Kerecis® Omega3 SurgiBind™

INSTRUCTIONS FOR USE

Fish skin for surgical use

Kerecis® Omega3 SurgiBind™

Kerecis® Omega3 SurgiBind™ is a medical device derived from fish skin and serves as a bioresorbable scaffold for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is sterile and is intended for one-time use.

INTENDED USE

Kerecis® Omega3 SurgiBind™ is indicated for:

- For implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic or reconstructive surgery.

CAUTION

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

CONTRAINDICATIONS

Kerecis® Omega3 SurgiBind™ is derived from a fish source and should not be used in patients with a known allergy or other sensitivity to fish material. Kerecis® Omega3 SurgiBind™ is not indicated for repairs where load bearing support from the mesh is required such as in the repair of any hernia. The device is not indicated for intraperitoneal organ contact. The device is not indicated for bridging defects.

PRECAUTIONS

- This device is designed for single use only. Do not reprocess, re-sterilize, or re-use.
- This device is fully resorbable, it should not be used in repairs where permanent support from the mesh is required.
- If excessive curling occurs during hydration, the device should be replaced with a new one for optimal handling charecteristics.
- Sterile if package is unopened and undamaged.
- Do not use if the package seal is 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 cutting or suturing.
- Failure to securely suture the device to healthy, well-vascularized tissue may result in lack of incorporation of device.
- The device may not have sufficient strength to support stress encountered in all ventral hernias or large-area, body-wall repairs.
- No studies have been done to evaluate the reproductive impact with the clinical use of the device.
- The device has not been studied for use in, the repair of direct inguinal hernias, ventral hernias, intraperitoneal use, central nervous system, contaminated and/or infected wounds, breast surgery or breast reconstruction The safety risk of use in these other situations are unknown.
- The safety and effectiveness of the device has not been established for urogynecology use.

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

SUGGESTED INSTRUCTION FOR USE

Required materials

- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Rehydration fluid: at least 50 mL of room temperature sterile saline or sterile lactated Ringer's solution for each sheet. The use of too warm rehydration solution may cause curling of the product.

Note: Always handle Kerecis® Omega3 SurgiBind™ using aseptic technique

1. Using aseptic technique, remove the sterile inner packaging from the outer packaging and place in the sterile field.
2. Open the sterile inner package carefully and aseptically remove Kerecis® Omega3 SurgiBind™ from the inner package.
3. Rehydrate Kerecis® Omega3 SurgiBind™ in sterile saline or other isotonic solution until desired handling characteristics are achieved. Note: The rehydration fluid's temperature is not to exceed room temperature. The graft requires approximately 60 seconds for rehydration.
4. Prepare the graft site using standard surgical techniques.
5. Trim the graft to fit the site, providing a small allowance for overlap.
6. Transfer the matrix to the graft site. Suture into place, ensuring that all layers are captured and avoiding excess tension. Note: Securely suture the matrix to maximize contact with healthy, well-vascularized tissue in order to encourage cell in-growth.
7. Complete the standard surgical procedure.
8. Place suction drains or the postoperative measures in place as per institutional guidelines for the procedure. **IMPORTANT: The liberal use of drains is recommended until output is less than 15cc in 24 hours.**
9. Discard any unused portions of the surgical graft according to institutional guidelines for medical waste.

ADVERSE EVENTS

Please report suspected adverse reactions from this product to the email adversereactions@kerecis.com leaving a phone number and email address. Adverse reactions might also be subject to mandatory reporting to the authorities. Please include the data on the package or pouch i.e., "lot number" and "use before" date.

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

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