

# TangenX® SC TFF Device

Data Sheet

TangenX® SC TFF Devices from Repligen is available in five sizes, with surface areas scalable from 0.5, 1.5, 2.5, 5, and 10 m<sup>2</sup> within the TangenX SC product family and are cross-scalable with traditional cassette formats from 0.01 m<sup>2</sup> to manufacturing scale. TangenX SC TFF Devices are accompanied by a detailed Regulatory Support File. A wide variety of molecular weight cutoffs, surface areas, and membrane chemistries (ProStream and HyStream) support diverse process needs. Potential applications include biomolecule concentration (ultrafiltration) and buffer exchange (diafiltration). The holderless design eliminates the need for cassette installation and alignment, torquing, and re-torquing, saving time and labor, and reducing risks due to loss of or inadequate compression.

TangenX SC Devices are designed for ultimate ease of use and repeatable performance. The product does not rely on positioning, alignment, or torquing. Simply snap the AseptiQuik® connections together to complete the sterile flow path. Run to run setup variability is eliminated because there is virtually no setup.

The TangenX SC is integrity tested in the factory as a complete assembly. While Repligen always recommends an integrity test at the user facility prior to use, testing of individual cassettes is no longer needed, nor will the test rely on assembly technique. Likewise, there is no threat of integrity loss and product bypass seen with loss of compression in a holder. It comes sterilized with a small hold up volume of sodium hydroxide (0.2 M NaOH). Conditioning for use is as easy as a WFI or buffer flush and you are ready to begin.

The TangenX SC TFF Device is a holderless, flat sheet, single-use device for tangential flow filtration (TFF). TangenX SC TFF Devices include:

- A fully assembled, capsule-style, device with aseptic connectors
- Gamma irradiated with a sterile claim
- Closed system to reduce contamination risk and operator exposure to hazardous material
- All fluid path materials meet USP Class VI requirements
- Certificate of quality
- Manufactured in an ISO 9001 certified ISO 8 clean room
- Validated manufacturing processes for consistent filter performance
- BioPhorum Operations Group (BPOG) leachables and extractables test data



RE\_0142\_0215\_15NOV2023

## Benefits

### Easy-to-use

- Plug and Play solution
- No cassette installation, stacking or aligning
- No holder, no torquing, no re-torquing

### Improved efficiency

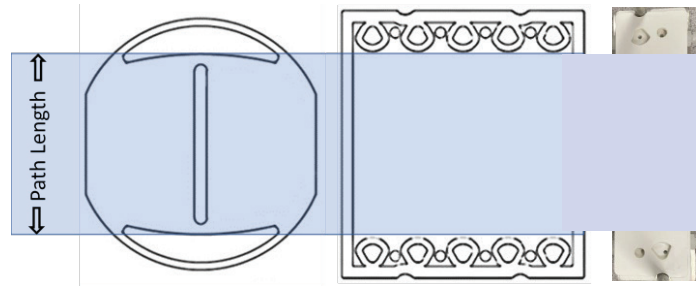
- Reduce setup time by 80%
- Minimal operator intervention and manipulation
- No bulky holders to move around

## Applications

- Monoclonal antibodies, recombinant proteins
- Antibody drug conjugates
- Gene Therapy modalities – AAV, lentivirus, adenovirus, lipid nanoparticles, pDNA

## Specifications

Module Characteristics	Surface Area				
	0.5 m <sup>2</sup>	1.5 m <sup>2</sup>	2.5 m <sup>2</sup>	5.0 m <sup>2</sup>	10 m <sup>2</sup>
Channel path length	16 cm				
Hold-up volume Feed/Retentate	0.17 L	0.44 L	0.65 L	1.17 L	2.34 L
Hold-up volume Permeate	0.16 L	0.40 L	0.58 L	1.03 L	2.07 L
Working volume	1 – 50 L	3 – 150 L	5 – 250 L	10 – 500 L	20 – 1,000 L
Temperature	4 – 40° C				
Maximum forward pressure	60 psi (4 bar)				
Maximum reverse pressure	7 psi (0.48 bar)				
Crossflow @ 10 psi/0.7 bar	2 – 4 L/min	6 – 12 L/min	10 – 20 L/min	20 – 40 L/min	40 – 80 L/min
Air integrity test pressure	7.3 psi (0.50 bar)				
Max air diffusion rate	323 ccm/m <sup>2</sup>				
Aseptic connector	G				L
Height	5.9 in (15.0 cm)	7.7 in (19.7 cm)	9.3 in (23.6 cm)	13.1 in (33.3 cm)	20.6 in (52.3 cm)
Diameter	10.0 in (25.4 cm)				
Tube stand-off length	7.5 in	6.75 in			7.25 in
Weight (in box)	20 lb (9 kg)	22 lb (10 kg)	24 lb (11 kg)	32 lb (14.5 kg)	47 lb (21.3 kg)



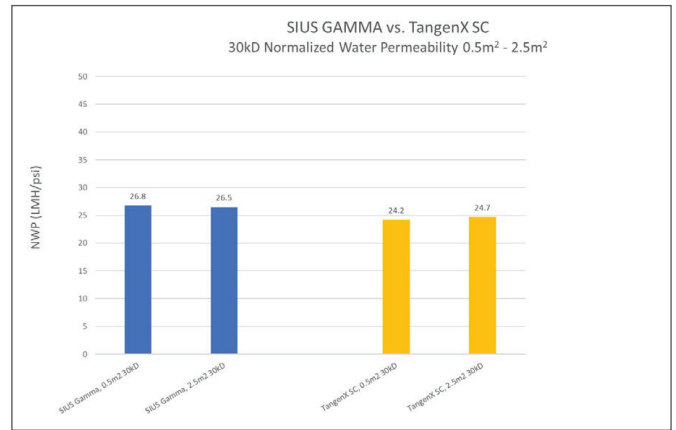
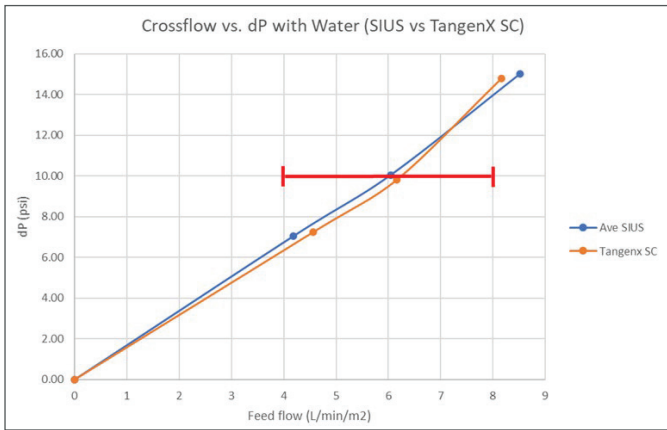
TangenX SC Devices use the same flow path length and channel height as our SIUS® single-use and PRO reusable cassettes. Channel height and screen type are also identical, allowing unparalleled versatility and cross-scalability between product lines.

Scale by Design

Surface Area	0.01 m <sup>2</sup>	0.02 m <sup>2</sup>	0.1 m <sup>2</sup>	0.5 m <sup>2</sup>	1.5 m <sup>2</sup>	2.5 m <sup>2</sup>	5 m <sup>2</sup>	10 m <sup>2</sup>
PRO								
SIUS								
SIUS Gamma	N/A							
TangenX SC	N/A							

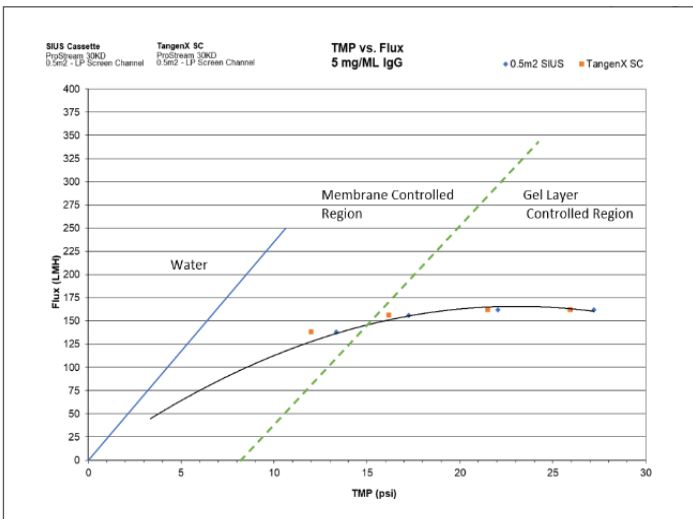
Vertical scalability allows TangenX Cassettes to scale from 0.01 m<sup>2</sup> cassettes through the 10 m<sup>2</sup> TangenX SC. Horizontal scalability allows you to seamlessly move across product formats, from SIUS Single-use, to PRO Reusable Cassettes. Now that scalability is extended to TangenX SC.

Crossflow & NWP



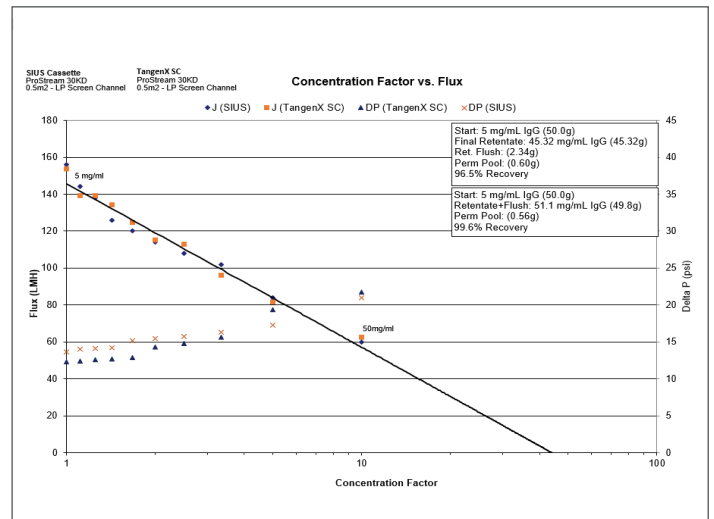
TangenX SC and SIUS have comparable crossflow vs pressure drop (dP) supporting the cross-scalability of the two formats. Normalized water permeability (NWP), a measure of the membrane resistance to flow as a function of pressure, of 30 kD TangenX SC and SIUS Gamma Devices is comparable.

Flux vs Transmembrane Pressure (TMP)



Cross-scalability between TangenX SC and SIUS Devices is demonstrated by equivalent flux vs TMP. A 30kD mPES membrane with L-screen was used to represent each cassette device format and both were tested with identical operating conditions.

Flux vs Concentration



The effect of concentration on flux and pressure for a 10-fold concentration of IgG solution using both a SIUS Cassette and a TangenX SC Device show similar results, indicating equivalent performance. Following the concentration operation, recovery of IgG from both formats was comparable.

## Ordering Information

MWCO	Surface Area	ProStream Membrane	HyStream Membrane
10 kD	0.5 m <sup>2</sup>	PP010S05L	XP010S05L
	1.5 m <sup>2</sup>	PP010S15L	XP010S15L
	2.5 m <sup>2</sup>	PP010S25L	XP010S25L
	5 m <sup>2</sup>	PP010S50L	XP010S50L
	10 m <sup>2</sup>	PP010S99L	XP010S99L
30 kD	0.5 m <sup>2</sup>	PP030S05L	XP030S05L
	1.5 m <sup>2</sup>	PP030S15L	XP030S15L
	2.5 m <sup>2</sup>	PP030S25L	XP030S25L
	5 m <sup>2</sup>	PP030S50L	XP030S50L
	10 m <sup>2</sup>	PP030S99L	XP030S99L
50 kD	0.5 m <sup>2</sup>	PP050S05L	XP050S05L
	1.5 m <sup>2</sup>	PP050S15L	XP050S15L
	2.5 m <sup>2</sup>	PP050S25L	XP050S25L
	5 m <sup>2</sup>	PP050S50L	XP050S50L
	10 m <sup>2</sup>	PP050S99L	XP050S99L
100 kD	0.5 m <sup>2</sup>	PP100S05L	XP100S05L
	1.5 m <sup>2</sup>	PP100S15L	XP100S15L
	2.5 m <sup>2</sup>	PP100S25L	XP100S25L
	5 m <sup>2</sup>	PP100S50L	XP100S50L
	10 m <sup>2</sup>	PP100S99L	XP100S99L
300 kD	0.5 m <sup>2</sup>	PP300S05L	XP300S05L
	1.5 m <sup>2</sup>	PP300S15L	XP300S15L
	2.5 m <sup>2</sup>	PP300S25L	XP300S25L
	5 m <sup>2</sup>	PP300S50L	XP300S50L
	10 m <sup>2</sup>	PP300S99L	XP300S99L

## Customer Service

Repligen Corporation  
 41 Seyon Street  
 Building 1, Suite 100  
 Waltham, Massachusetts 02453

[customerserviceUS@repligen.com](mailto:customerserviceUS@repligen.com)

(781) 250-0111

RE\_0142\_0215\_15NOV2023