

Singclean[®]

Singclean Peripheral Nerve Guide



Elastic Design



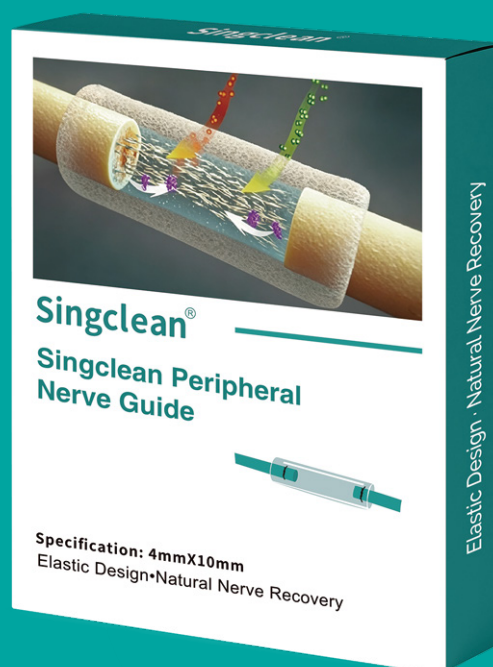
Natural Nerve Recovery

Product Introduction

01 About Singclean® Peripheral Nerve Guide

•Singclean® Peripheral Nerve Guide

It is a biocompatible, semi-permeable, absorbable chitosan tube. It provides a protective environment across nerve discontinuities, as well as an isolated conduit environment guiding axonal regrowth, and is resorbed via normal metabolic pathways.



•Indications

This product is intended for the repair of peripheral nerves.

The length of the nerve defect to be repaired does not exceed 20 mm.

•Specifications

2mmX10mm; 3mmX10mm; 4mmX10mm;
5mmX10mm; 6mmX10mm



02

Why is a Peripheral Nerve Guide Necessary?



Peripheral Nerve Injury (PNI)



Limitation Of Traditional Nerve Repair Methods



Direct Suturing: Only To Short
Nerve Defects+Vulnerable To Tension



Autologous Nerve Grafting:
Limited Donor+Secondary Trauma



Defect >5mm → Difficult Spontaneous Regeneration



Nerve Guide



→Biomimetic Microenvironment
→Alternative To Autologous Nerve Grafting
→Promote Directed Nerve Regeneration

Mode of Action

Constructs a protective channel



The two nerve stumps are inserted into the conduit and secured with sutures, leaving a small gap of no more than 2 mm between them, thereby forming a "protective chamber" spanning the nerve defect.

Provides directional guidance for regeneration



The inner lumen of the conduit serves as a "track," guiding regenerating axons to grow straight along the conduit and ensuring precise alignment between the proximal and distal nerve fibers.

Creates an isolated regenerative microenvironment

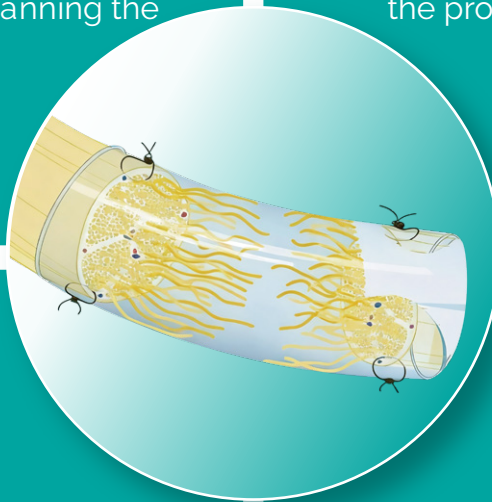


The conduit acts as a physical barrier, effectively preventing external muscle and fibrous tissue from infiltrating the regeneration area, thus avoiding interference with the natural nerve healing process.

Inhibits neuroma formation



By restricting the disorganized growth and outward sprouting of nerve fibers, the conduit significantly reduces the risk of neuroma formation and abnormal hyperplasia.



Singclean[®] Features



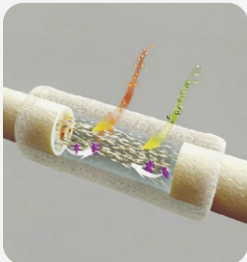
Raw material

Made of chitin, which can be 100% degraded in the human body and be safely absorbed, metabolized and excreted by the body.



Product appearance

The tube wall is semi-permeable, allowing direct visualization of the nerve stump for proper positioning, preventing kinking of the nerve stump inside the tube, and facilitating observation of potential large blood clots, as well as preventing nerve fibers from growing inward.



Support duration

Provides optimal mechanical support for up to 3 months, offering sufficient time for axonal regeneration.



Product function

Bridges the nerve defect while effectively preventing adhesion.



 Singclean® Advantages

01 Fully degradable and absorbable

Traditional silicone catheters are non-degradable and require removal via a second surgery. Singclean® eliminates the need for a second surgery and offers excellent biocompatibility with no immune response.

It completely degrades in the human body within 12 months.

02 Structural support ensures regenerative space

Existing peripheral nerve guide lose strength when wet and are easily compressed.

Singclean® maintains elasticity and toughness when wet, preserving original dimensions, securing regenerative space, and improving outcomes.

03 Ready to use

Existing peripheral nerve guide require rinsing and soaking. Singclean® is sterile and pre-soaked in water for injection, ready for direct use with no rinsing, making it more user-friendly.

04 High transparency

Existing nerve guide are opaque, making nerve stumps difficult to see. Singclean® is semi-permeable and allows clear visualization for more accurate suturing.

05 Tension-free repair

Avoids nerve stump stretching and the need for autologous nerve grafting, sparing patients a second surgery and achieving better recovery.

06 No neuroma, no pain

Prevents neuroma formation and lifelong pain.

Evaluation of Product Safety and Efficacy Performance

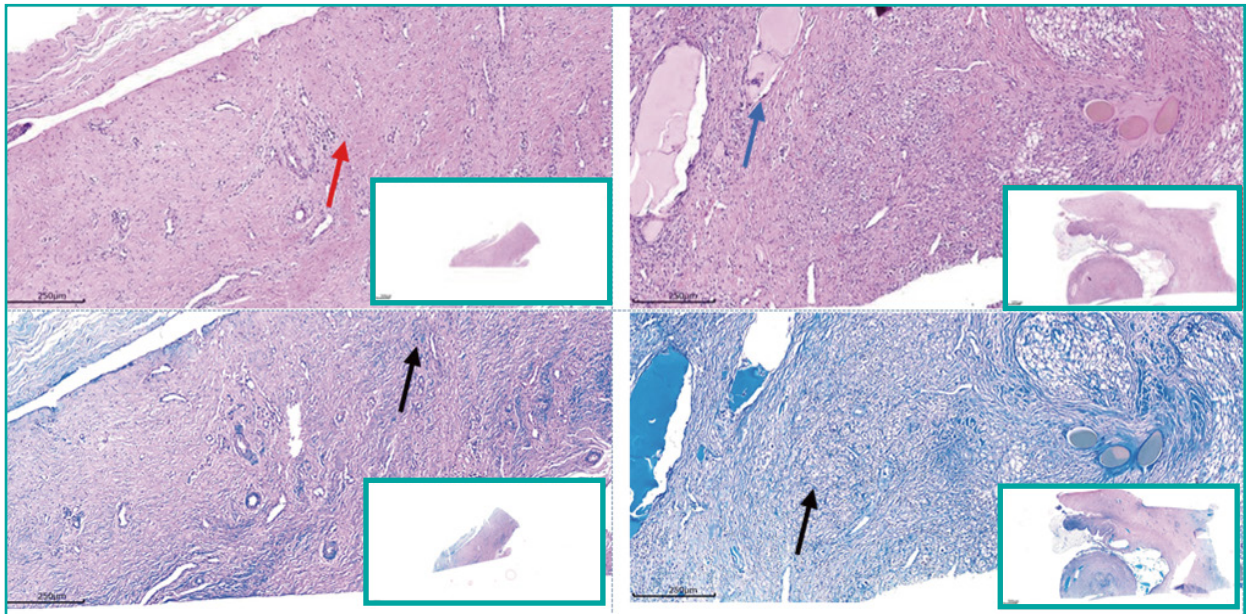
01

Evaluation of Nerve Regeneration and Repair Effects

Model group

Test group

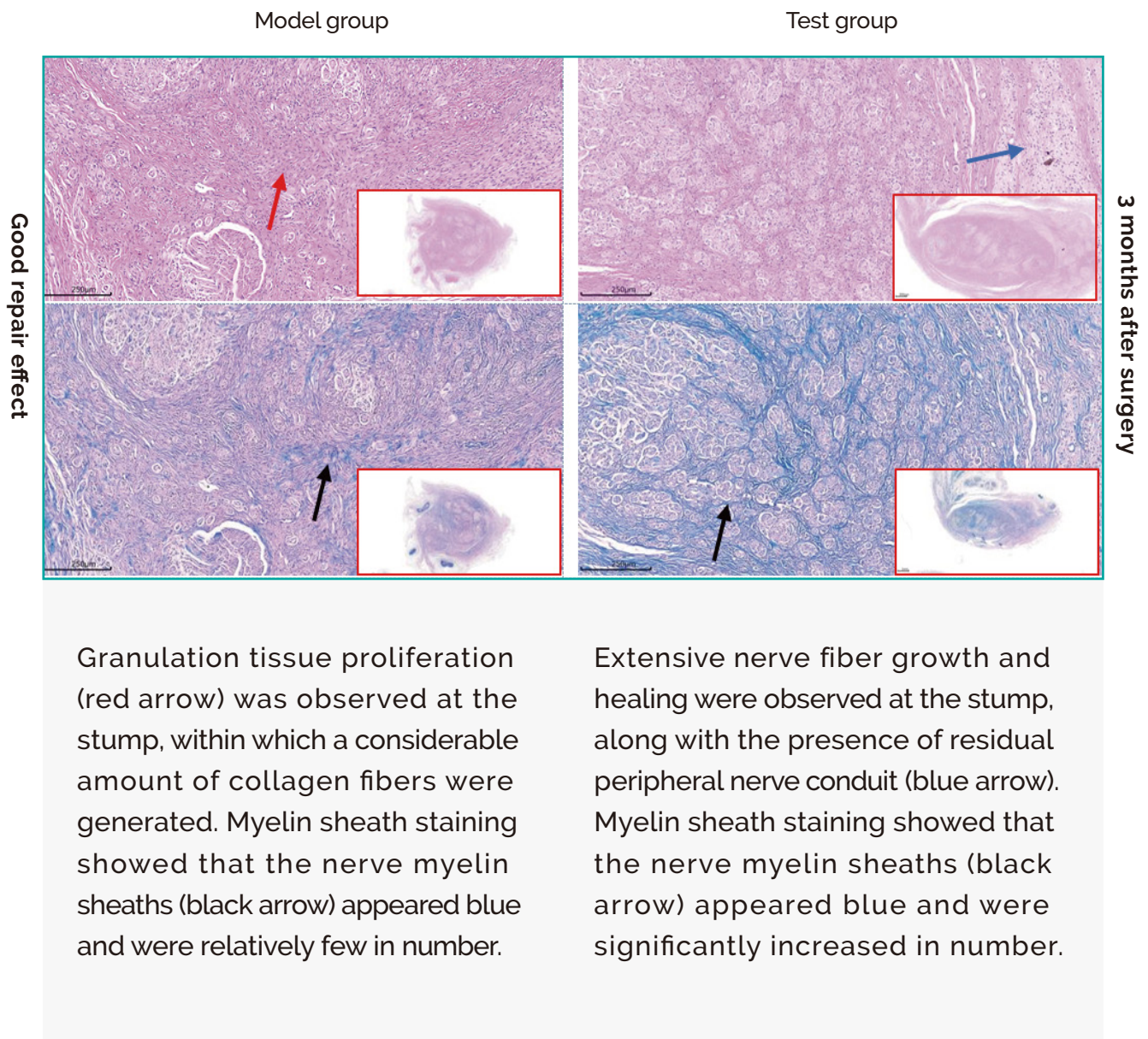
Good repair effect



14 days after surgery

Granulation tissue proliferation (red arrow) can be seen at the stump, with a considerable amount of collagen fiber formation. Myelin sheath staining shows that the nerve myelin sheaths (black arrow) appear blue and are relatively few in number.

A large number of nerve fibers are observed growing and healing at the stump, with residual peripheral nerve conduit visible (blue arrow). Myelin sheath staining shows that the nerve myelin sheaths (black arrow) appear blue and are noticeably increased in number.



02

Evaluation of Local Biological Reaction After Intramuscular Implantation of Peripheral Nerve Guide

Good Biocompatibility

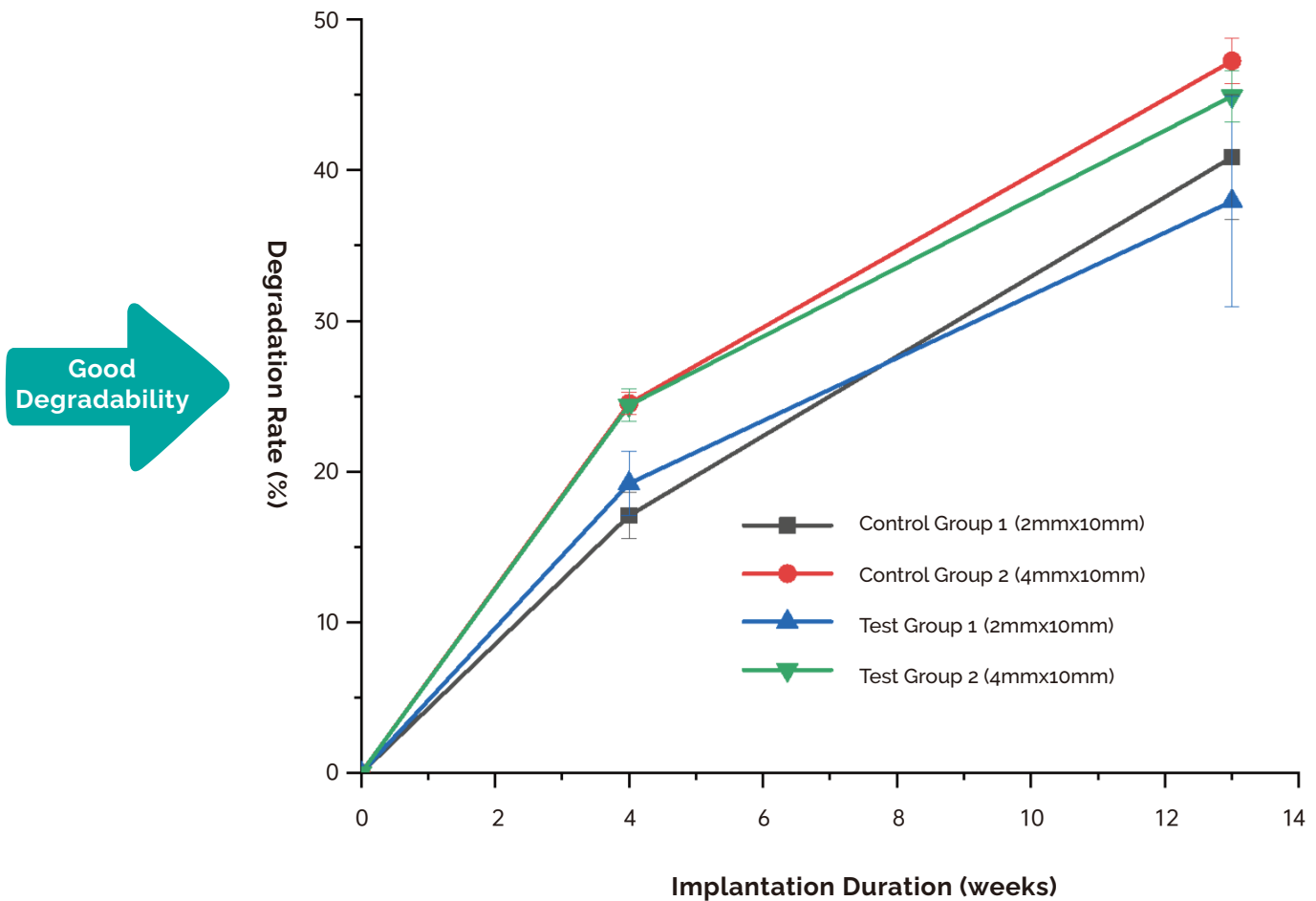
The local biological reaction was evaluated according to the scoring criteria specified in the Chinese standard GB/T 16886.6-2022 "Biological Evaluation of Medical Devices — Part 6: Tests for Local Effects After Implantation". The local biological reaction scores at 1 week and 4 weeks post-implantation were 0.00 and 0.80, respectively. Both scores were below 2.9, indicating no irritation.

Observation Time Point	1 Week Post-Implantation						4 Week Post-Implantation					
Animal ID	No.1						No.2					
Group	Test Group					Control Group	Test Group					Control Group
Slide Number	L1	L2	L3	R1	R3	R2	L1	L2	L3	R1	R3	R2
Polymorphonuclear Leukocytes (PMN)	3	3	3	3	3	3	3	2	3	2	3	2
Lymphocytes	1	1	1	1	1	1	2	2	2	2	2	2
Plasma Cells	0	0	0	0	0	0	0	0	0	0	0	0
Macrophages	3	3	3	3	3	3	3	3	3	3	3	3
Multinucleated Giant Cells	1	1	1	1	1	1	2	2	2	2	1	2
Necrosis	0	0	0	0	0	0	0	0	0	0	0	0
F1	8	8	8	8	8	8	10	9	10	9	9	9
Neovascularization	2	2	2	2	2	2	1	1	1	1	1	1
Fibrosis	1	1	1	1	1	1	2	2	2	2	2	2
Fatty Infiltration	0	0	0	0	0	0	0	0	0	0	0	0
F2	3	3	3	3	3	3	3	3	3	3	3	3
F	19	19	19	19	19	19	23	21	23	21	21	21
AV	19.00					19.00	21.80					21.00
Differential Value	0.00						0.80					

Note: F=2F1+F2

03

Evaluation of Product Degradation Performance



According to the Chinese Expert Consensus on the Preparation and Clinical Trial Process of Degradable Nerve Conduits for Nerve Repair, the peripheral nerve regeneration rate is 1–2 mm/day. After suturing, it generally takes 3 months for the proximal regenerating nerve to reach the target organ and restore optimal function.

After 3 months of implantation, **the degradation rate of the test group was lower than that of the control group (Competitor H, NMPA Certified)**. The test group maintained a relatively intact shape, continuously guiding the regeneration of the defective nerve, exhibiting degradability that matches the nerve regeneration process.

Comparison

Brand	USA Brand 1	USA Brand 2	USA Brand 3	Netherlands Brand 1
Raw Material	Bovine Type I collagen +Chondroitin-6-Sulfate (C6S)	Bovine Type I Collagen	Bioabsorbable polyglycolic acid (PGA)	Co-polymer of poly (DL-lactide-ε-caprolactone)
Specification	Diameters: 1.5mm to 7mm lengths: 20mm or 30mm	Diameters: 1.5mm to 7mm lengths: 20mm or 30mm	Diameter 2.3 mm X length 40 mm Diameter 4.0 mm X length 20 mm Diameter 8.0 mm X length 20 mm	Diameter: 4.0 mm,5.0 mm,6.0 mm, 7.0 mm,8.0 mm,10.0 mm length:30mm
Length of the peripheral nerve gap to be repaired)	≤ 30mm		≤ 30mm	≤ 20mm
Advantages	1.Absorbable with good biocompatibility. 2.Constructs a regenerative microenvironment; 3.Suitable for medium-length nerve defects.	1. The semipermeable membrane retains nerve growth factors and Schwann cells. 2. Mild postoperative neuralgia. 3. No significant complications and no painful neuroma formation.	1.Polyglycolic acid (PGA) synthetic products. 2.Microporous structure with selective permeability of the tube wall to nutrients, suitable for repairing extremely small and tension-deficient damaged nerves.	
Disadvantages	1.Risk of allergic reactions to bovine-derived materials; 2.Potential for collapse/kinking of the conduit; 3.Collagen material softens upon contact with water and offers no structural support.		1.The material is relatively hard and brittle. During degradation, the product produces glycolic acid, making the local environment weakly acidic, which can easily cause aseptic inflammation. 2.The degradation time is relatively short, limiting the length of defect repair; 3.The structure is soft, and as an orthopedic regeneration conduit, its mechanical strength still requires time for validation.	

Brand	USA Brand 4	Chinese Brand	Singclean
Raw Material	Porcine-derived Extracellular Matrix (ECM)	Chitosan material	Chitin is deacetylated into chitosan, followed by reacetylation
Specification	Diameters 1.5mm to 7mm lengths 10mm or 15mm	Diameter: 4mm, 6mm, 8mm, etc.; Length: 10mm, 15mm, 20mm, etc.	Diameter: 2mm, 3mm, 4mm, 5mm, 6mm, Length: 10mm
Length of the peripheral nerve gap to be repaired)	≤ 5 mm	≤ 20mm	≤ 20mm
Advantages	1. Reduces tension and ischemia in the regeneration zone. 2. Reduces inflammation. 3. Minimizes axon escape and assists in nerve alignment. 4. Capable of vascularization and remodeling into autologous tissue.	1.Prevents postoperative compression from surrounding tissues and provides a microenvironment for nerve repair. 2. Maintains strength without softening upon contact with water (e.g., blood).	1. Prevents postoperative compression from surrounding tissues and provides a microenvironment for nerve repair. 2. The product is sterile and immersed in water for injection, ready to use without rinsing, and maintains its strength without softening upon contact with water (e.g., blood).
Disadvantages	1. Porcine-derived material; contraindicated for individuals allergic to porcine components; 2. Only suitable for short-gap nerve repair; 3. Collagen material softens upon contact with water and offers no structural support.	It requires rinsing for at least 30 minutes before use, with a risk of glycerol residue.	/

Usage Steps

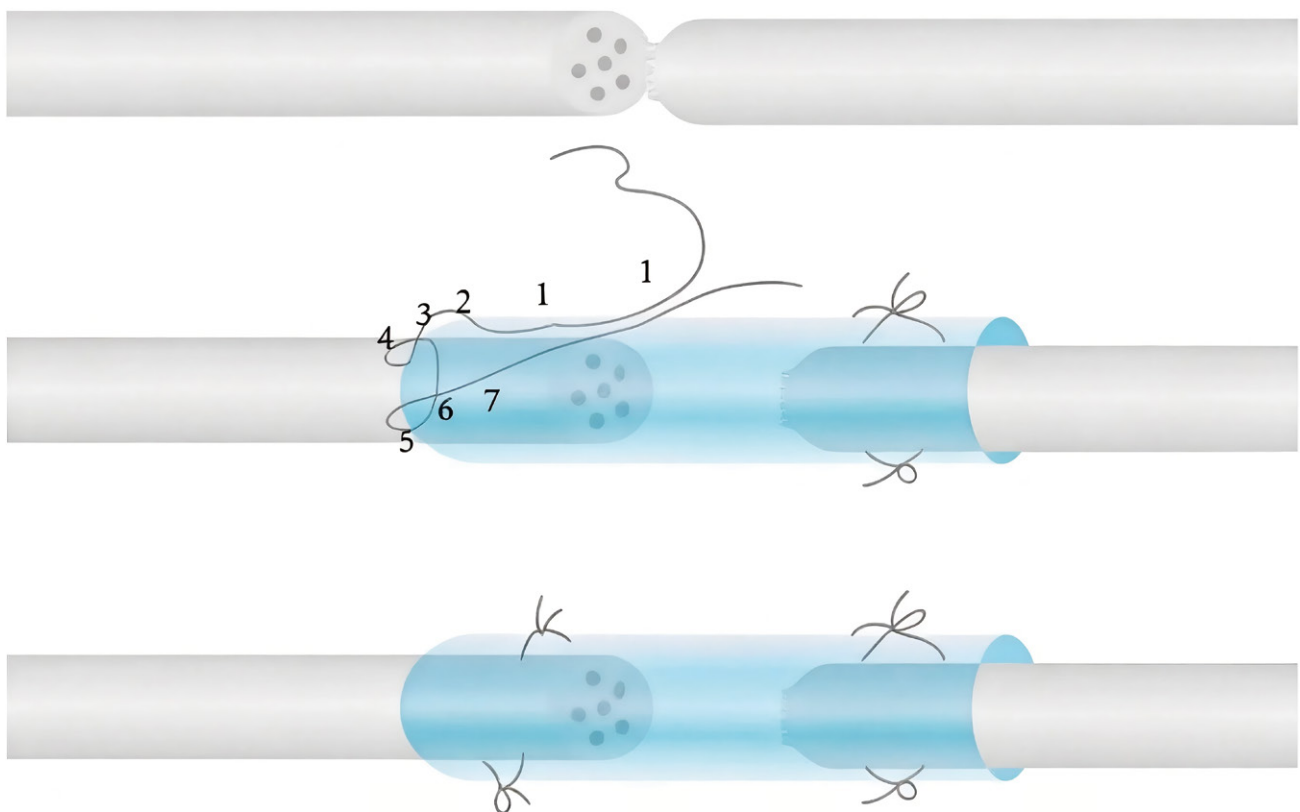
01 / Preoperative Preparation

Check that the outer packaging of the peripheral nerve guide is intact and shows no damage.

The preservation solution in the device is water for injection; the guide is ready for use immediately upon removal without any additional treatment.

02 / Surgical Procedure

The surgical procedure follows the standard technique of small-gap sleeve anastomosis. Using median nerve injury repair as an example, the specific steps are as follows:



01**Expose the injured nerve**

Make an incision at the site of nerve injury and, following the course of the median nerve, dissect layer by layer to expose the damaged median nerve. Handle tissues gently to avoid injuring other important blood vessels and nerves.

02**Debride the nerve stumps**

Use a blade or microscissors to trim away the damaged tissue (e.g., pseudoneuroma) from the median nerve stumps, exposing the healthy nerve fascicles.

03**Bridge the nerve stumps with the conduit**

Place the bridging conduit between the two nerve stumps, and suture the nerve stumps to the conduit to secure them in place.

04**Inspect and reposition**

Check that the nerve inside the conduit is neither twisted nor kinked. Once confirmed, reposition the repaired nerve and conduit within healthy tissue.

05**Closure and finishing**

Achieve hemostasis, irrigate the wound, and close the incision in layers. If necessary, place a drain to evacuate fluid accumulation.

Contraindications:

1. Severe decompensation of cardiac, pulmonary, hepatic, or renal function.
2. Cachexia caused by various chronic wasting diseases, rendering the patient unable to tolerate surgery.
3. Pathological peripheral nerve injury.
4. Presence of acute or chronic local infection near the peripheral nerve.
5. Long-segment nerve defect.
6. Infants, young children, adolescents, pregnant women, and patients planning to become pregnant within 1 year after surgery.
7. Allergy to chitin.

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