UltraGuide CTR™
CARPAL TUNNEL RELEASE

Instructions for Use

Intended Use:
UltraGuideCTR™ is intended to transect the transverse carpal ligament for the treatment of carpal tunnel syndrome.

Indications for Use:
UltraGuideCTR is a disposable device intended to create space within the carpal tunnel and transect the transverse carpal ligament (TCL) for the treatment of carpal tunnel syndrome.

Contraindications:
- Presence of infection.
- Distorted anatomy or other process within the carpal tunnel preventing safe and effective transection of the TCL.
- Presence of condition requiring surgical intervention beyond transection of the TCL.
- Additionally, in cases in which ultrasound guidance is used, inability to sonographically identify and protect relevant anatomic structures such as the nerves and vessels.

Possible Complications:
Operators should be familiar with the complications of carpal tunnel release using UltraGuideCTR, including but not limited to:
- Procedure related discomfort.
- Infection.
- Wound complications such as delayed healing, scarring or tenderness.
- Pillar pain.
- Bruising.
- Injury to vessels, tendons or other soft tissues.
- Injury to nerves such as the median nerve.
- Development of a chronic pain process such as complex regional pain syndrome.
- Recurrence.
- Incomplete symptom resolution.
- Additionally, in cases in which ultrasound guidance is used, inability to complete the carpal tunnel release with ultrasound guidance requiring discontinuation of the procedure.

Warnings:
- Safe and successful transection of the TCL using UltraGuideCTR is dependent upon appropriate training, 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.

- Inflating the balloons beyond the maximum inflation volume may cause the balloons to rupture before reaching the maximum inflation pressure of 40 psi.
- Inflating the balloons beyond the maximum inflation pressure may cause the balloons to rupture before reaching the maximum inflation volume.
- Use of UltraGuideCTR in conjunction with ultrasound guidance should only be performed by operators experienced in ultrasound guided procedures and who are properly trained and familiar with the correct operation of UltraGuideCTR as outlined in this document.
- The safety and effectiveness of UltraGuideCTR to transect the TCL in cases of recurrent carpal tunnel syndrome has not been established.
- The cutting blade of UltraGuideCTR is extremely sharp. Exercise caution to prevent injury.
- Device misuse, such as excessive prying, may damage the device, resulting in an inability to complete the procedure or potential injury.
- If visualization of the device or relevant anatomical structures is impaired during the procedure, DO NOT continue until proper visualization is restored.
- Following use, the device must be properly discarded as outlined in this document.
- Do NOT Re-sterilize. Single Use Only.

Packaging and Sterilization:
- UltraGuideCTR and syringe are supplied sterile.
- The Product should be accepted only if the factory packaging arrives intact.
- Contact Customer Service if the sterile package has been altered or damaged.

Product Users/Use Environment
- Customers: The device should be used by properly trained health care providers in hospital and clinic settings.
- Users: The device should be used by a physician, surgeon, or other medical personnel qualified to perform a carpal tunnel release and/or ultrasound guided procedures (herein referred to as the operator).
- Use Environments: Procedure room in a clinical facility such as an outpatient facility, physician's office or a hospital.

Precautions:
- Operators using UltraGuideCTR should be familiar with the surgical technique and the required instrumentation.
- Operators using UltraGuideCTR in conjunction with ultrasound guidance should be familiar with the use of ultrasound for interventional procedures.
- Carpal tunnel release using UltraGuideCTR represents a surgical procedure. Operators and staff should follow appropriate precautions and procedures.
- 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.

NOTE: Directions for Use are presented as two different techniques: Ultrasound Guided Technique, steps A – L, and Mini-Open Technique (non-ultrasound guided), steps M – V.

Directions for Using UltraGuideCTR – Ultrasound Guided Technique:

A. Pre-operative Planning
   1. See **Precautions**: Carpal tunnel release using UltraGuideCTR represents a surgical procedure. Operators and staff should follow appropriate precautions and procedures.
   2. Perform a pre-procedure diagnostic ultrasound of the carpal tunnel region if clinically indicated.

B. Stabilizing the Arm and Sterile Preparation
   1. Position the patient with the wrist on a stable surface in slight extension and in neutral radial-ulnar deviation.
   2. Prepare the patient's entire forearm, elbow to fingertips, using standard sterile techniques.
   3. Prepare the sterile field and place a sterile cover over the ultrasound transducer. In addition to a sterile cover, sterile ultrasound gel should be used throughout the procedure.
   4. See **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.

C. Identifying Anatomical Landmarks
   1. Using direct ultrasound visualization, identify the relevant anatomical structures such as the median nerve, hook of the hamate, TCL, ulnar vessels/superficial palmar arterial arch, and lunate.
   2. 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.
   3. Identify the incision site at the proximal wrist crease. Place the transducer across the TSZ. Scan proximally along the anticipated line of TCL transection to the lunate bone, which is located at the proximal wrist crease. During the scan, visualize the TCL and surrounding anatomy to ensure that the transection path is acceptable. Using an indelible ink marker, mark the skin in the region of the lunate along the anticipated line of TCL transection, noting the position of the median nerve and ulnar artery.
   4. Place the sterile marker into the sterile field for later use.

D. Delivering Local Anesthesia
   1. Operators should provide anesthesia in accordance with their usual practices and in consideration of the technique of carpal tunnel release using UltraGuideCTR and ultrasound guidance.
   2. 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 a blunt tipped dilator or elevator.

E. Preparing UltraGuideCTR

1. Remove UltraGuideCTR from its shipping box. UltraGuideCTR plastic tray is wrapped in blue wrapping paper and is contained within a sterile barrier pouch. Inspect the sterile barrier pouch for damage.

   NOTE: If there is any damage to the sterile barrier pouch, DO NOT use the device.

2. Open the sterile barrier pouch and place the sterile, wrapped UltraGuideCTR on a flat surface.
3. Open the blue wrapping to create the sterile field containing UltraGuideCTR tray.

   NOTE: All subsequent steps are performed using sterile technique.

4. Using sterile gloves, move UltraGuideCTR tray to the right side of the sterile field (placement onto the right side of the sterile field will ensure adequate room for device preparation as described below). Starting at angled corner of tray, remove the lid of UltraGuideCTR.

   NOTE: DO NOT discard the bottom portion of the tray, in which the device sits, because it is used to prime the device.

5. UltraGuideCTR is located in slot #1 of the tray. Carefully remove UltraGuideCTR from slot #1 and visually inspect for damage.

   NOTE: If there are any signs of damage, DO NOT use the device.

6. Remove the sterile filling syringe from the plastic tray and place into slot #1 for temporary storage.
7. Depress the balloon activation lever on UltraGuideCTR sufficiently to place the device into slot #2, where the Stealth MicroGuard® balloon priming will occur. Do not fully depress the balloon activation lever. Ensure UltraGuideCTR fits securely into slot #2.
8. Take the filling syringe from slot #1 and fill with 20 ml of sterile normal saline.
9. Attach the filling syringe to the Luer Lock filling port on UltraGuideCTR.

   NOTE: When the filling syringe is sufficiently attached to UltraGuideCTR an air bubble will appear in the syringe. At this point, DO NOT continue to tighten the filling syringe as it will prevent fluid flow.

10. Depress the filling syringe plunger to fill the Stealth MicroGuard balloons. As the plunger is depressed, observe the filling of the Stealth MicroGuard balloons. If they do not fill, loosen the filling syringe a ¼ turn and retry.
11. Draw back on the filling syringe plunger to create a vacuum, observing the deflation of the Stealth MicroGuard balloons, and hold for 5 seconds.
12. Once again, depress the filling syringe plunger to re-fill the Stealth MicroGuard balloons.
13. Draw back on the filling syringe plunger again to create a vacuum, observing the deflation of the Stealth MicroGuard balloons, and hold for 5 seconds.

14. For a third time, depress the filling syringe plunger to re-fill the Stealth MicroGuard balloons, observing their inflation. Hold the plunger in the depressed position for 1-2 seconds.
15. Release the plunger and allow the pressure within UltraGuideCTR and Stealth MicroGuard balloons to equalize with the pressure in the filling syringe. This will take 3-5 seconds. Do not draw back on the plunger.
16. Detach the syringe from the Luer lock mechanism and place back into slot #1 for storage.
17. The Stealth MicroGuard balloons are now primed. Remove UltraGuideCTR from slot #2 and allow the balloon activation lever to spontaneously un-depress.

F. Checking UltraGuideCTR Before Use
1. The cutting mechanism should be checked for normal function.
2. Depress and lock the balloon activation lever, re-activating the Stealth MicroGuard balloons. Visually inspect that the balloons are inflated.
3. When the Stealth MicroGuard balloons are activated, the cutting blade (TCL Blade®) becomes active and can be tested. See **Warning**: The cutting blade of UltraGuideCTR is extremely sharp. Exercise caution to prevent injury.
4. Gently move the slide button on the handle proximally to expose the TCL Blade from its distal recessed position. Use the slide button to cycle the TCL Blade a minimum of one time from its distal to proximal recessed positions to ensure functionality.

   NOTE: If the TCL Blade does not deploy after the balloon activation lever has been depressed, un-depress the balloon activation lever and re-depress. If the blade still does not deploy, DO NOT use the device. Similarly, if the TCL Blade is angled or does not track with minimal resistance, DO NOT use the device.

5. Replace the TCL Blade completely into its distal recessed position.

   CAUTION: The slide button (and TCL Blade) remain active when the Stealth MicroGuard balloons are inflated. Exercise caution to avoid unwanted exposure of the TCL Blade during the following steps, which could result in injury.

6. With the balloon activation lever remaining depressed and the balloons activated, proceed the with following “No-Go” Test.

G. Testing UltraGuideCTR tip in the “No-Go” slot
1. Rotate the axial depth indicator 90 degrees so that it is parallel to the top of UltraGuideCTR.
2. With the balloon activation lever depressed and the Stealth MicroGuard balloons inflated, carefully place the UltraGuideCTR tip onto slot #3 (i.e., the “No-Go” slot) on the left side of the UltraGuideCTR tray.

   NOTE: Simply place the UltraGuideCTR tip onto the “No-Go” slot. DO NOT attempt to force it into the slot.

3. If the tip does not fall into slot #3, the balloons are appropriately inflated.

NOTE: A properly functioning device with activated Stealth MicroGuard balloons should NOT fall into the No-Go slot when the device is held lightly. If the device falls into the slot, then the Stealth MicroGuard balloons are not functioning properly. Repeat the priming and testing procedure as described above. If the device fails a second time, then DO NOT use the device.

4. Visually inspect the entire device.
   a. Ensure that both balloons are inflated.
   b. Inspect for damage and/or sterile saline leakage from either balloon or the Luer-Lock.
5. Following satisfactory inspection, ensure that the TCL Blade has remained fully in its distal recessed position. If the blade is not completely in its distal recessed position, use the slide button to place it in its fully recessed position.

   NOTE: If the TCL Blade cannot be fully placed into the distal recessed position, DO NOT use the device.

6. Following confirmation that the blade is located in its distal recessed position, place UltraGuideCTR onto the sterilely prepared palm such that the device tip lies within the transverse safe zone and the distal end of the TCL Blade track lies at the level of the distal TCL. The distal tip of UltraGuideCTR will extend distal to this point. Place a mark on the skin at the end of the distal tip of UltraGuideCTR. This mark can be used as a reference during the procedure to confirm the desired placement of UltraGuideCTR within the carpal tunnel region. At this point the axial depth indicator can be positioned at the level of the proximal wrist skin entry site.
7. Un-depress the balloon activation lever.
8. Visually inspect the balloons to ensure that they have deflated.
9. UltraGuideCTR is ready to use.

   NOTE: The remaining steps are performed using direct ultrasound (sonographic) visualization.

H. Placing UltraGuideCTR Into the Carpal Tunnel
   1. Prior to insertion the operator should visually inspect UltraGuideCTR to ensure that the balloons are deflated, and the TCL Blade is completely in its distal recessed position.
   2. Reconfirm appropriate patient positioning as previously described.
   3. Use a scalpel blade to create a small incision at the entry site, penetrating the antebrachial fascia.
   4. If using a blunt tipped dilator or elevator for synovial dissection, pass the instrument into the carpal tunnel and perform synovial dissection along the anticipated path of TCL transection.
   5. Pass the blunt tipped UltraGuideCTR through the incision and antebrachial fascia and into the TSZ. The device should pass easily in the carpal tunnel – excessive force is not required. See **Warnings:** Device misuse, such as excessive prying, may damage the device, resulting in an inability to complete the procedure or potential injury.

      NOTE: During the procedure, UltraGuideCTR should remain approximately parallel to the patient's forearm so that the tip is perpendicular to the wrist

crease. The patient's hand should remain slightly extended, supinated and in neutral radial-ulnar deviation.

6. Position the blunt tip of UltraGuideCTR distal to the distal TCL so that the TCL Blade (when deployed) will engage the distal TCL. The position of the superficial palmar arterial arch should be noted to avoid injury.
7. Confirm the position of UltraGuideCTR within the carpal tunnel relative to surrounding anatomy.
8. Once proper positioning is confirmed, the axial depth indicator can be adjusted as necessary to position it against the forearm.

I. Cutting the Transverse Carpal Ligament (TCL) using UltraGuideCTR

See Warnings: If visualization of the device or relevant anatomical structures is impaired during the procedure, DO NOT continue until proper visualization is restored. If unable to restore adequate visualization, discontinue the procedure. Ensure that the TCL Blade is in its proximal or distal recessed position and the Stealth MicroGuard balloons are deactivated prior to device removal (see Removing UltraGuideCTR).

1. After confirming proper placement of UltraGuideCTR, activate the Stealth MicroGuard balloons. Reconfirm proper positioning of UltraGuideCTR as previously described.

   CAUTION: Attempting to deploy the TCL Blade without first activating the Stealth MicroGuard balloons will damage UltraGuideCTR and may result in injury.

   CAUTION: Once the Stealth MicroGuard balloons are deployed, the TCL Blade is active. Exercise caution to avoid unwanted exposure of the TCL Blade prior to initiating TCL transection, which may result in injury to the patient.

2. Deploy the TCL Blade by moving the slide button proximally to transect the TCL from distal to proximal until the TCL Blade passes into its proximal, recessed position.

   NOTE: If a balloon leak is detected, ensure that the TCL Blade is completely located in either its proximal or distal recessed position, deflate the Stealth MicroGuard balloons, and remove the device under direct ultrasound visualization. Following removal, confirm that the balloons are not operating properly. If the balloons are not operating properly, then obtain a new device to finish procedure.

3. Once the TCL is transected the TCL should be probed to ensure a complete release. Probing may be completed using UltraGuideCTR tip or a blunt tipped probe or elevator. If UltraGuideCTR will not be used for probing, carefully remove UltraGuideCTR following the instructions below (Removing UltraGuideCTR) and probe the TCL with the alternative instrument. If UltraGuideCTR will be used for probing, move the slide button distally to replace the TCL Blade completely into its distal recessed position, deflate the Stealth MicroGuard balloons, and proceed with probing.

4. If complete TCL transection is confirmed, carefully remove the instrument or device (if probing with UltraGuideCTR device follow the instructions below Removing UltraGuideCTR). If incomplete transection is suspected, additional attempts at TCL transection may be performed as described below (Suspected Incomplete TCL Transection).

J. Suspected Incomplete Transection
1. If incomplete TCL transection is suspected, additional attempts at TCL transection may be performed.
2. Ensure that the TCL Blade is completely in its distal, recessed position.
3. Reposition the device in the carpal tunnel as previously described.
4. Confirm the position of UltraGuideCTR within the carpal tunnel relative to surrounding anatomy. Note that the regional anatomy may have been significantly altered by the previously attempted TCL transection(s).
5. Once UltraGuideCTR is accurately repositioned, reactivate the Stealth MicroGuard balloons and re-check the position of the device relative to surrounding structures. Following confirmation, repeat the steps to transect the TCL as previously described. **See Warnings:** If visualization of the device or relevant anatomical structures is impaired during the procedure, DO NOT continue until proper visualization is restored. If unable to restore adequate visualization, discontinue the procedure. Ensure that the TCL Blade is in its proximal or distal recessed position and the Stealth MicroGuard balloons are deactivated prior to device removal (see Removing UltraGuideCTR).
6. Following repeat attempted TCL transection, re-probe the TCL as previously described to assess for complete TCL transection.

K. Removing UltraGuideCTR
1. After confirming that the TCL Blade is located completely in either its proximal or distal recessed position, deflate the Stealth MicroGuard balloons and carefully remove UltraGuideCTR while monitoring the removal using ultrasound guidance.

   NOTE: If Stealth MicroGuard balloon deflation does not occur when the balloon activation lever is released, the operator may manually deflate the balloons by connecting the sterile filling syringe to the Luer-Lock valve and pulling back on syringe plunger. This will release the pressure in the balloons and manually deflate them. The blade may still be active, ensure the blade stays in the proximal or distal recessed position. This method should **only** be used if the deflation lever fails to deflate the balloons when de-activated.

2. Following device removal, inspect the device to ensure that it is intact.

L. Wound Closure and Post-Operative Care
1. See **Precautions**: Carpal tunnel release using UltraGuideCTR represents a surgical procedure. Operators and staff should follow appropriate precautions and procedures.
2. Wound closure (i.e. standard adhesive bandage or strip, sutures, etc.) and care should be determined by operator. Standard post-operative wound care should be administered.

Directions for Using UltraGuideCTR – Mini-Open Technique (non-ultrasound guided)**:**

M. Pre-Operative Planning
   1. See **Precautions**: Carpal tunnel release using UltraGuideCTR represents a surgical procedure. Operators and staff should follow appropriate precautions and procedures.

N. Stabilizing the Arm and Sterile Preparation
   1. Operators should stabilize the arm and prepare the sterile field in accordance with standard procedures for mini-open carpal tunnel release.
   2. See **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.

O. Delivering Local Anesthesia
   1. As noted previously, operators should provide anesthesia in accordance with their usual practice when performing Mini-Open carpal tunnel release.

P. UltraGuideCTR should be prepared for use as described for the technique using Ultrasound Guided Technique:
   1. Prepare UltraGuideCTR.
   2. Check UltraGuideCTR before use.
   3. Test UltraGuideCTR tip in the "No-Go" slot.

Q. Exposing the TCL
   1. Complete the operator preferred surgical exposure for a Mini-Open carpal tunnel release. Identify the proximal and distal margins of the TCL, as well as the superficial palmar arterial arch lying distal to carpal tunnel.
   2. Further expose the TCL using retractors as necessary.

R. Placing UltraGuideCTR Into the Carpal Tunnel
   1. Expose the distal antebrachial fascia between the proximal and distal wrist creases. Create a small incision with a scalpel blade through the antebrachial fascia, ulnar to the palmaris longus tendon and along a line parallel to the radial aspect of the ring finger (i.e., in the transverse safe zone).
   2. Palpate the hook of the hamate, which identifies the ulnar extent of the distal carpal tunnel region (i.e. the transverse safe zone, TSZ).
   3. Under direct visualization, place UltraGuideCTR directly under the proximal aspect of the TCL and just radial to the hook of the hamate. UltraGuideCTR should be placed under the TCL so that its blunt tip and shaft are in direct contact with the undersurface of the TCL at all times.
   4. Advance UltraGuideCTR distally within the carpal tunnel, along the anticipated line of TCL transection. UltraGuideCTR should always be in contact with the undersurface of the TCL until it reaches beyond the distal extent of the TCL. Directly visualize the blunt distal tip passing beyond the TCL and engaging the distal TCL. Position the distal tip so that the cutting knife (TCL Blade) will engage the distal TCL upon deployment. Note the relationship of the distal tip to the superficial palmar arterial arch to avoid injury.

NOTE: During the procedure, UltraGuideCTR should remain approximately parallel to the patient's forearm so that the tip is perpendicular to the wrist crease. The patient's hand should remain slightly extended, supinated and in neutral radial-ulnar deviation.

5. Once proper positioning is confirmed, slide the axial depth indicator to position it against the forearm tissues.

S. Cutting the Transverse Carpal Ligament Using UltraGuideCTR

See Warnings: If visualization of the device or relevant anatomical structures is impaired during the procedure, DO NOT continue until proper visualization is restored. If unable to restore adequate visualization, discontinue the procedure. Ensure that the TCL Blade is in its proximal or distal recessed position and the Stealth MicroGuard balloons are deactivated prior to device removal

1. After confirming proper placement of UltraGuideCTR within the ulnar aspect of the carpal tunnel (i.e., the TSZ) activate the Stealth MicroGuard balloons by depressing the balloon activation lever towards the handle.

   CAUTION: Attempting to deploy the TCL Blade without first activating the Stealth MicroGuard balloons will damage UltraGuideCTR and may result in injury.

   CAUTION: Once the Stealth MicroGuard balloons are deployed, the TCL Blade is active. Exercise caution to avoid unwanted exposure of the TCL Blade prior to initiating TCL transection, which may result in injury to the patient.

2. Following balloon activation, re-confirm proper positioning of UltraGuideCTR within the carpal tunnel.
3. Deploy the TCL Blade by moving the slide button proximal to transect the TCL from distal to proximal until the TCL Blade passes into its proximal, recessed position.

   NOTE: If a balloon leak is detected, ensure that the TCL Blade is completely located in either its proximal or distal recessed position, deflate the Stealth MicroGuard balloons, and carefully remove the device. Following removal, confirm that the balloons are not operating properly. If the balloons are not operating properly, then obtain a new device to finish procedure.

4. Once the TCL is transected the TCL should be probed to ensure a complete release. Probing may be completed using UltraGuideCTR tip or a blunt tipped probe or elevator. If UltraGuideCTR will not be used for probing, carefully remove UltraGuideCTR following the instructions below (Removing UltraGuideCTR) and probe the TCL with the alternative instrument. If UltraGuideCTR will be used for probing, move the slide button distally to replace the TCL Blade completely into its distal recessed position, deflate the Stealth MicroGuard balloons, and proceed with probing.
5. If complete TCL transection is confirmed, carefully remove the instrument or device (if probing with UltraGuideCTR device follow the instructions below Removing UltraGuideCTR). If incomplete transection is suspected, additional

attempts at TCL transection may be performed as described below (Suspected Incomplete TCL Transection).

T. Suspected Incomplete Transection
   1. If incomplete TCL transection is suspected, additional attempts at TCL transection may be performed.
   2. Ensure that the TCL Blade is completely in its distal, recessed position.
   3. Reposition the device in the carpal tunnel as previously described.
   4. Confirm the position of UltraGuideCTR within the carpal tunnel relative to surrounding anatomy. Note that the regional anatomy may have been significantly altered by the previously attempted TCL transection(s).
   5. Once UltraGuideCTR is accurately repositioned, reactivate the Stealth MicroGuard balloons and re-check the position of the device relative to surrounding structures. Following confirmation, repeat the steps to transect the TCL as previously described. **See Warnings:** If visualization of the device or relevant anatomical structures is impaired during the procedure, DO NOT continue until proper visualization is restored. If unable to restore adequate visualization, discontinue the procedure. Ensure that the TCL Blade is in its proximal or distal recessed position and the Stealth MicroGuard balloons are deactivated prior to device removal.
   6. Following repeat attempted TCL transection, re-probe the TCL as previously described to assess for complete TCL transection.

U. Removing UltraGuideCTR
   1. After confirming that the TCL Blade is located completely in either its proximal or distal recessed position, deflate the Stealth MicroGuard balloons and carefully remove UltraGuideCTR.

      NOTE: If Stealth MicroGuard balloon deflation does not occur when the balloon activation lever is released, the operator may manually deflate the balloons by connecting the sterile filling syringe to the Luer-Lock valve and pulling back on syringe plunger. This will release the pressure in the balloons and manually deflate them. The blade may still be active, ensure the blade stays in the proximal or distal recessed position. This method should **only** be used if the deflation lever fails to deflate the balloons when de-activated.

   2. Following device removal, inspect the device to ensure that it is intact.

V. Wound Closure and Post-operative Care
   1. See **Precautions**: Carpal tunnel release using UltraGuideCTR represents a surgical procedure. Operators and staff should follow appropriate precautions and procedures.
   2. Wound closure and care, as well as post-operative rehabilitation, should be performed according to the operator preferred protocol for Mini-Open carpal tunnel release.

Disposal:
UltraGuideCTR should be disposed of in accordance with organizational policies and guidelines for sharps disposal.

Storage: Store the device in a cool, dry place.

Environmental Conditions	Operation	Storage and Transport
Temperature	5°C to 40°C	15°C to 25°C
Humidity	Up to 85% at 5°C and 90% at 40°	Up to 90%

Symbols Library:

Symbol	Title [#*, Definition]	Symbol	Title [#*, Definition]
	Do Not Re-use [5.4.2, Indicates a medical device that is intended for one single use only.]		Do not use if damaged [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 i*nstructions for use* for additional information.]
	Use by [5.1.4, Indicates the date after which the medical device is not to be used.]		Consult Instructions for Use [5.4.3, Indicates the need for the user to consult the instructions for use]
	Catalog Number [5.1.6, Indicates the manufacturers' catalog number so that the medical device can be identified.]		Temperature Limit [5.3.7, Indicates the temperature limits to which the medical device can be safely exposed.]
	Manufacturer [5.1.1, Indicates the medical device manufacturer.]		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"
	Sterilized using radiation [5.2.4, indicates a medical device that has been sterilized using irradiation.]		Batch Code [5.1.5, Indicates the manufacturer's batch code so that the batch or lot can be identified.]
	Keep dry [5.3.4, Indicates a medical device that needs to be protected from moisture.]		Keep away from sunlight [5.3.2, Indicates a medical device that needs protection from light sources.]
	Do not resterilize [5.2.6, Indicates a medical device that is not to be resterilized.]		Single sterile barrier system with protective packaging inside [5.2.13, Indicates a sterile barrier system with protective packaging inside.]
	Country of manufacture [5.1.11, To identify the country of manufacture of products.]		Medical device [5.7.7, Indicates the item is a medical device.]

* Standard Designation 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

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