

AseptiPrime KS are sterilizing grade PES membrane capsule filters specially designed for very high throughput.

The special asymmetric pre-filter membrane layer with high asymmetric proportion offers high loading and volume handling capacities to provide enhanced protection to the final membrane layer.

These are available in a wide range of sizes and end connections to suit a multitude of sterilization applications in biopharmaceuticals for process development, pilot scale and production batch sizes.

AseptiPrime KS filters meet key process requirements such as absolute retention, high protein recoveries and low extractables.

## Applications

### Sterile Filtration of

- Cell culture media
- Cell culture media containing serum
- Media additives
- Buffers
- pH adjusters
- Final product concentrates
- Small volume parenterals



**Microbiologically Validated as per ASTM F 838-05**

**Complies with USFDA 21 CFR 210.3(b)(6)**

**Meets and Exceeds USFDA 21 CFR 177.1520**

## Key features

- Absolute retention
- 100% integrity tested
- Low protein binding
- Low extractables
- Very low hold up volume in filters

## Specifications

Construction		
Pore Size	0.1 $\mu\text{m}$	
Membrane	Double layered Polyethersulfone with highly asymmetric prefilter membrane	
Plastic Components	Polypropylene	
Size		
Size	25 mm	50 mm
Effective Filtration Area (Nominal)	5 $\text{cm}^2$	20 $\text{cm}^2$
Integrity Testing/Retention		
Bubble Point (with 50% IPA/ Water)	$\geq 31$ psi (2.18 $\text{Kg}/\text{cm}^2$ )	
Microbial Retention	LRV>7 for <i>Acholeplasma laidlawii</i> (ATCC 23206) per $\text{cm}^2$	
Operational		
Max. Operating Temperature	55 $^{\circ}\text{C}$	60 $^{\circ}\text{C}$
Max. Differential Pressure	75 psi (5 $\text{Kg}/\text{cm}^2$ @25 $^{\circ}\text{C}$ )	42 psi (3 $\text{Kg}/\text{cm}^2$ ) @ 30 $^{\circ}\text{C}$
Sterilization	By Gas	Sterilizable by Ethylene Oxide
	By Autoclave	Autoclavable at 125 $^{\circ}\text{C}$ for 30 minutes, 25 cycles. Cannot be in-line steam sterilized
Assurance		
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>	
Toxicity	Passes Biological reactivity Test, <i>In Vivo</i> , as per USP <88> for Class VI plastics	
Cytotoxicity	Passes Biological Reactivity Tests, <i>In Vitro</i> , USP <87> for cytotoxicity	

## Assurance

Fiber Release	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
Particle Release	The filtrate complies with USP <788> test for particulate matter in injections
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after flushing with a specified volume of WFI
Extractables with WFI	Passes NVR test as per USP <661>
Oxidizable Substances	Passes test as per USP <1231>
pH Compatibility	Compatible with pH range of 1-10
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1: 1995

## Ordering Information

### 25 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size		
	Code		Code		Code		Code		Code				Code		Code	
AseptiPrime KS (0.3µm optimized pre-filter)	IKX9	25mm	06	0.1 µm	36	1/8" Hose Barb	H	1/8" Hose Barb	H				Non Sterile	1	100	04
						1/4" Hose Barb	B	1/4" Hose Barb	B							
						Female Luer Lock	M	Male Luer Slip	N							
AseptiPrime KS (0.5µm optimized pre-filter)	IKX7							Male Luer Lock	L				EO Sterile	2		

**Example:**

IKX7	06	36	M	N	X	X	1	04
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**Example for Non Sterile:** IKX70636MNXX104

**Example for EO Sterile:** IKX70636MNXX204

### 50 mm Inline Capsule Filters

Type		Size		Pore Size		Inlet		Outlet		X	X	Sterility		Pack Size		
	Code		Code		Code		Code		Code				Code		Code	
AseptiPrime KS (0.3µm optimized pre-filter)	VKX9	50 mm	10	0.1 µm	36	1/4" SHB	B	1/4" SHB	B				Non Sterile	1	10	02
						3/4" Sanitary Flange	S	3/4" Sanitary Flange*	S							
AseptiPrime KS (0.5µm optimized pre-filter)	VKX7												EO Sterile	2	100	04

\*In vented AseptiPrime KS 3/4" Sanitary Flange is available as outlet only

**Example:**

VKX7	10	36	S	S	X	X	1	04
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**Example for Non Sterile:** VKX71036SSXX104

**Example for EO Sterile:** VKX71036SSXX204