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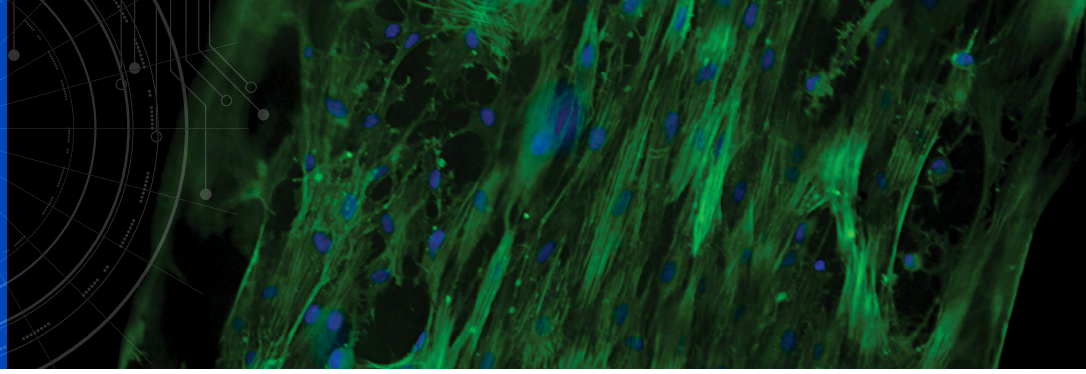
SOUTHWEST RESEARCH INSTITUTE



A Perfusion-based Scalable Bioreactor System for Anchorage-dependent Cell Expansion

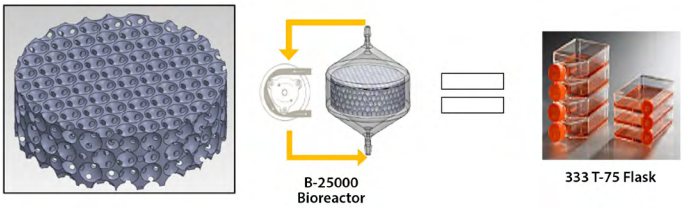
Southwest Research Institute® (SwRI®) offers expertise in diverse areas such as biomaterials and tissue engineering, materials characterization, biological encapsulation, and medical device design, prototyping, and testing. Engineers and scientists in the Pharmaceuticals and Bioengineering Department have developed a novel 3D-printed, single-use, scalable cell expansion bioreactor to propagate cells in a closed system.

Unique Features

- Mimics 2D monolayer culture but provides large culture surface area for scalable cell expansion
- Provides a low-shear (< 3×10^{-4} Pa) cell culture environment
- Facilitates automation through perfusion-based media/oxygen delivery
- Allows easy scaling up, down, and out while maintaining cell culture process
- Provides modular and closed cell manufacturing

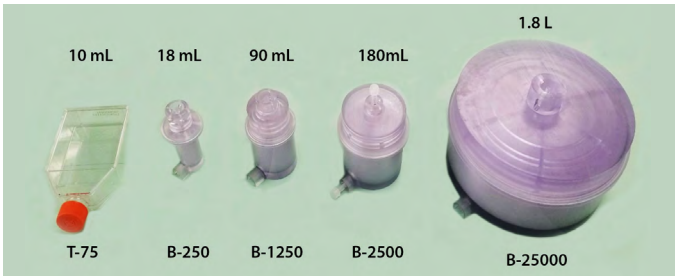
Impact

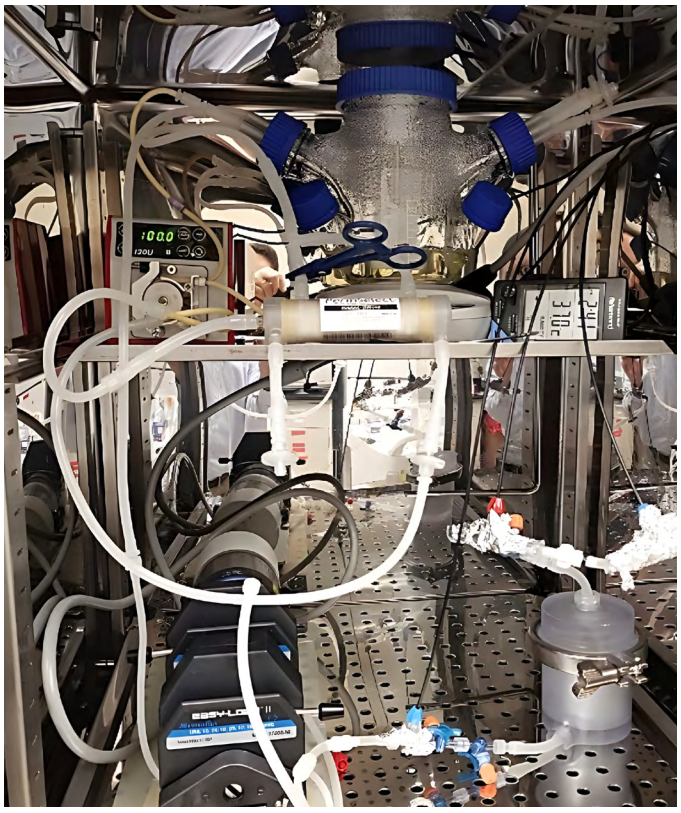
- A platform technology with broad applications in manufacturing of cells and cell-derived biologics

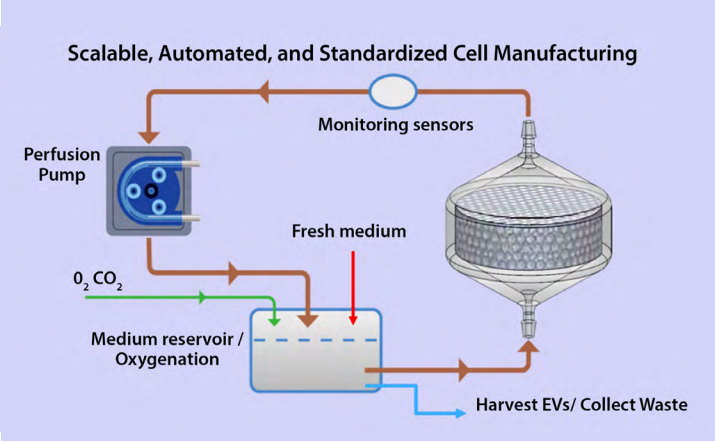


US 10,988,724 B2, US 11,149,244 B2, US 11,447,731 B2

SwRI® Patented Bioreactor

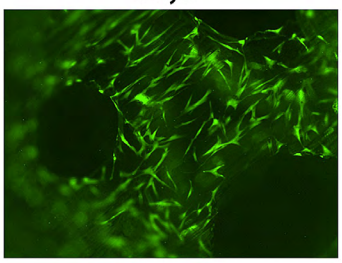




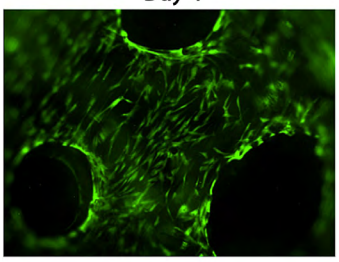


Expansion of Mesenchymal Stem Cells (MSCs) with SwRI Bioreactor

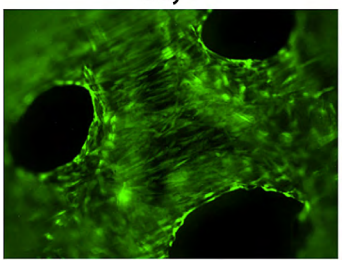
Day 3



Day 4

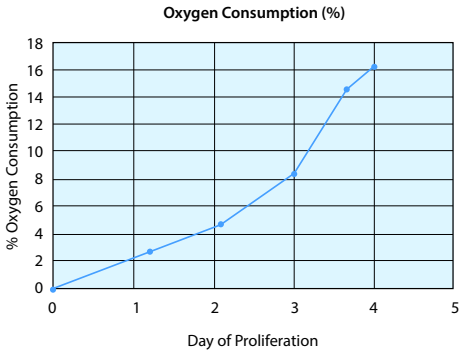


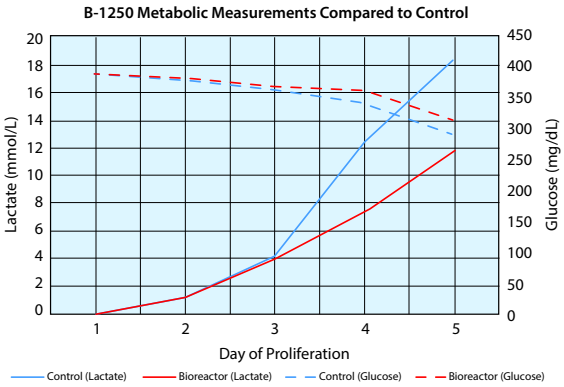
Day 5



Culture System	Seeding Density (cells/cm²)	Seeding Efficiency	Perfusion Rate* (mL/min)	PDT (hr)	Cells Harvested (x106)	Viability	Harvesting Efficiency
B-250	5000	94 ± 10%	0.25	33.5 ± 7.2	11.6 ± 0.7	96.0 ± 2.2%	94.4 ± 1.1
B-1250	5000	96.0 ± 2.9%	1.45	29.3 ± 1.9	61.2 ± 9.3	87.6 ± 0.2%	85.5 ± 5.3%
B-2500	5000	99.6%	2.50	40.16	150.7	96.4%	93.8%

*Linear flow rates are the same at 14.7 µm/sec for all bioreactors, low flow shear < $3x10^{-4}$ Pa.





MSCs expanded in the bioreactors are comparable to the MSCs grown in 2D flasks in viability, identity, safety, and potency.

Other demonstrated applications using SwRI Bioreactor

- Expansion of CAR-T cells, HEK293 cells, and iPSCs
- Production of exosomes and viral vectors

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