

3M Purification

LifeASSURE™ PSA Series Sterilising Grade Filter Cartridges and Capsules



Applications

LifeASSURE™ PSA Series filters are optimized for applications requiring critical Sterilisation where 0.1 or 0.2 micron absolute rated filtration is required.

- Parenterals (SVP & LVP)
- Cell Culture Media
- Reagents & Buffers
- Vaccines
- Serum & Blood Fractions
- Biologicals
- Chromatography Column Protection
- Solvent Filtration
- High-Purity DI Water and WFI Systems
- Bulk Pharmaceutical Chemicals
- Ophthalmics
- Orals & Topical

Encompassing two leading-edge processes, multi-zone microporous membrane construction and Advanced Pleating Technology (APT) design, LifeASSURE™ PSA Series filters offer robust 0.20 and 0.10 micron absolute-rated filtration and exceptionally long service life. Designed with two layers of pleated Nylon 6,6 membrane in an all-polypropylene cartridge construction, LifeASSURE PSA Series filters are ideally suited for a wide range of sterilising applications in the pharmaceutical, biological, and bioprocess industries.

- LifeASSURE PSA Series filters, coupled with a 3M Purification LifeASSURE™ PLA Series prefilter, outperform competitive prefilter-final filter systems by up to 5 times!
- LifeASSURE PSA Series filters, using double layer multi-zone microporous membrane, provide higher throughput than competitive 0.1 and 0.2 micron rated filters
- 3M Purification LifeASSURE PSA Series Sterilising grade final filters along with its LifeASSURE PLA Series prefilters are constructed from like materials to ease validation and reduce product compatibility concerns

Multi-zone Microporous Membrane Construction

LifeASSURE PSA Series filters incorporate an advanced 3M Purification multi-zone microporous membrane technology. It allows unmatched flexibility in creating a multi-zone membrane that offers maximum contaminant holding capacity while maintaining high retention efficiency. The SEM photograph, Figure 1, shows a single layer of LifeASSURE PSA multi-zone microporous construction consisting of an open zone and a tighter, qualifying zone. This multi-zone membrane construction capability results in a membrane that provides exceptionally high throughput. In making LifeASSURE PSA Series filter cartridges, two layers of multi-zone microporous membrane are combined to produce a robust sterilising grade filter. LifeASSURE PSA Series sterilising grade filters are available in cartridge and capsule configuration with absolute ratings of 0.1 and 0.2 micron. LifeASSURE PSA Series filters are designed for use with LifeASSURE PLA prefilter cartridges for optimal system performance.

Features & Benefits

Multi-zone, microporous membrane

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

Validated 0.1 and 0.2 micron absolute-rated membrane

- 0.1 µm membrane provides reliable retention of mycoplasma
- 0.2 µm membrane provides 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.

- Passes USP Biological Reactivity for Class VI Plastics Test.

Validation Guide and Drug Master File (DMF).

- Eases validation and regulatory submissions



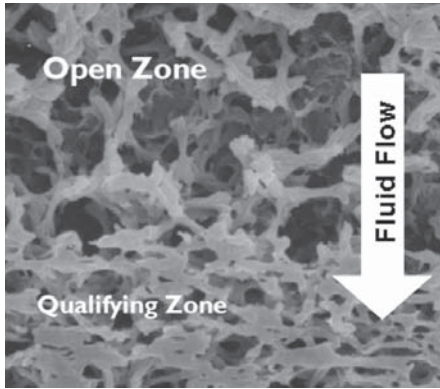


Figure 1 - SEM of Multi-zone Microporous Membrane

LifeASSURE™ PSA Series Filter Configurations.

Disposable capsule filters

- 2.5, 5, 10, 20, 30- inch sizes
- 0.14 to 2.83 m² filtration area
- Completely contained, no housing required
- Sanitary flange and hose barb connections (see ordering guide)
- Autoclaveable

Mini cartridges

- 2.5 and 5- inch sizes
- 0.14 to 0.33 m² filtration area
- 2.5 and 5 inch housings available for lowest hold up volume design
- Retrofit Pall Sealkleen® filter housings
- Steam in place (SIP) or autoclaveable

Full size cartridges

- 5 through 40- inch lengths
- > 0.86 m² filtration area/10-inch cartridge
- Double O-ring seal mechanism
- Fits 3M Purification and competitor filter housings
- Steam in place (SIP) or autoclaveable

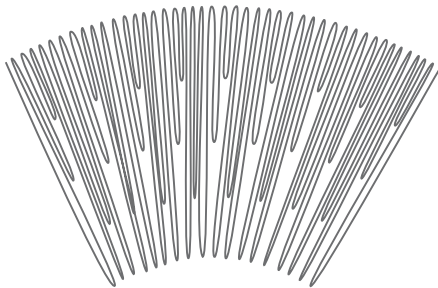


Figure 3. - Advanced Pleat Technology

Meeting Scale Up and Scale Down Requirements

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

LifeASSURE PSA Series Flow Rate Performance

Shown in Figure 2 are liquid flow curves for LifeASSURE PSA Series cartridge and capsule filter assemblies by membrane rating. For details of system sizing, please consult your local 3M Purification technical sales representative.

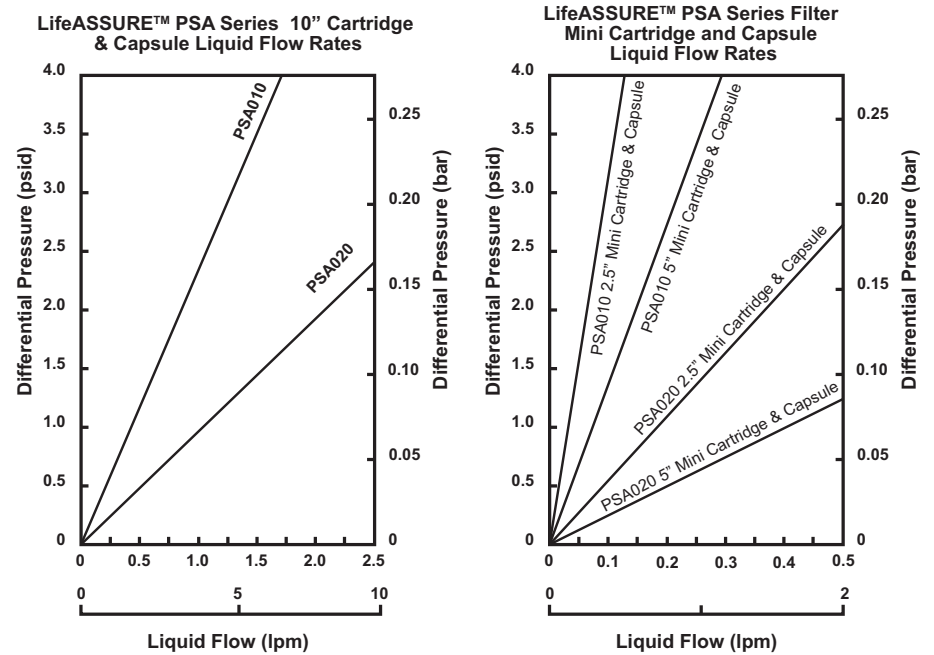


Figure 2. - LifeASSURE™ PSA Series Cartridge and Capsule Flow Rates (Clean Water @ 25°C)

Advanced Pleat Technology Design

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

Superior Microorganism Retention

LifeASSURE PSA Series 0.1 and 0.2 micron rated filters are qualified for absolute retention (Table 1) of *B. diminuta* (ATCC 19146) following American Society of Testing and Materials (ASTM) methodology at a minimum challenge level of 10⁷ CFU/cm² of filter area. The results of bacteria challenge testing are correlated to non-destructive integrity testing. LifeASSURE PSA Series 0.1 micron rated filters are further qualified for absolute retention of mycoplasma (*Acholeplasma laidlawii*, ATCC 23206). To request the LifeAssure PSA Series Validation Guide, please contact your 3M Purification Technical Representative.

Table 1 - Microorganism Retention Test Results

Filter	Challenge Organism	Challenge Level	Result
LifeASSURE™ PSA Series 0.1 µm	<i>B. diminuta</i>	> 10 ⁷ /cm ²	Sterile Effluent
LifeASSURE™ PSA Series 0.1 µm	<i>A. laidlawii</i>	> 10 ⁷ /cm ²	Sterile Effluent
LifeASSURE™ PSA Series 0.2 µm	<i>B. diminuta</i>	> 10 ⁷ /cm ²	Sterile Effluent

Optimized for Service Life and Sterilising Filtration Performance

As the data in Chart 1 demonstrates, LifeASSURE PSA Series filters are designed to provide both enhanced service life and performance. Using a model contaminant solution, the throughput of LifeASSURE PSA Series 0.2 micron rated filters was compared to competitive 0.2 micron rated filters. The results show the significantly higher throughput obtained with LifeASSURE PSA Series filters.

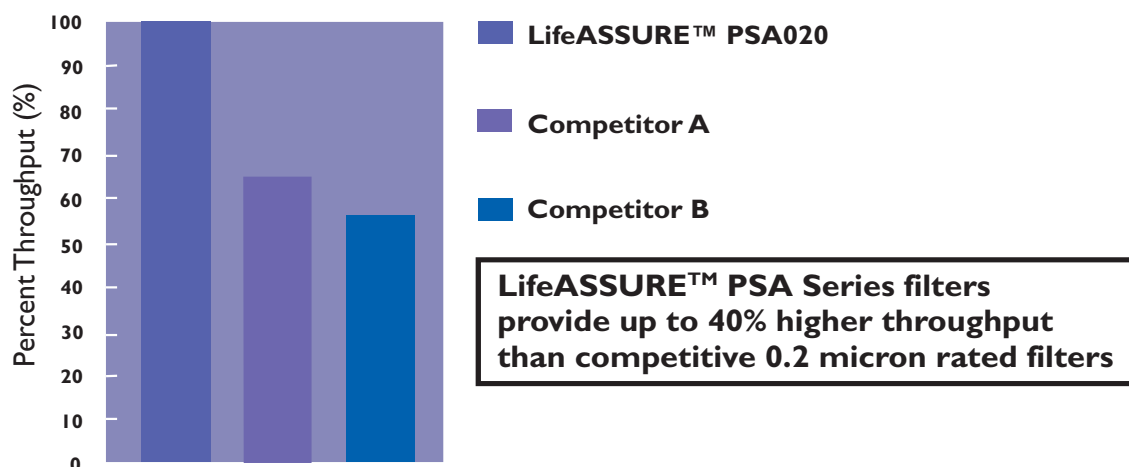
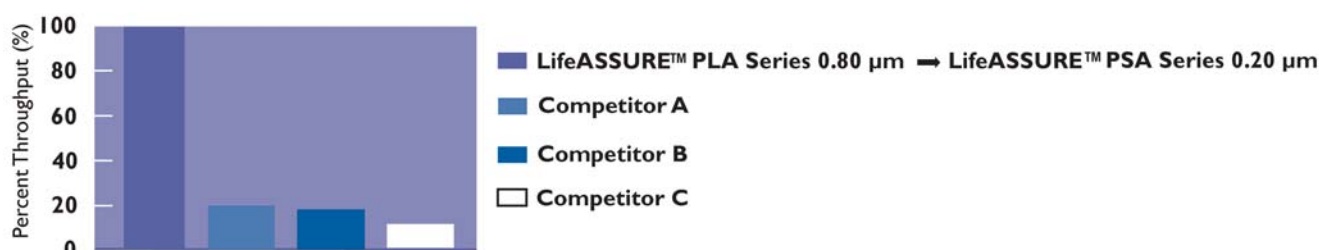


Chart 1. - 0.2 Micron Filter Life Testing Throughput Comparison



LifeASSURE™ PLA Series prefilter with LifeASSURE™ PSA Series final filter outperformed competitive filter systems by up to 5 times!

Chart 2 - Prefilter → Final Filter (0.2 micron) Combined Throughput (Life Testing)

Optimized for Service Life and Sterilising Filtration Performance (cont)

For optimum throughput, use LifeASSURE™ PLA series 0.80 µm rated filters upstream of LifeASSURE PSA™ 0.2 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 performance advantage by arranging an on-site filter test. For more information about testing and LifeASSURE PLA Series filters, contact your local 3M Purification Technical Representative.

Robust Filtration Performance

LifeASSURE PSA Series filters are constructed using two layers of multi-zone microporous membrane. The two membrane layers are laminated such that the qualifying zones are sandwiched in the center of the structure. This construction provides protection to the qualifying zones, enhancing filter robustness.

In order to measure design robustness, sample filters were subjected to multiple in-situ steam sterilisation cycles or exposure to 25°C, 1 molar caustic (NaOH) solution. 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 prefiltration where caustic fluids used for column sanitisation and regeneration can be passed directly through LifeASSURE PSA series filters.

Table 2. - Thermal and Chemical Compatibility

Test	Exposure Conditions	Post Exposure Integrity Test Result
<i>In-situ</i> Steam Sterilisation	135°C, minimum 15 cycles of 30 minutes	Pass
1 M Sodium Hydroxide exposure	5 hours cumulative exposure at 25°C	Pass

Performance Engineered Full Size Cartridge Design

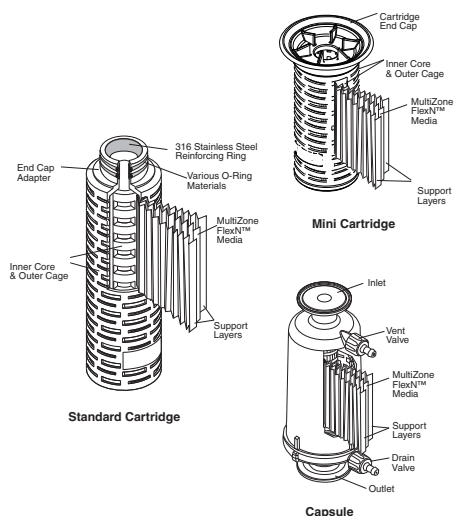
LifeASSURE™ PSA Series filter cartridges are available in 2.5, 5, 10, 20, 30, and 40-inch lengths. All polypropylene structural components (end caps, adapters, media support, inner core and outer cage) are used in the fabrication ensuring exceptional thermal and mechanical stability, broad chemical compatibility and low extractable levels. LifeASSURE PSA Series cartridge configurations are available to match dimension and sealing requirements of most currently available cartridge housings.

Mini Cartridges

For critical small volume applications, LifeASSURE™ PSA Series 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 Pall Sealkleen® housings, LifeASSURE PSA 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 PSA Series filters are available in 2.5, 5, 10, 20 and 30" disposable capsules. LifeASSURE PSA 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. Vent and drain o-rings are offered in silicone, fluorocarbon and EPR.



Read and follow all Instructions before installation and use of these systems.

LifeASSURE™ PSA Series Filter Specifications

Material of Construction		Cartridges		Mini Cartridges		Capsules				
				2.5" Length	5" Length	2.5"	5"	10"	20"	30"
Cage, Core, End Caps, Capsule Shell, and Media Support Layers		Polypropylene								
Membrane		Double Layer Multi-Zone Microporous Membrane Nylon 6,6								
Adapter Support Ring		316 Stainless Steel	NA							
Filtration Surface Area m ²	0.1µm	0.94*	0.16	0.33	0.16	0.33	0.94	1.89	2.83	
	0.2µm	0.86*	0.14	0.28	0.14	0.28	0.86	1.72	2.57	
Length		See Ordering Guide								
Operating Parameters										
Maximum Operation Temperature		80°C				40°C				
Maximum Differential Pressure		Forward: 5.5 bar @ 25°C 1.7 bar @ 80°C				5.2 bar @ 40°C				
		Reverse: 3.4bar @ 25°C								
Steam Sterilisation		Up to 135°C				Do Not <i>in situ</i> steam				
Autoclave Sterilisation		126°C								
Diffusion Flow** Test (Water Wet)	0.1µm (70psi)	18.0 cc/min.*	3.0 cc/min.	6.3 cc/min.	3.0 cc/min.	6.3 cc/min.	18.0 cc/min.	36.0 cc/min.	54.0 cc/min.	
	0.2µm (35psi)	13.1 cc/min.*	2.1 cc/min.	4.3 cc/min.	2.1 cc/min.	4.3 cc/min.	13.1 cc/min.	26.2 cc/min.	39.3 cc/min.	
* Per 10" Element, ** at 1 atmosphere pressure and 25°C										



CUNOCheck™ 2

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
- CUNOCheck™ 2 Integrity Test Instrument Training

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

Quality and Reliability

LifeASSURE™ PSA Series filters are manufactured to an ISO 9000:2008 registered quality system and are 100% diffusion flow 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) Class VI Biological Reactivity tests. All LifeASSURE PSA 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 PSA Series Validation Guide is available upon request.

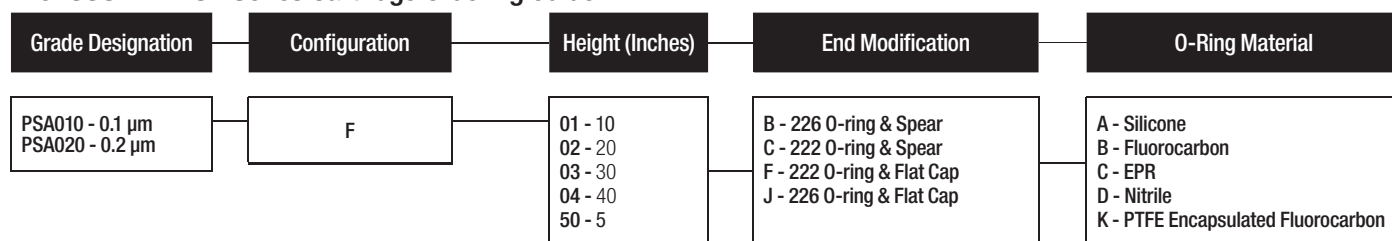
CUNOCheck 2 - Automated Integrity Test

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 cartridges, capsules and mini cartridges.

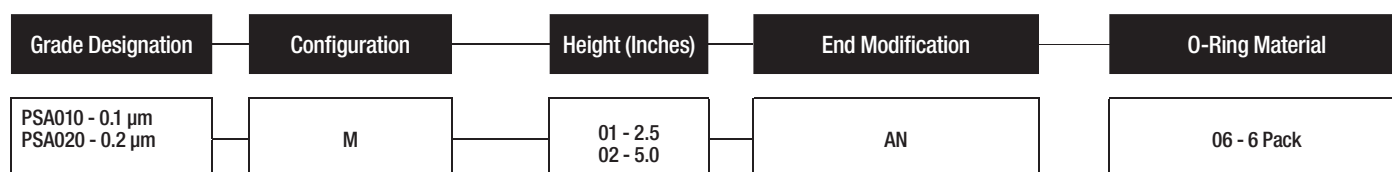
3M Purification Filter Housings

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 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 easy cleaning.

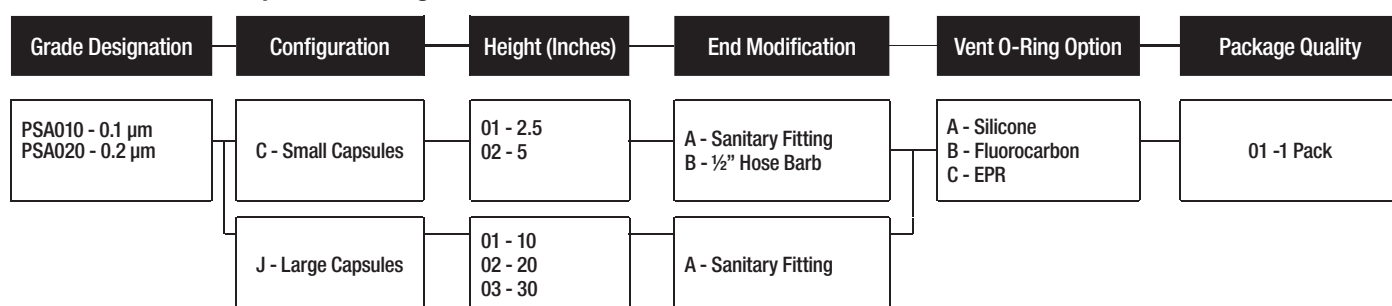
LifeASSURE™ PSA Series Cartridge Ordering Guide



LifeASSURE™ PSA Mini Cartridge Ordering Guide



LifeASSURE™ PSA Capsule Ordering Guide



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.

Limitation of Liability

3M Purification Pty Limited will not be liable, to the extent permitted by law, for any loss or damage from the use of the Product(s), whether direct, indirect, special, or consequential, regardless of the legal theory asserted, included warranty, contract, negligence or strict liability.



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