

Polyethersulfone Membrane Bioburden Reduction Small Capsule Filters

The *BioPro KSO* is designed for protecting your critical and high value downstream systems.

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

It improves the process efficiency by reducing filter sizing and prolonging life of expensive sterilizing filters.

These filters provide easy scalability from process development labs to actual manufacturing processes.

Special Features

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

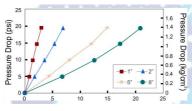
Applications

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

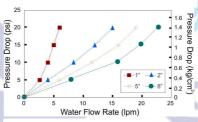


Typical Water Flow Rates

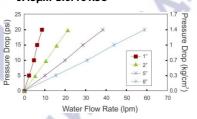
0.1μm BioPro KSO



0.2μm BioPro KSO



0.45μm BioPro KSO



Specifications

Integrity Test (Bubble Point)
Specifications (water wetted)
0.1µm: ≥ 40psi, 0.2µm: ≥ 30psi

Bacterial Retention

0.1μm: 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-Polypropylene

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.
Autociave	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

Indirect Food Additives:

Passes as per USFDA 21 CFR 177.1520

pH Compatibility:

Compatible with 1-14 pH

Ordering Information

Туре		Si	ize	Pore	Size	I/O Connection		Х	х	Sterility		Pack Size		
	Code		Code		Code		Code				Code	Qty	Code	
BioPro KSO	DBKO	1″	51	0.1μm	36	1/4" SHB A				Non Sterile	1	1	01	
		2″	52	0.2µm	01	½"Hose Barb	D			EO Sterile	2			
		5″	53	0.45μm	02	1½" Sanitary Flange	E							
		8″	57			¾" Sanitary Flange	S	*Single Step ½"Hose Barb and 3/8" hose barb end connection					tions are	
						Quick Connector	J			1" capsule filters				
						Single Step ½"Hose Barb*	Q	**Female luer lock is available in 1" and 2" capsule filters only ***Male luer slip is available only in 1" capsule filter as outlet						
						Female Luer Lock**	U	IVIG	ie idei sii	p is available only iii i	capsule IIII	ei as outi	et .	
						Male Luer Slip***	W							
			3/16" Hose Barb N											
Example:						3/8" Hose Barb*								
DBKO 57 01 EE		EE		Χ	Х	1		(01					



Polyethersulfone Membrane Bioburden Reduction Large Capsule Filters

The *BioPro KSO* 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 by reducing filter sizing and 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

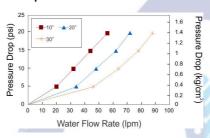
Applications

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

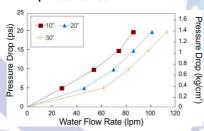
Hatter

Typical Water Flow Rates

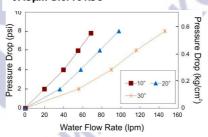
0.1μm BioPro KSO



0.2μm BioPro KSO



0.45µm BioPro KSO



Specifications

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

Bacterial Retention

0.1μm: 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-Polypropylene

Maximum Differential Pressure

 \leq 4 Kg/cm² @ 30° C

Maximum Operating Temperature 80° C @ < 2 Kg/cm²

Sterilization

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

Riosafety

Toxicity: Passes Bioreactivity test, *Invivo*, as per USP <88> for Class VI plastics

Indirect Food Additives:

Passes as per USFDA 21 CFR 177.1520

pH Compatibility:

Compatible with 1-14 pH

Ordering Information

Туре	,	S	Size	Pore	Size	Inlet/outlet	Х		
	Code		Code		Code		Code		
BioPro KSO	LBKO	5"	53	0.1µm	36	Single Step ½" hose barb	Q		lı
·		10"	54	0.2µm	01	1½" Sanitary Flange	E		T-
		20"	55	0.45µm	02	3/8" Hose Barb	- 1		
		30"	56			1" Hose Barb*	Z		ose b

X	Inline/I-	Line	Sterility	Pack size			
		code		code		code	
	Inline	Х	Non Sterile	1	1	01	
	T-Line**	T	EO Sterile	2			

- *1" hose barb connection is not available in 5" capsule filter
- **T-Line is not available in 5" capsule filters
- **T-Line Capsule filters are available with 1½" Sanitary Flange only

Example:							
LBKO	56	01	EE	Х	Х	1	01

Polyethersulfone Membrane

Bioburden Reduction Small Capsule Filters

The *BioPro KSO*-γ is designed for protecting your critical and high value downstream systems.

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

It improves the process efficiency by reducing filter sizing and prolonging life of expensive sterilizing filters.

These filters provide easy scalability from process development labs to actual manufacturing processes.

Special Features

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

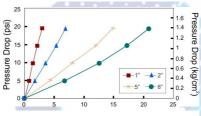
Applications

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

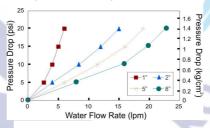
mdi secondo

Typical Water Flow Rates

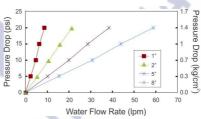
0.1μm BioPro KSO-y



0.2μm BioPro KSO-γ



0.45μm BioPro KSO-γ



Specifications

Integrity Test (Bubble Point)
Specifications (water wetted)
0.1 µm: > 40 psi, 0.2 µm: > 30 psi

Bacterial Retention

0.1μm: 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-Polyethylene

Maximum Differential Pressure

 \leq 4 Kg/cm² @ 30° C

Maximum Operating Temperature 80° C @ < 2 Kg/cm²

Sterilization

Irradiation	Gamma irradiatable upto 50 kGy
Autoclave	Autoclavable at 125° C for 30 minutes, 1 cycle after gamma Irradiation. Cannot be in-line steam sterilized.

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

Indirect Food Additives:

Passes as per USFDA 21 CFR 177.1520

pH Compatibility:

Compatible with 1-14 pH

Ordering Information

Sata Sheet

Туре		Size		Pore	Size	I/O Connection		Steriliz		Х	Sterility		Pacl	k Size	
	Code		Code		Code		Code		Code			Code	Qty	Code	
BioPro KSO	DBKO	1"	51	0.1µm	36	1/4" SHB	Α	Yes	R		Non Sterile	1	1	01	
		2"	52	0.2μm	01	1/2"Hose Barb	D	No****	Х		Gamma Sterile	3			
		5"	53	0.45µm	02	1½" Sanitary Flange	E								
		8"	57			¾" Sanitary Flange	S	*Single Step ½"Hose Barb and 3/8" hose barb end connections a available in 1" capsule filters					nnections are not		
						Quick Connector	J								
						Single Step ½"Hose Barb*	Q				ble in 1" and 2" capsul				
						Female Luer Lock**	U				e only in 1" capsule filt				
						Male Luer Slip***	W	****Gam	ıma Sterile	capsule	filters cannot be gam	ma Irradiat	ted again		
						3/16" Hose Barb	N								
Example:						3/8" Hose Barb*	I								
DBK	О.		57	0	1	EE		Х		Х	3			01	

DST DBKORXX1549C

mdi

BioPro KSO-γ Polyethersulfone Membrane

Bioburden Reduction Large Capsule Filters

The *BioPro KSO-y* 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 by reducing filter sizing and prolonging life of expensive sterilizing filters.

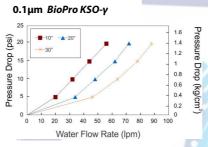
Special Features

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

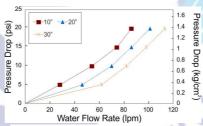
Applications

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

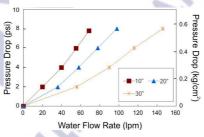
Typical Water flow rates



0.2μm *BioPro KSO-*γ



0.45μm BioPro KSO-γ



Specifications

1" Hose Barb'

Integrity Test (Bubble Point)
Specifications (water wetted)
0.1µm: ≥ 40psi, 0.2µm: ≥ 30psi

Bacterial Retention

0.1μm: 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-Polyethylene

Maximum Differential Pressure

 \leq 4 Kg/cm² @ 30° C

Maximum Operating Temperature 80° C @ < 2 Kg/cm²

Sterilization

Irradiation	Gamma irradiatable upto 50 kGy
Autoclave	Autoclavable at 125° C for 30 minutes, 1 cycle after gamma irradiation. Cannot be in-line steam sterilized.

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

Indirect Food Additives:

Passes as per USFDA 21 CFR 177.1520

pH Compatibility:

**Gamma sterile capsule filters cannot be gamma Irradiated again

***T-Line capsule filters are available with 11/2" sanitary flange only

***T-Line is not available in 5" capsule filters

Compatible with 1-14 pH

Ordering Information

Туре		Size		Pore Size		Inlet/outlet		Radiation S	terilizable	Inline/T	-Line	Sterility		Pac	k size
	Code		Code		Code		Code		Code		code		code		code
BioPro KSO LBKO		5"*	53	0.1µm	36	Single Step ½" hose barb	Q	Yes	R	Inline	Х	Non Sterile	1	1	01
		10"	54	0.2µm	01	1½" Sanitary Flange	Е	No**	Х	T-Line***	T	Gamma Sterile	3		
		20"	55	0.45µm	02	3/8" Hose Barb	I	*1" hose barb connection is not available in 5			5" capsule filter				

Evample :

- Lampie													
LBKO	56	01	QQ	R	X	1	01						

7