



BioPro[®] KSO-γ **Polyethersulfone Membrane** **Bioburden Reduction Capsule Filters**

Data Sheet

Biopharmaceutical processing requires microfiltration at multiple stages to meet specific process requirements.

Process managers are continuously looking for fast and efficient microfiltration solutions for buffer filtration, a key requirement for downstream chromatography applications. Some key concerns are:

- Absolute retentions of particulate matter and bioburden reduction to protect high cost downstream process steps such as.
- Minimizing protein losses due to adsorption to improve overall product yields
- High throughputs to achieve process economy
- Choice of filter end connections for easy and reliable quick connections

mdi BioPro[®] KSO-γ capsule filters are designed for protecting your critical and high value downstream systems such as TFF, ion chromatography, elution chromatography and affinity chromatography.

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 by reducing filter sizing and prolonging life of expensive sterilizing filters.

These filter devices are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as high retention efficiency, very high protein recoveries, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

BioPro[®] KSO- γ

Bioburden Reduction Capsule Filters

Datasheet

BioPro[®] KSO- γ capsule filters use **mdi** PES membrane in Polypropylene housing. No adhesives or glue are used in the manufacturing process and all bonding is done by heat welding.

The products are deeply validated for use in Biopharmaceutical applications and specially recommended for single use systems. BioPro[®] KSO- γ are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities. Packaging is done in double polybags for direct irradiation by gamma or for convenience of taking BioPro[®] in clean areas for making disposable assemblies for subsequent sterilization.

Applications

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

Key Features

- Validated for high bioburden
- High throughput
- 100% integrity tested
- Low protein binding
- High flow rates
- No media migrating
- Biologically Inert
- Easy Installation
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Widest range of end connections
- Products available for total scalability from a few ml to thousands of liters
- Total traceability through unique serial number for each filter
- Individual certificate of quality for each device
- Sterilizable by Gamma irradiation

Quality Assurance

mdi quality management system emphasizes on quality by design rather than by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

Certificate of Quality

Each capsule filter is accompanied by individual certificate of quality to ensure traceable documentation at user's end. It certifies the product compliance to various regulatory as well as user requirements.

100% Integrity Tested

Each *BioPro*® KSO- γ is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Flow Rate

Each lot is tested for clean water flow rates to ensure that flow rates are within the specifications.

Pressure, Temperature Endurance

BioPro® KSO- γ filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

These filters are also validated for high burst pressure to ensure user safety in case of inadvertent pressure build-up.

Extractables

Extractables/leachables from filters, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

BioPro® KSO- γ filters are validated to exhibit low extractables under harsh extraction conditions.

Bioburden Testing

Device bioburden is tested as per ISO 11737-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>.

Total Traceability

BioPro® KSO- γ filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

Packaging Integrity

BioPro® KSO- γ filters are fitted with vent caps and are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room assembly or process areas.

Other Regulatory Compliance

- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics
- Complete filter devices tested for cytotoxicity as per Biological Reactivity Tests, In-vitro, USP <87>

Widest Range of End Connections

Biopharmaceutical processes involve transfer of high value fluids through multiple process steps. Making high quality, reliable, flexible and functionally convenient connectivity with filters is of utmost value to the bio-processors.

mdi BioPro® KSO-γ filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand prevalent sterilization methods including gamma irradiation.



1/2" HB



1/2" Single Stepped
Hose Barb



1/4" MNPT



1/4" SHB



Quick Connector



Male Luer Slip



3/8" Hose Barb



Female Luer Lock



1 1/2" Sanitary Flange



3/4" Sanitary Flange



1/2" MNPT



1" Hose Barb

Variety of end connections

Customized Connectivity

mdi BioPro® KSO-γ filters are available in a wide range of end connections and are also customized to offer different inlet-outlet combinations to meet the unique connectivity needs in biopharmaceutical process assemblies where, for example, stainless steel components with sanitary flange connections are sometimes required to be connected to single use disposable systems through quick-connectors or hose barb connections.



1 1/2" Sanitary Flange
to 1/2" Barb Hose



1 1/2" Sanitary Flange
to 3/4" Sanitary Flange



BioPro® with HighSecurity
1/2" hose barb connection

Linear Upscaling from Process Development to Production

Datasheet

mdi offers a wide range of *BioPro*® KSO-γ filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process are identical for all filter devices starting from 250 cm² to 18000 cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *BioPro*® KSO-γ filters there by reducing the additional validation cost and time.



BioPro® KSO-γ
1", 250cm²



BioPro® KSO-γ
2", 500cm²



BioPro® KSO-γ
5", 1000cm²



BioPro® KSO-γ
8", 2000cm²



BioPro® KSO-γ
10", 6000cm²



BioPro® KSO-γ
20", 12000cm²



BioPro® KSO-γ
30", 18000cm²

| Filter Devices | EFA* (Nominal) | Hold up Volume |
|---------------------------|----------------------|----------------|
| <i>BioPro</i> ® KSO-γ 1" | 250cm ² | < 5ml |
| <i>BioPro</i> ® KSO-γ 2" | 500cm ² | < 25ml |
| <i>BioPro</i> ® KSO-γ 5" | 1000cm ² | < 45ml |
| <i>BioPro</i> ® KSO-γ 8" | 2000cm ² | < 60ml |
| <i>BioPro</i> ® KSO-γ 5" | 3000cm ² | < 80ml |
| <i>BioPro</i> ® KSO-γ 10" | 6000cm ² | < 150ml |
| <i>BioPro</i> ® KSO-γ 20" | 12000cm ² | < 250ml |
| <i>BioPro</i> ® KSO-γ 30" | 18000cm ² | < 350ml |

*EFA: Effective Filtration Area

Specifications

Small Capsule Filters

Datasheet

Construction

| | |
|----------------|-----------------|
| Membrane | Hydrophilic PES |
| Support Layers | Polypropylene |
| Plastic parts | Polypropylene |

Integrity Testing/ Retention

| | |
|---------------------|--|
| Bubble Point | 0.1µm: ≥ 40 psi (2.8 Kg/cm ²) with Water 0.2µm: ≥ 30 psi (2.1 Kg/cm ²) with Water |
| Microbial Retention | 0.1µm: LRV >6 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ² 0.2µm: LRV >5 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ² |

Size

| Size | 1" | 2" | 5" | 8" |
|---------------------------------------|--------------------------------------|--------------------|---------------------|----------------------|
| Effective Filtration Area (Nominal) | 250cm ² | 500cm ² | 1000cm ² | 2000 cm ² |
| Operational Radius (with Vent/ Drain) | 40 mm | 65 mm | 65 mm | 65 mm |
| Vent and Drain | ¼" Hose Barb with Silicone "O" rings | | | |

Operational

| | |
|------------------------------------|---|
| Max. Operating Temperature | 80 °C @ < 30 psi (2 Kg/cm ²) |
| Max. Differential Pressure | 60 psi (4 Kg/cm ²) @ 30 °C |
| Sterilization by Gamma Irradiation | Gamma Irradiatable up to 50 kGy. These filters must not be autoclaved or in-line steam sterilized. |
| Shelf Life | 2 years after Gamma Sterilization |

Assurance

| | |
|---------------------------|---|
| Toxicity | Passes Biological Reactivity Tests, In vivo, as per USP <88> for Class VI plastics |
| Cytotoxicity | Passes Biological Reactivity Tests, In vitro, USP <87> for cytotoxicity |
| Bacterial Endotoxin | Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85> |
| Non Fiber Releasing | Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release |
| TOC and Conductivity | Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 3 liters of WFI flush |
| pH Compatibility | Compatible with pH range of 1 - 14 |
| Extractables with WFI | Passes NVR test as per USP <661> |
| Indirect Food Additives | Comply with USFDA 21 CFR Part 177.1520 |
| Oxidizable Substances | Passes test as per USP <1231> |
| Quality Management System | ISO-9001 Certified |
| USFDA | DMF No. 015554 |

Specifications

Large Capsule Filters

Datasheet

Construction

| | |
|----------------|-----------------|
| Membrane | Hydrophilic PES |
| Support Layers | Polypropylene |
| Plastic parts | Polypropylene |

Integrity Testing/ Retention

| | |
|---------------------|--|
| Bubble Point | 0.1µm: ≥ 40 psi (2.8 Kg/cm ²) with Water 0.2µm: ≥ 30 psi (2.1 Kg/cm ²) with Water |
| Microbial Retention | 0.1µm: LRV >6 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ² 0.2µm: LRV >5 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ² |

Size

| Size | 5" | 10" | 20" | 30" |
|--------------------------------------|--------------------------------------|----------------------|-----------------------|-----------------------|
| Effective Filtration Area (Nominal) | 3000 cm ² | 6000 cm ² | 10000 cm ² | 18000 cm ² |
| Operational Radius (with Vent/Drain) | 78 mm | 78 mm | 78 mm | 78 mm |
| Vent and Drain | ¼" Hose Barb with Silicone "O" rings | | | |

Operational

| | |
|------------------------------------|---|
| Max. Operating Temperature | 80 °C @ < 30 psi (2 Kg/cm ²) |
| Max. Differential Pressure | 60 psi (4 Kg/cm ²) @ 30 °C |
| Sterilization by Gamma Irradiation | Gamma Irradiatable up to 50 kGy. These filters must not be autoclaved or in-line steam sterilized. |
| Shelf Life | 2 years after Gamma Sterilization |

Assurance

| | |
|---------------------------|---|
| Toxicity | Passes Biological Reactivity Tests, In vivo, as per USP <88> for Class VI plastics |
| Cytotoxicity | Passes Biological Reactivity Tests, In vitro, USP <87> for cytotoxicity |
| Bacterial Endotoxin | Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85> |
| Non Fiber Releasing | Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release |
| TOC and Conductivity | Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 3 liters of WFI flush |
| pH Compatibility | Compatible with pH range of 1 - 14 |
| Extractables with WFI | Passes NVR test as per USP <661> |
| Indirect Food Additives | Comply with USFDA 21 CFR Part 177.1520 |
| Oxidizable Substances | Passes test as per USP <1231> |
| Quality Management System | ISO-9001 Certified |
| USFDA | DMF No. 015554 |

Dimensions

Small Capsule Filters

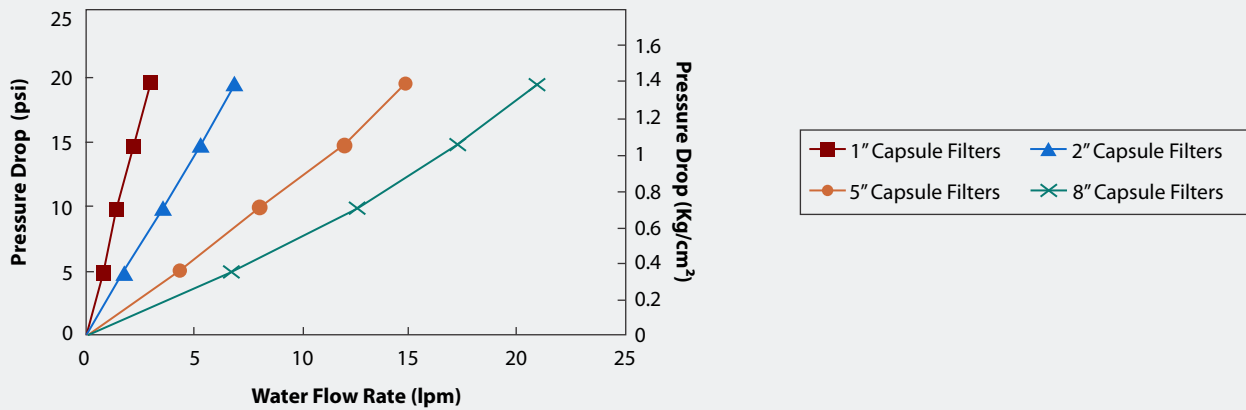
| Size | 1" | 2" | 5" | 8" |
|---|--------------------------|------------|-------------|-------------|
| Effective Filtration Area (cm²) | 250 | 500 | 1000 | 2000 |
| End Connections | End to End Length | | | |
| ¼" SHB I/O | 94 mm | 122 mm | 172 mm | 223 mm |
| ¾" Sanitary Flange Inlet I/O | 85 mm | 104 mm | 155 mm | 206 mm |
| 1½" Sanitary Flange I/O | 92 mm | 112 mm | 165 mm | 216 mm |
| ½" Hose Barb I/O | 90 mm | 112 mm | 162 mm | 214 mm |
| ½" Single Step Hose Barb I/O | - | 115 mm | 165 mm | 218 mm |
| 1½" Sanitary Flange Inlet ½" Hose Barb Outlet | - | 112 mm | 165 mm | 216 mm |
| Operational Radius | 40 mm | 65 mm | 65 mm | 65 mm |

Large Capsule Filters

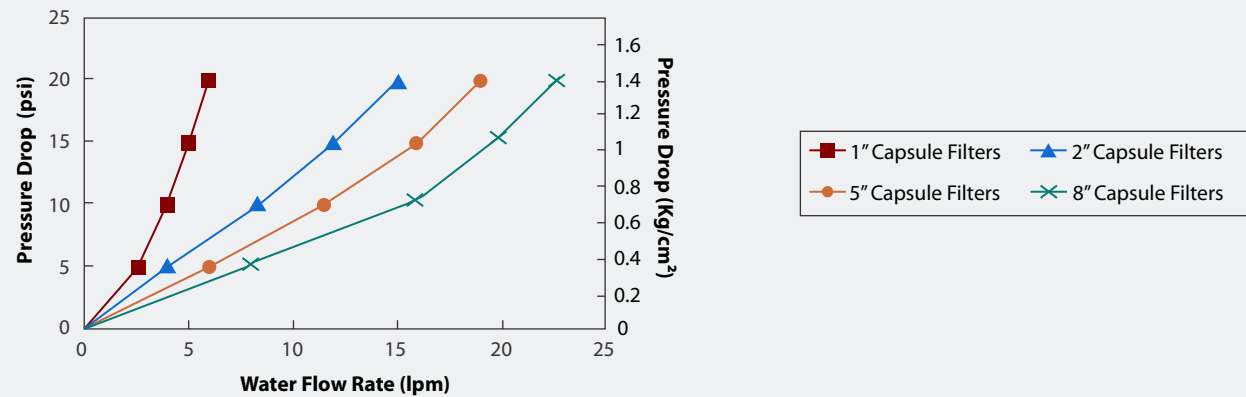
| Size | 5" | 10" | 20" | 30" |
|---|--------------------------|-------------|--------------|--------------|
| Effective Filtration Area (cm²) | 3000 | 6000 | 12000 | 18000 |
| End Connections | End to End Length | | | |
| 1½" Sanitary Flange I/O | 205 mm | 326 mm | 605 mm | 865 mm |
| ½" Single Step Hose Barb I/O | 218 mm | 332 mm | 628 mm | 888 mm |
| 1½" Sanitary Flange Inlet ½" Hose Barb Outlet | 212 mm | 332 mm | 618 mm | 878 mm |
| 3/8" Hose Barb I/O | 211 mm | 332 mm | 634 mm | 885 mm |
| ¾" Sanitary Flange I/O | 214 mm | 335 mm | x | x |
| Operational Radius | 78 mm | 78 mm | 78 mm | 78 mm |

Typical Water Flow Rates

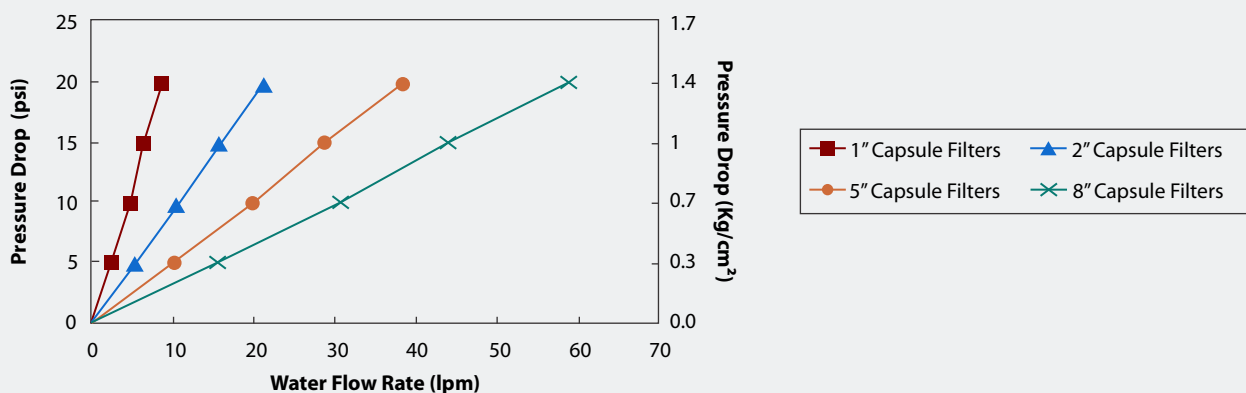
0.1µm BioPro® KSO-γ, Small Capsule Filter



0.2µm BioPro® KSO-γ, Small Capsule Filter

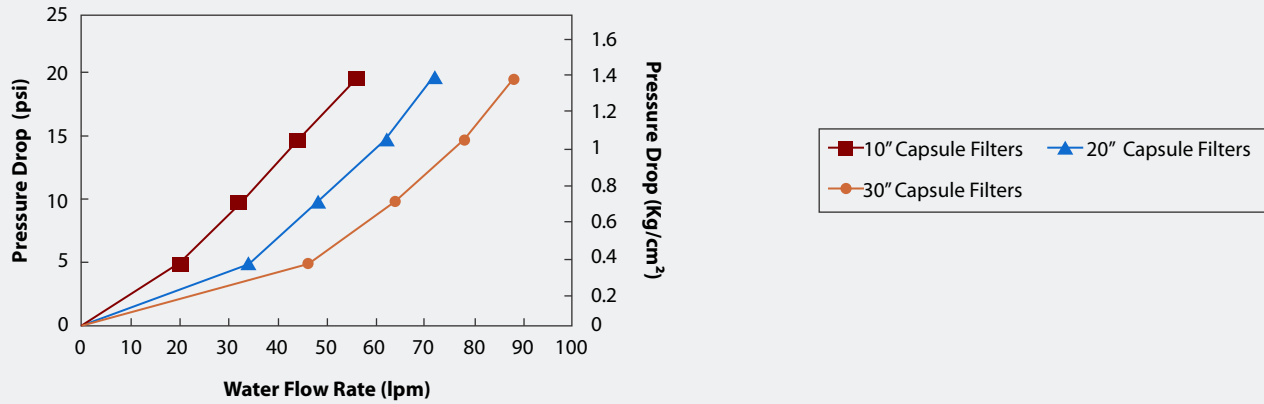


0.45µm BioPro® KSO-γ, Small Capsule Filter

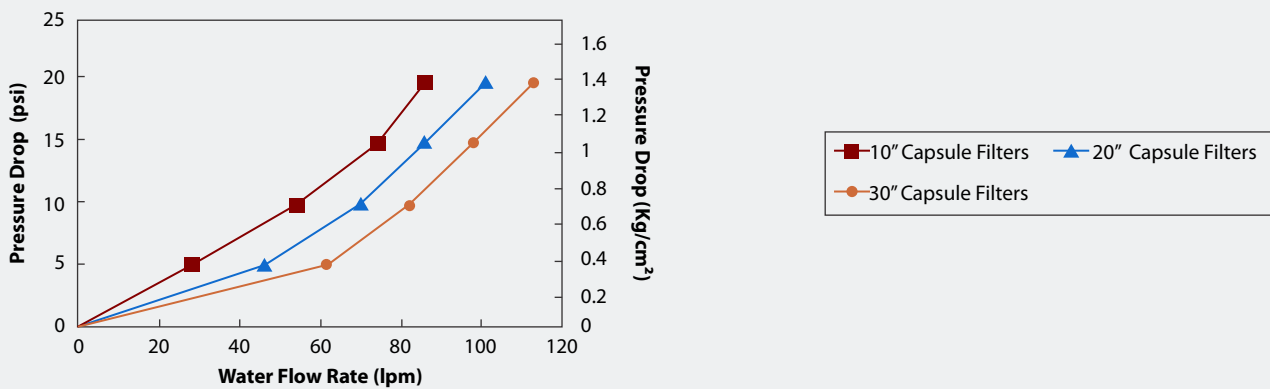


Typical Water Flow Rates

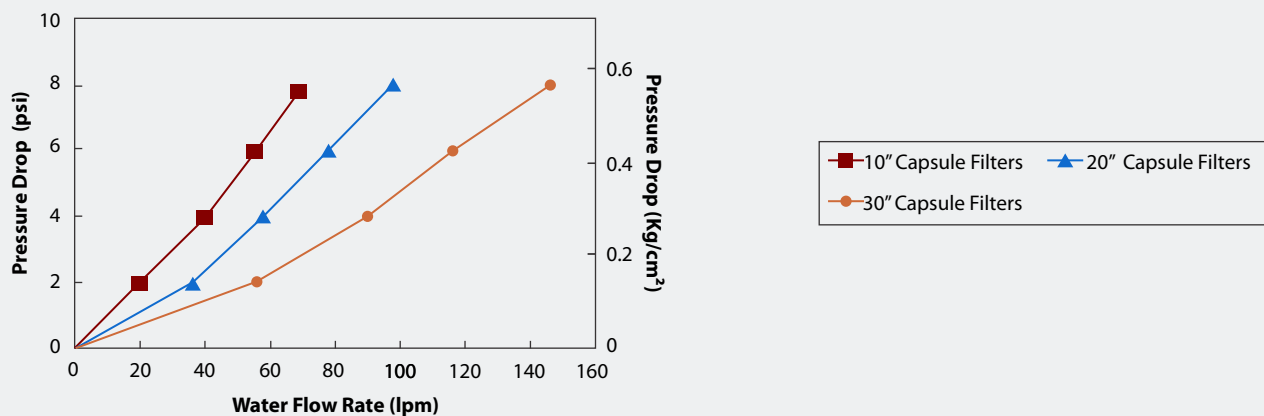
0.1µm BioPro® KSO-γ, Large Capsule Filter



0.2µm BioPro® KSO-γ, Large Capsule Filter



0.45µm BioPro® KSO-γ, Large Capsule Filter



Ordering Information Small Capsule Filters

Datasheet

BioPro KSO-γ PES Membrane Small Capsule filter

| Type | | Size | | Pore Size | | Inlet/Outlet | | Radiation Sterilizable | | Bell | | Sterility | | Pack Size | | |
|--------------|------|------|------|-----------|------|-----------------------------|------|------------------------|------|-----------------|------|---------------|------|-----------|------|--|
| | Code | | Code | | Code | | Code | | Code | | Code | | Code | | Code | |
| BioPro KSO-γ | DBKO | 1" | 51 | 0.1µm | 36 | ¼" SHB | A | Yes | R | Yes** | B | Non Sterile | 1 | 1 | 01 | |
| | | 2" | 52 | 0.2µm | 01 | ¼" MNPT (18 TPI) | B | No* | X | No Bell | X | Gamma Sterile | 3 | | | |
| | | 5" | 53 | 0.45µm | 02 | ¼" BSP (19 TPI) | M | | | Bell with cover | C | | | | | |
| | | 8" | 57 | | | ¼" BSP (19 TPI) with O-ring | P | | | | | | | | | |
| | | | | | | ¼" BSP | F | | | | | | | | | |
| | | | | | | ½" MNPT | C | | | | | | | | | |
| | | | | | | ½" Hose Barb | D | | | | | | | | | |
| | | | | | | 1½" Sanitary Flange | E | | | | | | | | | |
| | | | | | | ¾" Sanitary Flange | S | | | | | | | | | |
| | | | | | | Quick Connector | J | | | | | | | | | |
| | | | | | | ½" Single Step Hose Barb | Q | | | | | | | | | |
| | | | | | | Female Luer Lock | U | | | | | | | | | |
| | | | | | | Male Luer Slip | W | | | | | | | | | |
| | | | | | | ⅜" Hose Barb | N | | | | | | | | | |
| | | | | | | ⅝" Hose Barb | I | | | | | | | | | |

Example:

| | | | | | | | |
|------|----|----|----|---|---|---|----|
| DBKO | 57 | 01 | DD | R | X | 1 | 01 |
|------|----|----|----|---|---|---|----|

* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: DBKO5101QQRX101

Example for gamma Sterile: DBKO5101QQXX301

** Bell is available with

½" Hose Barb outlet connections in 1", 2", 5" and 8" capsule filters

¼" SHB outlet connection in 1" capsule filters only

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

| Inlet/Outlet | Size/Length | | | | Bell at outlet Available with (Size/outlet) |
|-----------------------------|-------------|----|-------------|----|---|
| | 1" | 2" | 5" | 8" | |
| ¼" Stepped Hose Barb | √ | √ | √ | √ | 1" / ¼" SHB |
| ½" Single Step Hose Barb | X | √ | √ | √ | 1", 2", 5", 8" / ½" HB |
| ½" Hose Barb | √ | √ | √ | √ | |
| 1½" Sanitary Flange | √ | √ | √ | √ | |
| ¾" Sanitary Flange | √ | √ | √ | √ | |
| Quick Connector | √ | √ | √ | √ | |
| ½" MNPT | X | √ | √ | √ | |
| ¼" MNPT (18TPI) | √ | √ | √ | √ | |
| ¼" BSP (19 TPI) | Inlet Only | X | X | X | |
| ¼" BSP (19 TPI) with O-ring | Inlet Only | X | X | X | |
| ¼" BSP | Inlet Only | √ | √ | √ | |
| Female Luer Lock | √ | √ | √ | √ | |
| Male Luer Slip | Outlet Only | X | X | X | |
| ⅜" Hose Barb | √ | √ | Outlet Only | X | |
| ⅝" Hose Barb | X | √ | √ | √ | |

Ordering Information Large Capsule Filters

Datasheet

BioPro KSO-γ PES Membrane Large Capsule filter

| Type | | Size | | Pore Size | | Inlet/Outlet | | Radiation Sterilizable | | Inline/T-Line | | Sterility | | Pack Size | |
|--------------|------|------|------|--------------|------|--------------------------|------|------------------------|------|---------------|------|---------------|------|-----------|------|
| | Code | | Code | | Code | | Code | | Code | | Code | | Code | | Code |
| BioPro KSO-γ | LBKO | 5" | 53 | 0.1μm | 36 | ½" Single Step Hose Barb | Q | Yes | R | Inline | X | Non Sterile | 1 | 1 | 01 |
| | | 10" | 54 | 0.2μm | 01 | 1½" Sanitary Flange | E | No* | X | T-Line** | T | Gamma Sterile | 3 | | |
| | | 20" | 55 | 0.45μm | 02 | ¾" Sanitary Flange | S | | | | | | | | |
| | | 30" | 56 | | | ¾" Hose Barb | I | | | | | | | | |
| | | | | 1" Hose Barb | Z | | | | | | | | | | |

Example:

| | | | | | | | |
|------|----|----|----|---|---|---|----|
| LBKO | 54 | 01 | EE | R | T | 1 | 01 |
|------|----|----|----|---|---|---|----|

* Gamma irradiated filters can not be gamma sterilized again

Example for Non Sterile: LBKO5301QQRX101

Example for gamma Sterile: LBKO5301QQXX301

**T-line is not available in 5" Capsule filter

**T-line Capsule Filter are available with 1½" Sanitary Flange I/O Connections Only

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

| Inlet/Outlet | Inline | | | | T-Line | | |
|--------------------------|--------|-----|-----|-----|--------|-----|-----|
| | 5" | 10" | 20" | 30" | 10" | 20" | 30" |
| ½" Single Step Hose Barb | √ | √ | √ | √ | X | X | X |
| 1½" Sanitary Flange | √ | √ | √ | √ | √ | √ | √ |
| ¾" Sanitary Flange | √ | √ | X | X | X | X | X |
| ¾" Hose Barb | √ | √ | √ | √ | X | X | X |
| 1" Hose Barb | X | √ | √ | √ | X | X | X |

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