SkinTE™

Harvest Box Instructions for Use

An Autologous Homologous Skin Construct

Where Self Regenerates Self®

PolarityTE®

Description & Intended Use

SkinTE is a fully autologous (from the patient for the patient), homologous (performing same basic functions of skin tissue) skin product that should only be used by licensed medical professionals.

SkinTE is intended to be used by physicians or other appropriate healthcare providers for homologous uses of the skin and integumentary system. SkinTE may be used for the repair, replacement, reconstruction or supplementation of skin tissue. Each package of SkinTE contains fresh human tissue. It is intended for a single-use patient-specific application.

Regulatory Classification

SkinTE is a human cell, tissue, and cellular and tissue-based product (HCT/P) registered with the US Food and Drug Administration (FDA) as human skin tissue regulated solely under Section 361 of the Public Health Service Act. It is processed and marketed in accordance with FDA's requirements for banked human tissue intended for transplantation (21 CFR, Part 1271).

Donor Eligibility, Screening and Testing

SkinTE is for AUTOLOGOUS USE ONLY and does not require donor-eligibility determination (see 21 CFR 1271.45, 1271.90(a)(1)).

Harvested skin sent to PolarityTE to produce SkinTE will be tested during tissue processing for the presence of endotoxin and microorganisms.

Harvested skin sent to PolarityTE to produce SkinTE is NOT EVALUATED FOR INFECTIOUS SUBSTANCES.

Contraindications

SkinTE is contraindicated for use in any patient who is sensitive to gentamicin.

Warnings

SkinTE is DONATED HUMAN TISSUE for AUTOLOGOUS USE ONLY.

DO NOT USE provided sterile conical tube if the packaging appears to have been damaged, manipulated or opened.

DO NOT USE SkinTE Harvest Box if packaging or related contents, including the NanoCool cooling system, appear to have been damaged, manipulated or opened prior to harvest.

DO NOT USE SkinTE if the packaging, or related contents, appear to have been damaged, manipulated, torn or opened prior to deployment.

DO NOT USE SkinTE Harvest Box if the expiration date on the box has passed.

DO NOT USE SkinTE if the patient name and patient information do not match the information on the SkinTE label.

DO NOT USE SkinTE after the expiration date noted on the label.

DO NOT USE SkinTE to treat infections.

DO NOT FREEZE harvested skin or SkinTE.

DO NOT STERILIZE harvested skin or SkinTE.

Treat SkinTE and harvested skin as a potential biohazard. SkinTE has not been evaluated for infectious substances.

Proper aseptic handling is **MANDATORY** when harvesting skin for SkinTE and handling SkinTE. Failure to ensure proper aseptic technique may result in contamination of the tissue product and donor site.

SkinTE may contain trace amounts of gentamicin.

SkinTE, is intended for single-use application only. Unused or expired tissue product should be discarded according to local, state and federal regulations.

The packaging that contains the **SkinTE is NOT STERILE.** Transfer SkinTE from packaging aseptically. **DO NOT PLACE** either the product packaging or the syringe in the sterile field.

Precautions

Patients with multiple comorbidities, who are severely immunocompromised, who are in poor general health, or who have any condition that could compromise recipient site vascularity and wound healing should be carefully evaluated prior to using SkinTE. Such conditions may prevent successful outcomes or lead to suboptimal results.

Contamination of the harvested skin, donor site, and/or wound bed could result in local, regional, or systemic infection, partial or complete failure of the graft to take upon deployment, failure of skin to heal and/or regenerate, or other serious injuries or death.

Failure to follow instructions may lead to suboptimal outcomes, product failure and/or patient harm.

It is the responsibility of the end-user clinician to maintain SkinTE in appropriate storage conditions prior to use, and to maintain records for the purpose of tracing tissue post-transplantation. Patient tracking labels are provided for convenience.

cGTP manufacturing of the tissue, laboratory testing and careful screening of incoming specimen minimize the risks of tissue product contamination. As with any processed tissues, SkinTE cannot be guaranteed to be free of all pathogens. No long-term studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of the SkinTE construct. SkinTE manufacturing complies with cGTP. Please contact PolarityTE immediately if there are concerns or questions regarding issues of potential contamination.

Adverse Events

An "adverse reaction" for SkinTE, which is registered with the United States Food and Drug Administration as a human cells, tissues, and cellular and tissue-based product (HCT/P) regulated solely under Section 361 of the Public Health Service Act, is defined as a noxious and unintended response to any HCT/P for which there is a reasonable possibility that the HCT/P caused the response (21 CFR 1271.3(y)). Whenever an HCT/P recipient experiences an unintended response, there may be multiple possible causes. Nevertheless, if one of the reasonable possibilities is that the HCT/P caused the response, then this would meet the definition of "adverse reaction."

Adverse reactions potentially attributable to SkinTE must be reported promptly to PolarityTE. Adverse reactions can be reported to PolarityTE by calling 1-800-476-6057 or emailing MedicalAffairs@PolarityTE.com.

Storage

Store SkinTE Harvest Box at room temperature.

Instructions for Use of Harvest Box

1. Inspect and ensure the provided conical tube has not been tampered with or previously opened.
2. The provided shipping box has an integrated cooling lid (NanoCool®) and appropriate labels for return shipping to a PolarityTE cGTP manufacturing center.
3. Select harvest location based on medical provider's clinical knowledge, experience, and expertise.
4. Shave and prepare the harvest site using a standard sterile preparation solution and drape the surgical area in a manner consistent with standard clinical practice and techniques that ensure sterility.
5. Using a scalpel, excise a full-thickness skin harvest including epidermis, dermis, and subcutaneous fat. Do not defat or remove the fat from the harvested skin.
6. Place small amount of sterile saline solution (or other crystalloid) into container. Place harvested skin into the conical tube and add 40mL of sterile saline/crystalloid solution — **or more** to ensure that the skin specimen is **completely submerged**.
7. Secure lid onto the container in a fashion to prevent leaks during transport and label specimen container with patient identification label.
8. Close the donor site primarily in a standard clinical fashion.

NOTE: It is also preferable not to use previously scarred tissue for the harvest. Do not use thermal devices or electrocautery while harvesting the full-thickness skin graft because the heat generated may damage the living cells and tissues within the excised specimen. Surgical excision of tissue should be performed following standard sterile procedural guidelines.

Prepare Skin Harvest for Shipping

1. Place conical tube with harvested skin into the bag that contains an absorbent pad (provided in Harvest Box).
2. Place the first bag that contains the conical tube and absorbent pad into the second bag (provided, which does not contain an absorbent pad).
3. On the bottom side of the NanoCool lid there is a button that, once pressed, will begin the cooling process —press this button.
4. The NanoCool logo will turn blue as the system cools.
5. Place the conical tube containing the harvested skin into the shipping container. Place the NanoCool lid tightly back into the shipping box.

Complete Patient Information Form and Ship

1. Complete ALL sections of the Patient Information Form and add a patient identification label (patient hospital sticker) to the marked location on the form. Alternatively, patient information can be typed or printed in the designated area.
2. Place the completed Patient Information Form on top of the NanoCool lid within the shipping box.
3. Close the box. Ensure prefilled shipping label is present on the exterior surface of the box.
4. Secure the lid of the box with at least one tamper evident tape (multiple provided). PolarityTE's logistics team will arrange a pick up. Call 1-800-657-8957 with any questions.
5. Deliver box to shipping location within your facility.

Inquiries

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