L Series PES 0.65µm/0.2µm – Dual Layer Filter Capsules

PureFlo® L-Series Full-size Capsule Filters feature an asymmetric hydrophilic PES membrane that demonstrates exceptional capacity and flow performance in liquid applications. The L-Series Full-size Capsule filters offer full-scale filtration in various applications in the biopharmaceutical industry. The L-Series product family has been designed for easy pre- and post-use integrity testing, assuring easy wetting for quick and accurate integrity test results. The 0.65 um / 0.2 um configuration has a state-of-the-art, highly asymmetrical DPES 0.65 um pre-filter, which yields 15%-20% more filtration volume than usual. The compact design and available inlet and outlet fittings allow efficient integration of L-Series Full-size Capsule Filters into a wide range of systems. L-Series Full-size Capsule Filters provide biopharmaceutical manufacturers with a filtration solution configured to meet their process needs. The filters are manufactured in accordance with GMP and comply with <USP 797> guidelines. The filters are flushed with pharmaceutical-grade purified pyrogens-free water, and 100% integrity tested prior to dispatch. Our filters and free from animal-derived components raw materials can be traced by Lot Number and are strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.

L Series Filter Capsules with various Inlet/Outlet Connections



Application

- Buffers and Media
- LVP (Large Volume Parenteral)
- Vaccines
- Scale up processing

- Product Sterilization
- Bio Bags Compatible
- Biologics
- Ultrapure Water

- Fermentation Broths
- Pharmaceuticals
- Antibiotics
- Serums







Technical Data Sheet

Micron Rating:

Final Membrane: 0.2 µm PES [Sterilizing Grade Membrane]

Pre-Filter: Highly Asymmetric 0.65 µm PES

Effective Filtration Area:

10-inch long; $7.5 ft^2 (0.7 m^2)$

20-inch long; 15 ft^2 (1.4 m^2)

30-inch long; 22.5 ft^2 (2.1 m^2)

40-inch long; 30 ft^2 (2.8 m^2)

Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

Membrane Feature: Hydrophilic, Low Protein Binding, High Flow Rate

Shell, Cage, Core, End Caps: Polypropylene

Valve O-Rings: Silicone (Standard)

Sealing: Thermally Bonded

Operating Conditions:

Maximum Forward Differential Pressure: Liquid: 5.5 bar (80psi) at 77°F/25°C

Gas: 4.1 bar (60psi) at 77°F/25°C

Minimum Burst Pressure: 8.3 bar (120psi) at 77°F/25°C

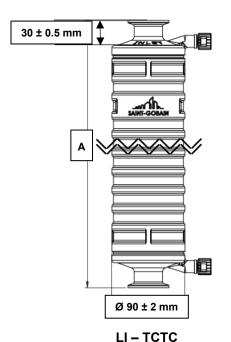
Maximum Reverse Differential Pressure: 3.0 bar (44psi) at 68°F/20°C

Maximum Operating Temperature: 176°F/80°C

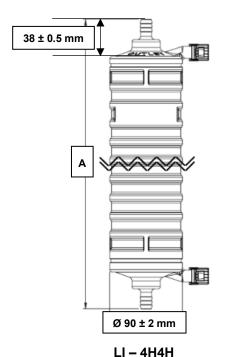




Nominal Dimension: In-Line



Part Number	Internal Filter Length (inches)	Inlet	Outlet	Vent / Drain	Overall Length [A] (± 2 mm)
LI1S020GTCTC	10"	1.5" Tri-Clamp	1.5" Tri-Clamp	1/4" Vent Valve	330 mm
LI2S020GTCTC	20"	1.5" Tri-Clamp	1.5" Tri-Clamp	1/4" Vent Valve	575 mm
LI3S020GTCTC	30"	1.5" Tri-Clamp	1.5" Tri-Clamp	1/4" Vent Valve	820 mm
LI4S020GTCTC	40"	1.5" Tri-Clamp	1.5" Tri-Clamp	1/4" Vent Valve	1,065 mm



Part Number	Internal Filter Length (inches)	Inlet	Outlet	Vent / Drain	Overall Length [A] (± 2 mm)
LI1S020G4H4H	10"	½" Hose Barb	½" Hose Barb	1/4" Vent Valve	360 mm
LI2S020G4H4H	20"	½" Hose Barb	½" Hose Barb	1/4" Vent Valve	605 mm
LI3S020G4H4H	30"	½" Hose Barb	½" Hose Barb	1/4" Vent Valve	850 mm
LI4S020G4H4H	40"	½" Hose Barb	½" Hose Barb	1/4" Vent Valve	1,095 mm

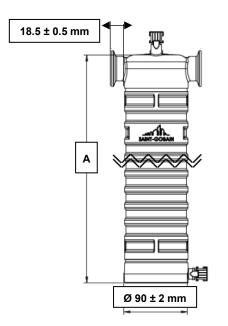






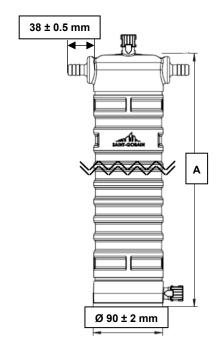


Nominal Dimension: T-Line



Part Number	Internal Filter Length (inches)	Inlet	Outlet	Vent / Drain	Overall Length [A] (± 2 mm)
LT1S020GTCTC	10"	1.5" Tri-Clamp	1.5" Tri-Clamp	1/4" Vent Valve	325 mm
LT2S020GTCTC	20"	1.5" Tri-Clamp	1.5" Tri-Clamp	1/4" Vent Valve	570 mm
LT3S020GTCTC	30"	1.5" Tri-Clamp	1.5" Tri-Clamp	1/4" Vent Valve	815 mm
LT4S020GTCTC	40"	1.5" Tri-Clamp	1.5" Tri-Clamp	1/4" Vent Valve	1,070 mm

LT - TCTC



Part Number	Internal Filter Length (inches)	Inlet	Outlet	Vent / Drain	Overall Length [A] (± 2 mm)
LT1S020G4H4H	10"	½" Hose Barb	½" Hose Barb	1/4" Vent Valve	352 mm
LT2S020G4H4H	20"	½" Hose Barb	½" Hose Barb	1/4" Vent Valve	600 mm
LT3S020G4H4H	30"	½" Hose Barb	½" Hose Barb	1/4" Vent Valve	840 mm
LT4S020G4H4H	40"	½" Hose Barb	½" Hose Barb	1/4" Vent Valve	1,085 mm

LT - 4H4H









Typical Filtered Volume:

Filter Size	Filter Area	Volume to be Filtered (Thru-Put in Liters)
10" Long Internal Filter	$0.7 m^2$	100 - 400
20" Long Internal Filter	1.4 m ²	200 - 800
30" Long Internal Filter	2.1 m ²	300 – 1200
40" Long Internal Filter	$2.8 \ m^2$	400 – 1600

*Volume Filtered is an estimated range for Pharmaceutical & Biological applications. The Filtration Volume is significantly influenced by your solution's viscosity, active ingredients, etc., properties. The best way to determine the exact filtration volume per filter is to try it with your solution.

Filter Integrity:

The finished product was sampled and shown to exhibit a minimum bubble point of \geq 18 psi (1.2 bar) in 60%IPA / 40% water and \geq 50 psi (3.5 bar) in DI Water (at 22°C).

Sterilization:

International Filter Products can provide ETO Sterilization for 10" Capsules only. Ethylene Oxide (ETO) Sterilization Process complies with ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7. Each filter is subjected to a validated ETO process. Sterilization of the fluid path has been validated per ANSI/AAMI/ISO 11135 which provides a minimum sterility assurance level (SAL) of 10-6.

Capsules can be autoclaved 25 times at 125 $^{\circ}$ C (257 $^{\circ}$ F) for 30 minutes or chemically sanitized in situ using common sanitizing agents or hot water at 90 $^{\circ}$ C (194 $^{\circ}$ F) for a limited time (dependent on time and temperature).

Warning: The filters cannot be sterilized by steam-in-place (SIP)

Regulatory Compliance 21CFR Part 177 & USP <88>:

The filters are constructed with polypropylene resins and filtration media in compliance with 21CFR Part 177 of the US Code of Federal Regulations and USP Class VI Biological USP <88>Test for Plastic.

USP <85> Bacterial Endotoxins:

The filters were tested to confirm that an aqueous extraction of this product contains <0.25 EU/ml as determined by the Limulus Amebocyte Lysate (LAL) Test







USP <645> Conductivity USP:

Effluent is tested during the manufacturing process and shown to meet the requirements for USP Sterile Water for Injection for conductivity.

Bacterial Retention ASTM F838-05:

The filters are quantitatively retentive towards *Brevundimonas diminuta* (ATCC #19146) at a minimum challenge level of 10^7 CFU per cm^2 of filtration area, consistent with ASTM F838-05

USP <87> / ISO 10993-5 Cytotoxicity:

Extract from this product is non-Cytotoxic.

Hemolysis ASTM F756-17:

Extract from this product is non-Hemolytic.

Human and Veterinarian Use:

The product is safe for Human and Veterinarian use. CGMP CFR part 210 & 211, additional requirements of 21 CFR part 600 and 21 CFR part 680 are applicable to the aseptic manufacturing process.

Animal-Derived Components & TSE/BSE Risk:

No animal-derived material is intentionally added or used during the manufacture of this product.

Shelf Life:

The L capsules have a shelf life of 3 years from the date of sterilization.

Ethylene Oxide (ETO) Sterilized product packaging provides adequate protection to maintain a sterile barrier throughout the product's distribution, handling, and 3-year shelf life.









L - Series PES Full-Size Capsules

Ordering Guide

L [1] [2] [3] [4] [5] [6] [7]						
[1]	[2]	[3]	[4]	[5] Inlet [6] Outlet	[7]	
Filter Configuration	Filter Size Code [Filtration Area]	Micron Rating [Pre-Filter /Final Filter]	Vent/Drain	Inlet and Outlet Connection	Sterilization	
I: In- LineT: T- Line	 1: 10-Inch [Filtration Area: 0.7 m²] 2: 20-Inch [Filtration Area: 1.4 m²] 3: 30-Inch [Filtration Area: 2.1 m²] 4: 40-Inch [Filtration Area: 2.8 m²] 	 S020: 0.2 μm DS065S020: Highly Asymmetric 0.65/0.2 μm DS045S020: Highly Asymmetric 0.45/0.2 μm DS045S010: Highly Asymmetric 0.45/0.1 μm S080020: 0.8/0.2 μm S020010: 0.2/0.1 μm 	 G: 1/4" bleed valve vent and drain J: 1/4" bleed valve vent (1) only A: 1/4" bleed valve drain (2) only 	• 1H: 1/8" Hose Barb • 2H: 1/4" Hose Barb • 3H: 3/8" Hose Barb • 4H: 1/2" Hose Barb • 5H: 9/16" Hose Barb • MT: 1/2" Tri-Clamp • TC: 1-1/2" Tri-Clamp	-ETO Ethylene Oxide Sterilization [Only Available for 10-Inch]	

Example:

LI1DS065S020G4H4H-ETO

PureFlo L Series In-Line Full-Size Capsule, Highly Asymmetric Dual Layer PES 0.65μm / 0.2μm Final Filter, 10.0", Filtration Area 0.7 m², ¼" bleed valve vent and drain, 1/2" Hose Barb (Inlet/Outlet), ETO Sterilized (Factory Sterilized)

Part Number Description







Special Configuration:

Layer Option:

- Single Layer
- Dual Layer

Micron Rating Option:

- S020 : 0.2 µm
- DS065S020 : Highly Asymmetric 0.65/0.2 μm
- DS045S020 : Highly Asymmetric 0.45/0.2 μm
- DS045S010 : Highly Asymmetric 0.45/0.1 μm
- S080020: 0.8/0.2 μm
 S020010: 0.2/0.1 μm

Vent/Drain Option:

- G: 1/4" bleed valve vent and drain
- J: 1/4" bleed valve vent (1) only
- A: 1/4" bleed valve drain
 (2) only

Inlet Fitting Option:

- 1H = 1/8" Hose Barb
- 2H = 1/4" Hose Barbs
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

Outlet Fitting Option:

- 1H = 1/8" Hose Barb
- 2H = 1/4" Hose Barbs
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp





