

INSTRUCTIONS FOR USE

Fish-Skin Graft for Burn Wound Management

INTENDED USE

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

- Partial and full thickness wounds
- Trauma wounds
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence).

CAUTION

Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

CONTRAINDICATIONS

The product is made from a fish source and should not be used in patients with a known allergy, other sensitivity to fish material.

PRECAUTIONS

- Discard unused portions of the product.
- Do not use after expiration date printed on the pouch.
- Sterile if package is unopened and undamaged.
- Do not use the product 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 complications occur, the product should be removed.

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

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

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.

Note: Handle the product using aseptic technique.

First Application

1. When applying the product 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 product from the pouch using aseptic technique.
3. Fit the product roughly to the size of the area to be covered. Pre-hydrate in sterile solution.
4. Apply product directly into the wound. The product should not overlap the wound edges.
5. More than one product may be necessary for complete coverage. Overlap product edges slightly to assure coverage of the entire wound.
6. To maintain direct product 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 management with the product, the wound should be checked regularly. Ensure that the cover dressing is maintaining a sufficiently moist wound environment and judge if a re-application of the product is needed.

1. Inspect wound every two days. The duration between inspections may be extended up to seven days as the healing progresses.
2. Insert a new product into the wound if the previously applied product 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. Makes sure to always use an appropriate cover wound dressing to maintain a moist, clean wound area.

ADVERSE EVENTS

Any adverse reaction or a serious incident suspected from this product should be reported to adversereactions@kerecis.com. Please include at least a contact phone number, e-mail address, and the device lot number and expiration date. Note that adverse reactions and serious incidents are subject to mandatory reporting to the competent authorities having jurisdiction.

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

MANUFACTURER

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KM-21-0111_05