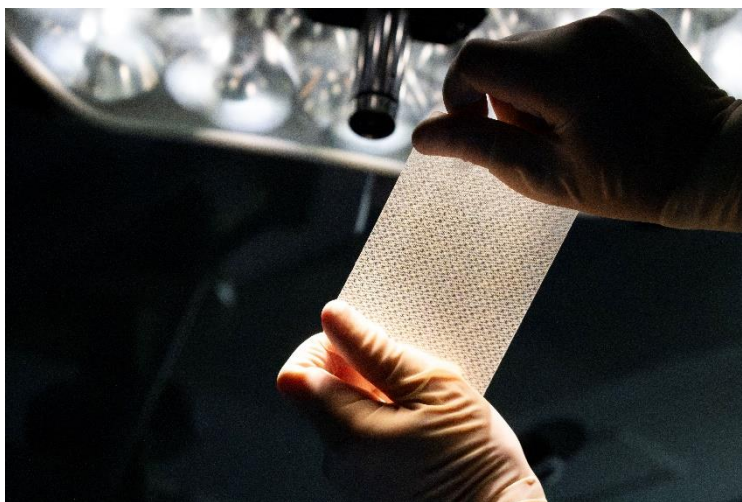


## NEWS RELEASE

**SYNFOLIUM®: Novel Cardiovascular Surgical Patch Receives Manufacturing and Marketing Approval in Japan**

Tokyo, Japan, July 12, 2023 --- The consortium of [Osaka Medical and Pharmaceutical University](#), [Fukui Tateami Co., Ltd.](#), and [Teijin Limited](#) announced today that a novel surgical patch (development code: OFT-G1), to be marketed under the brand name SYNFOLIUM®, has received a manufacturing and marketing approval in Japan from the Ministry of Health, Labor and Welfare on July 11. [Teijin Medical Technologies Co., Ltd.](#), a Teijin Group company, will serve as a commerce manufacturer and distributor of the SYNFOLIUM® during fiscal 2023.



SYNFOLIUM®

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

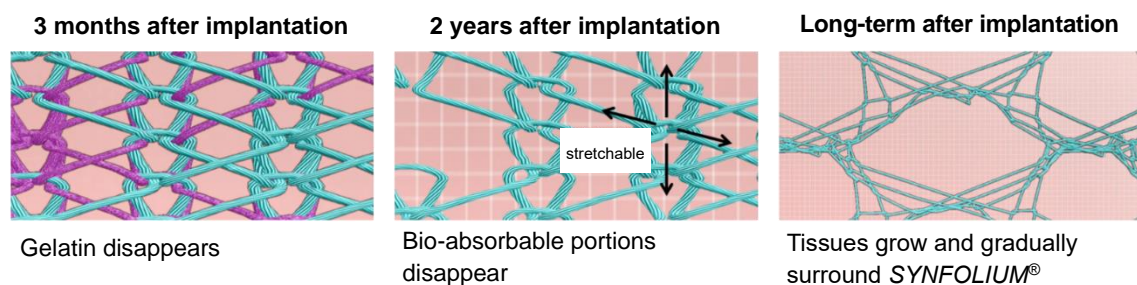
This new product is to be used in the surgical treatment for patients with congenital heart disease (CHD). Neonates and infants with CHD generally undergo surgeries to correct hemodynamic problems due to septal defects or narrowed blood vessels (stenosis). Over a long period after surgery, a considerable number of them eventually require re-interventions, such as repeat surgery or catheter therapy, due to the deteriorations above.

To address this clinical problem, Shintaro Nemoto, M.D., Ph.D., of Osaka Medical and Pharmaceutical University, created an idea of a patch that could accommodate the growth of patients' bodies by being restored by the patients' own tissues. Fukui Tateami,

a pioneer in warp-knitting technology, made Dr. Nemoto's idea into a novel concept of an expandable cardiovascular patch that has a special knitted fabric structure to accommodate tissue regeneration and developed a prototype. Teijin, with experience in the healthcare sector through its pharmaceutical and home healthcare businesses, integrated the product design, development and regulatory works into the *SYNFOLIUM*<sup>®</sup> patch. The three parties have been collaborating on development of this product since 2014.

Japan's Ministry of Health, Labor and Welfare designated the OFT-G1 as a "SAKIGAKE" device in April 2018, providing various incentives to accelerate its approval for clinical use. In clinical trials of CHD surgery conducted in Japan between 2019 to 2022, there occurred no reoperations and life-threatening events related to the patch. Based on these results, Teijin Medical Technologies submitted a marketing authorization application in Japan in January 2023.

Going forward, Osaka Medical and Pharmaceutical University, Fukui Tateami, Teijin and Teijin Medical Technologies will accelerate preparations for the launch of *SYNFOLIUM*<sup>®</sup> in Japan to deliver it to patients as quickly as possible. The consortium will continue to improve the current technology used for *SYNFOLIUM*<sup>®</sup>, and will also expand the product portfolio with the goal of improving the treatment and quality of life of patients with CHD in Japan and worldwide.

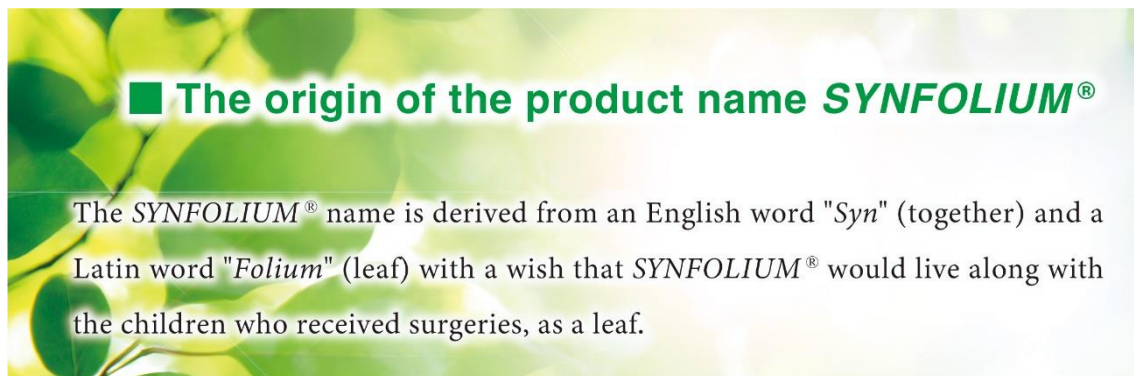


"The mission was very challenging, but our development team persevered with strong endurance. This significant milestone was achieved with incredible support from academic societies and regulatory authorities," said Shintaro Nemoto, M.D., Ph.D., Department of Thoracic and Cardiovascular Surgery of Osaka Medical and Pharmaceutical University. "However, there are still challenges to overcome. We will continue to work together to complete the process of making *SYNFOLIUM*<sup>®</sup> available to cardiac surgeons and their patients with CHD."

"We hope that *SYNFOLIUM*<sup>®</sup>, which we developed as a strong industry-academia team, will help reduce the burden of re-operation for patients and their families," said Yoshihide Takagi, President of Fukui Tateami Co., Ltd. "As we Fukui Tateami celebrate our 80th anniversary next year, we are delighted to contribute to the future of children and to society as a whole through *SYNFOLIUM*<sup>®</sup>."

"Many surgeons want to reduce repeat procedures as they cause heavy burdens on patients and their families," said Takayuki Nakano, Ph.D., Mission Executive and General Manager, Regenerative Medicine & Implantable Medical Device Division of Teijin Limited. "We sincerely hope that the *SYNFOLIUM*<sup>®</sup>, an achievement of an industry-academia collaboration with various stakeholders, will solve the issues of patients and their families and help improve their quality of life. In addition, as a manufacturer, we will work to expand the use of this groundbreaking surgical material from Japan to the world, and to develop further medical devices that make use of the concept of *SYNFOLIUM*<sup>®</sup>."

*SYNFOLIUM*<sup>®</sup> is a significant success made by an industry-academia project, in which academia extracted the concerns of patients in the treatment of CHD, medium and large-sized enterprises brought their technological capabilities and know-how together and their strong cooperative relationships led to industrialization.



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

Osaka Medical and Pharmaceutical University is a comprehensive institution that offers education and research in department of medicine, pharmacy, and nursing. The university has been providing thousands of clinical professionals by its unique curriculum. Not only basic scientific research but also interdisciplinary research activities are conducted to solve unmet medical needs. Of note, various medical devices have been invented there by active industry-academia-government collaborations.

The University Hospital provides various advanced medical treatments, such as the state-of-the arts cancer therapy including boron neutron capture therapy, robot surgery, and genomics medicine.

URL: <https://www.ompu.ac.jp/>

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**About Fukui Tateami Co., Ltd.**

Fukui Tateami with 79 years of experience and advanced technology, has become one of Japan's largest manufacturers of warp-knitted fabric with a wide spectrum of applications, including fashionwear, sportswear, automotive interiors, and industrial materials. After equipped with fully clean room in 2017, the company expanded its business field into the medical textiles to solve medical unmet needs. Fukui Tateami is the first textile company which obtained ISO13485 certification in Japan. Fukui Tateami posted sales of JPY3.1 billion (USD 20 million) and total assets of JPY 2.6 billion (USD 17 million) in the fiscal year ending on March 31, 2023.

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

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**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 aims 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 1,018.8 billion (USD 7.6 billion) and total assets of JPY 1,242.4 billion (USD 9.2 billion) in the fiscal year ending March 31, 2023.

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