**TK® Ti-KNOT® DEVICE DESCRIPTION**
Each sterile package contains one SINGLE PATIENT USE TK® Ti-KNOT® DEVICE. A Ti-KNOT® FASTENER is loaded into the distal tip of the 5mm diameter shaft 6. A white handle 7 and red lever 8 are located at the proximal end of the device. By squeezing the red lever, the TK® Ti-KNOT® DEVICE crimps the Ti-KNOT® FASTENER at the closure site and can trim away excess suture.

**TK® QUICK LOAD® UNIT DESCRIPTION**
Each TK® QUICK LOAD® UNIT provides one sterile Ti-KNOT® FASTENER 1 held in a customized loading unit consisting of a white target 2, a wire snare 3, and a blunt curved handle 4. Made from medical grade titanium, a Ti-KNOT® FASTENER is a mushroom-shaped hollow sleeve (knot), which is crimped by the TK® Ti-KNOT® DEVICE to fasten together segments of suture 5.

**INDICATIONS**
The TK® Ti-KNOT® DEVICE used in conjunction with a Ti-KNOT® FASTENER is indicated for use in the approximation of soft tissue.
LOADING A Ti-KNOT® FASTENER WITH A TK® QUICK LOAD® UNIT

Use proper operating room technique to pass the sterile TK® QUICK LOAD® UNIT from its packaging. While maintaining appropriate sterile technique, follow the steps indicated in the illustrations.

1. INSERT
   - The blunt tip of the curved handle into the distal slot at the end of the TK® Ti-KNOT® DEVICE.
   - Rotate the curved handle through the distal slot and out of the suture hole until the Ti-KNOT® FASTENER occupies the shaft’s distal slot. Fully engage the Ti-KNOT® FASTENER within the tip of the TK® Ti-KNOT® DEVICE by pushing on the white target or by pulling on the curved handle.
2. PUSH OUT and remove the white target.
3. RELEASE
   - The curved handle from the distal slot at the end of the TK® Ti-KNOT® DEVICE.
4. INSPECT
   - To ensure that the Ti-KNOT® FASTENER is well loaded and fully seated.

ACTIONS

When the TK® Ti-KNOT® DEVICE is loaded with a Ti-KNOT® FASTENER and appropriately positioned at a suture closure site, squeezing the red lever can instantly secure and trim the suture.

CONTRAINDICATIONS

- Endoscopic procedures should only be performed by physicians having adequate training and familiarity with endoscopic techniques. Medical literature should be consulted relative to techniques, complications and hazards prior to the performance of endoscopic procedures.
- The TK® QUICK LOAD® UNIT with Ti-KNOT® FASTENER is not intended to be used with any device other than the TK® Ti-KNOT® DEVICE. The TK® Ti-KNOT® DEVICE is not intended to be loaded with anything other than a TK® QUICK LOAD® UNIT with Ti-KNOT® FASTENER.
- The Ti-KNOT® FASTENERS are intended for use only with suture specified by LSI SOLUTIONS®.
- Each TK® Ti-KNOT® DEVICE is not intended to be fired more than 12 times.

WARNINGS

- Federal (U.S.A.) law restricts this device to sale, distribution and use by, or on, the order of a physician.
- Users should be familiar with standard procedures and techniques involving surgical suture and titanium usage before employing TK® Ti-KNOT® DEVICE with a TK® QUICK LOAD® UNIT for fastening and trimming suture.
- Adequate Ti-KNOT® FASTENER security requires reasonable clinical judgment and appropriate surgical techniques as warranted by surgical circumstances and the experience of the surgeon.
- Excessive suture tensioning can cause suture breakage.
- Single patient use only. Do not re-clip or re-strengthen. Adequate cleaning or removal of blood and other foreign materials from used TK® Ti-KNOT® products cannot be guaranteed. Validation of re-sterilization is not established. Failure to eliminate inflammatory or infectious agents may cause patient harm. Product functional performance may be compromised in reprocessed devices or Titanium Knots.
- Do not squeeze the red lever or to application of surgical instruments like forceps, needle holders, clamps, etc., and start again.
- Re-sterilization with the firing of TK® Ti-KNOT® DEVICE.
- TK® QUICK LOAD® UNIT components and each TK® Ti-KNOT® DEVICE, along with packaging, must be inspected, handled and disposed of consistent with standard, accepted medical device disposal procedures.
- Do not squeeze the red lever on the same Ti-KNOT® FASTENER more than once.
- Cut suture with scissors if the TK® Ti-KNOT® DEVICE fails to trim suture or release Ti-KNOT® FASTENER.
- Avoid crushing or crimping damage to the Ti-KNOT® FASTENER due to inappropriate squeezing of TK® Ti-KNOT® DEVICE red lever and/or to application of surgical instruments like forceps, needle holders, clamps, etc.
- If Ti-KNOT® FASTENER fails out of tip or is not properly loaded, retrieve loose FASTENER, reload with new FASTENER and start again.
- Check for hemostasis or leakage where appropriate.

ADVERSE REACTIONS

Adverse effects associated with the use of surgical suture and titanium can include, but are not limited to: wound dehiscence, thrombus formation, embolism, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infected wounds, minimal acute inflammatory tissue reaction, and transitory local irritation. Surgical titanium is not absorbed by the body and is generally not associated with significant inflammatory reactions.
THREADING SUTURE THROUGH A LOADED Ti-KNOT® FASTENER

Extracorporeally: surgeons typically use their non-dominant hand to hold the device near the end of its shaft and their dominant hand to complete the suture threading technique.

5. PASS both ends of the suture through the open wire snare at the end of the shaft.
6. PULL the curved handle with its attached wire snare containing the suture ends towards the red lever to draw the snared bends in the suture into the Ti-KNOT® FASTENER.
7. THREAD the suture through the Ti-KNOT® FASTENER and out of the suture hole near the end of the shaft by continuing to pull the curved handle until the wire snare and both ends of the suture exit through the suture hole.
8. GRASP both ends of the suture after passing off the curved handle with the wire snare.

9. SLIDE the Ti-KNOT® FASTENER over the partially tensioned suture down to the targeted site.

10. SQUEEZE & HOLD for one second to crimp Ti-KNOT® FASTENER.

11. TUG & RELEASE the suture gently to cut free both suture ends and release the red lever fully to ensure the crimped Ti-KNOT® FASTENER.

12. REMOVE DEVICE and inspect to ensure Ti-KNOT® FASTENER and suture tails are oriented away from delicate tissue.

SQUEEZE & HOLD / TUG & RELEASE / REMOVE DEVICE

With the distal tip on the targeted site, use one hand to apply sufficient suture tension to hold tissue in appropriate apposition, then the other hand to:

10. SQUEEZE the red lever until it stops, maintain the device tip’s position, HOLD lever for one second.

11. TUG the suture gently to cut free both suture ends and RELEASE the red lever fully to release the crimped Ti-KNOT® FASTENER.

12. REMOVE DEVICE and inspect to ensure Ti-KNOT® FASTENER and suture tails are oriented away from delicate tissue.

PLEASE NOTE While very rapidly squeezing and releasing of the red lever provides average suture holding forces above USP standards, this recommended SQUEEZE & HOLD technique takes only one second longer and assures extra knot suture holding force. Visually inspect each suture tail and Ti-KNOT® FASTENER.

If the crimped Ti-KNOT® FASTENER does not readily release from the distal tip, ensure red lever is released, then gently PUSH inward and ROTATE the handle 90° about the shaft. If still necessary, ROTATE the handle back and then turn 90° in the opposite direction. If Ti-KNOT® FASTENER will not release, cut suture. 

FAILURE TO PROPERLY LOAD SUTURE

NOTE: TO REMOVE A RETAINED Ti-KNOT® FASTENER IF THE WIRE SNARE IS INADVERTENTLY REMOVED WITHOUT PROPER SUTURE THREADING, ENSURE THE TK® Ti-KNOT® DEVICE IS OUTSIDE OF THE PATIENT, THEN SQUEEZE AND RELEASE THE RED LEVER AND THEN TAP THE DISTAL SHAFT ON A TABLE OR USE A SCALPEL TO PRY OUT THE CRIMPED Ti-KNOT® FASTENER.
Each TK® QUICK LOAD® UNIT provides one sterile Ti-KNOT® FASTENER (1) held in a customized loading unit consisting of a white target (2), a wire snare (3), and a blunt curved handle (4). Made from medical grade titanium, a Ti-KNOT® FASTENER is a mushroom-shaped hollow sleeve (knot), which is crimped by the TK® Ti-KNOT® DEVICE to fasten together segments of suture.
SUTURE CUTTING DIFFICULTY–THE CAUSES OF SUTURE NOT CUTTING EASILY WHEN USING A Ti-KNOT® DEVICE CAN INCLUDE:

• USER ERROR INDUCED DAMAGE DULLING THE SUTURE CUTTING BLADE OR

• DEVICE MALFUNCTION, WHICH MAY ALSO REDUCE FASTENER STRENGTH AND SECURITY

If suture cutting difficulty occurs while using any Ti-KNOT® DEVICE, discontinue its intraoperative use and REMOVE DEVICE from the surgical field. Visually INSPECT FASTENER to compare its crimp to other fasteners. Pull or tug on the fastener with a forceps or clamp to TEST FASTENER and suture security.

REMOVE DEVICE–INSPECT FASTENER–TEST KNOT–RETURN DEVICE

Ti-KNOT® DEVICE suture cutting difficulty can be induced by the inadvertent squeezing of the red lever while the metal loading components are still in the distal device shaft. This user error can lead to irreparable damage to the suture cutting blade by driving the blade into the metal curved handle or metal wire snare.

MRI TESTING

Based on MRI testing information, titanium Ti-KNOT® FASTENERS will not present an additional hazard or risk to a patient undergoing an MRI procedure using a scanner operating with a static magnetic field of 3-Tesla or less and under the MRI-related heating conditions (MRI for 15 min. at an MR system reported whole body averaged specific absorption rate, SAR, value of 3-W/kg).
Titanium Fasteners immediately after TLH

Encapsulated Titanium Fasteners 3 months after TLH

Titanium Fasteners in porcine tissue

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