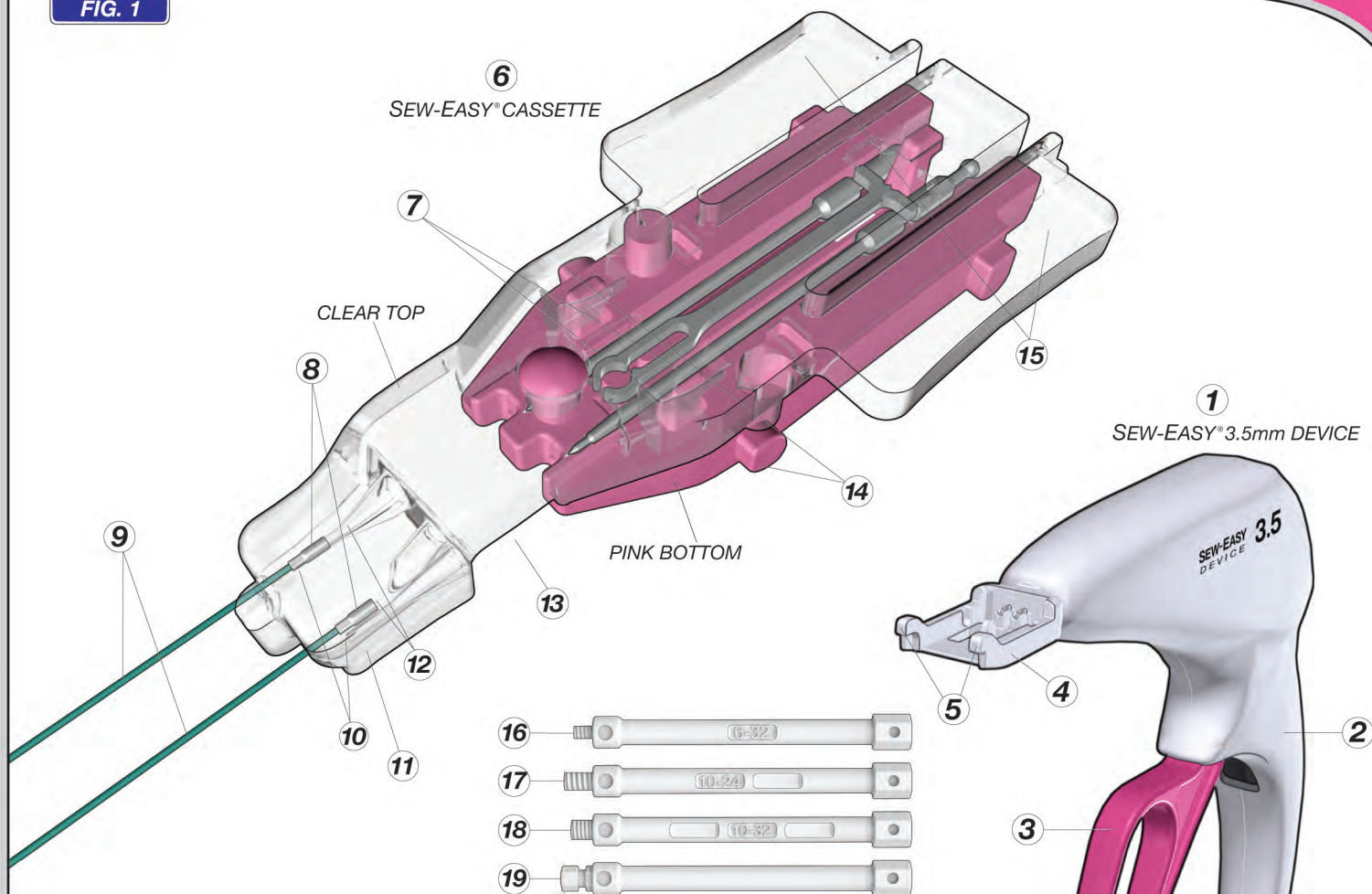


SEW-EASY® TECHNOLOGY GUIDE

 READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



SEW-EASY® SYSTEM

- ① SEW-EASY® DEVICE
- ② WHITE HANDLE
- ③ PINK LEVER
- ④ RECEIVER
- ⑤ ENGAGEMENT PRONGS
- ⑥ SEW-EASY® CASSETTE

- ⑦ DUAL NEEDLES
- ⑧ NEEDLE CAPS
- ⑨ SUTURE
- ⑩ NEEDLE CAP COMPARTMENTS
- ⑪ CASSETTE TIP
- ⑫ SUTURE SLOTS

- ⑬ CASSETTE JAW
- ⑭ LOCATING PEGS
- ⑮ SQUEEZE TABS
- ⑯ VALVE HANDLE 6-32
- ⑰ VALVE HANDLE 10-24
- ⑱ VALVE HANDLE 10-32
- ⑲ VALVE HANDLE HEX

SEW-EASY® DEVICE DESCRIPTION

Each sterile Combo Kit contains one (1) SINGLE PATIENT USE SEW-EASY® Suturing Device ①, twelve (12) SINGLE USE SEW-EASY® Cassettes ⑥, and four (4) SINGLE PATIENT USE Valve Handles ⑯ ⑰ ⑱ ⑲. 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 ⑧, are attached to each end of suture ⑨ in the RAM® COR-SUTURE® QUICK LOAD® Device. The needle caps are loaded into separate needle cap compartments ⑩ in the cassette tip ⑪ as shown in FIG. 1. The cassette is loaded (FIG. 3) into the SEW-EASY® Device by aligning the cassette locating pegs ⑭ under the engagement prongs ⑤ of 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, squeezing the pink lever advances the retracted needles ⑦ forward through the selected prosthetic material placed in the jaw ⑬ of the cassette tip and advances the needles into the needle caps which are attached to the suture in the cassette tip. Release of the pink lever retracts the needles, and pulls the 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 simultaneously squeezing the squeeze tabs ⑮ on the sides of the cassette and lifting upward. The device is now ready to receive the next cassette with loaded suture.

The SEW-EASY® SYSTEM is available in two (2) sizes of suture spacings (the distance between the needles): 3.5mm and 5mm. Refer to Product Ordering Chart on page 6.

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®

LOADING SUTURE

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



SEW-EASY
RAM

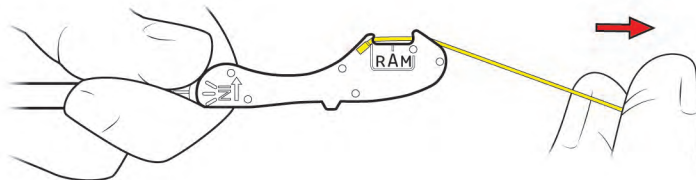
RAM

FIG. 2

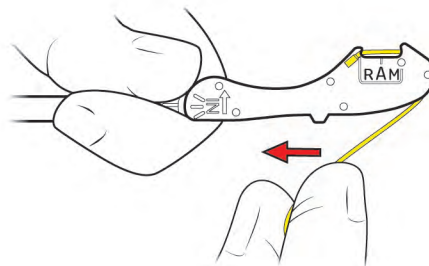
Option 1 Loading suture directly from RAM® Device

Ensure the 3.5mm SEW-EASY® Cassette is used only with the 3.5mm RAM® Device and the 5mm SEW-EASY® Cassette is used only with the 5mm RAM® Device.

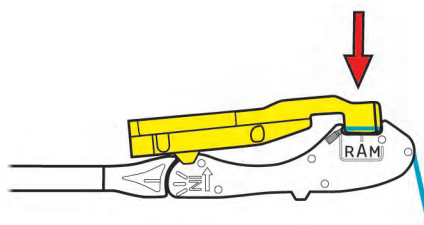
1 ALIGN both sutures in their corresponding suture slots across the jaw in the RAM® Device tip.



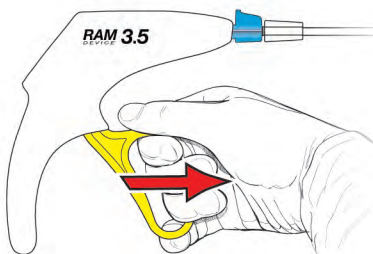
2 WRAP suture snugly around RAM® Device tip to secure taut within jaw.



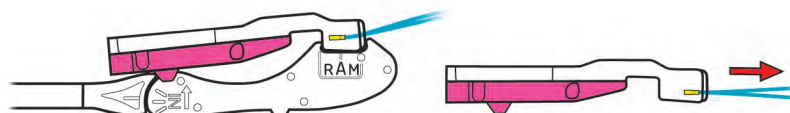
3 SET SEW-EASY® Cassette Tip in Tissue Gap of RAM® DEVICE.



4 RELEASE Needle Caps by pulling RAM® Device blue lever (shown yellow) fully forward.



5 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. Visually confirm proper needle cap placement.



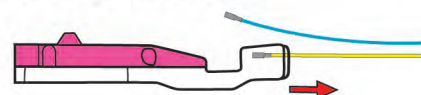
Option 2

MANUAL SUTURE LOADING WITHOUT RAM® DEVICE

INSERT suture into suture slot of SEW-EASY® Cassette



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



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 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 *SEW-EASY*® DEVICE is designed and intended for single patient use only. Do not reuse, reprocess, or resterilize this product. The performance of the *SEW-EASY*® 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 *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.
- The *SEW-EASY*® DEVICE is not intended for use in prosthetic materials through which the device needles cannot readily penetrate, based on the surgeon's judgment.
- The *SEW-EASY*® valve handles are not intended for use with prosthetic valves with which the valve handle does not readily connect.

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.
- Ensure 3.5mm *SEW-EASY*® Cassettes are used only with 3.5mm *SEW-EASY*® Devices and 3.5mm *RAM*® Devices. Similarly, ensure 5mm *SEW-EASY*® Cassettes are used only with 5mm *SEW-EASY*® Devices and 5mm *RAM*® Devices.
- 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.
- If the prosthetic sewing cuff does not readily release from the cassette jaw, or the cassette does not readily release from the device, ensure pink lever is fully released.
- 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 compartments 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 caps 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. Any serious device-related incident should be reported to the manufacturer and the country competent authority.

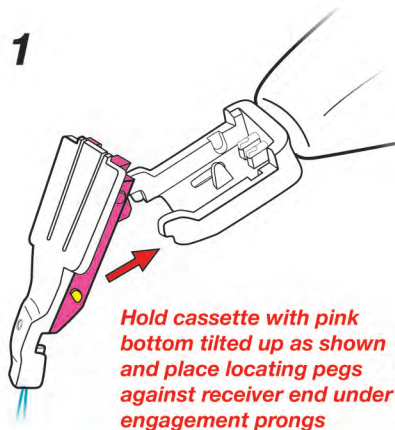
USING DEVICE

CASSETTE LOADING

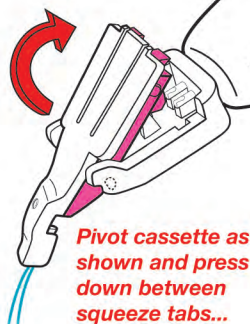
NOTE: Inspect suture alignment prior to needle cap seating and loading cassette.

FIG. 3

1



2

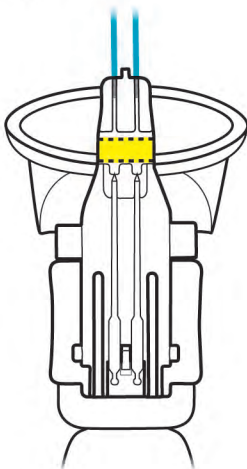


...until cassette snaps in place.

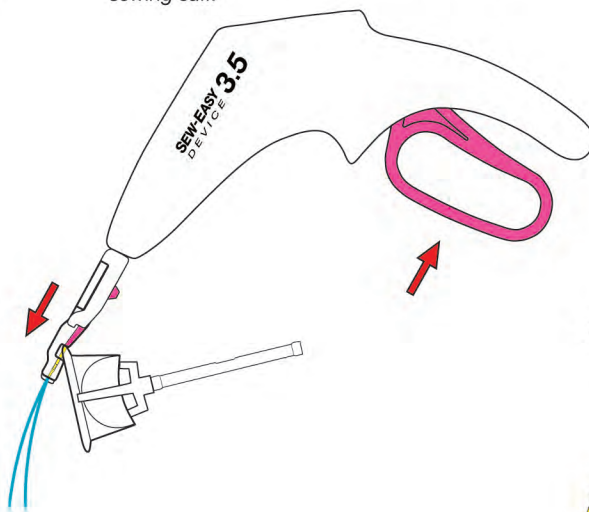


SUTURE PLACEMENT **NOTE:** Attach appropriate valve handle to prosthesis.

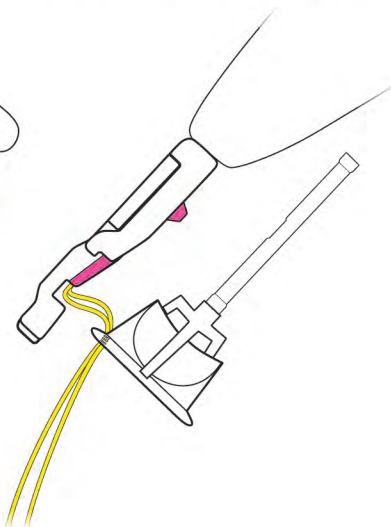
3 ALIGN cassette jaw over prosthetic sewing cuff. Look through the clear top and on both sides of the cassette jaw to observe needle entrance and exit positions carefully. Manipulate prosthesis with desired valve handle and follow manufacturer handling guidelines.



4 STABILIZE prosthesis and squeeze pink lever to advance both needles simultaneously forward through sewing cuff to pick up needle caps with suture. Do not move prosthesis with needles advanced within the sewing cuff.



5 RELEASE lever fully to pull suture back through prosthesis and retract the needles back into their compartments within the cassette. Carefully lift cassette jaw away from the prosthetic.



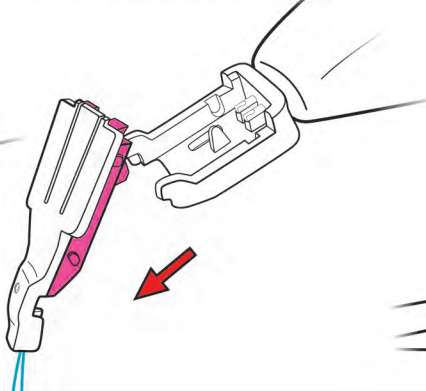
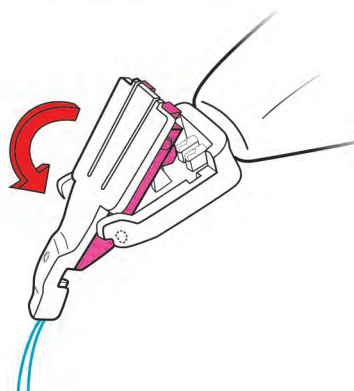
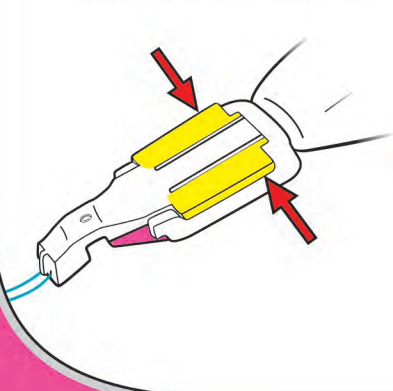
CASSETTE REMOVAL

6 Squeeze both cassette squeeze tabs as shown...

...and pivot cassette upward.

7 Lift Cassette out and away from SEW EASY® Device.

8 Cut both suture ends to remove cassette from suture.



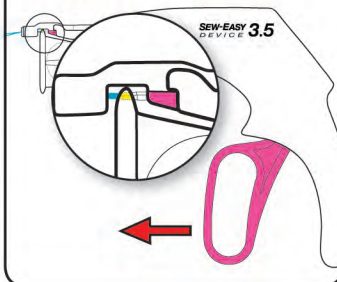
SEW-EASY® TECHNIQUE PEARLS

FIG. 4

COMPLETE SQUEEZE, COMPLETE RELEASE

Ensure that needles and needle caps are fully retracted into cassette.

IF NEEDLE CAPS ARE NOT FULLY RETRACTED INTO CASSETTE, PULL PINK LEVER FORWARD.



MOISTEN PROSTHETIC SEWING CUFF BEFORE FIRING SUTURE THROUGH

Refer to valve manufacturer's product insert.

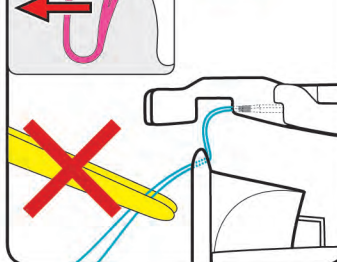
NO OBSTRUCTIONS

Avoid hitting metal instruments, prosthetic frame supports, prosthetic leaflets, stents, suture, or pledgets, etc.

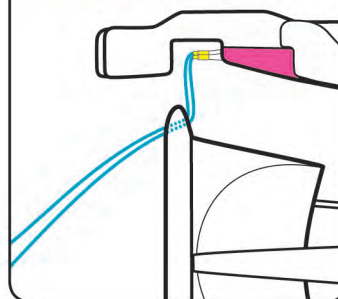
CONSULT PROSTHETIC PRODUCT INSERT TO ASSURE PROPER PLACEMENT IN PROSTHETIC VALVE RING

Incorrect placement can damage needles or prosthesis.

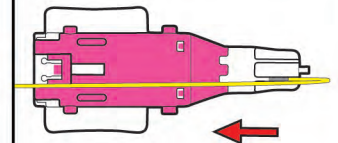
DO NOT HOLD SUTURE WHEN RELEASING LEVER



DO NOT REIRE DEVICE AFTER ENGAGING NEEDLE CAPS

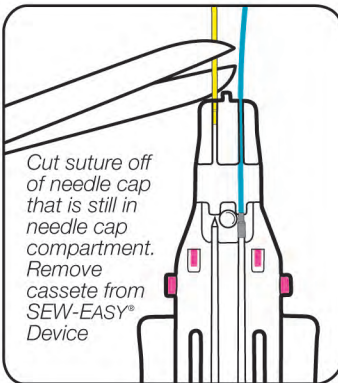


IF NECESSARY TO REMOVE SUTURE FROM CASSETTE, DOUBLE THE SUTURE AGAINST THE SUTURE SLOT AND PULL THE NEEDLE CAP STRAIGHT OUT.

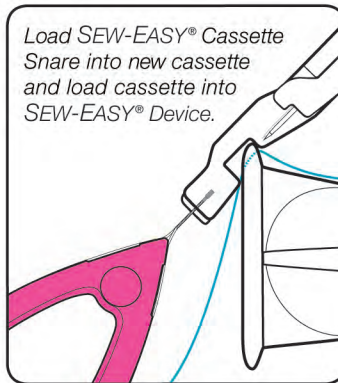


If device fails to pick up one needle cap:

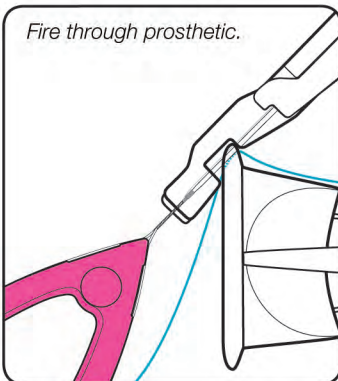
Cut suture off of needle cap that is still in needle cap compartment. Remove cassette from SEW-EASY® Device



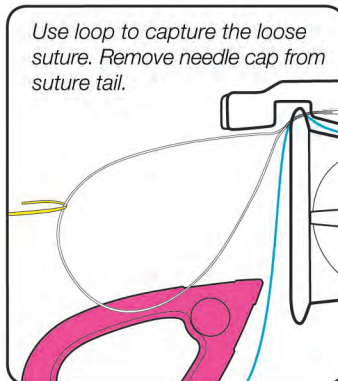
Load SEW-EASY® Cassette Snare into new cassette and load cassette into SEW-EASY® Device.



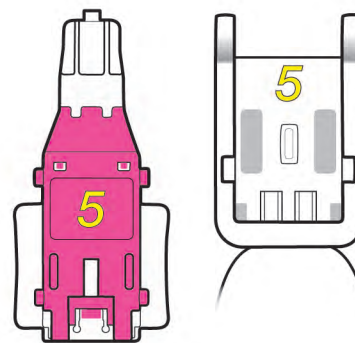
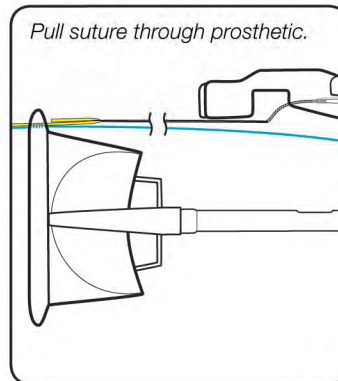
Fire through prosthetic.



Use loop to capture the loose suture. Remove needle cap from suture tail.



Pull suture through prosthetic.

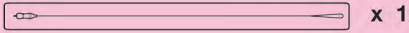
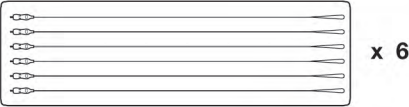


Ensure 5mm SEW-EASY® Cassettes are used only with 5mm SEW-EASY® Devices as shown. Similarly, ensure 3.5mm SEW-EASY® Cassettes are used only with 3.5mm SEW-EASY® Devices.

NOTE: 3.5mm SEW-EASY® Cassettes are not marked with their sizes.

FIG. 5 PRODUCT ORDERING

SUPPLIED: STERILE

	REORDER 3.5mm SPACING	REORDER 5mm SPACING	PRODUCT	DESCRIPTION
 x 6	REF 022200	REF 022797	SEW-EASY® COMBO KIT	Box of 6 Kits (1 Device, 12 Cassettes, and 4 Valve Handles per Kit)
 x 6	REF 022201	REF 022804	SEW-EASY® DEVICE KIT	Box of 6 Kits (1 Device and 4 Valve Handles per Kit)
 x 12	REF 022160	REF 022811	SEW-EASY® CASSETTE SINGLES	Box of 12 Cassettes (1 Cassette per Pouch)
 x 6	REF 021900	REF 022580	RAM® DEVICE	Box of 6 Kits (2 Devices per Kit)
 x 12	REF 022039	REF 022668	RAM® COR-SUTURE® QUICK LOAD® SINGLES Pledgeted 2-0 Polyester, Green, Non-Absorbable, 38"	Box of 12 Sutures (1 Suture per Pouch)
 x 12	REF 022047	REF 022671	RAM® COR-SUTURE® QUICK LOAD® SINGLES Pledgeted 2-0 Polyester, White, Non-Absorbable, 38"	Box of 12 Sutures (1 Suture per Pouch)
 x 12	REF 022335	REF 022674	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	REF 022677	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)
 x 12	REF 022540*		SEW-EASY® SNARE	Box of 12 Snares (1 Snare per Pouch)

*Not CE Marked

FIG. 6 INCLUDED VALVE HANDLES

Handle ID	Connection Type	Intended Compatibility	
 6-32	6-32 Thread	Medtronic	Hancock™ II, Hancock II Ultra™, Mosaic™, Mosaic Ultra™
 10-24	10-24 Thread	Edwards	Magna Ease, Magna Mitral Ease, Inspiris Resilia
 10-32	10-32 Thread	Medtronic	Avalus™
	HEX	Abbot	Epic™ Plus Supra

LSI SOLUTIONS®

The Basic UDI-DI for this device is 0850200006SEW-EASY68.

Patents: www.lsisolutions.com/patents

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STERILE EO

Rx Only



2797

EC REP

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