May 13, 2025
Japan Tissue Engineering Co., Ltd.

Japan Tissue Engineering Announces Approval for Expanded Indication of Autologous Cultured Cartilage "JACC" for Osteoarthritis

Aichi, Japan, May 13, 2025 --- Japan Tissue Engineering Co., Ltd. announced today that it has received approval for the expanded indication of its autologous cultured cartilage “JACC” for the treatment of osteoarthritis as of May 13, 2025. J-TEC aims to provide “JACC” to eligible patients as soon as possible and is working towards insurance coverage by December 2025.

Osteoarthritis is a condition where the cartilage in the knee wears down or becomes damaged due to aging or injury, leading to bone deformation and pain. It is estimated that there are approximately 10 million patients in Japan, and the number is increasing with the aging population.

Treatment for osteoarthritis includes conservative therapies such as medication (e.g., hyaluronic acid injections) and exercise therapy (e.g., muscle strengthening). When these treatments are ineffective, surgical options like joint replacement or osteotomy are considered. However, there are significant medical challenges as damaged knee cartilage has a very low chance of natural regeneration, and effective treatments for cartilage repair are lacking.

To address these challenges, J-TEC has been manufacturing and selling “JACC” in Japan since April 2013. In April 2019, J-TEC began clinical trials for the expanded indication, and after submitting the application for partial change approval in June 2024, the efficacy and safety were recognized, leading to the current approval.

“JACC” is a gel-like artificial cartilage made by culturing the patient's own healthy knee cartilage cells. It was developed based on the cartilage culturing technology by Mitsuo Ochi, President of Hiroshima University. The previous indications were "traumatic cartilage defects or osteochondritis dissecans in the knee joint (excluding osteoarthritis)," and it has been used in over 1,900 cases since its launch.

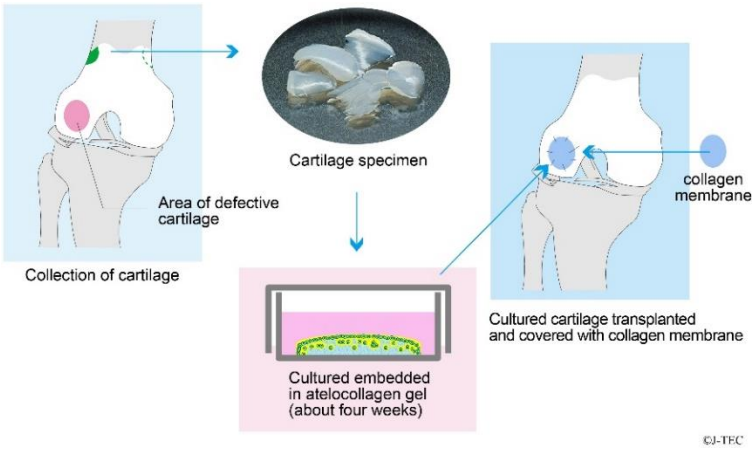
The newly approved indication is "osteoarthritis." Patients with cartilage defects larger than 2 cm^2 who do not respond to conservative treatments are eligible. Transplanting “JACC” into the cartilage defect area regenerates tissue similar to normal cartilage. Using the patient's own cartilage cells minimizes the risk of rejection, and once engrafted, it functions as natural cartilage, improving clinical symptoms. This offers a new treatment option for patients who do not respond to medication or exercise therapy and for those who face challenges with existing surgical treatments.

J-TEC will work closely with the Ministry of Health, Labor and Welfare to establish an environment for providing “JACC” to patients in need, aiming for insurance coverage by December 2025. Within a few years of its launch, J-TEC aims to use “JACC” in approximately 1,000 cases annually. To achieve this, J-TEC will promote awareness activities for the treatment of osteoarthritis using “JACC”.

About Japan Tissue Engineering Co., Ltd.

As a pioneer in regenerative medicine in Japan, J-TEC will continue to contribute to solving unmet medical needs worldwide and strive to realize its vision of "Creating a Future for Regenerative Medicine".

PHOTOGRAPH OF CULTURED CARTILAGE



FLOWCHART OF CULTURED CARTILAGE TRANSPLANTATION

OUTLINE OF APPROVAL

Product Name	JACC®
Approval Date (Additional Approval Date)	July 27, 2012 (May 13, 2025)
Generic Name	Human Autologous Tissue for Transplantation
Product Name	JACC®
Additional efficacy or effects	Improvement of clinical symptoms for osteoarthritis of the knee. However, it is only applicable to cases where clinical symptoms do not improve with conservative treatments such as exercise therapy, and the area of cartilage defect is 2 cm^2 or more.

[Contact information for inquiries about this announcement]

Japan Tissue Engineering Co., Ltd.
E-mail. jtec-info@jpte.co.jp