ADVERSE REACTIONS: Potential adverse events associated with the use of surgical sutures include wound dehiscence, infection, minimal acute inflammatory tissue reaction, irritation when skin sutures are left in place for greater than seven days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

MONOTEX PTFE sutures differ from USP requirements for nonabsorbable sutures only in diameter (oversized in diameter in some cases, see table below). This is stated on immediate product labelling whenever applicable.

Maximum MONOTEX Suture Oversize in Diameter (mm) from USP		
USP Size	**USP Diameter (mm)**	**Maximum Overage (mm)**
6/0	0.070-0.099	0.050
5/0	0.10-0.149	0.050
4/0	0.15-0.199	0.050
3/0	0.20-0.249	0.050
2/0	0.30-0.339	0.060
0	0.35-0.399	0.100
1	0.40-0.499	0.100
2	0.50-0.599	0.100
3&4	0.60-0.699	0.100
5	0.70-0.799	0.100

If you require additional technical information regarding the suturing material within the StitchKit, please contact Origami Surgical.

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

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DWG-0038AW-0
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Re-Order # SK-002 "StitchKit® PTFE"

Instructions for Use Part 1 of 2: Suturing Material

ATTENTION: The StitchKit® Instructions for Use ("IFU") has been divided into 2 parts: IFU part 1 of 2: suturing material and IFU part 2 of 2: canister. **Please read all the IFU materials provided before using the device.** 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 Summary

StitchKit® is a sterile, single-use plastic canister that is provided pre-loaded with six strands of suture with attached needles. The following is a description of the suturing materials contained within this "StitchKit® PTFE" (re-order # SK-002) device:

Suture Description	• Six strands of PTFE Size 2-0 suture • Strand length approx. 21 cm
Needle Description	Taper point, ½ Circle, 26 mm, black needle
How Supplied	StitchKit® is supplied in boxes containing 1 to 6 StitchKit® devices

Information on Monotex® PTFE Suture

Note: Monotex® is a registered trademark of Riverpoint LLC. Information provided under this section is obtained from Monotex® IFU.

DESCRIPTION: MONOTEX suture is nonabsorbable, monofilament surgical suture composed of polyetrafluoroethylene (PTFE) polymer that has been expanded under controlled conditions, resulting in microscopic pores in the structure of the material, while maintaining structural integrity and tensile strength. MONOTEX suture contains no coatings, dyes, or additives.

INDICATIONS: MONOTEX surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. MONOTEX sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. MONOTEX suture is provided sterile as a single use device.

NOTE: Please refer to IFU part 2 of 2: canister for indications for use on the StitchKit® device canister.

CONTRAINDICATIONS: There are no known contraindications for MONOTEX sutures.

NOTE: Please refer to IFU part 2 of 2: canister for contraindications on the StitchKit® device canister.

PERFORMANCE: MONOTEX sutures have been shown to elicit a minimal tissue reaction. MONOTEX sutures, being nonabsorbable, are not absorbed by the body or subject to weakening caused by enzymes or the presence of infection.

WARNINGS:

- Tissue ingrowth into the microscopic pores present on MONOTEX sutures can result in attachment of suture to the applicable tissue during long-term use. Removal of the suture may be difficult in these cases.
- MONOTEX sutures are not indicated for use during microsurgeries, ophthalmic procedures, or procedures involving peripheral neural tissues.
- Do not resterilize. Discard open packages and unused sutures. Discard suture that is past the expiration date listed on the suture packaging.
- As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary and biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of contamination of infected wounds.

NOTE: Please refer to IFU part 2 of 2: canister for warnings on the StitchKit® device canister.

PRECAUTIONS:

- Misuse of MONOTEX sutures (or any variety of suture) can result in serious patient injury or death. Medical professionals should familiarize themselves with this Instructions for Use prior to using MONOTEX sutures.
- Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated. Under some circumstances, notably orthopaedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.
- Avoid exposure to elevated temperatures.
- Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated.

PRECAUTIONS (Continued):

- Subcuticular sutures should be placed as deeply as possible in order to minimize the erythema and induration normally associated with absorption.
- Care should be taken to avoid damage when handling this, or any other surgical suture. Avoid the crushing or crimping application of surgical instruments such as forceps and needle holders to the suture strand except when grasping the free end of the suture during an instrument tie.
- MONOTEX sutures require even tension applied to each strand when creating knots. Grasp each strand and apply equal force in opposite directions to apply this tension to the knot. The suture needle is not to be grasped when applying this tension, and care should be taken to avoid the use of a jerking motion to avoid causing damage to the suture and/or suture needle. Improper or uneven tensioning of a square knot can result in an unsecure knot. Air present within the suture material will be forced out when tension is applied to the knot as described above. Accepted standard surgical knotting techniques of flat and square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon will result in secure knots when the above steps are followed. Grasp the needle in an area one-third (1/3) to one-half (1/2) the distance from the swaged end to the point to avoid damage to the swage areas and needle points when forming knots. Reshaping the needle may cause the needle to lose strength and be less resistant to bending and breaking. Care should be taken when handling surgical needles to avoid accidental sticks with the needle. Discard used needles in “sharps” containers.

NOTE: Please refer to IFU part 2 of 2: canister for precautions on the StitchKit® device canister.

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.

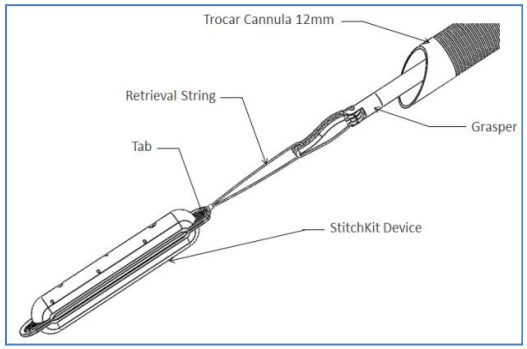

Figure 1 – Assistant should capture retrieval string to remove

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

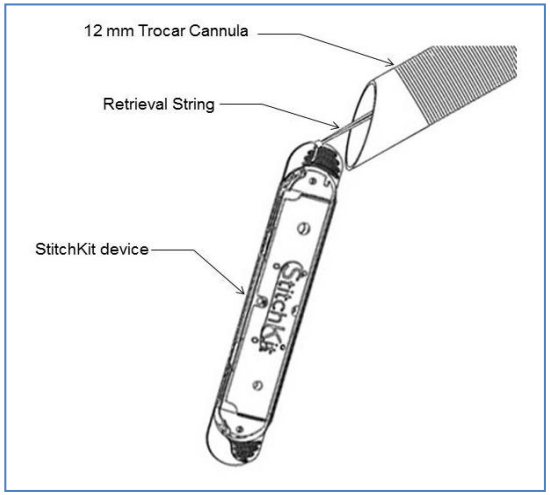

Figure 6 - Pulling out device through trocar using retrieval string

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
STERILE EO	**Sterilized using Ethylene Oxide**
	Do not use if package is damaged
	Do not reuse
2 STERILIZE	**Do not resterilize**
	Manufacturer
	"Use by" (expiration) date

℞ *Only*

Manufacturer:

Origami Surgical, LLC
42 Main Street
Suite A
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www.StitchKit.com

DWG-0021-5
Revised: 2017-06-19

StitchKit®

Suture Delivery Canister for use in Robotic Surgery

Instructions for Use Part 2 of 2: CANISTER

ATTENTION: The StitchKit® Instructions for Use ("IFU") has been divided into 2 parts: IFU part 1 or 2: suturing material and IFU part 2 of 2: canister. **Please read all the IFU materials provided before using the device.** 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® is a sterile, single-use plastic canister that is provided pre-loaded with suture strands 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.

Indication for Use

StitchKit® facilitates minimally invasive robotic surgery by transporting suture to the operative field and removing used needles after suturing.

NOTE: Please refer to IFU part 1 of 2: suturing material for indications for use for the suture used in the StitchKit® device.

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).

NOTE: Please refer to IFU part 1 or 2: suturing material for contraindications on the suturing material.

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.

NOTE: Please refer to IFU part 1 of 2: suturing material for warnings on the suturing material.

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® 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)

Note: Please refer to IFU Part 1 of 2: Suturing Material for Warnings on the suturing material.

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.

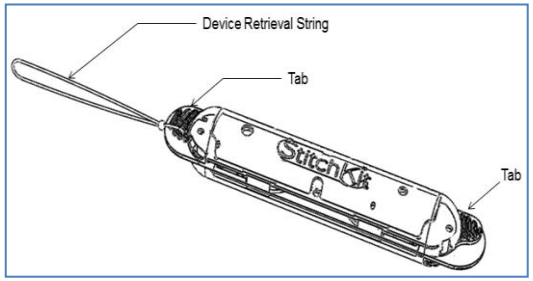

Figure 1 - View of StitchKit® Device when it is closed

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.

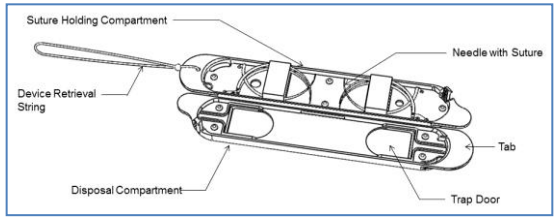

Figure 2 - View of StitchKit Device when it is open

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 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.

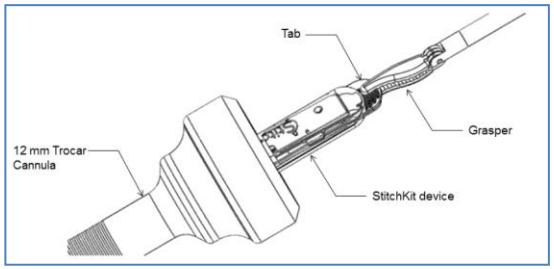

Figure 3 - Inserting the StitchKit® device using tab at end

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 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)

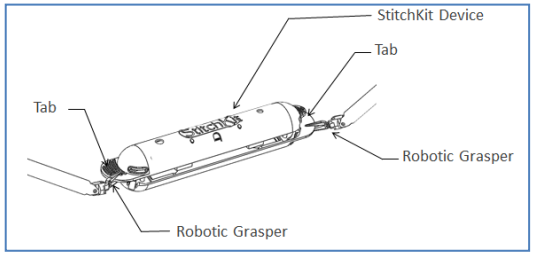

Figure 4 - Opening the StitchKit® Device using Robotic Graspers and tabs

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 2).

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.