

Integra®
Nerve Repair

CASE SERIES



INTEGRA®
LIMIT UNCERTAINTY

NeuraWrap™

Description:

NeuraWrap™ nerve protector is an absorbable collagen implant that provides a non-constricting encasement for injured peripheral nerves for protection of the neural environment. NeuraWrap nerve protector is designed to be an interface between the nerve and the surrounding tissue. When hydrated, NeuraWrap nerve protector is an easy to handle, soft, pliable, nonfriable, porous collagen conduit. The wall of the conduit has a longitudinal slit that allows NeuraWrap nerve protector to be spread open for easy placement over the injured nerve. The resilience of the collagen conduit allows NeuraWrap nerve protector to recover and maintain closure once the device is placed around the nerve. NeuraWrap nerve protector is provided sterile, non-pyrogenic, for single use only, in double peel packages in a variety of sizes.

Indications For Use:

NeuraWrap nerve protector is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

Contraindications:

NeuraWrap nerve protector is not designed, sold or intended for use except as described in the indications for use and is contraindicated for patients with a known history of hypersensitivity to bovine derived materials.

Surgeon Profile

Dr. John Barbour graduated with distinction from the University of Virginia and obtained his medical degree from the Georgetown University School of Medicine. He completed training in General Surgery as well as Plastic Surgery, including a Post-Doctoral research fellowship in vascular physiology and inflammatory mediators at the Medical University of South Carolina. He pursued additional specialized training in microsurgical reconstruction, complex peripheral nerve reconstruction and subspecialty training in Surgery of the Hand at the Barnes-Jewish Hospital/Washington University in Saint Louis's Center for Nerve Injury and Paralysis. He is Board Certified by both the American Board of Surgery as well as the American Board of Plastic Surgery and currently holds appointments as

NeuraGen®

Description:

NeuraGen® nerve guide is an absorbable implant for the repair of peripheral nerve discontinuities. NeuraGen® nerve guide provides a protective environment for peripheral nerve repair after injury, and is designed to be an interface between the nerve and surrounding tissue and to create a conduit for axonal growth across a nerve gap. When hydrated, NeuraGen® nerve guide is an easy to handle, soft, pliable, nonfriable, porous collagen tube. NeuraGen® nerve guide is supplied sterile, nonpyrogenic, for single use in double peel packages in a variety of sizes.

Indications For Use:

NeuraGen® nerve guide is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

Contraindications:

NeuraGen® nerve guide is not designed, sold or intended for use except as described in the indications for use and is contraindicated for patients with a known history of hypersensitivity to bovine derived materials.

an Assistant Professor of both Plastic Surgery and Neurosurgery at the MedStar Georgetown University Hospital.

Dr. Barbour's scope of practice includes management of nerve injuries and advanced compression neuropathy, treatment and resection of peripheral nerve tumors, complex soft tissue defects, and extremity reconstruction following trauma. He is an innovator in advanced peripheral nerve reconstruction techniques involving re-establishing motor or sensory function of the extremity following nerve injury His current position is Medical Director of the Peripheral Nerve Surgery Institute.

Case Study 1

Use of Integra NeuroWrap™ Nerve Protector in Medial Plantar Nerve Reconstruction

Type of Nerve Injury: Right medial plantar nerve hypesthesias with a traumatic neuroma formation

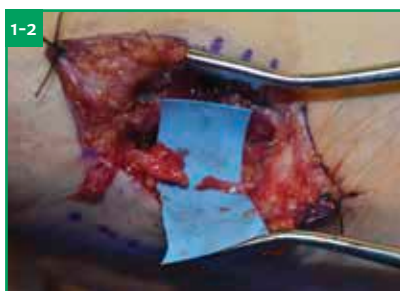
Mechanism of Injury: Plantar instep laceration with deep muscle and nerve injury

Patient: 56 year old male

The patient is a healthy 56-year-old male with well-controlled type II diabetes who stepped on a piece of glass in December 2012. He underwent suture repair of the wound and muscle coverage of the first metatarsal at the time, and has since developed pain in the proximal aspect of the incision and decreased sensibility in the great toe (Figure 1-1). Due to the trajectory of the injury, the pre-operative assessment was highly suspicious for a digital nerve injury to a branch of the medial plantar nerve. In addition, he presented with intense burning sensations at a focal point of the instep consistent with likely neuroma formation. Eight months later, surgical exploration was undertaken and the medial plantar nerve was found to be transected with development of a bulbous neuroma (Figure 1-2). He underwent distal and proximal neurolysis and an overlapping interposition placement of an Integra NeuroWrap Nerve Protector (3mm diameter, 2cm length) (Figures 1-3, 1-4).

Result: At one-year follow-up, the patient had no pain in the site of the previous neuroma and had a progressing distal Tinel sign consistent with nerve regeneration. He had no signs of swelling in the incision line, no erythema, and no opening of the wound.

Discussion: In this patient's case, Integra NeuroWrap Nerve Protector allowed for complete excision of the bulbous terminal neuroma and medial plantar nerve reconstruction without recurrence of the neuroma or need for autologous nerve donor site morbidity.



Case Study 2

Use of Integra NeuraGen® Nerve Guide in Radial Sensory Nerve Reconstruction

Type of Nerve Injury: Transected left radial sensory nerve

Mechanism of Injury: Traumatic glass laceration to forearm structures, including flexor muscle bellies, radial sensory nerve, and radial artery

Patient: 34 year-old male

The patient is a healthy 34 year-old right hand dominant male who sustained a deep laceration to the left forearm while transporting a large panel of glass (Figure 2-1). He underwent immediate operative exploration and repair of the radial artery with an interposition vein graft from the lower extremity. Multiple muscle bellies were re-approximated to appropriate tension and the radial sensory nerve was found to be severed at the proximal forearm level (Figure 2-2). Distal and proximal neurolysis was performed, with excision of the traumatized nerve fascicles (Figure 2-3), and interposition placement of an Integra NeuraGen Nerve Guide (5mm diameter, 3cm length) (Figure 2-4).

Result: At one-year follow-up, the patient had regained function in the hand with 5/5 flexion strength and normal wrist and finger extension. There was no pain in the site of the nerve repair, and he reported improving sensibility in the dorsal thumb, and 4-mm 2-point discrimination consistent with nerve regeneration.

Discussion: In this patient's case, Integra NeuraGen Nerve Guide allowed for sensory nerve reconstruction in the setting of arterial and muscle injury, protecting the nerve from adjacent scarring and preventing tension from disrupting the nerve repair during early range of motion of the fingers and wrist.



Case Study 3

Use of Integra NeuraGen® Nerve Guide in Radial Sensory Nerve Neuroma

Type of Nerve Injury: Right radial sensory nerve neuroma

Mechanism of Injury: Previous deep laceration to dorsal radial wrist

Patient: 33 year-old male

The patient is a healthy 33 year-old right hand dominant male who sustained a knife laceration to the distal radial aspect of the forearm approximately eight months ago. He underwent multi-layered suture repair of the wound immediately following the injury, and developed pain in the proximal aspect of the incision and decreased sensibility in the thumb and dorsal aspect of the index finger (Figure 3-1). Due to the trajectory of the injury, the preoperative assessment was highly suspicious for a nerve injury to the radial sensory nerve (Figure 3-2). Surgical exploration was undertaken and the radial sensory nerve was found to be transected with development of a bulbous neuroma (Figure 3-3). He underwent distal and proximal neurolysis and interposition placement of an Integra NeuraGen Nerve Guide (5mm diameter, 3cm length) (Figure 3-4)

Result: At one-year follow-up, the patient had no pain in the site of the previous neuroma, and had a progressing distal Tinel sign consistent with nerve regeneration. He had no signs of swelling or tenderness in the incision line and improved grip strength due to less tenderness with wrist motion.

Discussion: In this patient's case, Integra NeuraGen Nerve Guide allowed for sensory neuroma excision and repair of the nerve gap with an overlapping interpositional conduit. There was no neuroma recurrence and donor site morbidity from autograft harvesting was avoided.



Case Study 4

Use of Integra NeuraWrap™ Nerve Protector in Recurrent Ulnar Neuropathy

Type of Nerve Injury: Left ulnar nerve injury with severe neuropathy

Mechanism of Injury: Recurrent ulnar nerve compression following previous neurolysis

Patient: 16 year-old female










The patient is a healthy 16 year-old right hand dominant female who suffered trauma to her left ulnar nerve from a displaced distal humerus fracture approximately 4 years prior. She had previously undergone in situ ulnar nerve decompression with a partial medial epicondylectomy (Figure A). Although she did report an initial improvement in her symptoms, she described gradual worsening of paresthesias and pain in her ulnar digits starting at 6 weeks following this procedure. She presented eight months from her surgery with intense burning sensations along the ulnar digits in the hand and some clawing of the small and ring finger, consistent with recurrent ulnar neuropathy. Surgical exploration was undertaken and the ulnar nerve was found to be encased in scar tissue at the previous surgical scar (Figure B). She underwent distal and proximal neurolysis, freeing of the ulnar nerve from the surrounding scar, anterior transposition of the nerve (Figure C), and placement of an Integra NeuroWrap Nerve Protector (7mm, 4cm length) to protect nerve from scar tissue (Figure D).

Result: At one-year follow-up, she had no pain in the distal ulnar nerve distribution, and a progressing distal Tinel sign consistent with nerve regeneration.

Discussion: In this patient's case, Integra NeuroWrap Nerve Protector allowed for protection of the nerve from recurrent scar tissue and maintenance of the nerve in an anterior position to the medial epicondyle.



NeuraGen Nerve Guide Ordering Information

Reference	Description	Diameter (mm)**
PNG130	1.5mm (ID) x 3cm (length)	
PNG220	2mm (ID) x 2cm (length)	
PNG230	2mm (ID) x 3cm (length)	
PNG320	3mm (ID) x 2cm (length)	
PNG330	3mm (ID) x 3cm (length)	
PNG420	4mm (ID) x 2cm (length)	
PNG430	4mm (ID) x 3cm (length)	
PNG520	5mm (ID) x 2cm (length)	
PNG530	5mm (ID) x 3cm (length)	
PNG620	6mm (ID) x 2cm (length)	
PNG630	6mm (ID) x 3cm (length)	
PNG720	7mm (ID) x 2cm (length)	
PNG730	7mm (ID) x 3cm (length)	

NeuraWrap Nerve Protector Ordering Information

Reference	Description	Diameter (mm)**
NW320	3mm (ID) x 2cm (length)	
NW340	3mm (ID) x 4cm (length)	
NW520	5mm (ID) x 2cm (length)	
NW540	5mm (ID) x 4cm (length)	
NW720	7mm (ID) x 2cm (length)	
NW740	7mm (ID) x 4cm (length)	
NW1020	10mm (ID) x 2cm (length)	
NW1040	10mm (ID) x 4cm (length)	

** actual size

NeuraGen Nerve Guide

Adverse Events

Possible complications can occur with any nerve repair surgical procedure including pain, infection, decreased or increased nerve sensitivity, and complications associated with use of anesthesia.

NeuraWrap Nerve Protector

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Possible complications can occur with any peripheral nerve surgical procedure including pain, infection, decreased or increased nerve sensitivity, and complications associated with use of anesthesia.

* As the manufacturer of this device, Integra LifeSciences Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

For more information or to place an order, please contact:

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