

Front Cover:

Integra® Omnigraft™ Dermal Regeneration Matrix - Smart Solutions for Serious Wounds.

Patient Guide to Healing Diabetic Foot Ulcers

Inner Pages:

Diabetic foot ulcers are serious wounds and need special care. It can be frustrating to have a diabetic foot ulcer. This guide will provide you with information about your treatment with Integra® Omnigraft™ Dermal Regeneration Matrix (Omnigraft).

Omnigraft is designed to treat diabetic wounds. When used with standard wound care (cleaning the wound, covering the wound, keeping weight off the wound), more patients treated with Omnigraft experienced complete wound healing compared to patients treated with standard wound care alone.

This guide will help you understand what to expect during treatment with Omnigraft. It will also tell you how to care for your wound. Your dedication to a wound care routine is vital to successful wound healing.

This Guide will Cover:

- Glossary2
- Product Description2
- Uses3
- Safety3
- Omnigraft Application.....4
- Post Application Care.....7
- Your Role in Wound Healing.....8
- When to Call your Health Care Provider.....9
- Clinical Study9
- Questions or Comments?.....11

Glossary

Bovine: from or relating to cows or cattle.

Cellulitis: a common, potentially serious bacterial skin infection.

Collagen: part of the tissue that helps keep the skin firm.

Chondroitin: a natural protein derived from shark tissue.

Chronic: lasting for a long time or constantly recurring.

Debridement (Debrided): to clean out dead or callused areas of an ulcer.

Diabetic Foot Ulcer: a poorly healing wound that commonly occurs below the ankle in an individual with diabetes.

Offloading: the process of removing pressure or weight from an area, commonly the foot.

Osteomyelitis: an infection in a bone.

Sepsis: a bacterial infection in the bloodstream or body tissues.

Silicone: an artificial material that is often used in medical applications.

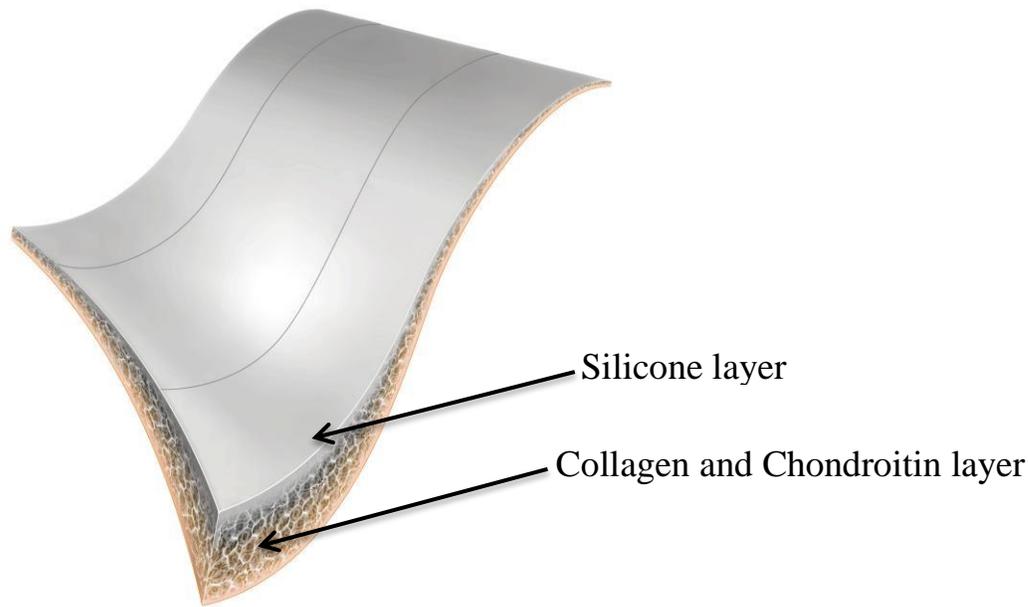
Sterilized: to make free from bacteria.

Sutures: medical grade stitches used by health care providers to close wounds or apply product.

Product Description

What is Omnigraft?

Omnigraft (also known as Integra[®] Dermal Regeneration Template) is a two-layered skin repair product. It is designed to help heal chronic diabetic foot ulcers. The bottom layer is made of bovine collagen and chondroitin. The top layer is a thin silicone layer. Omnigraft is processed and sterilized so that it can be used in humans.



How Does Omnigraft Work?

- The collagen and chondroitin layer of Omnigraft helps heal the damaged skin of your diabetic foot ulcer.
- The silicone layer, a thin protective layer, provides immediate wound coverage. The silicone layer also helps keep your wound moist.
- Eventually, your health care provider will remove the silicone layer and your body replaces the collagen and chondroitin layer with your own natural tissue.

Uses

Omnigraft is indicated for use in the treatment of partial and full-thickness diabetic foot ulcers that are greater than six weeks in duration. Omnigraft should be used along with standard diabetic wound care (cleaning the wound, covering the wound, and keeping weight off the wound).

Omnigraft, sold under the name Integra[®] Dermal Regeneration Template, is also approved for: treatment of life-threatening deep partial and full-thickness burn injuries where insufficient autograft is available; repair of scars that occur during the healing of burn injuries when donor sites are not available; and for treatment of partial and full-thickness diabetic foot ulcers that are greater than six weeks in duration.

Safety

Before Omnigraft is applied, discuss with your health care provider any allergies you may have. You should also discuss your ability to adhere to a wound care routine. Your health care provider will use this information to see if Omnigraft should be used.

Warning

Tell your health care provider:

- If you ever had a reaction to bovine (cow) or chondroitin (shark) materials, since serious allergic reactions may occur with use of Omnigraft.
- If you experience any redness, swelling, discharge, blistering, warmth, pain around your wound, fever, chills, or nausea. These symptoms may be signs of an infection. Omnigraft should not be used on infected wounds since they may not heal or may get worse.

Precautions to Consider

Once Omnigraft is applied, avoid getting your wound and dressings wet. If your wound becomes wet, Omnigraft may come off. This may require a new application. This may also delay wound healing. Getting the wound area wet may cause infection.

Placing weight on your wound may delay wound healing. It may also cause the Omnigraft to come off. This may require a new Omnigraft application.

Omnigraft has not been tested in pregnant women. If you are concerned, please ask your health care provider about the possible risks and benefits of using Omnigraft in pregnant women.

Possible Side Effects

Some patients whose diabetic foot ulcers were treated with Omnigraft experienced: a wound infection (23 of 154 patients, 15%); new, worsening, or recurring wounds (22 of 154 patients, 14%); pain around the wound (14 of 154 patients, 9%); an infection beyond the wound (either cellulitis or osteomyelitis, which occurred in 21 of 154 patients, 14%); swelling (7 of 154 patients, 5%), nausea (7 of 154 patients, 5%); and/or a worsening health condition (6 of 154 patients, 4%).

Omnigraft, sold under the name Integra® Dermal Regeneration Template, has also been used worldwide for over 20 years in many types of wounds including life-threatening burns. Adverse events (infection, poor take/graft loss, allergic reaction, events related to non-healing or poor quality healing) have been reported in approximately 6 out of 10,000 patients. These types of complications may be experienced with use of Omnigraft.

Omnigraft Application

- Your health care provider will clean and often debride your wound with a scalpel before Omnigraft application to remove dead tissue.
- Your health care provider will lay the Omnigraft directly over your clean wound, making sure it has good contact with the wound. Staples or sutures will be used to secure Omnigraft to provide stronger adherence to the wound.
- Once secured to the wound, Omnigraft will be covered with a dressing. Your health care provider may offer an offloading device (special shoe) to help protect your wound as it heals.

- Dressings will be changed by your health care provider. Your health care provider may schedule weekly visits to perform the dressing changes. Omnigraft will stay in place and must not be disturbed between and during these dressing changes.



Ulcer before debridement



Ulcer after debridement



Application of Omnigraft



Omnigraft is covered with a dressing



1 week after Omnigraft application



3 weeks after Omnigraft application

Post Application Care

- After the Omnigraft product has been applied, stay off of your ulcer. Always use your health care provider's prescribed offloading device.
- Keep your wound and the entire area surrounding your wound dry at all times. When bathing, keep your wound and dressings away from water.
- Omnigraft should not be removed or disturbed.
- Your health care provider will monitor the progress of wound healing during the dressing changes. When your health care provider feels Omnigraft is beginning to rebuild your skin, he or she will gently remove the silicone layer. This typically occurs two to three weeks after application. Staples or sutures will also be removed at this time.
- At the time of silicone removal, the collagen and chondroitin layer of Omnigraft will continue to heal your wound and rebuild your skin.
- Depending on the progress of your wound, your health care provider may recommend a second application of Omnigraft.
- Continue to use your offloading shoe and follow your health care provider's instructions for wound care.



Silicone layer and staples removed at 4 weeks after Omnigraft application



Healed at 6 weeks after Omnigraft application (individual results may vary)



19 weeks after Omnigraft application

Your Role in Wound Healing

Remember, Omnigraft can treat the ulcer but it is not a cure for diabetes, which is the underlying cause of these ulcers. Healing a diabetic foot ulcer takes an entire team of people – especially you!

Take control of your healing. To help your wound heal and stay healed, follow these important guidelines:

- **Remember to Offload:** Stay off your ulcer. Always use your health care provider's prescribed offloading device. Placing weight on your wound may delay or prevent healing. This may also cause Omnigraft to detach from the wound.
- **Keep wound dry:** Avoid getting your wound and dressings wet. When bathing, keep your wound and dressings away from water. Getting the wound area wet can lead to infection. It may also cause the Omnigraft to detach from the wound.
- **Manage your diabetes:** Control your blood sugar level.
- **Nutrition:** Maintain a healthy, balanced diet. Avoid smoking.

- **Stay on top of doctor visits:** Return to your health care provider for follow-up visits and follow your health care provider's instructions carefully.
- **Be aware of possible infection:** Call your health care provider if you experience redness, swelling, discharge, blistering, warmth, pain around your wound, an allergic reaction, fever, chills, nausea, or any other abnormal health problems.

When to Call your Health Care Provider

Call your health care provider:

- If Omnigraft becomes detached or if your dressings become wet.
- If you experience any unusual health problems such as redness, swelling, discharge, blistering, warmth, pain around your wound, an allergic reaction, fever, chills, nausea, or unusual odor of your wound.

Clinical Study

A study was done to evaluate the safety and efficacy of Omnigraft compared to standard wound care alone for the treatment of neuropathic diabetic foot ulcers over 6 weeks old. A total of 307 patients (232 males and 75 females) participated in the study. The age of patients (average 56.5 years) in the study ranged from 28 to 82 years. To be included in the study, patients had to have a diabetic foot ulcer on either surface of the foot: 154 patients were treated with Omnigraft; 153 patients were treated with standard wound care.

Before receiving either treatment, patients' wounds were debrided. If a patient was treated with Omnigraft, it was applied once in the beginning of the study. Omnigraft may have been reapplied at the doctor's direction. The wounds of all 307 patients were covered with the same secondary dressings. All patients received an offloading shoe or boot.

The results of the study show that patients treated with Omnigraft experienced:

- A greater chance of healing. 51% of patients treated with Omnigraft had healed ulcers compared to 32% of patients treated with standard wound care alone. 57 of 92 patients (62%) who received only a single Omnigraft application experienced healing of their wound.
- Faster wound closure. On average, ulcers treated with Omnigraft healed 5 weeks faster than ulcers treated with standard wound care alone.
- Improved quality of life, on average:
 - Reduction in the intensity of pain and/or reduced limitations of normal work activities due to pain.
 - Improvement in daily activities such as walking, climbing stairs, bending, bathing, carrying groceries, and moderate to vigorous activities.
- Less infections overall

The most common health problems (adverse events) experienced by patients treated with Omnigraft were: wound infection (23 of 154 patients, 15%); new, worsening, or recurring wounds (22 of 154 patients, 14%); pain around the wound (14 of 154 patients, 9%); infection beyond the wound (either cellulitis or osteomyelitis, which occurred in 21 of 154 patients, 14%); swelling (7 of 154 patients, 5%); nausea (7 of 154 patients, 5%); worsening health condition (6 of 154 patients, 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.

Some adverse events were considered serious. The most common serious adverse events were in the category of infections (27 of 154 patients, 18%) and included the following types of infections: wound infection (8 of 154 patients, 5%); infection beyond the wound (either cellulitis or osteomyelitis, which occurred in 14 of 154 patients, 9%). These serious infections occurred in a similar or lower percentage of patients treated with Omnigraft compared to patients treated standard wound care alone.

Not all of the adverse events listed above were determined to be related to Omnigraft treatment. The adverse events that were determined to be related to the Omnigraft treatment are: wound infection (5 of 154 patients, 3%); infection beyond the wound (either sepsis or cellulitis, which occurred in 2 of 154 patients, 1%); redness at the application location (1 of 154 patients, less than 1%); skin abrasion (1 of 154 patients, less than 1%). The sepsis, cellulitis, and two wound infections were also considered serious.

A similar percentage of healed ulcers reopened, regardless of treatment.

Questions or Comments?

If you have questions about your treatment, please contact your health care provider.

To learn more about Omnigraft Dermal Regeneration Matrix, visit www.omnigraft.com or call 1-800-XXX-XXXX Monday – Friday, 8:30 a.m. – 7:00 p.m. EST.

This information does not replace instructions received from your health care provider. Always follow your health care provider's directions.

References

Driver, V. R., Lavery, L. A., Reyzelman, A. M., Dutra, T. G., Dove, C. R., Kotsis, S. V., Kim, H. M. and Chung, K. C. (2015), A clinical trial of Integra Template for diabetic foot ulcer treatment. *Wound Repair and Regeneration*.

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