

**Submission of a Request of Approval for Partial Changes
to Autologous Cultured Cartilage JACC
Aimed at an Expansion of Indication to Include Knee Osteoarthritis**

Japan Tissue Engineering Co., Ltd. (Headquarters: Gamagori, Aichi Prefecture; President and CEO: Ken-ichiro Hata) is seeking an expansion of indication^{*1} for the regenerative medical product "Autologous Cultured Cartilage JACC[®]" (hereinafter JACC), which is used to treat traumatic cartilage defects or osteochondritis dissecans of the knee.

We are pleased to announce that we have submitted a request of approval to the Ministry of Health, Labor and Welfare for partial changes to JACC for the purpose of treating knee osteoarthritis^{*2}.

JACC is a regenerative medical product for which we obtained marketing approval in 2012 for the treatment of traumatic cartilage defects or osteochondritis dissecans of the knee. It is Japan's first regenerative medical product ever approved in the field of orthopedics and has been covered by health insurance since 2013.

We conducted a clinical trial, beginning in July 2018, with the aim of achieving an expansion of indication for JACC to include knee osteoarthritis. In February 2024, we notified the Pharmaceuticals and Medical Device Agency of the completion of the trial. Results of this trial show a statistically significant improvement in clinical symptoms among patients with autologous cultured cartilage transplantation compared to those administered sodium hyaluronate. In addition, the trial has confirmed that transplantation of autologous cultured cartilage repairs cartilage defects caused by knee osteoarthritis with hyaline cartilage-like tissue.

Committed to our vision of "Creating a Future for Regenerative Medicine," we strive to provide more patients with new treatment methods and contribute to improving their quality of life (QOL) by achieving an expansion of indication of JACC.

*1 Expansion of indication: To expand the scope of application of a drug for which marketing approval has already been obtained (add diseases treatable with the drug)

*2 Knee osteoarthritis: A disease that causes pain as the cartilage gradually wears away and deforms. In some cases, the cause is not clear while, in other cases, it is possible to identify the cause such as sports- or accident-related trauma. Aging and obesity lead to symptom progression. Currently, knee osteoarthritis is treated symptomatically by administering analgesics with anti-inflammatory properties to alleviate pain and other clinical symptoms, while retarding symptom progression is difficult. The methods to treat severe symptoms are limited to a few options such as high tibial osteotomy in which the angle of the knee is adjusted by cutting the tibia and artificial joint replacement.

About autologous cultured cartilage

Autologous cultured cartilage (brand name: “JACC”), based on technology developed by Professor Mitsuo Ochi (currently President of Hiroshima University) during his research at Shimane Medical University, is Japan’s first regenerative medical product in the field of orthopedics.

“JACC” is made by harvesting the patient’s own cartilage tissue and mixing it with gel-form atelocollagen to mold it into a three-dimensional form that is then transplanted at the site of cartilage loss in the patient’s knee. “JACC” was approved in July 2012, and it has been covered by public health insurance programs since April 2013.

In 2019, aiming to further reduce the invasiveness in regards to the patient’s body in treatment with autologous cultured cartilage, we introduced the method of using an artificial collagen membrane instead of the periosteum harvested from the patient’s tibia for transplantation. This reduced the physical burden on patients, as well as simplifying the transplanting procedure for doctors.

Transplantation of autologous cultured cartilage (knee-joint)



(Reference: About J-TEC)

J-TEC is a maker of regenerative medical products. Our vision is “Creating a Future for Regenerative Medicine”, and we have been a member of the Teijin Group since March 2021. As the top runner in Japan’s regenerative medicine industry, we provide a stable supply of regenerative medical products, and of the regenerative medical products that have been approved in Japan, the following five are J-TEC products.

- ✓ Approved Oct. 2007: Autologous Cultured Epidermis JACE®
– Japan’s first regenerative medical product
- ✓ Approved July 2012: Autologous Cultured Cartilage JACC®
– Japan’s first regenerative medical product in the orthopedics field
- ✓ Approved March 2020: Autologous Cultured Corneal Epithelium NEPIC®
– Japan’s first regenerative medical product in the ophthalmology field
- ✓ Approved June 2021: Autologous Cultured Oral Mucosal Epithelium OCURAL®
– The world’s first regenerative medical product using oral mucosal epithelial cells
- ✓ Approved March 2023: Autologous Cultured Epidermis Maintaining Melanocytes JACEMIN.
– Second regenerative medical product in Japan in the skin field

Please visit www.jpte.co.jp/en/

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