

- 5.1. other scissors. It is important to do so because the remnant suture could later prevent the StitchKit® from snapping closed properly, which in turn could interfere with its removal. Place all remnant suture material in a single pile for later removal.
- 5.2. Place the used needle (with remnant suture removed) into the disposal compartment via the trap door. It is typically easier to place the blunt aspect of the needle into the compartment first (Figure 2).
- 5.3. Repeat until either suturing is completed, or all sutures in the StitchKit® are consumed.

6. PREPARE DEVICE FOR REMOVAL

- 6.1. Carefully close the device.
- 6.2. Ensure that no needles are left behind in the body after surgery by counting them. The disposal compartment has been made transparent to enable easy visibility of disposed needles. Counting of the used needles can be done in one of two ways: (1) By visualizing through the 3D viewer screen, or (2) by manually counting the needles after the device has been withdrawn from the body.
- 6.3. Any remaining remnant suture should be gathered in a pile and removed from the patient.

7. REMOVE DEVICE

- 7.1. Using the robotic graspers, hold device by the tab on the opposite end from the removal string. Then, the assistant, using manual graspers, should reach in and grab the removal string.

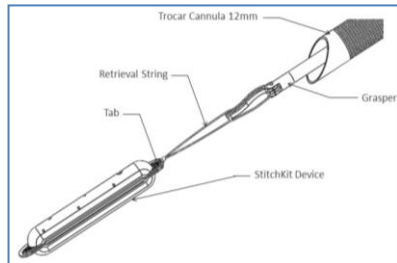


Figure 6 – Assistant should capture retrieval string to remove

- 7.2. When removing, be careful to avoid contact with adjacent organs. Also, ensure that the canister does not get opened accidentally and that none of the contents spill out.
- 7.3. The device can then be pulled out from the body through the trocar. See Figure 7.

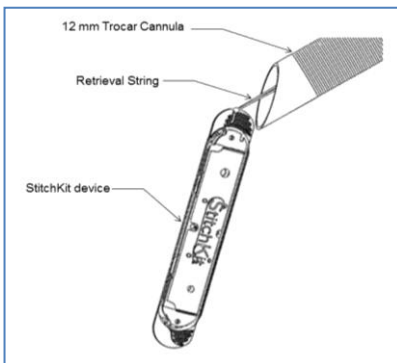


Figure 7 - Pulling out device through trocar using retrieval string

- 7.4. In cases where StitchKit is inserted into the surgical field through an 8mm trocar incision under direct endoscopic visualization

(see 2.2 above), it is removed through the same trocar site. To do so, the retrieval string is grasped and pulled until StitchKit is firmly in direct contact with the trocar, then the trocar and StitchKit should be removed together as a unit. If the surgeon wishes to do so, the trocar can then be replaced into the incision site under direct endoscopic visualization.



Figure 8 - Pulling out device through incision using retrieval

8. DISCARD DEVICE

- 8.1. If not already done, ensure that no needles are left behind in the body after surgery by counting them. The disposal compartment has been made transparent to enable easy visibility of disposed needles. Counting of the used needles can be done in one of two ways: (1) By visualizing through the 3D viewer screen, or (2) by manually counting the needles after the device has been withdrawn from the body.
- 8.2. Dispose the product and packaging in accordance with hospital, administrative and/or local government policy.
- 8.3. The StitchKit® may be put in Sharp's container for the final disposal of the device.

DO NOT REUSE. Reuse, reprocessing or re-sterilization may create a risk of contamination of the device and/or cause patient infection or cross infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Rx Only

Learn more at: www.OrigamiSurgical.com

Or contact us at: INFO@OrigamiSurgical.com



Origami Surgical Inc.
42 Main Street, Suite A
Madison, NJ 07940
(973) 765-6256

"StitchKit" is a registered trademark of Origami Surgical Inc.
This device is covered by US Patents 8,418,851; & 6,986,780; other patents pending. V-Loc and Polysorb are trademarks of Medtronic.
© Copyright 2021 Origami Surgical, Inc., All Rights Reserved.

DWG-0149-0 2025-05-16



StitchKit® FG SK-211

Instructions for Use

StitchKit® FG SK-211 is a sterile, single-use plastic canister that is provided pre-loaded with the suturing materials specified below, with attached needles.

DESCRIPTION

StitchKit® is a sterile, single-use plastic canister that is provided pre-loaded with suturing materials with attached needles. The device facilitates endoscopic robotic surgery by introducing multiple strands of suture to the surgical site at one time and allowing for the safe retrieval of the needles.

The canister may be inserted and removed in two alternative ways:

- It may be inserted and removed through a ≥12 mm trocar.
- Or, alternatively, it may be inserted through an incision sized for an 8 mm trocar under direct endoscopic visualization and removed (in tandem with the 8 mm trocar) through that same incision, also under direct endoscopic visualization. This is possible because the outer diameter of the StitchKit™ device is approximately the same as the outer diameter of the 8 mm trocar commonly used with the DaVinci Surgical Robot.

As suturing is completed with each strand, the used needle is placed into a compartment within the canister for safekeeping until the entire canister is removed.

INDICATION FOR USE

StitchKit® Suture Delivery Canister facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing. The suture contained within the StitchKit® device is intended for soft tissue approximation where use of the specific absorbable or non-absorbable sutures contained within it is appropriate.

How Supplied	This device is supplied only in boxes containing 6 devices per box.
--------------	---

NEEDLE INFORMATION

Needle Description	Taper point, 1/4 Circle, 26 mm, stainless steel needle.	V-20 TAPER 1/2 ∅ 26 mm
--------------------	---	------------------------------

SUTURING MATERIAL INFORMATION

There is a symbol printed on the device next to each needle so each suture can be identified during use. See "Symbol," below.	
StitchKit® FG SK-211	Symbol: PE Six (6) strands of Covidien™ brand Ti-Cron™ sutures, Size: 2-0, Length: Approx. 23 cm, Color: Blue Manufacturer's reference: 88863251-51 (cut to length)

OTHER CONTENTS OF THIS DOCUMENT

- Section 1:** **StitchKit® Canister Information.** Includes instructions, warnings, cautions, and other information relating to the use of the StitchKit® canister in robotic-assisted laparoscopic surgery.
- Section 2:** **Suturing Material Information.** Includes instructions, warnings, cautions, and other information relating to the suturing materials within the device.



Attention: Review this entire document carefully before using.

Section 1: StitchKit® Canister Information:

CONTRAINDICATIONS

StitchKit® is not designed to be inserted into or removed thru natural orifices such as the vagina or rectum.

WARNINGS

- Use care during surgery to ensure that the StitchKit® device is not accidentally misplaced in situ while performing the surgery.
- Count needles carefully and ensure that no needles are left behind in the patient.
- Ensure that no remnants of suture are left behind in the patient. While suturing, pile all suture remnants in one spot. At the conclusion of suturing, gather them together and place them in the disposal compartment prior to closing the StitchKit®.
- Be sure to trim suture from needles prior to placing them in the disposal compartment. The remnant suture could later prevent the StitchKit® from snapping closed properly, which in turn could interfere with its removal.
- This device is for single use only. Do not resterilize.
- When the StitchKit is inserted and removed through an incision sized for an 8 mm trocar, lengthening and/or stretching of the incision should not be performed. Unnecessary lengthening and/or stretching of the incision in anticipation of StitchKit insertion or removal could increase the risk of port-site hernias.

PRECAUTIONS

- Open and close the StitchKit® device with your hands (using sterile technique, of course) before inserting into patient to ensure that the device is functioning properly, and to familiarize yourself with how it works. Press on each disposal compartment door with your index finger to ensure that they open and close smoothly.
- Inspect device carefully prior to inserting into patient to ensure that it is intact and undamaged before inserting.
- StitchKit® is designed to be inserted into and removed from the surgical field either via a ≥ 12 mm trocar;

or

inserted through an incision sized for an 8mm trocar under direct endoscopic visualization, and subsequently removed through that incision in tandem with the 8 mm trocar, also under direct endoscopic visualization.

- StitchKit® should not be opened or closed using any instruments other than the robotic graspers while device is in use. In other words, using an instrument such as a Kelly clamp to open StitchKit® could damage the tabs on the device.
- Misuse of the suture within StitchKit®, like any other suture, can result in serious patient injury or death.
- In order to avoid tearing the foam inside the device, back each needle out of the foam when getting a new suture (rather than drive it through the foam)

1. GENERAL

StitchKit® has tabs at either end for easy gripping using robotic needle holders or similar robotic instruments. Once the StitchKit® device is delivered into the surgical field through a trocar, these tabs can be used to open the device thus exposing the suture compartment on one side and the disposal compartment on the other. In the suture compartment, the needles are held securely and should be removed and used one at a time.

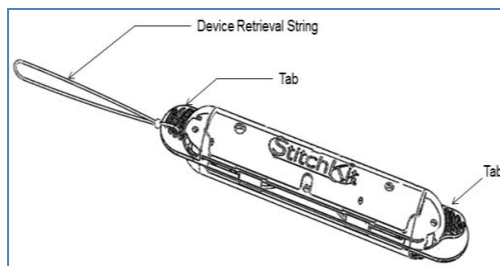


Figure 1 - View of StitchKit® Device when it is closed

Figure 2 shows two views of the StitchKit® device in its open configuration. In the top view key features such as the Disposal Compartment, Retrieval String, and Tabs at the ends of the device are highlighted.

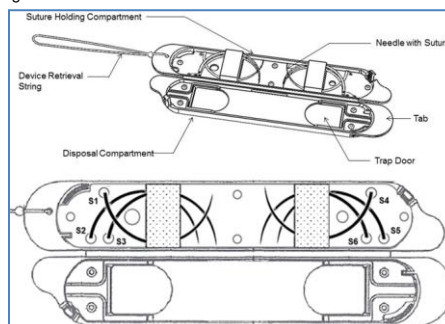


Figure 2 - Views of StitchKit® Device when it is open, illustrating key parts and symbols (S1, S2, etc.) on suture exit holes that identify each suture.

The lower view in Figure 2 illustrates how each suture exits the device through a unique Exit Hole labelled to identify the suture types. In an actual device the generic labels S1 through S6 are replaced with short symbols identifying the actual sutures within the device.

The disposal compartment has two "trap doors" through which discarded needles are placed into the disposal compartment. The disposal compartment is transparent so that needles may be counted before the device is removed, to help ensure that no needles are left behind inside the patient. When suturing is complete, the tabs are used to close the StitchKit® which snaps shut. A retrieval string is provided for easy grasping and removal.

2. STORAGE

Store the StitchKit® in a clean, dry area away from direct sunlight and at room temperature.

3. PREPARE DEVICE

- 3.1. Inspect the package. Do not use device if the package is opened or damaged, as sterility may have been compromised.
- 3.2. Check the expiration date. Do not use any part of the StitchKit® beyond the indicated expiration date.
- 3.3. Carefully unpack the device and place the StitchKit® in the sterile field. Ensure that the device does not come in contact with non-sterile surfaces.
- 3.4. Inspect the device. Do not use device if it appears to be damaged or defective.
- 3.5. Inspect any equipment to be used in conjunction with the StitchKit® for any signs of wear or damage. Do not use any equipment that appears to be damaged or defective.
- 3.6. If this device is being used for the first time, it is advisable that the surgeon should open and close the device with his / her hands

before actual insertion of the device in the body. This will ensure that the surgeon understands exactly how the opening and closing of the device is done. When doing this, be sure to use proper sterile technique.

4. INSERT DEVICE

- 4.1. Assistant should grasp device by one of its tabs with manual endoscopic forceps / grasper. Ensure at all times that the device is held only by the tabs.

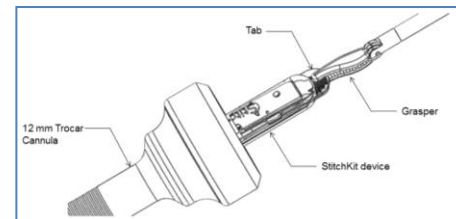


Figure 3 - Inserting the StitchKit® device using tab at end

- 4.2. Insert device through the trocar (Figure 3) and transfer it to the surgeon-controlled robotic graspers. Use caution while passing the device via the port to ensure appropriate placement of the device and avoid contact with adjacent organs. Take care to ensure that the canister does not get opened accidentally and that none of the contents spill out.
- 4.3. Alternatively, StitchKit may be placed through one of the 8 mm trocar sites under direct endoscopic visualization by removing one of the 8mm trocars and pushing StitchKit into the surgical field through that incision then replacing the trocar (Figure 4)– all under direct endoscopic visualization. When inserted this way, the resultant location of StitchKit should be noted, and the surgeon should retrieve StitchKit immediately after docking the robot and sitting at the surgeon console.

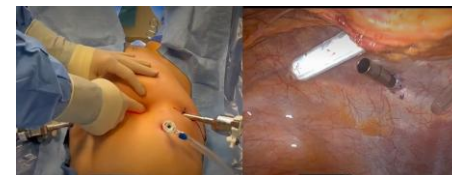


Figure 4 - Inserting the StitchKit® device through incision

5. OPEN THE DEVICE AND USE SUTURE

- 5.4. Gently open the StitchKit® using the side tabs. (Figure 5)

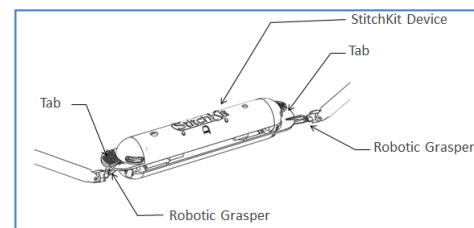


Figure 4 - Opening the StitchKit® Device using Robotic Graspers and tabs

- 5.5. Grip a suturing needle and slowly pull it out from the suture holding compartment of the device and use it for suturing.
- 5.6. When suturing is complete for that needle, trim the remnant suture thread from the needles using the robotic grasper or



StitchKit® FG SK-211

Instructions for Use

Section 2: Suturing Material Information

TI-CRON™ COATED BRAIDED NONABSORBABLE SUTURE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Ti-Cron™ braided polyester sutures are nonabsorbable, sterile, surgical sutures composed of Polyethylene Terephthalate. They are prepared from fibers of high molecular weight, long chain, linear polyesters having recurrent aromatic rings as an integral component. Ti-Cron™ braided sutures are available coated uniformly with silicone to increase surface lubricity, thereby enhancing handling characteristics, ease of passage through tissue, and knot run-down properties. Ti-Cron™ sutures are inert and elicit only minimal local tissue reaction. Ti-Cron™ sutures are available dyed with D&C Blue No. 6 colorant or undyed (white).

Ti-Cron™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for nonabsorbable surgical sutures.

INDICATIONS

Ti-Cron™ polyester sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological surgery.

ACTIONS

Ti-Cron™ polyester sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Ti-Cron™ polyester sutures are not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

CONTRAINDICATION

None known.

WARNINGS

As with any foreign body, prolonged contact of any suture with salt solutions may result in calculus formation.

Do not resterilize. Sterile unless packaging has been opened or damaged. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

Users should be familiar with surgical procedures and techniques involving sutures before employing Ti-Cron™ polyester nonabsorbable sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds

Rx Only

Learn more at: www.OrigamiSurgical.com

Or contact us at: INFO@OrigamiSurgical.com



Origami Surgical Inc.
42 Main Street, Suite A
Madison, NJ 07940
(973) 765-6256

"StitchKit" is a registered trademark of Origami Surgical Inc.
This device is covered by US Patents 8,418,851; & 6,986,780; other
patents pending. V-Loc and Polysorb are trademarks of Medtronic.
© Copyright 2021 Origami Surgical, Inc., All Rights Reserved.

DWG-0149-0 2025-05-16

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Adequate knot security requires the acceptable surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments.

ADVERSE REACTIONS

Adverse effects, which may be associated with the use of this product, include: wound dehiscence, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

HOW SUPPLIED

Ti-Cron™ polyester sutures are available undyed (white) or dyed with D&C Blue No. 6 and braided, coated, in sizes 5 (7 Metric) through 7-0 (0.5

Metric). The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needled or affixed to various needle types using both permanent and removable needle attachment techniques. The sutures are available in box quantities of one, two and three dozen. Ti-Cron™ polyester sutures are also available with PTFE (polytetrafluorethylene) pledgets for use as a pad between the suture area and the tissue surface to increase the load bearing area.

HOW SUPPLIED

Ti-Cron™ sutures in StitchKit® are supplied in size USP 2-0 packaged within the StitchKit device up to 6 strands per device. The suture length is pre-cut to 9 in; and affixed to a Covidien V20, 26 mm ½ circle taper point stainless steel needle.