**SYMBOL DEFINITIONS**

- **Do not Reuse**
- **Consult Instructions For Use**
- **Ethylene Oxide Sterilized**
- **Do not use if the product sterilization barrier or its packaging is compromised.**
- **CAUTION: Federal (USA) law restricts this device for sale by or on the order of a physician**

**PRODUCT SIZES**

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Nerve Gap</th>
<th>Size of Neurotube*</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEM0240NT</td>
<td>≥ 8mm ≤ 30mm</td>
<td>2.3 mm dia. X 40 mm length</td>
</tr>
<tr>
<td>GEM0420NT</td>
<td>≥ 8mm ≤ 10mm</td>
<td>4.0 mm dia. X 20 mm length</td>
</tr>
<tr>
<td>GEM0820NT</td>
<td>≥ 8mm ≤ 10mm</td>
<td>8.0 mm dia. X 20 mm length</td>
</tr>
</tbody>
</table>

* Nominal
INDICATIONS:
The Neurotube of 2.3mm diameter is intended for use in patients with an injury to a digital nerve with 8-30mm nerve gap. The Neurotubes of 4mm and 8mm diameters are intended for use in patients with an injury to a sensory nerve with 8-10mm nerve gap.

IMPORTANT NOTE: This Instructions for Use manual is designed to provide instructions for proper use of the Neurotube product. It is not intended as a reference to surgical technique.

DESCRIPTION:
The Neurotube® is an absorbable woven polyglycolic acid mesh tube, which is designed for primary or secondary peripheral nerve repair or reconstruction. The tube 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 is resorbed through the process of hydrolysis.

INSTRUCTIONS FOR USE:

1. Aseptically transfer the inner pouch into the sterile field.
2. Visually inspect the pouch for any holes or tears; do not use if damaged.
3. Open the pouch and inspect the tube; do not use if tube is kinked, brittle, or degraded.
4. The nerve is surgically exposed at the appropriate incision site with the extremity under tourniquet control.
5. The injured segment of the nerve must be resected distally and proximally until a nerve stump is identified with no residual intrafascicular scarring.
6. 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.
7. The tourniquet is released and meticulous hemostasis is obtained, so the resected end of the nerve will not fill the Neurotube with blood. The resulting blood clot would create a barrier to neural regeneration.
8. Measure the nerve gap (distance between the nerve ends).
9. Measure the nerve diameter and carefully select the appropriate nerve tube diameter so as not to compress the repaired nerve.
10. If using the 2.3 mm diameter Neurotube, trim the Neurotube 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 tube.
11. A horizontal mattress stitch is used to draw the nerve end 5 mm into the Neurotube. An 8-0 suture with a 140-micron, 135° curve needle is recommended. The stitch is passed through the Neurotube from the outside to inside, transversely through the epineurium of the nerve end, and back through the tube, from the inside to the outside. Irrigation with heparinized saline facilitates drawing the nerve end 5 mm into the Neurotube and a knot is tied. 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 tube.

12. The corrugated external surface of the Neurotube prevents kinking as the Neurotube goes about a curve or overlies a joint surface. After one end of the nerve is secured within the Neurotube, the tube is filled with heparinized saline (10 units per cc). The second nerve end is drawn into the opposite end of the Neurotube with a horizontal mattress stitch, and if necessary, an anchor stitch may be placed.

13. The tube is refilled with heparinized saline.

14. An attempt should be made to position the Neurotube in a soft tissue bed, which will facilitate mobilization of subcutaneous fat between the tube and the overlying skin.

15. Close the site.

**STORAGE:**

Store at room temperature, approximately 80°F (27°C) or less; avoid exposure to high humidity and prolonged extreme temperatures.

**WARNINGS:**

- Complete hemostasis should be obtained in the surgical field before the Neurotube is positioned to bridge the gap between the nerve ends.
- Blood clot(s) in the lumen of the tube will impede neural regenerations.
- For hand surgeries, the patient’s hand should be immobilized for three weeks following nerve reconstruction with the Neurotube. 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 become exposed by movement before neural regeneration has been completed through the tube, it is suggested that the tube be removed and replaced with an autologous nerve graft.
- The nerve ends should never be inserted into the Neurotube under tension.
- If the nerve gap is greater than 30 mm when applying the 2.3 mm diameter Neurotube, an autologous nerve graft should be used.
- If the nerve gap is greater than 10 mm when applying the 4 mm or 8 mm diameter Neurotube, an autologous nerve graft should be used.
- Do not resterilize.
- Discard open, unused Neurotubes.
DISCLAIMER OF WARRANTIES:
Synovis Micro Companies Alliance, Inc. (SMCA), a subsidiary of Synovis Life Technologies, 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.
产品尺寸

<table>
<thead>
<tr>
<th>号码</th>
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*注：*
适应症：
直径 2.3 毫米产品用于 8-30 毫米轻度缺损。直径 4 和 8 毫米产品用于 8-10 毫米轻度缺损。
重要说明：本使用手册指南旨在说明可吸收神经套接管产品的正确使用方法。它不能作为外科技术的参考。

说明：
Neurotube 可吸收神经套接管 是一种可吸收性的聚乙醇酸 (PGA) 纤维网状，主要用于一级或二级未梢神经修复或重建。它可以取代常用的神经移植技术来进行神经缺损修复。
管壁呈波纹状，可增加强度和灵活性。这些波纹可防止管网在正常的生理软组织压力下萎缩。可吸收神经套接管通过水解过程进行再吸收。

使用说明：
1. 在无菌条件下，将内置管放到灭菌处。
2. 在做检查前，管内是否存在任何洞或切口；如有损坏，请勿使用。
3. 打开内置管，检查网管，若网管弯曲、破碎或变坏，请勿使用。
4. 通过手术在适当的切口处露出神经，并用止血带绑紧。
5. 神经受损部分必须从近侧和远侧切除，直到确定神经残端内无剩余疤痕。
6. 将管段神经置于木制平（压舌板）上，用 11 号刀片 incest 切片。小号或大号剪刀可能会导致神经夹持构成部分被剪出。
7. 松开止血夹并进行细致的止血，以免神经被切开的两端使可吸收神经套管充血，形成血块可能会阻碍神经再生。
8. 测量神经缺损情况（神经两端之间的距离）。
9. 测量神经直径，并谨慎选择合适的神经管直径，以防止压迫修复的神经。
10. 若使用直径为 2.3 mm 的可吸收神经套接管，请用剪刀将其修整为比要测量的神经缺损略长 10 mm，以便神经两端都能进入网管每端 5 mm。
11. 使用水平柄缝合法将神经末端插入可吸收神经套接管 5 mm，推荐使用 8-0 缝线，140 微米、135°弯针。线头从外侧穿过可吸收套接管，并打结。如有必要，可使用另一条线（锁顶线）。将线从外侧穿过神经外膜以及该管末端。
12. 可吸收神经套接管外部连接管表面可防止可吸收神经套接管，可吸收神经套接管可吸收神经套接管在通过曲线或关节腔时出现扭结。神经末端在可吸收神经套接管内固定后，管内会充满肝素盐水（每立方厘米 10 单位），神经另一端使用水平柄缝合法植入可吸收神经套接管相对另一端，且如有必要，可放置一条髓钉缝线。
13. 管内重新充满肝素盐水。
14. 将可吸收神经套接管置于软组织床内，以便于皮肤下侧在管和外层皮肤之间流动。
15. 缝合切口处。

存放：
在大约 80°F (27°C) 或稍低的湿度下存放；避免受潮及温度长期过高或过低。

警告：
- 在放置可吸收神经套接管以弥补神经两端间的缺损前，应在手术室中获得整体的体内平衡。
- 管腔中的血栓将阻碍神经再生。
- 对于手部的外科手术，患者的血在使用可吸收神经套接管进行神经重建后，应保持此停止活动。第一周，可使用石膏或玻璃纤维固定。第二周到第三周可使用保护性夹板固定。三周之后，应谨慎监督手部运动，即使肌肉修复也与神经重建密切相关。剧烈运动可能导致该装置移到皮肤表面。如果在通过可吸收神经套接管完成神经再生之前由于运动该装置暴露在外，则建议使用自体固有的神经移植技术移除并取代该管。
- 永远不能在紧张状态下将神经末端插入可吸收神经套接管。
- 若应用直径为 2.3 mm 的可吸收神经套接管时发现神经缺损大于 30 mm，则应使用自体固有的神经移植技术。
- 若应用直径为 4 mm 或 8 mm 的可吸收神经套接管时发现神经缺损大于 10 mm，则应使用自体固有的神经移植技术。
- 切勿重新消毒。
- 切勿使用已开封的未使用可吸收神经套接管。
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产品标准号：

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U.S. Patents 4,870,966 and 5,147,399

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