# SurgiBind® Tendon Protect

## INSTRUCTIONS FOR USE

Fish Skin for Tendon Protection

Kerecis® SurgiBind Tendon Protect is a bioresorbable, implantable medical device made from fish skin intended for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The device is sterile and is intended for one-time use.

### INTENDED USE

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

### CAUTION

Federal law restricts this product to sale by or on the order of a physician or properly licensed practitioner. These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

### CONTRAINDICATIONS

- This product is not indicated to replace or repair the damaged tendon or to reinforce the strength of any tendon repair
- This product is made from a fish source and should not be used in patients with a known allergy or other sensitivity to fish material

### PRECAUTIONS

- This product is designed for single use only. Do not reprocess, re-sterilize, or re-use
- This product is fully resorbable
- If excessive curling occurs during rehydration, the device should be replaced with a new one for optimal handling characteristics
- Sterile if package is unopened and undamaged
- Do not use product if package seal has been broken or if handling has caused damage or contamination
- Discard unused portions of the medical device
- Do not use after printed expiration date
- Ensure that the device is rehydrated prior to suturing

### POTENTIAL COMPLICATIONS

The following complications are possible with the use of surgical graft materials. If any of these complications occur, and cannot be resolved, consider the removal of the surgical graft.

- Infection
- Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation)
- Allergic reaction
- Seroma formation

### STORAGE

This product should be stored in a clean, dry location at room temperature.

### STERILIZATION

This product has been sterilized using ethylene oxide.

### SUGGESTED INSTRUCTION FOR USE

**Required materials**

- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Use room temperature sterile saline or other isotonic solution for rehydrating products
- The use of a too-warm rehydration solution may cause curling of the product

**Note: Always handle the product in an aseptic manner.**

1. Using aseptic technique, remove the sterile inner packaging from the outer packaging and place it in the sterile field.
2. Open the sterile inner package carefully and aseptically remove the product from the inner package.
3. Rehydrate the product in sterile saline or other isotonic solution until desired handling characteristics are achieved.
4. Complete the tendon repair using standard surgical techniques.
5. Determine the appropriate size of product so that it covers or wraps around the repair site and the entire length of the damaged area.
6. Trim any excess product providing a small allowance of overlap when used to wrap around the tendon (0.5 cm or more as needed to suture securely).
7. Transfer the product to the repair site and suture into place, maximizing contact with the healthy tissue in order to encourage cell in-growth. The product can be sutured.
8. Complete the standard surgical procedure. Ensure postoperative measures are in place as per institutional guidelines for the procedure.
9. Discard any unused portions of the product according to institutional guidelines for medical waste.

### ADVERSE EVENT

Report suspected adverse reactions from this product to the email adversereactions@kerecis.com. Leave a contact phone number, email address and description of the event. Please include the data on the package or pouch, i.e., "lot number" and "use before" date. Note that adverse reactions may be subject to mandatory reporting to the authorities.

### SYMBOLS FROM PRODUCT LABEL


KEEP AWAY FROM SUNLIGHT


KEEP DRY

DOES NOT CONTAIN OR HAVE THE PRESENCE OF NATURAL RUBBER LATEX

UPPER LIMIT OF TEMPERATURE, 77°F, 25°C


CONSULT INSTRUCTION FOR USE


DO NOT USE IF PACKAGING IS DAMAGED


SINGLE USE ONLY

STERILIZED USING ETHYLENE OXIDE

MR SAFE, NON-MAGNETIC

### MANUFACTURER

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