

1. GENERAL

StitchKit® PARK™ 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 disposal compartment.

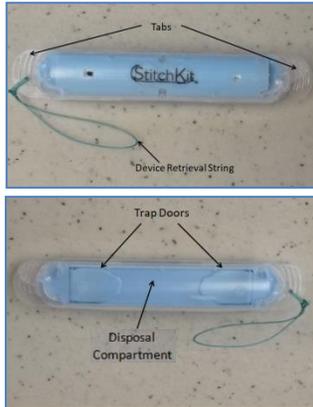


Figure 1 - View of StitchKit® PARK™ Device when it is closed

The StitchKit® PARK™ device has two white "Foam Blocks" that can be used to "park" suturing needles prior to passing the suture of your choice to the surgical site (see Figure 2). Rotate needles when inserting them into the foam and position them so that the needles will be enclosed and protected within the device when it is shut. Trim suture to approximately 8 to 9 inches. Allow the tails of the suture to extend beyond the canister ensuring that they exit on the same side as the retrieval string.

Opposite the foam blocks is a disposal compartment that 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.

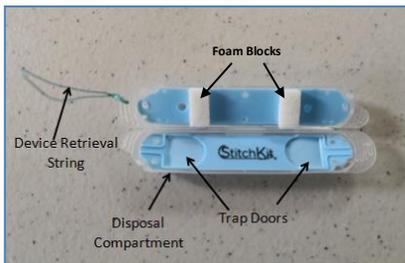


Figure 2 - View of StitchKit® PARK™ Device when it is open

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 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.
- 3.7. Load suture of your choice by inserting the needles into the Foam Blocks. Rotate them when inserting to avoid tearing the foam. Position them so that the needles will be enclosed and protected within the device when it is shut. Load them so that the suture tails exit on the same side as the Device Retrieval String.

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.

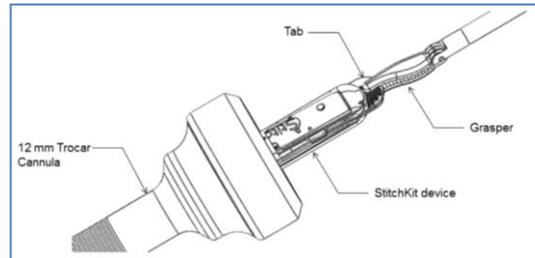


Figure 3 - Inserting the StitchKit® device using tab at end

- 4.2. Insert device through the trocar with the sutures facing down (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.

5. OPEN THE DEVICE

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

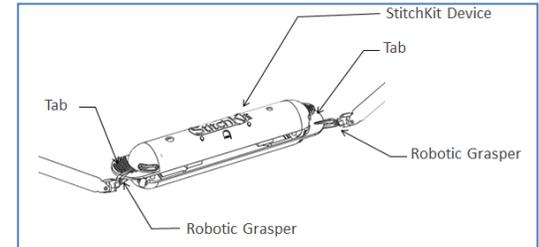


Figure 4 - Opening the StitchKit® Device using Robotic Graspers and tabs

- 5.2. Needles may be parked at any time simply by inserting them into the Foam Blocks. Use a rotating motion when inserting them to avoid tearing the foam.
- 5.3. When a needle is ready to be discarded after suturing is completed, 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 2).
- 5.5. Repeat until either suturing is completed.

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.

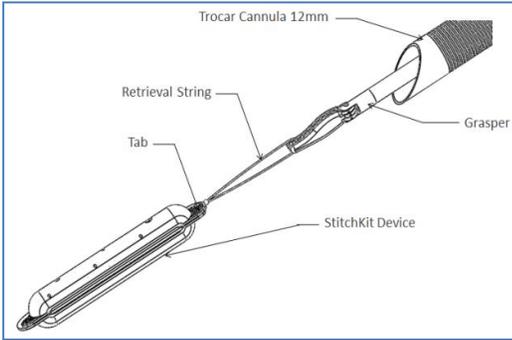


Figure 1 – Assistant should capture retrieval string to remove

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 6.

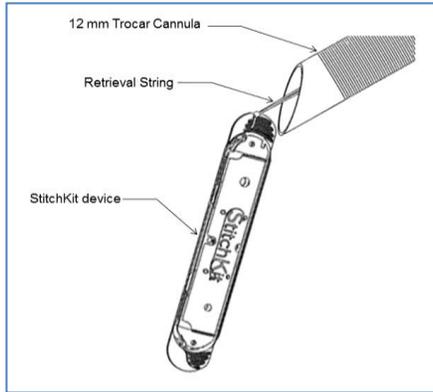


Figure 6 - Pulling out device through trocar using retrieval string

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.

Table 1 – 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_xOnly

"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.

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DWG-0040-0
Initial Release: 2020-08-25

StitchKit

StitchKit® PARK™ Canister
Instructions for Use

ATTENTION: Failure to carefully follow all the instructions may result in significant injury, and/or have an adverse effect on the outcome of procedures performed.

Device Description

StitchKit® PARK™ is a plastic canister that can be used to aid in the handling of suturing materials during robotic-assisted surgery.

Indication for Use

StitchKit® PARK™ facilitates minimally-invasive robotic-assisted surgery by protecting suturing needles when they are introduced or removed during a surgical procedure, and provides a convenient intraoperative "needle park."

Contraindications

StitchKit® PARK™ 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).

Warnings

- Use care during surgery to ensure that the StitchKit® PARK™ 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.
- Be sure to trim suture from needles prior to placing them in the disposal compartment. The remnant suture could later prevent the StitchKit® PARK™ from snapping closed properly, which in turn could interfere with its removal.
- This device is for single use only. Do not resterilize.

Precautions

- Open and close the StitchKit® PARK™ 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® PARK™ 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® PARK™ could damage the tabs on the device.
- Use care when using device to transport suture to the operative site, or parking needles, to avoid dislodgement or harm to suturing materials