Sanyo Chemical Industries, Ltd.
Kyoto University Hospital

# Notice of Regulatory Approval for Silk-Elastin Wound Healing Sheet, a Novel Recombinant Protein

KYOTO, JAPAN — [May 7, 2025] —Sanyo Chemical Industries, Ltd. hereby announces that it has obtained regulatory approval for the novel wound recombinant protein "Silk-Elastin Wound Healing Sheet" (hereinafter "the Product") in Japan. The Product was jointly developed with Professor Naoki Morimoto and his team at the Department of Plastic and Reconstructive Surgery, Kyoto University Hospital, and will be marketed exclusively in Japan by Kaken Pharmaceutical Co., Ltd. This product is the first medical device in Japan to utilize genetic engineering technology.

Following the recent regulatory approval in Japan, Sanyo Chemical is moving forward in earnest with preparations for FDA submission as part of its strategy to enter the U.S. market. In the United States, Sanyo Chemical is seeking marketing and distribution partners to bring this breakthrough treatment to patients as swiftly as possible.

**Product Information (**regulatory approval in Japan)
・**Product Name**: Silk-Elastin Wound Healing Sheet
・**Approval Number**: 30700BZX00089000
・**Generic Name**: Absorbable wound dressing and protectant
・**Intended Use or Effect**: The product is intended to support the healing process of full-thickness and partial-thickness wounds. It is also indicated for intractable wounds that are unresponsive to existing therapies.

**Breakthrough in Chronic Wound Treatment**
Chronic wounds, such as diabetic ulcers and pressure sores, pose significant healthcare challenges worldwide, leading to prolonged suffering and rising medical costs. These wounds often enter a cycle of delayed healing and increased infection risk, making treatment difficult. Current treatments often fail to achieve complete healing. Silk-Elastin offers a regenerative solution, promoting tissue repair while reducing inflammation and bacterial colonization, leading to better patient outcomes and improved quality of life.

**Silk-Elastin sponge**


**Application of Silk-Elastin wound dressing for intractable skin ulcar on the lower leg**

**About Silk-Elastin**

Silk-Elastin is a recombinant protein combining the strength of silk fibroin (derived from silk) with the elasticity and biocompatibility of elastin (found in human skin). Its gel supports tissue regeneration while minimizing inflammation. This novel approach offers hope for conditions with limited conventional options.

A recent peer-reviewed study published in Scientific Reports demonstrated the safety, feasibility, and efficacy of Silk-Elastin sponges in promoting wound healing, with high rates of wound bed preparation and successful treatment completion in patients with chronic wounds unresponsive to existing therapies.
Read the full article here.
https://www.nature.com/articles/s41598-025-88150-w

**About Sanyo Chemical**

Sanyo Chemical established in 1949 in Kyoto, Japan, is a global manufacturer and seller of performance chemicals. Beginning as a manufacturer 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 diverse 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 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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Cautionary notes regarding forward-looking statement
This release contains forward-looking statements regarding the business of Sanyo Chemical group. These statements are based on information available at the time of publication and may differ from actual results due to various factors. In addition, this release includes information related to medical devices and pharmaceutical products (including those under development), but such statements are not intended as advertisements or medical advice.