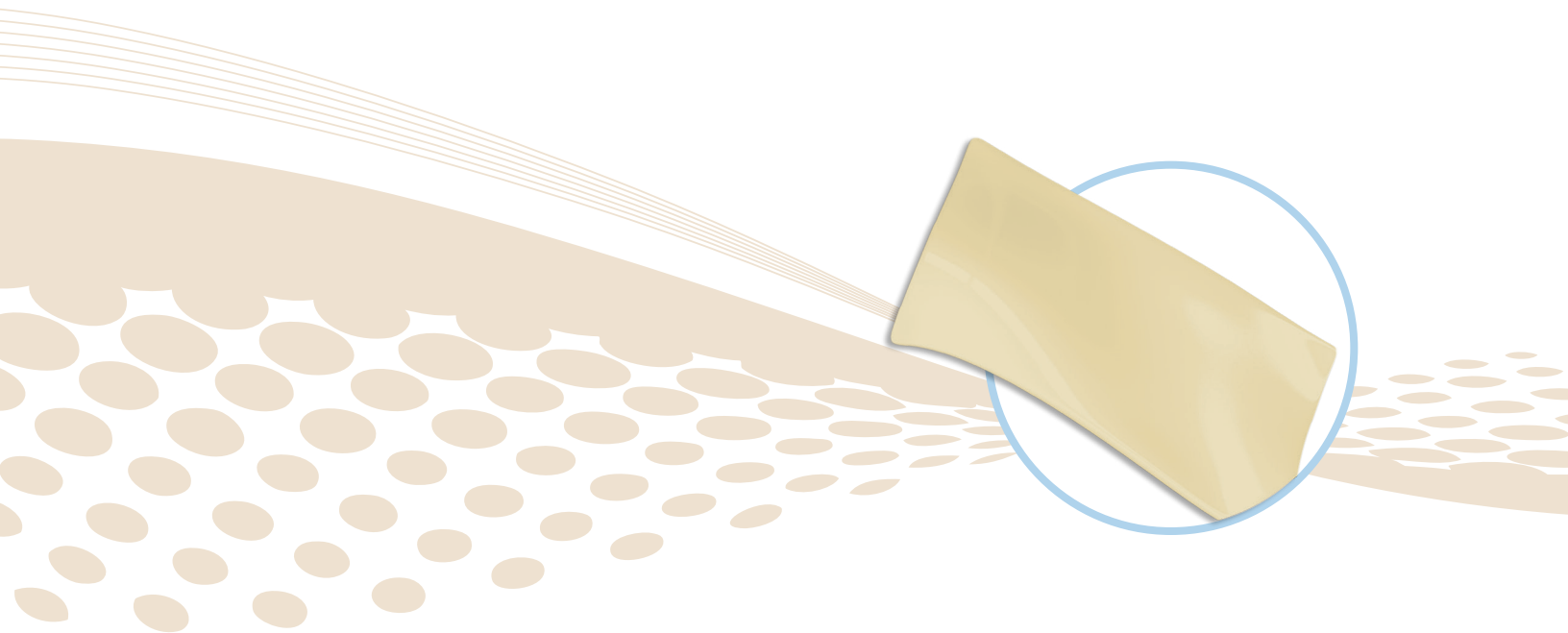


DermACELL[®]

Advanced Decellularized Dermis



Application Guide



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Decellularized Dermis Has Two Physically Distinct Sides



Reticular (Dermal):

Lighter in appearance, larger pores, absorbs blood

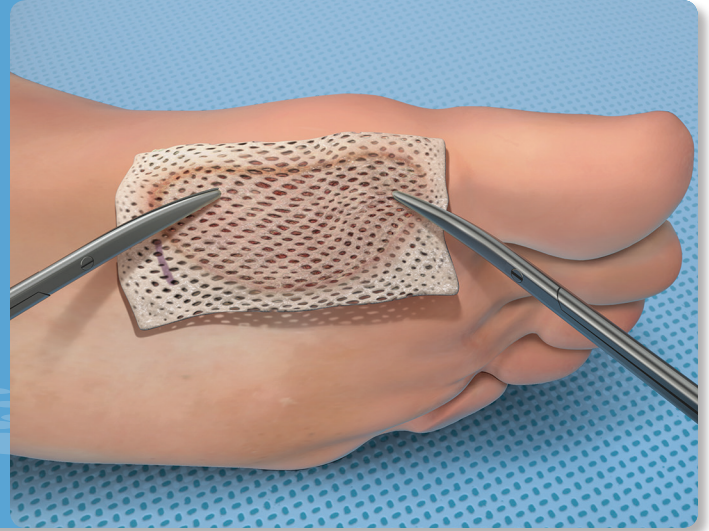


Papillary (Basement Membrane):

Duller with smaller pores, repels blood

The dermis is packaged with the papillary side visible through the clear side of the packaging. To maintain orientation of the dermis, the papillary side should be marked with a sterile marker immediately after opening the inner pouch. When applied, the reticular side is placed against the surgical wound or the most vascularized tissue.

DermACELL Application



- 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.³ 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.
- Non-sterile team member will open the cardboard sleeve and retrieve the pouch from within.
- Aseptically open the outer peel pack and present inner pouch to the sterile team member.
- Sterile team member will open the inner peel pouch and remove the dermis along with its slip sheet. Remove the slip sheet prior to application.

Rinsing is not required prior to application, however it may improve handling. If a rinse is preferred, follow rinse instructions provided on the IFU.¹

Rinse Instructions

- Prepare a sterile rinse basin with enough sterile isotonic solution (i.e., Sterile Saline) to completely cover the dermis. **CAUTION:** Ensure the rinse solution does not exceed 42°C as this may damage the dermis.
- After opening the packaging per the instructions, remove the dermis from the slip sheet and immerse the dermis in sterile isotonic solution for a minimum of one minute. Ensure the dermis is completely submerged in solution during the rinse.
- Keep the dermis completely submerged in sterile isotonic solution until needed.
- **CAUTION:** The maximum sterile isotonic solution exposure time for decellularized dermis is four hours.²

DermACELL Placement



- 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.

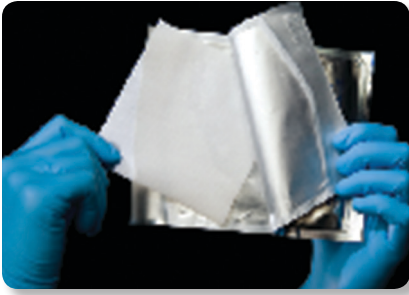


DermACELL Fixation

- 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.⁵
- 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.⁴



DermACELL Top Dressing Application



Ensure appropriate primary and secondary wound dressing selection. The matrix should be covered with a non-adherent primary dressing, bolster and/or padding, particularly if the wound has moderate to heavy exudate.

- Non-adherent dressings have a specially-designed contact layer that minimizes wound trauma and are designed so that they will not disrupt healing tissue by sticking to wound.⁶
- Some examples of non-adherent dressings are Telfa® (Covidien, Mansfield, MA), Tegaderm™ Contact Layer (3M™, Minneapolis, MN), Mepitel (Molnlyne, Norcross, GA).
 - ◇ If your wound requires more moisture, an impregnated non-adherent dressing can also be used. Examples are Curity™ Oil Emulsion Dressing (Covidien, Mansfield, MA) and Adaptic® (J&J, New Brunswick, NJ). Both are impregnated with a special blend of petrolatum to donate moisture to a dry wound. If a deodorizing product is desired, Xeroform Gauze (Covidien, Mansfield, MA) offers a petrolatum gauze impregnated with bizmuthtribromophenate.
 - ◇ Note: “Wet-to-dry dressings” are not considered continuously moist as they do dry out when not continuously moistened. Continuously moist saline gauze dressings are effective as other types of moist wound healing in terms of healing rate.³
 - ◇ If the wound covering and DermACELL are dry in appearance during the first dressing change, rehydrate by applying a sterile solution directly to the graft. Wait one to three minutes before attempting to remove the dressing.
 - You may also consider the use of an appropriate topical antimicrobial.

Use a secondary dressing to hold the matrix and wound dressings in place.⁴

- The primary dressing should be secured with an outer wrap. The covering not only secures the primary dressing but can act as a protectant to the graft itself. An example of a secondary dressing is a bandage roll. Bandage rolls can be heavy duty, which provide not only loft and bulk, but additional absorption (Kerlix®, Covidien, Mansfield, MA), or can be lighter weight, such as Curity™ Bandage Roll (Covidien, Mansfield, MA) or Kling® (J & J, New Brunswick, NJ).
 - ◇ **Note:** Some bandage rolls can provide a level of compression, so be certain to follow manufacturer’s recommendations for use.
- Please use caution when cleaning the wound or changing the dressings to ensure wound is not disrupted, or the DermACELL is inadvertently removed.
- Prevent recurrence by ensuring adequate compression/offloading, appropriate shoes/continued pressure reduction (i.e., Patients with diabetic foot ulcers need complete offloading 1 week post-application)⁴
- If the wound is located in a high movement area (i.e., Lateral malleolar), securement and reduced movement is suggested in order to prevent a premature re-opening of the wound.



* Progression photos courtesy of Dr. Eric J. Buchbaum, DPM.⁹

DermACELL Appearance Post Implantation

When an ADM is used in a chronic wound, the matrix is eventually displaced and may not be fully incorporated, so this appearance is not out of the ordinary. As such, it has been suggested that the ADM acts as a biological cover that modulates the wound environment to promote normal wound healing.

The landmarks towards achieving a successful outcome include:

- No clinical signs of infection or bioburden (i.e., Purulence, sliminess, unexpected malodour).
- Formation of granulation tissue, reduction in wound size and re-epithelization
- Removal of method of attachment (i.e., Staples, Sutures, or Steri-Strips)

When matrix is still present in the wound bed, it may produce a different appearance than normal granulation (i.e., The tissue may not have the typical bright red appearance; If silver dressings are used, it may look dry, silver/black in color with no signs of infection). It is important to know what the wound should look like when it is reviewed post-application and be able to identify when the wound is progressing normally and if further intervention is needed.

Complications

- Infection
 - ◇ Remove DermACELL, control the infection and apply a new matrix following adequate wound bed preparation
- Detached or displaced matrix
 - ◇ Remove DermACELL and assess to establish the reasons for failure. Perform adequate wound bed preparation before applying a new matrix.
- Excessive inflammation/allergic reaction
 - ◇ Remove DermACELL and do not reapply a new matrix.
- Failure to heal/lack of effect
 - ◇ Reassess the wound and the patient. When the wound is not healing the matrix may be displaced and there may be an increase in wound size.⁴

Decellularized Dermis | DermACELL® AWM™

| WOUND | Size | Room Temperature |
|------------------------------|----------|------------------|
| Thickness = 0.2 mm - 1.00 mm | 2 x 2 cm | DCELL100 |
| | 4 x 4 cm | DCELL101 |

| MESHED WOUND | Size | Room Temperature |
|------------------------------|----------|------------------|
| Thickness = 0.5 mm - 1.00 mm | 4 x 4 cm | DCELL112 |
| | 5 x 9 cm | DCELL155 |

| WOUND | Size | Room Temperature |
|------------------------------|----------|------------------|
| Thickness = 0.2 mm - 1.00 mm | 5 x 7 cm | DCELL102 |
| | 6 x 7 cm | DCELL103 |
| | 4 x 8 cm | DCELL104 |

| MESHED WOUND | Size | Room Temperature |
|------------------------------|----------|------------------|
| Thickness = 0.2 mm - 1.00 mm | 5 x 7 cm | DCELL152 |
| | 6 x 7 cm | DCELL153 |
| | 4 x 8 cm | DCELL154 |

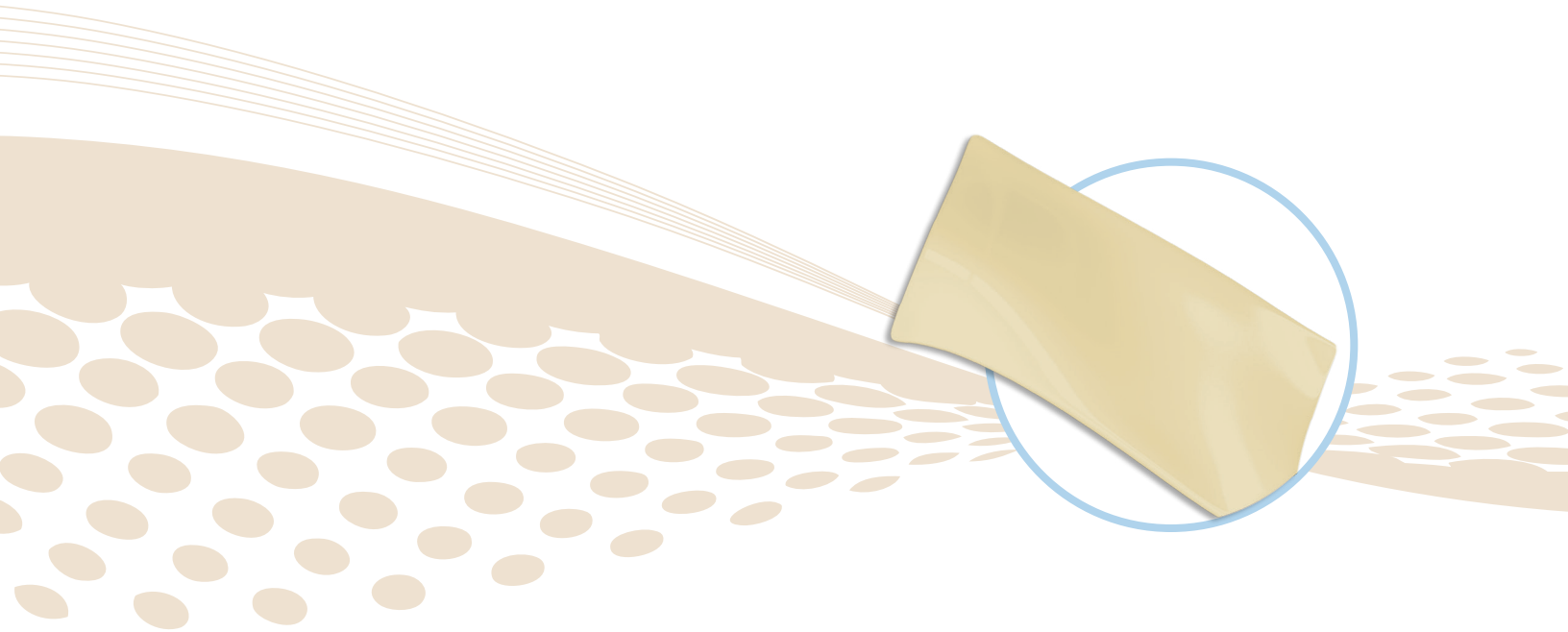
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1. DermACELL AWC Customer Facing Presentation: 68-10-155.02
2. Sterile Decellularized Dermis IFU: 63-0050-01 Rev. 08
3. Guidelines for the treatment of diabetic ulcers; David L. Steed, MD, et.al; Wound Repair and Regeneration; 2006 by the Wound Healing Society;
4. International Consensus: Acellular Matrices For The Treatment Of Wounds; An Expert Working Group Review; Wounds International
5. <http://www.ethicon360.com/products/dermabond-topical-skin-adhesive>
6. www.covidien.com
7. www.jnj.com
8. Photos (other than noted progression photos) and some information is courtesy of Adam Landsman, DPH, PhD, Cambridge Hospital, Cambridge, MA.
9. Treatment of Plantar Diabetic Ulcer with Human Acellular Dermal Matrix (ADM), by Dr. Eric Buchbaum
10. Reviewed by Adam Landsman, DPM, PhD and Giampietro Bertasi MD, PhD

A clinician must always rely on his or her own professional clinical judgment when deciding whether to use a particular product or surgical technique when treating a particular patient. LifeNet Health does not dispense medical advice and recommends that the clinician be trained in the use of any particular product or surgical technique according to the manufacturer before using it in clinical practice. The information presented is intended to demonstrate

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The Skin and Wound Allograft Institute (SWAI) is a wholly owned subsidiary of LifeNet Health.

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.

Speak to your local Sales Specialist for further information or contact us using the details below:

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