

Alfa Laval CultureOne Maxi

Separation system for single use processing

Introduction

For more than 100 years, Alfa Laval has supplied separators for demanding applications in a wide variety of 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 CultureOneTM separators are compact disc stack centrifuge systems developed for recovery of biological materials. 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 Maxi separator model is designed to match the capacity of the largest single use bioreactors available on the market while ensuring gentle product handling and excellent clarification.

Benefits

- High yield
- Handles a wide range of volume and cell densities
- Small footprint
- Easy to install
- Easy to operate
- Reduced waste over filtration
- Pre-sterilized product wetted parts

Design

CultureOne Maxi is designed as a plug and play mobile unit with simple and quick connections to upstream and downstream equipment.

The heart of the CultureOne separator is the single-use SpinsertTM, where separation takes place. With a fully hermetic and bottom fed design, the separation within the Spinsert provides gentle handling of the material, insuring against foaming, and high separation efficiency. The use of TopStreamTM technology provides for continuous flow of the highly concentrated solids phase. This allows for the processing of 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 only product contact materials and are designed to be replaced between product runs. These consumables are made from recyclable medical grade polymers. The tubing kits are quick and easy to install and installation can be done in just a few minutes.

Working principle

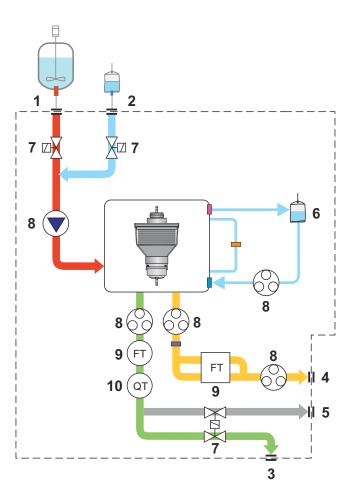
The system is primed via a sterile connection (2). This connection also allows for purging at the end of a process run to displace and collect all process material. Cell culture broth from the bioreactor enters the system via a sterile connector (1). The feedline is equipped with a single use centrifugal pump (8) to deliver the broth 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 is pumped from the system by a peristaltic pump (8) and regulated with a flow sensor (9). A turbidity sensor (10) in the outlet verifies the separation result.

Separated solids moves to the periphery of the SpinsertTM and exit continuously as a concentrated solids stream. This concentrated biomass exits the system continuously (4) via a positive displacement pump (8). The heavy phase flow is measured with high precision (9) to regulate the system and to ensure a controlled and consistent flow.

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



Spinsert separation insert for CultureOne Maxi *



- 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
- 10. Turbidity transmitter

Technical data

Performance data ¹	
Hydraulic capacity ²	2–12 lpm, or 120–720 l/h
Motor capacity	2.2 kW
Power supply	208-240V / 50-60Hz / 16A
Power consumption (motor)	1.3 kW
Sound pressure level	<70 dB (A)
Required air supply	6 barg

¹ Actual capacity and power consumption depends on operating conditions

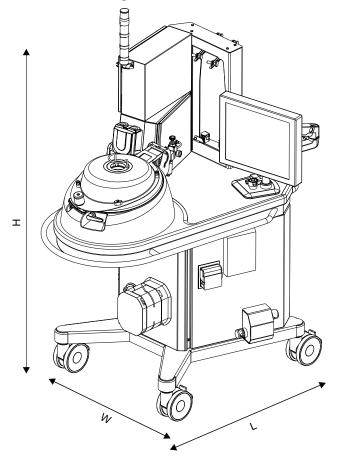
² Designed to process the harvest of bioreactors with 500–2000 liters capacity.

Connections Ø1/2" (12.7mm) I.D, CPC AseptiQuik® G Feed inlet and light phase Ø3/8" (9.5 mm) I.D, CPC AseptiQuik® G Solids outlet Weights System weight 370 kg (816 lbs) Spinsert weight 5.3 kg (11.6 lbs) 3.5 litre Process hold-up volume Material data Bowl body, hood High grade stainless steel Frame Stainless steel Process and utility tube sets Medical grade tubing, weldable Spinsert Medical grade polymers

Single-use consumables qualification

The media contact single use components	s 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	2.)
USP Class VI <88>	Bio compatibility
USP <85>	Bacterial Endotoxin
USP <788>	Particulates
USP <661>	Physiochemical
USP<665>	Extractables
AAMI/ISO 11737	Sterilization
ASTM D4169 / ISTA 2A	Packaging

Dimensional drawing



Dimensions

Н	1830 mm (72 inches)
L	1346 mm (53 inches)
W	890 mm (35 inches)

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