

LifeASSURE™ PDA Series

sterilizing grade polyethersulfone membrane filters

3M Purification Inc.'s LifeASSURE™ PDA series filter combines two asymmetric polyethersulfone (PES) membrane layers together with proprietary Advanced Pleat Technology (APT) design. This design 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 unique 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 Construction

LifeASSURE PDA series filters also feature an innovative Advanced Pleat Technology (APT) 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 APT design, the LifeASSURE PDA series filter provides lower pressure drops, longer service life and lower overall filtration costs.

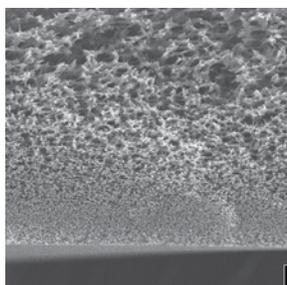


Figure 1: LifeASSURE™ PDA Series upstream layer

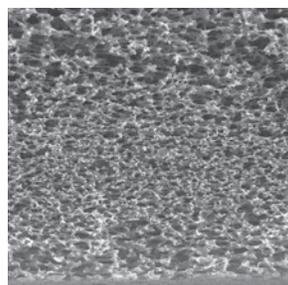


Figure 2: LifeASSURE™ PDA Series downstream layer

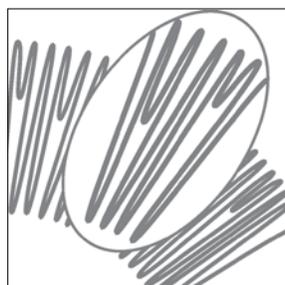


Figure 3: LifeASSURE™ PDA Series upstream layer



Applications

LifeASSURE PSA Series filters are optimized for applications requiring critical sterilization where 0.2 micron 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

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 performance 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

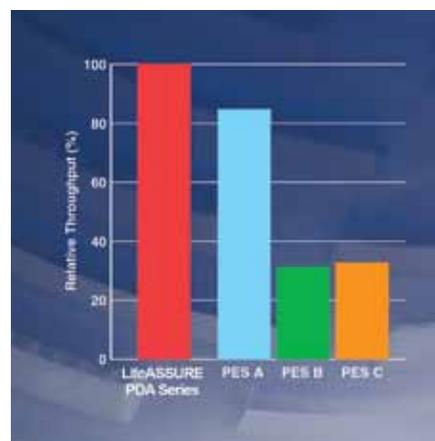
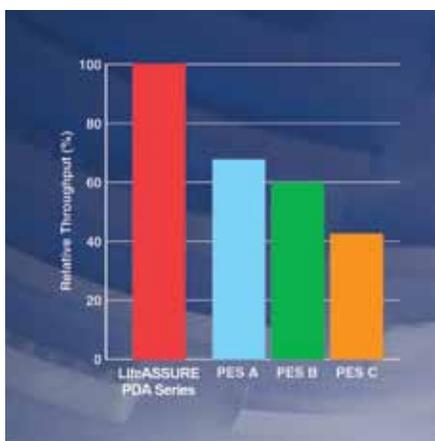
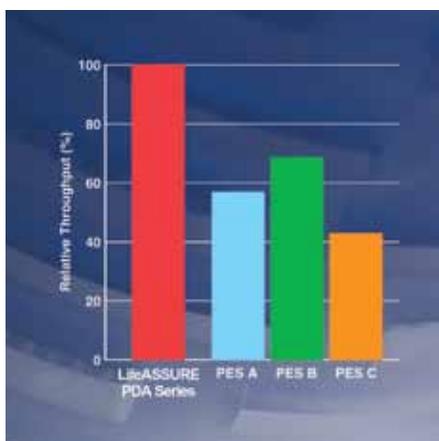


Meeting Scale Up Requirements

A full range of LifeASSURE PDA series sterilizing grade filters is available to meet your scale up process needs. LifeASSURE PDA series membrane is configured in disposable capsules, mini cartridges and full size cartridges. Smaller LifeASSURE PDA series membrane areas can be obtained by using LifeASSURE PDA series filter discs.

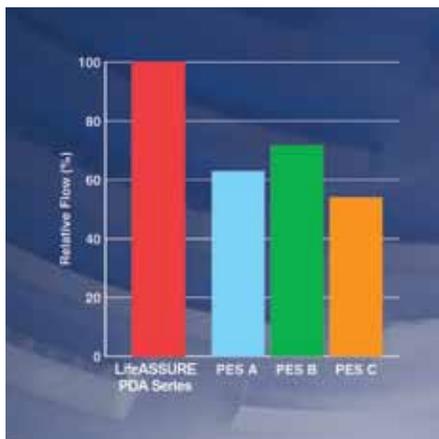
Superior Performance

The charts below show the superior performance of 3M Purification Inc.'s 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.



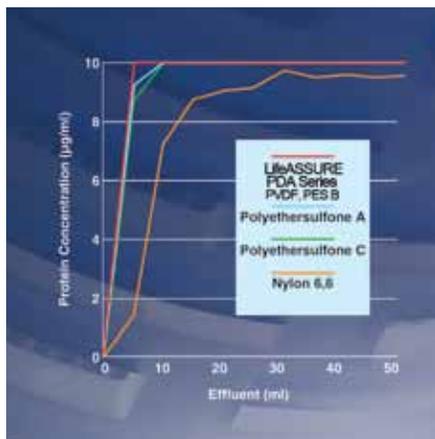
Water Flow

Relative water flow of 10-inch LifeASSURE PDA Series and commercially available PES cartridge filters. PES A, B, C cartridges water flow from competitive product literature.



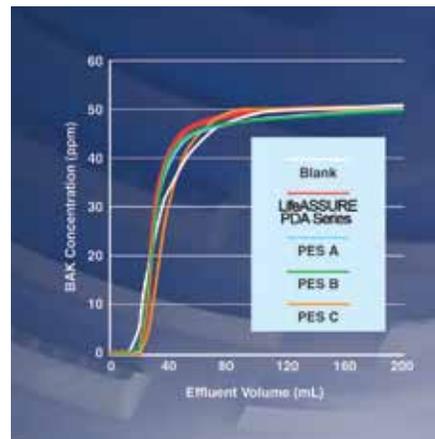
Bovine IgG

Relative throughput of bovine IgG (50 mg/ml) with equal area polyethersulfone membrane. Relative filtrate volume after 10 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 Purification Inc. Prefilter Cartridge and Capsule Filters

LifeASSURE PDA series sterilizing grade filters are designed for use with 3M Purification pre-filters. There are two pre-filter types referenced in Table 1 below.

Table 1: Pre-filter Selection

Pre-filter Type	Filter Media	Typical Applications
PolyPro™ XL filter cartridges	Polypropylene	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

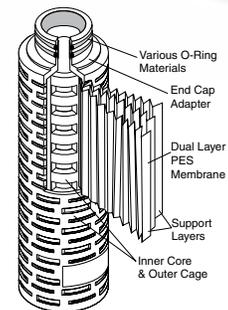
In order to measure design robustness, sample LifeASSURE PDA series filters were subjected to multiple *in-situ* steam sterilization cycles or exposure to aggressive acid and alkaline fluids. Table 2 shows the results of these studies. Thermal cycling represents a severe test of structural integrity 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

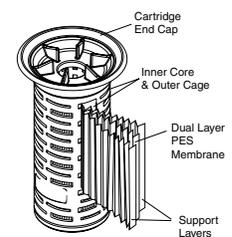
Test	Exposure Conditions	Post Exposure Integrity Test Result
<i>In-situ</i> Steam Cycle	20 cycles of 30 minutes at 135 °C	Pass
1 M Sodium Hydroxide	10 cycles of 60 minutes at 60 °C	Pass
1 M Acetic Acid	10 cycles of 60 minutes at 25 °C	Pass
1 M Hydrochloric Acid	10 cycles of 60 minutes at 25 °C	Pass

Performance Engineered Cartridge Design

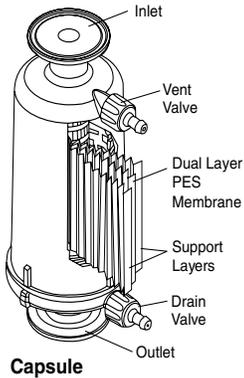
All polypropylene structural components (end caps, adapters, media support, inner core and outer cage) used in the device fabrication ensure exceptional thermal and mechanical stability, broad chemical compatibility, and low extractable levels. LifeASSURE PDA series filter cartridges are available in 5, 10, 20, 30, and 40-inch 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



Mini Cartridges

For critical small volume applications, LifeASSURE PDA series filters are available in 2.5 and 5 inch mini cartridges. Installed in a 3M Purification 2.5 or 5 inch mini cartridge housing, or in existing Pall Sealkleen™ housings, LifeASSURE PDA series 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 PDA series filters are available in 2.5, 5, 10, 20 and 30 inch disposable capsules. The capsules are supplied with sanitary vent and drain ports as well as 1.5 inch sanitary flange connections. The 2.5 and 5 inch mini capsules are available with your choice of 0.5 inch (13mm) hose barb inlet/outlet connections or 1.5 inch sanitary flange connections. Vent and drain o-rings are offered in silicone, fluorocarbon, and EPR.

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)	
	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				40 °C				
Maximum Differential Pressure	5.5 (80) @ 25 °C; 1.7 (25) @ 80 °C				4.5 (65) @ 40 °C				
Forward Pressure: bar (psid)	2.4 (35) @ 25 °C								
Reverse Pressure: bar (psid)									
<i>In-situ</i> Steam Conditions:	Up to 135 °C				Do not <i>in-situ</i> steam				
Autoclave Conditions:	Up to 126 °C								
	Cartridges	Mini Cartridges		Capsules					
	5 to 30"	2.5"	5"	2.5"	5"	10"	20"	30"	
Integrity Test Parameters (water wet at 25 °C)									
Diffusional Flow, cc/min @ 2.75 bar (40 psig)	5": 17.2 10": 38 20": 71	6.7	15	6.7	15	38	71	104	
Minimum Bubble Point: 3.10 bar (45 psig) (Contact 3M Purification Inc. for multiple assemblies)	30": 104 40": 137								

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

3M Purification Inc. 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 micro-inch Ra to limit microbial adhesion and provide for easy cleaning.

Table 4

Housing Model	ZMS	ZWB	ZVS	ZMS Mini Housing	Mini-Housing	
Basic Part Number / Cartridge Capacity	For 10, 20, 30, and 40" cartridges			5 inch Cartridge	2.5 inch Mini Cartridge	5 inch Mini Cartridge
	70220-01 / 1	70269 / 4	70221-01 / 1	70236-02	7023502 / 1	7023501 / 1
	70220-02 / 1	70270 / 8	70221-02 / 1			
	70220-03 / 1	70271 / 11	70221-03 / 1			
	70220-04 / 1	70272 / 21	70221-04 / 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	150 psi (10 bar) @ 300 °F (149 °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)		
Literature Number	70-0201-8883-8	70--201-8884-6	70-0201-8887-9	70-0201-8886-1		

Validation Support Services

3M Purification Inc. offers specialized support to the pharmaceutical and biotechnology industry through our Scientific Applications 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 Test Instrument Training

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



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). A complete LifeASSURE PDA series Validation Guide is available upon request (3M Purification Inc. document 70-0201-8841-6).

Automated Integrity Test - CUNOCheck™ 2

A full range of non-destructive integrity tests can be easily and automatically performed with the CUNOCheck 2 integrity test instrument. The CUNOCheck 2 integrity test instrument provides fast, reliable and accurate automated integrity testing of LifeASSURE PDA series cartridges, capsules and mini cartridges. For more information, see 3M Purification Inc. 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	O-Ring Material
PDA020 - LifeASSURE PDA Series 0.2 µm	M	01 - 2.5 02 - 5.0	AN	01 - 1 Pack

LifeASSURE PDA Series Capsule Ordering Guide

Grade Designation	Configuration	Height (Inches)	End Modification	Vent O-Ring Option	Package Quantity
PDA020 - LifeASSURE PDA Series 0.2 µm	C - Small Capsules	01 - 2.5 02 - 5	A - Sanitary Fitting B - 0.5 Hose Barb	A - Silicone B - Fluorocarbon C - EPR	N1 - 1 Pack
	J - Large Capsules	01 - 10 02 - 20 03 - 30	A - Sanitary Fitting		

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