

TX-Bone MicroTip Product Introduction



Agenda

- Tradename Update
- Product Indications
- Features & Benefits
- Technical Characteristics
- Training Requirements
- Technique Information
- TX System Console Upgrade Requirements
- Reimbursement
- Ordering Info / Pricing / Pricing Objections
- Sales & Marketing Materials



Official Product Name

Former Trade Name – 510k through Limited Use Release

TX-Plus (TXP) MicroTip



New Registered Trade Name

TX-Bone (TXB) MicroTip



TX-Bone Indications

510(k) K181367 – August 28, 2018

The Tenex Health TX System with TX-Bone MicroTip is indicated for...

- Fragmentation, emulsification, and aspiration (i.e. cutting and removal) of hard tissue (e.g. Bone)
- Fragmentation, emulsification, and aspiration of soft tissue (same indications as TX1 & TX2)



Features & Benefits – Tenex Health TX

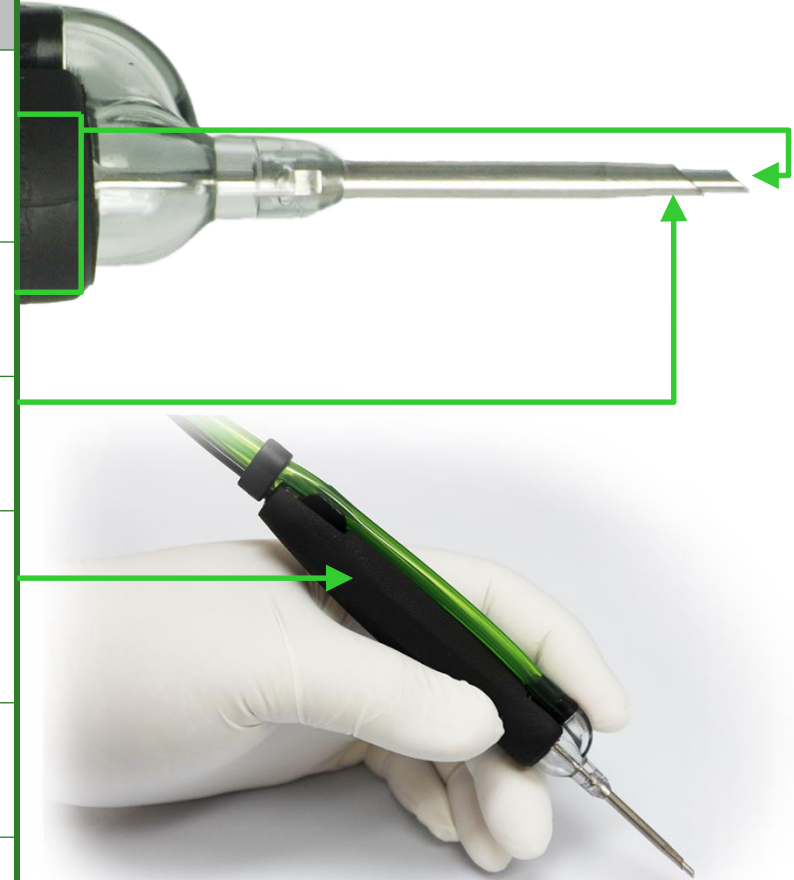
<i>Feature</i>	<i>Benefit</i>
➤ Minimally invasive technology (small gauge needle, rigid irrigation sheath, echogenic materials)	• Less discomfort and faster recovery times versus traditional open procedures
➤ Utilizes irrigation, aspiration and cutting modes	• <u>Removes</u> pain-generating tissue which relieves pain • Well-tolerated procedure
➤ Cutting is executed through ultrasonic vibration of a needle	• Stimulates (promotes) a healing response • Does not disturb surrounding healthy tissue (in tendon)
➤ Single-use, disposable MicroTip	• Limited setup requirements with no reprocessing of tubing, tips, etc.
➤ Includes convenience kit with disposable ultrasound probe cover	• Only local anesthetic and saline irrigation fluid are required to be supplied by the user

All of these existing features apply to the TX-Bone MicroTip!



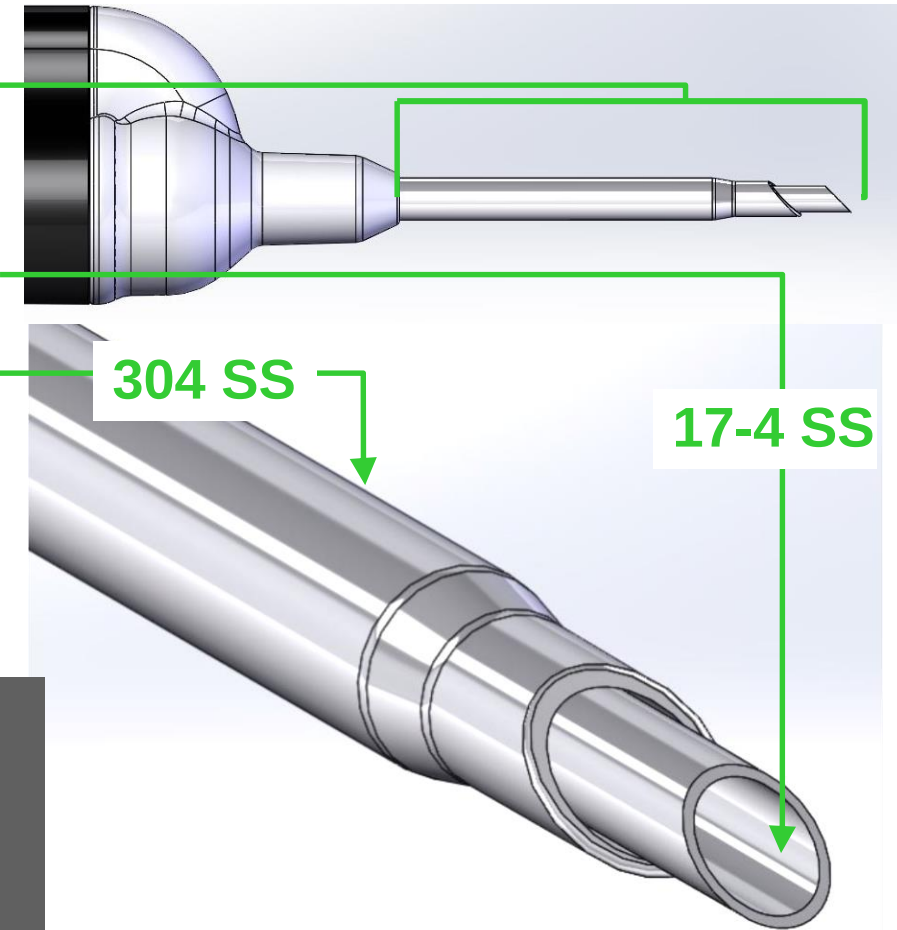
Features & Benefits – TX-Bone

<i>Feature</i>	<i>Benefit</i>
➤ Monolithic, stainless-steel needle	• High durability to withstand prolonged contact with cortical bone • Increased tip displacement over TX1/TX2
➤ Larger aspiration bore as compared to TX1 & TX2	• Increased tissue aspiration • Reduces occlusion potential in bone
➤ Beveled, stainless steel irrigation sheath	• Provides for easier navigation • Limits depth of penetration in bone
➤ New Case Grip on Handpiece Body	• Improves ergonomics of the handpiece • Improved control with wet gloves (from ultrasound gel, saline)
➤ Accommodates 1000cc of aspiration fluid	• Provides for increased available working time (labeled for 15-minute max cutting)
➤ Works with the existing TX System Console	• No new equipment required for use (except for larger inflation cuff)



Technical Characteristics

MicroTip Offerings	TX1	TX2	TX-Bone
Tip Length	25.4 mm	43.2 mm	33.0 mm
Tip Gauge (approximate inner lumen OD)	19 (1.1 mm)	18 (1.3 mm)	15 (1.9 mm)
Sheath Gauge (approximate outer lumen max OD)	11 (3.0 mm)	14 (2.1 mm)	11 (3.0 mm)
Volume as Percentage of TX1 Baseline (per stroke @26.5 kHz)	100%	200%	650%



Larger tip displacement and increased needle diameter result in greater volume of tissue contact per stroke



Training Requirements

- No mandatory user training; however...
- Users must review Setup & Use instructions provided with the product
- Users must review Information for Safety included in the Product Inserts
- We do recommend physicians take advantage of a wet lab demonstration to appreciate the efficiency of the device in bone



Technique Information

- Existing technique videos provide appropriate anatomical and approach overview
- Performed using a percutaneous approach through a #11 blade incision
- Placement and monitoring of the tip location is permitted through ultrasound guidance, palpation guidance, or other means of visualization (reviewed in TX-Bone 510k)



TX System Console Upgrade Requirements



1. Inflation Cuff

- The TX-Bone calls for use of a 1000cc saline irrigation bag
- 1000cc Inflation Cuffs must be supplied to the current install base

2. Product Inserts

- TX Console Operator's Manuals
- System Set-up Cards (Quick Reference Guide)



TX System Upgrade Requirements

Customer Upgrades

1. Upgrade Kit will be sent with 1st TX-Bone order
2. Consoles will be upgraded at the time of service (regardless of TX-Bone ordering status)

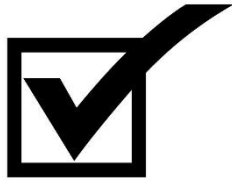
Distributor Upgrades

1. Upgrade kits are being shipped for delivery the week of May 20th

See MKT-231. Rev B. for detailed instructions

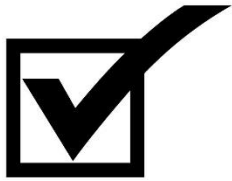


Reimbursement



Soft Tissue Reimbursement Landscape

- Same coding recommendations as TX1 and TX2
- Proper dictation remains essential
- Remember...Tenex is a tool, not a procedure



Hard Tissue (Bone) Reimbursement Landscape

- Existing, well-established codes can be utilized
- Proper dictation is essential
- Bone codes are more favorable in most instances



Reimbursement – Guidance

<i>Document Number & Description</i>	<i>Status</i>
REIM-002 – Dictation Template – Soft Tissue	Updated
REIM-005 – Pre-Authorization Template	No Change
REIM-009 – Soft Tissue Coding Reference	No Change
REIM-017 – Hard Tissue Coding Reference	New
REIM-018 – Dictation Template - Calcific Rotator Cuff	New
REIM-020 – Dictation Template - Bone	New
Available in print on the Tenex Streamline site <u>or</u> electronic form on the Resource Center and Streamline site	



Reimbursement – Tips and Pearls

- **Some indications include both soft and hard tissue components – multiple codes can be applied**
Ex. Haglund's Deformity: Cutting and removal of spur (hard tissue) & Treatment of the tendinopathy (soft tissue)
- **Calcific deposits are technically soft tissue and are appropriate for removal with the TX1 and TX2**
- **The TX-Bone is recommended for dense calcific deposits due to the increased efficiency and enhanced design**



Reimbursement - Support

- For issues or questions, contact:

Reimbursement@TenexHealth.com

- We are working to add new resources to support reimbursement related concerns and initiatives



Ordering Information

<i>Part Number & Desc.</i>	<i>List Price</i>
554-3003-001 TXB Procedure Pack	\$3,885.00 (Case of 3) \$3885/3 = \$1,295/MicroTip
554-2003-001 TX2 Procedure Pack	\$2,535.00 (Case of 3) \$2535/3 = \$845/MicroTip
554-1003-001 TX1 Procedure Pack	\$2,295.00 (Case of 3) \$2295/3 = \$765/MicroTip



Pricing Considerations



- Market is capable of supporting a higher price point as there is a clear increase in the value of the TX-Bone product

NOTE: Strong ASP on TX1 / TX2 indicate the market can bear higher list pricing on those models as well, although we are not implementing increases at this time.



- Higher price point provides for increased commission



Pricing Considerations



- Higher price point provides for improved ability to offer strategic discounts from list.



- Higher price allows for maintenance of floor price points when considering 'Best Price' expectations from GPO's.



Pricing Considerations

Remember...

- A good deal is a state of mind
- It's about how you position

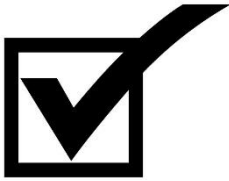
Would you rather buy a Mercedes or a Hyundai?

What would happen if a Mercedes sold for Hyundai prices?

The Brand Would Lose Value!

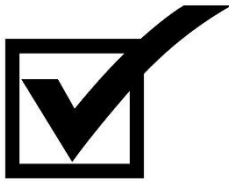


Price Objection Handling



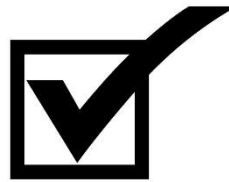
The TX-Bone MicroTip is technologically advanced

- Enhanced device design necessary to expand indications equates to higher cost of manufacture
- Improved efficiency compared to TX1/TX2 can reduce applied cutting time



Reimbursement for bone indications will be less prone to pushback and denials

- There are existing codes that are well established and reimburse well.



The TX-Bone is not intended to replace TX1 or TX2 when the enhanced design is not necessary or cost-effective.



Sales & Marketing Materials – Now Available

- **New Sales Sheets – Soft & Hard Tissue Indications**
- **New Reimbursement Documents**
- **New Physician's Office Marketing Materials**
- **New Clinical Publications Listings**
- **Updated Pre-Assembled Comprehensive Folders**
- **New Tradeshow Support Materials**
- **TX-Bone 510(k) Clearance Letter**
- **TX-Bone Demo Product**



Sales & Marketing Materials – Now Available

- Available on the Resource Center & Tenex Streamline Site
- 3 ways to access these materials

<https://TenexHealth.com>

<https://Tenexresources.com>

<https://TenexHealth.WorkSmartSuite.com/login.aspx>



- Access directly from your smart phone. Make sure to save your credentials for easy reference and ordering.
- *You can also view videos directly from the Resource Center*
- *For login support for any of these resources, contact:*

Marketing@TenexHealth.com



Q&A



Sales Support – Contact Your Regional Manager

Product Orders – Orders@TenexHealth.com

Technical Questions – TechSupport@TenexHealth.com

Reimbursement – Reimbursement@TenexHealth.com

Marketing Support – Marketing@TenexHealth.com

Quality/Regulatory Information – Info@tenexhealth.com

MKT-304. Rev. A.