

Diabetic Foot Ulcer Sales Presentation



Agenda

- Market
- What is DFU?
- Current Treatments
- Technique with TX-Bone
- Benefits of Ultrasonic
- Why Tenex?
- Clinical Outcomes
- Competition
- Targets
- Objection Handling
- Positioning and Marketing Info



Market

- Over 29 Million people are affected by diabetes in the US¹
- 4-10% of those patients develop DFU annually²
 - Some statistics show a rate as high as 25% lifetime risk
 - Opportunity, 4% = 1.16M people, 25% = 7.25M
- 40-80% of DFUs become infected³
- >25% of patients with DFUs require amputation.⁴
 - 73,000 amputations per year of the lower limb¹
 - Which can lead to depression and/or mortality
- Recurrence is common in patients
 - 40% in first year, 60% within 3 years, and 65% in 5 years⁵

¹ www.cdc.gov/media/releases/2014/p0610-diabetes-report.html

² Alexiadou, Diabetes Therapy, 2012

³ Geraghty, Expert Rev Pharm Out, 2019

⁴ Kim, Vasc Specialist Int, 2018

⁵ Armstrong, NE J. Med., 2017



Market

- DFU costs Medicare \$11 billion/year⁶
 - The most expensive costs associated with DFU are inpatient costs and hospital admissions
 - Costs are driven mostly by surgical procedures
 - Amputations can cost over \$70,000⁷
 - Foot ulcers - traditional initial care⁸
 - ~\$14,000/yr average
 - + \$3,200/yr 1 work-loss (employed, insured)
 - Skin grafts: \$1,700 - \$9,200/ea⁹
 - Negative pressure: \$26,000 - \$38,800¹⁰

⁶ Quilici, J Diabetes Res, 2016

⁷ www.apma.org/Media/PRdetail.cfm?ItemNumber=15108

⁸ Rice, Diabetes Care, 2013

⁹ Zelen, Intl Wound, 2014

¹⁰ Apelqvist, AM J Surg, 2008



What is DFU

- A diabetic foot ulcer is an open sore or wound that is commonly located on the bottom of the foot, usually over an osseous prominence
- DFU contributing factors:
 - Poor circulation
 - Peripheral neuropathy
 - A foot deformity (e.g., bunion, hammer toe)
 - Wearing inappropriate shoes
 - Uncontrolled blood sugar
- They are difficult to heal; prone to infection
- Can lead to amputation



The Wagner Ulcer Classification

- The Wagner diabetic foot ulcer classification system assesses ulcer depth and the presence of osteomyelitis or gangrene by using the following grades:
 - Grade 0 – intact Skin
 - Grade 1 – superficial ulcer of skin or subcutaneous tissue
 - Grade 2 – ulcers extend into tendon, bone, or capsule
 - Grade 3 – deep ulcer with osteomyelitis, or abscess
 - Grade 4 – partial foot gangrene
 - Grade 5 – whole foot gangrene
 - Contributing conditions:
 - Sepsis
 - Arteriopathy
 - Neuropathy



Patient Costs

- The estimated average cost/DFU patient is about \$28,000+/yr¹¹
 - Depends on severity, location and other factors

By the Numbers: Ulcer Severity and Costs

<i>Ulcer Severity</i>	<i>Avg. Episode Costs ('14)</i>
Wagner Grade 1: Superficial Ulcer involving the full skin thickness but not underlying tissue	\$3,352.89
Wagner Grade 2: Deep ulcer, penetrating down to ligaments and muscle, but no bone involvement or abscess formation	
Wagner Grade 3: Deep ulcer with cellulitis or abscess formation, often with osteomyelitis	\$6,917.84
Wagner Grade 4: Localized gangrene	\$27,448.86
Wagner Grade 5: Extensive gangrene involving the whole foot	

¹¹ https://opedge.com/Articles/ViewArticle/2015-08_02



Target Patients

- **Wagner Grade 2:** Deep ulcer, penetrating down to ligaments and muscle, but no bone involvement or abscess formation
- **Wagner Grade 3:** Deep ulcer with cellulitis or abscess formation
- This doesn't mean other patients are not candidates, but this is our sweet spot!



Wound Healing Phases

- How is the wound healing process broken down
 - There are 4 phases of the wound healing process:
 - Hemostasis, inflammation, proliferation and maturation
 - Hemostasis phase – The process of the wound being closed by clotting (most common)
 - Platelets stick together to form a wall of blood vessels
 - This happens very quickly
 - Inflammatory phase – The 2nd phase focuses on destroying bacteria and removing debris—essentially preparing the wound bed for the growth of new tissue
 - Dark granulation tissue can be a sign of infection, ischemia, or poor perfusion



Wound Healing Phases

- Proliferative Phase – This is the 3rd step which the body focuses on filling and covering the wound
 - The three distinct stages:
 - 1) filling the wound; 2) contraction of the wound margins; and 3) covering the wound (epithelialization)
 - This stage can last between four to 21 days
- Maturation phase – In phase 4, this is when the tissue usually gains strength and flexibility
 - Collagen fibers reorganize, the tissue remodels and matures
 - The Maturation phase varies greatly from wound to wound, often lasting anywhere from 21 days to two years
- These phases allow the clinician to decide treatment



Current Treatments

- Indirect treatment
 - Off-loading the foot
- Direct treatment (Superficial)
 - Debridement, which is the removal of dead skin and tissue
 - Topical, applying medication and dressing to prevent infection or to treat infection
 - Products range from normal saline to growth factors, ulcer dressings, and skin substitutes (grafts)
- Healing time can vary from a few weeks to months or years, depending on severity of case and patient; in some cases they never heal

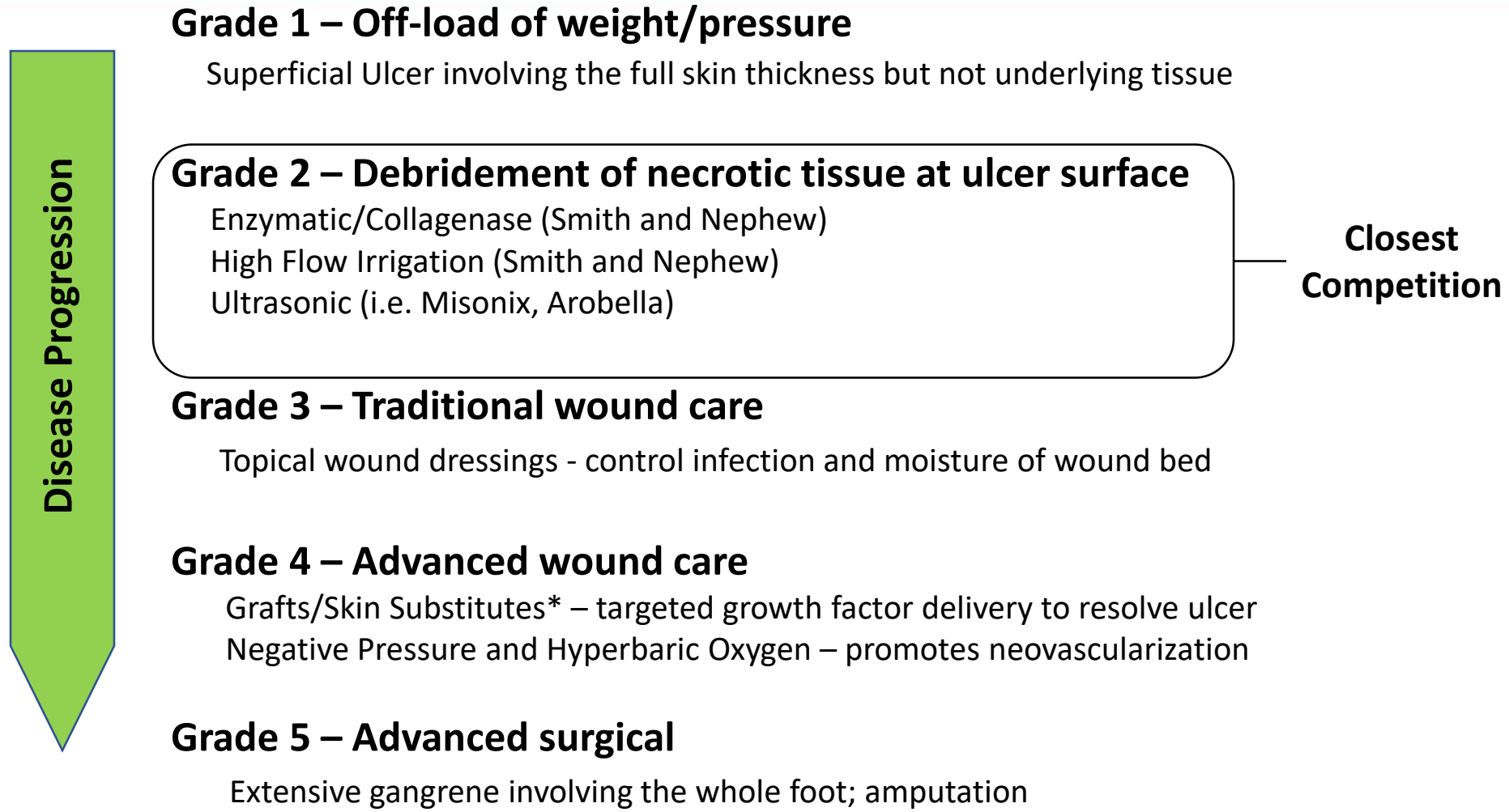


Current Treatments

- **Goal:** To heal the ulcer and attempt to reduce the recurrence
- **Approach:** Most products focus on promoting the healing of the superficial aspect of the ulcer and reducing bacterial burden
- **Clinical Measurements:**
 - “Healing” equals 50% reduction in ulcer size
 - “No recurrence” means it doesn’t return in 3 months



Current Treatments – Incremental Intervention



*Fastest growing technology segment by new products



Current Treatments

- Common problems with these treatments:
 - Prolonged – due to issues with healing
 - Provider intensive
 - Patient noncompliance issues
 - Variable results
 - Recurrence and Expensive
 - Remember, a high infection rate exists in many patients due to health or noncompliance, which leads to greater issues (possible amputation)
- All current treatments address the wound topically (except advanced surgical procedures)



Clinical Outcomes

- Best of the current outcomes show ulcer healing at 50 - 80%¹²
 - Once healed, 40% of DFUs will recur within 12 months, nearly 60% at three years, and nearly 65% at five years.¹³
- Provider intensive
 - Repeat treatments required
- Patients are non-compliant
 - Which leads to progression of disease and could contribute to depression
- Expensive
 - Can approach > \$28,000

¹² Smith-Strom, Plos One, 2017 and Alexiadou, Diabetes Ther, 2012.

¹³ Armstrong, N Engl J Med, 2017.



Ideal Treatment

- Goals:
 - Single treatment
 - Simple learning curve
 - Readily performed
 - Effective for:
 - Spectrum of ulcers
 - Complete healing/No recurrence
 - Safe
 - Bactericidal
 - Sustainable
 - Decreases cost of care

So what do we offer to help in this capacity?



DFU Technique with TX-Bone



Subcutaneous Debridement

- Procedure can be performed in:
 - OR in Hospital (best due to reimbursement)
 - Ambulatory Surgical Center
 - Procedure Room



Subcutaneous Debridement

- Antibiotic Prophylaxis:
 - day of and day after the procedure



Subcutaneous Debridement

- Does not enter wound directly
- Minimally invasive - percutaneous
- Local anesthetic
- Concurrent debridement and aspiration of necrotic tissue and excision of bony prominence if present, located subcutaneous to ulcer
- Ultrasonic energy from the TX system has been shown to be bactericidal¹⁴
- **Goal:** Circumferential debridement of necrotic soft tissue to promote regrowth of healthy tissue and elimination of bony pressure point to prevent recurrence

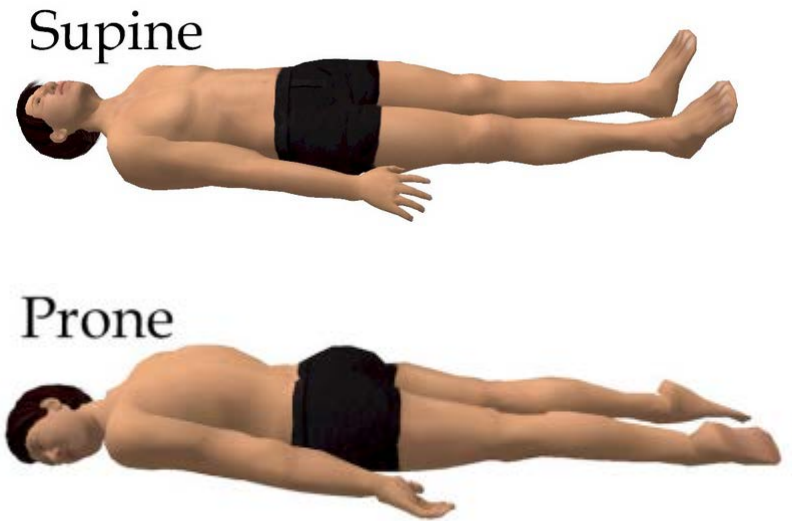


¹⁴ Kamineni, Mar 2019.



Technique

- Position patient in prone or supine position so that they are comfortable, and the surgeon has proper visualization and range of motion to treat the affected area of the foot
 - To prevent cross-infection, DO NOT use the device on multiple treatment sites
- Clean ulcer and surrounding area to be included in the procedure field properly with skin cleanser (e.g. Chlorhexidine)
- Square off affected area with sterile towels



Technique

- Deliver short acting local anesthetic (e.g. Lidocaine) in a circumferential manner around the border of the ulcer to properly deliver anesthetic into the subcutaneous tissue as well as create a skin wheal. The injection sites are typically delivered at a 3, 6, 9 and 12 o'clock orientation around the periphery of the ulcer. Wait 30 to 60 seconds for anesthetic to set



Technique

- Insert #11 blade through the skin just outside the periphery of the diabetic ulcer at either a 3, 6, 9 or 12 o'clock orientation.
- Direct the #11 blade down into the underlying subcutaneous tissue, directed towards the bony prominence located in the deep tissue, towards the center of the ulcer.
 - It is recommended to make all insertion site incisions prior to beginning treatment to facilitate saline egress and minimize swelling



Technique

- Following the tract created by the #11 blade, insert the TXB MicroTip and direct it through the skin in a direction towards bony prominence located in the deep tissue under the center of the diabetic ulcer. Move the TXB MicroTip in a forward and back motion (longitudinal displacement with “pistoning” action) in the subcutaneous tissue to cut and remove the necrotic deep tissue.



Technique

- Effective treatment of the targeted necrotic subcutaneous tissue is appreciated by direct palpation and a reduction in resistance when manipulating the TXB MicroTip.
- The dense scar tissue surrounding the ulcer is removed as the probe is directed toward the center of the wound, typically encountering a bony prominence in the depths of the ulcer.
- A depression of the ulcer bed and softening of the margin of the ulcer can be verified through palpation



Technique

- After treatment of the soft tissue, the TXB MicroTip should be orientated so that it is touching the bony prominence located underneath the ulcer bed.
- Palpation of the bony prominence and proper orientation of the TXB can be appreciated with the free hand.
 - Similar to the technique for cutting and removal of soft tissue, the TXB is maneuvered to debride the bony prominence. Always move the instrument in a forward and back motion.
- Effective treatment of the targeted bony prominence is appreciated by a reduction in resistance when manipulating the TXB MicroTip as well as a depression of the bony prominence through palpation.
 - If the prominence is located on a metatarsal head, the prominence should be 'peppered' with the probe until the probe with outer sheath can be inserted into the head



Technique

- Repeat previous steps at other points circumferential to the diabetic ulcer so that the entirety of the necrotic soft tissue and pathological bony prominence of the ulcer are treated.
 - This might require approximately 2 to 3 additional tracts created by the #11 blade and commensurate insertions of the TXB MicroTip
- Apply gauze with pressure to the insertion site to deliver hemostasis
- Wipe and clean the ulcer area properly
- Apply wound dressing as indicated



Technique

- Once technique is completed, make sure patient is off-loading foot in recovery
- Insufficient off-loading of the ulcer in the post treatment period, may lead to sub-optimal outcomes including recurrence of the ulcer (increased potential for skin break-down and associated infection)



Procedural Warnings

- Use prophylactic antibiotics
- Establish all portals at beginning of the case
- Clear scar from each portal at beginning of case to allow fluid to egress from all portals
- Avoid continuous energy, allow cooling period (3:1)
- Immediately discontinue energy if probe is clogged
- The probe should not be seen during debridement
 - It should never emerge from the depths of the ulcer during procedure
- Irrigate and aspirate after debriding to remove unwanted tissue
- Post procedure must off load; use good wound management



Ultrasonic Energy



Benefits of Ultrasonic Energy

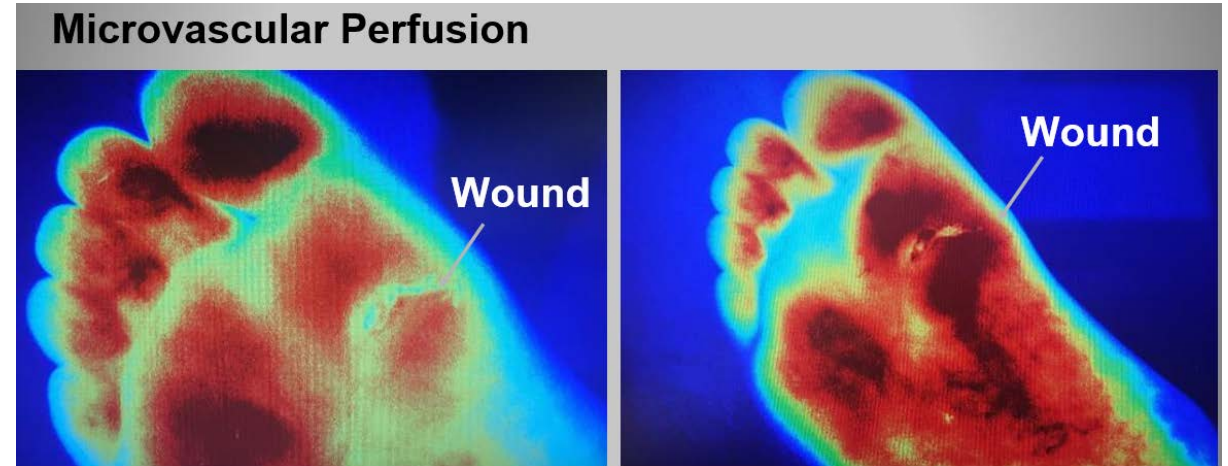
- Diabetic foot ulcers are known to have a polymicrobial flora, including Staphylococcus, which is part of the reason for recalcitrant persistence. Ultrasonic energy has an anti-staphylococcal effect¹⁵
- Ultrasonic energy from the TX System is bactericidal:
 - 64% kill rate with gram-negative bacteria
 - 60% kill rate with gram-positive bacteria
- It also promotes healing
 - By removing the sources of ischemia (that localize pressure and restrict blood flow) such as bony prominences
 - By increasing perfusion, around and at the bed of the wound

¹⁵ Kamineni, SICOT-J 2019.



Benefits of Ultrasonic Energy

- Microvascular Perfusion
- Images courtesy of Dr. Morrey¹⁶
 - Male, DFU patient
 - Duration of ulcer about 6 months
 - Healed in about 6 weeks



Pre-treatment

Red spots identify degree of micro-vascularization

Post-treatment

Increased perfusion identified as degrees of redness – particularly around and at bed of wound

¹⁶ <https://www.stryker.com/us/en/endoscopy/products/spy-elite.html>



Why Tenex?

- Curing the patient vs. continued treatment
- Benefits of Ultrasonic Energy
 - Antibacterial
 - Increases perfusion
- Removing the contributing factor of recurrence
- Reducing the total cost of care vs. traditional procedure or wound centers
 - The average treatment costs can be over \$28,000!



Why Tenex?

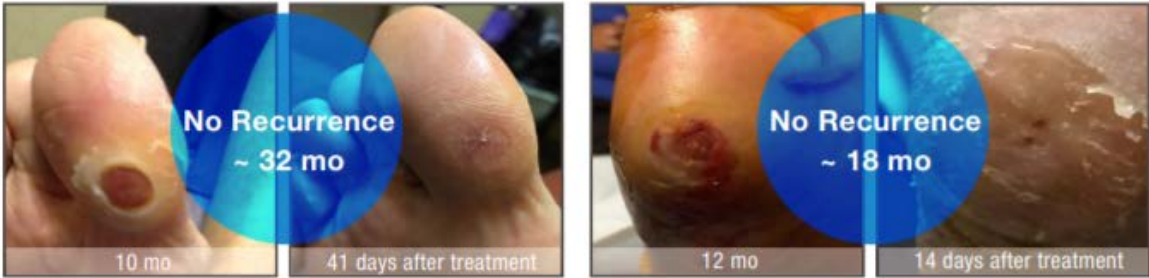
- Remember what the ideal treatment method is?
- ✓ • Single treatment
- ✓ • Simple learning curve
- ✓ • Readily performed
- ✓ • Predictably effective
- ✓ • Safe
- ✓ • Bactericidal
- ✓ • Sustainable
- ✓ • Decreases cost of care



*Clinical Outcomes



*Are We Approaching a Definitive
Solution for Diabetic Foot Ulcer?*



DFU Treatment with Ultrasonic Energy*



* Lewis H. Freed, DPM, podium presentation, The Windy City Podiatry Conference, Chicago, IL, December 2018.

* The studies and outcomes were the independent work of participating physicians. They were not promoted by Tenex Health, Inc. in any way. Tenex Health, Inc. does not promote use of the TX1 MicroTip or TX2 MicroTip for the treatment of hard tissue pathology or diabetic foot ulcers. The TX-Bone (TXB) MicroTip was developed, indicated, and FDA cleared for the treatment of hard tissue pathology and diabetic foot ulcers.



*Patient Examples¹⁷

- 50y F, BMI 48.09; L sub 1st Metatarsal ulcer
- 1 x 1 cm - 12 months
- Time to healing was around 2 weeks, no recurrence after 1 yr.



Figure 11A. Left plantar first metatarsal before treatment.

Pre-Op



Figure 11B. After treatment.

Post-Op



¹⁷ Ellis, http://www.podiatryinstitute.com/pdfs/Update_2015/2015_47.pdf

*Patient Examples¹⁷

- 68 y F; R Hallux ulcer
- 2.5 x 2.4 cm - 13 months
- Time to healing was 41 days, no recurrence after 1 yr.



Figure 13A. Right plantar hallux before treatment.

Pre-Op



Figure 13B. After treatment.

Post-Op

¹⁷ Ellis, http://www.podiatryinstitute.com/pdfs/Update_2015/2015_47.pdf



*Patient Examples¹⁸

- 58y M , BMI 29.83; L Hallux ulcer
- 2.5 x 1.8 cm, 17 months
- 5 Prior Treatments with total contact cast (TCC); breakdown after each time, serial debridements, wound care center, tar, silver, foams, gels, Regranex
- Time to healing was 14 days, no recurrence after 2 yrs.



Pre-Op

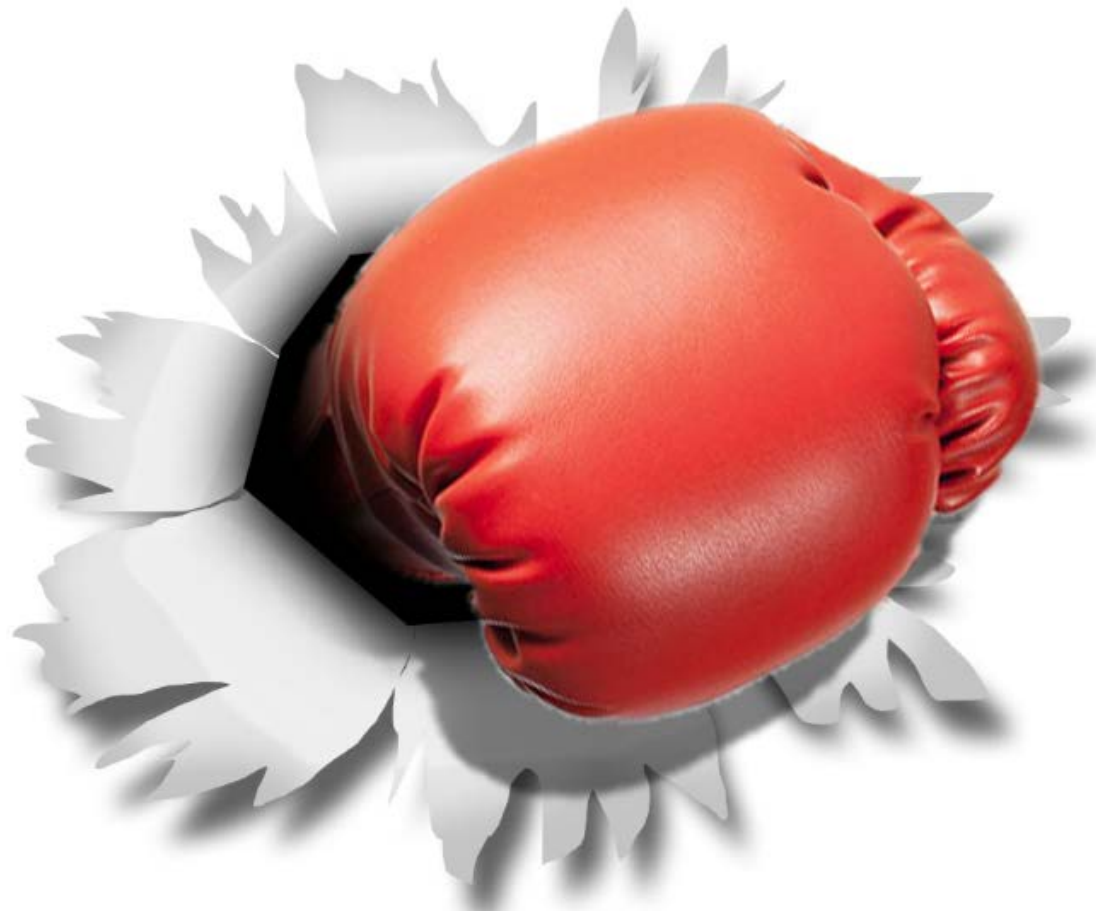


Post-Op

¹⁸ Freed, Case Study, 2016-2018.



Competition

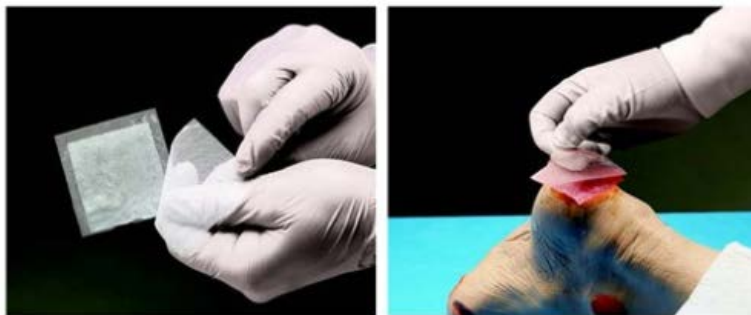


Market Leader – S&N/Advanced Wound Management

Product Portfolio (AWM)

- Mostly topical products
 - Various wound dressings (ALLEVYN)
 - Infection control ointments
 - Single-use, negative pressure (PICO)
 - Biologic debridement (SANTYL)
 - Biologic filler (DURAFIBER)
- Acquired Osiris in April which adds to their topical portfolio: Grafix, GrafixPL

GrafixPL



ALLEVYN
products



DURAFIBER

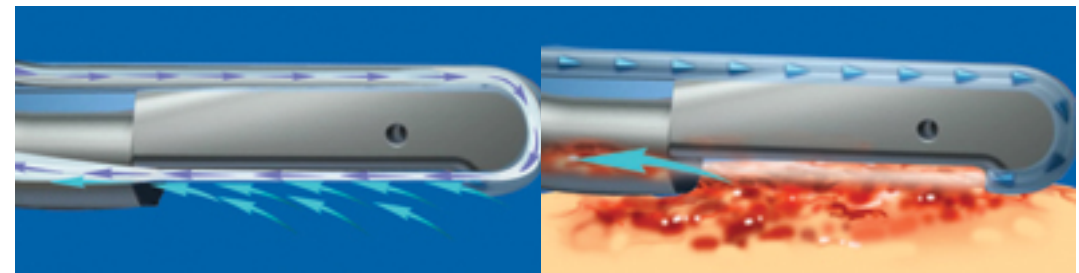


PICO



Smith & Nephew

- The VERSAJET II system enables a surgeon to excise and evacuate nonviable tissue, bacteria and contaminants from wounds, burns and soft tissue injuries
- As the handpiece travels tangentially over the soft tissue surface it creates a smooth wound bed while maximizing dermal preservation
- The tissue-preserving technique reduces time to closure which may reduce overall treatment costs.



Versajet: target necrotic tissue with hydro-dissection/surgery and aspiration



<http://www.smith-nephew.com/key-products/advanced-wound-management/versajet/>

Wound Care Centers

- Business model is not built on healing ulcers but treating them
- Address the DFU topically or with debridement
- Suggest 1-4 weeks follow-up depending on situation
- Continued issue or recurrence, skin grafts
 - Expensive
- Partner with hospitals; continued supply of patients
- Big business/revenue generating



Open Procedure

- Possible higher risk of infection due to larger open area
- Longer recovery due to large wound site
- Possibly more pain
- Larger scars
- Directly enters the wound site
 - Always enlarges the lesion



Misonix

- Publically traded (NASDAQ/MSON) – Founded in 1967
- Product Portfolio
 - BoneScalpel: ultrasonic energy to debride bone in open spine procedures
 - SonaStar: ultrasonic energy to resect tumors /soft tissue in open neurosurgery
 - SonicOne: ultrasonic energy to debride wounds (soft and bone); open
- US Sales: 1 sales director, 2 regional sales managers, 115 distributor sales reps
- Product pricing
 - Clinic: \$24,000 ASP or \$1,995 monthly rental for capital / \$100 disposable
 - Hospital/ASC: Consigned capital units / \$400 disposable



MKT-313 Rev A
Company Confidential



Arobella Medical

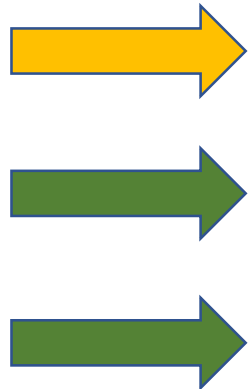
- Private company based in Minneapolis
- Founded in 2007 - US sales only
- 14 US sales reps (direct plus distributor)
- QOUSTIC WOUND THERAPY SYSTEM™
 - Lower frequency ultrasonic topical debridement
 - Has 4 application modes for debride wounds: Basic Treatment Mode, Cavitation Mode, and two Surgical/ Excisional Modes- Scooping & Edge
- Indication: Selective and non-selective dissection and fragmentation of soft and/or hard tissue
- Have clinical link on page only on wounds, and haven't had an updates since 2010
- \$75/disposable tip (handpiece is fixed)
- Reimbursement for soft tissue only (debridement)



Targets



Targets



Priority	Indications	Timeline	Suggested Follow-up
URGENT (active pathology)	▶ Open wound or ulcerative area, with or without signs of infection ▶ New neuropathic pain or pain at rest ▶ Signs of active Charcot deformity (red, hot, swollen midfoot or ankle) ▶ Vascular compromise (sudden absent DP/PT pulses or gangrene)	Immediate referral/consultation	As determined by specialist
HIGH (ADA risk category 3: the diabetic foot in remission)	▶ Presence of diabetes with a previous history of ulcer or lower-extremity amputation ▶ Chronic venous insufficiency (skin color change or temperature difference)	Immediate or "next available" outpatient referral	Every 1–2 months
MODERATE (ADA risk category 2)	▶ PAD ± LOPS ▶ DP/PT pulses diminished ▶ Presence of swelling or edema	Referral within 1–3 weeks (if not already receiving regular care)	Every 2–3 months
LOW (ADA risk category 1)	▶ LOPS ± longstanding, nonchanging deformity ▶ Patient requires prescriptive or accommodative footwear	Referral within 1 month	Every 4–6 months
VERY LOW (ADA risk category 0)	▶ No LOPS or PAD ▶ Patient seeks education on topics such as routine foot care, athletic training, appropriate footwear, or injury prevention	Referral within 1–3 months	At least annually for all people with diabetes

Ideal Patient Targets

DP, dorsalis pedis; LOPS, loss of protective sensation; PT, posterior tibial. Modified from Diabetes Care 2008;31:1679–1685 (ref. 6), with permission from the American Diabetes Association, ©2008.



Targets

- Hospital referrals
 - Physicians
- Podiatrists
 - Have a pool of patients
- Wound care centers
 - Patients who don't seem to be healing
 - Providing referrals – depending on relationship with clinician



Objection Handling

- I just do open procedures
 - Are you concerned with infection or the patient not healing quickly due to an enlarged wound site? Our product is minimally invasive and doesn't expand the wound area
- I just do standard care
 - How are your patients doing? Do they ever heal or just continue to deal with the painful issue? Our product removes the bony prominence and allows for the patient to heal
- I believe that grafts and topical treatment are sufficient
 - How often do your patients come back with recurrence? The bony prominence is not removed and will continue to break through the skin if not removed
- The technique is new to me and I am not comfortable with it
 - Understandable, how about we have you attend a lab or come into your facility and help train you and your staff, so you feel comfortable with the technique. I will also make sure that I attend your first few cases to make sure you have no issues



Positioning

- We provide a minimally invasive product for percutaneous treatment that heals the ulcer in one application and removes the contributing factor of recurrence by removing the bony prominence. Plus, it does not directly penetrate the wound surface allowing the site to heal properly. Our product also utilizes ultrasonic energy which has been shown to be bactericidal and increases perfusion.



Sales & Marketing Materials – Now Available

- New DFU Sales Sheet
- New Reimbursement Document
- New Tradeshow Support Materials
- TX-Bone 510(k) Clearance Letter
- TX-Bone Demo Product



Accessing Sales & Marketing Materials

- Available on the Resource Center & Tenex Streamline Site
- 3 ways to access these materials

<https://TenexHealth.com>

<https://Tenexresources.com>

<https://TenexHealth.WorkSmartSuite.com/login.aspx>

- Access directly from your smart phone. Make sure to save your credentials for easy reference and ordering.
- *You can also view videos directly from the Resource Center*
- *For login support for any of these resources, contact:*
Marketing@TenexHealth.com



Q&A



Sales Support – Contact Your Regional Manager

Product Orders – Orders@TenexHealth.com

Technical Questions – TechSupport@TenexHealth.com

Reimbursement – Reimbursement@TenexHealth.com

Marketing Support – Marketing@TenexHealth.com

Quality/Regulatory Information – Info@tenexhealth.com