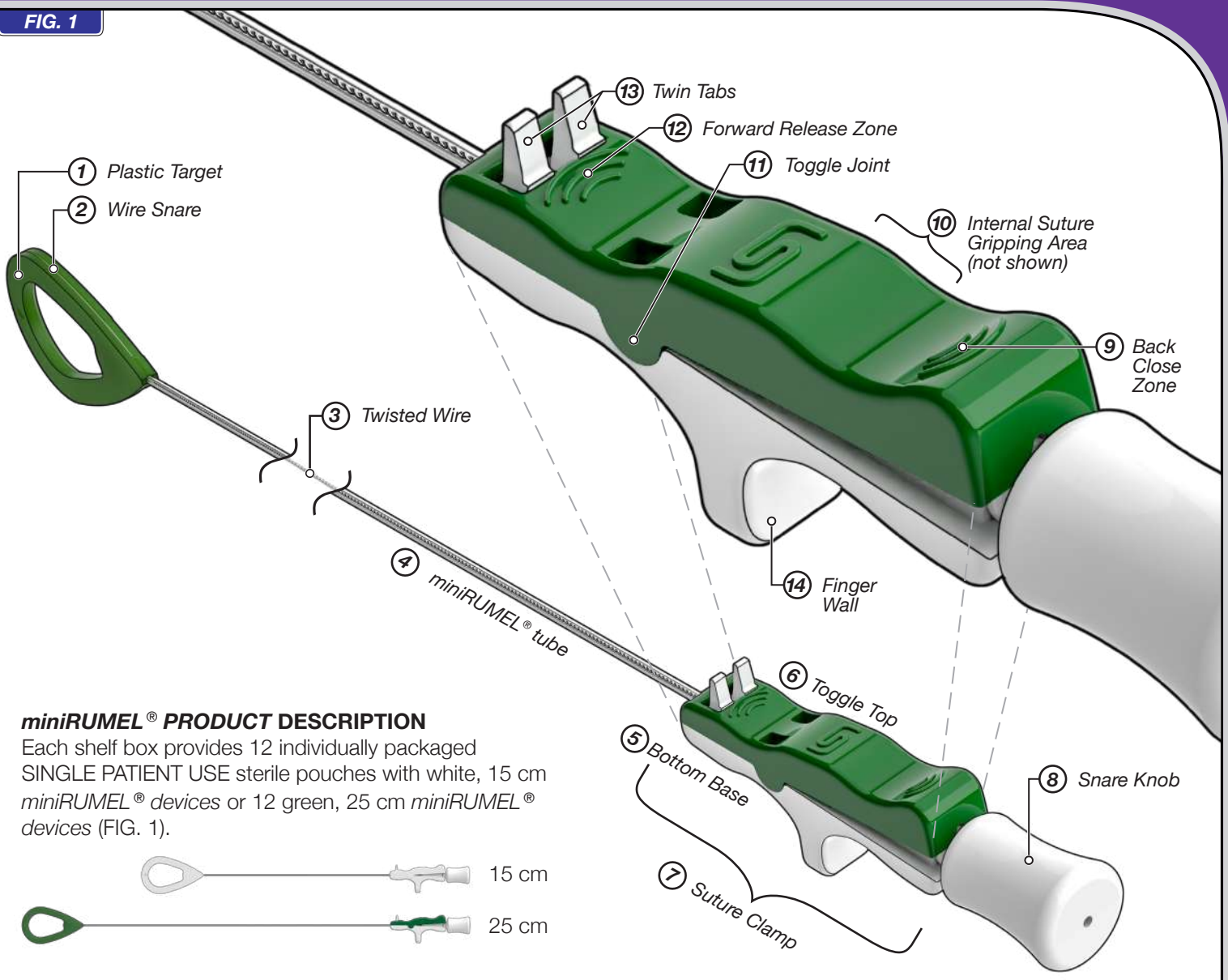
# *mini*RUMEL® DEVICE TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1




### *miniRUMEL® PRODUCT* DESCRIPTION

Each shelf box provides 12 individually packaged SINGLE PATIENT USE sterile pouches with white, 15 cm *miniRUMEL® devices* or 12 green, 25 cm *miniRUMEL® devices* (FIG. 1).




### *miniRUMEL® DEVICE* DESCRIPTION

A *miniRUMEL® DEVICE* has a white (15 cm) or green (25 cm) plastic target ① that is held by a wire snare ② connected to a twisted wire ③ that passes through the *miniRUMEL®* tube ④. The tube and twisted wire run through the bottom base ⑤ and toggle top ⑥ that comprise the suture clamp ⑦. After suture has been placed through the wire snare, the snare knob ⑧ is pulled out away from the suture clamp to thread the suture in the wire snare through the *miniRUMEL®* tube and suture clamp. After establishing the desired suture tension, the back close zone ⑨ can be pressed down to securely clamp the suture by engaging the features in the internal suture gripping area ⑩ (not shown here; see FIG. 2) as the toggle top rotates about the toggle joint ⑪, setting the *miniRUMEL®* into its clamped, closed position. While in this position, the suture is held relative to the *miniRUMEL®* tube and suture clamp. The forward release zone ⑫ is pressed down after pushing both twin tabs ⑬ forward to rotate the toggle top about the toggle joint, setting the *miniRUMEL®* 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. The finger wall ⑭ on the bottom base helps stabilize the suture clamp during opening and closing.

### INDICATIONS FOR USE

The *miniRUMEL® DEVICE* is indicated for use to temporarily hold 2-0 polypropylene, polyester or silk suture, or 3-0 polypropylene suture during surgery.

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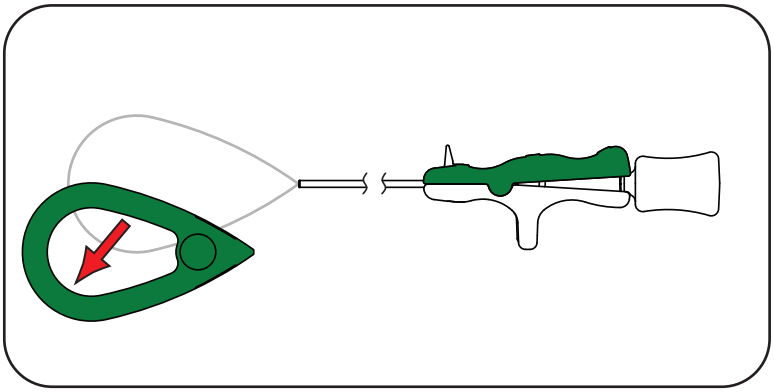
## LOADING

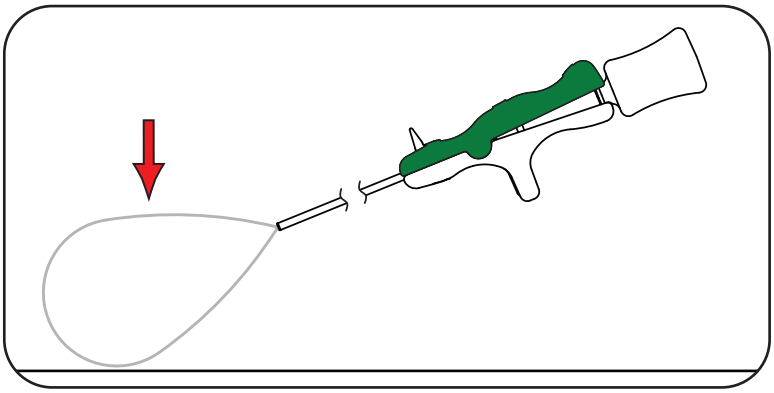
***NOTE:*** Ensure that attachments on the suture ends (e.g., needles, suture caps or ferrules, etc.) are removed prior to threading suture through the *miniRUMEL® DEVICE*.

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

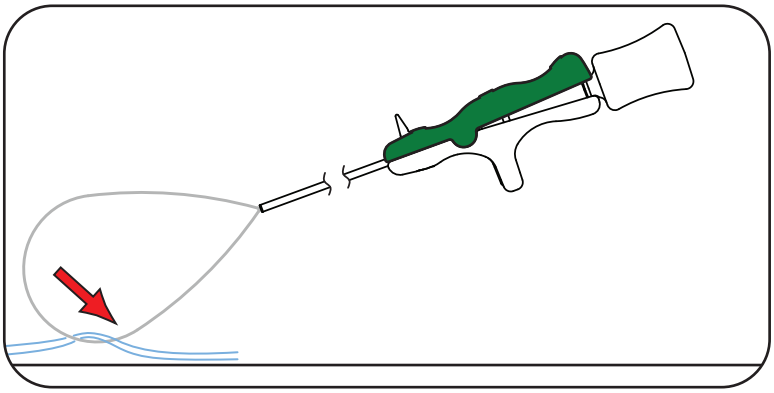
***1*** ***PUSH OUT*** and remove the white or green plastic target from the wire snare of the open *miniRUMEL® DEVICE*.



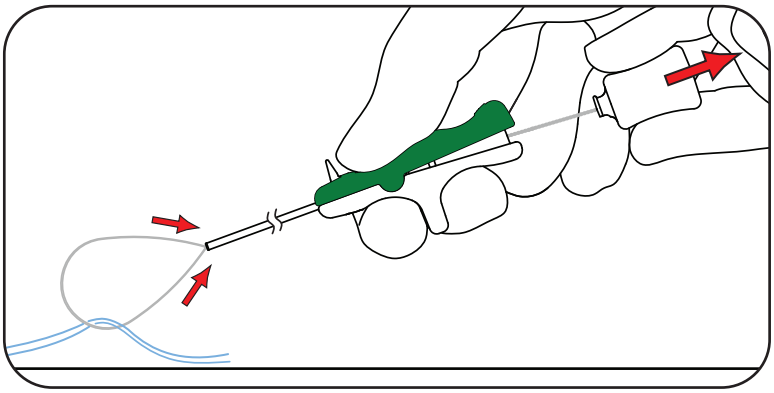
***2*** ***LOWER*** the *miniRUMEL®* wire snare near a sterile surface adjacent to the surgical site to avoid suture falling out of the wire snare.



***3*** ***PASS*** about 1–2 in (2–5 cm) of both ends of the suture through the wire snare.

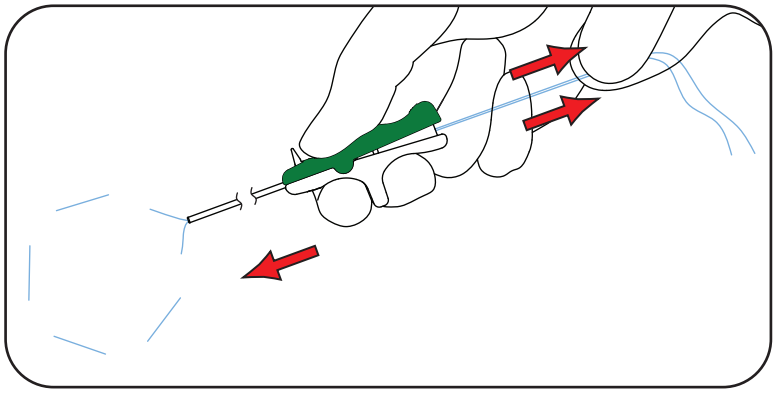


***4*** ***PULL*** the snare knob away from the suture clamp while slightly lowering the device to thread the suture through the *miniRUMEL®* tube and the suture clamp. If both suture ends are not pulled through the suture clamp, do not use this *miniRUMEL® DEVICE*.



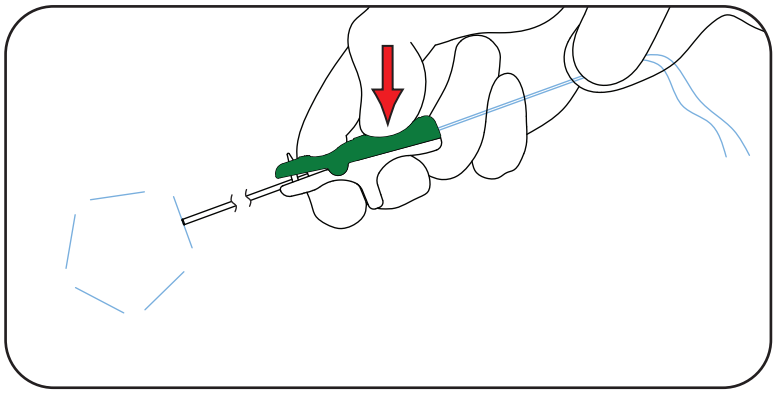
## CLOSING

**5** ***SLIDE*** the *miniRUMEL®* tube over the suture toward the tissue until appropriate tissue contact is established, then pull both suture ends to achieve the desired tension.



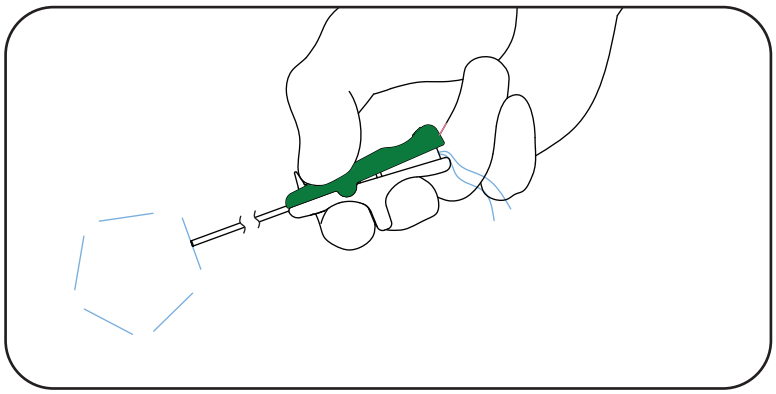
**6** ***CLOSE*** the suture clamp by pressing down on the textured back close zone to snap closed the internal features in the suture gripping area and set the suture clamp into its clamped, closed position.

**BACK DOWN** **CLAMP DOWN**



## OPENING

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



**8** ***REMOVE*** the *miniRUMEL® DEVICE* by sliding the *miniRUMEL®* over the suture and away from the tissue.

**BACK UP** **OPEN UP**

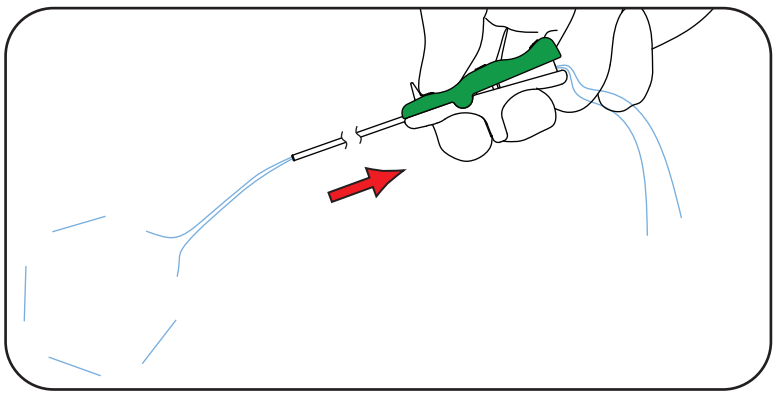
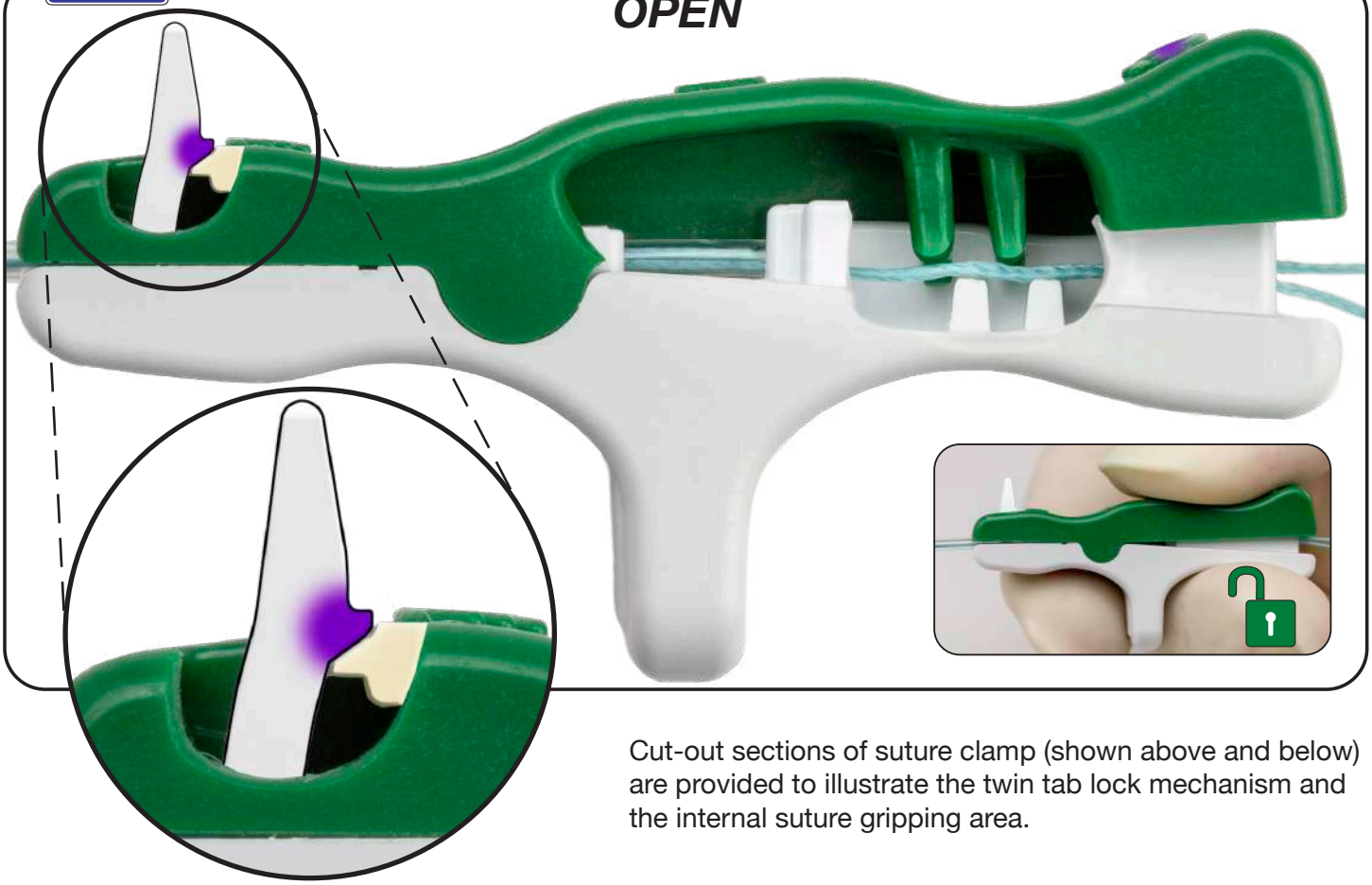


FIG. 2

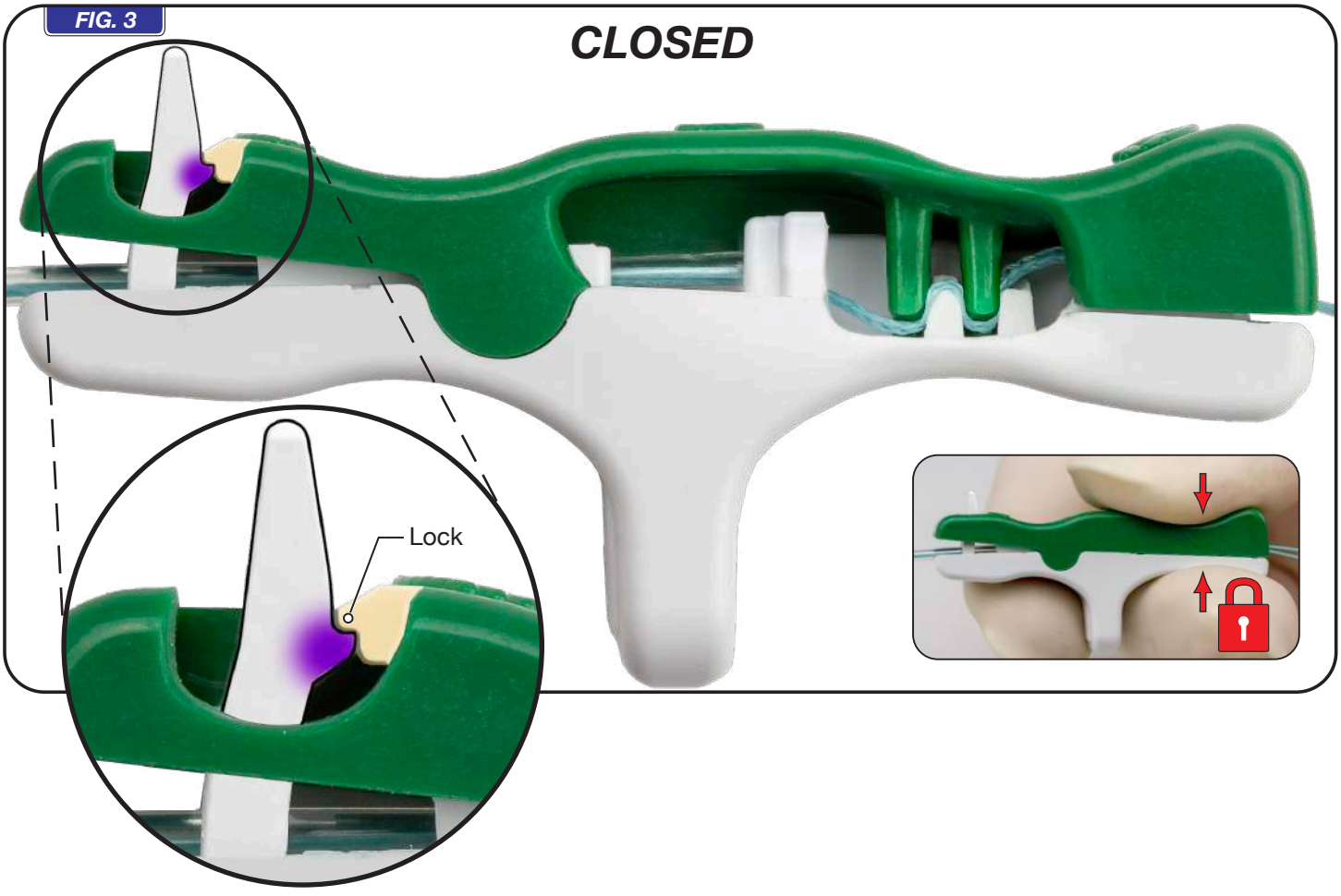
## OPEN



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.

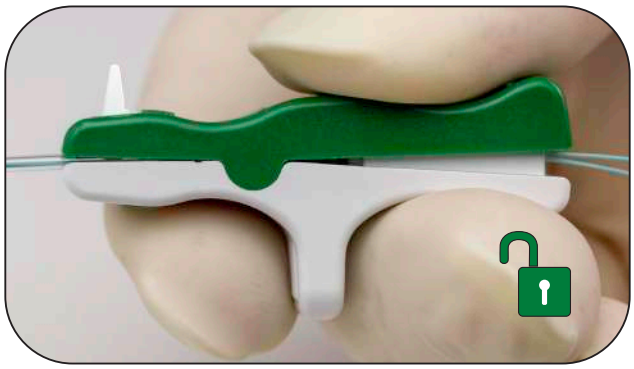
FIG. 3

## CLOSED

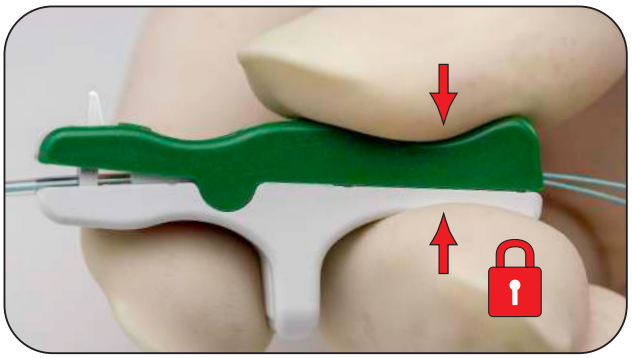


## *miniRUMEL® DEVICE* TECHNIQUE PEARLS

BACK UP OPEN UP



BACK DOWN CLAMP DOWN



If desired, the *miniRUMEL® DEVICE* wire snare may be passed over the shaft of a suturing device before suturing to ensure that both ends of suture are snared. **NOTE:** Remember to remove any needles, ferrules or suture caps, etc., before threading suture through the *miniRUMEL® DEVICE.*

*FIG. 4*

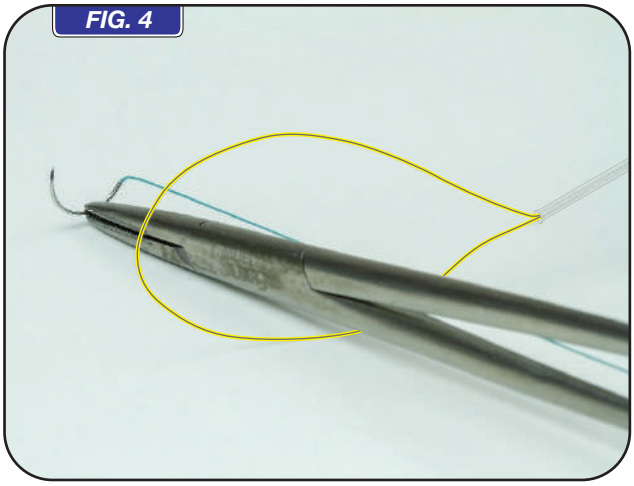
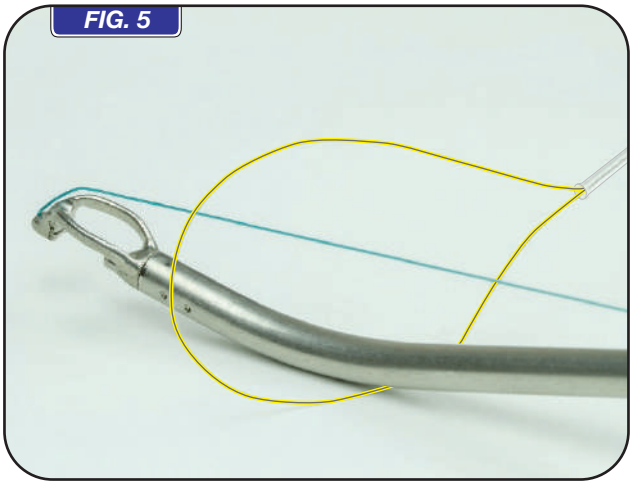


*FIG. 5*



**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 suture. Excessive suture tensioning can damage or tear tissue, cause bleeding, or adjacent structural injuries to tissue or cause suture breakage.
- Store at room temperature. Avoid prolonged exposure to elevated temperatures.
- Do not resterilize. The *miniRUMEL® DEVICE* is designed and intended for single patient use only. Do not reuse, reload, reprocess, or resterilize this product. The performance of the *miniRUMEL® 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.
- Ensure *miniRUMEL®* clamp is unclamped (i.e., fully released) and the suture slides freely through the *miniRUMEL®* tube prior to removing the *miniRUMEL® DEVICE*.
- Before loading suture through the *miniRUMEL®* wire snare, 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 *miniRUMEL®* suture lock 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.

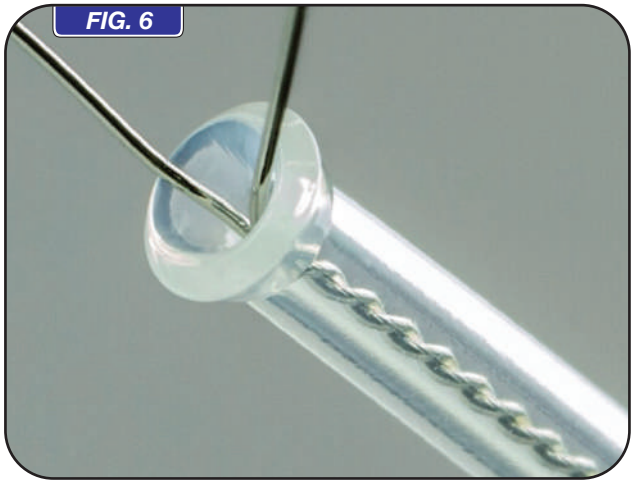
**PRECAUTIONS**

- Do not use the *miniRUMEL® 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 *miniRUMEL® DEVICE*, care should be taken to avoid damage.
- Ensure proper surgical techniques, including adequate tissue bites, as needed for the handling of tissue and suture for use of *miniRUMEL®* tubes.
- Adequacy of the suture holding force should be confirmed by the user.
- Check for and ensure hemostasis and/or proper tissue control upon securing the 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 2-0 Polypropylene, polyester or silk suture or 3-0 Polypropylene suture.
- For additional suture holding force, a surgical clamp can be applied onto the *miniRUMEL®* tube with its indwelling suture.
- A minimum suture length of 75cm (30 inches) is required for use with the 25 cm *miniRUMEL® DEVICE* and a minimum suture length of 55cm (22 inches) is required for use with the 15 cm *miniRUMEL® DEVICE*.
- Avoid holding excess tension on the suture, which can cause the suture to tear or cut through the tissue it is holding or, over time, cause ischemia or tissue strangulation by the tensioned suture.
- Inaccurately placed stay sutures can lead to tissue deformities, inadequate holding and/or tissue damage.
- 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.

**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***



***miniRUMEL®* Tube Flared End**

***FIG. 7***

***miniRUMEL® DEVICE***
**Approximate Suture Loop Holding Force**

| Suture Size and Type | Ave. Holding Force (kgf) |
|---|---|
| 2-0 Polypropylene | 1.9 |
| 2-0 Polyester | 1.1 |
| 2-0 Silk | 1.7 |
| 3-0 Polypropylene | 1.0 |

***miniRUMEL®* PRODUCT ORDERING** **SUPPLIED:** STERILE

| | REORDER | PRODUCT | DESCRIPTION |
|---|---|---|---|
| 15cm x 12 | REF 080990 | ***miniRUMEL®**, 15cm* | *(1) Box of (12) miniRUMEL® DEVICES, WHITE* |
| 25cm x 12 | REF 080995 | ***miniRUMEL®**, 25cm* | *(1) Box of (12) miniRUMEL® DEVICES, GREEN* |

P/N080886D 14 MAY 26

The Basic UDI-DI for the *miniRUMEL® Device* is 0850200006miniRUMELW7.

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