

Novel filtration technology for large

modality upstream process intensification

TFDF® (Tangential Flow Depth Filtration) Technology intensifies upstream processes through cell expansion, cell wash or perfusion for large biomolecules such as Lentivirus, Adenovirus, Adeno associated virus (AAV), exosomes and more. The thick-walled 2 - 5 μm tubular 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 solution. 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

Synergistic benefits

- **Upstream intensification** of large molecules
- **Short, highly-interconnected paths** do not retain product
- **2 - 5 micron pore size** for large biomolecules

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 m^2 for both pilot (31 inch x 42 inch) and process (37 inch x 42 inch) systems.



KrosFlo® TFDF® Lab System

Standard configuration



KrosFlo® TFDF® Pilot System

Customizable configuration

Single skid



Dual skid



KrosFlo® TFDF® Process System

Customizable single or dual skids



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Closed, single-use, complete flow paths

for optimized TFDF®

The single-use, Gamma-irradiated and closed ProConnex® Flow Path with integrated sensors enable seamless intensification using 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.

Repligen 06-01-2023



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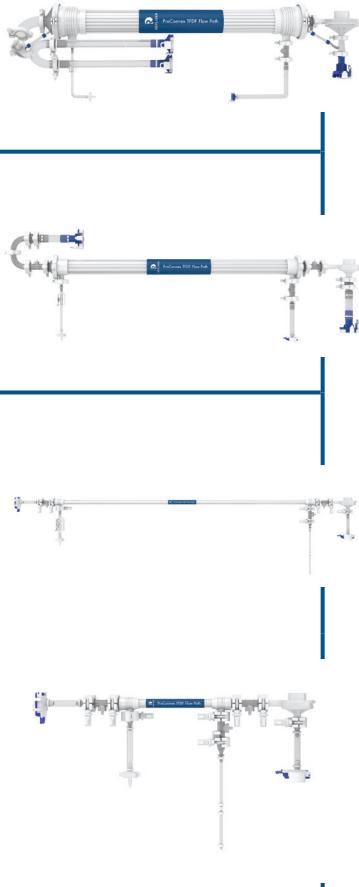
Specifications

KrosFlo® TFDF® System type	Lab System				Pilot System		Process System	
Filters	< 1 L	2 - 3 L GT vol	5 L GT vol	< 50 L	< 500 L		< 2000 L	
TFDF® Filter surface area	3 cm ²	30 cm ²	50 cm ²	150 cm ²	450 cm ²	750 cm ²	1500 cm ²	2100 cm ²
TFDF® Filter part number	TFDF-3	TFDF-30	ProConnex®	N/A	N/A		N/A	6000 cm ²
ProConnex® TFDF® Flow Path part number	STFDFCL15110S	STFDFCL15546S	STFDFCL15111S	STFDFCL15112S	*		*	
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		*			*	
Controller	PLC	PLC	PLC	PLC	PLC	PLC	PLC	PLC
User interface (HMI)	12" Color touch screen		*		*		*	
Operating temperature	5 - 40° C	5 - 40° C	5 - 40° C	5 - 40° C	5 - 50° C	5 - 50° C	5 - 50° C	5 - 40° C
Environmental requirements	5° - 50° C, Relative humidity 10 - 90 % (Non condensing)	Powder coated aluminum (enclosure), Delrin and powder coated/anodized aluminum	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)	10 - 90 % (Non condensing)	10 - 90 % (Non condensing)	/ -7 to 75 psi (-0.48 to 5.2 bar)	10 - 90 % (Non condensing)
Enclosure material of construction			Up to 2 (20 Kg) scales	Normal position	Extended position	N/A	N/A	Stainless steel 304
Connectivity - Pressure sensor range				1 Turbidity Photometer transmitter with 880 nm light source optional		*	*	
Connectivity - Weighing scales								
Stand								
Turbidity sensor								
Feed flow meter								
Permeate flow measurement								
Power								
Compliance								
Controller								
Pump station								
Controller weight								
Pump station weight								
System part number								
Summary								
Installation, test and basic user training (1 day)								
Installation, test, IQOQ and basic user training								
Factory warranty + 1 year extended warranty								

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

Specifications

ProConnex® TFDF® Flow Path		Lab-scale	Pilot-scale	Process-scale
Type	Filter	Flow path	Flow path	Flow path
Surface area (cm ²)	3, 30	3", 30", 50***	150	2100, 6000
Fibers	1	1	1	3, 5, 10
Total filter length (cm)	20	20, 36	108	108
Effective length (cm)	2, 20	2, 20, 36	108	108
Number of tubes	1	1	1	14, 40
Standard configuration made to stock	Yes	Yes	No	No
Customizable	Yes	Yes	Yes	Yes
Part number	N/A TFDF-3, TFDF-30	STDFCL15110S* STDFCL15546S** STDFCL15111S***	STDFCL15112S	-
ProConnex Flow Paths				



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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	Pump head	Polypropylene
Gaskets	Platinum cured silicone	Pressure sensors	Polysulfone
Reducers	Polysulfone	Connectors, hosebarb adaptors	Polypropylene
Tubing	Platinum-cured silicone, C-Flex®, PharmaMed®**	Air filter	PTFE, polyester, polypropylene
Asptic connectors	Polycarbonate, platinum-cured silicone, polyethylene	Various fittings*	PVDF, polypropylene
Manifold	PVDF		

*Materials of construction vary based on scale and subject to change based on customer specific designs. +Lab-scale only. **Pilot and process scales only.

