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MICROFLUOR® FP 0.20

Pharmaceutical Grade PTFE Filter Cartridge



MICROFLUOR® FP 0.20 micron Pharmaceutical Grade Cartridges are durable, biologically safe, and effective filters designed for critical filtration application. Microfluor FP filter cartridges have been validated for bacterial retention in liquids by the ASTM procedure and in gases by a six hour aerosol challenge procedure.

The Microfluor FP 0.20 is a hydrophobic cartridge constructed with a double layer of polypropylene reinforced GORE-TEX patented PTFE membrane. Polypropylene cartridge components, including DELNET up and down stream support, ensure both the membrane rigidity and compatibility required for severe operating conditions.

Every Microfluor FP filter cartridge is backed by an extensive validation guide. Drug Master File (DMF), and complete biological safety testing to ensure FDA compliance and process compatibility. For further information, contact CUNO Incorporated or your local distributor.

APPLICATIONS

Microfluor FP filter cartridges are designed for removal of microorganisms and other particulates from aggressive solvents, corrosive liquids and gases. The 020 FP is also suitable for steam and sterile vent applications.

- Chemicals: Fine Chemicals, Reagents, Solvents.
- Pharmaceutical: Solvents, Vent Filtration, Biologicals, Solvent Recovery Systems, and Process Gases.

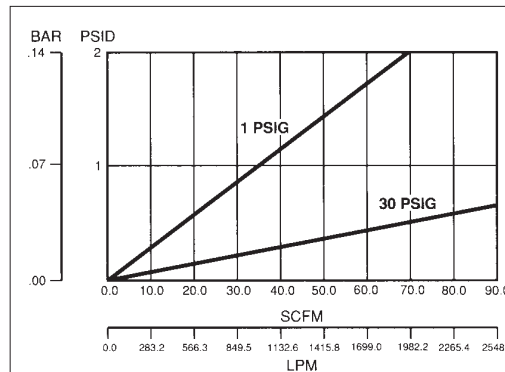
PERFORMANCE

Bacterial Retention

Microfluor FP 0.20 filter cartridges have passed the most comprehensive validation program to the industry. Bacteria retention in liquids has been demonstrated by the ASTM Challenge Procedure at 10^7 organisms/cm² of filter area. Bacteria retention in gases has been demonstrated by an Aerosol Challenge at 10^5 organisms/cm² with a flow rate of 0.70 SCFM/ft² over a six hour challenge period. Test results and challenge protocols of the validation test program are presented in the Validation Guide for Microfluor Cartridges. This extensive Validation Guide is available on request.

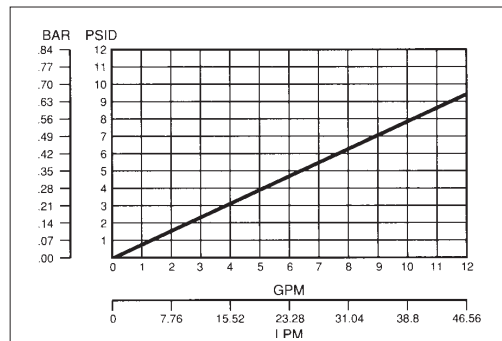
Flow Rates

The Microfluor 0.20 FP has been designed to allow high flow with low differential pressure. Graph 1 represents the average air flow rate for the tested cartridges at both 1 and 30 psig. The air flow rate is for a single 10" element at 25° C with housing losses deducted.



GRAPH 1 - AVERAGE AIR FLOW RATE

Graph 2 represents the average water flow rate for the tested cartridges per 10" element at 25° C with housing losses deducted.



GRAPH 2 - AVERAGE WATER FLOW RATE

BENEFITS

- Durable Polypropylene Construction
- Validated Bacterial Retention
- 100% Integrity Tested
- Biologically Safe
- Low Extractables
- Non-Pyrogenic
- DMF on File with FDA
- Broad Chemical Compatibility
- Various Cartridge Styles for Easy Installation



Fluid Purification

BIOLOGICAL SAFETY

The Microfluor 020 FP cartridge was subjected to the most extensive materials safety test program available in the industry today. The testing was conducted by an independent test facility operating under a Good Laboratory Practices (GLP) program. Testing included 12 safety tests in addition to USP XXI Class VI Safety Test to ensure safe use in pharmaceutical and food & beverage applications. The 12 additional tests are as follows:

Cytotoxicity

- Agar Overlay
- CHO Clonal Cells
- Direct Exposure
- Neutral Red Uptake

Metagenicity

- Salmonella/Microsome Preincubation (AMES)

Hemocompatibility

- Human Red Blood Cell Hemolysis
- Lymphocyte Compatibility
- Prothrombin Time

Histocompatibility

- Kligman Guinea Pig Maximization
- Primary Skin Irritation
- Single Dose Eye Irritation
- Single Dose Oral Toxicity

These 12 supplementary toxicity and biocompatibility tests confirm that the Microfluor cartridge is non-toxic, non-immunogenic, and non-mutagenic.

The Biological Safety Report for Microfluor cartridges is available upon request.

EXTRACTABLES

Gravimetric Extractables

The Microfluor cartridge is compatible with a wide range of solvents. Microfluor 020 FP cartridges were tested for bacteria retention after a four hour exposure to 30 different chemicals including aggressive acids, bases and solvents. Chemical compatibility was evaluated by subjecting the cartridges to both ASTM and Aerosol Bacteria Challenge Tests. The test sequence demonstrates that Microfluor cartridges are resistant to a wide range of process chemicals and can be safely used for sterilizing filtration of non-aqueous preparations and other applications involving aggressive solutions.

CHEMICAL COMPATIBILITY

The compatibility listing in Table 1 is intended as a guide. It is recommended that compatibility of these chemicals be established under actual filtration temperatures and conditions since operating parameters will affect compatibility. Consideration must also be given in selection of suitable gasket materials to assure complete compatibility. All data is shown at 20° C unless otherwise stated. All solutions were concentrated unless otherwise noted.

Solution	Rating
Acetic Acid	G
Acetone	G
Acetonitrile	G
Ammonium Hydroxide	G
n-Butyl Alcohol	G
tert-Butyl Alcohol	G
Carbon Tetrachloride	G
Chloroform	G
Dimethyl Formamide	G
Dimethyl Sulfoxide	G
Ethanol	G
Ether	N
Ethyl Acetate	G
Formaldehyde	G
Formic Acid*	G
Hydrochloric Acid*	G
Hydrofluoric Acid*	G
Hydrogen Peroxide (30%)	G
Isopropyl Alcohol	G
Methanol	G
Methylene Chloride	G
Methyl Isobutyl Ketone	G
Nitric Acid*	G
Pyridine	N
Sodium Hydroxide*	G
Sulfuric Acid*	G
Toluene	G
Water (90°C)	G
Xylene	G

G = Good Compatibility to the Temperatures Indicated

N = Not Recommended

* = Rating Based on Bacteria Challenge Data Only

TABLE 1 - CHEMICAL COMPATIBILITY

THERMAL STERILIZATION

Temperature resistance of the Microfluor FP cartridge was confirmed by validating in-situ steam compatibility at temperatures of 126° C and 145° C, both multiple short term (1 hour) and long term (100 hour). Performance after heat stress testing was confirmed by bacterial retention.

INTEGRITY TEST METHODS

Microfluor cartridges have been validated to confirm the correlation of 100% bacterial retention with four non-destructive integrity test methods. Each method, with the exception of the Water Intrusion Test, was validated using three wetting fluids for the greatest process flexibility. The water intrusion method should be considered for those applications where the presence of organic solvents cannot be tolerated. The test parameters are listed in Table 2.

Wetting Agent	Bubble Point Min (PSI)	Pressure (PSI)	DFT* (CC/Min)	PHT PSI/5 Min
100% Isopropyl Alcohol	18	5	20	1.25
60% Isopropyl Alcohol	18	10	10	0.8
25% Tertiary Butyl Alcohol	19	10	10	0.8
Water Intrusion	>55 psig			

Abbreviations Used:
PHT = Pressure Hold Test
DFT = Diffusion Flow Test
BP = Bubble Point Test
* = Per 10" Element

TABLE 2 - INTEGRITY TEST PARAMETERS

CARTRIDGE CONSTRUCTION

Microfluor cartridges contain two layers of reinforced PTFE membrane supported by polypropylene. The cartridge cage, core, end caps, and adapters are polypropylene. Multiple cartridge lengths are produced by thermally bonding individual 10" elements. No adhesives are used in the cartridge.

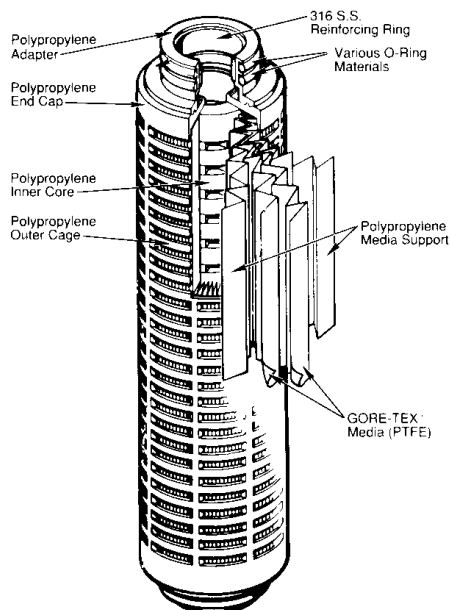


FIGURE - CARTRIDGE COMPONENTS

QUALITY ASSURANCE

Each Microfluor FP cartridge is integrity tested, by the diffusion flow method, prior to shipment. The first test is performed prior to adapting and the second after final assembly. In conformance with USP XXII monograph on Sterilization by Filtration, a random sample is taken, using Mil-Spec D-105 (Sampling Standards), from each manufactured lot and is tested for bacteria retention, flow, sterilization, and total extractables. Each cartridge element is individually identified by a serial number engraved on the cartridge end cap. The serial number provides traceability from raw materials to finished product.

CARTRIDGE SPECIFICATIONS

Rated Pore Size:	0.20 μ
Bacterial Removal Efficiency	
Liquid:	10 ⁷ P. diminuta/cm ²
Aerosol:	10 ⁵ P. diminuta/cm ²
Extractables:	30 mg
Filter Area:	7 ft ² per 10" element
Dimensions (Nominal):	2.8 in. OD, lengths to 40 inches

*Per 10" Element in IPA @ Ambient Temperature.

TABLE 3 - FP CARTRIDGE SPECIFICATIONS

OPERATING PARAMETERS

Forward Differential Pressure (psid):

80, 70, 60, 50, 40, 20, 10

Operating Temperature °C:

21, 38, 60, 85, 200, 212, 145

Autoclave Temperature:

121° C

In-Line Steam Temperature:

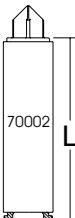
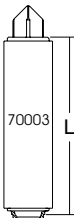
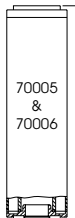
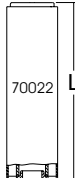
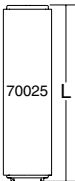
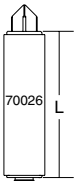
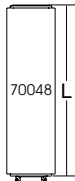
145° C

Cumulative Time @ Temperature:

100 hours @ 145° C

MICROFLUOR FP 0.20 ORDERING GUIDE

700XX		OX		X GASKET OR O-RING MATERIAL	020	F	P
BASIC CARTRIDGE DESIGN		NOMINAL CARTRIDGE LENGTH			MICRON RATING	FORMULATION	CONTROL GRADE
70002	70025	01	03	A - Silicone	020 (0.20 μ)	F	P - Reinforced
70003	70026	02	04	B - Fluorocarbon			
70012	70048	(See specific lengths)		C - EPR D - Nitrile			

 70002	Single Open End Code 7 (226) O-Ring Bayonet Lock <table><tr><th>Nominal Ctg. Length</th><th>70002 L</th></tr><tr><td>01</td><td>10 3/16</td></tr><tr><td>02</td><td>19 15/16</td></tr><tr><td>03</td><td>29 11/16</td></tr><tr><td>04</td><td>39 7/16</td></tr></table>	Nominal Ctg. Length	70002 L	01	10 3/16	02	19 15/16	03	29 11/16	04	39 7/16	 70003	Single Open End Code 8 (222) O-Ring <table><tr><th>Nominal Ctg. Length</th><th>70002 L</th></tr><tr><td>01</td><td>10 7/32</td></tr><tr><td>02</td><td>19 31/32</td></tr><tr><td>03</td><td>29 23/32</td></tr><tr><td>04</td><td>39 15/32</td></tr></table>	Nominal Ctg. Length	70002 L	01	10 7/32	02	19 31/32	03	29 23/32	04	39 15/32	 70005 & 70006	Double Open End Flat Gasket <table><tr><th>Nominal Ctg. Length</th><th>70005 L</th><th>70006 L</th></tr><tr><td>01</td><td>10</td><td>9 3/4</td></tr><tr><td>02</td><td>20</td><td>19 1/2</td></tr><tr><td>03</td><td>30</td><td>29 1/4</td></tr><tr><td>04</td><td>40</td><td>39</td></tr></table>	Nominal Ctg. Length	70005 L	70006 L	01	10	9 3/4	02	20	19 1/2	03	30	29 1/4	04	40	39
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04	40	39																																						
 70007	Double Open End Internal (120) O-Ring <table><tr><th>Nominal Ctg. Length</th><th>70007 L</th></tr><tr><td>01</td><td>9 5/8</td></tr><tr><td>02</td><td>19 5/8</td></tr><tr><td>03</td><td>29 5/8</td></tr><tr><td>04</td><td>39 5/8</td></tr></table>	Nominal Ctg. Length	70007 L	01	9 5/8	02	19 5/8	03	29 5/8	04	39 5/8	 70012	Single Open End (222) O-Ring <table><tr><th>Nominal Ctg. Length</th><th>70012 L</th></tr><tr><td>01</td><td>10 1/4</td></tr><tr><td>02</td><td>22</td></tr><tr><td>03</td><td>31</td></tr><tr><td>04</td><td>n/a</td></tr></table>	Nominal Ctg. Length	70012 L	01	10 1/4	02	22	03	31	04	n/a	 70022	Single Open End Internal O-Ring Seal <table><tr><th>Nominal Ctg. Length</th><th>70022 L</th></tr><tr><td>01</td><td>9 27/32</td></tr><tr><td>02</td><td>19 19/32</td></tr><tr><td>03</td><td>29 11/32</td></tr><tr><td>04</td><td>39 3/32</td></tr></table>	Nominal Ctg. Length	70022 L	01	9 27/32	02	19 19/32	03	29 11/32	04	39 3/32					
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 70025	Single Open End Code 3 (222) O-Ring <table><tr><th>Nominal Ctg. Length</th><th>70025 L</th></tr><tr><td>01</td><td>10 7/32</td></tr><tr><td>02</td><td>19 31/32</td></tr><tr><td>03</td><td>29 23/32</td></tr><tr><td>04</td><td>39 15/32</td></tr></table>	Nominal Ctg. Length	70025 L	01	10 7/32	02	19 31/32	03	29 23/32	04	39 15/32	 70026	Single Open End (226) & (218) O-Ring <table><tr><th>Nominal Ctg. Length</th><th>70026 L</th></tr><tr><td>01</td><td>9 15/16</td></tr><tr><td>02</td><td>19 11/16</td></tr><tr><td>03</td><td>29 7/16</td></tr><tr><td>04</td><td>39 3/16</td></tr></table>	Nominal Ctg. Length	70026 L	01	9 15/16	02	19 11/16	03	29 7/16	04	39 3/16	 70048	Single Open End (222) O-Ring <table><tr><th>Nominal Ctg. Length</th><th>70048 L</th></tr><tr><td>01</td><td>9 31/32</td></tr><tr><td>02</td><td>19 23/32</td></tr></table>	Nominal Ctg. Length	70048 L	01	9 31/32	02	19 23/32									
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CAUTION - Care must be exercised in applying equivalent cartridges to competitive housings. While very effort has been made to assure compatibility, exceptions may exist. A dimensional check of competitive products in the field is recommended.

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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.

Your Area Distributor is:

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The below 3M Cuno -series cartridge filters are all the models that are potentially possible in all variations.
Please note that not all models are actually produced or on stock and some model numbers and names have become obsolete.
Nevertheless this should help as cross reference table chart for Cuno filters nomenclature.

Microfluor

70002-01-A	70003-01-A	70012-01-A	70025-01-A	70026-01-A	70048-01-A
70002-01-B	70003-01-B	70012-01-B	70025-01-B	70026-01-B	70048-01-B
70002-01-C	70003-01-C	70012-01-C	70025-01-C	70026-01-C	70048-01-C
70002-01-D	70003-01-D	70012-01-D	70025-01-D	70026-01-D	70048-01-D
70002-02-A	70003-02-A	70012-02-A	70025-02-A	70026-02-A	70048-02-A
70002-02-B	70003-02-B	70012-02-B	70025-02-B	70026-02-B	70048-02-B
70002-02-C	70003-02-C	70012-02-C	70025-02-C	70026-02-C	70048-02-C
70002-02-D	70003-02-D	70012-02-D	70025-02-D	70026-02-D	70048-02-D
70002-03-A	70003-03-A	70012-03-A	70025-03-A	70026-03-A	70048-03-A
70002-03-B	70003-03-B	70012-03-B	70025-03-B	70026-03-B	70048-03-B
70002-03-C	70003-03-C	70012-03-C	70025-03-C	70026-03-C	70048-03-C
70002-03-D	70003-03-D	70012-03-D	70025-03-D	70026-03-D	70048-03-D
70002-04-A	70003-04-A	70012-04-A	70025-04-A	70026-04-A	70048-04-A
70002-04-B	70003-04-B	70012-04-B	70025-04-B	70026-04-B	70048-04-B
70002-04-C	70003-04-C	70012-04-C	70025-04-C	70026-04-C	70048-04-C
70002-04-D	70003-04-D	70012-04-D	70025-04-D	70026-04-D	70048-04-D

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