Kerecis MariGen®

INSTRUCTIONS FOR USE

Fish skin graft for wound management

INTENDED USE

Kerecis MariGen® is indicated for the management of wounds including:

- Partial-thickness wounds (extending through the epidermis or into dermis)
- Full-thickness wounds (extending through the dermis to deeper tissues such as subcutaneous fat, muscle, tendon or bone)
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs-surgery, post- laser surgery, podiatric, wound dehiscence)
- Draining Wounds

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 as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

CONTRAINDICATIONS

The 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

- Remove necrotic tissue prior to application of the product
- Remove exudate and control bleeding prior to device application
- Do not reuse or re-sterilize
- Discard unused portions of product
- Do not use after printed expiration date
- 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 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 product should be stored in a clean, dry location at room temperature.

STERILIZATION

This product has been sterilized using ethylene oxide.

SUGGESTED INSTRUCTIONS FOR USE

The following 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. Always handle the product in an aseptic manner.

First Application

1. Site Preparation: When applying the product for the first time, clean the wound bed by removing necrotic tissue to obtain a fresh tissue surface. Irrigate to remove debris and exudates. The sheet can be applied to a lightly bleeding wound bed.
2. Aseptic Handling: Remove the product sheet from the pouch using aseptic technique.
3. Sizing and Hydration: Select a product size that allows for full coverage of the wound bed and vertical walls (if depth is present), plus a sufficient margin for affixation. Pre-hydrate in NaCl solution.
4. Application and Fixation: Apply the product directly into the wound, ensuring contact with the entire wound bed. Extend the product approximately 0.5 cm beyond the wound margins onto the periwound skin to facilitate secure therapeutic affixation and anchoring.

4.1 Multi-Sheet and Micro Application: More than one product may be necessary for complete coverage.

4.1.1 Standard Sheets: Apply multiple sheets in contact with one another, overlapping edges slightly to prevent gapping during patient movement.

4.1.2 MariGen Micro: When applying multiple micro pieces, apply in an imbricated (shingled) fashion. Overlap individual pieces by up to 20% to ensure a continuous biological scaffold and no granulation tissue should be visible in the base or along the margins of the wound.
Make sure to slightly overlap the wound edge to support a moist wound healing environment at the wound edge.

5. Secondary Dressing: Apply appropriate secondary, non-adherent wound dressing to maintain a moist wound environment and secure the graft in place using surgically affix (suture, staple, glue, steri-strips, tie over sutures or other affixation)

Follow-Up Applications

After starting treatment with the product, 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 the product is needed.

1. Inspect wound regularly. The duration between inspections may be extended up to seven days as healing progresses.
2. Insert 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. Make sure to use an appropriate type of cover wound dressing at all times to maintain a moist, clean wound area.

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. Note that adverse reactions may 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 INSTRUCTION FOR USE


DO NOT USE IF PACKAGING IS DAMAGED


SINGLE USE ONLY

STERILIZED USING ETHYLENE OXIDE

MANUFACTURER

KERECIS LIMITED
Eyrargata 2
400 Isafjordur
Iceland
Phone +354 419 8000
Email: info@kerecis.com
www.kerecis.com