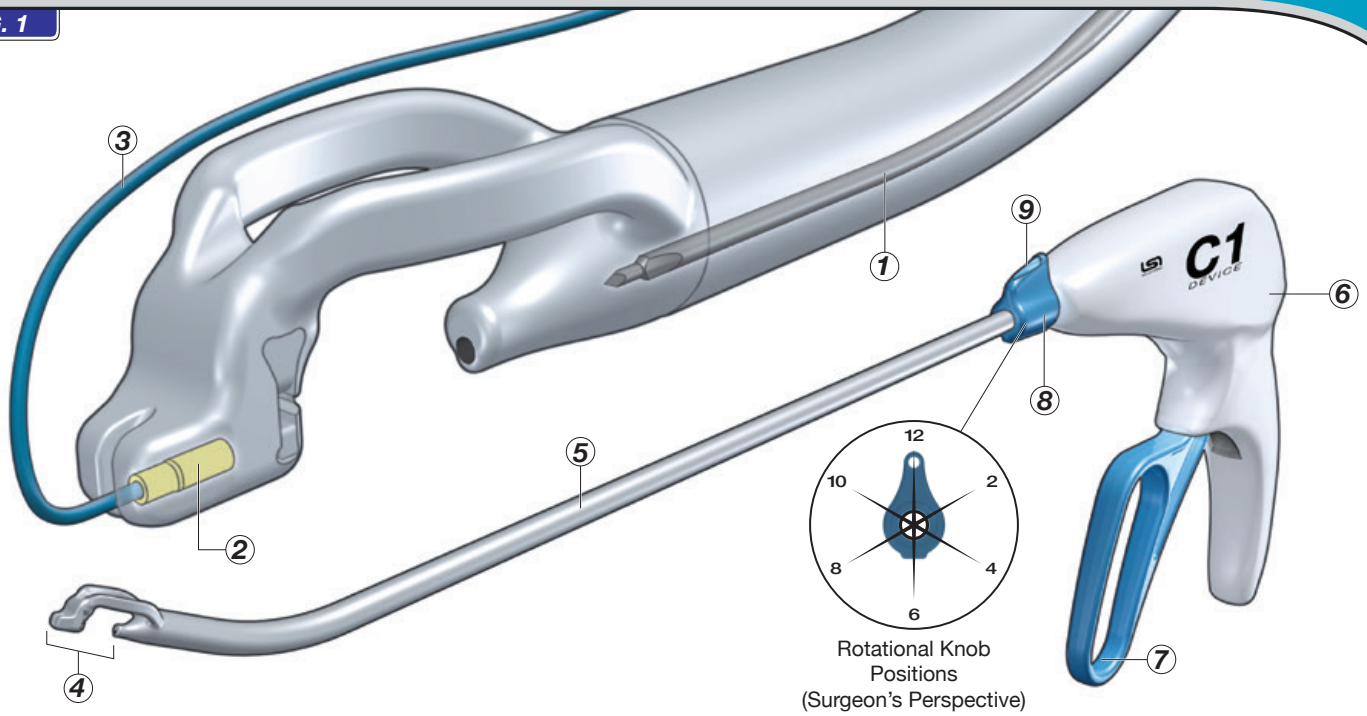
C1® TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



Rotational Knob Positions (Surgeon's Perspective)

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

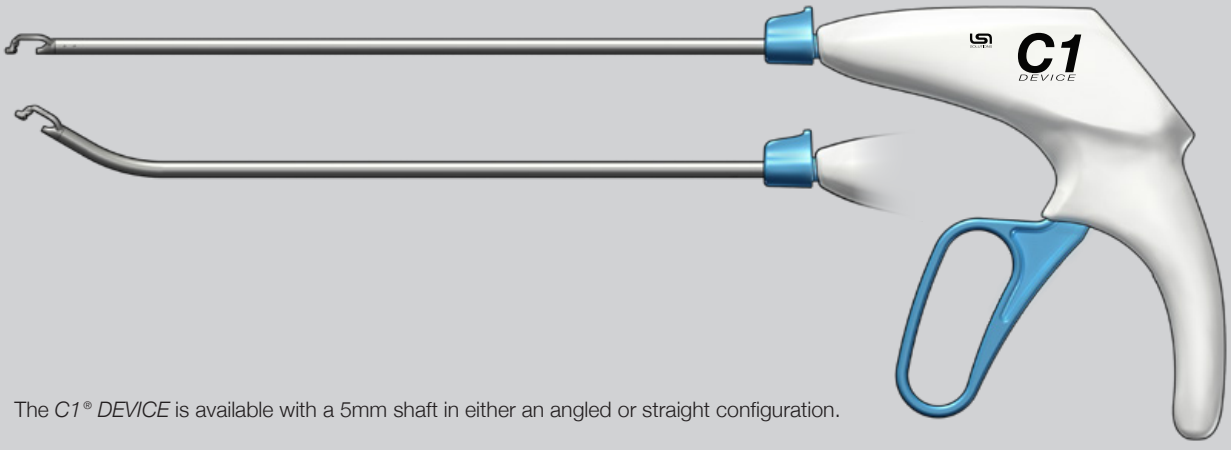
Each sterile package contains one (1) SINGLE PATIENT USE *C1*® suturing device available with an angled (FIG. 1) shaft or with a straight (Fig. 2) shaft. The *C1*® *DEVICE* is used for the placement of surgical suture as supplied in an appropriate *COR-SUTURE*® or *LS-5*™ ePTFE QUICK LOAD® surgical suture. 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.

LSSOLUTIONS®

FIG. 2

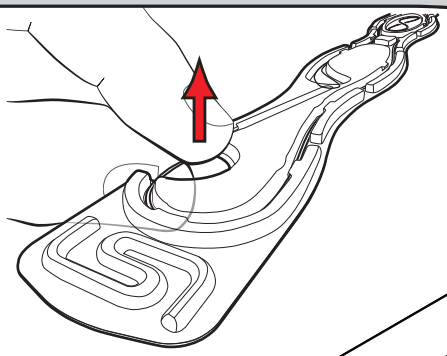


The *C1*® *DEVICE* is available with a 5mm shaft in either an angled or straight configuration.

LOADING SUTURE

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

FIG. 4



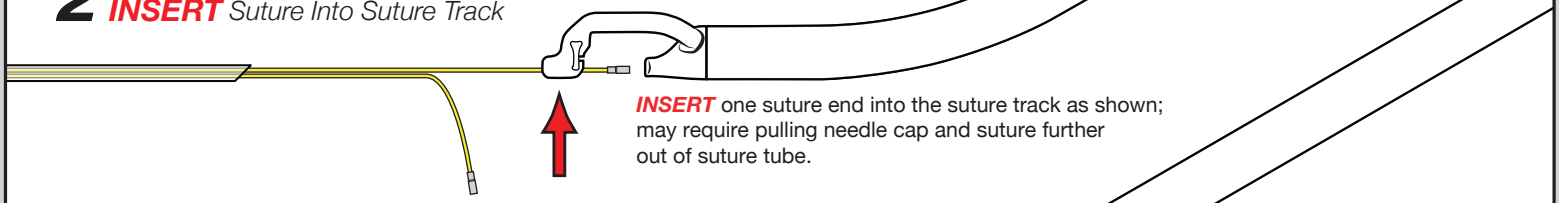
CAUTION: USE ONLY LSI SOLUTIONS *COR-SUTURE*® OR *LS-5*™ ePTFE QUICK LOAD® SURGICAL SUTURE WITH *C1*® *DEVICE*.

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.

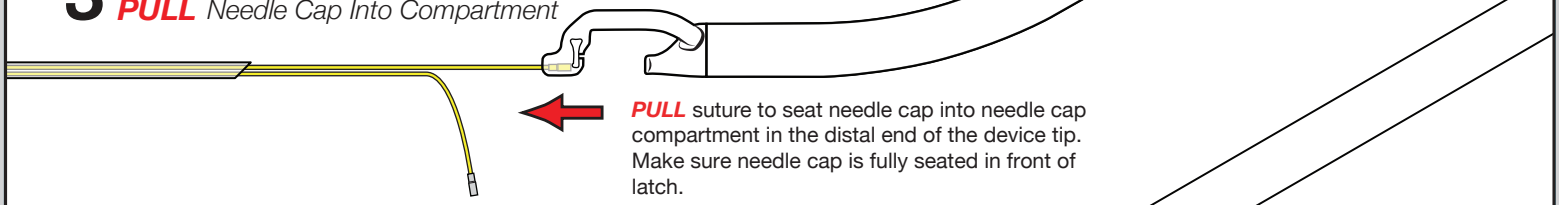
Straighten Tube

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.

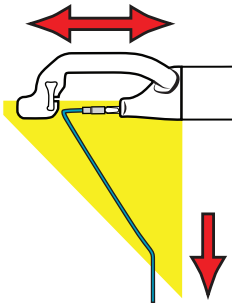
3 *PULL* Needle Cap Into Compartment



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*

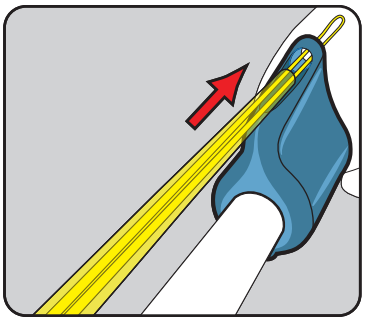
Orient Suture As Shown, Squeeze And Release Lever To Ensure Suture Is Ready In Distal End Of Device Tip



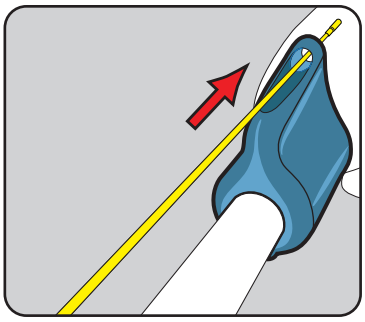
FIRE & REARM to ensure suture is loaded properly. To avoid jamming the needle cap into the needle cap compartment, orient the suture directly away from the jaw as shown. Squeeze the lever to advance the needle through the jaw and into the newly loaded needle cap. Release the lever to pick up and retract 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.

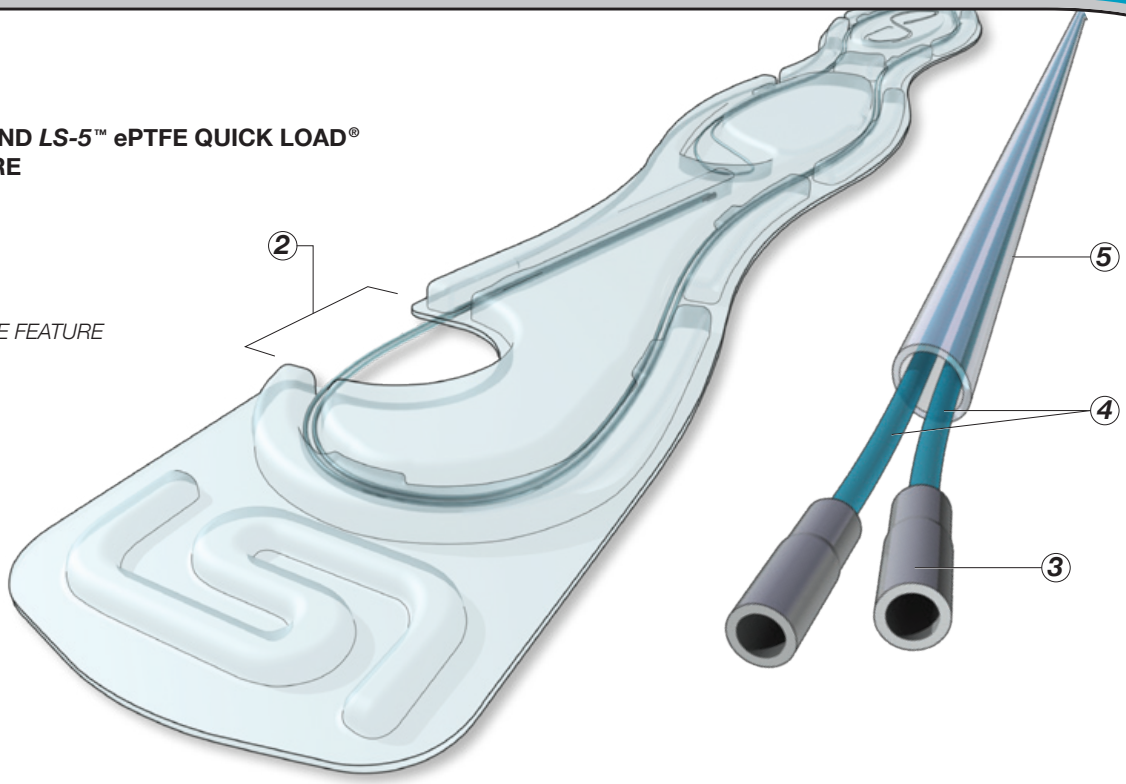


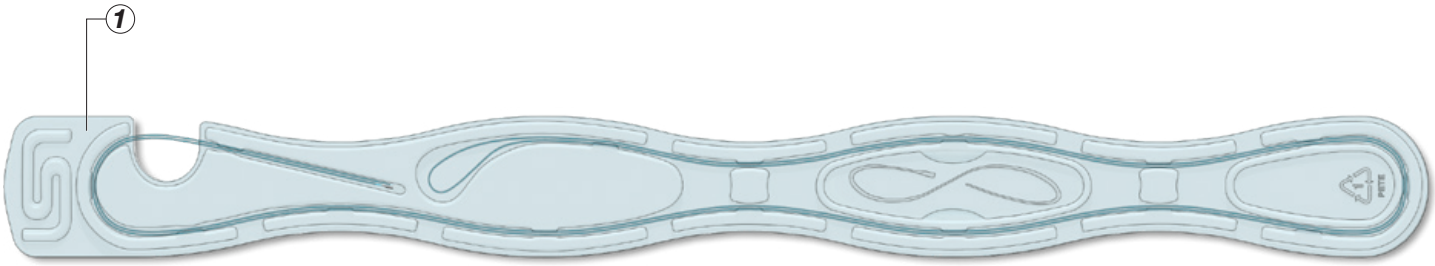
COR-SUTURE® AND *LS-5*™ ePTFE QUICK LOAD® SURGICAL SUTURE

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.

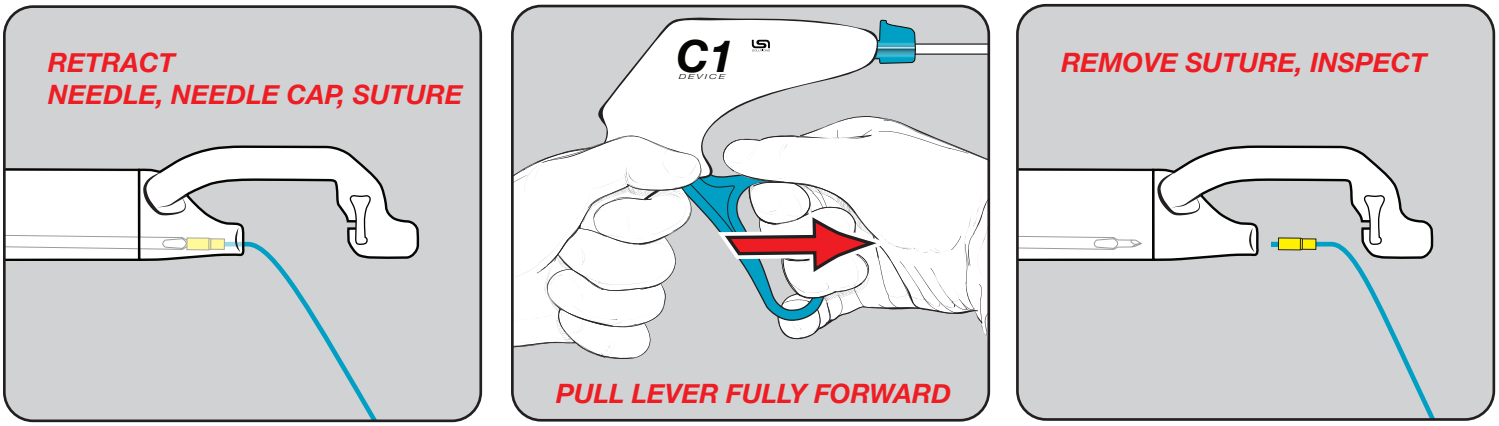
UNLOADING *C1® DEVICE*

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.

FIG. 5

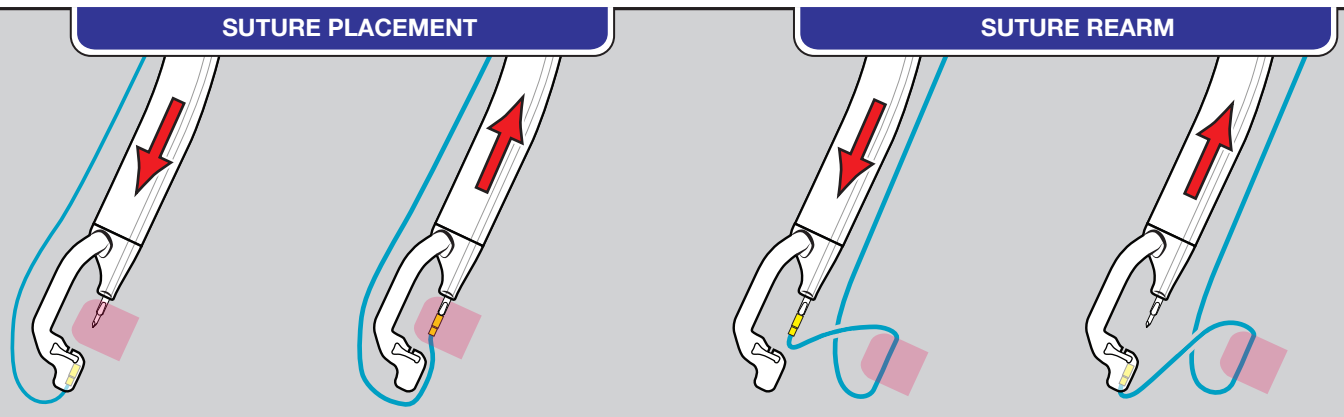
AUTO-RELEASE Technique *Retract Suture Back. Pull Lever Fully Forward. Remove Suture With Needle Cap.*



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



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 rearmed 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

- Minimally invasive surgical procedures should only be performed by physicians having adequate training and familiarity with minimally invasive techniques. In addition, medical literature should be consulted relative to techniques, complications and hazards prior to the performance of minimally invasive procedures.
- The *C1® DEVICE* is not intended to be used with any suture other than a *COR-SUTURE®* or *LS-5™* QUICK LOAD® surgical suture.
- Do not use this suture under conditions in which excessive suture tension can lead to tissue damage.

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 performance of the *C1® DEVICE* after cleaning or other reprocessing has not been verified and is not supported by LSI SOLUTIONS®.
- Discard open (unsealed), unused, expired or damaged devices or devices in damaged primary packaging.
- The *C1® DEVICE* will not fit through standard laparoscopic cannulas with seals.
- 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 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.
- The *C1® DEVICE* is not for use in neurological procedures.
- Applications other than for soft tissue closure, or to anchor prosthetic materials, 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 or other instruments.
- Do not leave any foreign material (e.g. suture remnant, needle cap, etc.) unattached in areas potentially exposed to circulating blood.
- If securing the *COR-SUTURE®* or *LS-5™* QUICK LOAD® surgical suture with any LSI SOLUTIONS® *COR-KNOT® DEVICE (COR-KNOT® MIS DEVICE, COR-KNOT MINI® DEVICE)*, or *Mi-KNOT™ DEVICE* ensure any needle caps are removed from the suture ends being loaded, prior to loading the suture through the *COR-KNOT® DEVICE*.

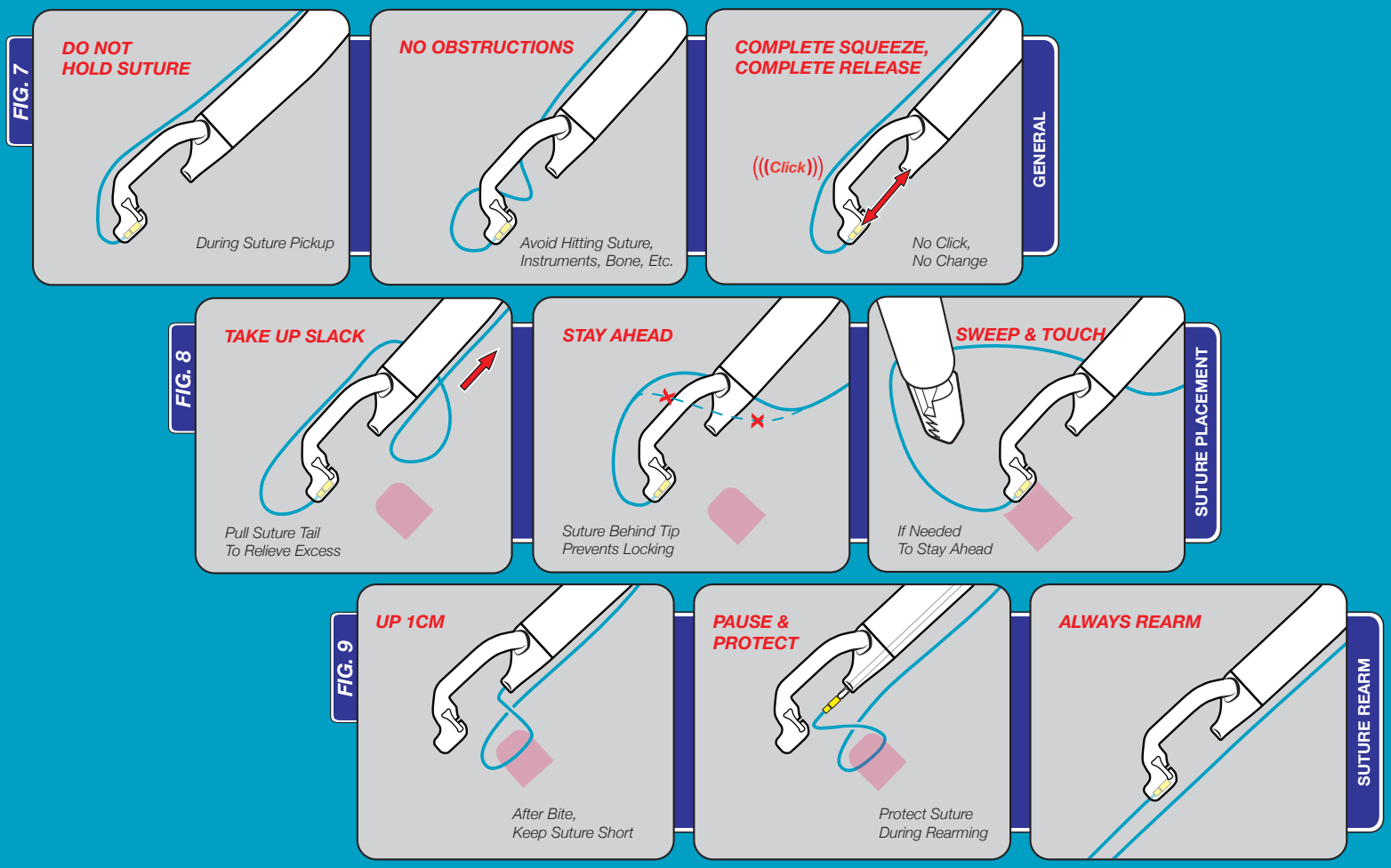
PRECAUTIONS

- Check for hemostasis or leakage where appropriate.
- Always assure device tip is viewed under direct visualization before advancing the needle.
- Ensure obstructions do not interfere with the movement of the needle of *C1®*.
- Do not squeeze the blue lever of the *C1® DEVICE* while loading a surgical suture; squeezing the blue lever may expose the sharp needle and/or damage the needle.
- 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 needle, suture or needle caps due to direct application of surgical instruments, like forceps, needle holders, clamps, etc.
- Adequate knot security requires accurate completion of accepted surgical techniques for constructing surgically tied knots or the use of the *COR-KNOT® MIS DEVICE, COR-KNOT MINI® DEVICE,* and *COR-KNOT®* QUICK LOAD® UNIT or *INTRA-KNOT®* QUICK LOAD® UNIT or *Mi-KNOT™ DEVICE* as warranted by surgical circumstances and the experience of the surgeon.
- Before instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that mechanical function and electrical isolation and 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 used needle caps 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 5) 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.
- 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.
- Ensure the advancing needle targets and enters the needle cap compartment. For example, during the suture placement, avoid using an extended needle to manipulate or lift tissue because such an action can cause the needle to deviate from its targeted course toward the needle cap compartment. A needle tip, not entering the needle cap compartment properly, can strike the distal tip of the device and lead to undesired outcomes, including needle tip fracture. For another example, during suture rearm, avoid applying tension to the suture from the needle cap on the needle. Tension on the suture can cause the needle to deviate off target and lead to the needle cap possibly striking the distal tip, which can cause needle tip fracture.
- Turning the rotational knob while squeezing the blue lever may damage tissue, and/or the *C1® DEVICE* and suture.

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 (Non-Sterile)*
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 Polyproylene, 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)*

P/N 021828C 05.23.18

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