Dermistat™

A PRODUCT OF THE MYOWN SKIN™ FAMILY

INSTRUCTIONS FOR USE

Product Description
Dermistat™ is an ambient temperature autologous skin-cell graft for advanced wound coverage. It contains a bovine collagen matrix as a preservative. Each pouch contains a tube with the autologous skin-cell product, created exclusively for the identified patient.

Donor Screening
After legal authorization or consent is obtained, acquisition of the donor tissue is performed by a healthcare provider, in an aseptic manner. The skin tissue is processed by BioLab Sciences using aseptic techniques and in a controlled cleanroom environment to prevent contamination. No testing, medical or physical evaluations are performed to qualify donors for transplant, as Dermistat is an autologous cell graft.

Precautions
To reduce the risk of complications, the Dermistat graft should not be transplanted in the presence of necrotic tissue, exposed bone or ligaments or infected tissue. Although the tissue has been rinsed multiple times during processing, the presence of a minimal amount of the patient's microflora may remain in the tissue.

Adverse Reactions
Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to BioLab Sciences at QA@biolabsciences.net or by calling 602-830-5152.

Data Collection
On the day of application, please submit wound data at https://www.biolabsciences.net/dermistat or scan the QR code with your smartphone that will take you directly to the link.

Warnings

- Each graft is intended for single-patient use (the same donor patient), on a single occasion only.
- Use is limited to specific qualified health professionals.
- This graft was not terminally sterilized.
- Do not sterilize. Discard all open and unused portions of the product in a biohazard bin.
- The integrity of the external packaging must be verified, as well as confirmation that the patient's identity on the packaging correlates to the medical record.
- Do not use if the integrity has been compromised, the package is opened or damaged, or if mishandling has caused possible damage or contamination.
- Prior to the product use, check the expiration date on the label. Do not use expired product!
- **FOR AUTOLOGOUS USE ONLY. NOT INTENDED FOR A PATIENT OTHER THAN THE DONOR.**
- **NOT EVALUATED FOR INFECTIOUS SUBSTANCES.**

Dermistat is intended only for wound coverage and for single external and autologous use. It must be used on the patient from which the skin biopsy was taken.

Ancillary products provided for your convenience to be used for the graft application (Please note that the clinic can use its own instruments, and the following have been provided to you as a courtesy):

1. Porous Silicone Wound Dressing(s)
2. Sterile Gauze(s)
3. Sterile Spatula(s)
4. Adhesive wound closure strips

- All contents included in the delivery box must be opened using aseptic technique.

Dermistat Application Instructions:

1. Debride the wound as necessary. There should be no remaining non-viable tissue prior to application.
2. Open the Dermistat tube in a vertical position to prevent leaking and spilling of the product.
3. Use a sterile spatula to aseptically extract portions of the product from the tube and gently apply over the patient's wound. In case of a tunneled wound, place the Dermistat product into the tunnel, to fill the cavity.
4. Apply the Dermistat product over the entire wound, spreading evenly. (Applying the silicone dressing on the Dermistat can aid in spreading the product equally).
5. Cover the Dermistat treated wound with a porous silicone dressing and secure the dressing using steri-strips.
6. Cover the treated area, expecting drainage, with an absorbable dressing, as appropriate for the current wound.

Remember that AFTER the application of Dermistat:

- The wound shall be evaluated by the healthcare provider every 5-7 days, or as often as needed.
- During each evaluation, remove the *secondary* dressing, taking care not to disturb the *primary* (silicone) dressing.
- Examine the appearance of the primary dressing; ensure the dressing has remained in place and there are no signs of infection or peri-wound dermatitis.
- Clean the area, as needed.
- Re-dress the treated area with a secondary fixation dressing, as appropriate for the current wound.
- Only after day 21, the porous silicone dressing can be removed for complete evaluation of the wound.

Autologous Tissue Processed By: BioLab Sciences, Inc.
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