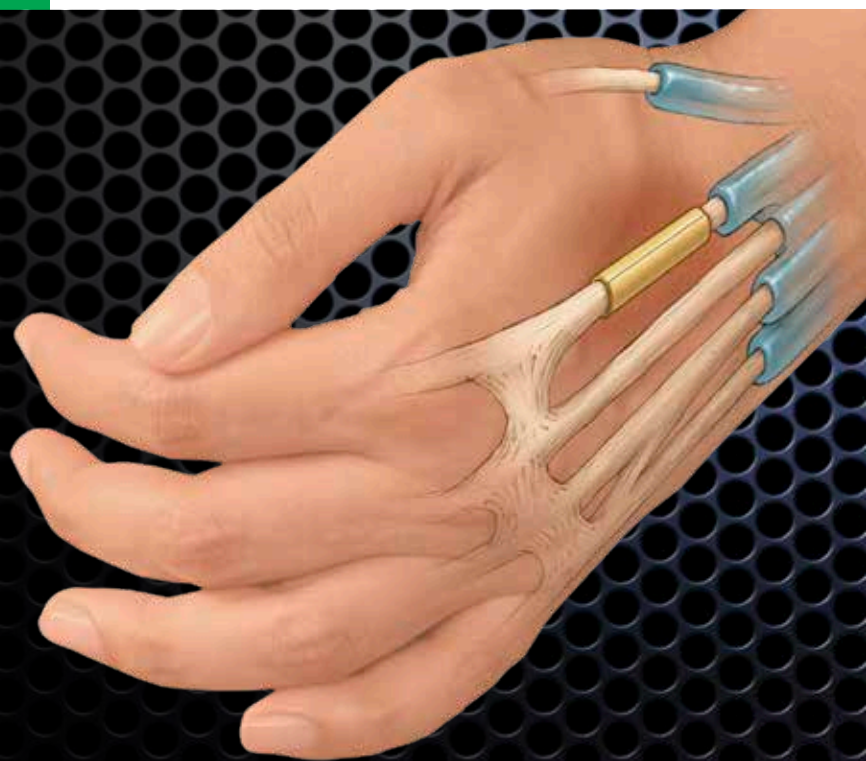


Integra®

TenoGlide® Tendon Protector Sheet

SURGICAL TECHNIQUE



INTEGRA®
LIMIT UNCERTAINTY

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Description

TenoGlide Tendon Protector is an absorbable implant (device) that provides a non-constricting, protective encasement for injured tendons. It is comprised of a porous matrix of cross-linked bovine Type I collagen and glycosaminoglycan (GAG). TenoGlide Tendon Protector is designed to serve as an interface between the tendon and tendon sheath or the surrounding tissues.

Indications

TenoGlide Tendon Protector is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Contraindications

TenoGlide Tendon Protector Sheet is not designed, sold or intended for use except as described in the indications for use and is contraindicated in the following situations:

- TenoGlide is not indicated to replace or repair damaged tendon or to reinforce the strength of any tendon repair.
- TenoGlide is contraindicated for patients with known hypersensitivity to bovine collagen or chondroitin materials.

Engineered to shield and protect tendon injuries during the healing process

Tendon repair is often associated with excessive scarring in the form of tissue that bridges the tendon sheath and the tendon. The formation of this scar tissue is associated with increased resistance to motion and therefore greater mechanical force required for movement of the tendon.

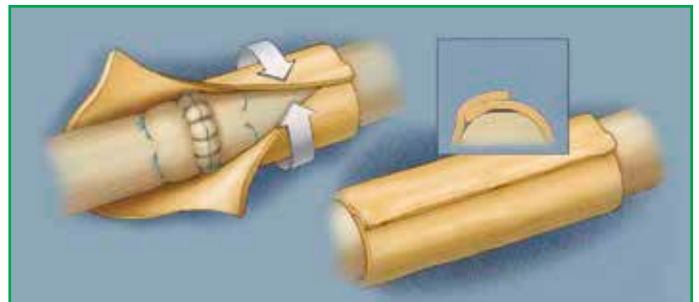
TenoGlide® tendon protector sheet is an advanced tendon protection device comprised of a porous matrix of highly purified Type I collagen and glycosaminoglycan (GAG). The collagen-GAG resorbable matrix provides a biocompatible interface, which provides a protective environment and gliding surface while the tendon is healing.

TenoGlide Tendon Protector Sheet:

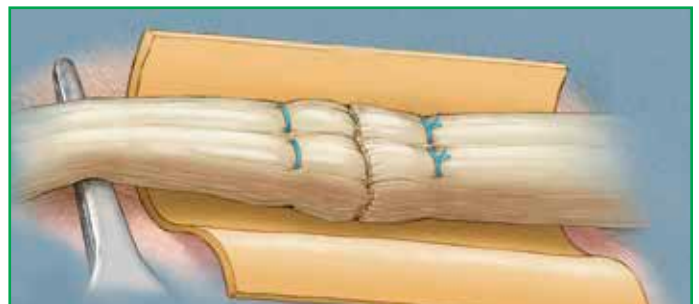
- Protects completely severed tendons after primary repair
- Protects tendons that are partially injured
- Protects tendons that are damaged by compression from trauma or the surrounding connective tissue

TenoGlide provides a protective biocompatible interface for the protection and management of tendon injuries during the healing process.

Flexor



Extensor



Designed to serve as an interface between the tendon and the surrounding tissue.

Following tenolysis or primary repair of tendon, determine appropriate size and then trim away excess. The TenoGlide sheet may either be wrapped around the affected region or slid between the tendon and the adjacent tissue.

Surgical Technique



As the manufacturer of this device, Integra 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 implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Step 1 • Surgical Approach

- 1-1 Following tenolysis or primary repair of the tendon, determine the appropriate size of the TenoGlide sheet needed.



Step 2 • Remove TenoGlide From The Pouch

- 2-1 TenoGlide Tendon Protector is supplied sterile, in single use, double peel packages containing phosphate buffer. Inner foil pouch remains sterile when handled with proper sterile technique upon removal from Tyvek pouch. Separate one of the polyethylene sheets slowly carefully peeling back from the corner edge. Handle with care as the product is fragile.



Step 3 • Cut TenoGlide To Fit

- 3-1 Cut the TenoGlide still on the polyethylene sheet to a size that extends the entire length of the incision or damaged area in the tendon sheath.



Step 4 • Product Insertion

- 4-1 Use instruments to raise the repaired tendon and pull the TenoGlide, while still on the polyethylene sheet, under the repair site.
- 4-2 Pull the TenoGlide under the tendon until you can effectively wrap the TenoGlide around the tendon



Step 5 • Remove Polyethylene Sheet

- 5-1 Use the forceps to remove the polyethylene sheet from the TenoGlide.



Step 6 • Wrap Repair Site

- 6-1 Fold one side of the TenoGlide over the repair site.



Step 7 • Secure TenoGlide Closure

- 7-1 Fold the other side of the TenoGlide over the repair site.
- 7-2 TenoGlide may be secured either to the tendon or adjacent tissues with absorbable sutures using a non cutting needle and a low-tension suture technique. You may also use fibrin glue to hold the TenoGlide in place.



Step 8 • Post Application

- 8-1 Application of TenoGlide does not modify postoperative treatment. The surgeon must determine motion and strength requirements according to standard practice based on the extent of the tendon repair.

TenoGlide Tendon Protector Sheet

| Reference | Description |
|-----------|---|
| TG221 | 2 inch x 2 inch (5cm x 5cm), 1 unit/box |
| TG451 | 4 inch x 5 inch (10cm x 12.5cm), 1 unit/box |

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Always refer to the appropriate instructions for use for complete clinical instructions.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

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

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