

Providing new treatment options with Japan’s first regenerative medical product in ophthalmology field
Obtained marketing approval for autologous cultured corneal epithelium “Nepic”

March 19, 2020
Japan Tissue Engineering Co., Ltd.

Fujifilm subsidiary Japan Tissue Engineering Co., Ltd. (J-TEC) obtained marketing approval for autologous cultured corneal epithelium “Nepic” on March 19. “Nepic” is intended for the treatment of corneal epithelial stem cell deficiency, and it is Japan’s first regenerative medical product in the ophthalmology field.

As a pioneer in regenerative medicine in Japan, J-TEC obtained marketing approval for Japan’s first regenerative medical product, autologous cultured epidermis JACE, in 2007, and marketing began in 2009. Later the indication for JACE was expanded from severe burns to giant congenital melanocytic nevus and epidermolysis bullosa. In 2013, J-TEC took the lead in the regenerative medicine industry by beginning to provide autologous cultured cartilage JACC, Japan’s first regenerative medical product in the orthopedic surgery field.

“Nepic”, for which J-TEC recently obtained marketing approval, is a product in which corneal epithelial stem cells from the patient’s own corneal limbus tissue are cultured in sheet form to be transplanted with the aim of regenerating the corneal epithelium. As part of its custom development & manufacturing business, J-TEC began development under contract from ophthalmological medical device maker NIDEK Co., Ltd. Clinical trials got underway in October of 2014, introducing corneal epithelium culturing technology from Professor Graziella Pellegrini and Professor Michele De Luca of Italy’s University of Modena and Professor Kohji Nishida of Osaka University Graduate School of Medicine (Department of Ophthalmology). In March of 2019, J-TEC submitted Japan’s first application for marketing approval of a regenerative medical product in the ophthalmology field to the Ministry of Health, Labour and Welfare. It is planned to have NIDEK handle marketing of “Nepic”.

J-TEC will go on contributing to the spread of regenerative medicine in the ophthalmological field and the improvement of quality of life (QOL) by providing new treatment options for corneal epithelial stem cell deficiency. By accelerating our development of regenerative medical products, we will promote the industrialization and practical application of regenerative medicine through our custom development & manufacturing business, which supports clinical research, clinical trials, and manufacturing.

1. Outline of marketing approval

Generic name	Corneal epithelial cell sheet derived from human (autologous) corneal limbus
Indication and performance	Corneal epithelial stem cell deficiency, with the exception of the following patients: <ul style="list-style-type: none">•Patients with Stevens-Johnson syndrome•Patients with Ocular pemphigoid•Patients with Graft versus host disease•Patients with aniridia or other congenital corneal epithelial stem cell dysplasia•Patients with recurrent pterygium•Patients with idiopathic corneal epithelial stem cell deficiency