Box size: 2.25 x 5
Overall size: 18 x 25.5
Folds to: 2.25 x 4.25

COVIDIEN

Maxon™ and Maxon™ CV

Monofilament Absorbable Suture

1300372

EN

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

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

Maxon™ and Maxon™ CV 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™ and Maxon™ CV sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in pediatric cardiovascular tissue, where growth is expected to occur, and in peripheral vascular tissue.

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

ACTIONS

Maxon™ and Maxon™ CV 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™ and Maxon™ CV 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™ and Maxon™ CV 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™ and Maxon™ CV synthetic absorbable sutures is minimal until about the 60th day after implantation. Absorption is substantially complete within six months.

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™ and Maxon™ CV 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 are available in USP and E.P sizes 1 (4 Metric) through 7-0 (0.5 Metric). Maxon™ CV sutures are available only in USP and EP sizes 4-0 (1.5 Metric) through 7-0 (0.5 Metric). Maxon™ and Maxon™ CV sutures are dyed with D&C Green No. 6. Maxon™ sutures are also available in clear (Undyed). The sutures are supplied sterile, in pre-cut lengths; non-needled or affixed to various needle types, using both permanent and removable needle attachment techniques. The sutures are available in box quantities of one, two 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 используйте изделие, если упаковка вскрыта или повреждена.
Pokud je balení otevřené nebo poškozené, produkt 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。
포장이 개봉되어 있거나 손상된 경우에는 사용하지 마십시오.
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.

Syneture™

STERILE EO

Rx ONLY

Caution, consult accompanying documents

130°F 54°C Upper temperature limit

CE 0123

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