

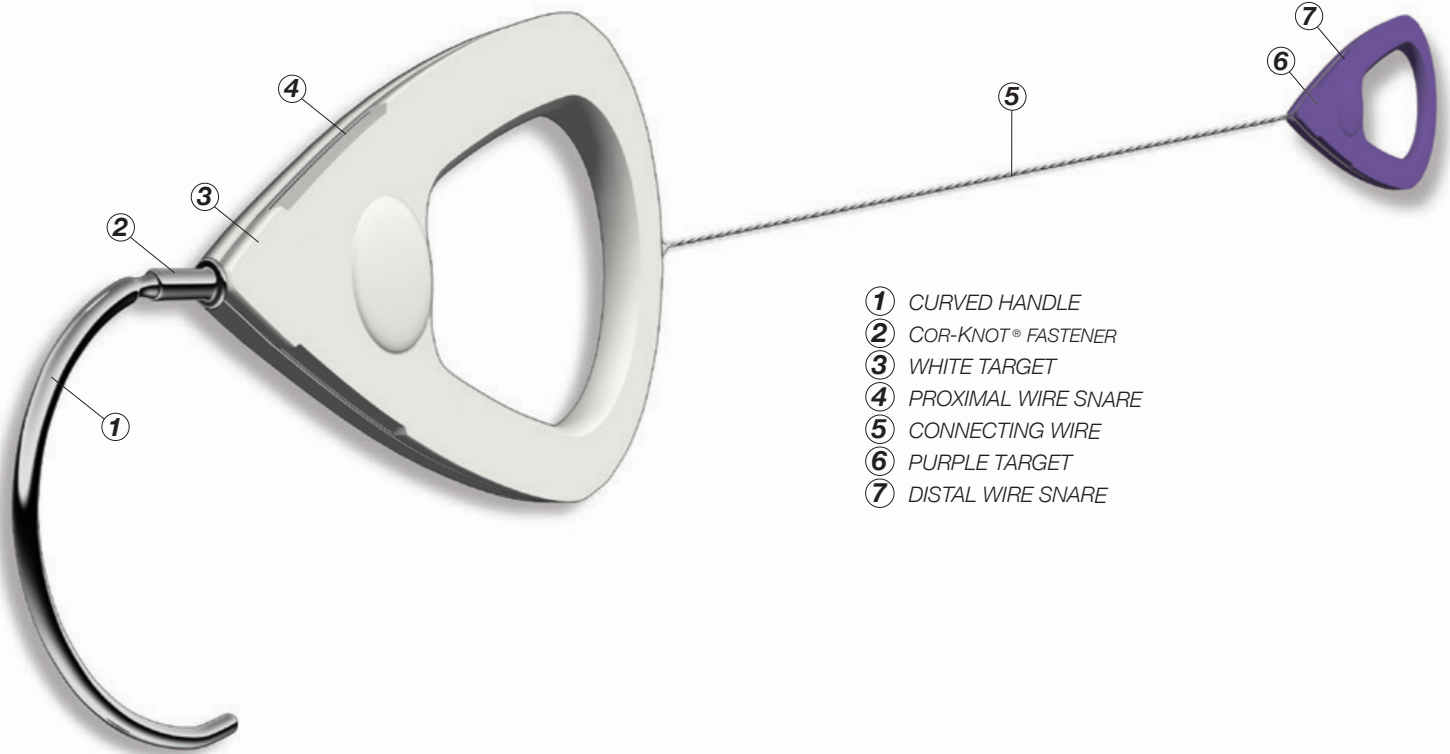
# INTRA-KNOT® TECHNOLOGY GUIDE

 READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1

## INTRA-KNOT® QUICK LOAD® UNIT DESCRIPTION

Each INTRA-KNOT® QUICK LOAD® UNIT consists of a blunt curved handle ①, one sterile COR-KNOT® FASTENER ② held in a customized loading unit consisting of a white target ③, a proximal wire snare ④, a connecting wire ⑤, a purple target ⑥, and a distal wire snare ⑦. Use only with LSI SOLUTIONS® specified 2-0 Polyester, 2-0 Polypropylene, or 3-0 Polypropylene suture.



- ① CURVED HANDLE
- ② COR-KNOT® FASTENER
- ③ WHITE TARGET
- ④ PROXIMAL WIRE SNARE
- ⑤ CONNECTING WIRE
- ⑥ PURPLE TARGET
- ⑦ DISTAL WIRE SNARE


## INDICATIONS

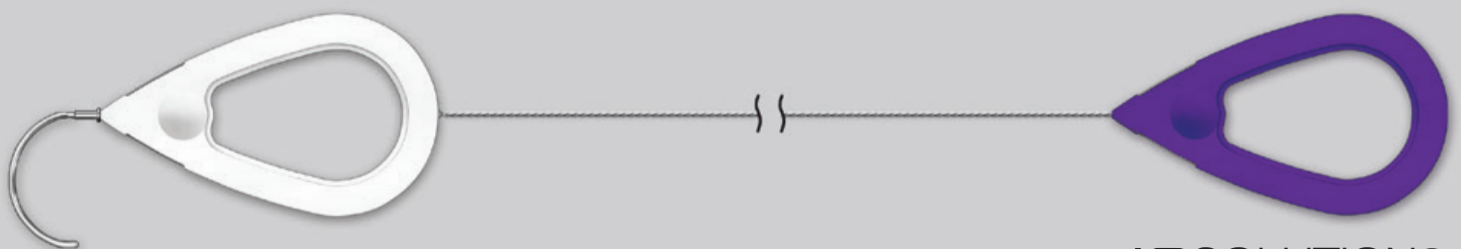
The INTRA-KNOT® QUICK LOAD® UNIT, used in conjunction with the COR-KNOT® DEVICE, is indicated for use in the approximation of soft tissue and prosthetic materials. Refer to the Indications in the COR-KNOT® MINI® Technology Guide or the COR-KNOT® MIS Technology Guide for compatibility with INTRA-KNOT® QUICK LOAD® UNIT.

FIG. 2

## INTRA-KNOT® PRODUCT ORDERING

SUPPLIED: STERILE

	REORDER	PRODUCT	DESCRIPTION
 x 12	REF 032040	INTRA-KNOT® QUICK LOAD® UNIT	Box of 12



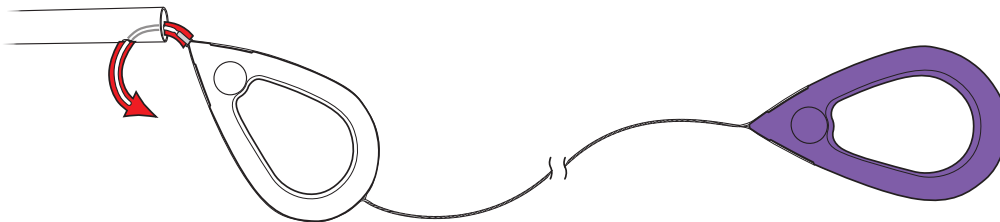
ACTUAL LENGTH: 40cm

LSI SOLUTIONS®

# LOADING AT SCRUB TABLE

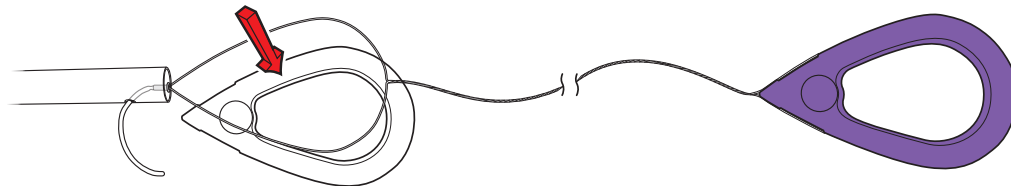
Use proper operating room technique to pass the sterile *INTRA-KNOT*<sup>®</sup> QUICK LOAD<sup>®</sup> UNIT from its packaging. While maintaining appropriate sterile technique, follow the steps indicated in the illustrations.

## 1 INSERT



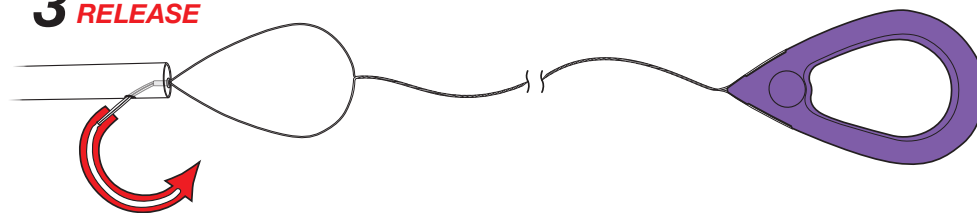
**INSERT** the blunt tip of the curved handle into the distal slot at the end of the *COR-KNOT*<sup>®</sup> *DEVICE* shaft. **ROTATE** the curved handle through the distal slot and out of the suture hole until the *COR-KNOT*<sup>®</sup> *FASTENER* occupies the shaft's distal slot. Fully **ENGAGE** the *COR-KNOT*<sup>®</sup> *FASTENER* within the tip of the *COR-KNOT*<sup>®</sup> *DEVICE* by pushing on the white target or by pulling on the curved handle.

## 2 PUSH-OUT



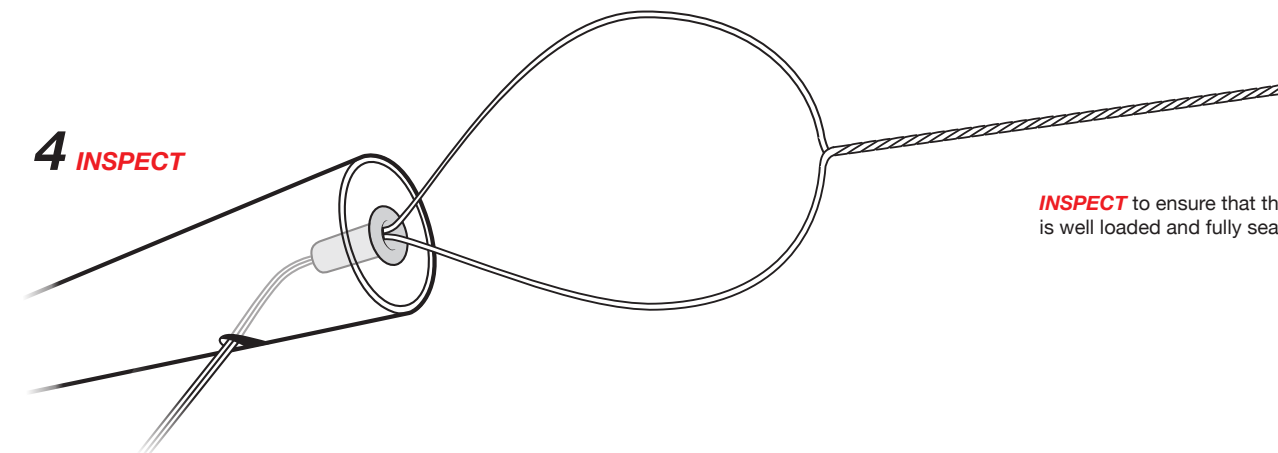
**PUSH-OUT** and remove the white target.

## 3 RELEASE



**RELEASE** the curved handle from the distal slot at the end of the *COR-KNOT*<sup>®</sup> *DEVICE* shaft.

## 4 INSPECT

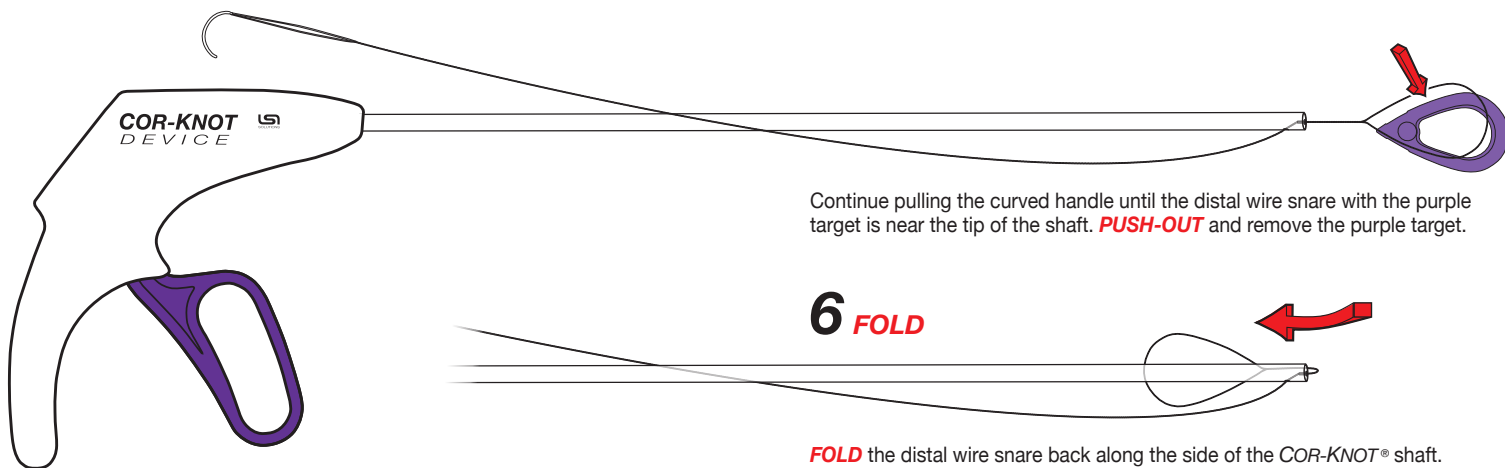


**INSPECT** to ensure that the *COR-KNOT*<sup>®</sup> *FASTENER* is well loaded and fully seated.

# INTRACORPOREAL MIS USE

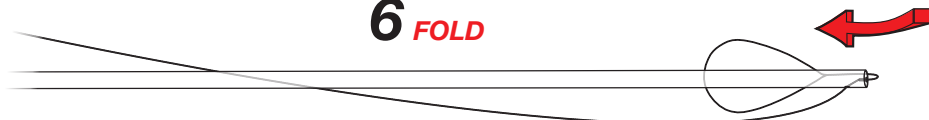
For minimally invasive procedures, the distal snare of the *INTRA-KNOT*® QUICK LOAD® UNIT can be used to intracorporeally thread the suture. Follow steps 1 through 4 to load the *INTRA-KNOT*® QUICK LOAD® UNIT.

## 5 PUSH-OUT



Continue pulling the curved handle until the distal wire snare with the purple target is near the tip of the shaft. **PUSH-OUT** and remove the purple target.

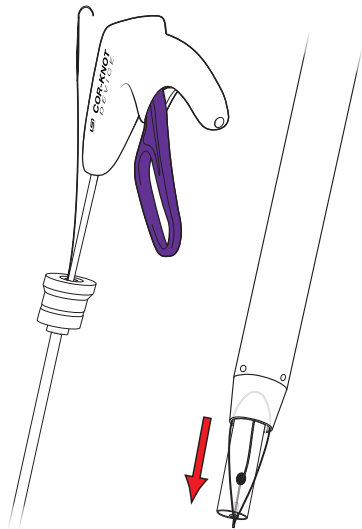
## 6 FOLD



**FOLD** the distal wire snare back along the side of the *COR-KNOT*® shaft.

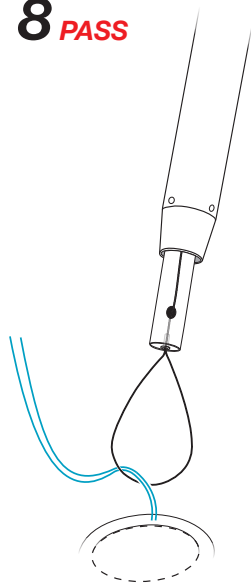
### INSIDE OF PATIENT

## 7 INSERT



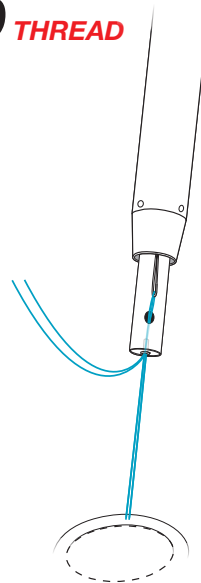
With the wire snare folded back against the shaft, **INSERT** the shaft through the cannula down to the targeted site.

## 8 PASS



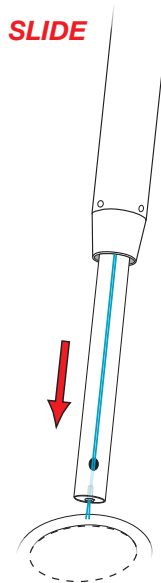
**PASS** both ends of the suture through the unfolded distal wire snare.

## 9 THREAD



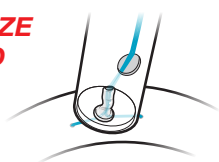
**THREAD** the suture through the *COR-KNOT*® FASTENER by continuing to pull the curved handle until the suture ends pass through the suture hole. Then **SLIDE** the *COR-KNOT*® DEVICE distal tip gently over the partially tensioned suture down to the targeted site.

## 10 SLIDE



## 11 SQUEEZE & HOLD

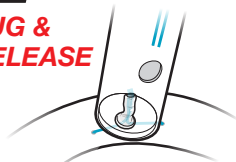
1 Second



To crimp *COR-KNOT*® FASTENER

**SQUEEZE** the purple lever to hard stop, maintain the device tip's position, **HOLD** it for one second.

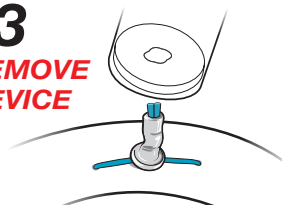
## 12 TUG & RELEASE



Tug to trim suture

While still squeezing the purple lever, **TUG** all the sutures gently to cut them and **RELEASE** the purple lever fully to release the crimped *COR-KNOT*® FASTENER.

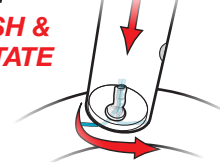
## 13 REMOVE DEVICE



Inspect *COR-KNOT*® FASTENER

**REMOVE DEVICE** Inspect to ensure *COR-KNOT*® FASTENER and suture tails are oriented away from delicate tissue and prosthetic structures.

## 14 PUSH & ROTATE

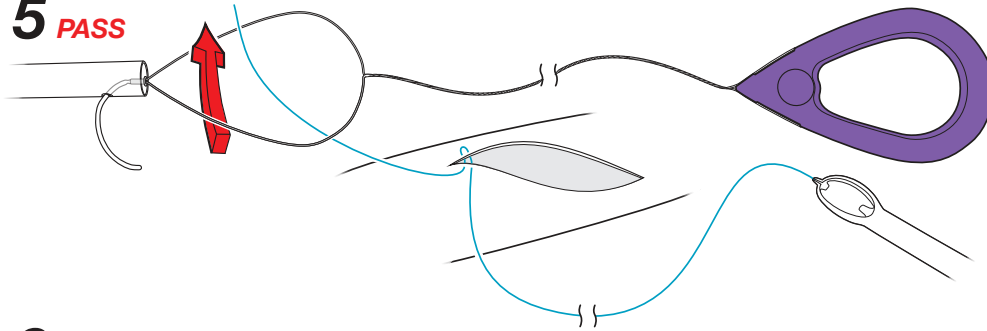


Rotate 1/4 turn

If the crimped *COR-KNOT*® FASTENER does not readily release from the distal tip, ensure purple 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 *COR-KNOT*® FASTENER will still not release, cut suture.**

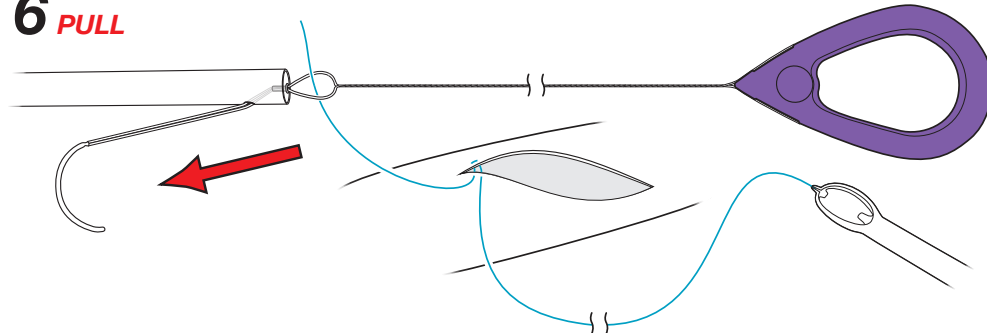
# OUTSIDE OF PATIENT

**5 PASS**



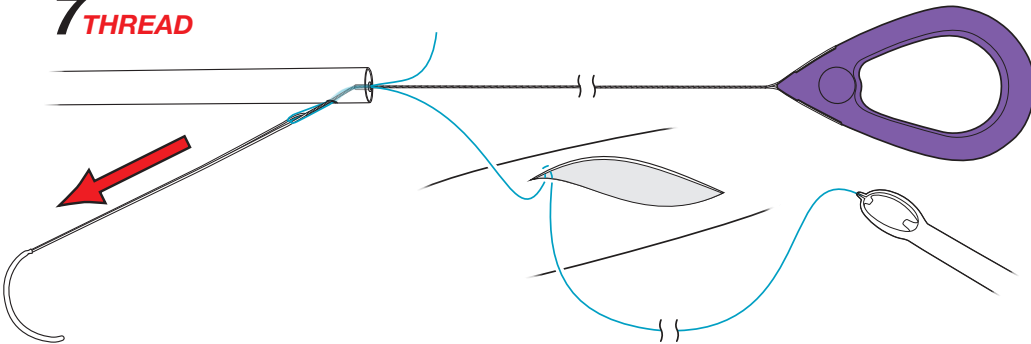
**PASS** the free end of the suture through the proximal wire snare at the end of the shaft.

**6 PULL**



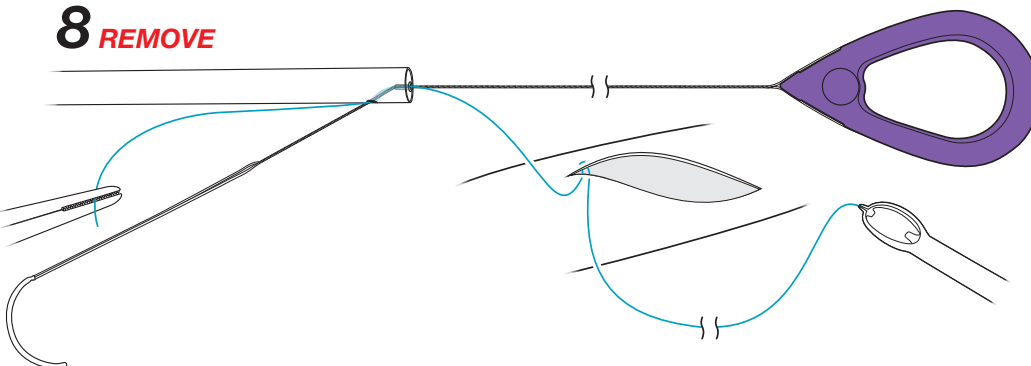
**PULL** the curved handle with its attached wire snare containing the suture end towards the purple lever to draw the snared bend in the suture into the COR-KNOT® FASTENER.

**7 THREAD**



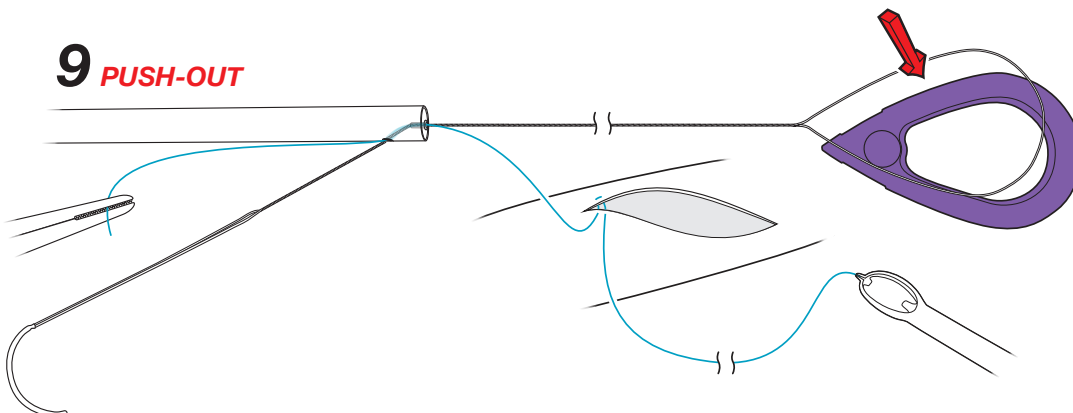
Continue to pull the curved handle until the proximal wire snare and the end of the suture exit through the suture hole.

**8 REMOVE**



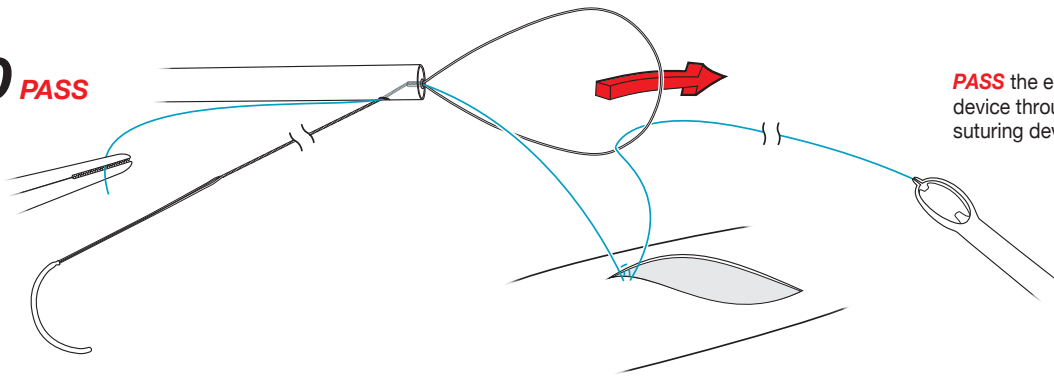
**REMOVE** the suture from the proximal wire snare. **GRASP** the suture with a clamp so that it doesn't become tangled.

**9 PUSH-OUT**



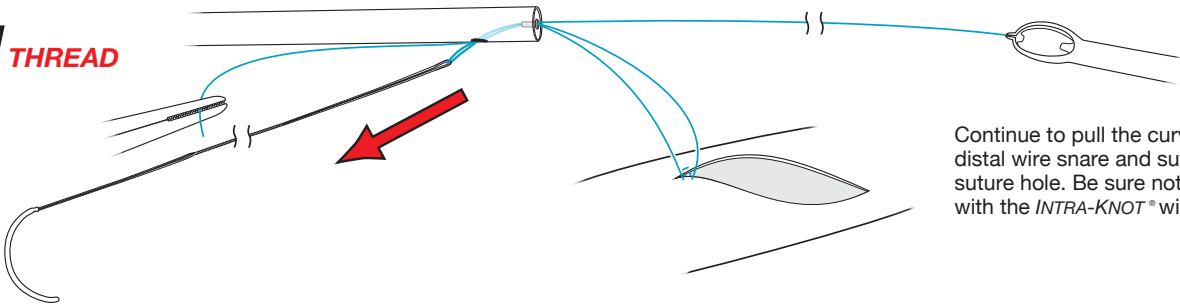
**PUSH-OUT** and remove the purple target.

## 10 PASS



**PASS** the end of the suture attached to the suturing device through the distal wire snare. If using a suturing device, fire device over the wire snare.

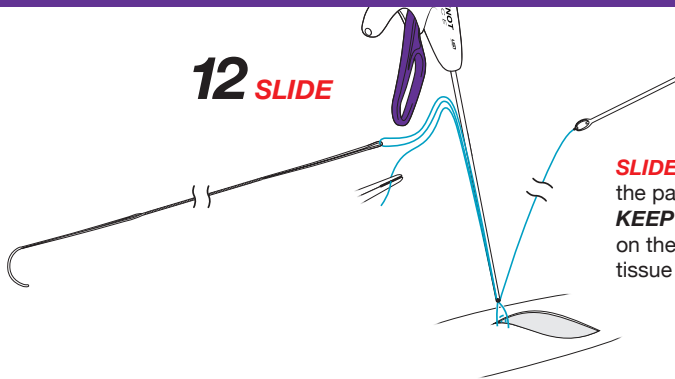
## 11 THREAD



Continue to pull the curved handle until the distal wire snare and suture exit through the suture hole. Be sure not to tangle the sutures with the *INTRA-KNOT*® wire.

# INSIDE OF PATIENT

## 12 SLIDE

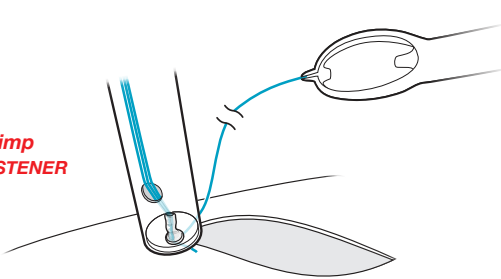


**SLIDE** the *COR-KNOT*® *DEVICE* distal tip gently over the partially tensioned suture down to the targeted site. **KEEP** suture next to shaft while pulling. With the distal tip on the tissue, maintain sufficient suture tension to hold tissue in appropriate apposition.

## 13 SQUEEZE & HOLD

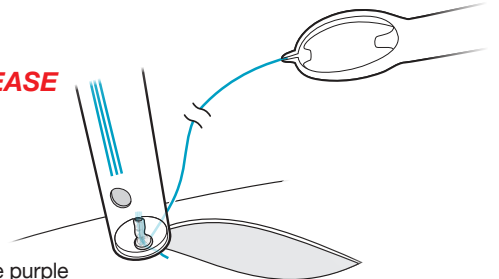
1 Second to crimp *COR-KNOT*® *FASTENER*

**SQUEEZE** the purple lever to hard stop, maintain the device tip's position, **HOLD** it for one second.



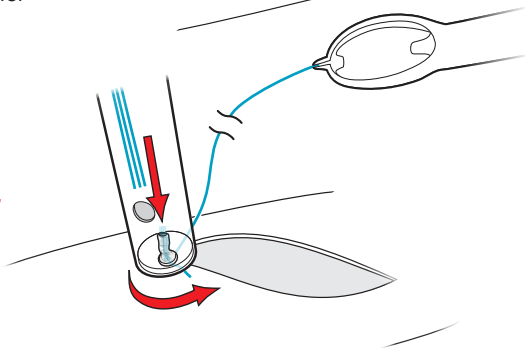
## 14 TUG & RELEASE

While still squeezing the purple lever, **TUG** all the sutures gently to cut them and **RELEASE** the purple lever fully to release the crimped *COR-KNOT*® *FASTENER*.



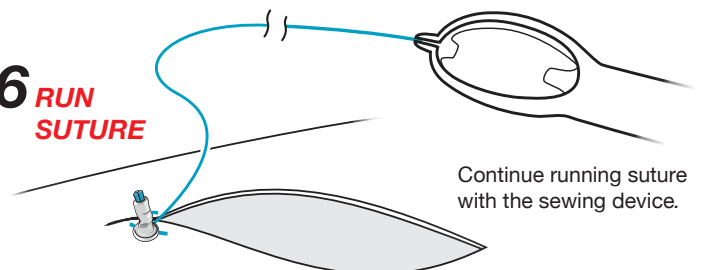
## 15 PUSH & ROTATE

If the crimped *COR-KNOT*® *FASTENER* does not readily release from the distal tip, ensure purple 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 *COR-KNOT*® *FASTENER* will still not release, cut suture.



## 16 RUN SUTURE

Continue running suture with the sewing device.



In the text below, the *COR-KNOT® DEVICE* refers to the LSI SOLUTIONS® *COR-KNOT®* family of suture fastening devices. Refer to *COR-KNOT MINI®* Technology Guide or the *COR-KNOT® MIS* Technology Guide Indications for compatibility with *INTRA-KNOT® QUICK LOAD® UNIT*.

## ACTIONS

When the *COR-KNOT® DEVICE* is loaded with a *COR-KNOT® FASTENER* using the *INTRA-KNOT® QUICK LOAD® UNIT* and appropriately positioned at a suture closure site, squeezing the purple lever will instantly secure and trim the suture. The surgical titanium used in a *COR-KNOT® FASTENER* is not absorbed by the body and is generally not associated with significant inflammatory reactions. The *INTRA-KNOT® QUICK LOAD® UNIT* can be used to secure 2, 3, or 4 strands of 3-0 suture or 2 strands of 2-0 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 *INTRA-KNOT® QUICK LOAD® UNIT* is not intended to be used with any device other than the *COR-KNOT MINI® DEVICE* or the *COR-KNOT® MIS DEVICE*.
- The *COR-KNOT MINI® DEVICE* and the *COR-KNOT® MIS DEVICE* are not intended to be loaded with anything other than a *COR-KNOT® QUICK LOAD® UNIT* or the *INTRA-KNOT® QUICK LOAD® UNIT*.
- The *COR-KNOT® FASTENER* is NOT intended for placement into circulating blood unless used with compatible suture under conditions judged by the surgeon to be clinically appropriate.
- Use only with LSI SOLUTIONS® specified 2-0 Polyester, 2-0 Polypropylene, or 3-0 Polypropylene suture.
- Each *COR-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 the *COR-KNOT® DEVICE* with a *COR-KNOT® FASTENER* for fastening and trimming suture.
- Adequate *COR-KNOT® FASTENER* security requires reasonable clinical judgment and appropriate surgical techniques as warranted by surgical circumstances and the experience of the surgeon.
- When securing suture with an LSI *COR-KNOT® DEVICE*, ensure any ferrules or needles are removed from the suture ends to be loaded prior to loading the suture through the *COR-KNOT® DEVICE*.
- Excessive suture tensioning can cause suture breakage.
- Single patient use only. Do not reclean or resterilize. Adequate cleaning or removal of blood and other foreign materials from used *COR-KNOT®* products cannot be guaranteed. Validation of reesterilization is not established. Failure to eliminate inflammatory or infectious agents may cause patient harm. Product functional performance may be compromised in reprocessed devices or *COR-KNOT® FASTENERS*.
- Discard any open (unsealed), unused, expired or damaged *COR-KNOT®* product.
- *INTRA-KNOT® QUICK LOAD® UNIT* components and each *COR-KNOT® DEVICE*, along with packaging, must be inspected, handled and disposed of consistent with standard, accepted medical device disposal procedures.
- Direct contact between sensitive tissue structures (e.g., pulsatile arteries, cardiac valve leaflets, valve chordae, etc.) and foreign materials can lead to tissue injury or damage, such as tissue erosion. Always orient *COR-KNOT® FASTENERS* and remnant suture tails to avoid direct contact between delicate tissue or prosthetic structures.
- 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.
- While the titanium of the *COR-KNOT® FASTENER* is physiologically very inert, routine surgical precautions must be employed whenever foreign materials are left in a patient.

## PRECAUTIONS

- When handling the *INTRA-KNOT® QUICK LOAD® UNIT* care should be taken to avoid damage.
- Do not squeeze the purple lever of the *COR-KNOT® DEVICE* while loading the *INTRA-KNOT® QUICK LOAD® UNIT*.
- Irreparable damage to *COR-KNOT® DEVICE* suture cutting blade will occur if the purple lever is squeezed while the *INTRA-KNOT® QUICK LOAD® UNIT* curved handle is in place at the tip of the instrument.
- Ensure that obstructions do not interfere with the firing of the *COR-KNOT® DEVICE*.
- Do not squeeze the purple lever of the loaded *COR-KNOT® DEVICE*, until the *COR-KNOT® FASTENER* has been appropriately positioned directly upon the tissue or prosthetic material and the suture accurately tensioned at the targeted site.
- Always squeeze and hold the purple lever and then fully release it before moving the *COR-KNOT® DEVICE* tip. Failure to appropriately release the purple lever can cause suture breakage. Inspect each *COR-KNOT® FASTENER* and its suture tails.
- Do not squeeze the purple lever on the same *COR-KNOT® FASTENER* more than once.
- Cut suture with scissors if the device fails to trim suture or release the *COR-KNOT® FASTENER*.
- Avoid crushing or crimping damage to the *COR-KNOT® FASTENER* due to inappropriate squeezing of the *COR-KNOT® DEVICE* purple lever and/or to the application of surgical instruments like forceps, needle holders, clamps, etc.
- If the *COR-KNOT® FASTENER* falls out of tip or is not properly loaded, retrieve loose fastener, reload with new fastener and start again.
- If the purple lever of the *COR-KNOT® DEVICE* does not return completely forward on its own (i.e., without assistance), manually push the lever forward all the way to release the *COR-KNOT® FASTENER*.
- 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.

## 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 inflammatory reactions.

## MRI TESTING

Based on MRI testing information, titanium *COR-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).

# LSI SOLUTIONS®

Patents: [www.lsisolutions.com/patents](http://www.lsisolutions.com/patents)

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STERILE EO

Rx Only



Symbol Glossary: [www.lsisolutions.com/symbols](http://www.lsisolutions.com/symbols)



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