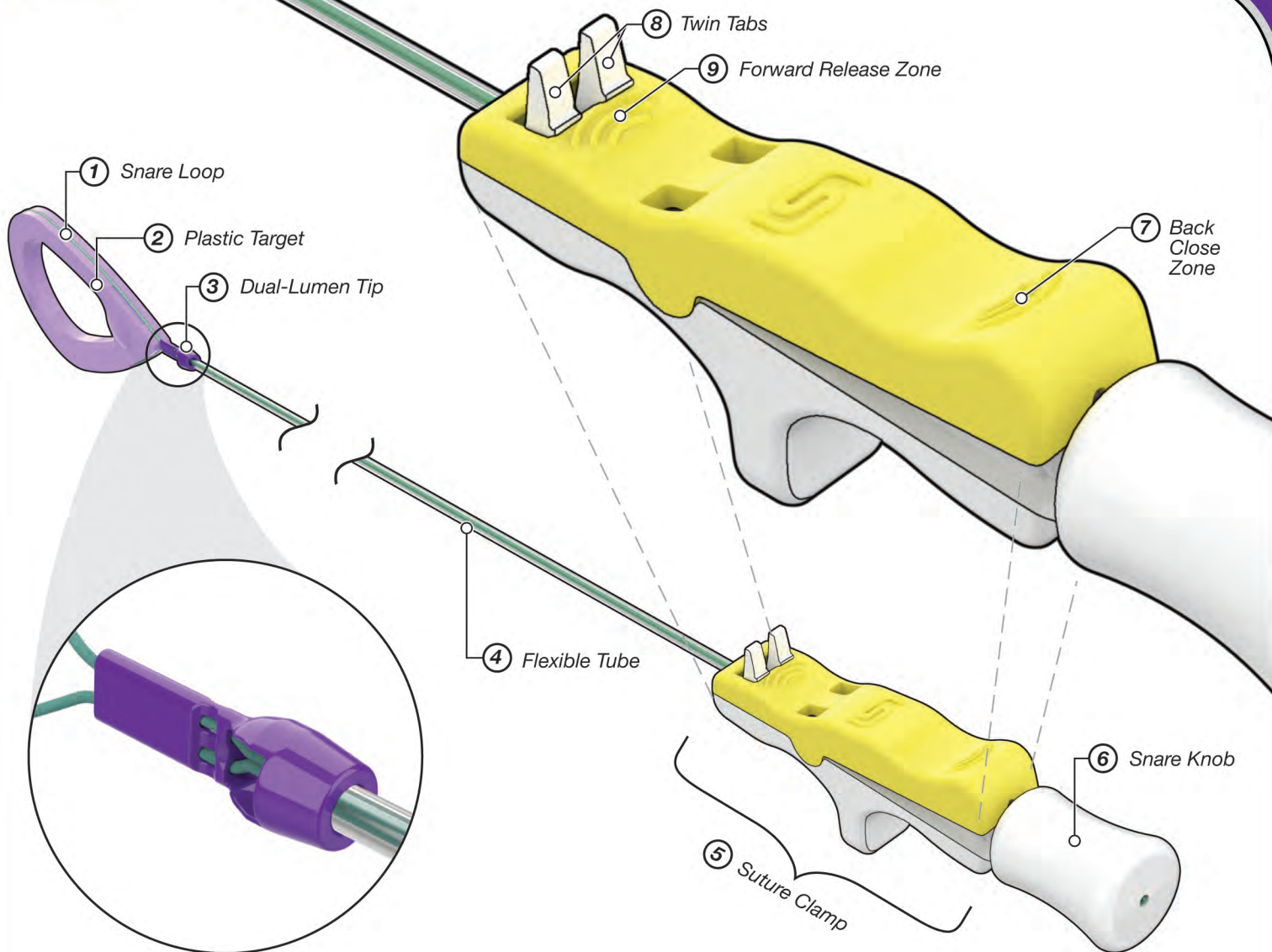


BOBSnare™ DEVICE TECHNOLOGY GUIDE

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



BOBSnare™ DEVICE DESCRIPTION

The BOBSnare™ DEVICE temporarily holds surgical suture to facilitate length evaluation and to stabilize the surgical suture during titanium fastener deployment or manual knot-tying. The BOBSnare™ DEVICE incorporates an adjustable size 2-0 green polyester suture snare loop (1) holding a lavender plastic target (2). The snare loop extends from the purple dual-lumen tip (3) through a clear flexible tube (4) and into the suture clamp (5), which can be locked and unlocked to control tension on the snare loop. Both ends of a surgical suture coming from the targeted tissue are passed through the snare loop after removing the lavender target. While holding the dual-lumen tip, the surgical suture can be pulled to adjust the length and tension. When desired surgical suture length and tension are established, pulling the snare knob (6) draws the snare loop tightly around the surgical suture at the dual-lumen tip. The snare loop can be locked by pressing down on the back close zone (7) on the suture clamp, temporarily maintaining the surgical suture's length and tension for observation and evaluation. Pressing the twin tabs (8) forward and pressing down on the forward release zone (9) releases the snare loop, allowing for surgical suture readjustment as desired. When appropriate surgical suture length and tension have been demonstrated, the surgical suture can be permanently secured using a titanium fastener or hand-tied knot. After the suture is secure, the snare loop can be released and the BOBSnare™ DEVICE removed from the surgical site.

INDICATIONS FOR USE

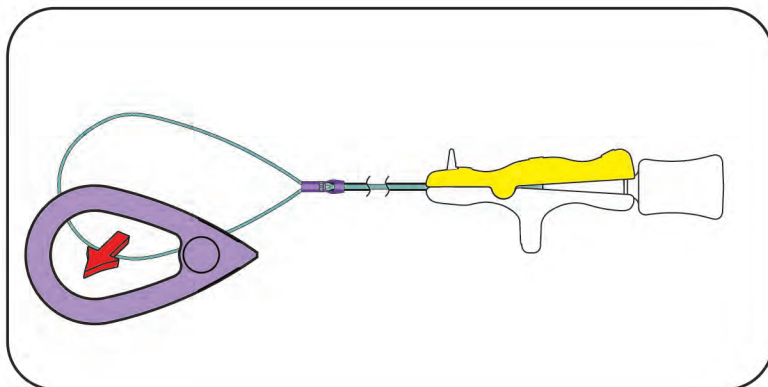
The BOBSnare™ DEVICE is indicated for use to temporarily hold LSI SOLUTIONS® 2-0 polypropylene, 2-0 polyester, or LS-5™ ePTFE suture during surgery.

 LSI SOLUTIONS®

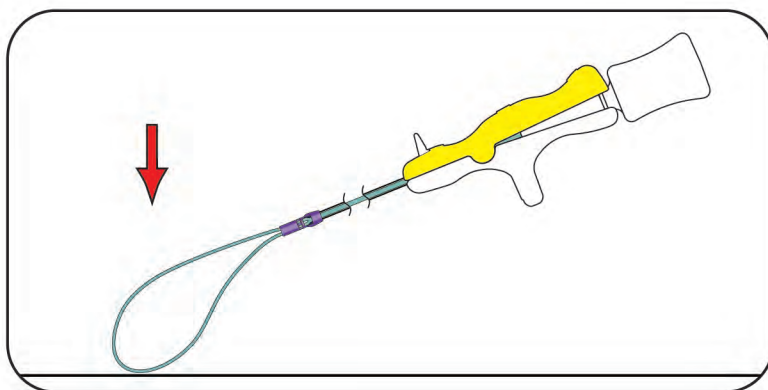
LOADING

NOTE: Remove device packaging and components from the surgical field when no longer in use and dispose of per hospital policy.

1 PUSH OUT and remove the lavender plastic target from the snare loop of the *BOBsnare™* DEVICE.



2 LOWER the snare loop near a sterile surface adjacent to the targeted tissue site to avoid surgical suture falling out of the snare loop.

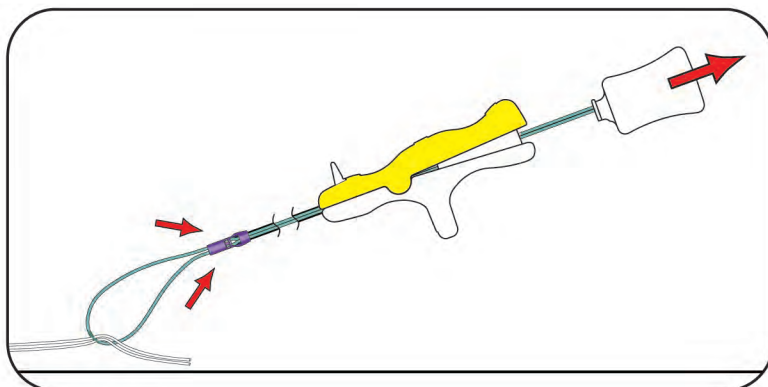


3 PASS both ends of the surgical suture through the snare loop.

NOTE: Ensure that needles or needle caps are removed from the surgical suture and properly disposed of before passing suture through the snare loop.



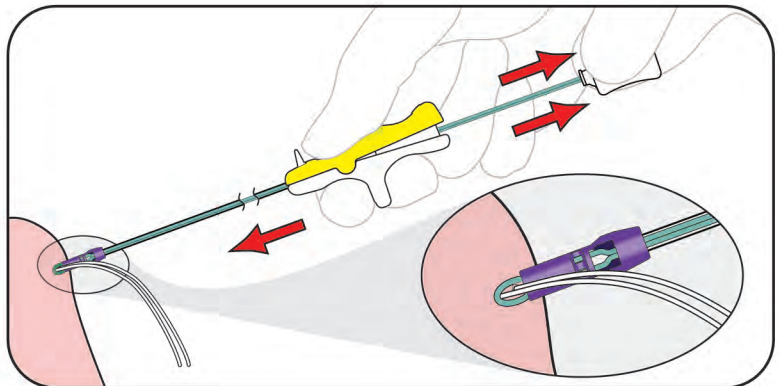
4 PULL the snare knob away from the suture clamp while slightly lowering the dual-lumen tip to partially tension the snare loop around the surgical suture.



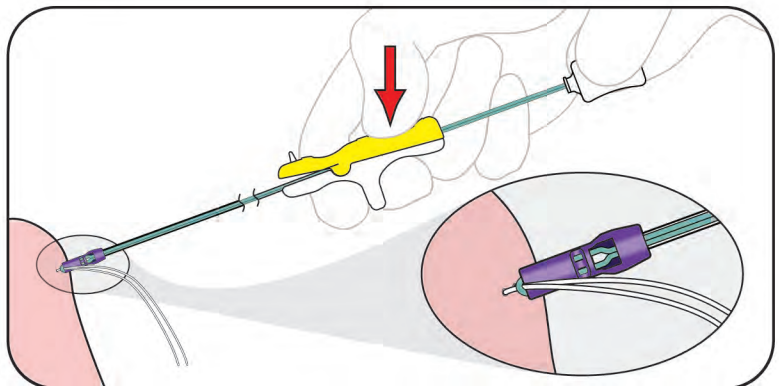
CLOSING

5 SLIDE the dual-lumen tip over the surgical suture until appropriate surgical suture tension and tissue contact is established, then pull the snare knob to draw the snare loop tightly around the surgical suture.

NOTE: Standard surgical tools, such as forceps or a grasper, may be used to guide the dual-lumen tip toward the targeted tissue.



6 CLOSE the suture clamp by pressing down on the textured back close zone to snap closed the internal features in the suture gripping area and set the suture clamp into its clamped, closed position securing the surgical suture at the dual-lumen tip.

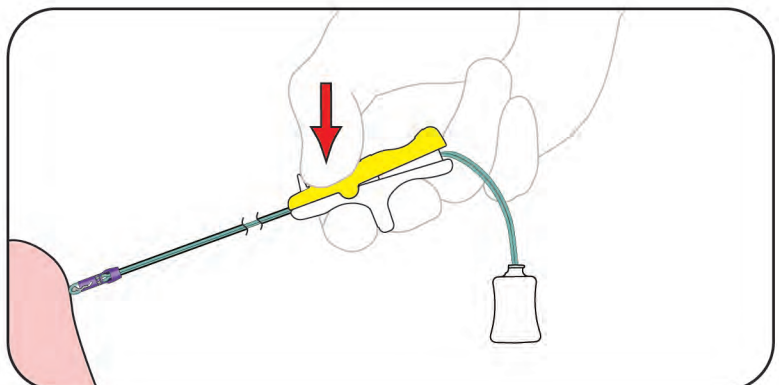


BACK DOWN  CLAMP DOWN

OPENING

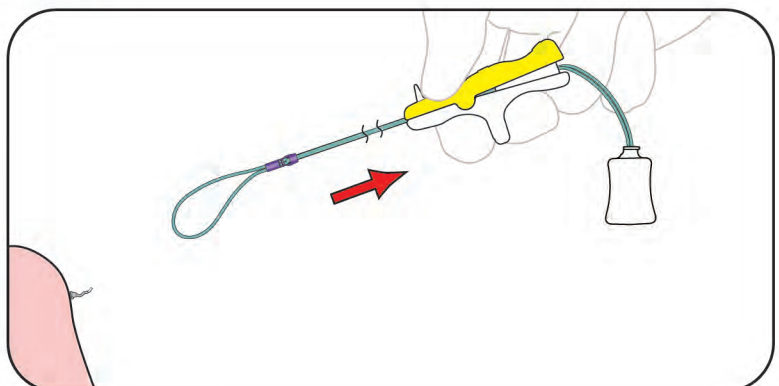
7 OPEN the suture clamp by pushing both white twin tabs forward and pressing down on the textured forward release zone to set the suture clamp into its unclamped, open position.

NOTE: If desired, surgical suture tension may be readjusted by repeating step 5 and step 6.



8 REMOVE the BOBSnare™ DEVICE by loosening the snare loop and passing the loop around the titanium fastener or hand-tied knot, then withdrawing the device.

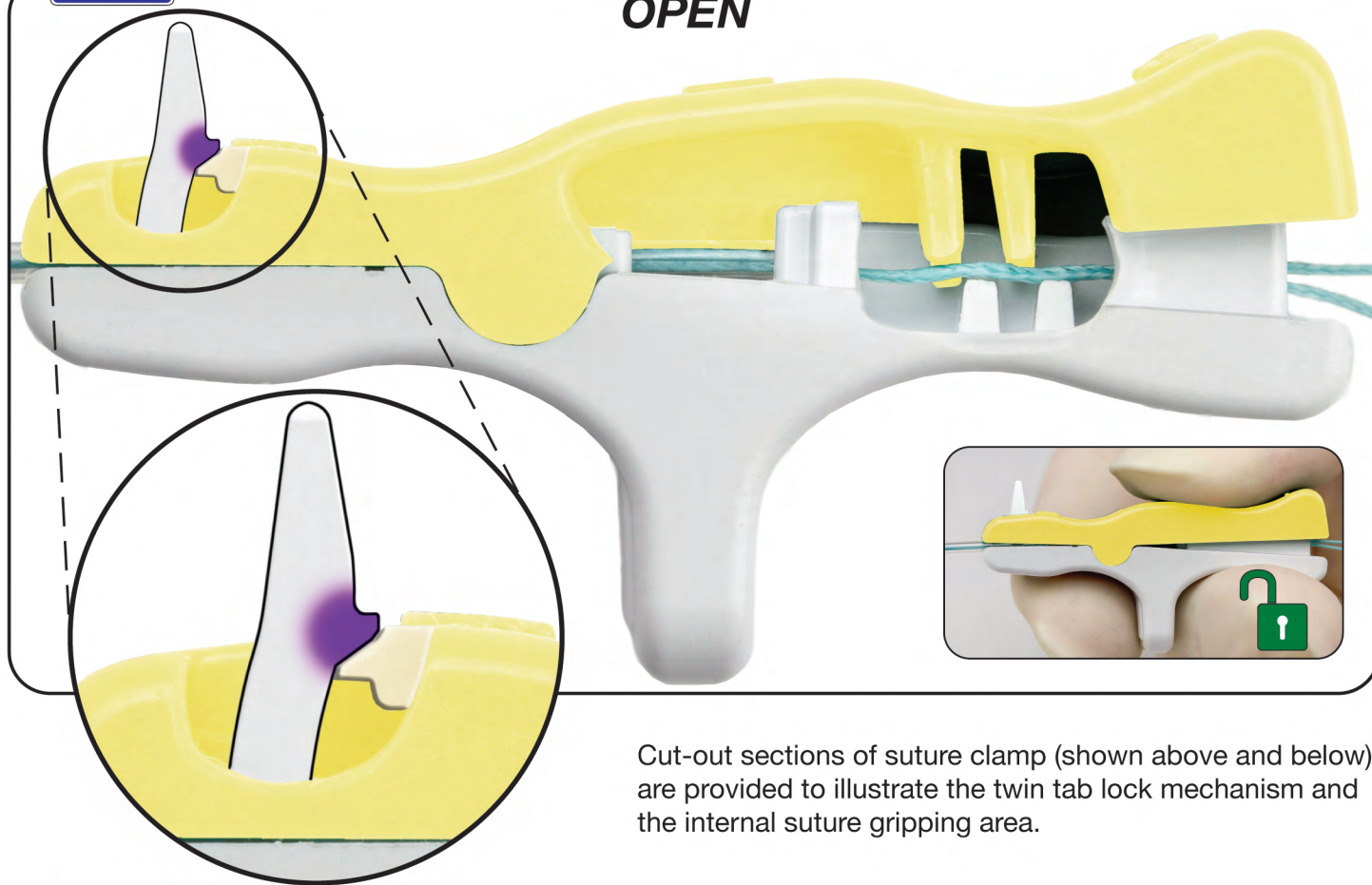
NOTE: Standard surgical tools, such as forceps or a grasper, may be used to loosen and pass the snare loop around the titanium fastener or hand-tied knot.



BACK UP  OPEN UP

FIG. 2

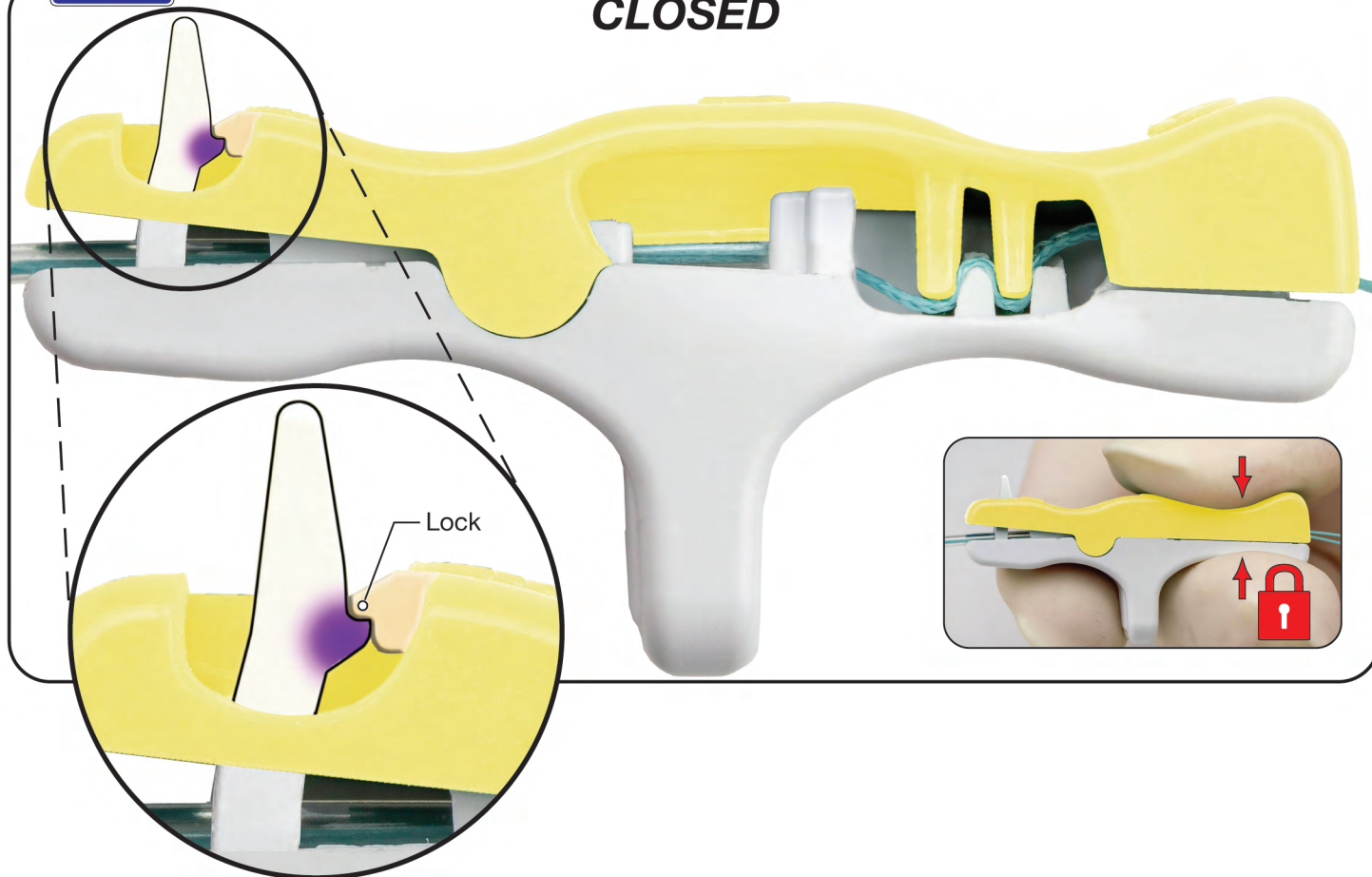
OPEN



Cut-out sections of suture clamp (shown above and below) are provided to illustrate the twin tab lock mechanism and the internal suture gripping area.

FIG. 3

CLOSED

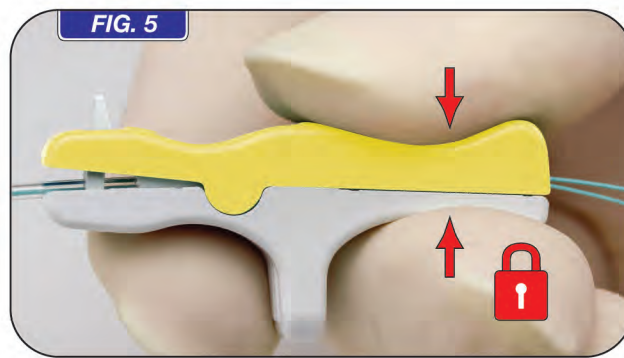


BOBSnare™ DEVICE TECHNIQUE PEARLS

BACK UP  OPEN UP



BACK DOWN  CLAMP DOWN



CONTRAINDICATIONS

- None known.

WARNINGS

- Federal law restricts this device to sale, distribution, and use by, or on, the order of a physician.
- Surgical procedures should only be performed by physicians having adequate training and familiarity with such techniques. In addition, medical literature should be consulted relative to techniques, complications, and hazards prior to the performance of open or minimally invasive procedures.
- Read and become familiar with all instructions, warnings, and precautions before using this product.
- Do not exert excessive tension on the surgical suture. Excessive suture tensioning can damage or tear tissue, cause bleeding, injure structures adjacent to the target site, and/or cause suture breakage.
- Store at room temperature. Avoid prolonged exposure to elevated temperatures.
- Do not resterilize. The BOBSnare™ DEVICE is designed and intended for single-patient use only. Do not reuse, reload, reprocess, or resterilize this product. The performance of the BOBSnare™ DEVICE after cleaning or other reprocessing has not been verified and is not supported by LSI SOLUTIONS®. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Do not use if package or product is damaged. Discard any open (unsealed), unused, expired, or damaged product.
- Direct contact between sensitive tissue structures and foreign materials can lead to tissue injury or damage.
- Leaving tissue under tension for a prolonged period of time can cause tissue ischemia or damage. This device is for temporary use during a surgical procedure by operators trained and competent in related techniques.
- Before passing surgical suture through the BOBSnare™ snare loop, ensure that any needles or needle caps are removed from the suture ends.
- It is the responsibility of the user to dispose of the device and packaging in accordance with applicable regulations and hospital procedures.
- The BOBSnare™ snare loop must be drawn tightly around the surgical suture to ensure tensioning and consistent engagement of the surgical suture and the snare loop. Loss of suture tension can lead to loss of control at the tissue site and bleeding.

PRECAUTIONS

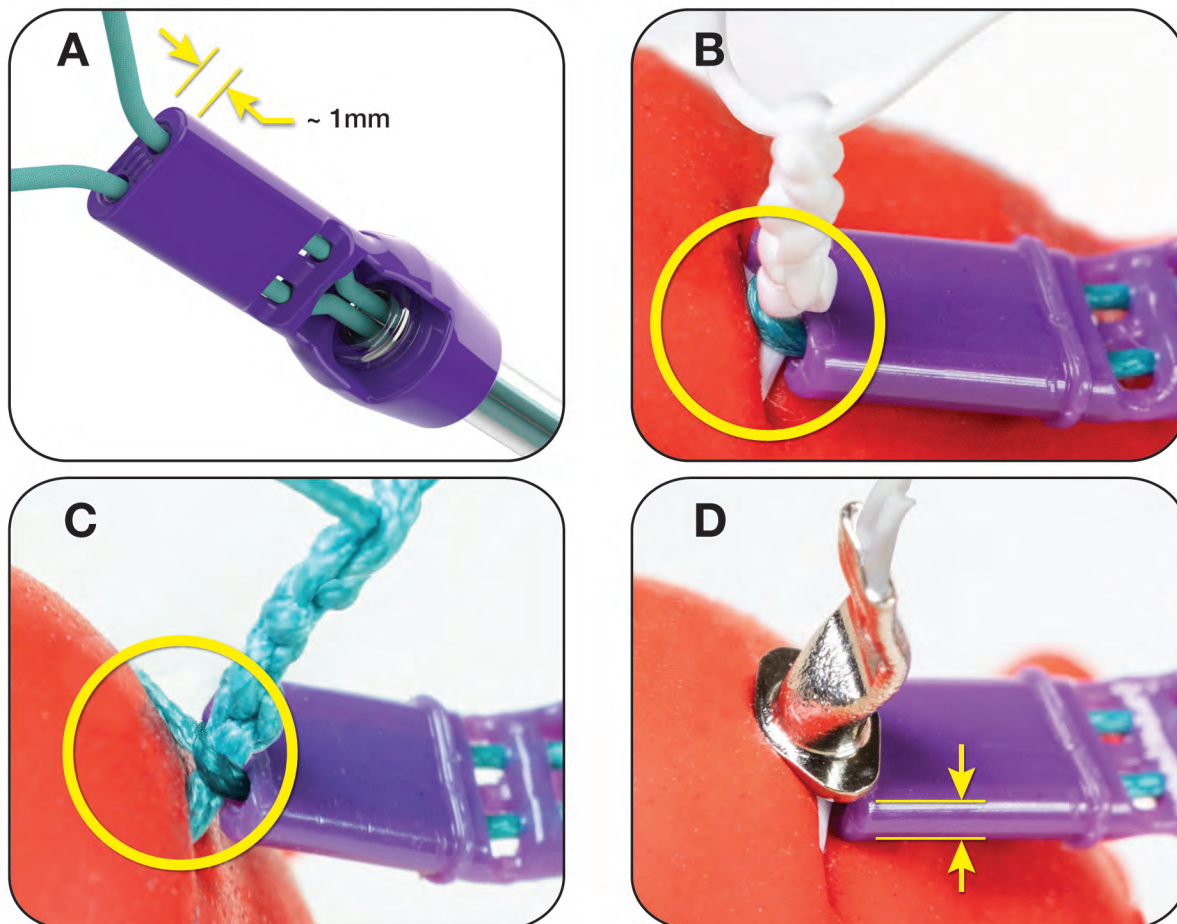
- Do not use the BOBSnare™ DEVICE if it does not satisfactorily perform its intended function or if it has physical damage. Avoid mechanical impact or overstressing the devices.
- When handling the BOBSnare™ DEVICE, care should be taken to avoid damage to the device.
- Ensure proper surgical techniques, including adequate tissue bites, as needed for the handling of tissue and surgical suture for use of BOBSnare™ devices.
- Adequacy of the surgical suture holding force should be confirmed by the user.
- Check for and ensure hemostasis and/or proper tissue control upon securing the surgical suture and thereafter when appropriate.
- Before instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that function is not compromised. Also, ensure that electrical isolation or grounding are not compromised.
- Use only with LSI SOLUTIONS® 2-0 polypropylene, 2-0 polyester, or LS-5™ ePTFE suture.
- Avoid holding excess tension on the surgical suture, which can cause the suture to tear or cut through tissue or, over time, cause ischemia or tissue strangulation by the tensioned surgical suture.
- Inadequate suture tensioning can lead to obstruction in viewing of the surgical view, improper setup of the surgical field, loss of tissue control, bleeding, or leakage.
- The BOBSnare™ DEVICE dual-lumen tip occupies a small amount of space between the targeted tissue site and the bottom of a hand-tied knot or titanium fastener. When adjusting the BOBSnare™ DEVICE on surgical suture, ensure that the suture loop length compensates for the removal of the device. Verify that surgical suture is of appropriate length following BOBSnare™ DEVICE removal.

NOTE:

- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the country competent authority.

FIG. 6

Close-up of *BOBSnare™* *DEVICE* showing **A:** *BOBSnare™* dual-lumen tip; **B:** *LS-5™* ePTFE secured with a hand-tied knot; **C:** *LSI SOLUTIONS®* 2-0 polyester secured with a hand-tied knot; **D:** *LS-5™* ePTFE secured with a titanium fastener.



The surgeon must anticipate and compensate for the thickness of the *BOBSnare™* *DEVICE* tip when determining appropriate suture loop length prior to device removal.

FIG. 7

***BOBSnare™* *DEVICE* Approximate Snare Loop Holding Force**

Suture Size and Type	Avg. Holding Force (kgf)
LSI SOLUTIONS® 2-0 Polypropylene	0.217
LSI SOLUTIONS® 2-0 Polyester	0.381
LS-5™ ePTFE	0.338

***BOBSnare™* *DEVICE* PRODUCT ORDERING**

SUPPLIED: STERILE

	REORDER	PRODUCT	DESCRIPTION
 x 12	REF 082000	<i>BOBSnare™</i> <i>DEVICE</i>, 30cm	(1) Box of (12) <i>BOBSnare™</i> <i>DEVICES</i>

The Basic UDI-DI for the *BOBSnare™* *DEVICE™* is 0850200006BOBSnareVV.

LSI SOLUTIONS®

Patents: www.lsisolutions.com/patents

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Symbol Glossary: www.lsisolutions.com/symbols

EC REP

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Westervoortsedijk 60
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The Netherlands



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UK.Registrations@ul.com



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