

## Large Polyethersulfone Membrane Capsule Filters

**mdi** AseptiCap KSO are polyethersulfone membrane capsule filters offering wide pH (1-14) compatibility. These filters are specially designed for alkaline fluid streams in bio-pharma manufacturing processes, with added advantages of high throughputs and low hold up volumes.

These capsule filters offer serial filtration incorporating a large pore size upstream membrane to protect the downstream membrane for enhanced throughput.

AseptiCap KSO are validated for use in pharmaceutical and bio-pharmaceutical applications.

### Application

- ◆ Bioburden removal from cell harvest supernatants
- ◆ Sterilization of bio-pharmaceuticals such as vaccines and therapeutic proteins
- ◆ Sterilization of oncology drugs
- ◆ Sterilization of buffers

### Special Features

- ◆ Wide pH compatibility (1-14)
- ◆ Absolute retention
- ◆ Low protein binding
- ◆ No Elastomer seals
- ◆ Light weight and self supporting
- ◆ Minimum cleaning requirement and low installation cost
- ◆ Low hold up volume
- ◆ Very high flow rates
- ◆ 100% Integrity tested
- ◆ Total traceability

### Ordering Information

Type	Code	Size			Pore Size		Inlet/Outlet		X	Inline/T-line		Sterility		Pack Size	
		EFA (cm <sup>2</sup> )	Code	Code	Code	Code	Code	Code		Code	Code	Code	Code		
AseptiCap KSO (0.45µm Upstream)	LKOX	5"	3000	53	0.2µm	01	1½" Sanitary Flange		E	Inline	X	Non-Sterile	1	1	01
		10"	6000	54	0.45 µm	02	Single Step ½" Hose Barb		Q	T-line	T	EO Sterile	2		
		20"	12000	55			3/8" Hose Barb		I						
AseptiCap KSO (0.8µm Upstream)	LKO5	30"	18000	56			1" Hose Barb		Z						

EFA: Effective Filtration Area

**Example:**

LKO5	56	01	EE	X	X	2	01
------	----	----	----	---	---	---	----



Microbially Validated as per ASTM F 838-05
Complies with USFDA 21 CFR Part 210.3 (b) (6)
Meets and Exceeds USFDA 21 CFR Part 177.1520

### Specification

**Maximum Differential Pressure**  
4 Kg/cm<sup>2</sup> @ 30 °C

**Maximum Operating Temperature**  
80 °C @ ≤ 2 Kg/cm<sup>2</sup>

**Sterilization**  
Autoclavable at 125° C for 30 minutes, 25 cycles

**Bacterial Retention**  
0.2µm: LRV > 7 for *B. diminuta* ATCC 19146 per cm<sup>2</sup> of filter area  
0.45µm: LRV > 7 for *S. marcescens* ATCC 14756 per cm<sup>2</sup> of filter area

**Oxidizable Matter**  
Passes test as per USP <1231>

**Fiber Release**  
Complies with USFDA CFR Title 21, 210.3 (b) (6)

**Particle Release**  
The filtrate complies with USP <788> test for particulate matter in injections

**Biosafety**  
Passes Bioreactivity test, *In-vivo*, as per USP <88> for Class VI plastics

**TOC (Total Organic Carbon)**  
Meets the WFI requirements of USP <643> for Total Organic Carbon after a 3 liter WFI flush

**Conductivity**  
Meets the WFI requirements of USP <645> for Conductivity after a 3 liter WFI flush

### Material of Construction

**Housing** : Polypropylene  
**Filter Media** : Polyethersulfone Membrane  
**Support Layer** : Polypropylene

### Integrity Test Data

#### Water Wetted Bubble Point

Pore Size	psi	Kg/cm <sup>2</sup>
0.2 µm	≥ 50	≥ 3.52
0.45 µm	≥ 30	≥ 2.11

#### Air Diffusion Flow (DI Water Wetted)

Pore Size	Test Pressure	Max. Air Diffusion Flow
0.2 µm	2.60 Kg/cm <sup>2</sup>	≤30 ml/min
0.45 µm	1.54 Kg/cm <sup>2</sup>	≤45 ml/min

### Typical Water Flow Rate (per 10" Capsule Filter)

Pore Size	Water Flow Rate @ 0.7 kg/cm <sup>2</sup> @ 27 °C
0.2µm	40 litres per minute
0.45µm	65 litres per minute

0.45µm upstream layer is not available with 0.45µm pore size  
T-Line Capsule filters are with 1½" Sanitary Flange only  
5" Capsule Filters are not available with T-Line