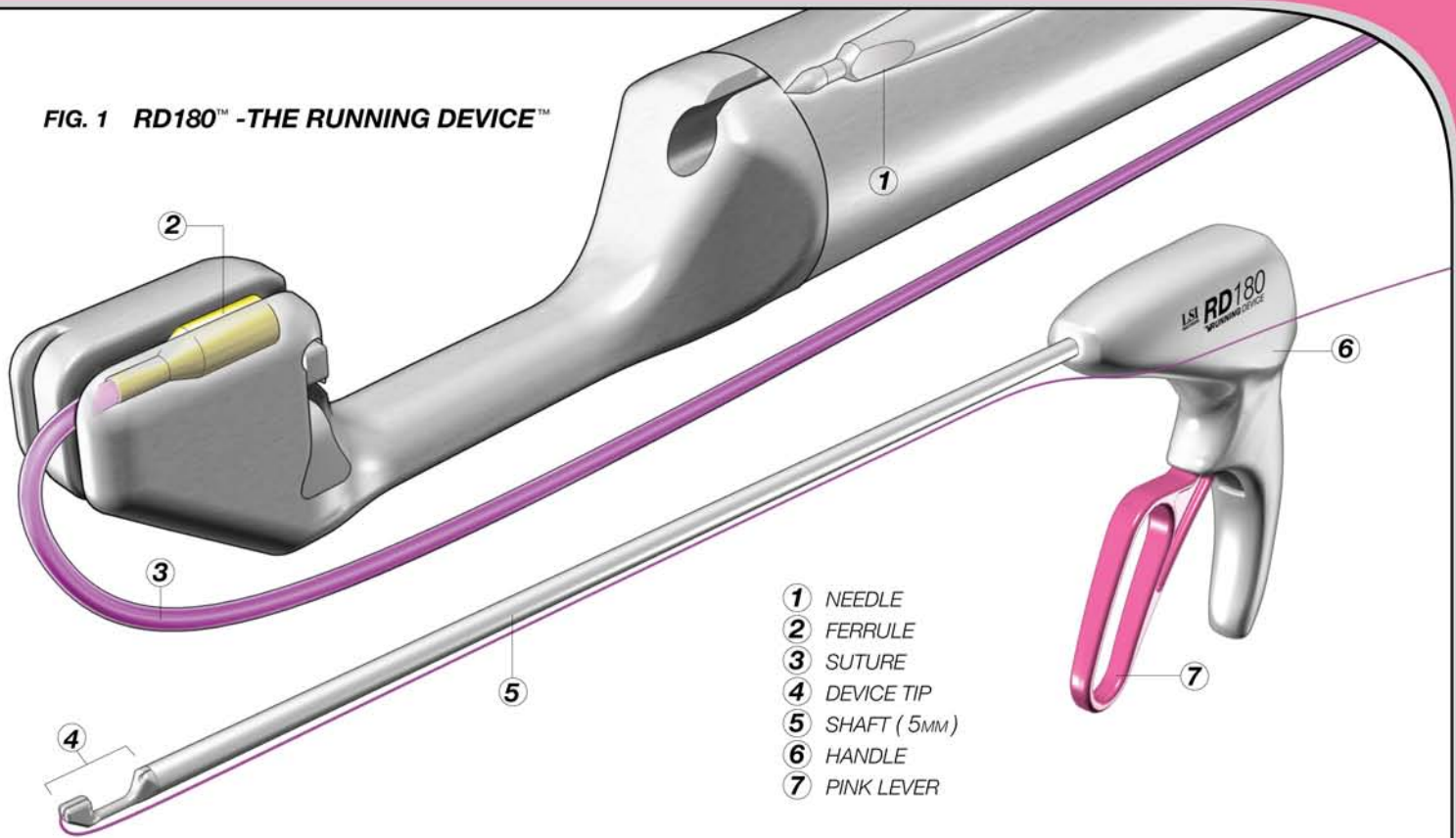


RD180™ TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1 RD180™ -THE RUNNING DEVICE™



RD180™ -THE RUNNING DEVICE™ DESCRIPTION

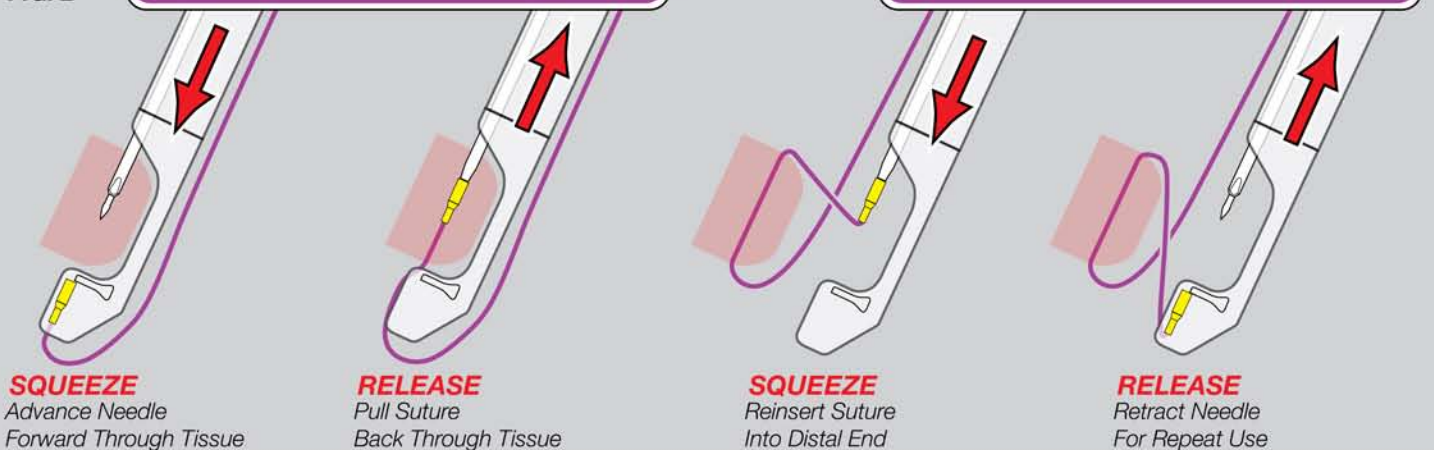
Each sterile package contains one (1) 5mm RD180™ suturing device (FIG. 1). RD180™ is used for the placement of surgical suture as supplied in an appropriate RD QUICK LOAD®. A short length of modified surgical stainless steel tubing, called a ferrule 2, is attached to one end of the suture 3 in the RD QUICK LOAD®. The ferrule is loaded into the ferrule compartment in the distal end of the device tip 4. Suture Placement and Suture Reset (FIG. 2) are each achieved by sequentially squeezing and releasing the pink lever 7. During Suture Placement, the initial squeeze of the pink lever advances the retracted needle forward through the selected tissue placed in jaw of the device tip; the full squeeze advances the needle into the ferrule attached to its suture held in the device tip's distal end. Release of the pink lever retracts the needle, which pulls the now engaged ferrule and suture back through the tissue. Next, with the device tip oriented for Suture Reset, a second squeeze of the pink lever advances the needle with its now engaged ferrule and suture forward through the empty jaw into the device tip's distal end, where a latch feature retains the ferrule and suture. Release of the lever returns the needle alone back to its retracted position in the distal shaft ready for repeat suture placement.

LSI SOLUTIONS®

FIG. 2

SUTURE PLACEMENT

SUTURE RESET



LOADING SUTURE

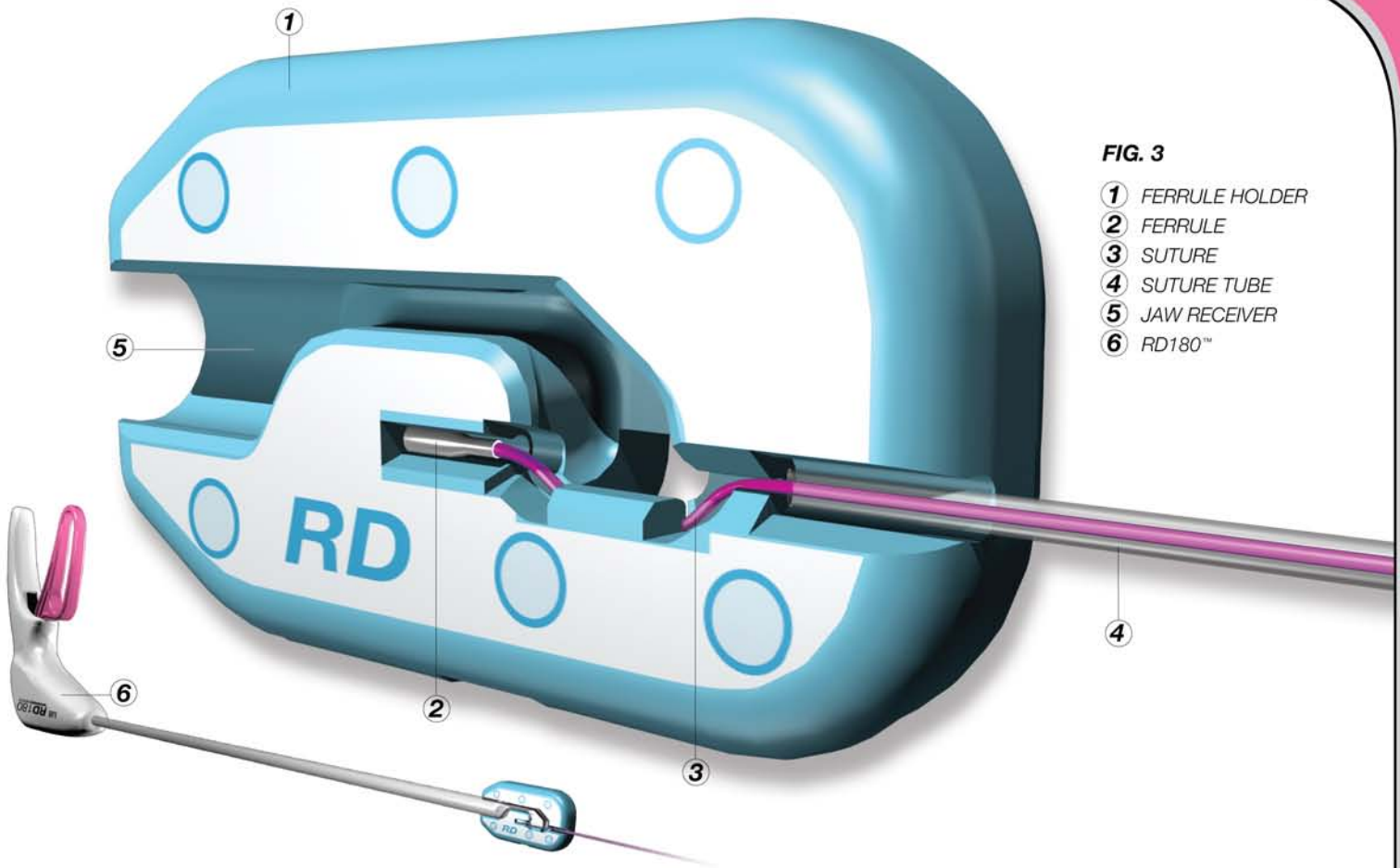


FIG. 3

- ① FERRULE HOLDER
- ② FERRULE
- ③ SUTURE
- ④ SUTURE TUBE
- ⑤ JAW RECEIVER
- ⑥ RD180™

INDICATIONS

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

DESCRIPTION

Each LSI SOLUTIONS® RD QUICK LOAD® contains a proprietary sterile surgical suture held in a customized ferrule holder (FIG. 3) designed to enable the rapid, easy and reliable loading of suture into RD180™. RD QUICK LOAD® products are available in excellent quality non-absorbable or absorbable suture materials in both braided and monofilament configurations (FIG. 7). The ferrule holder ① is made of semi-compliant blue plastic imprinted with a white front surface to highlight its specialized features. A short length of modified surgical stainless steel tubing, called a ferrule ②, is attached to the end of the suture ③ held within the ferrule holder. The RD QUICK LOAD® also includes a detachable clear suture tube ④ to keep the suture from tangling. The jaw receiver ⑤ feature of the ferrule holder is contoured to securely accept, align and then release the gapped metal jaw located at the distal end of RD180™ device tip.

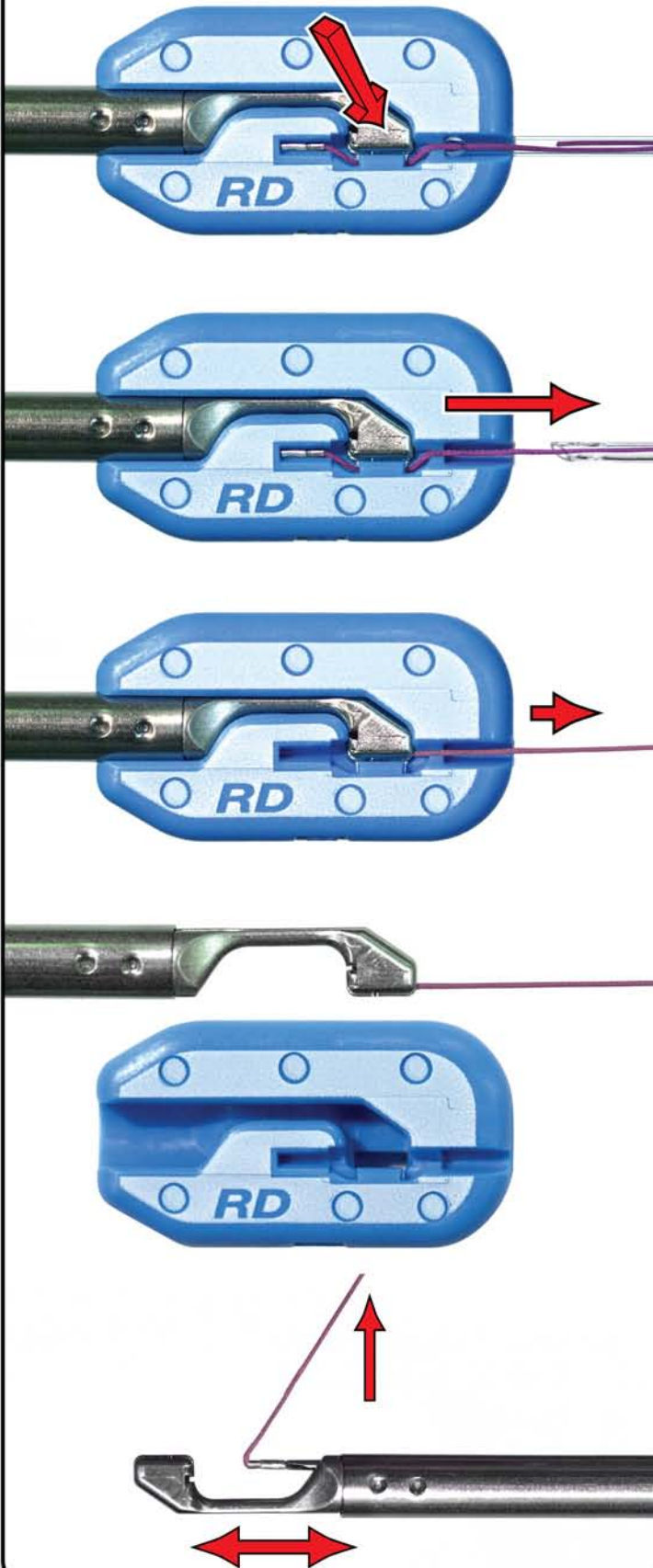
LOADING SUTURE WITH AN RD QUICK LOAD®

Use proper operating room technique to load the sterile RD QUICK LOAD® (FIG. 4).

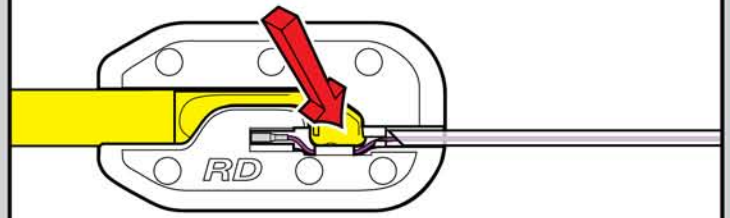
1. **PRESS** the gapped metal jaw in the device tip of RD180™ down (red arrow) into the RD jaw receiver feature in the RD QUICK LOAD®. **Ensure the ferrule holder remains fully engaged and aligned on the device until the ferrule is subsequently pulled fully into its compartment. Avoid disturbing or dislodging the ferrule, suture or suture tube from the ferrule holder while handling the ferrule holder and inserting the device jaw.**
2. **PULL TUBE** straight out from the long axis of the device shaft and from the ferrule holder (red arrow) to expose a length of suture.
3. **PULL SUTURE** straight out away from the ferrule holder as shown (red arrow). The suture only needs to be pulled approximately 1 cm to completely pull its attached ferrule from the ferrule holder across into the ferrule compartment in the distal end of the device tip.
4. **REMOVE** the blue plastic ferrule holder off of the device and any remaining clear suture tube off of the suture.
5. **FIRE & RESET.** To avoid jamming the ferrule into the ferrule compartment during this important step, orient the suture directly up and away from the jaw as shown by the red single-head arrow. Squeeze the lever to advance the needle through the jaw and into the freshly loaded ferrule. Release the lever to pick up and retract the ferrule 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, ferrule and suture forward through the jaw to reset the ferrule into its compartment in the distal end of the device tip. Release the lever again and retract back the now empty needle leaving the ferrule and suture in the distal end ready for patient use. The double-headed red arrow in Step 5 represents the advance and retraction of the needle.
6. **INSPECT** the distal end of the metal jaw to ensure that the ferrule is appropriately positioned in the compartment.
7. If desired, gently pull suture to RELIEVE any potential suture "memory" and/or LUBRICATE the suture using sterile saline either with or without the addition of a sterile water-soluble surgical lubricant.

LOADING SUTURE

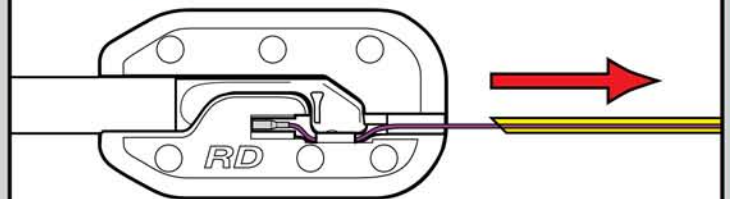
FIG. 4



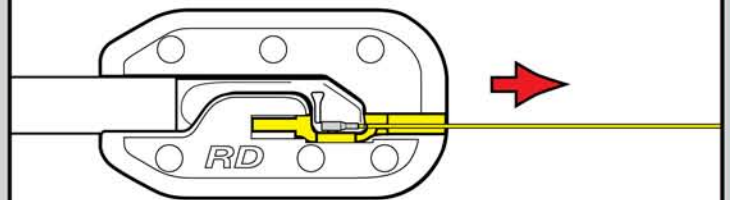
1 PRESS Device Tip into RD QUICK LOAD®



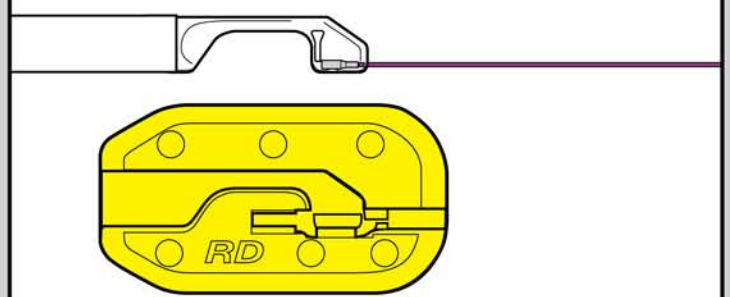
2 PULL TUBE Straight Out



3 PULL SUTURE Straight Out

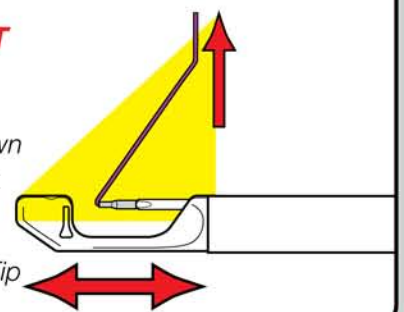


4 REMOVE Ferrule Holder Off of Device Tip



5 FIRE & RESET

Orient Suture as Shown
Squeeze and Release
Pink Lever to Ensure
Suture is Ready in
Distal End of Device Tip



UNLOADING RD180™

UNLOADING FERRULE AND REMAINING SUTURE FROM RD180™

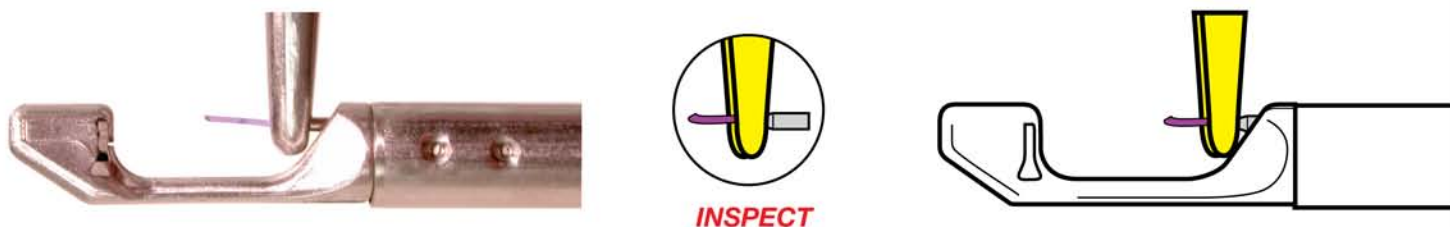
There are two simple and convenient options for removal of used ferrules from the needle prior to reloading RD180™. The technique used is typically dependent upon the available remaining length of suture left at the time of reloading and/or the preference of the operator. The easiest method is the *PULL-OFF Technique* as illustrated below (FIG. 5). This rapid approach requires an adequate length of suture remains attached to the ferrule throughout the unloading and does not utilize any other instruments. The other common unloading option, the *CLAMP Technique* (FIG. 6), is also simple and fast, but it requires an additional grasping device, such as a needle driver, to grasp and remove the used ferrule from the needle.

FIG. 5
PULL-OFF Technique *Retract Suture Back. Place Suture Over Distal Tip. Pull Suture with Ferrule Off Needle*



As the name implies, the ferrule is simply pulled away from and off the needle by hand grasping and pulling the suture during this unloading technique. When adequate suture remains attached to the ferrule, ensure that the needle attached to the ferrule and suture is retracted in its resting position in the distal shaft. To avoid pulling the ferrule back through the suture track into its ferrule compartment across the jaw from the needle, orient the suture over the distal jaw as illustrated by the bent red arrow in FIG. 5. One brisk pull on the suture in a direction away from the needle typically pops the ferrule off from the needle to free the used ferrule and suture from the device. *INSPECT*: the ferrule remains attached to the suture and the needle and device are undamaged.

FIG. 6
CLAMP Technique *Advance Needle Slightly. Grasp Ferrule With Clamp. Retract Needle Back*



A surgical grasping clamp, such as a needle driver, can be effectively used to remove the ferrule from the needle. Since this approach requires an additional tool and typically slightly more time than the *PULL-OFF Technique*, this secondary option is usually reserved for situations in which the suture has been cut too close to the ferrule or the suture is otherwise not available for hand grasping. Squeeze the device's lever to slightly advance the needle with its attached ferrule. Apply the tip of the jaws of the grasping tool, shown highlighted in yellow (FIG. 6) only to the distal ferrule. Care must be taken to avoid damaging the needle with the grasper. Do not rock or rotate the ferrule with the grasper because such motion may bend, fatigue or break the needle tip. Push the pink lever fully forward to retract back the needle and to slide the tip of the needle out of the ferrule held in the grasper. Inspect that the ferrule has been successfully removed from the needle and that the needle and device are undamaged.

FIG. 7 **RD180™ DEVICE ORDERING** REORDER # 021100 SUPPLIED: Box of 6, Sterile

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
Size	2-0 0	2-0		2-0	2-0
LSI Brand	POLYESTER POLYESTER	POLYPROPYLENE		STRONGSORB®	MONOGLIDE®
Color / Coating	Green / PTFE Green / PTFE	Blue / NONE		Purple / YES	Purple / NONE



ACTIONS

To facilitate the placement of multiple stitches of the same suture (i.e., “running” or tying the suture) without needing to manually reset each ferrule, the ferrule resetting mechanism of *RD180™* enables the remote return and resetting of the ferrule back into the ferrule compartment. The operator presents an appropriate tissue structure into the gap of the metal jaw in the device tip of the *RD180™*. During suture placement, the pink lever is squeezed to advance the retracted needle from the shaft of the device through the tissue in the jaw and into the ferrule. The distal contoured end of the *RD180™* needle engages and captures the ferrule with its attached suture. Releasing the pink lever retracts the needle with attached ferrule and suture back through the tissue. For Suture Reset, the distal tip is then moved away from any tissue structures to clear the jaw for ferrule resetting. The pink lever is again fully squeezed to advance the needle, ferrule and suture forward through the empty jaw toward the ferrule 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 ferrule is oriented to permit the suture to freely pass through the suture track opening in the ferrule compartment. Jamming misoriented suture into the ferrule compartment can damage suture and device. With the pink lever fully squeezed and the needle with its attached ferrule and suture completely forward, the now rotated needle will permit the ferrule reset latch to engage the face of the ferrule and cause its release from the needle. With the first tissue suture placement complete, the ferrule reset into the ferrule compartment, and the pink lever back in its starting location, *RD180™* is ready for another tissue bite. This sequence can be repeated for up to 12 bites (or 12 complete functional cycles) with a single *RD QUICK LOAD®* and with up to 12 *RD QUICK LOADS* per device.

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.
- *RD180™* is not intended to be used with any suture other than an *RD QUICK LOAD®* suture.
- 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.** The performance of *RD180™* after cleaning or other reprocessing has not been verified and is not supported by LSI SOLUTIONS®.
- Discard open, unused or damaged devices or devices in damaged primary packaging.
- 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 *RD180™* for wound closure, as the risk of wound dehiscence may vary with the site of application.
- Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.
- Redundant, cut-away suture remnants, used ferrules, and *RD180™* devices, along with packaging, must be accounted for and disposed of consistent with standard, accepted medical device disposal procedures.
- *RD180™* is indicated for use in the approximation of soft tissue. Applications other than for soft tissue closure, or to anchor another device, 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 ligamental tissue, or other instruments.

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.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. Before endoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure electrical isolation or grounding are not compromised.
- Care must be taken when inserting this or any device through a cannula 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.
- Always assure insufflation, camera position and device tip location are viewed under direct visualization before advancing the needle.
- Ensure obstructions do not interfere with the movement of the needle of *RD180™*.
- In handling *RD180™*, care should be taken to avoid jamming the suture into the ferrule compartment and damage to the needle.
- Avoid damage to the needle, suture or ferrules 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 *TK Ti-KNOT® DEVICE* and *TK QUICK LOAD®* as warranted by surgical circumstances and the experience of the surgeon.
- Do not squeeze the pink lever of *RD180™* while loading an *RD QUICK LOAD®*; squeezing the pink lever may expose the sharp needle and/or damage the needle.
- Before loading *RD180™* with another *RD QUICK LOAD®*, assure the remaining suture tail and ferrule from the previous load has been removed from the needle. Failure to appropriately remove used ferrules from the needle can result in damage to the device, including intracorporeal or extracorporeal fracturing off 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 pink lever to drive the needle forward into the new ferrule loaded into the ferrule compartment. If the ferrule is picked-up by the needle, then squeeze the lever again to reset the ferrule and suture back behind the latch. If the needle rotation is orientated to reset the ferrule, then the needle will retract back without the ferrule and suture attached. This “cycling” (FIG. 4, Step 5) of the needle helps ensure that the previous ferrule was properly removed, the new ferrule is installed properly and the operator receives the device with its needle orientated to pick-up the ferrule on its first needle advancement. If the previous ferrule was not properly removed from the needle prior to reloading the device, the needle will not fully advance into the new ferrule in the ferrule compartment. Failure to avoid driving a needle with a ferrule into another ferrule can lead to the breaking off of the tip of the needle.
- Do not use *RD180™* to dissect or aggressively manipulate tissue structures.
- Verify the ferrule is still retained within the ferrule 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 pink 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 ferrule always enters the ferrule compartment with its suture oriented to freely pass through the ferrule compartment’s suture track. Do not use damaged suture.
- Ensure the advancing needle targets and enters the ferrule 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 ferrule compartment. A needle tip, not entering the ferrule compartment properly, can strike the distal tip of the device and lead to undesired outcomes, including needle tip fracture. For another example, during suture reset, avoid applying tension to the suture from the ferrule on the needle. Tension on the suture can cause the needle to deviate off target and lead to the ferrule possibly striking the distal tip, which can cause needle tip fracture.

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.

MANUFACTURED UNDER ONE OR MORE OF THE FOLLOWING RELATED PATENTS

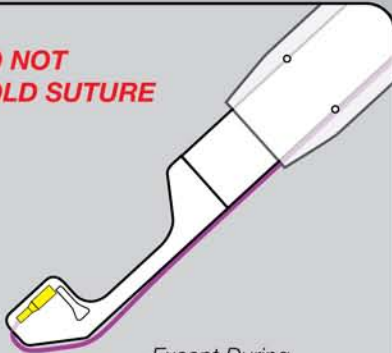
5,431,666; 5,520,702; 5,562,686; 5,643,289; 5,669,917; 5,766,183; 6,368,334; 6,533,796; 6,641,592; 6,997,931; CA2141911; CA2141912; CA2141913; CA2173520; EP0669101; EP0669102; EP0669103; EP0748612 and DE69505283.7; DE69512447.1; DE69512446.3. Additional patents pending.

RD180™ TECHNIQUE PEARLS

GENERAL

FIG. 8

DO NOT HOLD SUTURE



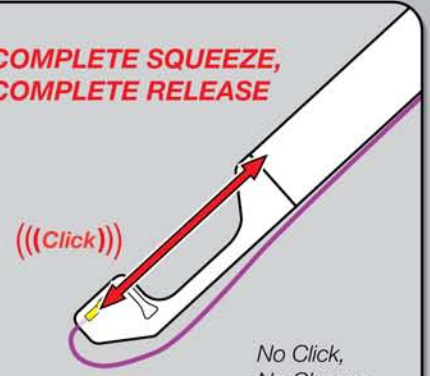
Except During Cannula Insertion

NO OBSTRUCTIONS



Avoid Hitting Suture, Instruments, Bone, etc.

COMPLETE SQUEEZE, COMPLETE RELEASE



No Click, No Change

SUTURE PLACEMENT

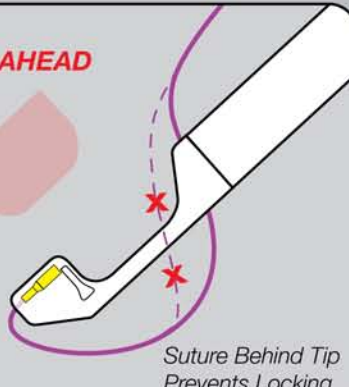
FIG. 9

TAKE UP SLACK



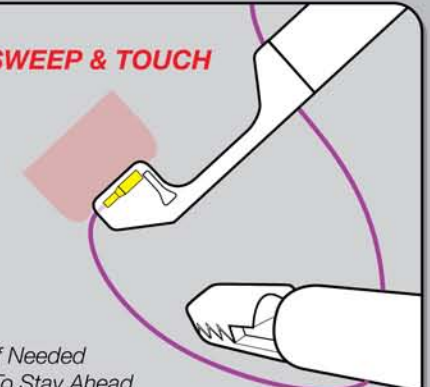
Pull Suture Tail To Relieve Excess

STAY AHEAD



Suture Behind Tip Prevents Locking

SWEEP & TOUCH

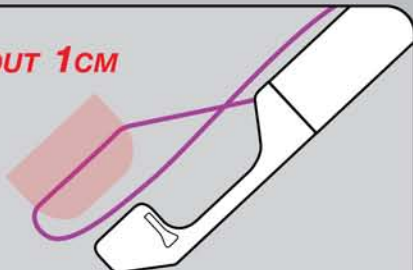


If Needed To Stay Ahead

SUTURE RESET

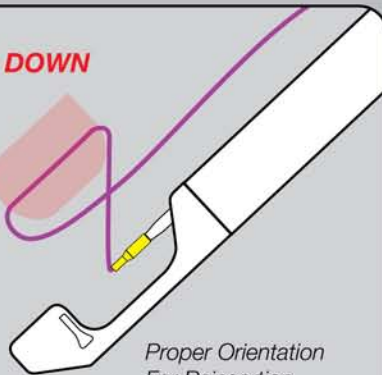
FIG. 10

OUT 1CM



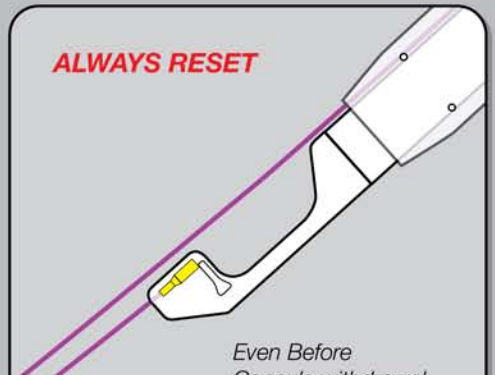
After Bite, Keep Suture Short

TIP DOWN



Proper Orientation For Reinsertion

ALWAYS RESET



Even Before Cannula withdrawal

P/N 021141A

LSI SOLUTIONS®

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