DESCRIPTION

TenoGlide™ Tendon Protector Sheet is an absorbable implant (device) that provides a non-constricting, protective encapsulation for injured tendons. TenoGlide 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 the surrounding tissues. TenoGlide Tendon Protector is an easy to handle, conformable, porous collagen-GAG sheet designed for easy placement under, around or over an injured tendon. TenoGlide Tendon Protector is supplied sterile, non-pyro- genic, for single use, in double peel packages in a variety of sizes.

INDICATIONS

TenoGlide Tendon Protector Sheet 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.

PRECAUTIONS

- DO NOT RESTERILIZE. Discard all opened and unused portions of TenoGlide Tendon Protector.
- Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.
- TenoGlide should not be applied until bleeding and infection are controlled.

INSTRUCTIONS FOR USE

Application

1. Always handle TenoGlide using aseptic technique.
2. Peel open the outer pouch and remove the inner foil pouch.
3. Place foil pouch flat on sterile surface and peel it open.
4. Remove product, including the protective polyethylene sheets.
5. Separate product from the polyethylene sheets by slowly and carefully peeling back from one of the corner edges. Handle with care as product is fragile.
6. Place product into basin containing a sterile, room temperature saline solution. Rinse the product free of storage buffer by immersing into sterile saline for 1-2 minutes.
7. Keep product in the basin until application.
8. Following tenolysis or primary repair of tendon, determine appropriate size, wrap the sheet around the affected region and then trim away excess. TenoGlide should be cut to a size that extends the entire length of the incision or damaged area in the tendon sheath.
9. TenoGlide may be secured either to the tendon or the adjacent tissues with absorbable sutures using a non-cutting needle and a low-tension suture technique. Use the minimum number of sutures to avoid irritation of the adjacent tissues.
10. TenoGlide may be rotated such that the suture line is away from the injured soft tissue (i.e. the skin suture line). Thoroughly irrigate the surgical site and close the incision in the standard fashion.

The following technique may also be used:

8a. Following tenolysis or primary repair of tendon, determine appropriate size and then trim away excess.
9a. Elevate the tendon and slide TenoGlide between the tendon and the adjacent tissue. TenoGlide should be secured to the adjacent tissue with absorbable sutures using a non-cutting needle and an interrupted low tension suture technique. Use the minimum number of sutures to avoid irritation of the adjacent tissues.
10a. Thoroughly irrigate the surgical site and close the incision in the standard fashion.

Post-Application

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.
SAFETY

TenoGlide Tendon Protector is manufactured from collagen obtained from bovine deep flexor tendon, which is classified by European Standards as Class IV material (no detectable infectivity for Bovine Spongiform Encephalopathy (BSE)). Bovine Tendon is known to be one of the purest sources of Type I collagen that is commercially available.

The collagen used to manufacture TenoGlide Tendon Protector is currently used in the manufacture of an artificial skin, absorbable hemostatic sponges, and absorbable wound dressings. The manufacturing process for TenoGlide Tendon Protector meets USA and European Standards for animal tissue sourcing, handling and inactivation of viruses and transmissible agents. This process involves a treatment with sodium hydroxide that is a recognized method of inactivation of Spongiform Encephalopathy pathogens.

A viral inactivation study for the TenoGlide Tendon Protector manufacturing process was conducted by an independent certified laboratory. In this study, the sodium hydroxide reduced the viral titer to non-detectable levels for the following viral strains: Human Immunodeficiency Virus Type I (HIV), Bovine Viral Diarrhea (BVD), Infectious Bovine Rhinotracheitis (IBR), Parainfluenza Virus Type 3 (PI3), Vesicular Stomatitis (VSV).

HOW SUPPLIED

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. TenoGlide Tendon Protector is available in the following sizes:

<table>
<thead>
<tr>
<th>Product Codes</th>
<th>Size Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>TG221</td>
<td>2 inch x 2 inch (5 cm x 5 cm)</td>
<td>1 unit/box</td>
</tr>
<tr>
<td>TG225</td>
<td>2 inch x 2 inch (5 cm x 5 cm)</td>
<td>5 units/box</td>
</tr>
<tr>
<td>TG451</td>
<td>4 inch x 5 inch (10 cm x 12.5 cm)</td>
<td>1 unit/box</td>
</tr>
<tr>
<td>TG455</td>
<td>4 inch x 5 inch (10 cm x 12.5 cm)</td>
<td>5 units/box</td>
</tr>
</tbody>
</table>

STORAGE

Store flat at room temperature. Avoid excessive heat (greater than 40°C). Avoid freezing. Shelf life is two years from the date of manufacture.

PRODUCT INFORMATION DISCLOSURE

INTEGRA HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES EXCEPT ITS APPLICABLE STANDARD WARRANTY, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. INTEGRA INTENDS THAT THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS HAVING RECEIVED PROPER TRAINING IN THE USE OF THE DEVICE.

RETURNED GOODS POLICY

- Authorization, from customer service, must be obtained prior to returning product.
- Sterile product must be returned in unopened, undamaged cartons, packed to prevent damage.
- Custom or special order products will not be accepted for credit.
- Credit will be issued for goods returned prior to ninety days from ship date with a restocking charge. This assumes that the product returned is not damaged and can be verified to have not been used or opened.

SYMBOLS USED ON LABELING

- Do not reuse after opening
- LOT: Lot number
- See instructions for use
- Expiration date
- Storage temperature range: 2°C–30°C
- STERILE: Sterile—method of sterilization: irradiation
- Federal (USA) law restricts this device to sale by or on the order of a physician or Practitioner
- REF: Catalog number

CAUTION: Federal law restricts this device to sale by or on the order of a physician or practitioner. For product ordering information or technical questions, please call 800-997-4868 or 609-275-0500.

Integra LifeSciences Corporation
311 Enterprise Drive, Plainsboro, NJ 08536, USA
www.Integra-US.com
TenoGlide is a trademark of Integra LifeSciences Corporation.
The Integra Wave logo is a trademark of Integra LifeSciences Corporation.