

Pellicon® Capsules for Single-Use Tangential Flow Filtration

Enhancing ease-of-use, batch turnaround, and process flexibility

Single-use TFF is used in biomanufacturing facilities to improve batch turnaround, process flexibility, and operator safety, all while reducing capital costs. The Pellicon® Capsule is the first of its kind — a true single-use TFF device that streamlines bioprocessing with its innovative, simplified design and user-friendly features. Pellicon® Capsules feature a holderless and torqueless design that reduces installation efforts. Supplied gamma sterilized and preservative-free, the capsules require minimal preparation before use. Single-use TFF with Pellicon® Capsules conserves time and resources associated with cleaning regimes and cleaning validation requirements of conventional stainless-steel TFF operations. This new addition to the Pellicon® family shares the same unbeatable performance of Pellicon® 2 and Pellicon® 3 cassettes and are linearly scalable, making it easy to transition from cassettes. With ease-of-use and reliable integration, Pellicon® Capsules offer fast, flexible, and cost-effective manufacturing of mAbs and other therapeutic proteins.

Why Pellicon® Capsules?

- Plug 'n play, holderless design
- Gamma sterilized with preservative-free RO water
- Ready to process in minutes
- Rapid batch turnaround
- Pellicon® TFF proven performance



Plug 'n Play

Pellicon® Capsules feature a streamlined holderless design to significantly reduce installation efforts. The capsules are self-contained and do not require a compression holder or other installation hardware to seal the flow path. The torqueless feature simplifies operation and prevents installation errors that could cause leakage from insufficient sealing of the device or damage to the membrane.

To install, the capsule is simply clamped on a facility fixture or inserted into the specially designed, stainless steel Pellicon® Capsule Stand (**Figure 1**). The capsule's ports allow for fractional sanitary flange connections for fast and easy connection to a single-use TFF system flow path using off-the-shelf components (**Figure 2**). This easier installation reduces the labor and operational time over current cassettes that require a holder and torquing.



Figure 1. Pellicon® Capsule Stand.

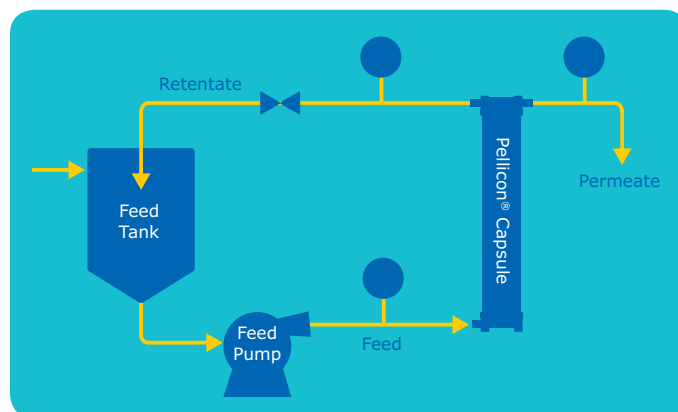


Figure 2. TFF setup with Pellicon® Capsule.

Ready in Minutes

Pellicon® Capsules are supplied gamma sterilized to eliminate the need for sanitization before use, which typically accounts for 20–30% of the preparation time. The capsules are provided with RO water and free of preservatives, significantly reducing flushing requirements (**Figure 3**).

The storage water can be quickly flushed out of the capsule with purified water or with processing buffer during conditioning, immediately after installation. These low preparation requirements allow Pellicon® Capsules to be ready for processing within minutes and significantly decrease the use of water and caustic solutions.

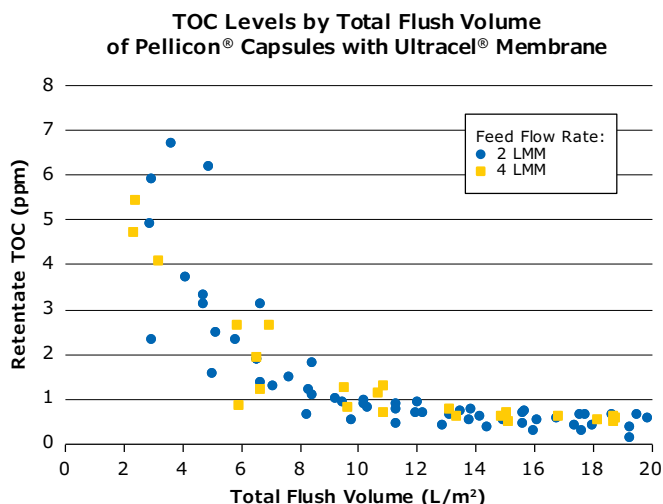


Figure 3. Low total organic carbon (TOC) levels are achieved with low flushing volumes of Pellicon® Capsule.

Rapid Batch Turnaround

The holderless, self-contained format of Pellicon® Capsules allows for a disposable flow path in a single-use TFF assembly: the capsule is typically discarded along with the tubing without opening the wetted flow path. Without any cleaning operations required after product recovery, the total process time could be reduced by 30–40% compared to a multi-use process. This decreases batch turnaround time for improved facility throughput, which is enhanced by the quick installation and reduced preparation time of the capsules to ultimately increase speed-to-market.

Capsule and flow path replacement after each batch also reduces cross-contamination risks for improved product safety, and increases operator safety from exposure to fluids that pose health risks. The ease of product changeover further provides facilities with the flexibility to change their processes more readily to enable multi-product manufacturing.

Pellicon® TFF Proven Performance

How do Pellicon® Capsules compare to proven Pellicon® 2 and Pellicon® 3 cassettes? Pellicon® Capsules were engineered to provide the same high performance as Pellicon® cassettes. Pellicon® Capsules are linearly

scalable within their own family as well as within the families of Pellicon® cassettes. The performance comparability and linear scalability between both filter formats interchangeably enables the use of similar membrane surface areas and pumps. This significantly facilitates development and scale-up studies to integrate Pellicon® Capsules into an existing TFF process run with Pellicon® cassettes.

Flux and Pressure Drop

Pellicon® Capsules exhibit the same high level of hydraulic and protein performance of Pellicon® cassettes that are ideal for today's therapeutic mAbs. **Figure 4** details the flux and pressure drop of Pellicon® Capsule 0.1 m² and Pellicon® 3 cassette 0.11 m² with 30 kD Ultracel® membranes and C screens during the concentration of bovine gamma globulin (BgG).

As the concentration and viscosity of the protein solution increases, the feed channel pressure drop increases and the antibody flux decreases, as expected by TFF theory. The close alignment of data points throughout the entire concentration demonstrates that the process flux and pressure drop are comparable for both filter formats. This performance comparability allows users of existing TFF systems with Pellicon® cassettes to transition quite easily to the new Pellicon® Capsules.

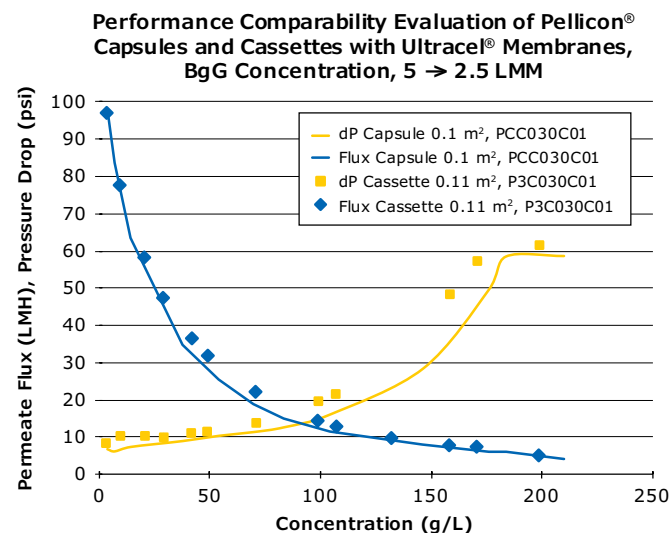


Figure 4. Pellicon® Capsules have comparable performance to Pellicon® cassettes.

Linear Scalability

The hydraulic and flux performance comparability between Pellicon® Capsules and Pellicon® cassettes facilitates linear scalability between both filter formats. **Figure 5** showcases the scalability profile of Pellicon® Capsules using flux as a function of transmembrane pressure.

The close data distribution for Pellicon® Capsules with 30 kD Ultracel® membrane and C screen, sizes 0.1 m² and 0.5 m², demonstrates linear scalability within the Pellicon® Capsule family. To assess capsule scalability to cassettes, the performance of Pellicon® 3 cassette with 30 kD Ultracel® membrane and C screen, size 0.11 m²

(shown as a range, $\pm 10\%$) was used as a benchmark. Both sizes of Pellicon® Capsules have data points within 10% of the cassette flux in both the polarized and non-polarized regions of the curve (**Figure 5**). This shows excellent linear scalability across both filter formats, further supporting reliable process consistency for an easy transition to Pellicon® Capsules.

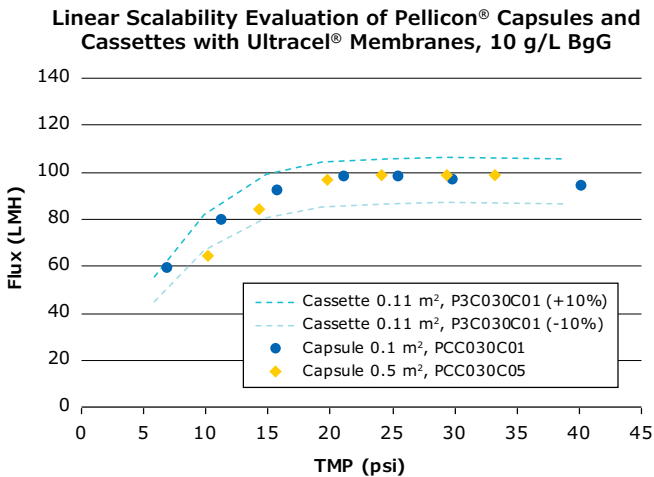


Figure 5. Pellicon® Capsules are linearly scalable within their own family and to Pellicon® cassettes.

Economical Benefits of Pellicon® Capsules

TFF systems for the filtration of mAbs have been traditionally operated for reuse. However, reuse of TFF devices requires major steps that add no value to the product, yet require significant time and labor. Single-use TFF with Pellicon® Capsules eliminates many of the steps of traditional TFF processes and offers additional user-friendly features to reduce process complexity, save time, and conserve resources in the filtration of mAbs and other biologics.

Time Savings

Use of single-use Pellicon® Capsules eliminates cleaning steps before and after product processing for increased facility throughput. This considerably shortens the total process time compared to that of a TFF process with a multi-use device (**Figure 6**). The ease-of-use of Pellicon® Capsules further cuts the process time through fast installation and disassembly. The time, labor, and costs saved from eliminating non-value-added TFF steps with Pellicon® Capsules could be allocated to improve plant productivity and benefit the overall downstream process.

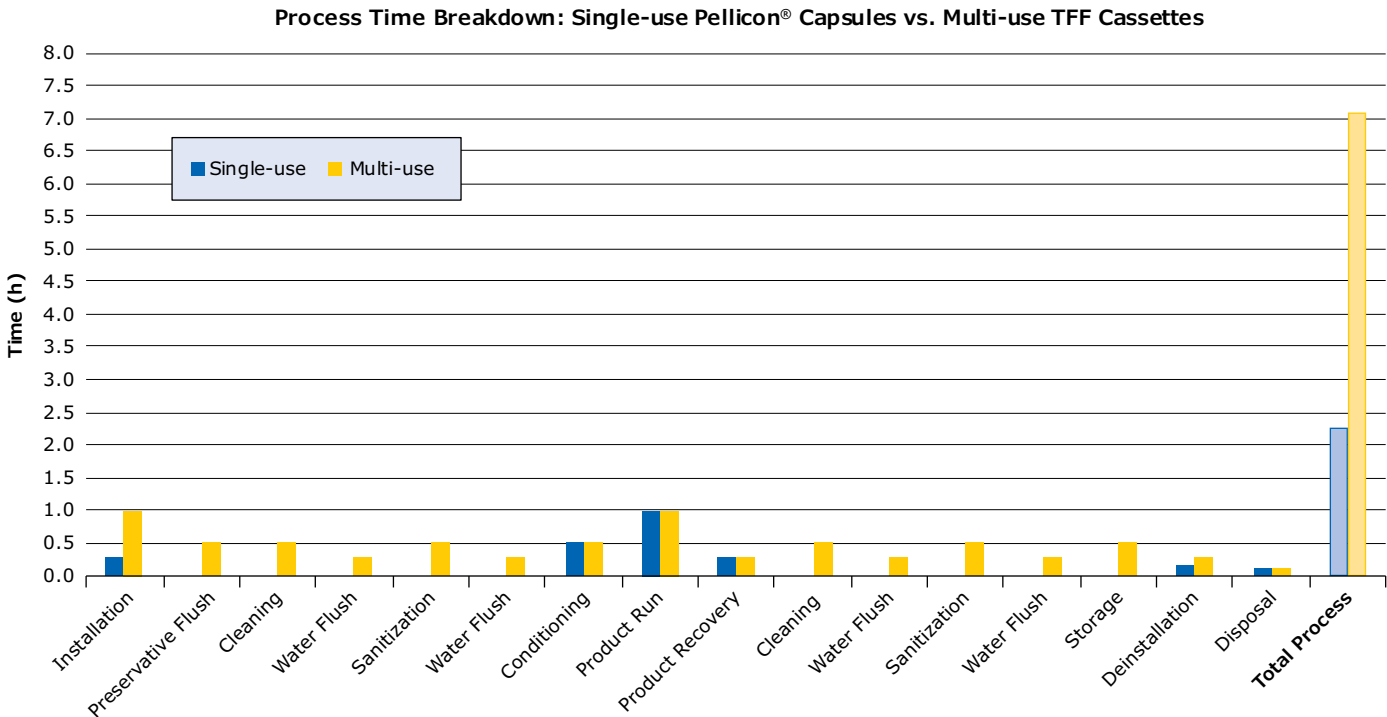


Figure 6. Significant time reduction in a TFF process is achieved with single-use TFF using Pellicon® Capsules. Times may vary based on the specific application and process.

Fluids Savings

Elimination of pre- and post-run steps by use of Pellicon® Capsules in single-pass TFF leads to significant savings of purified water and caustic agents (**Figure 7**), which would minimize the time and labor dedicated to preparing solutions and lower the total cost of fluids during a given filtration process.

Step		Volume (L/m ²)	
		Multi-use TFF Cassettes	Single-use TFF Pellicon® Capsules
New Device Prep/Pre-run	Preservative Flush	20	0
	Cleaning	15	0
	Water Flush	10	0
	Sanitization	5	0
	Water Flush	10	0
	Conditioning	20	20
Post-run Cleanup	Cleaning	15	N/A
	Water Flush	10	N/A
	Sanitization	5	N/A
	Water Flush	10	N/A
	Storage	10	N/A
Total		130	20

Figure 7. Compared to a typical multi-use TFF process, fluid usage is low during a single-use TFF process with Pellicon® Capsules. *Volumes may vary based on the specific application and process.*

Summary

Use of single-use Pellicon® Capsules is an effective strategy for improving operational flexibility, product safety, and turnaround of a TFF step. Pellicon® Capsules are holderless, gamma sterilized, and preservative-free. With these streamlining features, Pellicon® Capsules are quickly installed, used, and removed, making our capsules an attractive and cost-effective choice to improve plant productivity.

Because of their simplicity, Pellicon® Capsules can be easily integrated into existing facilities without major investments in new equipment. The transition from Pellicon® cassettes to Pellicon® Capsules is reliable for current users who will benefit from comparable high performance and linear scalability between both formats for streamlined process development and product validation.

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