BIOVEK®

EN

Braided Polyglycolic Acid (PGA)
ABSORBABLE Synthetic Suture

CE Mark CE 0297, Classification III
Colour Coding Suture pack - Violet
Thread – Violet or Clear

Needle Image / Length:
1/2 = 1/2 Circle needle 1/4 = 1/4 Circle needle
3/8 = 3/8 Circle needle 5/8 = 5/8 Circle needle
Straight needle
Length (e.g. 35mm) = Stretched length of the needle (mm)

- Round Bodied Taper
- Reverse Cutting
- Straight Cutting
- Conventional Cutting
- Fineline® Cutting
- A-Cute® (RB Cutting Tip)
- Reverse Premium Cutting Point (PCP)
- Blunt
- Special Cutting
- Lancet-Spatula (side cutting)

CE 0297 CE-Mark and Identification Number of the Notified Body. Product conforms to the Essential Requirements of the Medical Device Directive 93/42/EEC

CV300 Unique Stainless Steel Material (high bending resistance, yet flexible when bent)

Met Refers to the thread diameter in 1/10mm
The number above Met (eg. 2-0) explains the thread size in USP/EP

Expiry date (year, month)

LOT Refers to the batch number and allows full traceability

STERILE Sterile

STERILE EO Sterilisation method: Ethylene Oxide

Do not reuse

Caution

REF Reference number

Do not use if package is damaged

EC REP Authorised EU Representative

Date of manufacture

Manufacturer's name and address

Recyclable materials

Do not resterilize

Fragile, handle with care

Consult Instructions For Use

Keep away from sunlight

Keep dry

Store below 25°C

Store below 80% Relative Humidity (RH)

DESCRIPTION

BIOVEK® suture is a synthetic absorbable surgical suture composed of polymer made from Polyglycolic acid. **BIOVEK®** sutures coated with polycaprolactone and calcium stearate are available dyed (D&C Violet No.2) and undyed. Polyglycolic acid polymer has been found to be non-antigenic, non-pyrogenic with good biocompatibility and degradability.

BIOVEK® sutures are supplied in various sizes and lengths with or without needles.

BIOVEK® suture complies with requirements of USP and EP.

BIOVEK® suture is available sterile which is sterilized using ethylene oxide.

INDICATIONS

Biovek® suture is indicated for use in general soft tissue approximation and/or ligation including ophthalmic surgery.

ACTIONS

BIOVEK® suture elicits a minimal acute inflammatory reaction in tissue and is eventually replaced with an in-growth of fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of **BIOVEK®** suture occurs by means of hydrolysis. Absorption tests in rats indicate that **BIOVEK®** suture retains about 70% of the original tensile strength at 2 weeks post implantation, and after 3 weeks, about 35% of the original strength is retained. Absorption of **BIOVEK®** suture is essentially complete between 60 and 90 days.

CONTRAINDICATIONS

BIOVEK® suture, being absorbable, should not be used where extended approximation of tissue is required.

BIOVEK® suture is not for use in cardiovascular and neurological tissue approximation.

WARNINGS

1. Stop to use immediately when localized irritation occurs.
2. Under certain circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.
3. Do not re-sterilize

PRECAUTIONS

1. During the clinical application of **BIOVEK®** suture, acceptable surgical practice should be followed with respect to drainage and closure of infected wounds and special care should be taken.
2. Closure of skin and conjunctival over 7 days, if localized discomfort around suture occurs, the stitches should be snipped off or removed.
3. Attention should be paid to use method, specially the application in ophthalmology, such as the conjunctiva, eyelids, edema, etc.
4. In the case of needle body broken, the residual part should be retrieved.
5. **BIOVEK®** suture is only for single use. Do not reuse, re-use may cause cross-infection.

ADVERSE REACTIONS

1. Few individual patients may experience localized irritation, inflammatory tissue reaction and wound dehiscence.
2. When **BIOVEK®** suture has prolonged contact with salt solutions in urinary and biliary tracts, it may result in calculi formation.
3. The **BIOVEK®** suture fails to provide adequate wound support in elderly, malnourished or debilitated patients which may delay wound healing.

HOW TO USE

1. The users of **BIOVEK®** suture should be qualified medical staff.
2. Check the minimum package condition before use. Do not use if the validity date passed or breakage in minimum package. For easy handling and opening of the suture pack, please refer to Fig. 1.
3. Suture size should be selected depending on the application site of patients due to the tensile strength varies with different sites of the body.
4. Based on the actual surgery situation, flat and square ties can be made with additional windings according to the surgeon's experience.
5. To avoid damaging needle points and swage areas, grasp the needle in an area one third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Please refer to Fig. 2.
6. Do not use needle holders or forceps to grasp the attaching part between the needle and the suture and do not use the deformed needle or broken needle.
7. Waste disposal of **BIOVEK®** suture should be in accordance with the sanitary management regulations of medical institutions.

HOW SUPPLIED

Coated **BIOVEK®** suture is available sterile, as braided dyed (violet) in sizes 8-0 through 2 (EP/metric sizes 0.4 through 5) and undyed strands in sizes 6-0 through 2 (EP/metric sizes 0.7 through 5) in a variety of lengths with or without needles.

BIOVEK® suture is available in one or three dozen boxes.

STORAGE – This product should be stored below 25ºC in clean and well-ventilated room with relative humidity not greater that 80% without corrosive gas.

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