

	CLI-009	TXB & DFU Clinical Claims – Supporting Evidence		Rev. D
	Effective Date: 02/06/2020		Change Order: 4746	
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List of Claims and References to Supporting Evidence:

#	Claim	Reference
1.	Ultrasonic Energy from the Tenex Health TX System has been shown to be bactericidal	Kamineni S, Dhawan V, Huang C, Porphyromonas Gingivalis Response to Ultrasonication. International Journal of Clinical Microbiology, Open Access, Mar 2019. Kamineni S, Huang C. The antibacterial effect of sonication and its potential medical application. SICOT-J, EDP Sciences. Open Access. June 2019. Kamineni S, Kamineni E, Kamineni A and Huang, C. Anti-Staphylococcal Effect of Ultrasonication. Novel Techniques in Arthritis & Bone Research, January 2019, 3:3.
2.	Ultrasonic Energy from the Tenex Health TX System has been shown to be bactericidal against gram-positive bacteria. 60% kill rate (for <i>Staphylococcus Aureus</i>).	Kamineni S, Kamineni E, Kamineni A and Huang, C. Anti-Staphylococcal Effect of Ultrasonication. Novel Techniques in Arthritis & Bone Research, January 2019, 3:3.
3.	Ultrasonic Energy from the Tenex Health TX System has been shown to be bactericidal against gram-negative bacteria. 64% kill rate (for <i>Porphyromonas gingivalis</i>).	Kamineni S, Dhawan V, Huang C, Porphyromonas Gingivalis Response to Ultrasonication. International Journal of Clinical Microbiology, Open Access, Mar 2019.
4.	Removes avascular tissue	Necrotic, diseased tissue is targeted in the fragmentation, emulsification and aspiration performed with the device.
5.	Increases perfusion	Creates “bleeding edges” at the periphery of the treated tissue by nature of the treatment: tissue is fragmented and removed. Dr. Morrey patient profile, microvascular blood flow imaged with the SPY Elite fluorescence imaging system. (Pictures are included in Attachment 1.) Male DFU patient, ulcer duration 6 months, healed 6 weeks post-op.
6.	Promotes healing (of localized ischemia)	By removing avascular tissue (4.) and increasing perfusion (5.). By removing the sources of ischemia (that localize pressure and restrict blood flow) such as bony prominences.
7.	Removes a primary contributing factor to DFUs and their recurrence (bony prominence commonly at the base of the ulcer)	Technique Guide 460-0011-557. Design Validation VR-0059. Armstrong DG, Lavery LA. Diabetic Foot Ulcers: Prevention, Diagnosis and Classification. American Family Physician. 1998. Vol. 57(6), pp 1325-1332. Bernstein J. Diabetic foot disorders. Orthopaedics One – Musculoskeletal Medicine for Medical Students – Foot and Ankle Topics. 2017.

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		https://www.orthopaedicsone.com/display/MSKMed/Diabetic+foot+disorders Kleiber B. Diabetic Ulcer. American Orthopaedic Foot & Ankle Society, Physician Resource Center. 2015. http://www.aofas.org/PRC/conditions/Pages/Conditions/Diabetic-Ulcer.aspx
8.	Does not interfere with the body's natural wound healing process (i.e. proliferation and remodeling)	No penetration of the wound surface, and thus no disturbance of granulation already underway.
9.	Limits the spread of microbes (by not penetrating the wound surface)	Technique Guide 460-0011-557.
10.	Subcutaneous debridement with the Tenex Health TX System resulted in 83% successful healing, in an avg of 2 weeks, without recurrence for 6 months in 10 healed wounds. (n=12)*	Ellis M, Freed LH, Haddon TB. Percutaneous ultrasonic debridement for treatment of recalcitrant foot ulcers. The Podiatry Institute, Update 2015, Ch 47.* http://www.podiatryinstitute.com/pdfs/Update_2015/2015_47.pdf
11.	DFU Treatment with Ultrasonic Energy (or with the TX System) has yielded a 90% healing rate with <10% recurrence rate over 4 years of experience*	Lewis H. Freed, DPM, podium presentation, The Windy City Podiatry Conference, Chicago, IL, December, 2018.
12.	DFU Treatment with Ultrasonic Energy (or with the TX System) has yielded 94% healing with <4% recurrence, over 5 years of experience, with 81 patients. Average time to heal was <3 weeks. All had prior, advanced wound care.*	Lewis H. Freed, DPM FACFAS, "Percutaneous Ultrasonic Treatment of Tendon and Wounds," Texas Podiatric Medical Association (TPMA) Southwest Foot and Ankle Conference 2019, Frisco, Texas, September 2019. (Presentation included as Attachment 2.)
13.	105 ulcers treated: 101 healed, 4 didn't (>96% healing). 5 recurred between 14-33 mons (<5% recurrence). <3.5 wks avg time to heal. 6 infections (3 had chronic osteomyelitis prior, all healed w/ IV ABX, 2 infected > 1 mon after surgery.) Most (almost all) ulcers were treated with one procedure.*	Lewis H. Freed, DPM FACFAS, Percutaneous Ultrasonic Treatment of Foot & Ankle and DFU, Mesa, Arizona, Webinar for Tenex Health, Inc., Jan 21, 2020, (MKT-336).
14.	Safe	8 TXB adverse events out of 1,595 cases (1/31/20) = 0.5% adverse event rate. (Includes 4 infections that may not have been results of the TXB procedure.) Internal complaint files.
15.	Quick procedure	Simulated cadaver procedure time averaged 2:39 for soft and hard tissue cutting, per VR-0060 Design Validation. Average treatment (cutting) time for DFU was 4:36 in Limited Use Release VR-0065. Total procedure time averaged 31:18 in VR-0065. Device is limited to 15-minute cutting time (combined soft + hard tissue) per IFU 460-0001-557.

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* Disclaimers for citation of Freed, Ellis, Haddon, other TX-1 DFU data:

- Studies were the independent work of the participating physicians and 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.

OR:

- Studies were the independent work of participating physicians and were not promoted by Tenex Health. Tenex Health does not promote TX1/TX2 MicroTips for treating hard tissue or diabetic foot ulcers. The TXB MicroTip is FDA cleared for hard tissue and diabetic foot ulcers

Attachment 1: Dr. Morrey case evaluation with SPY imaging, demonstrating increased perfusion

Attachment 2: Dr. Freed's TPMA 2019 Course Presentation: "Percutaneous Ultrasonic Treatment of Tendon and Wounds"