

SterASSURE™

Sterilizing Grade Filter Cartridges and Capsules

New FlexN™ Multi-Zone Membrane Design

✓ Robust Sterile Filtration Performance

✓ High Throughput Capacity, Double Layer FlexN Membrane Construction with Advanced Pleat Technology™ Design

✓ Available in 0.1 and 0.2 Micron Absolute Ratings in Cartridge and Capsule Formats



SterASSURE™ filter cartridges and capsules are CUNO's latest advance in membrane filter technology.



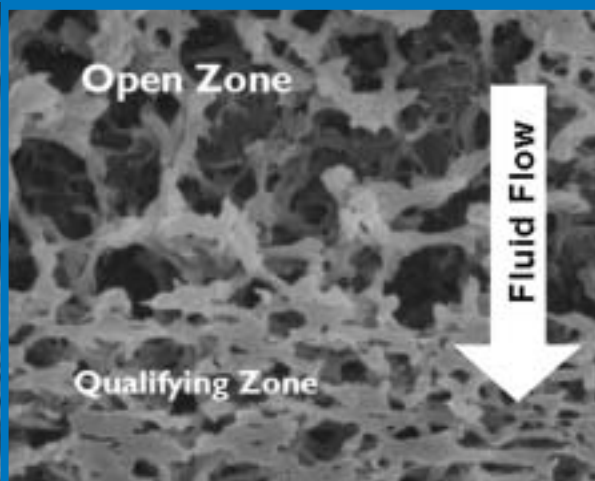
Encompassing two leading-edge processes, FlexN™ membrane manufacture and Advanced Pleating Technology™ (APT) design, SterASSURE filters offer robust 0.1 and 0.2 micron absolute-rated filtration and exceptionally long service life. Designed with two layers of pleated Nylon 6,6 membrane in an all-polypropylene cartridge construction, SterASSURE filters are ideally suited for a wide range of sterilizing applications in the pharmaceutical, biological, and bioprocess industries.

- ▶ **SterASSURE filters, coupled with a CUNO LifeASSURE® PB prefilter, outperform competitive prefilter-final filter systems by up to 5 times!**
- ▶ **SterASSURE filters, using double layer FlexN membrane, provide higher throughput than competitive 0.1 and 0.2 micron rated filters**
- ▶ **CUNO SterASSURE sterilizing grade final filters and CUNO LifeASSURE prefilters are constructed from like materials to ease validation and reduce product compatibility concerns**

FlexN™ Membrane Technology

SterASSURE filters incorporate an advanced CUNO FlexN 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 SterASSURE FlexN membrane 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 SterASSURE filter cartridges, two layers of FlexN membrane are combined to produce a robust sterilizing grade filter. SterASSURE sterilizing grade filters are available in cartridge and capsule configuration with absolute ratings of 0.1 and 0.2 micron. SterASSURE filters are designed for use with CUNO LifeASSURE PB prefilter cartridges for optimal system performance.

Figure 1. - SEM of FlexN™ Membrane



Features	Benefits
▶ Multi-zone, FlexN membrane	▶ Exceptionally high contaminant capacity for long on-stream life and maximum economy
▶ Validated 0.1 and 0.2 micron absolute-rated membrane	▶ Reliable sterilizing filtration and retention of mycoplasma
▶ 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
<ul style="list-style-type: none"> ▶ 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

* U.S. Patents 6,090,441; 6,264,044; 6,280,791

SterASSURE™ Cartridge and Capsule Filter Applications

SterASSURE filters are optimized for applications requiring critical sterilization where 0.1 or 0.2 micron absolute-rated filtration is required. The unique FlexN double layer membrane construction allows robust sterilizing performance and exceptionally high contaminant capacity. SterASSURE filters are designed for a broad range of aqueous and solvent based pharmaceutical, biological and bioprocess applications, including:

- ▶ 0.1 and 0.2 µm final sterilizing filtration
- ▶ Parenterals (SVP, LVP)
- ▶ Reagents & Buffers
- ▶ Biologicals
- ▶ Ophthalmics
- ▶ Cell Culture Fluids
- ▶ Chromatography Column Protection
- ▶ Media and Fermenter Feed Streams
- ▶ Solvent Filtration
- ▶ Orals & Topicals
- ▶ Serum & Blood Fractions
- ▶ Vaccines
- ▶ High-Purity DI Water and WFI Systems
- ▶ Bulk Pharmaceutical Chemicals

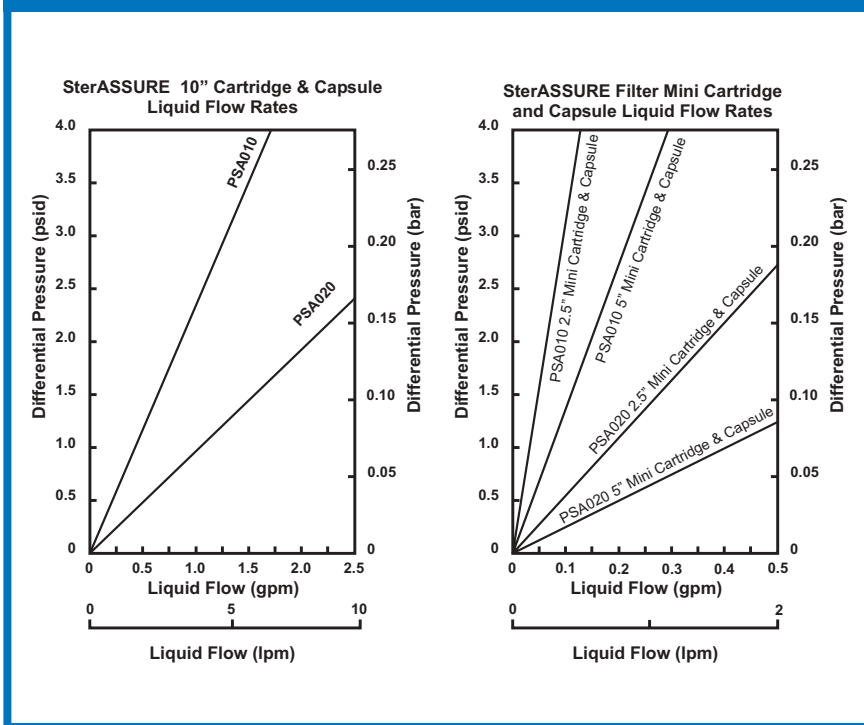
Meeting Scale Up and Scale Down Requirements

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

SterASSURE Flow Rate Performance

Shown in Figure 2 are liquid flow curves for SterASSURE cartridge and capsule filter assemblies by membrane rating. For details of system sizing, please consult your local CUNO distributor.

Figure 2. - SterASSURE Cartridge and Capsule Flow Rates (Clean Water @ 25°C)



SterASSURE Filter Configurations

Disposable capsule filters

- ▶ 2.5, 5, 10, 20, 30- inch sizes
- ▶ 1.5 to 30.4 ft² 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
- ▶ 1.5 and 3.6 ft² 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
- ▶ >9 ft² filtration area/10-inch cartridge
- ▶ Double O-ring seal mechanism
- ▶ Fits CUNO and competitor filter housings
- ▶ Steam in place (SIP) or autoclaveable

Advanced Pleat Technology™ Construction

SterASSURE™ 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 SterASSURE filter provides lower pressure drops, longer service life and lower overall filtration costs.

Superior Microorganism Retention

SterASSURE 0.1 and 0.2 micron rated filters are qualified for absolute retention (Table 2) of *B. diminuta* (ATCC 19146) following American Society of Testing and Materials (ASTM) methodology at a minimum challenge level of 10^7 CFU/cm² of filter area. The results of bacteria challenge testing are correlated to non destructive integrity testing. SterASSURE 0.1 micron rated filters are further qualified for absolute retention of mycoplasma (*Acholeplasma laidlawii*, ATCC 23206). For complete details ask for CUNO SterASSURE Validation Guide, LITVGSTA.

Figure 3. - Advanced Pleat Technology

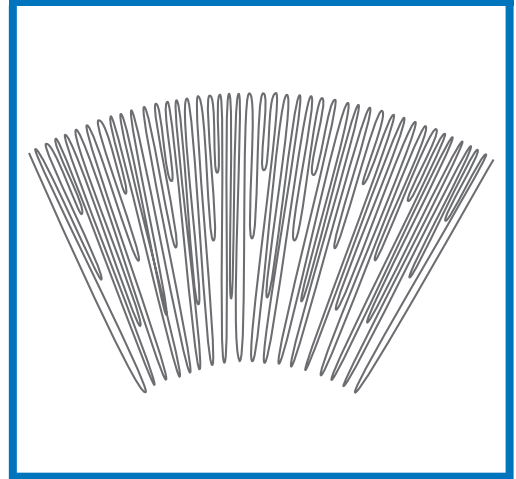


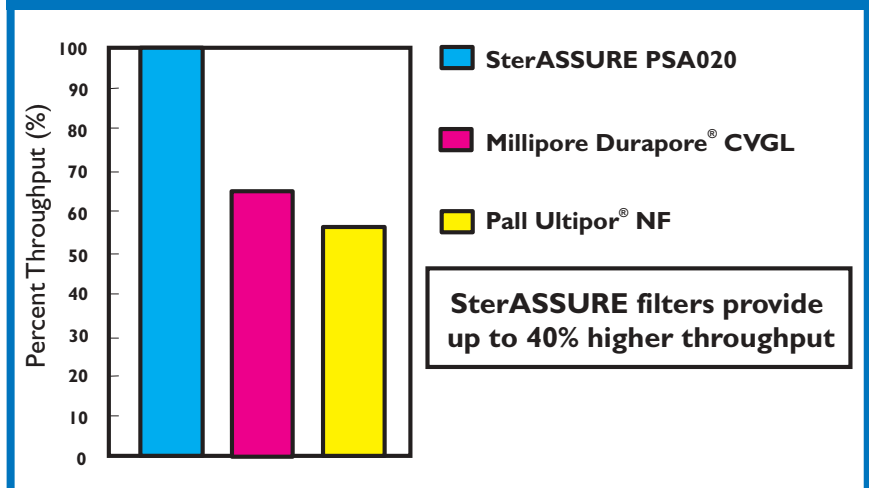
Table 2. - Microorganism Retention Test Results

Filter	Challenge Organism	Challenge Level	Result
SterASSURE 0.1 µm	<i>B. diminuta</i>	$> 10^7/\text{cm}^2$	Sterile Effluent
SterASSURE 0.1 µm	<i>A. laidlawii</i>	$> 10^7/\text{cm}^2$	Sterile Effluent
SterASSURE 0.2 µm	<i>B. diminuta</i>	$> 10^7/\text{cm}^2$	Sterile Effluent

Optimized for Service Life and Sterilizing Filtration Performance

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

Chart 1. - 0.2 Micron Filter Life Testing Throughput Comparison

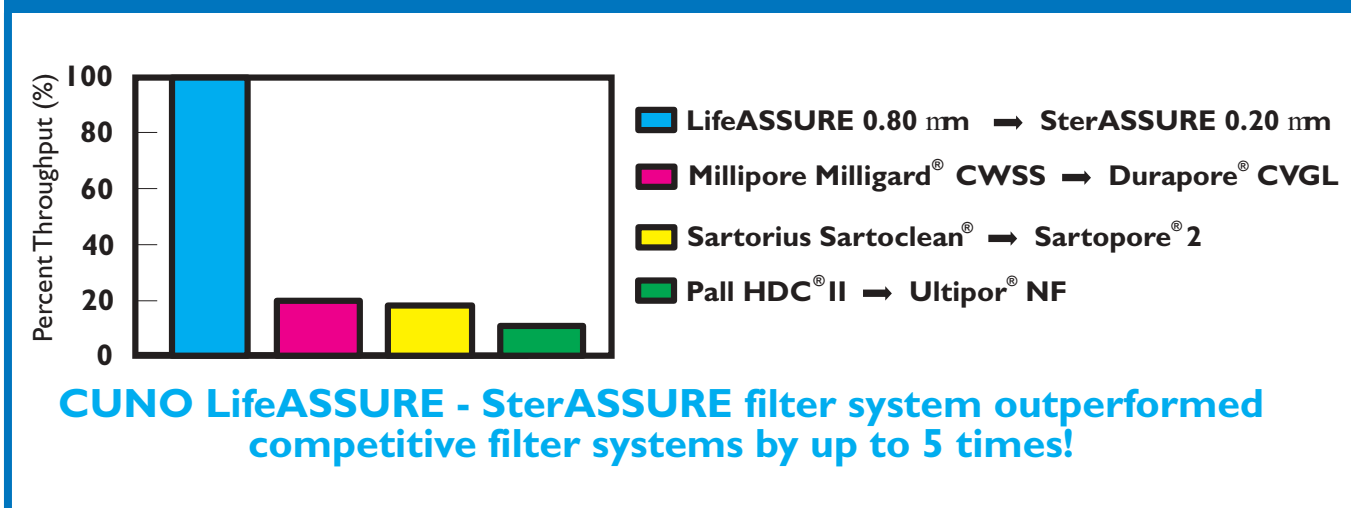


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Optimized for Use with LifeASSURE® PB Prefilter Cartridge and Capsule Filters

SterASSURE™ sterilizing grade filters are designed for use with CUNO LifeASSURE PB prefilters. Because both filters feature proprietary FlexN Nylon 6,6 filter membrane, the sources of extractables and potential product interactions are reduced compared to systems employing prefilters and final filters with different materials of construction. In addition, the unique FlexN membrane technology provides superior system throughput. In order to compare throughput performance of the CUNO LifeASSURE-SterASSURE filter system to competitive prefilter-final filter systems, studies were performed using a model contaminant. The results, as depicted in Chart 2, show that the *CUNO LifeASSURE - SterASSURE filter system outperformed competitive filter systems by 4 to 5 times!*

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



For optimum throughput, use LifeASSURE 0.80 µm rated filters upstream of SterASSURE 0.2 µm rated filters, and LifeASSURE 0.45 µm rated filters upstream of SterASSURE 0.1 µm rated filters. We encourage you to experience the CUNO Performance Advantage by arranging an on-site filter test. For more information about testing and LifeASSURE filters (LITCLAPB1) contact your local CUNO Distributor.

Robust Filtration Performance

SterASSURE filters are constructed using two layers of multi-zone FlexN 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 sterilization 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 sanitization and regeneration can be passed directly through SterASSURE filters.

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

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Performance Engineered Cartridge Design

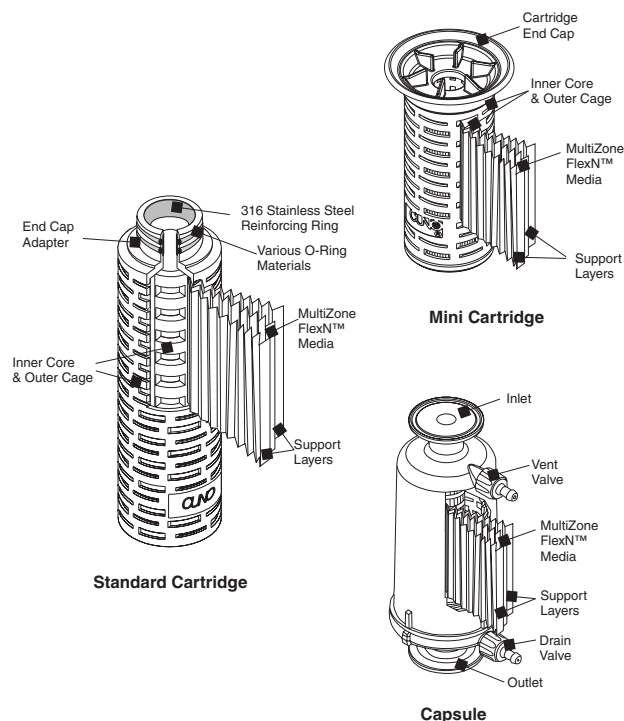
SterASSURE™ filter cartridges are available in 5, 10, 20, 30, and 40-inch lengths. All polypropylene structural components (end caps, adapters, media support, inner core and outer cage) are used in the fabrication ensuring exceptional thermal and mechanical stability, broad chemical compatibility and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

Mini Cartridges

For critical small volume applications, SterASSURE filters are available in 2.5" and 5" Mini Cartridges. Installed in a CUNO 2.5" or 5" Mini Cartridge housing, or in existing Pall Sealkleen™ housings, SterASSURE 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, SterASSURE filters are available in 2.5, 5, 10, 20 and 30" disposable capsules. SterASSURE 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.



SterASSURE 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 FlexN Nylon 6,6							
Adapter Support Ring		316 Stainless Steel	NA						
Filtration Surface Area ft ² (m ²)	0.1µm	10.1 (0.94)*	1.7 (0.16)	3.6 (0.33)	1.7 (0.16)	3.6 (0.33)	10.1 (0.94)	20.3 (1.89)	30.4 (2.83)
	0.2µm	9.2 (0.86)*	1.5 (0.14)	3.0 (0.28)	1.5 (0.14)	3.0 (0.28)	9.2 (0.86)	18.5 (1.72)	27.7 (2.57)
Length		See Ordering Guide							
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)				75 psid (5.2 bar) @ 104°F (40°C)			
		25 psid (1.7 bar) @ 176°F (80°C)							
		Reverse: 50 psid (3.4bar) @ 77°F (25°C)							
Steam Sterilization		Up to 275°F (135°C)				Do Not in situ steam			
Autoclave Sterilization		Up to 259°F (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									

Validation Support Services

CUNO 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 CUNO's Validation Support Services, please contact CUNO Technical Services.

Quality and Reliability

SterASSURE™ filters are manufactured to an ISO 9000 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 SterASSURE 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 SterASSURE Validation Guide is available upon request (LITVGSTA).

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 SterASSURE cartridges, capsules and mini cartridges. For more information, see CUNO document LITCCC2.

CUNOCheck 2



CUNO 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 SterASSURE 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.

Housing Model	ZMS	ZWC	ZWB	ZVS	ZMS Mini Housing	Mini-Housing	
	For 10, 20, 30, and 40 inch cartridges				5 inch Cartridge	2.5 inch Mini Cartridge	5 inch Mini Cartridge
Basic Part Number / Cartridge Capacity	70220-01 / 1	70180 / 4	70192 / 4	70221-01 / 1	70236-02	7023502 / 1	7023501 / 1
	70220-02 / 1	70189 / 8	70193 / 8	70221-02 / 1			
	70220-03 / 1	70190 / 11	70194 / 11	70221-03 / 1			
	70220-04 / 1	70191 / 21	70195 / 21	70221-04 / 1			
Housing Style	T-line Sanitary type connection			Sanitary type in-line			
Equivalent Cartridge Lengths	10, 20, 30, and 40 inches				5 inches	2.5 inches	5 inches
Materials of Construction	316L Stainless Steel						
Pressure & Temperature Ratings	150 psi (10 bar) @ 300°F (149°C)	75 psi (5.2 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)		
Literature #	LITZRH.104	LITZRH.106		LITZRH.104	LITZRHZMS2	LITZRHMCH	

SterASSURE™ Cartridge Ordering Guide

Grade Designation	Configuration	Height (Inches)	End Modification	O-Ring Material
PSA010 - 0.1 µm PSA020 - 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 - Teflon Encapsulated Viton

SterASSURE Mini Cartridge Ordering Guide

Grade Designation	Configuration	Height (Inches)	End Modification	Package Quantity
PSA010 - 0.1 µm PSA020 - 0.2 µm	M	01 - 2.5 02 - 5.0	AN	06 - 6 Pack

SterASSURE Capsule Ordering Guide

Grade Designation	Configuration	Height (Inches)	End Modification	Vent O-Ring Option	Package Quantity
PSA010 - 0.1 µm PSA020 - 0.2 µm	C - Small Capsules	01 - 2.5 02 - 5	A - Sanitary Fitting B - ½" Hose Barb	A - Silicone B - Fluorocarbon C - EPR	01 - 1 Pack
		J - Large Capsules	01 - 10 02 - 20 03 - 30		

Warranty

Seller warrants its equipment against defects in workmanship and material for a period of 12 months from date of shipment from the factory under normal use and service and otherwise when such equipment is used in accordance with instructions furnished by Seller and for purposes disclosed in writing at the time of purchase, if any. Any unauthorized alteration or modification of the equipment by Buyer will void this warranty. Seller's liability under this warranty shall be limited to the replacement or repair, F.O.B. point of manufacture, of any defective equipment or part which, having been returned to the factory, transportation charges prepaid, has been inspected and determined by the Seller to be defective. THIS WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EITHER EXPRESSED OR IMPLIED, AS TO DESCRIPTION, QUALITY, MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE OR USE, OR ANY OTHER MATTER. Under no circumstances shall Seller be liable to Buyer or any third party for any loss of profits or other direct or indirect costs, expenses, losses or consequential damages arising out of or as a result of any defects in or failure of its products or any part or parts thereof or arising out of or as a result of parts or components incorporated in Seller's equipment but not supplied by the Seller.



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