Kerecis® SurgiClose®

INSTRUCTIONS FOR USE

Fish-Skin Graft for Surgical Use

INTENDED USE

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

- Partial and full thickness wounds,
- Pressure ulcers,
- Chronic vascular ulcers,
- Diabetic ulcers,
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears),
- Surgical wounds (donor site/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. 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® SurgiClose® is derived from a fish source and should not be used on patients with a known allergy or other sensitivity to fish material.

PRECAUTIONS

- Remove most necrotic tissue under the graft area prior to productapplication.
- Remove exudate and control bleeding prior to product application.
- Do not reuse or re-sterilize.
- Discard unused portions of the product.
- 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 (intial 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 USING Kerecis® SurgiClose®

Always handle Kerecis® SurgiClose® in an aseptic manner.

First Application

1. When applying Kerecis® SurgiClose® 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 product can be applied to a lightly bleeding wound bed.
2. Remove the Kerecis® SurgiClose® product from the pouch using aseptic technique.
3. Fit the product roughly to the size of the area to be covered. Prehydrate in sterile saline 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. Apply an appropriate secondary, non-adherent wound dressing to maintain a moist wound environment.

Follow-Up Applications

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

1. Inspect wound every two days. The duration between inspections may be extended up to seven days as healing progresses.
2. Insert new Kerecis® SurgiClose® 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 EVENTS

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 INSTRUCTION FOR USE


DO NOT USE IF PACKAGING IS DAMAGED


SINGLE USE ONLY

STERILIZED USING ETHYLENE OXIDE

MANUFACTURER

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