A Diabetic Foot Ulcer and the Challenges that Patients with Diabetes Face can be Devastating

In fact, 45% of people with diabetes who have had a lower extremity amputation pass away within 5 years.³ 360° Advanced Wound Care is our commitment to providing effective solutions that help clinicians overcome some of the most common barriers to effective wound healing. This holistic approach is designed to meet our providers’ and patients’ needs at every stage of the wound healing process.

<table>
<thead>
<tr>
<th>DESCRIPTION OF WOUND</th>
<th>WOUND MANAGEMENT GOAL</th>
<th>SUGGESTED THERAPY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PARTIAL THICKNESS WOUNDS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Open wound</td>
<td>• Small wounds: epithelial closure</td>
<td>1 Autolytic Debridement</td>
</tr>
<tr>
<td></td>
<td>• Larger wounds: epidermal closure</td>
<td>2 Amniotic Tissue</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 Total Contact Cast</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DESCRIPTION OF WOUND</th>
<th>WOUND MANAGEMENT GOAL</th>
<th>SUGGESTED THERAPY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FULL THICKNESS WOUNDS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Involves tissue loss below the dermis</td>
<td>• Build re-vascularized dermal tissue</td>
<td>1 Autolytic Debridement</td>
</tr>
<tr>
<td>• Subcutaneous fat may be visible but bone, tendon or muscles are not exposed</td>
<td>• Achieve epithelial closure</td>
<td>3 Dermal Repair Scaffold</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 Regeneration Matrix</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 Total Contact Cast</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DESCRIPTION OF WOUND</th>
<th>WOUND MANAGEMENT GOAL</th>
<th>SUGGESTED THERAPY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EXPOSED BONE AND TENDON</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Full thickness tissue loss with exposed avascular structures</td>
<td>• Form granulation tissue</td>
<td>1 Autolytic Debridement</td>
</tr>
<tr>
<td>• Extensive destruction</td>
<td>• Build re-vascularized dermal tissue</td>
<td>3 Dermal Repair Scaffold</td>
</tr>
<tr>
<td>• Tissue necrosis, damage to muscle, bone, or supporting structure</td>
<td>• Achieve epithelial closure</td>
<td>5 Total Contact Cast*</td>
</tr>
</tbody>
</table>

* Depending on the clinician’s decision in the individual case.
**PREPARE**

**COMMON BARRIER TO HEALING:** Presence of necrotic/non-viable tissue

**SUGGESTED THERAPY**

1. Autolytic Debridement

**CASE STUDY**

Dimitrios Lintzeris, DO, CWS, et al  
*Holistic Approach: Advanced Wound Care product selection for the management of patients with complex challenging wounds.*

**Patient Profile:** 82 year old male with an ulcer of the right toe for 2 months. Treatment started with MediHoney® Calcium Alginate, foam, and TCC-EZ® Total Contact Casting System. Patient was seen weekly for debridement and cast change.

**PATIENT OUTCOME: 42 DAYS TO 100% CLOSURE**

**DAY 1** First application.

**WEEK 4** Significant wound depth reduction.

**WEEK 10** Wound closure.

---

**TREAT**

**COMMON BARRIER TO HEALING:** Unbalanced wound environment

**SUGGESTED THERAPY**

2. Amniotic Tissue

**CASE STUDY**

Shirshir Shah, DO and Lynne Solinski, RN, BSN, WCC, ACHRN  
*A case series with an objective to establish the efficacy of Dehydrated Amniotic Membrane Allograft (AmnioExcel®) tissue to assist with wound closure in a wound clinic setting.*

**Patient Profile:** 53 yo female, hx of DM type II, obesity, edema, neuropathy, right great toe plantar ulcer present for 9 months.

**PATIENT OUTCOME: 42 DAYS TO 100% CLOSURE**

**DAY 0** 1st application of AmnioExcel; wound size 1.9 x 1.5 x 0.3 cm

**DAY 14** 3rd application of AmnioExcel; wound size 0.9 x 0.9 x 0.1 cm

**DAY 42** Wound closure.
Revolutionary Off-loading
PROTECT

Innovative Tissue Technology Solutions
TREAT

CASE STUDY
Common Barrier to Healing: Significant tissue loss or deficit

Robert Snyder, DPM, MSC, CWS
An ongoing randomized, controlled trial investigating PriMatrix Dermal Repair Scaffold versus standard of care therapy.

Patient Profile: 61 year old male with type 2 diabetes. Patient has peripheral neuropathy as a complication of diabetes and had his right fifth toe amputated.

Patient Outcome: 70 days to 100% closure

Post debridement; ready for 1st application. WEEK 1 Visible newly forming tissue. WEEK 10 Wound is completely re-epithelialized.

CASE STUDY
Common Barrier to Healing: Pressure and shear forces

Andrew Ostapchuk, DPM
Use of Integra (Omnigraft) Dermal Regeneration Template along with Total Contact Casting (TCC-EZ) for Diabetic Foot Ulcer (DFU) treatment.

Patient Profile: 63 year old insulin-dependent male with a lower left foot heal ulcer. Patient has peripheral neuropathy, pulmonary disease, hypertension, and a history of severe non compliance.

Patient Outcome: 67 days to 100% closure

After debridement, Omnigraft was applied along with TCC-EZ. WEEK 7 Wound on a trajectory to closure after two Omnigraft applications. Weekly applications of TCC-EZ continued. WEEK 9 Wound closure. TCC-EZ applied for one additional week.

Dimitrios Lintzeris, DO, CWS, et al
Limb Salvage 101: Utilizing an easier Roll on Total Contact Cast System (TCC-EZ) along with Active Leptospermum Honey (MediHoney) and other Advanced Wound Care modalities to heal chronic wounds of the foot in less than 36 days.

Patient Profile: 62 year old male with co-morbidities of CHF, MI, hypertension, COPD, CA of gallbladder, diabetes, gout and cirrhosis. Previous treatment included HBO and off-loading with wedge shoe.

Patient Outcome: 47 days to 100% closure

DAY 1 5.0 x 5.0 x 0.4 cm
WEEK 4 1.0 x 1.0 x 0.1 cm
WEEK 7 Wound closure.
Industry-leading Product Solutions
Backed by science and clinical data, 360° Advanced Wound Care offers you the right product at the right time for the right clinical need.

**PREPARE**

**MEDIHONEY®**
Wound and Burn Dressing
Versatile and effective wound bed preparation

**TREAT**

**AmnioExcel®**
Amniotic Allograft Membrane
Providing key components found in the human amnion to repair, reconstruct, and replace wound tissue

**AmnioMatrix®**
Amniotic Allograft Suspension
Cryopreserved suspension allograft derived from the amniotic membrane and components of the amniotic fluid

**PROTECT**

**TCC-EZ®**
Total Contact Casting System
Effective off-loading protection for DFU management

**Omnigraft®**
Dermal Regeneration Matrix
The ONLY FDA-approved product to regenerate native dermal tissue for the treatment of DFUs

**PriMatrix®/PriMatrix® Ag**
Dermal Repair Scaffold
Novel acellular dermal repair scaffold that supports cellular repopulation and revascularization

**SUPPORTIVE DRESSINGS**

**Xtrasorb®**
Wound Dressing
Novel portfolio of dressings that maximizes absorption and fluid handling

**Bioguard®**
Barrier Dressing
Barrier protection against a broad spectrum of pathogens including MRSA

**Algicell® Ag**
Wound Dressing
Providing the power, performance and protection of silver for your wound management needs
Integra® Reimbursement Hotline Services

For assistance with the following:
- Insurance benefits verification
- Prior authorizations
- Predeterminations
- Claims review
- Navigating the approval process

Disclaimer: Integra intends to use reasonable efforts to provide insurance coding advice, but this advice should not be construed as providing clinical advice, dictating reimbursement policy or substituting for the judgment of a practitioner. It is always the provider’s responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered. Provider is responsible for verifying coverage with the patient’s insurance carrier. Integra LifeSciences Corporation assumes no responsibility for the timeliness, accuracy and completeness of the information contained herein. Since reimbursement laws, regulations, and policies change frequently, it is recommended that providers consult with their payers, coding specialists and/or legal counsel regarding coverage, coding, and payment issues.

Omnigraft: Dermal Regeneration Matrix Indications: Omnigraft is indicated for use in the treatment of partial and full-thickness neuropathic diabetic foot ulcers that are greater than six weeks in duration, with no capsule, tendon or bone exposed, when used in conjunction with standard diabetic ulcer care. Contraindications: Omnigraft should not be used in patients with known sensitivity to bovine or chondroitin materials. Omnigraft should not be used on clinically diagnosed infected wounds. Warnings: Debridement or excision must be done thoroughly to remove any remaining necrotic tissue that may delay healing or cause infection. Omnigraft will not incorporate into a wound bed of nonviable tissue. Leaving any remaining nonviable tissue may create an environment for bacterial growth. Precautions: The following complications are possible with the use of wound treatments. The product should be removed if any of these conditions occur: infection, chronic inflammation (initial application of wound products may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain, or swelling. There have been no clinical studies evaluating Omnigraft in pregnant women. Caution should be exercised before using Omnigraft in pregnant women. Such use should occur only when the anticipated benefit clearly outweighs the risk. Adverse Events: All adverse events that were reported in the study evaluating Omnigraft for the treatment of diabetic foot ulcers at a frequency of ≥ 1% in either cohort are presented in Table 1 in the Instructions for Use. This table includes adverse events that were both attributed to and not attributed to treatment. The most common adverse events experienced by patients treated with Omnigraft were wound infection (19%), new, worsening, or recurring wounds (14%), pain around the wound (9%), infection beyond the wound (either cellulitis or osteomyelitis, 14%), swelling (5%), nausea (5%), worsening health condition (4%). These adverse events occurred in a similar or lower percentage of patients treated with Omnigraft compared to patients treated with standard wound care alone. Omnigraft is also marketed as Integra Dermal Regeneration Template and has been studied extensively in life-threatening thermal injuries and scar contracture reconstruction. Refer to the Integra® Dermal Regeneration Template package insert for complete adverse event information.


For more information or to place an order, please contact: United States, Canada, Asia, Pacific, Latin America USA 877-444-1122 • 888-980-7742 fax International +1 609-936-5400 • +1 609-750-4259 fax integrallife.com

AmnioExcel, AmnioMatrix, Bioguard, MediHoney, Omnigraft, PriMatrix, TCC-EZ, Xtrasorb, Integra, and the Integra logo are registered trademarks of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries.

©2018 Integra LifeSciences Corporation. All rights reserved. Printed in USA. 1097614-1-EN

AmnioExcel and AmnioMatrix are regulated as Human Cellular and Tissue-Based Products (HCT/P) under Section 361 of the Public Health Service Act and as such are governed by the FDA Center for Biologics Evaluation and Research (CBER).