Box size: 2.25 x 5
Overall size: 18 x 21
Folds to: 2.25 x 4.2

COVIDIEN™

Biosyn™

Monofilament Absorbable Suture

1300960

EN

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Biosyn™ monofilament synthetic absorbable sutures are prepared from a synthetic polyester composed of glycolide, dioxanone, and trimethylene carbonate. Biosyn™ synthetic absorbable sutures are colored violet to increase visibility and are also available undyed.

Biosyn™ 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 U.S.P and E.P.		
U.S.P. Size	U.S.P. Size Designation (mm)	Maximum Overage (mm)
6-0	0.070-0.099	0.017
5-0	0.10-0.149	0.026
4-0	0.15-0.199	0.026
3-0	0.20-0.249	0.056
2-0	0.30-0.339	0.023
0	0.35-0.399	0.070
1	0.40-0.499	0.044

INDICATIONS

Biosyn™ synthetic absorbable sutures are indicated for use in general soft tissue approximation and/or ligation including use in ophthalmic surgery, but not for use in cardiovascular or neurological surgery.

ACTIONS

Biosyn™ 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 Biosyn™ synthetic absorbable sutures occurs by means of hydrolysis where the suture is broken down to glycolic acid, dioxanoic acid, propane diol and carbon dioxide which are subsequently absorbed and metabolized by the body.

Absorption begins as a loss of tensile strength without appreciable loss of mass. Studies in animals indicate tensile strength averages for Biosyn™ synthetic absorbable sutures are approximately 75% of U.S.P. and E.P. minimum knot strength at two weeks and approximately 40% at three weeks post-implant. Absorption of Biosyn™ synthetic absorbable sutures is essentially complete between 90 and 110 days.

CONTRAINDICATION

This suture, being absorbable, should not be used where extended approximation of tissue 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 absorbable sutures before employing Biosyn™ 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.

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

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, 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

Biosyn™ synthetic absorbable sutures are available undyed (natural) or dyed violet in U.S.P. and E.P. sizes 1 (4 Metric) through 6-0 (0.7 Metric). The sutures are supplied sterile, in pre-cut lengths or ligating reels, non-needled or affixed to various needle types. The sutures are available in box quantities of one, two and three dozen.

FR

Suture résorbable monofilament

DE

Monofiles resorbierbares Nahtmaterial

IT

Sutura assorbibile in monofilamento

ES

Sutura reabsorbible monofilamento

PT

Sutura absorvível monofilamentosa

NL

Absorbeerbare monofilamenthechtingen

SV

Monofil resorberbar sutur

DA

Resorberbar monofilamentsutur

FI

Yksisäikeinen resorboituva ommelaine

EL

Μονόκλωνο, απορροφήσιμο ράμμα

PL

Wchłanialne monofilamentowe nici chirurgiczne

TR

Monofilament Emilebilir Dikiş İpliği

RU

Нить из абсорбируемого моноволокна

CS

Jednovláknový vstřebatelný šicí materiál

HU

Egyszálas fonalú felszívódó fonalak

SK

Monofilamentné, syntetické, vstrebateľné nite

NO

Resorberbar monofilamentsutur

SL

Monofilamentna vpojna sutura

ZH

单纤维可吸收缝合线

ZH-T

單絲可吸收縫合線

KO

모노필라멘트 흡수성 봉합사

BG

Еднонишков абсорбируем хирургически конец

RO

Sutură absorbabilă cu monofilament

ET

Monofilamentne absorbeeruv haavaõmblusniit

LV

Viendzīslas absorbējama šuve

HR

Monofilamentni resorptivni konac

SR

Monofilamentni resorptivni konac

LT

Vienagijis absorbuojamasis siūlas

Do not use if package is opened or damaged.

Syneture™

STERILE EO

Rx ONLY

Caution, consult accompanying documents

Upper temperature limit 130°F 54°C

CE 0123

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