Smart Solutions for Serious Wounds™

Omnigraft™

An advanced bilayer dermal regeneration matrix FDA approved for the treatment of diabetic foot ulcers.
Introducing Integra® Omnigraft™ Dermal Regenerative Matrix - The Only FDA Approved Product that Regenerates Dermal Tissue

Based on DRM technology, Omnigraft is an advanced bilayer dermal regeneration matrix indicated for the treatment of diabetic foot ulcers.

Silicone Layer
- Temporary epidermal layer
- Provides immediate coverage to protect the wound
- Typically removed between 14 and 21 days

Collagen/Chondroitin-6-Sulfate Matrix
- Dermal replacement layer
- Bioengineered scaffold manufactured to promote dermal regeneration
- Designed with a controlled porosity and defined degradation rate

Supported by Over Two Decades of Proven Clinical Excellence

For over 20 years medical professionals have trusted Integra’s Dermal Regeneration Matrix (DRM) Technology to treat the most challenging wounds. The DRM Technology has been evaluated in four clinical trials involving 444 patients and has a long history of safe, effective use treating patients with third degree burns, scar reconstruction, and acute and chronic wounds in the operating room. Now this powerful, proven solution is available in the outpatient setting to treat patients with diabetic foot ulcers.
Shifting the Paradigm of Diabetic Foot Ulcer Care

- Unparalleled History of Clinical Safety & Efficacy
- 3.3x More Likely to Achieve Complete Wound Closure at 12 Weeks
- 50% Faster Wound Closure Rate
- Reduced Number of Applications
- Improved Quality of Life Metrics
- Strong Health Economics
Continuing a Heritage of Clinical Excellence

FOUNDER Study Demonstrates Omnigraft™ is Safe and Effective for the Treatment of Chronic, Hard-to-Heal DFUs

The FOOT Uler NEW DErmal Rerplacement (FOUNDER) Study was a multi-center, randomized, controlled, parallel group clinical trial conducted under an Investigational Device Exemption. The trial randomized 307 patients at 32 sites.

Higher Incidence of Wound Closure\(^1\)

- The odds of complete wound closure at 12 weeks were 3.3x higher than standard of care.\(^2\)

Faster Wound Closure\(^1\)

- Treatment with Omnigraft increased the wound closure rate by 50% vs. standard of care.
- Time to complete wound closure was reduced by 5 weeks vs. standard of care.

Healing Progression with Omnigraft™

Debrided  
Application  
2 Weeks After Application  
4 Weeks After Application  
3 Month Follow-up After Wound Closure

Individual results may vary.
Reduced Number of Applications

- Of those patients that healed, 92% healed with two or fewer applications.
- Of those patients that healed, 72% healed in one application.

Improved Quality of Life Metrics

- Patients who were treated with Omnigraft experienced a significant improvement in physical functioning and decreased bodily pain as defined by the SF-36 Health Survey.
- Patients treated with Omnigraft experienced improvements in activities of daily living (e.g., walking, climbing stairs, carrying groceries) and less pain, which may decrease reliance on caregivers.

Designed for Outpatient Setting

- Smart package design allows for easy handling and application.
- Room temperature storage.

Providing Clear Benefits to You and Your Patients

With reduced number of applications, faster healing rates and fewer adverse events, Omnigraft may help to reduce total cost of treatment.
**Description:** Integra® Omnigraft Dermal Regeneration Matrix (Omnigraft) is an advanced bilayer matrix for dermal regeneration. The dermal replacement layer consists of a porous, three-dimensional matrix, comprised of bovine collagen and chondroitin-6-sulfate (C6S) that is designed with a controlled porosity and defined degradation rate. The temporary epidermal layer is made of a thin polysiloxane (silicone) layer to provide immediate wound coverage and control moisture loss from the wound.

**Indications:** Integra® Omnigraft Dermal Regeneration Matrix is indicated for use in the treatment of partial and full-thickness neuropathic diabetic foot ulcers that are greater than six weeks in duration, with no capsule, tendon or bone exposed, when used in conjunction with standard diabetic ulcer care.

**Contraindications:** Omnigraft should not be used in patients with known sensitivity to bovine collagen or chondroitin materials. Omnigraft should not be used on clinically diagnosed infected wounds.

**Warnings:** Debridement or excision must be done thoroughly to remove any remaining necrotic tissue that may delay healing or cause infection. Omnigraft will not incorporate into a wound bed of nonviable tissue. Leaving any remaining nonviable tissue may create an environment for bacterial growth.

**Precautions:** The following complications are possible with the use of wound treatments. The product should be removed if any of these conditions occur: infection, chronic inflammation (initial application of wound products may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain, or swelling. There have been no clinical studies evaluating Omnigraft in pregnant women. Caution should be exercised before using Omnigraft in pregnant women. Such use should occur only when the anticipated benefit clearly outweighs the risk.

**Adverse Events:** All adverse events that were reported in the study evaluating Omnigraft for the treatment of diabetic foot ulcers at a frequency of ≥ 1% in either cohort are presented in Table 1 in the Instructions for Use. This table includes adverse events that were both attributed to and not attributed to treatment. The most common adverse events experienced by patients treated with Omnigraft were: wound infection (15%), new, worsening, or recurring wounds (14%), pain around the wound (9%), infection beyond the wound (either cellulitis or osteomyelitis, 14%); swelling (5%); nausea (5%); worsening health condition (4%). These adverse events occurred in a similar or lower percentage of patients treated with Omnigraft compared to patients treated with standard wound care alone.

Omnigraft is also marketed as Integra® Dermal Regeneration Template and has been studied extensively in life-threatening thermal injuries and scar contracture reconstruction. Refer to the Integra® Dermal Regeneration Template package insert for complete adverse event information.


2. Primary endpoint measured wound closure at 16 weeks.

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**Ordering Information**

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For more information, visit [www.omnigraft.com](http://www.omnigraft.com) or call 1-877-444-1122