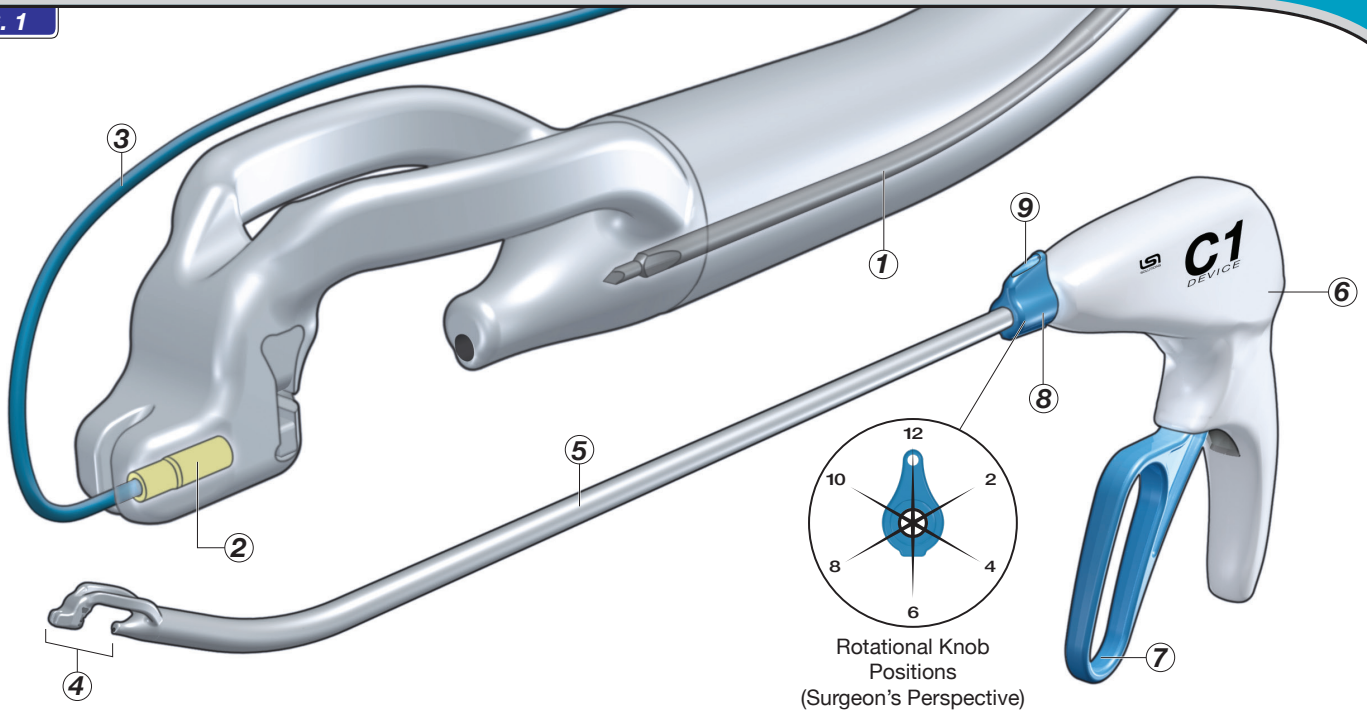


C1® TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



- | | | |
|--------------|--------------|-------------------|
| ① NEEDLE | ④ DEVICE TIP | ⑦ BLUE LEVER |
| ② NEEDLE CAP | ⑤ SHAFT | ⑧ ROTATIONAL KNOB |
| ③ SUTURE | ⑥ HANDLE | ⑨ INDICATOR FIN |

C1® DEVICE - DESCRIPTION

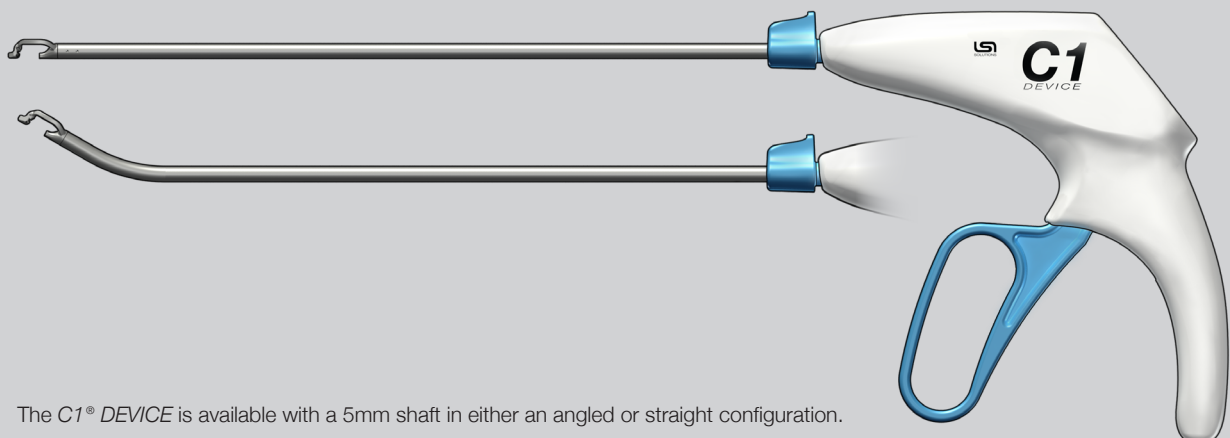
Each sterile package contains one (1) SINGLE PATIENT USE C1® suturing device available with an angled (FIG. 1) shaft or with a straight (Fig. 2) shaft. The C1® DEVICE is used for the placement of surgical suture as supplied in an appropriate COR-SUTURE® or LS-5™ ePTFE QUICK LOAD® surgical suture. A short length of modified surgical stainless steel tubing, called a needle cap (2), is attached to each end of the suture (3). The needle cap is loaded into the needle cap compartment in the distal end of the device tip (4). Suture Placement and Suture Rearm (FIG. 6) are each achieved by sequentially squeezing and releasing the blue lever (7). During Suture Placement, the initial squeeze of the blue lever advances the retracted needle (1) forward through the selected tissue placed in jaw of the device tip; the full squeeze advances the needle into the needle cap attached to its suture held in the device tip's distal end. Release of the blue lever retracts the needle, which pulls the now engaged needle cap and suture back through the tissue. Next, with the device tip oriented for Suture Rearm, a second squeeze of the blue lever advances the needle with its now engaged needle cap and suture forward through the empty jaw into the device tip's distal end, where a latch feature retains the needle cap and suture. Release of the blue lever returns the needle alone back to its retracted position in the distal shaft ready for repeat suture placement. The orientation of the device tip is set by rotating the rotational knob (8), which has six distinct positions, and an indicator fin (9) with an integrated suture management channel.

INDICATIONS

The C1® DEVICE is indicated for use in the approximation of soft tissue and prosthetic materials.

LS SOLUTIONS®

FIG. 2



The C1® DEVICE is available with a 5mm shaft in either an angled or straight configuration.

LOADING SUTURE

CAUTION: To avoid accidental needle exposure, **DO NOT** squeeze lever during suture loading.

FIG. 4

CAUTION: USE ONLY LSI SOLUTIONS COR-SUTURE® OR LS-5™ ePTFE QUICK LOAD® SURGICAL SUTURE WITH C1® DEVICE.

1 REMOVE Suture Tube From Tray

REMOVE suture tube from tray by grasping suture tube at suture release feature and pulling suture tube completely out of tray.

Straighten Tube

2 INSERT Suture Into Suture Track

INSERT one suture end into the suture track as shown; may require pulling needle cap and suture further out of suture tube.

3 PULL Needle Cap Into Compartment

PULL suture to seat needle cap into needle cap compartment in the distal end of the device tip. Make sure needle cap is fully seated in front of latch.

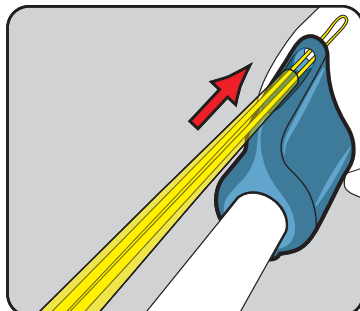
4 FIRE & REARM

Orient Suture As Shown, Squeeze And Release Lever To Ensure Suture Is Ready In Distal End Of Device Tip

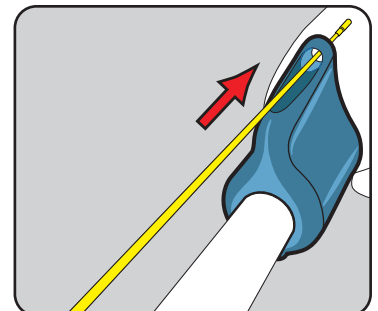
FIRE & REARM to ensure suture is loaded properly. To avoid jamming the needle cap into the needle cap compartment, orient the suture directly away from the jaw as shown. Squeeze the lever to advance the needle through the jaw and into the newly loaded needle cap. Release the lever to pick up and retract the needle cap with attached suture back on the needle into the shaft. While continuing to orient the suture as shown, squeeze the lever to advance the needle, needle cap, and suture forward through the jaw to rearm the needle cap into its compartment. Release the lever again and retract back the now-empty needle, leaving the needle cap and suture ready for patient use.

OPTIONAL SUTURE MANAGEMENT CHANNEL

The opposite end of the suture tube can be passed through the fin's suture management channel and subsequently removed to have the suture captured in the fin.



Alternatively, the suture tube can be removed and the opposite end of the suture can be passed directly through the suture management channel.

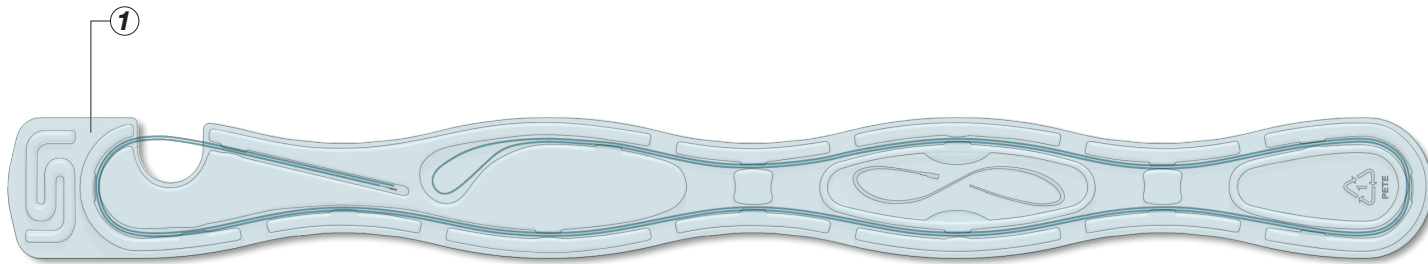
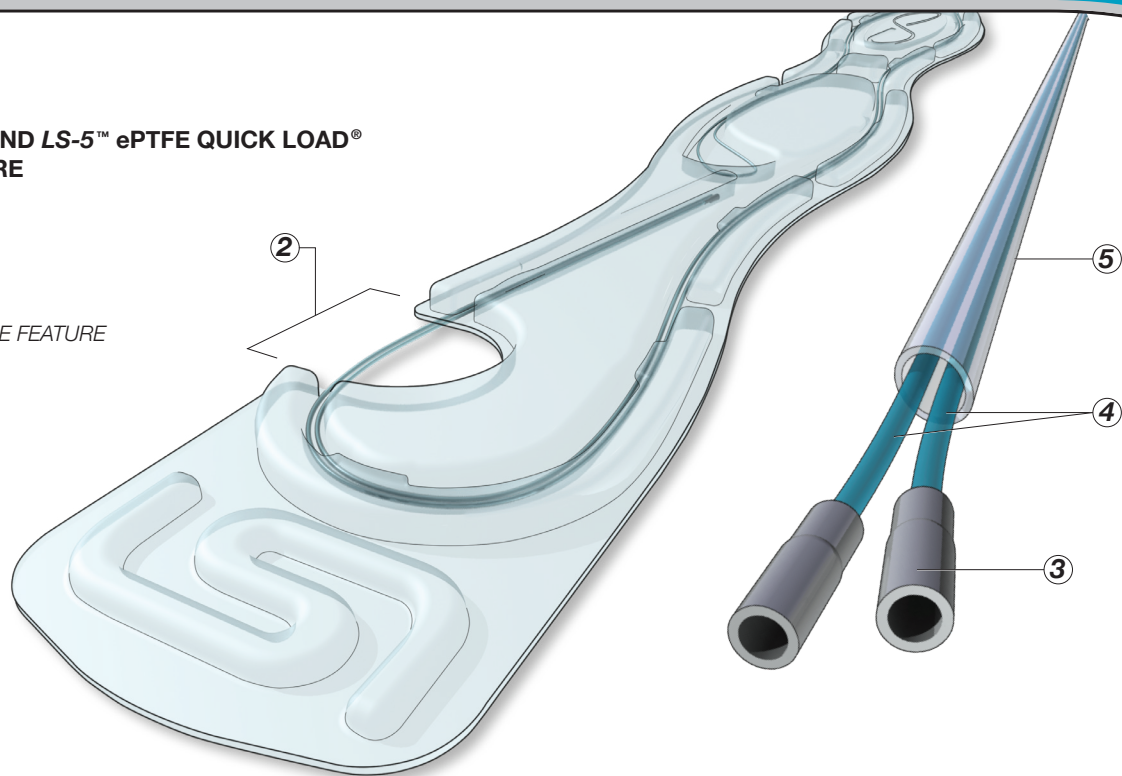


COR-SUTURE® AND LS-5™ ePTFE QUICK LOAD® SURGICAL SUTURE

FIG. 3

COR-SUTURE® AND LS-5™ ePTFE QUICK LOAD® SURGICAL SUTURE

- ① SUTURE TRAY
- ② SUTURE RELEASE FEATURE
- ③ NEEDLE CAP
- ④ SUTURE
- ⑤ SUTURE TUBE



DESCRIPTION

Each LSI SOLUTIONS® COR-SUTURE® and LS-5™ ePTFE QUICK LOAD® surgical suture is held in a customized tray (1) with suture release feature (2) designed to enable the rapid, easy and reliable loading of suture into C1® devices. COR-SUTURE® QUICK LOAD® surgical suture is available as a non-absorbable monofilament and braided polyester surgical suture (FIG. 10). LS-5™ ePTFE QUICK LOAD® surgical suture is a non-absorbable monofilament expanded polytetrafluoroethylene (ePTFE) suture. A short length of modified surgical stainless steel tubing, called a “needle cap” (3), is attached to each end of the suture (4). The COR-SUTURE® and LS-5™ ePTFE QUICK LOAD® surgical suture also include a detachable clear suture tube (5) to keep the suture from tangling. Each sterile COR-SUTURE® and LS-5™ ePTFE QUICK LOAD® surgical suture is individually packaged for single patient use.

CAUTION:
To avoid accidental needle exposure, **DO NOT** squeeze lever during suture loading.

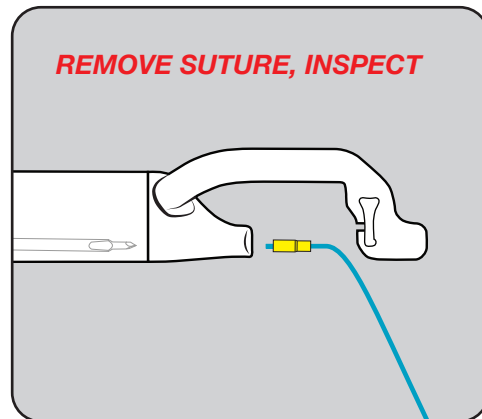
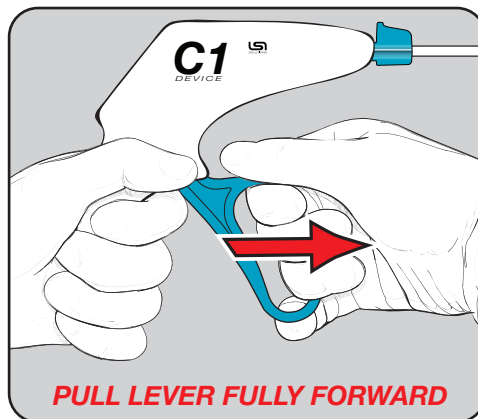
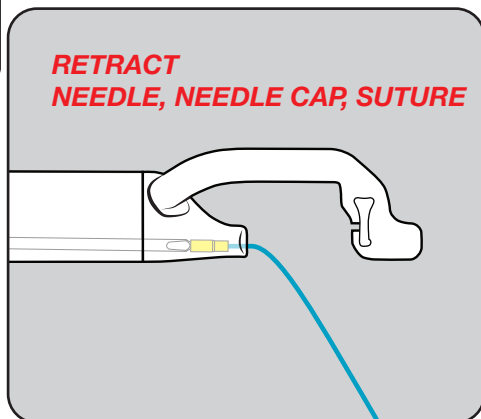
UNLOADING C1[®] DEVICE

UNLOADING NEEDLE CAP AND REMAINING SUTURE FROM C1[®] DEVICE

There is a simple and convenient method for removal of needle caps from the needles prior to reloading the C1[®] DEVICE. The AUTO-RELEASE Technique is illustrated below. This technique automatically removes the sutures and needle caps from the needle by simply pulling the lever fully forward.

AUTO-RELEASE Technique *Retract Suture Back. Pull Lever Fully Forward. Remove Suture With Needle Cap.*

FIG. 5

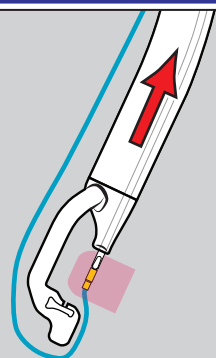
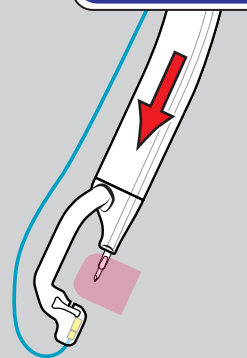


This unloading technique requires that the needle with its engaged needle cap and suture must first be retracted back into the distal end of the device shaft. If they are not, simply squeeze and release the blue lever to pick up and retract the needle cap, suture, and needle. Once the needle cap, suture, and needle are retracted into the shaft, pull the lever fully forward to automatically remove the needle cap and suture off of the needle. Inspect and discard the used needle cap and suture.

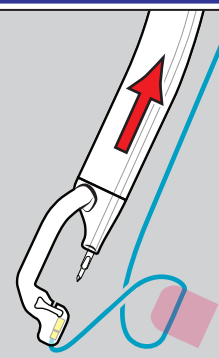
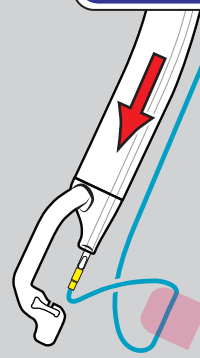
C1[®] DEVICE FUNCTION

FIG. 6

SUTURE PLACEMENT



SUTURE REARM



ACTIONS

To facilitate the placement of multiple stitches of the same suture (i.e., “running” the suture), the needle cap rearming mechanism of the *C1® DEVICE* enables the remote return and rearming of the needle cap back into the needle cap compartment. The operator selects the desired device tip orientation by turning the rotational knob and presents an appropriate tissue structure into the gap of the metal jaw in the device tip of the *C1® DEVICE*. During suture placement, the blue lever is squeezed to advance the retracted needle from the shaft of the device through the tissue in the jaw and into the needle cap. The distal end of the *C1® DEVICE* needle engages and captures the needle cap with its attached suture. Releasing the blue lever retracts the needle with attached needle cap and suture back through the tissue. For Suture Rearm, the device tip is then moved away from any tissue structures to clear the jaw for needle cap rearming. The blue lever is again fully squeezed to advance the needle, needle cap and suture forward through the empty jaw toward the needle cap compartment at the most distal end of the device tip. Care must be taken to ensure the suture crimped to the distal end of the needle cap is oriented to permit the suture to freely pass through the suture track opening in the needle cap compartment. Jamming misoriented suture into the needle cap compartment can damage suture and device. With the blue lever fully squeezed and the needle with its attached needle cap and suture completely forward, the now rotated needle will permit the needle cap rearm latch to engage the face of the needle cap and cause its release from the needle. With the first tissue suture placement complete, the needle cap rearm into the needle cap compartment, and the blue lever back in its starting location, the *C1® DEVICE* is ready for another tissue bite. This sequence can be repeated for up to 24 bites (or 24 complete functional cycles) with up to 4 sutures per device.

CONTRAINDICATIONS

- The *C1® DEVICE* is not intended to be used with any suture other than a *COR-SUTURE®* or *LS-5™ QUICK LOAD®* surgical suture.
- The *C1® DEVICE* is not for use in neurological and ophthalmic procedures.

WARNINGS

- Federal (U.S.A.) law restricts this device to sale, distribution and use by, or on, the order of a physician.
- **Do not resterilize.** The *C1® DEVICE* is designed and intended for single-patient use only. The performance of the *C1® DEVICE* after cleaning or other reprocessing has not been verified and is not supported by LSI SOLUTIONS®. Reuse, reprocessing, or resterilization may compromise the integrity of the devices and/or create a risk of contamination of the devices, which could result in patient injury, illness, or death.
- Discard open (unsealed), unused, expired or damaged devices or devices in damaged primary packaging.
- Invasive surgical procedures should only be performed by physicians having adequate training and familiarity with open direct visualization or video-enhanced endoscopic techniques. In addition, medical literature should be consulted relative to techniques, complications, and hazards prior to the performance of invasive procedures.
- Place the *C1® DEVICE* tip firmly against the target tissue. Failure to do so can result in inadequate tissue bite depth.
- Do not use this suture under conditions in which excessive suture tension can lead to tissue damage. For example, do not use *COR-SUTURE®* or *LS-5™ QUICK LOAD®* surgical suture through an excessively narrow, restrictive, or defective cannula access port, which could significantly impair easy and smooth passage of the suture or device.
- 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 surgical procedures and techniques involving suture before employing the *C1® DEVICE* for wound closure, as the risk of wound dehiscence may vary with the site of application.
- Acceptable surgical practice and good surgical judgement must be followed with respect to drainage and closure of infected or contaminated wounds.
- Redundant, cut-away suture remnants, used needle caps, and *C1® DEVICES*, along with packaging, must be inspected, handled and disposed of consistent with standard, accepted medical device disposal procedures.
- Applications other than the intended use, can result in failure to pick up suture or in damage to the device making it unsuitable for continued use.
- Never drive the needle into suture, bone, dense ligamentous tissue, severely calcific tissue, impenetrable prosthetics or other instruments.
- Do not leave any foreign material (e.g. suture remnant, needle cap, etc.) unattached in areas potentially exposed to circulating blood.
- Ensure that the blue lever is fully squeezed until it stops when actuating the *C1® DEVICE*. Failing to complete a full squeeze can result in the *C1® DEVICE* changing into a different mode before the desired time. Holding the lever completely squeezed for one second ensures full actuation.
- The *C1® DEVICE* is not intended for use in prosthetic materials through which the device needle cannot readily penetrate, based on the surgeon's judgement.
- After placing a stitch with the *C1® DEVICE*, ensure that the suture length traverses the tissue. Failure to do so can result in insufficient attachment of suture.
- Do not squeeze the blue lever of the *C1® DEVICE* without suture loaded into the needle cap compartment; squeezing the blue lever may expose the sharp needle, damage the needles, and/or damage the device tip.

PRECAUTIONS

- The *C1® DEVICE* is compatible with minimally invasive access devices, such as cannulas and trocars, that are capable of accommodating instruments 15mm in diameter.
- Check for hemostasis or leakage where appropriate.
- Failure to directly visualize or image the device can result in damage to the tissue.
- Ensure obstructions do not interfere with the movement of the needle of *C1®*. Obstructions may cause damage or breakage.
- In handling the *C1® DEVICE*, care should be taken to avoid jamming the suture into the needle cap compartment and damage to the needle.
- Avoid damage to the *C1® DEVICE* due to inappropriate squeezing of the blue lever and/or to application of surgical instruments like forceps, needle holders, clamps, etc. If damage is noted, ensure that there are no device pieces, needle fragments, or free suture sections in the surgical field.
- Adequate knot security requires accurate completion of accepted surgical techniques for constructing surgically tied knots as warranted by surgical circumstances and the experience of the surgeon.
- Surgical instruments may vary in size from manufacturer to manufacturer. Before open surgical or 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.
- Before loading the *C1® DEVICE* with another surgical suture, assure the remaining suture tail and needle cap from the previous load has been removed from the needle and needle cap compartment. Failure to appropriately remove a used needle cap from the needle can result in damage to the device, including intracorporeal or extracorporeal fracturing off of the tip of the needle, making it unsuitable for continued use.
- After each loading and re-loading of a new suture into this device, squeeze the blue lever to drive the needle forward into the new needle cap loaded into the needle cap compartment. If the needle cap is picked-up by the needle, then squeeze the lever again to rearm the needle cap and suture. If the needle rotation is oriented to rearm the needle cap, then the needle will retract back without the needle cap and suture attached. This “cycling” (FIG. 4, Step 4) of the needle helps ensure that the previous needle cap was properly removed, the new needle cap is installed properly, and the operator receives the device with its needle oriented to pick-up the needle cap on its first needle advancement. If the previous needle cap was not properly removed from the needle prior to reloading the device, the needle will not fully advance into the new needle cap in the needle cap compartment. Failure to avoid driving a needle with a needle cap into another needle cap can lead to the breaking off of the tip of the needle.
- Do not use the *C1® DEVICE* to dissect or aggressively manipulate tissue structures.
- Verify that the needle cap is still retained within the needle cap compartment and the device has not been damaged or deformed before attempting to place a stitch.
- Do not manipulate the device at any time with the blue lever partially actuated. This may expose sharp surfaces that can cause trauma to the patient, the device operator or other staff, or damage the device or prosthesis.
- To avoid inadvertent suture damage, ensure the needle cap always enters the needle cap compartment with its suture oriented to freely pass through the needle cap compartment's suture track. Do not use damaged suture or expired suture.
- To ensure that the advancing needle enters the needle cap during suture placement, avoid using an advanced needle to manipulate or lift tissue or prostheses. A needle that does not enter the needle cap compartment properly can strike the device tip and lead to undesired outcomes, including needle tip fracture.
- Turning the rotational knob while squeezing the blue lever may damage tissue or prosthetic, and/or the *C1® DEVICE* and suture.
- Care must be taken when inserting this or any device through minimally invasive access devices, such as cannulas or trocars, to avoid advancing the device incorrectly (e.g., too far or too quickly). Device insertion should be easy, smooth, and controlled to minimize the risks of trauma to the patient or damage to the device.
- Before squeezing the *C1® DEVICE* lever to advance the needle, always ensure that proper insufflation is achieved and the device tip location is adequately visualized.

ADVERSE REACTIONS

Adverse effects associated with the use of suture include wound dehiscence, failure of adequate wound support in closure sites where expansion, stretching or distension occur, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and pain, edema and erythema.

C1® TECHNIQUE PEARLS



If device fails to place a stitch, then under direct visualization and away from tissue, fire and rearm once or twice per Fig. 4, Step 4, then continue if appropriate. If suture placement is ineffective, try reloading with a new suture. If the device is still ineffective, replace device.

FIG. 10 C1® PRODUCT ORDERING

SUPPLIED: STERILE

	REORDER	PRODUCT	DESCRIPTION
x 6	REF 022000	C1® SUTURING DEVICE (ANGLED SHAFT)	Box of 6 Devices
x 6	REF 022600	C1® SUTURING DEVICE (STRAIGHT SHAFT)	Box of 6 Devices
x 1	REF 022012	C1® DEPTH LIMITER	Box of 1 Device
x 12	REF 022295	LS-5™ ePTFE QUICK LOAD® SURGICAL SUTURE Monofilament, Non-Absorbable, 38"	Box of 12 Sutures (1 SUTURE per Pouch)
x 12	REF 021860	COR-SUTURE® QUICK LOAD® SURGICAL SUTURE 3-0 Polypropylene, Non-Absorbable, 53"	Box of 12 sutures (1 SUTURE per Pouch)
x 12	REF 021861	COR-SUTURE® QUICK LOAD® SURGICAL SUTURE 2-0 Polyester, White, Non-Absorbable, 38"	Box of 12 sutures (1 SUTURE per Pouch)
x 12	REF 021862	COR-SUTURE® QUICK LOAD® SURGICAL SUTURE 2-0 Polyester, Green, Non-Absorbable, 38"	Box of 12 sutures (1 SUTURE per Pouch)

LSI SOLUTIONS®

Patents: www.lsisolutions.com/patents

The LSI logo, LSI SOLUTIONS, C1, Cor-Suture, Quick Load, LS-5, Cor-Knot, Cor-Knot Mini, Mi-Knot, Intra-Knot and Perfect Performance Policy are trademarks and registered trademarks of LSI SOLUTIONS, Inc. Copyright © 2014, LSI SOLUTIONS®. All Rights Reserved.



Symbol Glossary: www.lsisolutions.com/symbols



LSI SOLUTIONS®
7796 Victor-Mendon Road
Victor, New York 14564 U.S.A.
Phone: 585.869.6600
Customer Service: 866.575.3493
Technical Support: 866.428.9092
Fax: 585.742.8086
www.lsisolutions.com

MADE IN THE USA

This Product Comes
with our LSI SOLUTIONS®
Perfect Performance Policy®
Call us at 866.575.3493 any time.