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.

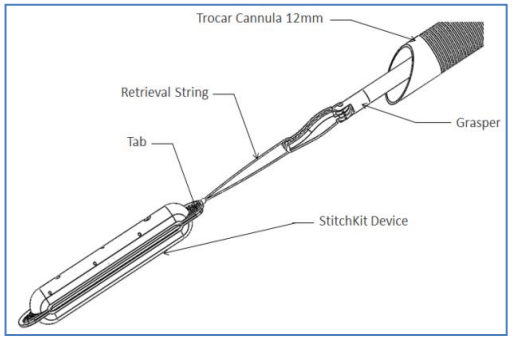

Figure 5 – Assistant should capture retrieval string to remove

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

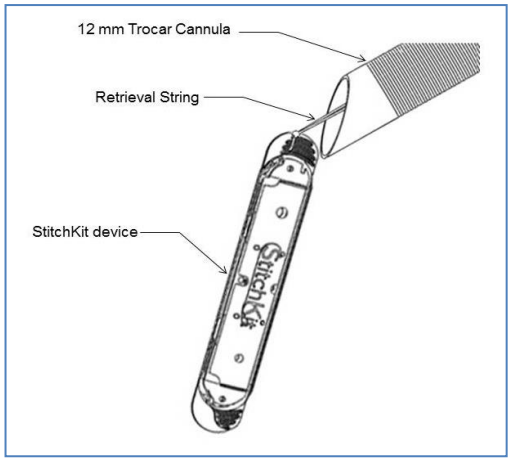

Figure 6 - Pulling out device through trocar using retrieval string

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(1) By visualizing through the 3D viewer screen, or (2) by manually counting the needles after the device has been withdrawn from the body.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

Rx Only

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

Or contact us at: **INFO@OrigamiSurgical.com**

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

DWG-0064-0 2021-03-19

StitchKit® BA SK-104

Instructions for Use

StitchKit® BA SK-104 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.

NEEDLE INFORMATION

Needle Description	Taper point, ½ Circle, 26 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® BA SK-104	**Symbol: SILK** Three (3) strands of Covidien™ brand SofSilk™ suture, Size: 2-0, Length: 7.7", Color: Black Manufacturer's reference: GS833 (cut to length)
	Symbol: PGA Two (2) strands of Covidien™ brand Polysorb™ suture Size: 2-0, Length: 7.7", Color: Violet Manufacturer's reference: GL333 (cut to length)
	Symbol: VL90 One (1) strand of Covidien™ brand V-Loc 90 Size: 3-0, Length 12 in, Color: Violet Manufacturer's reference: VLOCM0614

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

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.

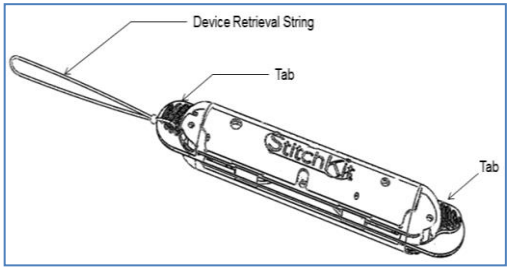

Figure 1 - View of StitchKit® Device when it is closed

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.

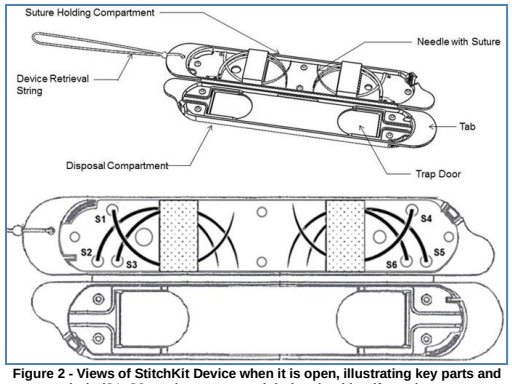

Figure 2 - Views of StitchKit Device when it is open, illustrating key parts and symbols (S1, S2, etc.) on suture exit holes that identify each suture.

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.

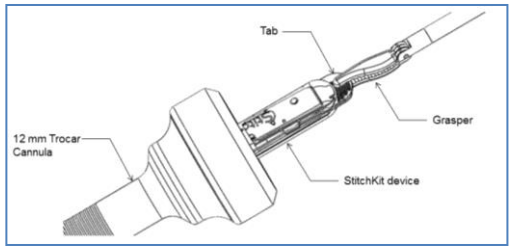

Figure 3 - Inserting the StitchKit® device using tab at end

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 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)

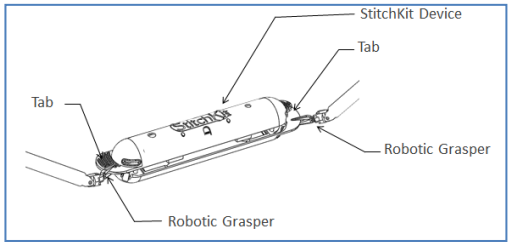

Figure 4 - Opening the StitchKit® Device using Robotic Graspers and tabs

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.

CONTRAINDICATIONS

The use of the V-Loc™ 90 absorbable wound closure device is contraindicated in patients with known sensitivities or allergies to its components.

The V-Loc™ 90 absorbable wound closure device is not for use where prolonged (beyond 2 weeks) approximation of tissues under stress is required or for fixation of permanent cardiovascular prostheses or synthetic grafts.

V-Loc™ 90 absorbable wound closure device should not be used for interrupted suture patterns.

V-Loc™ 90 absorbable wound closure device is not intended to be used by tying surgical knots.

V-Loc™ 90 absorbable wound closure device should not be used for ligating vessels or luminal structures.

WARNINGS AND PRECAUTIONS

1. The safety and effectiveness of the V-Loc™ 90 absorbable wound closure device has not been established for use in fascial closures (abdominal wall, thoracic, extremity fascial closures), gastrointestinal anastomoses, cardiovascular anastomoses, neurological, ophthalmic, orthopedic or microsurgery.

2. The V-Loc™ 90 absorbable wound closure device is intended to be used without the use of anchoring knots to begin or terminate the suture line. Do not tie knots. Tying knots may damage the barbs and potentially reduce their effectiveness.

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

4. Users should be familiar with surgical procedures, techniques, size choice, and tensile strength profiles involving absorbable devices before employing the V-Loc™ 90 absorbable wound closure device. The risk of wound dehiscence may vary with the site of application and the device material used.

5. V-Loc™ 90 absorbable wound closure device should only be used with continuous suture patterns. Do not use V-Loc™ 90 absorbable wound closure device in a continuous locking pattern.

6. Acceptable surgical practice must be followed with respect to the management of contaminated or infected wounds.

7. 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.

8. 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.

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

10. In handling this or any other device, 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.

11. Since 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. The V-Loc™ 90 absorbable wound closure devices did not enhance infection in animal studies. Dispose of contaminated devices and packaging materials utilizing standard hospital procedures and universal precautions for biohazardous waste.

12. During employment of the device, care should be taken to avoid damage to the surgical needles from handling. Grasp the needle in an area one-third to one half of the distance from the attachment end to the needle point. Grasping near the point could result in damage to the functional integrity or fracture the needle. Grasping at the attachment area could cause breakage of the needle barrel or the absorbable thread in the attachment area. Reshaping needles may result in decreased resistance to bending and breaking. To avoid inadvertent needle stick injury, which may result in transmission of blood-borne pathogens, the user should exercise caution during handling of surgical needles and consider use of Protect Point™ modified taper needles where appropriate.

INSTRUCTIONS FOR USE

V-Loc™ 90 absorbable wound closure device should only be used with continuous suture patterns.
V-Loc™ 90 absorbable wound closure device is intended to be used without the use of anchoring knots to begin or terminate the suture line.

1. To begin a continuous suture pattern take apposing bites on either side of the wound in standard fashion.
2. V-Loc™ 90 absorbable wound closure device is anchored by passing the needle end of the suture through the pre-formed loop end effector
3. Gentle traction on the suture will anchor the suture and appose the wound edges.
4. Approximate the tissue using a continuous pattern taking care not to over tighten the suture line while trailing.
5. To end the suture line for deep tissues, take 2 additional bites beyond the terminal commissure to anchor the line. While applying gentle traction on the free end of the suture, cut the suture flush with the surface of the tissue.
6. For terminating an intradermal closure, pass V-Loc™ 90 absorbable wound closure device perpendicular to the incision and exit the skin. Cut the suture flush with the surface of the skin.

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; 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.

ACTIONS

V-Loc TM 90 absorbable wound closure devices elicit a minimal acute inflammatory reaction in tissues, which is followed by a gradual encapsulation of the device by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of V-Loc™ 90 absorbable wound closure device occurs by means of hydrolysis where the device is broken down to glycolic acid, dioxanoic acid, propane diol and carbon dioxide which are subsequently absorbed and metabolized by the body.

V-Loc™ 90 absorbable wound closure devices have been formulated to provide predictable wound support and absorption through the wound healing period.

Absorption begins as a loss of tensile strength without appreciable loss of mass. Studies demonstrate the following approximate % of USP and EP knot pull minimum average specification for the labeled diameter size.

Time (in days)	Device Strength
7	90%
14	75%

Animal data indicates that the absorption is essentially complete between 90 and 110 days.

Comparative in-vitro simulated biodegradation testing was performed to compare the V-Loc™ 90 sutures within the original manufacturer's packaging and V-Loc™ 90 sutures packaged within the StitchKit® devices. It was found that the sutures within the StitchKit® device exhibited residual tensile strength comparable to that of the sutures packaged within their original manufacturer's packaging. The test results are summarized below.

Product	Time point (days)	Mean(SD), Tensile Strength, kgf		Difference(%)	p-value
		In Mfg Package	In StitchKit		
V-Loc™ 90	7	2.27(0.33)	2.27(0.18)	0.00(0%)	0.99
	14	2.50(0.18)	2.16(0.13)	0.34(14%)	<.0001

p-value calculated using two-tailed Student's t-test, $\alpha < 0.05$

Product	Time point (days)	Measured Strength Retained		Manufacurer's Specification for Strength Retained	StitchKit Significantly Exceeds Specification?
		In Mfg Package	In StitchKit		
V-Loc™ 90	7	128%	128%	90%	Yes
	14	141%	122%	75%	Yes

Strength retained is shown as a percentage of the USP knot pull minimum average specification for the labeled diameter size, as provided in suturing material manufacturers' IFU.

Note: In the above tables, MFG = Sutures in original manufacturer's packaging; StitchKit® = Sutures packaged within StitchKit® device; SD = Standard Deviation

When implanted in animal tissue, V-Loc™ 90 absorbable wound closure devices elicit a minimal tissue reaction characteristic of foreign body response to substance. The tissue reaction resolves as the device is absorbed.

AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

Rx Only

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

Or contact us at: **INFO@OrigamiSurgical.com**

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

DWG-0064-0 2021-03-19

StitchKit® BA SK-104

Instructions for Use

Section 2: Suturing Material Information

SOFSILK™ COATED BRAIDED SILK

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Sofsilk™ braided silk sutures are nonabsorbable, sterile, non-mutagenic surgical sutures composed of natural proteinaceous silk fibers called fibroin. This protein is derived from the domesticated silkworm species Bombyx mori of the family bombycidae. The silk fibers are treated to remove the naturally-occurring sericin gum and braided to produce Sofsilk™ surgical silk sutures. The braided sutures are available coated uniformly with either silicone or a special wax mixture to reduce capillarity and to increase surface lubricity which enhances handling characteristics, ease of passage through tissue, and knot run-down properties. Sofsilk™ sutures are available white or colored black with Logwood extract.

Sofsilk™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for nonabsorbable surgical sutures, except for size 8-0, which DIFFERS FROM USP MAXIMUM DIAMETER REQUIREMENTS BY UP TO 0.005 mm.

INDICATIONS

Sofsilk™ sutures are indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic, microsurgery, and neurological surgery.

ACTIONS

Sofsilk™ sutures elicit a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While Sofsilk™ sutures are not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of the suture's tensile strength over time.

CONTRAINDICATIONS

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

Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, Sofsilk™ sutures should not be used where permanent retention of tensile strength 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 nonabsorbable sutures before employing Sofsilk™ 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.

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.

ADVERSE REACTIONS

Adverse effects, which may be associated with the use of this product, include: wound dehiscence, gradual loss of tensile strength over time, allergic response in patients with known sensitivities to silk, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

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.

V-LOC™ 90 ABSORBABLE WOUND CLOSURE DEVICE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The V-Loc™ 90 absorbable wound closure device consists of a barbed absorbable thread, armed with a surgical needle at one end and a loop end effector at the other. The barb and loop end effector design allow for tissue approximation without the need to tie surgical knots.

The V-Loc™ 90 absorbable wound closure device is prepared from a synthetic polyester composed of glycolide, dioxanone, and trimethylene carbonate. The absorbable wound closure device is available undyed or violet. The device is sterile, inert, noncollagenous and nonantigenic.

USP designations for diameter are applicable to the V-Loc™ 90 absorbable wound closure device material prior to barbing. After the creation of barbs, the V-Loc™ 90 absorbable wound closure device is identified as one size smaller than the non-barbed suture. This modification reduces the tensile strength of the suture similar to effect of knot tying in non-barbed suture. Therefore, the straight pull tensile strength of the V-Loc ™ 90 absorbable wound closure device is comparable to the USP knot pull strength for a non-barbed suture of the equivalent size. The non-barbed size and equivalent size of the V-Loc™ 90 absorbable wound closure device is further clarified in Chart 1. The maximum oversize for non-barbed suture material from the USP size is further detailed in Chart 2.

The V-Loc™ 90 absorbable wound closure device meets requirements established by the United States Pharmacopoeia (USP) and European Pharmacopoeia (EP) for synthetic absorbable sutures for needle attachment only.

Tensile Strength / Size Equivalency Chart 1

V-Loc™ 90 Device Suture Size	Pre-Barbing Suture Size	Equivalent Non-Barbed Size (USP) /Tensile Strength (kgf)
0	1	0 / 3.90
2-0	0	2-0 / 2.68
3-0	2-0	3-0 / 1.77
4-0	3-0	4-0 / 0.95

Maximum Oversize for non-barbed suture material in Diameter (mm) from USP Chart 2

USP Size	USP size Designation (mm)	Maximum Oversize (mm)
0	0.35 - 0.399	0.144
2-0	0.30 - 0.339	0.130
3-0	0.20 - 0.249	0.113
4-0	0.15 - 0.199	0.106

INDICATIONS

V-Loc™ 90 absorbable wound closure devices are indicated for soft tissue approximation where use of an absorbable suture is appropriate.