

LifeASSURE™ PDA Series

Sterilizing Grade Polyethersulfone Membrane Filters

LifeASSURE™ PDA series filters combine two asymmetric polyethersulfone (PES) membrane layers with Advanced Pleat Technology design. This combination results in a robust filter that is optimized for both high throughput and fast flow applications while offering 0.2 µm absolute rated filtration for sterilizing performance. The unique hydrophilic polyethersulfone membrane wets easily for integrity testing and is ideal for applications where low protein binding is critical.

LifeASSURE™ PDA Series Membrane Technology

LifeASSURE PDA Series filters incorporate two layers of polyethersulfone membrane. The upstream layer (Figure 1) is highly asymmetric and provides optimized prefiltration capacity for the downstream layer (Figure 2) that contains a robust, centrally located, retention zone. Both membrane layers are asymmetric and together result in a filter with multiple filtration zones providing extremely high contaminant capacity, fast flow rates and reliable sterilizing filtration performance.

Advanced Pleat Technology Design

LifeASSURE PDA series filters also feature an innovative Advanced Pleat Technology design for extended service life. This design technology maximizes the useful surface area of the filter while maintaining open flow paths between media pleats (Figure 3). By employing Advanced Pleat Technology design, the LifeASSURE PDA series filter provides lower pressure drops, longer service life and lower overall filtration costs.

Meeting Scale Up Requirements

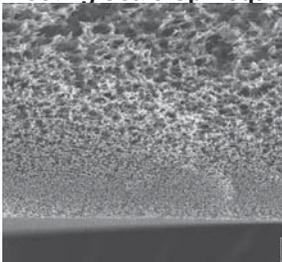


Figure 1: LifeASSURE™ PDA series upstream layer

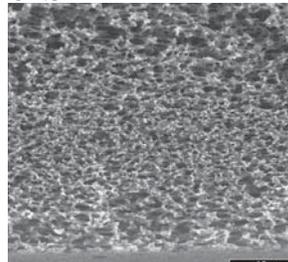


Figure 2: LifeASSURE™ PDA series downstream layer

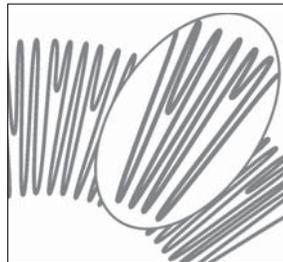


Figure 3: Advanced Pleat Technology



Applications

LifeASSURE™ PDA series filters are optimized for applications requiring critical sterilization where 0.2 µm absolute rated filtration is required.

Final 0.2 µm sterilizing filtration

Media and fermenter feed streams

Serum and blood fractions

Biologicals

Vaccines

Chromatography column protection

Cell culture fluids

High protein feed streams

Parenterals (SVP, LVP)

Reagents and Buffers

Solvent filtration Reagents & Buffers

Ophthalmics

High purity DI water and WFI systems

Bulk pharmaceutical chemicals

Orals and Topicals

Features & Benefits

Robust double membrane layer filter construction

- Exceptionally high contaminant capacity and fast flow rates for long on-stream life and maximum economy

Hydrophilic asymmetric polyethersulfone membrane

- Ensures easy wet out for integrity testing and low protein binding

Validated 0.2 µm absolute-rated membrane

- Reliable sterilizing filtration

Capsule filters are available in both *gamma* compatible and sterile formats

- Eliminate cleaning and cleaning validation step associated with stainless steel housings for maximal ease-of-use.

Advanced Pleat Technology construction

- Allows maximum fluid and contaminant access to filter surface area for highest throughput

100% Integrity tested prior to release

- Ensures consistent conformance to specification

21 CFR compliant materials of construction, USP Biological Reactivity Test for Plastics Class VI, Validation Guide and Drug Master File (DMF) .

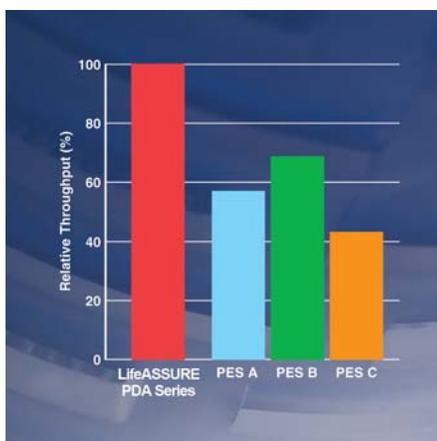
- Eases validation and regulatory submissions



A full range of LifeASSURE™ PDA series sterilizing grade filters is available to meet your scale up process needs. This range includes disposable capsules, mini-cartridges and full size cartridges. In addition, LifeASSURE PDA series filter discs are available when even smaller membrane surface area is required.

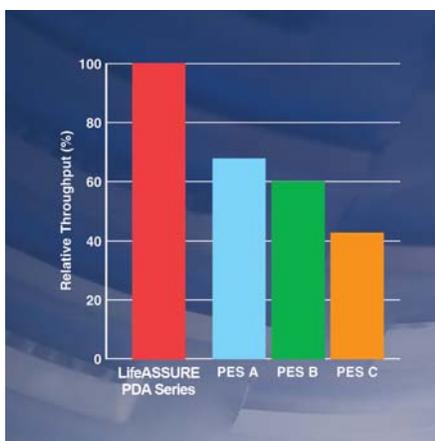
Superior Performance

The charts below show the superior performance of LifeASSURE PDA series filters in a variety of targeted applications. The results show both the high flow rate and high throughput capacity of LifeASSURE PDA series filters compared to other commercially available PES membrane filters. Also shown are comparisons of LifeASSURE PDA series filters to commercially available PES, PVDF and nylon membrane filters in adsorption related tests. These results show LifeASSURE PDA series filters are low protein and preservative binding, consistent with polyethersulfone membranes.



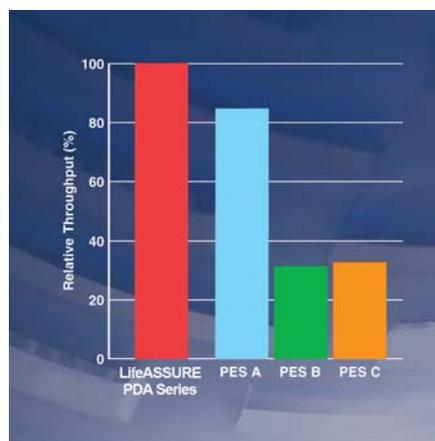
Water Flow

Relative water flow of 10" LifeASSURE PDA Series and commercially available PES cartridge filters. PES A, B, C cartridges water flows were taken from competitors' product literature.



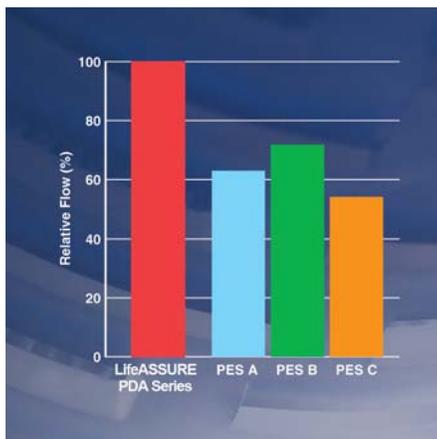
Bovine IgG

Relative throughput of bovine IgG (50 mg/ml) with equal area polyethersulfone membrane. Relative filtrate volume after 15 minutes at 15 psi feed pressure was measured.



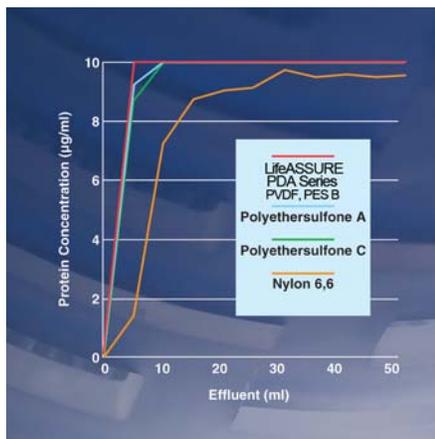
CHO Cell Media

Relative throughput of CHO cell media feed with equal area polyethersulfone membrane. Tests were conducted at a constant flow and throughput volume was measured at a terminal pressure of 25 psid.



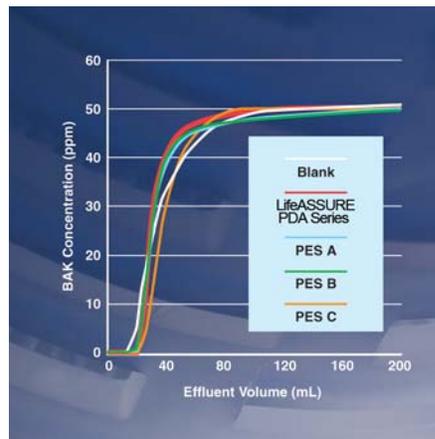
CHO Cell Biomass

Relative throughput of CHO cell biomass with equal area polyethersulfone membrane. Relative throughput volume after 10 minutes at 10 psi feed pressure was measured.



Protein Adsorption

Equal area membranes were evaluated for protein adsorption using bovine serum albumin at an inlet concentration of 10 µg/ml. All of the membranes tested, with the exception of Nylon 6,6 showed comparable, rapid saturation to baseline performance.



Preservative Adsorption

Equal area membranes were evaluated for adsorption of a commonly used ophthalmic preservative, benzalkonium chloride-BAK at an inlet concentration of 50 ppm. The results show all of the membranes tested had similar saturation profiles.

Optimized for Use with 3M Prefilter Cartridge & Capsule Filters

LifeASSURE PDA series sterilizing grade filters are designed for use with 3M prefilters. There are two prefilter types referenced in Table 1 below.

Table 1: Prefilter Selection

Prefilter Type	Filter Media	Typical Applications
LifeASSURE™ PNA Series Filters	Polyethersulfone	Buffers, media feeds
Zeta Plus™ EXT series filters	Cellulosic depth filter	Cell culture debris clarification, concentrated protein feeds, serum, difficult to filter biological fluids

Robust Filtration Performance

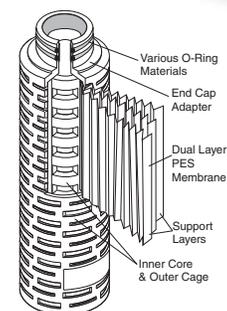
In order to measure design robustness, sample LifeASSURE PDA series filters were subjected to multiple *in situ* steam sterilization cycles or exposed to aggressive acid and alkaline fluids. Table 2 shows the results of these studies. Thermal cycling represents a severe test of structural integrity due to the elevated temperature exposure and expansion and contraction of filter components. Caustic compatibility is a desirable feature for chromatography column protection where caustic fluids used for column sanitization and regeneration can be passed directly through LifeASSURE PDA series filters. Compatibility with acids provides filtration performance with aggressive buffers, column regeneration fluids, and CIP protocols.

Table 2: Thermal & Chemical Compatibility

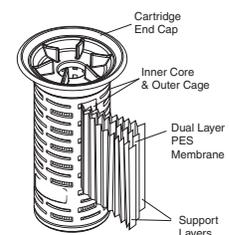
Test	Exposure Conditions	Post Exposure Integrity Test Result
<i>In situ</i> Steam Cycle (Cartridges Only)	20 cycles of 30 minutes at 135 °C	Pass
1 M Sodium Hydroxide	10 cycles of 60 minutes at 60 °C	Pass
1 M Acetic Acid	10 cycles of 60 minutes at 25 °C	Pass
1 M Hydrochloric Acid	10 cycles of 60 minutes at 25 °C	Pass

Performance Engineered Cartridge Design

All polypropylene structural components (end caps, adapters, media support, inner core and outer cage) used in the device fabrication offer exceptional thermal and mechanical stability, broad chemical compatibility, and low extractable levels. LifeASSURE PDA series filter cartridges are available in 2.5, 5, 10, 20, 30, and 40" lengths to match the dimension and sealing requirements of most currently available cartridge housings. Filters can also be supplied in a range of disposable capsule formats.



Standard Cartridge

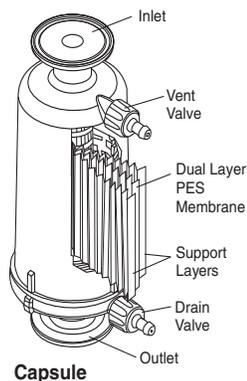


Mini Cartridge

Table 3: LifeASSURE™ PDA Series Filter Specifications

	Cartridges		Mini-cartridges		Capsules				
	5 to 40"		2.5"	5"	2.5"	5"	10"	20"	30"
Filter Rating	0.2 µm								
Materials of Construction									
Cage, Core, End Caps, Adapters	Polypropylene								
Membrane	Polyethersulfone								
Membrane Support Layer	Polypropylene								
Encapsulated Adapter Reinforcing Ring	Polysulfone	NA		NA					
	Cartridges		Mini-cartridges		Capsules				
	5 to 40"		2.5"	5"	2.5"	5"	10"	20"	30"
Filtration Surface Area: m² (ft²)	5": 0.35 (3.8) 10": 0.78 (8.4)*		0.12 (1.26)	0.26 (2.84)	0.12 (1.26)	0.26 (2.84)	0.78 (8.4)	1.56 (16.8)	2.35 (25.3)
Typical Water Flow Rate at 25 °C (77 °F) and 0.07 bar (1 psi) — lpm (gpm)	5": 8.8 (1.6) 10": 19.8 (3.6) 20": 35.7 (6.5) 30": 49.4 (9.0) 40": 49.4 (9.0)		2.7 (0.5)	6.6 (1.2)	2.7 (0.5)	6.6 (1.2)	19.8 (3.6)	35.7 (6.5)	49.4 (9.0)
Operating Parameters									
Maximum Operation Temperature	80 °C (176 °F)				40 °C (104 °F)				
Maximum Differential Pressure									
Forward Pressure: bar (psid)	5.5 (80) @ 25 °C (77 °F); 1.7 (25) @ 80 °C (176 °F)				4.5 (65) @ 40 °C (104 °F)				
Reverse Pressure: bar (psid)	2.4 (35) @ 25 °C (77 °F)								
<i>In situ</i> Steam Conditions:	Up to 135 °C (275 °F)				Do not <i>in situ</i> steam				
Autoclave Conditions:	Up to 126 °C (259 °F)								
<i>Gamma</i> Sterilization:									
Gamma Compatible	N/A				Up to 45 KGy				
Sterile	N/A				Do not resterilize				
Sterility (Sterile)	N/A				Meets current AAMI guidelines for sterility utilizing a validated sterilization cycle. DO NOT resterilize.				
	Cartridges		Mini-cartridges		Capsules				
Integrity Test Parameters (water wet at 25 °C [77 °F])	5 to 30"		2.5"	5"	2.5"	5"	10"	20"	30"
Diffusive Flow, cc/min @ 2.75 bar (40 psig) (Contact 3M Purification for multiple assemblies)	5": 17.2 10": 38 20": 71 30": 104 40": 137		6.7	15	6.7	15	38	71	104
Minimum Bubble Point:	3.10 bar (45 psig)								

*For multiple cartridge lengths, multiply by number of 10" equivalent lengths.



Mini-cartridges

For critical small volume applications, LifeASSURE™ PDA series filters are available in 2.5 and 5” mini-cartridges. Installed in a 3M 2.5 or 5” mini-cartridge housing, or in existing Pall Sealkleen™ housings, LifeASSURE PDA series mini-cartridges offer low hold-up volume and economical small volume filtration.

Gamma Compatible and Sterile Capsule Filters

For critical applications where convenience and ease of use are desired, LifeASSURE PDA series filters are available in 2.5, 5, 10, 20 and 30” disposable capsules. The capsules are supplied with sanitary vent and drain ports as well as 1.5” sanitary flange connections. The 2.5 and 5” mini-capsules are available with your choice of 0.5” (13 mm) hose barb inlet/outlet connections or 1.5” sanitary flange connections. The capsule filters eliminate the steps associated with assembling, cleaning and validating stainless steel housings, thus providing maximal ease-of-use and significant cost saving.

All capsule filters are available in both *gamma* compatible and sterile formats. *Gamma* compatible capsule filters are compatible with autoclaving or *gamma* irradiation up to 45 KGy. Sterile capsule filters are ready for use without further sterilization.

Filter Housings

A specialized range of filter housings is 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 PDA series 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 housings are polished to 20 microinch Ra to limit microbial adhesion and provide for easy cleaning.

Table 4

Housing Model	ZMS	ZWB	ZVS	ZMS Mini Housing	Mini- Housing 30”	
Basic Part Number / Cartridge Capacity	For 10, 20, 30, and 40” cartridges			5” Cartridge	2.5” Mini-cartridge	5” Mini-Cartridge
				70236-02	7023502 / 1	7023501 / 1
Housing Style	T-line Sanitary type connection		Sanitary type in-line			
Equivalent Cartridge Lengths	10, 20, 30, and 40”			5”	2.5”	5”
Materials of Construction	316L Stainless Steel					
Pressure & Temperature Ratings	10.3 bar (150 psi) @ 149 °C (300 °F)	10.3 bar (150 psi) @ 90 °C (200 °F)	10.3 bar (150 psi) @ 149 °C (300 °F)	10.3 bar (150 psi) @ 149 °C (300 °F)		
Literature Number	70-0201-8883-8	70-0201-8884-6	70-0201-8887-9	70-0201-8886-1		

Quality and Reliability

LifeASSURE™ PDA series filters are manufactured in accordance with an ISO 9001:2008 Quality Management System and are 100% integrity tested prior to shipment. All materials of construction are 21 CFR compliant and cartridge and capsule filter components have been tested in accordance with United States Pharmacopoeia (USP) Biological Reactivity Test for Plastics Class VI. All LifeASSURE PDA series cartridge and capsule filters are shipped with a Certificate of Quality affirming compliance with rigid manufacturing quality specifications. Supporting Drug Master File (DMF) documentation is on file with the United States Food and Drug Administration (FDA). LifeASSURE PDA series validation guides are available upon request (Documents 70-0201-8841-6 and 70-0202-8994-1).



Automated Integrity Test - 3M™ Series 200 Automated Integrity Testing Device

A full range of non-destructive integrity tests can be easily and automatically performed with the 3M™ Series 200 Automated Integrity Testing Device integrity test instrument. The 3M Series 200 Automated Integrity Testing Device integrity test instrument provides fast, reliable and accurate automated integrity testing of LifeASSURE PDA series cartridges, capsules and mini-cartridges. For more information, see document 70-0201-8692-3.



LifeASSURE™ PDA Series Cartridge Ordering Guide

Grade Designation	Configuration	Height (Inches)	End Modification	O-Ring Material
PDA020 - LifeASSURE PDA Series 0.2 µm	F	01 - 10 02 - 20 03 - 30 04 - 40 50 - 5	B - 226 O-ring & Spear C - 222 O-ring & Spear F - 222 O-ring & Flat Cap J - 226 O-ring & Flat Cap	A - Silicone B - Fluorocarbon C - EPR D - Nitrile K - PTFE Encapsulated Fluorocarbon

LifeASSURE PDA Series Mini-cartridge Ordering Guide

Grade Designation	Configuration	Height (Inches)	End Modification	Package Quantity I
PDA020 - LifeASSURE PDA Series 0.2 µm	M	01 - 2.5 02 - 5.0	AN - Flange Seal	01 - 1 Pack

LifeASSURE PDA Series Capsule Ordering Guide

Grade Designation	Configuration	Height (Inches)	End Modification	Vent O-Ring Option	Sterilization	Package Quantity
PDA020 - LifeASSURE PDA Series 0.2 µm	C - Small Capsules	01 - 2.5 02 - 5	A - 1.5" Sanitary Fitting B - 0.5 Hose Barb	A - Silicone	G - <i>Gamma</i> compatible S - Sterile	1 - 1 Pack
	J - Large Capsules	01 - 10 02 - 20 03 - 30	A - 1.5" Sanitary Fitting			

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sterilizing grade polyethersulfone membrane filters

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