

Integra®

PriMatrix®

Dermal Repair Scaffold

PATIENT
INFORMATION

Questions? Contact us:

Clinician:

Phone #:

In case of emergency, dial 9-1-1

INTEGRA®
LIMIT UNCERTAINTY



Your Path to Recovery

Your health care provider has chosen to use PriMatrix® Dermal Repair Scaffold (PriMatrix) to help manage your wound. This brochure will provide you with information about PriMatrix. It will also tell you how to care for your wound after PriMatrix is applied. Your dedication to a wound care routine is critical for successful wound management.

Table of Contents

Glossary	2
Product Description	3
Uses	3
Safety	3
PriMatrix Application	4
Post-Application Care.....	5
Clinical Studies	6
Questions or Comments	6

Glossary

Bovine: from or relating to cows or cattle

Chronic: lasting for a long time or constantly recurring

Collagen: part of the tissue that is important in the structure of skin

Compression Dressing: special type of bandage made with elastic type material that is wrapped around the lower leg to reduce swelling and increase blood flow

Infection: contamination of a wound, organ, or person caused by germs that have entered the body

Inflammation: a reaction to injury or infection that causes redness, swelling, warmth, and/or pain

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

Sterilized: to make free from bacteria

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

What is PriMatrix?

PriMatrix is a unique skin repair product designed for the management of a broad range of wound types. PriMatrix is made from **bovine** skin. The **bovine** skin contains **collagen** which is an important component of skin. PriMatrix is processed and **sterilized** so that it can be used in humans.

Uses

PriMatrix is indicated for the management of wounds that include:

- Partial and full thickness wounds
- Pressure, diabetic, and venous ulcers
- Second-degree burns
- Surgical wounds – donor site/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence
- Trauma wounds – abrasions, lacerations, and skin tears
- Tunneled/undermined wounds
- Draining wounds

Safety

Warnings

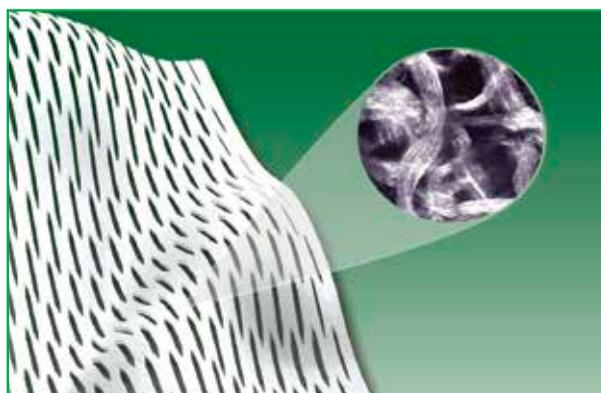
Tell your health care provider:

- If you have ever had a reaction to **collagen** or **bovine** materials, since serious allergic reactions may occur with use of PriMatrix.
- 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**. Infected wounds not properly managed may get worse. PriMatrix should be used with caution on infected wounds.

Possible Side Effects

The following complications are possible with use of PriMatrix. If you experience any of these symptoms, contact your health care provider immediately.

- **Infection**
- **Chronic inflammation**
- Allergic reaction
- Excessive redness, pain, swelling, or blistering



PriMatrix contains an abundance of Type III collagen, a collagen that plays an important role in developing and healing skin.

PriMatrix Application

Preparing the Wound

To prepare your wound for the application of PriMatrix, your health care provider will begin by cleaning the wound and by removing any non-living tissue.



Applying PriMatrix

Once the wound has been prepared, your health care provider will apply and secure PriMatrix directly to the wound. He or she may use adhesive strips, staples, or **sutures** to make sure PriMatrix stays in place.



Wound Dressings

Your health care provider will place several layers of dressings on top of PriMatrix, which will help protect the wound.



Off-Loading (Diabetic Foot Ulcers)

Your health care provider may put you in specialized footwear such as a boot to help off-load pressure from the wound.



Compression Dressing (Venous Ulcers)

Your health care provider may apply a **compression dressing** to your leg to help reduce swelling caused by excess fluid trapped in your body's tissues.



Wounds Managed in the Operating Room

Follow instructions provided by your health care provider on how to manage your wound site.



Post-Application Care



Manage Your Dressings

Do Not Remove Dressings

Your health care provider will provide you with instructions on your dressings. Follow instructions provided by your health care provider on how to manage your wound site.



Keep Your Dressings Dry

Following the application of PriMatrix, avoid getting the dressings and surrounding area 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 PriMatrix to detach from the wound. Call your health care provider if your dressings get wet.



Follow All Instructions

Be sure to follow all instructions your health care provider has given you. Contact your health care provider with any questions or concerns.



Diabetic Foot Ulcer Patients

If prescribed by your health care provider, it is essential to wear your specialized footwear. It will help off-load pressure from your wound. Placing weight on your wound may interfere with healing. It can also cause the PriMatrix to detach from the wound.



Venous Leg Ulcer Patients

Always wear your **compression dressing** as instructed by your health care provider.



Keep All Appointments

Always keep your scheduled appointments with your health care provider.



Be Aware of Possible Infection

Contact your health care provider if you experience 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.

These instructions are designed to serve only as a general guideline and not to supersede your health care provider's instructions.

Clinical Studies

PriMatrix has been found to be well tolerated in a series of published clinical studies, involving over 280 wound sites in 247 patients. These studies evaluated the use of PriMatrix in the management of diabetic foot ulcers, venous leg ulcers, pressure ulcers, as well as full and partial-thickness wounds, trauma wounds, and surgical wounds.

A recent study evaluated the use of PriMatrix in the management of diabetic foot ulcers. This study demonstrated that 76% of the subjects completing the study achieved closure of their study ulcer. The average time to healing was 53.1 days⁴. Other ulcer studies have demonstrated improved healing rates when compared to other products² as well as conservative treatments³. Additionally, the use of PriMatrix has been evaluated on **chronic** wounds of patients with multiple health issues. These studies demonstrate, on average, similar closure rates to that in the diabetic foot ulcer study. However, since these patients were in poorer health, the wounds took longer to close^{7,9}.

Use of PriMatrix was also studied in acute partial and full thickness wounds, trauma wounds, and surgical wounds. These studies demonstrated that PriMatrix becomes filled with the patient's own cells. This creates tissue that can support wound healing or have a split-thickness skin graft placed over it in as early as seven days^{1,5-10}.

Some patients treated with PriMatrix experienced adverse events (health complications). The adverse events include infected ulcers, degradation of PriMatrix, occurrence of another ulcer, and admittance to the hospital unrelated to PriMatrix. Adverse events have been reported in approximately 3 out of 43,000 patients treated with PriMatrix.

PriMatrix Clinical Studies

1. Hayn E. Successful treatment of complex traumatic and surgical wounds with a foetal bovine dermal matrix. *Int Wound J*. 2013;11:675-80.
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3. Kavros SJ. Acellular Fetal Bovine Dermal Matrix for Treatment of Chronic Ulcerations of the Midfoot Associated with Charcot Neuroarthropathy. *Foot Ankle Spec*. 2012;5(4):230-234.
4. Kavros SJ, Dutra T, Gonzalez-Cruz R, et al. The Use of PriMatrix, a Fetal Bovine Acellular Dermal Matrix, in Healing Chronic Diabetic Foot Ulcers: A Prospective Multicenter Study. *Adv Skin Wound Care*. 2014;27(8):356-362.
5. Kohanzadeh S, Martin MS, Lugo LM, et al. PriMatrix as an alternative to flap reconstruction. *Plast Reconstr Surg* 2013; 132:92.
6. Lineaweaver W, Bush K, James K. Suppression of Smooth Muscle Actin Accumulation by Bovine Fetal Dermal Collagen Matrix in Full Thickness Skin Wounds. *Ann Plast Surg*. 2015;00(00):1-4.
7. Lullove EJ. Acellular Fetal Bovine Dermal Matrix in the Treatment of Nonhealing Wounds in Patients with Complex Comorbidities. *J Am Podiatr Med Assoc*. 2012;102(3):233-239.
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9. Strauss NH, Brietstein RJ. PriMatrix Dermal Repair Scaffold in the Treatment of Difficult-to-Heal Complex Wounds. *Wounds*. 2012;24(11):327.
10. Strong A, Bennett D, Spreen E, Adhvaryu D, Littleton J, Mencer E. Fetal Bovine Collagen Matrix in the Treatment of a Full Thickness Burn Wound: A Case Report With Long-Term Follow-Up. *J Burn Care Res*. 2014:1-6.

Questions or Comments

If you have any questions about your treatment, please contact your health care provider. These instructions are designed to serve only as a general guideline. This information does not replace instructions received from your health care provider. Always follow your health care provider's directions.

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