



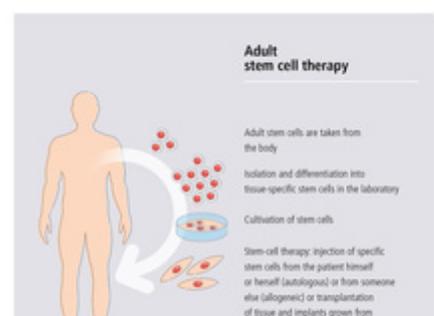
Heidelberg-based TICEBA GmbH is a highly innovative biopharmaceuticals company in the field of stem cell research. As a manufacturer of medicines, TICEBA produces stem-cell-based medicines for clinical trials conducted by its subsidiary RHEACELL GmbH & Co. KG, which is heavily involved in research into stem cell therapies in the field of regenerative medicine. The Research, Production, and Quality Control departments have a whole battery of Memmert INCOmed246 CO<sub>2</sub> incubators available for cell cultivation purposes.



Memmert INCOmed CO<sub>2</sub> incubator

## Stem cell therapy and regenerative medicine

Stem cell therapy is based on the capacity of the body's own stem cells to regenerate tissue and ensure organs remain functional. Regenerative medicine is part of the broader field of biomedicine and makes use of this capacity to cure functional impairments and diseases, with the help of stem



cells, by restoring tissue and organs that have degenerated or suffered damage.

The oldest and best-known form of stem cell therapy is the transplantation of stem cells from bone marrow or blood in the treatment of leukaemia. Since the 1990s, researchers around the world have isolated further stem cells (i.e. separated them from tissue and bodily fluids) and investigated their efficacy as potential therapies for a multitude of diseases. In strictly regulated countries like Germany, research is mainly focused on non-embryonic (adult) stem cells. These so-called pluripotent stem cells can be found in the human body after birth and are able to develop into a multitude of specialised cell types. For example, with the help of such stem cells, it could be possible to treat wounds associated with vascular disorders and diabetes that have so far proved unresponsive to therapy or even organ failure resulting from diseases of the liver and kidneys. Another potential application is regeneration of the cornea, which may have become cloudy due to a lack of limbal stem cells following injury. Conversely, the targeted switching off of stem cells in tumours could inhibit tumour growth in cancers which cannot currently be treated adequately.

## **The Memmert CO<sub>2</sub> incubator for cell cultivation at TICEBA**

One of the biggest challenges with stem cell therapy is how to minimise risk. This is why the stem-cell-based medicines produced by TICEBA are tested, like any other medicine, in strictly supervised clinical trials with support from scientists and academics?–?and these trials themselves are only run after extensive in vitro testing and modelling. For example, the TICEBA subsidiary RHEACELL is currently running clinical trials to study the efficacy and safety of pluripotent mesenchymal stem cells for various indications (chronic venous ulcer, diabetic foot ulcer, and peripheral arterial occlusive disease). In this context, therapeutic success is measured on the basis of various parameters associated with wound healing. Preparations are also ongoing for additional clinical trials with mesenchymal stem cells for the treatment of epidermolysis bullosa, acute-on-chronic liver failure, and acute kidney failure as well as for trials with



Adult stem cell therapy

### **Cell-based assay in the incubator**

Temperature control of a label-free screening test system in a Peltier-cooled incubator IPP and an incubator I.

[more information](#)

limbal stem cells for cases of limbal stem cell deficiency.

For the purpose of developing stem-cell-based medicines, ABCB5-positive stem cells are isolated from primary cultures of human mesenchymal or limbal stem cells. These cells carry the protein ABCB5 on their surface and are able to repair damaged tissue thanks to their anti-inflammatory and regenerative properties. The cell cultures are incubated in Memmert CO<sub>2</sub> incubators at 37 °C, 3.1% CO<sub>2</sub>, and 90% relative humidity. At the same time, so-called potency assays are conducted in the Quality Control department to test the regenerative and immunomodulatory capacity of the cell preparations produced. This cell cultivation also takes place at 37 °C, 3.1% CO<sub>2</sub>, and 90% relative humidity.

## **Compliance with all process parameters is a critical factor**

21 Memmert CO<sub>2</sub> incubators are in use round the clock at TICEBA. Time and again, the INCOmed246 ticks the various boxes. Top of the list, of course, are adjustment accuracy, process-controlled hot air sterilisation, and expert service.

A particularly critical factor for cell cultivation and therefore the success of clinical trials for stem cell therapy is compliance with any setpoints specified based on very narrow tolerance ranges. TICEBA makes similarly high demands of the CO<sub>2</sub> incubator it uses for production and quality control purposes. For example, the internal qualification requirements state that temperature deviation over time must not exceed 0.5 K and spatial temperature deviation must not exceed 0.8 K. All parameters are permanently monitored via the cleanroom monitoring system or calibrated data loggers.

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### **Overview of the main topics**

- Stem cell research, stem cell therapy
- Tissue engineering, tissue bank
- Cell cultivation, cell culture, tissue culture
- Chronic wounds, poorly healing wounds, wound

### **Laboratory equipment for incubation**

[Incubator I](#)

[Cooled incubator ICP](#)

[Peltier-cooled incubator IPP](#)

[CO<sub>2</sub> incubator ICO](#)

healing

- TICEBA clinical trials
- Memmert, incubator, CO<sub>2</sub> incubator

CO<sub>2</sub> incubator INCOmed

Cooled storage incubator IPS

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