

 [®] RP TECHNOLOGY

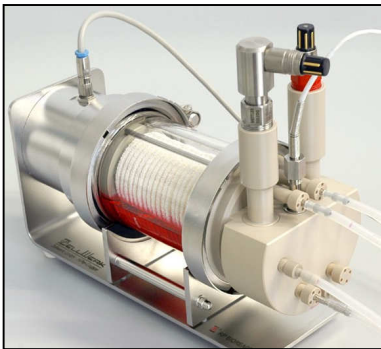
Expansion of Mesenchymal Stem Cells from
Human Umbilical Cord Tissue

Z[®]RP Cell Cultivation System - Equipment and Outcomes

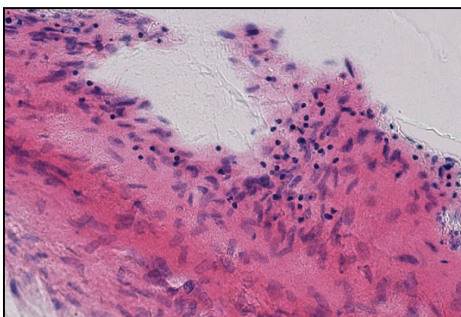
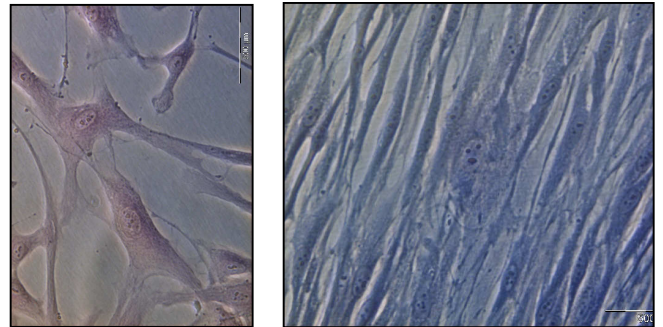
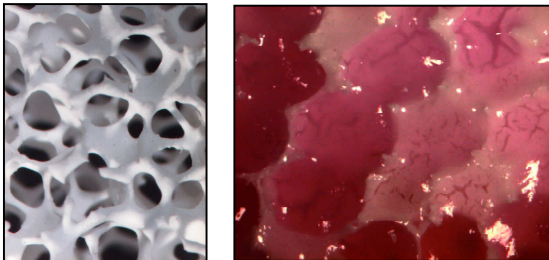
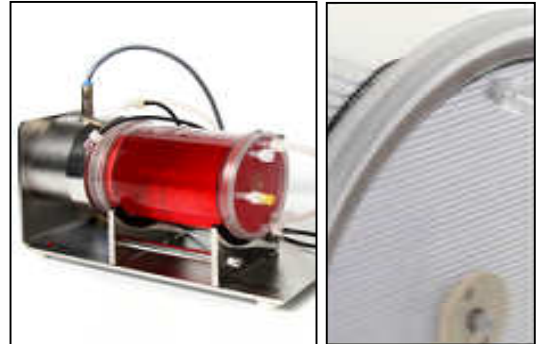
Mesenchymal Stem Cells from Human Umbilical Cord Tissue are popular in cell therapy and tissue engineering. In our Z[®]RP Cell Cultivation System these cells can be produced under GMP compliant and licensable conditions in nearly every wanted amount.



The different Z[®]RP Bioreactors are operated in the Z[®]RP Cell Cultivation System in perfusion modus. Bioreactors were placed inside the Z[®]RP GMP Breeder, which combines features of a laminar flow workbench and a cell culture incubator. Cell culture parameters, i. e. pH, pCO₂, medium temperature and perfusion are set by the Z[®]RP Control Unit.

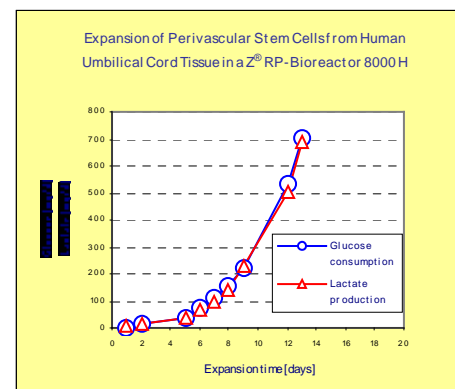


We offer Z[®]RP bioreactors that can be equipped with different cell carriers. Our Sponceram[®] carrier (left) are as well suited as beds made of a series of horizontal polymer sheets (middle and right), generating large cultivation areas per bioreactor volume.



Horizontal polymer discs colonized with UC MSCs. Left: Adhered cells after two days of cultivation. Right: Cells having reached confluency after two weeks of expansion. Lower figure: Diagram of glucose consumption and lactate generation indicating the exponential growth of UC MSCs in a Z[®]RP Bioreactor 8000 H, .

Sponceram[®] is a ceramic cell carrier material developed by Zellwerk with a porous structure (upper figures). Cells are seeded homogeneously on material surface and grow on it in a tissue like structure. Lower figure: Stained thin cut of the expanded UC MSCs in self-generated extracellular matrix for tissue engineering.



Bioreactor Types Available

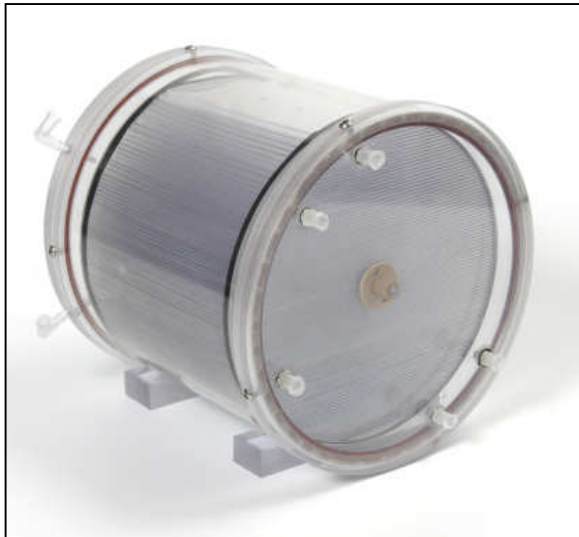
Zellwerk has developed different bioreactors depending on the requirements of cell culture. Stem cells as well as primary cells can be grown for cell therapy in Z[®]RP Bioreactors of the H series in a GMP compliant process, while tissue engineering can be performed in a Z[®]RP Bioreactor 500, either on Sponceram[®] cell carriers or material scaffolds. Types 2000 H and 8000 H are available pre-sterilized, equipped with tubes and Luer-Lock connectors



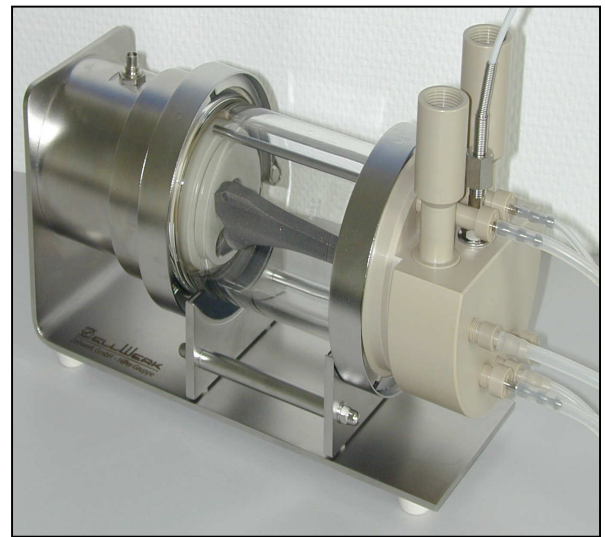
Z[®]RP Bioreactor 2000 H
1 - 2 * 10⁸ cells



Z[®]RP Bioreactor 8000 H
4 - 5 * 10⁸ cells



Z[®]RP Bioreactor 20000 H
1 - 2 * 10⁹ cells



Z[®]RP Bioreactor 500 modified for tissue engineering
Reactor bed for material scaffolds and implant blanks

GMP and Regulatory Documentation Package

Zellwerk offers a Regulatory Documentation Package for integration of the Z[®]RP System into a GMP environment:

- documents with regulatory requirements according to EU, FDA and ICH standards
- technical description and documentation of the validation of the system
- documents for quality risk management
- documents for qualification according to DQ, IQ, OQ and PQ
- standard operating procedures (SOPs)



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