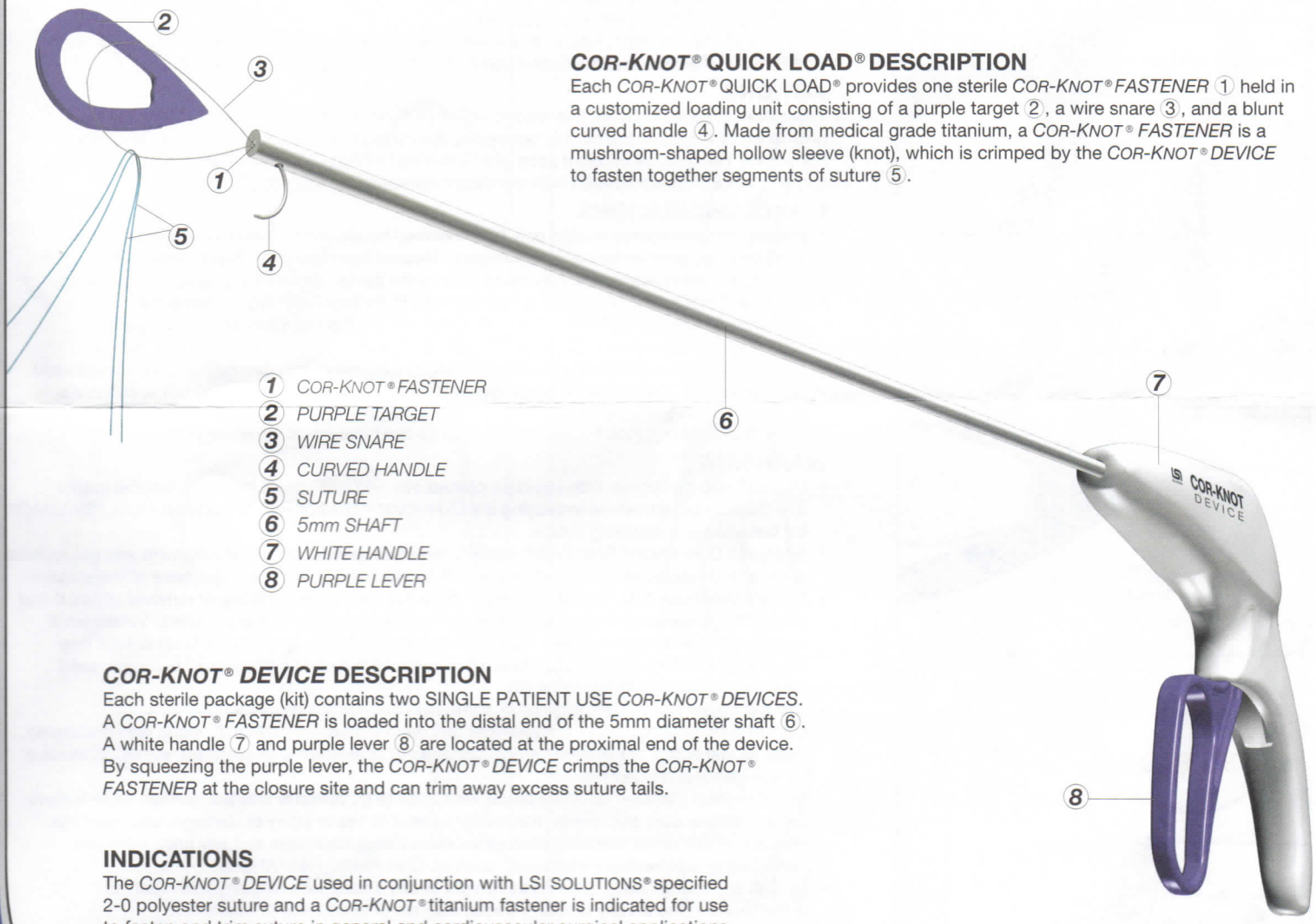
COR-KNOT® EU TECHNOLOGY GUIDE

READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



1. COR-KNOT® FASTENER
2. PURPLE TARGET
3. WIRE SNARE
4. CURVED HANDLE
5. SUTURE
6. 5mm 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 SINGLE PATIENT USE COR-KNOT® DEVICES. A COR-KNOT® FASTENER is loaded into the distal end of the 5mm diameter 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.

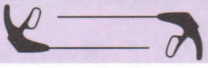
INDICATIONS

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.

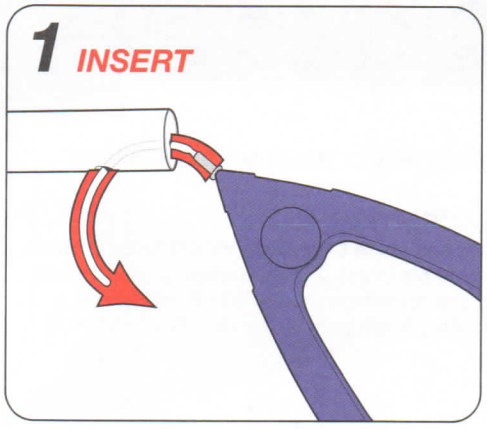
LSI SOLUTIONS®

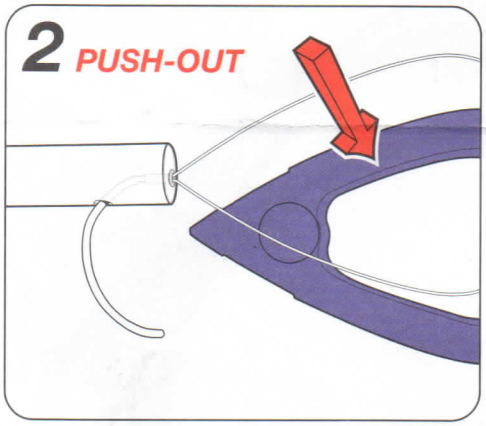
FIG. 2

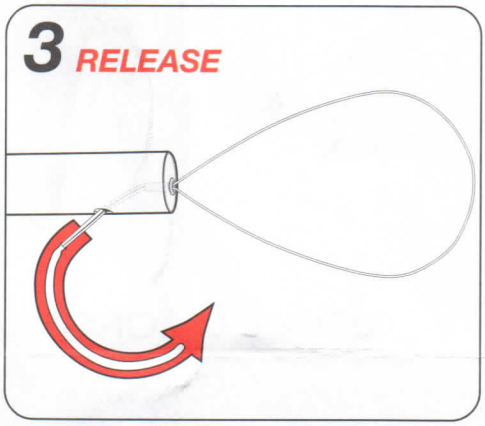
COR-KNOT® PRODUCT ORDERING — **SUPPLIED:** STERILE

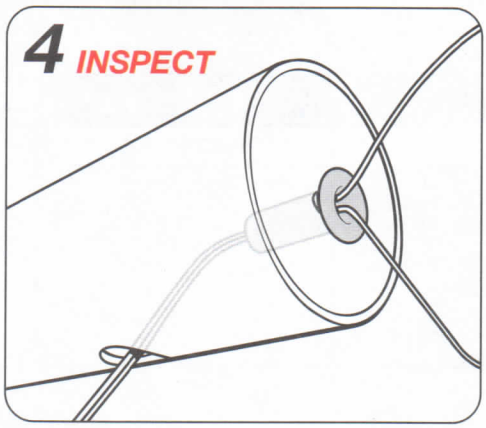
	CATALOG NO.	PRODUCT	DESCRIPTION
 x 6	REF 030925	**COR-KNOT® DEVICE KIT**	*Box of 6 Kits (2 Devices per Kit)*
 x 12	REF 030950	**COR-KNOT® QUICK LOAD®** SINGLES	*Box of 12 SINGLES (1 Knot per Pouch)*
 x 12	REF 030902	**COR-KNOT® QUICK LOAD®** 6-POUCH	*Box of 12 Pouches (6 Knots per Pouch)*

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 appropriately 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, unused, expired or damaged COR-KNOT® product.
- COR-KNOT® QUICK LOAD® components and each COR-KNOT® DEVICE, along with packaging, must be inspected, accounted for 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. Avoid direct contact between sensitive tissue structures and any knot, including hand-tied or mechanical metal knots, such as COR-KNOT® FASTENERS.
- 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.

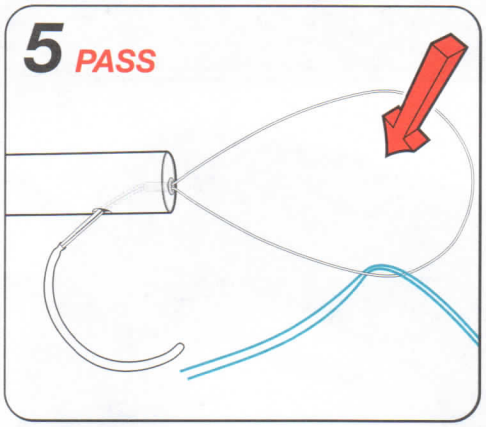
PRECAUTIONS

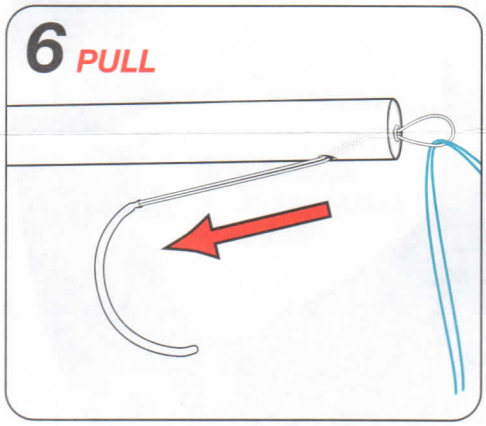
- Federal (U.S.A.) law restricts this device to sale, distribution and use by, or on, the order of a physician.
- When handling the COR-KNOT® QUICK LOAD® care should be taken to avoid damage.
- Do not squeeze the purple lever of CK® COR-KNOT® DEVICE while loading the COR-KNOT® QUICK LOAD®.
- Irreparable 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.
- 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.
- 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.

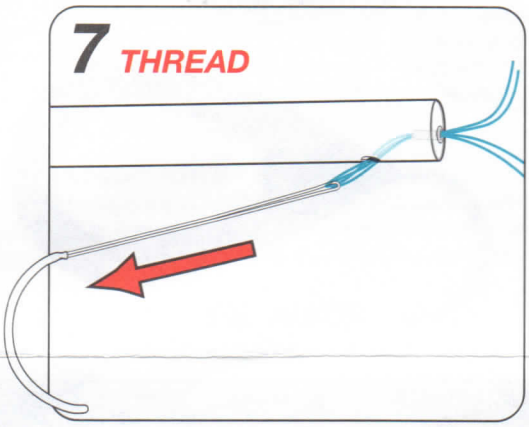
ADVERSE REACTIONS

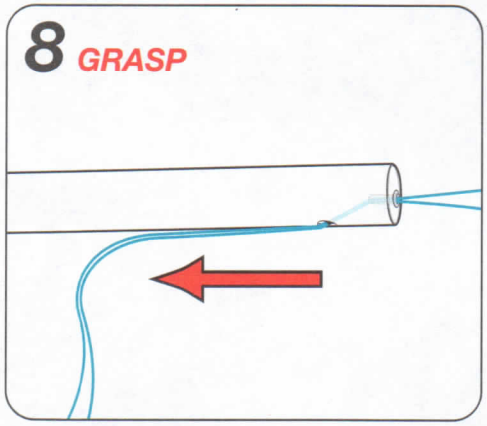
Adverse effects associated with the use of surgical suture and titanium can include, but are not limited to: wound dehiscence, thrombus formation, embolism, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infected wounds, minimal 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





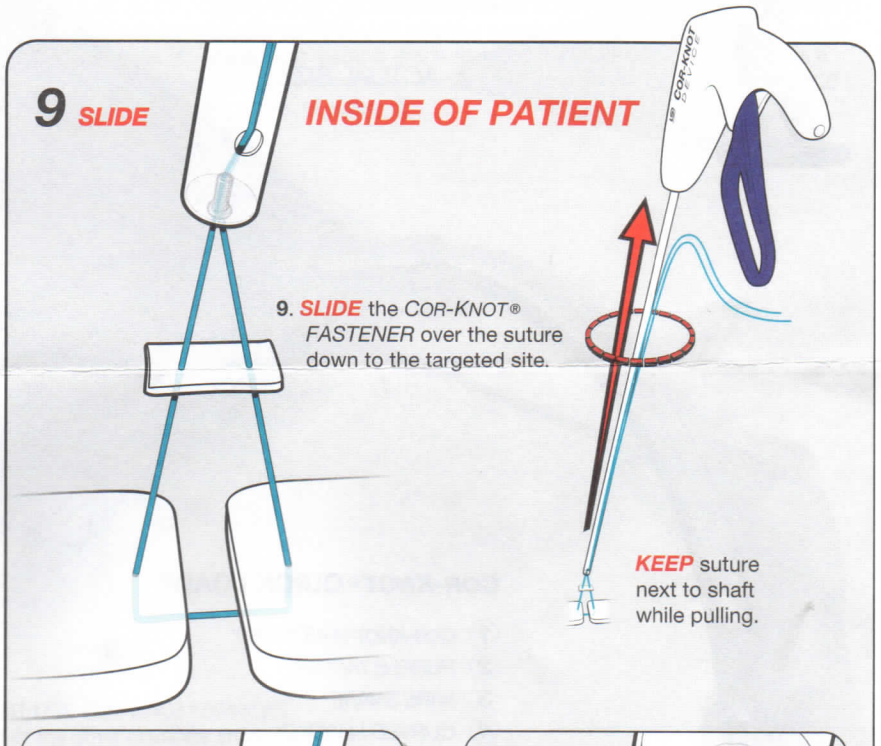


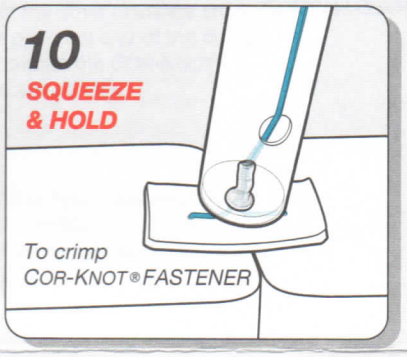


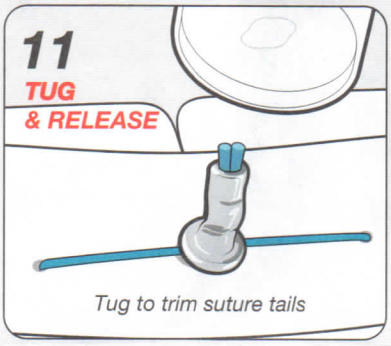
THREADING SUTURE THROUGH A LOADED *COR-KNOT® FASTENER*

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

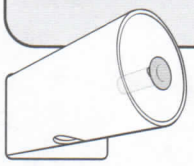
With the distal shaft on the prosthetic, maintain sufficient suture tension to hold tissue and prosthetic in appropriate apposition, then:

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*.

PLEASE NOTE

While very rapidly squeezing and releasing of the purple lever provides average suture holding forces above Ph. Eur. and USP standards, this recommended ***SQUEEZE & HOLD / TUG & RELEASE*** technique takes only one second longer and assures extra knot suture holding force.



FAILURE TO PROPERLY LOAD SUTURE

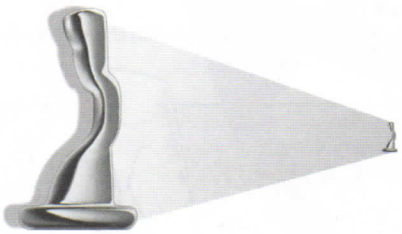
NOTE: TO REMOVE A RETAINED *COR-KNOT® FASTENER* IF THE WIRE SNARE IS INADVERTENTLY REMOVED WITHOUT PROPER SUTURE THREADING, SQUEEZE AND RELEASE THE PURPLE LEVER AND THEN TAP THE DISTAL SHAFT ON A TABLE OR USE A SCALPEL TO PRY OUT THE CRIMPED *COR-KNOT® FASTENER*

COR-KNOT® QUICK LOAD®

READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 3

CRIMPED COR-KNOT® FASTENER



ACTUAL SIZE

COR-KNOT® QUICK LOAD®

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

ACTUAL SIZE

LSI SOLUTIONS®

INNOVATIVE SOLUTIONS FOR MINIMALLY INVASIVE SURGERY

STERILE EO

℞ Only

LSI SOLUTIONS®
7796 Victor-Mendon Road
Victor, New York 14564
U.S.A.
Phone: +1.585.869.6600
Fax: +1.585.742.8086
www.lsisolutions.com

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands
Phone: +31.70.345.8570
Fax: +31.70.346.7299
www.emergogroup.com

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