August, 24th. 2021
Sanyo Chemical Industries, Ltd.

# "MATSUDAITO" (overseas brand name: AQUABRID®), an abiotic urethane-based hemostatic material independent of the blood coagulation ability of the patient, launched in Hong Kong

Sanyo Chemical Industries, Ltd. (Headquarters: Higashiyama-ku, Kyoto; President and CEO: Akinori Higuchi) announced that "Matsudaito (local brand name: Hydrofit®), overseas brand name: AQUABRID®," a non-absorptive topical hemostatic material for the central circulatory system was launched in Hong Kong in July 2021. The product has already been used clinically at medical institutions in Hong Kong, and the physicians reported that the product demonstrated the same hemostatic effect as that observed in Japan.

Hydrofit® is a surgical hemostatic material composed of urethane that reacts with water and forms an elastic film. On the basis of the results from a number of studies in Japan, we obtained CE marking*1 under the brand name AQUABRID® for the overseas market in July 2019 and began selling the product in the European market. CE marking is increasingly used as an approval requirement for export and sale in Asia and the Middle East as well as in the European Union (EU) member countries. We are accelerating overseas deployment by making the most of the CE marking approval.

Hong Kong will be the first market for the product in Asia, excluding Japan. We will continue to deploy the product in the Asian region on a full scale and accelerate the sales expansion in Japan and Europe, where the product is already in the market.

We will continue to meet the need of hemostatic materials in clinical settings with Hydrofit® and AQUABRID® in the future. Additionally, we will contribute in enhancing medical care worldwide and improving the quality of life (QOL) of the people.

[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.

Since its launch in 2014, Hydrofit® has been used as a hemostatic material on artificial vascular anastomosis*2 sites of the thoracic aorta in many cardiovascular surgeries. In addition to the results of the post-marketing studies, the efficacy and safety were recently confirmed in more patients by comparing the results reported in previous articles and presented at academic conferences with those of clinical studies conducted before marketing. On the basis of these results, in March 2020, the product was approved to expand the indication to hemostatic material that can be used for anastomosis sites of whole blood vessels, except cerebral blood vessels.

We acquired the trademark of AQUABRID® for the overseas market and have been deploying the product through Terumo Europe after obtaining CE marking in July 2019. It has been used in clinical settings in the European countries, including Germany and the surrounding countries such as Turkey, and has obtained satisfactory evaluation from doctors.

| Brand Name | AQUABRID® |
|---|---|
| GMDN (Global Medical Device Nomenclature) | 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) |

< Photo of AQUABRID® >


*1 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

*2 Anastomosis: One of the surgical procedures involving sewing and connecting blood vessels.

* 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

**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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