Kerecis® Shield™

INSTRUCTIONS FOR USE

Fish Skin with silicon cover for Wound Management

INTENDED USE

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

- Partial and full thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds (abrasions, lacerations, partial thickness burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Draining wounds

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

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

PRECAUTIONS

- This product is designed for single use only. Do not reprocess, re-sterilize, or re-use
- Remove as much necrotic tissue as possible prior to application of the product
- Remove exudate and control bleeding prior to application 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
- Remove the silicone contact layer of the product when the fish skin underneath is fully integrated, typically after 7 days. Apply a new device as needed.

POTENTIAL COMPLICATIONS

The following complications are possible with the use of medical device materials. If any of these complications occur, and cannot be resolved, consider the removal of the product:

- Infection
- Inflammatory reaction (initial application of the device surgical graft materials may be associated with transient, mild, localized inflammation)
- Allergic reaction

SUGGESTED INSTRUCTION FOR USE

Required materials

- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Sterile gloves
- Rehydration fluid: at least 50 mL of room temperature sterile saline for each product

Note: Handle the product using aseptic technique

1. Make sure that the fish skin of the product roughly fits the wound size. Prepare the wound using standard surgical techniques.
2. Open pouch and rehydrate product either in pouch or submerge in sterile saline in a sterile dish.

Note: The rehydration fluid's temperature is not to exceed room temperature. The device requires approximately 60 seconds for rehydration. Device edges may curl up when rehy

3. Remove the protective film from the silicone contact layer.
4. If required, using aseptic technique, trim the device to fit the site and apply immediately.
5. Apply to wound using aseptic technique. Secure into place, ensuring that all layers are captured and avoiding excess tension.

Note: It is critical that the fish skin is in direct contact with the prepared wound bed. The fish skin layer must be placed facing towards the wound. Do not apply inside out.

6. Apply appropriate cover dressing for bolstering and drainage.
7. Discard any used portions of the medical device according to institutional guidelines for medical waste.

Removal

1. Loose silicone contact layer edges can be trimmed away.
2. Remove the silicone contact layer of the device when the fish skin device underneath is fully integrated, typically after 7 days.
3. To remove the silicone contact layer, gently pull, starting at one side.

Note: If bleeding occurs, or if the patient complains about excessive pain, postpone removal of device for 1-2 days. Forced removal may result in wound injury.

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

MANUFACTURER

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