5.1. disposal compartment via the trap door. It is typically easier to place the blunt aspect of the needle into the compartment first (Figure 2).

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(1) By visualizing through the 3D viewer screen, or (2) by manually counting the needles after the device has been withdrawn from the body.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

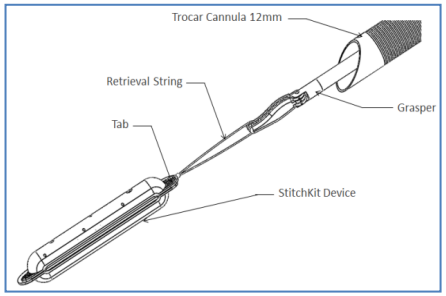

Figure 6 – Assistant should capture retrieval string to remove

7.2. When removing, be careful to avoid contact with adjacent organs. Also, ensure that the canister does not get opened 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 7.

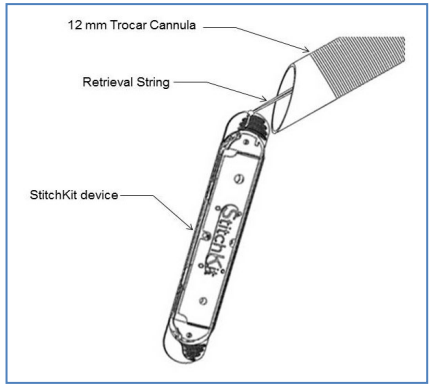

Figure 7 - Pulling out device through trocar using retrieval string

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.

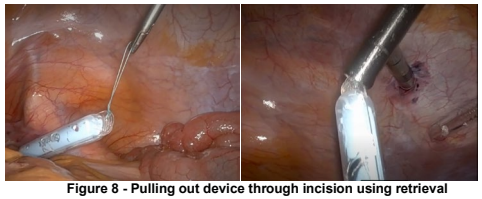

Figure 8 - Pulling out device through incision using retrieval

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.

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Learn more at: **www.OrigamiSurgical.com**

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Origami Surgical

StitchKit® URO SK-110

Instructions for Use

StitchKit® URO SK-110 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 8mm trocar under direct endoscopic visualization and removed (in tandem with the 8mm 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

Polysorb Size 0	Taper point, ½ Circle, 26 mm, stainless steel needle.	
Polysorb Size 2-0	Taper point, ½ Circle, 17 mm, stainless steel needle.	
Biosyn	Taper point, 5/8 Circle, 27 mm, stainless steel needle.	

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® URO SK-110	**Symbol: 0PGA** Two (2) strands of Covidien™ brand Polysorb™ suture Size: 0, Length: Approx. 20.8 cm, Color: Violet Manufacturer's reference: GL-124 (cut to length)
	Symbol: 2PGA Two (2) strands of Covidien™ brand Polysorb™ suture Size: 2-0, Length: Approx. 20.8 cm, Color: Violet Manufacturer's reference: UL-205 (cut to length)
	Symbol: BIO One (1) strands of Covidien™ brand Biosyn™ suture Size: 2-0, Length: Approx. 19.6 cm, Color: Violet Manufacturer's reference: UM-878 (cut to length)
	Symbol: BIO One (1) strands of Covidien™ brand Biosyn™ suture Size: 2-0, Length: Approx. 19.6 cm, Color: Undyed Manufacturer's reference: UM-978 (cut to length)

OTHER CONTENTS OF THIS DOCUMENT

Section 1: **StitchKit® Canister Information.** Incudes 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 through 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.

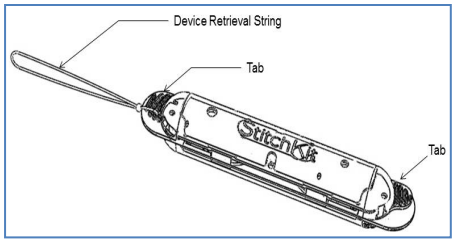

Figure 1 - View of StitchKit® Device when it is closed

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.

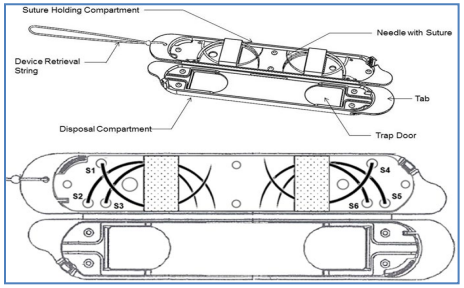

Figure 2 - Views of StitchKit Device when it is open, illustrating key parts and symbols (S1, S2, etc.) on suture exit holes that identify each suture.

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.

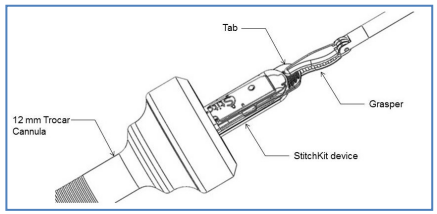

Figure 3 - Inserting the StitchKit® device using tab at end

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 accidently 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 ten 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.

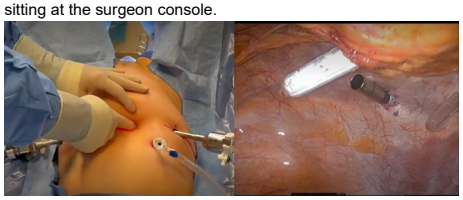

Figure 4 - Inserting the StitchKit® device through incision

5. OPEN THE DEVICE AND USE SUTURE

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

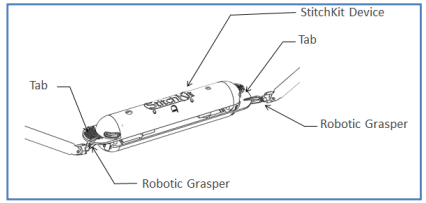

Figure 5 - Opening the StitchKit® Device using Robotic Graspers and tabs

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

5.5. 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.

5.6. Place the used needle (with remnant suture removed) into the

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DWG-0137-1 2023-11-14

StitchKit® URO SK-110

Instructions for Use

Section 2: Suturing Material Information

POLYSORB™ COATED BRAIDED ABSORBABLE SUTURE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Polysorb™ braided sutures are composed of Lactomer™ glycolide/lactide copolymer which is a synthetic polyester composed of glycolide and lactide (derived from glycolic and lactic acids). Polysorb™ sutures are prepared by coating the suture with a mixture of a caprolactone/glycolide copolymer and calcium stearoyl lactylate. Polysorb™ sutures are colored violet to increase visibility and are also available undyed.

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

Such variations are:

Maximum Suture Oversize in Diameter (mm) from USP		
USP Size	USP Size Designation (mm)	Maximum Overage (mm)
2-0	0.30-0.339	0.05
0	0.35-0.399	0.05

INDICATIONS

Polysorb™ sutures are indicated for use in soft tissue approximation or ligation and ophthalmic surgery, but not in cardiovascular or neural tissue.

ACTIONS

Polysorb™ sutures elicit a minimal acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue.

Progressive loss of tensile strength and eventual absorption of Polysorb™ sutures occurs by means of hydrolysis, where the Lactomer™ glycolide/ lactide copolymer is broken down to glycolic and lactic acids which are subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Studies indicate tensile strength averages for Polysorb™ sutures are approximately 140% of USP and E.P. minimum knot strength initially, are approximately 80% at two weeks and in excess of 30% at three weeks post implant. Absorption of Polysorb™ sutures is essentially complete between the 56th and 70th day.

The results of in vitro biodegradation testing of Polysorb™ when packaged within StitchKit® indicate that the suture exhibits residual tensile strength versus implant time that is comparable to the typical Polysorb™ residual strength versus time. This was observed in an Origami Surgical study based on ASTM F1635-16 method, using 10 strand samples per time-point of 2-0 Polysorb. This is illustrated in tabular form, below.

		Residual Strength %USP (kgf)	
Product	Time Point (days)	In manufacturer's packaging	In StitchKit®
Polysorb™ (size 2-0)	0	140% USP (3.75)	258% USP (6.91)
	14	80% USP (2.14)	168% USP (4.49)
	21	>30% USP (0.80)	41% USP (1.11)

CONTRAINDICATION

Polysorb™ sutures, being absorbable, should not be used where extended approximation of tissue is required.

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 temperatures.

In surgery of the urinary or 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 Polysorb™ sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, 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 in patients with any conditions which, in the opinion of the surgeon, may cause or contribute to delayed wound healing.

As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in closure of the abdomen, chest, joints or other sites subject to expansion or requiring additional support.

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

Skin sutures which must remain in place longer than 7 days may cause irritation and should be snipped off or removed as indicated.

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

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 distention occur, failure to provide adequate wound support in patients with conditions which may delay wound healing, localized irritation when skin sutures are left in place greater than 7 days, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

BIOSYN™ MONOFILAMENT ABSORBABLE SUTURE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Biosyn™ monofilament synthetic absorbable sutures are prepared from a synthetic polyester composed of glycolide, dioxanone, and trimethylene carbonate. Biosyn™ synthetic absorbable sutures are colored violet to increase visibility and are also available undyed.

Biosyn™ 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 U.S.P and E.P.

U.S.P. Size	U.S.P. Size Designation (mm)	Maximum Overage (mm)
6-0	0.070-0.099	0.017
5-0	0.10-0.149	0.026
4-0	0.15-0.199	0.026
3-0	0.20-0.249	0.056
2-0	0.30-0.339	0.023
0	0.35-0.399	0.070
1	0.40-0.499	0.044

INDICATIONS

Biosyn™ synthetic absorbable sutures are indicated for use in general soft tissue approximation and/or ligation including use in ophthalmic surgery, but not for use in cardiovascular or neurological surgery.

ACTIONS

Biosyn™ 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 Biosyn™ synthetic absorbable sutures occurs by means of hydrolysis where the suture is broken down to glycolic acid, dioxanoic acid, propane diol and carbon dioxide which are subsequently absorbed and metabolized by the body.

Absorption begins as a loss of tensile strength without appreciable loss of mass. Studies in animals indicate tensile strength averages for Biosyn™ synthetic absorbable sutures are approximately 75% of U.S.P and E.P. minimum knot strength at two weeks and approximately 40% at three weeks post-implant. Absorption of Biosyn™ synthetic absorbable sutures is essentially complete between 90 and 110 days.

CONTRAINDICATION

This suture, being absorbable, should not be used where extended approximation of tissue is required.

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 absorbable sutures before employing Biosyn™ 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.

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

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 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, failure to provide adequate wound support in sites where expansion, stretching, or distention occur, failure to provide adequate wound support in patients with conditions which may delay wound healing, localized irritation when skin sutures are left in place greater than 7 days, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

HOW SUPPLIED

Biosyn™ synthetic absorbable sutures are available undyed (natural) or dyed violet in U.S.P. and E.P. sizes 1 (4 Metric) through 6-0 (0.7 Metric). The sutures are supplied sterile, in pre-cut lengths or ligating reels, non-needled or affixed to various needle types. The sutures are available in box quantities of one, two and three dozen.