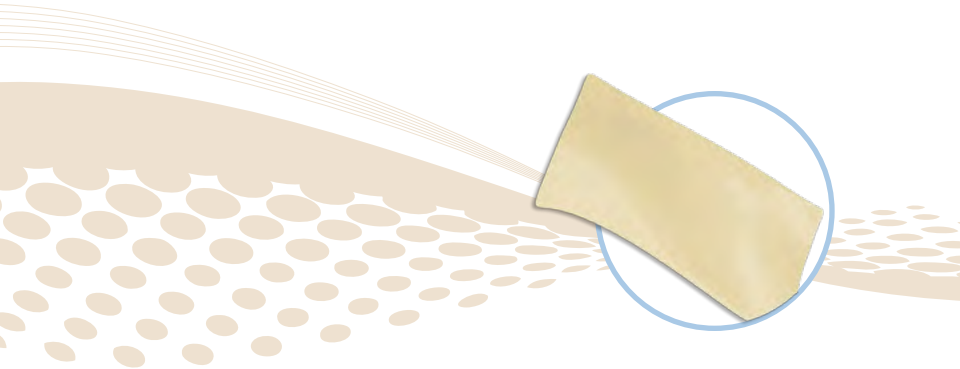


DermACELL[®]

Advanced Decellularized Dermis



DermACELL[®] AWM[™] Pictorial – Clinical Applications



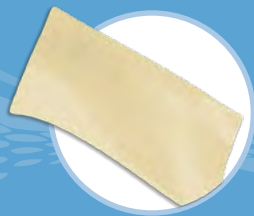
Clinical Applications

DermACELL[®] AWM[™]

DermACELL is a technologically advanced Acellular Dermal Matrix (ADM) that is used to treat diabetic foot ulcers and other chronic non-healing wounds. DermACELL is processed using MatrACELL[®] technology, which is a validated and patented process which renders the DermACELL graft acellular, without compromising the biomechanical or desired biochemical properties of the graft. This process is gentle, yet robust enough to ensure the native scaffold, vascular channels, growth factors and proteins are preserved to assist in the healing of the wound.³

Chronic wounds often have an excess of MMPs (Matrix Metalloproteinases) and reduced growth factor activity. Together, these result in the degradation of the native ECM (extracellular matrix). For wound healing to occur, the balance between protease and growth factor activity has to be adjusted. Pre-clinical information available about the mode of action of an acellular matrix (such as DermACELL) shows that it may assist in the following ways:

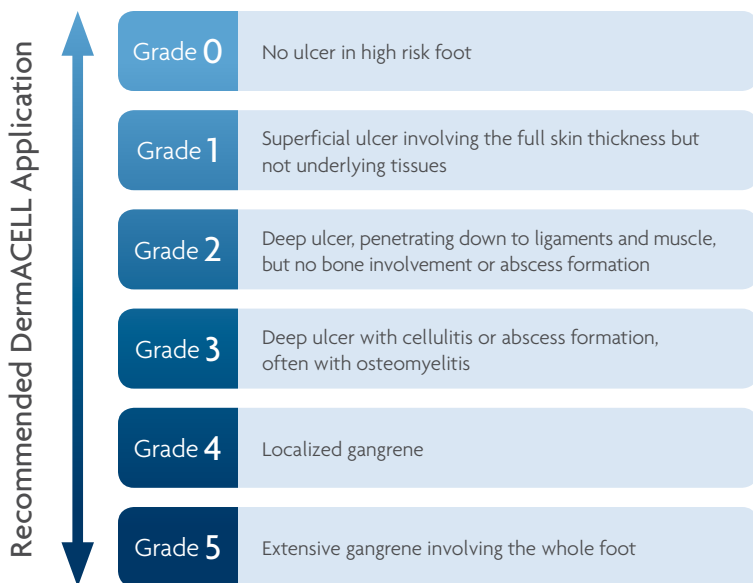
- Act as a scaffold to support cell in-growth and angiogenesis
- Have receptors that permit fibroblasts to attach to the scaffold
- Granulation tissue formation
- Contain certain growth factors²



Indications For Use

Decellularized dermis serves as a scaffold which is suitable for the reinforcement of damaged or inadequate integumental tissue at the surgical site.

WAGNER ULCER GRADING SYSTEM



A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. LifeNet Health does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the breadth of LifeNet Health product offerings. A surgeon must always refer to the package insert, product label, and/or instructions for use before using any LifeNet Health product. Products may not be available in all markets because product availability is subject to regulatory and/or medical practices in individual markets. Please contact your LifeNet Health representative if you have any questions about the availability of LifeNet Health products in your area. LifeNet Health, its divisions, or other wholly owned subsidiaries own, use or have applied for the following trademarks or service marks: LifeNet Health, ArthroFlex, and MatrACELL. All other trademarks are trademarks of their respective owners or holders. Copyright © 2014 LifeNet Health.

DermACELL Placement



Photo courtesy of Dr. Adam Landsman.

Prepare the wound bed per hospital protocol or per physician's practice. Initial debridement is required to remove the obvious necrotic tissue, excessive bacterial burden and cellular burden of dead and senescent cells; wound should be debrided until the wound is free of necrotic tissue and/or there is bleeding. Maintenance

debridement is needed to maintain the appearance and readiness of the wound bed for healing. Ensure that there is no evidence of infection present. Measure the length, width, and depth of the wound prior to application to establish a baseline measurement. Verify that vascularity is adequate. Stabilize the glycemia if unstable for those patients that have diabetes.

For wounds where there is little to no presence of exudate, use an unmeshed form of DermACELL. For wounds where there is exudate present, or if negative pressure will be used, use a meshed form of DermACELL.⁵

Apply DermACELL over the wound bed using sterile technique, with the reticular (dermal) side facing against the wound. If necessary, use a sterile marking pen to mark the papillary side (basement membrane) prior to removal from the packaging, and prior to application.

When applying DermACELL, it is beneficial to have DermACELL be in contact with as much of the wound bed as possible. The edges of the DermACELL can be gently pushed towards the middle of the wound to minimize open mesh areas when using meshed DermACELL, without doubling the layers of the DermACELL. When placing the DermACELL in the wound bed, you can trim the edges of the DermACELL so that they meet the perimeter of the wound bed.⁶

DermACELL Fixation

DermACELL should be secured to the wound bed, particularly if the wound is large. Consider applying fixation (suture, staple, liquid adhesive) in the center of the wound in order to ensure that the DermACELL remains in contact with the base of the wound. Secure DermACELL using Staples, Steri-strips® (i.e., For patients with sensitive surrounding skin); or Sutures (Caution is needed not to lift or pucker skin/disrupt product).⁴ Caution should be used when considering resorbable sutures, as progression of the wound may differ from the typical amount of time that they are left in and inadequate fixation may occur. Liquid skin adhesives (such as Dermabond®) can also be used, as they are intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations.⁶ Staples should be monitored as the wound heals and removed according to the surgeon's preference as well as according to manufacturer's instructions for use. Sutures are typically left in for a maximum of 14 days; and Steri-strips are typically left in place for 1 – 2 weeks. Minimize dressing changes; wound should not be disturbed for at least 1 week. Early inspection increases the risk of displacement. If DermACELL is accidentally displaced, remove and apply a new matrix.² Wound maintenance and/or debridement may need to be performed prior to application of a new matrix.²

Example
of wound
secured
with staples



Photo courtesy of Dr. Windy Cole, DPM.

Example
of wound
secured
with sutures



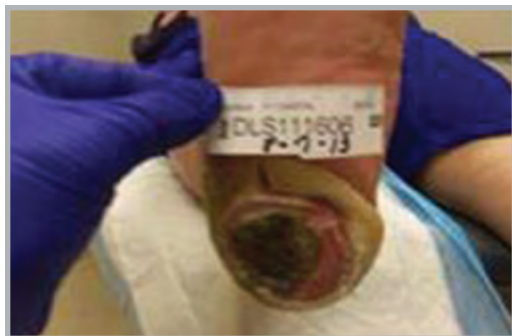
Photo on file at LifeNet Health.

Based upon the patient's particular history, compliance, and other various factors, the appearance of DermACELL post-application can vary. Below are some examples of the use of DermACELL, from pre-application through post-application and healing.

Case Study: **Patient 1**

56 Year-old insulin-dependent diabetic female presented to the wound care center with a Wagner Grade 3 ulcer of the right heel.

PRE-APPLICATION



Clinical photograph of ulceration during the preliminary examination.

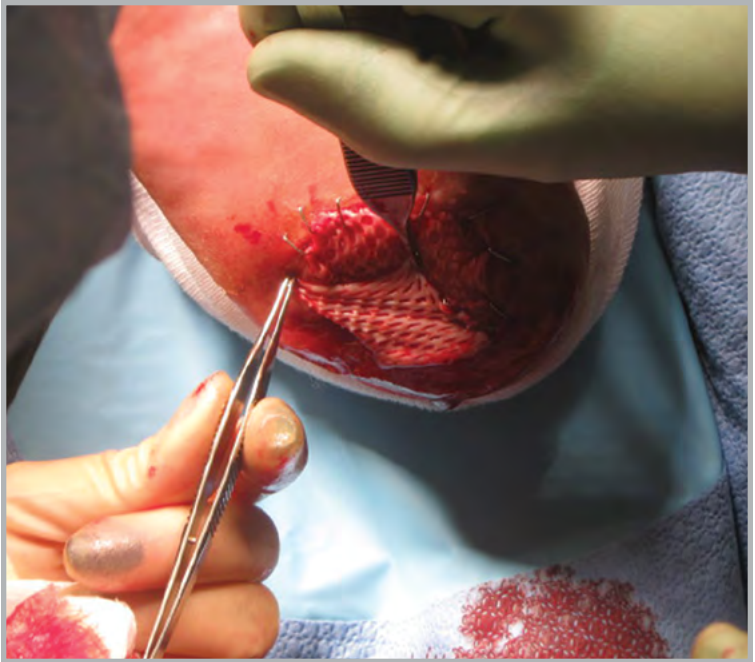


Surgical debridement of the wound.

Case Study: **Patient 1**

56 Year-old insulin-dependent diabetic female presented to the wound care center with a Wagner Grade 3 ulcer of the right heel.

APPLICATION



Application of DermACELL to the wound in a surgical setting; Adaptic, Steri-strips and a dry bulky dressing consisting of 4x4s, ABD pads, Kerlix, and an orthoglass posterior splint were then applied.

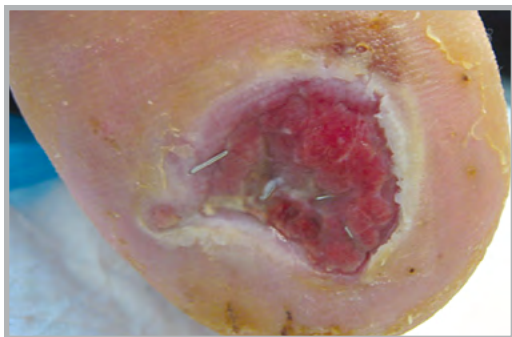
Case Study: **Patient 1**

56 Year-old insulin-dependent diabetic female presented to the wound care center with a Wagner Grade 3 ulcer of the right heel.

POST-APPLICATION



One week post-application.



Two weeks post-application.

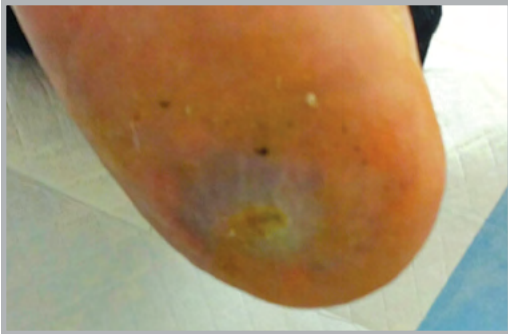
Case Study: **Patient 1**

56 Year-old insulin-dependent diabetic female presented to the wound care center with a Wagner Grade 3 ulcer of the right heel.

POST-APPLICATION



The wound had 92% closure at eight weeks post-graft application.



The wound has completely closed by 13 weeks post-application.

All photos of Patient 1 are courtesy of Dr. Windy Cole, DPM.

Case Study: **Patient 2**

Venous stasis ulcer, right medial malleolus.

BASELINE SCREENING



Wound appearance upon initial screening.

PRE-DEBRIDEMENT



Wound pre-debridement.

Case Study: **Patient 2**

Venous stasis ulcer, right medial malleolus.

POST-DEBRIDEMENT



Wound post-debridement. DermACELL was applied then covered with an oil emulsion dressing. DermACELL was secured with a bio-adhesive. Secondary bolstering was administered and a compression dressing was applied on top and patient was advised to off-load the foot.

Case Study: **Patient 2**

Venous stasis ulcer, right medial malleolus.

POST-APPLICATION



Wound one week post-application.



Wound two weeks post-application.

Case Study: **Patient 2**

Venous stasis ulcer, right medial malleolus.

POST-APPLICATION



Wound four weeks post-application.



Wound six weeks post-application.

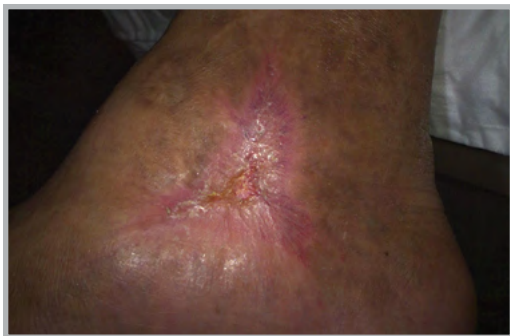
Case Study: **Patient 2**

Venous stasis ulcer, right medial malleolus.

POST-APPLICATION



Wound eight weeks post-application.



Wound 11 weeks post-application.

Case Study: **Patient 2**

Venous stasis ulcer, right medial malleolus.

POST-APPLICATION



Wound 13 weeks post-application.

All photos of Patient 2 are on file at LifeNet Health.

Case Study: **Patient 3**

Wagner Grade 2 diabetic foot ulcer, right plantar lateral forefoot.
Wound was wet upon presentation.

BASELINE SCREENING



Wound appearance upon initial screening.

Case Study: **Patient 3**

Wagner Grade 2 diabetic foot ulcer, right plantar lateral forefoot.
Wound was wet upon presentation.

PRE-DEBRIDEMENT



Wound pre-debridement (one week after screening).

POST-DEBRIDEMENT



DermACELL was applied, then covered with an oil emulsion dressing. DermACELL was secured with sutures and secondary bolsting was administered. Pressure dressing was applied on top and patient was advised to off-load the foot.

Case Study: **Patient 3**

Wagner Grade 2 diabetic foot ulcer, right plantar lateral forefoot.
Wound was wet upon presentation.

POST-APPLICATION



One week post-application.



Two weeks post-application.

Case Study: **Patient 3**

Wagner Grade 2 diabetic foot ulcer, right plantar lateral forefoot.
Wound was wet upon presentation.

POST-APPLICATION



Four weeks post-application.



Six weeks post-application.

Case Study: **Patient 3**

Wagner Grade 2 diabetic foot ulcer, right plantar lateral forefoot.
Wound was wet upon presentation.

POST-APPLICATION



Seven weeks post-application.



Nine weeks post-application.

Case Study: **Patient 3**

Wagner Grade 2 diabetic foot ulcer, right plantar lateral forefoot.
Wound was wet upon presentation.

POST-APPLICATION



16 weeks post-application



21 weeks post-application.

All photos of Patient 3 are on file at LifeNet Health.

Case Study: **Patient 4**

Grade 2 diabetic foot ulcer of the left plantar heel.

BASELINE SCREENING



Wound appearance upon initial screening.

Case Study: **Patient 4**

Grade 2 diabetic foot ulcer of the left plantar heel.

PRE-DEBRIDEMENT



Wound pre-debridement.

POST-DEBRIDEMENT



DermACELL was applied then covered with a gauze dressing. DermACELL was secured with sutures. Off-loading was advised through use of a boot.

Case Study: **Patient 4**

Grade 2 diabetic foot ulcer of the left plantar heel.

POST-APPLICATION



Wound one week post-application.



Wound two weeks post-application.

Case Study: **Patient 4**

Grade 2 diabetic foot ulcer of the left plantar heel.

POST-APPLICATION



Wound four weeks post-application.



Wound six weeks post-application.

Case Study: **Patient 4**

Grade 2 diabetic foot ulcer of the left plantar heel.

POST-APPLICATION



Wound eight weeks post-application.



Wound 10 weeks post-application.

Case Study: **Patient 4**

Grade 2 diabetic foot ulcer of the left plantar heel.

POST-APPLICATION



Wound 11 weeks post-application.

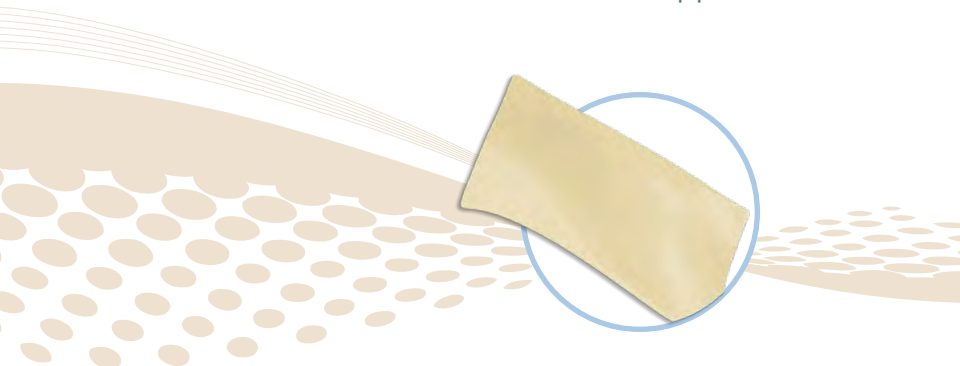
All photos of Patient 4 are on file at LifeNet Health.

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LifeNet Health helps to save lives and restore health for thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

References

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