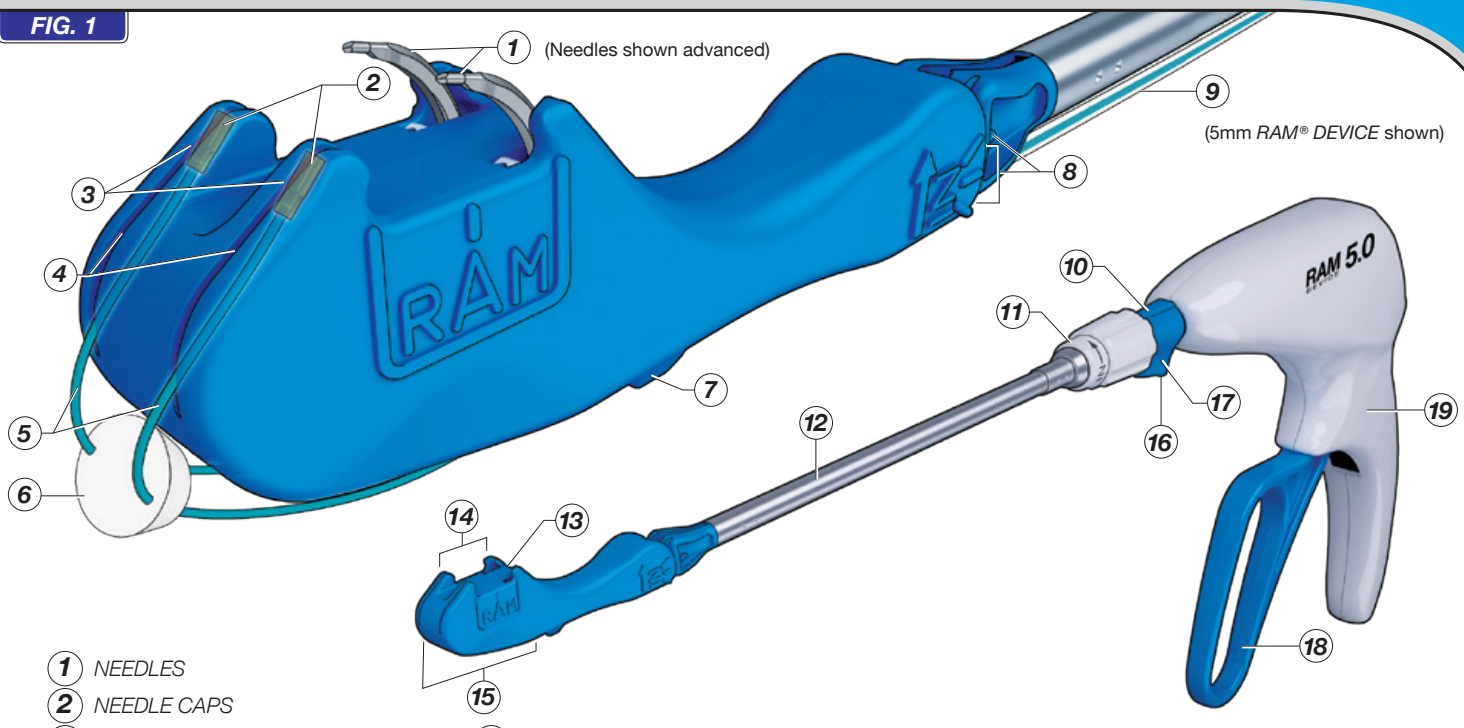
RAM® TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



1. *NEEDLES*
2. *NEEDLE CAPS*
3. *NEEDLE CAP COMPARTMENTS*
4. *SUTURE SLOTS*
5. *SUTURE*
6. *PLEDGET (OPTIONAL)*
7. *FIRST SUTURE TUBE HOLDER*
8. *ARTICULATING LIMIT INDICATOR*
9. *SUTURE TUBE*
10. *ROTATIONAL KNOB*
11. *ARTICULATION KNOB*
12. *SHAFT*
13. *RECEIVING NOTCH*
14. *TISSUE JAW*
15. *DEVICE TIP*
16. *SECOND SUTURE TUBE HOLDER*
17. *INDICATOR FIN*
18. *BLUE LEVER*
19. *WHITE HANDLE*

RAM® *DEVICE* - DESCRIPTION

Each kit contains two (2) sterile SINGLE PATIENT USE *RAM*® suturing devices (*FIG. 1*). The *RAM*® *DEVICE* is used for the placement of *RAM*® *COR-SUTURE*® QUICK LOAD® surgical suture (5). A short length of modified surgical stainless steel tubing, called a needle cap (2), is attached to each end of the suture. The needle caps are loaded into the needle cap compartments (3) in the device tip (15). Suture placement (*FIG. 2*) is achieved by sequentially squeezing and releasing the blue lever (18). During suture placement, squeezing of the blue lever advances the retracted needles (1) through the tissue which is placed in the tissue gap or tissue jaw (14) of the device tip; the full squeeze advances the needles into the needle caps which are attached to the suture ends. Release of the blue lever retracts the needles, which pulls the engaged needle caps and suture coupled to the needle caps, back through the tissue. The orientation of the device tip is set by rotating the articulation knob (11), and/or the rotational knob (10). The rotational knob, which has six distinct positions, and an indicator fin (17), may be turned to rotate the device shaft (12) and therefore the device tip at the end of the shaft. The angle of the device tip relative to the shaft may be adjusted by rotating the articulation knob. The device tip may be articulated within a range demarked by the articulating limit indicator (8). First and second suture tube holders (7), (16) are provided on the device tip and indicator fin for securing a suture tube (9) which comes preinstalled on the suture to assist with suture management. The *RAM*® *DEVICE* is available in two (2) sizes for suture spacings (the distance between needles): 3.5mm and 5mm. Refer to Product Ordering chart on Page 6.

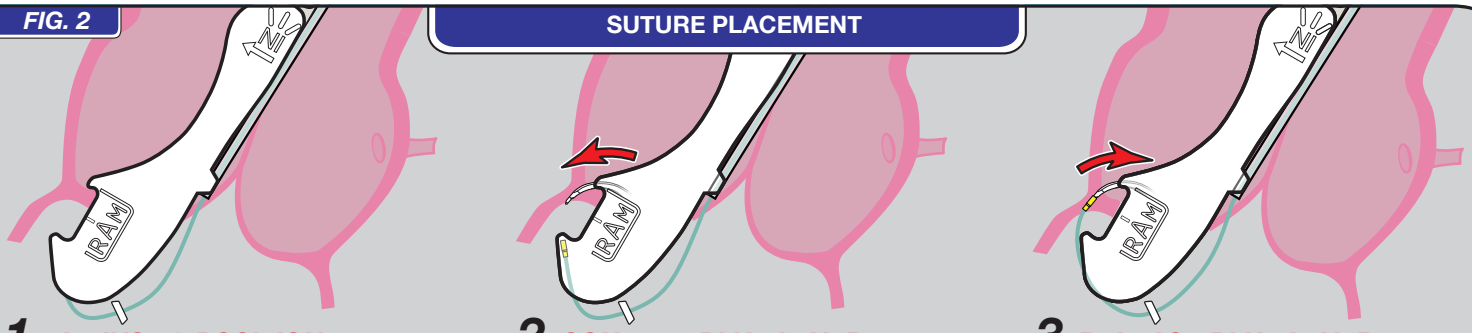
INDICATIONS

The *RAM*® *DEVICE* used in conjunction with *RAM*® *COR-SUTURE*® QUICK LOAD® surgical suture is indicated for use in the approximation of soft tissue and prosthetic materials.

LSI SOLUTIONS®

FIG. 2

SUTURE PLACEMENT



1 *ADJUST & POSITION*
device tip into proper orientation using articulation knob and rotational knob, and hold tissue jaw firmly against target.

2 *SQUEEZE BLUE LEVER*
to advance needles forward through tissue, hold and then remove suture tube from suture.

3 *RELEASE BLUE LEVER*
to retract needles with needle caps and suture back through tissue.

CAUTION: Before pulling away from tissue, ensure needles are fully retracted.

RAM® COR-SUTURE® QUICK LOAD® SURGICAL SUTURE

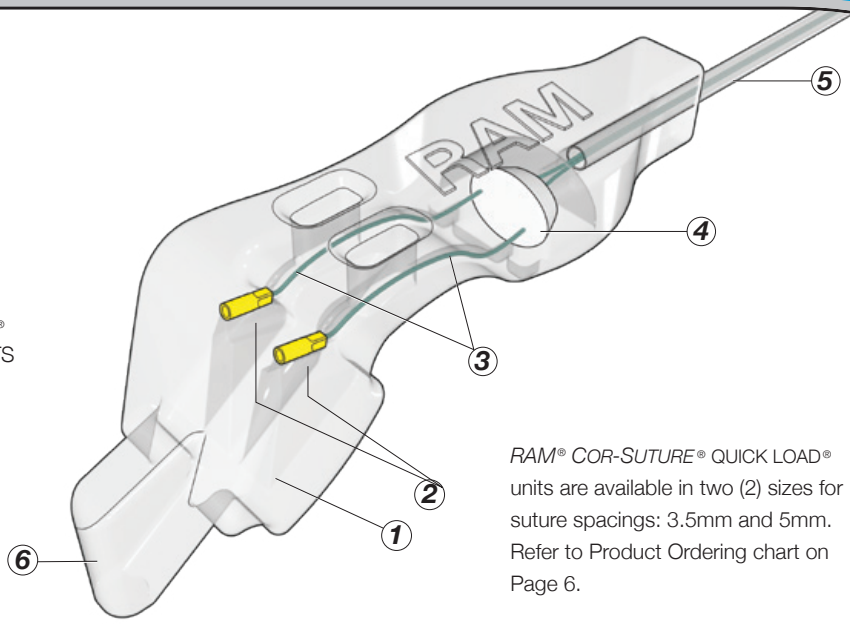
FIG. 3

***RAM® COR-SUTURE®* QUICK LOAD® SURGICAL SUTURE**

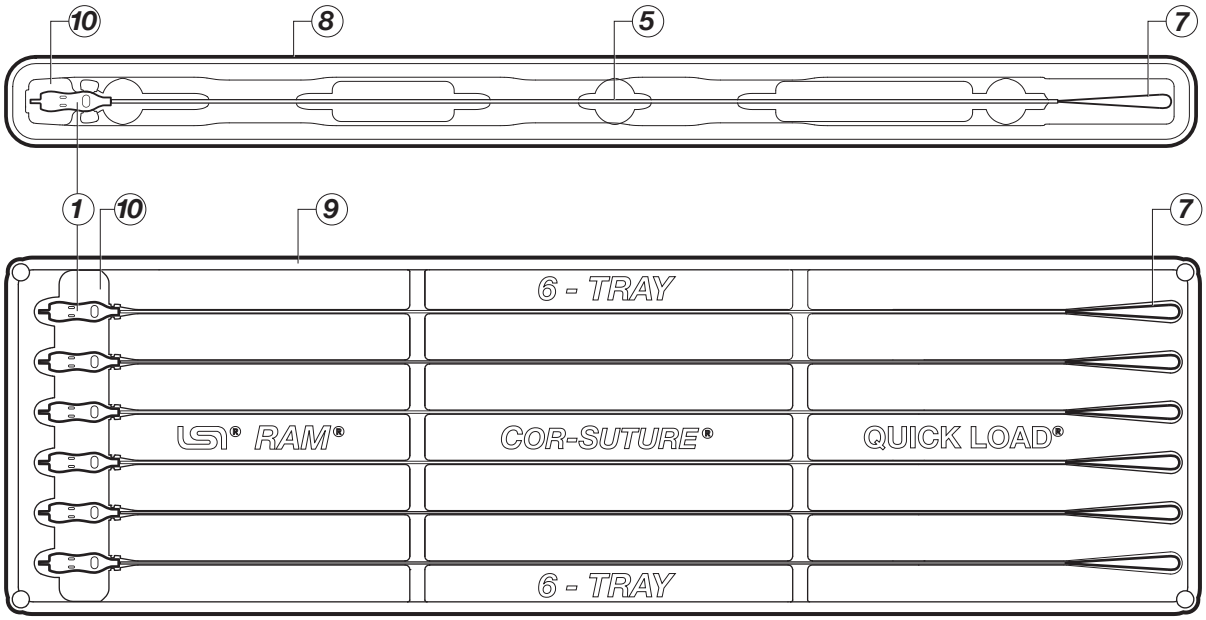
1. *NEEDLE CAP HOLDER*
2. *NEEDLE CAPS*
3. *SUTURE*
4. *PLEDGET (OPTIONAL)*
5. *SUTURE TUBE*
6. *ALIGNMENT TAB*
7. *SUTURE LOOP*

QUICK LOAD® COMPONENTS

8. QUICK LOAD® *SINGLE SUTURE TRAY*
9. QUICK LOAD® *6-TRAY*
10. QUICK LOAD® *RELEASE FEATURE*



RAM® COR-SUTURE® QUICK LOAD® units are available in two (2) sizes for suture spacings: 3.5mm and 5mm. Refer to Product Ordering chart on Page 6.



DESCRIPTION

RAM® COR-SUTURE® QUICK LOAD® sterile surgical suture is packaged for single patient use and is provided in a customized tray as a QUICK LOAD® Single suture tray (8), or as a QUICK LOAD® 6-TRAY (9) with a QUICK LOAD® release feature (10). Each QUICK LOAD® suture is designed to enable the rapid, easy and reliable loading of suture into an LSI SOLUTIONS® *RAM®* suturing device. The QUICK LOAD® suture (3) is available as a non-absorbable braided polyester surgical suture. A short length of modified surgical stainless steel tubing, called a needle cap (2), is attached to each end of the suture. An optional PTFE pledget (4) is attached behind the needle caps. The QUICK LOAD® suture also includes a detachable clear suture tube (5) to keep the suture from tangling, and a needle cap holder (1) that allows rapid and easy loading into a *RAM® DEVICE.* The QUICK LOAD® surgical suture is offered undyed (white), dyed green with the FDA approved colorant D&C Green No. 6, or striped green/white. There is no known significant change in tensile strength retention to occur in vivo. The QUICK LOAD® surgical suture is MR safe.

INDICATIONS

RAM® COR-SUTURE® QUICK LOAD® surgical suture is indicated for use in the approximation of soft tissue and prosthetic materials.

LSI SOLUTIONS®

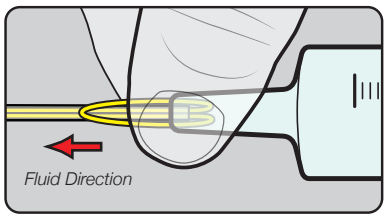
LOADING SUTURE

CAUTION: Use the 3.5mm *RAM® COR-SUTURE®* QUICK LOAD® surgical suture only with 3.5mm *RAM® devices*, and use 5mm *RAM® COR-SUTURE®* QUICK LOAD® surgical suture only with 5mm *RAM® devices.* To avoid accidental needle exposure, DO NOT squeeze lever during suture loading.

FIG. 4

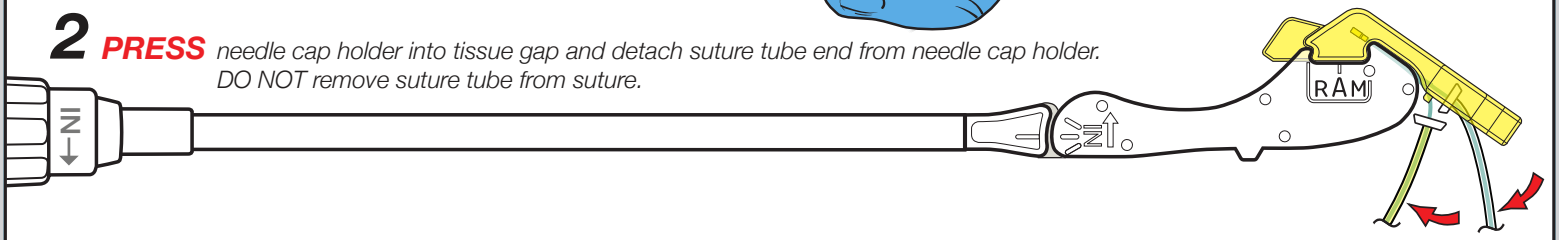
MOISTEN SUTURE

Fold suture loop over end of suture tube and insert suture tube end into syringe tip. While grasping syringe tip and suture tube, infuse normal saline to optimize suture pay out.

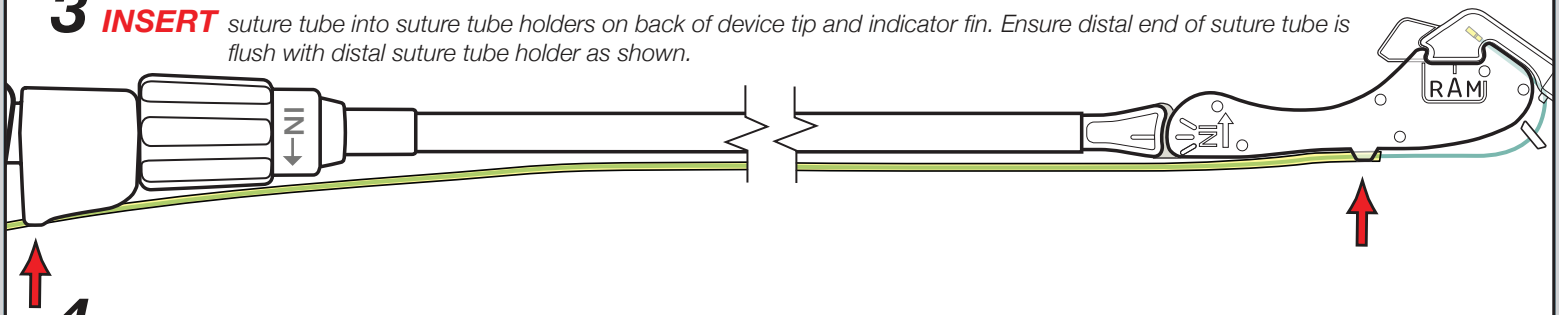


1 ENSURE *device tip is in neutral position as shown. While holding the RAM® DEVICE at distal end of shaft, position needle cap holder over RAM® DEVICE tissue gap, and align alignment tab with receiving notch of the device tip.*

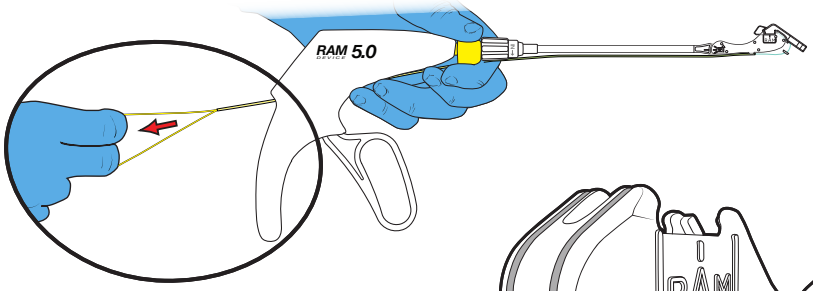
2 PRESS *needle cap holder into tissue gap and detach suture tube end from needle cap holder. DO NOT remove suture tube from suture.*



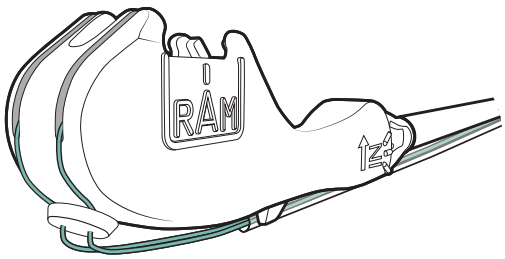
3 INSERT *suture tube into suture tube holders on back of device tip and indicator fin. Ensure distal end of suture tube is flush with distal suture tube holder as shown.*



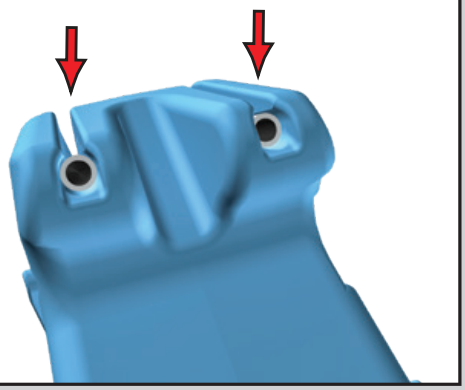
4 HOLD *the suture tube at the indicator fin with a finger and pull suture loop in the direction of the red arrow by placing two fingers in the suture loop to load needle caps into needle cap compartments and secure suture in suture slots. Watch suture to confirm movement. Rock the two fingers in the loop while pulling.*



5 REMOVE *the needle cap holder.*



6 CONFIRM *both needle caps are fully seated in their needle cap compartments and suture is secured in suture slots. If the needle caps are not fully seated, follow the alternative loading procedure in FIG. 5.*



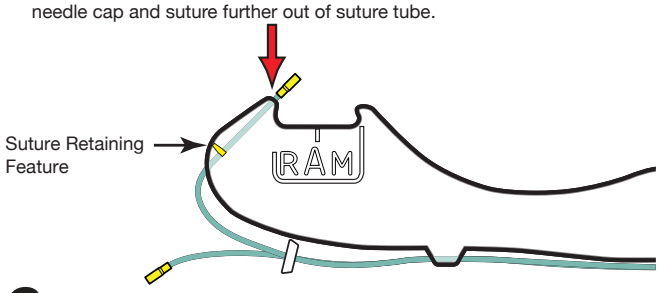
LOADING SUTURE WITHOUT A NEEDLE CAP HOLDER AND/OR SUTURE TUBE

FIG. 5

If needed, suture can be loaded without the use of a needle cap holder and/or a suture tube.

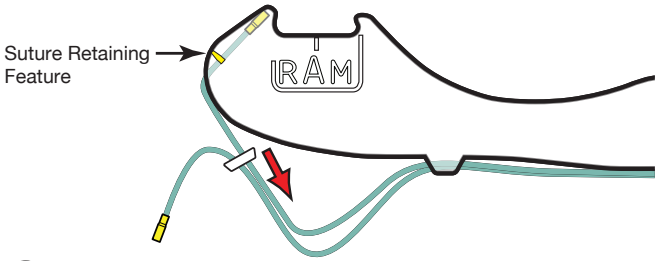
1 ***INSERT*** *suture into suture slot.*

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

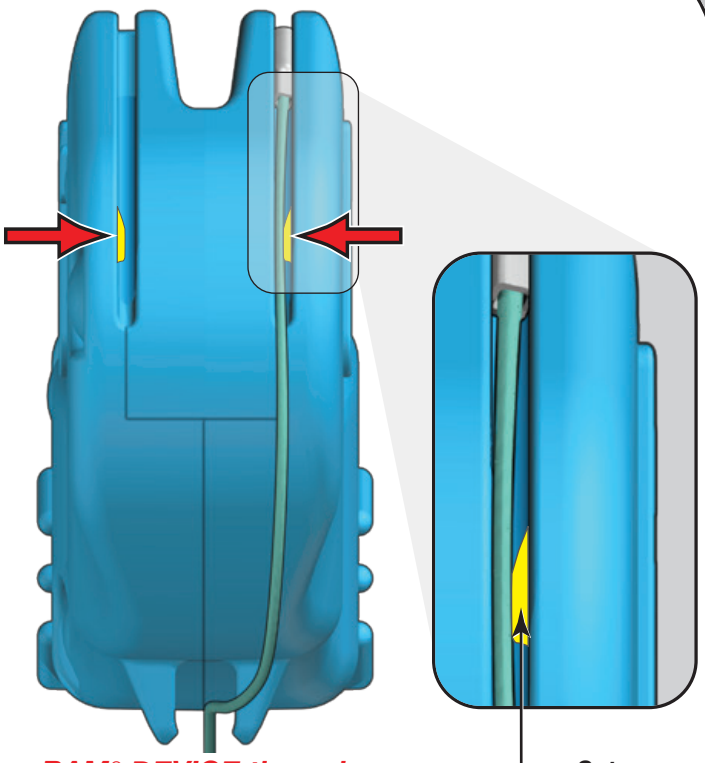


2 ***PULL*** *needle cap into needle cap compartment.*

Wrap suture around device tip, ensuring suture is in suture slot, and ***PULL*** suture in the direction indicated to secure needle cap into needle cap compartment and retain suture in suture slot in the end of the device tip (see end view to the right). It may help to guide the needle cap with a finger. **MAKE SURE NEEDLE CAP IS FULLY SEATED IN NEEDLE CAP COMPARTMENT AND MAKE SURE SUTURE IS RETAINED IN SUTURE SLOT.**



3 ***LOAD*** *second suture end and needle cap into the other suture slot and needle cap compartment as in steps 1 and 2.*

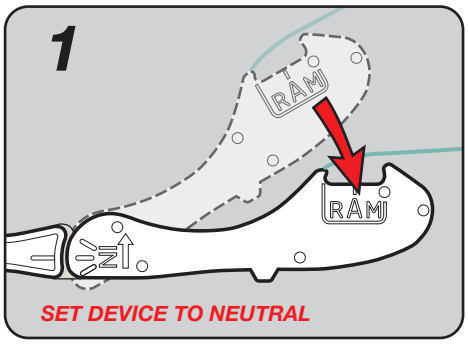


RAM® DEVICE tip end view showing green suture compressed by suture retaining feature (red arrows).

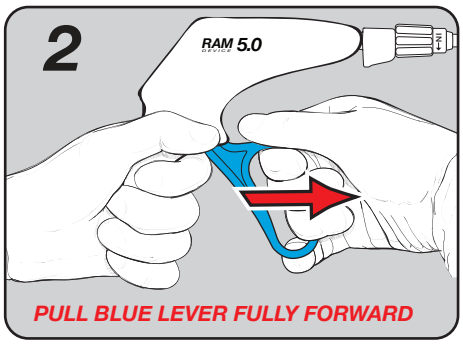
UNLOADING SUTURE

FIG. 6

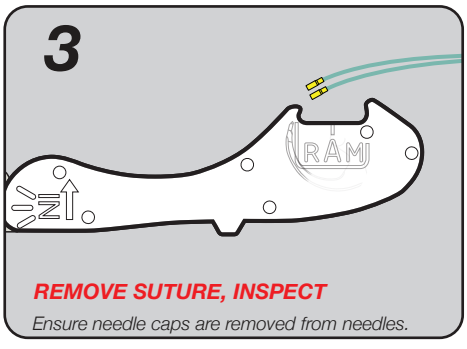
AUTO-RELEASE Technique



SET DEVICE TO NEUTRAL



PULL BLUE LEVER FULLY FORWARD



REMOVE SUTURE, INSPECT

Ensure needle caps are removed from needles.

This unloading technique requires that the needles with their engaged needle caps and suture must first be retracted back into the device tip. Once the needles, needle caps, and suture ends are retracted into the device tip, use the articulating knob to return the device tip to a neutral position. Then, pull the blue lever fully forward to automatically release the needle caps and suture from the needles. Inspect the needle caps and suture to ensure needle caps are removed from needles.

ACTIONS

The *RAM® DEVICE* facilitates the placement of multiple sutures through tissue and prostheses. *RAM® COR-SUTURE®* QUICK LOAD® brand suture can be loaded into the device tip with or without assistance of a *RAM® COR-SUTURE®* QUICK LOAD® device. The suture has needle caps on its ends which are held by needle cap compartments in the device tip. The operator has several options to select a desired device tip orientation. The rotational knob may be turned to rotate the device tip along with the device shaft. The angle of the device tip relative to the shaft may be adjusted by rotating the articulation knob. The white handle may also be used to manipulate the device tip to present an appropriate tissue structure into the tissue jaw of the device tip of the *RAM® DEVICE*. During suture placement, the blue lever is squeezed towards the white handle to advance the retracted needles through the tissue in the tissue jaw to engage corresponding needle caps. The tips of the needles capture the needle caps with their attached suture. Releasing the blue lever retracts the needles with attached needle caps and suture back through the tissue. With the device tip removed from the targeted tissue site, the blue lever is pulled away from the white handle to auto-release the needle caps from the needles. The *RAM® DEVICE* can be loaded with another *RAM® COR-SUTURE®* QUICK LOAD® surgical suture, and the sequence can be repeated up to 12 sutures per device. Each suture must only be fired one time by the *RAM® DEVICE.*

CONTRAINDICATIONS

- The *RAM® DEVICE* used in conjunction with *RAM® COR-SUTURE®* QUICK LOAD® surgical suture is contraindicated for use in ophthalmic and neurologic surgery.
- The *RAM® DEVICE* is not intended to be used with any suture other than a *RAM® COR-SUTURE®* QUICK LOAD® surgical suture.

WARNINGS

- Federal law restricts this device to sale, distribution and use by, or on, the order of a physician.
- Minimally invasive surgical procedures should only be performed by physicians having adequate training and familiarity with endoscopic techniques. In addition, medical literature should be consulted relative to techniques, complications and hazards prior to the performance of surgical procedures.
- 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.
- **Do not resterilize.** The *RAM® DEVICE* is designed and intended for single patient use only. Do not reuse, reprocess, or resterilize this product. The performance of the *RAM® DEVICE* after cleaning or other reprocessing has not been verified and is not supported by LSI Solutions, Inc. Reuse, reprocessing, or resterilization may compromise the integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Discard open (unsealed), unused, expired or damaged devices or devices in damaged primary packaging.
- Store at room temperature. Avoid prolonged exposure to elevated temperatures.
- Users should be familiar with surgical procedures and techniques involving surgical suture before employing the *RAM® DEVICE*, as the risk of wound dehiscence may vary with the site of application and the suture material used.
- Acceptable surgical practice must be followed with respect to drainage and closure of contaminated or infected wounds.
- Redundant, cut-away suture remnants, used needle caps and *RAM® devices*, along with packaging, must be inspected, handled and disposed of consistent with standard, accepted medical device disposal 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.
- The *RAM® DEVICE* is not intended for use in prosthetic materials through which the device needles cannot readily penetrate, based on the surgeon's judgment.
- Never drive the needle into suture, pledgets, bone, dense ligamentous tissue, severely calcific tissue or other instruments.
- Do not drive needles through tissue while needle caps are on needles. To avoid tissue damage, ensure needle caps are within the needle cap compartments by visualizing the device tip under open direct or video-enhanced endoscopic visualization prior to suture placement.
- 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 *RAM® DEVICE*.
- Place the *RAM® DEVICE* tip firmly against the target tissue. Failure to do so can result in inadequate tissue bite depth.
- If securing the *RAM® COR-SUTURE®* QUICK LOAD® suture with any LSI SOLUTIONS® *COR-KNOT® DEVICE (COR-KNOT® MIS DEVICE, COR-KNOT MINI® DEVICE)*, ensure both needle caps are removed from the suture, prior to loading the suture ends through the *COR-KNOT® DEVICE*.
- After placing a stitch with the *RAM® DEVICE*, ensure that both suture lengths traverse the tissue. Failure to do so can result in insufficient attachment of suture.
- Do not squeeze the blue lever of the *RAM® DEVICE* without suture loaded into the needle cap compartments; squeezing the blue lever may expose the sharp needles, damage the needles and/or damage the device tip.
- Do not use this suture under conditions in which excessive suture tension can lead to tissue damage.

PRECAUTIONS

- 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 is not compromised.
- Ensure that 3.5mm *RAM® COR-SUTURE®* QUICK LOAD® surgical suture is only used with 3.5mm *RAM®* devices. Similarly, ensure that 5mm *RAM® COR-SUTURE®* QUICK LOAD® surgical suture is only used with 5mm *RAM®* devices.
- 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 *RAM® DEVICE* lever to advance the needles, always ensure that proper insufflation is achieved and the device tip location is adequately visualized.
- Failure to directly visualize or image the device can result in damage to the tissue.
- Ensure that obstructions do not interfere with the firing of a *RAM® DEVICE*; obstruction may cause needle damage or breakage.
- Do not squeeze the blue lever of the *RAM® DEVICE* while loading a *RAM® COR-SUTURE®* QUICK LOAD® suture; squeezing the blue lever may expose the sharp needles, damage the needles and/or damage the device tip.
- In handling the *RAM® DEVICE*, care should be taken to avoid jamming the suture into the needle cap compartment and damaging the needle.
- Do not fire the *RAM® DEVICE* after initial needle cap pickup, without first removing needle caps and loading a new suture.
- Avoid damage to the needles, suture or needle caps due to direct application of surgical instruments, like forceps, needle holders, clamps, etc.
- If suture placement is ineffective, try reloading with a new suture and confirm that needle tips are properly aimed at the needle caps by partially squeezing and observing that needle tips are entering needle caps. If a tip of a needle is bent or misaligned, then replace the device.
- Adequate knot security requires accurate completion of accepted surgical techniques for constructing surgically tied knots or the use of the *COR-KNOT® MIS DEVICE or, COR-KNOT MINI® DEVICE,* along with the *COR-KNOT®* QUICK LOAD® *DEVICE* or *INTRA-KNOT®* QUICK LOAD® *DEVICE* as warranted by surgical circumstances and the experience of the surgeon.
- Before loading the *RAM® DEVICE* with another *RAM® COR-SUTURE®* QUICK LOAD® suture, assure the remaining suture and needle caps from the previous load have been completely removed from the needles and needle cap compartments. Failure to appropriately remove used needle caps from the needles 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, carefully inspect that the new needle caps are fully seated in the needle cap compartment (see *FIG. 1 and FIG. 4, Step 6*). If the needle caps are not fully seated in the needle cap compartment, damage to the needles or needle caps may result, including fracturing off of the tips of the needles.
- Do not use the *RAM® DEVICE* to dissect or aggressively manipulate tissue structures.
- Verify that the needle caps are still fully seated within the needle cap compartment and the device has not been damaged or deformed before attempting to place a suture.
- Do not manipulate the device at any time with the blue lever partially actuated, which may expose sharp surfaces that can cause injury to the patient, the device operator or other staff, or damage to the prosthesis or the device. Do not apply surgical instruments to *RAM®* needles or needle caps.
- Ensure the advancing needles enter the needle cap compartments. During suture placement, avoid using advanced needles 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.
- To avoid inadvertent suture damage, ensure that the needle caps always enter the needle cap compartments with the suture ends oriented to freely pass through the needle cap compartment's suture channel. Do not use damaged suture.
- The *RAM® DEVICE* is compatible with minimally invasive access devices, such as cannulas and trocars, that are capable of accommodating instruments 15 mm in diameter.

ADVERSE REACTIONS

Adverse effects associated with the use of the *RAM® DEVICE* include wound and/or prosthetic dehiscence, failure to provide adequate wound support in closure of sites where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, 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 at the wound site.

LSI SOLUTIONS®

Patents: www.lsisolutions.com/patents

STERILE EO | Rx Only | MD | MR | CE 0344

Symbol Glossary: www.lsisolutions.com/symbols

EC REP

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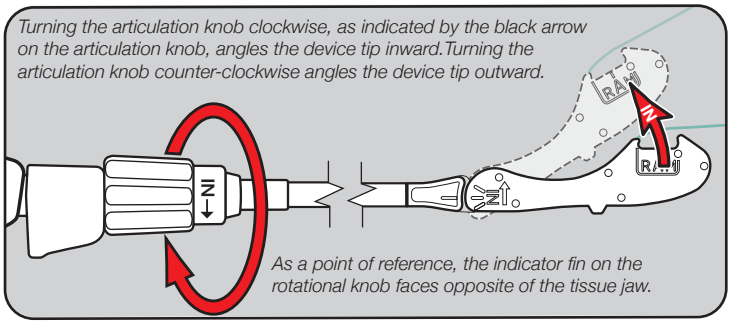
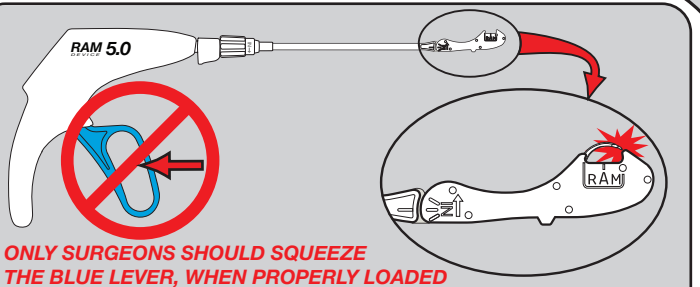
RAM® TECHNIQUE PEARLS

FIG. 7

Turning the articulation knob clockwise, as indicated by the black arrow on the articulation knob, angles the device tip inward.Turning the articulation knob counter-clockwise angles the device tip outward.

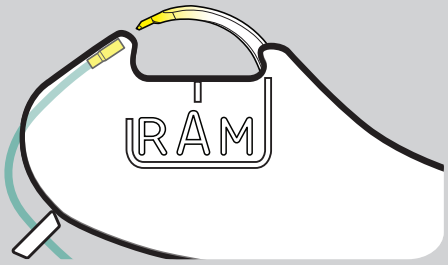


As a point of reference, the indicator fin on the rotational knob faces opposite of the tissue jaw.



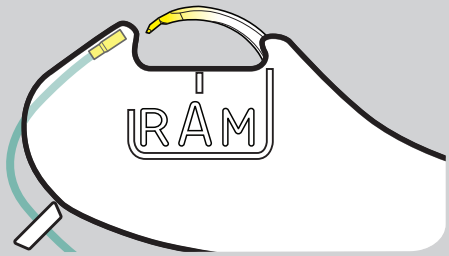
ONLY SURGEONS SHOULD SQUEEZE THE BLUE LEVER, WHEN PROPERLY LOADED WITH SUTURE, UNLESS TESTING THE DEVICE

ALIGNED NEEDLE: CORRECT

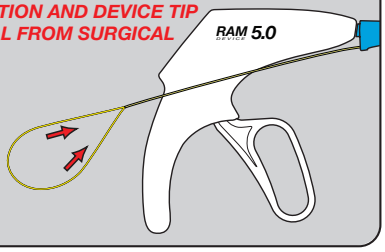


If suture placement is ineffective, try reloading with a new suture and confirm that needle tips are properly aimed at the needle caps by partially squeezing lever, and observing that needle tips are entering needle caps. If the device is still ineffective, replace the device.

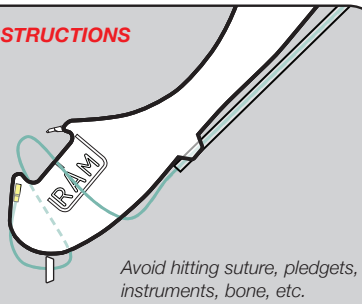
BENT NEEDLE: REPLACE DEVICE



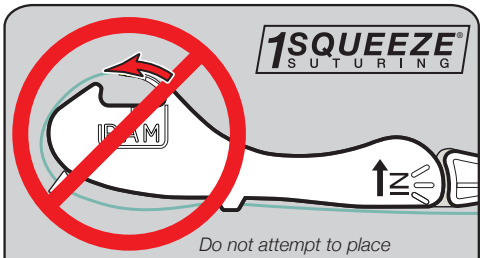
ENSURE SUTURE PAYOUT IS NOT OBSTRUCTED DURING NEEDLE ENGAGEMENT AND RETRACTION AND DEVICE TIP REMOVAL FROM SURGICAL SITE



NO OBSTRUCTIONS



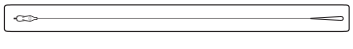
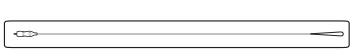
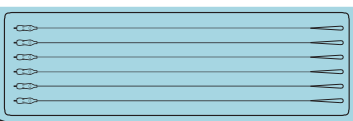
Avoid hitting suture, pledgets, instruments, bone, etc.



Do not attempt to place needle caps back into needle cap compartments using needles.

FIG. 8 PRODUCT ORDERING

SUPPLIED: STERILE

	REORDER 3.5MM SPACING	REORDER 5MM SPACING	PRODUCT	DESCRIPTION
 x 6	REF 021900	REF 022580	***RAM® DEVICE***	*Box of 6 Kits (2 Devices per Kit)*
 x 6	REF 022200	REF 022797	***SEW-EASY® COMBO KIT***	*Box of 6 Kits (2 Devices, Various Valve Handles, and 12 Cassettes per Kit)*
 x 6	REF 022201	REF 022804	***SEW-EASY® DEVICE KIT***	*Box of 6 Kits (2 Devices and Various Valve Handles per Kit)*
 x 12	REF 022160	REF 022811	***SEW-EASY® CASSETTES***	*Box of 12 Cassettes (1 Cassette per Pouch)*
 x 12	REF 022540*		***SEW-EASY® SNARE***	*Box of 12 Snares (1 Snare per Pouch)*
 x 12	REF 022039 PLEDGETED REF 022325 NON-PLEDGETED	REF 022668 PLEDGETED REF 022680 NON-PLEDGETED	***RAM® COR-SUTURE® QUICK LOAD® SINGLES*** **2-0 Polyester, Green, Non-Absorbable, 38”**	*Box of 12 Sutures (1 Suture per Pouch)*
 x 12	REF 022047 PLEDGETED REF 022320 NON-PLEDGETED	REF 022671 PLEDGETED REF 022683 NON-PLEDGETED	***RAM® COR-SUTURE® QUICK LOAD® SINGLES*** **2-0 Polyester, White, Non-Absorbable, 38”**	*Box of 12 Sutures (1 Suture per Pouch)*
 x 12	REF 022335 PLEDGETED REF 022340 NON-PLEDGETED	REF 022674 PLEDGETED REF 022686 NON-PLEDGETED	***RAM® COR-SUTURE® QUICK LOAD® SINGLES*** **2-0 Polyester, Green/White Striped, Non-Absorbable, 38”**	*Box of 12 Sutures (1 Suture per Pouch)*
 x 6	REF 022090	REF 022677	***RAM® COR-SUTURE® QUICK LOAD® 6-TRAY*** **Pledgeted 2-0 Polyester, Green (3) and White (3), Non-Absorbable, 38”**	*Box of 6 Trays (6 Sutures per Tray)*

***Not CE Marked**

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