

Dermagraft® Product Fact Sheet

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Dermagraft is a cryopreserved human fibroblast-derived dermal substitute; it is composed of fibroblasts, extracellular matrix, and a bioresorbable scaffold.

Dermagraft is manufactured from human fibroblast cells derived from newborn foreskin tissue. During the manufacturing process, the human fibroblasts are seeded onto a bioresorbable polyglactin mesh scaffold. The fibroblasts proliferate to fill the interstices of this scaffold and secrete human dermal collagen, matrix proteins, growth factors, and cytokines to create a three-dimensional human dermal substitute containing metabolically active, living cells.

Dermagraft does not contain macrophages, lymphocytes, blood vessels, or hair follicles.

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 who have adequate blood supply to the involved foot. 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.

Dermagraft is supplied frozen in a clear bag containing one piece of approximately 2" x 3" for a single-use application.

Dermagraft Overview

- **Description** Human fibroblast-derived dermal substitute
- **Composition** Composed of human fibroblasts, extracellular matrix, and bioresorbable scaffold; does not contain macrophages, lymphocytes, blood vessels, or hair follicles
- **Cultured** In vitro
- **Mode of Action** Re-epithelialization—assists in the restoration of the dermal bed, allowing wounds to heal (when implanted into adequately prepared diabetic foot ulcers)
- **Primary Indication** For use in the treatment of full-thickness diabetic foot ulcers
- **Product Number** 11045
- **NDC Number** 08541-0001-01



Dermagraft is manufactured by Advanced BioHealing, of La Jolla, CA. Dermagraft is a registered trademark of Advanced BioHealing, Inc. Caution: Federal [US] law restricts this device to sale by or on the order of a physician or properly licensed practitioner.



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