

# Dermagraft®

## Human Fibroblast-Derived Dermal Substitute

### Essential Prescribing Information

Numbers in parentheses ( ) refer to sections in the Directions for Use of the product labeling.

**Device Description:** Dermagraft is a cryopreserved human fibroblast-derived dermal substitute. (1)

**Intended Use/Indications:** Dermagraft is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than 6 weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. Dermagraft should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot. (2)

### Contraindications:

- Dermagraft is contraindicated for use in ulcers that have signs of clinical infection or in ulcers with sinus tracts
- Dermagraft is contraindicated in patients with known hypersensitivity to bovine products, as it may contain trace amounts of bovine proteins from the manufacturing medium and storage solution (3)

**Warnings:** None (4)

### Precautions:

**Caution:** The product must remain frozen at  $-75^{\circ}\text{C} \pm 10^{\circ}\text{C}$  continuously until ready for use.

**Caution:** Do not use any topical agents, cytotoxic cleansing solutions, or medications (e.g., lotions, ointments, creams, or gels) on an ulcer being treated with Dermagraft as such preparations may cause reduced viability of Dermagraft.

**Caution:** Do not reuse, refreeze, or sterilize the product or its container.

**Caution:** Do not use the product if there is evidence of container damage or if the date and time stamped on the shipping box has expired.

**Caution:** Dermagraft is packaged with a saline-based cryoprotectant that contains 10% DMSO (Dimethylsulfoxide) and bovine serum. Skin and eye contact with this packaging solution should be avoided.

**Caution:** Dermagraft has not been studied in patients receiving greater than 8 device applications.

**Caution:** Dermagraft has not been studied in patients with wounds that extend into the tendon, muscle, joint capsule, or bone. Dermagraft has not been studied in children under the age of 18 years, in pregnant women, in patients with ulcers over a Charcot deformity of the mid-foot, or in patients receiving corticosteroids or immunosuppressive or cytotoxic agents.

**Caution:** To ensure the delivery of metabolically active, living cells to the patient's wound, do not hold Dermagraft at room temperature for more than 30 minutes. After 30 minutes, the product should be discarded and a new piece thawed and prepared consistent with Preparation for Use instructions.

**Caution:** The persistence of Dermagraft in the wound and the safety of this device in diabetic foot ulcer patients beyond 6 months has not been evaluated. Testing has not revealed a tumorigenic potential for cells contained in the device. However, the long-term response to these cells is unknown.

**Caution:** Always thaw and rinse product according to the Preparation for Use instructions to ensure the delivery of metabolically active, living cells to the patient's wound.

**Caution:** Do not use Dermagraft after the expiration date indicated on the labeled unit carton. (5)

**Adverse Events:** In clinical studies conducted to date, the overall incidence of reported adverse events was approximately the same for patients who received Dermagraft compared to those who received the Control treatment. (6)

**Maintaining Device Effectiveness:** Dermagraft must be stored continuously at  $-75^{\circ}\text{C} \pm 10^{\circ}\text{C}$ . Dermagraft must be thawed and rinsed according to the Preparation for Use instructions. After the initial application of Dermagraft, subsequent sharp debridement of the ulcer should continue as necessary. Additional wound preparation should minimize disruption or removal of previously implanted Dermagraft. (13)

**Patient Counseling Information:** After implantation of Dermagraft, patients should be instructed not to disturb the ulcer site for approximately 72 hours (3 days). After this time period, the patient, or caregiver, should perform the first dressing change. The frequency of additional dressing changes should be determined by the treating physician. Patients should be given detailed instructions on proper wound care so they can manage dressing changes between visits. Compliance with off weight-bearing instructions should be emphasized. Patients should be advised that they are expected to return for follow-up treatments on a routine basis, until the ulcer heals or until they are discharged from treatment. Patients should be instructed to contact their physician, if at any time they experience pain or discomfort at the ulcer site or if they notice redness, swelling, or discharge around/from the ulcer. (8)

**How Supplied:** Dermagraft is supplied frozen in a clear bag containing one piece of approximately 2 in x 3 in (5 cm x 7.5 cm) for a single use application. The clear bag is enclosed in a foil pouch and labeled unit carton.

**Caution:** Dermagraft is limited to single-use application. Do not reuse, refreeze, or sterilize the product or its container.

Dermagraft is manufactured using sterile components and is grown under aseptic conditions. Prior to release for use, each lot of Dermagraft must pass USP Sterility (14-day), endotoxin, and mycoplasma tests. In addition, each lot meets release specifications for collagen content, DNA, and cell viability.

Dermagraft is packaged with a saline-based cryoprotectant. This solution is supplemented with 10% DMSO (Dimethylsulfoxide) and bovine serum to facilitate long-term frozen storage of the product. Refer to the step-wise thawing and rinsing procedures to ensure delivery of a metabolically active product to a wound bed. (9)

**Customer Assistance:** For product orders, technical support, product questions, reimbursement information, or to report any adverse reactions or complications, please call the following number which is operative 24 hours a day:

**Advanced BioHealing  
Customer Service**  
1-877-Dermagraft  
1-877-337-6247



**Caution:** Federal (U.S.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Manufactured and distributed by:  
Advanced BioHealing, Inc.  
10933 N. Torrey Pines Road, Suite 200  
La Jolla, CA 92037

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