

KrosFlo[®] EZ-Bags

Disposable & Customized
Fluid Containment Products
from 60 ml to 2,000 L



SPECTRUMLABS.COM
Leading the Way in Bioseparation

ISO
9001:2000
CERTIFIED

The KrosFlo® Family of Products

THE TOTAL SOLUTION FOR DOWN-STREAM BIOPROCESSING

Spectrum's KrosFlo® brand offers complete scalability of process filtration systems, disposable & steamable (SIP) hollow fiber filtration modules and process fluid containment products for the biopharmaceutical, diagnostic, medical and fluid processing industries. From drug discovery to full-scale production, KrosFlo® truly is *the Total Solution* for sterile & non-sterile fluid handling and processing.

KrosFlo® EZ-BAG PRODUCTS

Spectrum provides the full array of disposable products for complete containment and separation of process fluids ranging from 60 ml to 2,000 liters; including disposable KrosFlo® EZ-Bags (4 types), KrosFlo® EZ-Bag Liners (2 types), KrosFlo® EZ-Bag Manifolds, KrosFlo® EZ-Bag Containers and KrosFlo® EZ-Filtration Module Flow-paths.

KrosFlo® EZ-Bag Disposable Fluid Containment Products

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 - Cylindrical Tank Bags
 - Cubic Tank Bags
 - Container Tank Bags
 - Tank Liners
 - Multi-Bag Manifolds
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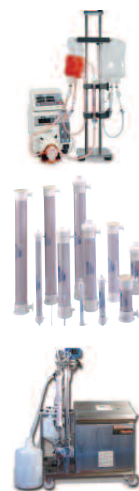
ADVANTAGES OF DISPOSABLE PROCESS FLUID CONTAINMENT

- Improved batch control
- No cross-contamination
- Lower production costs
- Less process down-time
- Quicker and easier set-up
- Easier and faster FDA validation

KrosFlo® EZ-Filtration Systems & Disposable Module Flow-paths

KrosFlo® Disposable & Re-usable Hollow Fiber Modules

KrosFlo® Systems for Tangential Flow Filtration



FILM TECHNOLOGY & QUALITY

The KrosFlo® EZ-Bag products are based on a core technology that produces a state-of-the-art synthetic film to meet the demands of the bioprocessing industry. This film used to make KrosFlo® brand bags is a multilayer laminate with excellent gas barrier characteristics; offers great strength and durability, yet is pliable and easy to handle. The robustness withstands rigorous use as well as irradiation. The following quality tests are performed during the manufacturing and assembly of the KrosFlo® brand bags.

In-Process Quality Testing

- 100% IPC Leak Tests
- 100% IPC Seal Strength Tests of the Film
- 100% IPC Seal Strength Tests of the Ports and Mounted Components
- 100% Visual Control of Finished Products
- Process Parameter Exposure Criteria (temperature, pressure & time)

FILM VALIDATION & BIOCOMPATIBILITY TESTS

All synthetic film products are manufactured in full compliance to cGMP guidelines in a Class 10,000 cleanroom. The manufacturing facility meets all requirements for FDA & EMEA, ISO 14644-1, Class 4 Certification. The film and the KrosFlo® brand bags have passed an extensive validation study. The complete, comprehensive regulatory and validation file is available upon request.

Physical Tests

- O₂ Gas Transfer (ASTM D-3985)
- CO₂ Gas Transfer (ASTM D-1434)
- H₂O Vapor Transmission (ASTM E-96-80)
- Elongation & Tensile Strength Tests
- 100% Modulus Test (ASTM D-638)
- Tear Resistance Test (ASTM D-1004)
- Implantation Test (ISO 10993-6)
- Cytotoxicity Test (ISO 10993-5)
- Sensitization Test (ISO 10993-10)
- Irritation Test (ISO 10933-10)
- Acute System Toxicity Test (ISO10993-11)
- Kinetic LAL (USP 26, NF21, 2003 <85>)

USP Chemicals

- Material Characterization Study
- USP 26, Physicochemical Testing (<661>"Containers – physicochemical tests – plastic")

EP Conformity Testing

- EP 3rd. Edition, Chapter 3.1.5

Extractables Validation

- Water For Injection (WFI)
- NaOH (pH > 11)
- HCl (pH < 2)
- Ethanol
- NaCl
- PBS buffered Tween

Sterilization Validation

- AAMI/TIR 27 VD max



DISPOSABILITY ... SPECTRUM ANSWERS THE CALL

The pharmaceutical and bioprocess industries have become increasingly dependent upon disposable products for achieving high quality and high yield in process applications of modern medicines and drugs at a lower cost. For this reason, a large number of pharmaceutical manufacturing plants are turning to disposability in their validated processes to take advantage of the benefits disposability offers over material re-use.

Spectrum is at the forefront of this paradigm shift toward disposability. In doing so, Spectrum has become the premier company in the industry as the only manufacturer of disposable hollow fiber tangential flow filtration (TFF) modules. As an adjunct to TFF modules, Spectrum now launches a complete line of irradiated, self-contained fluid handling systems.

KrosFlo® EZ-BAGS

Disposable Bags Customized to Fit Your Application

Spectrum offers four types of disposable KrosFlo® EZ-Bags (*Pillow Bags*, *Cylindrical Tank Bags*, *Container Tank Bags* and *Cubic Tank Bags*) and two types of KrosFlo® EZ-Bag liners (*Cylindrical Tank Liner* and *Cubic Tank Liner*) that can be customized with *Flexible Tubing* and *Tubing Connections* to fit your specific application. Additional convenience can be built into the bags by incorporating disposable *In-line Filters* and other components. Multiple EZ-Bags can be combined into a single *Multi-bag Manifold* to eliminate fluid handling steps for ultimate time & cost savings and insure complete sterile process containment. Lastly, all bag configurations are available non-irradiated or irradiated. And you determine the *Packaging* quantity.

Using the easy 6-Step Customization Guide below, simply record your preferred EZ-Bag options on the included **KrosFlo® EZ-Bag Quotation Request** to receive a custom KrosFlo® EZ-Bag quotation...

...Designed specifically by you for your application!

6-Step Customization Guide:

1 BAG TYPE, VOLUME SIZE & PORTS

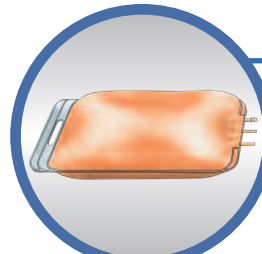
2 FLEXIBLE TUBING

3 TUBING CONNECTIONS

4 IN-LINE FILTERS

5 MULTI-BAG MANIFOLDS

6 PACKAGING



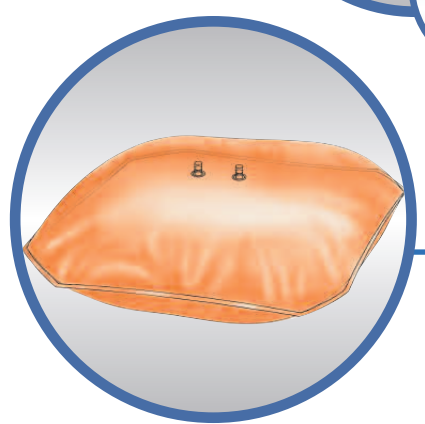
PILLOW BAGS

Volume 60ml, 300ml, 1L, 5L, 10L, 20L & 50L
Sizes (bags > 1L come with handle rod)
Ports 1 – 4 ports possible with diameters from ¼" to ¾" (sampling/injection port also available)



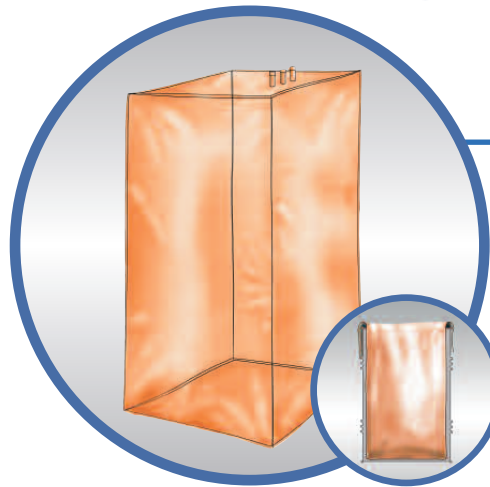
CYLINDRICAL TANK BAGS & LINERS

Volume 50 – 750+ liters (fits into commercially available and custom designed cylindrical tanks)
Sizes available and custom designed cylindrical tanks
Ports 1 – 4 ports possible with diameters from ¼" to 1" (bottom drain/outlet port also possible)
Tank Liner Open-ended top with option for single bottom drain port.



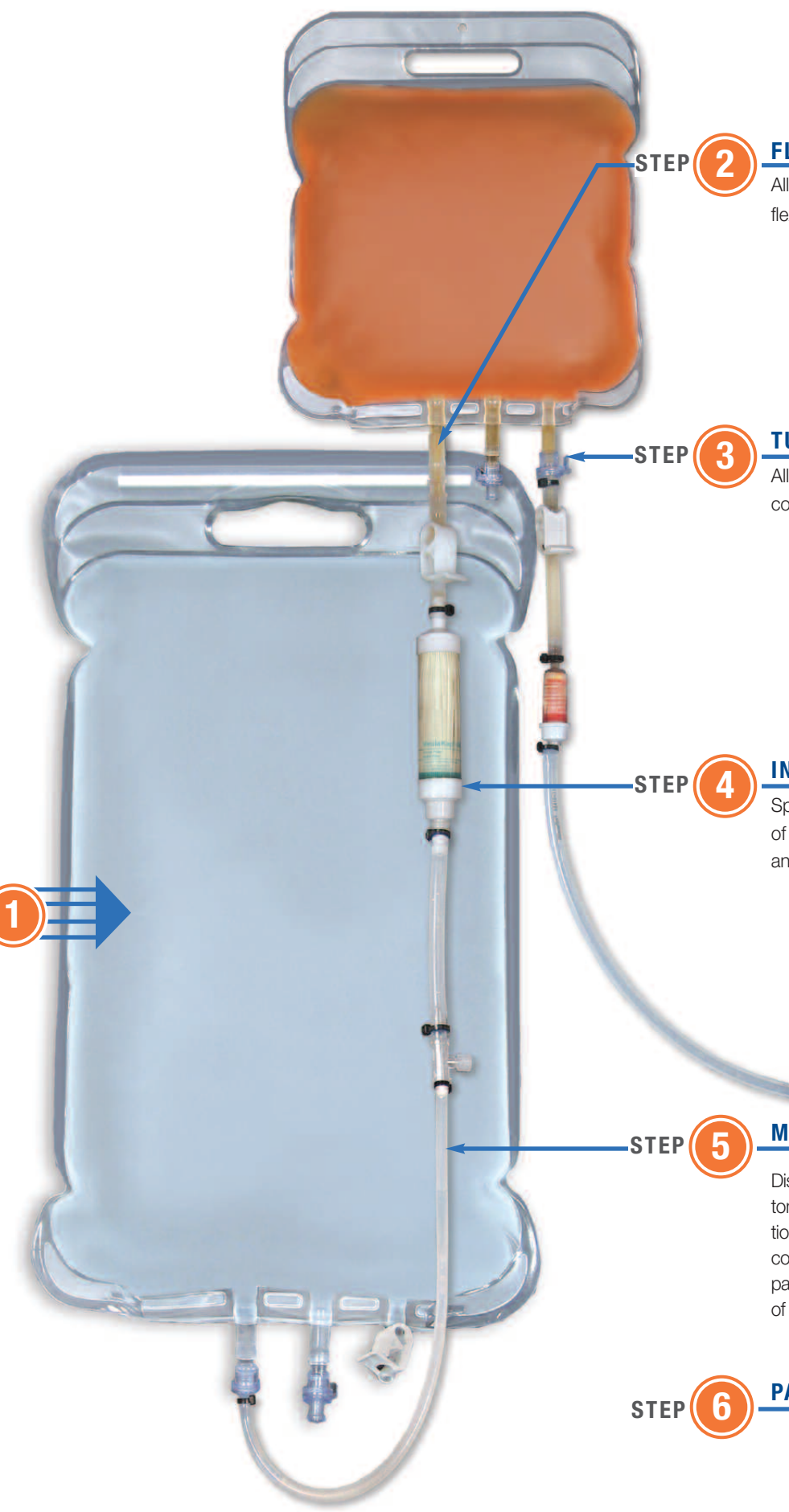
CONTAINER TANK BAGS

Volume 500 – 1,000+ liters (fits into commercially available and custom designed rectangular tanks)
Sizes custom designed rectangular tanks
Ports 1– 4 ports possible with diameters from ¼" to 1" (bottom drain/outlet port also possible)



CUBIC TANK BAGS & LINERS

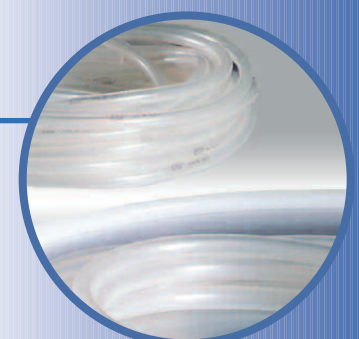
Volume 200 – 2,000+ liters (fits into commercially available and custom designed cubic tanks)
Sizes cubic tanks
Ports 1 – 4 ports possible with diameters from ¼" to 1" (bottom drain/outlet port also possible)
Tank Liner Open-ended top with option for single bottom drain port.



STEP 2 FLEXIBLE TUBING

All types of commercially available flexible tubing including:

- C-Flex™
- Pt-cured silicone
- Reinforced silicone
- Pharmed™ (Neoprene)
- Tygon 3350™ silicone
- Injection septum



STEP 3 TUBING CONNECTIONS

All types of commercially available connections including:

- CPC™ Quick-Disconnect
- Steamable single-use CPC™
- Sterile connections
- Y and straight connectors & reducers
- Plastic Tri-Clover hose-barb adaptors
- Luer-lok™



STEP 4 IN-LINE FILTERS

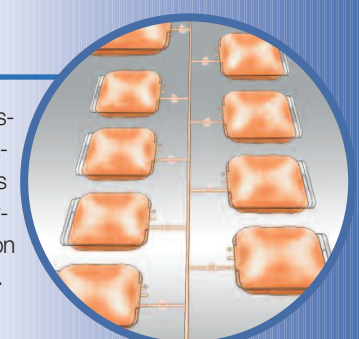
Spectrum offers a comprehensive line of hollow fiber filters for in-line filtration and separation of the process fluid.

- MediaKap® Media Filters
- MiniKap® Water (buffer) Filters
- CultureGard® Media Filters
- DynaGard® Syringe Tip Filters
- KrosFlo® Hollow Fiber TFF Modules



STEP 5 MULTI-BAG MANIFOLDS

Disposable bag manifolds can be customized for specific process applications, whether made of small bags connected through a network of flow-paths or a larger bag with the addition of smaller bags for process sampling.



STEP 6 PACKAGING

- Irradiated or non-irradiated
- Quantity/package

KrosFlo® EZ-BAG CONTAINERS

Spectrum offers two types of robust containers, *Stainless Steel Containers* and *Plastic Containers*, which provide support, protection and transportation for the *Container Tank* and *Cubic Tank* type KrosFlo® EZ-Bags.

STAINLESS STEEL CONTAINER (200, 500 & 1000 LITERS)

Constructed of stainless steel, these container systems are ideal for the support, transportation and storage of large production volumes (200, 500 or 1000 liters) in *Container Tank* and *Cubic Tank* KrosFlo® EZ-Bags. While the main chamber is designed to support the KrosFlo® EZ-Bag's full volume, the container features height adjustment to accommodate and protect varying batch volumes within the bag.

COMPARTMENTILIZATION

The stainless steel container also features 2 additional compartments that provide easy access to the bottom drain tubing assembly and the top tubing assembly while the KrosFlo® EZ-Bag's valuable contents remain protected in the main chamber.

TRANSPORTATION & STORAGE

The container is available with caster wheels for carting and can easily and safely be transported by all forklift types. A tag rack on the front provides proper product identification and batch record retainment for storage.

PLASTIC CONTAINER (250 LITERS)

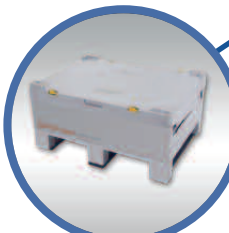
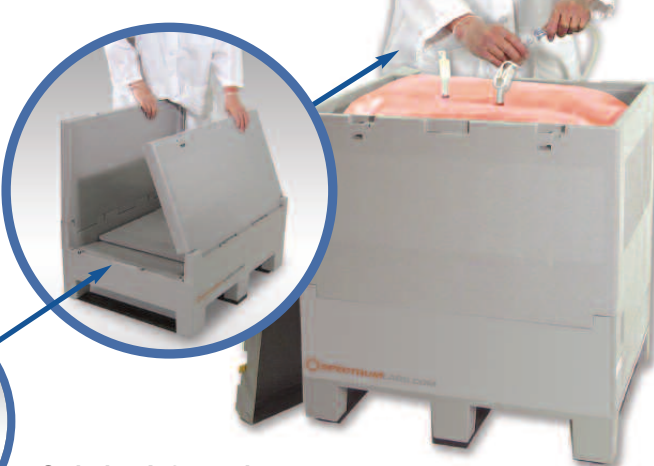
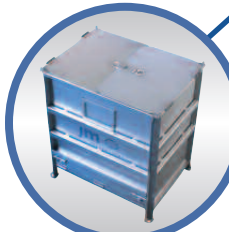
Since these standard hard-plastic containers are inexpensive compared to the valuable production batch, they offer the distinct advantage of serving as expendable and protective shipping packaging for 250 liter *Container Tank* and *Cubic Tank* KrosFlo® EZ-Bags. Sturdy and light-weight, the plastic container can be transported by all forklift types and is available with caster wheels for easy carting.

EASY ASSEMBLY FOR USE

Designed to quickly and easily assemble into a single 250 liter chamber by un-folding and locking the sides in place, the container also features viewing windows and volume graduation for filling, draining and in-process monitoring.

COLLAPSIBLE FOR STORAGE

When not in use, the plastic containers conveniently collapse down to conserve space for easy return shipping as well as stacking & storage for later use.



Ordering Information:

Part Number	Description	Volume	Size
EZC-SS-200	Stainless Steel Container	200 liter	
EZC-SS-500	Stainless Steel Container	500 liter	
EZC-SS-1000	Stainless Steel Container	1000 liter	
EZC-PP-250	Plastic Container	250 liter	

ALSO AVAILABLE:

KrosFlo® EZ-FILTRATION

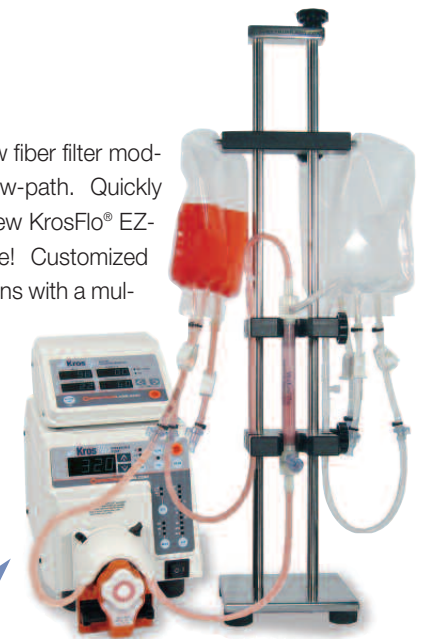
Spectrum has expanded the concept of disposability by incorporating irradiated KrosFlo® hollow fiber filter modules into sterile KrosFlo® EZ-Bag *Manifolds* to provide a totally disposable process filtration flow-path. Quickly and easily installed on a KrosFlo® EZ-Filtration System for R&D or Process Development, the new KrosFlo® EZ-Module Flow-path provides a revolutionary approach: pre-packaged, disposable and complete! Customized to your specific application, the Module Flow-paths are available in two different bag configurations with a multitude of KrosFlo® brand hollow fiber modules.

2-BAG CONFIGURATION

Providing separate containment of both retentate and filtrate, the 2-Bag Flow-path utilizes an initial "process bag" in the filter loop to concentrate retentate while a second bag collects filtrate. When complete simply clamp off, disconnect and remove the product filled bag for easy transport and storage.

3-BAG CONFIGURATION

While the retentate is circulating, a third bag can be used to add either more product for large volume concentrations or wash buffer for purification. In these applications, the complete and separate fluid containment includes the feed solution, as well as the retentate and filtrate.

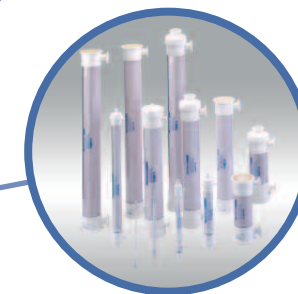
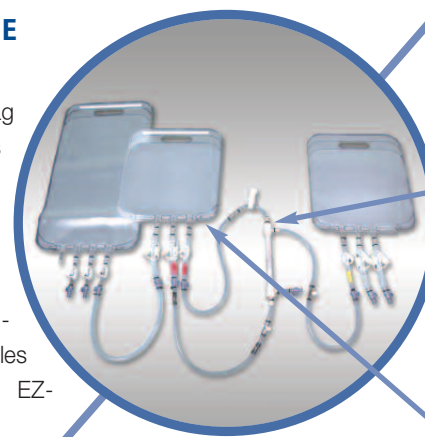


KrosFlo® EZ-Filtration System for R&D
Refer to brochure for ordering info.

KrosFlo® EZ-MODULE FLOW-PATHS

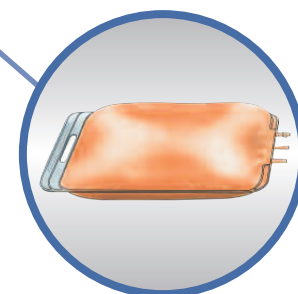
Disposable 2-Bag and 3-Bag Flow-path configurations combine a standard or irradiated KrosFlo® Hollow Fiber Filter and standard or sterile KrosFlo® EZ-bags for complete process containment that quickly assembles and disassembles on an EZ-Filtration System.

Refer to brochure for ordering information.



KrosFlo® HOLLOW FIBER FILTERS

Standard or irradiated Hollow Fiber membranes enclosed in a housing that provide gentle and efficient filtration and direct scalability. Refer to catalog for ordering info.



KrosFlo® EZ-BAGS (PILLOW TYPE ONLY)

Standard or sterile multi-layer film bags for the containment, transportation and storage of process fluids. Standard pillow bags available for replacement.



KrosFlo® EZ-Filtration System for Process Development
Refer to brochure for ordering information.

Ordering Information:

Part Number	Description	Volume	Size
EZB-P006-A	KrosFlo® EZ-Bag, Pillow Type	60 ml	A
EZB-P300-B	KrosFlo® EZ-Bag, Pillow Type	300 ml	B
EZB-P01L-C	KrosFlo® EZ-Bag, Pillow Type	1 liter	C
EZB-P05L-E	KrosFlo® EZ-Bag, Pillow Type	5 liter	E
EZB-P10L-F	KrosFlo® EZ-Bag, Pillow Type	10 liter	F
EZB-P20L-G	KrosFlo® EZ-Bag, Pillow Type	20 liter	G

Spectrum's hollow fiber in-line filters can easily be incorporated into a KrosFlo® EZ-Bag Multi-bag Manifold to provide a disposable, ready-to-use fluid handling system. The hollow fiber membrane geometry has a self-containing support structure that provides greater surface area and superior flow rates within a smaller filtration device than flat sheet membranes.

MediaKap Plus® HOLLOW FIBER MEDIA/BUFFER FILTERS

Sterile 0.2 µm filters that dramatically reduce the time for sterilization and clarification of aqueous streams like culture media or buffers. Also available without sterile filling bells.

Part Number	Description	Qty/Pkg	Inlet	Outlet
MP2M-02B-12S	MediaKap® 2 Plus	12	FLL	1/4" HB
MP2M-05B-12S	MediaKap® 5 Plus	12	FLL	1/4" HB
MP2M-10B-12S	MediaKap® 10 Plus	12	1/4" HB	1/4" HB
MP2M-25B-06S	MediaKap® 25 Plus	6	Var. HB	Var. HB
MP2M-50B-06S	MediaKap® 50 Plus	6	Var. HB	Var. HB

Water Flow Description	DMEM	
	at 10 PSIG	DMEM
		w/ Serum w/o Serum
MediaKap® 2 Plus	400 ml/min	0.2 – 2 L 5 L
MediaKap® 5 Plus	750 ml/min	2 – 5 L 10 L
MediaKap® 10 Plus	1 L/min	5 – 10 L 20 L
MediaKap® 25 Plus	1.4 L/min	10 – 25 L 50 L
MediaKap® 50 Plus	2 L/min	25 – 50 L 100 L

CultureGard® CULTURE PROTECTION FILTERS FOR MEDIA-FEED

Sterile 0.2 µm filters designed to protect cultures during media feed from contamination. Connect two filters in series to provide a sterile barrier. Simply remove the first one if it becomes plugged, reconnect to the second and continue feeding the culture.

Part Number	Description	Qty/Pkg	Inlet	Outlet
MP2M-02B-12S	CultureGard® Filter	12	FLL	MLL

DynaGard® SYRINGE TIP FILTERS

Designed as a sterile 0.2 µm syringe tip filter, DynaGard® is ideal for the in-line filtration of small fluid volumes while minimizing hold up volume.

Part Number	Description	Qty/Pkg	Inlet	Outlet
DG2M-23L-50S	DynaGard® w/ Luer, Irr	50	FLL	MLL
DG2M-23L-100	DynaGard® 2/ Luer	100	FLL	MLL

KrosFlo® HOLLOW FIBER MODULES FOR PROCESS FILTRATION

Refer to catalog for ordering information.



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