Filters

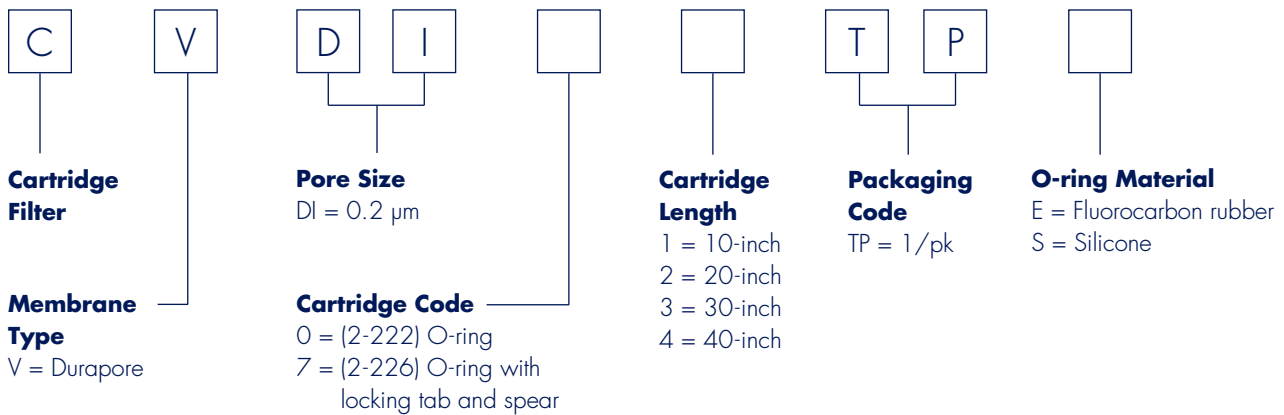


## Regulatory Compliance

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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## To Place an Order or Receive Technical Assistance

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In the U.S., Canada and Puerto Rico, fax orders to  
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Outside of North America contact your local office.

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