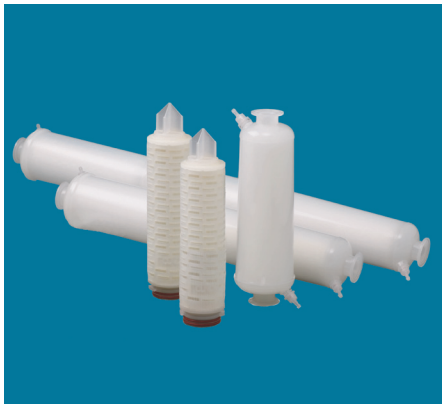
LifeASSURE™ 020SP Series

sterilizing grade filter cartridges and capsules

3M Purification Inc. pioneered the development of positively charge modified Nylon 6,6 filters for the pharmaceutical industry. LifeASSURE™ 020SP series sterilizing grade filters and capsules are validated for absolute bacteria retention and provide reliable sterile filtration performance. In addition to a fixed bacteria retentive pore structure, LifeASSURE 020SP series membrane is charge modified to provide enhanced reduction of negatively charged biological contaminants such as endotoxin, virus and nucleic acid fragments. The combination of a validated bacteria retentive membrane, together with enhanced reduction of negatively charged contaminants, make LifeASSURE 020SP series membrane an ideal choice for pharmaceutical and biopharmaceutical sterilizing applications.

Each LifeASSURE 020SP series cartridge and capsule filter is supplied with a Certificate of Quality. A Validation Guide is available for ease of compliance with regulatory requirements. The Quality Management System is approved by an internationally recognized accrediting body to an ISO 9001:2008 Registered Quality System Standard.



Applications

- Large volume parenterals
- Biologicals
- Bioprocess-derived protein solutions
- Vaccines
- Diagnostics
- Purified water systems
- Solvents
- Ophthalmics
- Blood and serum fractions
- Cell culture media
- Reagents & buffers
- Pharmaceutical bulk chemical solutions

Features & Benefits

Charge-modified Nylon 6,6 filter medium

- Retention of negatively-charged biological and particulate contaminants including endotoxins
- Inherently hydrophilic membrane for easy wet-out

High area, pleated membrane design

- High flow rates, low pressure drop
- Smaller filter systems, longer service life for reduced filtration costs

Reliable 0.2 µm validated performance

- Meets FDA definition of 0.2 µm sterilizing grade filter (10^7CFU/cm^2 *B. diminuta* retention)
- Integrity test correlated with sterile filtration performance data and supported by Validation Guide

Robust cartridge construction

- Cartridges withstand mechanical and thermal stress including Steam In Place operations

Cartridges 100% integrity tested

- Ensures consistent performance to specifications, integrity testable pre-and post-use

ISO 9001:2008 - Registered Quality System

- Quality Management System approved by an accrediting body to an ISO 9001:2008 Quality Systems Standard

Tested and optimized for pharmaceutical and biological processing

- Materials of construction tested for biological safety (USP Class VI) and listed in Drug Master File (DMF) at FDA

Low extractable levels, no surfactants or adhesives used in manufacturing

- Minimal effect on filtrate quality and purity

3M

Optimized for Use with LifeASSURE™ PLA Series Prefilter Cartridge and Capsule Filters

LifeASSURE™ 020SP Series sterilizing grade filters are designed for use with LifeASSURE™ PLA series prefilters. Both filters feature Nylon 6,6 filter membrane. 3M Purification Inc.'s unique multi-zone micropourous membrane technology, used in LifeASSURE PLA series prefilters, provides superior life extension of LifeASSURE 020SP series final filters. Used together, LifeASSURE PLA series prefilters and LifeASSURE 020SP series final filters provide high system flow rates and safe, reliable microorganism retention.

For most applications, LifeASSURE™ PLA045 series is the best first choice for prefiltration prior to LifeASSURE 020SP series sterilizing grade final filters. For applications where the particulate or colloidal level is extremely low and maximum final filter life is desired, choose LifeASSURE™ PLA020 prefilters.

LifeASSURE 020SP Series Membrane Advantage

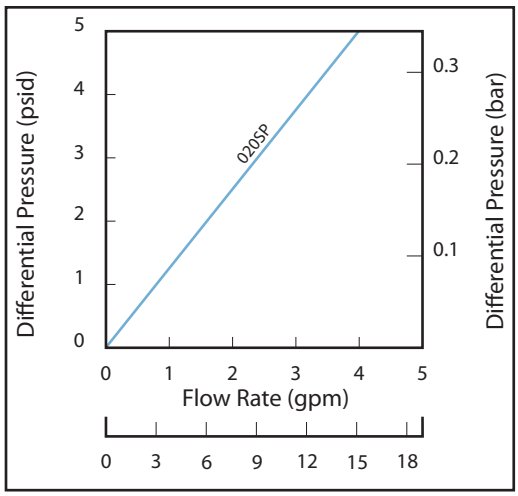
Absolute Bacterial Retention

LifeASSURE 020SP series filters are qualified for absolute retention of *B. diminuta* (ATCC 19146) following American Society of Testing and Materials (ASTM) methodology at a minimum challenge level of 10^7CFU/cm^2 of filter area. The results of bacteria challenge testing correlated to non destructive integrity testing are available in 3M Purification Inc. LifeASSURE™ Series 020SP Validation Guide (70-0201-8844-0).

Enhanced Retention of Negatively Charged Contaminants

LifeASSURE 020SP series Nylon 6,6 membrane is manufactured with positively charged functional groups. This feature provides enhanced retention of negatively charged contaminants including bacteria, endotoxins, viruses and nucleic acids.

Graph 1. - LifeASSURE™ 020SP Series 10" element water flow rates @ 77 °F (25 °C)



Low Extractables and Broad Chemical Compatibility

LifeASSURE 020SP series hydrophilic Nylon 6,6 filter membrane is inherently low in extractables. Because the membrane is hydrophilic, surfactants are not required to achieve water wettability. The broad chemical compatibility of Nylon 6,6 membrane allows use with a wide range of process fluids.

High Cartridge and Capsule Flow Rates

LifeASSURE 020SP series cartridge and capsule filters offer high flow rates. Each configuration contains the highest possible pleat density without compromising access to the effective filtration surface area. Graph 1 shows the water flow rate and pressure drop characteristics of LifeASSURE 020SP series 10" cartridge and capsule filters.

Regulatory Compliance & Quality Assurance

LifeASSURE 020SP series sterilizing grade filters are 100% integrity tested during manufacture to ensure that they are integral. LifeASSURE 020SP series filters are manufactured in a controlled environment using an ISO 9001:2008 Registered Quality System. An identification system permits traceability of all raw material components. All materials of construction are 21 CFR listed and have passed USP Class VI Biological Test for Plastics at 121 °C. A Certificate of Quality is included with every filter certifying quality attributes and lot release testing. Representative sample filters from each manufacturing lot are tested for microbial retention, endotoxin, oxidizable substances, and forward flow integrity

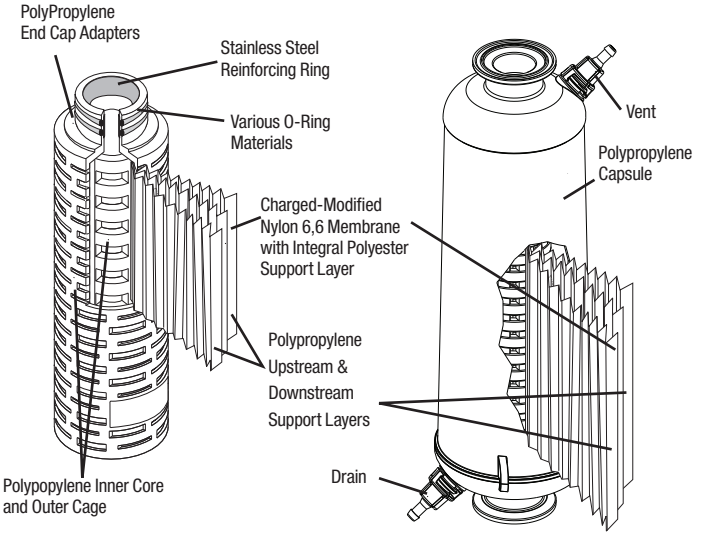
LifeASSURE 020SP series sterilizing grade filters are qualified for absolute retention of *B. diminuta* (ATCC 19146) following ASTM methodology at a minimum challenge level of 10^7CFU/cm^2. LifeASSURE 020SP series filters meet the definition of a sterilizing grade filter as described in the "FDA Guideline on Sterile Drug Products Produced by Aseptic Processing" (September 2008) and are manufactured in accordance with 3M Purification Inc.'s active Drug Master File (DMF).

Performance-Engineered Cartridge Design

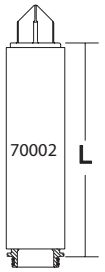
All polypropylene structural components (end cap adaptors, inner core and outer cage) are used in the fabrication of LifeASSURE™ 020SP series filter cartridges assuring exceptional thermal and mechanical stability, broad chemical compatibility and low extractable levels. LifeASSURE 020SP series cartridge configurations are available to match dimension and sealing requirements of most currently available cartridge housings.

Disposable Filter Capsules

For critical applications where convenience and ease of use are desired, LifeASSURE 020SP series filters are available in 10", 20", and 30" disposable capsules. LifeASSURE 020SP series capsules are supplied with sanitary vent and drain ports, as well as 1.5" sanitary flange inlet and outlet connections.

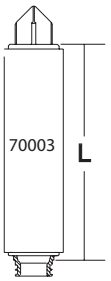


LifeASSURE™ 020SP Series Filter Specifications				
Filter Configuration	Cartridge	Capsule		
		10"	20"	30"
Filter Rating	0.2 µm			
Materials of Construction				
Membrane	Charge-modified Nylon 6,6			
Membrane Support Layer	Polyester			
Pleat Support/Drain Layers	Polypropylene			
Inner Core, Outer Cage, End Cap Adapters	Polypropylene			
End Cap Adapters Reinforcing Ring	Stainless Steel	NA	NA	NA
O-rings	See ordering guide	Silicone (vent and drain)		
Cartridge Dimensions				
Length	See illustrations (right)			
Diameter	2.75" (6.9 cm)	3.8" (9.7 cm)		
Filtration Surface Area	8 ft² (0.74 m²)*	8 ft2 (0.74 m²)	16 ft² (1.4 m²)	24 ft² (2.2 m²)
Cartridge Operating Parameters				
Maximum Differential Pressure Forward Pressure	80 psid (5.5 bar) @ 77 °F (25 °C) 25 psid (1.7 bar) @ 176 °F (80 °C)	75 psid (5.2 bar) @ 104 °F (40 °C)		
Reverse Pressure	4.5 bar (65 psid) at 25 °C			
Maximum Operating Temperature	176 °F (80 °C)	104 °F (40 °C)		
Integrity Test Parameters				
Forward Air Diffusion (water wet)	10 cc/min @ 2.75 bar (40 psig)*			
Pressure hold is dependent on housing volume and is available on request				
Sterilization				
Autoclave	Up to 268 °F (131 °C)	Up to 259 °F (126 °C)		
In-situ steam	Up to 275 °F (135 °C)	Do not *In-situ* steam		
* per 10" element				



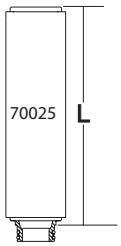
(226) O-Ring Bayonet With Spear

Cartridge Length	
Code	Inches (mm)
01	10 3/16" (259)
02	19 15/16" (506)
03	29 11/16" (754)
04	39 7/16" (1002)



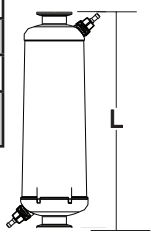
(222) O-Ring Plug-in With Spear

Cartridge Length	
Code	Inches (mm)
01	10 7/32" (260)
02	19 31/32" (507)
03	29 23/32" (755)
04	39 15/32" (1003)



(222) O-Ring Flat Cap

Cartridge Length	
Code	Inches (mm)
01	10 7/32" (260)
02	19 31/32" (507)
03	29 23/32" (755)
04	39 15/32" (1003)



CAPSULE	
Nominal Length	
Code	Inches (mm)
01	10 7/32" (305)
02	19 15/16" (559)
03	29 11/16" (813)

LifeASSURE™ 020SP Series Filters

LifeASSURE™ 020SP Series Filter Ordering Guide

Basic Cartridge Design	Cartridge Length	Gasket or O-Ring	Micron Rating	Formulation
70002 70003 70025	01, 02, 03, or 04 (See Cartridge Specification)	A - 60D* (Standard) Silicone B - Fluorocarbon C - EPR D - Nitrile J - 70D* (Harder) Silicone	020 - 0.2 µm	SP - Pharmaceutical

* Durometer rating

LifeASSURE 020SP Series Filter Ordering Guide

Capsule Grade	Configuration	Nominal Length (inches)	End-modification	Vent/Drain O-Ring	Packaging Option
PSZ020 - 0.2 µm	J - Capsule	01 - 10 02 - 20 03 - 30	A - Sanitary Flange	A - Silicone	01 - Single Capsule

Your Local Distributor:

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