



AsterFlow™

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AsterFlow™ is a 21 CFR part 11 compliant single use compact configurable filtration platform tool optimized for crossflow/tangential flow filtration.

The system is a standalone model capable of processing batches up to 5 liters, across different membrane types from 50 cm² to 0.14 m².

The system is configured to operate with a variety of filtration modules including hollow fiber cartridges, tubular ceramic modules, spiral wound, and cassettes suited for laboratory and pilot scale.

Applications

- Concentrate and desalt proteins and peptides.
- Concentrate and desalt nucleic acids [DNA/RNA/ oligonucleotides].
- Recover and purify antibodies or recombinant proteins from cell culture media.
- Recover and purify plasmid DNA from cell lysates or chromosomal DNA from whole blood.
- Fractionate dilute protein mixtures.
- Clarify cell lysates or tissue homogenates.
- Depyrogenate (remove endotoxin from) water, buffers, and media solutions.
- Prepare samples prior to column chromatography.
- Harvest cells.
- Purify and concentrate viruses.
- Filter viruses.

PROCESS CONTROL	
Manual (M Mode)	Operate the system manually, allowing the user to input commands as required.
Concentration (C Mode)	Used to concentrate the product down to a final level.
Diafiltration (D Mode)	Used to diafilter/ buffer exchange to the required media.
Concentration>Diafiltration (CD Mode)	Used to concentrate product to a pre-defined level and to diafilter the product to required media.
Diafiltration> Concentration (DC Mode)	Used to diafilter product before concentrating to final level.
Concentration>Diafiltration> Concentration (CDC Mode)	Used to concentrate product to a pre-defined level and to diafilter product before concentrating to final level.
Concentration>Diafiltration> Concentration>Diafiltration (CDCD Mode)	Used to concentrate product to a pre-defined level and to diafilter product before concentrating to final level and ultimately diafilter the product to required media.
Concentration>Diafiltration> Diafiltration>Concentration (CDDC Mode)	Used to concentrate product to a pre-defined level and to diafilter product with two different media before concentrating to final level.
Flushing	Rinse the system by flushing with WFI, acidic or alkaline solutions
Drain / Harvesting	Drain or harvest the product from the system
Filling	Fill the tank or bag with product
Tare Weight	Automatically zero the load cell and permeate balance
Tare Pressure	Automatically zero all pressure sensors

Parts of AsterFlow™

1 Body and flow paths:

A robust stainless steel body with platinum-cured silicone flow paths, assuring high effectiveness due to the elasticity, compressibility and resistance providing long-term quality.

2 Main membrane pump:

A low shear peristaltic membrane pump suited for working with shear sensitive products, providing a varying range of flow rates across different membrane types from 50cm² to 0.14m² suited for small volumes and scaling studies. Pump output ranges from 0.24 to 1632 mL/min with maximum inlet pressure of 3bar(43.5psi).

3 Recirculation tank:

Provides the medium for the filtration process and receives the retentate. It is a graduated reservoir made of transparent Polyethylene terephthalate glycol (PETG) with self-sealing lid, available in dimensions of 125ml to 2000ml. The tank is located on a device base with a load cell, connected to HMI for level control.

HMI/PLC: 4

Siemens touch enabled 12" HMI/PLC screen that is user-friendly and offers a full view and control of the in-process parameters.

External Peristaltic pump: 5

A standalone peristaltic diafiltration pump to allow loading product or buffer as a discrete process unit step.

Permeate Pump: 6

An auxiliary pump to allow efficient pumping of the permeate into the permeate tank.

Pressure sensors: 7

Three pressure sensors located within the feed, retentate and permeate line for operating the system in user-defined operating set points.

Permeate tank: 8

Graduated tank made up of transparent Polyethylene terephthalate glycol (PETG) placed on an electronic balance connected to the HMI to monitor the quantitative collection of the permeate and its collection rate.

Customization

Further configurations can be customized based on the process requirement:

- **Filter holders:** Flexible operation with a variety of cassette filters with surface areas ranging from 50cm² to 0.14m², provided with interchangeable parts.
- Inline-pH, conductivity, and/or temperature sensors to monitor the product.
- Buffer / product feed pump.
- Full single use options including stand for single use re-circulation bags having the same functions as the mixing tank, as well as stands for permeate and retentate bags.

Tangential Flow Filtration Membranes Modules

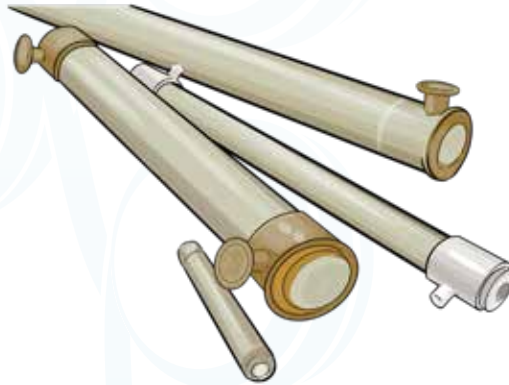
*Please note that these membranes are NOT sold by Esco.

Hollow Fibers

Comprised of a bundle of permeable membrane tubes with narrow diameter (0.1mm to 2mm) which are typically sealed into a housing on both ends by potting in a shell and tube design.

The feed stream is pumped into the lumen(inside) of the tube and the retentate passes through the membrane to the shell side, where it is removed.

- ✓ Cell Therapy / Gene Therapy.
- ✓ Pharmaceutical grade/apyrogenic water purification
- ✓ Protein removal from antibiotics
- ✓ Depyrogenization of amino acids
- ✓ Concentration and clarification (enzymes/ vitamins)
- ✓ Food and beverage industry
- ✓ Perfusion



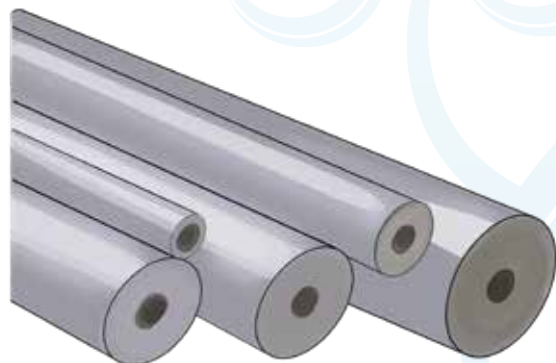
Spiral Wound

Spiral-wound elements consist of membranes, feed spacers, permeate spacers, and a permeate tube. First, a membrane is laid out and folded in half with the membrane facing inward. Feed spacer is then put in between the folded membranes, forming a membrane sandwich. The purpose of the feed spacer is to provide space for water to flow between the membrane surfaces, and to allow for uniform flow between the membrane leaves.

Next, the permeate spacer is attached to the permeate tube, and the membrane sandwich prepared earlier is attached to the permeate spacer using glue. The next permeate layer is laid down and sealed with glue, and the whole process is repeated until all of the required permeate spacers have been attached to the membranes. The finished membrane layers then are wrapped around the tube creating the spiral shape.

Feed travels through the flow channels tangentially across the length of the element. Filtrate smaller than the molecular weight cut-off will then pass across the membrane surface into the permeate spacer, where it is carried down the permeate spacer towards the permeate tube. The remainder of the feed then becomes concentrated at the end of the element body.

- ✓ Food and beverage industry
- ✓ Dairy industry
- ✓ Concentration and purifications of biologics
- ✓ Clarification and fractionation
- ✓ Extraction
- ✓ Product recycling and recovery
- ✓ Product and effluent upgrading

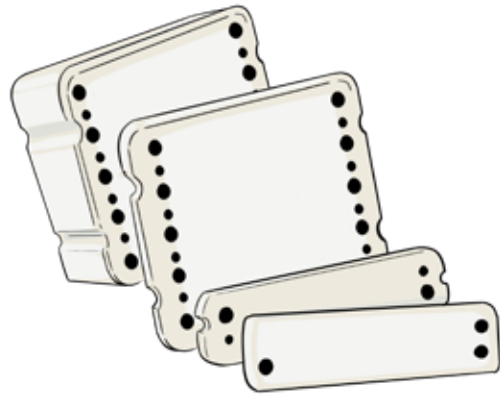


Cassettes

The framework for the cassette consists of layers of polymeric flat-sheet membranes stacked together and separated by permeate and feed flow channels. Feed flow channels can be open but usually consist of turbulence promoting screens to minimize concentration polarization. In addition, rigid and porous spacer plates may also be inserted to increase the channel width.

The flow channels are made up of two membranes facing each other. The upstream feed side is sealed to separate the downstream permeate side of the membrane. A silicone or polymeric shell is used to encapsulate the membranes, screens, and space plates.

- ✓ Gene Therapy
- ✓ Concentration/Buffer exchange in the purification of biologics

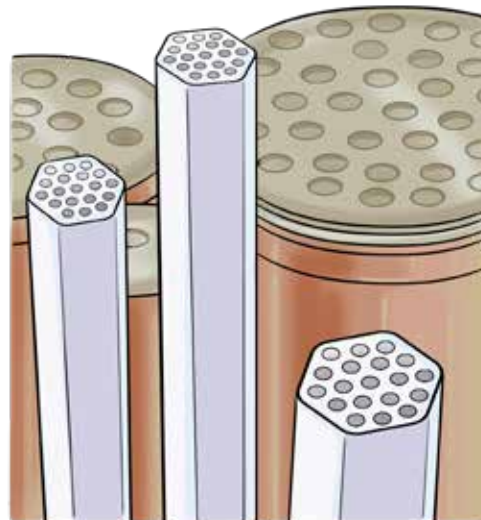


Tubular Ceramic Modules

A tubular membrane is characterized by its discrete tubes and large lumen sizes which are typically larger in 1mm in diameter. These tubular membranes can be made from sintered ceramic, metallic or polymeric materials and provide strong structural support for the membranes.

Tubular membranes flow from inside out with turbulent flow in the retentate stream keeping the membrane surface clean. Permeate flows through the wall of the tubes and is collected on the shell side (outside) of the modules.

- ✓ Clarification of bulk fermentation broths
- ✓ Protein removal from antibiotics
- ✓ Processing of alginates and other excipients
- ✓ Clarification of solvent extracts
- ✓ Pyrogen and bacteria removal in high purity systems



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