

Kerecis® Omega3 GraftGuide™

INSTRUCTIONS FOR USE

FISH SKIN FOR WOUND MANAGEMENT

INTENDED USE

Kerecis® Omega3 GraftGuide™ is indicated for the management of wounds, including:

- Partial and full thickness wounds
- Trauma wounds including second-degree burns
- Surgical wounds including donor sites/grfts

CAUTION

Federal law restricts this device 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

Kerecis® Omega3 GraftGuide™ is from a fish source and should not be used on patients with a known allergy or other sensitivity to fish material.

PRECAUTIONS

- Remove all necrotic tissue under the graft area prior to device application.
- Remove exudate and control significant bleeding prior to device application.
- Do not reuse or re-sterilize.
- Discard unused portions of device.
- Do not use after printed expiration date.
- Sterile if package is unopened and undamaged.
- Do not use device if package seal has been broken or if handling has caused damage or contamination.
- Do not use in case of known fish allergies.

POTENTIAL COMPLICATIONS

The following complications are possible. If any of these conditions occur, the device should be removed.

- Infection
- Chronic inflammation (Initial application of wound dressings may be associated with transient, mild, localized inflammation)
- Allergic reaction
- Excessive redness, pain, swelling, or blistering

STORAGE

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

STERILIZATION

This device has been sterilized using ethylene oxide.

SUGGESTED INSTRUCTIONS FOR USING

Kerecis® Omega3 GraftGuide™

Always handle Kerecis® Omega3 GraftGuide™ in an aseptic manner.

First Application

1. When applying Kerecis® Omega3 GraftGuide™ for the first time, debride the wound bed to obtain a fresh tissue surface by removing necrotic tissue or tangential excision. Irrigate to remove debris and exudates. Control bleeding after applying the fish skin graft.

2. Remove the Kerecis® Omega3 GraftGuide™ sheet from the pouch using aseptic technique.
3. Cut the sheet roughly to the size of the area to be covered and pre-hydrate in sterile saline solution.
4. Apply sheet directly into the wound. The sheet should not overlap the wound edges.
5. More than one sheet may be necessary for complete coverage. Overlap sheet edges slightly to assure coverage of the entire wound.
6. To maintain direct device contact with wound bed/surface the device can be secured with steristrips, sutures, or staples.
7. Apply an appropriate secondary, non-adherent wound dressing to maintain a moist wound environment.

Follow-Up Applications

After starting treatment with Kerecis® Omega3 GraftGuide™, the wound should be checked regularly to ensure that the cover dressing is maintaining a sufficient moist wound environment and if a re-application of Kerecis® Omega3 GraftGuide™ is needed.

1. Inspect wound every two days. The duration between inspections may be extended up to seven days as healing progresses.
2. Insert a new Kerecis® Omega3 GraftGuide™ sheet into the wound if the previously applied sheet has been absorbed and is no longer visible.
3. Change the cover dressing as needed to maintain a moist, clean wound area.

As wound healing occurs, redness and swelling of wound edges will decrease and the level of exudate will be reduced. These are signs of wound healing and are often seen before epithelization is obvious. Make sure to always use an appropriate type of cover wound dressing to maintain a moist, clean wound area.

Should you suspect any adverse reaction from this product please report to: adversereactions@kerecis.com, leaving a phone number and Email address. Adverse reactions might also be subject to mandatory reporting to the authorities. Please submit 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 instructions for use



do not use if package is damaged



do not reuse



sterilized with ethylene oxide

MANUFACTURER

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