GEM
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NEUROTUBE Device

Absorbable Woven
Polyglycolic Acid Mesh Tube

Symbols referenced on labeling

Symbol Glossary per US FD&C Act:

Standard	Symbol	Symbol Title	Symbol Meaning	Symbol Number
ISO 15223-1*		Manufacturer	Manufacturer	5.1.1
ISO 15223-1		Date of manufacture	Date of manufacture	5.1.3
ISO 15223-1		Use-by date	Use-by date	5.1.4
ISO 15223-1	LOT	Batch code	Lot number	5.1.5
ISO 15223-1	REF	Catalog Number	Catalog Number	5.1.6
ISO 15223-1	STERILE EO	Sterilized using ethylene oxide	Sterilized using ethylene oxide	5.2.3
ISO 15223-1		Do not resterilize	Do not resterilize	5.2.6
ISO 15223-1		Do not use if package is damaged	Do not use if the product sterilization barrier or its packaging is compromised	5.2.8
ISO 15223-1		Do not re-use	Do not re-use	5.4.2
ISO 15223-1		Consult Instructions for use	Consult Instructions for use	5.4.3
ISO 15223-1		Caution	Caution: Consult instructions for use for warning and precaution information	5.4.4
	Rx Only		Federal (USA) law restricts this device to sale by or on the order of a physician	

*ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

Additional symbols and graphics on the product labeling that are not requird by the US FD&C Act:

Symbol	Symbol Description
MADE IN THE U.S.A.	Made in USA
PN	Manufacturer part number
TN	Internal tracking number

Graphic	Graphic Meaning
	Inner diameter
	Length

Product Size Table

Catalog Number	Nerve Gap	Size of Neurotube Device*
GEM0240NT	≥8mm ≤ 30mm	2.3 mm dia. X 40 mm length
GEM0420NT	≥8mm ≤10mm	4.0 mm dia. X 20 mm length

* Nominal

Description

The NEUROTUBE device Absorbable Woven Polyglycolic Acid Mesh Tube is designed for primary or secondary peripheral nerve repair or reconstruction. The NEUROTUBE device replaces the classic nerve graft technique for the repair of nerve gaps. The walls are corrugated for strength and flexibility. The corrugations prevent the tube from collapsing under normal physiological soft tissue pressures.

The NEUROTUBE device is resorbed through the process of hydrolysis.

Indications For Use:

The NEUROTUBE device is intended for single use in patients requiring peripheral nerve repair, in which the nerve gap is greater than or equal to 8mm, but less than or equal to 30mm.

IMPORTANT NOTE:

This Instructions for Use manual is designed to provide instructions for proper use of the NEUROTUBE device. It is not intended as a reference to surgical technique.

Contraindications:

Use of the NEUROTUBE device is contraindicated for anyone with a known allergy to polyglycolic acid.

Warnings:

- Complete hemostasis should be obtained in the surgical field before the NEUROTUBE device is positioned to bridge the gap between the nerve ends.
- Blood clot(s) in the lumen of the NEUROTUBE device will impede neuroregeneration.
- For hand surgeries, the patient's hand should be immobilized for three weeks following nerve reconstruction with the NEUROTUBE device. A plaster or fiberglass cast may be used for the first week and extension-block protective splint may be used for the second and third weeks. Cautiously supervised movement of the hand may be initiated before three weeks if a tendon repair is associated with the nerve reconstruction.

Aggressive movement may cause the device to migrate to the surface of the skin. Should the NEUROTUBE device become exposed by patient movement before neuroregeneration has been completed through the NEUROTUBE device, it is suggested that the NEUROTUBE device be removed and replaced with an autologous nerve graft.

- The nerve ends should never be inserted into the NEUROTUBE device under tension.
- If the nerve gap is greater than 30 mm when applying the 2.3 mm diameter NEUROTUBE device, an autologous nerve graft should be used instead.
- If the nerve gap is greater than 10 mm when applying the 4 mm diameter NEUROTUBE device, an autologous nerve graft should be used instead.
- Do not resterilize.
- Discard open, unused NEUROTUBE devices.

Storage:
Recommend to store at controlled room temperatures ranging from 20° C to 30° C.

Instructions For Use:

1. Measure the nerve gap (distance between the nerve ends). (Refer to the Product Size Table).
2. Measure the nerve diameter and carefully select the appropriate NEUROTUBE device diameter so as not to compress the nerve ends.
3. Visually inspect the pouch for any holes or tears; do not use if damaged.
4. Aseptically transfer the inner pouch into the sterile field.
5. Open the pouch and remove the tray.
6. Carefully open the tray. Inspect the NEUROTUBE device. Do not use if the NEUROTUBE device is kinked, brittle, or degraded.
7. Surgically expose the nerve at the appropriate incision site with the extremity under tourniquet control.
8. Resect the injured segment of the nerve distally and proximally until a nerve stump is identified with no residual intrafascicular scarring.
9. Place the nerve on a wooden support (tongue depressor) and serially section with a #11 blade. Micro-scissors and larger scissors can cause the extrusion of intrafascicular components of the nerve.
10. Release the tourniquet and obtain meticulous hemostasis, so the resected end of the nerve will not fill the NEUROTUBE device with blood. The resulting blood clot would create a barrier to neuroregeneration.
11. If using the 2.3 mm diameter NEUROTUBE device, trim the NEUROTUBE device with scissors to a length 10 mm longer than the measured nerve gap, so the nerve ends may be inserted 5 mm into each end of the NEUROTUBE device.
12. Use a horizontal mattress stitch to draw the nerve end 5 mm into the NEUROTUBE device. An 8-0 suture with a 140-micron, 135° curve needle is recommended. Pass the stitch through the NEUROTUBE device from the outside to inside, transversely through the epineurium of the nerve end, and back through the NEUROTUBE device, from the inside to the outside.
13. Irrigate with heparinized saline to facilitate drawing the nerve end 5mm into the NEUROTUBE device and tie a knot. **NOTE:** It may be necessary to use a second stitch (anchor stitch) placing the suture superficially through the epineurium of the nerve and through the end of the NEUROTUBE device.
14. Fill the NEUROTUBE device with heparinized saline (10 units per cc), after one end of the nerve is secured within the NEUROTUBE device. The corrugated external surface of the NEUROTUBE device prevents kinking as the NEUROTUBE device goes around a curve or overlies a joined surface.
15. Draw the second nerve into the opposite end of the NEUROTUBE device with a horizontal mattress stitch, and if necessary, place an anchor stitch.
16. Refill the tube with heparinized saline.
17. Make an attempt to position the NEUROTUBE device in a soft tissue bed, which will facilitate mobilization of subcutaneous fat between the NEUROTUBE device and the overlying skin.
18. Close the site.

Disclaimer Of Warranties:
Synovis Micro Companies Alliance, Inc. (SMCA), a subsidiary of Baxter International Inc., warrants that reasonable care has been used in the manufacture of this device.This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including, but not limited to, any implied warranties of merchantability or fitness. Since SMCA has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration, or its handling after it leaves its possession, SMCA does not warrant either a good effect or against an ill effect following its use. The manufacturer shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. SMCA will replace any device which is defective at the time of shipment. No representative of SMCA may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

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Synovis Micro Companies Alliance, Inc. (a subsidiary of Baxter International Inc.), 439 Industrial Lane, Birmingham, AL 35211-4464 USA. (Tel) **205.941.0111** (Toll free) **800.510.3318** (Fax) **205.941.1522**
www.synovismicro.com

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