

MONOCOL™ Monofilament Polydioxanone Suture

DESCRIPTION

MONOCOL is a sterile synthetic absorbable monofilament suture formed by polymerising the monomer Polydioxanone to form a strong pliable monofilament. It is dyed with D & C Violet #2, Color Index reference C.I. Solvent Violet 13 (=C.I.# 60725). MONOCOL complies with all the requirements of EP.

INTENDED USE

MONOCOL is intended for use in general soft tissue approximation, including use in pediatric cardiovascular tissue, in microsurgery and in ophthalmic surgery. MONOCOL is particularly useful where extended wound support (upto six weeks) is desirable.

MODE OF ACTION

MONOCOL elicits a minimal initial inflammatory reaction in tissues and is eventually replaced with an in growth of fibrous connective tissue. Absorption of the bio-absorbable suture occurs by hydrolysis; beginning with loss of tensile strength followed by loss of mass. MONOCOL retains 50% of the original tensile strength in 28 days and 25% in 45 days. Absorption tests in rats show that the absorption is minimal until about the 90th post implantation day and is essentially complete during 180-210 days.

CONTRAINDICATIONS

MONOCOL, being Absorbable should not be used where prolonged tissue approximation of tissue under stress is required or in conjunction with prosthetic devices, i.e. heart valves or synthetic grafts.

PRECAUTIONS

Acceptable surgical practice should be followed with respect to drainage & closure of infected wound. MONOCOL Sutures require the standard surgical technique of flat & square ties with additional throws if indicated by the surgical circumstances & the experience of the Surgeon. Skin Sutures which remain in place longer than 7 days may cause localised irritation and should be snipped off or removed. When working with MONOCOL sutures, great care should be taken to ensure that the use of surgical instruments such as tweezers and needle holders, does not cause damage by pinching or kinking. The user of MONOCOL suture material should be familiar with surgical suture techniques.

ADVERSE REACTIONS

Reported adverse reactions include inflammatory tissue reaction, localised irritation and wound separation. No usage in direct contact with the heart or the central nervous system.

WARNINGS

Opened, unused packs should be discarded. Do not resterilize. MONOCOL should be stored in between 15°C to 32°C, away from moisture & direct heat. **DO NOT AUTOCLAVE.** Do not reuse, may cause infection.

APPLICATION

Use as required.

Symbols used on labeling :-	
	Do not reuse.
	Manufacturing year + Month.
	Use until Year + Month.
	Batch Number.
	Sterile unless package is opened or damaged. Method of Sterilization-Ethylene Oxide Sterilization.
	Caution
	Product code.
	Tear Open
	Consult Instructions for use.
	Do not resterilize.
	Do not use if package is damaged.
	Temperature Limitation.
	Moisture Limitation.
	Keep away from sunlight.
	Keep away from moisture.
	Non-pyrogenic
	Single sterile barrier system with protective packaging inside.
	Medical device
	Unique Device Identifier
	Patient information website

TECHNIQUE FOR OPENING OVERWRAP.



Hold pack in left hand, seize foil flap between right hand thumbs and finger, hence exposing transparent plastic flap.



Separate the transparent plastic flap and paper flap with thumbs and fingers of both hands gripping pack between knuckles.



Apply constant pressure between knuckles and roll thumb outward to separate the flaps, exposing the sterile primary pouch.



Now the scrub nurse removes the sterile Primary pouch pack with sterile forceps or with sterile gloved hand.

Recommended technique for opening and handling Primary Foil Pack



Hold sterile primary pouch with the printed top facing towards the scrub nurse. Hold the sterile primary pouch with left hand close to the V-Shaped (∇) cut marked located at the top right corner of the primary pouch.



Tear the pouch from the V-Shaped notch with right hand, down towards the scrub nurse.



Take out the sterile suture wadded in suture carrier.

PROD54-04 (R03)

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MONOCOL™

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