Box size: 6.5 x 9
Overall size: 18 x 22
Folds to: 3 x 7.333

COVIDIEN

# V-Loc™ 90

## Absorbable Wound Closure Device

1303569

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**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 Pharmacopeia (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.

**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 device 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. Grasp 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 healing.
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™ 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 devices 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.

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.

Experimental animal studies for this absorbable material produced no evidence of antigenicity, systemic toxicity, carcinogenicity, mutagenicity, teratogenicity or adverse effects on reproductive performance.

**HOW SUPPLIED**

The V-Loc™ 90 absorbable wound closure devices are available in USP and EP sizes 4-0 (1.5 Metric) through 0 (3.5 Metric). The V-Loc™ 90 absorbable wound closure devices are available dyed violet or undyed (natural). The devices are supplied sterile, in pre-cut lengths affixed to various needle types. The devices are available in box quantities of one dozen.

**AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.**

Do not use if package is opened or damaged.
Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage.
Bei geöffneter oder beschädigter Verpackung nicht verwenden.
Non utilizzare se la confezione è aperta o danneggiata.
No usar el dispositivo si la envoltura está abierta o dañada.
Não utilizar se a embalagem estiver aberta ou danificada.
Niet gebruiken als de verpakking beschadigd of geopend is.
Får ej användas om förpackningen är öppnad eller skadad.
Må ikke anvendes, hvis emballagen er åbnet eller beskadiget.
Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut.
Μη χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά.
Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone.
Ambalaj açılmış ya da zarar görmüşse kullanmayın.
Не используйте изделие, если упаковка вскрыта или повреждена.
Pokud je balení otevřené nebo poškozené, produkt nepoužívejte.

STERILE EO
Rx ONLY
Caution, consult accompanying documents
Upper temperature limit 130°F 54°C
Store at room temperature 59°F 15°C – 86°F 30°C
CE 0123

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