



DermGEN™ is provided in a hydrated state and does not require rehydration.

** DermGEN™ is provided with a **basement membrane surface that repels blood** and a **dermal surface that absorbs blood**. To identify the surfaces, a small “V” notch is provided that indicates the basement membrane on the upper surface when the “V” notch is located in the upper right corner of the graft. When applied to the wound bed in a grafting procedure, **the dermal side should be placed against the wound bed**, with the basement membrane side facing up.

DermGEN™ is secured in a sterile inner pouch. **Only the inside of the inner pouch is to be considered sterile.** An outer pouch and final outer packaging is used for shipping to protect the package from damage.

DIRECTIONS FOR APPLICATION:

- 1. It is imperative** that the Diabetic Foot Ulcer (DFU) wound site be properly prepared to ensure the best possible result with DermGEN™. Proper sharp or surgical debridement is recommended to remove all dry, slough and necrotic tissue from the wound. The debrided wound should have edges made up of living tissue and have a good bleeding base. Even if a good granulation base is present, the surface of the granulation tissue should be scraped to promote a bleeding base. (Figure 1)
- 2.** Peel back the outer package (Non-sterile).
- 3.** Remove DermGEN™ from the inner pouch (Figure 2.) and using sterile gloves/forceps place in a sterile container such as a kidney dish. (Figure 3)
- 4.** DermGEN™ may be aseptically trimmed to fit the dimensions of the application site. **It is imperative** that DermGEN™ be applied to the wound site with the **dermal side** (blood absorbing side) in contact with the bleeding wound (**see note above). DermGEN™ can then be removed and the blood stain pattern on the dermal side used as a guide to trim and shape DermGEN™ for the wound. The tissue can be shaped with scissors or scalpel allowing for an approximate 3-5 mm border beyond the wound edges. (Figure 4) At this point DermGEN™ is ready for application on the wound site.

Figure 1. DFU before (left) and after (right) sharp debridement

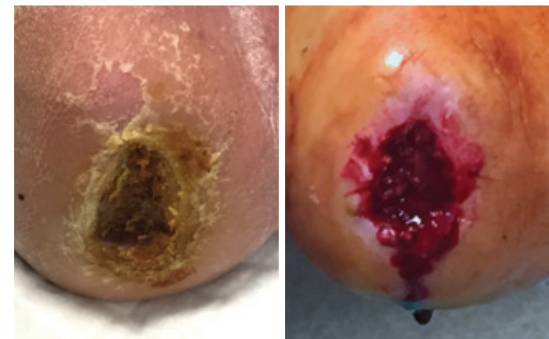


Figure 2.



Figure 3.





5. DermGEN™ normally does not require securing with sutures or staples to the surgical site if utilized properly. In some applications, minimal securing of DermGEN™ to the surgical site may be required due to unavoidable movement in the area treated. Place the properly trimmed DermGEN™ with the dermal side in contact with the bleeding wound bed. With the dermal side in contact with the bleeding wound bed, you should notice that DermGEN™ is “sucked” down into the wound and blood will appear at the exposed surface of through natural pores in the product. (Figure 5). If DermGEN™ does not adhere securely to the wound, the wrong surface (basement membrane side) of the product may be in contact with the wound and should be corrected to **dermal side**.

6. The wound can now be dressed with a dressing that possess a non-adherent contact layer and a moisture controlling foam layer(s). **Moisture control is important to prevent maceration of DermGEN™.** It is recommended that dry gauze then be wrapped around the dressing to add slight pressure to the wound site in order to prevent movement of DermGEN™ during the first 1-2 weeks of healing. See Figures 6 and 7 for examples of proper dressing applications.

7. Off-loading of the wound site is critical to the healing performance of DermGEN™. Appropriate offloading using devices such as orthotic insoles, offloading boot, total contact cast, or removable boot are to be used. Best practices on off-loading techniques should be consulted.

8. Weekly wound dressing changes are recommended until healed. After 1-2 weeks, once DermGEN™ is well incorporated within the wound, dressings may be changed to a type that is suited for a more “dry” wound type.

9. DermGEN™ works best when left alone once placed onto the wound. After placement, DermGEN™ should not be touched and no further debridement, washing, or cleansing of the wound area is required nor is desired. Only wound dressing changes should be performed until the wound is healed. For examples of typical and desired look of wounds healing with DermGEN™, refer to our handout “What to Expect During Healing with DermGEN™: Diabetic Foot Ulcers”.

10. If signs of infection become present after DermGEN™ is applied, antibiotic ointments may be applied onto the graft and wound. Antimicrobial dressings—such as silver (Ag) containing products—can also be used to treat the infection.

Figure 4.



Figure 5.





NOTE:

- Once the inner pouch containing DermGEN™ has been opened and exposed, the tissue shall be transplanted within 30 minutes, otherwise, it should be discarded.
- Only one patient is to be treated with each graft. Pieces from one graft cannot be used to treat another patient.

EXAMPLES OF DIFFERENT DRESSINGS APPLICATIONS USED WITH DERMGEN™



Figure 6. Dressing of a DermGEN™ treated DFU on the plantar surface of the foot.



Figure 7. Dressing of a DermGEN™ treated DFU on the heel.