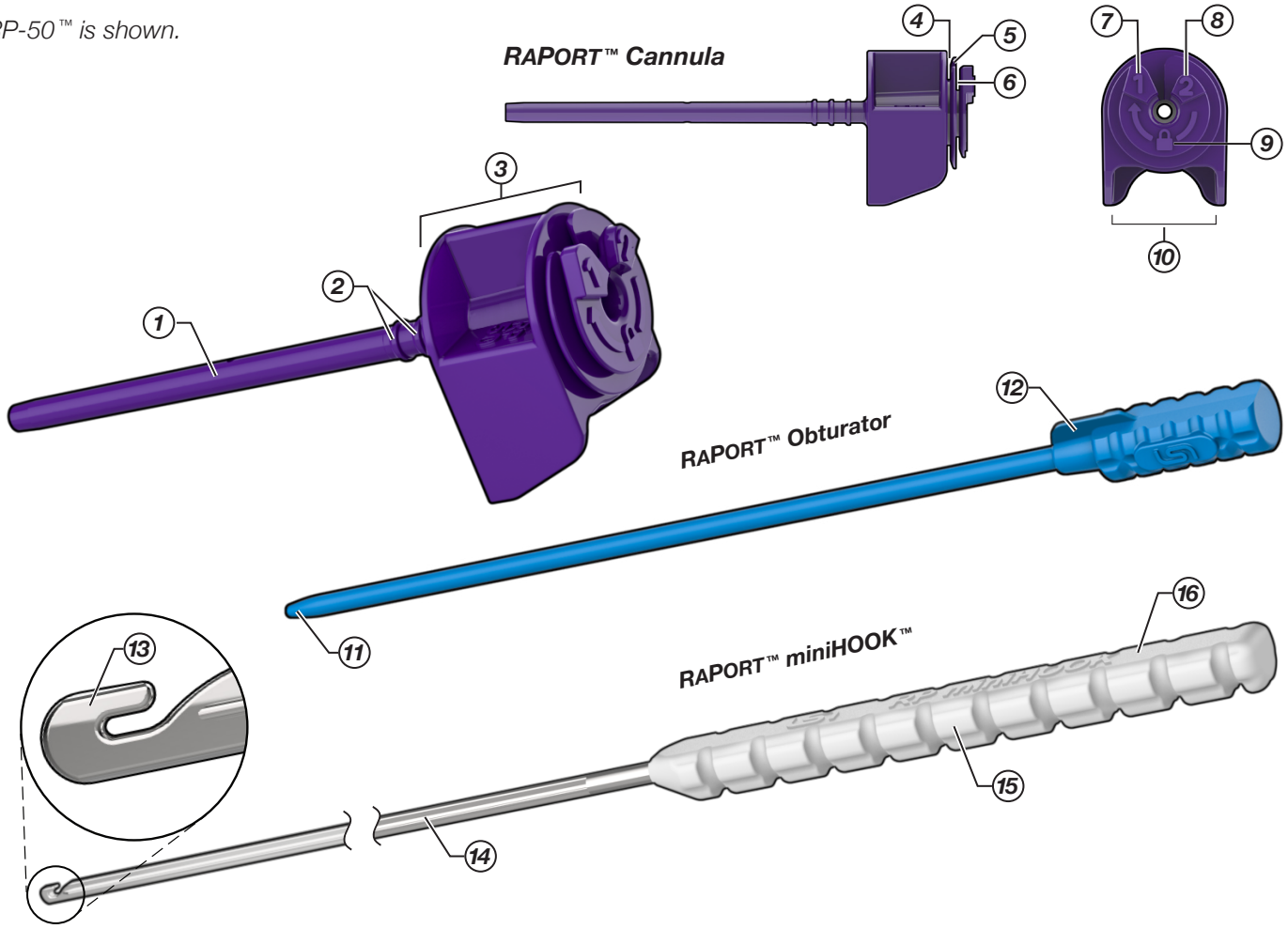
RAPORT™ KIT TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1

RP-50™ is shown.



RAPORT™ Cannula

1. *CANNULA TUBE*
2. *RETENTION RINGS*
3. *CANNULA HUB*
4. *LOWER SUTURE CHANNEL*
5. *CHANNEL DIVIDER*
6. *UPPER SUTURE CHANNEL*
7. *NUMBER 1*
8. *NUMBER 2*
9. *LOCK SYMBOL*
10. *HUB WINGS*

RAPORT™ Obturator

11. *BLUNT TIP*
12. *ALIGNMENT FIN*

RAPORT™ miniHOOK™

13. *SUTURE HOOK*
14. *miniHOOK™ SHAFT*
15. *miniHOOK™ HANDLE*
16. *FLAT SURFACE*

RAPORT™ KIT DEVICE DESCRIPTION

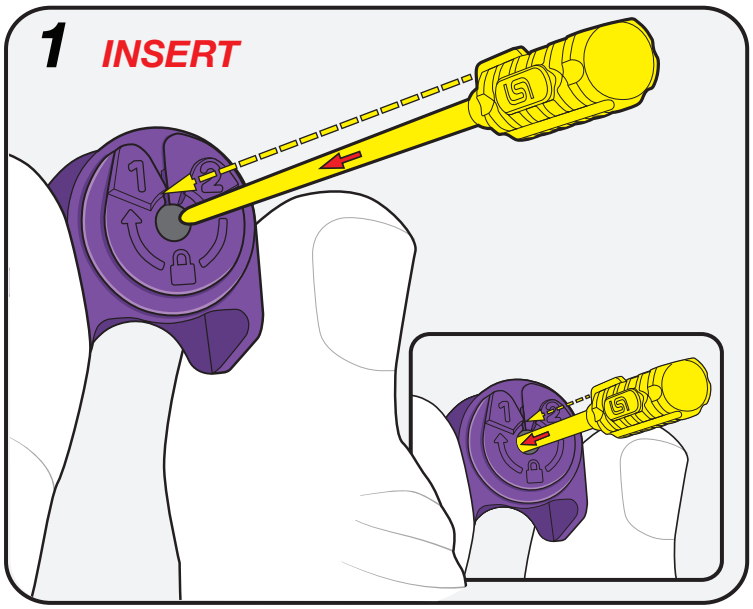
The *RAPORT™ KIT* is a single-patient–use system to temporarily hold tension on sutures during surgery. The kit is available in three different sizes: the *RP-50™*, *RP-75™*, and *RP-100™*. Each sterile package includes the *RAPORT™ Cannula*, *RAPORT™ Obturator*, and *RAPORT™ miniHOOK™*. The *RAPORT™ Cannula* tube ① features a lumen that enables the passage of suture from a surgical site to outside of the patient. Retention rings ② on the cannula tube can be used to more firmly secure the *RAPORT™ Cannula* to a skin puncture site. The cannula hub ③ incorporates a circumferential lower suture channel ④ separated by a channel divider ⑤ from a circumferential upper suture channel ⑥. The lower and upper suture channels are indicated by the number 1 ⑦ and number 2 ⑧, respectively. The purple arrow, indicated by the lock (🔒) symbol ⑨ illustrates the clockwise direction suture is wrapped into the suture channels. The hub wings ⑩ can be grasped to secure and stabilize the *RAPORT™ Cannula*. The *RAPORT™ Obturator* has a blunt tip ⑪ that allows the obturator and cannula to be introduced to the surgical site. The *RAPORT™ Obturator* has an integrated alignment fin ⑫ that orients with the slot between numbers 1 and 2 to appropriately engage the obturator with the *RAPORT™ Cannula*. After the *RAPORT™ Cannula* is in place and the *RAPORT™ Obturator* is removed, the *RAPORT™ miniHOOK™* is used to engage, capture, and guide sutures through the cannula. The *RAPORT™ miniHOOK™* includes a smooth-edged suture hook ⑬ at the opposite end of the *miniHOOK™* shaft ⑭ from the textured *RAPORT™ miniHOOK™* handle ⑮. Note that the opening in the suture hook is oriented toward the smooth, flat surface ⑯ of the handle, where the LSI *RP miniHOOK™* label is featured.

INDICATIONS

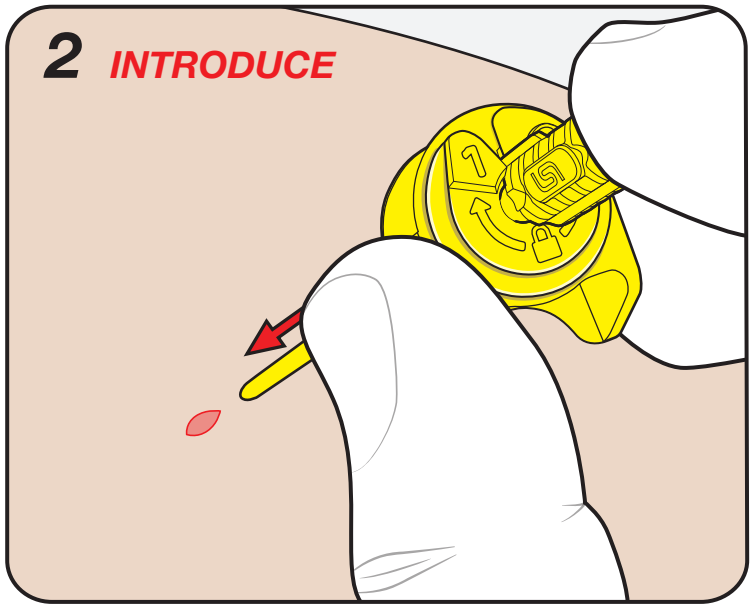
The *RAPORT™ KIT* is indicated for use to temporarily hold 2-0 polypropylene, polyester, or silk suture, or 3-0 polypropylene suture during surgery.

LSI SOLUTIONS®

USING THE RAPORT™ KIT

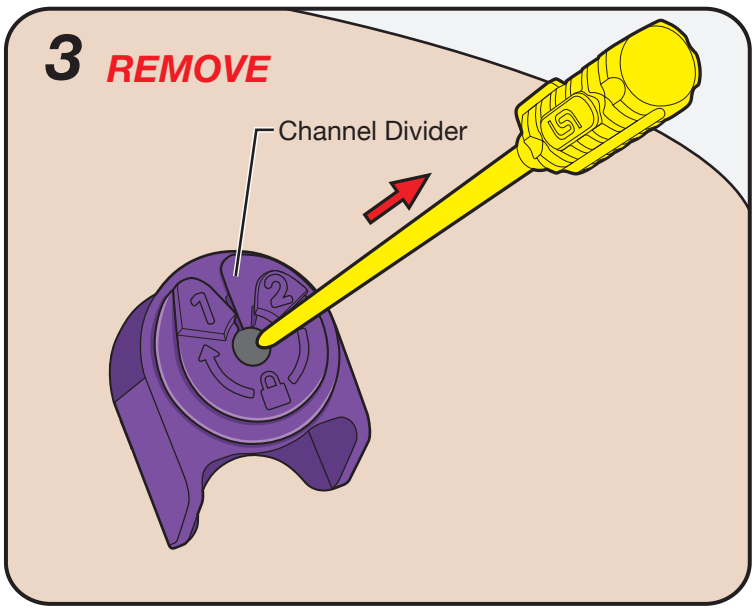


1. ***INSERT*** obturator into the *RAPORT™ Cannula*, ensuring that the obturator alignment fin is oriented with the slot between numbers 1 and 2 on the cannula.



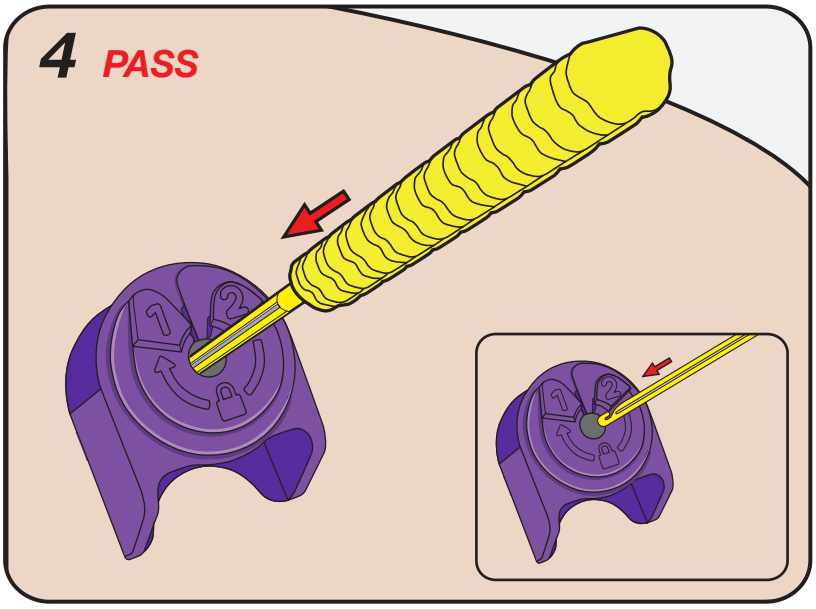
2. ***INTRODUCE*** obturator and cannula to the surgical site through an appropriately sized incision with the axis of the cannula and obturator oriented toward the surgical site and suture.

NOTE: Hold obturator and cannula to maintain the position of obturator relative to cannula as insertion takes place.



3. ***REMOVE*** obturator from the cannula after the cannula is positioned at the desired location.

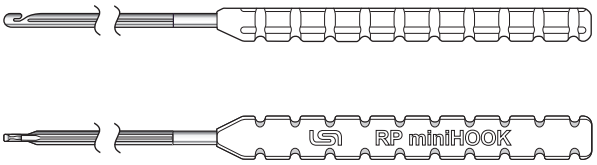
NOTE: Use the hub wings to stabilize the cannula.

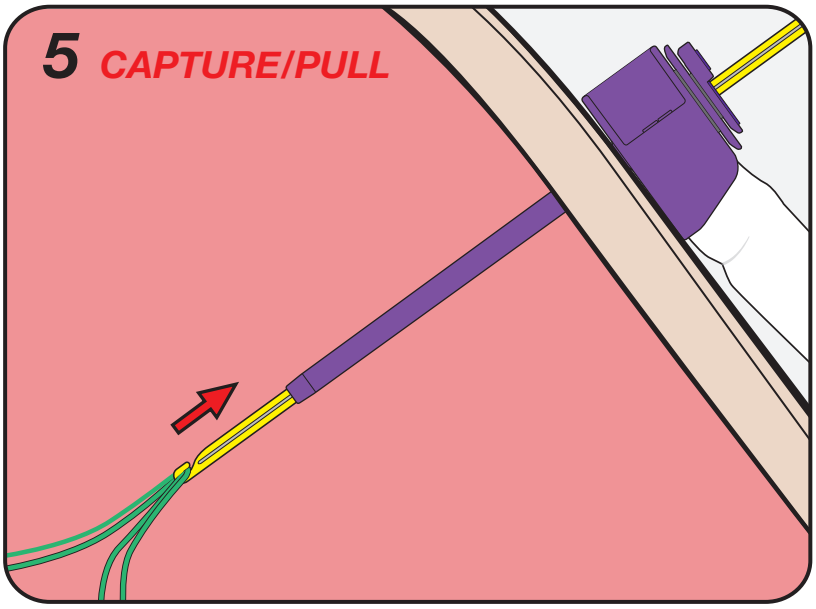


4. ***PASS*** *miniHOOK*™ through the cannula to capture suture within the suture hook.

NOTE: The *miniHOOK*™ can capture 1 or 2 segments of tensioned suture at a time.

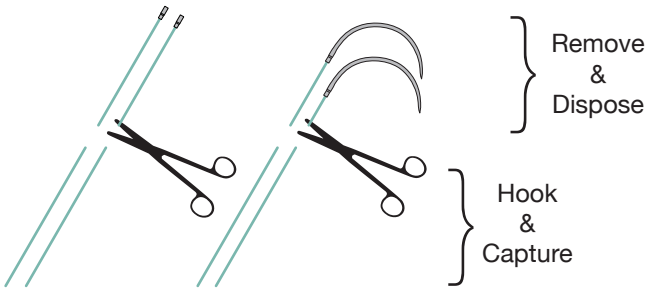
HOOK FLAT

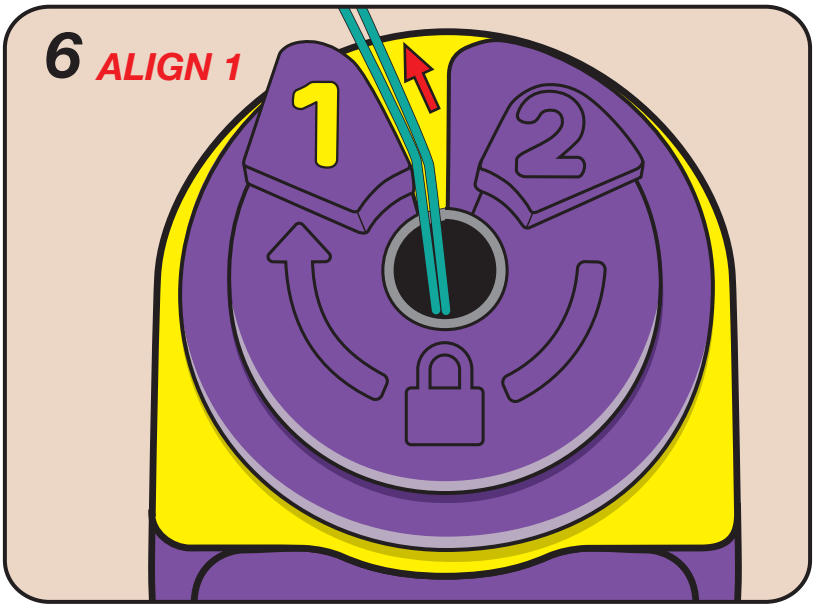




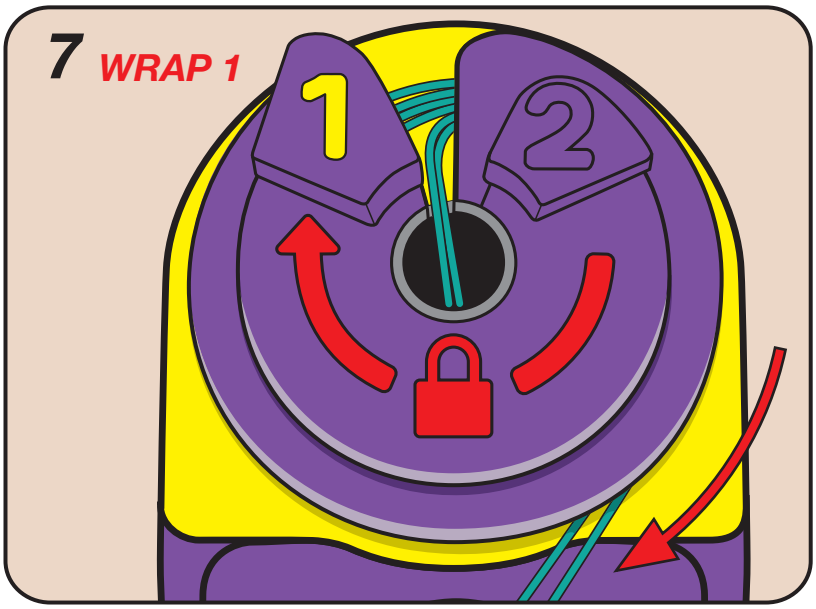
5. ***CAPTURE/PULL*** the suture out through the cannula using the *miniHOOK*™.

NOTE: Ensure that needles or needle caps are removed from the suture and properly disposed of before pulling suture through the cannula.



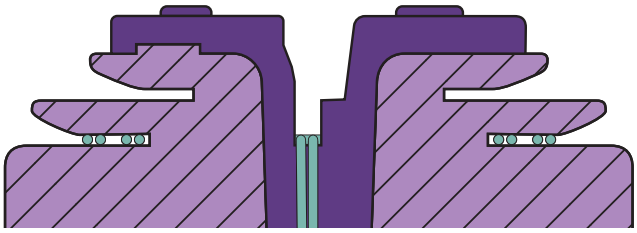


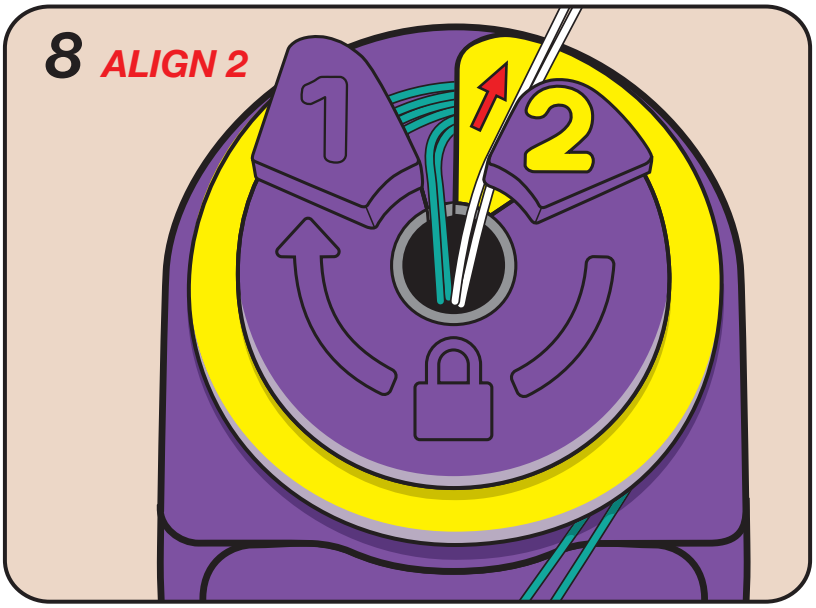
6. ***ALIGN 1:*** the suture by pulling it out radially and placing it on the lower suture channel level.



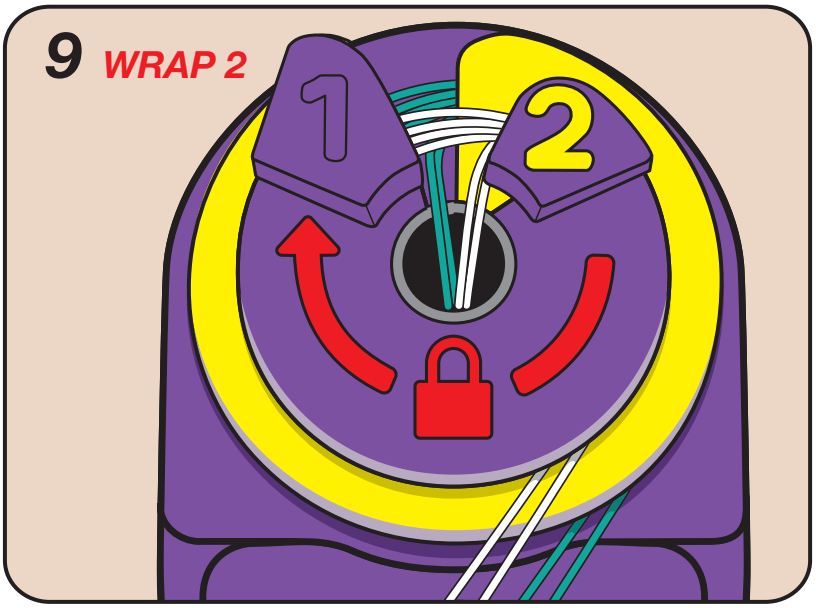
7. ***WRAP 1:*** Wrap the tensioned first suture clockwise at least 2 times within the lower suture channel, below the channel divider, while pulling slightly downward (toward the patient) to lock the first suture.

Cross-sectional view showing green suture in lower suture channel.



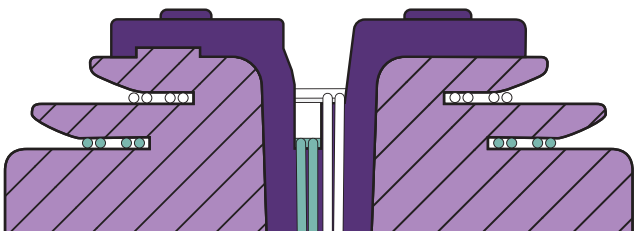


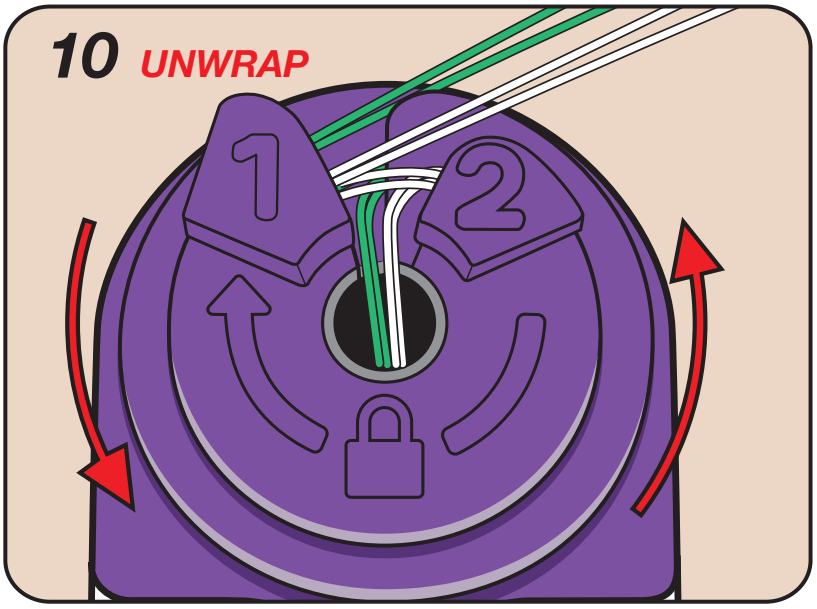
8. ***ALIGN 2:*** Align the suture by pulling it out radially and placing it on the upper suture channel level.

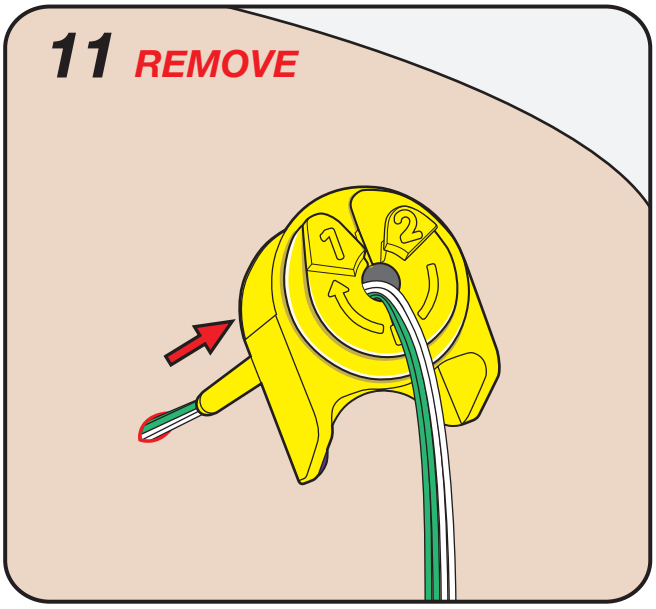


9. ***WRAP 2:*** Wrap the tensioned second suture clockwise at least 2 times within the upper suture channel, above the suture channel divider, while pulling slightly downward (toward the patient) to lock the second suture.

Cross-sectional view showing green suture in lower suture channel and white suture in upper suture chanel.







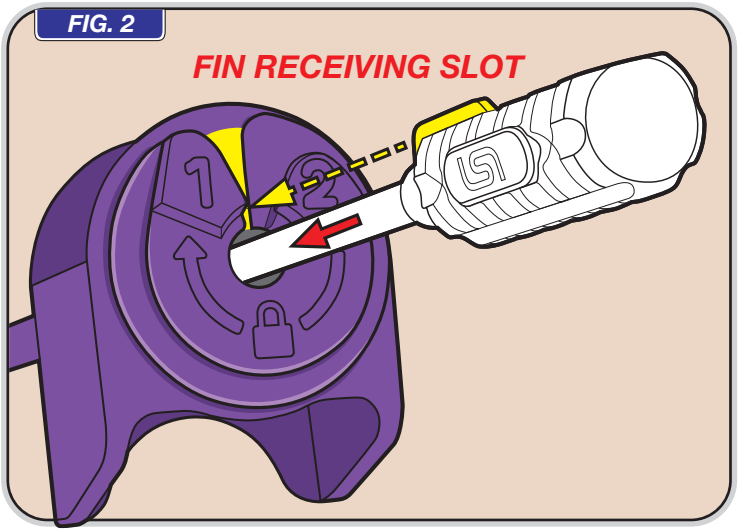
10. ***UNWRAP*** sutures counterclockwise to release them from the cannula hub.

    NOTE: If 2 sets of sutures are held within the cannula hub, unwrap the suture from the upper suture channel before unwrapping suture from the lower suture channel.

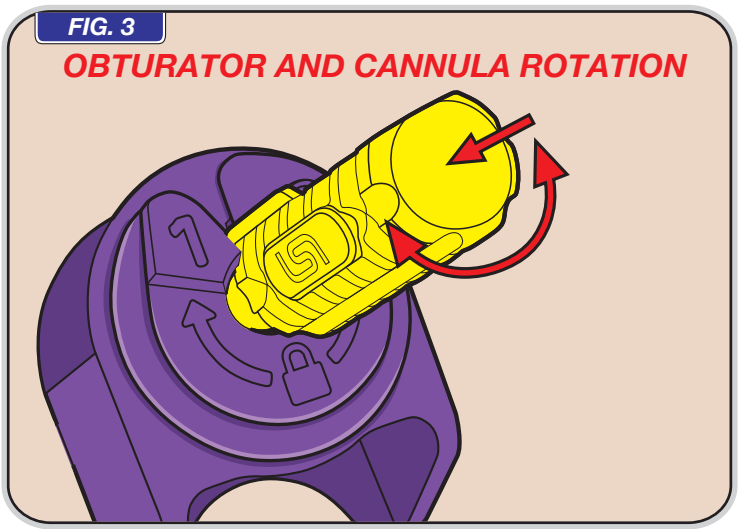
11. ***REMOVE*** the cannula by gently pulling it away from the surgical site after all sutures have been unwrapped.

    NOTE: Remove suture using surgeon's preferred surgical technique.

RAPORT™ *KIT* TECHNIQUE PEARLS



The *RAPORT*™ *Obturator* alignment fin is used to radially orient the obturator into the *RAPORT*™ *Cannula.* The obturator alignment fin should be oriented with the slot between numbers 1 and 2 on the cannula.



With the obturator appropriately oriented and held within the cannula, the alignment fin ensures that the cannula and obturator will rotate simultaneously.

CONTRAINDICATIONS:

- Use only with LSI specified suture: 2-0 Polypropylene, 2-0 Polyester, 2-0 Silk, or 3-0 Polypropylene.
- The *RAPORT™ KIT* is contraindicated for use under conditions that, in the surgeon's judgement, create unacceptable risk of patient injury during placement, use, and/or removal.

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 suture. Excessive suture tensioning can cause damage to or tear tissue and/or suture; cause bleeding; and/or lead to injury of adjacent tissue structures.
- Do not resterilize. The *RAPORT™ KIT* is designed and intended for single-patient use only. Do not reuse, reprocess, or resterilize this product. The performance of the *RAPORT™ KIT* 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 and unused (unsealed), expired, or damaged devices or devices in damaged primary packaging.
- 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.
- Each *RAPORT™ KIT*, along with packaging, must be inspected, handled, and disposed of consistent with standard, accepted medical device disposal procedures.

PRECAUTIONS:

- Do not forcibly advance or withdraw the cannula, obturator, and/or *miniHOOK™* if resistance is encountered. If it becomes difficult to advance or withdraw the cannula, obturator, and/or *miniHOOK™*, stop its motion and determine the cause of the resistance.
- When handling the *RAPORT™ KIT*, care should be taken to avoid damage.
- Adequacy of the suture holding force should be confirmed by the user.
- Inaccurately placed stay sutures can lead to tissue deformities, inadequate holding, and/or tissue damage.
- Inadequate suture tensioning can lead to obstruction of the surgical view, improper setup of the surgical field, loss of tissue control, bleeding, or leakage.
- Ensure that suture is appropriately placed to be used with the *RAPORT™ KIT*. Inadequate tissue bites may result in the suture damaging or being pulled through tissue.
- Ensure that needles or needle caps are removed from suture before pulling it through the cannula.
- Before instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that function is not compromised.
- Do not rotate the cannula while suture is secured within the cannula hub.

ADVERSE REACTIONS:

- No known or documented adverse reactions.

NOTES:

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

FIG. 4 *RAPORT™ KIT* PRODUCT ORDERING — **SUPPLIED:** STERILE

	REORDER	PRODUCT	DESCRIPTION
x 4 x 2 x 1 **x 6**	REF **081510**	***RAPORT™ KIT*** ***RP-50™***	*Box of 6 Kits* *4 RAPORT™ Cannulas,* *2 RAPORT™ Obturators,* *1 RAPORT™ miniHOOK™ per kit*
x 3 x 2 x 1 **x 6**	REF **081730**	***RAPORT™ KIT*** ***RP-75™***	*Box of 6 Kits* *3 RAPORT™ Cannulas,* *2 RAPORT™ Obturators,* *1 RAPORT™ miniHOOK™ per kit*
x 2 x 2 x 1 **x 6**	REF **081720**	***RAPORT™ KIT*** ***RP-100™***	*Box of 6 Kits* *2 RAPORT™ Cannulas,* *2 RAPORT™ Obturators,* *1 RAPORT™ miniHOOK™ per kit*

The Basic UDI-DI for the *RAPORT™ KIT* is 0850200006RaPortAT.

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Patents: www.lsisolutions.com/patents

STERILE EO | Rx Only | MD

Symbol Glossary: www.lsisolutions.com/symbols

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