



# CultureOne™

A groundbreaking range of premium separators  
for single-use biopharmaceutical processing





## The premium and proven answer to improved productivity

### **Leading separation technology for single-use biopharma processing**

First of its kind, Alfa Laval CultureOne is a premium range of centrifugal separators for single-use biopharmaceutical processing. With proven innovations for gentle product treatment and increased yield, CultureOne provides unmatched separation efficiency of high-density cell cultures. Overcoming previous limitations to single-use harvesting.

With product recovery yields up to 99%, CultureOne Primo is the GMP-ready solution for harvesting smaller cell culture batches. CultureOne Maxi enables processing of large volumes with the same premium performance. Together, they bring increased product recovery and a more efficient workflow to biopharma processing, from R&D to production scale.

### **Putting a new spin on cell culture harvesting**

CultureOne is based on the all-new Alfa Laval Spinsert™. A patented, disposable and recyclable bowl assembly for secure and efficient separation.



# Higher yield. Better value.

Every drop of harvested product adds significant value to biopharma processing. In this example, product recovery was increased from 92.5% to 98% with other parameters constant, representing the transition from a less efficient single-use harvesting method to CultureOne. For actual evaluation, contact Alfa Laval.

## Exceptional separation performance

>300 MORE DOSES PER BATCH\*



VALUE OF INCREASED PRODUCT RECOVERY, PER BATCH\*

\$73,500

\* Bioreactor volume: 1000 liters. Product concentration (titre) 3 grams/liter. Packed cell volume 10%. Value per gram of material following depth filtration \$500/gram

### High product yield

CultureOne enables higher product yields than other single-use alternatives, with a typical yield of 95% and peak yields of 99%. The centrifuge continuously discharges the highly concentrated cells during separation, maximizing concentrate recovery and concentrate clarity. Minimal product loss in the primary harvest step greatly improves overall profitability.

### Low additional lysis

Our proven Hermetic Design provides gentle acceleration of the fermentation broth, reducing cell lysis. Very little intracellular material is released into the liquid phase, greatly facilitating downstream purification. And after separation, the undamaged cells can be recovered with protein producing mechanisms intact.

### High downstream filterability

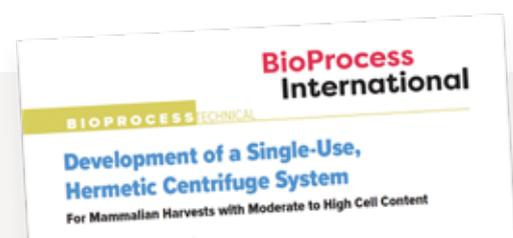
Highly efficient separation and gentle material handling gives a clarified concentrate containing only trace amounts of solids, making secondary filtration easier. Batch processing can then be completed using a significantly smaller filter area.

### Proven and published

In October 2020, *BioProcess International* published a study detailing the performance of CultureOne Primo. Made in collaboration with Genentech, the study shows exceptionally efficient separation and recovery yield rates up to 98%. Download at [alfalaval.com/cultureone](http://alfalaval.com/cultureone).

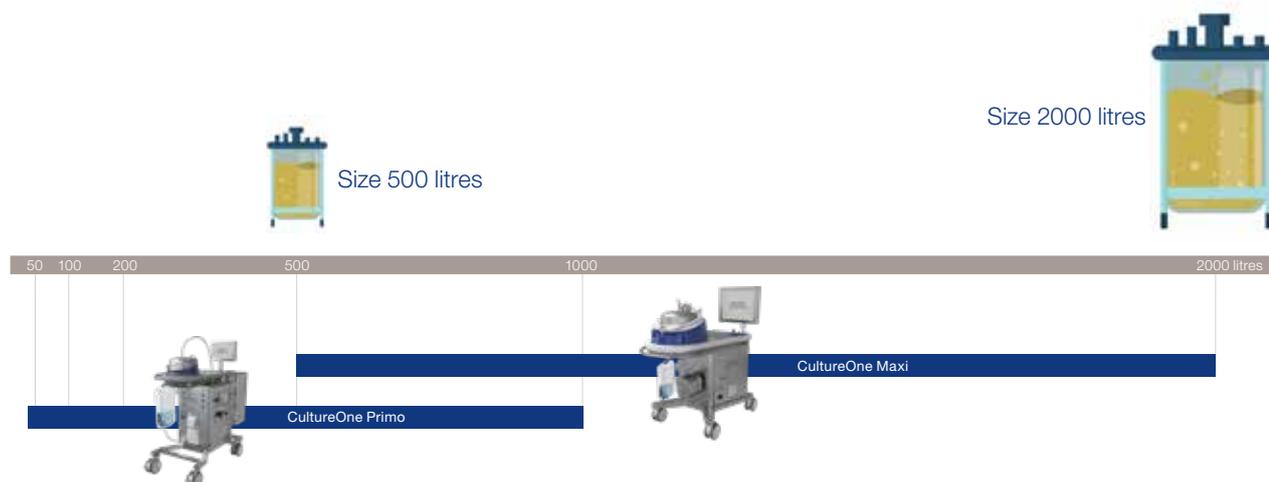
### Advantages in every step

- Easy assembly of single-use Spinsert and tube kits.
- No flocculant or filter aid needed.
- Efficient separation independent of packed cell volumes.
- Continuous processing at a steady state across entire batch.
- State of the art automation with Siemens, Allen Bradley, and Delta V automation packages available.
- Low noise levels  $\leq 67$  dB(A).
- Intuitive interface provides complete process overview.



# The right fit for your single-use setup

The CultureOne range brings new levels of flexibility and productivity to single-use biopharma processing. From research- and pilot scales to full-scale production; CultureOne has you covered.



## Real scalability

Alfa Laval has long set the standard for high-quality cell culture separation. With the introduction of CultureOne, the same exceptional separation performance can be achieved at every scale of biopharmaceutical processing. Now you can move from single-use R&D to industrial production, relying on the same set of proven innovations to maximize yield and optimize product quality at every scale.



### CultureOne Primo

### CultureOne Maxi

### Culturefuge

Product recovery yield	98 %	98 %	98 %
Turbidity after harvest	78 NTU*	78 NTU*	78 NTU*
Processing capacity	200 litres/hour	600 litres/hour	2200+ litres/hour

\* Turbidity and capacity figures for fed batch mammalian cell culture materials. Turbidity compared to baseline turbidity figure of 63 NTU achieved by high speed test tube spin. Actual process performance is a function of individual material characteristics.

# Validation guide summary

The chart shows validation test results for CultureOne Primo with Spinsert.

Test	Metod used	Acceptance criteria	Validated result
Sterilization validation by X-ray	ISO 11137-2 (sterility tests according to ISO 11737-2)	Bioburden growth in < 1/10 units after verification	Zero growth. SAL 10 <sup>-6</sup>
X-ray dose mapping	ISO 11137-1	25-40 kGy	27.2 – 37.2 kGy
Bioburden estimation	ISO 11137-1	≤ 1 000 CFU/devise	Average 3 batches 107 CFU/unit
Bioburden method validation - recovery	ISO 11137-1	50 – 200 % recovery	53.7 %
Biocompatibility	USP <88>	Class VI	All polymeric materials in contact with process fluid
Bacterial endotoxins	USP <85>	< 0.25 EU/ml	< 0.05 EU/ml (detection limit)
Sub-visible particles	USP <788>	< 25 particles/mL (≥ 10 µm) < 3 particles/mL (≥ 25 µm)	< 0 particles/m (≥ 10 µm) < 1 particles/m (≥ 25 µm)
Extractables	Drafted USP <665>	Report results	Results reported in a detailed report
Packaging qualification	ASTM D4169 - DC3	No noticeable loss of vaccum in the bags, no visible damage to the foam sheets, product shall pass functional test.	Pass
Accelerated ageing	ASTM F1980	Demonstrate at least 12 months shelf-life	12 months shelf-life

## Safety and quality with Spinsert™

Spinsert is at the core of CultureOne's performance. The patented, disposable and recyclable bowl assembly comes fully sterilized and ready for processing. Easy to set up and replace, Spinsert is the key to simplified workflow and faster turnaround time. The bowl assembly incorporates all of Alfa Laval's proven separation innovations:

- Hermetic Design provides low shear and higher product recovery yield.
- TopStream™ enables continuous ejection of concentrated solids during separation.
- UniDisc™ increases disc area for improved separation efficiency.



# A better harvest with centrifugal separation

Product recovery during primary harvest is a crucial factor determining the productivity of cell culture operations. Today, single-use biopharma processing utilizes a variety of primary harvest solutions. Many of these cannot efficiently separate the high-density cell cultures that are becoming more common. Resulting in high rates of product loss.

This problem is overcome by centrifugal force in Alfa Laval separators. The central disc stack clarifies the product-rich cell culture fluid, while the higher-density cell suspension is concentrated at the periphery of the separator bowl. This maximizes the separation of materials and gives a highly clarified centrate with less need for secondary depth filtration.

CultureOne combines the benefits of high-efficiency centrifugal separation with the assurance and convenience of single-use processing. It enables a straightforward and clean harvesting process, eliminating the cost and complexity of additives such as flocculants and filter aids. With the disposable Spinsert bowl assembly greatly reducing the total volume of consumables per batch.



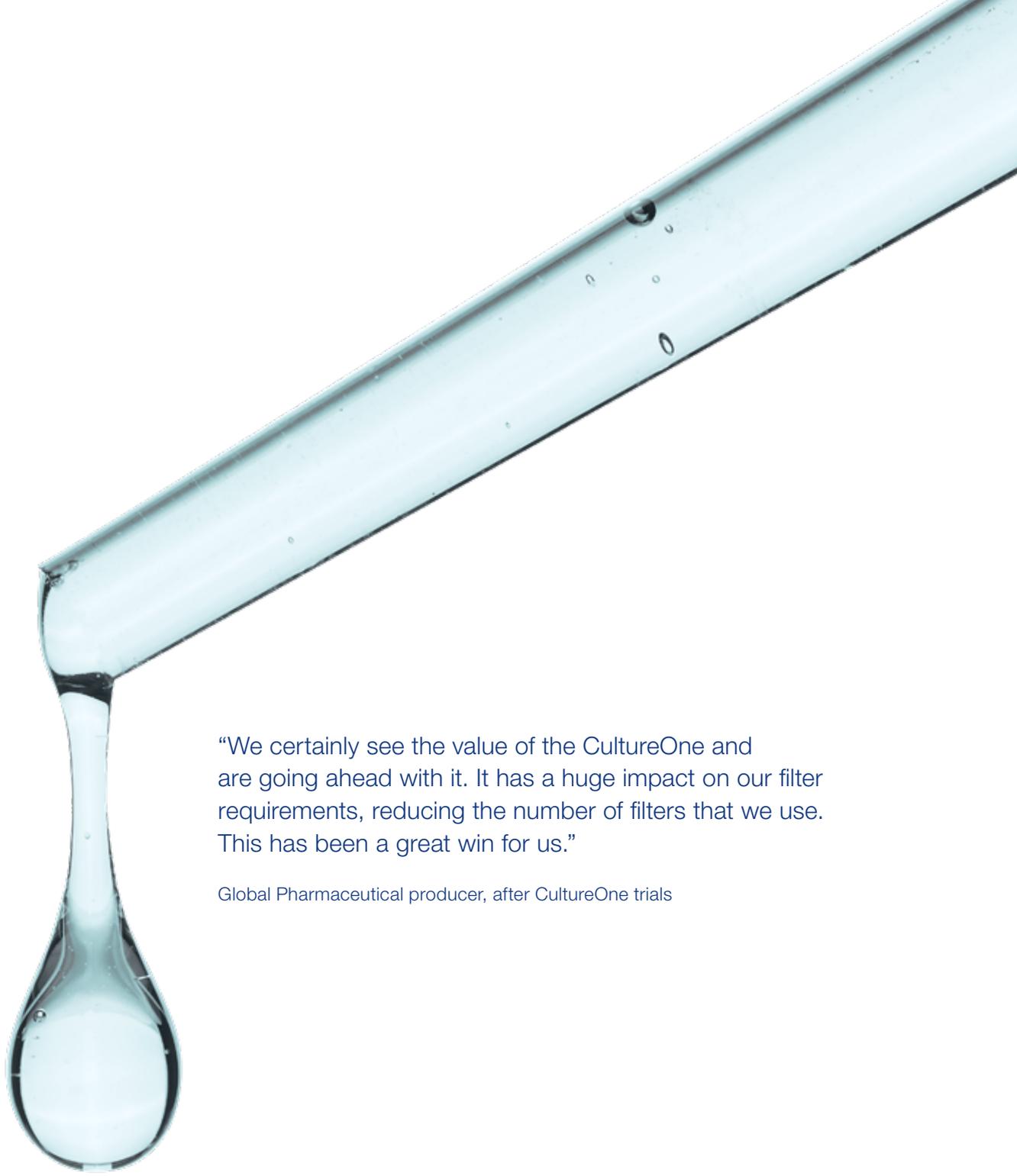
## Reducing plastic waste

By significantly cutting the amount of consumables involved in single-use biopharma processing, CultureOne adds sustainability to your production. This example compares the total amount of plastics required for primary harvest.

CULTUREONE PLASTICS SAVINGS

14,3 KG 

- Bioreactor volume: 1000 litres
- Product concentration: 3 g/litre
- Depth filtration system: 14 filter pods à 1.2 kg non-recyclable = 16.8 kg.
- CultureOne Primo: one Spinsert™ assembly, recyclable = 2.5 kg.



“We certainly see the value of the CultureOne and are going ahead with it. It has a huge impact on our filter requirements, reducing the number of filters that we use. This has been a great win for us.”

Global Pharmaceutical producer, after CultureOne trials



### **This is Alfa Laval**

Alfa Laval is active in the areas of Energy, Marine, and Food & Water, offering its expertise, products, and service to a wide range of industries in some 100 countries. The company is committed to optimizing processes, creating responsible growth, and driving progress – always going the extra mile to support customers in achieving their business goals and sustainability targets.

Alfa Laval's innovative technologies are dedicated to purifying, refining, and reusing materials, promoting more responsible use of natural resources. They contribute to improved energy efficiency and heat recovery, better water treatment, and reduced emissions. Thereby, Alfa Laval is not only accelerating success for its customers, but also for people and the planet. Making the world better, every day. It's all about *Advancing better™*.

### **How to contact Alfa Laval**

Contact details for all countries are continually updated on our web site. Please visit [www.alfalaval.com](http://www.alfalaval.com) to access the information.

