



Skin transplants save lives – Human skin cell cultures are incubated at DIZG in BINDER incubators for clinical use

The first clinical use of cultured autologous skin produced at DIZG was in 1995. The culture made a significant contribution to the life-saving treatment of a severely burned patient. Today, the Biotechnology Division of the institute is still primarily engaged in making cultured autologous skin available to such patients in burn centers quickly and reliably.

The treatment of large-area burn patients who no longer have enough healthy skin intact to close the wound represents a major challenge for medicine. Human skin cell transplants are used on patients when more than 60% of body surface is covered by grade 2 or 3 burns.

DIZG has had a manufacturing license according to §13 AMG (German Medicines Act) since 2001. Such cell cultures have been classified as "Advanced Medicinal Therapy Products (ATMPs)" since 2011. DIZG filed appropriate applications for approval in regards to AMG §4b by the required deadline at the Paul-Ehrlich-Institut and anticipates issuance of three corresponding permits over the course of 2013. For the preparation of cell cultures, DIZG has a 4-person team, an ISO/GMP-compliant clean room area and a certified quality management system.

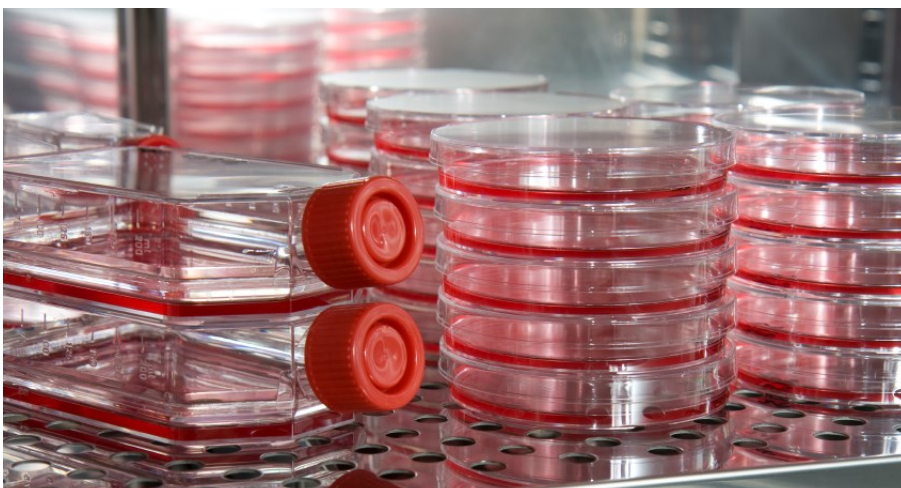
In 18 years, the institute has contributed to saving the lives of nearly 100 severe burn patients.

Requirements

- ▶ Incubator for human skin cell cultures
- ▶ Homogeneous CO₂ distribution
- ▶ Controlled humidification
- ▶ Minimized risk of contamination
- ▶ Reliable sterilization
- ▶ Optimal use of space

BINDER solution

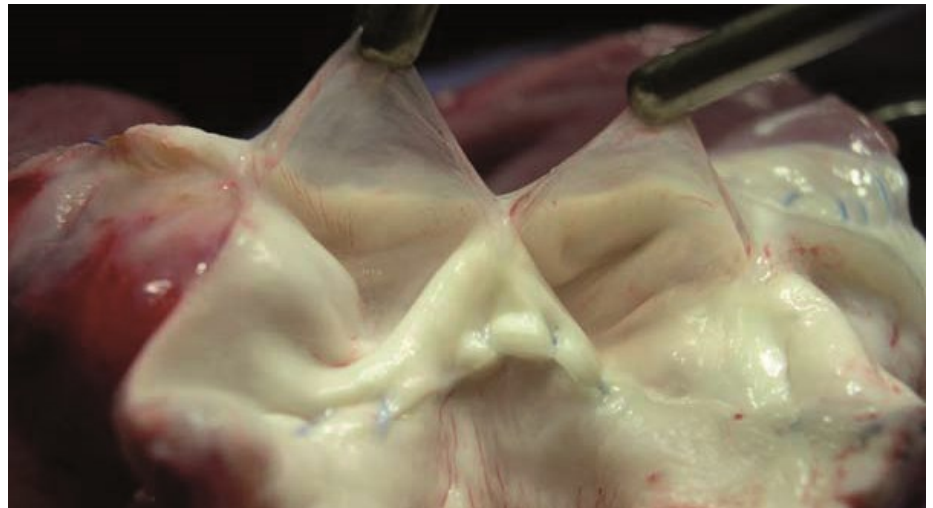
- ▶ BINDER CB series CO₂ incubator
- ▶ Homogeneous CO₂ distribution due to gas mixing head with venturi effect
- ▶ Drift-free infrared CO₂ measurement system
- ▶ Permadyr™ humidity system for controlled humidification
- ▶ Electronically controlled APT.line™ preheating chamber technology
- ▶ Seamless deep-drawn inner chamber made of stainless steel with integrated shelf support system
- ▶ Standard-compliant hot air sterilization at 180 °C
- ▶ Electronic self-diagnostic system



▲ Growing cell cultures

CB150 incubator creates standardized conditions

To incubate human skin cell cultures, the institute uses several BINDER incubators of the CB150 series. Institute employees appreciate the optimal use of space of the chambers among other things. For cultivation, one to three postage-stamp sized samples of healthy skin are taken from the patient. From the samples, the body's own epidermal cells, so-called keratinocytes, are isolated for subsequent reproduction in a special culture system under standardized conditions. Cell cultures are incubated in cell culture flasks in



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Gabriele Dietz, DIZG

incubators at 37 °C and a supply of 5% CO₂ under high humidity. Small cell islands begin to form after just a few days in the cell culture vessels. From these islands, epidermal cell suspensions can be harvested to spray onto the wounds. After prolonged cultivation, epidermal membranes can be harvested, which are placed on the wounds like a bandage. Within three to five weeks, it is possible to cultivate such "sheets" to cover a surface area of 0.5 to 1.5 m². The cultures can then be delivered to the clinic by the transplant date agreed upon by the treating physician and DIZG.

▲ Tissue Engineering

Low risk of contamination

The production of human cell cultures for clinical use requires authorization granted by the EMA according to ATMP or authorization granted by the Paul-Ehrlich-Institut according to AMG §4b, as well as manufacturing authorization granted by the local regional health authority, e.g. according to AMG §13. Such authorization requires ISO/GMP compliance. Cultivation is carried out entirely in strictly controlled class A and B clean rooms. Gabriele Dietz, medical technology director at DIZG, explicitly points out that "We must always ensure that the risk of contamination is kept as low as possible. Due to their sterilization capabilities and surfaces that can be disinfected, BINDER incubators are particularly well-suited for our requirements." Fans, large-surface racks and freestanding fixtures in conventional incubators often re-

present an unacceptable risk of contamination. BINDER GmbH has recognized this problem and thus minimizes such risks in all units. Hidden contamination areas are eliminated by an inner chamber cast from a single mold and rounded corners in the inner chamber. Under the name ANTI.PLENUM Design, this unique minimization of contamination surfaces ensures maximum safety.

DIZG pursues non-profit purposes exclusively and directly and provides numerous hospitals, clinics and doctors' offices both domestically and abroad with human cell and tissue transplants. DIZG is certified in accordance with DIN EN ISO 13485 and follows the ethical code and quality standards of the European Association of Tissue Banks (EATB).

Customer benefits

- ▶ Hot air sterilization at 180 °C
- ▶ Seamless deep-drawn inner chamber made of stainless steel
- ▶ Patented BINDER technology
- ▶ Quality "Made in Germany"

Areas of application

- ▶ Bio Tissue Engineering
- ▶ In vitro Fertilization (IVF)
- ▶ Clinics and University Hospitals



▲ CO₂-incubator CB 150

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