stryker®

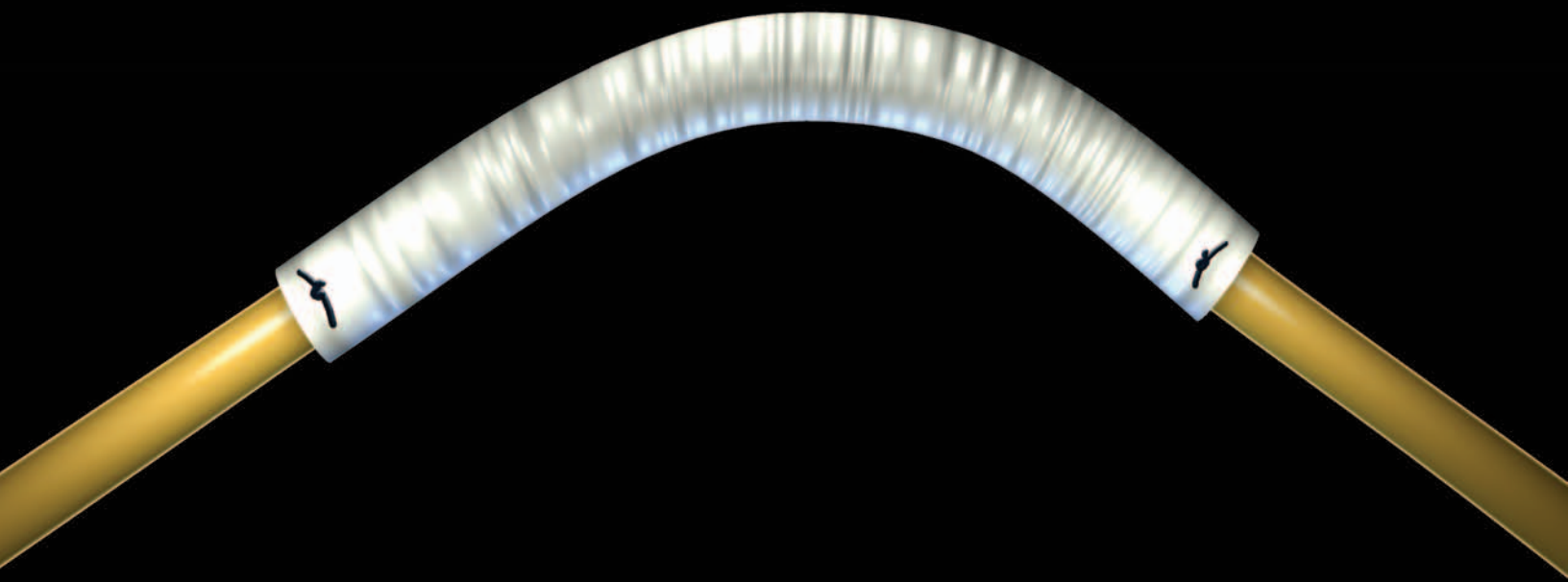
Trauma

Neuroflex™

Flexible Type 1 Collagen Conduits

Operative Technique

- Peripheral Nerve Repair



Indications and Contraindications

Common Indications

The Neuroflex™ conduit allows repair without tension of peripheral nerve discontinuities of less than 3cm. Nerve gaps may occur in the following types of discontinuities (gaps) injuries:

1. **Crushing Injury (damaged nerve may need to be resected)**
2. **Penetrating Injury**
   - **Lacerations/Stabbing injuries**
   - **Severe Fractures or Dislocations**
3. **Oncology related excision**
4. **Repair of Iatrogenic Nerve Injury**
5. **Failed Primary Repair**

Contraindications

1. **Acute infections**
2. **Contaminated wound in the immediate area surrounding the peripheral nerve discontinuity**
3. **Known history of allergic reactions to collagen and/or bovine-derived products**

See package insert for warnings, precautions, adverse effects and other essential product information.

Contributing Surgeon

Melvin P. Rosenwasser, MD
Robert E. Carroll, Professor of Hand Surgery
Chief, Orthopaedic Hand & Trauma Service
Director, Trauma Training Center
New York Orthopaedic Hospital

Introduction

Repairing Peripheral Nerve Injuries (PNI) where the gap is less than 3.0cm with a type 1 collagen conduit offers several potential advantages:

Eliminates the need to harvest an autograft in a second surgical procedure

- Reduces associated morbidity at the donor site, which may include: scarring, neuroma formation, and loss of donor site function.[1]
- May improve OR efficiency.
- Removing the need to harvest autograft from the lower extremity (sural nerve), may allow regional anesthesia and use at an ambulatory surgery center.

Multiple nerve conduits are readily available at the time of surgery, and can be size-matched to fit the nerve repair site/s. This may be a benefit to surgeons addressing multiple nerves or segmental nerve injuries.

Approximation of nerve fascicles is not required.

- Studies suggest regenerating axons are able to align themselves as a result of various neurotropic and neurotrophic factors.[2,3,4] This allows growth factors to influence the proximal growth cone as a severed nerve ending grows across a confined gap.

Allows tensionless repair of the nerve

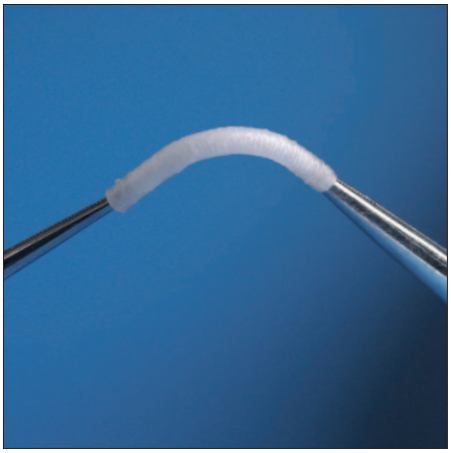
- In many situations, a primary tensionless repair of the nerve is not possible, even with extensive mobilization. Extensive mobilization may also negatively influence the epineurial vasculature. The Neuroflex™ nerve conduit allows for a tensionless repair.
- In many cases, the hand may be positioned in a more anatomic position following nerve repair where the gap is bridged by a conduit than when the surgeon re-approximates the nerve endings. This is often helpful to lessen swelling and stiffness.

Type 1 Collagen is ideally suited to peripheral nerve repair.[5]

- Selective permeability allows nutrients to diffuse, yet acts as a barrier to larger fibroblast cells.
- Type 1 collagen may be better accepted by soft tissue than PGA based conduits.[2,6,7]
- Degrades via normal metabolic pathways within 3-6 months following implantation.
- Hypo-immunogenic.[8]

Neuroflex™, the only type 1 collagen conduit with additional flexibility

- In addition to these benefits, Neuroflex™ adds the patented feature of being kink-resistant.[9] When flexed, the type 1 collagen conduit will bend up to approximately 60 degrees without forming an occlusion, potentially impacting nerve repair. Standard type 1 collagen conduits will occlude at approximately 20 degrees.[10]
- The corrugated sides of the conduit allow additional flexibility without changing the established benefits of standard type 1 collagen conduit properties, including permeability and resorption time.



Operative Technique

Step 1: Prepare Nerve

Expose nerve at the appropriate incision site according to standard procedures.

Prepare the nerve bed. Examine the local tissues (fat/muscle), resecting scar tissue as needed.

The proximal and distal segments of the injured nerves are debrided to normal tissue by visual and tactile cues (Figure 1).

Note: Axoplasmic fluid often will weep out of the resected nerve ending, and may be one indication of adequate debridement.

Figure 1

Figure 2

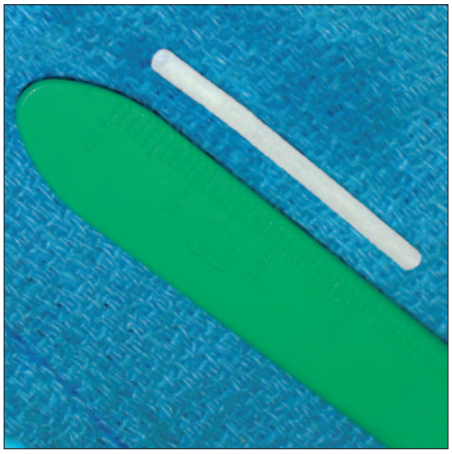


Figure 3

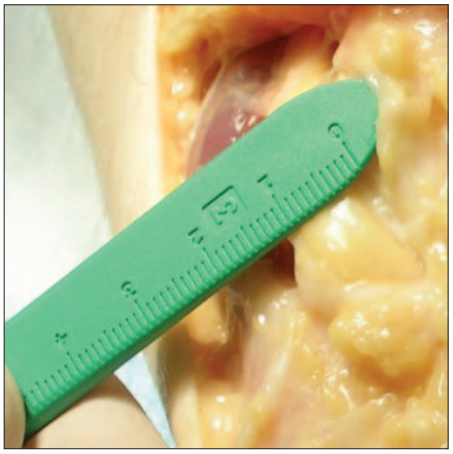


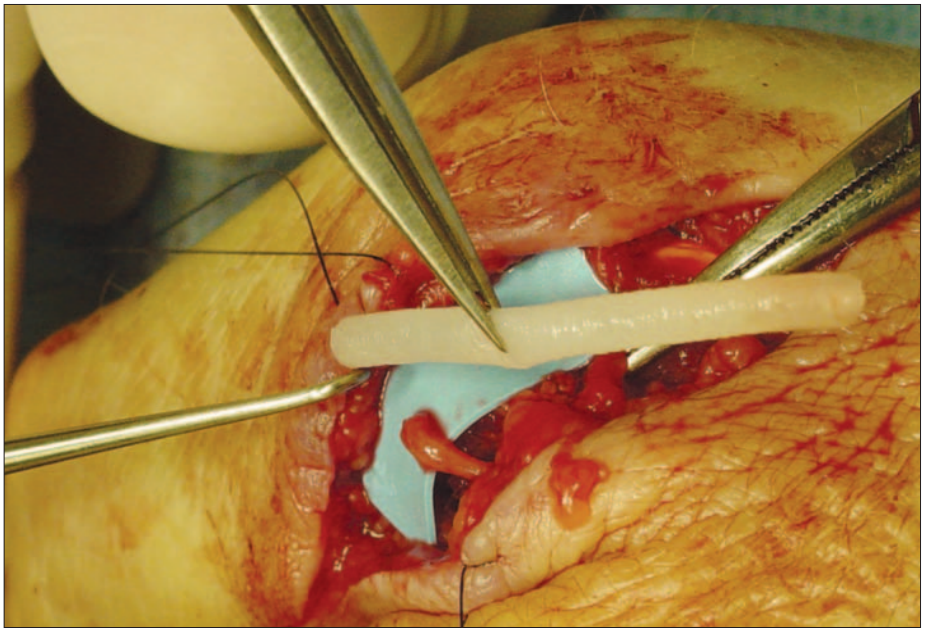
Figure 4

Operative Technique

Step 2: Select and prepare appropriate size Neuroflex™ conduit

The diameter of the nerve is measured and an appropriate size Neuroflex™ conduit is selected. The internal diameter of the chosen nerve cuff should be slightly larger than the nerve diameter (Figures 2,5).

Note: For late repairs when a neuroma/schwanoma exist, there is often significant swelling of the nerve. This may be an important consideration when sizing the nerve conduit.



Measuring the Neuroflex™ conduit for repair of radial sensory nerve. Figure 5

Step 3: Hydrate Neuroflex™ Conduit

Hydrate nerve conduit in sterile physiological saline solution for 5 minutes. Upon hydration, Neuroflex™ will expand approximately 20-30% of its dry length.

After hydration, the nerve conduit is trimmed accordingly to at least a minimum length of 5mm longer than the measured nerve gap, so that both the proximal and distal nerve stumps can be inserted adequately into each end of the nerve conduit.

Operative Technique

Step 4: Suture nerve into Neuroflex™ conduit (Entubulation)

Horizontal Mattress Suture Technique

Using atraumatic (8.0 - 9.0 nylon) suture, pass the suture through the Neuroflex™ conduit from the outside to inside, at least 2mm from the end of the tube.

Pass the suture longitudinally through the epineurium of the nerve stump and back through the epineurium again (u-shape) (Figure 7). Pass the suture through the inside of the Neuroflex™ conduit to the outside.

Gently draw the nerve stump into the Neuroflex™ conduit by pulling the suture such that the nerve stump is drawn into the conduit.

The final length of insertion of the nerve stump into the conduit should be greater than or equal to the nerve diameter. A tensionless secure knot is tied in the suture (Figure 8).

Using a syringe gently flush the lumen of the nerve cuff with sterile saline or Lactated Ringer's solution (USP) (Figure 9). Repeat the suturing procedure for the other nerve stump (Figure 10). Repeat the flushing procedure and fill the interior of the nerve cuff with saline or Lactated Ringer's solution (USP) (Figure 12).

Typically three sutures are placed approximately 120 degrees apart in a 'triangulation' technique (Figure 13).

Note: Avoid tension of the peripheral nerve to be repaired during the entire procedure.

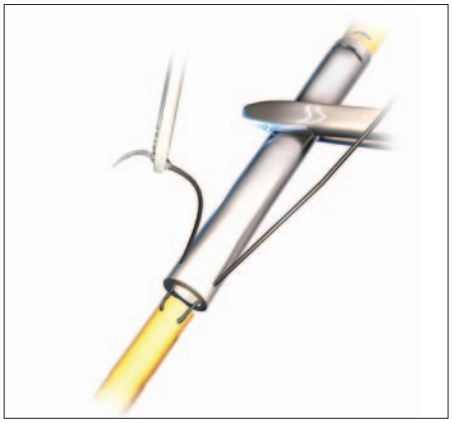


Figure 6

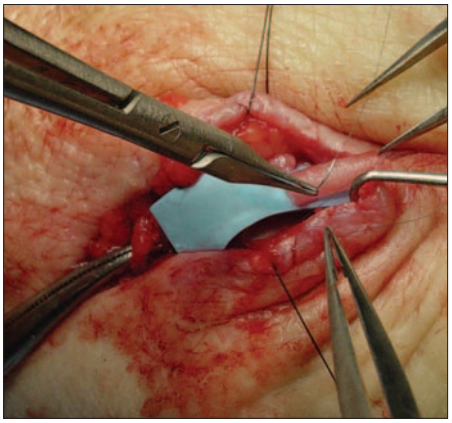


Figure 7

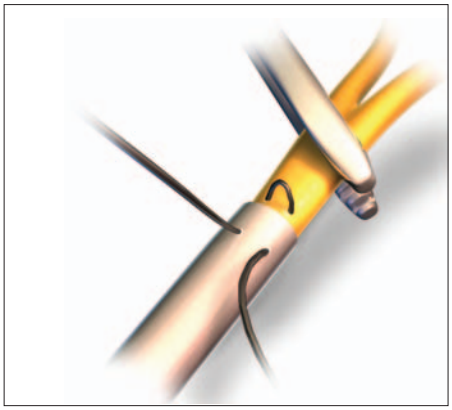


Figure 8

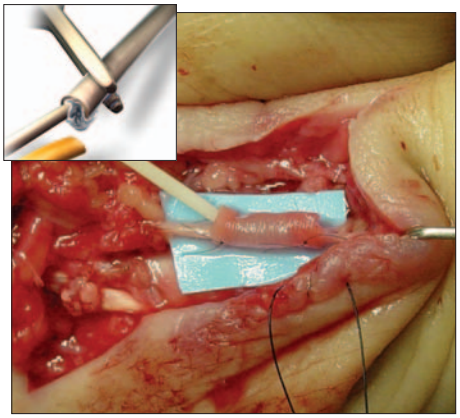


Figure 9

Figure 10

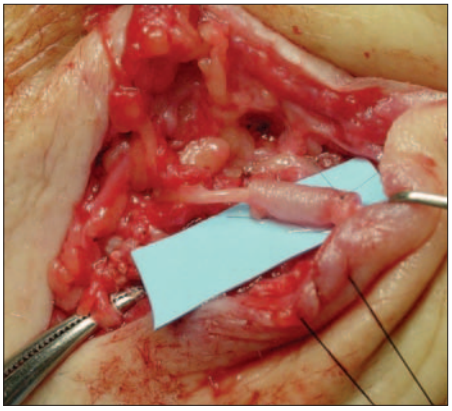


Figure 11

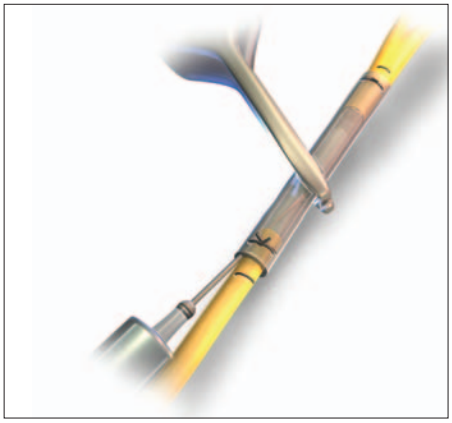


Figure 12

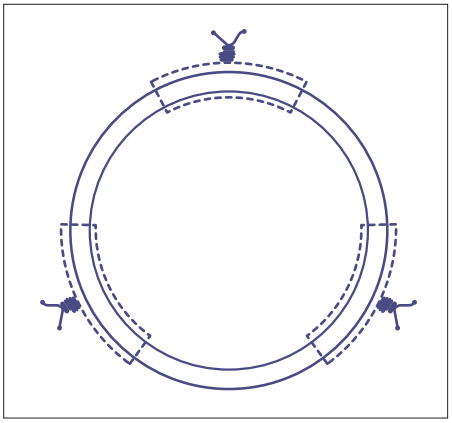


Figure 13

Operative Technique

Step 5: Post-operative Considerations

Closure of the surgical field by layers is routine. Excessive and uncontrolled movement of the extremity where nerve repair was performed must be avoided to prevent possible migration of the device and failure of the repair.

Figure 14

Case Examples

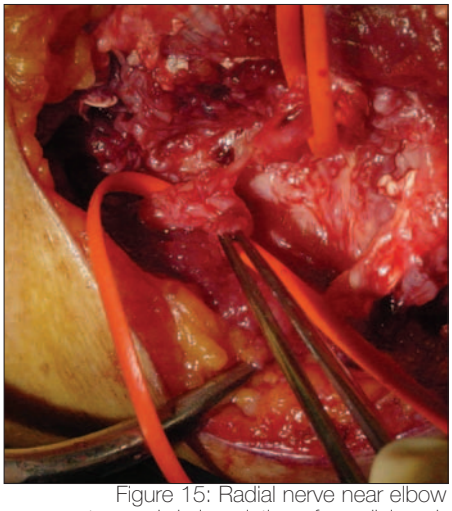


Figure 15: Radial nerve near elbow entrapped during plating of a radial neck fracture. Four months post-op nerve injury referred for treatment

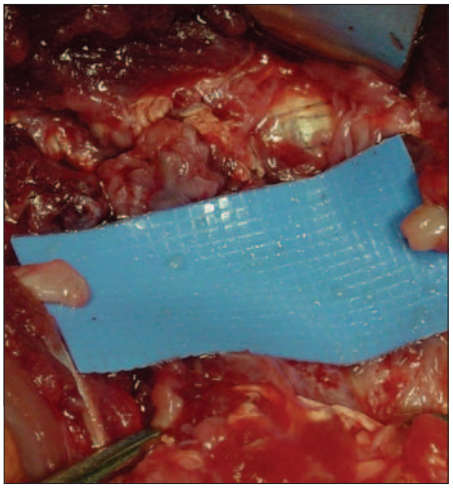


Figure 16: Nerve resected to healthy tissue

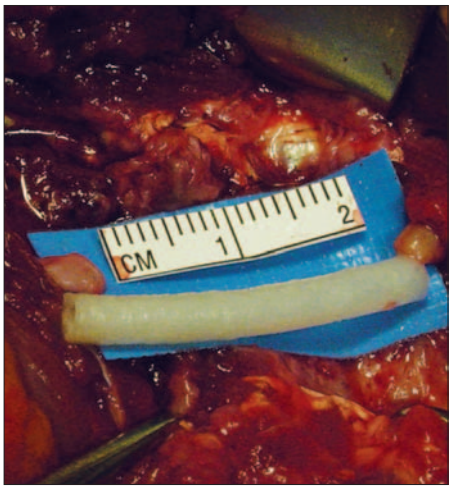


Figure 17: Measuring the conduit

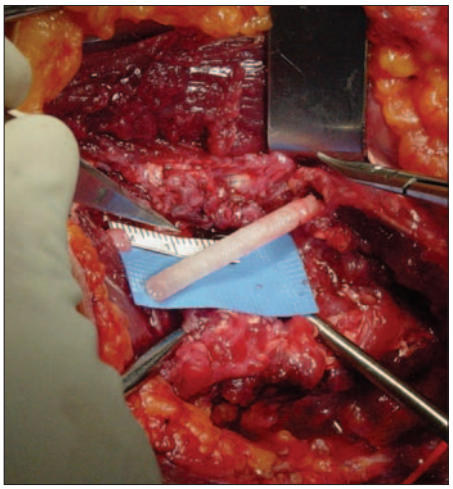


Figure 18: Suturing the Neuroflex conduit in place

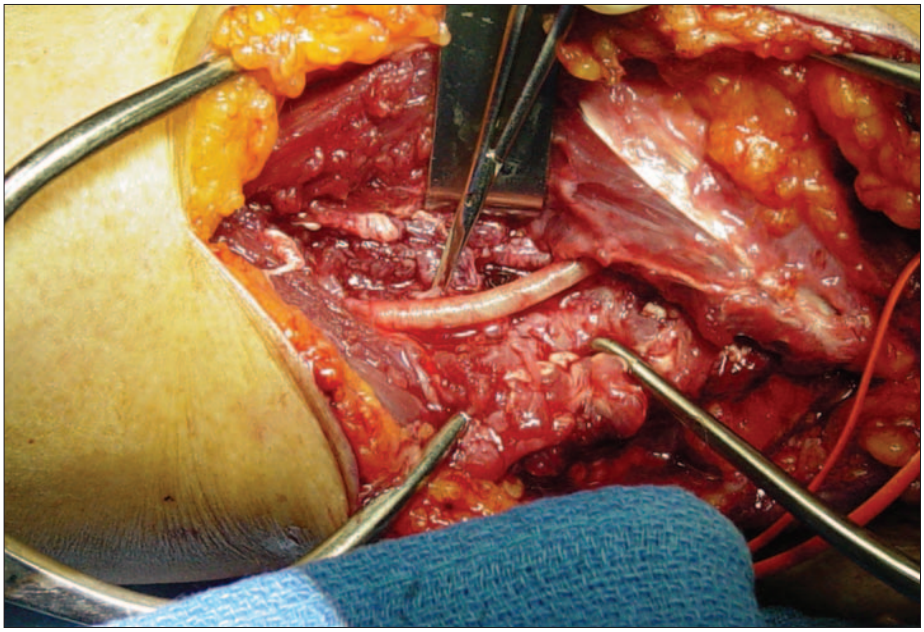


Figure 19: Final repair of radial nerve with Neuroflex conduit

Ordering Information

Catalog Number	Inner Diameter	Length
CNCF2025	2.0mm	2.5cm
CNCF2525	2.5mm	2.5cm
CNCF3025	3.0mm	2.5cm
CNCF4025	4.0mm	2.5cm
CNCF5025	5.0mm	2.5cm
CNCF6025	6.0mm	2.5cm

Bibliography

1. Taras JS, Nanavati V, Steelman P. Nerve conduits. J Hand Ther. 2005 Apr-Jun; 18(2):191-7. Review.
2. Trumble TE, Parisi D, Archibald S, Allan CH. Synthetic Nerve Conduits. pp 121-128 Peripheral Nerve Surgery. Practical Applications in the Upper Extremity. Slutsky and Hentz. Elsevier 2006.
3. Lundborg G, Dahlin LB, Danielson N, Nachemson AK. Tissue specificity in nerve regeneration. Scand J Plast Reconstr Surg. 1986; 20:279-83.
4. Mackinnon SE, Dellon AL, Lundborg G, Hudson AR, Hunter DA. A study of neurotropism in a primate model. J Hand Surgery [Am]. 1986; 11:888-94.
5. Li, ST. Peripheral Nerve Repair with Collagen Conduits. Clinical Materials 9 (1992) 195-200.
6. Weber RA, Breidenbach WC, Brown RE, Jabaley ME, Mass DP. A randomized prospective study of polyglycolic acid conduits for digital nerve reconstruction in humans. Plast Reconstr Surg 2000 Oct; 106 (5): 1036-45; discussion 1046-8.
7. Bostman O, Pihlajamaki H. Clinical Biocompatibility of biodegradable orthopaedic implants for internal fixation: a review. Biomaterials 21 (2000) pp 2615-2621.
8. Li ST, Rodkey WG, Yuen D, Hansen P, Steadman JR. Type 1 Collagen-Based Template for Meniscus Regeneration. Tissue Engineering and Biodegradable Equivalents. Scientific and Clinical Applications. 2002 pp 237-266.
9. Li ST, Yuen D: U.S. Patent #6,716,225, Implant Devices for Nerve Repair, 2004.
10. Data on file at Collagen Matrix, Inc.

The following products are also available through your Stryker Sales Representative:

HydroSet – Injectable HA Bone Substitute

Inion OTPS – Biodegradable Plates, Screws and Pins

Profyle Modular – Small Fragment System

Twinfix – Cannulated Compression Screw

Hoffmann II Micro – Small Bone External Fixation and Lengthening System

VariAx – Variable Angle Distal Radius Locked Plating System

KnifeLight – Minimally Open Carpal Tunnel Ligament Release

AxSOS – Fixed Angle Locking Plate System

Dynamic Joint Distractor II – Hinged Elbow Fixation System

T2 Proximal Humeral Nail – Intermedulary Nail System

T2 Humeral Nail – Intermedulary Nail System

stryker®

Joint Replacements

Trauma, Extremities & Deformities

Craniomaxillofacial

Spine

Biologics

Surgical Products

Neuro & ENT

Interventional Pain

Navigation

Endoscopy

Communications

Imaging

Patient Handling Equipment

EMS Equipment

325 Corporate Drive
Mahwah, NJ 07430
t: 201 831 5000

www.stryker.com

A surgeon must always rely on his or her own professional clinical judgment when deciding to use which products and/or techniques on individual patients. Stryker is not dispensing medical advice and recommends that surgeons be trained in orthopaedic surgeries before performing any surgeries.

The information presented is intended to demonstrate the breadth of Stryker product offerings. Always refer to the package insert, product label and/or user instructions before using any Stryker product. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Literature Number: LNF-OT
MS/GS 2.5m 06/07