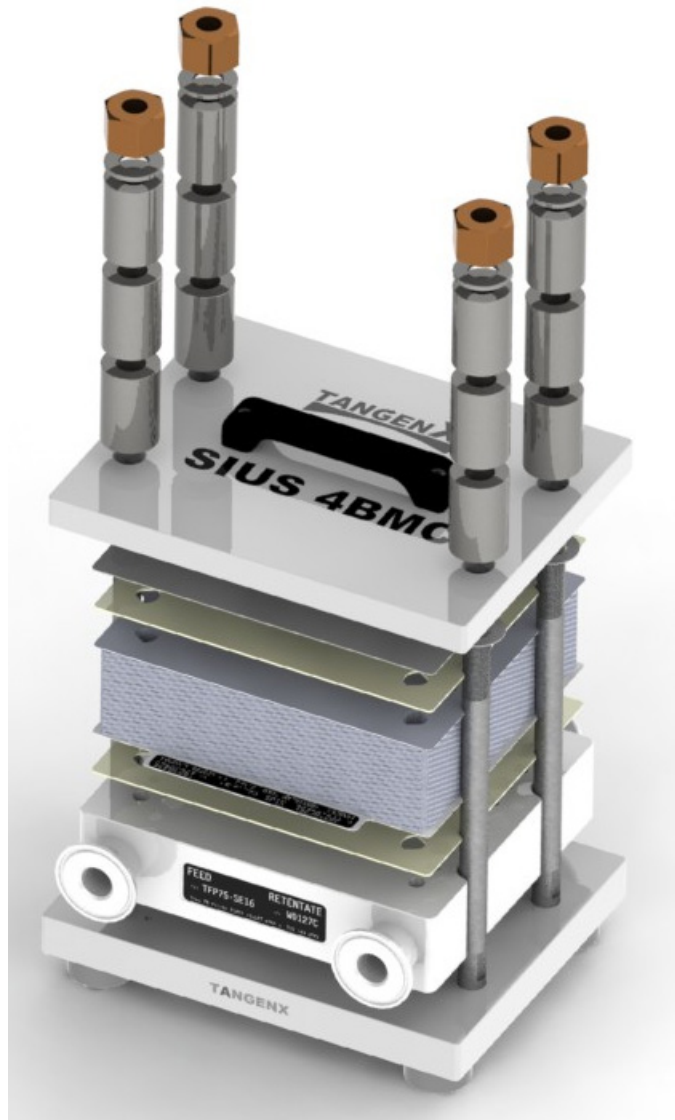


TangenX™ SIUS™ Filter Plate and 4-Bolt Clamp Assembly

USER GUIDE



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1. Diagram

Filter Area: 0.5 m² to 5 m² Clamp Weight: 52 lbs
 Max Cross Flow: 49 LPM Clamp Weight (loaded): 53 lbs to 65 lbs
 Filter Plate Certificate: Provided with each FPI kit

Figure 1.1 Diagram, Materials, Consumables

TSPDI-4BMC		MATERIALS
1	Plates (2)	Type 304 Stainless Steel
2	Threaded Rods (4)	
3	Spacers (12)	
4	Washers (4)	
5	Hex Nuts (4)	Silicon Bronze
6	Footpad (4)	Rubber
7	Handle (1)	Nylon / Rubber
8	Footpad Screw ^(a) (4)	18-8 Stainless Steel
9	Handle Screw ^(a) (2)	
Compatibility ^(c)		Sius™ Cassette / Block
Torque Range ^(b)		300-450 in-lbs (35-50 N-m)
Hydraulic Option		No
Hex Socket		1-1/4"
CONSUMABLES		
10	Filter Plate TFP75-SE16	Polypropylene
11	Isolation Plate	Polypropylene
12	TangenX™ SIUS™	G05L, J or K G15L, J, or K G25L, J, or K
13	Gasket	EPDM
(a) Not Shown		
(b) Always check and, if necessary, re-torque your holder prior to use.		
(c) COMPATIBLE with Millipore, Pall, Sartorius and GE reusable cassettes. Use cassette manufacturer's recommended torque.		

TSPDI-4BMC is not in contact with process fluid.
 The process fluid is isolated from contact with stainless steel by Filter Plate Insert and Isolation Plate.

2. Product Contents

- **TSPDI-4BMC package includes the following:**
 - Stainless steel clamp as shown in Figure 1.1 (Items 1-9)
 - Certificate of Conformance
- **TFP75-SE16 package includes the following**
 - Filter Plate Insert
 - Isolation Plate
 - Certificate of Conformance
- **Cassette package includes the following**
 - (1) TangenX™ SIUS™ membrane filtration cassette available with
 - 0.5m², 1.5m², or 2.5m² area
 - LP screen, J or K open channel
 - (2) EPDM gaskets
 - Certificate of Conformance

3. Important information before you begin

1. **HOLDER / CLAMP**
 - TSPDI-4BMC is shipped assembled, remove the plastic shipping plate from between stainless plates before use.
 - The clamp may be cleaned with alcohol or any other detergent solution commonly used to clean tables and lab equipment.
 - TSPDI-4BMC weighs approximately 52 lbs, use caution when lifting.
2. **FILTER PLATE INSERT**
 - Filter Plate Insert kits are shipped cleaned, dry and ready for use.
 - TFP75-SE16 is compatible with all TangenX™ single-use and re-usable cassettes.
 - Filter Plate Inserts are designed for single-use, since Repligen does not recommend re-use, it is the responsibility of the end user to define a suitable cleaning protocol.
3. **CASSETTE**
 - Product is packaged wet and must remain hydrated for optimal performance. Keep bag sealed until cassette installation (step 3 below).
 - TangenX™ SIUS™ cassettes are compatible with all TangenX™ cassette holders.
 - Cassettes may be stacked to increase filtration surface area; however, use only one type of membrane molecular weight cutoff at one time. **DO NOT install a mixture of cassettes with different pore sizes in the hardware – one pore size only per cassette stack installation.**
 - Cassettes must be equilibrated with an appropriate buffer (i.e. phosphate buffered saline) to ensure the neutralization of the 0.2M sodium hydroxide storage agent in the membrane filter. It is important to use pre-filtered buffer to avoid fouling the membrane or introducing contaminants into the system that could affect membrane performance and product recovery.
4. **GASKET**
 - Gaskets are intended to be single use; Repligen recommends that you replace gaskets with each cassette changeover. Repligen supplies two gaskets per cassette. Installation of the first cassette requires two gaskets; stacking additional cassettes requires only one gasket. Extra gaskets should be saved to replace worn or damaged gaskets.
5. **PUMP**
 - When using TangenX™ cassettes, select a pump with adequate capacity. Crossflow rate ranges (see Table 12.1) are feed channel type and process fluid dependent.

4. Tools Required

- 200 to 1000 in-lb Torque Wrench (TangenX C/N TX026) or equivalent
- 3/16" Allen Wrench (may be needed to tighten handle or feet – not provided)
- Adjustable Wrench (may be needed to tighten threaded rods – not provided)
- Integrity Test Apparatus

5. Clamp Setup

1. Remove clamp from shipping box.
2. Place clamp on table top or other stable surface and remove nuts, washers, spacers and top plate.
3. Check top plate handle and base plate rubber feet. If any are loose, tighten screws with specified allen wrench.
4. Check threaded rods, each should be seated snugly into base plate. If loose, place adjustable wrench on flats and turn clockwise.

6. Filter Plate Installation

1. The steps from "CLAMP SETUP" are complete.
2. Remove Filter Plate Insert (FPI) and Isolation Plate from outer carton, if not already removed.
WARNING: Wear gloves to avoid contamination.
3. Using scissors, carefully open the FPI bag and remove the FPI.
4. Again using scissors, carefully open the Isolation Plate bag but do not remove the Isolation Plate from its bag. The isolation plate is the last item loaded before the top plate. To avoid contamination, leave it in its bag.
5. Place the Filter Plate Insert between TSPDI-4BMC with the ports facing up, as shown. The label information should be right-side-up. If not, flip the FPI over.
NOTE: It is recommended that all sanitary fitting connections are made prior to cassette installation, and after the FPI is loaded in TSPDI-4BMC, as shown below.

Figure 6.1 Sanitary fitting connections

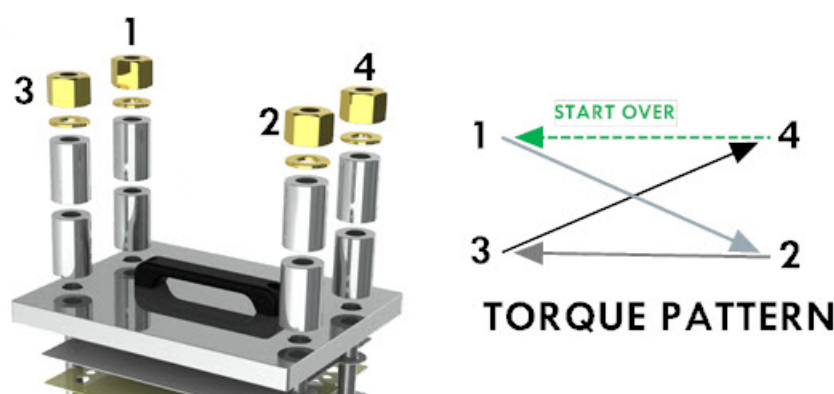


6. Connect appropriate Feed, Retentate and Filtrate connections to FPI.
7. CAUTION: Please be careful when tightening any tri-clamp connectors to the Filter Plate. It is possible to crack the Filter Plate sanitary connection by squeezing it too tightly. Hand tightening should be sufficient to any gaskets. In addition, any attached fitting packages should be supported under one of the components to reduce or eliminate any torque effect on the Filter Plate fitting. Simply put, long fitting runs consisting of tees with valves and gauges create a lever that may cause the plastic Filter Plate connection to crack and/or break off.
8. Clean work area and in preparation for cassette installation. See next section for the applicable sequence of events.

7. TangenX™ SIUS™ Cassette Installation

1. Filter Plate Insert is installed in clamp and ready for use.
2. Rinse the EPDM gaskets with deionized water or WFI. Place a rinsed gasket flat against the bottom FPI; ensure that the holes in the gasket line up with the holes in the manifold.
3. Using scissors, carefully open the cassette bag to remove cassette.
WARNING: Each cassette is stored in 0.2M sodium hydroxide solution as a preservative. Follow standard safety procedures for handling 0.2M sodium hydroxide, including the use of gloves, safety goggles, and lab coat.
4. Place the cassette onto the Filter Plate Insert flat against the gasket. Place another gasket on top of the cassette. Ensure that the holes in the manifold, gaskets, and cassette are completely aligned. If you are using multiple cassettes, continue the same gasket/cassette/gasket pattern, ending with a gasket between the last cassette, followed by the FPI Isolation Plate and 4BMC top plate (see Figure 1.1).
5. 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 rod. 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 to within the recommended torque values shown in Figure 1.1 using a calibrated manual torque wrench.
6. Using the calibrated torque wrench with a 1-1/4" deep style socket, tighten each hex nut ¼ turn following the torque sequence illustrated below.

Figure 7.1 Torque sequence



The applied torque should fall between the minimum value **300 in-lbs** and the maximum value of **450 in-lbs**. Place the socket on bolt "1" and tighten the nut ¼ turn. Then move the wrench diagonally to bolt "2" and tighten the nut ¼ turn. Next, move the wrench to bolt "3" and tighten the nut ¼ turn. Then move the wrench diagonally to bolt "4" and tighten the nut ¼ turn. Alternate back and forth using this crisscross pattern until the torque wrench "clicks" at each

nut. Repeat this sequence until the wrench "clicks" without turning the nut. The "click" of the torque wrench indicates that the nut has reached the set point torque value.

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.

7. Wait 5-10 minutes and allow the gaskets to relax before re-torquing. Check each nut, per Figure 7.1 sequence, using the torque wrench at its set point torque value.
8. Re-torque as needed to create a liquid-tight seal, but do not exceed the maximum torque limit for the 4BMC clamp.

WARNING: The hex nuts should be checked for adequate torque PRIOR to every run using the procedure described herein. In addition, torque may change during processing as the cassettes may expand or contract with temperature changes. Periodically check the torque of each nut and adjust as needed.

9. Repligen highly recommends running an integrity after cassette installation. Refer to TangenX™ Application Note AN1002 for instructions and information on cassette integrity testing.

8. TangenX™ SIUS™ Cassette Equilibration

Cassettes must be equilibrated with an appropriate buffer (i.e., phosphate buffered saline) to ensure the neutralization of the 0.2M sodium hydroxide storage agent in the membrane filter. Verify the pH of the effluent from the cassette is neutralized to minimize any possible interaction with your particular application. For most applications, further sanitization is not required.

9. Cassette System Cleaning

TangenX™ SIUS™ cassettes are intended for single use, therefore post-use cleaning and re-use is not recommended nor supported by Repligen. Similarly, the Filter Plate Insert Kit is also designed for single use, and like TangenX™ SIUS™ cassettes, post-use cleaning is not supported by Repligen.

1. Remove clamp top plate.
2. Remove from clamp the following: Isolation Plate, all gaskets, all cassettes and Filter Plate Insert.
3. Wipe down any spillage from clamp components.
4. Store clamp top plate on clamp base (or other location) along with nuts, washers and spacers.

FOR TRADITIONAL SANITARY HARDWARE SYSTEM: To clean the TFF system following use, recirculate 0.5M sodium hydroxide through the system with all valves open. Cassettes are left in place during the system cleaning procedure to provide a flow path for the cleaning solution. Alternatively the cassettes may be removed and replaced with a CIP spacer gasket (see Table 9.1). Upon completion of the cleaning cycle, flush the system with WFI, or DI water prior draining and discarding the cassettes. Table 2 lists possible recommended cleaning solutions.

Table 9.1 Recommended cleaning solutions

CLEANING AGENT	CLEANING CONDITIONS
0.5N Sodium Hydroxide	Contact Time Temperature = 35°C (95°F)
1.5% Alconox® Detergent	Contact Time = 30 - 60 minutes Temperature = 40°C (104°F)
TX047 Process Scale EPDM Clean-in-Place Gasket (5 pk)	
TX048 Process Scale Silicone Clean-in-Place Gasket (5 pk)	

10. Used TangenX™ SIUS™ Cassette Disposal

TangenX™ SIUS™ cassettes are removed from the clamp by reversing the cassette installation procedure. If the cassettes are difficult to separate and remove from the stack, a thin plastic spatula* can be slid under the edge of the cassette to break the seal. Cassettes can then be disposed of in a similar fashion to other disposable process equipment.

One cassette extractor is included with each shipment of TangenX™ SIUS™ cassettes.

11. Unused TangenX™ SIUS™ Cassette Storage

Membrane cassettes must remain sealed in their original packaging prior to use to maintain their characteristics, integrity, and prevent microbial growth. Below are critical factors to remember when storing unused TangenX™ SIUS™ cassettes:

- Recommended storage temperature:
 - 4°C to 25°C longer than 7 days (long term)
 - 50°C less than 7 days (short term)
 - Do not freeze cassettes

12. Membrane Operating Characteristics

Take care to use the membrane at the lowest pressure possible while still producing consistent permeate flow. Although higher operating pressures initially improve flow rate, they also promote increased concentration polarization and membrane compaction, which ultimately limits flow. With very low NMWL membranes, lower operating pressure may also reduce the retention of salts and very low molecular weight species.

Maximum operating temperature: 50°C

Table 12.1 Recommended crossflow rates

Crossflow (L/min/m ²)	
"LP" Screen	4-8 @ 10 psi (0.7 bar)
"J" Channel	10-15 @ <1 psi (0.07 bar)

Table 12.2 Maximum operating pressures

Maximum Operating Pressures at 30°C	
Forward	100 psi (7 bar)
Reverse	7 psi (0.48 bar)

Table 12.3 Air integrity test specifications

Air Diffusion Rates	
Ultrafiltration 1kD thru 5kD	≤ 323 sccm/m ² @ 15 psi (1 bar)
Ultrafiltration 10kD thru 300kD	≤ 323 sccm/m ² @ 7.3 psi (0.5 bar)
Microfiltration ≥ 0.1 um	≤ 323 sccm/m ² @ 3 psi (0.2 bar)

13. Chemical Restrictions

TangenX™ membrane cassettes are compatible with the following:

- ACN (<15%)
- DMF, DMSO (<40%)
- DMAC (<15%)
- Phosphoric Acid (<1M)
- Sodium Hypochlorite (<400ppm)
- Sodium Hydroxide (<0.5M)

TangenX™ membrane cassettes are NOT compatible with the following:

- Pure aromatic and chlorinated hydrocarbons
- Ketones
- Polar aromatics
- Aliphatic esters

CAUTION

In the event that the cassette is subjected to any of the conditions listed below, it is recommended that you perform both cassette integrity and water flux tests to ensure your cassette is not damaged. 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 membrane that is allowed to dry out can permanently damage the pore structure.

TangenX™ SIUS™ cassettes must remain wet at all times to maintain product integrity and performance.

14. Repligen TangenX™ Standard Warranty

Repligen Corporation warrants its TangenX™ products will meet their applicable published specifications when used in accordance with their applicable instructions for a period of one year from shipment of the products. **REPLIGEN MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** The warranty provided herein and the data, specifications and descriptions of Repligen TangenX™ products appearing in published catalogues and product literature may not be altered except by express written agreement signed by an officer of Repligen. Representations, oral or written, which are inconsistent with this warranty or such publications are not authorized and if given, should not be relied upon.

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