



A complete single-use TFF solution from pre-clinical to clinical
cGMP biomanufacturing

Sius™ Single use TFF membranes & skids

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Why Single use ?

- Shorter inter-campaign changing
- Reduced risk of cross contamination
- Reduced installation time
- Reduction of initial investment
- System flexibility
- Simplification of the equipment

- Two kinds of waste
 - Solid waste : more important in single-use systems
 - Liquid waste : more important in re-usable systems

- Energy consumption :
 - Sterilization, cleaning et materials



Thorne et al. Biopharma (2012)

**Lower total cost of waste
treatment generally**

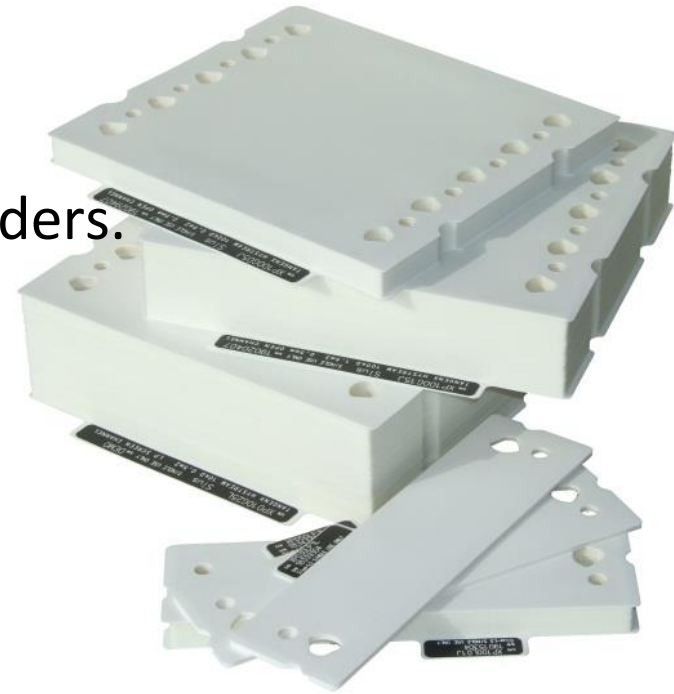
**50% reduction of
energy costs**

[See. Jean Guillerme talk](#)

*Solutions pour minimiser les coûts de développement et de production
(Session 4.)*

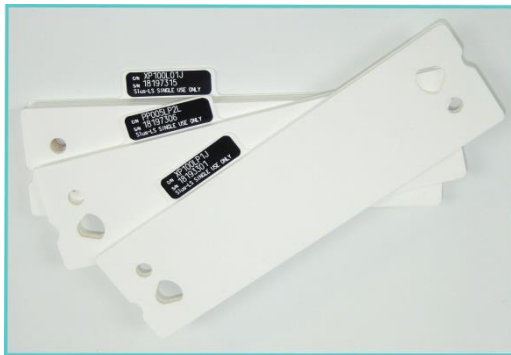
A Complete filtration solution: What does that Mean?

- Novasep Sius™ TFF cassettes.
- Novasep Sius™ TFF Filter plate Insert/holders.
- Novasep Sius™ TFF skid.

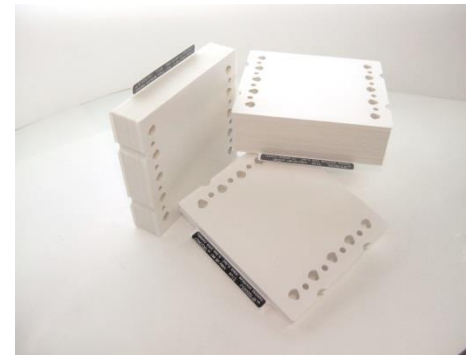


Easy Installation for an user friendly use!

- Sius™ family of single-use cassettes
 - Purpose built for single-use
 - Ready to Use - Reduced preparation time
 - Delivered in 0.2M NaOH – Pre-sanitized
- Cassette design for PD to process scale



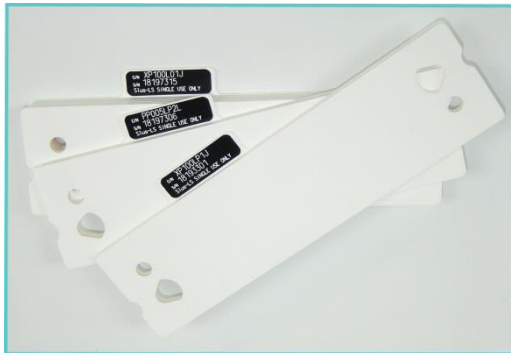
Sius™-LS 0.01 –0.1 m² surface area



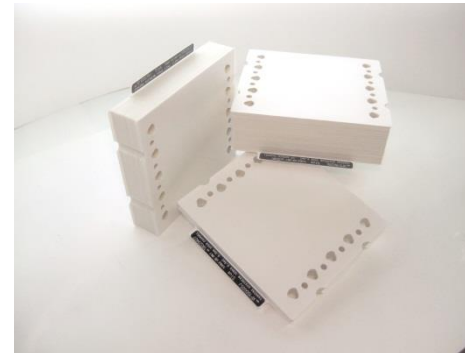
Sius™ 0.5 –2.5 m² surface area

Perfect Scalability of Filtration Surface Area!

- Membrane Surface Areas Available
 - 100 cm², 200 cm², 0.1 m² : [Process development](#)
 - 0.5 m², 1.5 m², 2.5 m²: [Pilot/Process](#)

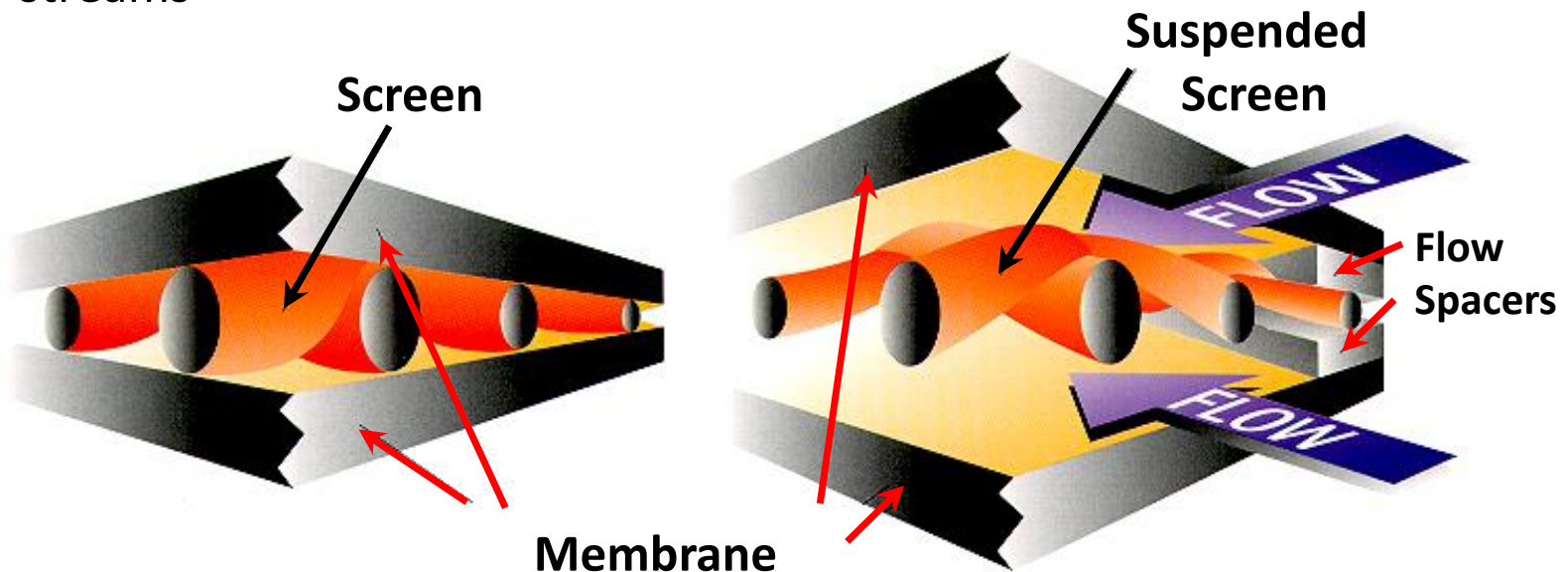


Sius™-LS 0.01 –0.1 m² surface area



Sius™ 0.5 –2.5 m² surface area

- 2 types of membrane chemistry with ProStream™ and HyStream™ membranes (mPES)
- Complete range of cut-offs: 1kD, 3kD, 5kD, 10kD, 30kD, 50kD, 100kD, 300kD, 0.1μm, 0.2μm, 0.45μm, 0.65μm (HyStream™ only)
- 3 different channel configurations available depending on the nature of streams



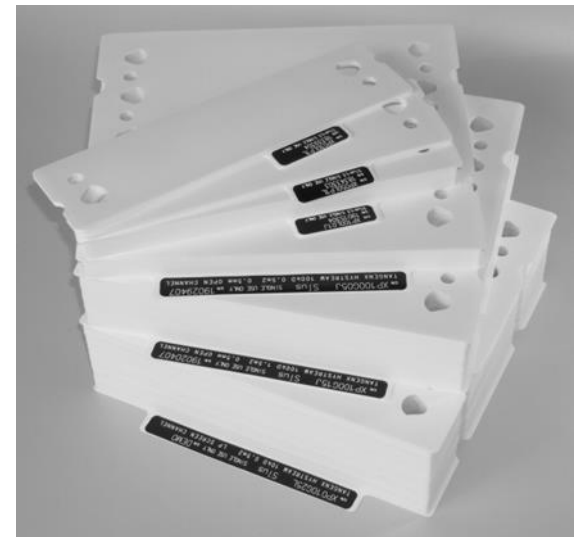
Sius™ Materials and Specifications

- **Materials of Construction**

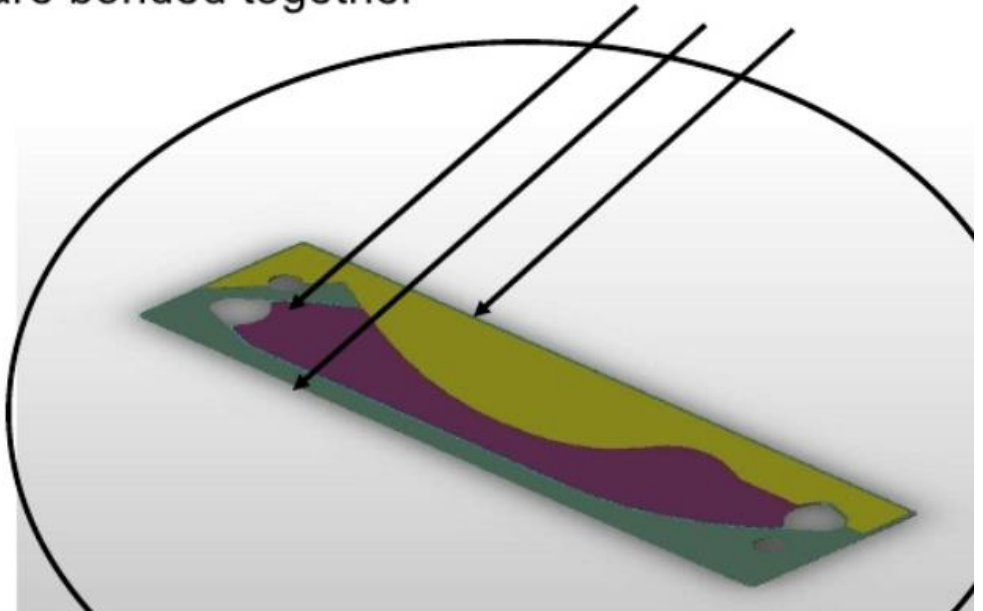
- Membrane PES
- Membrane Support Polypropylene
- Screen Polypropylene
- Channel Spacer HDPE
- Filtrate Seals Urethane
- Gasket EPDM

- **Specifications**

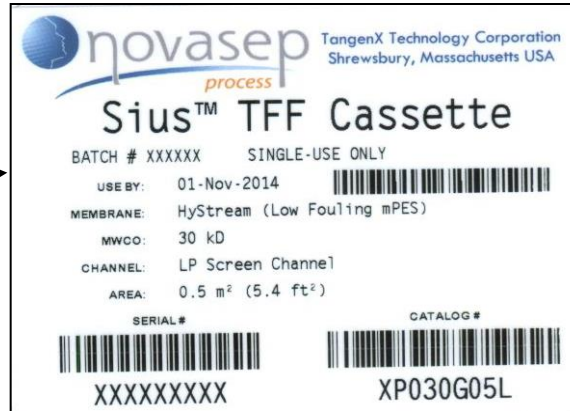
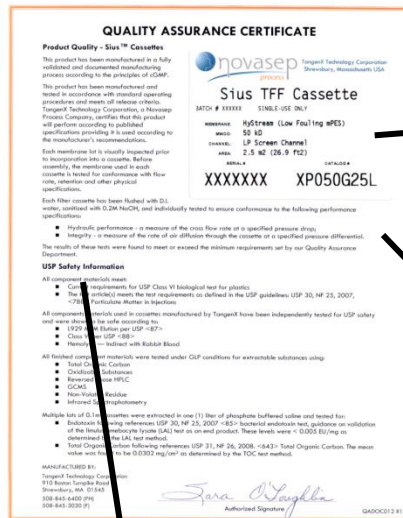
- Maximum Pressure
 - 7 bar (100 psi) forward; 0.33 bar (3 psi) reverse
- Air Integrity
 - UF cassette ≤ 30 sccm @ 1 bar (15 psi)
 - MF cassette ≤ 30 sccm @ 0.2 bar (3 psi)
- Recirculation Flow
 - 'L' Screen 6-9 lpm/m² @ 0.7 bar (10 psi)
 - 'J' Channel 1-1.5 lpm /m² @ 0.3 bar (1.5 psi)



- Sius™ Single Use TFF Cassettes utilize an innovative 2 stage assembly process
- Membranes and permeate channels are bonded together
- Retentate channels consist of rigid plastic frames and turbulence promoting screens
- The assembly is instantly bonded together using medical grade silicone pressure sensitive adhesive



100% and individually tested!



Each filter cassette has been flushed with D.I. water, sanitized with 0.2M NaOH, and individually tested to ensure conformance to the following performance specifications:

- Hydraulic performance - a measure of the cross flow rate at a specified pressure drop;
- Integrity - a measure of the rate of air diffusion through the cassette at a specified pressure differential.

The results of these tests were found to meet or exceed the minimum requirements set by our Quality Assurance Department.

USP Safety Information

All component materials meet:

- Current requirements for USP Class VI biological test for plastics
- The test article(s) meets the test requirements as defined in the USP guidelines: USP 30, NF 25, 2007, <788> Particulate Matter in Injections

Novasep Sius™ Family for Single use filter plate inserts

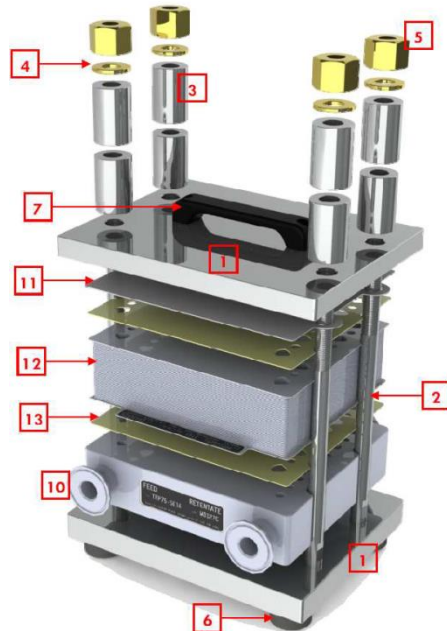
- Provides a single use flow-path for Sius Cassettes
- No Need to clean
- No product contact between stream and stainless
- Ease to use
 - Presanitized
 - Compatible with existing holders
 - Low cost existing holder
 - Two sizes



Holder 2BMC => 0.1 m² to 0.5 m²



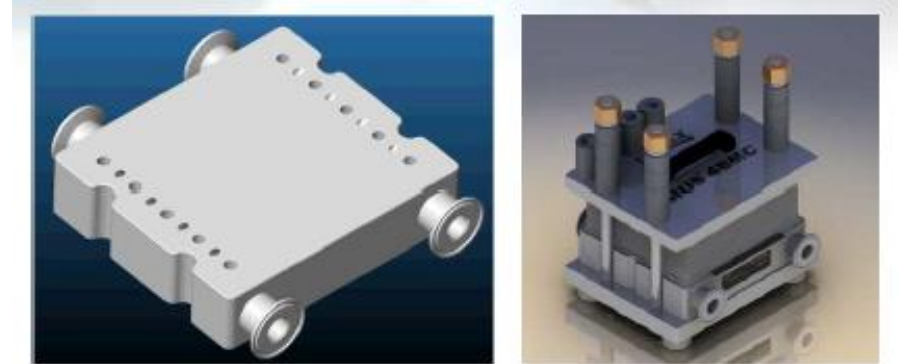
Holder 4BMC => 0.5 m² to 2.0 m²



Novasep Sius™ Family for Single use filter plate inserts

■ USP Class VI Materials

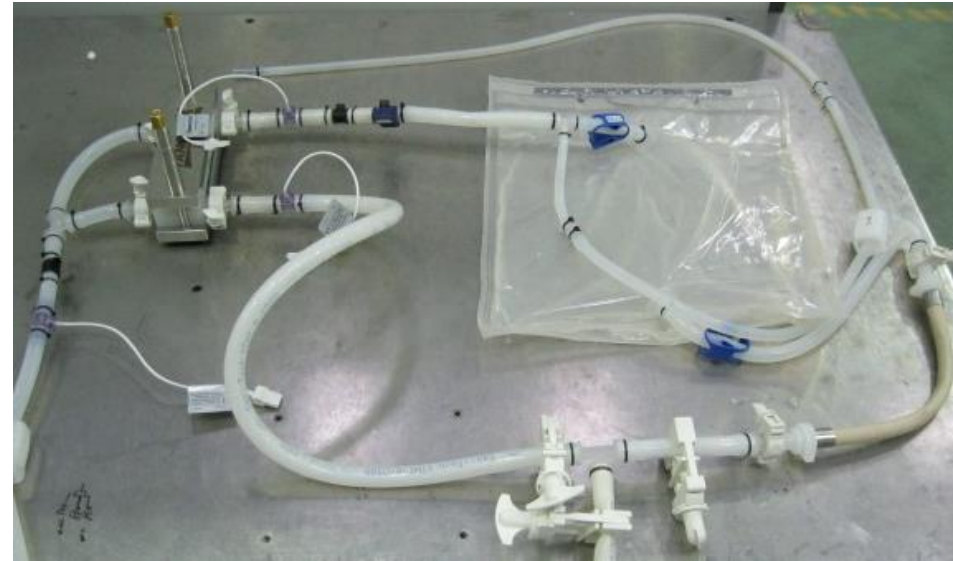
- Type 304L/316 Stainless Steel
 - Clamp Base, Cover
 - Washers / Spacers
 - Screws
- Brass Nuts
 - 1-¼" Socket Hex Nut
- Polyethylene (Contact Surface)
 - Filter Plate Insert
 - Barbed Fittings
- Polypropylene (Contact Surface)
 - Luer Lock Fittings
- EPDM (Contact Surface)
 - O-Rings



Novasep Sius TFF skid



+



Skid

- High treatment capacity
- Completely automated
- Batch record
- 21 CFR Part 11 compliance

Single use flowpath

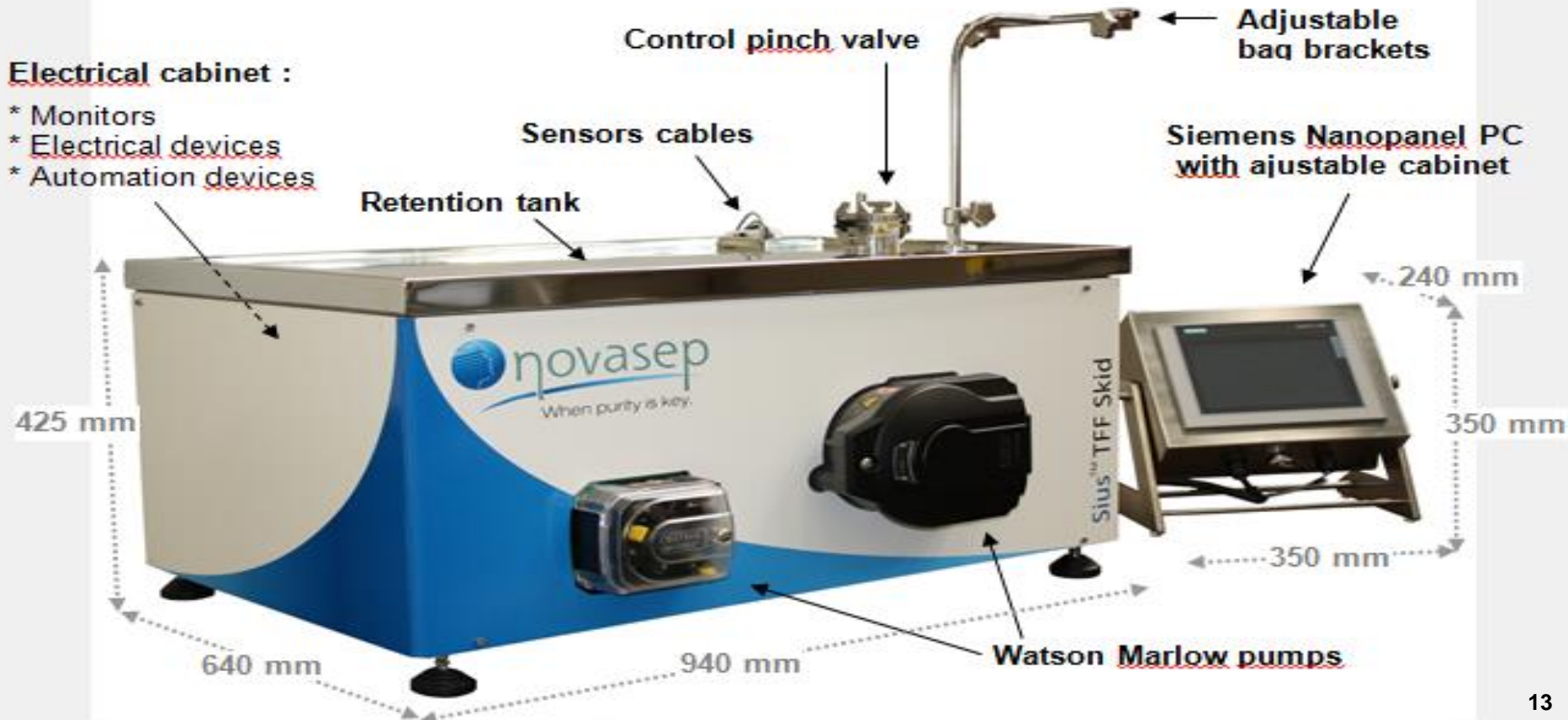
- Gamma irradiated
- Pre-connected
- 3 bars resistant
- 2 sizes available
- Completely single use
- Integrity testing line integrated

Novasep Sius TFF skid: The hardware

- 1 x recirculation pump : peristaltic pump, up to 900 L/h capacity
- 1 x secondary pump : peristaltic pump, up to 150 L/h capacity
- 1 x control valve : pinch valve to control the TMP
- 1 x weight sensor : to measure the weight into the feed bag
- 1 x pressure and flow monitor : to connect the single-use sensors
- 1 x conductivity monitor : to connect the single-use conductivity sensor
- 1 x supervisor : Siemens Nanopanel PC with adjustable cabinet

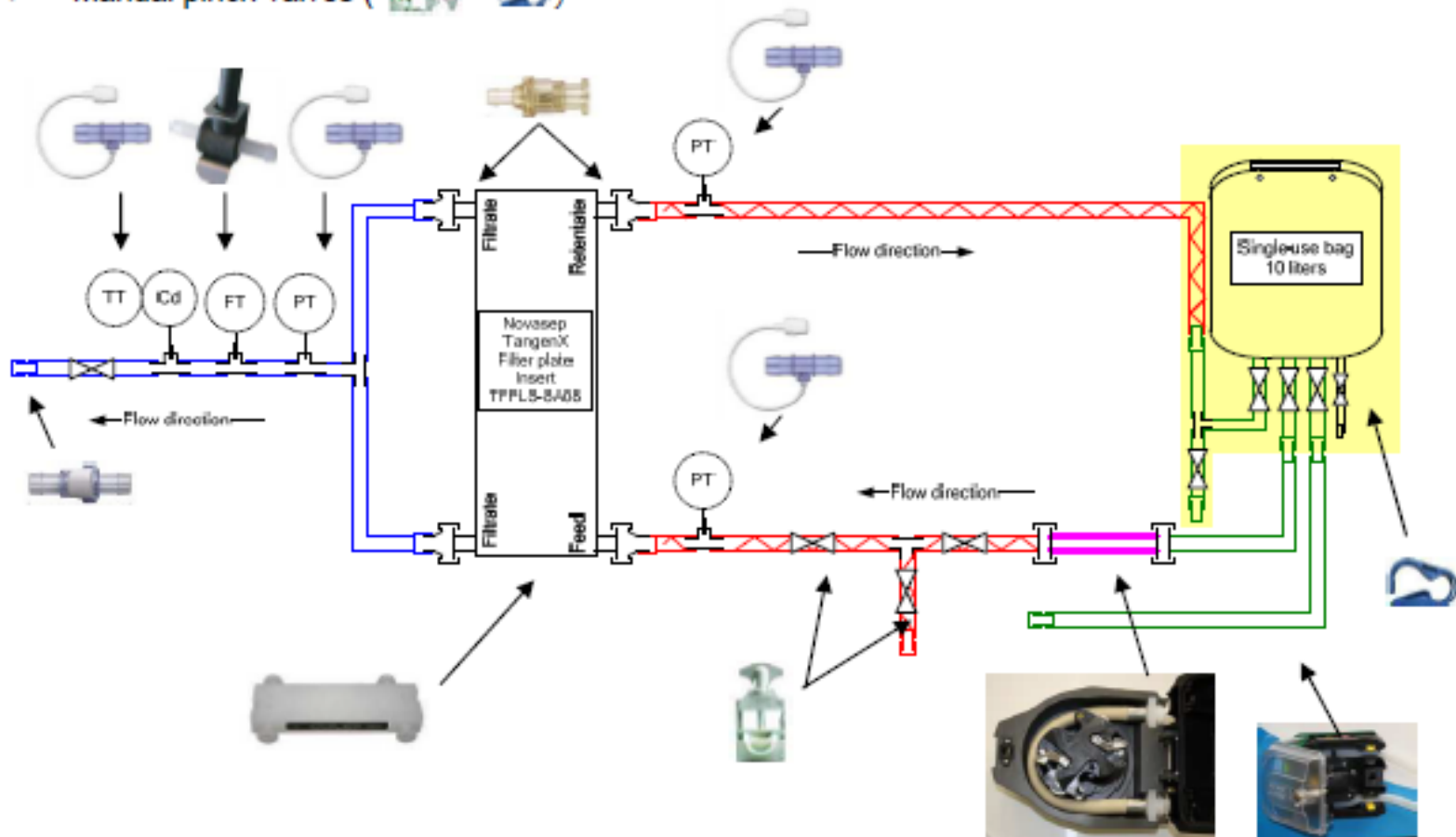
Electrical cabinet :

- * Monitors
- * Electrical devices
- * Automation devices

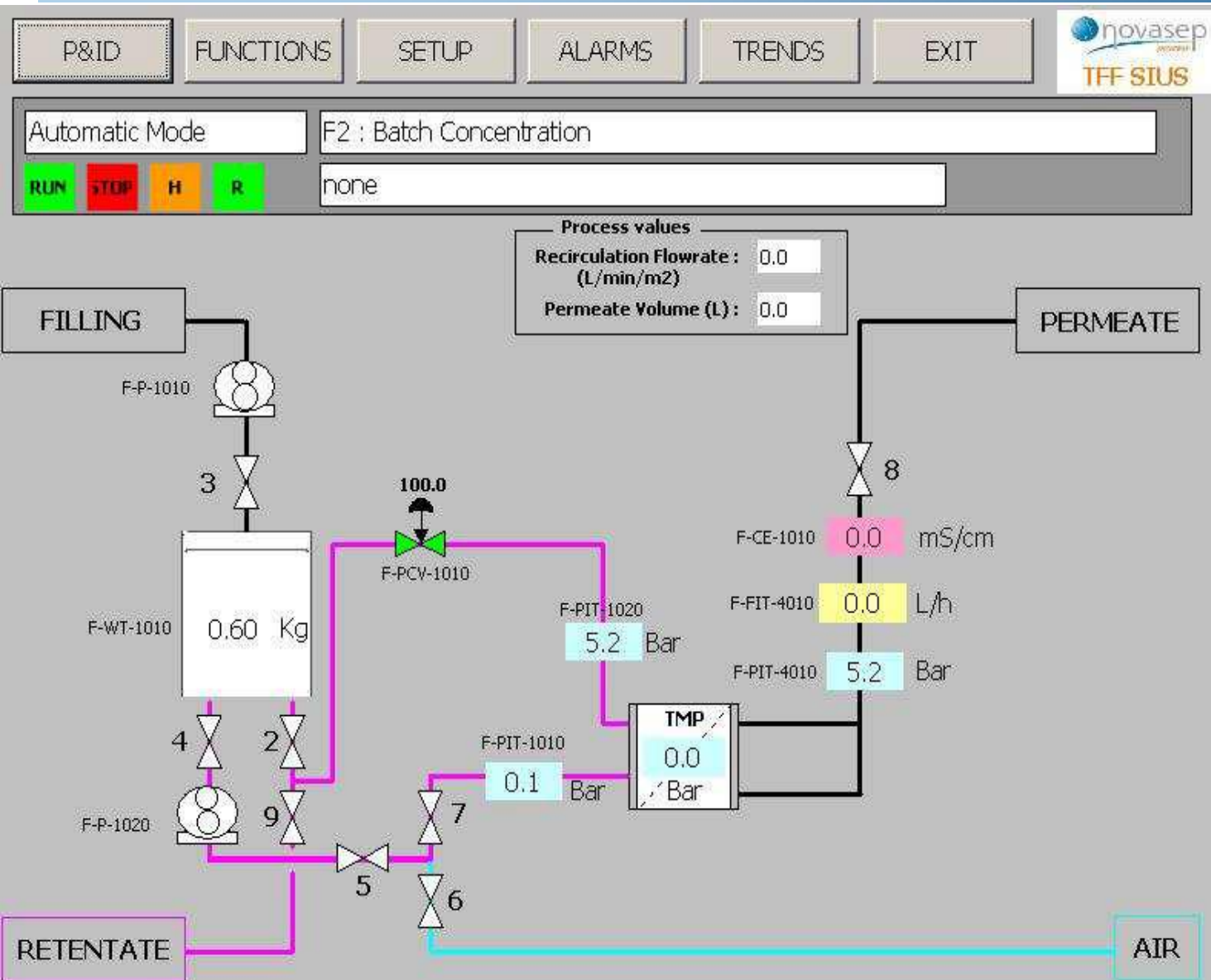


Novasep Sius TFF skid: The consumables

- Low pressure tubing: Platinum-cured silicone (— + —)
- High pressure tubing: Platinum-cured braid-reinforced silicone and Bioprene® (— + II —)
- Sensors: single-use flowmeter, pressure sensors and conductivity sensor
- Connectors: Colder Products Company® single-use quick connectors (— + —)
- Single-use TangenX® Sius™ Filter Plate Insert (FPI) for 2BMC holder (ref: TSLDI-2BMC)
- Single-use feed bag: 10 liters (option: customer supplied bag)
- Manual pinch valves (— + —)



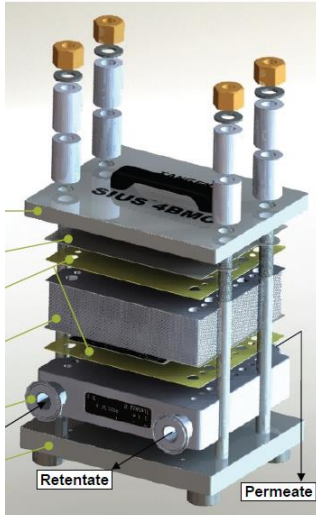
Novasep Sius TFF skid: The software



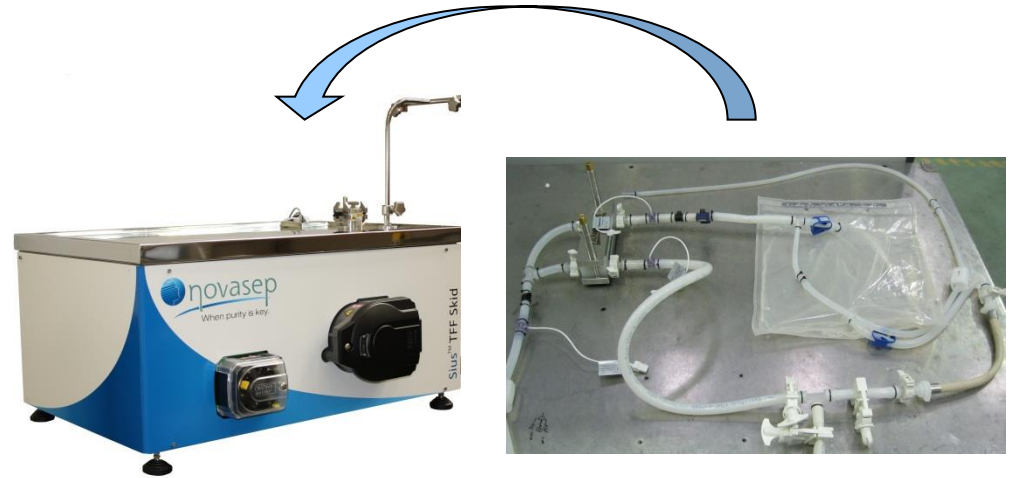
- 3 control Modes (Manual, automatic and recipe)
- 7 functions covering all common TFF steps
- 3 levels of alarms
- Real time data acquisition & Batch record
- Data export in CSV file

Novasep Sius TFF skid

1) Install the membrane on the kit



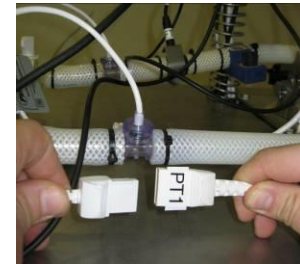
2) Install the kit on the skid



3) Install the tubing inside the pumps and the valve



4) Plug the sensors

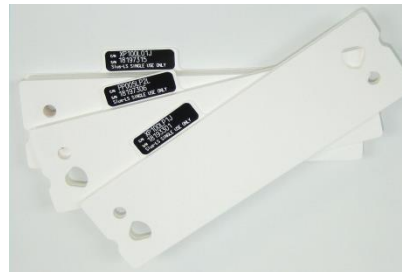


- **Sius TFF cassette suits to any biopharma process**
 - 2 chemistries, different cut-offs,
 - Full range of format,
 - Different channel configurations
- **Sius flowpath and filter plate insert**
 - USP classVI, gamma irradiated,
 - 2 sizes available
- **Sius skid**
 - High treatment capacity,
 - completely automated, batch record, 21 CFR Part 11 compliance,

Pre-Clinical

TFF Area:
0.01 m² to 0.5 m²

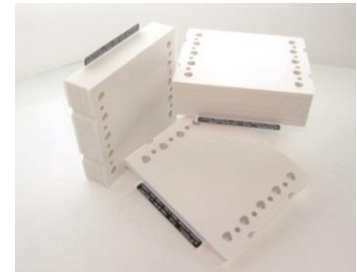
Single-use solution:
Sius™-LS cassettes



Clinical Phase I, II, III

TFF Area:
0.5 m² to 2.0 m²

Single-use solution:
Sius™ cassettes



Guaranteed Scalability



Thank you for your attention!
