

STERILENE™

Monofilament Polypropylene Suture

DESCRIPTION

STERILENE is a sterile, monofilament, non-absorbable surgical suture material produced from polypropylene. STERILENE is colored blue with Solvent Blue 104 Cl. No. 61568. STERILENE fulfills all the requirements of USP/EP. STERILENE 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

STERILENE Suture is indicated for application where surgical practice requires the use of Non Absorbable suture material, particularly in Cardiovascular surgery, where the low thrombogenic properties of Sterilene has a positive influence on wound healing.

CONTRAINDICATION

Not known

MODE OF ACTION

When STERILENE suture materials are employed there is a mild inflammation reaction, which is typical for an endogenous reaction to a foreign body. As time passes the suture material is encapsulated by fibrous connective tissue.

PRECAUTIONS

When working with suture materials great care must be taken to ensure that the use of surgical instruments such as tweezers or needle holders, does not lead to damage by pinching or kinking. The user of Sterilene suture materials must be familiar with surgical suture techniques.

ADVERSE REACTIONS

As with all suture materials long contact with salt solution, such as urine and bile, can lead to lithiasis. No usage in 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.

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

Incase of storage other than 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.
	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.
	Authorized European Representative.
	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
	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 wound in suture carrier.

EC REP

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