June 27, 2022
Japan Tissue Engineering Co., Ltd.

Re-examination of Autologous Cultured Cartilage “JACC”

Japan Tissue Engineering Co., Ltd. (“J-TEC”; headquarters in Gamagori, Aichi; President & CEO Kenichiro Hata) is pleased to announce that re-examination* of “Autologous Cultured Cartilage JACC” (hereinafter “JACC”) by the Ministry of Health, Labour and Welfare has been completed.

“JACC” is used for the purpose of treating traumatic cartilage deficiency or osteochondritis dissecans of the knee joint (with the exception of osteoarthritis of the knee). To confirm the effectiveness and safety of “JACC”, J-TEC has conducted the post-marketing surveillance of all cases using “JACC” over the course of the 7 years that was the re-examination period. The summary of this post-marketing surveillance has been completed, and as a result of the re-examination, the effectiveness of “JACC” at the time of approval has been reconfirmed by the Ministry of Health, Labour and Welfare, and there has been no change in the indication.

Autologous Cultured Cartilage

[Indication]
Traumatic cartilage defects or osteochondritis dissecans of the knee (excluding knee osteoarthritis), limited to cases where no other treatment method is available and the applicable cartilage defect has a cartilage loss area of at least 4 cm^2.

This development makes “JACC” the first regenerative medical product to have completed re-examination in the field of orthopedic surgery, and J-TEC the sole corporation in Japan to have manufactured and marketed two regenerative medical products that have completed re-examination. Through the manufacture and marketing of Autologous Cultured Epidermis “JACE” and Autologous Cultured Cartilage “JACC”, J-TEC has constructed a business model for regenerative medical products that use the patient’s own cells. As in the results of the re-examination of “JACE” (for severe thermal burns) that was completed in July 2017, it has been confirmed in this re-examination that “JACC” has the indication applied for at the time of approval.

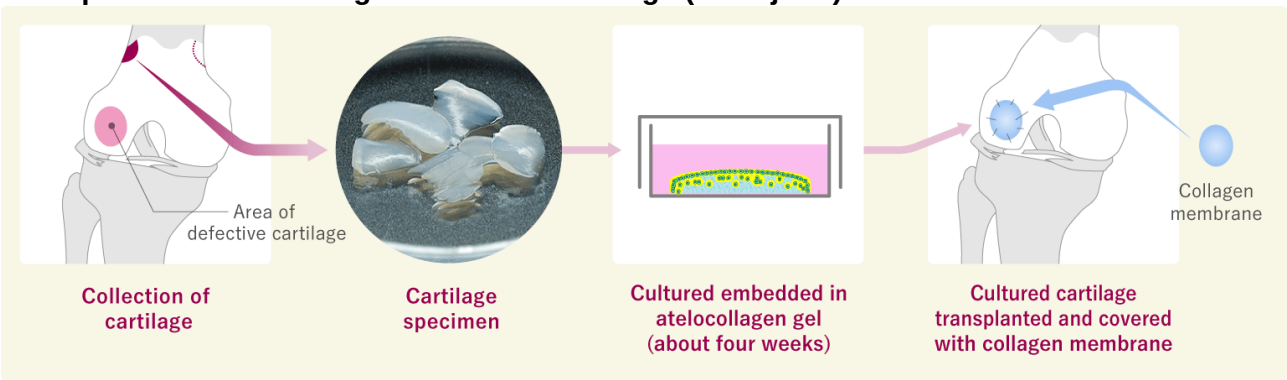
*Re-examination is a system under which a product is again subjected to review once a certain period has passed since its approval. On the basis of data that the corporation has collected on the actual use of the product at medical institutions, the indication (effects and benefits) and safety of the product are re-examined. As a result of the re-examination, one of the following actions will be taken: “rescinding of approval”, “elimination or modification of the indication”, or “no action in particular”.

J-TEC is also conducting a clinical trial for the expansion of the indication of “JACC” to include osteoarthritis of the knee, and we will continue to promote activities for providing “JACC” to many more patients. While aiming to promote the spread of “JACC” and the further development of regenerative medicine in the future, J-TEC will also go on contributing to the improvement of patients’ QOL (quality of life).

Product Summary

- “JACC” is autologous cultured cartilage that 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 as Japan’s first regenerative medical product in the field of orthopedic surgery. It has been covered by public health insurance programs since April 2013.
- The approval for “JACC” was partially changed in 2019 to further reduce the invasiveness of treatment using “JACC” for patients. Before the change, “JACC” was used to treat the defect by covering it with periosteum harvested from the patient’s tibia. After the change in approval, it became possible to use artificial collagen film instead of periosteum, which achieved a reduction in the physical burden on the patient and simplified the transplantation procedure for the physician.

Transplantation of autologous cultured cartilage (knee-joint)



(Reference: About J-TEC)

J-TEC is a maker of regenerative medical products whose corporate vision is “creating a future for regenerative medicine”. As Japan’s top runner in regenerative medicine, J-TEC obtained marketing approval for autologous cultured epidermis “JACE”, Japan’s first regenerative medical product, in October of 2007, and began marketing the product in January of 2009. J-TEC then went on to obtain marketing approval for Autologous Cultured Cartilage “JACC” in July of 2012, for Autologous Cultured Corneal Epithelium “Nepic” in March of 2020, and for Autologous Cultured Oral Mucosal Epithelium “Ocural” in June 2021. “JACC” was Japan’s first regenerative medical product for use in orthopedic surgery, and “Nepic” was the first for use in ophthalmology. Of the 16 regenerative medical products that have been approved in Japan, four are J-TEC products.

[Contact information for inquiries about this announcement]

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