

Manufactured by:



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Description:

The TX1/TX2 MicroTip is an ultrasonic handpiece used by the clinician for the purpose of emulsifying and removing soft tissue. The TX1/TX2 MicroTip comes complete with the cutting handpiece, associated cartridge with tubing and collection bag.

Characteristics:

The TX1/TX2 MicroTip is made from materials commonly used in medical applications, including Lexan®, Silicone, ABS and PVC plastics and stainless steel. The TX1/TX2 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 removal of the emulsified tissue.

Sterile:

The TX1/TX2 MicroTip is Sterile if package is unopened and undamaged.

Method of Sterilization:

E-Beam radiation

Storage and Handling:

Store the TX1/TX2 MicroTip and TX Supply Kit components (if present) in the original shelf packaging. Always store and handle sterile items in a manner that reduces the potential for contamination.

Indication for use:

The Tenex Health TX System with the TX1/TX2 MicroTip is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

Contraindications:

- 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/Batch Code
	Catalog Number
	Sterilized using irradiation
	CAUTION
	DO NOT Reuse
	DO NOT Use if Package is Damaged.
	Consult Instructions for Use
	Manufacturer
	Peel-off Label
	CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.
	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.

Instructions for Use:

Please refer to the following instructions on how to properly use the TX1/TX2 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 500cc 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 enclosure or touchscreen.
 -  **CAUTION:** Gown and 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 TX2 MicroTips should not be used on hard tissue such as bone.

-  **CAUTION:** The Tenex Health TX System 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:** DO NOT use this device if it fails to function as described in the Operator's Manual supplied with your TX Console.
 -  **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 TX1 or TX2 Microtip for a total cutting time exceeding 10–minutes. Failure to limit use beyond the maximum cutting time could result in device damage or failure.
 -  **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.