SONEX HEALTH

UltraGuide TFR™
TRIGGER FINGER RELEASE

Instructions for Use

Intended Use:
UltraGuideTFR™ is a single-use, hand-held orthopedic manual surgical instrument to be used for trigger finger release.

Indications for Use:
UltraGuideTFR is indicated for the treatment of stenosing tenosynovitis (known as trigger finger) by incising the tendon sheath and A1 pulley, and as needed part of the A2 pulley (Excluding thumbs).

Contraindications:
- Presence of infection.
- Distorted anatomy, deformity, or other processes within the hand or finger preventing safe and effective incision of the tendon sheath and pulley.
- Presence of a condition requiring surgical intervention beyond incision of the tendon sheath and pulley.
- Use of the device on thumbs.
- Additionally, in cases in which ultrasound guidance is used, inability to sonographically identify and protect relevant anatomic structures such as the arteries, veins, and nerves.

Possible Complications:
Operators should be familiar with the complications of trigger finger release using UltraGuideTFR, including but not limited to:
  - Procedure related discomfort.
  - Infection.
  - Wound complications such as delayed healing, scarring, tenderness and tenosynovial fistula.
  - Bruising.
  - Injury to arteries, veins, tendons, or other soft tissues.
  - Skin laceration.
  - Injury to nerves such as the digital nerves.
  - Injury to the A2 pulley.
  - Development of a chronic pain process such as complex regional pain syndrome.
  - Stiffness and/or tenosynovitis.
  - Recurrence of symptoms.
  - Incomplete symptom resolution.
  - Additionally, in cases in which ultrasound guidance is used, inability to complete the trigger finger release with ultrasound guidance requiring discontinuation of the procedure.

Warnings:

- Safe and successful incision of the tendon sheath and A1 pulley (and as needed a portion of the A2 pulley) using UltraGuideTFR is dependent upon appropriate training, medical expertise regarding stenosing tenosynovitis (i.e., trigger finger) 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.
- Use of UltraGuideTFR 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 UltraGuideTFR as outlined in this document.
- The safety and effectiveness of UltraGuideTFR to incise the tendon sheath and pulley in cases of recurrent stenosing tenosynovitis/trigger finger has not been established.
- The cutting Blade of UltraGuideTFR is extremely sharp. Exercise caution to prevent injury.
- Device misuse 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. Do not attempt to clean, re-sterilize, or resharpen this device. After use, this product may be a potential biohazard.
- UltraGuideTFR is to be used only as described by the surgical technique. The operator should be familiar with the surgical procedure prior to performing the surgery.
- Postoperative care is important. The patient should be warned that failure to follow post-operative care instructions can lead to failure of the procedure or increase the risk of complications. The patient should be made aware and warned of the general surgical risks and the possible adverse effects as listed.

Packaging and Sterilization:

- UltraGuideTFR is 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 trigger finger 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 UltraGuideTFR should be familiar with the surgical technique and the required instrumentation.
- Operators using UltraGuideTFR in conjunction with ultrasound guidance should be familiar with the use of ultrasound for interventional procedures.
- Trigger Finger release using UltraGuideTFR represents a surgical procedure. Operators and staff should follow appropriate precautions and procedures.
- The position of the patient's hand and finger should be controlled during the procedure. Unwanted hand or finger movement may make the procedure more difficult or result in injury.

Figures Table for UltraGuideTFR:

Figure 1: Device while placing into the Flexor Tendon Sheath

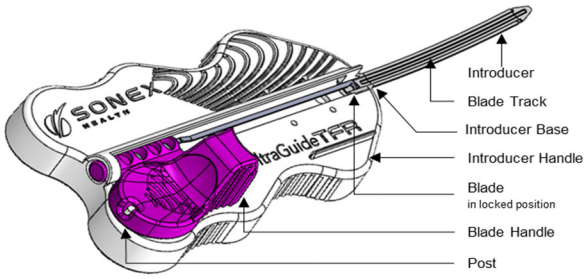


Figure 2: Unlock the Blade Handle from the Post

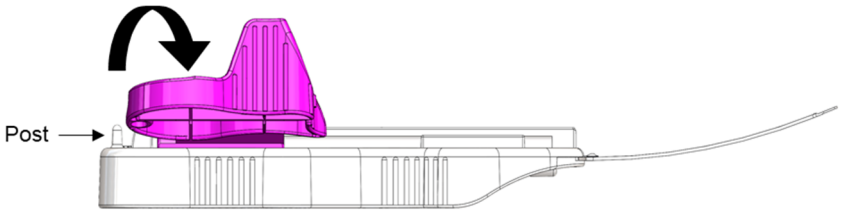


Figure 3: Start Position

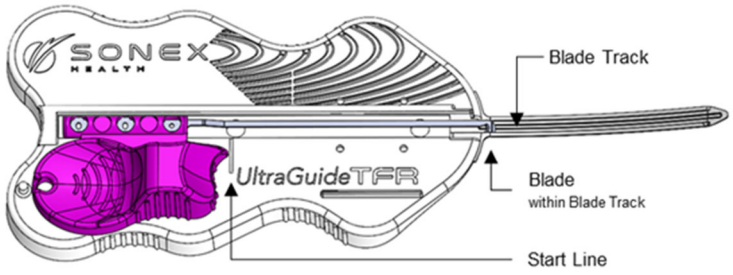


Figure 4: Advance the Blade to Desired Position on Introducer

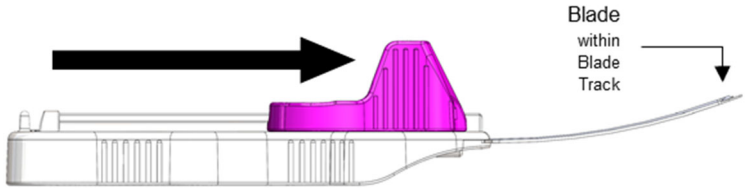


Figure 5: Rotate the Blade Handle 90 degrees

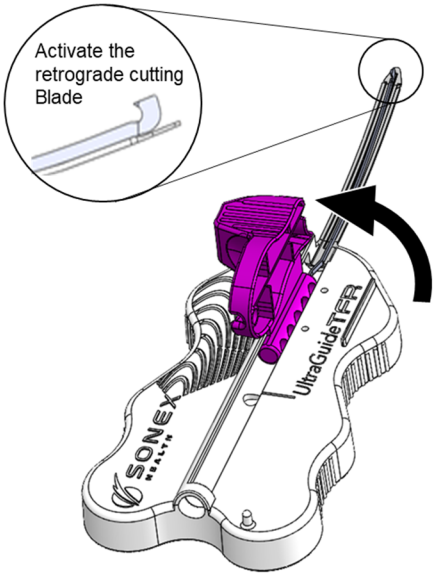


Figure 6: Incise in a distal to proximal direction

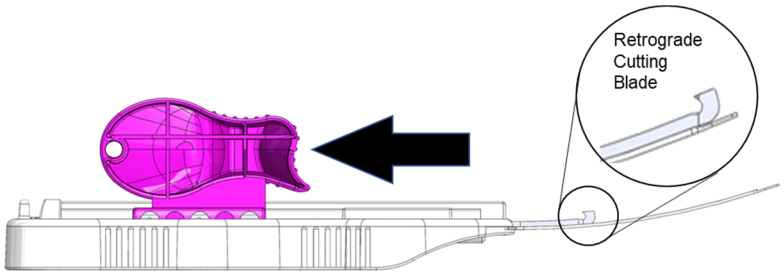


Figure 7: At Finish Line, Blade is 1 cm distal to Introducer Base

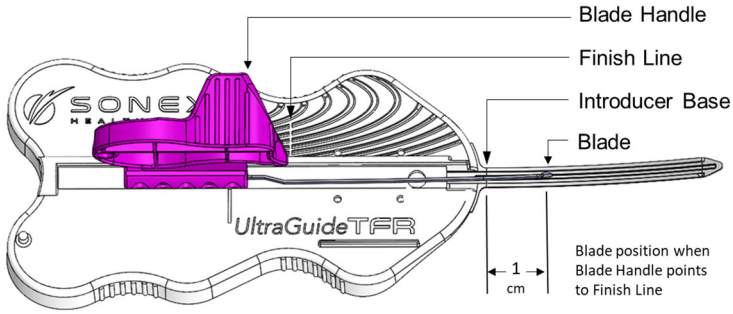
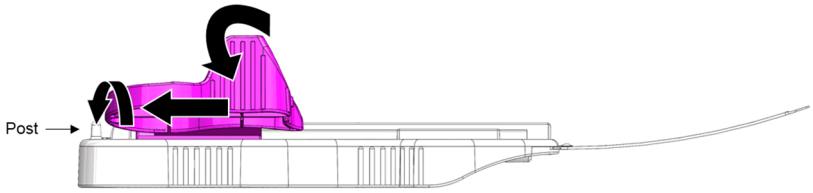


Figure 8: Rotate Blade Handle down and move proximally to the locked position on the Post



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

Directions for Using UltraGuideTFR – Ultrasound Guided Technique:

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

      NOTE: Operators should be aware of the relatively oblique course of the flexor tendons and adjacent neurovascular structures relative to the underlying bones with performing trigger finger release in the pinky and index fingers. Appropriate caution should be used to minimize the risk of neurovascular injury.

B. Stabilizing the Hand and Sterile Preparation
   1. Position the patient with the hand on a stable surface and the palm and palmar aspect of the finger visible.
   2. Prepare the surgical site 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 and finger should be controlled during the procedure. Unwanted hand or finger 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 flexor tendons, tendon sheath, A1 pulley, A2 pulley, and digital arteries, veins, and nerves.
   2. Use a sterile marker to identify and mark the desired incision site in the region of the palmar flexion creases. Use direct ultrasound visualization to place the incision mark over the center of the tendon and tendon sheath, avoiding the adjacent digital arteries, veins, and nerves.

D. Delivering Local Anesthesia
   1. Operators should provide anesthesia in accordance with their usual practices and in consideration of the technique of trigger finger release using UltraGuideTFR and ultrasound guidance.
   2. Adequate anesthesia should be provided at both the skin incision site and the site of anticipated tendon sheath (and pulley) incision.
   3. Appropriate caution should be taken to avoid injury to the digital arteries, veins, and nerves during delivery of local anesthesia.

E. Preparing and Checking UltraGuideTFR
   1. Remove UltraGuideTFR from its shipping box. Inspect the sterile barrier pouch and device for damage.

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

   2. Open the sterile barrier pouch and place the sterile UltraGuideTFR on a sterile surface.

      NOTE: All subsequent steps are performed using sterile technique.

   3. See **Warning**: The cutting Blade of UltraGuideTFR is extremely sharp. Exercise caution to prevent injury.

   NOTE: Unless otherwise noted, the remaining steps are performed using direct ultrasound (sonographic) visualization.

F. Placing UltraGuideTFR into the Flexor Tendon Sheath
   1. Reconfirm appropriate patient positioning as previously described.
   2. Use a scalpel blade to create a small incision and advance the scalpel to just penetrate the tendon sheath. Avoid the adjacent digital arteries, veins, and nerves.

      NOTE: Do not advance the scalpel into the tendon, which may result in tendon injury.

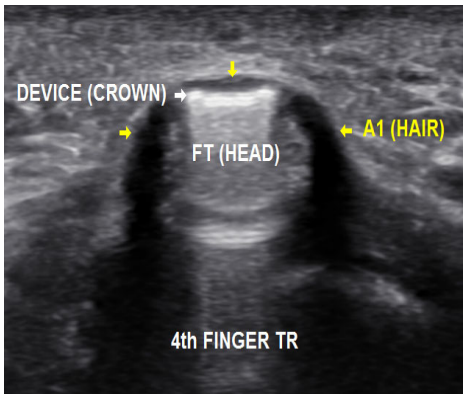
   3. Prior to insertion, inspect UltraGuideTFR to ensure that the Blade Handle is in the locked position on the Post and the Blade is positioned within the Blade Track (Figure 1).
   4. Place the Introducer through the incision. Use the tip of the Introducer to dissect down to the tendon sheath, taking care to protect the digital arteries, veins, and nerves.
   5. Advance the Introducer to enter the tendon sheath proximal to the A1 pulley. Use the curvature of the Introducer to stay superficial to the flexor tendons but deep to the tendon sheath.
   6. Advance the Introducer distally within the tendon sheath, passing deep and distal to the A1 pulley. Verify the desired position of the Introducer tip relative to the A1 and A2 pulleys.

      NOTE: The Introducer can typically be maneuvered to advance the tip out of the tendon sheath between the distal A1 and proximal A2 pulleys.

NOTE: Using excessive force to advance the Introducer into the tendon sheath and deep to the A1 pulley may damage the tendons or the device. If excessive resistance is encountered, verify the position of the device and re-position within the sheath as necessary. In some circumstances, the incision may need to be extended.

NOTE: The operator should use direct ultrasound visualization to confirm the appropriate positioning of the Introducer for subsequent incision, including avoiding unintentional incision of A2. Incising the A2 pulley may result in bowstringing, deformity, pain, weakness, and disability. In some cases, the operator may choose to incise proximal A2 (see section J).

7. Using a transverse ultrasound view, verify that the Introducer is directly deep to the A1 pulley. There should be no intervening tissue between the undersurface of the A1 pulley and the Introducer. The appearance will be like a crown on Mona Lisa's head (Leonardo da Vinci's famous painting) but deep to her hair (head = flexor tendons (FT), crown = Introducer profile (device), hair = A1 pulley). There should be no tendon tissue between the Introducer and the A1 pulley.



8. Verify the lateral position of the digital arteries, veins, and nerves along the length of the device and anticipated tendon sheath/pulley incision.
9. Probe the A1 pulley to further confirm appropriate positioning. Attempt to move UltraGuideTFR radially and ulnarly. If the Introducer is appropriately positioned within the sheath and deep to the A1 pulley, the Introducer will not be able to be moved radial or ulnar to the tendon (i.e., the crown will stay on Mona Lisa's head but deep to her hair).

G. Incising the Tendon Sheath and A1 Pulley Using UltraGuideTFR

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.

1. Unlock the Blade Handle (purple) from the Post by rotating it up, moving it distally, and placing it back down on the device just in front of (i.e., distal to) the Post (Figure 2). If positioned correctly, the distal end of the Blade Handle will be behind the Start Line on the Introducer Handle (Figure 3).

   NOTE: Improper positioning of the Blade Handle may result in the Blade being too distal within the Blade Track. This may result in injury to the skin and soft tissues at the incision site, difficulty advancing the Blade through the incision, or damage to the device.

2. Maintaining slight downward pressure on UltraGuideTFR at the incision site, use the Blade Handle to advance the Blade distally through the incision site. Visually confirm the passing of the Blade through the incision site.
3. Advance the Blade to the desired position on Introducer, distal to the A1 pulley. Visualize the Blade passing along the Blade Track and deep to the A1 pulley (Figure 4).
4. Rotate the Blade Handle 90 degrees to activate the retrograde cutting Blade (Figure 5).
5. Confirm that the Blade is positioned within the tendon sheath and deep to the A1 pulley, the digital arteries, veins, and nerves are laterally located, and there is no intervening tendon tissue between the retrograde cutting Blade and the pulley. As necessary, passively move the flexor tendons to confirm free tendon motion.
6. Scan the length of the anticipated tendon sheath and pulley incision to confirm the safe positioning of cutting Blade with respect to the flexor tendons, digital arteries, veins, and nerves.

   Note: Once the safety of the tendons and digital arteries, veins, and nerves is confirmed, the operator may choose to incise the tendon sheath and pulley without using US guidance (i.e., remaining steps in section G).

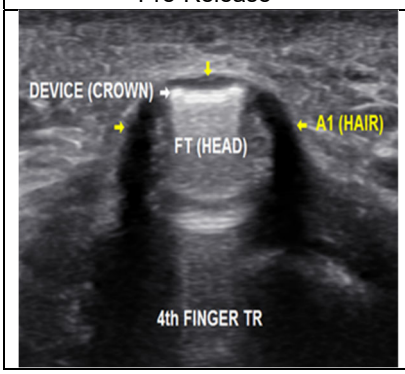
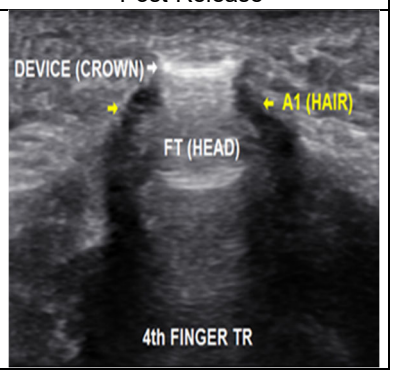
7. Use the Blade Handle to incise the A1 pulley and tendon sheath in a distal to proximal direction. During the incision, place Introducer Handle on the patient's palm to stabilize the device and engage the cutting Blade into the tendon sheath and A1 pulley (Figure 6).
8. Following the desired incision of the flexor tendon sheath and pulley, de-rotate the Blade Handle 90 degrees to replace the Blade into the Blade Track on the Introducer (i.e., the inactive position). Note that the Blade should be replaced into the inactive position prior to the Blade passing proximally out of the skin incision. For reference, when the front end of the

Blade Handle passes the Finish Line, the Blade is 1 cm distal to Introducer Base (Figure 7).

9. Move the Blade Handle proximally until it hits the Post. Rotate the Blade Handle up and into the locked position on the Post (Figure 8).

H. Ensuring Complete Release of the Tendon Sheath and A1 Pulley

1. Using a transverse ultrasound view, verify that the Introducer is now located superficial to the A1 pulley. The appearance will be like a crown on top of Mona Lisa's hair (i.e., superficial to the A1 pulley). To visualize the "crown" above the "head", the operator may need to gently lift the Introducer towards the palm.

Pre-Release	Post-Release
	

2. Probe the A1 pulley to further confirm a complete release. Similar to pre-incision, attempt to move UltraGuideTFR radially and ulnarly. If the A1 pulley is completely released, the Introducer will now be able to be moved radial or ulnar to the tendon (i.e., it can move off Mona Lisa's head).

   NOTE: During visual inspection and probing to ensure a complete release, ensure that the Introducer tip is not under the A2 pulley. Positioning of the tip deep to the A2 pulley will immobilize the device tip and prevent accurate assessment for a complete release of the A1 pulley and the tendon sheath.

3. If an incomplete release is suspected, additional attempts may be performed.

   NOTE: During any subsequent attempts to incise the tendon sheath or A1 pulley, use extra caution to ensure the safe positioning of the Introducer and cutting Blade as the anatomy may be distorted by previous incision attempts. Continuous ultrasound guidance should be used throughout the procedure, including the tendon sheath and pulley incision.

NOTE: Excessive incision attempts may injure the soft tissues overlying the pulley system, resulting in pain, bruising and in extreme cases skin laceration.

I. Device Removal and Clinical Assessment of Triggering Resolution
   1. Remove the device and inspect to ensure it is intact.
   2. Have the patient flex and extend the finger or make a fist to ensure resolution of triggering. If there is persistent triggering, perform additional incision of the pulley system as clinically indicated.

J. A2 Pulley Incision
   1. In some situations, the operator may desire to incise a portion of the proximal A2 pulley. Incision of the proximal A2 pulley can be performed using the procedures described above, with the Introducer tip placed deep to the A2 pulley to incise the desired length of A2.

      NOTE: Incising the A2 pulley may result in bowstringing, deformity, pain, weakness, and disability.

      NOTE: Continuous ultrasound guidance should be used throughout the procedure when incising the A2 pulley, including the tendon sheath and pulley incision.

K. Wound Closure and Post-Operative Care
   1. See **Precautions**: Trigger Finger release using UltraGuideTFR 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 UltraGuideTFR – Non-Ultrasound Guided Technique:

L. Pre-operative Planning

1. See **Precautions**: Trigger Finger release using UltraGuideTFR represents a surgical procedure. Operators and staff should follow appropriate precautions and procedures.

   NOTE: Operators should be aware of the relatively oblique course of the flexor tendons and adjacent neurovascular structures relative to the underlying bones with performing trigger finger release in the pinky and index fingers. Appropriate caution should be used to minimize the risk of neurovascular injury.

M. Stabilizing the Hand and Sterile Preparation

1. Position the patient with the hand on a stable surface and the palm and palmar aspect of the finger visible.
2. Prepare the surgical site using standard sterile techniques.
3. See **Precautions**: The position of the patient's hand and finger should be controlled during the procedure. Unwanted hand or finger movement may make the procedure more difficult or result in injury.

N. Delivering Local Anesthesia

1. Identify the desired incision site proximal to the proximal A1 pulley.
2. Operators should provide anesthesia in accordance with their usual practices and in consideration of the technique of trigger finger release using UltraGuideTFR.
3. Adequate anesthesia should be provided at both the skin incision site and the site of anticipated tendon sheath (and pulley) incision.
4. Appropriate caution should be taken to avoid injury to the digital arteries, veins, and nerves during delivery of local anesthesia.

a. Preparing and Checking UltraGuideTFR

1. Remove UltraGuideTFR from its shipping box. Inspect the sterile barrier pouch and device for damage.

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

2. Open the sterile barrier pouch and place the sterile, UltraGuideTFR on a sterile surface.

   NOTE: All subsequent steps are performed using sterile technique.

3. See **Warning**: The cutting Blade of UltraGuideTFR is extremely sharp. Exercise caution to prevent injury.

O. Placing UltraGuideTFR into the Flexor Tendon Sheath

1. Reconfirm appropriate patient positioning as previously described.
2. In accordance with usual practices, use a scalpel blade or other instrument as appropriate to create an incision, dissect the subcutaneous tissues and expose the tendon sheath and A1 pulley. Avoid the adjacent digital arteries, veins, and nerves.

   NOTE: Do not advance the scalpel into the tendon, which may result in tendon injury.

3. Prior to insertion, inspect UltraGuideTFR to ensure that the Blade Handle is in the locked position on the Post and the Blade is positioned within the Blade Track (Figure 1).
4. Advance the Introducer tip through the tendon sheath proximal to the A1 pulley. The tip of the Introducer will incise the tendon sheath to provide an entry point. Take care to protect the digital arteries, veins, and nerves.
5. Advance the Introducer to enter the tendon sheath and pass deep to the A1 pulley. Use the curvature of the Introducer to stay superficial to the flexor tendons but deep to the tendon sheath and pulley.
6. Advance the Introducer distally, passing distal to the A1 pulley. Verify the desired position of the Introducer tip relative to the A1 and A2 pulleys. Note the Introducer can typically be maneuvered to advance the tip out of the tendon sheath between the distal A1 and proximal A2 pulleys.

   NOTE: Using excessive force to advance the Introducer into the tendon sheath and deep to the A1 pulley may damage the tendons or the device. If excessive resistance is encountered, verify the position of the device and re-position within the sheath as necessary. In some circumstances, the incision may need to be extended.

   NOTE: The operator should use direct visualization to confirm the appropriate positioning of the Introducer for subsequent incision, including avoiding unintentional incision of A2. Incising the A2 pulley may result in bowstringing, deformity, pain, weakness, and disability. In some cases, the operator may choose to incise proximal A2 (see section I).

7. Visually confirm that the Introducer is deep to the tendon sheath and A1 pulley, but superficial to the flexor tendons. As appropriate, passively move the finger to ensure free tendon motion.
8. Verify the lateral position of the digital arteries, veins, and nerves along the length of the device.
9. Probe the A1 pulley to further confirm appropriate positioning. Attempt to move UltraGuideTFR radially and ulnarly. If the Introducer is appropriately positioned within the sheath and deep to the A1 pulley, the Introducer will not be able to be moved radial or ulnar to the tendon.

P. Incising the Tendon Sheath and A1 Pulley Using UltraGuideTFR

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.

1. Unlock the Blade Handle (purple) from the Post by rotating it up, moving it distally, and placing it back down on the device just in front of (i.e., distal to) the Post (Figure 2). If positioned correctly, the distal end of the Blade Handle will be behind the Start Line on the Introducer Handle (Figure 3).

   NOTE: Improper positioning of the Blade Handle may result in the Blade being positioned too distal within the Blade Track. This may result in injury to the skin and soft tissues, difficulty advancing the Blade into the tendon sheath, or damage to the device.

2. Maintaining slight downward pressure on UltraGuideTFR at the tendon sheath incision site, use the Blade Handle to advance the Blade distally through the tendon sheath incision site. Visually confirm the passing of the Blade through the incision site.
3. Advance the Blade to the desired position on Introducer, distal to the A1 pulley. Visualize the Blade passing along the Blade Track and deep to the A1 pulley (Figure 4).
4. Rotate the Blade Handle 90 degrees to activate the retrograde cutting Blade (Figure 5).
5. Confirm that the Blade is positioned within the tendon sheath and deep to the A1 pulley, the digital arteries, veins, and nerves are laterally located and there is no intervening tendon tissue between the retrograde cutting Blade and the pulley. As necessary, passively move the flexor tendons to confirm free tendon motion.
6. Use the Blade Handle to incise the A1 pulley and tendon sheath in a distal to proximal direction. During the incision, place Introducer Handle on the patient's palm to stabilize the device and engage the cutting Blade into the tendon sheath and A1 pulley (Figure 6).
7. As the cutting Blade passes proximal to the A1 pulley and the desired amount of tendon sheath is released, de-rotate the Blade Handle 90 degrees to replace the Blade into the Blade Track (i.e., the inactive position). For reference, when the front end of the Blade Handle passes the Finish Line, the Blade is 1 cm distal to Introducer Base (Figure 7).
8. Move the Blade Handle proximally until it hits the Post. Rotate the Blade Handle up and into the locked position on the Post (Figure 8).

Q. Ensuring Complete Release of the Tendon Sheath and A1 Pulley

1. Visually inspect and use the Introducer as probe to confirm that the tendon sheath and A1 pulley are completely released.

NOTE: During visual inspection and probing to ensure a complete release, ensure that the Introducer tip is not under the A2 pulley. Positioning of the tip deep to the A2 pulley will immobilize the device tip and prevent accurate assessment for a complete release of the A1 pulley and the tendon sheath.

2. If an incomplete release is suspected, additional attempts may be performed.

   NOTE: During subsequent attempts to incise the tendon sheath or A1 pulley, use extra caution to ensure the safe positioning of the Introducer and cutting Blade as the anatomy may be distorted by previous incision attempts.

R. Device Removal and Clinical Assessment of Triggering Resolution
   1. Remove the device and inspect the device to ensure that it is intact.
   2. Have the patient flex and extend the finger or make a fist to ensure resolution of triggering. If there is persistent triggering, perform additional incision of the pulley system as clinically indicated.

S. A2 Pulley Incision
   1. In some situations, the operator may desire to incise a portion of the proximal A2 pulley. Incision of the proximal A2 pulley can be performed using the procedures described above, with the Introducer tip placed deep to the A2 pulley to incise the desired length of A2.

      NOTE: Incising the A2 pulley may result in bowstringing, deformity, pain, weakness, and disability.

T. Wound Closure and Post-Operative Care
   1. See **Precautions**: Trigger Finger release using UltraGuideTFR 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.

Disposal:
UltraGuideTFR 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 package is 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 date [5.1.4, Indicates the date after which the medical device is not to be used.]		Consult electronic 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 irradiation [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

Manufactured For:

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