Box size: 2.25 x 5
Overall size: 18 x 22
Folds to: 2.25 x 4.4

COVIDIEN

Velosorb™ Fast

Braided Fast Absorbable Suture

PT00013964

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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Velosorb™ braided fast absorbable sutures are composed of an absorbable synthetic polyester comprised of glycolide and lactide (derived from glycolic and lactic acids). Velosorb™ fast sutures are prepared by coating the suture with a mixture of a glycolide and lactide copolymer and calcium stearate. Velosorb™ fast absorbable sutures are provided dyed and undyed.

Velosorb™ fast absorbable sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for collagen sutures of the labeled USP size, 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)
6-0	0.070-0.099	0.021
5-0	0.10-0.149	0.036
4-0	0.15-0.199	0.041
3-0	0.20-0.249	0.036
2-0	0.30-0.339	0.021
0	0.35-0.399	0.056
1	0.40-0.499	0.046

INDICATIONS

Velosorb™ fast absorbable sutures are indicated for use in soft tissue approximation of the skin and mucosa, where only 7–10 days of wound support is required, but not for use in ligation, ophthalmic, cardiovascular or neurological procedures.

ACTIONS

Velosorb™ fast absorbable 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 Velosorb™ fast absorbable sutures occurs by means of hydrolysis, where the 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 Velosorb™ fast absorbable sutures are no less than 45% of its original tensile strength 5 days post implantation. All of the original tensile strength is essentially gone by 14 days. Absorption of Velosorb™ fast absorbable sutures is essentially complete between the 40th and 50th day.

CONTRAINDICATION

Velosorb™ fast absorbable sutures, being absorbable, should not be used where extended approximation of tissue beyond 7 days 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 Velosorb™ fast absorbable 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.

HOW SUPPLIED

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.

Velosorb™ fast absorbable sutures are available in USP sizes 1 (4 Metric) through 6-0 (0.7 Metric). They are available dyed and undyed (natural). The sutures are supplied sterile, in pre-cut lengths or affixed to various needle types. The sutures are available in box quantities of one and three dozen.

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 использовать изделие, если упаковка вскрыта или повреждена. / Pokud je balení otevřené nebo poškozené, nepoužívejte. / Tilos felhasználni, ha a csomagolás kinyílt vagy megsérült. / Nepoužívajte, ak je obal otvorený alebo poškodený. / Skal ikke brukes hvis emballasjen er åpnet eller skadet. / Ne uporabljajte, če je embalaža odprta ali poškodovana. / 如果包装已打开或破损，请勿使用。/ 如果包裝已開啟或損毀，則請勿使用。/ / Не използвайте, ако опаковката е отворена или повредена. / A nu se utiliza în cazul în care ambalajul este deschis sau deteriorat. / Ärge kasutage, kui pakend on avatud või kahjustatud. / Nelietot, ja iepakojums ir atvērts vai bojāts. / Ne koristite ako je pakiranje otvoreno ili oštećeno. / Ne koristiti ako je pakovanje otvoreno ili oštećeno. / Nenaudokite, jei pakuotė atidaryta arba pažeista.

STERILE R — Single use

Rx ONLY — Caution, consult accompanying documents — CE 0459

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