Single-Use TangenX® Sius™ Cassettes
For Lab to Process Scale Tangential Flow Filtration

Disposable Sius™ Cassettes Benefits:

- In combination with TangenX® Sius™ Filter Plate Insert, obtain a complete disposable system for Tangential Flow Filtration (TFF)!
- Pre-sanitized single-use and ready-to-use cassettes for easy and simple processing
- Shorter process time due to minimum preparation and cleaning
- Cost-effective solution
- Reproducible and reliable scale-up performance from lab through to process
- Compatible with traditional holders and hardware

Why are Disposable Cassettes Necessary?

TFF cassettes are repeatedly used in a process until their process performance has deteriorated below acceptable limits and their productivity is reduced. Between uses, they are cleaned with a clean in place (CIP) operation. This method of reuse requires a significant investment of raw materials, utilities, energy and time, which can be drastically increased when CIP validation is required.

That is why Novasep offers the first truly single-use TFF cassettes for the biopharmaceutical industry. The disposable Sius™ cassette family, well established for the concentration and diafiltration of biomolecules, has been designed using an innovative manufacturing approach that provides comparable or better performance to reusable products at a fraction – 1/4th to 1/5th – of the cost.

Sius™ cassettes offer exceptional value when considering the basic steps of a TFF unit operation.

Those steps include pre-use activities, process and post-use activities. Typically, only 50% of the total process time is devoted to processing the product; the remaining 50% is spent in preparing and cleaning the TFF system. The time needed in preparing and cleaning the Sius™ single-use cassettes is drastically reduced: much more time is devoted to processing the product, increasing process efficiency and saving a significant portion of the overall process time.

Furthermore, validations of membrane cleaning studies and performance studies after reuse are eliminated. Lastly, using Sius™ single-use cassettes also improve process safety, reducing the risk of cross-contamination.
Product Description

The Sius™ cassette family offers the same performance or even better than traditional reusable cassettes. See Application Performance.

These Sius™ cassettes are fully compatible with TangenX® Novaset™ reusable cassettes, hence providing seamless transition between development and large scale production.

Moreover, the cassettes are completely interchangeable with existing cassette hardware, including our TangenX® Sius™ Flow Path Insert (FPI), making them an ideal choice for many TFF processes. Please refer to the datasheet titled “TangenX® Sius™ Filter Plate Insert and Holder” or contact us for more information.

Each cassette is integrity tested for both air integrity and for their hydrodynamic performance. Then, cassettes arrive pre-sanitized, packaged in 0.2M sodium hydroxide and ready to be used for processing after equilibration with buffer.

Each cassette is supplied with a user guide, a compatibility guide, a quality certificate and an EPDM gasket. In addition, we can provide you with the validation guide to meet cGMP guidelines and pass regulatory inspections.

Close to their customers, Novasep experts can perform trials with you in your laboratories, as well as our local distributors of TangenX® products. Thus, do not hesitate to contact us!

Application Performance

Is the early stage of process development, even if the process has not yet been established, the type of membrane has been narrowed down. Feed pressure, TMP and screen geometry need to be decided since they must coalesce into an efficient and robust process that can be easily scaled up to a commercial manufacturing process.

Below is a comparative study of several TFF cassettes for the purification of monoclonal antibodies, from a conference at the IBC’s 6th International Single-Use Applications for Biopharmaceutical Manufacturing, June 2009.

Graph 1 and Graph 2 show that whatever the monoclonal antibody, Mab 1 or Mab 2, Sius™ membranes have highest average flux during both concentration and diafiltration steps.

In Graph 3, the flux decreases due to the increasing protein concentration.

Graph 2 and Graph 3 show that at low and high protein concentration, Sius™ membranes have the highest flux performance, thus minimizing total process time for both concentration and diafiltration operations.
Cassettes Selection and Optimization

Many factors affect the type of cassette and membrane surface area that is best suited for a specific application. Significant differences from molecule to molecule and process to process demand that a range of cassettes be available to ensure the most advantageous balance of performance and capacity.

Sius™ cassettes are available in a wide range of membrane pore sizes from 1 kD to 0.65 µm, single cast manufactured in modified polyethersulfone membrane chemistries:

- **ProStream™ membrane**: neutrally charged membrane designed for extremely low protein binding.
- **HyStream™ membrane**: extremely hydrophilic membrane designed for streams with a higher level of foulants.

The Sius™ cassette family is available with three different retentate channel configurations:

- “L” type (Low Pressure Screen) is ideal for low to medium viscosity streams where high flux and lower recirculation rates are desired.
- 0.5 mm “J” type and 1.0 mm “K” type open channels are ideal for streams of high viscosity or those containing particulates. This geometry is ideal for cell clarification.

Sius™-LS (lab scale) cassettes are available in 0.01 m², 0.02 m² and 0.1 m² surface area formats and Sius™ cassettes in 0.5 m², 1.5 m² and 2.5 m². Both cassettes can be stacked together to provide greater surface areas.

Concentration factors obtained with Sius™ are typically 3-100X when used in conjunction with a Novasep engineered TFF system. The TangenX line of cassettes represents the latest development in TFF cassette design and performance: They have been designed to deliver optimal performance as well as demonstrate exceptional batch-to-batch reproducibility.

Applications

Biopharma, Biotech, Life Sciences:

- Microfiltration, ultrafiltration / diafiltration
- Concentrate and desalt proteins, peptides, nucleic acids (DNA, RNA, oligonucleotides)
- Separate and purify biopharmaceuticals
- Recover and purify antibodies or recombinant proteins from cell culture media
- Fractionate diluted protein mixtures
- Remove pyrogens from water, buffer, and media solutions
- Sample preparation prior to chromatography
- Buffer exchange an formulation

Quality & Properties and Compatibility

- Manufacturing & Quality

Sius™ cassettes are manufactured and quality controlled in a facility modeled for cGMP compliance. Each cassette undergoes rigorous preparation and QA lot release testing to verify it meets specification. Quality Control (QC) performance testing includes hydrodynamic (pressure drop) and air integrity measurements. Each cassette is flushed with purified water and sanitized after completing QS testing. Stringent testing ensures cassette-to-cassette consistency, resulting in scalable process development and reproducible manufacturing. Each Sius™ device is sanitized and individually sealed in a foil-lined vapour barrier bag, then packaged in an outer cardboard carton. Sodium hydroxide at 0.2M concentration is used as a sanitizing agent and to prevent membrane drying and loss of performance.
### Ordering & Specifications

<table>
<thead>
<tr>
<th>Membrane Type</th>
<th>Membrane Cut-Off</th>
<th>Configuration Code</th>
<th>Membrane Area</th>
<th>Channel Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>P X</td>
<td>001 003 005 010 030 050 100 300 M10* M20* M45* M65*</td>
<td>L M G</td>
<td>P1 P2 01 05 15 25</td>
<td>L J K</td>
</tr>
</tbody>
</table>

**P** - ProStream™

**X** - HyStream™

For other type, please contact us.

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### Product Data Profile

**EUROPE – Novasep Process**

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54340 Pompey – France

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Fax: + 33 (0) 3 83 49 70 02

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Fax: + 1 508 845 3030

sius@novasep.com

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### Specifications

<table>
<thead>
<tr>
<th>Material of Construction</th>
<th>Properties</th>
<th>Slus™-LS Dimension</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Membrane</td>
<td>Length</td>
<td>20.5 cm (8.1 in)</td>
<td>21.2 cm (8.3 in)</td>
</tr>
<tr>
<td>Membrane Support</td>
<td>Width</td>
<td>5.6 cm (2.2 in)</td>
<td>19.2 cm (7.6 in)</td>
</tr>
<tr>
<td>Screens</td>
<td>Thickness</td>
<td>0.4-1.4 cm (0.16-0.55 in)</td>
<td>1.4-5.8 cm (0.6-2.3 in)</td>
</tr>
<tr>
<td>Channel Spacer</td>
<td>Membrane Area</td>
<td>0.01, 0.02, 0.1 m² (0.11, 0.22, 1.1 ft²)</td>
<td>0.5, 1.5, 2.5 m² (5.4, 16.2, 26.9 ft²)</td>
</tr>
<tr>
<td>Encapsulant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gasket</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Preservative</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTES:**

* From FDA approved material and Class VI tested
** To remove preservative, equilibrate with buffer and process, no flushing required

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### Products

- **L** Screen
  - Max pressure at 30°C
    - Forward: 7 bar (100 psi)
    - Reverse: 0.48 bar (7 psi)
  - Cross-Flow (L/min/m²): 4-8 at 0.7 bar (10 psi)

- **J** Channel
  - Max pressure at 30°C
    - Forward: 7 bar (100 psi)
    - Reverse: 0.48 bar (7 psi)
  - Cross-Flow (L/min/m²): 10-15 at 0.07 bar (< 1 psi)

- **K** Channel
  - Max pressure at 30°C
    - Forward: 7 bar (100 psi)
    - Reverse: 0.48 bar (7 psi)
  - Cross-Flow (L/min/m²): 20-30 at 0.07 bar (< 1 psi)

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### Properties

- **Ultrafiltration**
  - ≤ 323 sccm/m² at 1 bar
    - ≤ 30 sccm/ft² at 15 psi
  - ≤ 323 sccm/m² at 0.5 bar
    - ≤ 30 sccm/ft² at 7.3 psi
  - ≤ 323 sccm/m² at 0.2 bar
    - ≤ 30 sccm/ft² at 3 psi

- **Microfiltration**
  - ≤ 0.1 µm
    - ≤ 30 sccm/ft² at 3 psi

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### Air Diffusion Rates

- **Ultrafiltration**
  - ≤ 323 sccm/m² at 1 bar
    - ≤ 30 sccm/ft² at 15 psi
  - ≤ 323 sccm/m² at 0.5 bar
    - ≤ 30 sccm/ft² at 7.3 psi
  - ≤ 323 sccm/m² at 0.2 bar
    - ≤ 30 sccm/ft² at 3 psi

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### Membrane Cut-Off

<table>
<thead>
<tr>
<th>Ultrafiltration (kD)</th>
<th>Microfiltration (µ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 1 kD etc.</td>
<td>M10* = 0.1 µ etc.</td>
</tr>
</tbody>
</table>

*Only for HyStream™ membrane

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### Contact Information

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81, Boulevard de la Moselle – BP 50
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### Material of Construction

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<th>Encapsulant</th>
<th>Gasket</th>
<th>Preservative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified Polyethersulfone</td>
<td>Polypropylene</td>
<td>Polypropylene</td>
<td>Polyethylene (HDPE)*</td>
<td>Polylactide*</td>
<td>White EPDM*</td>
<td>0.2M NaOH**</td>
</tr>
</tbody>
</table>

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### Configuration Code

- **P1** - 0.01 m² (0.11 ft²)
- **P2** - 0.02 m² (0.22 ft²)
- **01** - 0.1 m² (1.1 ft²)
- **05** - 0.5 m² (5.4 ft²)
- **15** - 1.5 m² (16.2 ft²)
- **25** - 2.5 m² (26.9 ft²)

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### Channel Type

- **L** - Low pressure screen
- **J** - Open channel: 0.5mm
- **K** - Open channel: 1.0 mm

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### Published Information

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### Notes

- From FDA approved material and Class VI tested
- To remove preservative, equilibrate with buffer and process, no flushing required

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### Microfiltration

- ≤ 0.1 µm
  - ≤ 30 sccm/ft² at 3 psi