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Toyobo's Nerbridge™, a Conduit for Peripheral Nerve Regeneration, Achieves FDA 510(k) clearance for U.S. marketing

Toyobo achieved 510(k) clearance with the U.S. Food and Drug Administration (FDA) on June 22 to sell Nerbridge™, a conduit for regenerating peripheral nerves that have been severed or damaged due to injuries, in the United States. The company has already boosted production capacity of the product in Japan, and plans to select a partner to market the product—a medical treatment device that significantly eases the burden on surgery patients—while accelerating efforts to promote global sales of the cutting-edge product.

1. History of Nerbridge™

Toyobo received approval from Japan's Ministry of Health, Labor and Welfare in March 2013 to manufacture and sell Nerbridge™, the nation's first medical device to treat nerves that have been severed or impaired due to injuries.

Since then, more than 400 Japanese medical institutions have used Nerbridge™, treating 1,500 patients and producing results that demonstrate the product's superior effectiveness and safety.

As a part of its global strategy, the company subsequently filed an application with the FDA to sell Nerbridge™ in the United States.



Nerbridge™

2. Characteristics of Nerbridge™

Nerbridge™ considerably reduces the burden on patients requiring nerve reconstruction, as it is unnecessary to harvest undamaged nerves to treat damaged ones—an essential step in a treatment known as autologous nerve grafting.

Nerbridge™ is made of polyglycolic acid and medical-use collagen, both of which are dissolved and absorbed by the patient's body in about three months.

3. Marketing strategy

To deal with an expected expansion in global sales of Nerbridge™, Toyobo has boosted production capacity of the product at its Research Center in Otsu City, Shiga Prefecture, at a cost of ¥1 billion. The company is also developing a quality management system for products to be marketed abroad.

Toyobo is set to promote sales in the United States and develop its markets in European countries, in addition to Singapore and Taiwan—two advanced medical care providers in Asia, targeting overseas sales of ¥2 billion for 2020.



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