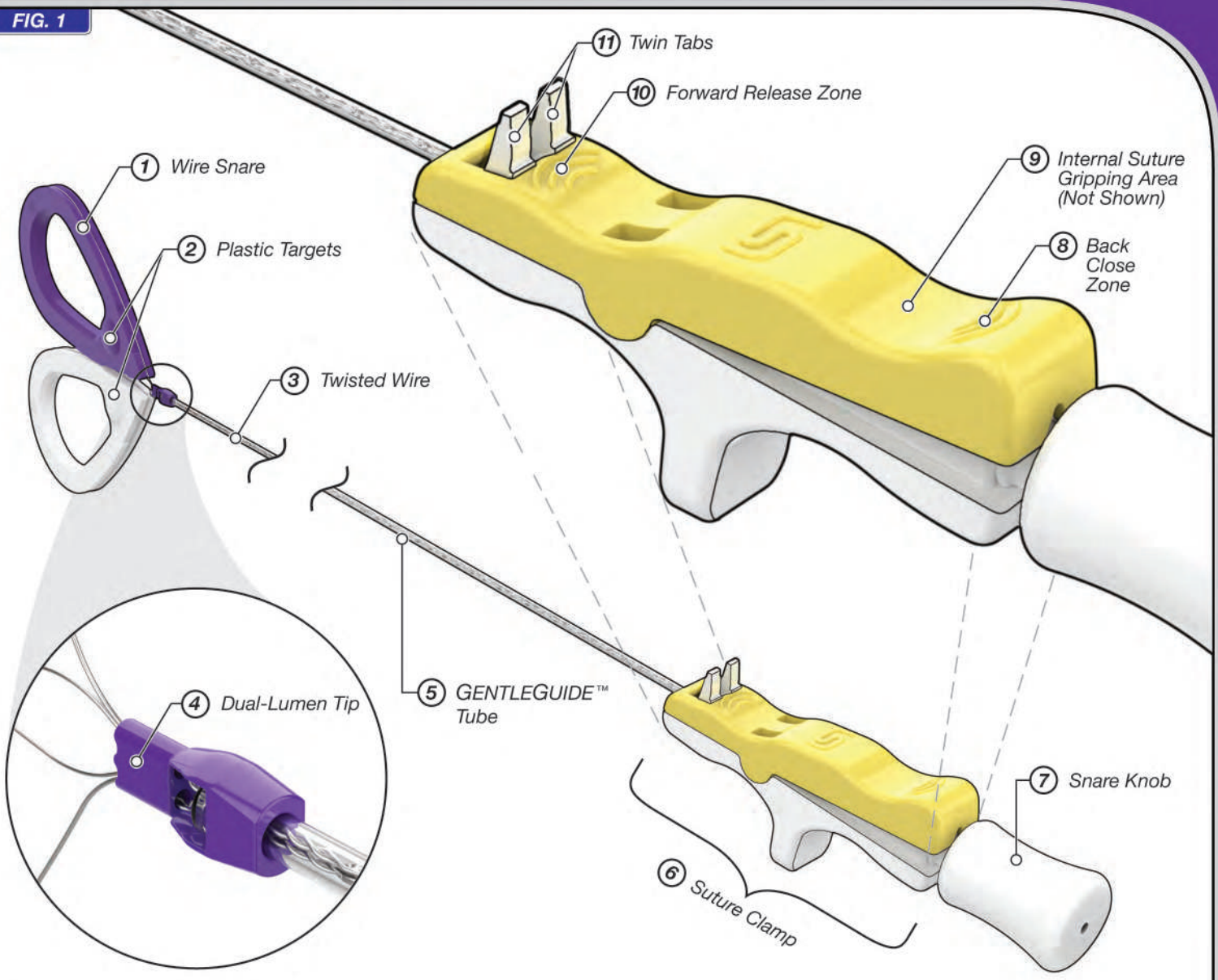
GENTLEGUIDE™ *DEVICE* TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



GENTLEGUIDE™ *DEVICE* DESCRIPTION

The *GENTLEGUIDE*™ *DEVICE* consists of two wire snares ① that hold purple and white plastic targets ②. The wire snares are connected to twisted wires ③ that pass through the dual-lumen tip ④ and through the *GENTLEGUIDE*™ tube ⑤. The tube and twisted wires run through the suture clamp ⑥. After the plastic targets are removed, each end of a surgical suture is passed through one of the wire snares. The snare knob ⑦ is then pulled out away from the suture clamp to thread the suture through the *GENTLEGUIDE*™ tube and suture clamp. After establishing desired suture tension, the back close zone ⑧ on the suture clamp can be pressed down to securely clamp the suture by engaging features in the internal suture gripping area ⑨ (not shown here; see FIG. 3), setting the *GENTLEGUIDE*™ into its clamped, closed position. While in this position, the suture is held relative to the *GENTLEGUIDE*™ tube and suture clamp. Pressing down on the forward release zone ⑩ while pressing the twin tabs ⑪ forward sets the *GENTLEGUIDE*™ into its unclamped, open position. While in this position, the internal suture gripping area features are no longer holding the suture, so that it may be adjusted as necessary. The suture clamp can be repeatedly opened or closed as desired.

INDICATIONS FOR USE

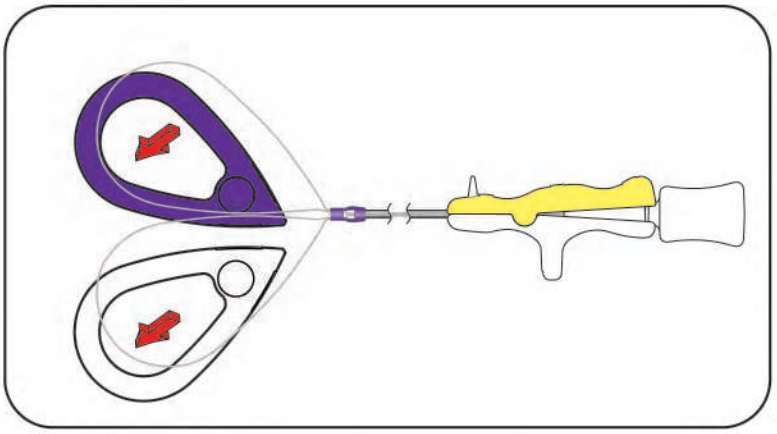
The *GENTLEGUIDE*™ *DEVICE* is indicated for use to temporarily hold LSI SOLUTIONS® suture during surgery.

LSI SOLUTIONS®

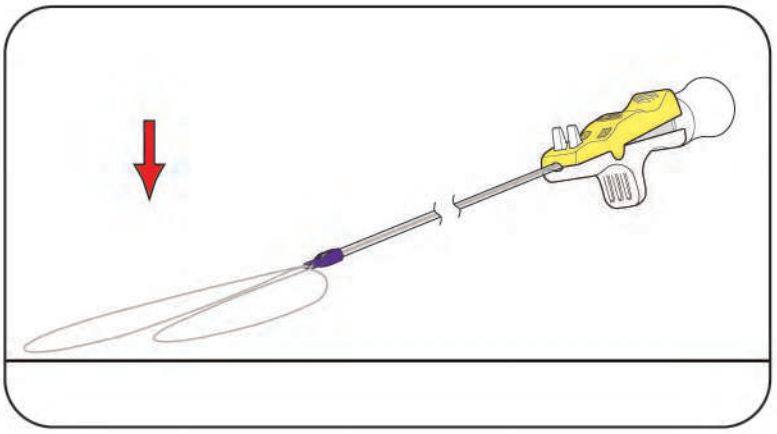
LOADING

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 purple and white plastic targets from the wire snares of the *GENTLEGUIDE™ DEVICE*.

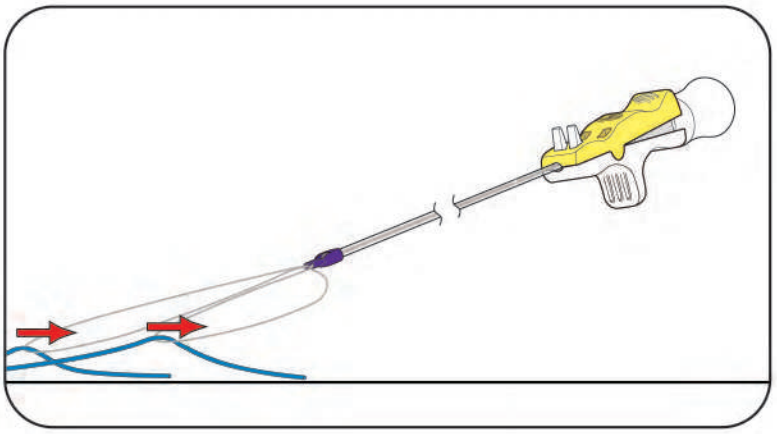


2 ***LOWER*** the *GENTLEGUIDE™* wire snares near a sterile surface adjacent to the targeted tissue site to avoid surgical suture falling out of the wire snares.

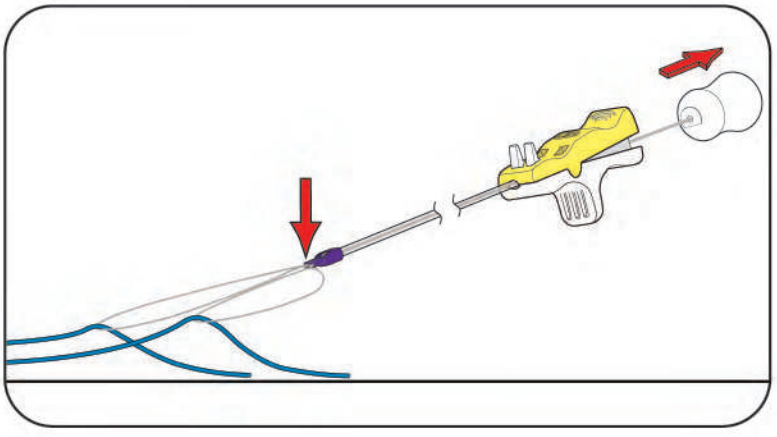


3 ***PASS*** about 1–2in (2–5cm) of each end of a single suture through a separate wire snare.

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



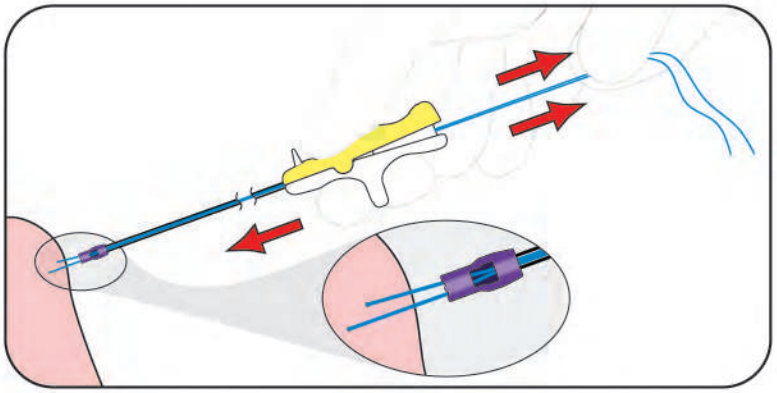
4 ***PULL*** the snare knob away from the suture clamp while stabilizing the distal end of the device and slightly lowering the device to thread the suture through the *GENTLEGUIDE™* tube and suture clamp.



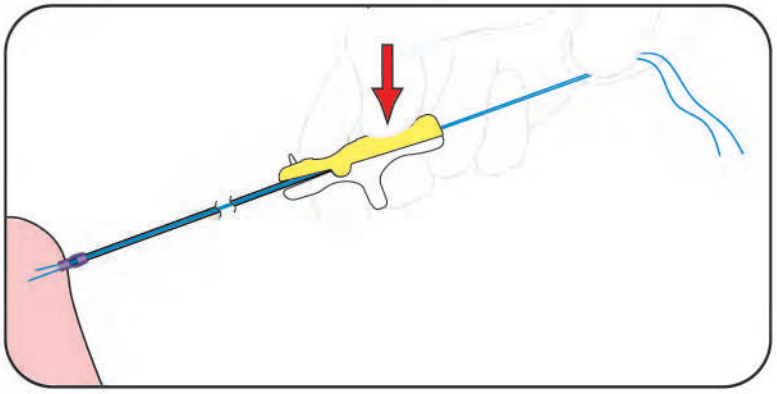
GENTLEGUIDE™ DEVICE CLOSING/OPENING

CLOSING

5 ***SLIDE*** the dual-lumen tip over the surgical suture toward the tissue until appropriate tissue contact is established, then pull both suture ends to achieve desired tension.



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.

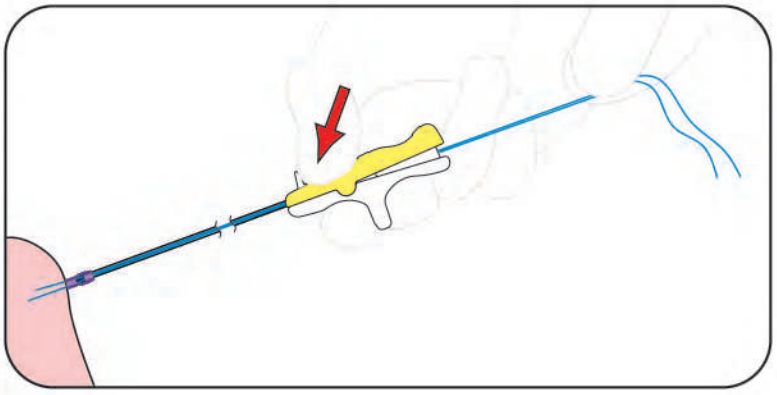


BACK DOWN **CLAMP DOWN**

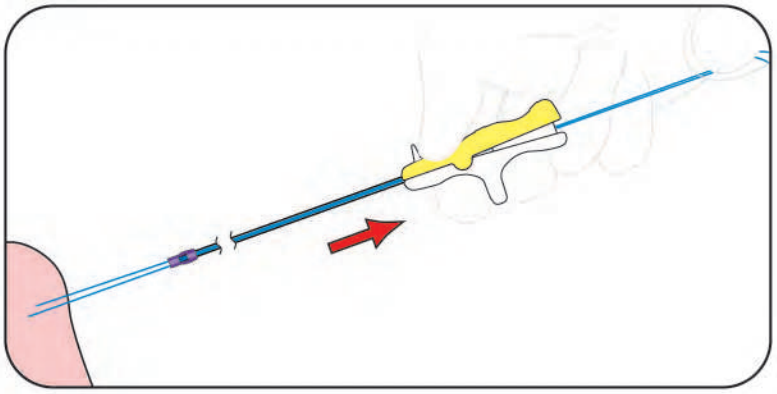
OPENING

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 after the desired suture tension is achieved.



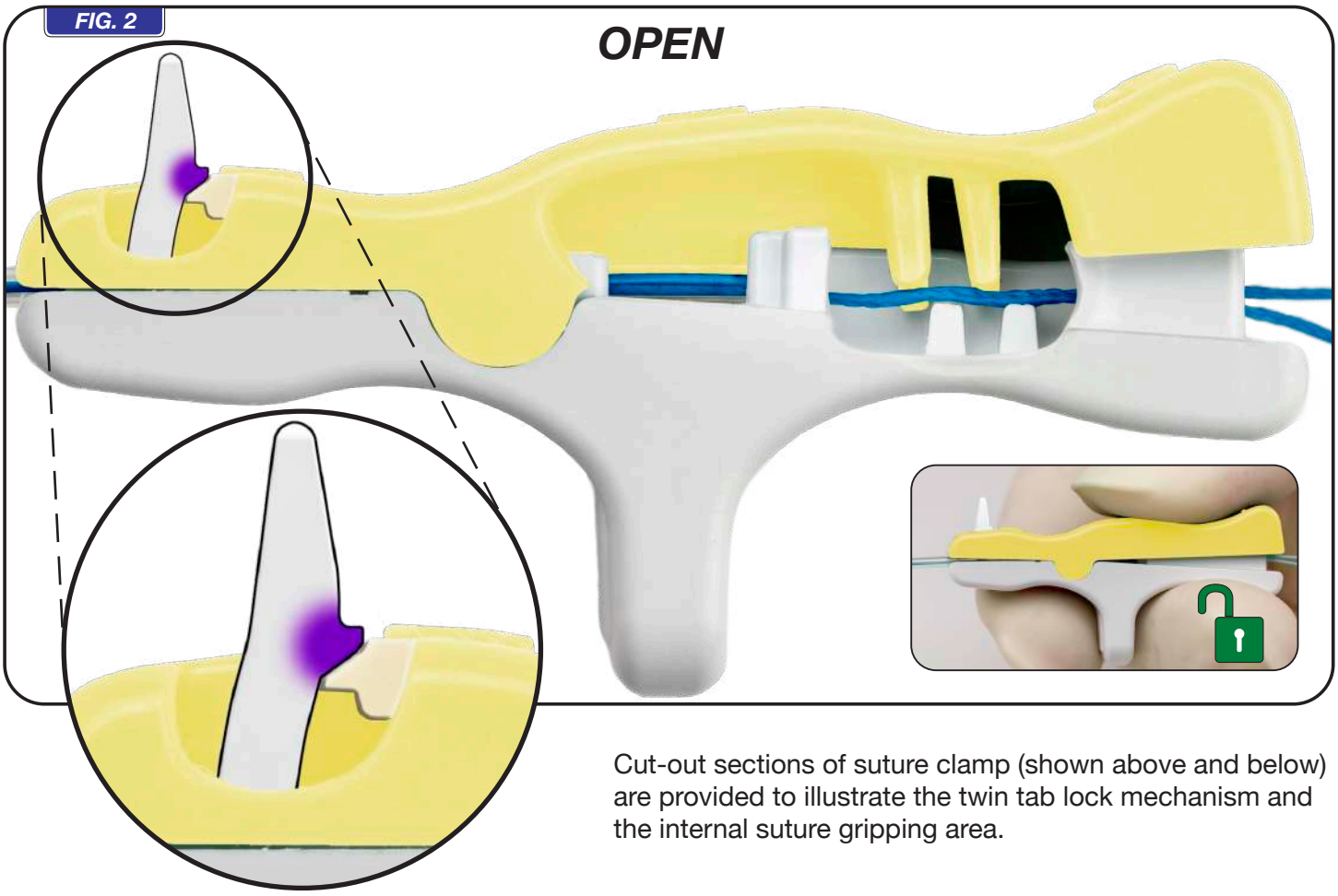
8 ***REMOVE*** the *GENTLEGUIDE™ DEVICE* by sliding the *GENTLEGUIDE™* tube over the suture and away from the tissue.



BACK UP **OPEN UP**

FIG. 2

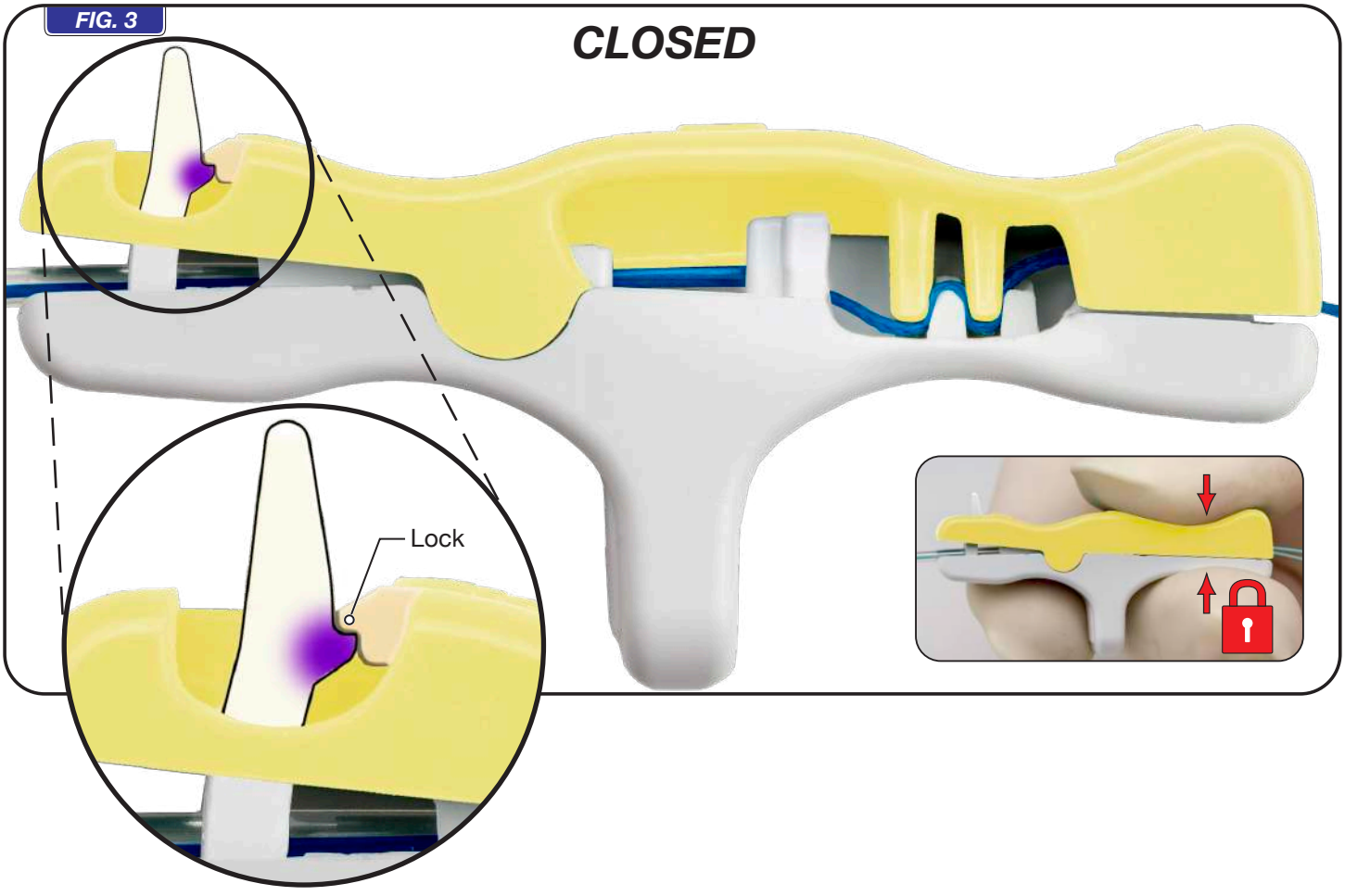
OPEN



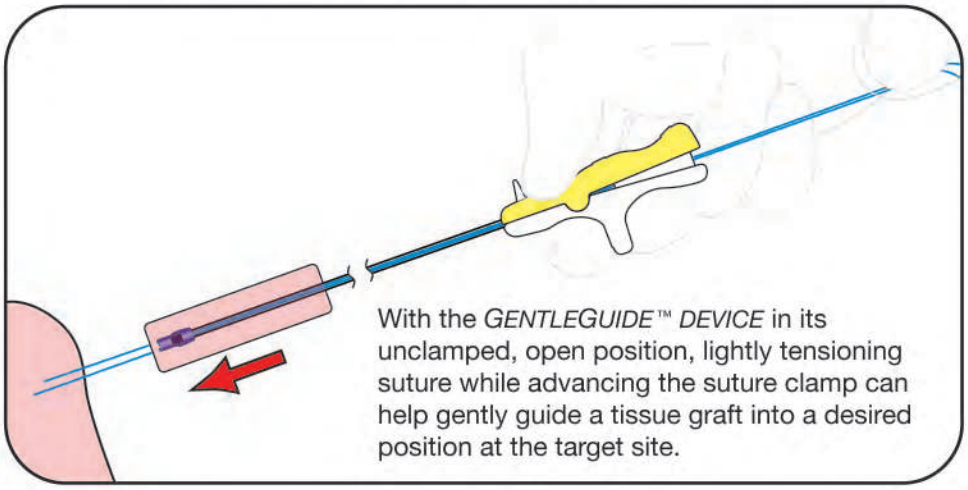
Cut-out sections of suture clamp (shown above and below) are provided to illustrate the twin tab lock mechanism and the internal suture gripping area.

FIG. 3

CLOSED



GENTLEGUIDE™ DEVICE TECHNIQUE PEARLS



With the *GENTLEGUIDE™ DEVICE* in its unclamped, open position, lightly tensioning suture while advancing the suture clamp can help gently guide a tissue graft into a desired position at the target site.

CONTRAINDICATIONS

- The *GENTLEGUIDE™ DEVICE* is contraindicated for use in circulating blood.

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 *GENTLEGUIDE™ DEVICE* is designed and intended for single-patient use only. Do not reuse, reload, reprocess, or resterilize this product. The performance of the *GENTLEGUIDE™ 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 (opened), 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.
- Ensure that the *GENTLEGUIDE™* clamp is unclamped (i.e., fully released) and that the suture slides freely through the *GENTLEGUIDE™* tube to removing the *GENTLEGUIDE™ DEVICE*.
- Before passing suture through the *GENTLEGUIDE™* wire snares, ensure that any needle caps or needles 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 *GENTLEGUIDE™* suture clamp must be fully closed to ensure tensioning and consistent engagement of the suture within the tube. Loss of suture tension can lead to loss of control at the tissue site and bleeding.

PRECAUTIONS

- Do not use the *GENTLEGUIDE™ 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 *GENTLEGUIDE™ 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 *GENTLEGUIDE™* 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. Ensure that electrical isolation or grounding are not compromised.
- Use only with LSI SOLUTIONS® 2-0 polyester, 2-0 Strongsorb®, 2-0 Monoglide®, and 2-0 or 3-0 polypropylene sutures.
- For additional suture holding force, a surgical clamp can be applied onto the *GENTLEGUIDE™* tube with its indwelling 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.
- Inaccurately placed sutures can lead to tissue deformities, inadequate holding, and/or tissue damage.
- Inadequate suture tensioning can lead to obstruction in the surgical view, improper setup of the surgical field, loss of tissue control, bleeding, or leakage.
- A minimum suture length of 135 cm (53 in) is required for use with the *GENTLEGUIDE™ DEVICE*.

FIG. 4

***GENTLEGUIDE™* Dual-Lumen Tip**

FIG. 5

GENTLEGUIDE™ DEVICE
Suture Compatibility

Suture Size and Type	Compatibility
LSI SOLUTIONS® 2-0 Polyester	√
LSI SOLUTIONS® 2-0 Strongsorb®	√
LSI SOLUTIONS® 2-0 Monoglide®	√
LSI SOLUTIONS® 2-0 Polypropylene	√
LSI SOLUTIONS® 3-0 Polypropylene	√

***GENTLEGUIDE™ DEVICE* PRODUCT ORDERING** **SUPPLIED:** STERILE

	REORDER	PRODUCT	DESCRIPTION
x 12	REF 082030	***GENTLEGUIDE™ DEVICE***, *33cm*	*(1) Box of (12) GENTLEGUIDE™ DEVICES*

P/N082043B 25 AUG 26

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