

Polyethersulfone Membrane Bioburden Reduction Large Capsule Filters

The BioPro KS capsule filters are designed for protecting your critical and high value downstream systems.

These help in significant reduction of bioburden and complete removal of particulate contamination and are ideal for applications which do not require sterilization but where reduction in bio load in the process fluid is the objective.

These improve the process efficiency reducing filter sizing prolonging life of expensive sterilizing filters.

Special Features

- Validated for high bio-burden reduction
- High flow rates
- High throughput
- Low protein binding
- No media migrating
- Biologically inert
- Easy installation

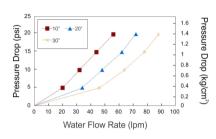
Applications

- Clarification of cell harvest
- Buffer filtration
- In process protein filtration
- Prefiltration to sterile filtration
- Prefiltration to virus filtration

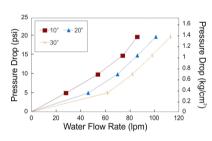
Ordering Information

Typical Water Flow Rates

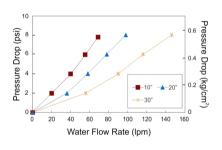
0.1μm *BioPro KS*



0.2um BioPro KS



0.45µm BioPro KS



Specifications

Integrity Test (Bubble Point) Specifications (water wetted) 0.1 \mum: \geq 40psi, **0.2\mum:** \geq 30psi

Bacterial Retention

0.1um: LRV> 6 for *B.diminuta* ATCC

19146 per cm² of filter area

0.2μm: LRV> 5 for *B.diminuta* ATCC 19146 per cm² of filter area

Material of Construction

Housing – Polypropylene Filter - Polyethersulfone Drainage Layer-Polyester

Maximum Differential Pressure

 \leq 4 Kg/cm² @ 30° C

Maximum Operating Temperature

80° C @ < 2 Kg/cm²

Sterilization

| Autoclave | Autoclavable at 125° C for 30 minutes for 25 cycles. Cannot be in-line steam sterilized. | | | | |
|-----------|------------------------------------------------------------------------------------------|--|--|--|--|
| Gas | Sterilization by Ethylene Oxide | | | | |

Oxidizable Matter

Passes test as per USP <1231>

Extractables

Passes NVR test as per USP <661>

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by LAL Test as per USP <85>

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

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

Cytotoxicity: Passes Biological Reactivity Tests, In Vitro, USP <87> for Cytotoxicity

Indirect Food Additives:

Passes as per USFDA 21 CFR 177.1520

| Туре | | Size | | Pore Size | | Inlet/outlet | |
|-----------|------|------|------|-----------|------|----------------------------|------|
| | Code | | Code | | Code | | Code |
| BioPro KS | LBKS | 5"* | 53 | 0.1µm | 36 | Single Step 1/2" hose barb | Q |
| | | 10" | 54 | 0.2µm | 01 | 1½" Sanitary Flange | Е |
| | | 20" | 55 | 0.45µm | 02 | 3/4" Sanitary Flange*** | S |
| | | 30" | 56 | | | 3/8" Hose Barb | 1 |
| | | , | | - | | 1" Hose Barb | Z |

| Inline/T-Line | | Sterili | Pack size | | |
|---------------|------|-------------|-----------|---|------|
| | code | | code | | code |
| Inline | Х | Non Sterile | 1 | 1 | 01 |
| T-Line** | Т | EO Sterile | 2 | | |

*5" Capsule Filters are not available with T-Line

**T-Line Capsule filters are available with 1½" Sanitary Flange only

***3/4" Sanitary Flange is available only in 5" and 10" capsule filters

| LBKS | 56 | 01 | QQ | Χ | Χ | 1 | 01 |
|------|----|----|----|---|---|---|----|

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