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Steam-In-Place (SIP) Hollow Fiber Modules for Re-use!

Kros*Flo*

The new KrosFlo[®] SIP Modules combine the benefits of hollow fiber tangential flow filtration (TFF) with a robust design for processes requiring SIP and product re-use. Validated for 5 SIP cycles, these superior filter modules incorporate a thermally stable potting compound with a durable membrane support sleeve to withstand the

extreme conditions of multiple steam sterilization cycles and NaOH cleaning/sanitization. Ideal for production scale applications, the KrosFlo[®] SIP Modules can be operated singly to process 50 to 1,000 liters or in parallel up to 10,000 liters. **Efficient and Re-usable!**

ADVANTAGES OF RE-USABLE KrosFlo[®] SIP MODULES:

- Robust Re-usable Design
- Steam-In-Place (SIP)
- Clean-In-Place (CIP)
- Low Shear Filtration
- Scalable for Production
- Easy Retrofit for other HF modules
- Low Protein Binding PES for Microfiltration

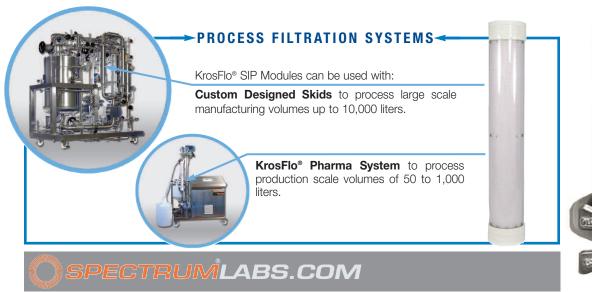
GENERAL DESCRIPTION

The Size C version of the KrosFlo® SIP Module is specifically designed for production scale applications with 4.4 m² (1.0 mm ID fibers) and 6.0 m² (0.5 mm ID fibers). Scaling up from the "2X" or "3X" length MiniKros®, KrosFlo® and CellFlo® disposable modules, the Size C SIP module easily and securely fits into Spectrum's Size C, stainless steel KrosFlo® SIP Housing, as well as retrofitting other commercially

available SIP housings. The SIP module and housing assembly can be connected to any SIP process system via 2" sanitary retentate ports and 1½" sanitary filtrate ports.

QUALITY ASSURANCE

Spectrum modules are manufactured under cGMP in an ISO Class 209 E (US Fed. Class 10,000) cleanroom and are 100% integrity tested and 100% lot traceable.



KrosFlo[®] SIP HOLLOW FIBER MODULES, SIZE C⁼

The KrosFlo[®] SIP modules consist of microfiltration or ultrafiltration hollow fibers (0.5 or 1.0 mm ID) potted with epoxy in a polysulfone sleeve and include a pair of silicone seals. Precise perforation on the sleeve allows maximum flux while reducing permeate hold up. Size C KrosFlo[®] SIP modules are designated by a part number starting with "**KS**" and "**C**" for the module size.

Example Part No: KS2E-100-C1N

The membrane is available in two types:

Membrane	ID	MWCO	
Polyethersulfone	1.0 & 0.5 mm	0.2 µm & 0.5 µm	
Polysulfone	1.0 mm	20 nm (500 kD)	
Polysulfone	0.5 mm	0.05 µm, 400 kD, 100 kD	
		50 kD & 10 kD	

KrosFlo® SIP APPLICATIONS:

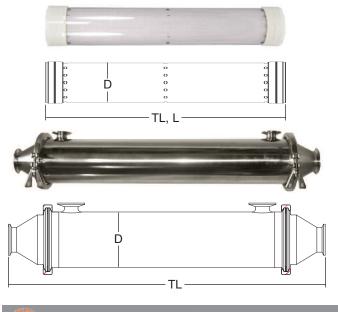
Cell lysate clarification	0.5, 0.2 & 0.1 µm	
Microparticle diafiltration	0.5, 0.2 & 0.1 µm	
E. coli concentration	0.2 & 0.1µm	
Fermentation harvest	0.2 & 0.1µm	
Nanofiltration	0.05 µm & 20 nm	
Virus purification	0.05 µm, 20 nm & 400 kD	
Viral removal	20 nm & 400 kD	
Antibody purification (IgM & IgG)	400, 100 & 50 kD	
Protein concentration	400, 100, 50 & 10 kD	
Buffer exchange, pH change, desalt	100, 50 & 10 kD	
Albumin purification	50 kD	
Depyrogenation	50 & 10 kD	

ACCESSORIES: KrosFlo® SIP Seals, Size C

The Size C SIP silicone seals (2/pk) are specifically designed to form a leak free seal and eliminate dead-space in the KrosFlo[®] SIP Size C Housing, typically found in other SIP filter assemblies.

KrosFlo[®] SIP Seals, Size C (2/pk) Part No: ACKS-4SL-C2N

DIMENSIONS & SPECIFICATIONS



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KrosFlo[®] SIP HOUSING, SIZE C[®]

The Size C KrosFlo[®] SIP module is encased in the Size C KrosFlo[®] SIP Housing, a stainless steel (SS) pressure vessel that supports the module and protects the operator during the SIP and CIP processes. The module easily and snugly inserts into the SS housing cylinder and is then sealed in place with seals, gaskets and SS end-cap reducers.



KrosFlo® SIP Housing, Size C Part No: ACKS-400-C1N (SS Cylinder, SS End-cap Reducers, clamps & gaskets)

RECOMMENDED STEAM-IN-PLACE PROCEDURE

The KrosFlo® SIP Modules are validated for 5 SIP cycles.

- 1. Pre-soak the module in water for 2 hrs.
- 2. Pre-warm installed SIP assembly at 100°C for 30 min.
- 3. Steam at 121°C for 30 min.
- 4. Cool the module for at least 4 hrs.

WARNING: Change the temp. 1–2°C/min to avoid thermal shock.

RECOMMENDED CLEAN-IN-PLACE PROCEDURE

- 1. Flush the installed SIP assembly with buffer/water for 20 min.
- 2. Flush the installed SIP assembly with 0.5N NaOH for 1 hr.
- 3. Flush out NaOH with water or buffer.

WARNING: Flushing with water first may precipitate protein.

Module Materials of Construction:

Sleeve:	Clear & pigmented polysulfone	
Potting:	Ероху	
Membrane:	PES or PS	
Seals, Size C:	White silicone	

Housing Materials of Construction:

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Cylinder, Side-port, 1½" Sanitary:		Stainless Steel					
End-cap Reducer, 4" - 2" Sanitary:		Stainless Steel					
Clamps, 4" Sanitary:		Stainless Steel					
Gaskets, 4" Sanitary:		Silicone					
Assembly Component	D (cm)	TL (cm)	L (cm)	EL (cm)			
Size C SIP Module	10.8	62.2	62.2	53.3			
Size C SIP Housing	11.4	77.1	N/A	N/A			
D = Outer Diameter L = Hollow Fiber Length							
TL = Total Length EL = Hollow Fiber Effective Length							
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