Trice Medical Tenex® 2nd generation MicroTips

Instructions for Use

Device Name:

Tenex® 2nd generation MicroTip

Device Overview:

The Tenex 2nd generation MicroTips are part of the Tenex 2nd generation system that consists of a reusable Control Unit (Console) and Single-Use MicroTips. The Tenex 2nd generation system is a portable device that includes the ultrasonically operated MicroTips to provide percutaneous debridement, fragmentation, emulsification, irrigation, and aspiration of both soft and hard tissues. The MicroTips provide sharp debridement of soft and hard tissue in wounds such as neuropathic ulcers.

The Console consists of the following sub systems: electronics, foot pedal, software, and a screen. The Console generates the ultrasonic energy required to operate the MicroTips and manages the irrigation and aspiration of fluid through the system.

MicroTip Configurations:

Catalogue Number	Working Length (inches)
T600-013	1.3
T600-020	2.0
T600-025	2.5
T600-030	3.0

Device Materials

The Tenex 2nd generation MicroTips are made from materials commonly used in medical applications, including PC, Silicone, ABS and PVC plastics, and stainless steel.

NOTE: The Tenex 2nd generation is not made with natural rubber latex.

Method of Sterilization: Gamma Irradiation

Indications for Use:

The Tenex 2nd generation system 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 2nd generation system 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:

- The Tenex 2nd generation system should not be used in any anatomy with an active infection.
- This ultrasonic surgical aspirator device is not indicated for and should not be used for the fragmentation, emulsification, and aspiration of uterine fibroids.

Warning:

⚠ WARNING: This device is intended for single-use only. Do not attempt to re-use or re-sterilize. Re-use could damage the device and pose risks of infection and/or sharps-related tissue damage to the user and patient.

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, histological or toxic reaction, infection, irritation, fever, pain, tissue (tendon/nerve) injury, foreign body reaction, electrical shock, and burns.

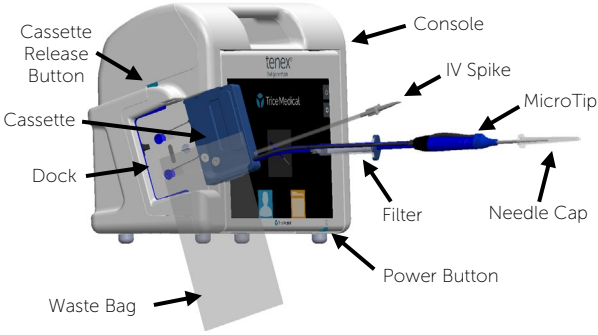
Possible Side Effects:

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

Clinical Benefits:

The intended clinical benefits of the Tenex 2nd generation system are alleviation from pain, improvement of function, and the arresting or resolution of disease progression in patients with disorders of the targeted tissue type, as specified in the indications for use of the device.

The Tenex 2nd generation system is intended to be used by licensed healthcare professionals in an appropriate surgical or medical treatment facility. The intended patient population is adults with soft tissue and hard tissue pathology, and hard tissue conditions including bone spurs, osteophytes and prominences, or diabetic foot ulcers.



Instructions for Use:

Please refer to the following instructions on how to properly use the Tenex 2nd generation MicroTips. For additional instructions and operating conditions, please refer to the User Manual supplied with your Tenex 2nd generation Console.

1.0 Device Preparation and Set Up

1.1 Insert power cord and foot pedal cable into back of Console.

1.2 Turn ON Console by pressing the power switch on the back panel to the ON position. Depress the Power Button located on the bottom right of the Console to turn on the screen. Wait for the Home Screen to appear.

⚠ WARNING: DO NOT service the Console while the system is in use with a patient.

1.3 Set up and position the Console near the patient to allow for an easier procedure, and so that non-sterile supplies do not enter the sterile field.

⚠ CAUTION: DO NOT position the Console to make it difficult to operate the device.

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

1.4 Inspect the MicroTip packaging to ensure product sterility has not been compromised.

⚠ WARNING: The MicroTip is sterile if the package is unopened and undamaged. DO NOT use the device if the sterile package has been compromised. DO NOT use the device if there are signs of damage or if it has been previously opened.

1.5 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.

1.6 Wear sterile gloves and lift the internal tray lid off the tray and discard.

NOTE: Ensure the Needle Cap is securely attached to the MicroTip so it will not fall from the sterile field when the MicroTip is removed from the tray.

1.7 Using a sterile gloved hand, remove the MicroTip from the tray.

⚠ CAUTION: DO NOT pull the Waste Bag to remove the MicroTip from the tray or the Waste Bag may tear.

1.8 Inspect the MicroTip and ensure the device is undamaged.

NOTE: The Tenex 2nd generation Console is not sterile.

1.9 Align the Cassette with the Console Dock. The Waste Bag should be positioned on the left of the Cassette, and the tubing (IV Tube and the tubing connected to the MicroTip) is positioned away from the Console, as shown in the image on Page 2. Press the Cassette into the Console until it is latched.

⚠ CAUTION: Ensure the Waste Bag does not get caught between the Cassette and the Dock when inserting the Cassette or the Waste Bag may tear.

1.10 Acquire and spike a 500cc or 1000cc saline irrigation bag. The saline bag can be placed on a flat surface adjacent to the Console.

1.11 Select the correct saline bag size and the anatomy on the Console touchscreen.

⚠ CAUTION: Use up to a maximum of 1000cc total saline.

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

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

1.12 With the Needle Cap on, hold the MicroTip handpiece in a vertical position (needle pointing upward) and press the PRIME button on the Console.

NOTE: If the MicroTip does not prime right away, lightly squeeze the saline bag to push fluid into the cassette. Release the saline bag once the system begins to prime on its own.

1.13 After successful priming, leave the Needle 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 the 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 User Manual.

1.14 Prepare the patient for procedure using the appropriate surgical clinical supplies.

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

NOTE: See the Operations Section of the User Manual for detailed information regarding each function.

1.16 Remove the Needle Cap from the MicroTip. Set the cap aside in the sterile area (for possible use for re-priming).

1.17 The Tenex 2nd generation 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.

⚠ 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: To facilitate proper cooling, do not use the probe continuously. Always follow a duty cycle of 15 seconds on, 30 seconds off.

⚠ CAUTION: DO NOT use the 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 overfilling the Waste Bag.

⚠ CAUTION: For device usage 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 or bend 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: Keep the MicroTip moving to prevent occlusion. The Console will generate a triple beeping sound to indicate an occlusion during use. Release and depress foot pedal to remove occlusion.

⚠ WARNING: Verify the integrity of the MicroTip needle and the 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.

1.18 Upon completion of the procedure, use appropriate clinical supplies and techniques to treat the surgical site.

⚠ CAUTION: Minimal edema associated with the Tenex 2nd generation can occur and is considered a routine response to treatment.

2.0 Patient Preparation:

Diseased Soft and Hard Tissue

2.1 Use a fast-acting local anesthetic to make skin wheal at the site of anticipated entry of the MicroTip.

2.2 Use the #11 blade to create an introduction portal introduction of the MicroTip into the field directed under ultrasound guidance to the pathologic tissue.

2.3 Insert the MicroTip into the treatment portal, directing it towards the diseased tendon or tissue.

2.4 Advance the MicroTip 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 MicroTip.

2.5 Orient the MicroTip tip so its bevel is pointing away from the bone and the end point contacts the bone. Advance the MicroTip using a "pistoning" motion over the outer surface of the bone to cut and remove targeted diseased bone with a "planing action" to remove thin layers from the bone.

NOTE: Do not initiate power to the MicroTip with the tip pressed against hard tissue (e.g.: bone).

2.6 At the end of the procedure, turn off the Cutting and Irrigation functions. Aspirate to remove fluid and debris tissue.

2.7 Clean the treatment areas appropriately.

2.8 Apply sterile gauze with light pressure to the area.

Diabetic Foot Ulcer

⚠ WARNING: If there is weakness of the posterior muscle group with a calcaneal gait disorder, it is recommended to defer treatment of the ulcer until the calcaneal gait is corrected. A calcaneal gait disorder causes heel pressure that interferes with ulcer healing and contributes to the risk of recurrence.

⚠ WARNING: Use standard wound care management pre and post treatment. This should include administration of prophylactic antibiotics as appropriate. 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 MicroTip. Take care not to significantly enlarge the ulcer. Unless sensation is completely 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.

2.9 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).

2.10 Clean ulcer and surrounding area to be included in the procedure field properly with skin cleanser.

2.11 Square off affected area with sterile towels.

2.12 Unless sensation is completely 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 MicroTip insertion (e.g., at 12, 3, 6, and 9 o'clock positions around the periphery of the ulcer).

2.13 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 MicroTip and irrigation fluid egress.

2.14 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 MicroTip with the tip in air as immediate damage may occur.

⚠WARNING: The MicroTip tip should never be removed from the portal (or directly visualized) when it is actively treating tissue (when the MicroTip is cutting), in order to avoid unintended tissue damage and dispersion of fluids. Always release the foot switch prior to removing the MicroTip from the anatomy.

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

⚠CAUTION: If the MicroTip handle gets uncomfortably warmer, release the foot pedal for a few seconds to let it cool down.

⚠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: To facilitate proper cooling, do not use the probe continuously. Always follow a duty cycle of 15 seconds on, 30 seconds off.

⚠CAUTION: DO NOT use the MicroTip 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 overfilling the Waste Bag.

2.15 Insert the MicroTip into the first portal site, directing it towards the bony prominence.

2.16 Advance the MicroTip 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 MicroTip.

2.17 Use the MicroTip to remove the avascular scar tissue surrounding the ulcer, as the MicroTip is advanced to the bony prominence. The bony prominence can be located by palpation with the free hand and the tip of the MicroTip (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 MicroTip side to side,

to avoid placing undue stress on the MicroTip. Retract, reorient, and repeat the axial motion as tissue is cleared.

2.18 Repeat the MicroTip 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 MicroTip through the soft tissue.

2.19 In some instances, it may be useful to "pepper" the bony prominence with the MicroTip until the MicroTip tip and its outer sheath can insert through the weakened cortex, which allows for the removal of subcortical bone.

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

2.21 If additional saline is required, spike a new saline irrigation bag, reattach the Needle Cap if it remains sterile, and re-prime the system by following the prompts on the Console touchscreen.

2.22 At the end of the procedure, turn off the Cutting and Irrigation functions. Aspirate to remove fluid and debris tissue.

2.23 Clean the treatment areas and ulcer appropriately.

2.24 Apply sterile gauze with light pressure to the area.

2.25 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).

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

⚠ WARNING: Verify the integrity of the MicroTip needle and the 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.

3.0 SHUT DOWN

⚠WARNING: DO NOT recap the tip of the MicroTip.

⚠WARNING: The MicroTip is single use. DO NOT resterilize or 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.

3.1 Select OFF for IRRIGATION, ASPIRATION, and CUTTING POWER.

3.2 Remove the spike and discard the saline irrigation bag.

3.3 Depress the Cassette release button and remove the Cassette from the Console.

4.0 Disposal Instructions:

4.1 Follow standard guidelines and facility requirements for the disposal of sharps and medical devices that have been in contact with a patient's bodily fluid and tissue.

Packaging/Storage:

The Tenex 2nd generation MicroTip is provided sterile and is designed to remain sterile unless the primary packaging seal has been opened or damaged. Store in a cool, dry place. The Tenex 2nd generation MicroTip has a shelf life as indicated by the Use By Date on the packaging label. Store the Tenex 2nd generation MicroTip in the original shelf packaging. Always store and handle sterile items in a manner that reduces the potential for contamination.

Symbols:

Symbol	Meaning
	Sterilized using irradiation
	Do not resterilize
	Do not reuse
	Use By Date (YYYY-MM-DD)
	Catalog Number
	Lot Number (Batch Code)
	Consult instructions for use
	Manufacturer
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged, and consult instructions for use
	Medical Device
Rx Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician
	Caution
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Shock protection afforded by the device is Type B (Applied Part) per EN 60601-1
	Peel-off Label
IP22	Protected against solid objects greater than 12.5mm, and from water spray less than 15 degrees from vertical

Manufactured For:

Trice Medical, Inc
40 General Warren Blvd. Suite 100
Malvern, PA 19355
U.S.A
Tel: 610.989.8080
Fax. 610.644.3073
www.TriceMedical.com

NOTE: Report any Serious Incidents involving the Tenex 2nd generation system to Trice Medical, Inc. at tricecomplaints@tricemedical.com or +1 (610) 989-8080.

Serious Incident is defined as any incident that directly or indirectly led, might have led, or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health, or (c) a Serious Public Health Threat.

Pat. https://tricemedical.com/patents/

PRODUCT DISCLAIMER:

Products, or product accessories, may not be available in all markets because product, and accessory, availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Trice Medical representative if you have questions about the availability of specific Trice Medical products in your area. Trice Medical products that are CE marked are marked according to the applicable EU Regulations and Directives.