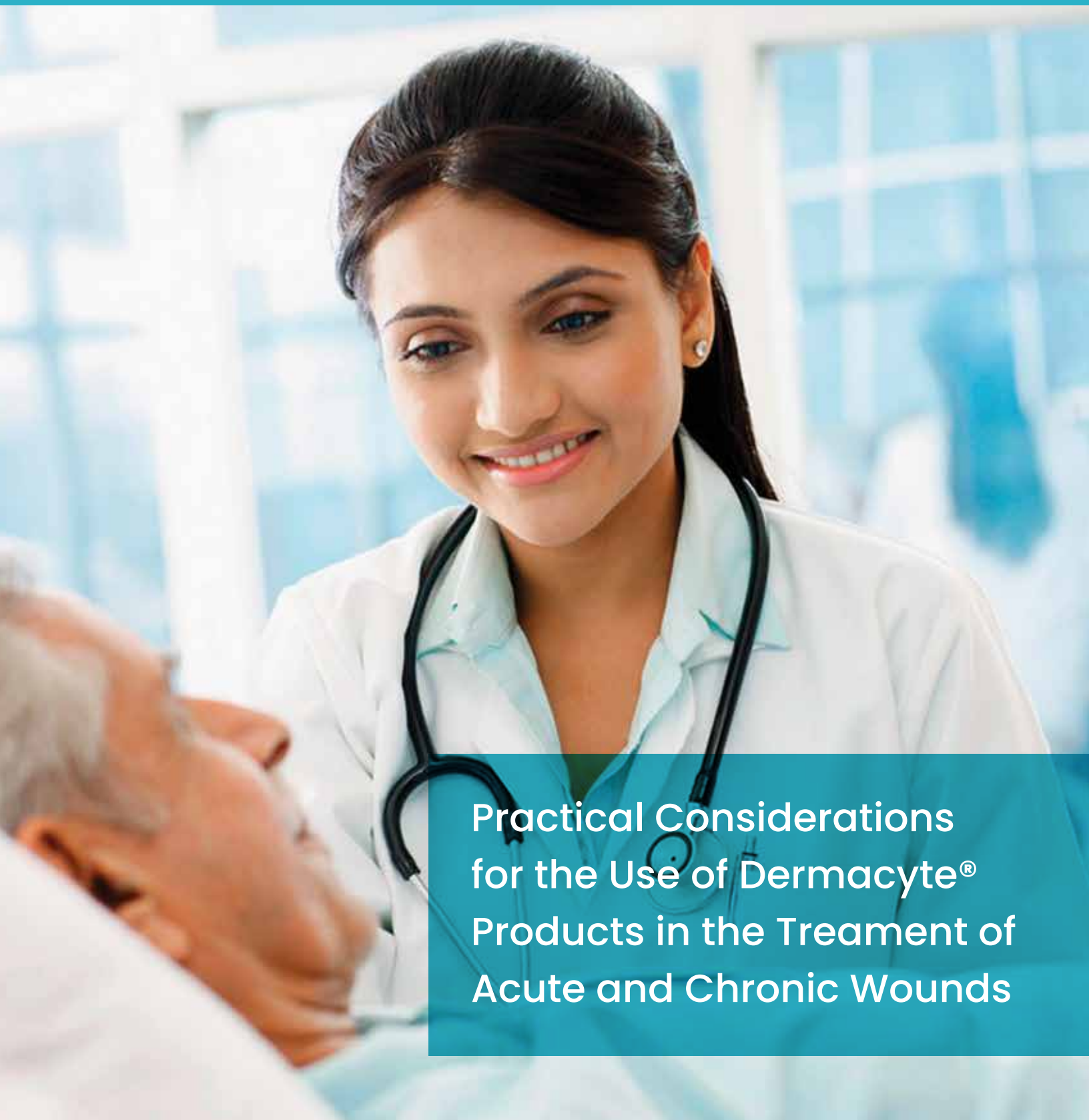
Dermacyte®
Regenerative Wound Care



Practical Considerations for the Use of Dermacyte® Products in the Treament of Acute and Chronic Wounds

DERMACYTE® IS EASY-TO-USE

A step-by-step guide to clinical considerations when using Dermacyte® for the treatment of wounds

Patient Selection | Preparation | Treatment | Patient Assessment

Product Description

Dermacyte® Matrix is human allograft prepared from donated amniotic tissue collected using aseptic techniques during Cesarean birth. The surgical site is prepped according to AORN standards for incision disinfection. The tissue is retrieved and processed within 72 hours from the time of C-section. Dermacyte® is available in ideal sizes appropriate for various surgical uses. HCPCS CODE Q4248

Actual sizes:

Contact Us

For information related to Dermacyte® Insurance benefit verifications, assistance or claims appeal assistance, please contact our **Reimbursement Support Line.**

Phone: (919) 921-8105 Ext 119
Fax: (919) 267-3753
Email: info@merakris.com
https://merakris.com/wound-care-dermacyte-matrix/

PATIENT SELECTION

Discuss treatment options with patients

Optimal Patient Profile

- A single, full-thickness foot and/or leg wound
  - Diabetic, pressure, arterial, or venous[2]

- Unresponsive to other therapies (e.g. periodic debridement, moist dressings, antibiotics, hyperbaric oxygen, glycemic control)[2, 3]

- No clinical signs of infection, although the anti-microbial properties of amnion have been shown to reduce infection[2, 3]

- Wound duration 1 to 12 months[2, 3]

- Typical wound size: >1 sq. cm and <25 sq. cm.[2, 3]
  - Wound size is measured by multiplying wound length by width[2, 3]

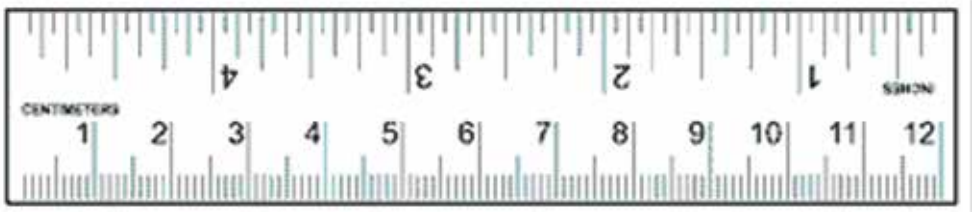
PATIENT ASSESSMENT

Evaluate effectiveness by tracking wound size

Patient Evaluation

- Consider weekly evaluation of patient until 1 week after complete healing
- Patient education and support for best at-home wound care practices (e.g. offloading and dressing changes)

Wound measurement evaluations should include: Length, Width, and Depth
- Use of photographic evaluation[1] recommended



- The mean interval to healing after first application of the amnion allograft is 2.6 months[2]

IMPLANT TRACKING

Achieve regulatory compliance with implant tracking

Tissue Utilization Record

- Applicable regulations require implant reconciliation with recipient patient
- Consult your local representative to ensure each usage of Dermacyte is documented for traceability

For Questions Regarding Compliance

Merakris Therapeutics: (919) 921-8105
Mon-Fri 9AM-6PM EST

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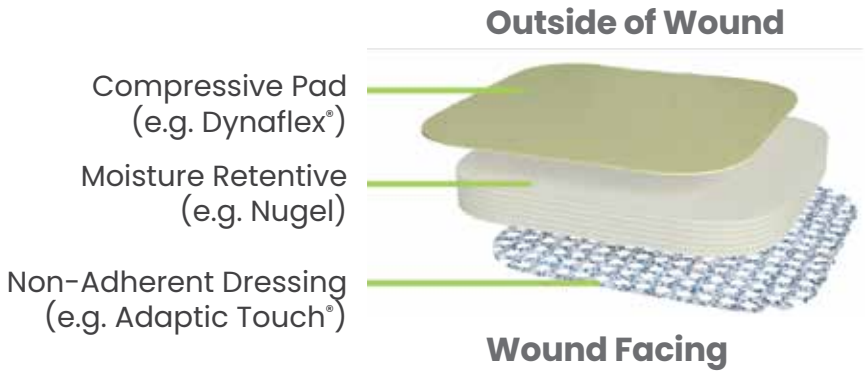
PATIENT TREATMENT

Improve the patient care experience by discussing the treatment plan

Caring for the Wound

- Initiate treatment on same day as surgical debridement[2]
- The allograft should be applied in a manner to prevent displacement[1]
- 3-layer wound dressing after amnion placement:[3]



- Replace Dermacyte Matrix every 7-14 days[2] until wound closure
  - Consider debridement if eschar is present over wound

- Change dressing weekly and cleanse wound with sterile normal saline (rinse, swab, or irrigate)[3]

- Dressing can be changed more frequently as needed – BE CAREFUL NOT TO DISTURB AMNION – leave non-adherent dressing in place

- Consider glycemic control, wound off-loading, edema control[2,3]

WOUND SITE PREPARATION & APPLICATION

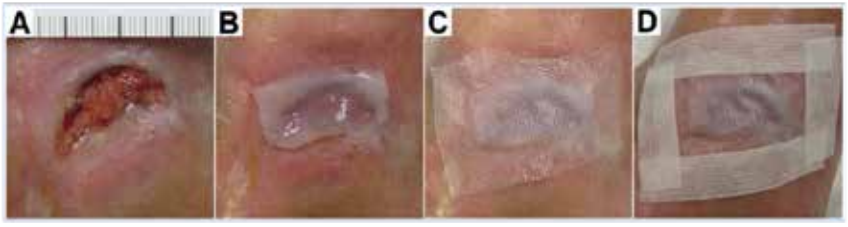
Amnion is safe, and may be considered an alternative for treating chronic non-healing lower limb ulcers[4]

Wound Site Preparation

- Host bed should be devoid of debris; proper preparation is required[1]
- Aggressive sharp surgical debridement to healthy bleeding tissue
  - critical when eschar is present in wound bed[2, 3]
- Do not use chemical debridement[2]

Large Lesion and Vascular Disease Treatment Considerations

- Get a thorough vascular consult as needed



Application Guide: Matrix[4]

A. Debridement

B. Apply amnion to wound bed

C. Place non-adherent contact layer over amnion

D. Use adhesive strips to secure a moisture-retentive layer and a compress

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PRODUCT PREPARATION

Handle with care to preserve sterility and integrity

Dermacyte® Wound Care Matrix: [1]

- Slowly pull apart wings of package, and aseptically pass the inner package containing the graft to the nurse / surgical assistant

- When opening inner pouch, be sure to identify the epithelial side and maintain that orientation until implanted
  - The epithelial side is applied to patient's affected area.

- Remove the dehydrated product from the inner pouch. Handle the amnion with care, as it is very fragile and may tear - do not rehydrate.

- Cut as needed to appropriate size based on wound shape and diameter and place either side of the membrane onto the affected area.

- Fluid from the patient will gradually and naturally hydrate the amnion
  - add sterile saline as needed for optimal conformance onto wound bed.

Review package insert for complete usage instructions.

QUALITY ASSURANCE & SAFETY

Use with confidence knowing the rigorous safety and testing requirements

Donor Testing Requirements

All donors have tested negative for the following:

- HBsAg (Hepatitis B Surface Antigen)
- HBcAb (hepatitis B core antibody)
- HCV (hepatitis C antibody)
- HIV 1/11-Ab (Antibody to Human Immunodeficiency Virus Types 1 & 2)
- Syphilis detection test, HIV NAT (HIV Nucleic Acid Test)
- HCV NAT (HCV Nucleic Acid Test)

Additional tests may include West Nile Virus, T. Cruzi, Cytomegalovirus and Epstein Barr Virus.

Donor screening tests are performed by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) using FDA licensed tests.

References:

1. Dermacyte® Matrix [package Insert]. Research Triangle Park, NC: Merakris Therapeutics Inc; 2021
2. Werber et al. A prospective study of 20 foot and ankle wounds treated with cryopreserved amniotic membrane and fluid allograft. J. Foot and Ankle Surg. 2013; 52(5): 615-621.
3. Zelen et al. A prospective, randomised comparative study of weekly versus biweekly application of dehydrated human amnion/chorion membrane allograft in the management of diabetic foot ulcers. Int. Wound J. 2014; 1(2): 122-8.
4. Chua et al. An Open label prospective pllot study to evaluate the efficacy of cryopreserved amniotic tissue grafts for chronic nonhealing ulcers. Wounds. 2014; 26(5):E30-E38

MK-0002.03

Manufactured for and marketed by:
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