Nerbridge®

Directions for Use

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Revision 7

Description

Nerbridge® is a product composed of polyglycolic acid and collagen derived from porcine skin. Nerbridge® is a flexible, resorbable and semipermeable tubular membrane matrix filled with porous collagen that provides a non-constricting encasement for injured peripheral nerves for protection of the neural environment. Nerbridge® is designed to be an interface between the nerve and the surrounding tissue. When hydrated, Nerbridge® is an easy to handle, pliable, soft, non-friable, porous conduit. The resilience of Nerbridge® allows the product to recover and maintain closure without constricting the nerve once the device is placed around the nerve. Nerbridge® is manufactured using validated viral inactivation and removal processes for the collagen. The product is provided sterile, non-pyrogenic, for single use only, in a variety of sizes. The outer pouch is for protection only and is not a sterile barrier. Only contents of the inner foil pouch are sterile.

Indications for Use

Nerbridge® is intended for the repair of peripheral nerve injuries in which there is no gap or where a gap closure can be achieved by flexion of the extremity.

Contraindications

Use of Nerbridge® is contraindicated for anyone with a known allergy to porcine derived materials and polyglycolic acid.

Instructions for Use

Preparing Procedure; Follow standard procedures for exposure and mobilization of severed nerve. Determine the nerve diameter in millimeters (mm) using a suitable measuring instrument. Select a Nerbridge® of sufficient diameter to allow easy insertion of the nerve stumps into Nerbridge®. Account for normal edema following traumatic nerve injury. Carefully transfer Nerbridge® into the clean field. Hydrate Nerbridge® in sterile saline for 3 minutes or more before use.

Suturing Procedure; Using non-absorbable monofilament nylon or polypropylene sutures from 6-0 to 10-0 sizes, suture the proximal side first. Pass the suture across the wall of Nerbridge® at the point about 1-2 mm from its end and from the outside to the inside. Pass the suture through the epineurium of one nerve stump so that the tip of the needle can come out at the point about 1-2 mm from the nerve stump. Reverse the suture and pass it through the epineurium and from its outside to the nerve stump, at a closer point to the operator and away from the position where the needle has been stuck out. Take care not to damage the axons in suturing the epineurium. And then, pass the suture through the wall of Nerbridge® from the inside to the outside. Then, slowly rotate both the nerve stump and Nerbridge® by 180 degrees, and suture the reverse sides of Nerbridge® and the nerve stump in the same manner as above. In rotating them, be careful so that the thread is not crossed. After this, gently draw the nerve stump into Nerbridge® by pulling the suture such that the nerve stump is drawn into Nerbridge®. The approximate lengths of the nerve stumps to be inserted into Nerbridge® should be greater than or equal to the inner diameter of Nerbridge®. A secure knot must be made in the suture, but be careful not to apply tension on the suture itself.

Nerbridge® must be long enough to allow each nerve stump to be drawn into the lumen of Nerbridge® at a distance greater than or equal to the inner diameter of Nerbridge®. If needed, Nerbridge® may be cut to an appropriate length. The suturing on the distal side should follow the same manner as that on the proximal side.

Postoperative Procedure; Immobilize the limb using standard procedures for immobilization following any peripheral nerve repair.

When Nerbridge® is implanted at the location close to the joint, immobilize the limb for 1 week at least, then start rehabilitation giving attention to positional relation between the implanted site and the joint in addition to repair situation of the surrounding bone soft tissues.

Note: Proceed to rehabilitation depending on the condition of scars, presence or absence of subjective and objective symptoms, and the result of ultrasound imaging and physical examination.

Warnings

- Do Not Resterilize.
- Do not use if the product package is damaged or opened.
- Do not use the product in cerebrospinal dura mater.
- In the case of the implanted site close to the joint, immobilize the limb for 1 week at least to avoid disconnection of Nerbridge® to nerve stumps and its breakage. There are no patients who had a motion range training within 1 week postoperatively in the clinical study in Japan.
- Use Nerbridge® appropriately by doctors who have sufficient knowledge and experience on nerve reconstruction.
- Carefully implant Nerbridge® at the location close to the joint to allow for postoperative rehabilitation. Otherwise, there may be a possibility of rearrangement and kinking of the product that may cause insufficient nerve reconstruction and joint contracture.
- Do not apply more than one Nerbridge® device in a surgical procedure, because Nerbridge®'s effectiveness and safety have not been confirmed for multiple applications.
- The safety of early therapeutic exercise has not been confirmed when simultaneous application of the product and tendon suturing has occurred.
- In applying the product, insert both ends of nerve stumps into the product at an adequate length for suturing lest both nerve ends are removed from the tube.
- Because a study on effectiveness and safety of Nerbridge® for a population of patients including elderly and infant patients, as well as pregnant, parturient and lactating women, has not been performed, no recommendation is made for use of Nerbridge® on that population of patients.

Precautions

- Rinse surgical gloves to remove any glove powder prior to handling Nerbridge®.
- Hemostasis of the nerve stumps must be achieved prior to placement of Nerbridge®. A blood clot in the lumen of Nerbridge® will impede axon growth.
- Tensionless repair technique should be used to prevent tension along the length of the nerve.
- Nerbridge® should be used with caution in infected regions.

Potential Product Complications

Possible device-related complications can occur with any surgical nerve repair procedure including pain, infection, wound opening, decreased or increased nerve sensitivity, hypersensitivity that may be caused by polyglycolic acid and collagen and complications associated with use of anesthesia.
Possible device defects may include protrusion, rearrangement, kinking and breakage of Nerbridge®.

Storage

Store at temperature 1-30℃ or 33.8-86.0°F. Avoid excessive heat or humidity.

How Supplied

Nerbridge® is supplied sterile and for single use. The outer pouch is for protection only and is not a sterile barrier. Contents of the inner foil pouch are guaranteed sterile and nonpyrogenic unless the package is opened or damaged.

Catalog number	Size	Quantity
RN01025E	1.0 mm ID x 25mm Length	1
RN02025E	2.0 mm ID x 25mm Length	1
RN03025E	3.0 mm ID x 25mm Length	1
RN04025E	4.0 mm ID x 25mm Length	1

Symbols Used on Labeling

Do not reuse after opening.

Consult Instructions for use.

Caution:Consult instructions for use for warning and precaution information.

Sterile unless package is opened or damaged.
Method of sterilization – ethylene oxide.

Do not resterilize

Storage temperature limits

Do not use if the product sterilization barrier or its packaging is compromised.

Caution; Federal (USA) law restricts this device to sale by or on the order of a physician.

REF

Catalog number

Expiration date

Lot number

Manufacturer

Inner diameter

Length

Distributed by Synovis Micro Companies Alliance, Inc. Phone: 205.941.0111
439 Industrial Lane, Birmingham, AL 35211, U.S.A.

Manufactured by TOYOBO CO., LTD.
2-1-1, Katata, Otsu, Shiga 520-0292, Japan