

Preparation Protocol

** Verify that the patient has arrived before opening TheraSkin shipping container.**

Materials That May Be Needed for Preparation

- Scissors
- 2,000 ml Sterile solution (Sterile Saline, Physiosol or Lactated Ringer's may be used)
- 2 Sterile Basins
- Sterile Forceps
- Sterile Gloves

Contents of LifeNet Health Shipper

- TheraSkin / SWAI Instructions for Use sheet
- TheraSkin / SWAI Tissue Tracker card
- SWAI Thanks To You card
- Dry Ice
- Thermal container with TheraSkin
- TheraGauze™ + FN (cover dressing for TheraSkin)

CAUTION

- **Do not use TheraSkin after the expiration date indicated on the labeled unit carton.**
- **Follow all instructions to ensure the dermis, white side, is placed on the wound site.**
- **Use aseptic techniques at all times.**
- **Keep TheraSkin frozen until preparing for implantation. Thaw each piece of TheraSkin individually.**

Preparation for Use

- Prepare the wound bed per protocol by removing all necrotic tissue, residual blood or exudate, and cytotoxic agents. Ensure there is no infection present.
- Visually inspect the outer packaging to ensure that it is intact and that its integrity has not been breached. If the outer packaging is damaged, the enclosed TheraSkin may be contaminated and should not be used.



- 1. Non Sterile Team Member:** Open the SWAI box to expose the inner thermal container.



- 6. Sterile Team Member:** Remove TheraSkin from the plastic pouch and place it into the first sterile basin.



- 2. Non Sterile Team Member:** Lift the lid of the thermal container and remove the TheraSkin envelope from the dry ice.



- 7. Sterile Team Member:** Allow the TheraSkin to thaw completely. It will be readily pliable when thawed, at which time you may unfold the mesh pack. Do not exceed 42°C, as it may damage the TheraSkin.



- 3. Non Sterile Team Member:** Open the TheraSkin envelope and remove the inner foil pouch.



- 8. Sterile Team Member:** Fill second basin with 500-1000 ml room temperature sterile saline/water solution, not exceeding 42°C. Remove TheraSkin mesh pack from first basin and carefully lift TheraSkin away from mesh lining.



- 4. Non Sterile Team Member:** Inspect inner pouch for damage. Use scissors to open the foil pouch and remove the plastic pouch containing the TheraSkin.



- 9. Sterile Team Member:** Place TheraSkin only (without mesh lining) in the second basin and soak for a minimum of 5 minutes. TheraSkin is now ready for application. Keep TheraSkin completely submerged in sterile saline water solution until it is time for application. Do not allow TheraSkin to dry before application.



- 5. Non Sterile Team Member:** Pour 500-1000ml of room temperature sterile saline/water solution into the first sterile basin. Do not exceed 42°C (108°F). Continuing to use clean handling techniques, peel open the plastic pouch and present to the Sterile Team Member.

Application Protocol

Follow TheraSkin Preparation Protocol to prepare TheraSkin prior to application.

TheraSkin Application

- Prepare the wound bed per protocol by removing all necrotic tissue, residual blood or exudate, and cytotoxic agents. Ensure there is no infection present.

Materials that may be needed for application

- Sterile gloves
- Sterile forceps
- Choose fixation (see 2 below)
- Cover dressing (TheraGauze +FN)
- Outer dressing(s)

CAUTION

- Do not use TheraSkin after the expiration date indicated on the labeled unit.
- Follow all instructions in preparation protocol to ensure delivery of growth factors to the patients wound.
- Use aseptic techniques at all times.



Figure 1

1. Placement

Remove TheraSkin from the basin using sterile pick-up.

Apply TheraSkin over the wound bed using aseptic techniques, with the epidermis (pigmented side) away from the wound bed (facing up) and the dermis (collagen, white side) in contact with the wound bed (facing down).

When applying TheraSkin, it is beneficial to have as much TheraSkin in contact with the wound bed as possible. The edges of the TheraSkin can be gently pushed toward the middle of the wound to minimize open mesh areas, without doubling the layers of the TheraSkin.



Figure 2: Fixation with sutures using a "baseball" stitch.



Figure 3: Fixation with steri-strips.

2. Fixation

Leave a 2-5 mm rim of overlapping TheraSkin around the wound wherever possible, trim away the excess TheraSkin.

For large wounds, consider placing a suture in the center of the wound, to ensure that the TheraSkin stays in close contact with the wound bed.

Secure TheraSkin in place, using sutures (FIGURE 2), staples, steri-strips (FIGURE 3) or Dermabond as needed.

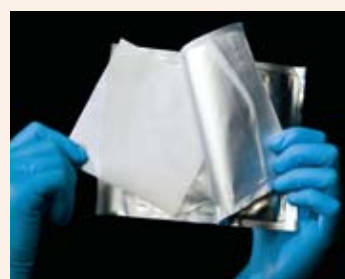


Figure 4



Figure 5



Figure 6



Figure 7



Figure 8

3. Top Dressing Application

TheraGauze+FN is recommended as the cover dressing for TheraSkin. Remove TheraGauze+FN from foil package. (FIGURE 4) Place TheraGauze+FN dressing over the wound.

If wound is dry and desiccation may be a factor; a second piece of TheraGauze+FN can be layered on top of TheraSkin. (FIGURE 5) For a small wound, TheraGauze+FN may be folded over to obtain two layers.

Place a gauze pad on top of TheraGauze+FN, and secure dressings in place with gauze wrap. (FIGURE 6) This dressing should be left in place for 5-7 days to maximize effectiveness.

4. Dressing Change

If TheraGauze+FN is dry in appearance during the first dressing change, rehydrate by applying sterile solution to the TheraGauze+FN and wait 1-3 minutes before attempting to remove. (FIGURE 7)

If/once the TheraGauze+FN is moist, grasp the edge of the dressing and slowly lift from the skin and wound site. Inspect TheraSkin incorporation into the wound bed. (FIGURE 8)

Re-dress wound if necessary.