

March 26, 2026
Japan Tissue Engineering Co., Ltd.

J-TEC Announces Application for Marketing Approval for the World's First Dried Allogeneic Cultured Epidermis

Aichi, Japan, March 26, 2026 ----Japan Tissue Engineering Co., Ltd. (J-TEC) applied to the Ministry of Health, Labour and Welfare today to obtain marketing approval for "Allo-JaCE03" (development name), a medical device intended for the treatment of skin defects.

This application the world's first application for marketing approval of a dry cultured epidermis derived from allogeneic (non-self) cells. Because this product contains no living cells and can be stored long-term at room temperature, it can be kept in stock at medical institutions. This enables a rapid response for the urgent treatment of skin defects, such as severe burns.

To date, J-TEC has provided five autologous regenerative medicine products, including "JACE[®]," a custom-made autologous cultured epidermis cultivated from the patient's own cells. However, products utilizing autologous cells require a certain cultivation period prior to delivery, presenting a challenge in fully addressing the immediate needs of clinical settings where urgent treatment is required.

To resolve this issue, J-TEC has been developing a product that can be utilized immediately at medical institutions. In November 2021, the company initiated a clinical trial targeting patients with burns—a representative condition among skin defects—which has now culminated in this application for marketing approval.

"Allo-JaCE03" was developed to overcome the aforementioned challenges by applying the cell culture technologies J-TEC has cultivated over many years.

- **Long-term room-temperature storage and on-site inventory at medical institutions**

By drying and sterilizing epidermal cell sheets cultured from allogeneic cells, J-TEC has achieved long-term storage at room temperature. Since the product can be kept in stock at medical institutions, it is available for immediate use when required.



- **Capability for mass production**

Utilizing allogeneic cells as the raw material allows for systematic mass production, rather than custom-made manufacturing. This ensures a stable and reliable supply to medical institutions nationwide.



- **Efficacy and safety demonstrated in clinical trials**

In domestic clinical trials, the product demonstrated favorable results, with the primary endpoint—the epithelialization rate** on day 7 following the initial application—surpassing the efficacy of existing treatments. Furthermore, no problematic adverse events were observed regarding safety.

* Based on J-TEC's research as of the date of announcement

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- **Reduced burden on patients and healthcare professionals**

The availability of a ready-to-use product allows patients to begin treatment immediately after an injury. Applying the product to the defect (wound) early post-injury promotes healing, which is expected to shorten the treatment period, lower the risk of infection, and minimize scarring, thereby significantly reducing the burden on both patients and healthcare professionals.

3. Future Outlook

Given the advantages of room-temperature storage and easy transportation, J-TEC will promote the development of this product with an eye toward expanding into overseas markets, rather than limiting its scope to Japan. Through this product, J-TEC aims to deliver a new treatment option and will continue its efforts to obtain marketing approval, working toward the realization of its corporate vision: "Making regenerative medicine a standard of care."

[Contact information for inquiries about this announcement]

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