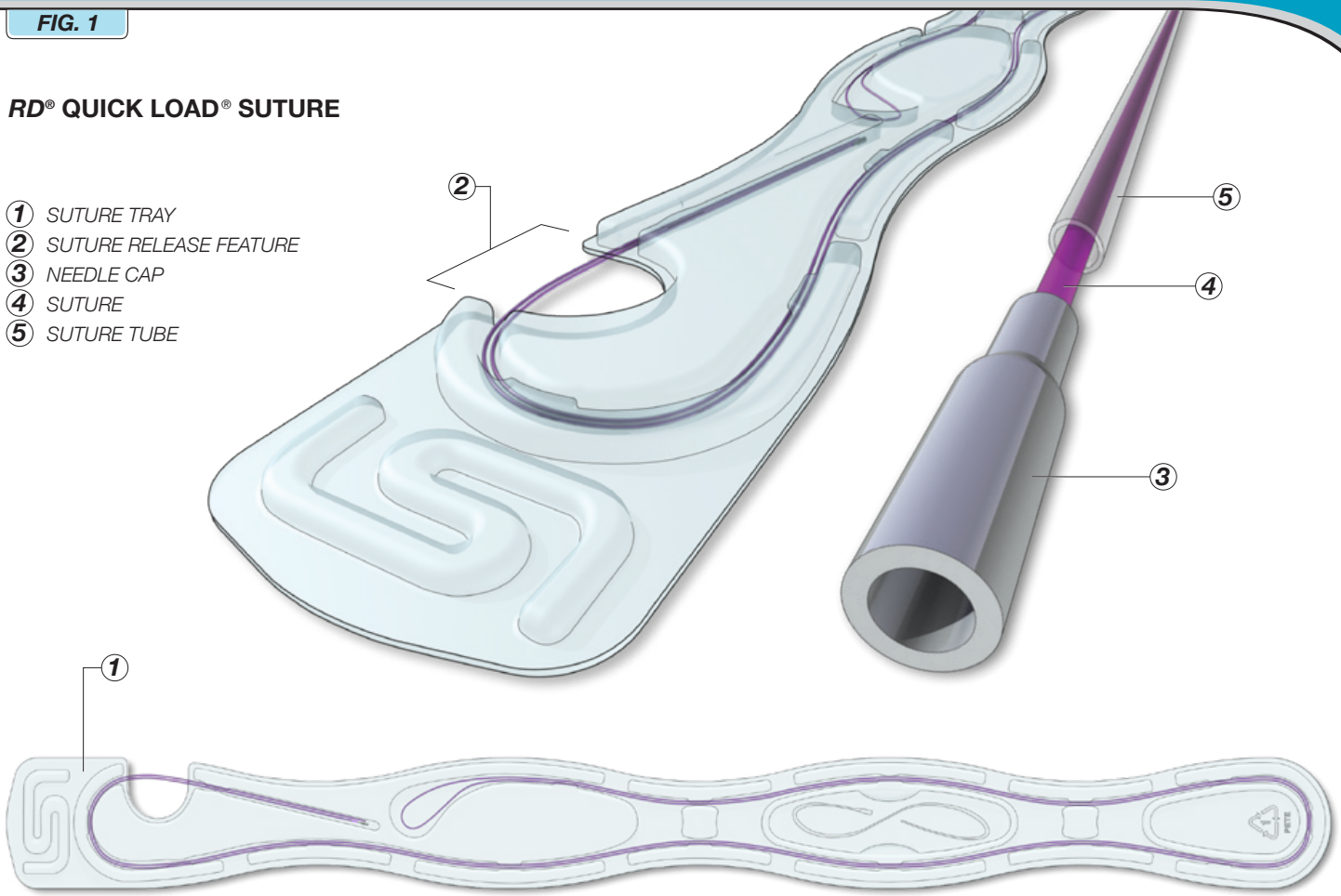
RD® QUICK LOAD® SUTURE

READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1

***RD*® QUICK LOAD® SUTURE**

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



DESCRIPTION

Each LSI SOLUTIONS® *RD*® QUICK LOAD® sterile 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 *RD*® and *RD180*® devices. *RD*® QUICK LOAD® products are available in excellent quality non-absorbable or absorbable suture materials in both braided and monofilament configurations (*FIG. 2*). A short length of modified surgical stainless steel tubing, called a "needle cap" (3), is attached to the end of the suture (4). The *RD*® QUICK LOAD® suture also includes a detachable clear suture tube (5) to keep the suture from tangling. Each sterile *RD*® QUICK LOAD® suture is individually packaged for single patient use.

INDICATIONS

RD® QUICK LOAD® surgical suture is indicated for use in general soft tissue approximation, but not for use in cardiovascular and neurological procedures.

LSI SOLUTIONS®

FIG. 2

RD® QUICK LOAD® SUTURE

SUPPLIED: Box of 12, Sterile, Suture Length 53"

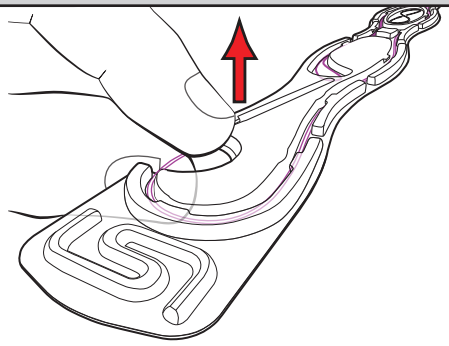
	Non-Absorbable			*Absorbable*		
Suture Material	**Polyester**		**Polypropylene**	**PGA**	**PDO**	
Suture Type	*Braided*		*Monofilament*	*Braided*	*Monofilament*	
Reorder #	**020979**	**021010**	**020989**	**021025**	**021030**	**021506**
Size	**2-0**	**0**	**2-0**	**2-0**	**2-0**	**0**
LSI Brand	**POLYESTER**	**POLYESTER**	**POLYPROPYLENE**	**STRONGSORB®**	**MONOGLIDE®**	**MONOGLIDE®**
Color / Coating	Green / PTFE	Green / PTFE	Blue / NONE	Purple / YES	Purple / NONE	Purple / NONE

LOADING SUTURE

FIG. 3

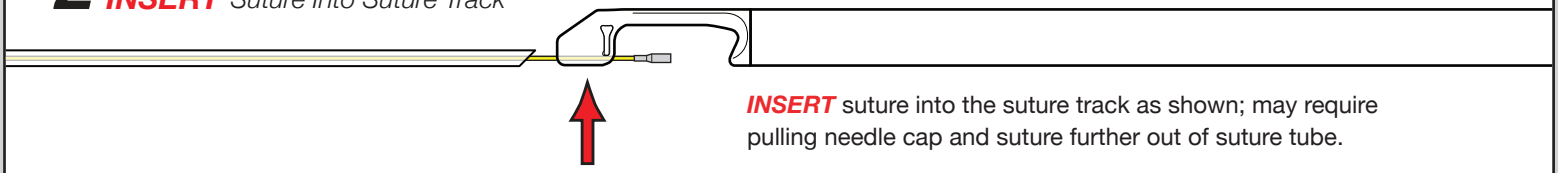
CAUTION: To avoid accidental needle exposure, **DO NOT** squeeze lever during suture loading.

1 *REMOVE* *Suture And Suture Tube From Tray*



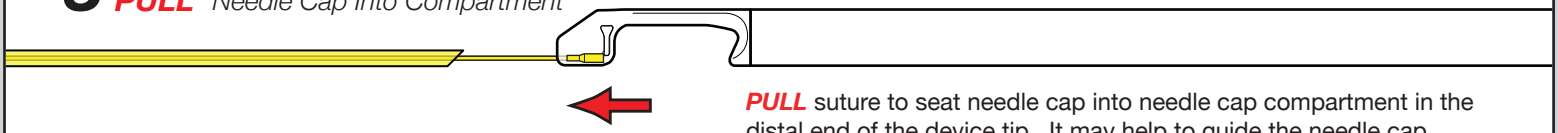
REMOVE suture and suture tube from tray by grasping suture tube at suture release feature and pulling suture tube completely out of tray.

2 *INSERT* *Suture Into Suture Track*



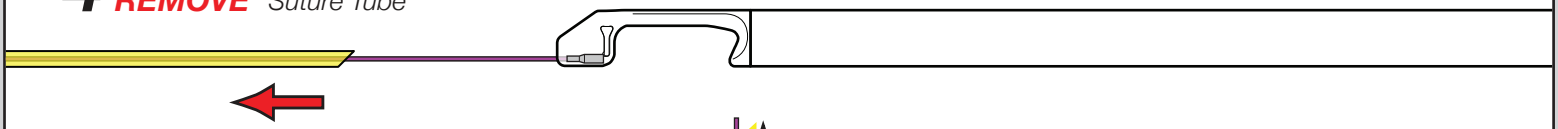
INSERT suture into the suture track as shown; may require pulling needle cap and suture further out of suture tube.

3 *PULL* *Needle Cap Into Compartment*



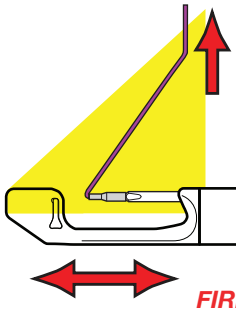
PULL suture to seat needle cap into needle cap compartment in the distal end of the device tip. It may help to guide the needle cap with a finger. Make sure needle cap is fully seated behind latch.

4 *REMOVE* *Suture Tube*



5 *FIRE & RESET*

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



FIRE & RESET 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 reset 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.

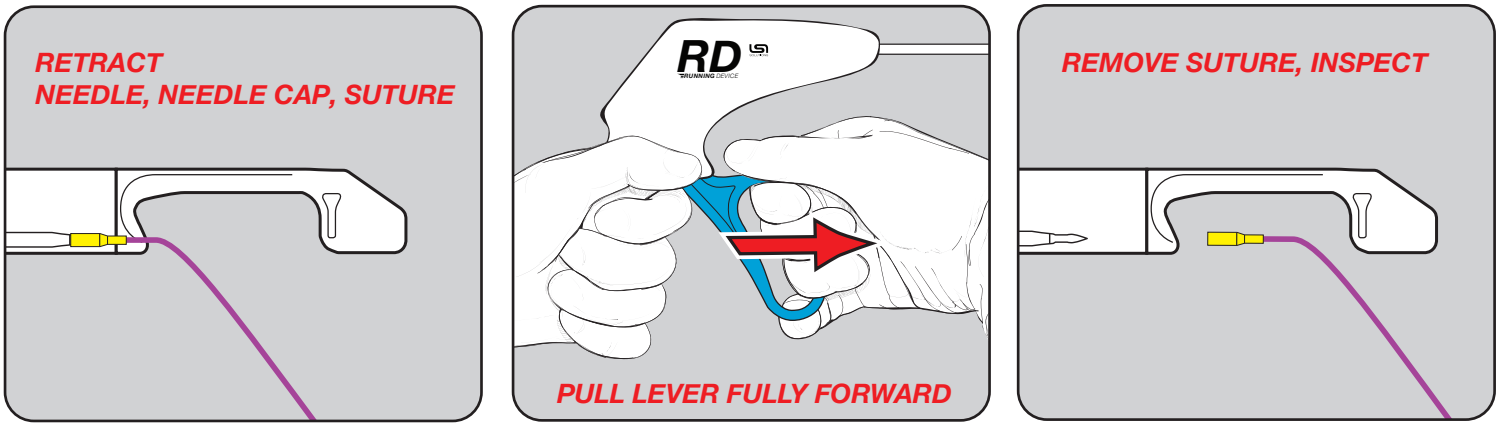
UNLOADING SUTURE

UNLOADING NEEDLE CAP AND REMAINING SUTURE FROM SUTURING DEVICE

There are two simple and convenient options for removal of used needle caps from the needle prior to reloading a suturing device. The easiest method is the *AUTO-RELEASE Technique* as illustrated below (*FIG. 4*). This technique automatically removes the suture and needle cap from the needle by simply pulling the lever fully forward. The next common unloading option, the *CLAMP Technique* (*FIG. 5*), is also simple and fast, but it requires an additional grasping device, such as a needle driver, to grasp and remove the used needle cap from the needle. Since this approach requires an additional tool and typically slightly more time than the other technique, this option is usually reserved for situations in which the *AUTO-RELEASE Technique* is not effective.

FIG. 4

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 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.

FIG. 5

CLAMP Technique *Advance Needle Slightly. Grasp Needle Cap With Clamp. Retract Needle Back.*

A surgical grasping clamp, such as a needle driver, can be effectively used to remove the needle cap from the needle. Since this approach requires an additional tool, this secondary option is usually reserved for situations in which the suture has been cut too close to the needle cap or the suture is otherwise not available for hand grasping. Squeeze the device's lever to slightly advance the needle with its attached needle cap. Apply the tip of the jaws of the grasping tool, shown highlighted in yellow (*FIG. 5*) only to the distal needle cap. Care must be taken to avoid damaging the needle with the grasper. Do not rock or rotate the needle cap with the grasper because such motion may bend, fatigue or break the needle tip. Push the device lever fully forward to retract back the needle and to slide the tip of the needle out of the needle cap held in the grasper. ***INSPECT*** to ensure needle cap has been successfully removed from the needle, shown highlighted in yellow (*FIG. 5*), and that the needle and device are undamaged.

ACTIONS

RD® QUICK LOAD® surgical suture typically elicits a minimal acute inflammatory reaction in tissues and gradual encapsulation of the suture by fibrous connective tissue. Both non-absorbable sutures, braided polyester and monofilament polypropylene suture, are not absorbed, nor is any significant change in tensile strength retention known to occur *in vivo*. With the absorbable sutures, STRONGSORB® (PGA - polyglycolic acid), MONOGLIDE® (PDO – polydioxanone), progressive loss of tensile strength and eventual absorption occurs by means of hydrolysis. Suture strength retention studies indicate that STRONGSORB® and MONOGLIDE® retain approximately 49% and 77%, respectively, of original tensile strength at three weeks; absorption of these sutures is essentially complete between 60 and 110 days. All *RD*® QUICK LOAD® surgical suture meets applicable requirements established by the United States Pharmacopoeia when used with the LSI SOLUTIONS® *TK*® *DEVICE* with the exception of MONOGLIDE® for straight pull tensile strength.

CONTRAINDICATIONS

- 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 minimally invasive procedures.
- *RD*® QUICK LOAD® surgical suture is intended for use only with *RD*® and *RD180*® devices.
- Do not use this suture under conditions in which excessive suture tension can lead to tissue damage. For example, do not use *RD*® 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.

WARNINGS

- **Do not resterilize. Discard open, unused, expired or damaged *RD*® QUICK LOAD® components.**
- 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 *RD*® QUICK LOAD® suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material being used.
- Acceptable surgical practice must be followed throughout every operation, especially with respect to drainage and closure of contaminated or infected wounds.
- Store suture at room temperature. Avoid prolonged exposure to elevated temperatures.
- Absorbable suture should not be used where extended approximation of tissue is required.
- Especially with absorbable suture material, the use of supplemental non-absorbable sutures should be considered by the surgeon in the closure of sites which may undergo expansion, stretching or distention, or which may require additional support.
- The use of suture may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.
- Redundant, cut-away suture remnants, used needle caps, and other components of the *RD*® QUICK LOAD®, along with packaging, must be accounted for and disposed of consistent with standard, accepted medical device disposal procedures.

PRECAUTIONS

- Federal (U.S.A.) law restricts this device to sale, distribution and use by, or on, the order of a physician.
- Check for hemostasis or leakage where appropriate.
- Care must be taken to avoid damaging suture, needle caps or other surgical materials through inappropriate handling; avoid crushing or damaging suture or needle caps by the overly aggressive 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 *TK*® *Ti-KNOT*® *DEVICE* and *Ti-KNOT*® FASTENERS as warranted by surgical circumstances and the experience of the surgeon.
- Before endoscopic 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. Always ensure that the inside diameter of any cannula access port selected is of sufficient size and shape to readily enable smooth simultaneous passage of the suture material and related devices.
- Before loading the *RD*® QUICK LOAD® suture into *RD*® or *RD180*® devices, the excess suture tail and previous needle cap must be removed from the device's needle.
- Ensure that obstructions do not interfere with the firing of *RD*® and *RD180*® devices. Obstructions may cause damage to the needle, suture, etc.
- Do not squeeze the lever of *RD*® or *RD180*® devices in steps 1-3 (*FIG. 3*) while loading; squeezing the lever may expose a sharp needle or cause damage.
- 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.
- Appropriate surgical judgment must be employed during suture handling and payout to avoid excessive tension on suture and tissue.
- Before using a reloaded *RD*® QUICK LOAD® suture, ensure the new needle cap is accurately installed and no used needle caps are left on the needle.
- **Always *FIRE & RESET* every newly loaded *RD*® QUICK LOAD® suture before using the device in a patient.**

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.

LSI SOLUTIONS®

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STERILE EO

Symbol Glossary: www.lsisolutions.com/symbols

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