

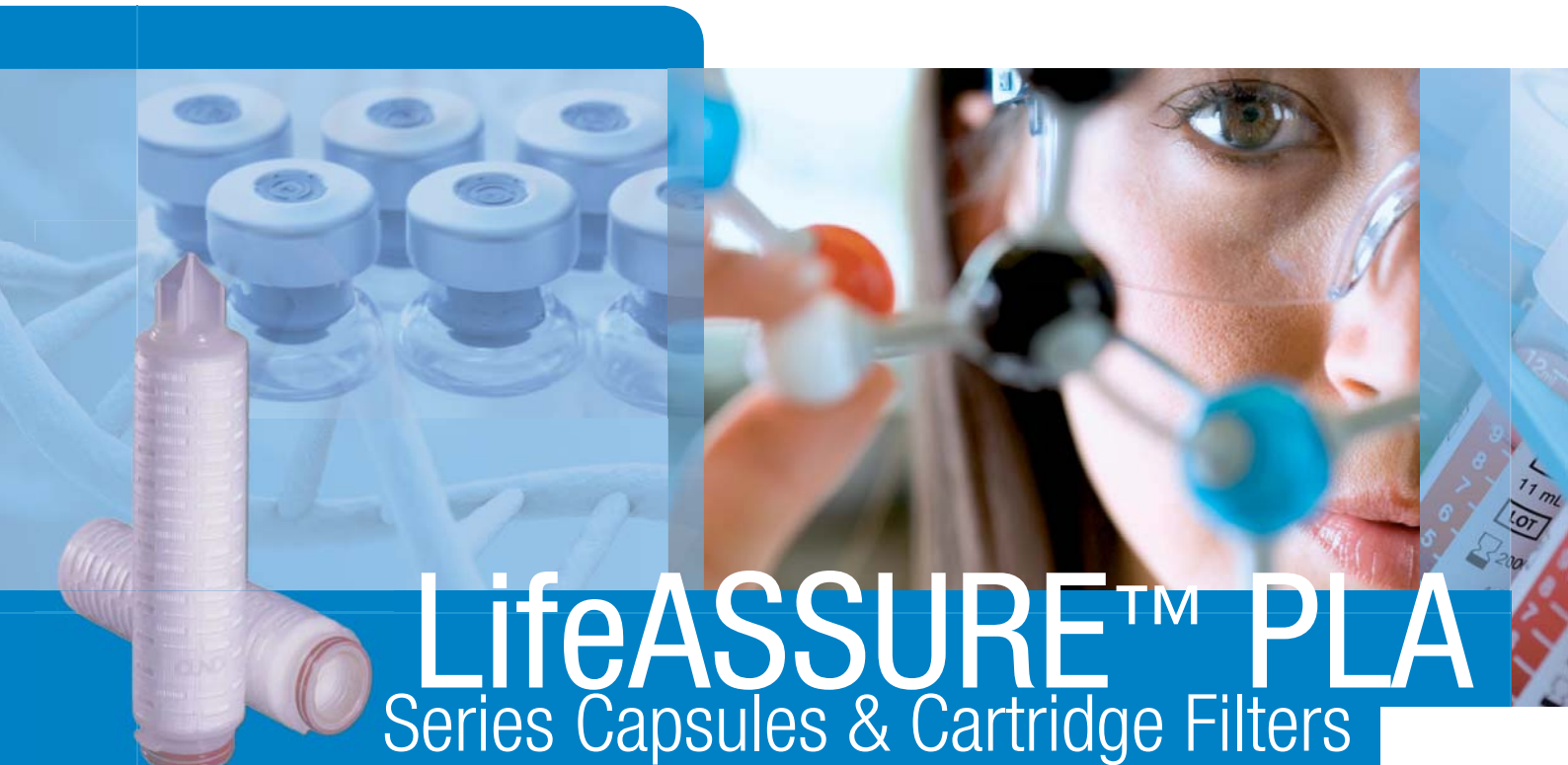
3M Purification

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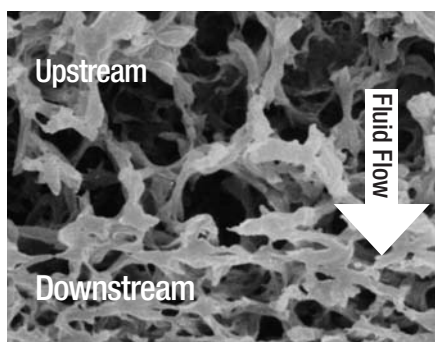
LifeASSURE™ PLA

Series Capsules & Cartridge Filters

Log reduction grade Nylon 6,6 membrane filter
for pharmaceutical and biological Service

- ☑ New name for CUNO LifeASSURE PB capsules and cartridges
- ☑ Multi-zone microporous membrane design and APT (Advanced Pleat Technology) construction
- ☑ High cartridge flow rates for smaller filter assemblies and lower running costs
- ☑ Superior microorganism reduction and exceptional protection of downstream membranes

3M



LifeASSURE PLA cartridge and capsule filters

LifeASSURE™ PLA filter cartridges and capsules, formerly known as CUNO LifeASSURE PB, are one of 3M Purification's advances in membrane filter technology. Encompassing two leading-edge processes, multi-zone microporous membrane manufacture and APT (Advanced Pleat Technology) construction, the LifeASSURE PLA series of filters offers unmatched protection of final membrane filters, as well as exceptionally long service life. Designed with pleated Nylon 6,6 membrane in an all- polypropylene cartridge construction, LifeASSURE PLA 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 PLA filters protect and significantly extend the service life of 3M Purification's sterilising-grade LifeASSURE 020SP and LifeASSURE PSA final filter, as well as other membrane filters.

LifeASSURE PLA Filters will:

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

Multi-zone microporous membrane technology

LifeASSURE PLA filters incorporate 3M Purification's multi-zone microporous 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 on the left shows that the single layer LifeASSURE PLA 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 prefilter 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 multi-zone microporous technology, request 3M Purification.

Features and Benefits

Multi-zone microporous 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

- Higher Integrity

Meets USP Class VI Biological Test for Plastics and 21CFR materials of construction

- Safe for product contact

APT (Advanced Pleat Technology) construction advantage

LifeASSURE™ PLA cartridge filters also feature 3M Purification's APT construction for extended service life. This design technology helps maximise 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 PLA filter provides lower pressure drops, longer service life and lower overall filtration costs.

Superior microorganism reduction

3M Purification's LifeASSURE PLA 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 prefiltration of pharmaceutical and biological products, microorganism reduction is a critical parameter resulting in economical, reliable filter systems. LifeASSURE PLA 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.

Optimised for service life and effluent quality

As the data in chart 2 demonstrates, LifeASSURE PLA cartridges are designed to provide both enhanced service life and performance. When compared to competitive products, LifeASSURE PLA 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 PLA filters allow significantly more throughput than the competitive filters and provide up to double the service life.

Figure 1: Cartridge cross-section revealing the pleat configuration of the LifeASSURE™ PLA filter

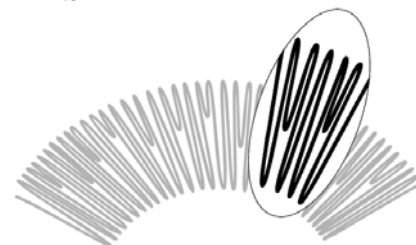


Table 1: Comparative log reduction values

Product	LRV
LifeASSURE™ PLA020	7.3
Cartridge A	4.5
LifeASSURE™ PLA045	3.5
Cartridge B	2.6
Cartridge C	0.41

Chart 1: Surface area comparison of 10" cartridges

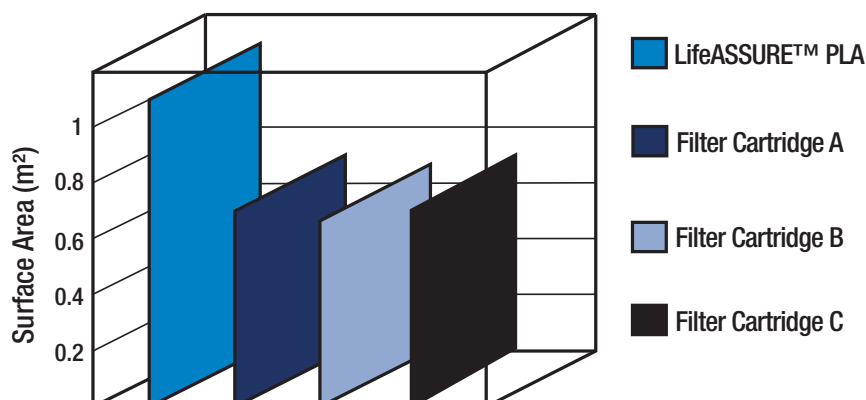
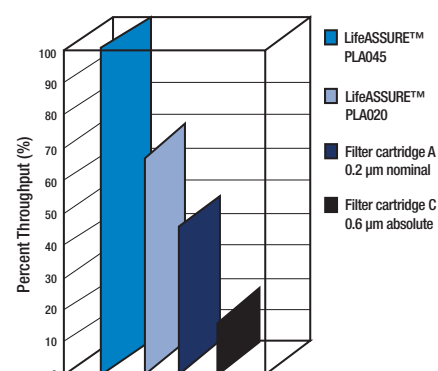


Chart 2: Prefilter throughput comparison using a model contaminant solution



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

Chart 4: LifeASSURE™ PLA 10" cartridge water flow rates at 25 °C

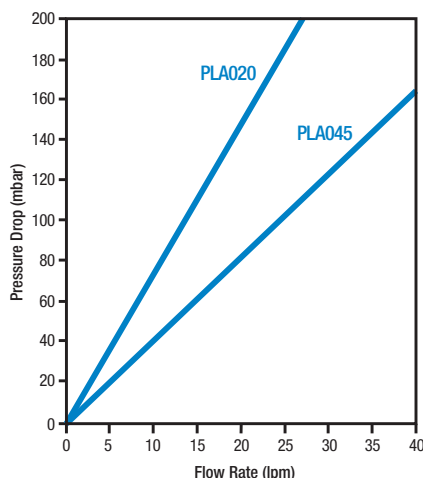
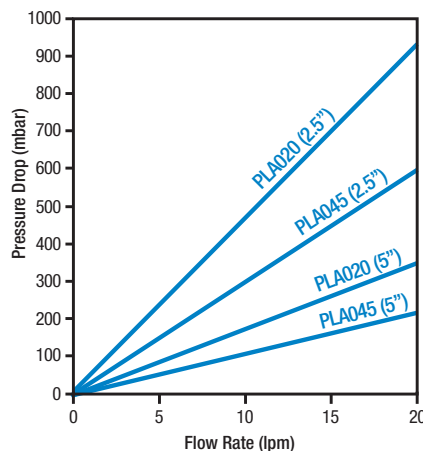


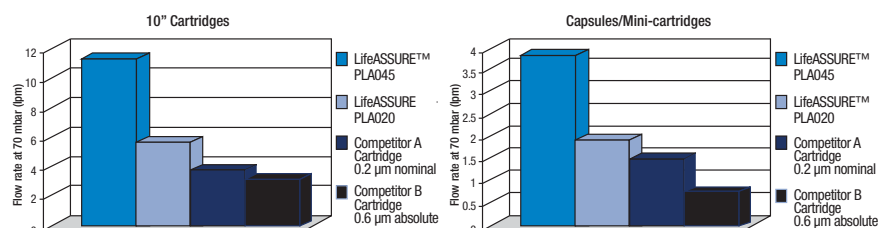
Chart 5: LifeASSURE™ PLA mini-cartridge and disposable capsule water flow rates at 25 °C



Benefits of higher per-cartridge flow rates

The LifeASSURE™ PLA 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" cartridges and mini-cartridges. Typical flow vs. mbar for LifeASSURE PLA filters are shown in charts 4 and 5.

Chart 3: Comparative flow vs. pressure drop



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 PLA filter cartridges provide longer service life and require fewer cartridge change-outs. This greatly reduces filter costs, disposal costs, CIP/SIP, labour and downtime.

Use smaller more efficient 3M Purification 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.

Table 2: Number of 10" filter cartridge required for a 76 l/min water flow at 70 mbar.	
LifeASSURE™ PLA045	7
LifeASSURE™ PLA020	14
Competitor A cartridge 0,2 µm	20
Competitor C cartridge 0,6 µm	25

Prefilter selection

The table below is provided as a guide to prefilter selection, although actual process conditions may dictate the use of a more open or closed prefilter, than specified below. Prefilter selection can be aided by smaller scale pilot tests or flow decay studies using membrane discs or LifeASSURE PLA Capsules. Consult 3M Purification’s Scientific Applications and Support Services (SASS) or 3M Purification Technical Sales for more information.

Grade	PLA020	PLA045
Upstream Zone	0.65 µm	0.8 µm
Downstream Zone	0.2 µm	0.45 µm
Fluid Condition	Low particulate/colloid content	High particulate/colloid content
Prefilter for:	LifeASSURE™ 020SP, 020ST LifeASSURE™ PSA	LifeASSURE™ 020SP, 020ST LifeASSURE™ PSA

LifeASSURE PLA cartridge construction

LifeASSURE™ PLA filter cartridges are constructed of a single-layer, Nylon 6,6 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 Safety Test for Plastics at 121 °C. Cartridges are manufactured under an ISO certified quality system using the most advanced thermoplastic welding techniques to ensure filter integrity. LifeASSURE PLA 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.

LifeASSURE PLA mini-cartridge construction

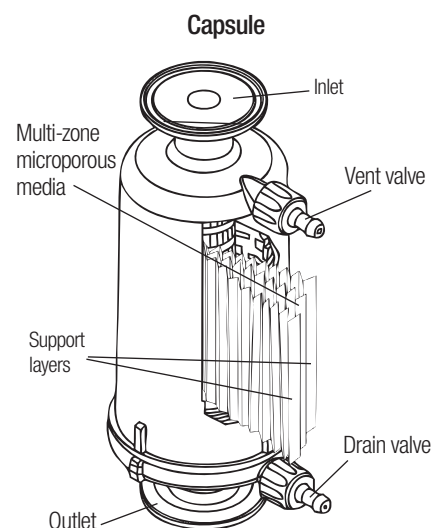
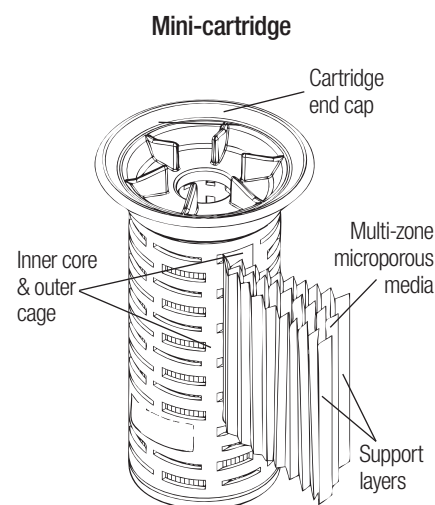
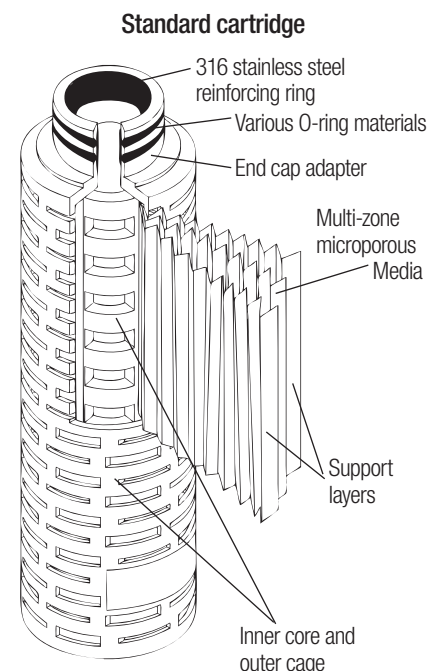
3M Purification's 2.5" and 5" mini-cartridges can be installed in existing competitor housings or 3M Purification's mini-cartridge housing. The significant LifeASSURE PLA flow advantage (chart 3) results in greater batch capacity than competitive filters, greatly reducing filter costs.

LifeASSURE PLA disposable filter capsule construction

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

LifeASSURE PLA specifications

	Cartridges	Mini-cartridges		Capsules	
		2.5" length	5" length	2.5" length	5" length
Material of construction					
Cage, core, end caps, capsule shell and media support layers	polypropylene				
Membrane	multi-zone microporous Nylon 6,6				
Adapter support ring (full length cartridges only)	316 stainless steel	N/A	N/A	N/A	N/A
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 ½" sanitary inlet/outlet	
				13 cm	19.4 cm
				½" 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 at 25 °C			5.2 bar at 40 °C	
	1.7 bar at 80 °C				
	Reverse: 3.4 bar at 25 °C				
Steam sterilisation	30 minutes at 126 °C			Do Not <i>in situ</i> steam	
Autoclave sterilisation				30 minutes at 126 °C	
Installation integrity test methods	Consult 3M Purification for appropriate values for the specific filter and housing in use				





Applications

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

- protection of 0.2 µm final sterilising membrane filter
- Fermenter feed streams
- Parenterals (SVP, LVP)
- Solvent filtration
- Reagents and buffers
- Orals and topicals
- Particulate and bioburden reduction
- Vaccines
- Cell culture fluids
- High-Purity DI water and WFI systems

Safety and regulatory compliance

Installation integrity test

LifeASSURE PLA filter cartridges are 100% tested for integrity in manufacturing prior to shipment. Additionally, LifeASSURE PLA 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 PLA filters are employed in intermediate process steps not requiring a sterilising grade final membrane filter.

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

Final Filters

LifeASSURE™ 020SP and LifeASSURE™ PSA Filters – employed as the final filter in critical applications, LifeASSURE 020SP and LifeASSURE PSA series filter cartridges and capsules are constructed with a charge-modified nylon membrane and polypropylene components.

LifeASSURE 020SP and LifeASSURE PSA sterilising-grade filters are qualified for complete retention ($>10^7$ CFU's/cm²) of *B. diminuta* following ASTM methodology. LifeASSURE 020SP and LifeASSURE PSA filters are supported with a 3M Purification Validation Guide.

Validation support services

3M Purification offers specialised 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 optimisation studies

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

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 PLA filter cartridges are sealed securely, thus eliminating the possibility of fluid bypass. All housings are constructed using 316L stainless steel to help maximise corrosion resistance. Internal surfaces of the filter housings are polished at least 0.8 µm Ra to limit microbial adhesion and provide easy cleaning. Alternative materials such as Hastelloy® (C-22®) and low ferrite are also available to order.

For further information on our housing capabilities, please contact your local 3M Purification representative.

Housing IW Specifications	01 IWN / 03 IWN / 05 IWN / 08 IWN	12 IWN	18 IWN / 24 IWN
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 IWN) Category II (24 IWN)
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.

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



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



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

LifeASSURE™ PLA cartridges - Ordering guide

Cartridge grade	Configuration	Length (inch)	End modification	Gasket/O-ring material
PLA020 – 0.2 µm PLA045 – 0.45 µm	B – APT configuration	01 – 10" 02 – 20" 03 – 30" 04 – 40"	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 – EPDM (EPDM)** D – nitrile (NBR)** H – clear silicone*

* O-Ring only
** ISO Designation

LifeASSURE™ PLA mini-cartridges - Ordering guide

Cartridge grade	Configuration	Length (inch)	End modification	Packaging option
PLA020 – 0.2 µm PLA045 – 0.45 µm	M – mini-cartridge	01 – 2.5" 02 – 5"	A – standard	6 – 6 cartridges

LifeASSURE™ PLA capsules - Ordering guide

Cartridge grade	Configuration	Length (inch)	End modification	Packaging option
PLA020 – 0.2 µm PLA045 – 0.45 µm	C – capsule	01 – 2.5" 02 – 5"	A – sanitary flange B – hose barb	1 – 1 capsule

NOTE: LifeASSURE PLA is new name for CUNO LifeASSURE PB.

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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PLA020 B 01 B	PLA020 M 01 A	PLA020 C 01 A
PLA020 B 01 C	PLA020 M 02 A	PLA045 C 01 B
PLA020 B 01 D		PLA020 C 02 A
PLA020 B 01 E		PLA045 C 02 B
PLA020 B 01 F		
PLA020 B 01 J		
PLA020 B 02 B		
PLA020 B 02 C		
PLA020 B 02 D		
PLA020 B 02 E		
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PLA020 B 03 C		
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