

## **Toyobo signs an agreement with U.S. distributor to expand Nerbridge<sup>®</sup> sales**

Toyobo Co., Ltd. has signed an exclusive U.S. agreement with Synovis Micro Companies Alliance Inc. (hereafter Synovis MCA), a subsidiary of Baxter International Inc., as distributor for Nerbridge<sup>®</sup>, a conduit for regenerating damaged peripheral nerves. Synovis MCA plans to start selling the product in the United States in September 2018.

### 1. Background

In 2013, Toyobo began domestic sales of Nerbridge<sup>®</sup> as Japan's first medical device to facilitate regeneration of peripheral nerves severed or damaged due to external injury. Nerbridge<sup>®</sup> differs from existing treatment methods, because it allows treatment without the harvesting of healthy nerves taken from the patient for autografting. Accordingly, it is considered to be an effective and safe nerve regeneration device that reduces the physical burden on the patient. Since its market debut, Nerbridge<sup>®</sup> has been used at medical institutions across Japan.

### 2. How the agreement with Synovis MCA was reached

Synovis MCA's initial entry into the nerve market was in 2005 with the nerve conduit named "Neurotube". The company boasts outstanding sales records on the strength of its robust sales networks and extensive networks with the medical care sector. Toyobo concluded a distributor agreement with Synovis MCA because Nerbridge<sup>®</sup>'s unique advantages and reliability backed up by its sales record in Japan matches the needs in the U.S., which is the world's largest market of such nerve regeneration devices.

### 3. Business schedule

After Nerbridge<sup>®</sup> is introduced at the American Society for Surgery of the Hand meeting to be held in Boston, September 13-15, Synovis MCA will start limited sales of the product as a precursor to full-fledged sales in 2019. Furthermore, Toyobo plans to expand its sales outside the United States in 2020.

### Main features of Nerbridge<sup>®</sup>

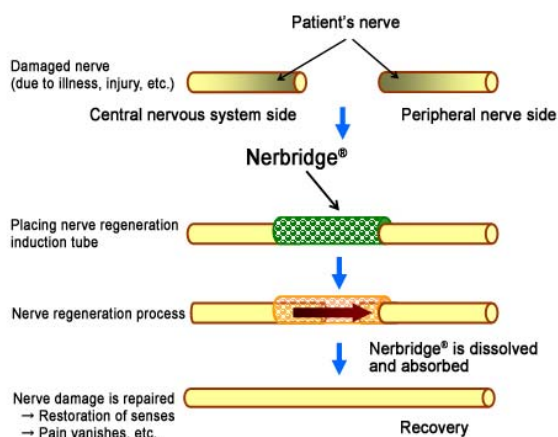
Nerbridge<sup>®</sup> is a tube made of polyglycolic acid filled with collagen to facilitate nerve growth, which differentiates it from other products currently available in the U.S. By inserting and fixing Nerbridge<sup>®</sup> between the ends of a severed nerve, the product induces regeneration and extension of the nerve from the central nervous system side into the peripheral nerve through the

*(more)*

tube, restoring the nerve functions. Using Nerbridge<sup>®</sup> makes it unnecessary to harvest healthy peripheral nerves for autografting, considerably reducing the patient's burden and shortening the time needed for surgical treatment. The polyglycolic acid and collagen used in Nerbridge<sup>®</sup> dissolve and are absorbed by the patient's body after the nerve is regenerated.



Nerbridge<sup>®</sup>



Process of treating damaged nerves with Nerbridge<sup>®</sup>

Outline of the two U.S. firms

**Synovis Micro Companies Alliance Inc.**

Headquarters: 439 Industrial Lane, Birmingham, AL 35211, USA

President: Michael K. Campbell

Main business operations: Sales of devices for precision surgeries

**Baxter International Inc.**

Headquarters: 1 Baxter Parkway, Deerfield, IL 60015, USA

Chairman, President and CEO: José E. Almeida

Main business operations: Development, manufacturing and sales of drugs and medical equipment to treat immunodeficiency, cancers, infectious diseases, kidney diseases and external injuries

###

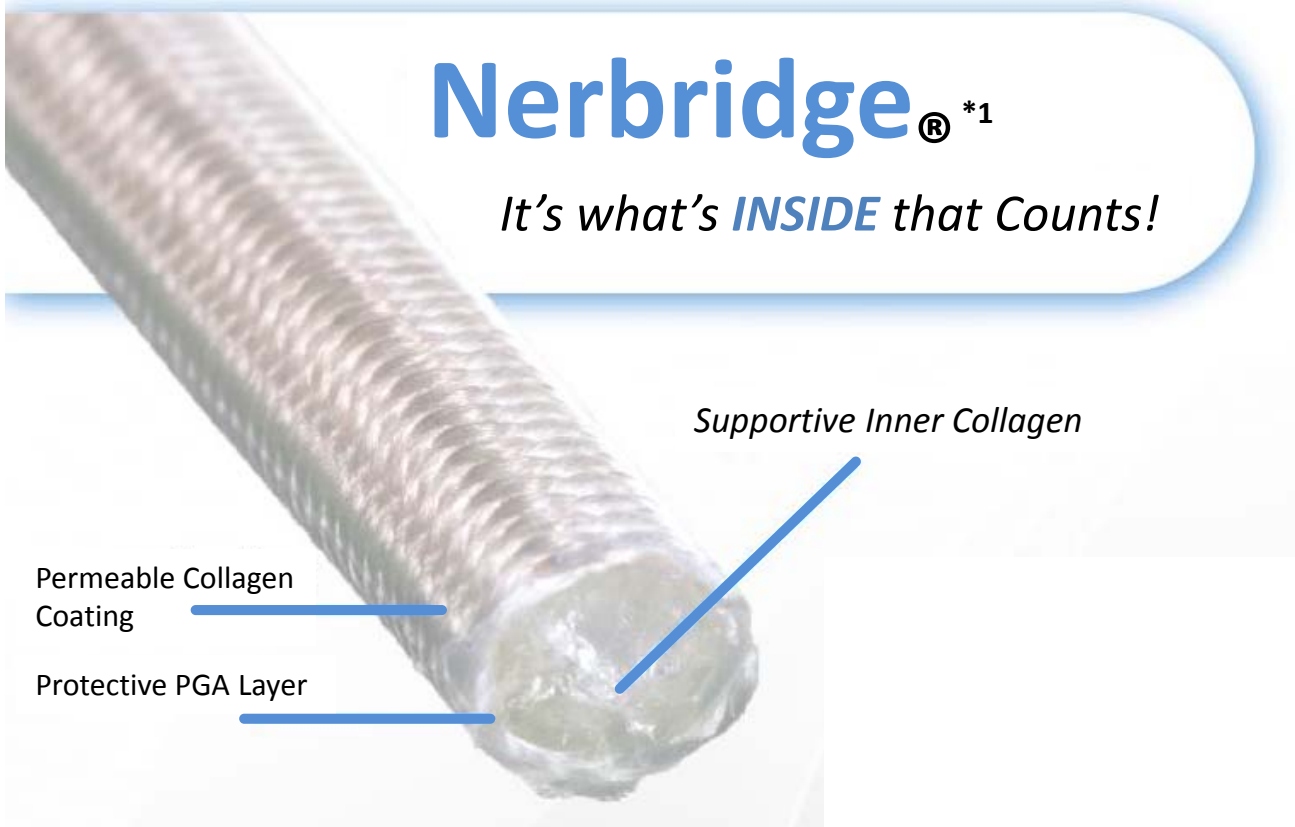
For more information, contact:

Public Relations Group, Corporate Communication Department, Toyobo Co., Ltd.

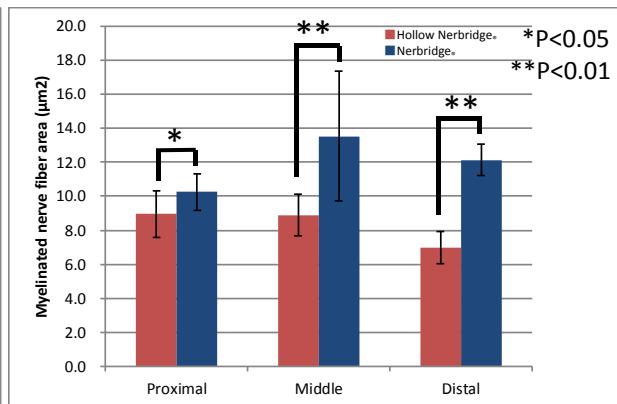
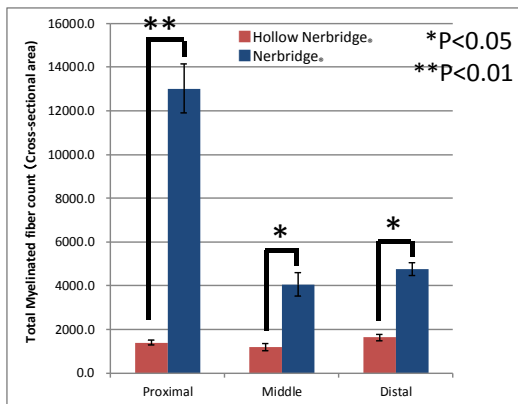
E-mail: pr\_g@toyobo.jp

# Nerbridge® \*1

It's what's *INSIDE* that Counts!



## Nerbridge® vs Hollow Nerbridge®, 12 wks, Rat Sciatic Nerve



\*Data on file

### Key Features/Claims

- Inner Collagen Scaffolding designed to support Schwann cell migration and axonal growth
- Improved speed of nerve regeneration and increased nerve fiber area with Inner Collagen Scaffolding
- Room temperature storage
- Flexible handling
- 8 diameters; 25 mm length

\*1: Regenerable Nerve Guide Tube Nerbridge

## How Nerbridge® fulfills basic clinical needs

Desired attributes	Nerbridge® features/benefits
Biocompatible	ISO 10993 certified, proven safety including cytotoxicity, sensitization and hemolysis <sup>1</sup>
Resorbable	Until it resorbs, Nerbridge® protects nerves minimizing compression to the growing axons <sup>2, 3</sup>
Protective	
Flexibility	Nerbridge® softens with hydration and shows no kinking after implantation <sup>4</sup>
Semi-permeable	Nerbridge® allows 600 kDa particles to pass through its conduit walls <sup>5</sup>

1) Biocompatibility testing per ISO 10993 2) Rabbit study submitted to FDA for 510(k) 3) Tensile strength per ISO 527-1:2012  
 4) Rat study (Toyobo in-house) shows no kinking after 3 days of implantation 5) Performance test submitted to FDA for 510(k)

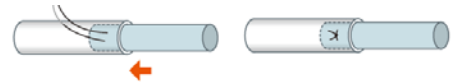
### Nerbridge® Suturing Technique

- After hydration, suture Nerbridge® to the proximal side of the nerve ending as follows using a non-absorbable monofilament nylon or polypropylene suture from size 6-0 to 10-0.

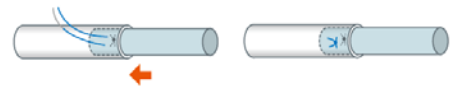


- Gently draw the end of the nerve into Nerbridge® by pulling on the suture.

The final length of the nerve ending inserted into Nerbridge® should be greater than or equal to the diameter of the nerve.



- Suture the other side, 180° from the first suture.
- Suturing on the distal side should be performed in the same way as on the proximal side.



Please read the package insert before use

### Size

Inner diameter								Length	
○	○	○	○	○	○	○	○		
0.5mm	1.0mm	1.5mm	2.0mm	2.5mm	3.0mm	3.5mm	4.0mm	2.5cm	*Actual size

TOYOBO CO., LTD.  
 2-8, Dojima Hama 2-chome, Kita-ku  
 Osaka, Japan 530-8230  
<http://www.toyobo-global.com/>