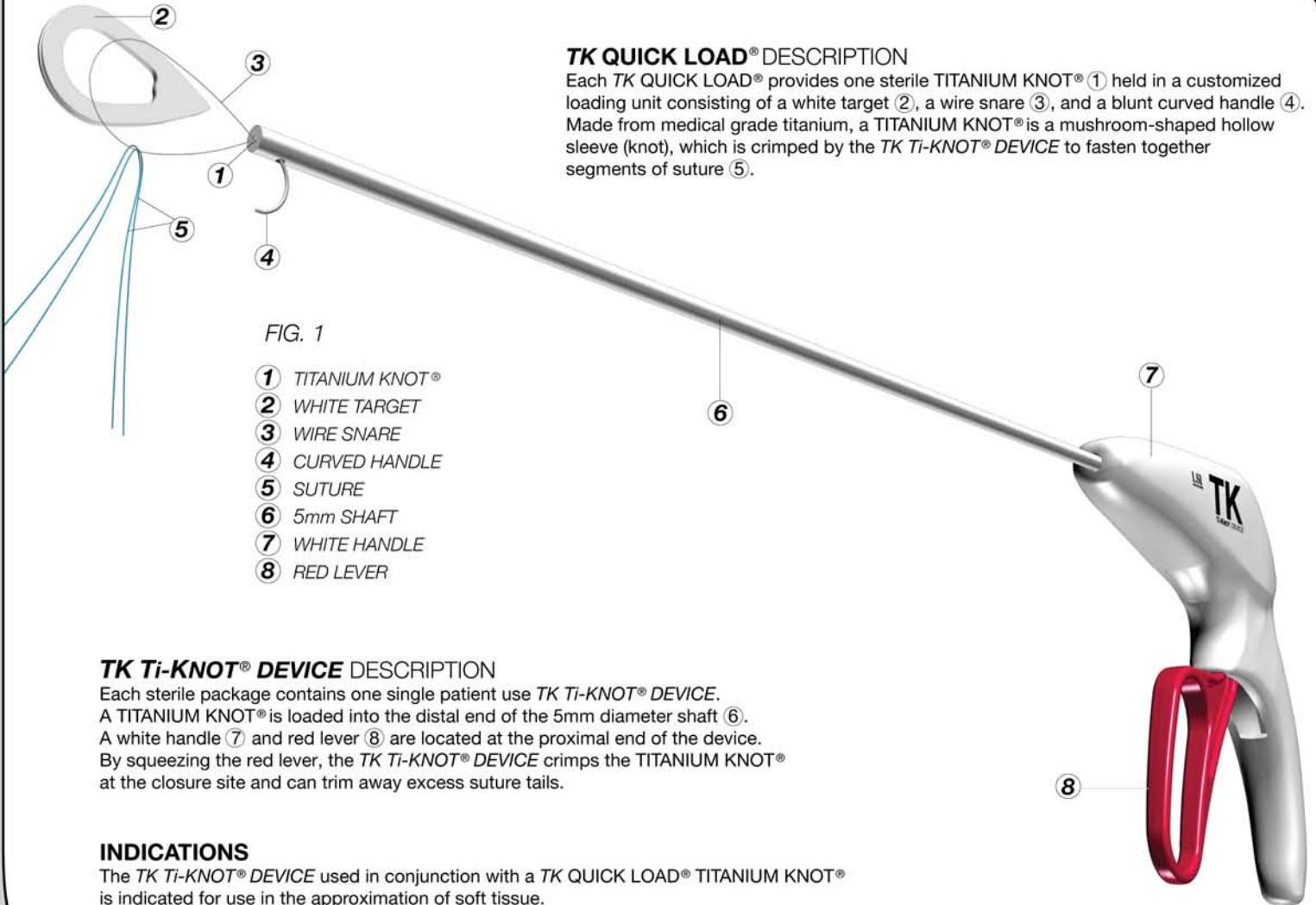


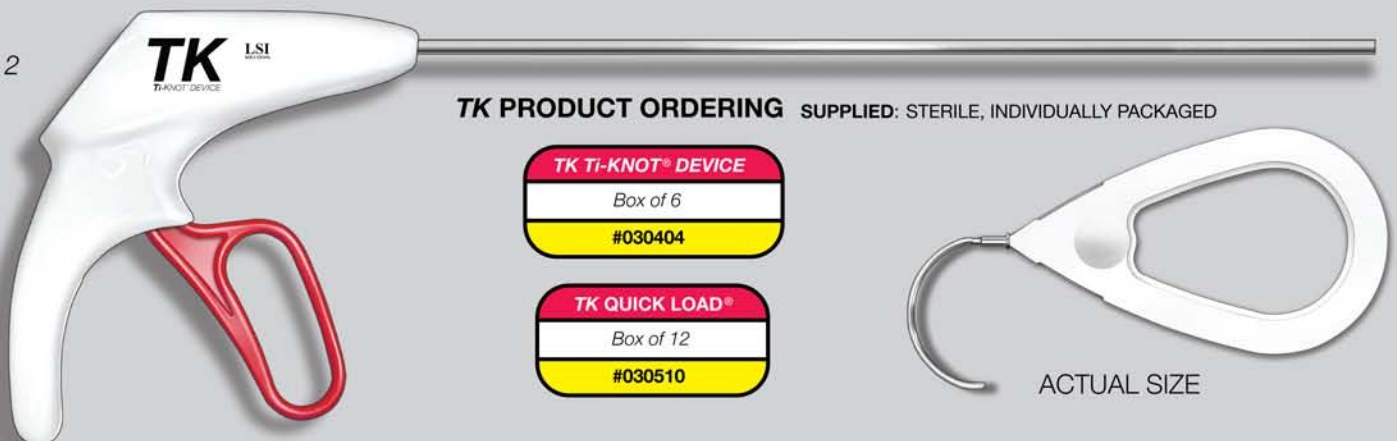
# TK TECHNOLOGY GUIDE

READ PRODUCT INSERT THOROUGHLY BEFORE USE

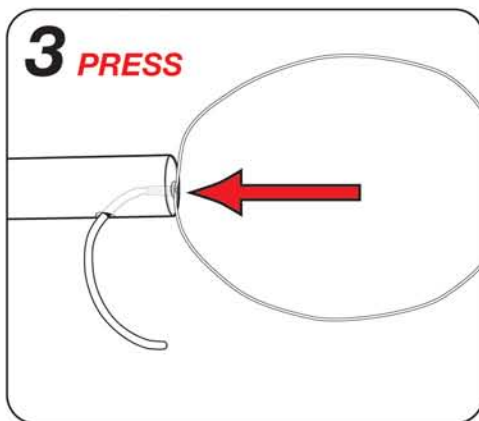
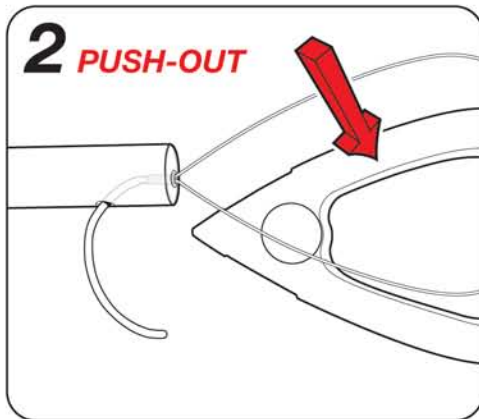
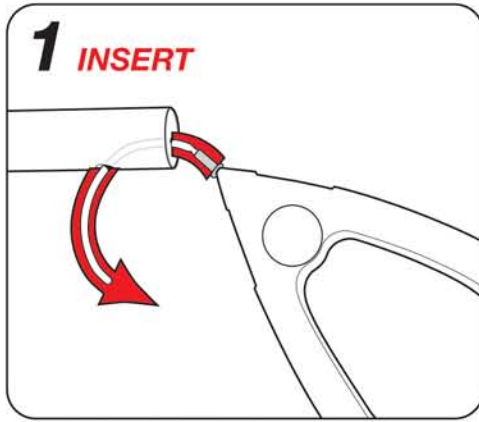


LSI SOLUTIONS®

FIG. 2



## AT SCRUB TABLE



## LOADING A TITANIUM KNOT® WITH A TK QUICK LOAD®

Use proper operating room technique to pass the sterile TK QUICK LOAD® 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 shaft. ROTATE the curved handle through the distal slot and out of the suture hole until the TITANIUM KNOT® occupies the shaft's distal slot. Fully ENGAGE the TITANIUM KNOT® within the tip of the TK Ti-KNOT® DEVICE by pushing on the white target.
- 2. PUSH OUT** and remove the white target.
- 3. PRESS** the TITANIUM KNOT® firmly into the tip of the device.
- 4. INSPECT** to ensure that the TITANIUM KNOT® is appropriately seated.

## ACTIONS

When the TK Ti-KNOT® DEVICE is loaded with a TITANIUM KNOT® and appropriately positioned at a suture closure site, squeezing the red lever can instantly secure and trim the suture. The surgical titanium used in a TITANIUM KNOT® is not absorbed by the body and is generally not associated with significant inflammatory reactions.

## 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® with TITANIUM KNOT® 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® with TITANIUM KNOT®.
- The TITANIUM KNOT® is NOT intended for placement into circulating blood.
- Titanium Knots are intended for use only with suture specified by LSI SOLUTIONS®.
- The TK Ti-KNOT® DEVICE is not intended to be fired more than 12 times.

## WARNINGS

- Do not resterilize.
- Discard any open, unused or damaged TK QUICK LOAD® or TK Ti-KNOT® DEVICE.
- TK QUICK LOAD® components and each TK Ti-KNOT® DEVICE, along with packaging, must be accounted for and disposed of consistent with standard, accepted medical device disposal procedures.
- As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.
- 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® for wound closure.
- While the titanium of the TITANIUM KNOT® is physiologically very inert, routine surgical precautions must be employed whenever foreign materials are left at a wound closure site.
- Do not squeeze the lever of the loaded TK Ti-KNOT® DEVICE, until the TITANIUM KNOT® has been appropriately positioned and the suture accurately tensioned at the closure site.

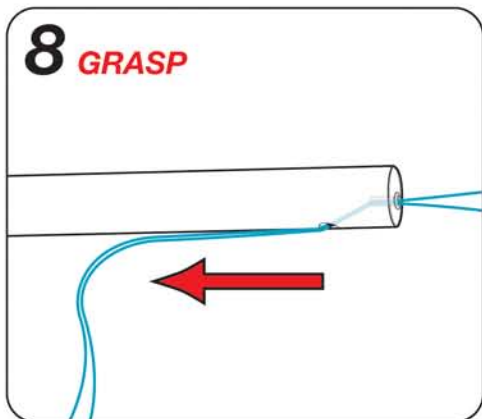
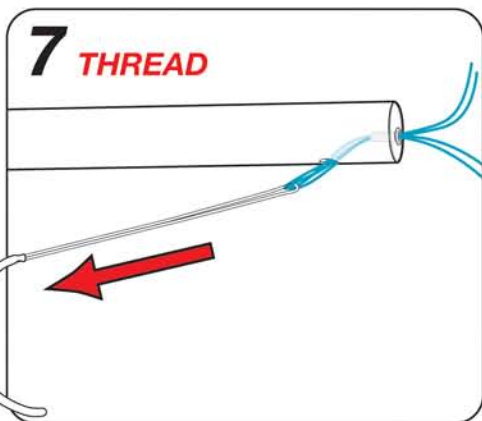
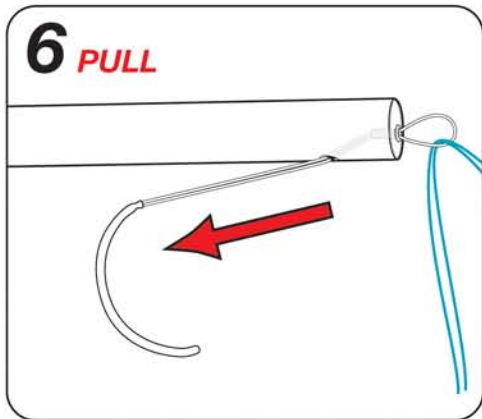
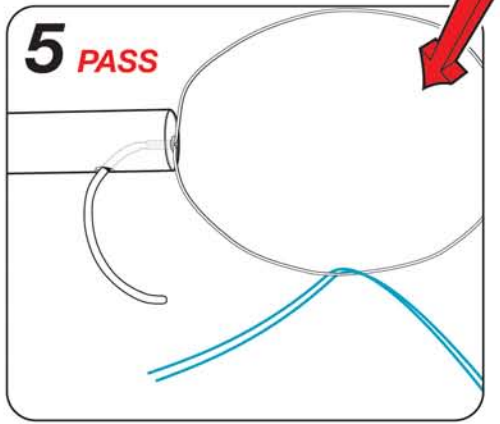
## PRECAUTIONS

- Federal (U.S.A.) law restricts this device to sale, distribution and use by, or on, the order of a physician.
- Check for hemostasis or leakage where appropriate.
- Before endoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that electrical isolation or grounding are not compromised.
- Ensure that obstructions do not interfere with the firing of TK Ti-KNOT® DEVICE.
- Do not squeeze the red lever of TK Ti-KNOT® DEVICE while loading the TK QUICK LOAD®.
- When handling the TK QUICK LOAD® care should be taken to avoid damage.
- Avoid crushing or crimping damage to the TITANIUM KNOT® due to inappropriate squeezing of TK Ti-KNOT® DEVICE red lever, and/or to application of surgical instruments like forceps, needle holders, clamps, etc.
- Adequate TITANIUM KNOT® security requires appropriate surgical techniques as warranted by surgical circumstances and the experience of the surgeon.
- Irreparable damage to TK Ti-KNOT® DEVICE suture cutting blade will occur if the red lever is squeezed while the TK QUICK LOAD® curved handle is in place at the tip of the instrument.

## ADVERSE REACTIONS

Adverse effects associated with the use of surgical suture and titanium include, but are not limited to: wound dehiscence, 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 inflammatory reactions.

## OUTSIDE OF CANNULA



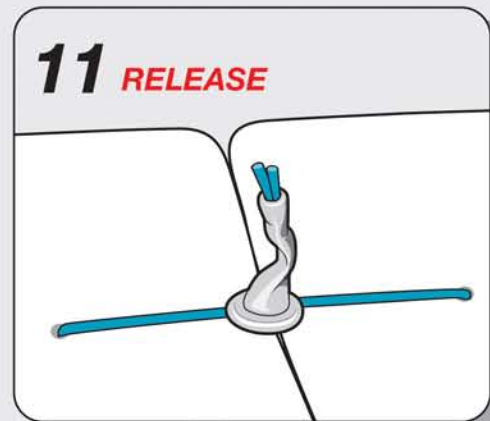
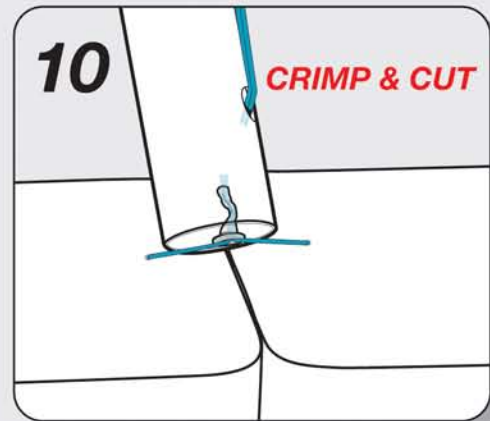
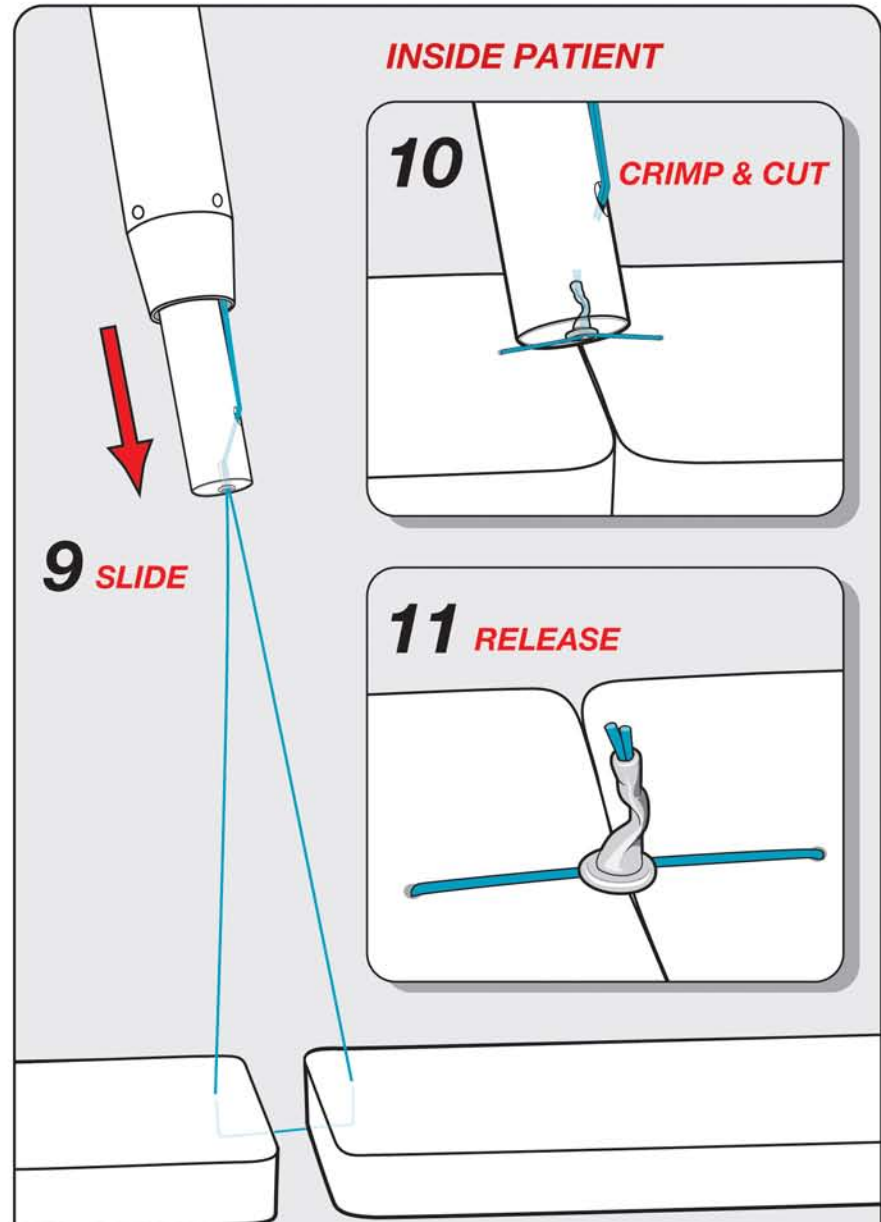
## THREADING SUTURE THROUGH A LOADED TITANIUM KNOT®

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 TITANIUM KNOT®.
- 7. THREAD** the suture through the TITANIUM KNOT® 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.

NOTE: TO REMOVE A RETAINED TITANIUM KNOT® IF THE WIRE SNARE IS INADVERTANTLY REMOVED WITHOUT PROPER SUTURE THREADING, SQUEEZE AND RELEASE THE RED LEVER AND THEN TAP THE DISTAL SHAFT ON A TABLE OR USE A SCALPEL TO PRY OUT THE CRIMPED TITANIUM KNOT®

## INSIDE PATIENT



## SECURE KNOT & TRIM SUTURE

- 9. SLIDE** the TITANIUM KNOT® in the distal shaft over the suture, through the cannula and down to the closure site.
- 10. CRIMP & CUT** by positioning the distal tip on the closure site and tensioning the suture, then squeeze the red lever to crimp the TITANIUM KNOT® and, if desired, pull the suture to trim both suture tails.
- 11. RELEASE** the TITANIUM KNOT® now crimped on the suture by returning the red lever to its fully forward position. Remove the device and trimmed suture tails.

# TK QUICK LOAD<sup>®</sup> WITH TITANIUM KNOT<sup>®</sup>

READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 3 CRIMPED TITANIUM KNOT<sup>®</sup>



FIG. 4

- ① TITANIUM KNOT<sup>®</sup>
- ② WHITE TARGET
- ③ WIRE SNARE
- ④ CURVED HANDLE

**LSI SOLUTIONS<sup>®</sup>**

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**MANUFACTURED UNDER ONE OR MORE OF THE FOLLOWING PATENTS**  
5,520,702; 5,643,289; 5,669,917; 5,766,183; 6,368,334; 6,641,592; EP 0669101;  
0669103; CA2141911; CA2141913 DE69512447.1 and DE69512446.3.  
Additional patents pending.

