At Novasep, we can prove true savings in cutting your TFF filtration costs.

Tangential Flow Filtration Solutions:
TangenX® Sius Single-Use Products
TangenX® NovaSet Reusable Cassettes
TangenX® TFS Holders & Systems

www.novasep.com
We have developed a complete range of optimized Tangential Flow Filtration (TFF) cassettes & systems based on innovative and proven technologies for your biopharmaceutical purifications. We offer a broad range of TFF units, cassettes and systems with membrane areas from 0.01 m² to 40 m² and more... as well as a large range of cut-offs from 1 kD to 0.65 μm. We provide the solution adapted to your filtration strategy from lab to process scale:

- **TangenX® Hystream™ and Prostream™** modified PES (mPES) membranes for microfiltration and ultrafiltration applications for most biopharmaceutical processes. Our membranes offer the advantage of high flux with extremely low protein binding properties.
- **TangenX® Sius™** single-use TFF cassettes
- **TangenX® Sius™ disposable FPI (Flow Path Inserts)**
- **TangenX® NovaSet™** reusable TFF cassettes
- **TangenX® TFS**: TFF holders and systems from lab to industrial scale

Our solutions for biopharmaceutical manufacturing provide you with:

**Guaranteed Performance**

With experience in most purification technologies, we can offer integrated process design and solutions, from lab to industrial scale. We **guarantee the process transfer** from pre-clinical to commercial scale and **from disposable to reusable** since Novasep’s entire range of filtration solutions are composed of the same materials and chemistry.

**Shorter Time-to-Market**

Our process expertise enables us to **reduce upstream and downstream development times** using advanced methodologies including, where applicable, proprietary computer modeling tools.

**Regulatory Compliance**

The biopharmaceutical industry cannot compromise when it comes to **quality and patient safety**. All our packets, cassettes and blocks are individually tested. Our solutions comply with all regulatory and quality requirements. They ensure the highest quality and safety levels while optimizing purity and yield.

### Range of Novasep TFF Solutions

<table>
<thead>
<tr>
<th>TangenX Products</th>
<th>Novasep Product Name</th>
<th>Key Features</th>
<th>Filtration Surface Area/Capacities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Packet</strong></td>
<td>Sius™-LS</td>
<td>Single-Use</td>
<td>0.01 m² – 0.02 m²</td>
</tr>
<tr>
<td></td>
<td>NovaSet™-LS</td>
<td>Reusable</td>
<td></td>
</tr>
<tr>
<td><strong>Cassette</strong></td>
<td>Sius™-LS</td>
<td>Single-Use</td>
<td>0.1 m²</td>
</tr>
<tr>
<td></td>
<td>NovaSet™-LS</td>
<td>Reusable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sius™</td>
<td>Single-Use</td>
<td>0.5 m²</td>
</tr>
<tr>
<td></td>
<td>NovaSet™</td>
<td>Reusable</td>
<td></td>
</tr>
<tr>
<td><strong>Block</strong></td>
<td>Sius™</td>
<td>Single-Use</td>
<td>1.5 m² and 2.5 m²</td>
</tr>
<tr>
<td></td>
<td>NovaSet™</td>
<td>Reusable</td>
<td></td>
</tr>
<tr>
<td><strong>Flow Path Insert</strong></td>
<td>Sius™-LS LHV FPI</td>
<td>Single-Use</td>
<td>up to 0.48 L/min</td>
</tr>
<tr>
<td></td>
<td>Sius™-LS FPI</td>
<td>Single-Use</td>
<td>up to 9 L/min</td>
</tr>
<tr>
<td></td>
<td>Sius™ 75 FPI</td>
<td>Single-Use</td>
<td>up to 49 L/min</td>
</tr>
<tr>
<td><strong>Holder</strong></td>
<td>Sius™-LS 2BMC</td>
<td>Stainless Steel</td>
<td>0.01 m² – 0.5 m²</td>
</tr>
<tr>
<td></td>
<td>Sius™ 4BMC</td>
<td>Stainless Steel</td>
<td>0.5 m² – 5.0 m²</td>
</tr>
<tr>
<td></td>
<td>NovaSet™-LS LHV</td>
<td>Low Hold Up Volume</td>
<td>0.01 m² – 0.04 m²</td>
</tr>
<tr>
<td></td>
<td>NovaSet™-LS Pilot</td>
<td>Multipurpose</td>
<td>0.1 m² – 0.5 m²</td>
</tr>
<tr>
<td></td>
<td>NovaSet™ N50/N75</td>
<td>Stainless Steel</td>
<td>0.5 m² – 7.5 m²</td>
</tr>
<tr>
<td><strong>Lab System</strong></td>
<td>NovaSet™-LS LHV</td>
<td>Low Hold Up Volume</td>
<td>15 mL - 5 L sample</td>
</tr>
<tr>
<td></td>
<td>NovaSet™-LS Pilot</td>
<td>Multipurpose</td>
<td>150 mL – 20 L sample</td>
</tr>
</tbody>
</table>
TangenX® Sius: the first truly disposable TFF Cassette provides tangible benefits for your biomolecule purification

**Designed for Single-Use to Drastically Reduce Cost**

Sius™ cassettes cost five times less than our average competitor’s reusable cassettes and offer an unmatched price/performance ratio (figure 1). With Sius™ pre-sanitized and individually tested cassettes, we provide an economical breakthrough solution in TFF for the bioprocess industry.

**Improved Performance**

The Sius™ cassette incorporates a unique patented design allowing a consistent flux over time. Its superior performance versus competing products has been demonstrated by customers in controlled side-by-side comparisons with competitors’ membranes (table 1).

**Improved Quality**

The Sius™ cassette automated process assembly and individual cassette release-testing ensure exceptional cassette-to-cassette reproducibility.

**Cleaning Validation Made Easier**

With no need to flush or measure water permeability rates, Sius™ cassettes reduce the amount of time and resources needed for testing and integration. With no need for membrane cleaning and measurement of water flux recovery, using Sius™ in single-use TFF operations will minimize cleaning and cross-contamination risks.

**Shorter TFF Process Time**

With reusable products, typically 50% of the total process time is devoted to processing the product, the remaining time is spent preparing and cleaning the TFF system. With Sius™ the process amounts to 80% of the total time, increasing process efficiency by 60%.

**Cost-Effective Choice for Short Campaigns**

Sius™ TFF technology is most beneficial at development and pilot scales (<5 m²). Larger scales benefit when the number of process cycles is fewer than 20 (figure 2). Multi-purpose manufacturing suites are ideal candidates for single-use TFF.

**Seamless Transfer to Reusable TFF for Long Term Production**

All membranes and process contact materials of our Novaset™ reusable cassettes are also used in Sius™, thereby ensuring full compatibility and consistent results when switching from a disposable to a reusable process strategy. We guarantee the process transfer to commercial scale.

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**Table 1. Process Time**

Data extracted from Evaluation and comparison of tangential flow filtration cassettes for use in a monoclonal antibody purification process- at IBC’s 6th International Single-Use Applications for Biopharmaceutical Manufacturing, June 2, 2009 at La Jolla, CA.

Membranes evaluated: Novasep cassettes are PES Sius™ cassettes, 92.8 cm² surface area, 50 kD MWCO, protein loaded 307 g/m² and cross-flow rates (mL/min) 60, 70, 80. All competitors PES cassettes have 50 kD MWCO and a surface area from 88 to 100 cm².

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Process Time (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membrane Type</td>
<td>Trials</td>
</tr>
<tr>
<td></td>
<td>mAb 1</td>
</tr>
<tr>
<td></td>
<td>mAb 2</td>
</tr>
<tr>
<td>Concentration (10 mg/mL to 30 mg/mL)</td>
<td>0.6</td>
</tr>
<tr>
<td>Dialfiltration (30 mg/mL in SP Elution Buffer to 30 mg/mL in formulation Buffer)</td>
<td>1.9</td>
</tr>
<tr>
<td>Total Process Time</td>
<td>2.5</td>
</tr>
<tr>
<td>Average Time Savings</td>
<td>32%</td>
</tr>
<tr>
<td>with Sius™</td>
<td>31%</td>
</tr>
</tbody>
</table>
Commercial Manufacturing (2,000 L to 20,000 L)
NovaSet™ Cassettes (10 m² to 40 m²)

TangenX® NovaSet Cassettes: The most affordable reusable TFF cassettes using robust validated technology for your commercial biopharmaceutical production

NovaSet™ TFF cassettes have been designed to provide you with optimal performance:
- **Reliable scale-up**, from lab to manufacturing scale
- **Optimized channel geometry** and enhanced device rigidity ensure hydraulic performance
- Validated manufacturing process compliant with cGMP principles
- QC lot release testing includes **100% device integrity** and **hydrodynamic testing**
- **Individually packaged** in a sealed foil lined bag and outer cardboard carton
- Wet packed in 20% Glycerin and 0.1% Sodium Azide
- Cut-offs from **1 kD to 0.65 µm**
- Membrane areas from **0.01 m² to 2.5 m²**
- Stackable for a membrane area up to 40 m² and greater...
- Adaptable with all existing holders

TangenX® TFS: TFF Systems & Holders

We offer state-of-the-art TFF holders & systems for ultrafiltration and microfiltration from laboratory to industrial scale. **Our holders & systems can accommodate all your existing cassettes, including TangenX® reusable (NovaSet™) or disposable (Sius™) TFF cassettes.**

All our equipment has sanitary design and is fully compatible with GMP operations. Our equipment also complies with EC directives (DESP guidance).

New!!!! Sius™ FPI: disposable flow path inserts and low cost SS holder

The combination of Sius™ single-use cassettes with Sius™ FPI allows you to obtain a **complete disposable filtration** system, further reducing cleaning validation burden. Disposable flow path inserts are pre-sanitized and comply with USP Class VI. Sius™ FPI are available from laboratory to pilot scale. Each flow path insert is sold with a disposable polypropylene isolation plate in order to decrease the risk of contamination. Special low-cost Sius™ Stainless Steel holders have been designed to accommodate Sius™ FPI and cassettes, significantly **reducing capital investment** for new disposable TFF set-ups.
• Tangential Flow Filtration

• Cross Flow Filtration

Cassettes

• Systems & Holders

• Single-Use

• Ultrafiltration/Diafiltration

Protein Concentration

• Buffer Exchange

• Fractionation

Disposable
Expert Downstream Process Development Services

Whether you need to develop a complete DSP or a single filtration step, our teams of chemists, biochemists & process engineers, each with recognized expertise in downstream processes, will provide you with a complete and guaranteed solution:

- We develop and optimize your process.
- We design customized chromatography & TFF units that suit your facilities and specific process needs.
- We provide process performance guarantees for our tangential flow filtration systems.

Full Customer Service for your Filtration System

More than 2,000 Novasep laboratory and production units (including filtration cassettes, skids and complete systems) are installed worldwide for the production of pharmaceuticals and biopharmaceuticals.

Local Technical Support Services

- Customer service teams in Europe, the USA & China for prompt and courteous service, when and where you need it
- Local inventory of standard parts and consumables to ensure quick delivery

Training Services & Expertise

- Tailored on-site training provided by our experienced technical staff to help your team maintain optimum process performance
- Performance optimization for new or existing equipment

Novasep combines the expertise of specialists in purification processes, biomanufacturing and chemical synthesis. We strive to provide our customers with the best solution for obtaining pure active molecules.

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