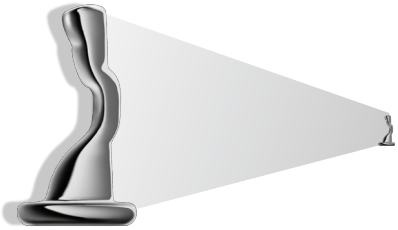
COR-KNOT® QUICK LOAD® UNIT EU TECHNOLOGY GUIDE

READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1

CRIMPED *COR-KNOT*® *FASTENER*



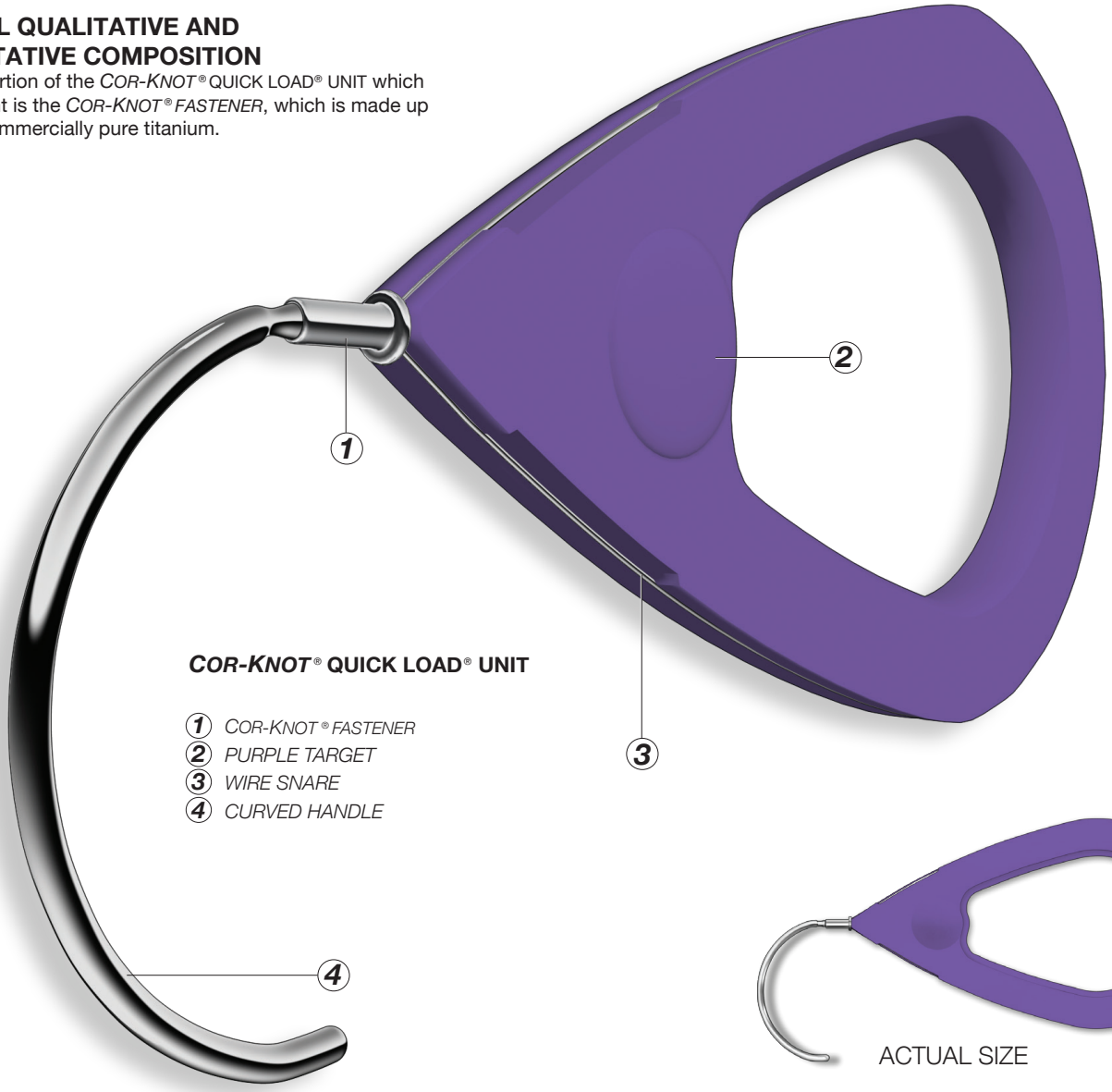
ACTUAL SIZE

COR-KNOT® QUICK LOAD® UNIT DESCRIPTION

Each *COR-KNOT*® QUICK LOAD® UNIT 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. Use only with LSI SOLUTIONS® specified 2-0 Polyester suture and a *COR-KNOT*® *DEVICE or COR-KNOT MINI*® *DEVICE*.

OVERALL QUALITATIVE AND QUANTITATIVE COMPOSITION

The only portion of the *COR-KNOT*® QUICK LOAD® UNIT which is an implant is the *COR-KNOT*® *FASTENER*, which is made up of 100% commercially pure titanium.



***COR-KNOT*® QUICK LOAD® UNIT**

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

ACTUAL SIZE

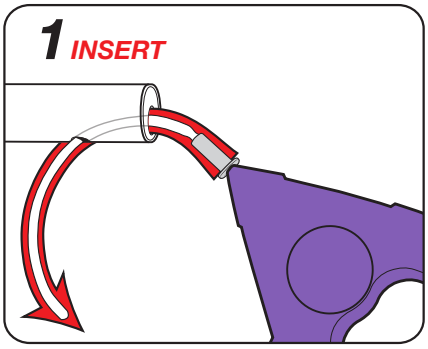
INDICATIONS

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.

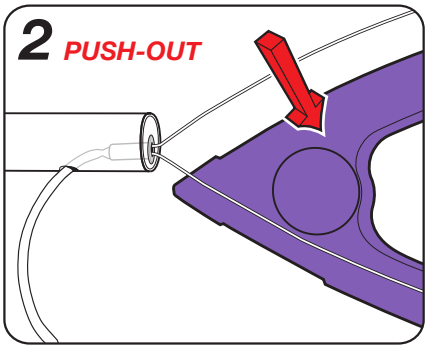
LOADING WITH A *COR-KNOT*® QUICK LOAD® UNIT

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

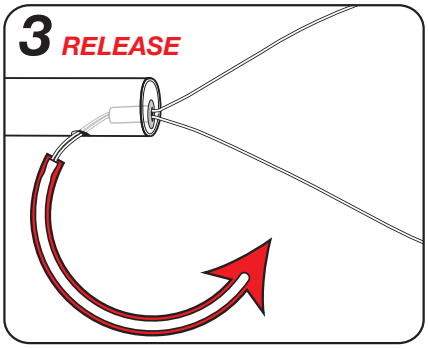
AT SCRUB TABLE



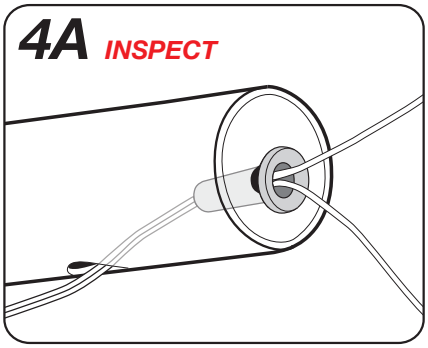
INSERT the blunt tip of the curved handle into the distal slot at the end of the *COR-KNOT*® *DEVICE* shaft. ROTATE the curved handle through the distal slot and out of the suture hole until the *COR-KNOT*® *FASTENER* occupies the shaft's distal slot. Fully ENGAGE the *COR-KNOT*® *FASTENER* within the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



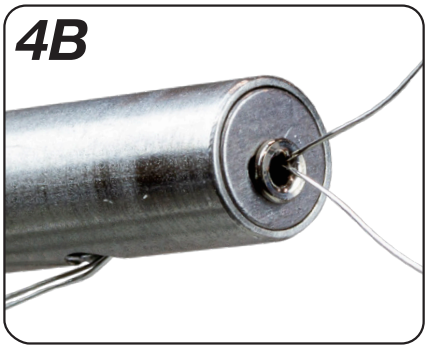
PUSH-OUT and remove the purple target.



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



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



In the text below, the *COR-KNOT® DEVICE* refers to the LSI SOLUTIONS® *COR-KNOT® DEVICE* or *COR-KNOT MINI® DEVICE*. Refer to the corresponding *COR-KNOT®* Technology Guide Indications for compatibility with the *COR-KNOT®* QUICK LOAD® UNIT.

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® UNIT is not intended to be used with any device other than the *COR-KNOT MINI® DEVICE* or the *COR-KNOT® DEVICE*. The *COR-KNOT MINI® DEVICE* and the *COR-KNOT® DEVICE* are not intended to be loaded with anything other than a *COR-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 suture.
- 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® UNIT 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 a *COR-KNOT® DEVICE*, ensure any needle caps or needles are removed from the suture ends to be loaded prior to loading the suture through the *COR-KNOT® DEVICE*.
- 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® 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 *COR-KNOT®* QUICK LOAD® UNIT care should be taken to avoid damage.
- Do not squeeze the purple lever of *COR-KNOT® DEVICE* while loading the *COR-KNOT®* QUICK LOAD® UNIT.
- Irreparable damage to *COR-KNOT® DEVICE* suture cutting blade will occur if the purple lever is squeezed while the *COR-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 *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 *COR-KNOT® FASTENER*.
- 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. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the country competent authority.

MRI SAFETY INFORMATION – MR CONDITIONAL

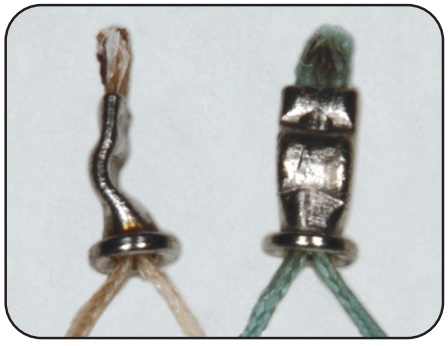
Non-clinical testing demonstrated that the *COR-KNOT®* Titanium Fastener is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the *COR-KNOT®* Titanium Fastener is expected to produce a maximum temperature rise of 1.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the *COR-KNOT®* Titanium Fastener extends approximately 2-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

HARVESTED AT 18 MONTHS



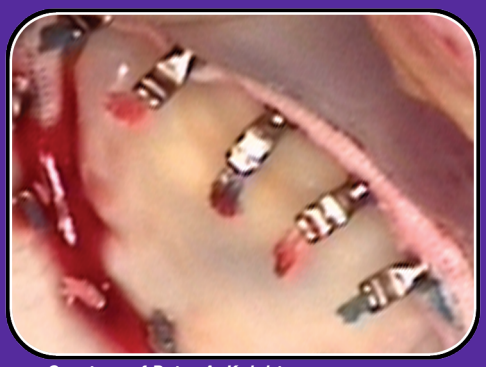
Courtesy of Scott M. Goldman, M.D.

FIG. 2 *COR-KNOT*® QUICK LOAD® UNIT PRODUCT ORDERING

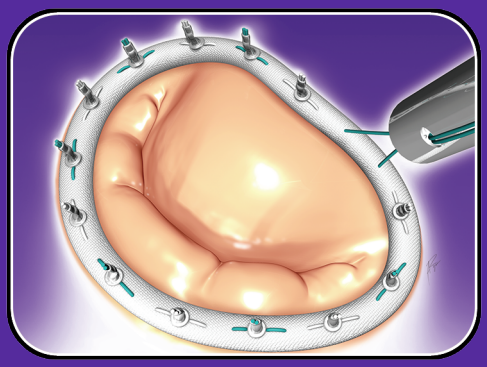
SUPPLIED: STERILE

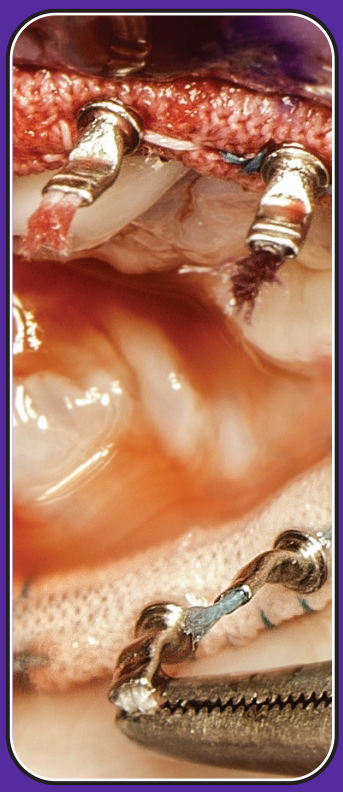
	REORDER	PRODUCT	DESCRIPTION
x 12	REF 030950	***COR-KNOT*® QUICK LOAD®** SINGLES	*Box of 12 Singles (1 Fastener per Pouch)*
x 12	REF 030902	***COR-KNOT*® QUICK LOAD®** 6-POUCH	*Box of 12 Pouches (6 Fasteners per Pouch)*

INTRA OP



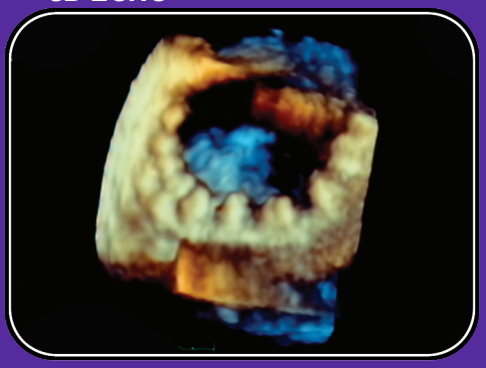
Courtesy of Peter A. Knight, M.D.



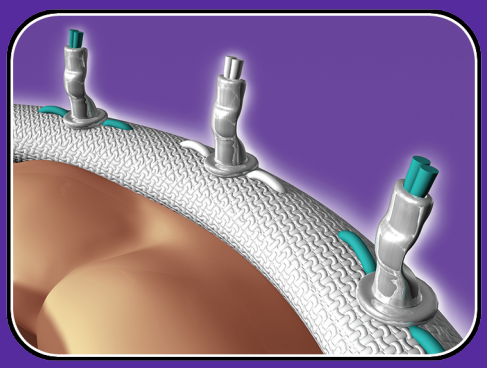


Courtesy of Peter A. Knight, M.D.

3D ECHO



Courtesy of Peter A. Knight, M.D.



LSI SOLUTIONS®

The Summary of Safety and Clinical Performance (SSCP) Report, with information on device suitability and patient target group, shall be made available in the European database on medical devices (EUDAMED) at http://ec.europa.eu/tools/eudamed once the database is publicly accessible. The Basic UDI-DI for this device is 0850200006COR-KNOT2N.

Patents: www.lsisolutions.com/patents

STERILE EO | Rx Only | MD | MR

QTY An indication of the net quantity of contents.

Symbol Glossary: www.lsisolutions.com/symbols

LSI SOLUTIONS®
7796 Victor-Mendon Road
Victor, New York 14564 U.S.A.
Phone: +1.585.869.6600
Customer Service: +1.866.575.3493
Technical Support: +1.866.428.9092
Fax: +1.585.742.8086
www.lsisolutions.com

EC REP

EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CE 0344

MADE IN THE USA

This Product Comes with our LSI SOLUTIONS® *Perfect Performance Policy*® Call us at +1.866.575.3493 any time.

P/N 032488A 01.09.23