Please read the entire SkinTE™ Instructions for Use prior to using the PolarityTE™ autologous, homologous skin construct. If you have questions, please contact our customer service line or download the PolarityTE Real-Time Assistant (RTA) application for face-to-face consultation with an RTA Team member 24 hours a day.

Customer Service:
Tel: 1-800-560-3983
Email: CustomerService@PolarityTE.com

Medical Affairs:
Tel: 1-800-476-6057
Email: MedicalAffairs@PolarityTE.com

Clinical Operations:
Tel: 1-833-631-9954
Email: ClinicalOperations@PolarityTE.com

Corporate Inquiries:
Tel: 1-800-378-2694
Email: CorporateInquiries@PolarityTE.com

Real-Time Assistant (RTA) Team:
Tel: 1-800-743-2302
Fax: 1-800-287-2710
Email: RTA@PolarityTE.com

Reimbursement Team:
Tel: 1-800-284-0262
Email: Reimbursement@PolarityTE.com
DESCRIPTION & INTENDED USE

SkinTE is a fully autologous (from the patient for the patient), homologous (performing same basic functions of skin tissue) cutaneous construct 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. Patients who have suffered from an event, disease, process or who have an acquired defect that has resulted in the functional loss or absence of the skin and integumentary system can use SkinTE as an adjunct and/or in place of split-thickness skin grafting, full-thickness grafting, temporizing skin coverage and/or skin substitute products. Each package of SkinTE is intended for autologous use that is patient-specific and for a single application.

PROCESS

Utilization of SkinTE requires (3) steps:
1. Harvest a Full-Thickness Skin Graft from an Unaffected Area
2. PolarityTE cGTP Processing and Construct Development
3. Deploy the SkinTE Tissue Product into a Prepared Wound Bed

REGULATORY CLASSIFICATION

SkinTE is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation and is processed and marketed in accordance with the FDA's requirements for banked human tissue (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)).

A specimen that is sent to PolarityTE will be tested during and/or after processing for the presence of endotoxin and microorganisms.

Due to limitations in technology, state of the art testing cannot completely eliminate the risk that human source material will transmit disease.

Embracing Complex Simplicity™
WARNINGS

SkinTE is for AUTLOGOUS USE ONLY.

Aseptic technique is MANDATORY at all times when harvesting skin as well as during the deployment of SkinTE.

ONLY USE occlusive, non-meshed, non-adherent, non-absorbent primary dressings over the SkinTE treated wound bed (e.g., silicone).

DO NOT USE SkinTE if the patient identification number (PIN) and the patient name on the product does not match the patient identification number and name for the specific patient.

DO NOT USE antibiotics listed on the SkinTE packaging in patients who are allergic, may be hypersensitive, or have had a previous reaction to them.

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

DO NOT USE SkinTE if there is questionable contamination of the materials.

DO NOT USE SkinTE if the temperature tracker depicts a violation of the temperature boundaries (outside of 1–10°C).

DO NOT USE SkinTE if the expiration date on tissue product has passed.

DO NOT USE SkinTE if the tissue product has leaked outside of its intended carriers.

DO NOT RE-USE SkinTE, as the product is packaged for deployment and is intended for single-use application. Cryopreservation: SkinTE active units can be cryopreserved for later autologous use following current good tissue practices (cGTP) processing, but this request must be communicated to and confirmed by PolarityTE prior to processing.

DO NOT FREEZE SkinTE, it should be refrigerated upon receipt between 1–10°C (34–50°F) if not intending to use the SkinTE construct the same day as arrival.

DO NOT STERILIZE SkinTE, as the product contains living autologous, homologous tissue for a specific indicated patient. Sterilization of the tissue product will result in death of the cells and tissues and prevent appropriate biological function.

WARNING: 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 national standards for tissue processing and monitors for contamination following clinical deployment. Please contact PolarityTE immediately if there are concerns or questions regarding issues of potential contamination.
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.

Whenever clinical circumstances require use in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures must be taken. If there are signs of compromise of the tamper evident seal, please contact Clinical Operations immediately to determine if SkinTE can be transplanted or must be discarded. Unused or expired tissue product should be discarded according to local, state, federal and institutional regulations.

Proper aseptic procedural and/or surgical handling is mandatory when using SkinTE. Failure to ensure proper aseptic technique may result in contamination of the tissue product and wound bed. Contamination of the tissue product and/or wound bed could result in local, regional, or systemic infection, partial or complete failure of graft take, healing, and/or regeneration, serious injury, and/or death.

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

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 the Medical Affairs Division by calling 1-800-476-6057 or emailing MedicalAffairs@PolarityTE.com.

STORAGE

Refrigerate upon receipt between 1–10°C (34–50°F) if not intending to use the SkinTE construct the same day as arrival.

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

The expiration date printed on the labeling is valid as long as the SkinTE is stored properly and remains unopened.

HOW SUPPLIED

SkinTE is an autologous, homologous product that arrives in a sterile syringe. The SkinTE deployment box includes standard disposable supplies to facilitate deployment of the tissue product into a viable wound bed. Refer to product instructions prior to use. Providers are not required to use any supplies in the deployment box if alternatives are preferred based on their own clinical judgment.
GENERAL OVERVIEW OF SKIN HARVEST PROCESS

An overview of the process is located online (https://www.PolarityTE.com/IFU) or on the RTA application. An instructional animation of the process can be viewed at https://pte.cool/SkinTE_IFUa.

1. Shave and prepare a full-thickness skin excisional harvest site in a manner that is consistent with current clinical techniques.

2. Once harvested, place the excised full-thickness graft in the sterile container and add the provided solutions.

3. Close the sterile specimen container tightly and place container into the two transport barrier bags which contain an absorbent pad.

4. Place the packaged specimen container into the included FedEx®–NanoCool® shipping box and activate the NanoCool cooling system by pressing the button on the underside of the NanoCool lid. It should feel cool within 1 minute, and the NanoCool logo will turn blue.

5. Do not use the NanoCool lid if it does not become cool. Instead, use the NanoCool lid from another box and contact PolarityTE Clinical Operations for a replacement by calling 1-833-631-9954 or emailing ClinicalOperations@PolarityTE.com.

6. Activate the temperature tracking strips on the bottom of the NanoCool lid by bending and pulling the tab on each strip.

7. 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.

8. Use the Form Submission feature of the RTA application to take a photo of the completed Patient Information Form to submit to PolarityTE in a HIPAA-compliant manner (see page 8 for instructions).

9. If you do not have access to the RTA application, please submit the form by emailing RTA@PolarityTE.com or fax to 1-800-287-2710. If you have further questions, please contact the RTA Team by calling 1-800-743-2302.

10. Place the completed Patient Information Form into the underside of the lid of the FedEx–NanoCool shipping box.

11. Close the FedEx–NanoCool shipping box and ensure that the prefilled shipping label is present on the exterior surface of the box.

12. Secure the lid of the box with at least one tamper evident tape (multiple provided) and contact the FedEx carrier number on the shipping label (1-800-GO-FEDEX) to confirm today’s pickup.
QUICK REFERENCE OVERVIEW FOR HARVEST BOX

1. Open the All-In-One Harvest Box and Ensure All Contents are Intact.

2. Obtain Full-Thickness Skin Graft with Fat.

3. Place Specimen in Sterile Cup, Add Crystalloid Solution and Add Antibiotic (if patient not allergic).

4. Place Specimen, Activate the NanoCool® Lid and Start the Temperature Tracking System.

5. Place NanoCool® Lid, Complete the Patient/Defect Information and Add Patient Sticker as Indicated.

6. Fill to 40 cc.

7. Bag #1

8. Bag #2

9. Add 0.5 cc gentamicin (if not allergic).

10. Complete ALL sections of the form here, then submit form with RTA (instructions on other side).
QUICK REFERENCE GUIDE FOR FORM SUBMISSION USING RTA APPLICATION

1. Log in to RTA account
2. Click Services tab
3. Click Form Submission button
4. Center the form in viewport and take photo
5. If photo preview is acceptable, then select Use Photo
6. Send confirmation will appear once form is uploaded
USE OF ALL-IN-ONE HARVEST BOX

1. Obtain the PolarityTE SkinTE Harvest Box.
2. Open the all-in-one Harvest Box and remove the contents.
3. Inspect and ensure that contents have not been tampered with or previously opened.
4. Procedural materials are sterile and should be used under clinical standard operating procedures.
5. The enclosed FedEx–NanoCool shipping box has an integrated NanoCool lid and appropriate labels for return shipping to a PolarityTE cGTP center.

OBTAIN FULL-THICKNESS SKIN GRAFT SPECIMEN(S)

1. Shave and prepare the harvest site using a standard sterile preparation solution and drape the surgical area in the standard fashion to ensure sterility.
2. Inject local anesthetic at the harvest site in a standard clinical fashion.

Harvest Locations for Full-Thickness Skin Graft

These sites are only suggestions. The provider should select harvest location based on their clinical knowledge, experience, and expertise.
3. Using a scalpel, excise a full-thickness specimen including epidermis, dermis, and subcutaneous fat. Do not defat or remove the fat from the specimen.

4. Place the specimen into the sterile specimen container and add 40 mL of crystalloid solution and 0.5 cc (40 mg/mL) of gentamicin antibiotic. Ensure that the patient has no allergy or sensitivity to the specific antibiotic included in the kit. If patient is sensitive to the supplied antibiotic, the provider should clean the specimen thoroughly and refrain from adding the antibiotic as instructed.

5. Close the specimen donor site primarily in a standard clinical fashion.

NOTE: When excising the full-thickness skin for downstream SkinTE applications, it is best to use a sharp scalpel and include all layers of the skin from epidermis to subcutaneous fat. 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.

NOTE: Place the excised skin into the sterile specimen container with the crystalloid solution and gentamicin antibiotic. Secure the lid onto the container in order to prevent leak during transport.
PREPARE SPECIMEN FOR BARRIER SHIPPING

1. Place container with specimen into the first bag containing the absorbent pad. Excess air should be removed prior to sealing the bag.

2. Place this bag into the second bag, and again, remove excess air and seal.

3. Once the specimen is in the two provided bags as instructed, remove the NanoCool lid from the top of the FedEx–NanoCool shipping box.

4. Place the bags/container into the payload compartment of the FedEx–NanoCool shipping box.

ACTIVATE COOLING SYSTEM AND TEMPERATURE TRACKING SYSTEM

1. On the bottom side of the NanoCool lid there is a button that, once pressed, will induce an endothermic reaction—press this button.

2. The lid will begin to feel cool (NanoCool logo will turn blue as the system cools).

3. Ensure there are two temperature tail strips on the bottom side of the NanoCool lid and activate the temperature tail by bending and pulling the tab on each strip.

4. Place the NanoCool lid tightly back into the return FedEx–NanoCool shipping box, which should already have the packaged specimen and an activated temperature tracking system.

NOTE: Shipping of specimen requires multiple barriers of protection from spills, as depicted in the figures above. Activation of the NanoCool lid permits a temperature-controlled transport environment.
ADD PATIENT DOCUMENT 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. Use the Form Submission feature of the RTA application to take a photo of the completed Patient Information Form to submit to PolarityTE in a HIPAA-compliant manner (see page 8 for instructions).

3. If you do not have access to the RTA application, please submit the form by emailing RTA@PolarityTE.com or fax to 1-800-287-2710. If you have further questions, please contact the RTA Team by calling 1-800-743-2302.

4. Place the completed Patient Information Form into the underside of the lid of the FedEx–NanoCool shipping box.

5. Close the FedEx–NanoCool shipping box and ensure that the prefilled shipping label is present on the exterior surface of the box.

6. Secure the lid of the box with at least one tamper evident tape (multiple provided) and contact the FedEx carrier number on the shipping label (1-800-GO-FEDEX) to confirm today’s pickup.

7. Ship box via FedEx carrier or courier and maintain a copy of the tracking number.

8. Updates on transport will be provided by PolarityTE and can also be viewed by using the PolarityTE RTA application 24 hours a day.
USE OF ALL-IN-ONE DEPLOYMENT BOX

The SkinTE Deployment Box:

1. Upon receipt of the SkinTE deployment box, ensure the following:
   a. The tamper seal is in place and there are no signs of tampering, contamination or tissue product leakage.
   b. Identify the tissue product label and ensure that the expiration date has not passed and the PIN correlates with the intended patient.
   c. Refrigerate upon receipt between 1–10°C (34–50°F) if the tissue product is not going to be used the same day.

2. Once the product is ready to use, open the SkinTE deployment box. The tissue product is enclosed in an insulated cooling pack system with (3) additional sequential barrier bags. Validate that the specimen PIN located on the FedEx label and internal sticker match the patient identity.

3. Each bag is sterile on the inside. Remove the bagged product and allow someone with sterile gloves to reach into bag 3 to remove bag 2.
4. Once the patient’s wound bed is prepared per clinical guidelines, deploy the SkinTE graft onto the surface of the wound bed. Spread the full-thickness construct evenly across the surface of the wound bed using the back of a pair of forceps (or similar).

5. Secure the full-thickness autologous skin construct using an occlusive, non-meshed, non-adherent, non-absorbent primary dressing (e.g. silicone) placed directly over the SkinTE treated wound bed. This dressing should be cut to fit with 1 cm overlap around the edges of the wound bed. Recommended dressings have been included in the Deployment Box if needed. Failure to use a non-adherent, occlusive, non-absorbent dressing may prevent successful outcomes or lead to suboptimal results.

6. If the patient is amenable, secure the primary dressing with staples or suture. Otherwise, please secure the dressing using clinical judgment (e.g. Steri-Strip™).

7. After the dressing is secured, please ensure that the edges of the dressing are caulked with Bacitracin (or similar) to create an effective seal and ensure a moist wound environment. If the wound is highly exudative and the dressing is effectively sealed based on the provider’s clinical judgment, Bacitracin may not be necessary.

8. Place a secondary dressing of Xeroform® (or similar) to bolster the primary dressing. For highly exudative wounds, the provider can use a foam dressing (e.g. DermaFoam™, Mepilex®) over the secured primary dressing (e.g. silicone) to
help control excess moisture outside the wound bed. Please ensure the primary dressing is secure and NOT fenestrated before placing the secondary dressing.

9. Alternatively, providers can deploy negative-pressure wound therapy as a secondary dressing over the secured primary dressing. Please ensure the foam does not directly contact the wound bed or surrounding native skin. Please secure the foam with standard adhesive dressing.

10. Please COMPLETE THE EXCEPTIONAL RELEASE DOCUMENT included in the Deployment Box indicating provider acknowledgment of the receipt of SkinTE in advance of final microbial results. This form can be sent securely using the Form Submission feature of the RTA app (instructions on page 8), or it can be emailed to RTA@PolarityTE.com, faxed to PolarityTE at 1-800-287-2710 or mailed to 1960 S 4250 W, Salt Lake City, UT 84104.

NOTE: Following placement of the secondary dressing the provider can use his or her clinical judgment to secure dressings (e.g. multi-layer dressing, compression dressing, etc.). Dressing changes, showering, range of motion exercises and monitoring follow in the same manner that would be used for application of a skin graft. Failure to ensure a moist wound environment early can prevent successful outcomes or lead to suboptimal results.

THE POLARITYTE 24 HOUR REAL-TIME ASSISTANT (RTA)

PolarityTE has created the PolarityTE Real-Time Assistant (RTA) application to enhance customer service and communication. Features of the RTA application include:

- Call, video chat, text, email.
- Share images and videos.
- One-touch document transfer and delivery.
- Track shipments for specific patients and receive automatic reminders.

All by using the simple, free and HIPAA-compliant PolarityTE Real-Time Assistant (RTA) application available on iOS, Android, and the web (https://RTA.PolarityTE.com).
INQUIRIES

PolarityTE, Inc.
1960 S 4250 W
Salt Lake City, Utah 84104

Customer Service:
Tel: 1-800-560-3983
Email: CustomerService@PolarityTE.com

Medical Affairs:
Tel: 1-800-476-6057
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