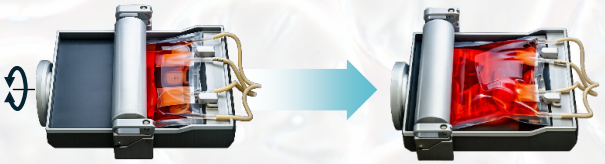
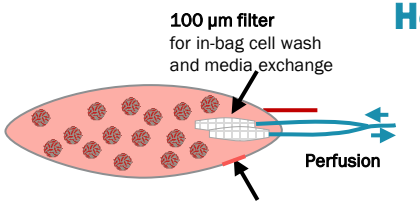
Scaling MSC manufacturing with Osilaris™



The challenges of MSC expansion:

- Limited expansion folds per passage and large seed train requirements
- Multiple open handling steps, and passaging increasing contamination risk
- Poor process control with oxygen and nutrient gradients across 2D and 3D matrices
- High operational costs (media, labor, infrastructure)
- Inefficient, open and harsh cell harvesting processes with large media quenching requirements

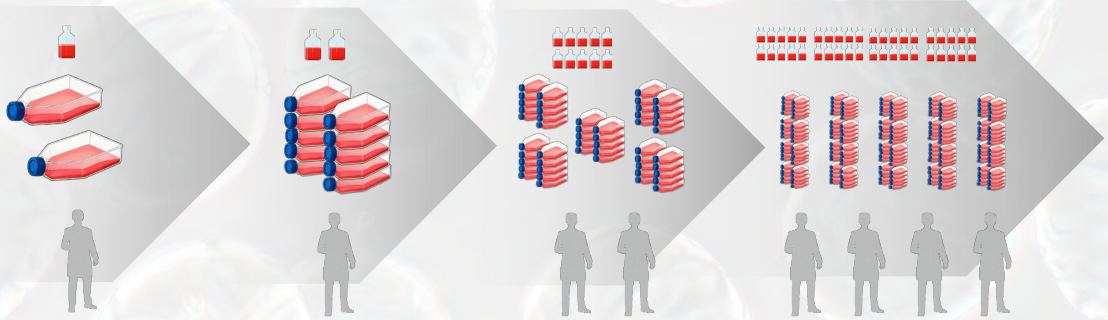


Side view of the Osilaris™ adherent culture bag

How Osilaris™ works:

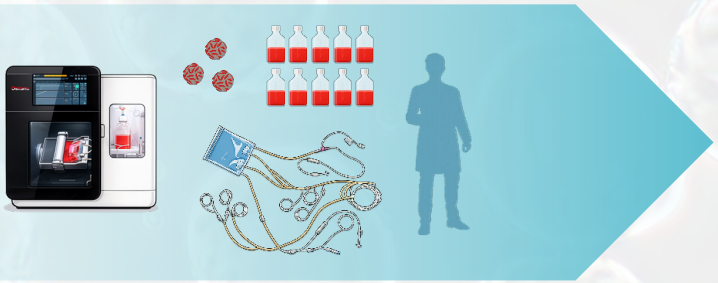
- A closed, single-use, volume expandable culture bag, that doesn't need open passaging steps
- Homogeneous, low shear, headspace-free culture bag
- Automated In-line optical sensors for pH and dissolved oxygen (DO) control, allowing hypoxic conditions.
- Weldable tubing and aseptic sampling ports for universal USP and DSP integration.
- On-device audit trail functionality aligned with 21 CFR Part 11 and EU Annex 11 requirements

3 passages, 4 operators,
>70 FTE hours, >50 liters of media,
>200 T175 flasks

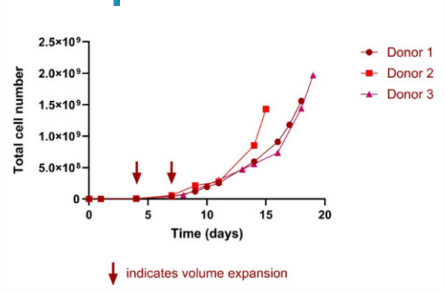


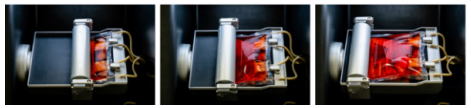
Costs of expansion
of 1 million cells to
2 billion MSCs

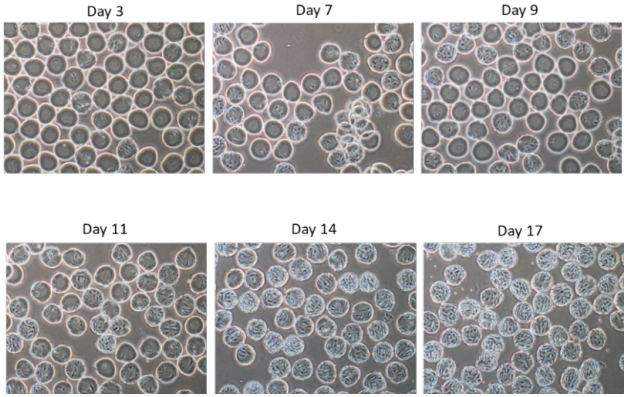
2 closed volume expansions, 1 operator,
10 FTE hours, ~10 liters of media,
1 Osilaris™ adherent culture bag,
your microcarriers of choice



Proven performance







Bead-to-bead transfer explained:

Bead-to-bead transfer allows adherent cells growing on microcarriers to move directly onto fresh beads during culture, without the need for a full harvest and re-seeding step. The gentle mixing and controlled culture environment help maintain bead contact and support efficient cell migration, making scale-up simpler and less labor-intensive. This can reduce handling steps, save time, and support a more streamlined closed manufacturing workflow.

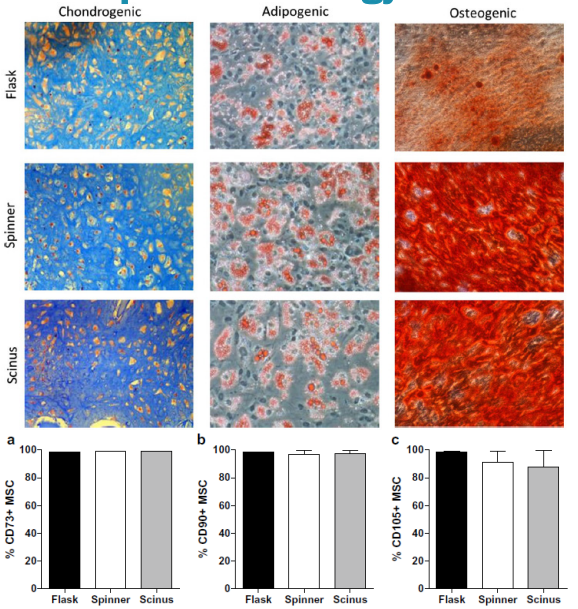
Validated with:

- Adipose, Umbilical Cord, and Bone Marrow-derived primary MSCs
- Animal serum, hPL-containing and xeno-free media
- Multiple dissolvable or non-dissolvable microcarriers

Built for efficient decentralization.

Closed.
Controlled.
GMP ready.

Uncompromised biology:



Maintained MSC identity, with proven immunomodulatory and tri-lineage differentiation properties.

Das, R., Roosloot, R., van Pel, M. *et al.* Preparing for cell culture scale-out: establishing parity of bioreactor- and flask-expanded mesenchymal stromal cell cultures. *J Transl Med* 17, 241 (2019).

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CELL EXPANSION

Learn more about Osilaris™