

Alfa Laval CultureOne Primo

Separation system for single use processing

Introduction

For more than 100 years, Alfa Laval has been supplying separators for various industries. Today, Alfa Laval has the most complete and diverse offering of separators – each fully optimized for its specific duty and supplied with all auxiliary systems and key components.

Alfa Laval CultureOne™ separators are compact disc stack centrifuge systems developed for cell harvest. The product contact surfaces are designed as consumable parts for single use batch processing.

Application

Intended primarily for the harvest of cell culture bioreactors, CultureOne can handle a wide range of operating conditions. The CultureOne Primo separator model is designed for a flow capacity up to 240 L/h and for gentle product handling and excellent clarification.

Benefits

- High separation efficiency
- Continuous clarification
- Minimal additional lysis
- Excellent turndown ratio
- Pre-sterilized product wetted parts
- Minimal maintenance
- Low sound level

Design

CultureOne Primo is designed as a plug and play mobile unit simple and quick connection to upstream and downstream equipment.

The heart of the CultureOne separator is the single-use bowl insert, the Spinsert™, where separation takes place. With a fully hermetic and bottom fed design, the separation within the Spinsert provides gentle handling of the material and high separation efficiency. The use of TopStream™ technology provides for continuous flow of the solids phase creating the ability to handle high cell densities and improves centrate quality during harvest.

Feed and discharge lines are easy to integrate with upstream and downstream equipment. Aseptic connectors ensure safe and easy exchange between batches. The Spinsert and tubing kits are the parts in contact with product, and therefore



designed as consumables, made from recyclable biopharmaceutical grade polymers. The complete assembly is placed in the stainless steel bowl inside the drive unit.

Working principle

The system is primed via a sterile connection (2). This connection also allows for purging at the end of a process run to displace and collect all process material. Cell culture broth from the bioreactor enters the system via a sterile connector (1). The feedline is equipped with a single use centrifugal pump (8) and flowmeter (9) to deliver and measure flow to the separator. Product enters the separator bowl insert from below. Separation takes place between the bowl discs as a

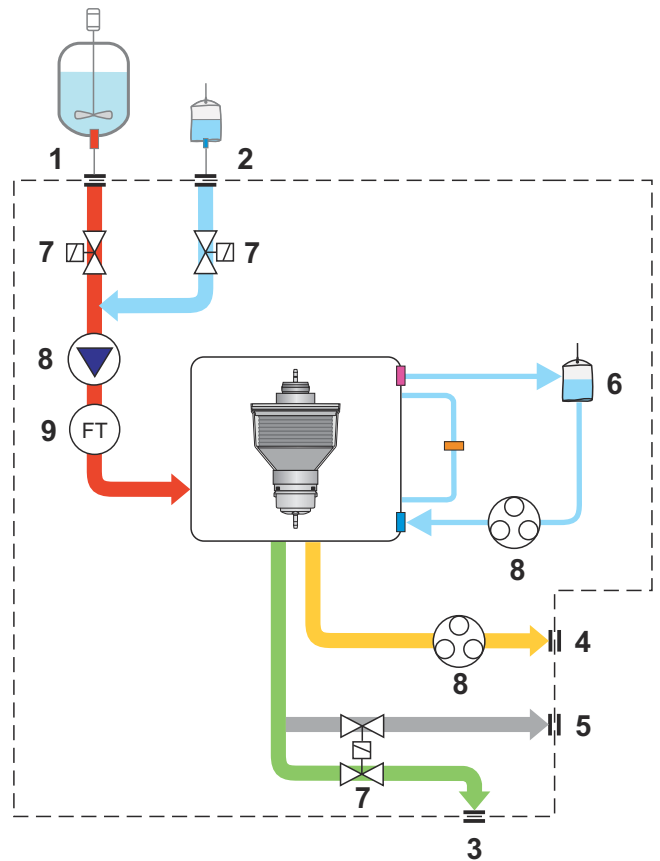
result of the centrifugal force that causes the solids to move towards the periphery. The clarified liquid exits the system via single use tubing and another sterile connector (3). A flow regulation device is included in the line (10).

Separated solids move to the periphery of the Spinsert and exit as a concentrated solids stream. This concentrated biomass exits the system continuously via a positive displacement pump (8) to ensure controlled and consistent flow.

Temperature and pressure are continually monitored for feed, clarified liquid and concentrated solids.



Spinsert separation insert for CultureOne Primo*



1. Feed/cell culture inlet
2. Priming liquid (Buffer)
3. Liquid product outlet
4. Concentrated outlet
5. Divert line/drain
6. Cooling liquid (Buffer)
7. Valve
8. Pump
9. Flow meter

Technical data

Performance data¹

Hydraulic capacity ²	0.5–4.0 lpm, or 30–240 l/h
Motor capacity	1.5 kW
Power supply	208-240V / 50-60Hz
Power consumption (motor)	0.9 kW
Sound pressure level	67 dB (A)

¹ Actual capacity and power consumption depends on operating conditions

² Designed to process the harvest of culture bioreactors with 50–1000 liters capacity.

Connections

Feed inlet	Ø3/8" (9.6mm) I.D., CPC AseptiQuik®
Light phase and solids outlet	Ø1/4" (6.4mm) I.D., CPC AseptiQuik®

Weights

System weight	220 kg (485 lbs)
Insert weight	2.5 kg (5.5 lbs)
Process hold-up volume	1.1 litre

Material data

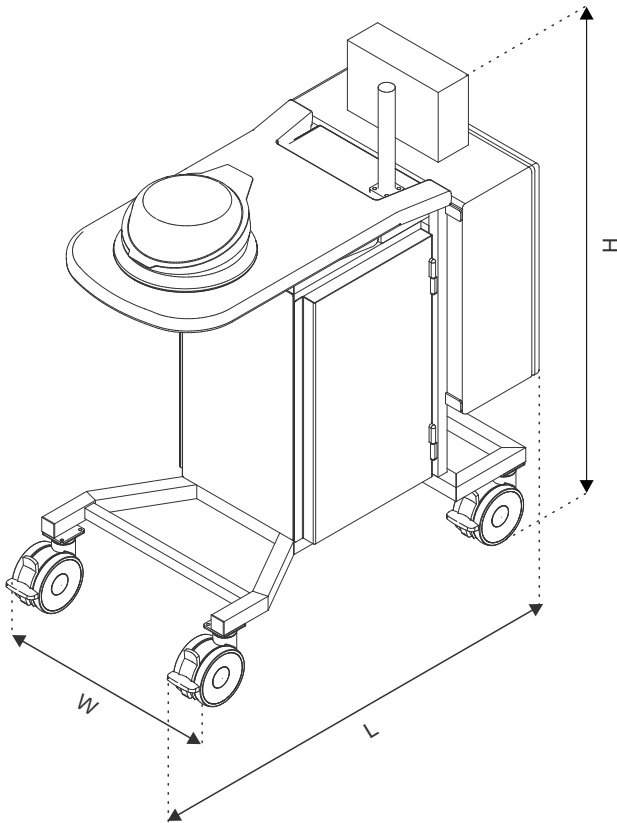
Bowl body, hood	High grade stainless steel
Frame	Stainless steel
Process and utility tube sets	Medical grade tubing, weldable
Insert	Pre-sterilized biopharmaceutical polymers

Single-use consumables qualification

The media contact single use components have been qualified and tested to ensure the most stringent quality requirements are met.

X-ray sterilization	> 25kGy
Functional testing	
Regulatory statements, (ADI free, BPA, etc.)	
USP <88>	Class VI, Bio compatibility
USP <85>	Bacterial Endotoxin
USP <788>	Particulates
USP <661>	Physiochemical
USP <665>	Extractables
Sterilization per	AAMI/ISO 11737
Packaging	ASTM D4169 / ISTA 2A

Dimensional drawing



Dimensions

H	1700 mm (67 inches)
L	1100 mm (44 inches)
W	650 mm (26 inches)

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