

3M Purification

Life Sciences Process Technologies Markets



LifeASSURE™ 020SP

Series Capsules & Cartridge Filters

Sterilising-grade Nylon 6,6 membrane filters for pharmaceutical, biological & bioprocess Industries

- ☑ New name for CUNO Zetapor SP 020
- ☑ Reliable sterile filtration performance
- ☑ Enhanced removal of negatively charged molecules including viruses, endotoxins and nucleic acids
- ☑ Charge-modified Nylon 6,6 hydrophilic filter medium





LifeASSURE™ 020SP sterilising-grade cartridge filters

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

Each LifeASSURE 020SP cartridge 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 recognised accrediting body to an ISO Quality Systems Standard.

Meeting scale-up and scale-down requirements

A full range of LifeASSURE 020SP sterilising-grade filters are available to meet your scale-up and scale-down process needs. The LifeASSURE 020SP membrane is configured in disposable capsules, mini-cartridges and full-size cartridges. Assemblies with filter area ranging from 0.13 m² to > 62 m² are available. Smaller LifeASSURE 020SP membrane areas can be obtained by using LifeASSURE 020SP filter discs.

Mini-cartridges

- 2.5" and 5" sizes
- 0.13 m² and 0.33 m² filtration area
- two housing sizes available for lowest hold-up volume design
- retrofit competitor filter housings
- steam in place (SIP) or autoclaveable

Full-size cartridges

- 10" through 40" lengths
- 0.74 to 3 m² filtration area per cartridge
- double O-ring seal mechanism with various code adapters
- fit 3M Purification and competitor filter housings
- steam in place (SIP) or autoclaveable

Optimised for use with LifeASSURE™ PLA prefilter cartridge and capsule filters

LifeASSURE 020SP sterilising-grade filters are designed for use with LifeASSURE™ PLA prefilters, but they can also be used alone. Both filters feature a Nylon 6,6 filter membrane. 3M Purification's multi-zone microporous membrane technology, used in LifeASSURE PLA prefilters, provides superior life extension of LifeASSURE 020SP final filters. Used together, LifeASSURE PLA prefilters and LifeASSURE 020SP final filters provide high system flow rates and safe, reliable microorganism retention.

For most applications, LifeASSURE PLA 045 is the best first choice for prefiltration prior to LifeASSURE 020SP 0.2 µm rated sterilising-grade final filters. For applications where the particulate or colloidal level is extremely low and maximum final filter life is desired, choose LifeASSURE PLA 020 prefilters.

Applications

LifeASSURE™ 020SP 0.2 µm cartridge filters are designed for the sterile filtration of liquid solutions such as:

- Large and small volume parenterals
- Biologicals
- Diagnostics
- Purified water systems
- Solvents
- Blood and serum fractions
- Cell culture media
- Reagents and buffers
- Pharmaceutical bulk chemical solutions



LifeASSURE 020SP sterilising-grade (0.2 µm) membrane filters are manufactured from charge-modified Nylon 6,6 membrane and polypropylene cartridge components. Providing high flow rates, low extractables, broad chemical compatibility and reliable sterile filtration performance, LifeASSURE 020SP cartridges are 100 % integrity tested during manufacture to ensure performance in critical pharmaceutical and bioprocess applications where absolute bacterial retention is essential.

Features and Benefits

Charge-modified Nylon 6,6 filter medium

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

High area, pleated membrane design

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

Reliable 0.2 µm validated performance

- Meets FDA definition of a 0.2 µm sterilising-grade filter ($10^7/cm^2$ *B. diminuta* retention following ASTM methodology).
- Integrity test correlated with sterile filtration performance data supported by Validation Guide

Robust cartridge construction

- Cartridges withstand mechanical and thermal stress including SIP operations

Cartridges 100% integrity tested

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

ISO-registered Quality System

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

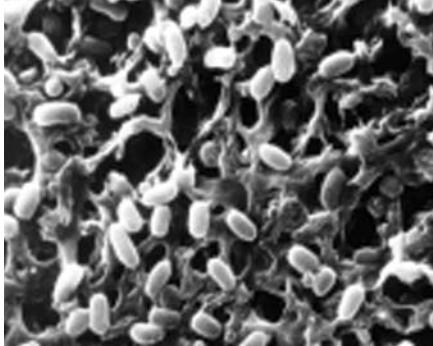
Tested and optimised for pharmaceutical and biological processing

- Materials of construction are 21CFR and tested for biological safety (USP Class VI) and listed in Drug Master Files (DMF's) at FDA

Low extractable levels, no surfactants or adhesives used in manufacturing

- Minimal effect on filtrate quality and purity

SEM showing the capture of *B. diminuta* within the LifeASSURE™ 020SP membrane filter matrix



The LifeASSURE™ 020SP membrane advantage

Absolute bacterial retention

LifeASSURE™ 020SP 0.20 micron 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 10^7 CFU/cm² of filter area. The results of bacteria challenge testing correlated to non destructive integrity testing are available in 3M Purification Validation Guide.

Enhanced removal of negatively charged contaminants

The LifeASSURE 020SP 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.

Low extractables and broad chemical compatibility

The LifeASSURE 020SP 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 range of process fluids and further reduces extractable formation.

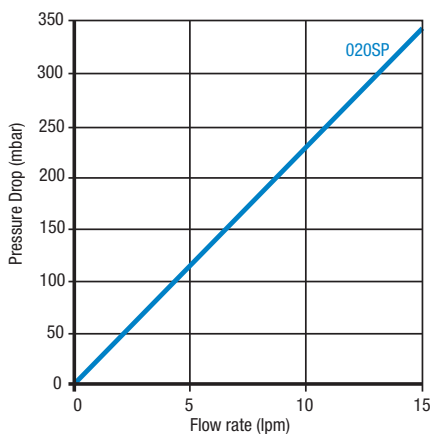
High cartridge and capsule flow rates

LifeASSURE 020SP 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. The tables at the left show the water flow rate and pressure drop characteristics of LifeASSURE 020SP cartridge and capsule filters.

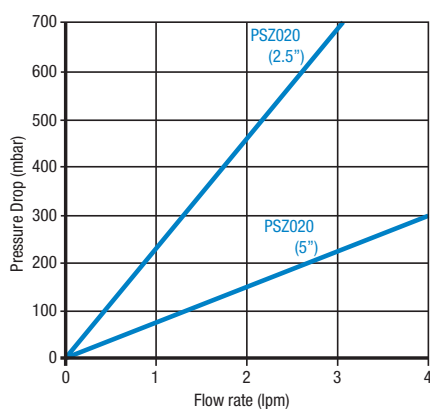
Highest system flow rates

The system concept of LifeASSURE™ PLA prefilters and LifeASSURE 020SP final filters offers the highest possible flow rates and lowest system pressure drop. Lower pressure drop means longer filter system life and smaller assemblies for the most economical system. The combined pressure drop of 10" LifeASSURE PLA/ LifeASSURE 020SP filter systems for a 11 lpm water flow rate is compared to competitive 10" filter systems in the table below. The data does not include housing pressure drop.

LifeASSURE™ 020SP 10" cartridge water flow rates at 25 °C



LifeASSURE™ 020SP mini cartridge and disposable capsule water flow rates at 25 °C



Pre-filter	Final filter	Pressure drop (mbar)/10" Filter
3M Purification LifeASSURE™ PLA 045	LifeASSURE™ 020SP	286
3M Purification LifeASSURE™ PLA 020	LifeASSURE™ 020SP	327
Cartridge A	Cartridge B	500
Cartridge C	Cartridge D	510

Performance-engineered cartridge design

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

Mini-cartridges

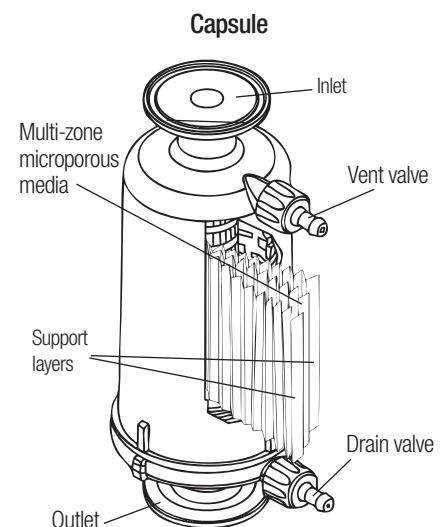
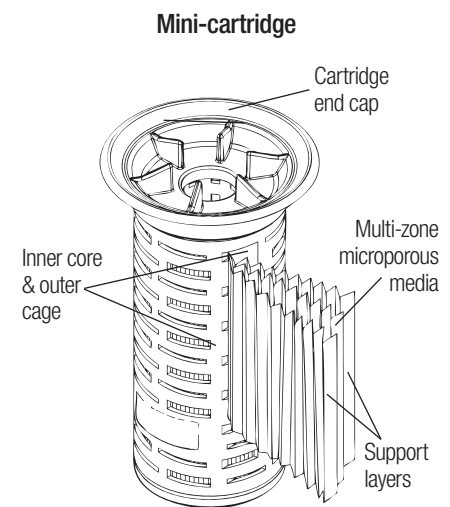
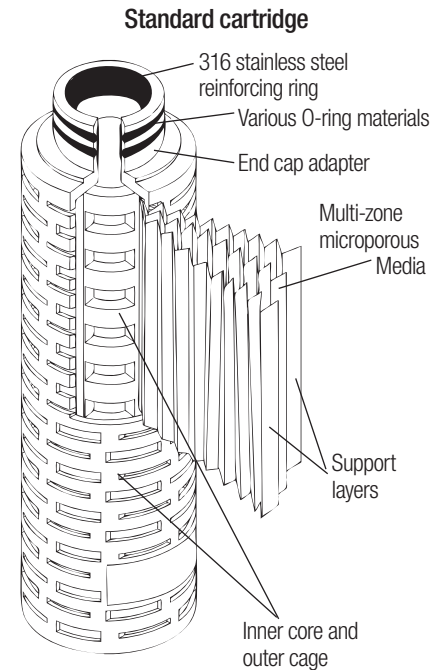
For critical small volume applications, LifeASSURE 020SP filters are available in 5" and 2.5" mini-cartridges. Installed in 3M Purification's 2.5" or 5" mini-cartridge housing or in existing competitor housings, LifeASSURE 020SP mini-cartridges offer low hold-up volume and economical small volume filtration.

Disposable filter capsules

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

LifeASSURE 020SP specifications

Types	Cartridges	Mini-cartridges		Capsules		
		2.5" Length	5" Length	10"	20"	30"
Filter rating	0.2 µm					
Material of construction						
Membrane	charge-modified Nylon 6,6					
Membrane support layer	polyester					
Pleat support/drain layers	polypropylene					
Core, cage, end caps and adaptors	polypropylene					
End cap reinforcing ring	stainless steel	N/A	N/A	N/A	N/A	N/A
O-rings	see ordering guide			silicone (vent and drain)		
Cartridge dimensions						
Length	10", 20", 30" & 40" (25, 50, 75 & 100 cm)	7.9 cm	14 cm	9.7 cm		
Filtration surface area	0.74 m ² per 10" element	0.13 m ²	0.3 m ²	0.74 m ²	1.4 m ²	2.2 m ²
Outside diameter	6.9 cm	5.7 cm				
Cartridge operating parameters						
Maximum operating temperature	80 °C			40 °C		
Maximum differential pressure				5.2 bar at 40°C		
Forward	5.5 bar at 25°C 1.7 bar at 80 °C					
Reverse	4.5 bar at 25 °C					
Integrity test parameters						
Forward air diffusion (water wet)	10 cc/min at 2.75 bar per 10" Element	2.0 cc/min at 2.75 bar	3.5 cc/min at 2.75 bar	10 cc/min at 2.75 bar per 10" element		
Pressure hold is dependent on housing volume and is available on request.						
<i>In situ</i> steam sterilisation	135 °C for 30 minutes			do not <i>In situ</i> steam		
Autoclave sterilisation	131 °C for 60 minutes			up to 126 °C		





Meeting the needs of the pharmaceutical industry

Regulatory compliance and quality assurance

LifeASSURE™ 020SP sterilising-grade filters are 100% integrity tested during manufacture to ensure that they are defect-free. LifeASSURE 020SP filters are manufactured in a controlled environment using an ISO 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, oxidisable substances and forward flow integrity.

A LifeASSURE 020SP Validation Guide is available to ease compliance with regulatory requirements. LifeASSURE 020SP sterilising-grade filters are qualified for absolute retention of *Brevundimonas diminuta* (ATCC 19146) following ASTM methodology at a minimum challenge level of 10⁷ CFU/cm². LifeASSURE 020SP filters meet the definition of a sterilising-grade filter as described in the “FDA Guideline on Sterile Drug Products Produced by Aseptic Processing” (June 1987) and are manufactured in accordance with 3M Purification’s active Drug Master File (DMF).

Filter systems for pharmaceutical manufacturing

Since pharmaceutical and biological solutions encompass a wide range of fluid conditions, 3M Purification provides a range of filters optimised for efficient and economical separations. 3M Purification scientists and engineers have a history of innovative new product developments aimed at solving complex pharmaceutical filtration requirements. Summarised below are some of the specialised filter products developed by 3M Purification to offer the specific filter solution for your separation needs.

Membrane prefiltration

3M Purification *LifeASSURE™ PLA* filters are constructed using multi-zone Nylon 6,6 technology to provide optimal prefiltration to final sterilising-grade membrane filters. The multi-zone microporous membrane provides built-in prefiltration and bacteria retention in a single membrane layer while maintaining high flow rates.

Zeta Plus™ Depth Filter

For over 25 years, *Zeta Plus* cellulose based depth filtration media has been the premier clarification filter for the biopharmaceutical industry. The *Zeta Plus* family of filters offer a wide range of specially developed media. *Zeta Plus EXT Series* filters feature a new dual zone, graded-density media construction with significantly increased throughput while optimising effluent clarity. *Zeta Plus VR* filters offer enhanced log reduction of viruses from biological fluids.

Scientific Applications Support Services (SASS)

The cornerstone of 3M Purification's philosophy is service to customers, not only in product quality and prompt service, but also in problem solving, application support and in the sharing of scientific information. 3M Purification's Scientific Applications Support Services (SASS) group is a market-oriented group of scientists and engineers who work closely with customers to solve difficult separation problems and aid in the selection of the most effective and economical filtration systems. 3M Purification offers specialised support to the pharmaceutical and biotechnology industry through our validation support service program. SASS routinely provides end-users with:

- Validation And Regulatory Support
- Extractable And Compatibility Analysis
- Filter System Optimisation Studies

For more information regarding 3M Purification's validation support services, please contact 3M Purification Technical Services.

3M Purification filter housings

A specialised range of filter housings are available to meet the needs of the pharmaceutical, biological and bioprocess. They provide easy access for filter change-out and the greatest assurance that LifeASSURE™ 020SP filter cartridges are sealed securely, thus eliminating the possibility of fluid bypass. All housings are constructed using 316L stainless steel to maximise corrosion resistance. Internal surfaces of the housings are polished to > 0.8 µm Ra to limit microbial adhesion and provide easy cleaning.

For more information on our housing range, please contact your local 3M Purification representative.



3M Purification's offering of IW sanitary style filter housings accommodate from 1 to 24 filter cartridges in 10" through 40" lengths

Housing IW Specifications	01 IWV / 03 IWV / 05 IWV / 08 IWV	12 IWV	18 IWV / 24 IWV
Design code	AD Merkblätter 95		
Housing material (in contact)	316L (1.4404) stainless steel		
Surface finish	mechanical polish < 0.8 micron Ra		
Closure	clamped	bolted	bolted
Number of cartridges	1 - 3 - 5 - 8	12	18 - 24
Standard gasket material	silicone (others on request)		
Cartridge height	1, 2, 3 and 4 high		3 and 4 high
Connection sizes	• threaded Male DIN 11851 • triclover	• DIN 2633 flanges • MACON	
Vent connections	½" TC		
Max. operating pressure	10 bar g	9 bar g	8 bar g
Max. operating temperature	150 °C		
PED 97/23/CE	Category I		Category I (18 IWV) Category II (24 IWV)
ATEX 94/9/CE	II-2-G/D-T5		

Table 1 is intended as a guide. Grade selection and performance should be confirmed with small-scale pilot trial.



3M Purification's mini-cartridge filter housings provide the user with low product hold-up volume for critical small scale applications.

Housing model	Mini-housing	
Cartridge capacity	For 2.5" mini-cartridges	For 5" mini-cartridges
Housing style	sanitary type in-line	
Equivalent cartridge lengths	2.5" (63 mm)	5" (125 mm)
Materials of construction	electropolished 316L stainless steel	
Pressure and temperature	10 bar at 149 °C	10 bar at 149 °C

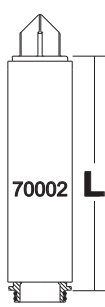
LifeASSURE™ 020SP cartridges - Ordering guide

Cartridge grade	Cartridge length	Gasket/O-ring material	Micron Rating	Formulation
70002 70003 70025	01	A – 60D* (standard) silicone (MVQ)**	020 – 0.2 µm	SP – pharmaceutical
	02	B – fluorocarbon (FPM)**		
	03	C – EPR (EPDM)**		
	04	D – nitrile (NBR)**		
	(See Cartridge Specifications)	J – 70D* (harder) silicone		

* Durometer rating


** ISO Designation

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




Cartridge Length	
Code	mm
01	259
02	506
03	754
04	1002

Single Open End
Code 8 (222) O-Ring
Bayonet Lock



Cartridge Length	
Code	mm
01	260
02	507
03	755
04	1003

Single Open End
(222) O-Ring
with Flat Cap



Cartridge Length	
Code	mm
01	260
02	507
03	755
04	1003

LifeASSURE™ 020SP mini-cartridges - Ordering guide

Cartridge grade	Configuration	Length (inch)	End modification	Packaging option
PSZ020 – 0.2 µm	M – mini-cartridge	01 – 2.5 02 – 5	A – standard	6 – 6 cartridges

LifeASSURE™ 020SP capsules - Ordering guide

Cartridge grade	Configuration	Length (inch)	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

NOTE: LifeASSURE 020SP is new name for CUNO Zetapor SP 020.

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 BE RESPONSIBLE FOR DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM THE USE OF OR RELIANCE UPON INFORMATION.

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