

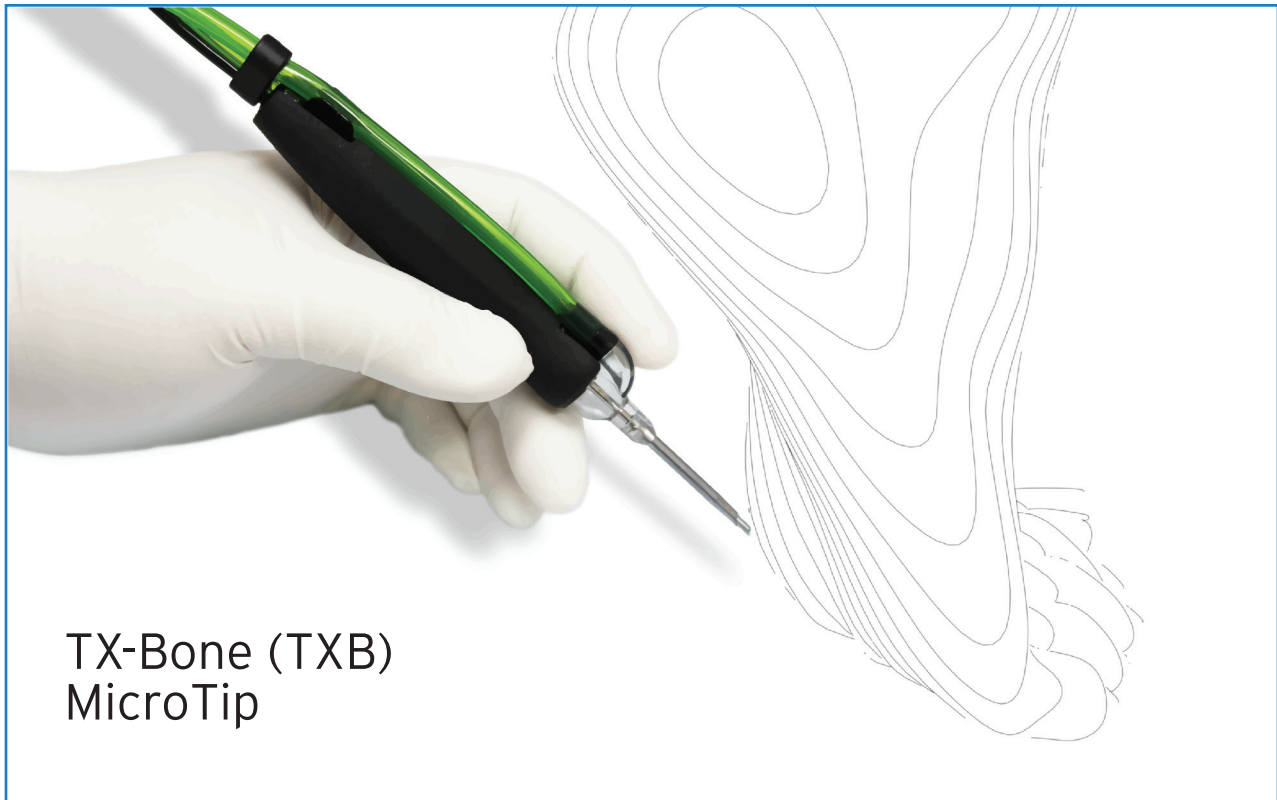
Tenex Health TX[®] System
Diabetic Foot Ulcer
Technique Guide



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TX-Bone (TXB)
MicroTip

Introduction

The TX-Bone (TXB) MicroTip is an ultrasonic handpiece used by the clinician for the purpose of fragmenting, emulsifying, and aspirating soft tissue and hard tissue. The handpiece delivers irrigation fluid directly to the target site, while simultaneously aspirating emulsified tissue. TXB comes complete with the cutting handpiece, associated cartridge with tubing and collection bag. The TXB is to be used with the Tenex Health TX® System Console.

The TXB provides for subcutaneous treatment that promotes healing of the ulcer in one application and removes the contributing factor of recurrence, the bony prominence. Importantly, the probe does not directly penetrate the wound surface, which allows for more rapid and effective healing, as it does not disturb any tissue granulation already underway.

Here are the steps of the technique. Prior to starting, make sure the system is functioning properly. Refer to the TX Console Operator's Manual and System Set-Up card supplied with the console for further information.

Patient Selection

The ideal patient has a Meggitt-Wagner Grade 0 to Grade 2 ulcer, 3cm in diameter or less, that has failed 3 months or more of good wound management. Larger ulcers are treatable but are expected to require more extensive subsequent wound management. Ulcers of the heel, involving the calcaneus, may also require additional wound management.

Infections must be treated and cleared prior to treatment with TXB.

Contraindications

(Reference the IFU for additional information.)

- Active Infections.
- Weakness of the posterior muscle group with a calcaneal gait disorder.

Preparation

System Set-Up

(Per the IFU and TX Console Operator's Manual)

- A** Set Up the TX Console.
- B** Connect the TXB MicroTip to the Console.
- C** Be sure to use a 1000mL saline irrigation bag, and the pressure cuff provided with the TX Console
- D** Prime the System.
- E** Ensure proper function of the TXB MicroTip (ultrasonic activation and irrigation).
- F** Typical settings for both soft scar tissue and bone (Fig. 1):
 - Aspiration: High
 - Cutting: Medium



Tenex Health TX® System Console

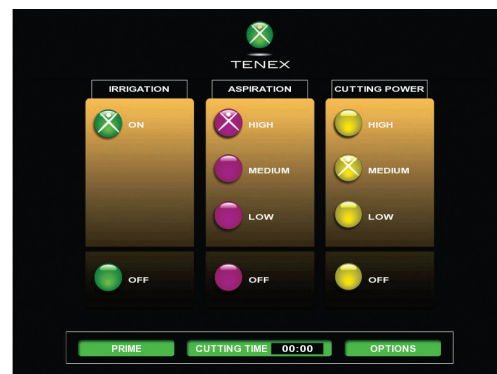


Figure 1. The TX Console is typically placed in the high setting for aspiration and on medium setting for the ultrasonic energy cutting function for both soft and osseous tissue.

Patient Preparation

WARNING: Use standard wound care management pre and post treatment. This should include administration of **prophylactic antibiotics** as appropriate due to the risk of infection.

Note that bacterial colonization of diabetic ulcers is often polymicrobial and may require multiple agents for most effective prophylaxis. Verify that any antibiotic agents metabolized by the kidneys are compatible with the renal function of the diabetic patient. *The information presented here is not intended to supersede the clinical judgment of the physician. Always ensure treatment is appropriate for the condition and needs of each specific patient.*

If there is excessive scarring around the margin of the ulcer, limited sharp debridement may be necessary prior to use of the TXB. Take care not to significantly enlarge the ulcer. Unless sensation is totally absent, a fast acting local anesthetic is administered, as for any ulcer debridement.

Preparation (cont'd)

- 1 Position patient in a supine or prone position, with proper visualization and range of motion to treat the affected area of the foot. In most instances, it is desirable to extend the foot past the edge of the table for ease of access and drainage of fluids.
- 2 Clean ulcer and surrounding area to be included in the procedure field with appropriate skin cleanser.
- 3 Square off affected area with sterile towels.
- 4 Unless sensation is totally absent, administer a fast acting local anesthetic in a circumferential manner around the border of the ulcer. Typically, injections are placed in the anticipated sites of probe insertion (e.g., at 12, 3, 6, and 9 o'clock position around the periphery of the ulcer).

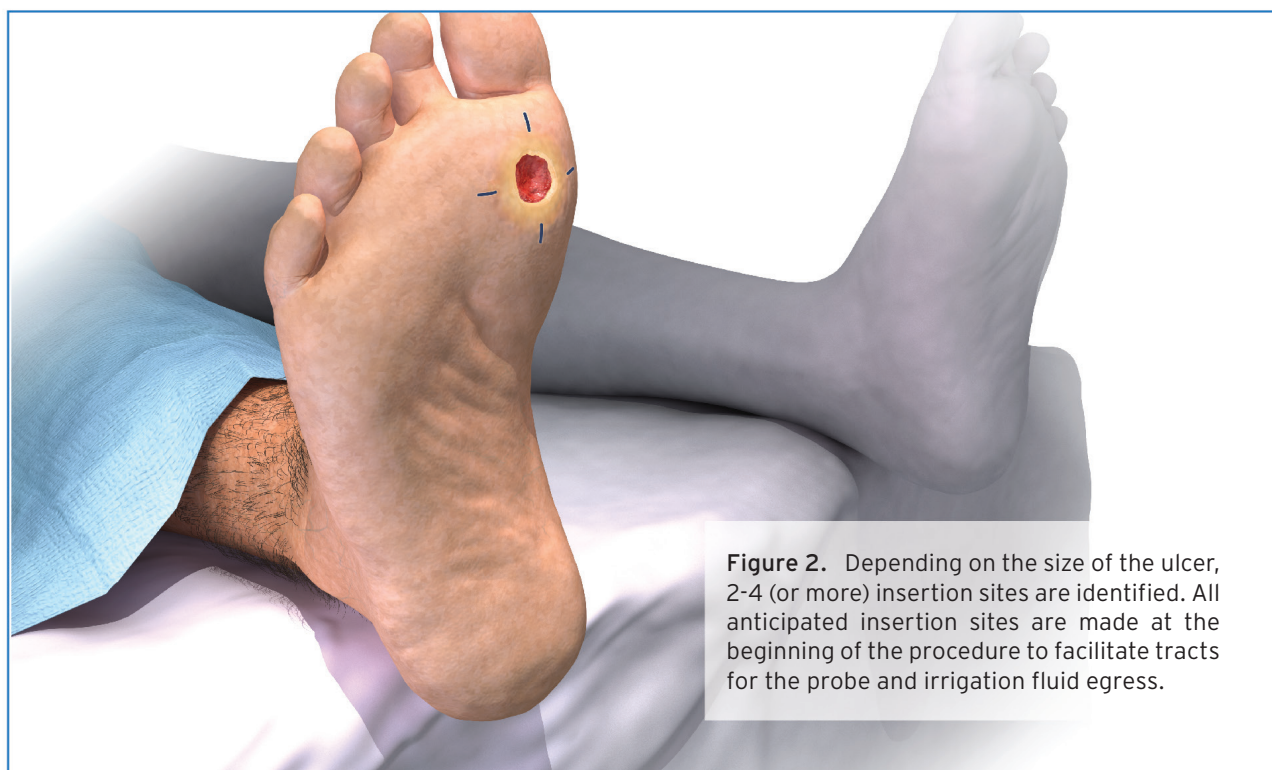


Figure 2. Depending on the size of the ulcer, 2-4 (or more) insertion sites are identified. All anticipated insertion sites are made at the beginning of the procedure to facilitate tracts for the probe and irrigation fluid egress.

Portal Site Creation

- 5 At least 2 portal sites are required, even for small ulcers, to facilitate egress of irrigation fluid. For ulcers larger than 2 cm, 3 or 4 portal sites are typically used (e.g., at 12, 3, 6, and 9 o'clock position around the periphery of the ulcer) (Fig. 2).

It is important that the sites are located **at least**
- 6 **1 cm from the margin** of the ulcer.

Use the #11 blade to create the portal sites. Insert the blade at each site at an angle, directing it toward the bony prominence underneath the ulcer, always remaining subcutaneous, at the margins of the ulcer and deep to the ulcer granulation tissue.

Scar Tissue and Bony Prominence Removal

- 7 Insert the TXB probe into the first portal site, directing it towards the bony prominence (Fig. 3).
- 8 Advance the probe using a “pistoning” or axial (forward and back) motion. Do not force it or hold it static in the target tissue to avoid clogging the probe.

NOTE: When using the cutting function on the console, there will be a 1 second delay between activation of the foot pedal and delivery of ultrasonic cutting power. This is to provide sufficient irrigation fluid at the probe tip.

NOTE: The probe tip should never be removed from the portal (or directly visualized) when it is actively treating tissue. No part of the probe should be visualized through the ulcer.

- 9 Use the probe to remove the avascular scar tissue surrounding the ulcer, as the probe is advanced to the bony prominence. The bony prominence can be located by palpation with the free hand and the tip of the probe. (fluoroscopy or other visualization may also be used) Skin surrounding the portal will become soft and pliable as the tissue is removed. Do not “sweep” the probe side to side, to avoid placing undue stress on the probe (Fig. 4). Retract, reorient and repeat the axial motion as tissue is cleared.
- 10 Orient the TXB probe tip so its bevel is pointing away from the bone, and the endpoint contacts the bone. Advance the probe using a “pistoning” motion over the outer surface of the bone to cut and remove material **with a “planing action”** to remove thin layers from the bone.

CAUTION: To facilitate proper cooling, do not use the probe continuously. Always follow a duty cycle of 15 seconds on, 45 seconds off.



Figure 3. The probe is introduced into the subcutaneous scar tissue, which is removed with a “pistoning” back and forth motion.

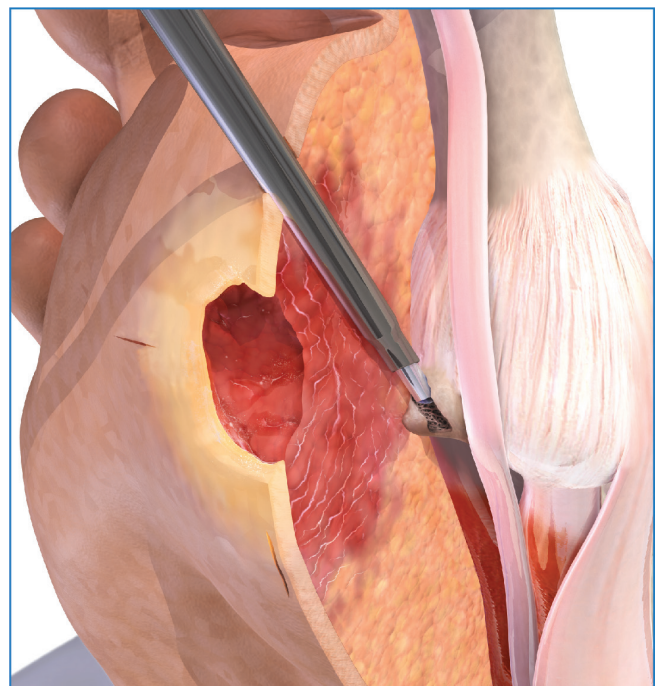


Figure 4. The scar tissue may be dense, and the probe may enter the osseous prominence. A sweeping or out of plane motion must not be performed as this places undue stress on the probe.

Scar Tissue and Bony Prominence Removal (cont'd)

- 11 Repeat the probe insertion and treatment at all portal sites, until all scar tissue and the bony prominence is removed. Use palpation, fluoroscopy, or ultrasound to verify the removal of the bony prominence.

Adequate treatment of the targeted necrotic subcutaneous tissue is further appreciated by direct palpation and a reduction in resistance when manipulating the TXB probe through the soft tissue.

- 12 In some instances, it may be useful to “pepper” the bony prominence with the probe until the probe tip and its outer sheath can insert through the weakened cortex, which allows for the removal of subcortical bone (Fig. 5).

CAUTION: To facilitate proper cooling, do not use the probe continuously. Always follow a duty cycle of 15 seconds on, 45 seconds off.

NOTE: The probe tip should never be removed from the portal (or directly visualized) when it is actively treating tissue.

- 13 After removal of the bony prominence, use thumb pressure directed through the ulcer to depress any residual bony points and flatten the area.

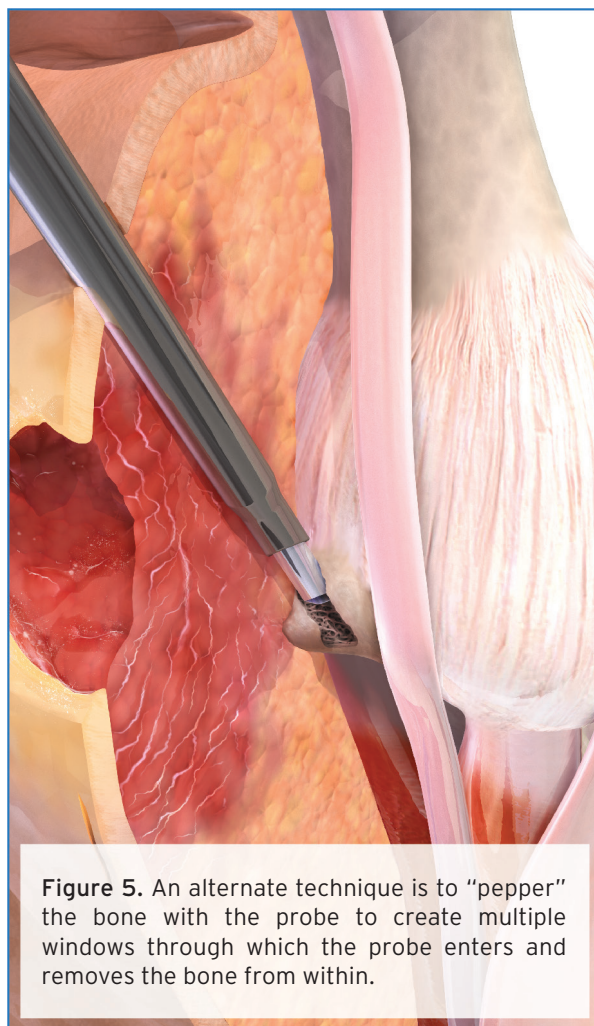


Figure 5. An alternate technique is to “pepper” the bone with the probe to create multiple windows through which the probe enters and removes the bone from within.

Aspirating and Dressing

- 14 At the end of the procedure, turn off the Cutting and Irrigation functions. Aspirate to remove fluid and debris tissue.
- 15 Clean the treatment areas and ulcer appropriately.
- 16 Apply sterile gauze with light pressure to the area.
- 17 Continue standard wound care as the ulcer heals (including off-loading).

WARNING: This should include the appropriate administration of **prophylactic antibiotics**, due to the risk of infection.

CAUTION: 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 infection).

- 18 Minimal edema and erythema may occur locally for several days and are considered a routine response to treatment.

WARNINGS AND CAUTIONS

WARNINGS

- Use standard wound care management pre and post treatment. This should include administration of prophylactic antibiotics as appropriate. Failure to utilize standard wound care management pre and post treatment may increase the risk of infection or crossinfection.
- To prevent cross-infection, DO NOT use the device on multiple treatment sites.
- DO NOT hold MicroTip static. Keep the TXB moving using axial motion when targeting and emulsifying tissue to prevent damage to the MicroTip and/or occlusion of the tip. Due to friction related to ultrasonic vibration, appropriate technique is necessary for thermal management at the treatment site and will minimize the potential for tissue burns.
- Verify integrity of the TXB needle and irrigation sheath upon completion of treatment. Failure to do so may result in device remnants left in the patient in the event of device damage.

CAUTIONS

- DO NOT activate the TXB with the tip in air until the TX System is successfully primed, as immediate damage may result.
- Only use 1000cc saline irrigation bag. Use of an alternate volume irrigation bag in the inflation cuff may result in possible contamination of the surgical environment, lack of irrigation flow during use, or electrical hazard.
- DO NOT use the device if the tip of the TXB is received bent or is bent during use.
- Maximum tip temperature can approach 47 degrees C. This does not present a hazard to the patient if the TX Console is used according to the recommended duty cycle: 15 seconds on, 45 seconds off.
- DO NOT use the TXB for a total cutting time exceeding 10 minutes on hard tissue or 15 minutes cumulative (hard and soft tissue). Failure to limit use to the maximum cutting time could result in device damage or failure.
- Utilize Universal Precautions and Sterile Technique at all times. Failure to do so can lead to increased risk of infection or aggravation of a recent infection.
- Use caution when removing potentially malignant or harmful tissues, to isolate contamination from surrounding tissue.
- Insufficient off-loading of the ulcer in the post-treatment period and subsequently may lead to sub-optimal outcomes, including recurrence of the ulcer (increased potential for skin breakdown and associated infection).

The Tenex Health TX® System with the TX-Bone (TXB) MicroTip is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of both soft and hard (e.g.: bone) tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

The Tenex Health TX System with the TXB MicroTip is also indicated for use in the debridement of wounds, such as, but not limited to, diabetic ulcers, in application, in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement.

This document is intended solely for the use of healthcare professionals. A physician must always rely on his or her professional clinical judgment when deciding whether to use a particular product to treat a particular patient. Tenex Health does not dispense medical advice and recommends that the physician is familiar with the use of any particular product before using it in a procedure. Physicians should refer to the Instructions for Use (package insert) before using any Tenex Health product.

