

Novel, high-flux single-use filtration for fed-batch clarification

TFDF® (Tangential Flow Depth Filtration) unites the benefits of tangential flow (TF) and depth filtration (DF) in an integrated solution with filter, flow path and system. The thick-walled tubular depth filter captures cells and cell debris with negligible product retention. Operation in tangential mode reduces fouling associated with concentration polarization. The combination produces a high-flux, high-capacity clarification solution with low permeate turbidity and minimal dilution. Incorporation of the filter into a single-use, Gamma-irradiated ProConnex® Flow Path with integrated sensors provide rapid validation and seamless operation on a KrosFlo® TFDF® System programmed with application-specific process control logic.

TFDF® Filter



Sweeping action for reduced concentration polarization and fouling

ProConnex® TFDF® Flow Path



Closed, Gamma-irradiated and customizable flow paths

KrosFlo® TFDF® System



Integrated hardware, software and flow path

- **Thick-walled depth filter:** High capacity with negligible product retention
- **Tangential flow:** Low concentration polarization
- **Integrated system:** typically 3 - 6 hour run time at > 1000 LMH

KrosFlo® TFDF® Systems

The KrosFlo® TFDF® System delivers application-specific process control logic for optimal TFDF® process performance. Systems scale from 1 L to 2000 L in a small footprint of 1 m² for both pilot (31 inch x 42 inch) and process (37 inch x 42 inch) systems.



KrosFlo® TFDF® Lab System

*1 L - 50 L volume
Standard configuration



KrosFlo® TFDF® Pilot System

*50 L - 500 L volume
Customizable configuration



KrosFlo® TFDF® Process System

*500 L - 2000 L volume
Customizable single or dual skids



*Process volumes shown are for typical mAb harvest applications. Actual products subject to change. All images shown for reference only.



Closed, single-use, complete flow paths

for optimized TFDF®

The single-use, Gamma-irradiated and closed ProConnex® Flow Path with integrated sensors enable seamless operation on a KrosFlo® TFDF® (Tangential Flow Depth Filtration) System. ProConnex® TFDF® Flow Paths arrive dry, sodium hydroxide, glycerin, preservative and ethanol free for a zero flush start state. Feed stream enters the bottom port. Retentate travels through the lumen and exits the top of the tube. Permeate exits the enclosure through the lower permeate port.



ProConnex® TFDF® Flow Paths include:

- TFDF® Filter
- Disposable pump head
- Integrated sensors
- Tubing
- Aseptic connectors

To ensure linear scalability from 1 to 2000 L, the number of tubes per enclosure and the tube length increases. Tube length increases from 20 cm to 108 cm. The effective length of the filter may be less than the physical length of the filter. The number of tubes increases from 1 - 40 per enclosure.



Number of tubes	1	3	5	10	14	40
Surface area (cm ²)	3 - 150	450	750	1500	2100	6000

Length (cm)	20, 36	108
Surface Area (cm ²)	3, 30, 50	150

Actual products subject to change. All images shown for reference only.








Specifications

	KrosFlo® TFDF® System type			Lab System		Pilot System		Process System	
Filters	Recommended process volume - rProtein and Gene Therapy	< 1 L	2 - 3 L GT vol	5 L GT vol	< 50 L	< 500 L		< 2000 L	
	TFDF® Filter surface area	3 cm²	30 cm²	50 cm²	150 cm²	450 cm²	750 cm²	1500 cm²	2100 cm²
Provided equipment	TFDF® Filter part number	TFDF-3	TFDF-30	ProConnex®	N/A	N/A		N/A	
	ProConnex® TFDF® Flow Path part number	STDFDCL15110S	STDFDCL15546S	STDFDCL15111S	STDFDCL15112S	*		*	
Options	Feed pump - Magnetic levitating pump (1)	10 LPM recommended, 20 LPM maximum							
	Auxiliary pumps (2)	Maximum 340 ml/min with 4.8 mm ID and 1.6 mm thick tube							
Utilities	Controller	PLC							
	User interface (HMI)	12" Color touch screen							
Dimensions	Operating temperature	5 - 40° C							
	Environmental requirements	5 - 50° C, Relative humidity 10 - 90 % (Non condensing)		5 - 50° C, Relative humidity 10 - 90 % (Non condensing)		5 - 50° C, Relative humidity 10 - 90 % (Non condensing)		5 - 50° C, Relative humidity 10 - 90 % (Non condensing)	
Ordering	Enclosure material of construction	Powder coated aluminum (enclosure), Delrin and powder coated/anodized aluminum							
	Connectivity - Pressure sensor range	Up to 5 single-use sensors / -7 to 75 psi (-0.48 to 5.2 bar)		Up to 5 single-use sensors / -7 to 75 psi (-0.48 to 5.2 bar)		Up to 5 single use sensors / -7 to 75 psi (-0.48 to 5.2 bar)		Up to 5 single use sensors / -7 to 75 psi (-0.48 to 5.2 bar)	
Service	Connectivity - Weighing scales	Up to 2 (20 Kg) scales		Extended position		N/A		N/A	
	Stand	Normal position							
Options	Turbidity sensor	1 Turbidity Photometer transmitter with 880 nm light source optional							
	Feed flow meter	Clamp on flow sensor for 9/16" OD tubing							
Utilities	Permeate flow measurement	Permeate weigh scale							
	Power	110 - 240 V AC, 1 Phase, 50/60 Hz							
Dimensions	Compliance	UL and CE Certified							
	Controller	16 x 13 x 21 in (40 x 33 x 53 cm)		11 x 11 x 19 in (28 x 28 x 48 cm)		11 x 11 x 39 in (28 x 28 x 99 cm)		N/A	
Ordering	Pump station	N/A							
	Controller weight	34 lbs (15.5 kg)		20 lbs (9 kg)		N/A		N/A	
Service	Pump station weight	N/A							
	System part number	TFDFLP2S2F1T0NCFRS							
<p>Controller - PLC, HMI - 12" Color TFT 800x600 SVGA, Power supply, Analog/Digital I/O Modules, Pump Station - MagLev pump (1), Peristaltic pumps (2), Pressure transmitter boards (2) to support max. 5 SU Pressure sensors, weight transmitters (2), Flow transmitters (1), 20 Kg scales (2), Optional 60 Kg scale - PN: SCL-0060-SCLR</p>									
Service	Installation, test and basic user training (1 day)	SV-IT-TFDF-LAB-1		SV-IT-TFDF-PLT-1		SV-IT-TFDF-PRO-1		SV-IT-TFDF-PRO-1	
	Installation, test, IQOQ and basic user training	SV-IT-TFDF-LAB-10Q-1		SV-IT-TFDF-PLT-10Q-1		SV-IT-TFDF-PRO-10Q-1		SV-IT-TFDF-PRO-10Q-1	
<p>Factory warranty + 1 year extended warranty SV-WA-TFDF-LAB-1+1YR-1 for KrosFlo® TFDF® Lab System</p>									

* Contact your Repligen sales representative to customize your TFDF® System.



Specifications

ProConnex® TDF® Flow Path	Lab-scale			Pilot-scale	Process-scale
	Filter	Flow path	Flow path		
Type	3, 30	3', 30", 50"	150	Flow path	Flow path
Surface area (cm²)	1	1, 10, 50	< 50 L	450, 750, 1500	2100, 6000
Fibers	1, 10	20, 36	108	3, 5, 10	14, 40
Recommended process volume (L) for mAb application ⁵	20	2, 20, 36	108	< 500 L	< 2000 L
Total filter length (cm)	1	1	1	108	108
Effective length (cm)	Yes	Yes	Yes	3, 5, 10	14, 40
Number of tubes	N/A	Yes	Yes	No	No
Standard configuration made to stock	TFDF-3, TFDF-30	STDFCL15110S [†] STDFCL15546S ^{**} STDFCL15111S ^{***}	STDFCL15112S	Yes	Yes
Customizable				-	-
Part number					
ProConnex Flow Paths					

Actual products subject to change. All images shown for reference only. ⁵Recommended process volumes for mAb use 3 cm² per 1 L process volume. Gene Therapy (Lentivirus applications) use 30 cm² for 2 - 3 L batch-size.

Product Contact Materials of Construction	
TFDF filter module	Polysulfone, polypropylene, polyethylene terephthalate, urethane
Gaskets	Platinum cured silicone
Reducers	Polysulfone
Tubing	Platinum-cured silicone, C-Flex ^{®†} , PharmaMed ^{®**}
Aseptic connectors	Polycarbonate, platinum-cured silicone, polyethylene
Manifold	PVDF
	Pump head
	Pressure sensors
	Connectors, hosebarb adaptors
	Air filter
	Various fittings**

*Materials of construction vary based on scale and subject to change based on customer specific designs. [†]Lab-scale only. ^{**}Pilot and process scales only.

