Follow Up Protocol

Dressing Changes
The secondary dressing should be changed 3 to 7 days after the initial application depending on the wound type. Important: primary interface dressing should be left undisturbed for 5 to 7 days.

At the 5-7 day follow-up, remove the secondary dressing and carefully remove the primary interface dressing for wound inspection and evaluation. Avoid potentially stripping TheraSkin from the wound.

Given the various wound etiologies and the fact that TheraSkin provides a robust extracellular matrix (ECM) and living cell therapy, the wound bed may have many different appearances after 5-7 days of initial TheraSkin application (Wounds A-C).

Do not disturb or debride the wound bed. If necessary, gently clean the wound with a light saline wash (avoid disrupting the TheraSkin/wound interface). Re-dress the wound appropriately with a non-stick primary interface dressing and secondary dressing depending on the wound type (See Application Protocol 7-9).

Subsequent dressing changes can occur once every 3-7 days depending on the wound type and the physician’s discretion.

Reapplication of TheraSkin
Reapplication of TheraSkin is recommended every two (2) weeks. The epidermal layer will slough off within the first 2-7 days. After two (2) weeks some intact TheraSkin ECM may be present.

When reapplying TheraSkin, debride the periphery of the wound bed and gently clean the wound bed with a light saline wash to remove any slough or non-adherent tissue (top left). Be sure not to disrupt any adherent TheraSkin ECM.

Apply the new TheraSkin graft over the remaining TheraSkin ECM (bottom left) and follow the usual protocol of fixation and dressings as described in Sections 1-4. Soluble Systems recommends that clinicians be trained in the use of TheraSkin before using it in clinical practice.

Cautions
• Do not use TheraSkin after expiration date.
• Follow all instructions.
• Ensure dermis (white) side is placed on wound site.
• Use aseptic techniques at all times.
• Keep TheraSkin frozen until implantation prep.
• If multiple TheraSkin units are being used, they may be thawed and soaked together.
• Do not allow the graft to dry. Keep graft completely submerged in the sterile solution until application.

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Photos courtesy of
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A clinician must always rely in their professional judgment when deciding to use a particular product or surgical technique. Soluble Systems does not dispense medical advice. Clinicians should be trained in any product or surgical technique before use. The information presented is intended to demonstrate broadly used techniques. A clinician should refer to the package insert and instructions for use before using TheraSkin.
Preparation Protocol
Application Protocol
Follow Up Protocol

REAL Human Skin
HEALING REAL Human Wounds
Preparation Protocol

1. Open the LifeNet Health box to expose the inner thermal container.
2. Lift lid of the thermal container and remove the TheraSkin envelope from the dry ice.
3. Open the envelope and retrieve the pouch from within.
4. Fill the two sterile basins with enough sterile solution to allow TheraSkin graft to be completely submerged.
5. Open the inner peel pouch and place TheraSkin in the aseptic field utilizing established aseptic technique. (Alternately, use optional Thaw and Soak Procedure.)
6. Place Theraskin in the first sterile basin. Allow TheraSkin to thaw for 2 minutes. Do not allow the solution to exceed 42ºC as it may compromise the cellular viability of the living cells in the TheraSkin unit.
7. Remove TheraSkin from the first basin and place TheraSkin into the second basin for 2 minutes. Do not allow the solution to exceed 42ºC per above.
8. Take TheraSkin out of the second basin, unfold and carefully remove the mesh from both sides of the graft prior to applying and securing the graft to the patient’s wound.

Optional Thaw & Soak Procedure

A 6. *Pour enough Sterile Solution into the inner pouch to completely submerge TheraSkin. Allow TheraSkin to thaw for 2 minutes.
A 7. *Pour out and replace the Sterile Solution in the pouch. Completely submerge the graft. Soak again for 2 minutes.
A 8. *Take TheraSkin out of pouch and carefully remove the mesh from both sides of graft prior to applying and securing to the patient’s wound.

Materials Needed

- Scissors
- Room Temperature Solution (Sterile Saline, Physiosol or Lactated Ringers may be used)
- 2 Sterile Containers (Optionally, the inner pouch may be used)
- Sterile Forceps or Pickups
- Sterile Gloves

Do not allow solution to exceed 42ºC (see number 6 above).
**Application Protocol**

**Materials Needed**
- **Use aseptic techniques at all time**
- Sterile gloves
- Sterile forceps
- Choose fixation (see 2 below)
- Primary Interface Dressing (eg. TheraGauze+FN®)
- Secondary dressing(s)

**Pre-Application**
- Follow TheraSkin Preparation Protocol to prepare TheraSkin prior to application.
- Prepare the wound bed by removing all necrotic tissue, residual blood or exudate, and cytotoxic agents. Ensure there is no apparent infection present.
- Verify patient arrival before opening TheraSkin container.

**Placement of TheraSkin:** Apply TheraSkin over the wound bed using aseptic technique (Fig.1). The dermis side of the graft should be face down and in contact with the wound bed. The dermis side is white, opaque and shiny while the Epidermis side is pigmented side of the graft with a duller appearance (Fig.2).

When applying TheraSkin it is beneficial to have as much of the dermal layer of TheraSkin in contact with the wound bed. By gently pulling the graft (Fig.3), with moistened thumbs, one can minimize the meshed areas assuring maximum dermal contact without doubling the layer of Theraskin.

**Fixation of TheraSkin:** If possible, trim away excess TheraSkin leaving a 5-10mm rim of overlapping TheraSkin around the wound (Fig.4).

Secure TheraSkin using sutures (Fig.4), staples, steri-strips (Fig.5), Hypafix® tape or Dermabond® as needed.

For large wound and/or multiple gafts, consider placing a suture in the center of the wound or creating a bolster dressing (Fig.6) to ensure that TheraSkin stays in direct contact with wound bed.

**Dressing(s) Application:** A non-stick interface dressing is recommended as the primary dressing for TheraSkin (i.e. TheraGauze+FN®, Mepitel®, Adaptic Touch®, Wound Veil®). Remove dressing from the sterile package and place dressing over the wound (Fig.7). Non-cytotoxic antimicrobials may also be applied at this time.

Apply an appropriate secondary dressing(s) and cover as determined by the wound type. (Fig. 8,9)