

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.

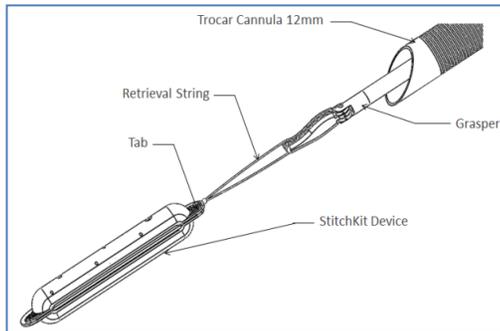


Figure 5 – Assistant should capture retrieval string to remove

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.

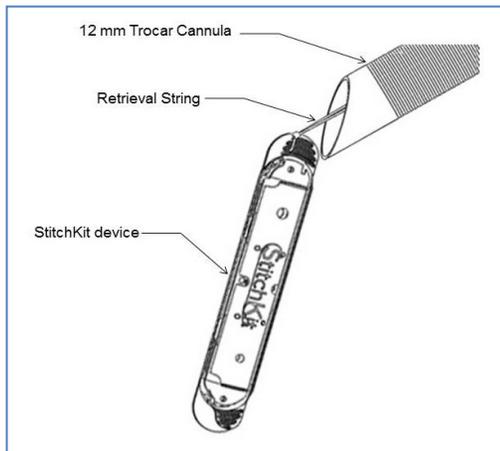


Figure 6 - Pulling out device through trocar using retrieval string

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(1) By visualizing through the 3D viewer screen, or (2) by manually counting the needles after the device has been withdrawn from the body.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



StitchKit® RSCP SK-106
Instructions for Use

StitchKit® RSCP SK-106 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 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 safekeeping until the entire canister is removed through the trocar using the attached retrieval string.

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.
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NEEDLE INFORMATION

Needle Description	Taper point, ½ Circle, 26 mm, stainless steel needle.	 1/2 ∅ 26 mm
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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® RSCP SK-106	Symbol: MAX Four (4) strands of Covidien™ brand Maxon™ sutures, Size: 2-0, Length: 7.7", Color: Green Manufacturer's reference: 8886623351 (cut to length)
	Symbol: PTFE Two (2) strands of Riverpoint™ brand Monotex® (PTFE) sutures, Size: 2-0, Length: 7.7", Color: Black Manufacturer's reference: T-7902-DA (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.

Rx Only

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"StitchKit" is a registered trademark of Origami Surgical Inc.
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Section 1: StitchKit® Canister Information:

CONTRAINDICATIONS

The StitchKit® canister 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® 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.

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)

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.

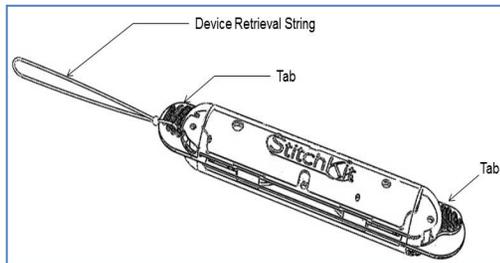


Figure 1 - View of StitchKit® Device when it is closed

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.

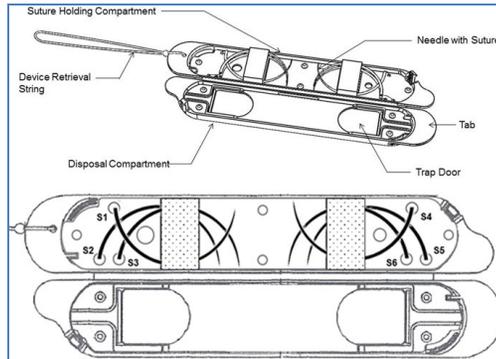


Figure 2 - Views of StitchKit Device when it is open, illustrating key parts and symbols (S1, S2, etc.) on suture exit holes that identify each suture.

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

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.

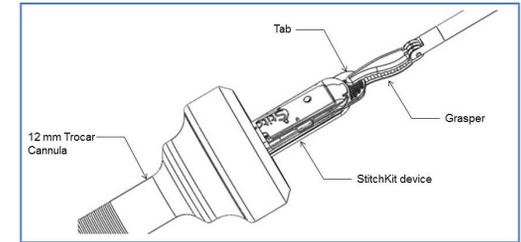


Figure 3 - Inserting the StitchKit® device using tab at end

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.

5. OPEN THE DEVICE AND USE SUTURE

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

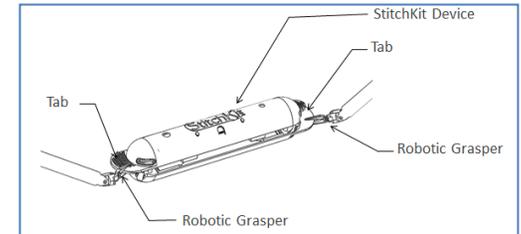


Figure 4 - Opening the StitchKit® Device using Robotic Graspers and tabs

- 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.

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.

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

Rx Only

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StitchKit® RSCP SK-106
Instructions for Use

Section 2: Suturing Material Information

MAXON™ MONOFILAMENT ABSORBABLE SUTURE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Maxon™ monofilament polyglyconate synthetic absorbable sutures are prepared from a copolymer of glycolic acid and trimethylene carbonate. Maxon™ synthetic absorbable sutures are dyed with D&C Green No. 6 to increase visibility and are also available clear (undyed).

Maxon™ synthetic absorbable sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for synthetic absorbable surgical sutures, except for minor variations in suture diameter.

Such variations are:

Maximum Suture Oversize in Diameter (mm) from USP & EP		
USP Size	USP Size Designation (mm)	Maximum Overage (mm)
7-0	0.050-0.069	0.015
6-0	0.070-0.099	0.025
5-0	0.10-0.149	0.035
4-0	0.15-0.199	0.040
3-0	0.20-0.249	0.055
2-0	0.30-0.339	0.055
0	0.35-0.399	0.070
1	0.40-0.499	0.070

INDICATIONS

Maxon™ sutures in StitchKit® are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation.

Maxon™ sutures are not indicated for use in adult cardiovascular tissue, ophthalmic surgery, microsurgery, and neural tissue.

ACTIONS

Maxon™ synthetic absorbable sutures elicit a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Maxon™ synthetic absorbable sutures occurs by means of hydrolysis where the suture is broken down and subsequently absorbed and metabolized by the body.

Studies indicate that tensile strength for Maxon™ sutures is approximately 80% of the original suture strength at one week post-implant. Approximately 75% of the original suture strength remains at two weeks, 65% at three weeks, 50% at four weeks and 25% at six weeks post-implant. Absorption of Maxon™ synthetic absorbable sutures is minimal until about the 60th day after implantation. Absorption is substantially complete within six months.

Origami Surgical evaluated the residual strength of Maxon™ suture when it is packaged in the StitchKit® device per ASTM F1635-16, "Standard Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants." The results of this testing are shown in the table, below:

	Time Point (weeks)	Residual Strength %USP (kgf)	
		Manufacturer's specification	In StitchKit® (measured)
Maxon™ (size 2-0)	1	80% USP (2.14)	265% USP (7.10)
	2	75% USP (2.01)	264% USP (7.08)
	3	65% USP (1.74)	214% USP (5.74)
	4	50% USP (1.34)	179% USP (4.81)
	6	25% USP (0.67)	107% USP (2.88)

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to its components.

This suture, being absorbable, should not be used where extended approximation of tissue is required or fixation of permanent cardiovascular prostheses or synthetic grafts.

WARNINGS

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

In surgery of the urinary and biliary tracts, care should be taken to avoid prolonged contact of this, or any other, suture with salt solutions, as calculus formation may result.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Maxon™ synthetic absorbable 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 contaminated or infected wounds.

The use of this suture may be inappropriate for patients with any conditions which, in the opinion of the surgeon, may cause or contribute to delayed wound healing.

The use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of sites subject to expansion, stretching or distention, or requiring additional support.

PRECAUTIONS

Under some circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

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 accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstances and the experience of the surgeon.

The use of additional throws may be particularly appropriate when knotting monofilaments.

Care should be exercised when knotting sutures used in continuous mass or layered closure of the abdomen, i.e. non-slip locking knots should be used at both ends of the continuous closure.

The commonly used looped-to-stand knot during termination of a running suture is a configuration, which may lead to slippage. Extreme care must be utilized to ensure that multiple square knots are well secured.

Sutures in vaginal mucosa or skin that remains in place for extended periods may be associated with localized irritation and should be removed as indicated.

Since any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, standard surgical practice should be followed with respect to drainage and closure of infected wounds.

Dispose of contaminated suture and packaging materials utilizing standard hospital procedures and universal precautions for biohazardous waste.

ADVERSE REACTIONS

Adverse effects, which may be associated with the use of this product, include: wound dehiscence, failure to provide adequate wound support in sites where expansion, stretching or distension occur; failure to provide adequate wound support in patients with conditions which may delay wound healing; tissue granulation or fibrosis; wound suppuration and bleeding, as well as sinus formation; localized irritation when skin sutures are left in place for 7 or more days; calculi formation when prolonged contact with salt solutions occurs; enhanced bacterial infectivity; minimal acute inflammatory reaction; and pain, edema, and erythema at the wound site.

HOW SUPPLIED

Maxon™ 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 7.7 in; and affixed to a Covidien V20, 26 mm ½ circle taper point stainless steel needle.

MONOTEX® PTFE SUTURE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

MONOTEX suture is nonabsorbable, monofilament surgical suture composed of polytetrafluoroethylene (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.

CONTRAINDICATION

There are no known contraindications for MONOTEX sutures.

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 microsurgies, 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.

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. 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 insecure 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