



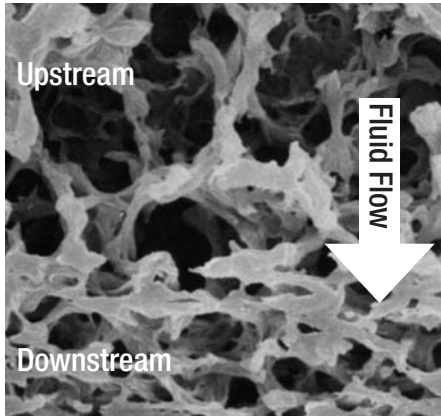
LifeASSURE® PB Capsules & Cartridges

for pharmaceutical &
biological Service

FlexN™ Multi-Zone Membrane Design combined with the
Innovative APT™ (Advanced Pleat Technology) Construction

- Exceptional protection of downstream membranes
- High cartridge flow rates for smaller filter assemblies and lower running costs
- Superior microorganism reduction

LifeASSURE PB Cartridge and Capsule Filters



LifeASSURE PB filter cartridges and capsules are one of 3M CUNO's advances in membrane filter technology. Encompassing two leading-edge processes, FlexN™ membrane manufacture and APT™ (Advanced Pleat Technology) construction, the LifeASSURE PB series of filters offers unmatched protection of final membrane filters, as well as exceptionally long service life. Designed with pleated Nylon N₆₆ membrane in an all-polypropylene cartridge construction, LifeASSURE filters are ideally suited for a wide range of pre-filtration and clarification applications in the pharmaceutical, biological, and bioprocess industries.

Optimal System Performance

Used as a prefilter, LifeASSURE PB filters protect and significantly extend the service life of 3M CUNO's sterilizing grade Zetapor® final filter, as well as other membrane filters.

LifeASSURE PB filters will :

- increase final filter life substantially, often by 10 times or more
- decrease filter change-outs, greatly reducing filter costs, and
- provide superior microorganism reduction

FlexN™ Membrane Technology

LifeASSURE PB filters incorporate 3M CUNO's advanced FlexN™ membrane technology*. It allows unmatched flexibility in creating a multi-zone membrane that offers the maximum in contaminant holding capacity while maintaining high retention efficiency. The SEM photograph at right shows that the single layer LifeASSURE PB membrane consists of an "open" zone on the upstream side of the membrane and a "tighter" zone on the downstream side. In effect, the open zone acts as a pre-filter by capturing larger particles and colloids while the tighter zone provides the retention of smaller contaminants. This multi-zone structure eliminates dual-layer membrane construction to provide a larger surface area, significantly increased contaminant holding capacity, and longer service life. For an in-depth technical presentation of FlexN™ technology, request 3M CUNO.

Features and benefits

Multi-zone, FlexN™ Nylon membrane

- Maximum membrane protection
- Increased contaminant capacity
- Extended service life
- Lower total filtration costs

APT™ (Advanced Pleat Technology) construction for extremely high surface area

- Faster flow rates and smaller filter assemblies
- Lower total filtration costs

100% Integrity tested in manufacturing

- Ensures product quality

Installation integrity testable by the user

- Ensures proper installation and operation

True membrane construction

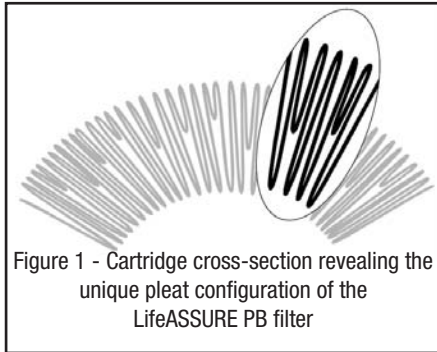
- True membrane construction

Meets USP Class VI Biological Test for Plastics

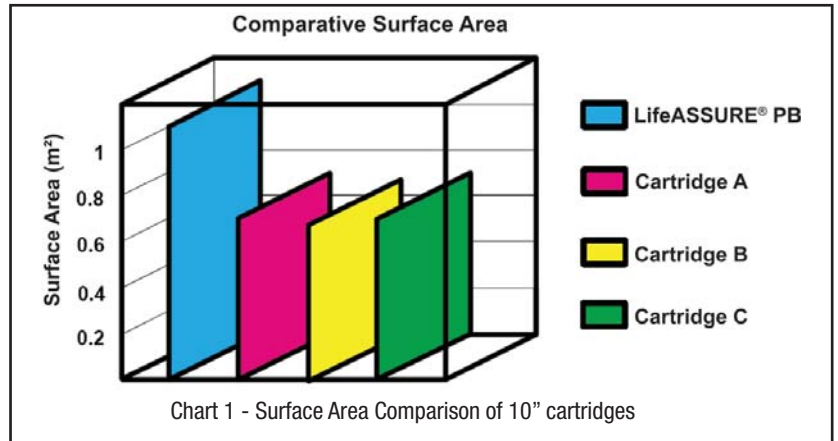
- Safe for product contact

* USA Patents 6,090,441 ; 6,264,044 ; 6,513,666 and 6,280,791.

APT™ (Advanced Pleat Technology) Construction Advantage



LifeASSURE PB cartridge filters also feature 3M CUNO's innovative APT™ construction for extended service life. This design technology maximizes the useful surface area of the filter while maintaining proper flow paths between media pleats. By employing as much as 50% more effective surface area than competitive filters (see chart 1), the LifeASSURE PB filter provides lower pressure drops, longer service life and lower overall filtration costs.



Product	LRV
LifeASSURE PLA020	7.3
Cartridge AS	4.5
LifeASSURE PLA045	3.5
Cartridge AC	2.6
Cartridge C	0.41

Table 1 - Comparative Log Reduction Values

Superior Microorganism Reduction

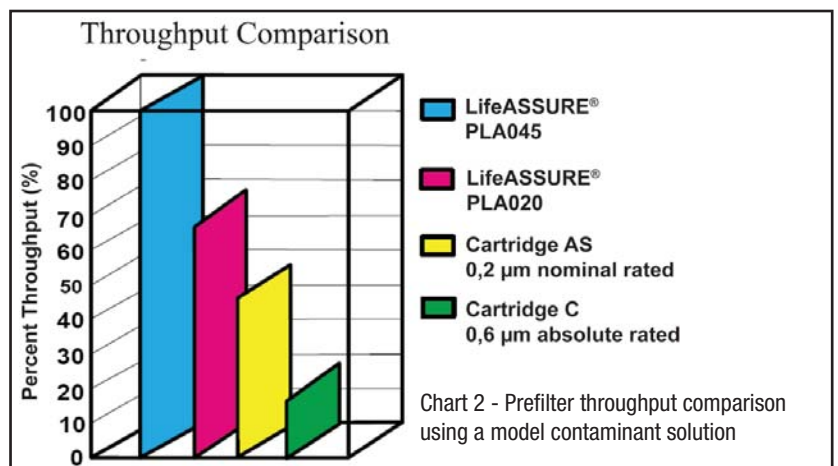
3M CUNO LifeASSURE PB filters consistently exhibit a greater reduction of microorganisms than competitive filters that are constructed of polypropylene fibres, or filters that are constructed with less efficient membranes. For effective pre-filtration of pharmaceutical and biological products, microorganism reduction is a critical parameter resulting in economical, reliable filter systems. LifeASSURE PB filters ensure compliance with your GMP requirements to maintain low system bioburden.

In tests with *Brevundimonas diminuta*, (considered one of the smallest bacteria) LifeASSURE PLA020 grade filters exhibited an average log reduction value* (LRV) of 7.3 and the LifeASSURE PLA045 grade filters exhibited an average LRV of 3.5.

* LRV = \log_{10} (number of organisms in/number of organisms out).

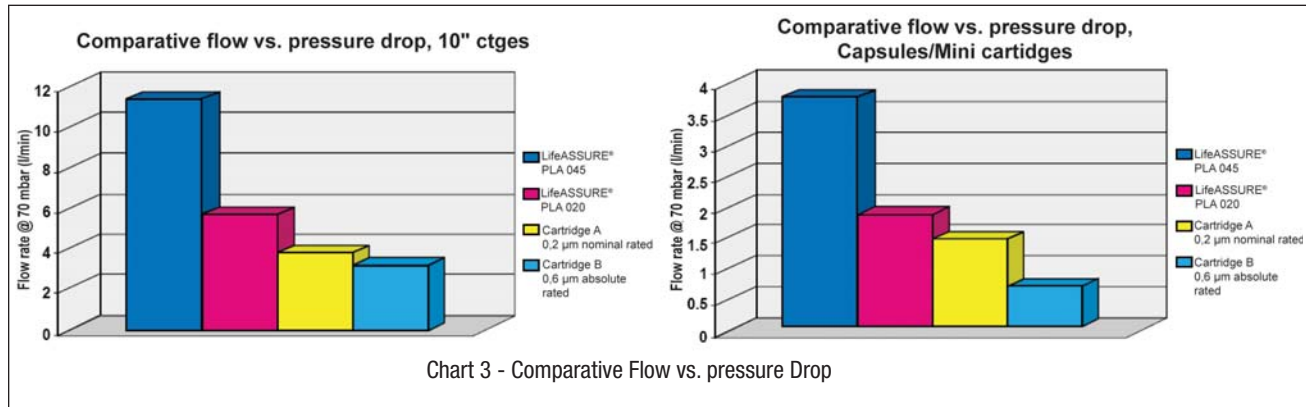
Optimized for Service Life and Effluent Quality

As the data in Chart 2 demonstrates, LifeASSURE PB cartridges are designed to provide both enhanced service life and performance. When compared to competitive products, LifeASSURE PB filters allow the user to select equivalent effluent quality with vastly superior life, or improve the effluent quality with reduced, yet competitively superior, service life. Either way, the result is the same, LifeASSURE PB filters allow significantly more throughput than the competitive filters and provide up to double the service life.



Benefits of Higher Per-Cartridge Flow Rates

The unique LifeASSURE PB filter construction results in a higher per-cartridge flow rate at the same pressure drop when compared to competitive filters. Shown in Chart 3 is the water flow versus pressure drop of commonly used 10-inch cartridges and mini cartridges. Typical flow vs. mbar for LifeASSURE PB filters are shown in Charts 4 and 5.

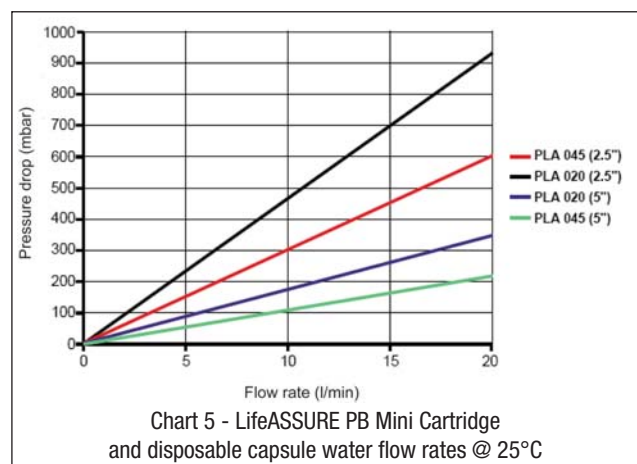
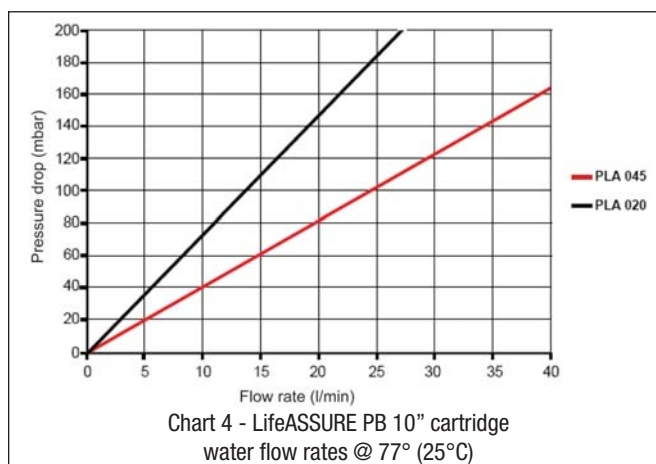


Higher flow at a lower pressure drop reduces filter cost two ways?

Higher flow at a lower pressure drop reduces filter cost two ways – For existing applications at a given flow rate, filter cartridges with more surface area per-cartridge have a lower flux (flow per unit surface area) than those filter cartridges with less surface area. Since service life is inversely proportional to flux (lower flux = longer service life) in most applications, LifeASSURE PB filter cartridges provide longer service life and require fewer cartridge change-outs. **This greatly reduces filter costs, disposal costs, CIP/SIP, labour and downtime.**

Filter Type	Number of Cartridges
CUNO LifeASSURE PLA 045	7
CUNO LifeASSURE PLA 020	14
Cartridge AS 0,2 µm	20
Cartridge C 0,6 µm	25

Use smaller more efficient CUNO filter Systems - For new applications where filter housing size is selected based on a desired "clean" initial pressure drop, filter cartridges that provide a higher flow rate per-cartridge at a given pressure drop will require fewer cartridges, and hence a smaller filter housing, to complete the task. **This results in a substantial reduction in system costs.**

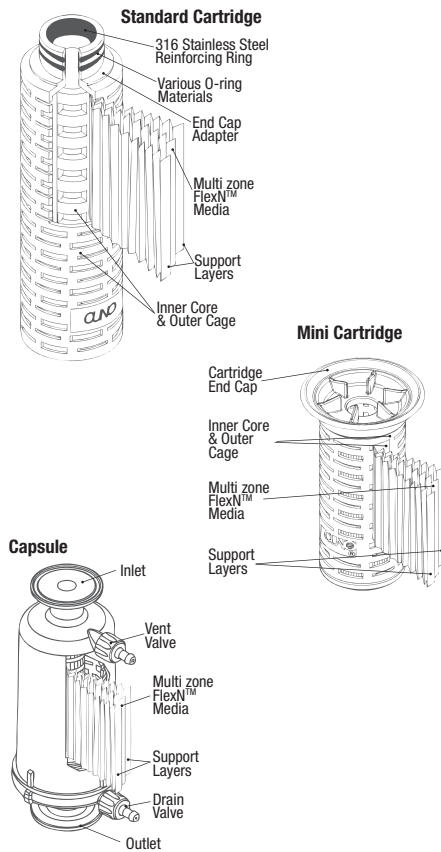


Pre-filter Selection

The table below is provided as a guide to pre-filter selection, although actual process conditions may dictate the use of a more open or closed pre-filter, than specified below. Prefilter selection can be aided by smaller scale pilot t-tests or flow decay studies using membrane discs or LifeASSURE PB Capsules. Consult 3M CUNO's Scientific Applications and Support Services (SASS) or 3M CUNO Technical Sales for more information.

Grade	Upstream Zone	Downstream Zone	Fluid Condition	Pre-filter for:
PLA020	0,65 µm	0,2 µm	Low particulate/colloid content	Zetapor® 020SP, 020ST ; SterASSURE®
PLA045	0,8 µm	0,45 µm	High particulate/colloid content	Zetapor® 020SP, 020ST ; SterASSURE®

LifeASSURE Construction



Cartridge

LifeASSURE PB filter cartridges are constructed of single-layer, patented* Nylon N₆₆ microporous membrane pleated with polypropylene upstream and downstream support materials. The cage, core, end-caps and capsule shell are made of polypropylene. All materials of construction are CFR 21 listed and have passed USP Class VI Biological Tests for Plastics at 121°C. Cartridges are manufactured under an ISO 9001:2000 certified quality system using the most advanced thermoplastic welding techniques to ensure filter integrity. LifeASSURE PB filters are 100% integrity tested after manufacture to ensure quality and are supplied with a Certificate of Quality. A regulatory support file (RSF) is available to assist in regulatory control and documentation.

Mini Cartridges

3M CUNO's 2.5" and 5" mini cartridges can be installed in existing competitor housings or 3M CUNO's Mini Cartridge housing. The significant LifeASSURE PB flow advantage (Chart 3) results in greater batch capacity than competitive filters, greatly reducing filter costs.

Disposable Filter Capsules

For critical small-volume applications where convenience and ease of use are desired, LifeASSURE PB filters are available in 5" and 2.5" disposable capsules. LifeASSURE PB capsules are supplied with sanitary vent and drain ports, as well as a choice of 1.5" sanitary flange connections or 1/2" (13 mm) hose barb inlet/outlet connections.

LifeASSURE PB Specifications					
Material of Construction	Cartridges	Mini Cartridges		Capsules	
		2.5" Length	5" Length	2.5" Length	5" Length
Cage, Core, End-Caps, Capsule Shell, and Media Support Layers	Polypropylene				
Membrane	FlexN™ Nylon N ₆₆				
Adapter Support Ring (full length cartridges only)	316 Stainless Steel	NA	NA	NA	NA
Dimensions					
Filtration Surface Area	1 m ² per 10" Element	0,13 m ²	0,3 m ²	0,13 m ²	0,3 m ²
Outside Diameter	70 mm nominal	5,7 cm	5,7 cm	7,9 cm	7,9 cm
Length	Nominal 10", 20", 30" and 40" (nominal 250 mm, 500 mm, 750 mm, and 1000 mm)	7,9 cm	14 cm	1 1/2" Sanitary Inlet/Outlet	
				13 cm	19,4 cm
				1/2" Hose Barb Inlet/Outlet	
				14 cm	20,3 cm
Operating Parameters					
Maximum Operating Temperature	80°C			40°C	
Maximum Differential Pressure	Forward: 5,5 bar @ 25°C 1,7 bar @ 80°C			5,2 bar @ 40°C	
	Reverse: 3,4 bar @ 25°C				
Steam Sterilization	30 minutes @ 126°C			Do Not in situ steam	
Autoclave Sterilization				30 minutes @ 126°C	
Installation Integrity Test Methods	Consult 3M CUNO for appropriate values for the specific filter and housing in use				



Applications

LifeASSURE cartridges are designed for a broad range of aqueous based pharmaceutical, biological and bioprocess prefiltration and fine particle removal applications, including:

- 0.2 μm final sterilizing filter protection
- Fermenter Feed Streams
- Parenterals (SVP, LVP)
- Solvent Filtration
- Reagents & Buffers
- Orals & Topicals
- Particulate & Bioburden Reduction
- Serum & Blood Fraction
- Ophthalmics
- Vaccines
- Cell Culture Fluids
- High-Purity DI Water and WFI Systems

Safety and Regulatory Compliance

Installation Integrity Test

Unlike other filters, LifeASSURE PB filter cartridges are 100% tested for integrity in manufacturing prior to shipment. Additionally, LifeASSURE PB filter cartridges are installation integrity testable in situ by the user. The installation integrity test is a non-destructive measurement of filter's ability to function as intended. Conducting an installation integrity test assures the user that the filter is installed and sealed correctly in the filter housing and is ready for service. This is of particular value where LifeASSURE PB filters are employed in intermediate process steps not requiring a sterilizing grade final membrane filter.

For installation integrity test procedures and values, please consult 3M CUNO.

Automated Integrity Test - MicroCheck 2

The installation integrity test can also be performed with the MicroCheck[®] 2 automated integrity test device. The MicroCheck[®] 2 integrity tester provides fast, reliable and accurate automated installation integrity testing of LifeASSURE PB cartridges, capsules and mini cartridges.



CUNO Final Filters

Zetapor[®] Filters – Employed as the final filter in critical applications, Zetapor[®] series filter cartridges and capsules are constructed with proprietary charge-modified nylon membrane and polypropylene components.

Zetapor[®] 020SP sterilizing grade filters are qualified for complete retention ($>10^7$ CFU's/cm²) of *B. diminuta* following ASTM methodology Zetapor[®] 020 SP filters are supported with a 3M CUNO Validation Guide.





Validation Support Services

3M CUNO offers specialized support to the pharmaceutical and biotechnology industry through our Scientific Application Support Service (SASS) Group. SASS routinely provides end-users with:

- Validation And Regulatory Support
- Extractable And Compatibility Analysis
- Filter System Optimization Studies
- Microcheck® 2 integrity Tester Validation

For more information regarding 3M CUNO's Validation Support Services, please contact 3M CUNO Technical Services.

CUNO™ 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 PB filter cartridges are sealed securely, thus eliminating the possibility of fluid bypass. All housings are constructed using 316L stainless steel to maximize corrosion resistance. Internal surfaces of the ZWB & ZWC filter housings are polished at least 0.8µm R_a to limit microbial adhesion and provide easy cleaning.

Housing Model	ZWC	ZWB	ZL	Mini-Housing	
Cartridge Capacity	For 10, 20, 30, and 40" cartridges			For 2.5" Mini Cartridges	For 5" Mini Cartridges
Part number	1	1	-	2787002/1	2787001/1
	3	3	-		
	4	4	5		
	8	8	-		
	11	11	12		
	21	21	22		
Housing Style	T-line Sanitary type connection			Sanitary type in-line	
Equivalent Cartridge Lengths	10", 20", 30", 40"			2.5" (63 mm)	5" (125 mm)
Materials of Construction	Electropolished 316L Stainless Steel				
Pressure & Temperature	5 bar @ 90°C	10 bar @ 90°C	10 bar @ 90°C (5ZL) 5 bar @ 90°C (12 or 22 ZL)	10 bar @ 149°C	10 bar @ 149°C



3M CUNO's offering of sanitary style filter housings accommodate from 1 to 21 LifeASSURE filter cartridges in 10" through 40" lengths



3M CUNO's Mini Cartridge filter housings provide the user with low product hold-up volume for critical small scale applications.

LifeASSURE PB Cartridge Ordering Guide

Cartridge Grade	Configuration	Length (mm)	End-Modification	Gasket/O-ring Material
PLA020 – 0.2 µm PLA045 – 0.45 µm	B – APT™ Configuration	01 –250 02 – 500 03 – 750 04 – 1000	B – 226 O-ring & Spear (Code 7) C – 222 O-ring & Spear (Code 8) D – Double open end (10" Length) E – Double open end (9 ¾" Length) F – 222 O-ring & Flat Cap (Code 3) J – 226 O-ring & Flat Cap	A – Silicone (MVQ)** B – Fluorocarbon (FPM)** C – EPR (EPDM)** D – Nitrile (NBR)** H – Clear Silicone*

* O-Ring only

** ISO Designation

LifeASSURE PB Mini Cartridge Ordering Guide

Cartridge Grade	Configuration	Length (mm)	End-Modification	Packaging Option
PLA020 – 0.2 µm PLA045 – 0.45 µm	M – Mini Cartridge	01 – 64 02 – 127	A – Standard	6 – 6 cartridges

LifeASSURE PB Capsule Ordering Guide

Cartridge Grade	Configuration	Length (mm)	End-Modification	Packaging Option
PLA020 – 0.2 µm PLA045 – 0.45 µm	C – Capsule	01 – 64 02 – 127	A – Sanitary Flange B – Hose Barb	1 – 1 Capsule 3 – 3 Capsules

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 unauthorised 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 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.

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