

# LeSiever® Bioburden Reduction Filters with 0.45 µm hydrophilic PES

LeSiever® Bioburden Reduction Filters with 0.45 µm PES provide effective bioburden reduction and particulate control of different process streams. Filtration costs can be well-managed by implementing robust highly efficient filters to increase the throughput capacity of sterilizing filters and improve process efficiency. They can also be used as an alternative to sterilizing filters for bioburden reduction when both sterilizing-grade filters and dedicated bioburden control filters are effective, not all processes require a sterile filtrate. The typical application is preparative filtration of growth media, serum, chromatography buffers.

## Typical applications

LeSiever® Bioburden Reduction Filters with 0.45 µm PES are ideal for bioburden control filtration, prefiltration of high particulate-containing biological process streams before sterilizing filters and apply on scenario that sterilizing-grade filters are not essential but reliable bioburden control is required. Typical applications are as following:

- ⦿ Biologics Reagents
- ⦿ Chromatography buffers
- ⦿ Downstream intermediates and column guards
- ⦿ Preparative filtration of Cell Culture Media, serum

## Specification

LePure offers in a broad range of sizes and formats of LeSiever® Bioburden Reduction Capsule Filters. The wide range of membrane areas are from 180 cm<sup>2</sup> to 1.32 m<sup>2</sup> per filter. It provides scale-up from small piloting to production scale and gives the greatest flexibility and most economy.

For traceability and easy identification, each LeSiever® Bioburden Reduction Capsule Filters is labeled with its catalogue number, lot number, serial number. Each filter is supported by documentation to comply with regulatory requirements. LeSiever® Bioburden Reduction Capsule Filters are designed, developed, and manufactured in accordance with ISO 9001 Quality Systems Standard and are shipped with a Certificate of Quality.



## Advantage

- ⦿ Good choice for bioburden reduction & particle removal
- ⦿ Broad compatibility and easy scalability
- ⦿ Low adsorption, high transmission of proteins and active ingredients
- ⦿ High flow rates and throughputs of aqueous solutions
- ⦿ Gamma-irradiatable, autoclavable or available pre-sterilized
- ⦿ Choice of connection options
- ⦿ Chemical compatibility across pH 1-14
- ⦿ Identified by a lot number and unique serial number for complete traceability

## Technical specification

Size	Size 1	Size 5	2"	4"	5"	10"	20"
Filtration Area ft <sup>2</sup>   m <sup>2</sup>	0.19   0.018	0.59   0.055	1.4   0.13	2.5   0.23	3.6   0.33	7.1   0.66	14.2   1.32
Materials of Construction							
Filter media	Polyethersulfone (PES)						
Pore size	0.45 µm (single layer)						
Structural components	Polypropylene						
O-ring	Silicone (SI)						
Supports	Polypropylene						
<b>Maximum Differential Pressure, bar (psid) Integrity Test</b>							
Diffusion Test @ 0.7 bar 10.2 psi	≤2.4	≤3.2	≤6.4	≤11	≤15	≤25.5	≤45
Bubble Point at 23 °C	2400 mbar (34.9 psig)						
Bacterial Endotoxins	Aqueous extraction contains ≤0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test						
Gravimetric Extractables	≤1.0 mg in 70/30 % IPA/water						
Sterilization							
gamma compatible format	Gamma irradiation 25-40 kGy						
autoclavable format	5 autoclave cycles of 60 min @ 126 °C						
Non-Fiber Releasing	Component materials meet the "non-fiber releasing" criteria as defined in 21 CFR 210.3 (b) (6).						

## Ordering information

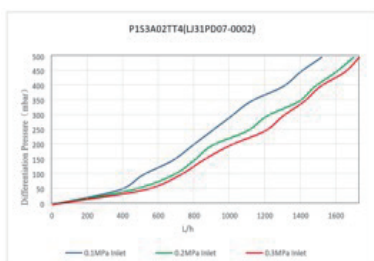
### LeSiever® Bioburden Reduction Filters with 0.45 µm PES

<b>P</b>	<b>1</b>	<b>S</b>	<b>3</b>	<b>D</b>	<b>0 5</b>	<b>T T</b>	<b>1</b>
Product Code	Product type	Membrane Material	Pore Size	Sterilization	Size	Inlet/Outlet	Packaging
P: Plated filter	1: Capsule filter	S: PES	3: 0.45 µm	D: Gamma compatible A: Autoclavable S: sterile (gamma irradiated)	S1: 180cm <sup>2</sup> S5: 550cm <sup>2</sup> 02: 2inch 04: 4inch 05: 5inch 10: 10inch 20: 20inch	T: 3/2" (38.1mm) Tri-Clamp F: 3/4" (19.1mm) Tri-Clamp H: 1/2" (12.7mm) Hose Barb B: 3/4" (19.1mm) Hose Barb O: 1/4" (6.4mm) Hose Barb	1: 1/pack 3: 3/pack 4: 4/pack 6: 6/pack M=Manufacture

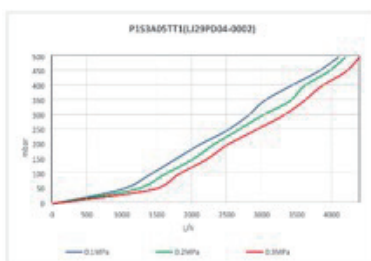
Size	Catalogue Number	Filtration Area	Package
S1	P1S3DS1--6	180cm <sup>2</sup>	6/pack
S1	P1S3AS1--6	180cm <sup>2</sup>	6/pack
S1	P1S3SS1--6	180cm <sup>2</sup>	6/pack
S5	P1S3DS5--4	550cm <sup>2</sup>	4/pack
S5	P1S3AS5--4	550cm <sup>2</sup>	4/pack
S5	P1S3SS5--4	550cm <sup>2</sup>	4/pack

Size	Catalogue Number	Filtration Area	Package
2inch	P1S3D02--4	0.13m <sup>2</sup>	4/pack
2inch	P1S3A02--4	0.13m <sup>2</sup>	4/pack
2inch	P1S3S02--4	0.13m <sup>2</sup>	4/pack
4inch	P1S3D04--3	0.23m <sup>2</sup>	3/pack
4inch	P1S3A04--3	0.23m <sup>2</sup>	3/pack
4inch	P1S3S04--3	0.23m <sup>2</sup>	3/pack
5inch	P1S3D05--1	0.33m <sup>2</sup>	1/pack
5inch	P1S3A05--1	0.33m <sup>2</sup>	1/pack
5inch	A1S3S05--1	0.33m <sup>2</sup>	1/pack
10inch	P1S3D10--1	0.66m <sup>2</sup>	1/pack
10inch	P1S3A10--1	0.66m <sup>2</sup>	1/pack
10inch	P1S3S10--1	0.66m <sup>2</sup>	1/pack
20inch	P1S3D20--1	1.32m <sup>2</sup>	1/pack
20inch	P1S3A20--1	1.32m <sup>2</sup>	1/pack
20inch	P1S3S20--1	1.32m <sup>2</sup>	1/pack

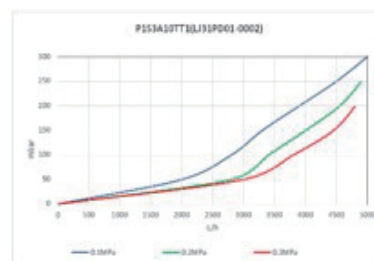
## Standard Flow Rate versus Pressure Drop



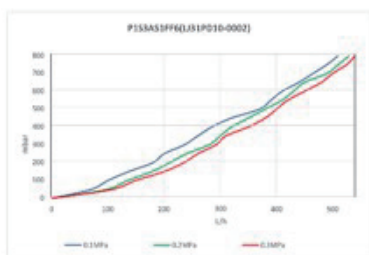
2" Capsule Filter TC inlet/outlet autoclaved



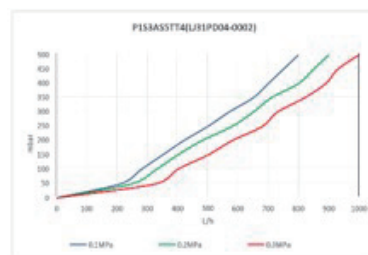
5" Capsule Filter TC inlet/outlet



10" Capsule Filter TC



S1 Capsule Filter TC inlet/outlet



S5 Capsule Filter TC inlet/outlet