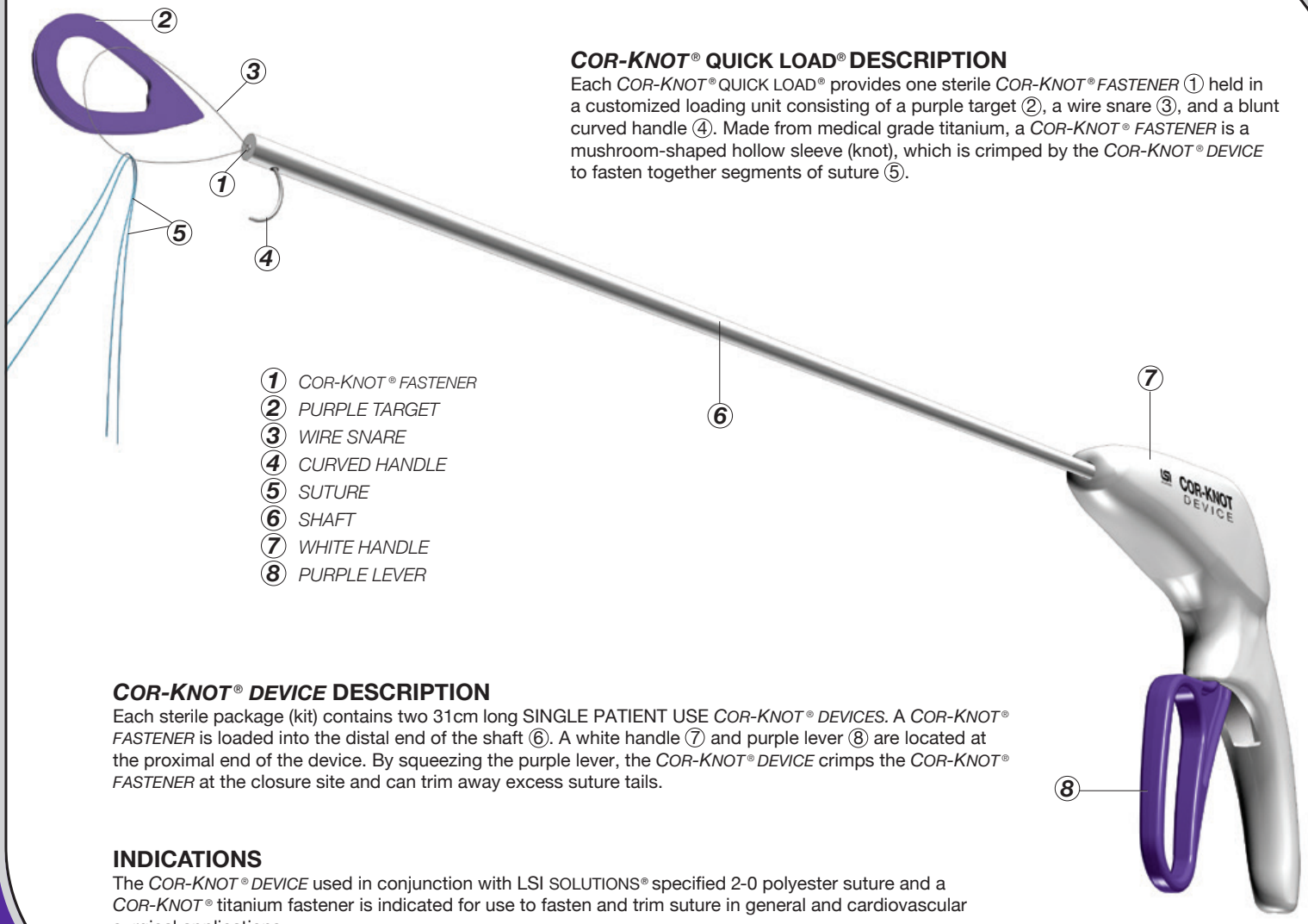
COR-KNOT® EU TECHNOLOGY GUIDE

READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



1. COR-KNOT® FASTENER
2. PURPLE TARGET
3. WIRE SNARE
4. CURVED HANDLE
5. SUTURE
6. SHAFT
7. WHITE HANDLE
8. PURPLE LEVER

COR-KNOT® QUICK LOAD® DESCRIPTION

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

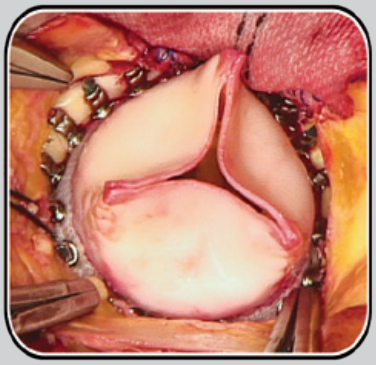
COR-KNOT® DEVICE DESCRIPTION

Each sterile package (kit) contains two 31cm long SINGLE PATIENT USE COR-KNOT® DEVICES. A COR-KNOT® FASTENER is loaded into the distal end of the shaft ⑥. A white handle ⑦ and purple lever ⑧ are located at the proximal end of the device. By squeezing the purple lever, the COR-KNOT® DEVICE crimps the COR-KNOT® FASTENER at the closure site and can trim away excess suture tails.

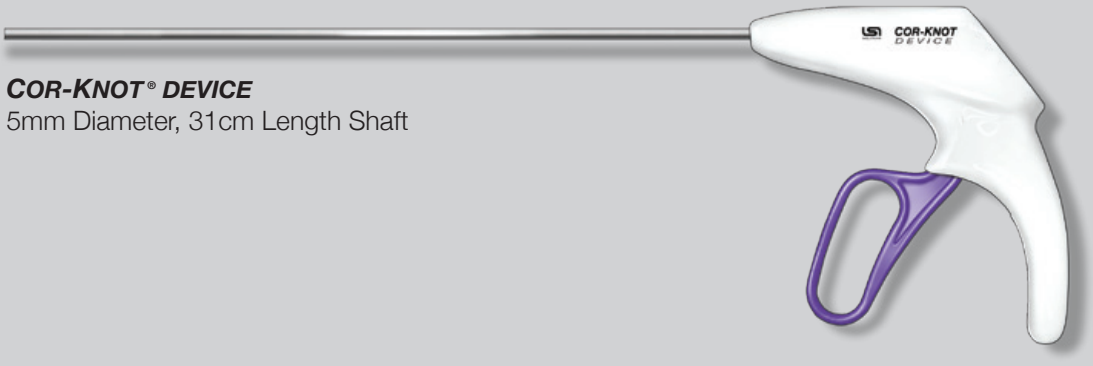
INDICATIONS

The COR-KNOT® DEVICE used in conjunction with LSI SOLUTIONS® specified 2-0 polyester suture and a COR-KNOT® titanium fastener is indicated for use to fasten and trim suture in general and cardiovascular surgical applications.

FIG. 2



Courtesy of Peter A. Knight, M.D.

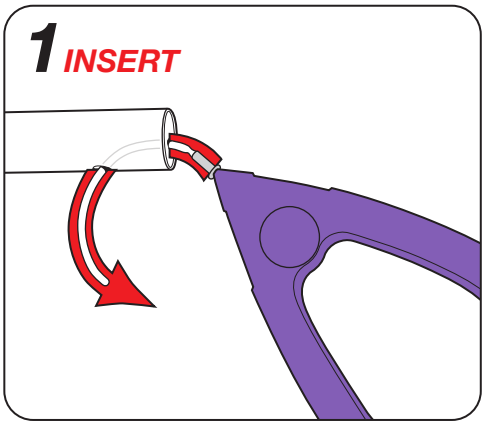


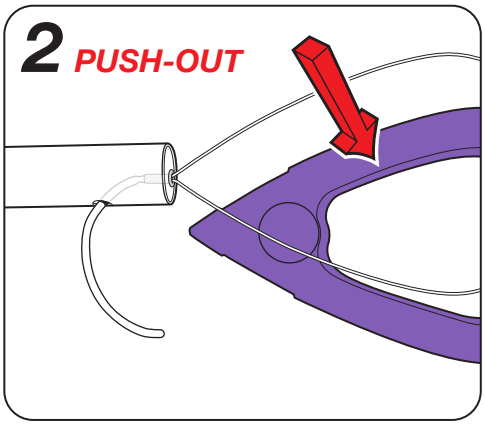
COR-KNOT® DEVICE

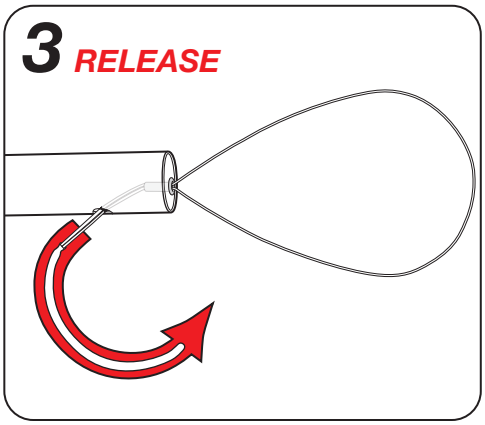
5mm Diameter, 31cm Length Shaft

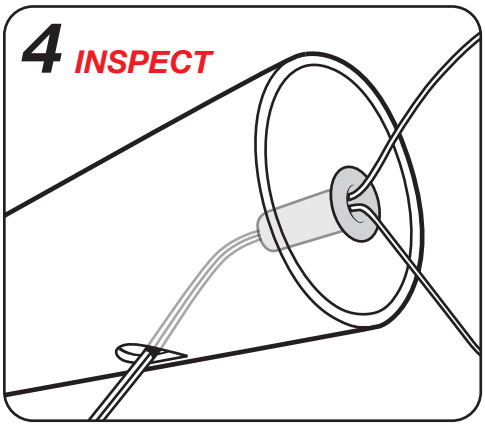
LSI SOLUTIONS®

AT SCRUB TABLE









LOADING WITH A COR-KNOT® QUICK LOAD®

Use proper operating room technique to pass the sterile COR-KNOT® 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 *COR-KNOT® DEVICE* shaft. ROTATE the curved handle through the distal slot and out of the suture hole until the *COR-KNOT® FASTENER* occupies the shaft's distal slot. Fully ENGAGE the *COR-KNOT® FASTENER* within the tip of the *COR-KNOT® DEVICE* by pushing on the purple target.
2. ***PUSH-OUT*** and remove the purple target.
3. ***RELEASE*** the curved handle from the distal slot at the end of the *COR-KNOT® DEVICE* shaft.
4. ***INSPECT*** to ensure that the *COR-KNOT® FASTENER* is well loaded and fully seated.

ACTIONS

When the *COR-KNOT® DEVICE* is loaded with a *COR-KNOT® FASTENER* and appropriately positioned at a suture closure site, squeezing the purple lever can 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.

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 *COR-KNOT®* QUICK LOAD® is not intended to be used with any device other than the *COR-KNOT® DEVICE*. The *COR-KNOT® DEVICE* is not intended to be loaded with anything other than a *COR-KNOT®* QUICK LOAD®.
- 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 2-0 Polyester suture by LSI SOLUTIONS®.
- Each *COR-KNOT® DEVICE* is not intended to be fired more than 12 times.

WARNINGS

- 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®* QUICK LOAD® 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.
- 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 resterilization 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.
- *COR-KNOT®* QUICK LOAD® 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.

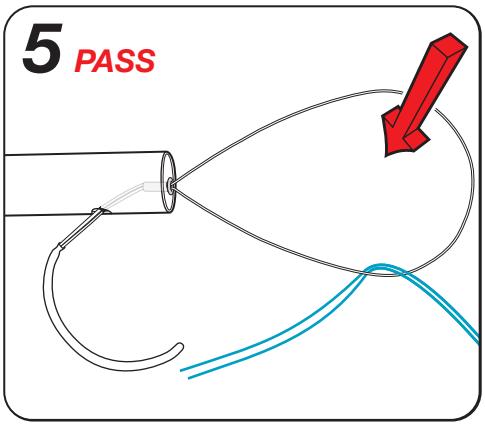
PRECAUTIONS

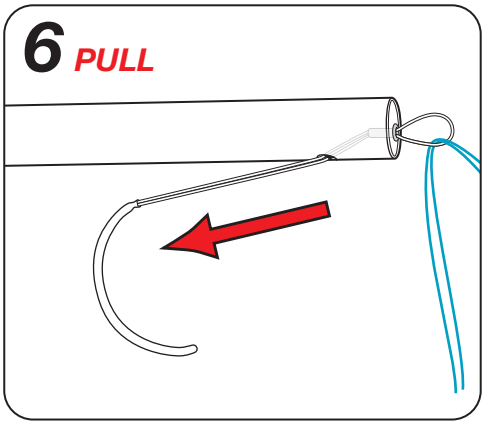
- Federal (U.S.A.) law restricts this device to sale, distribution and use by, or on, the order of a physician.
- When handling the *COR-KNOT®* QUICK LOAD® care should be taken to avoid damage.
- Do not squeeze the purple lever of *COR-KNOT® DEVICE* while loading the *COR-KNOT®* QUICK LOAD®.
- Irreparable damage to *COR-KNOT® DEVICE* suture cutting blade will occur if the purple lever is squeezed while the *COR-KNOT®* QUICK LOAD® curved handle is in place at the tip of the instrument.
- Ensure that obstructions do not interfere with the firing of *COR-KNOT® DEVICE*.
- Do not squeeze the 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 pulling the *COR-KNOT® DEVICE* away from the wound closure site. Inspect each *COR-KNOT® FASTENER*.
- Do not squeeze the purple lever on the same *COR-KNOT® FASTENER* more than once.
- Cut sutures with scissors if the *COR-KNOT® DEVICE* fails to cut.
- Avoid crushing or crimping damage to the *COR-KNOT® FASTENER* due to inappropriate squeezing of *COR-KNOT® DEVICE* purple lever, and/or to application of surgical instruments like forceps, needle holders, clamps, etc.
- If *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.

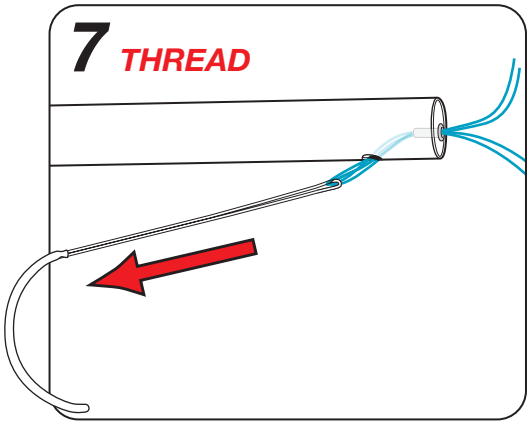
ADVERSE REACTIONS

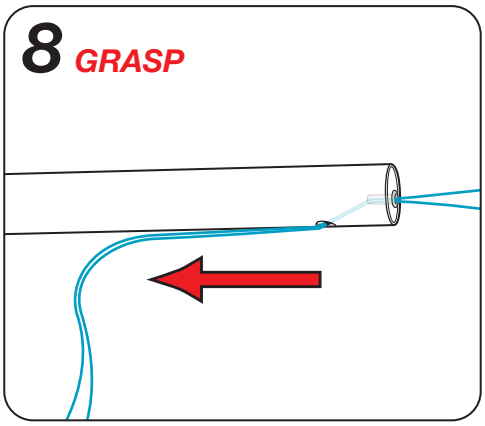
Adverse effects associated with the use of surgical suture and titanium can include, but are not limited to: wound dehiscence, thrombus formation, embolism, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infected wounds, minimal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

OUTSIDE OF PATIENT





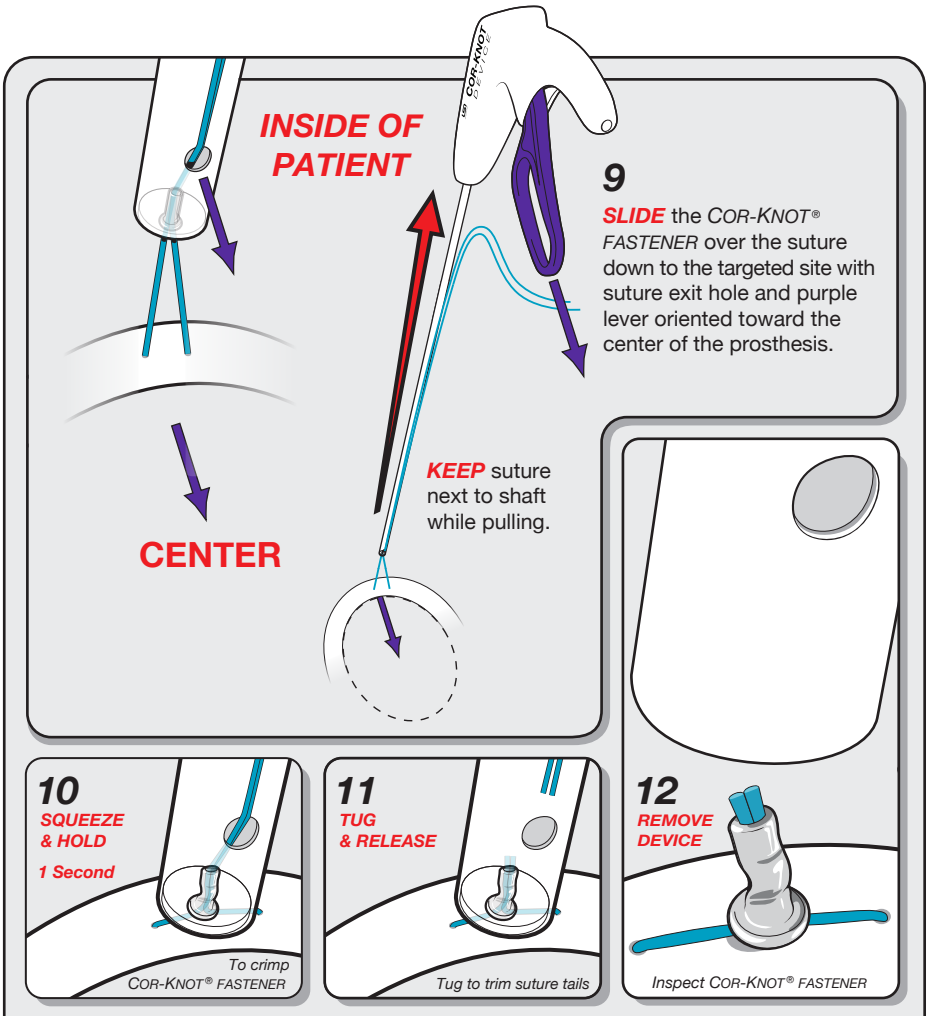




THREADING SUTURE THROUGH A LOADED COR-KNOT® FASTENER

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 purple lever to draw the snared bends in the suture into the *COR-KNOT® FASTENER*.
7. ***THREAD*** the suture through the *COR-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.



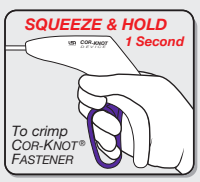
SQUEEZE & HOLD / TUG & RELEASE / REMOVE DEVICE

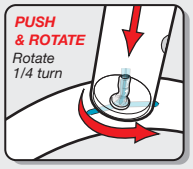
With the distal shaft on the prosthetic, maintain sufficient suture tension to hold tissue and prosthetic in appropriate apposition, then:

10. ***SQUEEZE*** the purple lever until it stops, ***HOLD*** it for one second.
11. ***TUG*** the suture to cut free both suture tails and ***RELEASE*** the purple lever fully to release the crimped *COR-KNOT® FASTENER*.
12. ***REMOVE DEVICE*** and inspect to ensure *COR-KNOT® FASTENER* and suture tails are oriented away from delicate tissue and prosthetic structures.

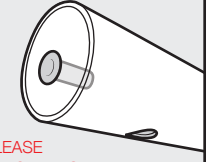
PLEASE NOTE

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





(OPTIONAL) If the crimped *COR-KNOT® FASTENER* does not readily release from the distal shaft, gently ***PUSH*** inward and then ***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.**



FAILURE TO PROPERLY LOAD SUTURE

NOTE: TO REMOVE A RETAINED *COR-KNOT® FASTENER* IF THE WIRE SNARE IS INADVERTENTLY REMOVED WITHOUT PROPER SUTURE THREADING, SQUEEZE AND RELEASE THE PURPLE LEVER AND THEN TAP THE DISTAL SHAFT ON A TABLE OR USE A SCALPEL TO PRY OUT THE CRIMPED *COR-KNOT® FASTENER.*

COR-KNOT® QUICK LOAD®

READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 3

CRIMPED *COR-KNOT*® *FASTENER*

ACTUAL SIZE

COR-KNOT® QUICK LOAD® DESCRIPTION

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

***COR-KNOT*® QUICK LOAD®**

① *COR-KNOT*® *FASTENER*
② *PURPLE TARGET*
③ *WIRE SNARE*
④ *CURVED HANDLE*

ACTUAL SIZE

COR-KNOT® MISCELLANEOUS

"ONLY THE SURGEON SQUEEZES THE PURPLE LEVER."

SUTURE CUTTING DIFFICULTY - THE CAUSES OF SUTURE NOT CUTTING EASILY WHEN USING A *COR-KNOT® DEVICE* CAN INCLUDE:

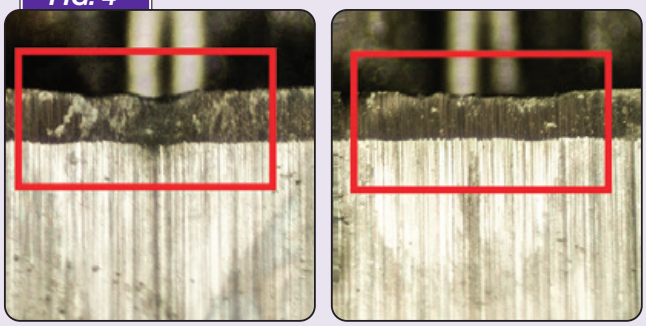
- **USER ERROR INDUCED DAMAGE DULLING THE SUTURE CUTTING BLADE OR**
- **DEVICE MALFUNCTION, WHICH MAY ALSO REDUCE KNOT STRENGTH AND SECURITY**

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

REMOVE DEVICE–INSPECT KNOT–TEST KNOT–RETURN DEVICE

COR-KNOT® DEVICE suture cutting difficulty can be induced by the inadvertent squeezing of the purple 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.

FIG. 4



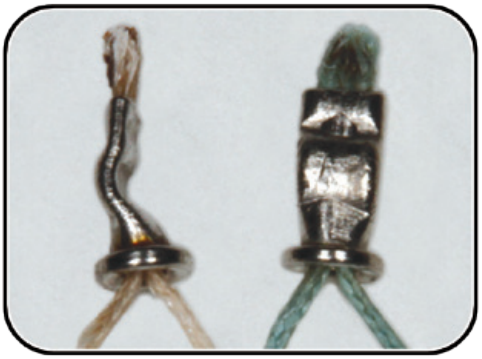
The photographs above show close-up views of two suture cutting blades from two devices damaged in the same surgical procedure. The subsequent evaluation of the returned devices demonstrated irreparable blade dulling caused by user error. The red rectangles highlight the areas of each blade's previously sharp cutting edge now dulled by the unintended striking of the blade into the metal loading unit components.

FIG. 5

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).

HARVESTED AT 18 MONTHS

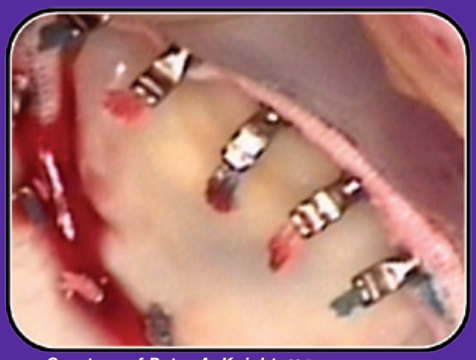


Courtesy of Scott M. Goldman, M.D.

FIG. 6 *COR-KNOT®* PRODUCT ORDERING — **SUPPLIED**: STERILE

	CATALOG NO.	PRODUCT	DESCRIPTION
 x 6	REF 030925	***COR-KNOT® DEVICE KIT***	*Box of 6 Kits (2 Devices per Kit)*
 x 12	REF 030950	***COR-KNOT®* QUICK LOAD®** SINGLES	*Box of 12 SINGLES (1 FASTENER per Pouch)*
 x 12	REF 030902	***COR-KNOT®* QUICK LOAD®** 6-POUCH	*Box of 12 Pouches (6 FASTENERS per Pouch)*

INTRA OP



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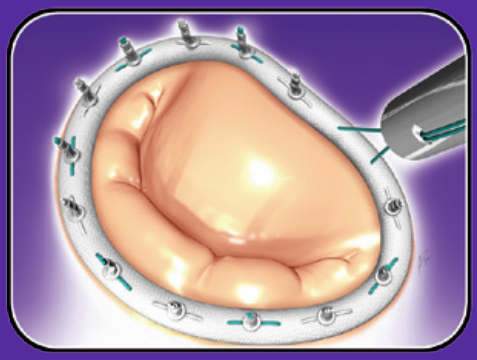
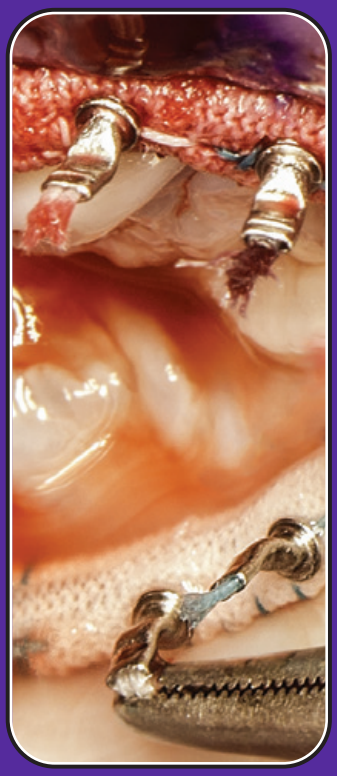
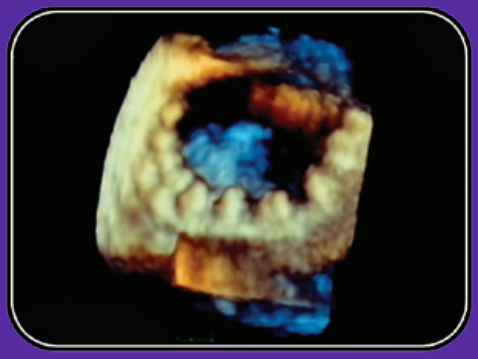




Courtesy of Peter A. Knight, M.D.

3D ECHO



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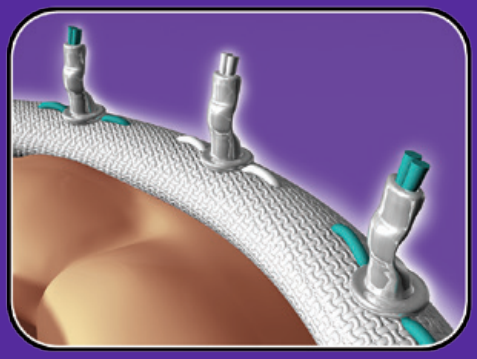

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