

Data Sheet

BioPro[®] KS

Bioburden Reduction Hydrophilic Polyethersulfone (PES) Membrane Cartridge Filters

mdi BioPro[®] KS PES membrane cartridge filters are designed for protecting your critical and high value downstream systems.

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



Applications

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

PES Membrane Cartridge Filters

mdi BioPro[®] KS cartridge filters are deeply validated for use in Biopharmaceutical applications. These filters are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities.

Key Features

- Validated for high bio-burden reduction
- High flow rates
- High throughput
- Low protein binding
- No media migrating
- Biologically inert
- Easy installation
- Pre-flushed to minimize particulate release after installation
- Non-toxic material of construction
- 100% integrity tested
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Unique identification number is laser etched on each filter
- Individual certificate of quality for each device
- Sterilizable by Autoclaving/Steaming in place (SIP)

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 cartridge 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.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each *BioPro*[®] *KS* 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.

Adsorption

BioPro[®] *KS* filters are validated for low protein binding to ensure minimal active ingredient losses when used for filtration of high value proteins.

Pressure, Temperature Endurance

BioPro[®] *KS* filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

Extractables

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

BioPro[®] *KS* filters are validated to exhibit low extractables under harsh extraction conditions.

Bioburden Testing

BioPro[®] *KS* 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[®] *KS* 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[®] *KS* filters are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room process areas.

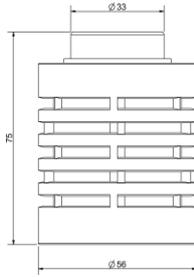
Other Regulatory Compliance

- 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>

Adapters and Dimensions

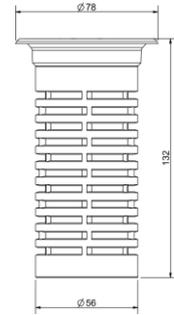
2.5" Mini Cartridge Filters

4463 Adapter (E0)



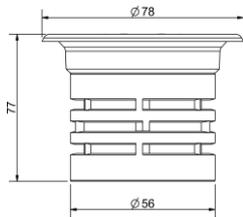
Total Length : 75 mm
Diameter : 56 mm

Seal-K Adapter (G0)



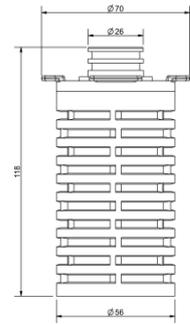
Total Length : 132 mm
Diameter : 56 mm

Seal-K Adapter (G0)



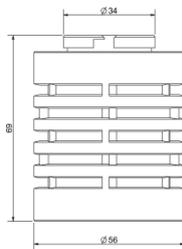
Total Length : 77 mm
Diameter : 56 mm

4440 Adapter (U0)



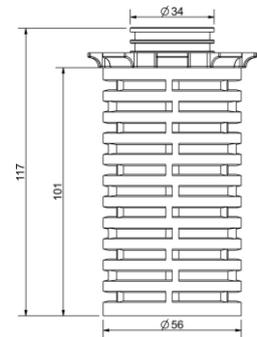
Total Length : 118 mm
Diameter : 56 mm

4463B Adapter (H0)



Total Length : 69 mm
Diameter : 56 mm

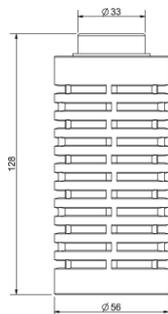
Seal-O Adapter (F0)



Total Length : 117 mm
Diameter : 56 mm

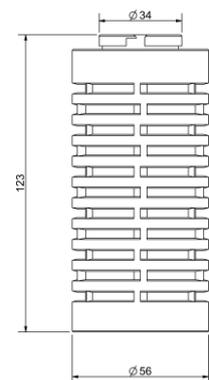
5" Mini Cartridge Filters

4463 Adapter (E0)



Total Length : 128 mm
Diameter : 56 mm

4463B Adapter (H0)

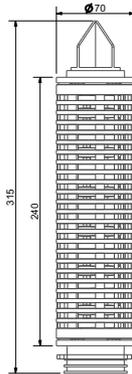


Total Length : 123 mm
Diameter : 56 mm

Adapters and Dimensions

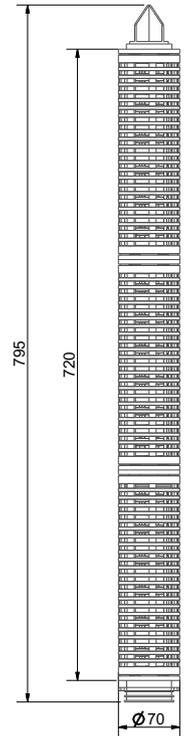
Standard Cartridge Filters

10" Cartridge Filter- 7P Adapter with Fin (A0)



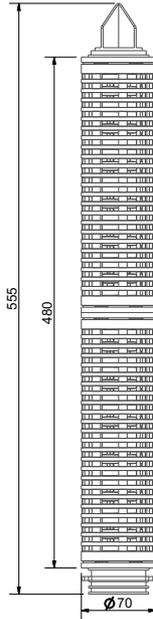
Total Length : 315 mm
Diameter : 70 mm

30" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 795 mm
Diameter : 70 mm

20" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 555 mm
Diameter : 70 mm

Adapter and Elastomers Availability Chart

Mini Cartridge Filters		
Adapters	2.5"	5"
4463	√	√
4463B	√	√
4440	√	√
Seal-K	√	√
Seal-O	X	√
Seal-M	√	√

Mini Cartridge Filters	
Adapters	Elastomer
	Silicone
4463	√
4463B	√
4440	√
Seal-K	X
Seal-O	√
Seal-M	√

Standard Cartridge Filters				
Adapters	5"	10"	20"	30"
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	X	√	√	√
'O'	X	√	√	√

Standard Cartridge Filters				
Adapters	Elastomers			
	Silicone	Viton	EPDM	FEP Encapsulated Viton
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	√	√	√	X
'O'	√	√	√	X

Linear Upscaling from Pilot Scale to Production Process

Scientists are concerned about filter fluid interaction impacting the stability, purity, strength etc. of the drug product, and they take a keen interest in filter selection at the formulation development stage itself. Although preliminary compatibility data support initial filter selection, for stability studies detailed filter validations are required to provide enough documented evidence to justify specific filter use.

A critical requirement that needs to be addressed at this stage is of scalability from pilot scale to full scale production processes.

mdi offers a wide range of *BioPro*[®] KS 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 3000 cm² to 18000cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *BioPro*[®] KS filters there by reducing the additional validation cost and time.



BioPro[®] KS, 2.5"
EFA: 1000 cm²



BioPro[®] KS, 5"
EFA: 2000 cm²



BioPro[®] KS, 5" Large
EFA: 3000 cm²



BioPro[®] KS, 10"
EFA: 6000 cm²



BioPro[®] KS, 20"
EFA: 12000 cm²



BioPro[®] KS, 30"
EFA: 18000 cm²

*EFA: Effective Filtration Area

Specifications

Mini Cartridge Filters

Datasheet

Construction

Membrane	Hydrophilic PES
Plastic Parts	Polypropylene
O rings	Silicone
	Viton
	EPDM
	FEP Encapsulated Viton

Integrity Testing / Retention

Pore Size	0.1µm	0.2µm
Bubble Point	≥ 40psi (2.8 Kg/cm ²) with Water	≥ 30psi (2.11Kg/cm ²) with Water
Microbial Retention	LRV >6 for <i>Brevundimonas diminuta</i> (ATCC 19146) per cm ²	LRV >5 for <i>Serratia marcescens</i> (ATCC 14756) per cm ²

Size

Size	2.5"	5"
Effective Filtration Area (Nominal)	1000cm ²	2000cm ²

Operational

Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm ²)
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C
Reverse Pressure	< 0.7 Kg/cm ² (10 psi) @ 25 °C
Sterilization	Autoclavable/In-line steam sterilizable at 121 °C for 30 minutes, 30 cycles

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>
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
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 specified WFI flush
Extractables with WFI	Passes NVR test as per USP <661>
Indirect Food Additives	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications

Standard Cartridge Filters

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Size

Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000cm ²	6000cm ²	12000cm ²	18000cm ²

Operational

Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm ²)
Max. Differential Pressure	50 psi (3.5 Kg/cm ²) @ 25 °C
Reverse Pressure	< 0.7 Kg/cm ² (10 psi) @ 25 °C
Sterilization	Autoclavable/In-line steam sterilizable at 121 °C for 30 minutes, 30 cycles

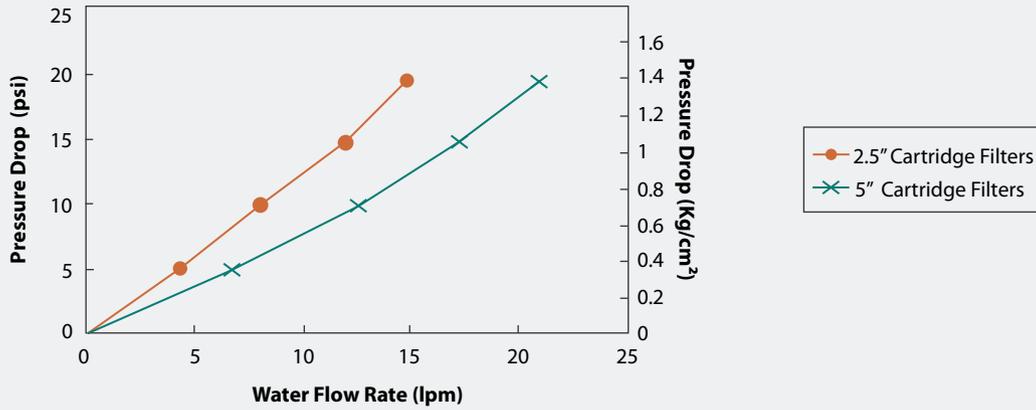
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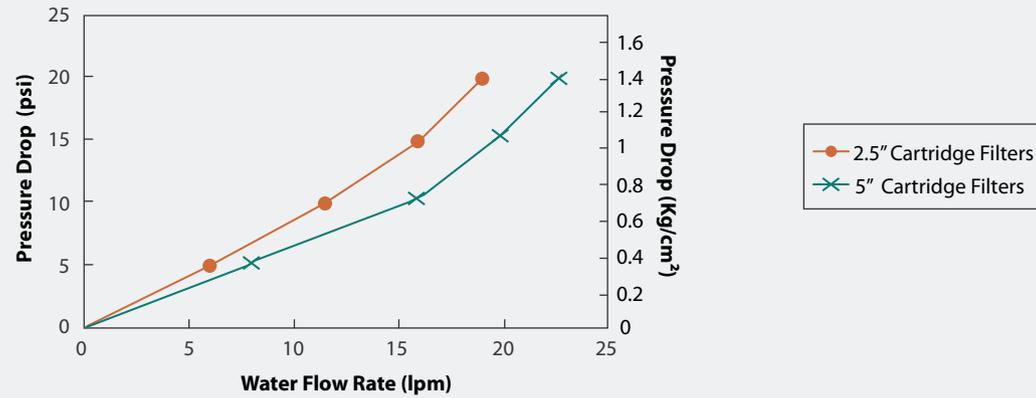
Typical Water Flow Rates Mini Cartridge Filters

Datasheet

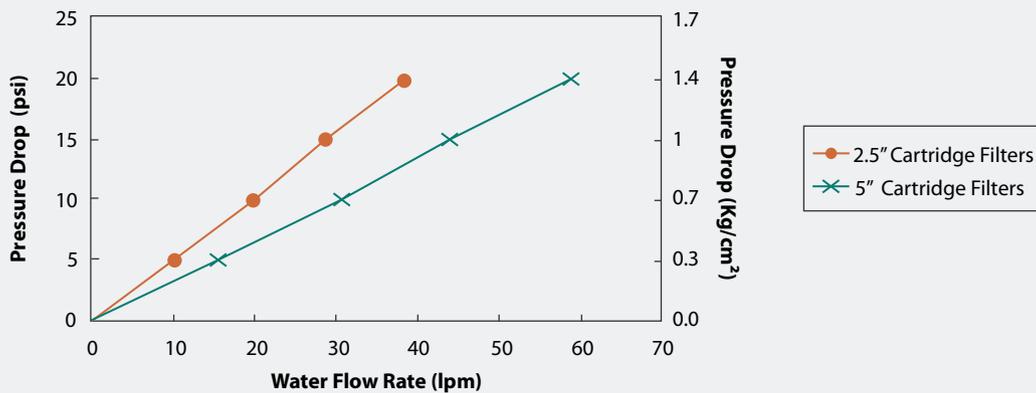
0.1µm BioPro® KS Cartridge Filters



0.2µm BioPro® KS Cartridge Filters

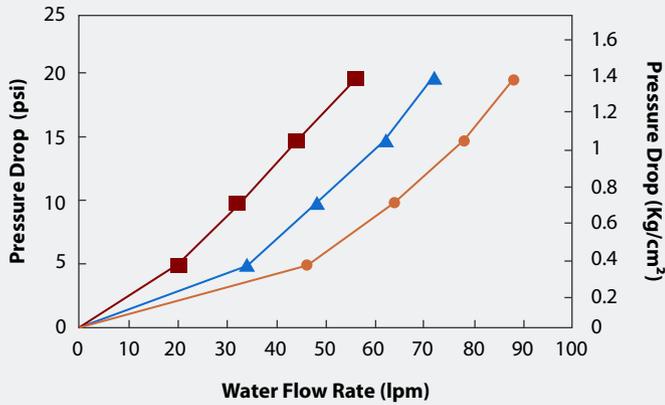


0.45µm BioPro® KS Cartridge Filters

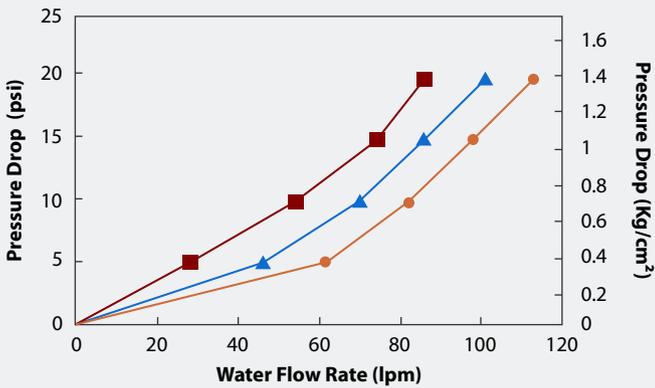


Typical Water Flow Rates Standard Cartridge Filters

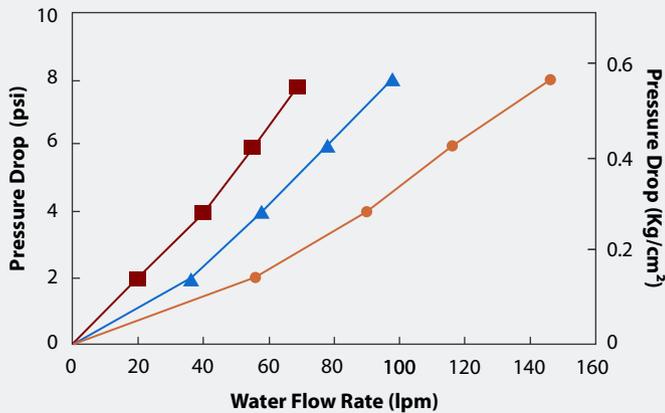
0.1µm BioPro® KS Cartridge Filters



0.2µm BioPro® KS Cartridge Filters



0.45µm BioPro® KS Cartridge Filters



Ordering Information

Datasheet

BioPro® KS PES Membrane Mini Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
BioPro® KS	CBKS	2.5"	50	0.1µm	36	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	0.2µm	01	4463B	H0						
				0.45µm	02	4440	U0						
						Seal-K	G0*						
						Seal-O	F0**						
						Seal-M	J0						

Example:

CBKS	50	36	E0	SS	1	01
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*G0 adapter code is not available with any elastomer. Please mention XX in place of elastomer code while ordering

**Adapter code F0 is available only in 5" cartridge filters.

BioPro® KS PES Membrane Standard Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
BioPro® KS	CBKS	5"*	53	0.1µm	36	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	0.2µm	01	7P without fin	A1	EPDM	SE				
		20"	55	0.45µm	02	28 with fin	C0	Viton	SV				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV**				

Example:

CBKS	54	01	A1	SS	1	01
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*Size 5" is available in Adapter Code A0 (7P) and A1 (7P without fin) only

**FV is available in adapter code A0 (7P) and A1 (7P without fin) only

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