Each sterile package contains one (1) RD180® SP™ suturing device (FIG. 1). The RD180® SP™ DEVICE is used for the placement of RD® QUICK LOAD® surgical suture. A short length of modified surgical stainless steel tubing, called a needle cap, is attached to one end of the suture. The needle cap is loaded into the needle cap compartment in the distal end of the device tip. Suture Placement and Suture Rearm (FIG. 2) are each achieved by sequentially squeezing and releasing the pink lever. During Suture Placement, the initial squeeze of the pink lever advances the retracted needle forward through the selected tissue placed in the 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 pink 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 pink 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 lever returns the needle alone back to its retracted position in the distal shaft ready for repeat suture placement.

INDICATIONS
The RD180® SP™ DEVICE is indicated for use in the approximation of soft tissue and prosthetic materials.
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. 10). 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 the approximation of soft tissue and prosthetic materials.

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

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 & 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.
UNLOADING RD180® SP™ DEVICE

UNLOADING NEEDLE CAP AND REMAINING SUTURE FROM RD180® SP™ DEVICE
There are two simple and convenient options for removal of used needle caps from the needle prior to reloading the RD180® SP™ DEVICE. The easiest method is the AUTO-RELEASE Technique as illustrated below (FIG. 5). 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. 6), 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.

AUTO-RELEASE Technique

RETRACT NEEDLE, NEEDLE CAP, SUTURE
PULL LEVER FULLY FORWARD
REMOVE SUTURE, INSPECT

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 pink 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 pink lever fully forward to automatically remove the needle cap and suture off of the needle. Inspect and discard the used needle cap and suture.

CLAMP Technique

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. 6), 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. 6), and that the needle and device are undamaged.
**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.

- The RD180® SP™ DEVICE is not intended to be used with any suture other than RD® QUICK LOAD™ surgical 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**

- 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 RD180® SP™ 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.

- 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 RD180® SP™ DEVICE 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 needle caps, and RD180® SP™ DEVICES, along with packaging, must be inspected, handled and disposed of consistent with standard, accepted medical device disposal procedures.

- The RD180® SP™ DEVICE 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.

- The RD® QUICK LOAD® suture is not for use in cardiovascular and neurological procedures.

**PRECAUTIONS**

- 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 insulation, 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 the RD180® SP™ DEVICE.

- In handling the RD180® SP™ 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 Ti-KNOT™ DEVICE and TK® QUICK LOAD™ UNIT as warranted by surgical circumstances and the experience of the surgeon.

**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, calculus formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and pain, edema and erythema.