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Instructions For Use

TX-Bone (TXB) Microtip

Part of the Tenex Health TX System

Manufactured by:

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Description:

The TXB MicroTip is an ultrasonic handpiece used by the clinician for the purpose of fragmenting, emulsifying, and aspirating soft tissue and hard tissue. The TXB MicroTip comes complete with the cutting handpiece, associated cartridge with tubing and collection bag. The TXB MicroTip is to be used with the TX System Console.

Characteristics:

The TXB MicroTip is made from materials commonly used in medical applications, including Lexan ®, Silicone, ABS and PVC plastics and stainless steel. The TXB MicroTip is not made with natural rubber latex. The handpiece is of coaxial design, enabling the delivery of Irrigation fluid directly to the target site while simultaneously allowing aspiration of the emulsified tissue.

Sterile:

The TXB MicroTip is Sterile if package is unopened and undamaged.

Method of Sterilization:

E-Beam radiation

Storage and Handling:

Store the TXB MicroTip and TX Supply Kit (if present) in the original shelf packaging. Always store and handle sterile items in a manner that reduces the potential for contamination.

Indications for Use:

The Tenex Health TX System with the 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 applications in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement.

⚠ Contraindications:

- Active Infections.
- Weakness of the posterior muscle group with a calcaneal gait disorder.
- This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

Symbols Used on Labeling:

Symbol	Description
	Use By Date (YYYY-MM-DD)
LOT	**Lot/Batch Code**
REF	**Catalog Number**
STERILE R	**Sterilized using irradiation**
	CAUTION
	DO NOT Reuse
	DO NOT Use if Package is Damaged.
	Consult Instructions for Use
	Manufacturer
	Peel-off Label
Rx Only	**CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.**
MD	**Medical Device**
	Single sterile barrier system with protective packaging inside

Adverse Effects:

There is a possibility of a delay in the procedure from system issues. Other possible adverse effects include edema at the treatment site, delayed healing, bone degradation, increased morbidity or sub-optimal outcomes, sensitization and allergic reaction, infection, irritation, fever, pain, tissue injury, foreign body reaction, electrical shock, and burns.

Possible Side Effects:

Pain, soreness, bleeding, drainage, bruising, swelling, inflammation, infection and allergic reaction.

See reverse side for Instructions for Use

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Technique Guide for Diabetic Foot Ulcer Application (Continued)

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Continued from previous side

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

NOTE: Keep the TXB MicroTip moving to prevent occlusion. Release and depress foot pedal to remove occlusion.

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.

7. Insert the TXB probe into the first portal site, directing it towards the bony prominence.
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.
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. 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 end point contacts the bone. Advance the probe using a "pistoning" motion over the outer surface of the bone to cut and remove materialand 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.

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.

NOTE: 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.

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.
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.

⚠ **WARNING:** Verify integrity of the MicroTip 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.

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Instructions For Use

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Instructions for Use:

Please refer to the following instructions on how to properly use the TXB MicroTip. For additional instructions, please refer to the Operator's Manual supplied with your TX Console:

SETUP

1. Insert power cord and foot pedal cable into back of console.
2. Turn ON console by pressing the power switch on the back panel to the ON position. Wait for the Main Mode screen to appear.
3. Insert saline irrigation bag into inflation cuff.

CAUTION: 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.

CAUTION: Always check the saline irrigation bag for leaks prior to surgical procedures.

4. Insert air tube fitting on inflation cuff into AIR receptacle on side panel by twisting clockwise until snug.
5. Rest cuff with saline bag on flat surface near console or hang from side of cart, if available.

CAUTION:DO NOT rest the saline irrigation bag on the TX Console or touchscreen.

NOTE: Gown and/or prepare the necessary instrumentation for STERILE procedures according to your institution's requirements.

6. Peel back the Tyvek seal of the MicroTip beginning with the easy access tab on the bottom right of the tray.

WARNING:DO NOT use the MicroTip after the expiration date indicated on the package.

WARNING: The MicroTip is sterile if package is unopened and undamaged. DO NOT use if the sterile package has been compromised.

7. Wear sterile glove and lift the internal tray lid off of the tray and discard.
8. Using the sterile gloved hand, remove the MicroTip from the thermoform tray.
9. Ensure that the aspiration tube is properly centered on the bottom side of the cartridge and then insert cartridge into side of console, pressing straight down firmly until locked in place. NOTE: The TX Console is not sterile.
10. Align the Red Dot on the MicroTip electrical connector with the Red Dot on the console side panel CUT receptacle, and then insert straight into the receptacle.

CAUTION: Failure to align the Red Dot on the MicroTip connector with the Red Dot on the console receptacle may damage the connector pins.

11. Spike saline irrigation bag.
12. With the tip cap on, hold the MicroTip handpiece in a vertical position (needle pointing upward) and press the PRIME key on the TX Console.
13. After successful priming, leave the tip cap on. Select IRRIGATION to ON, ASPIRATION to MEDIUM or HIGH, and CUTTING POWER to MEDIUM or HIGH, then depress foot pedal to test for acoustic signal.

CAUTION: Ensure successful priming cycle and presence of acoustic signal prior to incising the patient.

WARNING:DO NOT check function of the MicroTip by placing hand or finger against the tip or unintended damage to healthy tissue may result.

NOTE: For a description of setup related error messages, consult the Troubleshooting and Factory Default Settings sections of the TX Console Operator's Manual.

14. Prepare the patient for procedure using the TX Supply Kit and/or other appropriate clinical supplies.

CAUTION: Individual TX Supply Kit components (if present) are sterile if the individual package is unopened and undamaged.

15. Select desired settings for IRRIGATION, ASPIRATION, and CUTTING POWER.

NOTE: See Operations section of the TX Console Operator's Manual for detailed information regarding each function.

16. Remove the tip cap from the handpiece.
17. The Tenex Health TX System is now ready to use.

WARNING: Monitor the location of the MicroTip during use. Failure to monitor the location of the tip of the device may present a hazard to the user, result in damage to unintended tissue or limit the ability to detect device malfunction or damage to the MicroTip related to use.

NOTE: Identify the target pathology via ultrasound imaging, direct visualization and/or by palpation, as appropriate.

CAUTION: The MicroTip should not be used on bone cement.

CAUTION: Use caution when removing potentially malignant or harmful tissues, to isolate contamination from surrounding tissue.

CAUTION:DO NOT activate the MicroTip with the tip in air as immediate damage may result.

CAUTION:DO NOT use the device if the tip of the MicroTip is received bent or is bent during use.

CAUTION: Maximum tip temperature can approach 47 degrees C. This does not present a hazard to the patient if the TX System is used according to the recommended duty cycle: 15 seconds on, 45 seconds off on HIGH cutting power.

WARNING:DO NOT hold MicroTip static. Keep the MicroTip 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.

CAUTION:DO NOT use the TXB Microtip for a total cutting time exceeding 10-minutes on hard tissue or 15-minutes cumulative (hard and soft tissue). Failure to limit use beyond the maximum cutting time could result in device damage or failure.

CAUTION: For use on hard tissue, use multiple cortical penetrations using axial motion to facilitate entry into bone. Attempting to breach cortical shell through a single insertion point will not provide for adequate tip cooling and maneuverability of the tip and may result in damage to the sheath of the device or tissue burns.

CAUTION:DO NOT laterally load the MicroTip during use. Failure to follow appropriate technique could result in potential hazard to adjacent tissue due to excessive heating or damage to the MicroTip such as a broken needle and/or damage to irrigation sheath.

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

NOTE: Keep the MicroTip moving to prevent occlusion. A triple beeping sound will be generated by the console to indicate occlusion during use. Release and depress foot pedal to remove occlusion.

NOTE:A user-controlled duty cycle of 15 seconds ON, 45 seconds OFF (15s/45s) is to be followed when using HIGH CUTTING POWER. This is equal to a ratio of 1:3 of FOOT PEDAL ON time to FOOT PEDAL OFF time with a maximum of 15 seconds of continuous FOOT PEDAL ON time.

WARNING: Verify integrity of the MicroTip 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.

18. Upon completion of the procedure, prepare the patient using the TX Supply Kit and/or other appropriate clinical supplies.

CAUTION: Minimal edema associated with the TX system occurs only occasionally and is considered a routine response to treatment.

SHUT DOWN

WARNING:DO NOT recap the tip of the MicroTip.

WARNING: The MicroTip is single use. DO NOT resterilize/reuse. Reusing the device could result in compromised device performance, cross-infection, and other safety hazards.

WARNING: Surgical waste presents a biological hazard and must be handled and disposed of properly. The MicroTip must be disposed of according to local regulations.

1. Select OFF for IRRIGATION, ASPIRATION, and CUTTING POWER.
2. Deflate the inflation cuff by disconnecting the air tube fitting from the AIR receptacle on the console side panel OR by turning off the console by pressing the power switch on the back panel to the OFF position.
3. Remove the saline irrigation bag from the inflation cuff. DO NOT discard the inflation cuff.
4. Remove the spike and discard the saline irrigation bag.
5. Disconnect the MicroTip electrical connector from the CUT receptacle on the console side panel.
6. Depress the cartridge release button and remove the cartridge from side of console.
7. Dispose of the MicroTip in a receptacle designated for sharps/biohazard according to your facility requirements.

CAUTION: FEDERAL (US) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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Technique Guide for Diabetic Foot Ulcer Application

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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.

NOTE: 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**.**

CAUTION: 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.

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.

WARNING: To prevent cross-infection, DO NOT use the device on multiple treatment sites (ulcers).

2. Clean ulcer and surrounding area to be included in the procedure field properly with 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).
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). It is important that the sites are located **at least 1 cm from the margin of the ulcer.**

NOTE: All anticipated insertion sites are made at the beginning of the procedure to facilitate tracts for the probe and irrigation fluid egress.

6. 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.

CAUTION: Use caution when removing potentially malignant or harmful tissues, to isolate contamination from surrounding tissue.

CAUTION: DO NOT activate the TXB MicroTip with the tip in air as immediate may result.

CAUTION: DO NOT use the device if the tip of the TXB MicroTip is received bent during use.

CAUTION: 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 on HIGH cutting power.

WARNING: DO NOT hold MicroTip static. Keep the MicroTip 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.

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Continued on reverse side