7.2. When removing, be careful to avoid contact with adjacent organs. Also, ensure that the canister does not get opened accidently 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 6.

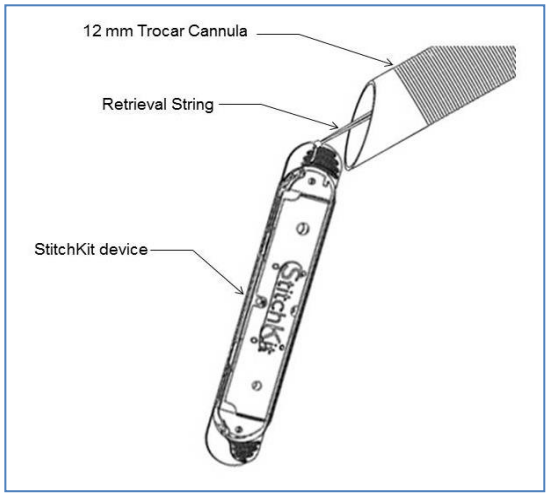


Figure 1 - Pulling out device through trocar using retrieval string

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(1) By visualizing through the 3D viewer screen, or (2) by manually counting the needles after the device has been withdrawn from the body.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.

8.4. 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.

USP Information Provided for Reference and Comparison

The suture within StitchKit® differs from USP requirements. The information below is provided so that the diameter and strength characteristics of the suture within StitchKit® can be compared to common USP sizes.

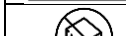
Table 1 - Diameter and Strength Characteristics for the suture within StitchKit®

Suture Size	Mean Diam. Suture (mm)	Suture Knot-Pull Tensile Strength (kg)
CV-4	.307	1.67

Table 2 - Provided for reference only - information on the Diameter and Strength Characteristics for common USP suture sizes

USP Size	USP Diam. (mm) Min.	Max.	USP Limits on Avg. Knot-Pull Tensile Strength (kg)
0	.35	.399	2.16
2–0	.30	.339	1.44
3–0	.20	.249	0.96
4–0	.15	.199	0.60
5–0	.10	.149	0.40
6–0	.070	.099	0.20
7–0	.050	.069	0.11
8–0	.040	.049	0.06

Table 3 – Meanings of Symbols Used in StitchKit® Labelling

	**Caution, consult Instructions for Use**
	**Sterilized using Ethylene Oxide**
	Do not use if package is damaged
	**Do not reuse**
	**Do not resterilize**
	**Manufacturer**
	**"Use by" (expiration) date**

R_x **Only**

"StitchKit" is a registered trademark of Origami Surgical LLC. This device is covered by US Patent 8,418,851; & 6,986,780. Other patents pending.

Tyvek® is a registered trademarks of E. I. du Pont de Nemours and Company or its affiliates.

Manufacturer:

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DWG-0021-2
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StitchKit®

Suture Delivery Canister for use in Robotic Surgery

Re-Order # SK-002 "StitchKit® ePTFE"

INSTRUCTIONS FOR USE

Device Description

StitchKit® is a sterile, single-use plastic canister that is provided pre-loaded with six strands of suture 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 is sized to be passed through a ≥12 mm trocar. As suturing is completed with each strand, the used needle is placed into a compartment within the canister for safe keeping until the entire canister is removed through the trocar using the attached retrieval string. It is supplied sterile in a plastic tray with Tyvek® lid. The following is a description of the suturing materials contained within this "StitchKit® ePTFE" (re-order # SK-002) device:

Suture Description	• Six strands of ePTFE Size CV-4 suture • The suture within StitchKit® is a nonabsorbable monofilament manufactured from polytetrafluoroethylene (PTFE) that has been expanded to produce a porous microstructure which is approximately 50% air by volume. • mean diameter (unexpanded) 0.307 mm, • diameter range (expanded) approx. 0.294 mm < dia <0.383 mm • Strand length approx. 21 cm • The suture within StitchKit® differs from USP requirements. See section at the end of this document to understand how this suture differs from USP. • The suture within StitchKit® is not dyed or coated.
Needle Description	TH-26, Taper point, ½ Circle, 26 mm

Indication for Use

StitchKit® facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing. The ePTFE suture contained within StitchKit® is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery and dura mater repair. It is recommended for use where reduced suture line bleeding during cardiovascular anastomotic procedures is desired.

Contraindications

- StitchKit® is designed to be inserted into and removed from the surgical field via a ≥ 12 mm trocar. It is not designed to be inserted into or removed from the surgical field via any other route (such as the vagina or rectum).
- The suture within StitchKit® is contraindicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.

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.
- The safety and effectiveness of the suture within StitchKit® in peripheral neural, microsurgical and ophthalmic applications has not been established.
- Tissue invasion of the suture within StitchKit® can result in attachment of the suture to the tissue it penetrates. Such attachment may make later removal of the Suture difficult.
- This device is for single use only. Do not resterilize.

Precautions

- Misuse of the suture within StitchKit®, like any other suture, can result in severe injury or death to the patient.
- As with any suture, care should be taken to avoid damage when handling. Avoid crushing or crimping the suture with surgical instruments or exposing the suture to sharp edges.
- In order to minimize needle damage, do not drive the needle from the channel where the suture is attached.
- As with all sutures, knot security requires standard surgical techniques of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon.
- When tying knots with the suture, tension should be applied by pulling each strand of the suture in opposite directions with equal force.
- As the knot is tensioned, the air in the suture is forced out. Care should be taken to avoid using a jerking motion which could break the suture.
- Uneven tensioning of a well formed square knot may result in an unsecure knot. When the suture is properly tensioned and formed, standard surgical knotting techniques will produce a secure knot.

Adverse Reactions

The suture within StitchKit® is made from PTFE, which is one of the most inert materials known and has been shown in clinical trials to elicit minimal tissue reaction. The suture within StitchKit® is not absorbed or subject to weakening by the action of tissue enzymes. It does not degrade in the presence of infection. Adverse effects associated with the use of suture, in general, include wound dehiscence, failure of adequate wound support in closure sites where expansion, stretching or distension occur, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and pain, edema and erythema.

Instructions for Use (IFU)

Attention: Failure to carefully follow these instructions may result in significant injury, and/or have an adverse effect on the outcome of procedures performed. Please read all instructions and information before using the device.

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.

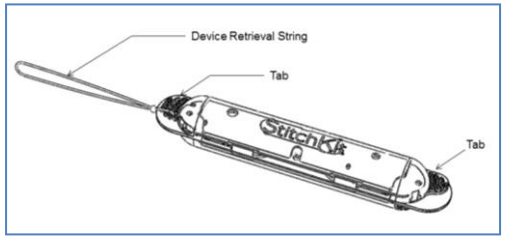

Figure 2 - View of StitchKit® Device when it is closed

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.

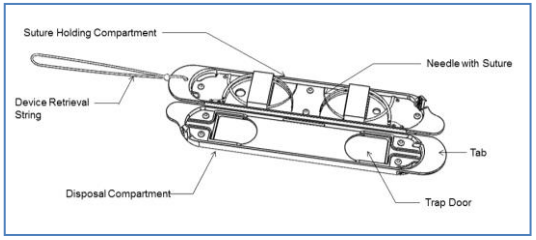

Figure 3 - View of StitchKit Device when it is open

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 by peeling lid and depositing 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. Care should be taken to see that this trial is performed in an aseptic environment.

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.

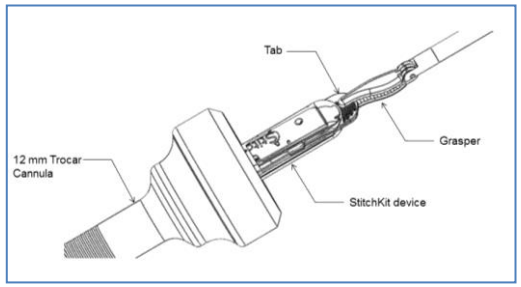

Figure 4 - Inserting the StitchKit® device using tab at end

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 accidently and that none of the contents spill out.

5. OPEN THE DEVICE AND USE SUTURE

5.1. Gently open the StitchKit® using the side tabs. (Figure 4)

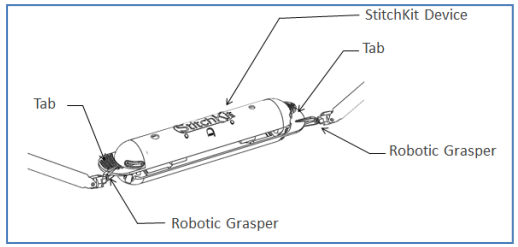

Figure 5 - Opening the StitchKit® Device using Robotic Graspers and tabs

5.2. Grip a suturing needle and slowly pull it out from the suture holding compartment of the device and use it for suturing.

5.3. When suturing is complete for that needle, trim the remnant suture thread from the needles using the robotic grasper or 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.

5.4. 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 5).

5.5. 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.

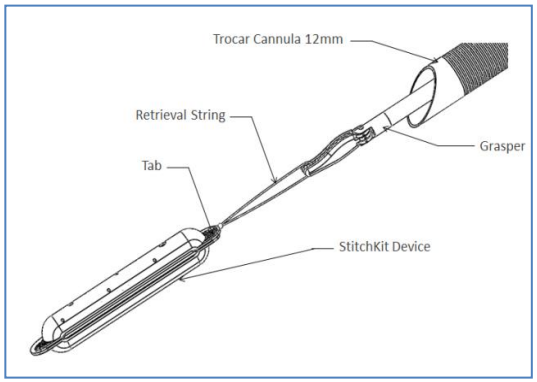

Figure 6 – Assistant should capture retrieval string to remove