

STERICRYL™

Monofilament Polyglycolide-co-polycaprolactone (PGA-PCL)

DESCRIPTION

STERICRYL is a Synthetic Absorbable Monofilament suture EP composed of Polyglycolide co-polycaprolactone and have been found to be inert, non-antigenic and non-pyrogenic. STERICRYL 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.

INTENDED USE

STERICRYL sutures are indicated for use in Gastro-Intestinal Anastomosis, Urology, Pediatric Surgery and plastic surgery. It is not indicated for cardiovascular and neurological tissue approximation.

APPLICATION

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

MODE OF ACTION

STERICRYL sutures elicit minimal tissue reaction and in growth of fibrous connective tissue. Absorption of Stericryl sutures occurs by hydrolysis: beginning with the loss of strength followed by loss of mass.

STERICRYL - DYED retains approximately 60-65% of the original tensile strength at 7 days post implantation and 25-30% at 14 days, with wound support continuing up to 28 days.

STERICRYL - UNDYED retains approximately 50-55% of the original tensile strength at 7 days post implantation and 20-25% at 14 days, with wound support continuing up to 21 days. Absorption of STERICRYL sutures is essentially complete in 90-120 days.

CONTRA-INDICATIONS

STERICRYL sutures are contraindicated where extended approximation of tissue under stress is required.

PRECAUTIONS

Acceptable surgical practice should be followed with respect to drainage & closure of infected wound. STERICRYL 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

that remain in place longer than 7 days may cause localized irritation and should be snipped off or removed. When working with STERICRYL 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.

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.





















WARNING

Opened, unused packs should be discarded. Do not resterilize. STERICRYL should be stored in between 15°C to 32°C. Away from moisture & direct heat. DO NOT AUTOCLAVE.

DOSAGE AND ADMINISTRATION

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

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 wound in suture carrier.

PROD54-05 (R03)

Peters
SURGICAL

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