Box size: 2.25 x 5
Overall size: 18 x 14
Folds to: 2.25 x 4.667

COVIDIEN™

Novafil™

Monofilament Polybutester

1301692

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BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Novafil™ monofilament polybutester sutures are nonabsorbable, sterile, surgical sutures composed of a copolymer of butylene terephthalate and polytetramethylene ether glycol. The sutures are clear or pigmented with Copper Phthalocyanine Blue.

Novafil™ polybutester sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for nonabsorbable surgical sutures.

INDICATIONS

Novafil™ polybutester sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic surgery, but not in microsurgery and neural tissue.

ACTIONS

Novafil™ polybutester sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Novafil™ polybutester sutures are not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

CONTRAINDICATIONS

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

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 Novafil™ 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 infected or contaminated 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. 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, gradual loss of tensile strength over time, calculi formation when prolonged contact with salts solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

HOW SUPPLIED

Novafil™ polybutester sutures are available clear or pigmented with Copper Phthalocyanine Blue, in sizes 2 (5 Metric) through 7-0 (0.5 Metric). The sutures are supplied sterile, in pre-cut lengths and ligating reels, 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 R

Rx ONLY

Caution, consult accompanying documents

130°F 54°C Upper temperature limit

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Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.
EC REP Covidien Ireland Limited,
IDA Business & Technology Park, Tullamore.
www.covidien.com
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