



Biotech

USD 2902b

## Cadence® Single-Use Tangential Flow Filtration (TFF) Modules



### *A simpler, easier and safer single-use TFF solution for R&D, clinical or commercial manufacturing*

Pall's single-use tangential flow filtration (SUTFF) modules are ready-to-use gamma-irradiated cassette modules that can be integrated into single-use TFF set-ups. They provide ease-of-use, quick turnaround and increased flexibility and safety in cGMP operations.

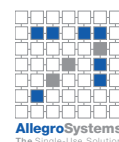
Pall's Cadence single-use TFF modules can be easily implemented in single-use TFF systems for concentration and diafiltration steps from R&D to commercial production of biotech products or vaccines.

Integrating the process-proven Omega™ polyethersulfone (PES) membrane, Cadence single-use TFF modules are available in scalable formats from 93 cm<sup>2</sup> up to 2.5 m<sup>2</sup> of membrane area.

#### **Key Attributes**

- ▶ Simpler and easier solutions: preassembled, ready-to-use modules for easy integration into single-use TFF systems.
- ▶ Safer solutions: single-use, gamma-irradiated modules for product and operator safety.

**Filtration. Separation. Solution.<sup>SM</sup>**



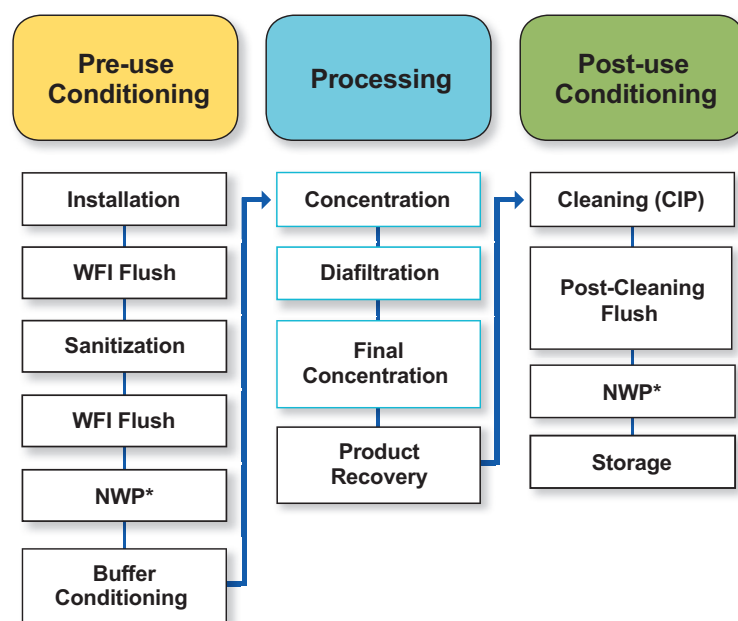
## Features and Benefits

Feature	Benefit
<ul style="list-style-type: none"> <li>▶ Cadence single-use TFF modules are delivered as preassembled modules that have been gamma irradiated at <math>\geq 25</math> kGy.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Ease of installation and integration in single-use TFF systems</li> </ul>
<ul style="list-style-type: none"> <li>▶ Supplied preconditioned, stored in water and gamma-irradiated, the modules do not require comprehensive conditioning steps prior to use (see Figure 1). Typically less than 20 L/m<sup>2</sup> flush volumes are required to reach total organic carbon (TOC) levels below 1 ppm.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Improved productivity, reducing downtime and allowing focus on product processing operations only</li> <li>▶ No chemical handling</li> <li>▶ Reduction of buffer or water for injection (WFI) consumption</li> </ul>
<ul style="list-style-type: none"> <li>▶ Cadence single-use TFF modules integrate the process-proven Omega PES membrane and are scalable.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Scalable formats, streamlining product development and process optimization</li> </ul>
<ul style="list-style-type: none"> <li>▶ Tests have shown that the process performances of Cadence single-use TFF modules are comparable to reusable Omega T-series cassettes, thus offering the flexibility to switch from single-use to reuse TFF options and vice-versa with limited validation work.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Improved process robustness</li> <li>▶ Reliable and flexible process solutions</li> </ul>

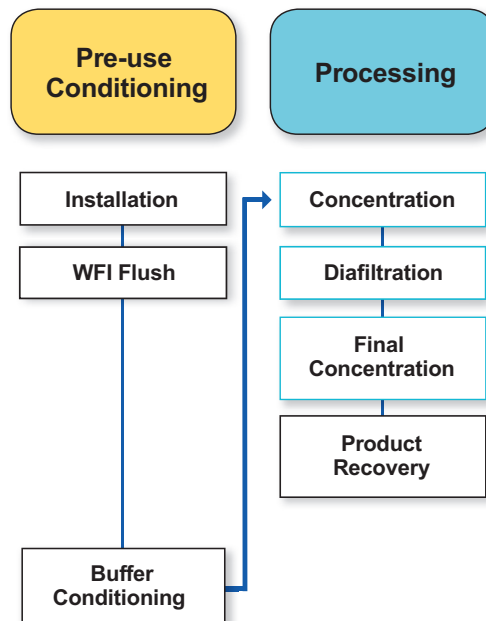
**Figure 1**

*Comparison of TFF operations, reusable cassettes versus single-use with Pall's Cadence modules*

### TFF with reusable cassettes



### SUTFF with Pall's Cadence modules



\* Normalized water permeability

## Applications

Typical applications for Cadence single-use TFF modules are in the downstream processing operations for the concentration and/or diafiltration of biological products in the biotech and vaccines industries.

Cadence single-use TFF modules can be implemented from R&D lab to commercial production. Fully scalable, the drug product development and validation steps can be streamlined.

Purpose-designed for single-use, they are especially recommended for multipurpose facilities or contract manufacturing organizations (CMOs), for clinical material or for commercial production with batch sizes up to several hundred liters.

## Product Platform

Cadence single-use TFF modules are available in five formats with the following membrane areas:

- 93 cm<sup>2</sup>      – 2.5 m<sup>2</sup>
- 186 cm<sup>2</sup>    – 0.5 m<sup>2</sup>
- 0.1 m<sup>2</sup>

They integrate process-proven Pall Omega polyether-sulfone (PES) membranes to offer high flux and selectivities. The Omega membranes have been specifically modified to minimize protein binding.

Cadence single-use TFF modules are available with Omega membrane in three different nominal molecular weight cutoffs (NMWC) – 10, 30 and 100 kDa – meeting the majority of the needs for single-use TFF applications in the biotech and vaccines industries.

They can be installed and torqued into Pall's specially designed holders and with single-use set-ups (Figure 3 and 4). See specifications of Pall's holders for Cadence SUTFF modules on page 7.

**Figure 2**

*Cadence single-use TFF modules with 186 cm<sup>2</sup>, 0.1 m<sup>2</sup> and 0.5 m<sup>2</sup> membrane area (from left to right)*

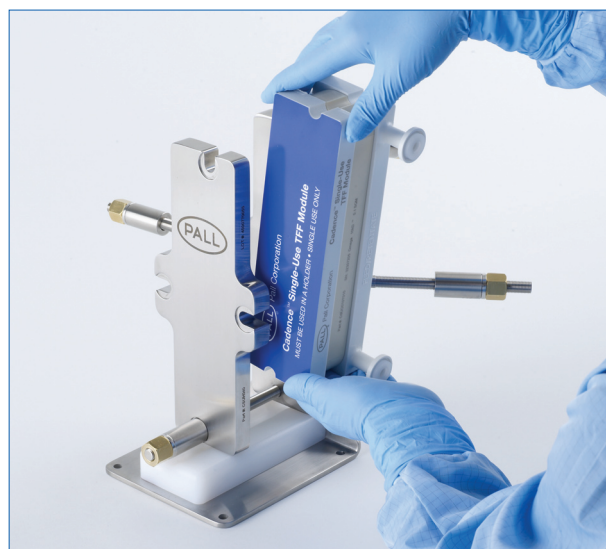


## Quality Standards

- ▶ Manufactured in a controlled environment
- ▶ Manufactured under a quality management system certified to ISO 9001 standards
- ▶ Supplied with a Certificate of Quality confirming the quality standards and quality control tests performed by Pall
- ▶ The fluid path meets all regulatory requirements for:
  - Biological Reactivity Tests (*in vivo*) for Class VI-70 °C Plastics, USP <88>
  - Biological Reactivity Tests (*in vitro*) for Cytotoxicity, USP <87>

**Figure 3**

*Installation of the Cadence single-use TFF module into its holder (vertically)*



**Figure 4**

*Pall's Cadence SUTFF module installed horizontally in its holder*



## Technical Specifications

Cadence TFF modules are single-use and supplied after receiving a gamma irradiation dose of  $\geq 25$  kGy.

Module Component	Material of Construction
Membrane	Polyethersulfone
Support	Polyolefin
Screens	Polypropylene
Encapsulant	Polyurethane with white pigment (TiO <sub>2</sub> )
Seals	Platinum cured silicone and thermoplastic elastomer
Manifold plates	Glass bead reinforced polypropylene with white pigment (TiO <sub>2</sub> )
Port caps	Polypropylene for luer lock connections, polyethylene for sanitary fittings
Covers	High impact polystyrene

## Operating Parameters

Recommended maximum operating feed pressure	4 barg (58 psig)
Maximum transmembrane pressure (TMP)	4 barg (58 psig)
Temperature range during processing	4 – 40 °C
Temperature range during pre-use sanitization	18 – 25 °C
Recommended cross flow rate	5 – 7 L/min/m <sup>2</sup> (0.5 – 0.7 L/min/ft <sup>2</sup> )
Typical operating time	8 hours

Cadence single-use TFF modules must be used in an appropriate holder. They are integrated in single-use TFF systems. The operating limits of the system should also be considered.

## Integrity Testing

Parameter	Value
Test pressure	2 barg (30 psig)
Maximum air Forward Flow	$\leq 1600$ mL/min/m <sup>2</sup> ( $\leq 150$ mL/min/ft <sup>2</sup> ) at 20 °C



## Nominal Dimensions

(see Dimensional Drawings on next page)

Part Number <sup>(1)</sup>		CSUMxxxT001	CSUMxxxT002	CSUMxxxT010	CSUMxxxT050	CSUMxxxT250
Reference Drawing		Drawing 1	Drawing 1	Drawing 2	Drawing 3	Drawing 3
Nominal Dimensions		mm (in.)	mm (in.)	mm (in.)	mm (in.)	mm (in.)
Length	A	212 (8.4)	212 (8.4)	212 (8.4)	218 (8.6)	218 (8.6)
Overall length	B	212 (8.4)	212 (8.4)	212 (8.4)	232 (9.2)	232 (9.2)
Thickness (for reference only)	C	44 (1.7)	44 (1.7)	55 (2.2)	74 (2.9)	130 (5.1)
Overall thickness (for reference only)	D	44 (1.7)	44 (1.7)	60 (2.4)	86 (3.4)	142 (5.6)
Width	E	62 (2.4)	62 (2.4)	62 (2.4)	186 (7.3)	186 (7.3)
Overall width	F	76 (3.0)	76 (3.0)	112 (4.4)	245 (9.6)	245 (9.6)
Feed /retentate fitting		Female luer	Female luer	½ in. sanitary flange	1 in. sanitary flange	1 in. sanitary flange
– Outer diameter	G	NA <sup>(2)</sup>	NA	25 (1.0)	50 (2.0)	50 (2.0)
– Inner diameter	H	NA	NA	11 (0.4)	22 (0.9)	22 (0.9)
Permeate fitting		Female luer	Female luer	½ in. sanitary flange	¾ in. sanitary flange	¾ in. sanitary flange
– Outer diameter	J	NA	NA	25 (1.0)	25 (1.0)	25 (1.0)
– Inner diameter	K	NA	NA	10 (0.4)	16 (0.6)	16 (0.6)
Retentate port location	L	175 (6.9)	175 (6.9)	177 (7.0)	182 (7.2)	182 (7.2)
	M	20 (0.8)	20 (0.8)	20 (0.8)	18 (0.7)	18 (0.7)
	N	11 (0.4)	11 (0.4)	9 (0.3)	13 (0.5)	13 (0.5)
Permeate port location	P	169 (6.7)	169 (6.7)	168 (6.6)	161 (6.3)	161 (6.3)
	Q	20 (0.8)	20 (0.8)	23 (0.9)	28 (1.1)	28 (1.1)
	R	11 (0.4)	11 (0.4)	9 (0.4)	15 (0.6)	15 (0.6)
Notch diameter	S	10 (0.4)	10 (0.4)	10 (0.4)	16 (0.6)	16 (0.6)
Notch locations	T	13 (0.5)	13 (0.5)	13 (0.5)	89 (3.5)	89 (3.5)
	U	24 (1.0)	24 (1.0)	24 (1.0)	49 (1.9)	49 (1.9)

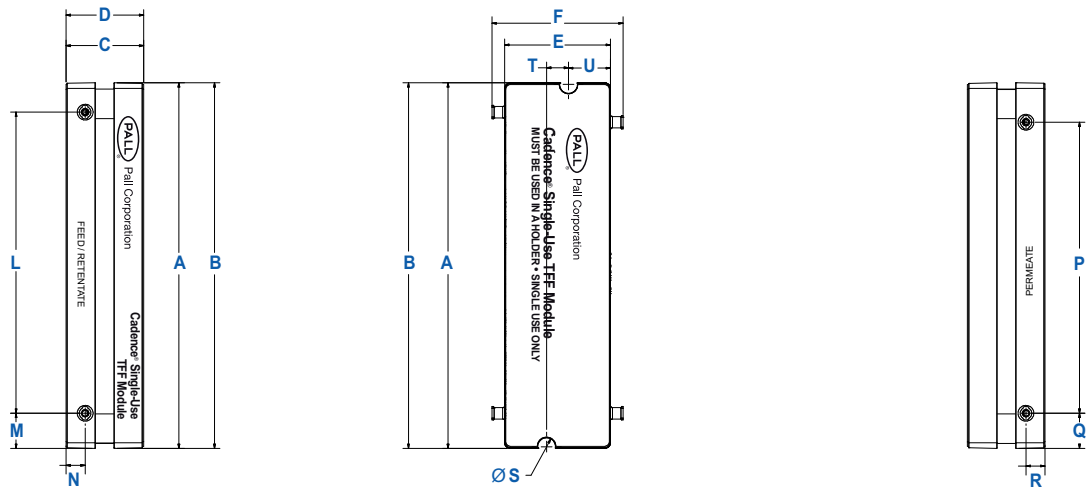
<sup>(1)</sup> xxx is corresponding to the nominal molecular weight cutoff code: 010 for 10 kDa, 030 for 30 kDa, 100 for 100 kDa  
(see ordering information)

<sup>(2)</sup> NA = Not applicable

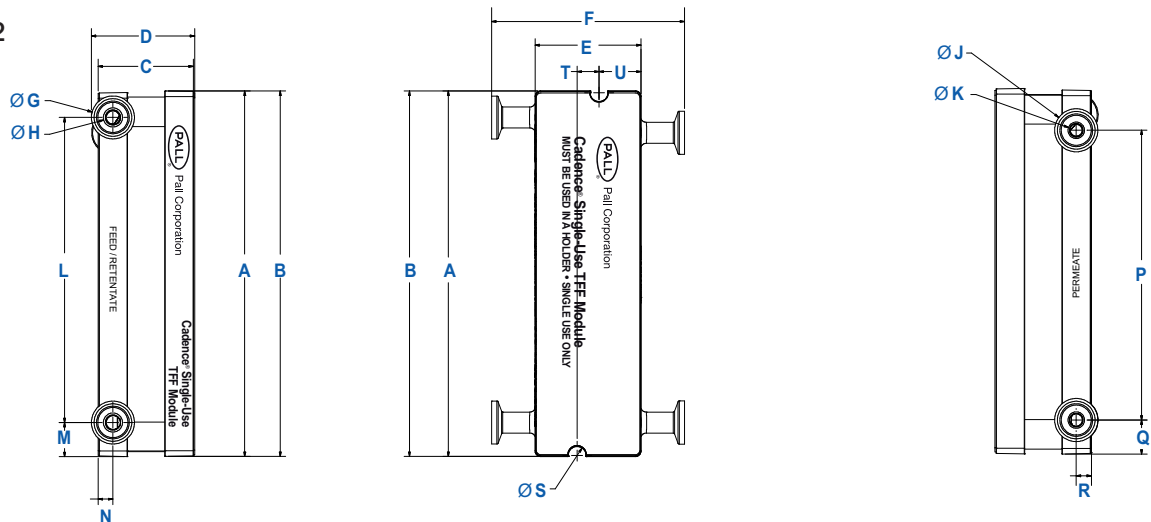
The dimensions provided are nominal. Actual dimensions may vary slightly.

## Dimensional Drawings

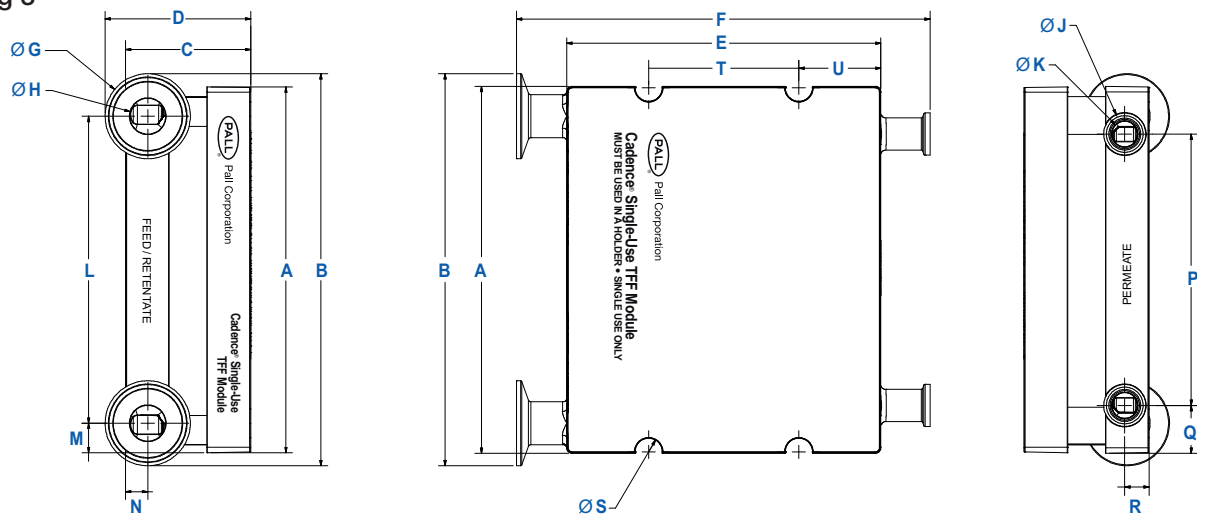
Drawing 1



Drawing 2



Drawing 3



## Ordering Information

### Pall's Cadence SUTFF Modules

Part Number	Description	Format	Nominal Molecular Weight Cutoff	Effective Membrane Filtration Area
CSUM010T001	Cadence single-use TFF module with Omega membrane	Centramate™	10 kDa	93 cm <sup>2</sup> (0.1 ft <sup>2</sup> )
CSUM010T002		Centramate		186 cm <sup>2</sup> (0.2 ft <sup>2</sup> )
CSUM010T010		Centramate		0.1 m <sup>2</sup> (1.1 ft <sup>2</sup> )
CSUM010T050		Centrasette™		0.5 m <sup>2</sup> (5.4 ft <sup>2</sup> )
CSUM010T250		Centrasette		2.5 m <sup>2</sup> (27 ft <sup>2</sup> )
CSUM030T001		Centramate	30 kDa	93 cm <sup>2</sup> (0.1 ft <sup>2</sup> )
CSUM030T002		Centramate		186 cm <sup>2</sup> (0.2 ft <sup>2</sup> )
CSUM030T010		Centramate		0.1 m <sup>2</sup> (1.1 ft <sup>2</sup> )
CSUM030T050		Centrasette		0.5 m <sup>2</sup> (5.4 ft <sup>2</sup> )
CSUM030T250		Centrasette		2.5 m <sup>2</sup> (27 ft <sup>2</sup> )
CSUM100T001		Centramate	100 kDa	93 cm <sup>2</sup> (0.1 ft <sup>2</sup> )
CSUM100T002		Centramate		186 cm <sup>2</sup> (0.2 ft <sup>2</sup> )
CSUM100T010		Centramate		0.1 m <sup>2</sup> (1.1 ft <sup>2</sup> )
CSUM100T050		Centrasette		0.5 m <sup>2</sup> (5.4 ft <sup>2</sup> )
CSUM100T250		Centrasette		2.5 m <sup>2</sup> (27 ft <sup>2</sup> )

### Holders for Pall's Cadence SUTFF Modules

Holder Part Number	CSUH040	CSUH250SA
Format of compatible Cadence SUTFF modules	Centramate	Centrasette
Orientation: vertical or horizontal	Both	Horizontal
Part numbers of compatible Cadence SUTFF module	CSUM010T001	CSUM010T050
	CSUM010T002	CSUM010T250
	CSUM010T010	CSUM030T050
	CSUM030T001	CSUM030T250
	CSUM030T002	CSUM100T050
	CSUM030T010	CSUM100T250
	CSUM100T001	–
	CSUM100T002	–
	CSUM100T010	–
Number of Cadence SUTFF modules that fit in holder	1	1

In addition to Cadence single-use cassette modules, Pall's TFF module holders can also accommodate standard cassettes when used with single-use distribution manifolds as the end plates. Please contact your Pall representative for more information about the maximum number and types of cassettes that can be accommodated, or about the use of standard cassettes in Pall's TFF module holders.



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