POLYCOL™

Polyglactin 910 (PGA-PLA) Sutures

DESCRIPTION

POLYCOL sutures are synthetic absorbable sterile surgical sutures composed of a copolymer made from 90% glycolide and 10% L-lactide and complies with requirement of USP/EP.

Braided POLYCOL sutures are coated with a mixture composed of Poly(glycolide-co-L-lactide) [Glycomer-37] and calcium stearate and have been found to be nonantigenic, nonpyrogenic and elicit only a slight tissue reaction during absorption.

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

POLYCOL is available in a range of gauge sizes and lengths, non-needled or attached to stainless steel needles of varying types and sizes. Such as 1/2, 3/8 ,1/4, 5/8 & Straight.

POLYCOL meets all the requirement established by the United States Pharmacopoeia (USP) / European Pharmacopoeia (EP) for Sterile Synthetic Absorbable Braided Sutures (except for an occasional slight oversize in some gauges).

INTENDED USE

POLYCOL : Synthetic Absorbable Sutures are indicated for use in general soft tissue approximation, device are useful for skin closure, episiotomies, circumcision and closure of oral mucosa.

APPLICATION

Sutures should be selected and implanted depending on patient condition, surgical experience, surgical technique and wound size.

MODE OF ACTION

POLYCOL 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 POLYCOL retains approximately 75% of the original tensile strength at two weeks post implantation and 45% in 21 days. Absorption of POLYCOL suture is essentially complete between 60 to 75 days.

CONTRA-INDICATONS

POLYCOL sutures are contraindicated where extended approximation of tissue under stress is required. No usage in direct contact with the heart or the central nervous system.

PRECAUTIONS

Acceptable surgical practice should be followed with respect to drainage and closure of infected wounds. POLYCOL 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 POLYCOL 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 POLYCOL suture material should be familiar with Surgical Suture techniques.

ADVERSE REACTIONS

Reported adverse reactions include inflammatory tissue reaction, localized 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.

POLYCOL must not be resterilize. Opened, unused packages should be discarded. POLYCOL 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.

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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