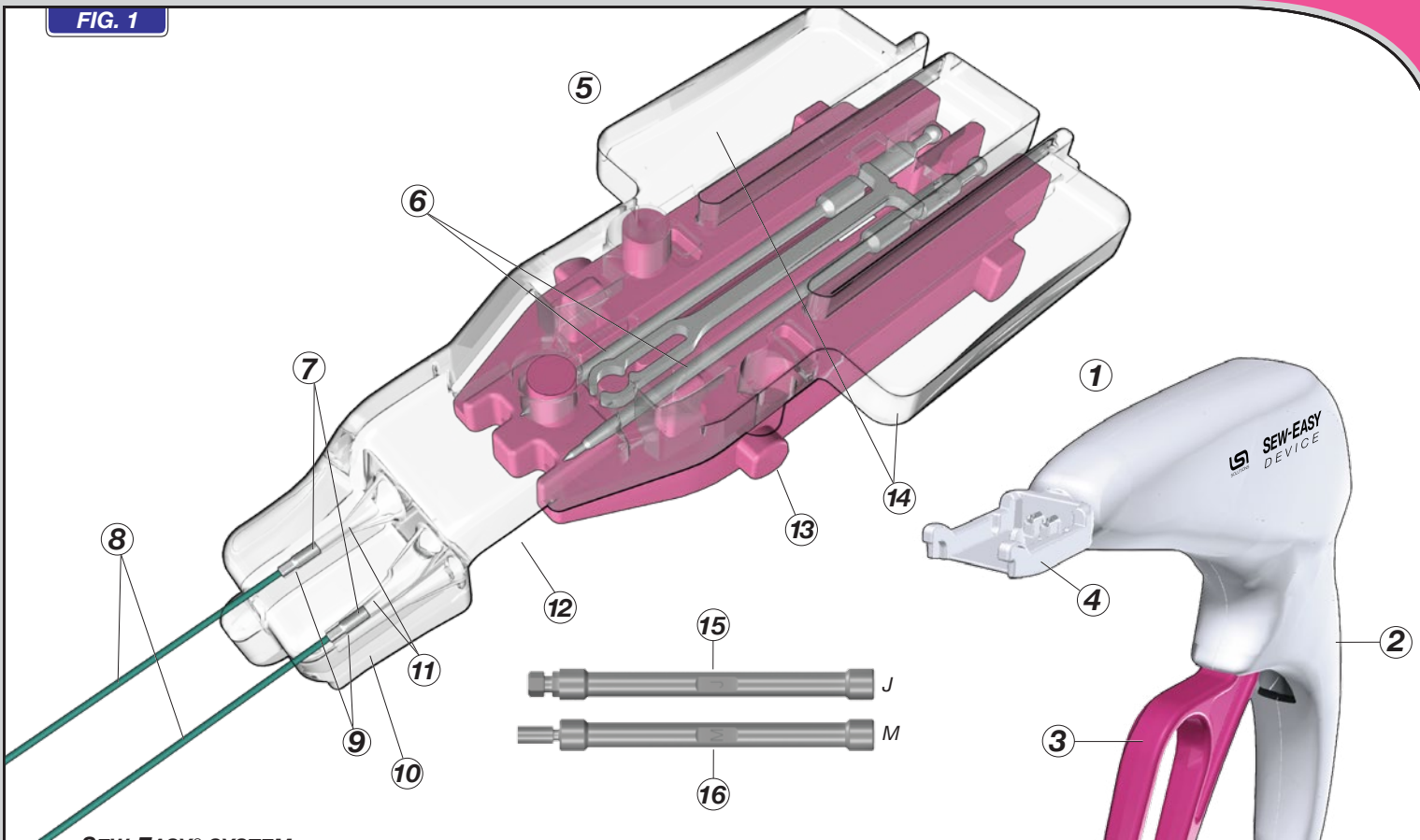


SEW-EASY® TECHNOLOGY GUIDE

 READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



SEW-EASY® SYSTEM

- | | | |
|----------------------|---------------------------|------------------|
| ① SEW-EASY® DEVICE | ⑥ DUAL NEEDLES | ⑪ SUTURE SLOTS |
| ② WHITE HANDLE | ⑦ NEEDLE CAPS | ⑫ CASSETTE JAW |
| ③ PINK LEVER | ⑧ SUTURE | ⑬ LOCATING PEGS |
| ④ RECEIVER | ⑨ NEEDLE CAP COMPARTMENTS | ⑭ RELEASE TABS |
| ⑤ SEW-EASY® CASSETTE | ⑩ CASSETTE TIP | ⑮ VALVE HANDLE J |
| | | ⑯ VALVE HANDLE M |

SEW-EASY® DEVICE DESCRIPTION

Each sterile Combo Kit contains two (2) SINGLE PATIENT USE SEW-EASY® Suturing Devices ①, twelve (12) SINGLE USE SEW-EASY® Cassettes ⑤, and two (2) SINGLE PATIENT USE Valve Handles ⑮ ⑯. The SEW-EASY® System is used for the placement of a RAM® COR-SUTURE® QUICK LOAD® surgical suture through the sewing cuff of a prosthetic heart valve. Separate short lengths of modified surgical stainless steel tubing, called needle caps ⑦, come preattached to each end of the suture ⑧ in the RAM® COR-SUTURE® QUICK LOAD® Device. The needle caps are loaded into separate needle cap compartments ⑨ in the cassette tip ⑩ as shown in FIG. 1. The cassette is loaded (FIG. 3) into the SEW-EASY® Device by aligning the cassette locating pegs ⑬ into the device receiver ④ and then pivoting the cassette until it snaps into place. Suture Placement (FIG. 3) is achieved by squeezing and releasing the pink lever ③. During Suture Placement, the squeeze of the pink lever advances the retracted needles ⑥ forward through the selected prosthetic material placed in the jaw ⑫ of the cassette tip; the full squeeze advances the needles into the needle caps which are attached to the suture held in the cassette tip. Release of the pink lever retracts the needles, which pulls the now-engaged needle caps and suture back through the prosthesis. Unloading the cassette from the device (FIG. 3) is achieved by removing the cassette tip from the prosthesis, and then squeezing the release tabs ⑭ on the sides of the cassette and lifting upward. The device is now ready to receive the next cassette with loaded suture.

INDICATIONS

The SEW-EASY® Device used in conjunction with RAM® COR-SUTURE® QUICK LOAD® Surgical Suture and RAM® Suturing Device, is indicated for use in the approximation of soft tissue and prosthetic materials.

 SOLUTIONS®

Handle ID	Manufacturer	Model	Model Number
M	Medtronic	Hancock II	T505C
		Hancock II Ultra	T505U
		Mosaic	305
		Mosaic Ultra	305U
		Trifecta Glide Technology (GT)	TFGT
J	St. Jude Medical (Abbot)	Trifecta	TF

LOADING SUTURE

Suture must be loaded into cassette before loading cassette into device.

CAUTION: The SEW-EASY® DEVICE should only be used with a RAM® COR-SUTURE® QUICK LOAD® suture that has been placed by a RAM® Suturing Device.

FIG. 2

Option 1

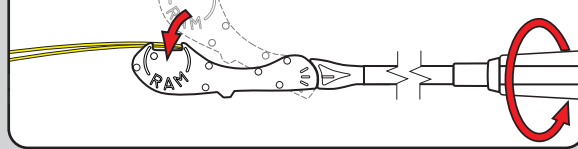
MANUAL SUTURE LOADING WITHOUT RAM® DEVICE

INSERT suture into suture track of SEW-EASY® Cassette.

PULL suture with needle cap into compartment. Repeat for second suture tail.

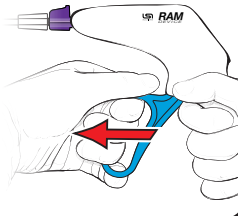
Option 2

1 ADJUST RAM® Device Tip to Neutral and align suture in suture tracks.



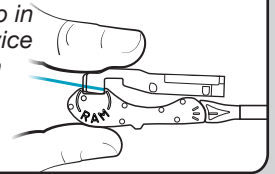
3 PULL RAM® Lever Fully Forward

Pull RAM® lever fully forward to strip needle caps from RAM® needles.



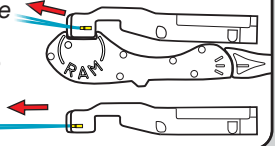
2 SET Cassette Tip in Tissue Gap of RAM® DEVICE

Set SEW-EASY® Cassette tip in the tissue gap of RAM® Device while maintaining sutures in the RAM® suture tracks. Secure with thumb and finger as shown.

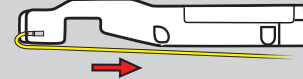


4 PULL needle caps Into Compartment

Pull suture to seat needle caps into needle cap compartments in the cassette tip. Remove Cassette and individually pull each suture end to confirm needle caps are fully seated.

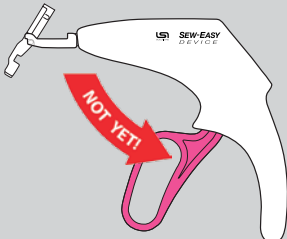


If necessary to remove suture from cassette, double the suture against the suture slot and pull the needle cap straight out.



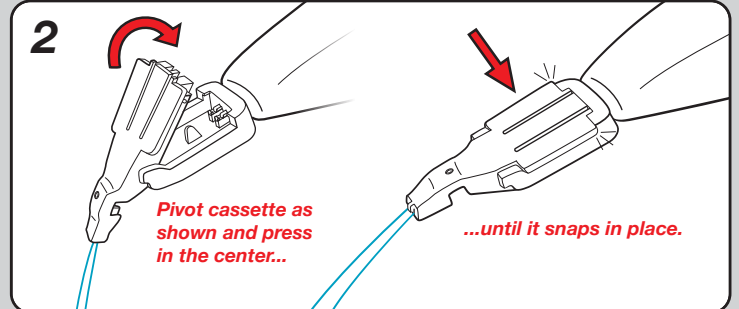
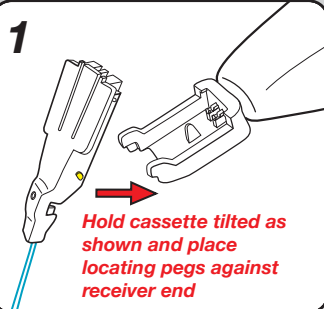
USING DEVICE

FIG. 3



DO NOT squeeze pink lever during cassette loading.

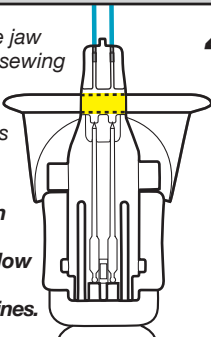
CASSETTE LOADING NOTE: Inspect suture alignment prior to needle cap seating and loading cassette.



SUTURE PLACEMENT NOTE: Affix appropriate valve handle to prosthesis.

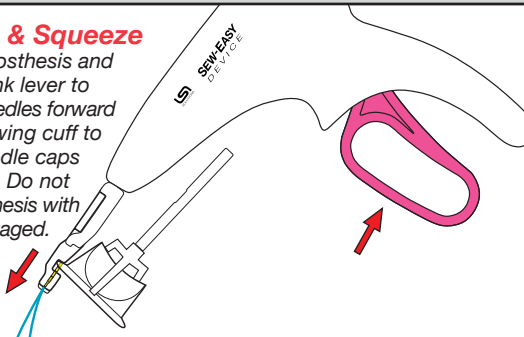
3 Align cassette jaw over prosthetic sewing cuff. Observe needle entrance and exit positions carefully.

Manipulate prosthesis with desired valve handle and follow manufacturer handling guidelines.

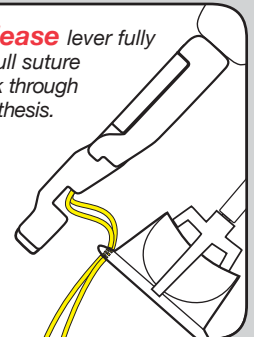


4 Stabilize & Squeeze

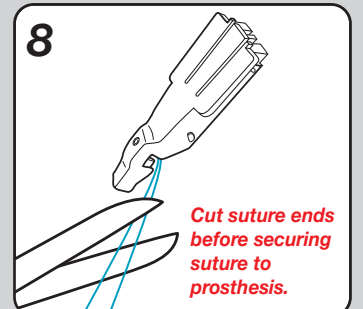
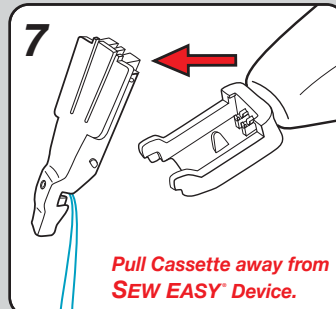
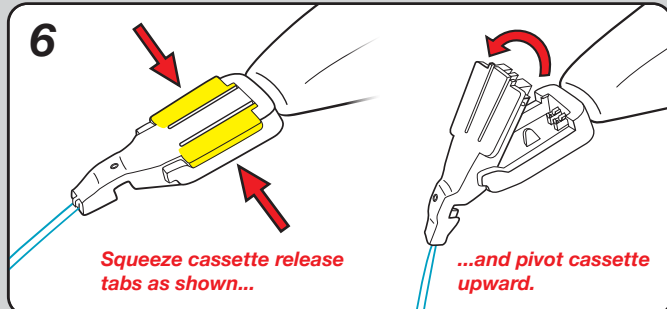
Stabilize prosthesis and squeeze pink lever to advance needles forward through sewing cuff to pick up needle caps with suture. Do not move prosthesis with needles engaged.



5 Release lever fully to pull suture back through prosthesis.



CASSETTE REMOVAL



SEW-EASY® TECHNIQUE PEARLS

FIG. 4

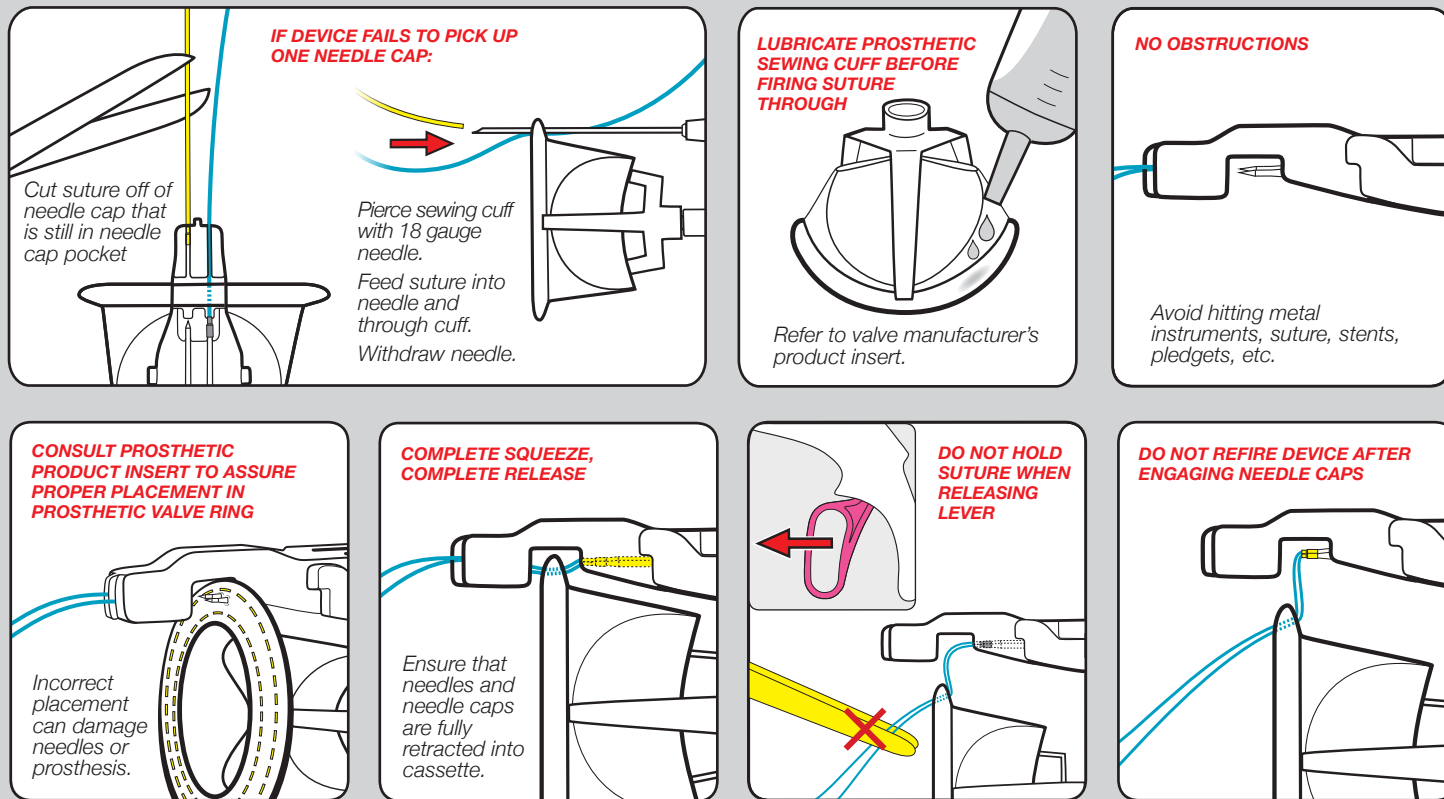





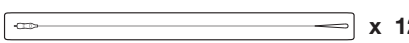

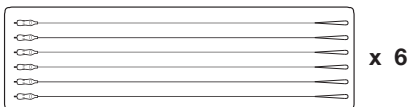


FIG. 5 PRODUCT ORDERING

SUPPLIED: STERILE

	REORDER	PRODUCT	DESCRIPTION
 x 6	REF 022200	SEW-EASY® COMBO KIT	Box of 6 Kits (2 Devices, 12 Cassettes, and 2 Valve Handles per Kit)
 x 6	REF 022201	SEW-EASY® DEVICE KIT	Box of 6 Kits (2 Devices and 2 Valve Handles per Kit)
 x 12	REF 022160	SEW-EASY® CASSETTE SINGLES	Box of 12 Cassettes (1 Cassette per Pouch)
 x 6	REF 021900	RAM® DEVICE	Box of 6 Kits (2 Devices per Kit)
 x 12	REF 022039	RAM® COR-SUTURE® QUICK LOAD® Pledgeted 2-0 Polyester, Green, Non-Absorbable, 38"	Box of 12 Sutures (1 Suture per Pouch)
 x 12	REF 022047	RAM® COR-SUTURE® QUICK LOAD® Pledgeted 2-0 Polyester, White, Non-Absorbable, 38"	Box of 12 Sutures (1 Suture per Pouch)
 x 12	REF 022335	RAM® COR-SUTURE® QUICK LOAD® SINGLES Pledgeted 2-0 Polyester, Green/White Striped, Non-Absorbable, 38"	Box of 12 Sutures (1 Suture per Pouch)
 x 6	REF 022090	RAM® COR-SUTURE® QUICK LOAD® 6 TRAY Pledgeted 2-0 Polyester, White (3) and Green (3), Non-Absorbable, 38"	Box of 6 Trays (6 Sutures per Tray)

ACTIONS

The *SEW-EASY*[®] *SYSTEM* facilitates the placement of multiple sutures through a prosthesis. The operator loads suture having needle caps on its ends into a *SEW-EASY*[®] Cassette, and loads the cassette into the *SEW-EASY*[®] *DEVICE*. The operator presents an appropriate prosthetic structure into the cassette jaw of the cassette tip attached to the *SEW-EASY*[®] *DEVICE*. During suture placement, the pink lever is squeezed to advance the retracted needles in the cassette through the prosthesis in the jaw and into the needle caps. The *SEW-EASY*[®] needles engage and capture the needle caps with their attached suture. Releasing the pink lever retracts the needles with attached needle caps and suture back through the prosthesis. The prosthesis is removed from the cassette jaw and the cassette is removed from the device. The needle caps of a new suture set are loaded into the needle cap compartment of a new cassette, which is loaded into the *SEW-EASY*[®] *DEVICE* and the device is ready to place the next suture into the prosthesis. This sequence can be repeated for up to 24 sutures per *SEW-EASY*[®] *DEVICE*.

CONTRAINDICATIONS

- The *SEW-EASY*[®] *SYSTEM* is not intended to be used with any suture other than a *RAM*[®] *COR-SUTURE*[®] *QUICK LOAD*[®] suture in conjunction with a *RAM*[®] Suturing Device.
- Do not use this suture under conditions in which excessive suture tension can lead to tissue damage.

WARNINGS

- Endoscopic or minimally invasive procedures should only be performed by physicians having adequate training and familiarity with associated techniques. In addition, medical literature should be consulted relative to techniques, complications and hazards prior to the performance of such procedures.
- Federal (U.S.A.) law restricts this device to sale, distribution and use by, or on, the order of a physician.
- 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 performance of the *SEW-EASY*[®] *SYSTEM* after cleaning or other reprocessing has not been verified and is not supported by LSI SOLUTIONS[®], Inc.
- 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 *SEW-EASY*[®] *SYSTEM*, as risks may vary with the site of application and the suture material used. Proper orientation of the prosthesis is required. Avoid crossing or twisting suture.
- 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, *SEW-EASY*[®] Cassettes, and *SEW-EASY*[®] Devices, along with packaging, must be inspected, handled and disposed of consistent with standard, accepted medical device disposal procedures.
- The *SEW-EASY*[®] *SYSTEM* used in conjunction with *RAM*[®] *COR-SUTURE*[®] *QUICK LOAD*[®] suture is not for use in neurological procedures.
- Applications other than for soft tissue approximation, or to approximate soft tissue and 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 needles into suture, pledgets, bone, dense ligamentous tissue, calcific tissue, metal features, stents, struts, components 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 *RAM*[®] *COR-SUTURE*[®] *QUICK LOAD*[®] suture with any LSI SOLUTIONS[®] *COR-KNOT*[®] *DEVICE* (*COR-KNOT*[®] *MIS DEVICE*, *COR-KNOT MINI*[®] *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 where appropriate.
- The *SEW-EASY*[®] *SYSTEM* will not fit through standard laparoscopic cannulas with seals.
- 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.
- Always assure cassette tip is viewed under direct visualization before advancing the needle.
- Ensure that obstructions do not interfere with the firing of the *SEW-EASY*[®] *SYSTEM*; obstruction may cause damage to the needles.
- Do not squeeze the pink lever of the *SEW-EASY*[®] *SYSTEM* while loading a *RAM*[®] *COR-SUTURE*[®] *QUICK LOAD*[®] suture; squeezing the pink lever may expose the sharp needles and/or damage the needles.
- In handling the *SEW-EASY*[®] *SYSTEM*, care should be taken to avoid jamming the suture into the needle cap compartment which can damage the needles.
- Avoid damage to the needles, 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*[®] *DEVICE* or *INTRA-KNOT*[®] *QUICK LOAD*[®] as warranted by surgical circumstances and the experience of the surgeon.
- After each loading and re-loading of a new suture into a cassette, carefully inspect that the new needle caps are fully seated in the needle cap compartment (see FIG. 2). 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 *SEW-EASY*[®] *SYSTEM* to dissect or aggressively manipulate tissue structures.
- Verify that the needle caps are 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 pink lever partially actuated. This may expose sharp surfaces that can cause trauma to the patient, the prosthesis, the device operator or other staff, or damage the device.
- Ensure the advancing needles target and enter the needle cap compartment. For example, during the suture placement, avoid using an extended needle to manipulate or lift tissue or prosthetic 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 cassette tip of the device and lead to undesired outcomes, including needle tip fracture, missed needle cap, or non-needle cap pickup.

ADVERSE REACTIONS

Adverse effects associated with the use of the *SEW-EASY*[®] *SYSTEM* include wound or prosthetic dehiscence or damage, failure to provide adequate wound support in closure of sites where expansion, stretching, distension, or leakage 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

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