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LifeASSURE™ 020ST Series pharmaceutical grade cartridge

The LifeASSURE™ 020ST series pharmaceutical grade cartridge is a titer reducing membrane filter cartridge. The series has been designed to provide the user with a high capacity, efficient, and reliable filter device for applications where a low bioburden (final filter) or high bioburden (prefilter) is present. The LifeASSURE 020ST series cartridge has passed the USP Class VI Safety Test for Plastics and has been validated for bacteria reduction in excess 10^5 *Ps. diminuta*/cm². The non-pyrogenic filter cartridge is also capable of reducing contaminants smaller than the rated pore size because of electrokinetic adsorption, which provides a highly efficient vehicle for particle retention and pyrogen reduction.

Performance

The LifeASSURE 020ST series capsules has passed a validation test program that documents the correlation of bacterial retention and integrity test methods. In addition, supplementary validation testing supports all product claims. The extent of the program is as follows:

Bacterial Retention

Bacterial retention to levels in excess of 10^6 cells/cm² was verified using ASTM challenge procedures with *B. diminuta* as the test organism.

Integrity Test

The Diffusion Flow Integrity Test was correlated to 100% bacterial retention.

Flow Rates

The LifeASSURE 020ST series filter provides consistent water flow rates. The average data from the water flow analysis is represented by the solid line on Graph 1.

Sterilization

The LifeASSURE 020ST series cartridges can be sterilized by *in situ* steam or autoclaved for up to 5, one hour cycles at 145 °C.

Defined flow rates provide process consistency and a means for system sizing.

Biological Safety

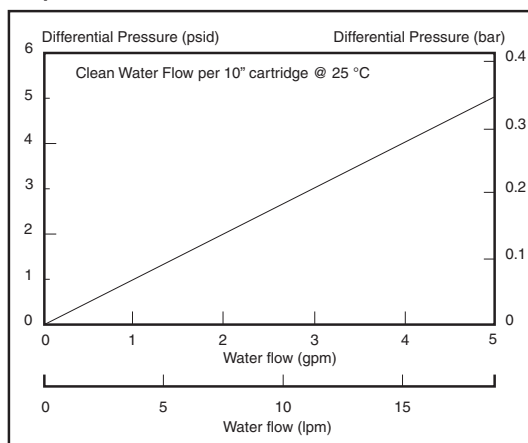
The LifeASSURE 020ST series cartridge is biologically safe as determined by the USP Class VI Safety Test for Plastics. The complete Biological Safety Test Report is available upon request.

Benefits

- Validated Titer Reduction
- DMF on File with the FDA
- Biologically Safe as determined by the USP Class VI Safety Test for Plastics
- Low Extractables
- Non-Pyrogenic
- Reinforced Nylon 6,6 Membrane
- Integrity Testable
- High Flow Rate



Graph 1. - Water Flow Rate @ 25 °C



Applications

- Final Filtration of Various Solutions with Low Influent Bioburden
- Prefiltration to Protect Sterile Fill Operations
- Filtration of Make-Up Water for Drug Products
- Filtration of Diagnostic Reagents

Quality Assurance

LifeASSURE™ 020ST Series cartridges are 100% integrity tested, by the diffusion flow method, prior to shipment. In addition, each cartridge lot is sample tested for pyrogenicity, bacteria retention, total extractables, and oxidizable substances. To ensure traceability from raw materials through the finished product, each cartridge element is engraved with a unique serial number.

Extractables

Oxidizable Substances and Pyrogenicity

The LifeASSURE 020ST series cartridge is low in extractable oxidizable substances and is nonpyrogenic. However, it is recommended as a good manufacturing practice to rinse the cartridge with 1000 ml of WFI or product per 10□element prior to use.

Gravimetric Extractables

The LifeASSURE 020ST series cartridges was tested for total gravimetric extractables by a 4-hour soak test. Extractable values are contained in the validation guide.

Chemical Compatibility

The LifeASSURE 020ST series cartridges exhibits a wide range of chemical compatibility. The compatibility data that follows (Table

Table 1.- Chemical Compatibility

Solution	Temperature (°C)	Compatibility
Acetic Acid 25%	22	G
Acetic Acid 70%	22	L
Acetic Acid Glacial	22	L
Acetone	22	G
Ammonia 10%	22	G
Acetonitrile	22	L
Acetonitrile	80	N
Ammonium Hydroxide 28%	22	G
Benzene	22	L
Benzyl Alcohol	22	G
n-Butanol	22	G
n-Butyl Acetate	22	G
Butyl Carbitol	22	G
Carbon Tetrachloride	22	L
Carbon Tetrachloride	77	N
Cellosolve Acetate	22	G
Cellosolve Solvent	22	G
Chloroform	22	N
Cotton Seed Oil	22	G
Cyclohexane	22	L
Cyclohexanone	22	L
Diethyl Acetamide	22	L
Diethyl Formamide	22	N
Dimethyl Formamide	22	N
Dimethyl Sulfoxide	22	L
Ethanol Absolute	22	G
Ethanol Absolute	28	L
Ethanol 50%	22	G
Ethyl Acetate	22	L
Ether, Diethyl	22	L

Solution	Temperature (°C)	Compatibility
Ether, Diethyl	35	L
Ethylene Dichloride	22	G
Ethylene Glycol	22	G
Ethylene Oxide 12 - 88%	22	L
Formaldehyde 37%	22	G
Glycerol	22	G
n-Heptane	22	L
Hexane	22	L
Hydrochloric Acid 3.7%	22	N
Isobutyl Alcohol	22	G
Isopropyl Alcohol	22	G
Methanol	22	G
Methylene Chloride	22	N
Methyl Isobutyle Ketone	22	G
Monethanolamine	22	L
n-Propanol	22	G
Propylene Glycol	22	G
Pyridine	22	L
Sodium Hydroxide 10%	22	G
Sodium Hypochlorite	22	G
Toluene	22	L
Trichlorotrifluoroethane (Freon)	22	G
Water	22	G
Water	82	G
Xylene	22	L
Explanation of Ratings		
G = Good compatibility to the temperature indicated		
L = Limited compatibility - consult factory		
N = Not recommended		
(Recommendations based on 4-hr. soak test		

1.) are intended as a guide only. 3M Purification Inc. recommends that the compatibility of the chemical considered for use with the cartridge be established under actual process conditions since the operating parameters may affect the interaction between the cartridge and chemical. Consideration must also be given to the selection of suitable o-ring/gasket material to ensure complete compatibility.

Construction

The LifeASSURE™ 020ST series cartridge is produced from reinforced, pleated filter composite membrane containing two layers of charge-modified Nylon 6,6. The membrane is supported on both the up and downstream sides by polypropylene. Multiple length cartridges of various end cap adapter styles are produced by thermoplastic bonding with no adhesives or surfactants used in the cartridge assembly. All materials used in the construction of the LifeASSURE 020ST series cartridge are FDA (CFR 21) listed for food contact.

CARTRIDGE SPECIFICATIONS

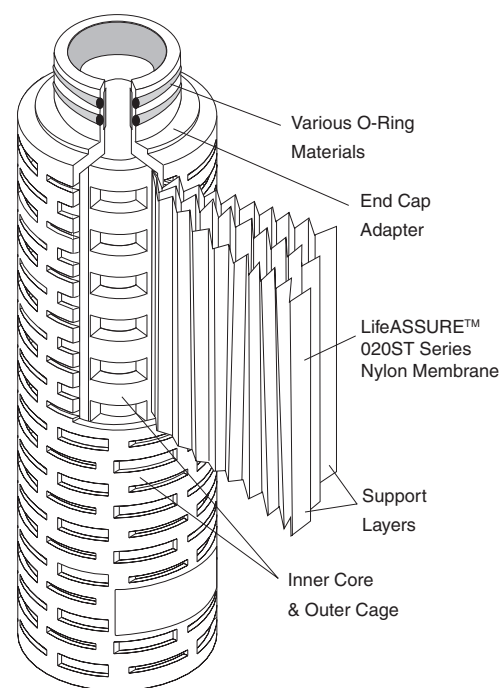
When referring to Table 2, all specifications are given per 10" Cartridge.

TABLE 2 - LifeASSURE 020ST Series SPECIFICATIONS

Rated Pore Size	0.20 µm
Filter Area	6.6 ft²
Demension (nominal)	2.8" O.D., lengths to 40"
Extractables	< 20 mg at 25 °C
Bacterial Reduction Efficiency	10 ⁵ <i>B. diminuta</i> /cm²
Diffusion Flow Rate	< 10 cc/minute at 30 psid
Pyrogenicity	< 25 pg/ml for first 250 ml aliquot
Oxidizable Substances	Neg. after 1000 ml flush

OPERATING PARAMETERS

Maximum Operating Temperature	175°F (80 °C)
Maximum Differential Pressure @ 25 °C	Forward: 65 psid (4.49 bar)
	Reverse: 65 psid (4.49 bar)
Sterilization	<i>In situ</i> steam or Autoclave for 5 hours
Recommended Rinse Volume	1000 ml (minimum) per 10" element



Standard Cartridge

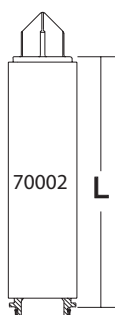
LifeASSURE™ 020ST Series Cartridge Ordering Guide

Plant Code 08 Product Code 103 Type NMC

Basic Cartridge Design	Nominal Cartridge Length *	Gasket or O-Ring Material	Micron Rating	Formulation	Control Grade
70002 70003 70012 70025 70048	01 02 03 04	A - Silicone B - Fluorocarbon C - EPR D - Nitrile	020 (0.20 µm)	S	T - Titer Reduction

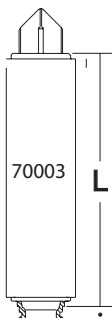
*Specific lengths illustrated on following page

LifeASSURE™ 020ST Series Filters



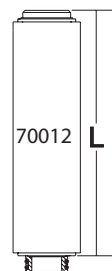
Single Open End Code 7 (226)
O-Ring Bayonet Lock with Spear

NOMINAL CARTRIDGE LENGTH	70002
	L
01	10 3/16"
02	19 15/16"
03	29 11/16"
04	39 7/16"



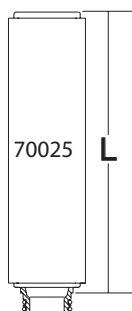
Single Open End Code 8 (222)
O-Ring with Spear

NOMINAL CARTRIDGE LENGTH	70003
	L
01	10 7/32"
02	19 31/32"
03	29 23/32"
04	39 15/32"



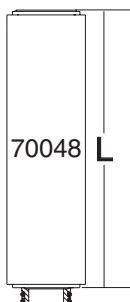
Single Open End (222) O-Ring
and Flat Top

NOMINAL CARTRIDGE LENGTH	70012
	L
01	10 1/14"
02	22"
03	31"



Single Open End Code 3 (222)
O-Ring and Flat Top

NOMINAL CARTRIDGE LENGTH	70025
	L
01	10 7/32"
02	19 31/32"
03	29 23/32"
04	39 15/32"



Single Open End (222) O-Ring
and Flat Top

NOMINAL CARTRIDGE LENGTH	70048
	L
01	9 31/32"
02	19 23/32"

Important Notice

The information described in this literature is accurate to the best of our knowledge. A variety of factors, however, can affect the performance of the product(s) in a particular application, some of which are uniquely within your knowledge and control. **INFORMATION IS SUPPLIED UPON THE CONDITION THAT THE PERSONS RECEIVING THE SAME WILL MAKE THEIR OWN DETERMINATION AS TO ITS SUITABILITY FOR THEIR USE. IN NO EVENT WILL 3M PURIFICATION INC. BE RESPONSIBLE FOR DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM THE USE OF OR RELIANCE UPON INFORMATION.**

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70002 01 B 020ST	70025 01 B 020ST
70002 01 C 020ST	70025 01 C 020ST
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