

Follow your doctor’s or nurse’s advice on how to prevent your ulcer from coming back



Ask your doctor for more information about **DIABETIC FOOT ULCERS** and Dermagraft.

www.organogenesis.com
1.888.HEAL.2.DAY
(1.888.432.5232)

Please see the enclosed Dermagraft Directions For Use for complete prescribing information and contraindications, or visit www.organogenesis.com

References: **1.** Singh et al. *J Amer Med Assoc.* 2005;293:217-28. **2.** Lavery et al. *Diabetes Care.* 2003;26:1435-38. **3.** Ramsey et al. *Diabetes Care.* 1999;22:382-87. **4.** Dermagraft Directions for Use. Organogenesis Inc. 2015. **5.** Marston et al. *Diabetes Care.* 2003;26(6):1701-05.

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Empowering Healing



Important Safety Information

Indication

Dermagraft is indicated for use in the treatment of diabetic foot ulcers (also known as sores) greater than 6 weeks duration that extend through the full thickness of the skin, 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.

Contraindication

Dermagraft should not be used on ulcers that have signs of clinical infection, sinus tracts (narrow passages extending from the wound), or exposed tendon, muscle, joint capsule, or bone. Dermagraft should not be used in patients with known allergy to bovine (cow) products, as it may contain small amounts of bovine proteins from the manufacturing and storage solutions.

Common Adverse Events

In a study of patients with diabetic foot ulcers treated with Dermagraft, the most common adverse events included infection, accidental injury, skin blister, flu syndrome (e.g., fever, chills, flushing), need for additional surgery involving the ulcer, occurrence or worsening of other ulcers, and peripheral edema (swelling of the extremities).

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If at any time you notice infection or experience pain or discomfort at the diabetic foot ulcer site, contact your healthcare provider right away.

WELCOME TO
DERMAGRAFT®



Treating Your Diabetic Foot Ulcer

Q What is a diabetic foot ulcer?

A Diabetic foot ulcers (DFUs), one of the most common complications of diabetes, are chronic wounds that can develop on the feet of people with diabetes. Among people with diabetes, up to 25% experience a DFU in their lifetime¹, and approximately 3.4%^{2,3} develop a DFU each year. If not properly treated, DFUs may lead to other serious complications.

Q What is Dermagraft?

A Dermagraft is a “skin substitute” that is placed on your ulcer to cover it and to help it heal. It is manufactured in an aseptic environment. It also contains a temporary mesh fabric that will eventually dissolve and go away by itself. Dermagraft is used to treat foot ulcers that have been present for at least 6 weeks in patients with diabetes. It is used together with standard methods of treating DFUs, including cleaning and preparing the ulcer, applying cover dressings to hold it in place, and wearing special shoes to take the pressure off the ulcer (called “offloading”).

Q Why has my healthcare provider prescribed Dermagraft?

A Your healthcare provider has chosen Dermagraft specifically for you because your DFU has not healed. Dermagraft has been shown to heal DFUs in significantly more patients than standard treatment alone^{4,5}. A DFU can be a serious problem if not properly treated and healed.



Q What common adverse events have occurred in patients treated with Dermagraft?

A In a study of patients with DFUs treated with Dermagraft, the most common adverse events included:

Infection	Need for additional surgery involving the DFU
Accidental injury	Occurrence or worsening of other DFUs
Skin blister	Peripheral edema (swelling of the extremities)
Flu syndrome (e.g., fever, chills, flushing)	

Please contact your healthcare provider if you have any concerns while being treated with Dermagraft.

Q Who should not receive Dermagraft?

A Dermagraft should not be used on foot ulcers that have signs of clinical infection, sinus tracts (narrow passages extending from the wound), or exposed tendon, muscle, joint capsule, or bone. Dermagraft should not be used in patients with known allergy to bovine (cow) products, as it may contain small amounts of bovine proteins from the manufacturing and storage solutions.

Q What should I expect before receiving Dermagraft?

A Before treating your DFU, your healthcare provider may perform a physical examination and explain the types of tests and treatments you will be receiving. You may also receive an X-ray to make sure that the bones in your feet are not infected. A tissue sample may be collected from the ulcer and tested for the presence of bacteria in order to determine if an antibiotic is necessary before treatment with Dermagraft.



Applying Dermagraft

Q What will happen during my clinic visits?

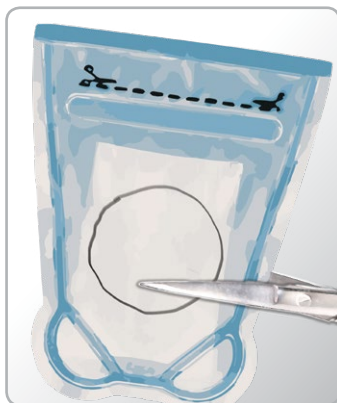
A Your healthcare provider will apply Dermagraft to your DFU on a regular schedule, typically once a week. The duration of treatment varies, but Dermagraft may be applied on your ulcer weekly for up to 8 applications over 12 weeks. It is very important that you keep each of your scheduled appointments to ensure that your healthcare provider can monitor your progress.

Your healthcare provider will explain that Dermagraft should not cause pain or irritation when in place. However, debridement—the removal of diseased and dead tissue from the ulcer site—can cause some discomfort.

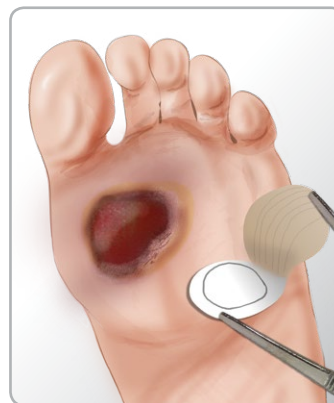
Your healthcare provider will perform a short series of steps at each visit:



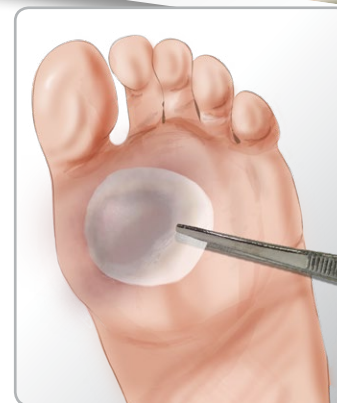
1. Your healthcare provider may debride the ulcer and then clean it with a sterile saline solution. This is to make sure there is a clean surface for application of Dermagraft.



2. Dermagraft will be thawed, rinsed, and cut to the size of your ulcer.



3. Dermagraft will be placed on your ulcer and covered with another dressing to keep it clean and protected.



4. Once Dermagraft and the protective dressing are in place, you will be instructed on how to care for your ulcer, including how to change the dressings when appropriate, and how to keep pressure off your ulcer to help it heal.



Tips Following Dermagraft Application

Here are several ways you can help your diabetic foot ulcer heal:



MANAGE YOUR DRESSINGS.

Do not disturb your ulcer or dressings for at least 72 hours (three days) after the application of Dermagraft. After this, dressing changes are at the discretion and direction of your healthcare provider.

Your healthcare provider will determine the frequency of additional dressing changes and provide detailed instructions on proper wound care.



RETURN FOR YOUR DERMAGRAFT APPOINTMENTS.

You are expected to return for follow-up treatments on a routine basis until the ulcer heals or until you are discharged from treatment.



KEEP WEIGHT OFF THE ULCER.

Offloading relieves pressure around the ulcer. Increased pressure or stepping on an unprotected foot can slow the healing process.



WATCH FOR INFECTION.

Check your feet daily for changes in the ulcer. Signs of infection may include:

- Swollen, red, or red-streaked skin near the ulcer
- Discharge, drainage, foul odor, warmth, and/or pain around the ulcer
- A rise in temperature/fever
- An unexpected increase in blood sugar



AVOID TOPICAL AGENTS.

Refrain from applying any topical agents (i.e. creams or lotions) or medications on the ulcer.



COVER YOUR ULCER WHEN BATHING.

Keep the ulcer and dressing dry, as instructed by your healthcare provider.



CONTACT YOUR HEALTHCARE PROVIDER.

If at any time you notice infection or experience pain or discomfort at the DFU site, contact your healthcare provider right away.



WEAR YOUR OFFLOADING DEVICE.

Wear the treatment shoe or offloading device if prescribed by your healthcare provider. Do not go barefoot, even when inside.

If your walking aid is not comfortable to use, or you are having problems with it, let your healthcare provider know immediately.



USE PROVIDED WALKING AID.

If your healthcare provider has asked you to use a walking aid such as a cane, crutches, walker, or wheelchair, be sure to use this aid according to the instructions. These devices may help with balance, especially if you are not used to wearing a treatment shoe.



WEAR PROPER FOOTWEAR.

If a shoe insert becomes worn out, let your healthcare provider know immediately.

If your treatment shoe or offloading device does not seem to fit properly, let your healthcare provider know immediately. Report any new areas of redness or irritation to your healthcare provider. Small adjustments may be needed to ensure optimal healing and to prevent new ulcers from developing.



CHECK THE CONDITION OF YOUR SOCKS.

Wear clean, dry, properly fitting socks with your treatment shoe. Do not wear socks or stockings that are torn, have been mended, or have seams in them.



Discuss the Following with Your Healthcare Provider:

Related medical issues

If you have a medical problem that you think may be related to the treatment of your ulcer, talk to your healthcare provider.

Dermagraft has not been studied in patients under 18 years of age, in ulcers over a Charcot deformity of the midfoot, or in patients receiving corticosteroids or immunosuppressive or cytotoxic agents.

Pregnancy

Dermagraft has not been studied in pregnant women. Before treatment, make sure your healthcare provider knows if you are pregnant or if you may become pregnant.

Other medicines

Because some medicines may interfere with the healing of your ulcer, it is especially important that your healthcare provider knows if you are taking any other medications.