# SkinTE™

# Deployment 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

Refrigerate upon receipt between 1–10˚C (34–50˚F)

The expiration date for SkinTE is recorded on the outer package. Do not use SkinTE after expiration date.

SkinTE cannot be returned.

## SkinTE Use

1. Inspect and ensure the provided packaged syringe has not been tampered with or previously opened.
2. Allow SkinTE to come to room temperature (approximately 20 to 25˚C) for smooth deployment.
3. Prepare patient wound bed according to clinical standards and guidelines for skin autografts.
4. Once the patient's wound bed is prepared per clinical guidelines, deploy the SkinTE graft onto the surface of the wound bed. Spread SkinTE evenly across the surface of the wound bed using the back of a pair of forceps (or similar).
5. Fixate SkinTE within the wound bed using a primary dressing (e.g. silicone) which maintains an appropriate level of moisture and is non-adherent. The primary dressing can be fenestrated or meshed.
6. Please COMPLETE THE EXCEPTIONAL RELEASE DOCUMENT included in the SkinTE Box indicating provider acknowledgment of the receipt of SkinTE in advance of final microbial results. This form can be sent securely to PolarityTE by fax at 1-800-287-2710 or mailed to 1960 S 4250 W, Salt Lake City, UT 84104.

## Inquiries

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