

Osilaris™

BIOREACTOR SYSTEM BY



SCALABLE, COMPLIANT, AND EFFICIENT BUILT FOR THE FUTURE OF CELL THERAPY

- » **Closed, controlled bioreactor platform** — built for GMP-compliant cell therapy production
- » **Fully adaptable** — suitable broad range of cell types and applications, adherent or suspension
- » **Seamless scale-up** — expand cells from biopsy to clinically relevant numbers with stepless volume expansion
- » **Unique agitation technology** — superior to conventional stirred-tank systems
- » **Real-time monitoring** — continuous insight into critical culture parameters
- » **Lower production costs** — reduced operator involvement, medium consumption, and clean room needs

INTRODUCTION

Producing cell therapies typically requires hundreds of millions to billions of cells per treatment, yet cell numbers from starting material are often very low. Scaling up these cells efficiently and safely is a major challenge. Traditional flask-based culture is labor-intensive, costly, and prone to variability and contamination.

Osilaris™ transforms cell expansion into a streamlined, reliable process. Its fully closed, automated system supports both adherent and suspension cells, enabling expansion from minimal starting material, such as a single biopsy, to clinically relevant numbers. With unique stepless volume expansion, cells can be cultivated without passaging, reducing handling, lowering costs, and improving product consistency.

OSILARIS™ OVERVIEW

The Osilaris bioreactor consists of a single-use Osilaris™ culture bag (Figure 1) placed within a controller cabinet (Figure 4). The system supports expansion of both adherent cells (using microcarriers) and suspension cells through two specialized single-use culture bags.

SINGLE-USE OSILARIS™ CULTURE BAG

The Osilaris™ culture bag is the core of the system. It forms part of a closed perfusion loop (Figure 2) that maintains pH and dissolved oxygen (DO) levels. Sterile welding ensures a fully closed environment for all operations: cell addition, medium exchange, waste removal, sampling, and integration with upstream and downstream processes (USP/DSP).

Integrated sensors continuously monitor the culture environment at the site of cell growth. The roller mechanism defines the culture volume: by starting the expansion

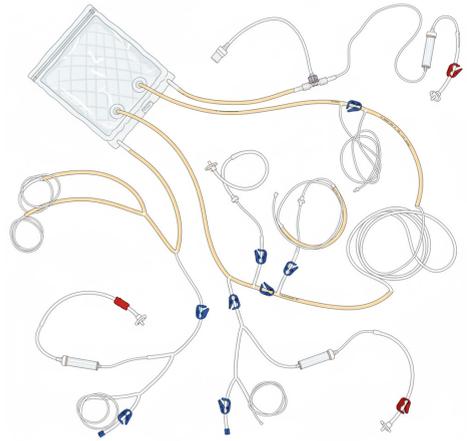
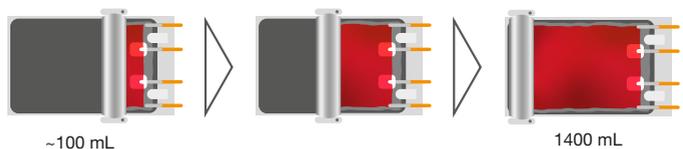


FIGURE 1 Overview of the Osilaris™ culture bag complete with tubing set (depicted is the Osilaris™ suspension bag), featuring:

- USP Class VI plastic
- Integrated sensors for pH and dissolved oxygen
- Filters to prevent cells entering the perfusion loop
- Inflow port for medium addition
- Outflow ports for medium removal, harvest, and gas removal
- Pressure sensor
- Weldable Tygon tubing for connections to medium, waste, sampling, and third-party USP/DSP systems

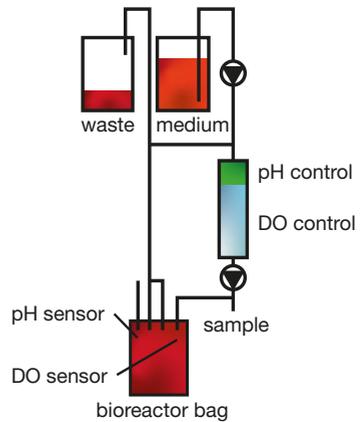


FIGURE 2 Schematic representation of the perfusion loop of the Osilaris bioreactor bag

FIGURE 3 Stepwise volume increase of the Osilaris culture bag allows for optimal cell density during entire cell expansion process

process with a small culture volume (~100 mL) and gradually increasing the volume to 1,400 mL (Figure 3) the cell population is kept in the optimal density through the entire expansion process.

OSILARIS™ CABINET

The Osilaris™ bioractor cabinet integrates the volume expansion platform, controller software, oxygenation system, and all necessary hardware, including pumps and heaters, into a compact enclosure (Figure 4).



FIGURE 4 The Osilaris™ bioractor cabinet, featuring:

- Full touchscreen interface with multiple access control
- Innovative agitation (rocker) and volume-expandable roller platform with integrated sensor transmitters
- Automated control loops for pH, dissolved oxygen, and temperature
- Patented oxygenation system for precise gas control
- On-device data logging, storage, and audit trails
- Compact footprint: 86 x 54 x 84 cm, 125 kg

EXPANSION PLATFORM

The Osilaris expansion platform provides a controlled, homogeneous environment for optimal cell growth (Figure 5). The culture bag rests on a gentle rocking platform that continuously mixes the contents, ensuring even distribution of cells.

- Fully adjustable agitation settings to match cell type, growth rate, or shear sensitivity
- Volume-defining clamp allows easy adjustment of culture volume as the cell population grows



FIGURE 5 The rocking bed expansion platform of the Osilaris™ bioractor cabinet

PARAMETER	RANGE
Volume range	0.05 – 1.4 L
Rocking angle	+/- 100°
Rocking velocity	0 – 500°/s
Rocking time	0 – 100 hours
Horizontal hold	0 – 100 hours

ENVIRONMENTAL CONTROL

The Osilaris™ cabinet maintains precise control over temperature, DO, and pH. Sensors integrated within the culture bag measure DO and pH, while transmitters in the rocking expansion platform provide real-time data to the controller software. The system automatically adjusts gas addition to maintain pre-set culture conditions.

- Patented oxygenation system maintains setpoints within tight tolerances
- Rocking motion ensures homogeneous mixing with minimal shear stress
- Temperature regulation for stable culture conditions
- Mass-flow controllers for precise gas delivery

PARAMETER	REQUIREMENTS
DO control	N ₂ and O ₂ or compressed air
pH control	CO ₂
DO range	0 – 500% air saturation
pH range	5.5 – 8.5
Temperature range	Ambient to 45°C

RECIPE MANAGEMENT AND DATA ACQUISITION

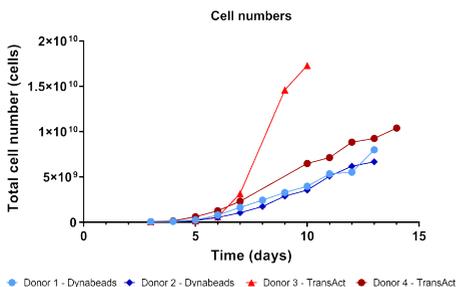
Osilaris™ features on-device data logging, secure storage, and full audit trail capabilities. All culture data is recorded locally and can be accessed at any time. The audit trail tracks all modifications, ensuring accuracy and traceability.

- 21CFR Part 11 compliant
- OPC compatible for seamless integration with existing process control systems
- Reliable, traceable, and easily integrated into workflows

LARGE-FOLD EXPANSION

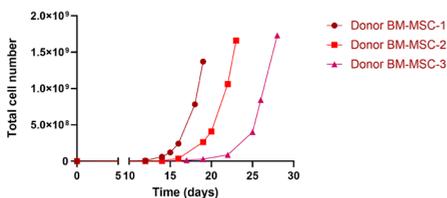
The Osilaris™ cabinet's volume-expansion roller enables culture of cells from limited starting material to clinically relevant numbers, without passaging.

- **Suspension cells:** Figure 6 depicts an example of expansion of 50 million to 10-20 billion T cells in a single culture.



↑ **FIGURE 6** Large-fold expansion of T-cells in the Osilaris™ bioreactor. T cells were either activated with DynaBeads or with Transact

↓ **FIGURE 7** Direct, large-fold expansion of MSCs from 25 mL bone marrow biopsies in the Osilaris™ bioreactor



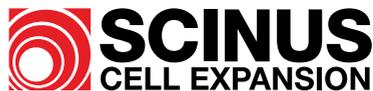
- **Adherent cells:** Leveraging bead-to-bead transfer with volume expansion to reach clinically relevant numbers, without trypsinization. Figure 7 depicts an example where MSCs are expanded directly from a bone marrow biopsy into 1-2 billion cells.

REPRESENTATIVE SAMPLING

- Enables sampling of both cells and medium at any point during culture
- Samples suitable for quality control assays, including phenotyping and potency testing
- Provides full oversight and confidence in product quality

CONTROLLED, HOMOGENEOUS ENVIRONMENT & FLEXIBILITY

- Gentle rocking maintains a fully homogeneous culture with minimal shear stress
- Integrated sensors for pH, oxygen, and temperature ensure optimal conditions at the cell site
- Culture environment can be customized for medium, pH, oxygen, and agitation, to specific cell culture needs
- Adherent cultures can use different microcarriers depending on cell substrate requirements
- Suitable for a wide range of cell types and organoids across a vast range of applications



SCINUS CELL EXPANSION

Utrechtseweg 48

3704 HE Zeist

The Netherlands

Phone: +31 85 050 93 00

Email: info@scinus.com

Web: www.scinus.com