MONOVEK®

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Monofilament Polydioxanone (PDO)
ABSORBABLE Synthetic Suture

CE Mark CE 0297, Classification III
Colour Coding Suture pack – Grey
Thread – Violet
Needle Image / Length 1/2 = 1/2 Circle needle
3/8 = 3/8 Circle needle
Length (eg. 35mm) = Stretched length of the needle in 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)


Refers to the batch number and allows full traceability


Sterile

Sterilisation method: Ethylene Oxide


Do not reuse


Caution


Reference number

Do not use if package is damaged


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

MONOVEK® monofilament suture is a synthetic absorbable monofilament suture composed of Poly(p-dioxanone) and is available dyed using FDA-approved color additives D&C violet No.2

MONOVEK® monofilament suture meets all the requirements of the European Pharmacopoeia (EP) for Sterile Synthetic Absorbable Monofilament Sutures.

MONOVEK® monofilament suture is sterilized by ethylene oxide.

INDICATIONS

MONOVEK® suture is indicated for use in general soft tissue approximation and/or ligation, including ophthalmic surgery. **MONOVEK®** suture is not indicated for cardiovascular and neurological tissue approximation or microsurgery.

ACTIONS

MONOVEK® suture elicits a minimal tissue reaction and ingrowth of fibrous connective tissue. Absorption of bioabsorbable sutures occurs by hydrolysis, beginning with loss of tensile strength followed by loss of mass. Absorption test in rats show that **MONOVEK®** suture retains approximately 75% of the original tensile strength at 2 weeks post implantation and retains approximately 65% at 4 weeks, retains approximately 50% at 7 weeks.

Absorption of **MONOVEK®** suture is essentially complete after 6 months.

CONTRAINDICATIONS

MONOVEK® suture is contraindicated where extended approximation of tissue under stress is required and is not to be used in suturing of synthetic implants (i.e., synthetic grafts).

WARNINGS

Do not re-sterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.

Sterile unless packaging has been opened or damaged. Discard opened packages and unused sutures.

Do not use after expiry date.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing **MONOVEK®** suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the *in vivo* performance (under ACTIONS section) when selecting a suture.

The use of **MONOVEK®** suture may not be advised in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.

As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of the sites which may undergo expansion, stretching or distention, or which may require additional support.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

As an absorbable suture, **MONOVEK®** suture may act transiently as a foreign body.

Acceptable surgical practice should be followed for the management of contaminated or infected wounds.

PRECAUTIONS

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

Conjunctival and vaginal mucosal sutures remaining in place for extended periods may be associated with localized irritation and should be removed as indicated.

Under certain circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Consideration should be taken in the use of absorbable sutures in tissues with poor blood supply as suture extrusion and delayed absorption may occur.

PRECAUTIONS Cont.
When working with **MONOVEK®** suture and 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, to the strand except when grasping the free end of the suture during an instrument tie. For easy handling and opening of the suture pack, please refer to Fig. 1.

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 attachment end to the point. 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. In the case of needle body broken, the residual part should be retrieved. Please refer to Fig. 2.

Adequate knot security requires the accepted surgical technique of flat and 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.

Waste disposal of **MONOVEK®** suture should be in accordance with the sanitary management regulations of medical institutions.

ADVERSE REACTIONS
Adverse effects associated with the use of this device include wound dehiscence, failure to provide adequate wound support in closure of the sites where expansion, stretching, or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing, infection, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, suture extrusion and delayed absorption in tissue with poor blood supply, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood-borne pathogens.

HOW SUPPLIED
MONOVEK® suture is available sterile, as dyed (violet) strands in sizes 6-0 through 2 (EP/metric sizes 0.7 through 5) in a variety of lengths with or without needles.
MONOVEK® suture is available in one or three dozen boxes.

STORAGE – This product should be stored below 25°C in clean and well-ventilated room with relative humidity not greater than 80%.

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