

## NEWS RELEASE

**SYNFOLIUM<sup>®</sup>, a Novel Cardiovascular Surgical Patch,  
to Be Marketed in Japan on June 12**

**Tokyo, Japan, May 27, 2024** --- The consortium of Teijin Limited, Fukui Tateami Co., Ltd., and Osaka Medical and Pharmaceutical University announced today that a novel surgical patch (development code: OFT-G1), to be marketed under the brand name SYNFOLIUM<sup>®</sup>, will be released for manufacturing and distribution by Teijin Medical Technologies Co., Ltd., a Teijin Group company, on Wednesday, June 12, 2024.

SYNFOLIUM<sup>®</sup> is a surgical patch with knitted fabric consisting of both bio-absorbable and non-absorbable yarns, which are coated with cross-linked gelatin. After the patch is surgically implanted in the body, the patient's tissue grows and gradually surrounds the expandable, non-absorbable portion, while the bio-absorbable portion degrades. The regenerated tissue has the potential to reduce the risk of inflammatory reactions, foreign body reactions and cell death, which often cause deterioration of the implants.

This new product is designed to be used in surgical treatment of patients with congenital heart disease (CHD). The prevalence of CHD is 1 in 100 people globally, and in Japan, it is estimated that approximately 10,000 neonates are born with the disease each year. Newborns and infants with CHD generally undergo surgeries to correct hemodynamic problems due to septal defects or narrowed blood vessels (stenosis) by implanting a medical patch, usually made from synthetic or animal-derived materials. However, over a long period after surgery, a considerable number of patients eventually require re-interventions, such as repeat surgery or catheter therapy, due to the deterioration of the implanted patch. This deterioration can be caused by an immune-mediated foreign body reaction or the development of stenosis due to the inability of the patch to stretch in response to the growth of cardiac and vascular tissue.

To address this clinical problem, Shintaro Nemoto, M.D., Ph.D., of Osaka Medical and Pharmaceutical University, created an idea for a patch that could accommodate the growth of patients' bodies through restoration by the patient's own tissues. In 2012, he began research and exploration to make this idea a reality.

Fukui Tateami, a pioneer in warp-knitting technology based in Fukui Prefecture, turned Dr. Nemoto's idea into the novel concept of an expandable cardiovascular patch. Based on advanced warp knitting technology it developed over the 80 years since its founding, the company created a special knitted fabric structure to accommodate tissue regeneration.

Teijin developed the technology to coat knitted fabric with gelatin, which can prevent blood leakage and can be replaced by the patient's own tissue. The company has been proceeding with design and development, clinical trials, establishment of a commercial production system, and application for

manufacturing and marketing approval in Japan.

The three parties have been collaborating on the development of this product since 2014.

The development of *SYNFOLIUM*<sup>®</sup> has been supported by the Ministry of Economy, Trade and Industry since 2014, as well as by a program launched in 2017 by the Japan Agency for Medical Research and Development (AMED) to facilitate collaboration between medical academia and industry. Japan's Ministry of Health, Labor and Welfare designated *SYNFOLIUM*<sup>®</sup> as a "SAKIGAKE" device in April 2018, providing various incentives to speed up approval for clinical use. In addition, the Japanese Society of Pediatric Cardiology and Cardiac Surgery cooperated by assisting with clinical trials and providing advice on creating guidelines for appropriate use.

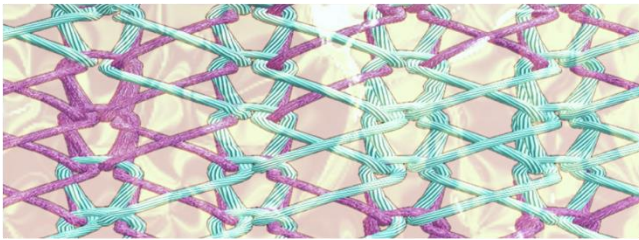
Clinical trials that began in 2019 were completed in 2022, and Teijin Medical Technologies applied for manufacturing and sales approval to the Ministry of Health, Labor and Welfare in January 2023. The company received approval in July of the same year.

Going forward, Teijin and Teijin Medical Technologies, Fukui Tateami, and Osaka Medical and Pharmaceutical University will provide clinical information about this product to medical institutions to facilitate its use in patients with CHD. Teijin and Teijin Medical Technologies will continue to collect and analyze cases using *SYNFOLIUM*<sup>®</sup> to establish its long-term safety and efficacy.

Furthermore, to help improve the quality of life of patients with CHD around the world, the consortium plans to market *SYNFOLIUM*<sup>®</sup> overseas by working to gain manufacturing and marketing approval in the United States, the European Union and other countries.

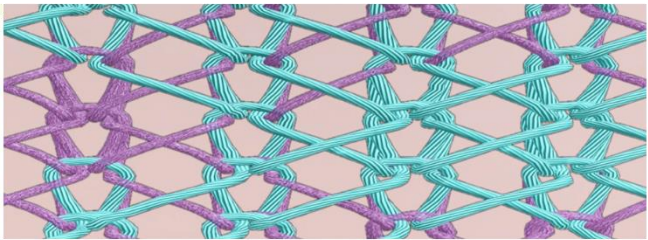
Using knowledge and technology gained through the development of this product, the consortium will work on developing other products targeting unmet medical needs, such as valved conduit for the treatment of CHD and materials for valve reconstruction.

### ① Before implantation



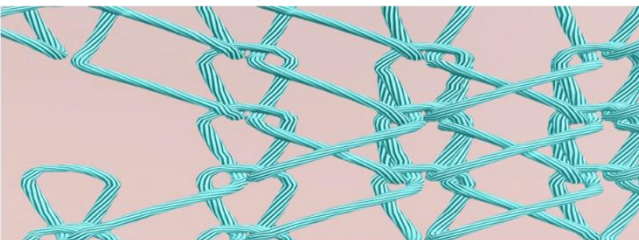
Bio-absorbable yarn (pink) and non-absorbable yarn (light blue) are coated with a gelatin membrane.

### ② Short-term after implantation



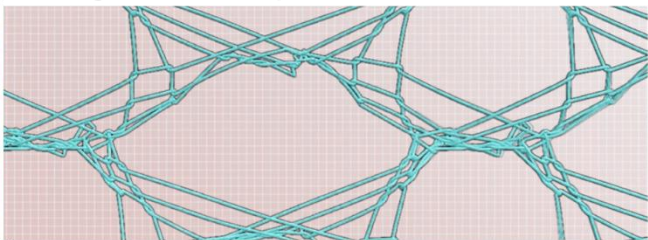
The gelatin membrane is degraded and replaced with self-tissue.

### ③ Mid-term after implantation



Bio-absorbable portions disappear.

### ④ Long-term after implantation



Becomes an expandable structure as the tissue grows.

## About the Teijin Group

Teijin (TSE: 3401) is a technology-driven global group with two core businesses: high-performance materials and healthcare solutions. Established in 1918 as Japan's first rayon manufacturer, Teijin today comprises some 170 companies employing 20,000 people in 20 countries. Through "Human Chemistry, Human Solutions," Teijin relentlessly strives to aim to be a company that supports the society of the future by protecting the global environment and addressing the needs of people and communities. Teijin posted consolidated sales of JPY 1,032.8 billion (USD 6.6 billion) and total assets of JPY 1,251.0 billion (USD 8.0 billion) in the fiscal year ending March 31, 2024.

Visit [www.teijin.com](http://www.teijin.com).

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## About Fukui Tateami Co., Ltd.

With 80 years of experience and advanced technology, Fukui Tateami has become one of Japan's largest manufacturers of warp-knitted fabric used in a wide spectrum of applications, including fashionwear, sportswear, automotive interiors and industrial materials. After installing a fully equipped clean room in 2017, the company expanded its business into medical textiles. Fukui Tateami was the first textile company

in Japan to obtain ISO13485 certification. It posted sales of JPY 3.2 billion (USD 20 million) and total assets of JPY 2.7 billion (USD 17 million) in the fiscal year ending March 31, 2024.

Please visit <http://www.fukutate.co.jp/en>

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### **About Osaka Medical and Pharmaceutical University**

Osaka Medical and Pharmaceutical University is a comprehensive institution that offers education and research in medicine, pharmacy and nursing. The university educates thousands of clinical professionals through its unique curriculum. Not only basic scientific research but also interdisciplinary research activities are conducted there to solve unmet medical needs. Various medical devices have been invented at the university by active industry-academia-government collaborations. The University Hospital provides advanced medical treatments such as state-of-the art cancer therapy, including boron neutron capture therapy, robotic surgery and genomic medicine.

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