I-COL™

Polyglycolic Acid Coated Braided Sutures

DESCRIPTION

I-COL is a synthetic absorbable suture based on Polyglycolic acid. I-COL sutures, coated with polycaprolactone and calcium stearate, have been found to be inert, nonantigenic and nonpyrogenic and complies with the requirement of USP/EP.

I-COL sutures are dyed by adding D and C Violet #2, Color Index reference C.I. Solvent Violet 13 (=C.I.# 60725) during polymerisation and also available in undyed form.

I-COL is crimped with needle (AISI 420 & AISI 300) having the shape and size as 1/2, 3/8 ,1/4, 5/8 & Straight.

INTENDED USE

Synthetic Absorbable Sutures are indicated for use in general soft tissue approximation, perineal repair and skin closure.

MODE OF ACTION

I-COL sutures elicits a minimal tissue reaction and ingrowth of fibrous connective tissue. Absorption of bioabsorbable sutures occurs by hydrolysis : beginning with the loss of tensile strength followed by loss of mass. Absorption test in rats show that I-COL retains approximately 70% of the original tensile strength at two weeks post implantation. Absorption of I-COL suture is essentially complete between 60 to 75 days.

CONTRAINDICATIONS

I-COL sutures are contraindicated where extended approximation of tissue under stress is required.

PRECAUTIONS

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds.

I-COL Sutures require the standard surgical technique of flat and square ties with additional throws if indicated by the surgical circumstances and the experiences of the surgeon. Skin suture which remain in place longer than 7days may cause localised irritation and should be snipped off or removed. When working with I-COL suture materials great care should be taken to ensure that the use of surgical instruments, such as tweezers and needle holders, does not cause the material to be damaged by being pinched or kinked. The user of I-COL suture material should be familiar with Surgical Suture techniques.

TARGET POPULATION

I-Col should only be used by a physician, surgeon, nurse, midwife or under their supervision. Users should be trained in surgical techniques and procedures involving the use of sutures.
The device is intended for use in all patients regardless of age or sex.

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

Read Instruction for use:-

Use of device is restricted to qualified doctor or paramedic. Keep out of reach of children. After use of products must be disposed off as per country law of bio-waste handling rule. The Firm does not hold any responsibility, if device reused that may cause serious problems to patients such as HIV, Hepatitis, contagious Disease/communicable disease etc. Mishandling or improper transport can cause damage to the device or packaging. The product is non-toxic and sterile if the packaging is intact.

I-COL must not be resterilize. Opened, unused packages should be discarded. I-COL should be stored in between 15°C to 32°C. Do not expose to extreme temperature and humidity.

Incase of storage other then above temperature range during any circumstances the intended purpose of device may get effected and this may impact on the performance and safety.
Do not open the pouch in uncontrolled environment.

Do not reuse, may cause infection.

Do not use after the expiry date.

Peters Surgical does not hold any responsibility for any consequences from misuse of the products.

KNOWN CHARACTERISTIC OF DEVICE IN CASE OF RE-USE.

Since the cleaning/sterility of the device cannot be guaranteed, chances of infection or disease can transfer.

DISPOSAL SYSTEM

Discard the suture in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste.

RETURN OF DEVICE

The return of defective device it should be carried out within a week of receipt of the product along with the evidence or damaged product and the product should not have been used under any circumstances, at any condition.

Symbols used on labeling :-

	Do not reuse.
/ Mfg.	Manufacturing year + Month.
/ Exp.	Use until Year + Month.
LOT	Batch Number.
STERILE EO	Sterile unless package is opened or damaged. Method of Sterilization-Ethylene Oxide Sterilization.
	Caution
REF	Product code.
	Tear Open
	Consult Instructions for use.
	Do not resterilize.
	Do not use if package is damaged.
32°C 15°C	Temperature Limitation.
EC REP	Authorized European Representative.
70% 60%	Moisture Limitation.
	Keep away from sunlight.
	Keep away from moisture.
	Non-pyrogenic
	Single sterile barrier system with protective packaging inside.
MD	Medical device
UDI	Unique Device Identifier
	Patient information website
CE 2460	CE- mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.

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

1

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 .

2

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

3

Take out the sterile suture winded in suture carrier.

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Peters SURGICAL

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