3M Purification

Life Sciences Process Technologies Markets

LifeASSURE™ PDA

Series Capsules & Cartridges

Robust Sterilising-grade PES Membrane Filters

- ☑ New name for CUNO BioASSURE capsules and cartridges
- ☑ Robust sterilising-grade PES (polyethersulfone) membrane
- ☑ Optimised for both superior throughput and superior flow for improved processing
- ☑ Easy to use cartridge and disposable capsule configurations
- ☑ Easy to wet for reliable integrity testing

LifeASSURE PDA sterilising-grade filter cartridges and capsules

3M Purification's LifeASSURE™ PDA filter, formerly known as CUNO BioASSURE, combines two asymmetric polyethersulfone (PES) membrane layers together with the Advanced Pleat Technology (APT). This design results in a robust filter with a high surface area that is optimised for both high throughput and fast flow applications while offering 0.2 µm absolute rated filtration for sterilising performance. The hydrophilic polyethersulfone membrane wets easily for integrity testing and is ideal for applications where low protein binding is critical.

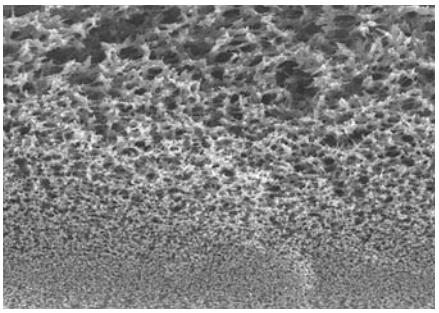


Figure 1: LifeASSURE™ PDA upstream layer

LifeASSURE PDA membrane technology

LifeASSURE PDA filters incorporate two layers of polyethersulfone membrane. The upstream layer (figure 1) is highly asymmetric and provides optimised prefiltration capacity for the downstream (figure 2) layer 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 sterilising filtration performance.

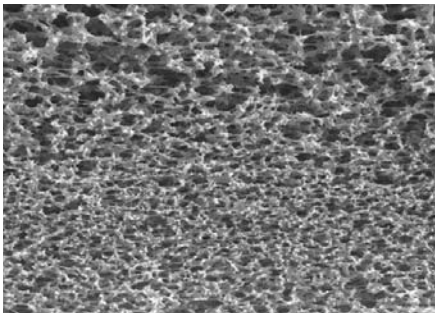


Figure 2: LifeASSURE™ PDA downstream layer

Advanced Pleat Technology construction

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

Figure 3: Advanced Pleat Technology design

Features and Benefits

Robust double layer membrane 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 sterilising 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 materials of construction
USP Biological Safety Tested 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 sterilising-grade filters are available to meet your scale-up process needs. The LifeASSURE PDA membrane is configured in disposable capsules, mini cartridges and full-size cartridges. Smaller LifeASSURE PDA membrane areas can be obtained by using LifeASSURE PDA filter discs.

Applications

Below is a list of typical LifeASSURE™ PDA filter applications. LifeASSURE PDA filters provide fast flow, high capacity, easy wetting and reliable sterilising filter performance.

- Final 0.2 µm sterilising 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
- Ophthalmics
- High purity DI water and WFI systems
- Bulk pharmaceutical chemicals
- Orals and topicals

Superior performance

The charts on the right show the superior performance of 3M Purification LifeASSURE PDA filters compared to competitive products in a variety of targeted applications. The results show both the high flow rate and higher throughput capacity of LifeASSURE PDA filters compared to other commercially available PES membrane filters. Also shown are comparisons of LifeASSURE PDA filters to commercially available PES, PVDF and nylon membrane filters in adsorption related tests. These results show 3M Purification LifeASSURE PDA filters are low protein and preservative binding, which are consistent with polyethersulfone membranes.

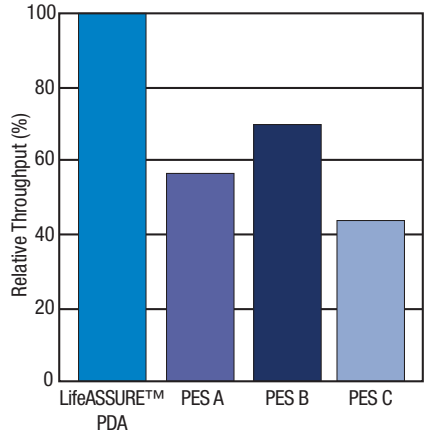
Optimised for use with 3M Purification prefilter cartridge and capsule filters

LifeASSURE PDA sterilising-grade filters are designed for use with 3M Purification prefilters. There are three prefilter types referenced in the table below.

Table 1: Prefilter selection

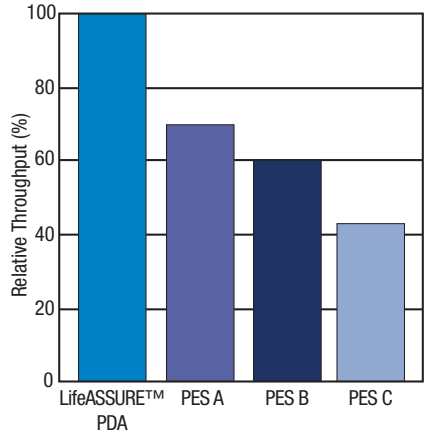
Prefilter type	Material of construction	Typical applications
Betapure™ PBG and PPG Series filter cartridges	polypropylene	Buffers, media feeds
Zeta Plus™ EXT Series filter cartridges	cellulose depth filter	Cell culture debris clarification, concentrated protein feeds, serum, difficult to filter biological fluids
LifeASSURE™ PLA Series filter cartridges	nylon	Buffers, media feeds

Water flow



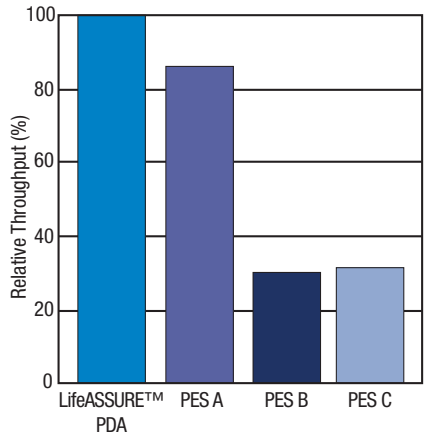
Relative water flow of 10-inch LifeASSURE™ PDA and commercially available PES cartridge filters. PES A, B, C cartridges water flow from product literature.

Bovine IgG



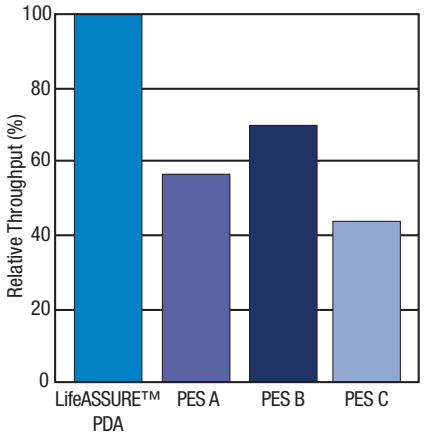
Relative throughput of bovine IgG (50 mg/ml) with equal area polyethersulfone membrane. Relative filtrate volume after 10 minutes at 1.1 bar feed pressure was measured.

CHO cell media



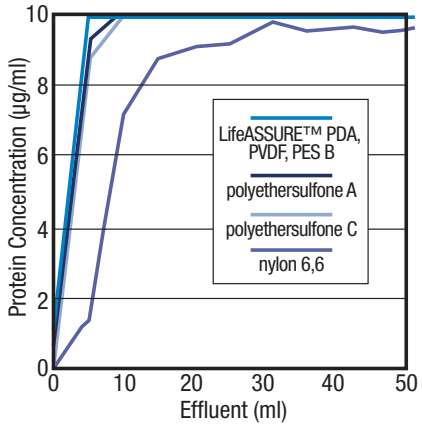
Relative throughput of CHO cell media feed with equal area polyethersulfone membrane. Tests were conducted at a constant flow and throughput volume was measured at a terminal pressure of 1.75 bar.

CHO cell biomass



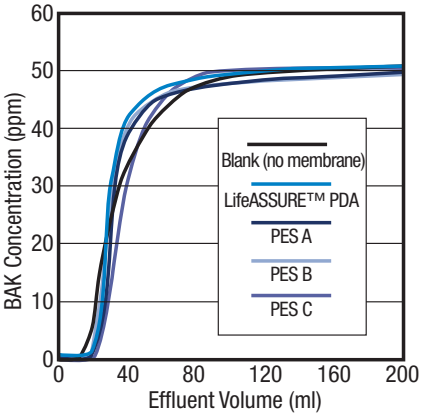
Relative throughput of CHO cell biomass with equal area polyethersulfone membrane. Relative throughput volume after 10 minutes at 0.7 bar feed pressure was measured.

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.

Robust filtration performance

In order to measure design robustness, sample LifeASSURE™ PDA filters were subjected to multiple *in situ* steam sterilisation 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 sanitisation and regeneration can be passed directly through LifeASSURE PDA filters. Compatibility with acids provides filtration performance with aggressive buffers, column regeneration fluids and CIP protocols.

Table 2: Thermal and Chemical Compatibility

Test	Exposure condition	Post exposure integrity test result
In situ 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 filter cartridges are available in 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.

Mini-cartridges

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

Disposable filter capsules

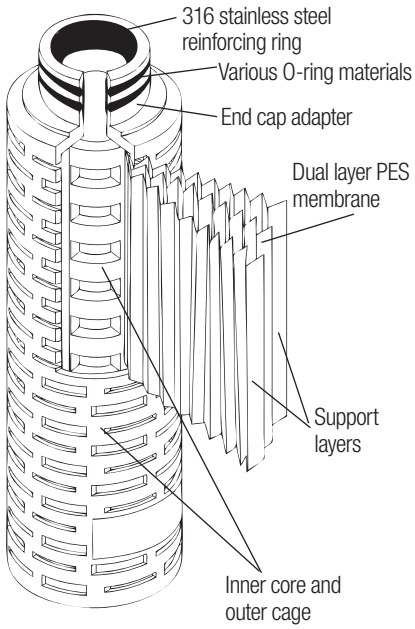
For critical applications where convenience and ease of use are desired, LifeASSURE PDA filters are available in 2.5”, 5”, 10”, 20” and 30” disposable capsules. The capsules are supplied with sanitary vent and drain ports as well as 1 ½” sanitary flange connections. The 2.5” and 5” mini-capsules are available with your choice of ½” (13 mm) hose barb inlet/outlet connections or 1.5” sanitary flange connections. Vent and drain O-rings are offered in silicone, fluorocarbon and EPR.

LifeASSURE PDA specifications

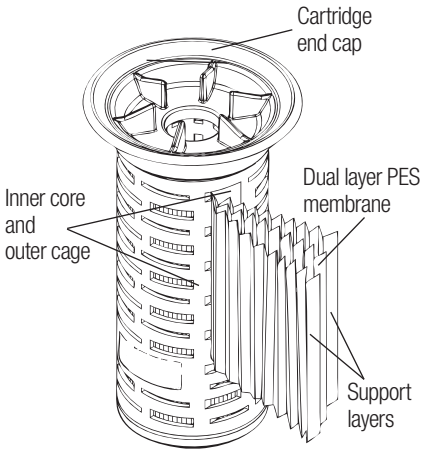
	Cartridges	Mini-cartridges		Capsules				
	5 to 40”	2.5” length	5” length	2.5”	5”	10”	20”	30”
Filter rating	0.2 µm							
Materials of construction								
Cage. core, end caps and adaptors	polypropylene							
Membrane	polyethersulfone							
Membrane support layer	polypropylene							
Encapsulated adapter reinforcing ring	polysulfone	N/A						
Filtration surface area (m^2)	5”: 0.35 10”: 0.78*	0.12	0.26	0.12	0.26	0.78	1.56	2.35
Operating parameters								
Typical water flow rate at 25 °C: lpm/100 mbar	5”: 8.8 10”: 19.8 20”: 35.7 30”: 49.4 40”: 49.4	2.7	6.6	2.7	6.6	19.8	35.7	49.4
Maximum operation temperature	80 °C			40 °C				
Maximum differential pressure Forward pressure: Reverse pressure:	5.5 at 25 °C ; 1.7 at 80 °C 2.4 at 25 °C			4.5 at 40 °C				
In situ steam conditions	Up to 135 °C (10 cycles, 30 minutes each)			Do not *in situ* steam				
Autoclave conditions	Up to 126 °C (20 cycles, 30 minutes each)							
Integrity test parameters (water wet at 25 °C) Diffusional flow. cc/min at 2.75 bar Minimum bubble Point: 3.10 bar (Contact 3M Purification for multiple assemblies)	5”: 17.2 10”: 38 20”: 71 30”: 104	6.7	15	6.7	15	38	71	104

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

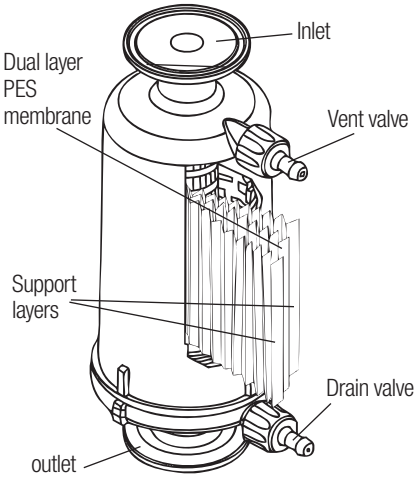
Standard cartridge



Mini-cartridge



Capsule



Filter housings

A specialised 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 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 housings are polished to Ra 0.8 µm to limit microbial adhesion and provide for easy cleaning.

Housing model	IW	Mini-housing	
Cartridge capacity	- 1IWN to 12IWN: 10" to 40" - 18IWN & 24 IWN: 30" & 40"	For 2.5" mini-cartridges	For 5" mini-cartridges
	1 3 5 8 12 18 24	1	1
Housing style	sanitary type		
Materials of construction	1.4404 / 316L stainless steel		
Pressure & temperature	- 1IWN to 8IWN: 10 bar at 150 °C - 12IWN: 9 bar at 150 °C - 18IWN & 24 IWN: 8 bar at 150 °C	10 bar at 149 °C	10 bar at 149 °C

Quality and Reliability

LifeASSURE PDA filters are manufactured in accordance with an ISO Quality Management System and are 100% integrity tested prior to shipment. All materials of construction are 21 CFR listed and cartridge and capsule filter components have been tested in accordance with United States Pharmacopoeia (USP) Biological Safety test for Plastics - Class VI. All LifeASSURE PDA 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 Validation Guide is available upon request.

Validation support services

3M Purification offers specialised 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 optimisation studies.

For more information regarding 3M Purification's validation support services, please contact 3M Purification Technical Services.

LifeASSURE™ PDA cartridges - Ordering guide

Grade designation	Configuration	Height (inches)	End modification	O-ring material
PDA 020 - 0.2 µm	**F**	**50** - 5 **01** - 10 **02** - 20 **03** - 30 **04** - 40	**B** - 226 O-ring & spear **C** - 222 O-ring & spear **F** - 222 O-ring & flat cap **J** - 226 O-ring & flat cap	**A** - silicone (MVQ)* **B** - fluorocarbon (FPM)* **C** - EPR (EPDM)* **D** - nitrile (NBR)* **K** - PTFE-encapsulated fluorocarbon

*ISO Designation

LifeASSURE™ PDA mini-cartridges - Ordering guide

Grade designation	Configuration	Height (inches)	End modification	Package quantity
PDA 020 - 0.2 µm	**M**	**01** - 2,5 **02** - 5	**AN**	**01** - 1-Pack

LifeASSURE™ PDA capsules - Ordering guide

Grade designation	Configuration	Height (inches)	End modification	Vent O-ring option	Package quantity
PDA 020 - 0.2 µm	**C** - Small Capsules	**01** - 2,5 **02** - 5	**A** - 1 ½“ sanitary fitting **B** - Hose barb 13 mm	**A** - silicone **B** - fluorocarbon **C** - EPR	**N1** - 1-Pack
	J - Large Capsules	**01** - 10 **02** - 20 **03** - 30	**A** - 1 ½“ sanitary fitting		

All units are packaged one per box.

NOTE: LifeASSURE PDA is new name for CUNO BioASSURE.

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.

It is your responsibility to determine if additional testing or information is required and if this product is fit for a particular purpose and suitable in your specific application.

3M PURIFICATION MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER NATURE HEREUNDER WITH RESPECT TO INFORMATION OR THE PRODUCT TO WHICH INFORMATION REFERS.

Limitation of Liability

3M Purification will not be liable for any loss or damage arising from the use of the Product(s), whether direct, indirect, special, incidental, or consequential, regardless of the legal theory asserted, including warranty, contract, negligence or strict liability. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

3M

3M United Kingdom plc
3M Centre, Cain Road
Bracknell, RG12 8HT
United Kingdom
Tel.: 0845 602 5237
Fax: +44 (0)1344 858559
E-mail: purification.uk@mmm.com
Website: www.3M.co.uk/filtration

3M Ireland
The Iveagh Building, The Park,
Carrickmines, Dublin 18
Republic of Ireland
Tel.: +353 (0)1 280 3555
Fax: +353 (0)1 280 3509
E-mail: innovation.ie@mmm.com
Website: www.3M.ie

For more contact addresses visit our website www.3M.eu/filtration or www.3Mpurification.com/international.

Data may be subject to change without further notice.

v.4 - DOC10156
LITCTLAPDA1.E - 1211