Product Data Profile

# Sius™-LS Cassettes

## Single-Use TFF Cassette

## For Early Stage Process Development and Process Optimization

### Benefits of Selecting Sius™-LS Cassettes:

- Pre-sanitized single-use and ready-to-use cassette
- Reproducible cassette performance
- Ease and simplicity in processing
- Cost-effective solution
- Reliable scale-up performance


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Pure Performance for the Life Sciences

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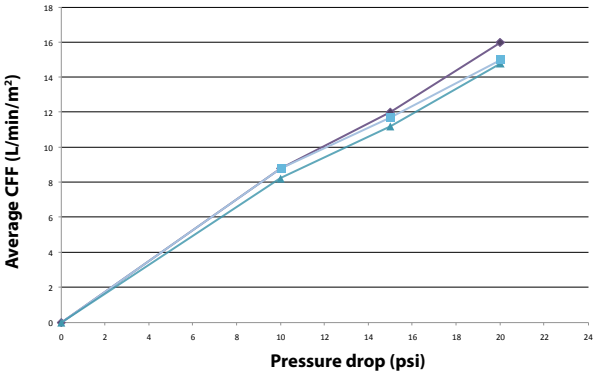
## Product Description

Novasep is proud to offer the first truly single-use tangential flow filtration cassette for the biopharmaceutical industry. The Sius™-LS single-use cassette has been designed to offer **comparable performance to reusable products at a fraction of the cost**.

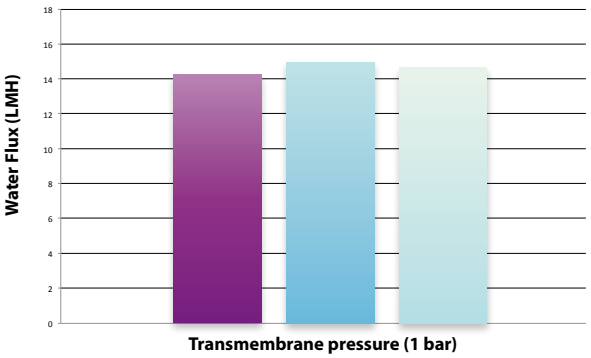
Tangential flow filtration (TFF) cassettes are well established for the concentration and diafiltration of biomolecules. TFF cassettes are typically used in a process and then cleaned between uses with a clean-in-place (CIP) operation. This method of reuse requires a significant investment of raw materials, utilities, energy, and time. The cassette is used repeatedly until its process performance has deteriored below acceptable limits and its productivity is reduced. Novasep now offers the **first purpose-built, single-use, tangential flow filtration cassette** for the biopharmaceutical industry. Additionally, each cassette arrives pre-sanitized, packaged in 0.1M sodium hydroxide and **ready for processing** after equilibration with buffer. The cassette is simply installed, conditioned with buffer to neutralize the pH and ready for process. Finally, validation of membrane cleaning studies and performance studies after reuse are eliminated.

The Sius™-LS and Sius™ cassette family is also **completely interchangeable with existing cassette hardware**. Cassettes are tested for both air integrity and for their hydrodynamic performance. This testing ensures cassette-to-cassette consistency. The result: scalable process development and reproducible manufacturing. *Graph1* shows the pressure drop vs. cross-flow specification for the Sius™-LS cassettes. *Graph 2* shows the TMP vs. water flux for the 10 kD Sius™-LS cassettes through scale-up from 0.01 $m^2$ to 0.1 $m^2$.




**NOTES:**
Sius™-LS "LP" Screen
Purified water at 20° C
Cassette Torque = 140 in/bs

*Graph 1: Pressure drop vs. cross-flow flux- Sius™-LS "LP" screen*




**NOTES:**
Sius™-LS 10 kD ProStream™
Purified water at 20° C
Cassette Torque = 140 in/bs

*Graph 2: Transmembrane pressure vs. water flux - Sius™-LS 10 kD*

### Application Performance:

In the early stages of process development, time and process material are of utmost importance. At this stage, even though the process has not yet been established, the type of membrane has been narrowed down. Decisions need to be made regarding feed pressure, TMP and screen geometry. All these elements must coalesce into an efficient and robust process that can be easily scaled up to a commercial manufacturing process. Process development using Sius™-LS single-use cassettes saves valuable time and resources by eliminating cleaning cycles between experiments. Sius™-LS 0.01$m^2$, 0.02 $m^2$ & 0.1 $m^2$ devices are designed for processing volumes from tens of milliliters to several liters. This variety of device size allows efficient processing over a wide range of operating volumes.

- Sius™-LS processing volume capability:
  For example, depending on the characteristics of the feed stream, a 10 kD membrane run at 2 bar TMP typically handles 2 L/hr. for the 0.01 $m^2$, 4 L/hr. for the 0.02 $m^2$ and 20 L/hr. for the 0.1$m^2$.

- Concentration factors obtained with Sius™-LS:
  Typically 3-100 X used in conjunction with a Novasep engineered system

**Sius™ cassettes represent the latest development in tangential flow filtration cassette design and performance. The line of cassettes has been designed to deliver optimal performance as well as demonstrate exceptional batch-to-batch reproducibility.**

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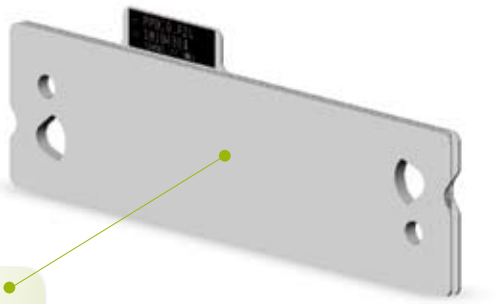
## Cassette Selection and Optimization:

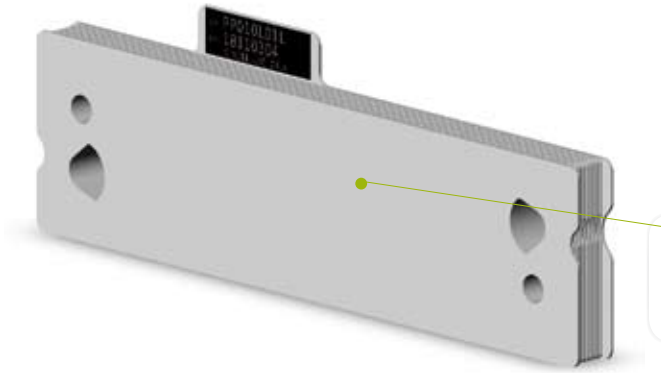
Many factors affect the type of cassette and membrane surface area that is best suited for a specific application. Significant differences from molecule to molecule and process to process demand that a range of cassettes be available to ensure the most advantageous balance of performance and capacity.

The Sius™-LS cassettes are available in a wide range of membrane pore sizes from 1 kD to 0.2 µm, in both ProStream™ (cross-flow membrane designed for extremely low protein binding for low concentrated proteins) and HyStream™ (extremely hydrophilic cross-flow membrane designed for high concentrated proteins) mPES membrane formats. Sius™-LS cassettes are available in 0.01 $m^2$, 0.02 $m^2$ and 0.1 $m^2$ surface area formats as well as three different channel configurations:

- "LP" 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.



**0.01 $m^2$, 0.02 $m^2$ Sius™-LS Packet**
All-in-one processing convenience for 15 mL to 500 mL biopharmaceutical samples



**0.1$m^2$ Sius™-LS Cassette**
All-in-one processing convenience for 50 mL to 5 L biopharmaceutical samples

# Applications

## Biopharma, Biotech, Life Sciences:

- 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, buffers, and media solutions
- Sample preparation prior to chromatography

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# Quality & Membrane Physical Properties and Chemical Compatibility

## Manufacturing & Quality:

Sius™-LS cassettes are manufactured and quality controlled in a cGMP compliant manufacturing facility. Quality control lot release testing includes 100% testing to verify that each cassette meets release specifications. Cassettes are tested for both air integrity and hydrodynamic performance. This release testing ensures cassette-to-cassette consistency. The result is scalable process development and reproducible manufacturing. Each Sius™-LS device is sanitized and individually packaged in a sealed foil-lined bag and outer cardboard carton. Each cassette is packaged in 0.1M sodium hydroxide as a sanitizing agent and to prevent membrane drying or loss of performance.

## Specifications:

| Materials of Construction* | |
|---|---|
| Membrane | Polyethersulfone |
| Membrane support | Polypropylene/Polyethylene |
| Screens | Polypropylene |
| Channel spacer | Polyethylene (HDPE)** |
| Encapsulant | 1) Polyurethane**<br>2) Silicone*** |
| Gasket | White EPDM** |
| Preservative | 0.2 M NaOH**** |

| Dimensions (Sius™-LS) | |
|---|---|
| Length | 20.5 cm (8.1 in) |
| Width | 5.6 cm (2.2 in) |
| Thickness | 0.4-2.0 cm (0.16 - 0.79 in) |
| Membrane Area | 0.01 $m^2$, 0.02 $m^2$, 0.1 $m^2$ (0.11 $ft^2$, 0.22 $ft^2$, 1.1 $ft^2$) |

**NOTES:**

* Apply for Sius™ also
** From FDA Approved material and Class VI Tested
*** Class VI Tested
**** To remove preservative - equilibrate with buffer and process, no flushing required.

| Channel Type | | Max Pressure (bar) at 30°C | Cross-Flow (L/min/$m^2$) |
|---|---|---|---|
| "LP" Screen | Forward | 4.1 (60 psi) | 4-8 at 0.7 bar (10 psi) |
| | Reverse | 0.48 (7 psi) | |
| "J" Open Channel (0.5 mm) | Forward | 4.1 (60 psi) | 12 at 0.07 bar (< 1 psi) |
| | Reverse | NOT RECOMMENDED | |
| "K" Open Channel (1.0 mm) | Forward | 4.1 (60 psi) | 24 at 0.07 bar (< 1 psi) |
| | Reverse | NOT RECOMMENDED | |

| Air Diffusion | | |
|---|---|---|
| "LP" Screen<br>"J" Channel<br>"K" Channel | Ultrafiltration 1 kD - 5 kD | ≤ 323 ccm/$m^2$ at 1 bar (≤30 ccm/$ft^2$ at 15 psi) |
| | Ultrafiltration 10 kD - 300 kD | ≤ 323 ccm/$m^2$ at 0.5 bar (≤30 ccm/$ft^2$ at 7.3 psi) |
| | Microfiltration ≥ 0.1 µm | ≤ 323 ccm/$m^2$ at 0.2 bar (≤30 ccm/$ft^2$ at 3 psi) |

**NOTE:** Reverse pressure is not recommended for "J" or "K" channel

# Ordering & Specifications

__ P __ __ __ __ ____ __

**Membrane Type**
- **P** - ProStream™
- **X** - HyStream™

**Polypropylene**

**Membrane Cut Offs UF MWCO -kD**
- 001 = 1 kD etc.

**Pore Size - µ**
- M = 0.1 µ etc.

001, 003, 005, 010, 030, 050, 100, 300, M10, M20

**Configuration Code Holder Retrofit**
- **L** - TangenX® / Pall
- **M** - Millipore / Sartorius / GE

L, M

**Membrane Area**
- **P1** - 0.01 $m^2$
- **P2** - 0.02 $m^2$
- **01** - 0.1 $m^2$

P1, P2, 01

**Channel Type**
- **L** - Low Pressure Screen
- **J** - Open Channel-0.5 mm
- **K** - Open Channel-1.0 mm

L, J, K

## Contacts


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