TangenX™ SIUS™ Gamma Closed TFF Cassette

Set-up Guide

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Intended use

The TangenX™ SIUS™ Gamma Cassette was designed to concentrate biomolecules and exchange buffers through ultrafiltration and diafiltration processes. TangenX™ SIUS™ Gamma and TangenX™ SIUS™ Cassettes are constructed from the same membrane chemistry and should be expected to deliver comparable performance.

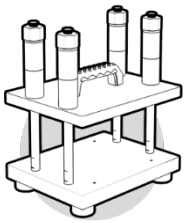
- All fluid path materials meet USP Class VI requirements
- Certificate of quality included with lot certification
- Manufactured in an ISO 9001 certified facility; ISO 8 clean room
- Gamma-irradiated
- Validated manufacturing processes for consistent filter performance

Warnings

Warning: 	**Damage may occur as a result of the following:** • Dropping on hard surfaces, or other mechanical shock • Poking with sharp objects on screened surfaces • Excessive feed pressure • Excessive permeate backpressure or pressurizing the filtrate port • Exposure to harsh chemicals • Freezing • Excessive heat • Drying out – ultrafiltration or microfiltration membrane that is allowed to dry out can incur permanent damage to the pore structure
Warning: 	**MEMBRANE CASSETTES MUST REMAIN WET AT ALL TIMES TO MAINTAIN PRODUCT INTEGRITY AND PERFORMANCE.**
Warning: 	**All cassettes are stored in 0.2 sodium hydroxide as a preservative.**
Warning: 	**Follow standard safety procedures for handling 0.2 M sodium hydroxide, including the use of gloves, safety goggles, and lab coat.**
Information: 	**It is recommended that you perform a cassette integrity test to ensure your cassette has been installed and clamped in the cassette holder properly. Reference the air integrity test procedure AN1002 and specifications listed in table below.**

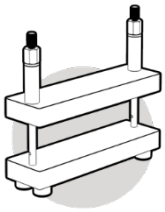
Required components and tools

4-Bolt



Holder
TSPDI-4BMC
(or equivalent)

2-Bolt



Holder
TSLDI-2BMC
(or equivalent)

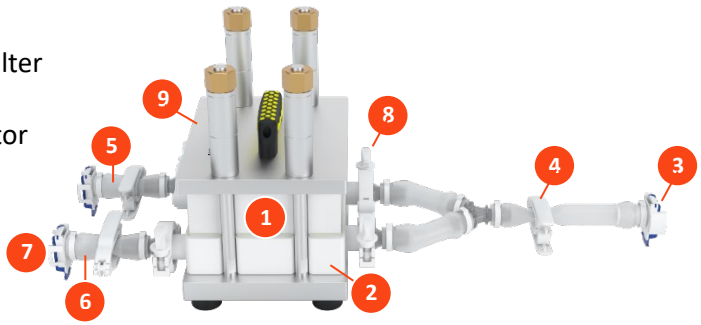
Tools

Scissors

Torque wrench
with 11/16” socket for 0.1 m^2
or 1 ¼” socket for > 0.5 m^2

Product description

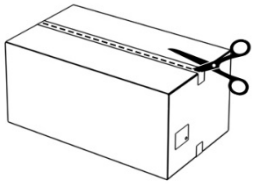
1. TangenX™ SIUS™ Gamma Cassette/Filter
2. Filter plate insert manifold
3. Permeate output port with Y connector
4. Pinch clamp (3)
5. Feed input port with tubing
6. Retentate port with tubing
7. AseptiQuik® sterile connector (3)
8. Tri-clamp connector (4)
9. Top plate



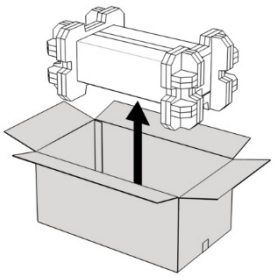
Module characteristics	Surface area: 0.1 m^2	Surface area: 0.5 m^2	Surface area: 1.5 m^2	Surface area: 2.5 m^2
Channel path length	16 cm			
Hold-up volume	61 ml	509 ml	874 ml	1026 ml
Working volume	200 ml	1000 ml	3000 ml	5000 ml
Max temperature	40° C			
Max pressure (forward)	60 psi (4 bar)			
Max pressure (reverse)	7 psi (0.48 bar)			
Crossflow LP		2-4 L/min	6-12 L/min	10-20 L/min
Crossflow EP		3-6 L/min	9-18 L/min	15-30 L/min
ΔP LP screen	10 psi (0.7 bar)			
ΔP EP screen	5 psi (0.35 bar)			
Air integrity test pressure	7.3 psi (0.5 bar)			
Max air diffusion rate	323 ccm/m^2			
AseptiQuik® connector	G			
Torque range	120-180 in-lbs (14-20 N-m)	300-450 in-lbs (35-50 N-m)		

Unpacking

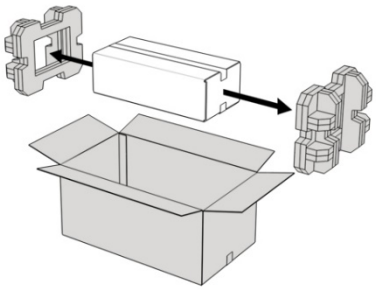
1. Cut open box 1.



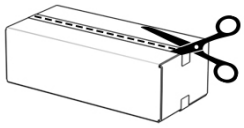
2. Remove box 2 from box 1.



3. Remove packaging ends.

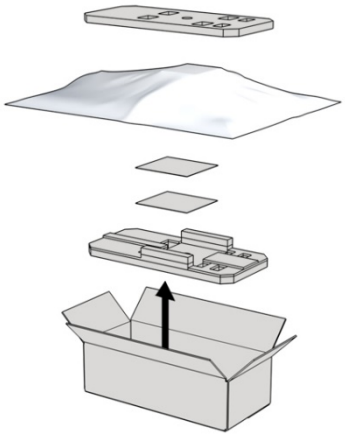


4. Cut open box 2
-OR- put in storage.

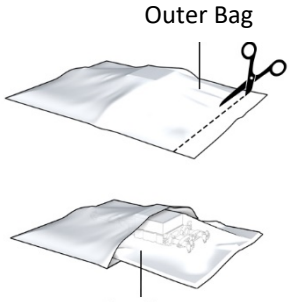


Storage temperature:
- 4 - 25 °C long term (> 7 Days)
- 40 °C short term (< 7 Days)
- Do not freeze cassettes

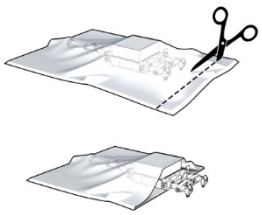
5. Remove contents from box 2.

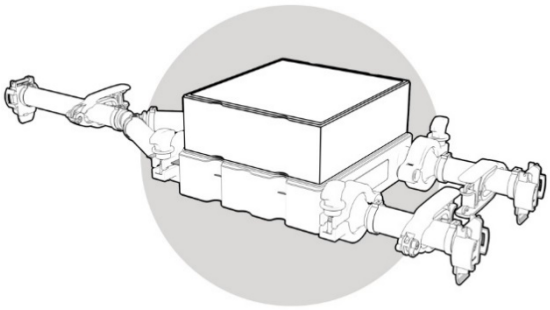


6. Cut open Outer Bag and remove Inner Bag.



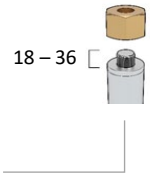
7. Cut open Inner Bag and remove cassette.



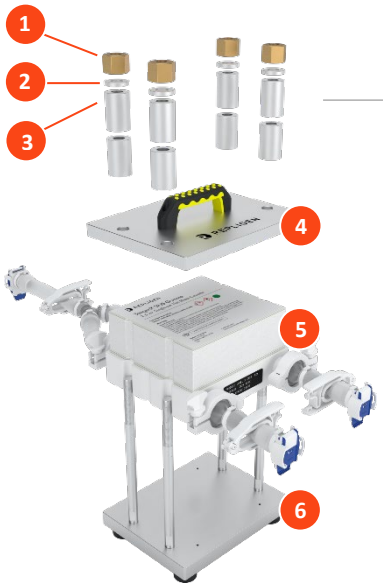


WARNING: Each cassette is stored in 0.2 M sodium hydroxide solution as a preservative. Follow standard safety procedures for handling 0.2 M sodium hydroxide, including the use of gloves, safety goggles, and lab coat.

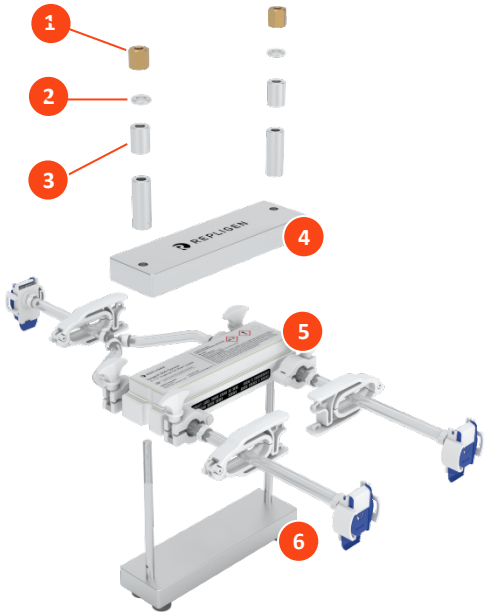
Assembly



Add tie-rod spacers to 18 mm (0.75 inch) – 36 mm (1.5 inch)



SIUS™ Gamma Filtration Device installed in 4-Bolt holder

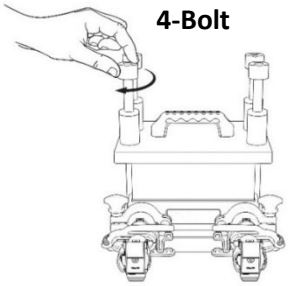


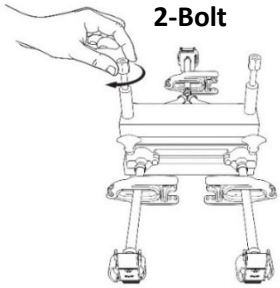
SIUS™ PD Gamma Filtration Device installed in 2-Bolt holder

1. Hex nut
2. Washer
3. 2” or 1” Tie-rod spacer(s)
4. Holder top plate
5. TangenX™ SUIS™ Gamma Cassette
6. Holder bottom plate

Torque sequence | Part 1

Install the tie-rod spacers (if used) and washers on each bolt leaving a minimum of 18 mm (0.75 inch) of thread exposed on the rods. By hand, screw the nut on each bolt and hand tighten evenly by alternating from one nut to the other. Bolts must be further tightened using a torque wrench.

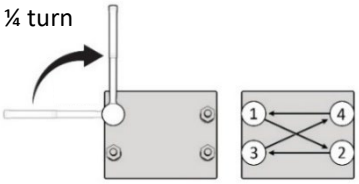




Torque sequence | Part 2a

Using the calibrated torque wrench tighten each hex nut ¼ turn at a time following the torque sequence illustrated in Figure 1A (4-Bolt) or Figure 1B (2-Bolt).

Figure 1A. 4-Bolt numbered sequence | Appropriate for 0.5 m^2, 1.5 m^2 and 2.5 m^2 cassettes.



- Torque range for 4-Bolt SIUS™ Cassette Holder is 350 - 400 in-lbs (35 – 50 N-m)
- Each nut should be tightened to a maximum of 450 in-lbs (50 N-m)
- Skip nut once 450 in-lbs is reached
- Repeat sequence one additional time when specified torque is reached (300 – 450 in-lbs)

Example of 4-Bolt tightening order:

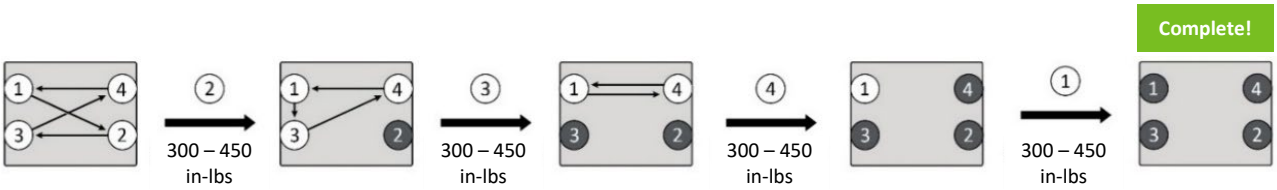
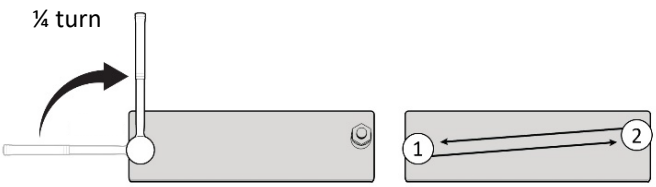
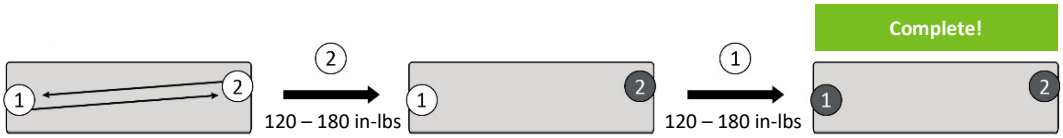


Figure 1B. 2-Bolt numbered torque sequence | Appropriate for 0.1 m^2 cassettes



- Torque range for 2-Bolt SIUS™ Cassette Holder is 120 - 180 in-lbs (14 – 20 N-m)
- Each nut should be tightened to a maximum of 180 in-lbs (20 N-m)
- Skip nut once 180 in-lbs is reached
- Repeat sequence one additional time when specified torque is reached (120 – 180 in-lbs)

Example of 2-Bolt tightening order:



= Numbers in grey have been tightened to 180 in-lbs.

Torque sequence | Part 2b

Wait 5 - 10 minutes and allow the cassette to relax before re-torqueing. Check each nut, per the Figure 1 sequence, using the torque wrench at its set point torque value.

Re-torque to a maximum of 180 in-lbs (20 N-m) for the 0.1 m^2 holder and 450 in-lbs (50 N-m) for the larger > 0.5 m^2 holder, as needed, to create a liquid-tight seal.

CAUTION:
Nuts must be tightened uniformly to avoid damaging the cassette. Leakage may result from non-parallel plate alignment or over compression of the cassettes at one end.

Flow path assembly

1. Connect the SIUS™ Gamma Cassette to your flow path using AseptiQuik® connectors and route the flow path through the pumps.
2. Direct permeate and retentate to waste and flush the cassette with 5 L/m^2 of water through the retentate and 10 L/m^2 of water through the permeate to displace the 0.2 M NaOH preservative.
3. (Recommended) Execute integrity testing according to your internal protocol or Repligen protocol AN1002 with a specified air diffusion rate of < 322 sccm/m^2 @ 7.3 psi (0.5 bar).
4. Recirculate 2 L/m^2 of equilibration buffer through the cassette.
5. Execute your concentration and/or diafiltration process.
6. Recovery: Open the retentate, close the permeate, re-circulate the concentrate for 5 – 10 minutes. Turn off feed pump, direct retentate to a collection vessel, turn on pump at 50% reduced flow rate and collect the concentrate. Flush lines with minimum volume of buffer to maximize recovery.
7. Disposal: Remove from cassette holder and dispose of cassette in biohazard container. (Disposal will be dependent on the feed stream used).

Additional references

www.repligen.com/resources

TangenX™ SIUS™ PD Filter Plate and 2-Bolt Clamp Assembly: **IF.PUG.019**

TangenX™ SIUS™ Filter Plate and 4-Bolt Clamp Assembly: **IF.PUG.018**

TangenX™ Cassette Preservative Sodium Hydroxide Solution Safety data sheet: **IF.SD2-POP.1034**