

Microfluor® II PTFE Membrane Sterilizing Grade Cartridge and Capsule Filters

New, High Flow, Air Filtration Solutions

✓ Flow enhancing construction provides exceptionally high air flow rates with low differential pressures

✓ Hydrophobic PTFE membrane provides absolute bacteria and bacteriophage retention

✓ Full range of cartridge and capsule filter configurations available to meet all process conditions





Microfluor® II Critical Sterilizing Grade PTFE Cartridge and Capsule Membrane Filters

Microfluor II PTFE membrane filters offer the ultimate in microorganism retention for air and gas streams while providing superior air flow capacity.

- ▶ CUNO'S Microfluor II filters with flow enhanced construction allow use of smaller, more economical air filter assemblies compared to competitive air filters.
- ▶ Microfluor II filters provide absolute retention based on liquid bacteria challenge and aerosol bacteriophage challenge.
- ▶ Microfluor II filters are available in a wide range of cartridge and capsule configurations to provide the most economical solution to air, gas and aggressive liquid filtration applications.

New flow enhanced cartridge and capsule filter construction provides lower differential pressure than competitive filters

Cartridge and Capsule Configurations to Meet Any Process Requirement

Microfluor II membrane filters are available in 5 through 40 inch cartridges, 2.5 and 5 inch Mini Cartridges and 2.5, 5, 10, 20 and 30 inch capsules. With the exceptionally high Microfluor II flow rates, smaller and more economical assemblies can provide the same air flow as larger, more costly competitive PTFE filters.

| Feature | Benefit |
|---|--|
| ▶ Unique flow enhancing layer construction | ▶ Higher air flow for fermenter aeration and smaller, more economical vent filter assemblies |
| ▶ Liquid validation of <i>B. diminuta</i> retention | ▶ Reliable sterilizing performance in wet or dry conditions |
| ▶ Hydrophobic PTFE membrane | ▶ Membrane will not become blocked with moisture |
| ▶ 21 CFR Materials of Construction, USP Biological Safety Test, Validation Guide and Drug Master File Listing | ▶ Eases validation and regulatory submissions |

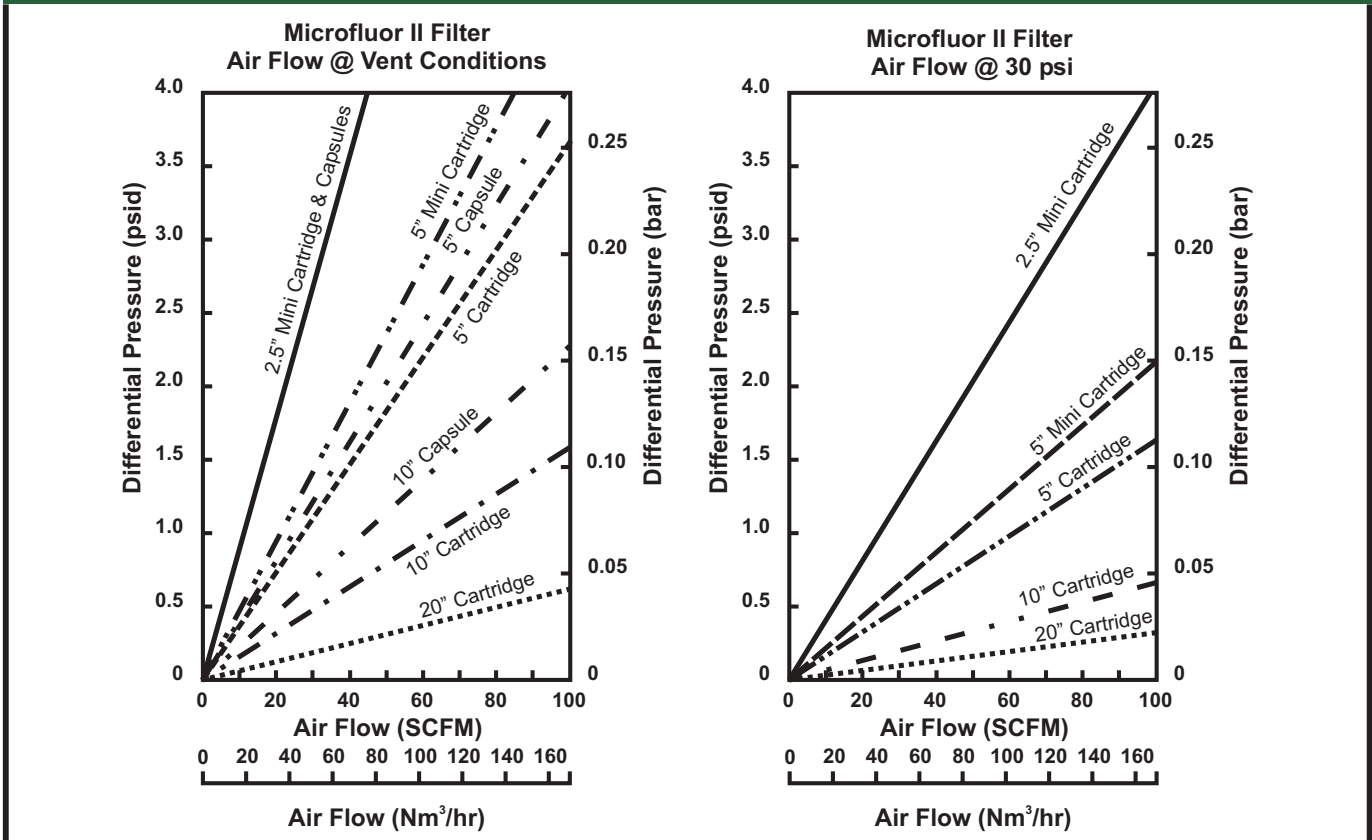
Microfluor® II Cartridge and Capsule Filter Applications

Microfluor II filters are optimized for applications requiring sterilization of air, gas, or aggressive solvents and chemicals. The hydrophobic PTFE filter membrane prevents wetting with aqueous liquids or moisture that can block free air flow. Some applications, however, may require filtration of aggressive fluids such as acids or bases. Depending on compatibility, Microfluor II filters can be used to provide sterile filtration of these fluids by prewetting the membrane with a low surface tension fluid such as alcohol. A list of Microfluor II filter applications includes:

- ▶ Sterile venting of process tanks
- ▶ Sterile filtration of process air and aseptic filling lines
- ▶ Sterile venting of lyophilizers
- ▶ Sterile venting of autoclaves
- ▶ Sterile air filtration on blow, fill, and seal machines
- ▶ Sterilizing filtration of fermentation inlet and exhaust air
- ▶ Sterile filtration of aggressive liquids

Microfluor II filters have been designed to provide exceptionally high flow rates with low differential pressures (Figure 1). Microfluor II filters are available in a range of cartridge and capsule filter configurations to meet any process requirement. Shown in Figure 1 are flow curves for cartridge and capsule filter assemblies at atmospheric (vent) and compressed air conditions. For details of sizing vent and compressed air assemblies, please ask for CUNO Automated Sizing Program assistance.

Figure 1. - Microfluor II Air Flow vs. Differential Pressure*



* Cartridge airflow values with housing pressure loss subtracted (excluding capsules).

The Microfluo[®]r II Membrane Advantage

Microfluo[®]r II filter cartridges and capsules combine high flow with a liquid validated, bacteria retentive, hydrophobic PTFE filter membrane. Capsule and cartridge filter structural components are polypropylene, optimized for long on-stream air service. The most important characteristics for a sterilizing grade air filter include:

Validated PTFE Membrane

Microfluo[®]r II filters are validated by liquid bacteria challenge for complete retention. Liquid bacteria challenge represents the most severe test of filter performance and provides the highest assurance level of reliable sterilizing performance. In addition, Microfluo[®]r II filters have demonstrated complete aerosol retention of the bacteriophage Φ X-174. For complete details, request the Microfluo[®]r II Validation Guide (LITVGMR2). The scanning electron micrograph (Photo 1) shows the structure of the PTFE membrane with a tortuous pore pathway of flow channels.

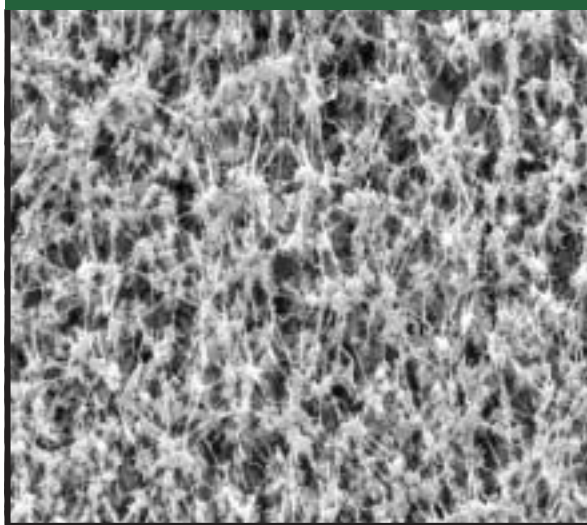
Hydrophobicity

Free air flow with little resistance requires that the filter membrane not wet with water or moisture. Membrane wetting can result in filter pore blockage, which in turn prevents free air flow and can cause filter failure. In order to prevent pore blockage, an extremely hydrophobic PTFE membrane is used which prevents wetting with water or moisture. Graph 1 shows the relative hydrophobicity of filter media used in air filters. As can be seen, PTFE offers the highest level of hydrophobicity ensuring optimum air flow service.

High Air Flow

Efficient performance requires maximum air flow at minimum pressure drop. Microfluo[®]r II air filters utilize a patent pending construction to achieve higher air flow vs. pressure drop compared to competitive air filters. This unique CUNO development involves the use of specially designed PTFE filter membrane and polypropylene flow enhancing layers. This construction is applied to Microfluo[®]r II cartridge and capsule filters. Photo 2 shows how each layer is positioned within the cartridge and capsule filters.

Photo 1. - SEM of Microfluo[®]r II PTFE membrane



Graph 1. - Comparative Hydrophobicity

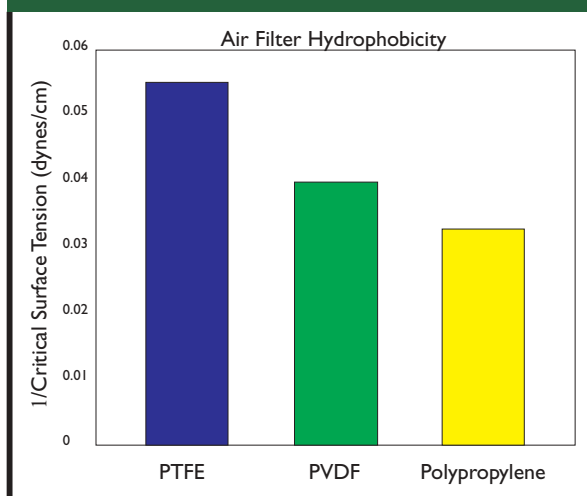


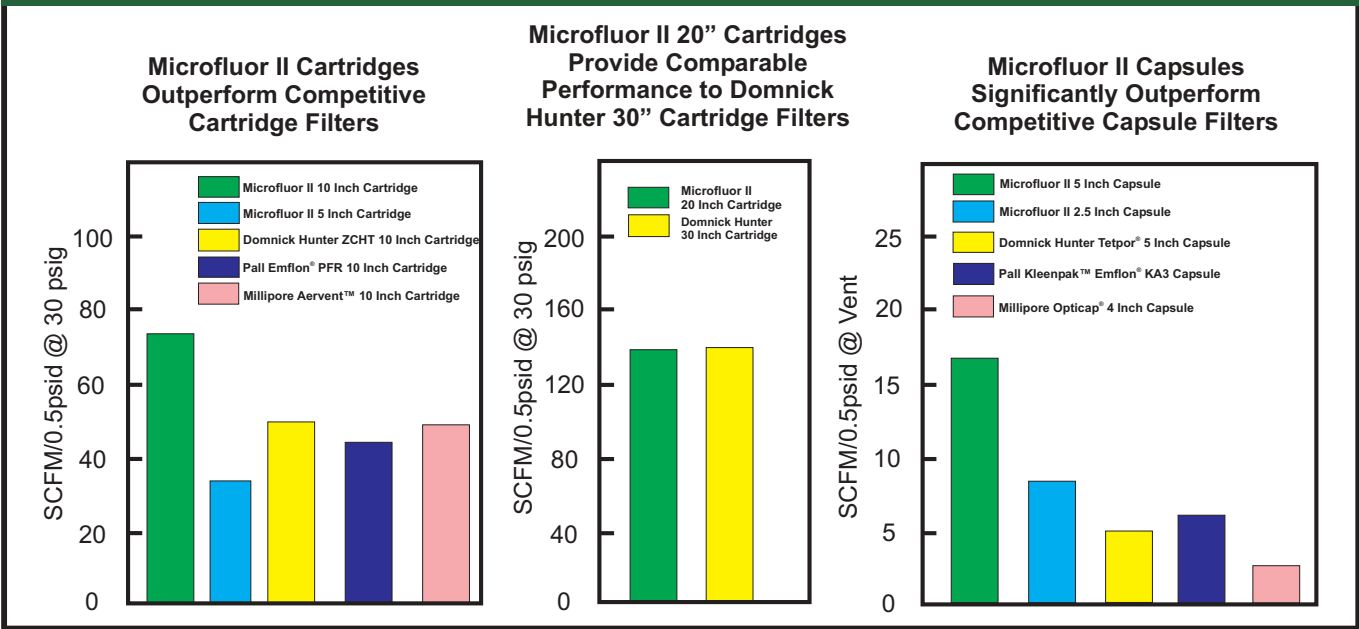
Photo 2. - Microfluo[®]r II Filter Construction



Superior Flow Rate Performance

Microfluor II filter cartridges and capsules offer outstanding flow rate performance at low differential pressures. Whether used for tank venting, lyophilizer or autoclave vacuum breaking, blow, fill, seal machines or fermentation air sterilization, filter flow rate is a critical parameter. Using the design enhancements described, Microfluor II filters provide maximum flow performance. Graph 2 presents the comparison of Microfluor II cartridge and capsule filter performance to competitive air filters.

Graph 2. - Air Flow Rate Comparisons



Reliable Microorganism Retention Performance.

Microfluor II filters are validated for sterilizing performance using a liquid bacteria (*B. diminuta*) challenge test method. Liquid bacteria retention testing is the most critical test of sterilizing filter performance and provides the user with the utmost assurance that critical product or fermentation broth will be protected from contamination. In addition to demonstrating sterilizing performance in liquid, Microfluor II filters were tested for complete bacteriophage retention using aerosol challenge test methods. Aerosol retention performance assures users that Microfluor II filters will provide reliable air and gas sterilization. Aerosol challenge testing was performed using ΦX-174 bacteriophage which are small organisms that infect bacteria cells and can ruin bacteria fermentation processes. Complete retention of bacteriophage was observed as shown in Table 1. For complete details request the CUNO Microfluor II Validation Guide (LITVGMR2).

Table 1. - Microfluor II Retention Performance

| Test Method | Test Organism | Test Result |
|---------------------------|----------------------|------------------------|
| Liquid Bacteria Challenge | <i>B. diminuta</i> | Sterile |
| Aerosol Virus Test | ΦX-174 Bacteriophage | 0 Plaque Forming Units |

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Robust Filter Construction

Many applications for air filtration require steam sterilization of filter cartridges. In vent or fermentation air service applications, filters may be steam sterilized multiple times. For fermentation processes, air sterilizing filters may be used for up to two years, and if sterilization is performed weekly, this results in exposure to over 100 steam cycles. Microfluor II air filters were tested for ability to withstand multiple forward and reverse steam cycles and were demonstrated to retain integrity for 200 steam cycles at 145°C. For complete details, request the Microfluor II Validation Guide (LITVGMR2).

Microfluor II Cartridge and Capsule Filter Configurations

Cartridge Filters

Microfluor II filters are available in 5 through 40 inch cartridge filters with a variety of end fittings and o-ring options to meet hardware and process requirements.

Mini-Cartridges

CUNO 2.5" and 5" Microfluor II Mini Cartridges can be installed in existing Pall Sealkleen™ housings or CUNO Mini Cartridge housing (LITZRMCH).

Capsule Filters

Microfluor II filters are available in 2.5, 5, 10, 20 and 30-inch capsule filter configurations. Capsule filters may be autoclave sterilized and offer a convenient, easy to use format for air sterilization. As with Microfluor II cartridge filters, the capsule filters have been specially designed to provide optimum air flow. **Capsules are not recommended for continuous compressed gas service.**

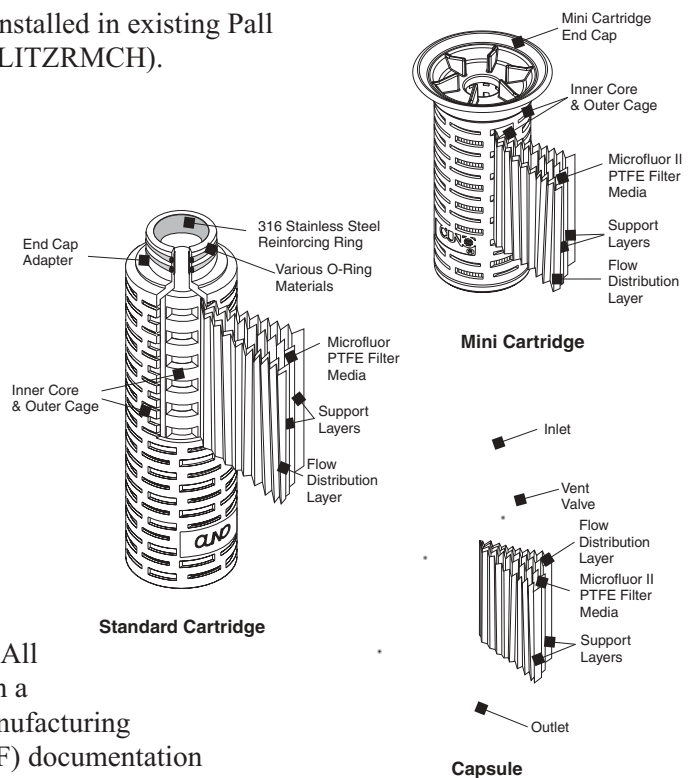
Quality and Reliability

Microfluor II filters are manufactured to an ISO 9000 registered quality system and are 100% diffusion flow tested prior to shipment. All materials of construction are 21 CFR listed and cartridge and capsule filter components have been tested in accordance with United States Pharmacopoeia (USP) Class VI Biological Safety. All Microfluor II cartridge and capsule filters are shipped with a Certificate of Quality affirming compliance with rigid manufacturing quality specifications. Supporting Drug Master File (DMF) documentation is on file with the United States Food and Drug Administration (FDA). A complete Microfluor II Validation Guide is available upon request (LITVGMR2).

Integrity Testing

Microfluor II cartridge and capsule filters can be easily and automatically tested to verify filter integrity pre and post use using the CUNOCheck® 2 integrity test instrument. Filters can be tested using diffusive flow, pressure hold, bubble point or water intrusion test (WIT) methods. Refer to CUNO publication LITDDMR2INTG - Integrity Testing Microfluor II Cartridge and Capsule Filters.

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| Operating Parameters and Specifications | | | | | | | | |
|--|---|----------------|-------------|----------------------------------|-------------|--------------|--------------|--------------|
| Filter Configuration | Cartridge | Mini Cartridge | | Capsules** | | | | |
| | 5 to 40" | 2.5" | 5" | 2.5" | 5" | 10" | 20" | 30" |
| Filter Rating | 0.2 µm | | | | | | | |
| Materials of Construction | | | | | | | | |
| Membrane | PTFE | | | | | | | |
| Membrane Support Layer | Polypropylene | | | | | | | |
| Core, cage, end caps, and adaptors | Polypropylene | | | | | | | |
| Adapter Reinforcing Ring | Stainless Steel | NA | | | | | | |
| Filtration Surface Area -ft ² (m ²) | 11 (1.02)* | 1.8 (0.17) | 3.7 (0.34) | 2.8 (0.26) | 5.5 (0.51) | 11 (1.02) | 22 (2.04) | 33 (3.06) |
| Cartridge Operating Parameters | | | | | | | | |
| Maximum Differential Pressure | | | | | | | | |
| Forward Pressure | 80 psid (5.5 bar) @ 75°F (25°C) 25 psid (1.7 bar) @ 180°F (80°C) | | | 75 psid (5.2 bar) @ 104°F (40°C) | | | | |
| Reverse Pressure | 65 psid (4.5 bar) @ 75°F (25°C) | | | 65 psid (4.5 bar) @ 75°F (25°C) | | | | |
| Maximum Operating Temperature | 180°F (80°C) | | | 104°F (40°C) | | | | |
| Integrity Test Parameters - Diffusion Flow Test - @ 25°C and 1 atm.*** | | | | | | | | |
| 25%/75% TBA/Water @ 16 psig (1.11 bar) | 8.7 cc/min.* | 1.4 cc/min. | 2.9 cc/min. | 2.2 cc/min. | 4.4 cc/min. | 8.7 cc/min. | 17.5 cc/min. | 26.2 cc/min. |
| 55%/45% IPA/Water @ 16 psig (1.11 bar) | 14.7 cc/min.* | 2.4 cc/min. | 5.0 cc/min. | 3.8 cc/min. | 7.4 cc/min. | 14.7 cc/min. | 29.5 cc/min. | 44.2 cc/min. |
| Autoclave Conditions | Up to 259°F (126°C) | | | | | | | |
| <i>In-situ</i> Steam Conditions | Up to 293°F (145°C) | | | Do not <i>In-situ</i> steam | | | | |
| * per 10 inch element **not for continuous compressed gas service. *** Consult factory for other methods | | | | | | | | |

CUNO Filter Housings

A complete line of sanitary design, stainless steel filter housings is available for Microfluor II cartridge filters. Options are available for heat traced (electrical and steam jacketed) housings where condensate is a concern. Specialized configurations and housing designs are also available for high flow, fermentation air filtration applications.

| Housing Model | Mini ZMS | ZMS | ZWC | ZWB | ZVS | Mini Cartridge Housing | |
|--|----------------------------------|--|---------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| Basic Part Number / Cartridge Capacity | For 5 inch Cartridge | For 10, 20, 30, and 40 inch cartridges | | | | For 2.5 inch Mini Cartridges | For 5 inch Mini Cartridges |
| | 70236 / 1 | 70220-01 / 1 | 70180 / 4 | 70192 / 4 | 70221-01 / 1 | 7023502 / 1 | 7023501 / 1 |
| | | 70220-02 / 1 | 70189 / 8 | 70193 / 8 | 70221-02 / 1 | | |
| | | 70220-03 / 1 | 70190 / 11 | 70194 / 11 | 70221-03 / 1 | | |
| | | 70220-04 / 1 | 70191 / 21 | 70195 / 21 | 70221-04 / 1 | | |
| Housing Style | T-line Sanitary type connection | | | | Sanitary type in-line | | |
| Equivalent Cartridge Lengths | 5 inch | 10, 20, 30, and 40 inches | | | | 2.5 inches | 5 inches |
| Materials of Construction | 316L Stainless Steel | | | | | | |
| Pressure & Temperature Ratings | 150 psi (10 bar) @ 300°F (149°C) | 75 psi (5 bar) @ 200°F (90°C) | 150 psi (10 bar) @ 200°F (90°C) | 150 psi (10 bar) @ 300°F (149°C) | 150 psi (10 bar) @ 300°F (149°C) | 150 psi (10 bar) @ 300°F (149°C) | 150 psi (10 bar) @ 300°F (149°C) |
| Literature # | LITZRHZMS2 | LITZRH.104 | LITZRH.106 | LITZRH.104 | LITZRHMCH | | |

Scientific Applications Support Services (SASS)

CUNO's 90 years of experience are synonymous with quality, performance and high-level technical support. The cornerstone of CUNO's philosophy is service to customers, not only in product quality and prompt delivery, but also in validation assistance, applications support and in the sharing of scientific information. CUNO's Scientific Applications Support Services group works closely with customers to solve difficult separations problems and to recommend the most economical and efficient filter system. SASS Specialists are skilled in performing on-site testing and relating test results to full-scale manufacturing operations.

Microfluor II Cartridge Ordering Guide

| Grade Designation | Configuration | Height (Inches) | End Modification | O-Ring Material |
|-------------------|---------------|--|--|---|
| PFS020 | A | 01 - 10 02 - 20 03 - 30 04 - 40 50 - 5 | B - 226 O-ring & Spear C - 222 O-ring & Spear F - 222 O-ring & Flat Cap J - 226 O-ring & Flat Cap | A - Silicone B - Fluorocarbon C - EPR D - Nitrile K - Teflon Encapsulated Viton |

Microfluor II Mini Cartridge Ordering Guide

| Grade Designation | Configuration | Height (Inches) | End Modification | Package Quantity |
|-------------------|---------------|--------------------|------------------|------------------|
| PFS020 | R | 01 - 2.5 02 - 5 | AN | 06 - 6 Pack |

Microfluor II Capsule Ordering Guide

| Grade Designation | Configuration | Height (Inches) | End Modification | Vent O-Ring Option | Package Quantity |
|-------------------|---------------|---|----------------------|---|------------------|
| PFS020 | J | 01 - 10 02 - 20 03 - 30 25 - 2.5 50 - 5 | A - Sanitary Fitting | A - Silicone B - Fluorocarbon C - EPR | 01 - 1 Pack |

CUNO: A World Leader in Fluid Purification

CUNO's manufacturing sites have ISO 9000 registered quality systems. Global manufacturing together with trained stocking distributors and state-of-the-art laboratory support bring quality solutions to existing and challenging new filtration applications.



WARRANTY

Seller warrants its equipment against defects in workmanship and material for a period of 12 months from date of shipment from the factory under normal use and service and otherwise when such equipment is used in accordance with instructions furnished by Seller and for purposes disclosed in writing at the time of purchase, if any. Any unauthorized alteration or modification of the equipment by Buyer will void this warranty. Seller's liability under this warranty shall be limited to the replacement or repair, F.O.B. point of manufacture, of any defective equipment or part which, having been returned to the factory, transportation charges prepaid, has been inspected and determined by the Seller to be defective. THIS WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EITHER EXPRESSED OR IMPLIED, AS TO DESCRIPTION, QUALITY, MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE OR USE, OR ANY OTHER MATTER. Under no circumstances shall Seller be liable to Buyer or any third party for any loss of profits or other direct or indirect costs, expenses, losses or consequential damages arising out of or as a result of any defects in or failure of its products or any part or parts thereof or arising out of or as a result of parts or components incorporated in Seller's equipment but not supplied by the Seller.



a 3M company

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