

LifeASSURE™ PLA series

Filters for Pharmaceutical and Biological Service

LifeASSURE™ PLA Series Filters

LifeASSURE™ PLA series filters are 3M Purification Inc.'s latest advance in membrane filter technology. Encompassing two leading-edge processes, multi-zone microporous membrane manufacture and Advanced Pleat Technology (APT) pleating construction, the LifeASSURE PLA series 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 construction, LifeASSURE PLA series 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 series filters help protect and significantly extend the service life of 3M Purification Inc.'s sterilizing grade LifeASSURE™ PSA series final filter, as well as other membrane filters. LifeASSURE PLA series 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 series filters incorporate 3M Purification Inc.'s advanced 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 page two shows that the single layer LifeASSURE PLA series filter 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 than competitive filters. For an in-depth technical presentation of multi-zone microporous membrane technology, request 3M Purification Inc. Technical Publication 70-0201-8812-7, or visit www.3Mpurification.com.

Features & Benefits

Multi-zone microporous nylon membrane

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

Advanced Pleat Technology for extremely high surface area

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

100% Integrity tested in manufacturing

- Ensures product quality

Installation integrity testable by the user

- Ensures proper installation and operation

True membrane construction

- Superior removal of microorganisms

Meets the requirements of USP Class VI Biological Test for Plastics

- Complies with requirements of The Pure Food, Drug, and Cosmetic Act for contact with food.

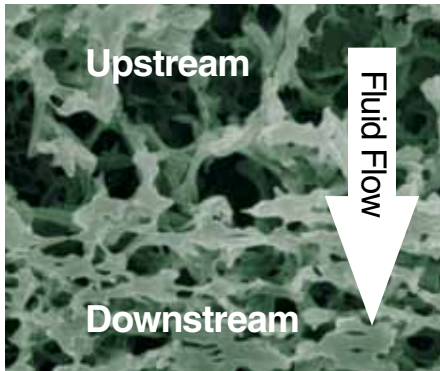


Applications

LifeASSURE PLA series filters are designed for a broad range of aqueous based pharmaceutical, biological and bioprocess pre-filtration and fine particle removal applications, including:

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





The Advanced Pleat Technology (APT) Advantage

LifeASSURE™ PLA series filters also feature 3M Purification Inc.'s 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 PLA series filters provides lower pressure drops, longer service life and lower overall filtration costs.

Superior Microorganism Removal

LifeASSURE PLA series filters consistently exhibit a greater reduction of microorganisms than competitive filters that are constructed of polypropylene fibers, or filters that are constructed with less efficient membranes.

Products	LRV
LifeASSURE™ PLA020	7.3
Millipore Milligard® CWSS	4.5
LifeASSURE™ PLA045	3.5
Millipore Milligard® CWSC	2.6
Pall HDC® J006	0.41

Table 1 - Comparative Log Reduction Values

Comparative Surface Area

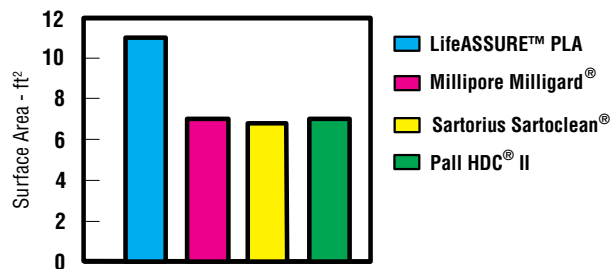


Chart 1 - Surface Area Comparison

For effective prefiltration of pharmaceutical and biological products, microorganism reduction is a critical parameter resulting in economical, reliable filter systems. LifeASSURE PLA020 grade 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 series 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.

LifeASSURE PLA Series Prefilter and LifeASSURE™ PSA Series Final Filter System Filtration Advantage

Chart 2 shows the significant throughput advantage of the LifeASSURE PLA series prefilter/ LifeASSURE™ PSA series final filter combination compared to competitive prefilter/ final filter selections. The throughput advantage is the result of multi-zone microporous membrane construction. LifeASSURE PLA080 series (0.8 micron) filters contain an upstream zone of 2.5 micron and a downstream zone of 0.8 micron.

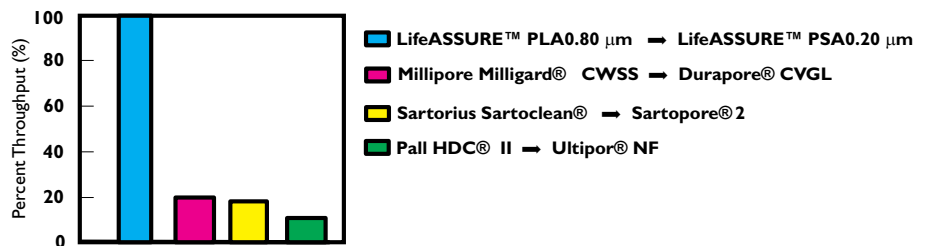


Chart 2 - Prefilter - Final Filter Throughput Comparison Using A Model Contaminant Solution Out Performed Competitive Filter Systems By Up To 5 Times.

* Competitive filter surface area data are from the manufacturers' published literature.

** LRV = log₁₀ (number of organisms in/number of organisms out).

LifeASSURE™ PSA020 Series (0.20 micron) contain an upstream zone of 0.65 micron and a downstream zone of 0.20 micron. The result of this combination is superior system throughput. Finer grades of LifeASSURE™ PLA series prefilters may be required to protect competitive 0.20 micron rated final filters. For best results, please consult 3M Purifications Inc. Sales Specialists.

For optimum throughput, use LifeASSURE PLA series 0.80 µm rated filters upstream of LifeASSURE PSA series 0.20 µm rated filters, and LifeASSURE PLA series 0.45 µm rated filters upstream of LifeASSURE PSA series 0.1 µm rated filters.

We encourage you to experience the 3M Purification Inc. performance advantage by arranging an on-site filter test. For more information about testing and LifeASSURE PSA series filters, document 70-0201-8893-7, contact your 3M Purification Inc. Sales Specialist or local Distributor.

Higher Flow At A Lower Pressure Drop Reduces Filter Cost Two Ways:

Change-Out Filters Less Frequently - For existing applications at a given flow rate, filters with more surface area per filter have a lower flux (flow per unit surface area) than those filters with less surface area. Since service life is inversely proportional to flux (lower flux = longer service life) in most applications, LifeASSURE PLA series filters provide longer service life and require fewer filter change-outs. This greatly reduces filter costs, disposal costs, CIP/SIP, labor and downtime.

Use Smaller, More Efficient 3M Purification Inc. Series Filter Systems - For new applications where filter housing size is selected based on a desired “clean” initial pressure drop, filters that provide a higher flow rate per filter at a given pressure drop will require fewer filters. A smaller filter housing will be required to complete the task, resulting in a substantial reduction in system costs.

Benefits of Higher Per-Cartridge Flow Rates

The relative water flow rate performance of LifeASSURE PLA series prefilter and LifeASSURE PSA series final filter was compared to conventional prefilter and final filter combinations commonly used by pharmaceutical manufacturers. The combined pressure drop of 10” LifeASSURE PLA/PSA series filter systems for a 3 gallon per minute (11.4 lpm) water flow rate is compared to competitive 10” filter systems in Table 2. The results of water flow versus differential pressure testing show a combined system flow rate/pressure drop of less than 1/2 that of competitive filter systems.

Prefilter	Final Filter	Pressure Drop (psid)
3M Purification Inc. LifeASSURE™ PLA080 Series	3M Purification Inc. LifeASSURE™ PSA020 Series	3.25
3M Purification Inc. LifeASSURE™ PLA045 Series	3M Purification Inc. LifeASSURE™ PSA020 Series	3.5
Millipore Milligard®* CWSS	Millipore Durapore® CVGL	7.25
Pall HDC® J006	Pall Ultipor® NF	7.4

Table 2.- Combined Prefilter/Final Filter Pressure Drop Comparison

The table located on the next page provides a guide to LifeASSURE PLA series prefilter selection, although actual process conditions may dictate the use of a more open or tighter

* Millipore Milligard mini cartridges are 4” long, all others are 5”.
** For capsules with Hose Barb Fittings, add .36psi @ 2gpm

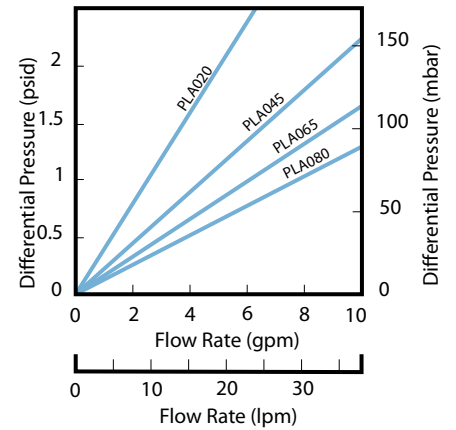


Chart 3 - Typical water flow rates @ 77°F (25°C) for 10 inch Cartridges and J Style Capsules

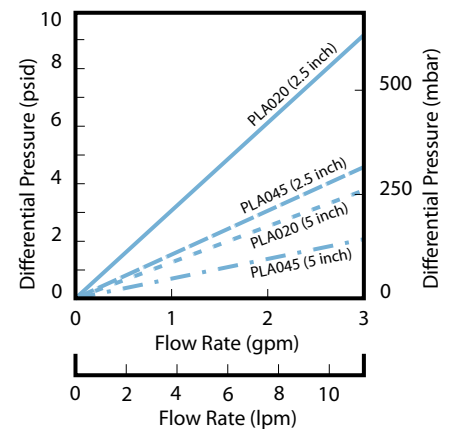


Chart 4 - Typical water flow rates @ 77°F (25°C) for Mini Cartridges and Sanitary Style Capsules with .20 & .45 µm media**

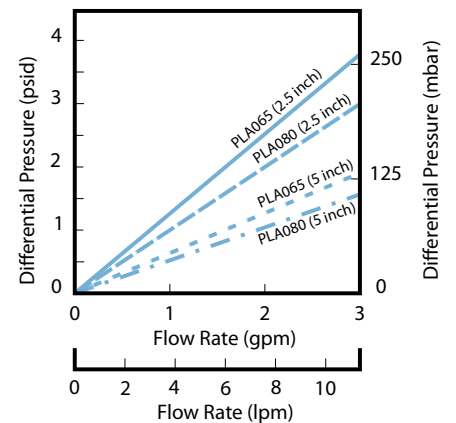


Chart 5 - Typical water flow rates @ 77°F (25°C) for Mini Cartridges and Sanitary Style Capsules with 0.65 & 0.80 µm media**

pre-filter, than specified below. Pre-filter selection can be aided by smaller scale pilot tests or flow decay studies using membrane discs or LifeASSURE™ PLA series Capsules. Consult 3M Purification Inc. Scientific Applications Support Services (SASS) or your 3M Purification Sales Specialist for more information.

Grade	Upstream Zone	Downstream Zone	Pre-filter for:
PLA020	0.65 micron	0.20 micron	LifeASSURE™ SA020SP Series, LifeASSURE™ PSA010 Series
PLA045	0.8 micron	0.45 micron	LifeASSURE™ SA020SP Series, LifeASSURE™ PSA010, PSA020 Series
PLA065	1.2 micron	0.65 micron	LifeASSURE™ PSA010 Series
PLA080	2.5 micron	0.80 micron	LifeASSURE™ PSA010 Series

LifeASSURE™ PLA series Cartridge Construction

LifeASSURE PLA series filters are constructed of single-layer, Nylon 6,6 microporous membrane pleated with polypropylene upstream and downstream support materials. The outer cage, inner core, end-cap adapters 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. Filters are manufactured under an ISO 9001:2008 certified quality system using the most advanced thermoplastic welding techniques to ensure filter integrity. LifeASSURE PLA series 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 (request 70-0201-8821-8).

LifeASSURE™ PLA Specifications								
Material of Construction	Cartridges	Mini Cartridges		Capsules				
		2.5" Length	5" Length	2.5" Length	5" Length	10" Length	20" Length	30" Length
Outer Cage, Inner Core, End-Cap Adapters, Capsule Shell, and Media Support Layers	Polypropylene							
Membrane	multi-zone microporous membrane Nylon 6,6							
Adapter Support Ring (full length cartridges only)	316 Stainless Steel	NA						
Dimension								
Filtration Surface Area (ft ² / m ²)	11 / 1 per 10" Element	2.5" Length	5" Length	2.5" Length	5" Length	10" Length	20" Length	30" Length
Outside Diameter (inch / cm)	2¾ / 7 nominal	2 ¼ / 5.7	2 ¼ / 5.7	3 1/8 / 7.9				
Length (Nominal inches / Nominal cm)	5, 10, 20, 30, and 40 / 13, 25, 50, 75, and 100	3 1/8 / 7.9	5 ½ / 14.0	1.5" Sanitary Inlet/Outlet				
				5 1/8 / 13.0	7 5/8 / 19.4	12 3/16 / 30.9	22 1/16 / 56	32 / 81.3
				½" Hose Barb Inlet/Outlet				
				5 ½ / 14.0	8 / 20.3	NA	NA	NA
Operating Parameters								
Maximum Operation Temperature	176°F (80°C)			104°F (40°C)				
Maximum Differential Pressure	Forward: 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: 50 psid (3.4bar) @ 77°F (25 °C)							
Steam Sterilization	30 minutes @ 259 °F (126 °C)			Do Not in situ steam				
Autoclave Sterilization				30 minutes @ 259 °F (126 °C)				
Installation Integrity Test Methods	Consult 3M Purification Inc. for appropriate values for the specific filter and housing in use.							

Mini-Cartridges

3M Purification Inc.'s 2.5" and 5" mini cartridges can be installed in Pall Sealkleen® housings or the 3M Purification Inc. Mini Cartridge housing, document 70-0201-8886-1. The significant LifeASSURE PLA series filters' flow advantage (Charts 4 & 5) 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 PLA series filters are available in 2.5, 5, 10, 20, and 30" disposable capsules. LifeASSURE PLA series capsules are supplied with sanitary vent and drain ports, as well as a choice of 1.5" sanitary flange connections or ½" (13mm) hose barb inlet/outlet connections (2.5 and 5" only).

Safety and Regulatory Compliance

Installation Integrity Test

Unlike other prefilters, LifeASSURE PLA series filters are 100% tested for integrity in manufacturing prior to shipment. Additionally, LifeASSURE PLA series filter cartridges are installation integrity testable *in situ* by the user. The installation integrity test is a non-destructive measurement of a 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 series filters are employed in intermediate process steps not requiring a sterilizing grade final membrane filter.

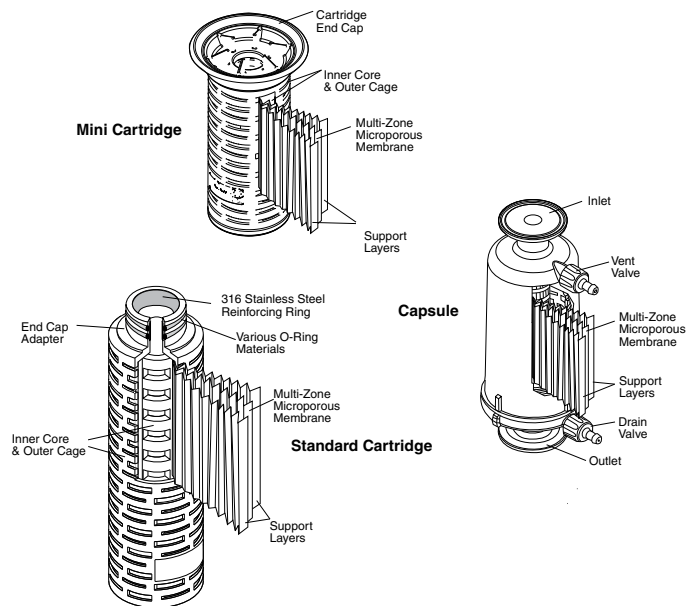
For installation integrity test procedures and values, please consult 3M Purification Inc. document 70-0202-2027-6.

Automated Integrity Test - CUNOCheck™ 2

The installation integrity test can also be performed with the CUNOCheck™ 2 automated integrity test device. The CUNOCheck 2 integrity tester provides fast, reliable and accurate automated installation integrity testing of LifeASSURE PLA series filters, capsules and mini cartridges. For more information, see 3M Purification Inc. document 70-0201-8692-3.

3M Purification Inc. Final Filters

LifeASSURE PSA series Filters - Employed as the final filter in critical applications, LifeASSURE PSA series filter and capsules are constructed with multi-zone microporous membrane nylon 6,6 membrane and polypropylene components (see 3M Purification Inc. document 70-0201-8893-7). LifeASSURE PSA series sterilizing grade filters are qualified for complete retention (>107 CFU/cm²) of *B. diminuta* following ASTM methodology. LifeASSURE PSA series filters are supported with a 3M Purification Validation Guide, document 70-0201-8848-1.





Validation Support Services

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

- Validation and Regulatory Support
- Extractable and Compatibility Analysis
- Filter System Optimization Studies
- CUNOCheck™ 2 Integrity Tester Validation.

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

3M Purification Filter Housings

A specialized range of filter housings are available to meet the needs of the pharmaceutical, biological, and bioprocess industries. They provide easy access for filter change-out and the greatest assurance that LifeASSURE™ PLA series filters 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 housings are polished to limit microbial adhesion and provide easy cleaning.

Housing Models	ZMS Mini	ZMS	ZWC	ZWB	ZVS	Mini-Housing		
Basic Filter Part Number / Cartridge Capacity	For 5" Filter Cartridge	For 10, 20, 30, and 40" cartridges				For 2.5" Mini Cartridges	For 5" Mini Cartridges	
	70236-02 / 1	70220 / 1	70180 / 4	70269 / 4	70221 / 1	70235-02 / 1	70235-01 / 1	
			70189 / 8	70270 / 8				
			70190 / 11	70271 / 11				
			70191 / 21	70272 / 21				
Housing Style	T-line Sanitary type connection				Sanitary type in-line			
Equivalent Cartridge Lengths	5"	10, 20, 30, and 40 inches				2.5"	5"	
Materials of Construction	316L Stainless Steel							
Pressure & Temperature Ratings	150 psi (10 bar) @ 300 °F (149 °C)		* 75 psi (5 bar) @ 200 °F (90 °C)	150 psi (10 bar) @ 200 °F (90 °C)	150 psi (10 bar) @ 300 °F (149 °C)	150 psi (10 bar) @ 300 °F (149 °C)	150 psi (10 bar) @ 300 °F (149 °C)	
Literature #	70-0201-8887-9	70-0201-8883-8	70-0201-8884-6		70-0201-8883-8	70-0201-8886-1		
* 21ZWC rated at 68 psi								

LifeASSURE PLA series

Filter Series for Pharmaceutical & Biological service



3M Purification Inc. offering of sanitary style filter housings accommodate from 1 to 21 LifeASSURE™ PLA series filters in 10" through 40" lengths.



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

LifeASSURE PLA

Filter Series for Pharmaceutical & Biological service

LifeASSURE PLA Cartridge Ordering Guide

Filter Grade	Configuration	Length (Inches)	End-modification	Gasket/O-ring Material
PLA020 - 0.20 micron PLA045 - 0.45 micron PLA065 - 0.65 micron PLA080 - 0.80 micron	B - Pleated Configuration	01 - 10" 02 - 20" 03 - 30" 04 - 40" 50 - 5" *	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 3/4" Length) F - 222 O-ring & Flat Cap (Code 3) J - 226 O-ring & Flat Cap	A - Silicone B - Fluorocarbon C - EPR D - Nitrile

* Not Available with D or E end-modification.

LifeASSURE PLA Mini Cartridge Ordering Guide

Filter Grade	Configuration	Nominal Length (inches)	End-modification	Packaging Option
PLA020 - 0.20 micron PLA045 - 0.45 micron PLA065 - 0.65 micron PLA080 - 0.80 micron	M - Mini Cartridge	01 - 2.5 02 - 5	A - Standard	6 - 6 Cartridges

LifeASSURE PLA 2.5" & 5" Capsule Ordering Guide

Filter Grade	Configuration	Nominal Length (inches)	End-modification	Packaging Option
PLA020 - 0.20 micron PLA045 - 0.45 micron PLA065 - 0.65 micron PLA080 - 0.80 micron	C - Capsule	01 - 2.5 02 - 5	A - Sanitary Flange B - Hose Barb	1 - Single Capsule

LifeASSURE PLA 10", 20", & 30" Capsule Ordering Guide

Filters	Configuration	Nominal Length (inches)	End-modification	Packaging Option
PPLA020 - 0.20 micron PPLA045 - 0.45 micron PPLA065 - 0.65 micron PPLA080 - 0.80 micron	C - Capsule	01 - 2.5 02 - 5	A - Sanitary Flange B - Hose Barb	1 - Single Capsule 3 - 3 Capsule

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