

ClariPro GK hydrophilic PES membrane large capsule filters are ready to use, disposable filtration devices. These are specially designed filters incorporating a microglassfiber upstream layer and a downstream PES membrane final layer and are used as pre-filters in biopharmaceuticals process development as well as manufacturing process for difficult to filter solutions.

The microglass fiber layer offers high dirt holding capacity and efficient retention of colloidal particles to give clear downstream in case of difficult to filter turbid solutions. The downstream PES membrane offers absolute retention, and low protein binding along with high flow rates.

### Quality Assurance

These filter devices are manufactured in class 10,000 clean rooms under ISO 9001 certified quality management systems and are deeply validated to meet compendia and regulatory requirements.

### Applications

- Precipitate removal post viral inactivation
- Pre-filtration of serum solutions
- Clarification of cell harvest supernatants
- Polishing of turbid solutions

### Specifications

#### Pore Size

0.1 μm, 0.2 μm and 0.5 μm

#### Materials of Construction

Membrane	Hydrophilic Polyethersulfone
Pre-filter	Microglassfiber
Support layer	Polyester
Body and Core	Polypropylene

#### Maximum Operating Temperature

80 °C @ ≤30 psi (2 Kg/cm<sup>2</sup>)

#### Maximum Differential Pressure

60 psi (4 Kg/cm<sup>2</sup>) @ 30 °C

#### Sterilization

**By Gas:** Sterilizable by Ethylene Oxide

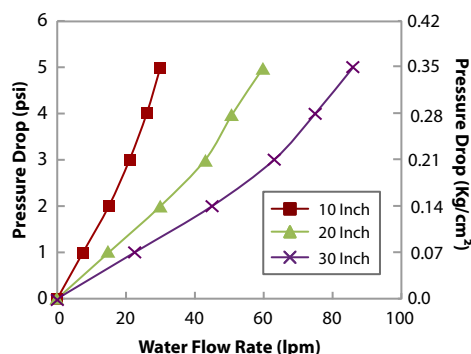
**By Autoclave:** Autoclavable at 125°C for 30 minutes, 25 cycles. Cannot be in-line steam sterilized

#### Toxicity

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

#### Typical Water Flow Rates

ClariPro GK - 0.5 μm



#### Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test

#### 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

#### Indirect Food Additives

All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520

#### Extractables with WFI

Passes NVR test as per USP <661>

#### Oxidizable Substances

Passes test as per USP <1231>

#### Bioburden

Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 117371

### Ordering Information

Type	Size		Pore Size		Inlet /Outlet		X	Inline/T-line		Sterility		Pack Size	
	Code	Length & EFA	Code	Code	Code	Code		Code	Code	Code	Code	Code	
ClariPro GK	LGKX	5" (2500 cm <sup>2</sup> )*	53	0.1 μm	36	1 1/2" Sanitary Flange	E	Inline	X	Non-Sterile	1	1	01
		10" (5000 cm <sup>2</sup> )	54	0.2 μm	01	Single Step 1/2" Hose Barb	Q	T-line***	T	EO Sterile	2		
		20" (10000 cm <sup>2</sup> )	55	0.5 μm	04	3/8" Hose Barb	I						
		30" (15000 cm <sup>2</sup> )	56			1" Hose Barb**	Z						

EFA: Effective Filtration Area

\*5" capsule filters are available as inline filter only

\*\*1" Hose Barb is not available in 5" capsule filters

\*\*\*T-line is not available in 5" Capsule Filter

\*\*\*T-line Capsule filters are available with 1 1/2" Sanitary Flange I/O Connection Only

#### Example

LGKX	54	04	EE	X	T	1	01
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