Derma Sciences is a tissue regeneration company focused on advanced wound and burn care. We offer a line of products with patented technologies to help better manage chronic and hard-to-heal wounds, many of which result from diabetes and poor vascular functioning.

**AMNIOEXCEL®**

AMNIOEXCEL® Amniotic Allograft Membrane is a novel human placental-based tissue product. The membrane forms a protective covering over the wound while providing the key components found in human amnion including an intact ECM (extracellular matrix), cytokines and other growth factors. It easily integrates into the wound and helps provide the optimal environment to repair, reconstruct and replace wound tissue.

AMNIOEXCEL® is a minimally manipulated amniotic membrane donated by pre-screened mothers during planned C-sections. The membrane is dehydrated using the proprietary DryFlex™ process which keeps the tissue intact and malleable, gives it a five year shelf life at room temperature and retains the key components of human amnion. It is intended for homologous use as a wound covering to aid in closing chronic wounds.

**AMNIOMATRIX®**

AMNIOMATRIX® is a cryopreserved suspension allograft derived from the amniotic membrane and components of the amniotic fluid. It is cryopreserved using the patented CryoPrime™ processing method that preserves the structural properties of the collagen, cytokines, growth factors, ECM and viable cellular materials. The liquid based suspension is especially suited to help repair wounds where membrane products might not be as effective (i.e. tunneling or deep wounds). AMNIOMATRIX® is intended for homologous use to help supplement the recipient’s tissue and aid in the closing of chronic wounds.
Diabetic Foot Ulcer (DFU)

**Patient History:** A 36 year old female patient with poorly controlled Type I diabetes and a history of neuropathy and chronic ulcerations had significant bony deformities in her left foot secondary to Charcot arthropathy.

**Challenges:** Poorly controlled diabetes, neuropathy, chronic wound, and Charcot arthropathy.

**Initial Assessment:** She presented with a Wagner Grade 2 full thickness DFU on the medial aspect of her left ankle that was present for 4 years. The wound area measured 5.8 cm² (Figure 1).

**Previous Treatments:** Standard wound care including debridement, exudate management, and off-loading.

**Treatment Strategy:** AMNIOEXCEL® was applied every 2 weeks.

**Wound Progress:** Wound improved rapidly showing contraction, granulation, and a 74% decrease in area to 1.5 cm² at week 3 (Figure 2).

**Outcome:** The wound closed at week 6 following 3 applications of AMNIOEXCEL® (Figure 3).

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**Case provided by Barry Rosenblum, DPM, FACFAS as part of a poster presentation at the Symposium of Advanced Wound Care Fall 2014 with encore presentations at subsequent conferences.**
Diabetic Foot Ulcer on Charcot Foot

**Patient History:** 61 year old female with history of diabetes, neuropathy, osteomyelitis and Charcot foot presented with right plantar mid-foot ulcer.

**Challenges:** Diabetes, neuropathy, Charcot deformity, and a chronic wound.

**Initial Assessment:** Wound size was 1.7 cm x 0.6 cm x 0.5 cm (area: 1.02 cm²; volume: 0.51 cm³, Figure 1).

**Previous Treatments:** Patient had a long history of failed therapies including standard wound dressings such as calcium alginates.

**Treatment Strategy:** AMNIOEXCEL® was applied every 2 weeks with a secondary dressing of petrolatum non-adherent gauze followed by plain gauze and TCC-EZ®.

**Wound Progress:** By week 2, the wound decreased in size to 0.4 cm x 0.3 cm x 0.1 cm (area: 1.02 cm², volume: 0.01 cm³, Figure 2) representing an 88% and 98% area and volume reduction, respectively.

**Outcome:** Complete closure occurred at week 7.5 after a total of 3 applications of AMNIOEXCEL® (Figure 3).

*Case provided by Barry Rosenblum, DPM, FACFAS as part of a poster presentation at the Symposium of Advanced Wound Care Fall 2014 with encore presentations at subsequent conferences.*
Case 3

**Diabetic Foot Ulcer with Vascular Insufficiency**

**Patient History:** 91 year old male with CVA, diabetes, ABI 0.49, DFU with exposed tendon following failed vascular intervention.

**Challenges:** Diabetes and vascular insufficiency.

**Initial Assessment:** Wound measured 1.2 cm x 1.2 cm x 0.7 cm ambulatory with a brace (Figure 1).

**Treatment Strategy:** AMNIOEXCEL® was applied every 2 weeks.

**Wound Progress:** Wound progressively decreased in size as new granulation tissue formed (Figure 2).

**Outcome:** The wound closed at week 6 following 2 applications of AMNIOEXCEL® (Figure 3). As of week 9, the patient tolerated independent ambulation and resumed wearing diabetic footwear with inserts.

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*Case provided by Margaret Doucette, DO, FABPM, CWSP as part of a poster presentation at the Symposium of Advanced Wound Care Spring 2015 with encore presentations at subsequent conferences.*
Diabetic Foot Ulcer

**Patient History:** A 59 year old female with Type I insulin dependent diabetes (or IDDM), hypertension, Charcot, thyroid disease, diabetic neuropathy. Reoccurring ulcers on the plantar surface of foot. Patient is well known to the facility. Non-compliant and just out of hospital for treatment of infection.

**Challenges:** Wound had been present for 2 months at the time of admission. On presentation the wound was a non-healing Wagner Grade 2 of the left proximal medial foot with status as not healed.

**Initial Assessment:** The size of the wound was 1.4 cm x 1.5 cm x 0.9 cm. The wound was treated for 4 weeks with felt and foam, bovine forestomach matrix and antibacterial foam with gentian violet and methylene blue, prior to baseline, with slow progress prior to application of AMNIOEXCEL®.

**Treatment Strategy:** The patient underwent protocol using a combination of TCC-EZ® and AMNIOEXCEL® applied weekly (4 applications).

**Wound Progress:** After 28 days, the wound showed complete resolution with full epithelialization. Notable is the significant reduction in depth after 1 week from 0.9 cm to 0.1 cm.

*Case provided by Bradley Herbst, DPM, Diplomat American Board of Podiatric Surgery
St. Vincent’s Wound Care Center, Jacksonville, Florida*
Trauma, Post-Surgical Diabetic Foot Ulcer

**Patient History:** 68 year old male stepped on a nail. He had surgical I & D with wash out and MRSA treated with intravenous antibiotics in hospital and oral antibiotics following discharge. He has diabetes, hypertension, neuropathy and severe supination of left foot.

**Challenges:** Neuropathy, supination, and diabetes.

**Initial Assessment:** One week post-surgery (Figure 1).

**Treatment Strategy:** AMNIOEXCEL® and TCC-EZ®.

**Wound Progress:** The wound decreased in size (Figures 2, 3).

**Outcome:** Wound closed at week 7 (Figure 4).

*Case provided by Brian Allen, MD of Rockdale Medical Center, Conyers, GA.*
Post-Amputation Complications

**Patient History:** 64 year old male with diabetes presented after having had resection of the right second toe 2 months prior. Treatment prior to presentation: saline wet-to-dry dressing and no off-loading. Patient came for a second opinion after being managed by his surgeon and vascular surgeon/wound care physician.

Initial treatments were Negative Pressure Wound Therapy (NPWT) (5:2 intermittent) and forefoot off-loading shoe was recommended. Hyperbaric Oxygen Therapy (HBOT) was discussed and screening started. Initial wound measurements: 0.4 cm x 1.3 cm x 1.6 cm.

**Challenges:** Surgeon discontinued the NPWT 2 weeks into therapy. Patient refused HBOT. Patient developed cellulitis (treated for 2 weeks)

**Initial Assessment:** Initial measurements prior to AMNIOMATRIX® application and 4 weeks post initial evaluation were 0.2 cm x 0.1 cm x 2.5 cm.

**Previous Treatments:** Standard of care was received, but wound did not show significant progress after one month.

**Treatment Strategy:** AMNIOMATRIX® was initiated 4 months after initial surgical procedure to aid in closing sinus track that had formed.

**Wound Progress:** By week 2 the wound measured 0.9 cm x 0.3 cm x 0.9 cm and AMNIOMATRIX® reapplied.

**Outcome:** Complete closure occurred after 4 weeks and 2 applications of AMNIOMATRIX®.

Case provided by Dimitrios Lintzeris, DO, CWS as part of a poster presentation at the Symposium of Advanced Wound Care Fall 2014 with encore presentations at subsequent conferences.
Trauma to Foot with Infection

**Patient History:** 52 year old male with right dorsal wound due to intermetatarsal abscess positive for *Streptococcus*. He had surgery for incision and drainage with post-operative NPWT.

**Challenges:** Alcoholism, cellulitis, wound odor, and lack of off-loading.

**Initial Assessment:** Wound measured 8.9 cm x 1.3 cm x 0.2 cm (area: 11.57 cm²; volume: 2.31 cm³) (Figure 1).

**Treatment Strategy:** AMNIOEXCEL® was covered with a non-adherent dressing, a secondary dressing, and a gauze wrap.

**Wound Progress:**

- **Week 2 (second AMNIOEXCEL® application):** Wound decreased in size to 7.9 cm x 1.5 cm x 0.1 cm (area: 11.85 cm², volume: 1.19 cm³).

- **Week 4 (third AMNIOEXCEL® application):** Confirmed presence of hypergranulation tissue so debridement was performed.

- **Week 6 (fourth AMNIOEXCEL® application):** Since initiation of AMNIOEXCEL®, the wound decreased in area by 56% and volume by 78% (3.9 cm x 1.3 cm x 0.1 cm, area: 5.07 cm², volume: 0.51 cm³) (Figure 2).

- **Week 8 (fifth AMNIOEXCEL® application):** Wound further decreased in size to 2.5 cm x 0.5 cm x 0.1 cm (area: 1.3 cm², volume: 0.13 cm³) representing an overall decrease in area and volume of 89% and 94%, respectively, since initiation of AMNIOEXCEL® (Figure 3).

**Outcome:** Wound closed at week 12 following 5 applications of AMNIOEXCEL® (Figure 4).
Figure 1

Figure 2

Figure 3

Figure 4

WEEK 0

WEEK 6

WEEK 8

WEEK 12

WOUND CLOSURE

Case provided by Tracey L. Basso, DPM as part of a poster presentation at the Symposium of Advanced Wound Care Spring 2015 with encore presentations at subsequent conferences.
Venous Insufficiency, Peripheral Arterial Disease (PAD) & Diabetes

**Patient History:** A 64 year old male with a history of long-standing venous insufficiency and 5 – 6 years of ulcerations.

**Challenges:** Smoker, diabetes (HgB A1C = 8.4%), hypertension, chronic venous insufficiency and PAD.

**Initial Assessment:** He presented with a Venous Leg Ulcer (VLU) on his right medial malleolus that measured 3.8 cm x 1.5 cm x 0.2 cm (area: 5.7 cm²; volume: 1.14 cm³). It was a large full thickness ulceration with significant slough and bioburden. Following surgical debridement, the wound bed remained very fibrotic. The wound had slight periwound erythema and tenderness to palpation. (Figure 1)

**Previous Treatments:** High-grade multi-layer compression wraps, bi-layered bioengineered skin substitute (used 5 times without a significant impact on wound healing).

**Treatment Strategy:** After a lack of recent progression following advanced treatments, AMNIOEXCEL® was applied every 2 weeks.

**Wound Progress:** Within 2 weeks marked improvement was noted (Figure 2).

**Outcome:** Following a total of 3 applications, the wound closed 6 weeks after initiating AMNIOEXCEL® treatment (Figure 3).

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**Case provided by Dimitrios Lintzeris, DO, CWS as part of a poster presentation at the Symposium of Advanced Wound Care Fall 2014 with encore presentations at subsequent conferences.**
Traumatic Wound and Venous Insufficiency

Patient History: A 74 year old male with history of chronic venous insufficiency with DVT presented with a traumatic wound to his lower left anterior leg after striking his leg with a leaf blower 15 weeks prior. His medical history included sarcoidosis, peripheral vascular disease, recurrent phlebitis, DVT and foot drop on the left side.

Challenges: Failed treatments and venous insufficiency.

Initial Assessment: The wound measured 5.9 cm x 5.2 cm x 0.2 cm (Figure 1).

Previous Treatments: The wound was treated with a variety of advanced wound care strategies including 2 applications of bi-layered bioengineered skin substitute without significant success.

Treatment Strategy: AMNIOEXCEL® was applied every 2 weeks.

Wound Progress: Within 2 weeks, a decrease in wound size was observed.

Outcome: The wound closed at 8 weeks following a total of 4 applications of AMNIOEXCEL® (Figure 2).

Case provided by Dimitrios Lintzeris, DO, CWS as part of a poster presentation at the Symposium of Advanced Wound Care Fall 2014 with encore presentations at subsequent conferences.
Heterotopic Ossification after Trauma

Patient History: A 25 year old male with heterotopic ossification (HO) throughout his posterior calf.

Challenges: HO

Initial Assessment: 6 open wounds from HO formation after limb salvage following an IED blast. Wounds ranged in size from 3.0 cm x 4.0 cm x 0.5 cm to 0.5 cm x 0.5 cm x 0.5 cm (Figure 1).

Treatment Strategy: AMNIOEXCEL® was applied every week.

Wound Progress: The wounds decreased in size by an average of 20% reduction in area per week. (Figure 2)

Outcome: 4 of the 6 wounds closed completely after 4 weeks and 4 applications of AMNIOEXCEL®, the remaining 2 were almost closed (Figure 3).

Case provided by Kara S. Couch, MS, CRNP, CWS as part of a poster presentation at the American College of Wound Healing and Tissue Repair 2014 Meeting.
Post Amputation Injury with PAD

**Patient History:** An 89 year old male with severe non-reconstructable PAD, left below-knee amputation. Doctors recommended above-the-knee amputation but the patient declined.

**Challenges:** PAD and post-amputation.

**Initial Assessment:** The wound measured 5.0 cm x 4.7 cm with 2.3 cm x 0.1 cm of exposed bone (Figure 1).

**Treatment Strategy:** AMNIOEXCEL® applied every 1-2 weeks.

**Wound Progress:**

**Week 1:** The wound decreased in size and had 2 areas of bone exposure. Area with white wick sticking out in photograph was a tract 2.0 cm length (Figure 2).

**Week 8:** Wound continued to decrease in size. AMNIOMATRIX® was injected to manage the tract, which closed after one application (Figure 3).

**Outcome:** After 13 weeks and 8 applications of AMNIOEXCEL®, the wound closed (Figure 4). The patient was able to live independently due to limb salvage.

Case provided by Margaret Doucette, DO, FABPM, CWSP as part of a poster presentation at the Symposium of Advanced Wound Care Spring 2015 with encore presentations at subsequent conferences.
Neonate IV extravasation

**Patient History:** 12 week old neonate born premature at 24 weeks gestation had an IV extravasation of TPN/IL on right foot.

**Challenges:** Neonate

**Initial Assessment:** Wound measured 3.5 cm x 2.5 cm x 0.1 cm (area: 8.75 cm²; volume: 0.88 cm³) (Figure 1).

**Treatment Strategy:** MEDIHONEY® Gel and Calcium Alginate dressings were applied to the wound daily or every other day for 2 weeks. The eschar was then easily removed with sharp debridement technique. At this point, the wound measured 0.3 cm x 1.6 cm x 0.3 cm (area: 4.8 cm²; volume: 1.44 cm³) (Figure 2). Treatment with AMNIOEXCEL® was initiated and the dressing remained in place for 7 days.

**Wound Progress:** Following one application of AMNIOEXCEL®, the wound decreased in area by 69% to 1.5 cm x 1.0 cm x 0.2 cm (area: 1.5 cm²; volume: 0.3 cm³) and the wound bed was covered in granulation tissue (Figure 3). A second AMNIOEXCEL® was applied.

**Outcome:** The wound closed at week 2 following 2 applications of AMNIOEXCEL® (Figure 4).

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Case Provided by Rene Amaya, MD, FAAP, CWSP, Pediatric Infectious Disease and Wound Care Specialist.
Post-Burn Trauma to Hand

**Patient History:** 35 year old male with full thickness wounds on the dorsum of the 4th digit on his right hand following 3rd degree burns from a car accident 6 months prior. The 5th digit was not salvageable due to osteomyelitis.

**Challenges:** Osteomyelitis

**Initial Assessment:** The wound measured 1.5 cm x 1.0 cm x 0.0 cm (1.5 cm³) and was covered with hypergranulation tissue (Figure 1).

**Treatment Strategy:** AMNIOEXCEL® was applied every 2 weeks and covered with a non-adherent dressing and a foam bolster dressing.

**Wound Progress:** At week 2, AMNIOEXCEL® was visible on the wound bed of ring finger (Figure 2). The wound improved after 2 applications of AMNIOEXCEL®, and it was 100% covered with granulation tissue and had started to epithelialize (Figure 3).

**Outcome:** The wound closed at week 5 following 2 applications of AMNIOEXCEL® (Figure 4).

*Case provided by Kara S. Couch, MS, CRNP, CWS as part of a poster presentation at the American College of Wound Healing and Tissue Repair 2014 Meeting*
Case 14

**WOUND TYPE: MOH’S, CARCINOMA**  **PRODUCTS USED/APPLICATIONS: AMNIOEXCEL® x 2**  **TIME TO CLOSE: 4 WEEKS**

### Post-MOH’s Surgery

**Patient History:** An 80 year old white female status post full thickness excision of an invasive squamous cell carcinoma of the apex of the scalp resulting in a full thickness defect measuring 8.0 cm x 4.0 cm involving a 4.0 cm² area of exposed cranium.

The surgical defect was treated initially with standard dressings and did not progress significantly in one month’s time. The defect was thereupon treated with two applications of AMNIOEXCEL® 10 days apart which resulted in the development of a thick scaffolding base. This allowed for epithelialization and a normal thickness and stable scalp integument.

**Initial Assessment:** Full-thickness wound that measured 8.0 cm x 4.0 cm and involved a 4.0 cm² area of exposed cranium (Figure 1).

**Previous Treatments:** Standard of care was received, but wound did not show significant progress after one month.

**Treatment Strategy:** AMNIOEXCEL® was applied every 10 days.

**Wound Progress:** After the second application of AMNIOEXCEL®, the wound was covered with red granulation tissue (Figure 2).

**Outcome:** Wound closed at Week 4 following 2 applications of AMNIOEXCEL® (Figure 3).

*Case provided by John B. Harris, MD, as part of a poster presentation at the American College of Wound Healing and Tissue Repair 2014 Meeting*
Post-Cosmetic Surgical Procedure

**Patient History:** A 60 year old female underwent a facelift surgical procedure, which resulted in bilateral retro-auricular skin loss.

**Challenges:** Area of compromised healing due to previous surgery and scarring.

**Initial Assessment:** Wound measured 2.0 cm x 2.0 cm x 0.1 cm with exposed fibrin at the base (Figure 1 and Figure 2).

**Treatment Strategy:** Two applications of AMNIOEXCEL® were used to provide for development of the scaffolding over the fascia and a resulting stable skin coverage that is indistinguishable from the surrounding integument.

**Wound Progress:** The defect was thereafter treated with AMNIOEXCEL® 10 days apart which resulted in the development of a scaffolding base allowing for epithelialization and a normal thickness and stable integument.

**Outcome:** Wound closed at Week 4 (Figure 3). Scar revision which would be the normal secondary procedure for this clinical situation will not be necessary.

*Case provided by John B. Harris, MD and Susan Whittingslow, RN of Ponte Vedra Beach, FL.*
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Conyers, GA

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Forrest General Wound Healing Center
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Boston, MA

Most cases shown here have been previously presented as blind reviewed clinical posters at leading wound and podiatry meetings. Derma Sciences would like to thank all of the authors for their assistance in developing these cases and their commitment to patient care.
1. Infection free
   - Perform sharp debridement

2. Measure the wound
   - Select the appropriate size of AMNIOEXCEL®

3. Open the outer foil pouch
   - Note: Visually locate the graft prior to opening the inner foil package.

4. Open the inner pouch
   - Use sterile forceps to extract membrane from package.
   - Carefully separate the membrane from the plastic mesh backing.
• Apply AMNIOEXCEL® immediately to wound.

• Use sterile forceps to gently apply pressure to the membrane to maximize contact with the wound bed.

• If needed, roll a sterile cotton-tip swab moistened with sterile saline
  
  Note: AMNIOEXCEL® is NOT side specific and can be applied in any direction and side.

• AMNIOEXCEL® can be secured to the area with suture strips or a bolster to secure the graft.

• Cover the wound with a non-adherent contact layer.

• Use an appropriate moisture management dressing such as XTRASORB® Foam dressing, per the wound type and treatment protocol.

• Secure dressing using a conforming bandage such as BIOGUARD®. The wound should not be disturbed, if possible, until follow up.
Ordering and Reimbursement Information

The Derma Sciences Reimbursement Hotline team of reimbursement professionals from Argenta reSource will help with:

- Case preauthorization
- Verification of benefits
- Coding and reimbursement
- Appeal support for denied claims

The Derma Sciences Reimbursement Hotline is an ongoing Derma Sciences commitment to healthcare professionals and facilities using our regenerative medicine products to treat patients.

### AMNIOTIC ALLOGRAFT MEMBRANE

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### AMNIOTIC ALLOGRAFT SUSPENSION

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The Patient Access Network (PAN) Foundation is an independent 501(c)(3) organization dedicated to providing help and hope to people with chronic or life-threatening illnesses for whom cost limits access to breakthrough medical treatments. Please refer to http://www.panfoundation.org for additional information.

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