INSTRUCTIONS FOR USE (IFU)

[EN]

INTENDED USE:
The UltraGuideCTR® image guided system using real-time ultrasound visualization and guidance is intended for use in minimally invasive ligament or fascia release.

INDICATIONS FOR USE:
The UltraGuideCTR® image guided soft tissue release system using real-time ultrasound visualization and guidance with integrated safety-engineered Sharps Injury Prevention is indicated for use in minimally invasive soft tissue release:

- Carpal tunnel release in the wrist

℞ONLY For Prescription Use Only: Federal (USA) law restricts this device to sale by or on order of a physician.

LIMITATIONS:
- None.

CONTRAINDICATION:
- Distorted anatomy or other processes within the carpal tunnel preventing safe and effective transection of the soft tissue.

ADVERSE EFFECTS/SIDE EFFECTS/RESIDUAL RISKS:
- Operators should be familiar with the potential risks and complications of carpal tunnel release using UltraGuideCTR, including but not limited to:
    - Procedure related discomfort.
    - Wound complications such as delayed healing, scarring or tenderness.
    - Bleeding, bruising, and hematoma.
    - Infection.
    - Injury to vessels, tendons or other soft tissues.
    - Injury to nerves such as the median nerve.
    - Neuropraxia.
    - Pillar pain.
    - Development of chronic pain processes such as complex regional pain syndrome.
    - Recurrence.
    - Delayed or incomplete symptom resolution.

WARNINGS:
- Do NOT Re-sterilize or Re-use. UltraGuideCTR is designed for Single Use Only, one patient, one wrist. Re-use and/or re-sterilization may cause infection, device malfunction, device failure, and/or injury to the patient or operator.
- Safe and successful transection of the TCL using UltraGuideCTR is dependent upon appropriate training (including ultrasound guided procedures), knowledge of carpal tunnel anatomy, and careful study and adherence to the surgical

technique. Failure to properly follow the instructions, warnings and precautions may lead to serious surgical consequences or injury to the patient or operator.

- Inability to sonographically identify and protect relevant anatomic structures such as the nerves, tendons, and vessels, may prevent safe transection of the TCL.
- If image visualization of the device or pertinent anatomical structures is impaired during the procedure, DO NOT continue until proper visualization is restored. If visualization cannot be restored, DO NOT continue the procedure. Remove the device after ensuring the TCL Blade® is in the distal recessed position. Follow the procedure steps (see section D14) below for device removal.
- The presence of infection may predispose to surgical site infection.
- Do NOT use excessive force to insert the device. Using excessive force during insertion may cause patient injury, operator injury, and/or device damage.
- Mechanical dissection of synovial tissue from the undersurface of the TCL should not require excessive force. Using excessive force may result in loss of control and injury to the patient or operator.
- Do not engage the TCL Blade before a safety check is completed to confirm position of the device and surrounding anatomy. Premature or accidental activation of the TCL Blade may result in patient injury.
- TCL transection should not require excessive force. Using excessive force may result in loss of control and injury to the patient or operator.
- Probing the TCL after transection to confirm a complete release should not require excessive force. Using excessive force may result in loss of control and injury to the patient or operator.
- UltraGuideCTR is intended for use with adult patients who are suffering from carpal tunnel syndrome.
    1. The safety and effectiveness of UltraGuideCTR to transect the TCL in cases of recurrent carpal tunnel syndrome has not been established.
    2. Data regarding applications and use in pediatric patients has not been collected or analyzed.

PRECAUTIONS:

- The position of the patient's hand should be controlled during the procedure. Unwanted hand movement may make the procedure more difficult or result in injury to the patient or operator.
- Device misuse may damage the device resulting in an inability to complete the procedure or potential injury to the patient or operator.
- The cutting TCL Blade of UltraGuideCTR is extremely sharp. Exercise caution to prevent injury. Following use, the device must be discarded in a Sharps-Safe container.

ANCILLARY EQUIPMENT, ACCESSORIES, AND CONSUMABLE COMPONENTS:

- Surgical equipment for a carpal tunnel release procedure
- Ultrasound machine and ultrasound probe
- Sterile probe cover and associated supplies for ultrasound guided procedures
- Sterile ultrasound gel
- Sterile saline
- Blunt tip elevator or dilator (optional)

ULTRASOUND EQUIPMENT SPECIFICATIONS:

- Operators should be familiar with the use of ultrasound to image the structures of the carpal tunnel region, including but not limited to appropriate transducer selection and image optimization. High frequency (typically >10 MHz) linear transducers are recommended. In general, imaging should be performed at the highest possible frequency that will provide adequate visualization. Depth, focus, gain, frequency, and other controls should be adjusted as necessary.
- It is recommended that operators follow institutional and/or relevant guidelines for cleaning and preparing ultrasound transducers and equipment, including appropriate use of ultrasound gel and transducer covers.

- It is recommended that operators follow institutional and/or relevant guidelines for performing ultrasound guided procedures, including but not limited to appropriate transducer selection, image optimization, infection control, and needle/device visualization.
- Ultrasound equipment, including transducers and cords, should be used, cleaned, and maintained in accordance with manufacturer recommendations as included in the manufacturer's IFU.
- Transducer covers and ultrasound gel should be used according to manufacturer recommendations as included in the manufacturer's IFU.

QUALIFICATIONS, SPECIAL SKILLS, SPECIAL TRAINING AND SPECIAL KNOWLEDGE:

- UltraGuideCTR should be used by a physician, a surgeon, or other medical personnel qualified to perform carpal tunnel release and ultrasound guided procedures (herein referred to as the operator).

USE ENVIRONMENT/SPECIAL FACILITIES:

- UltraGuideCTR should be used in a procedure room in a clinical facility (ASC, physician's office, or a hospital).

SPECIAL OPERATING INSTRUCTIONS:

- None.

STORAGE CONDITIONS:

- It is recommended that UltraGuideCTR be stored in a dry location with the temperature controlled between 15°C - 25°C, away from moisture, direct heat, and direct light. Do not use UltraGuideCTR after the expiration date.

CLINICAL BENEFITS[1,2,3]:

- Typically performed in a procedure room or office setting using local anesthesia
- Small incision typically closed without sutures
- Most patients only require acetaminophen or NSAIDs (nonsteroidal anti-inflammatory drugs) for pain management
- Immediate motion of the hand for rapid recovery
- Most patients can typically return to work and activities within 3-6 days
- Postoperative therapy typically not required

1. Fowler JR, Chung KC, Miller LE. Multicenter pragmatic study of carpal tunnel release with ultrasound guidance. Expert Review of Medical Devices. 2022 Mar;19(3):273-280. https://doi.org/10.1080/17434440.2022.2048816
2. Eberlin KR, Amis BP, Berkbigler TP, Dy CJ, Fischer MD, Gluck JL, Kaplan FTD, McDonald TJ, Miller LE, Palmer A, Perry PE, Walker ME, Watt JF. Multicenter randomized trial of carpal tunnel release with ultrasound guidance versus mini-open technique, Expert Rev Med Devices. May 2023; 20(7):597-605. https://doi.org/10.1080/17434440.2023.2218548
3. Pistorio AL, Marwin VM, Paterson PD, Alexander RD, Nelson JT, Miller LE, PhD, PStat. Office-based carpal tunnel release with ultrasound guidance: 6-month outcomes from the multicenter ROBUST trial. J Hand Surg Global Online. 2024. https://doi.org/10.1016/j.jhsg.2023.12.005

TECHNICAL DEVICE DESCRIPTION:

The UltraGuideCTR® image guided soft tissue release system with Sharps Injury Prevention feature is comprised of a disposable Handpiece with inflatable Balloons and a Blade assembly (UltraGuideCTR® device) that is utilized with Ultrasound imaging (continuous real-time Ultrasound visualization and guidance). The device is gamma sterilized and intended for single-use only.

Continuous real-time multi-planar ultrasound imaging throughout the procedure enables the user to visually identify pertinent anatomical structures of the hand and wrist and to visualize and navigate the device throughout the procedure. The device design and components enhance the echogenicity and visualization of the device and ensures the device is compatible with any musculoskeletal (MSK) Ultrasound system. The echogenic features of the device include:

- Inflatable Balloons located along the Shaft on either side of the Blade track, which, once inflated with saline, appear under Ultrasound as two dark circles.
- Metal Shaft/Tip of Blade – the Shaft, which houses the recessed blade at the distal Tip, appears as a bright echogenic line, with a visible notch indicating the point where the recessed Blade will be deployed from the Tip of the Shaft.
- After deployment, the Blade appears on Ultrasound as a bright star-shaped structure moving along the track in the Shaft.

Collectively, these echogenic features facilitate visualization and navigation of the device within the critical anatomy throughout the procedure.

The low-profile of the Tip allows the device to be inserted through a single, percutaneous incision in the proximal wrist flexor crease. The device is operated using an ergonomic Handle with separate controls to activate and inflate the integrated Balloons and actuate the Blade. The two inflatable Balloons are integrated on either side of the Blade track in the Shaft and once inflated, function as both anatomical guards and visual confirmation of desired device placement, as well as a safety mechanism before the Blade can be deployed from the Tip.

The Balloons are inflated in the intracarpal space of the carpal tunnel to create additional space and protect the surrounding anatomy while the Blade is actuated to transect the TCL. The design of the Blade includes a safety-engineered Sharps Injury Prevention feature. The Blade remains recessed in the Tip of the device until the Balloons are inflated using the Activation Lever on the Handle. Once the Balloon inflation/Blade interlock safety mechanism is released, the Blade Slider on the Handle is pulled back in a retrograde motion to actuate the Blade in a distal-to-proximal direction along the Blade track in the Shaft to transect the TCL. The Blade must be retracted into the fully recessed position in the Shaft before the Balloons are deflated, and the device is removed.

This integrated design of the Metal Tip/Shaft/Blade and Balloons serves to protect the surrounding anatomy during the palmar pressure that is applied to the device during the insertion, navigation, TCL transection, and removal of the device, and prevents deployment of the Blade prior to inflation and subsequent to deflation of the Balloons.

Device Components	
A	Syringe Port
B	Activation Lever
C	Blade Slider
D	Shaft
E	Tip
F	Stabilizer
G	Stealth MicroGuard Balloons®
H	TCL Blade®

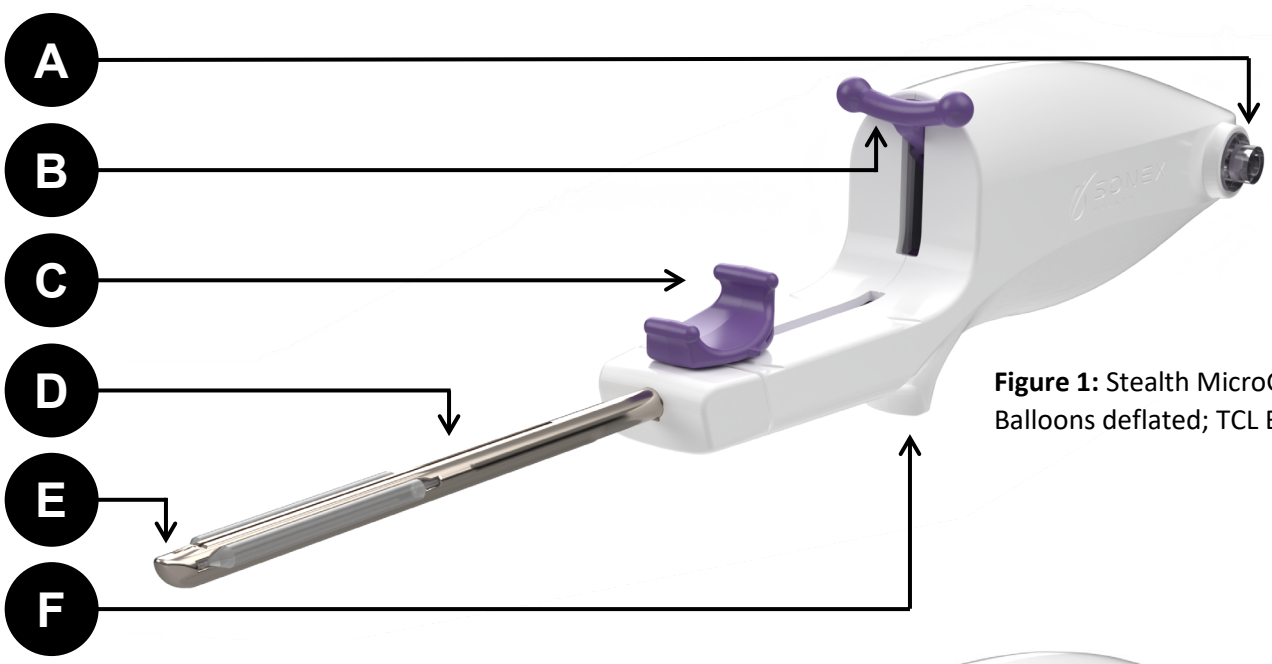


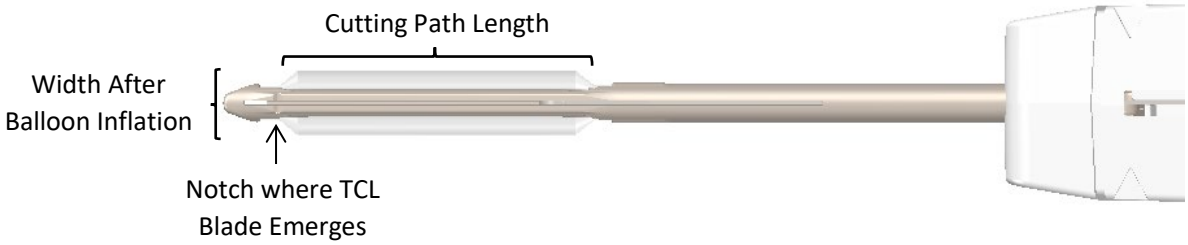
Figure 1: Stealth MicroGuard Balloons deflated; TCL Blade locked

Figure 2: Stealth MicroGuard Balloons inflated; TCL Blade unlocked/activated

Device Features:

- Device Width after Stealth MicroGuard Balloon Inflation = 8.5mm
- TCL Blade Maximum Profile Height: 3.0mm, with exposed blade edge of 2.7 mm
- Full Height TCL Blade Travel: 32.3mm

Figure 3: Overhead view of the UltraGuideCTR Tip & Shaft



Safety Interlocks:

The UltraGuideCTR device contains two interlocking features to support control of the TCL Blade.

1. The TCL Blade and Blade Slider are locked in the inactive position (i.e., cannot be moved) unless the Stealth MicroGuard Balloons are inflated (see Figure 1).
2. The Stealth MicroGuard Balloons are locked in the active position (i.e., cannot be deflated) unless the TCL Blade is fully recessed in either the distal or proximal position (see Figure 2).

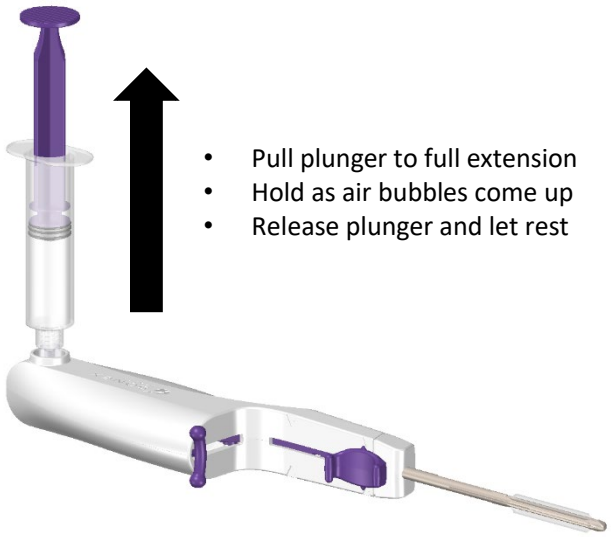
DIRECTIONS FOR USING ULTRAGUIDECTR:

A. Pre-Procedure Ultrasound Scan
   1. Perform a pre-procedure diagnostic ultrasound scan of the carpal tunnel region if clinically indicated.

B. Device Preparation/Priming
   1. Inspect the box, sterile barrier tray lid and sterile-barrier tray for damage.
   2. Peel the tray lid open from the curved side of the tray, indicated by the “Open Here” symbol on the packaging. Using proper sterile technique, present the sterile contents for transfer onto a flat sterile surface.
   3. Using sterile gloves, inspect UltraGuideCTR for damage. Make sure all controls are in the inactive position as shown in Figure 1. **IMPORTANT:** Do NOT try to reposition the controls during this step.
   4. Place the device on a flat, sterile surface with the Syringe Port facing up.
   5. Draw between 3 to 4 ml of sterile saline into the provided 10 cc syringe. Remove any air from the syringe. **IMPORTANT:** Minimizing air is a key step. Leaving air in the syringe will prevent the balloons from reaching the recommended inflation pressure.
   6. Attach the syringe and tighten fully. Due to the presence of a valve located within the Syringe Port slight downward pressure will need to be applied to the base of the syringe when attaching to the device. **IMPORTANT:** Do NOT push saline into the device at any point during the following sequence.

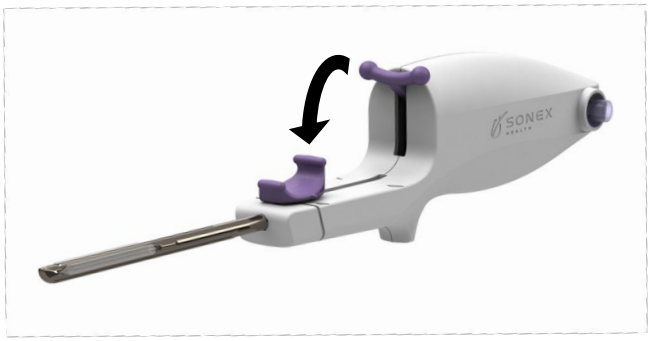
7. With one hand stabilizing UltraGuideCTR on the flat sterile surface, complete the following sequence, abbreviated as *PULL – REMOVE AIR – PULL* (see Figure 4):
    a. *PULL:* Use the other hand to *PULL* back the plunger to full extension (i.e., when the plunger head is flush with the end of the barrel) and hold while air bubbles rise from the device into the syringe. As the plunger is pulled, a vacuum is created in which the saline trades places with the air that was previously in the device. After air bubbles stop appearing, release the plunger. **IMPORTANT:** Do NOT push down on the plunger at any point during this step.
    IMPORTANT: If the syringe is not drawn to full extension the balloons will not reach the recommended inflation pressure.

Figure 4: *PULL* plunger to full extension.



    b. *REMOVE AIR:* Detach the syringe from the Syringe Port and *REMOVE* any *AIR* now captured in the syringe.
    c. *PULL:* Reattach the syringe and repeat the step described in 7a: *PULL* back the plunger to full extension. Hold at full extension while air bubbles rise. Then release the plunger. **IMPORTANT:** Do NOT push down on the plunger at any point during this step. **IMPORTANT:** If the syringe is not drawn to full extension the balloons will not reach the recommended inflation pressure.
    d. Detach the syringe from the Syringe Port. UltraGuideCTR is now prepared for use.
8. Check for appropriate preparation/priming of the device:
    a. Visually inspect the Stealth MicroGuard Balloons® to ensure they are not inflated. **IMPORTANT:** If the Stealth MicroGuard Balloons are inflated or steps were not followed correctly, use the syringe to pull saline back out of the device then repeat steps 5-7.
    b. Keeping the device in a horizontal position (i.e. the hand, Shaft and Tip in the same horizontal plane), confirm that the Stealth MicroGuard Balloons inflate correctly and are filled with saline by pressing down on the Activation Lever (shown in Figure 5) and visually inspecting the balloons. The balloons should fill completely with saline and have little to no air inside (micro-bubbles are acceptable). **IMPORTANT:** Pressing the Activation Lever down also unlocks the Blade Slider and the TCL Blade. Keep the device in the horizontal position to prevent unwanted movement of the Blade Slider and TCL Blade. **IMPORTANT:** When the Activation Lever is pressed down, sterile saline *might* vent from the Syringe Port to help regulate the system pressure.

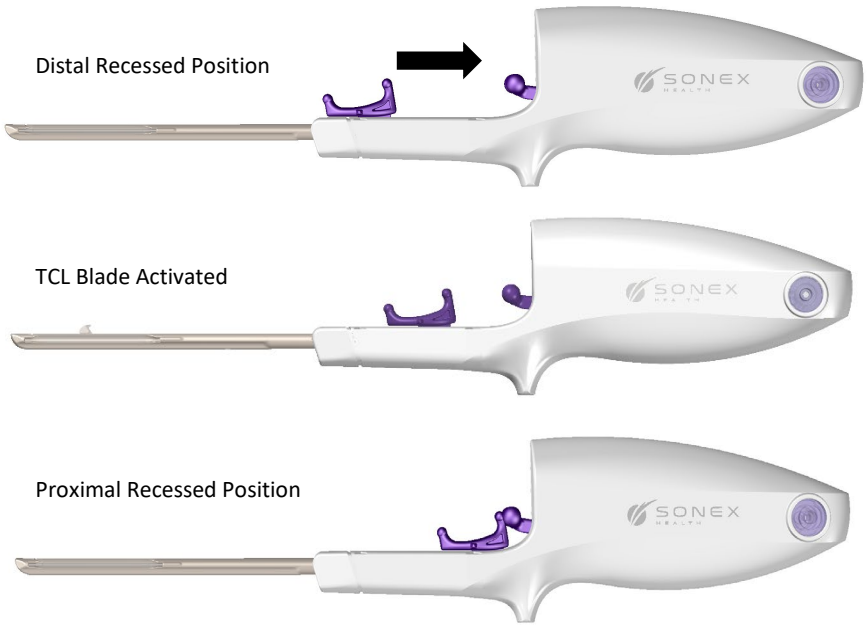
Figure 5: Push down the Activation Lever to inflate the Stealth MicroGuard Balloons**.**



    c. With the Activation Lever down and the balloons inflated, the TCL Blade is now unlocked and can move freely. Use the Blade Slider to expose the TCL Blade from the distal recessed position, slide it to the

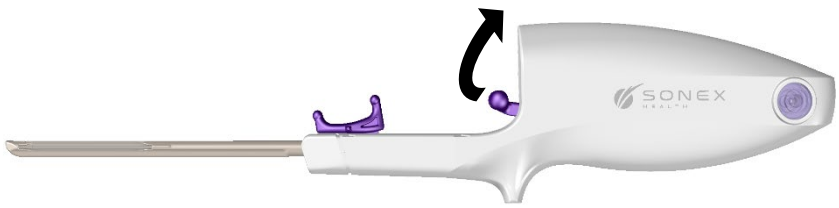
proximal recessed position (shown in Figure 6), and return it to the distal recessed position. Ensure the blade travels smoothly, can be completely recessed in the proximal recessed position, and can easily be returned to the distal recessed position. Visually inspect the Tip after returning the TCL Blade to the distal recessed position to ensure the TCL Blade is completely recessed.

Figure 6: Pull the Blade Slider proximally to activate the TCL Blade from the distal recessed position to the proximal recessed position.



d. With the TCL Blade in the distal recessed position, raise the Activation Lever (shown in Figure 7) to return the Stealth MicroGuard Balloons to the deflated position. **IMPORTANT:** The Activation Lever cannot be raised to the inactive position unless the TCL Blade is *fully recessed* in either the proximal or distal position. Raising the Activation Lever should not require excessive force. Using excessive force may overcome the interlock feature.

Figure 7: Raise the Activation Lever to deflate the Stealth MicroGuard Balloons.



e. Make sure all controls and the TCL Blade are in the inactive position as shown in Figure 1. UltraGuideCTR is now ready for use. **IMPORTANT:** If the device does not function as described above at any point during priming or the procedure, do NOT use the device. Obtain a new device to complete the procedure.

9. **Troubleshooting:** If the balloons do not fully inflate with saline or have large air bubbles remaining after completing this process, reattach the syringe and pull the plunger to full extension a third time. Next detach the syringe and repeat the visual inspection. This extra step helps remove any remaining air in the system. Note that in some cases, this extra step may cause saline to vent from the syringe port to help regulate system pressure and prevent device damage due to overinflation.

C. Patient Preparation

1. Position the patient with the wrist on a stable surface in slight extension and in neutral radial-ulnar deviation. Stabilize the arm.
2. Use standard sterile techniques to prepare the patient's entire hand, wrist, and forearm.
3. Prepare the sterile field and sterile ultrasound gel and place a sterile cover over the ultrasound transducer.
4. Using real-time ultrasound visualization:
    a. Identify the pertinent anatomical structures such as the median nerve, the third common palmar digital nerve and any communicating branches, hook of the hamate, TCL, ulnar vessels/superficial palmar arterial arch, lunate, flexor tendons, and any relevant anatomic variations.
    b. Identify the Transverse Safe Zone (TSZ) between the ulnar aspect of the median nerve and the radial aspect of the ulnar vessels or the hook of the hamate, whichever lies more radial.
    c. Identify the anticipated transection line of the TCL. During the scan, visualize the TCL and surrounding anatomy to ensure that the anticipated transection line is acceptable.
    d. Mark the incision site in the region of the proximal wrist crease, typically in the region of the proximal lunate, along the anticipated line of TCL transection, noting the position of the median nerve and ulnar artery.

D. Procedure

Complete the following steps under real-time ultrasound guidance. **WARNING: If visualization of the device or pertinent anatomical structures is impaired during the procedure, DO NOT continue until proper visualization is restored. If visualization cannot be restored, DO NOT continue the procedure.**

1. Provide anesthesia. **IMPORTANT:** Ultrasound guided dissection of the synovial tissue from the undersurface of the TCL may be performed via hydrodissection (using a small or medium-gauge needle) and/or via mechanical dissection (using the Tip of UltraGuideCTR or a blunt tipped elevator/dilator). If performing hydrodissection, complete during this step. Mechanical dissection will be completed in a future step.
2. Use a scalpel to create a small incision at the incision site, penetrating the antebrachial fascia.
3. If hydrodissection was not completed in step #1, dissect the synovial tissue from the undersurface of the TCL via mechanical dissection. The Tip of the device or a blunt tipped elevator/dilator may be used. If using the Tip of the device, complete mechanical dissection during step #5. If using an elevator or dilator, complete mechanical dissection now. **WARNING: Mechanical dissection of synovial tissue from the undersurface of the TCL should not require excessive force. Using excessive force may result in loss of control and injury to the patient or operator.**
4. Prior to UltraGuideCTR insertion, ensure device controls match Figure 1:
    a. The Activation Lever is *UP*, and the Stealth MicroGuard Balloons are deflated.
    b. The Blade Slider is *DISTAL* (i.e., towards the device Tip) and the TCL Blade is completely in its distal recessed position.
    c. **IMPORTANT:** During the procedure, UltraGuideCTR should remain approximately parallel to the patient's forearm so that the Shaft is perpendicular to the wrist crease. The patient's hand should remain slightly extended, supinated and in neutral radial-ulnar deviation.
5. Insert UltraGuideCTR through the incision and antebrachial fascia and into the TSZ. The device should pass easily into the carpal tunnel. The device should be placed into the carpal tunnel so that it lies directly below the TCL, without any intervening tissue along the anticipated transection line. Complete mechanical dissection if not completed in step #3. **WARNING: Do NOT use excessive force to insert the device. Using excessive force during insertion may cause injury to the patient or operator and/or device damage.**
6. Position the Tip distal to the distal TCL so that the TCL Blade (when deployed) will engage the distal TCL. The position where the TCL Blade will emerge from its distal recessed position is indicated by the Notch on the distal Shaft as shown in Figure 3.
7. Perform safety check: Use ultrasound to confirm the position of UltraGuideCTR within the carpal tunnel relative to surrounding anatomy. Confirm the following:
    a. The device lies in the TSZ.

b. The device lies directly below the TCL along the entire cutting path, without any intervening tissue. No critical structures (e.g., nerves, tendons, vessels) cross the TCL Blade path. As needed, finger flexion and extension can be used to confirm the position of the flexor tendons.
c. **IMPORTANT**: In the distal carpal tunnel region, the position of the superficial palmar arterial arch, third common palmar digital nerve, and any communicating branches should be specifically noted to avoid injury.

8. Maintain position and press down on the Activation Lever down to inflate the Stealth MicroGuard Balloons as shown in Figure 5. **IMPORTANT:** Pressing the lever down also unlocks the Blade Slider and the TCL Blade. **WARNING: Do NOT engage the TCL Blade until the safety check in step #9 is completed. Premature or accidental activation of the blade may result in patient injury.**
9. Perform an additional safety check: With the Stealth MicroGuard Balloons inflated, visualize the device, and ensure its position has not changed from step #7. As in step 7, ensure the following:
    a. The device lies in the TSZ.
    b. The device lies directly below the TCL along the entire cutting path, without any intervening tissue. No critical structures (e.g., nerves, tendons, vessels) cross the TCL Blade path. As needed, finger flexion and extension can be used to confirm the position of the flexor tendons.
    c. **IMPORTANT**: In the distal carpal tunnel region, the position of the superficial palmar arterial arch, third common palmar digital nerve, and any communicating branches should be specifically noted to avoid injury.
    d. **IMPORTANT:** If a leak is detected or the Stealth MicroGuard Balloons don't inflate properly, return the TCL Blade to the fully recessed distal position, deflate the Stealth MicroGuard Balloons, and remove the device under real-time ultrasound visualization. Following removal, obtain a new device to complete the procedure.
    e. **IMPORTANT:** If the device is repositioned at any point during the remainder of the procedure, an additional safety check should be completed to confirm device position relative to surrounding anatomy.
10. While maintaining the position of the device, pull the Blade Slider proximally to raise TCL Blade and transect the TCL from distal to proximal until the TCL Blade lowers into its proximal recessed position. During this step, the device should remain directly under the TCL without any intervening tissue. Refer back to Figure 6.
    a. WARNING: The surrounding anatomy should be monitored continuously, as in the safety checks. If visualization is lost, STOP. Do NOT proceed until visualization is restored. If visualization cannot be restored, return the TCL Blade to the fully recessed distal position, and do NOT continue the procedure.
    b. WARNING: TCL transection should not require excessive force. Using excessive force to transect the TCL may result in loss of control and injury to the patient or operator.
11. To perform additional pass (if desired) with the TCL blade:
    a. Return the TCL Blade to the distal recessed position. The distal facing portion of the TCL Blade is non-cutting.
    b. Reposition the device in the carpal tunnel as previously described relative to surrounding anatomy. **IMPORTANT:** Regional anatomy may have been significantly altered by the transection. Repeat safety checks as described in step #9.
    c. Repeat transection as described in step #10.
12. Following TCL transection, ensure the TCL Blade is fully recessed in either the proximal or distal position. Raise the Activation Lever to deflate the Stealth MicroGuard Balloons and lock the Blade Slider. Refer back to Figure 7. **IMPORTANT:** The Activation Lever cannot be raised unless the TCL Blade is *fully recessed* in either the proximal or distal position. Raising the Activation Lever should not require excessive force. Using excessive force may overcome the interlock feature.
13. Probe the TCL under ultrasound to ensure a complete release along the entire length of the TCL. Probing may be completed using the Tip of the device or a blunt tipped elevator/dilator. If UltraGuideCTR will not be used for probing, carefully remove UltraGuideCTR following step #14 and probe the TCL with the alternative instrument. **WARNING: Probing after transection to confirm a complete release of the TCL should not require excessive**

force. Using excessive force to transect the TCL may result in loss of control and injury to the patient or operator.

14. Remove the device using ultrasound guidance after confirming the TCL Blade is fully recessed in the proximal or distal position and the Stealth MicroGuard Balloons are deflated. Inspect device and then discard.
15. Perform a post procedure scan of the anatomy.

SAFE DISPOSAL INFORMATION:

- After use, discard the device in accordance with local environmental regulations for biohazard material. Place device in a sharps disposal container.

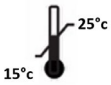
WOUND CLOSURE AND POST-OPERATIVE CARE:

- Wound closure (i.e. standard adhesive bandage or strip, sutures, etc.) should be determined by the operator. Standard post-operative wound care should be administered.

SYMBOLS LIBRARY:

Standard and Reference # - ISO 15223-1:2021(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements

Symbol	Title [#, Definition]
	Do NOT Re-use [5.4.2, Indicates a medical device that is intended for one single use only.]
	Use-by date [5.1.4, Indicates the date after which the medical device is not to be used.]
	Catalogue Number [5.1.6, Indicates the manufacturer's catalogue number so that the medical device can be identified.]
	Sterilized using irradiation [5.2.4, indicates a medical device that has been sterilized using irradiation.]
	For Prescription Use Only [21 CFR part 801.109(b), Indicates "Warning: Federal law (USA) restricts this device to sale by or on the order of a physician"]
	Do NOT re-sterilize [5.2.6, Indicates a medical device that is not to be re-sterilized.]
	Keep dry [5.3.4, Indicates a medical device that needs to be protected from moisture.]
	Unique Device Identifier [Indicates a carrier that contains unique device identifier information

Symbol	Title [#, Definition]
	Do NOT use if package is damaged and consult instructions for use. [5.2.8, Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.]
	Consult Instructions for Use [5.4.3, Indicates the need for the user to consult the instructions for use]
	Caution [5.4.4 Indicates that caution is necessary when operating the device]
	Single sterile barrier system [5.2.11, Indicates a single sterile barrier system]
	Single sterile barrier system with protective packaging outside [5.2.14 Indicates a single sterile barrier system with protective packaging outside.]
	Temperature Limit [5.3.7, Indicates the temperature limits to which the medical device can be safely exposed.]
	Keep away from sunlight [5.3.2, Indicates a medical device that needs protection from light sources.]
	Medical device [5.7.7, Indicates the item is a medical device.]

LOT	Batch Code [5.1.5 Indicates the manufacturer's batch code so that the batch or lot can be identified]
	Open Here [ISO 7000 – Reference No: 3079, Indicates "To identify the location where the package can be opened and to indicate the method of opening it."]

	Not made with natural rubber latex [Guidance for Industry and FDA Staff, Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex, December 2, 2014]

REPORTABILITY:

- Report any serious incident that has occurred in relation to the UltraGuideCTR to Sonex Health via contact information specified below and the authority having jurisdiction in their locale.

CONTACT INFORMATION:

Sonex Health, Inc.
950 Blue Gentian Road, Suite 200
Eagan, MN 55121 USA
T: 1-888-518-8780
www.sonexhealth.com

REVISION HISTORY:

Revision	Details	Date
A	Initial release for commercialization	2025-04
B	Update indications for use, intended use, device description No safety related updates	2025-08