

**Non-biological surgical sealant independent of blood coagulation of patients
AQUABRID® commences clinical use in Taiwan.**

Sanyo Chemical Industries, Ltd. (Head Office: Higashiyama-ku, Kyoto; President and CEO: Akinori Higuchi; hereinafter "Sanyo Chemical") announces that AQUABRID (local brand name: Hydrofit® has obtained regulatory approval* as a medical device in Taiwan and clinical use commenced in December 2021. AQUABRID is a non-absorbent topical hemostatic sealant for the central circulatory system manufactured by Sanyo Chemical and marketed by Terumo Corporation, a medical device manufacturer, (Head Office: Shibuya-ku, Tokyo; CEO: Shinjiro Sato).

Hydrofit® is a surgical hemostatic sealant made of urethane pre-polymer that reacts with water to form a flexible coating. After demonstrating substantial results in Japan, we obtained the CE marking*2 under the proprietary name AQUABRID® for use in overseas markets in July 2019 and started sales in the European market. We have been accelerating overseas expansion after the acquisition of the CE marking. In August 2021, we entered the Hong Kong market and subsequently received favorable evaluations.

Taiwan is the second country in Asia market we have entered and in which the clinical use of the product was started. We will continue our full-scale deployment in the Asian region, one of our key markets.

We will meet the needs of clinical practice through Hydrofit® and AQUABRID® and contribute to the development of healthcare and healthy living of people worldwide in the future.

Terumo Taiwan Co., Ltd. is the license holder of this regulatory approval. Sanyo Chemical obtained the approval as the overseas manufacturer.

Brand Name	"Terumo" AQUABRID Surgical Sealant (台湾名 : 爾凝得)
GMDN	Adhesive, soft tissue approximation
Indication	AQUABRID is indicated for use as an adjunct to standard methods of cardiovascular surgical repair to seal (such as sutures, staples, electrocautery, and/or patches) related to aorta surgery. Indicated sites are sutured sites and anastomosis of aorta (associated dissection, rupture or aneurysm)
Certification No.	034031
Certificate issued:	November, 2, 2020

[About Hydrofit®]

Hydrofit® is a hemostatic material developed by Professor Takehisa Matsuda, former Dean of National Cerebral and Cardiovascular Center's Bioengineering Department (subsequently, professor emeritus at Kyushu University), in mid-1980 with an aim to achieve hemostasis in vascular surgery, and then, was commercialized by Sanyo Chemical. (1) Hydrofit® is an abiotic

material consisting of a urethane pre-polymer prepared using our urethane technology; (2) it achieves hemostasis by reacting with the water in the blood, independent of the blood coagulation ability of the patient; (3) it is designed to form a film that adheres to the hemostatic tissue with a single liquid to eliminate mixing; and (4) it is designed to form an elastic film.

Hydrofit® has been used in cardiovascular surgery procedures since its launch in 2014. In addition to these clinical results, it was confirmed anew that there were no problems in efficacy and safety after reexamination*3 based on clinical evaluations in papers and presentations at academic conferences. As a result, we obtained approval in March 2020 for an expanded indication as a hemostatic sealant for anastomosis of whole blood vessels except cerebral blood vessels.

We have also acquired the trademark of AQUABRID® for use overseas. After obtaining the CE marking in July 2019, we have been deploying the product to the European and Hong Kong markets through Terumo Europe. AQUABRID® has been clinically used in many countries and regions. It has obtained favorable evaluation of doctors, and an efficacy similar to the hemostatic effect shown in Japan has been demonstrated overseas.

< Photo of AQUABRID® >



*1 Reviewed by the Taiwan Food and Drug Administration (equivalent to the US Food and Drug Administration and the Pharmaceutical and Medical Devices Agency in Japan) and certified by Taiwan's Ministry of Health and Welfare (equivalent to the Ministry of Health, Labour and Welfare in Japan).

*2 CE Marking: A mark that can be obtained when a product is certified as meeting the standards for quality, safety, and efficacy according to the European Medical Device

Directives. Medical devices in the EU are classified into 4 classes; devices belonging to Class I carry the lowest risk, and those belonging to Class IIa, IIb, and III have the highest risk. AQUABRID® belongs to Class III, which includes products that are directly used for the heart, circulatory system, and nervous system and have a major impact on the biological functions of the human body. Thus, products belonging to this class undergo a strict review.

Learn more about CE marking:

<https://www.jetro.go.jp/world/qa/04S-040011.html>

*3 Reexamination system

In order to confirm the approved efficacy and safety for new medical devices, it is necessary to conduct a large-scale post-marketing surveillance for a certain period of time after receiving marketing approval, collect data from actual use at medical institutions, and receive an examination (reexamination) by the Minister of Health, Labour and Welfare again based on the Pharmaceuticals and Medical Devices Act (old Pharmaceutical Affairs Law).

* Please note that the medical device information presented in this release is not intended to promote or advertise the product or its effects.

<Reference>

• Sanyo Chemical obtains CE marking of innovative surgical sealant (September, 2019)

<https://www.sanyo-chemical.co.jp/eng/archives/3070>

• Sanyo Chemical launches AQUABRID® in Hong Kong (August, 2021)

<https://www.sanyo-chemical.co.jp/eng/archives/4717>

About Sanyo Chemical

Sanyo Chemical established in 1949 in Kyoto, Japan, is a global manufacturer and seller of performance chemicals. Beginning as a manufacture of soap and texture agents we have since diversified our product portfolio to meet the needs of the market, Today, we feature over 3,000 different types of products and have established an international presence. Our portfolio of chemicals spans a variety of industries and types, from automotive components to daily-use electronics, as well as cosmetics and medical equipment, all with the aim of creating ore safe and environmentally friendlier offerings, improving lives and societies across the world. We aim to contribute to realize a sustainable society through our corporate activities.

<https://www.sanyo-chemical.co.jp/eng>

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