STERISIL™

Braided Silk Suture

DESCRIPTION

STERISIL is a strand of braided silk fibrils and is produced from filaments of Bombyx Mori Silk worm. STERISIL suture dyed with Hematein HCK "S" conforms to US Code of Federal regulations 21 CFR 73.1410. STERISIL suture is coated with Nusil Med 2174 Silicon. Product manufactured in compliance of USP/EP.

STERISIL 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

STERISIL is indicated for application in G.I. tract, general closure, skin, plastic surgery.

MODE OF ACTION

STERISIL elicits an inflammatory reaction in the tissue, after which it is gradually encapsulated by a fibrous connective tissue. Although STERISIL is not absorbed, an in-vivo biodegradation of the proteinaceous Silk fibres can lead to long term gradual loss of the total strength.

CONTRAINDICATIONS

On account of the gradual loss of strength, which can occur in vivo over a longer period, the use of STERISIL is not recommended when a permanent retention of strength is required.

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 STERISIL Suture material must be familiar with surgical suture techniques.

APPLICATION

Employ according to surgical requirements.

ADVERSE REACTIONS

As with all other materials, lithiasis can occur on prolonged contact with saline solutions, such as urine and bile. 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.

STERISIL must not be resterilize. Opened, unused packages should be discarded. STERISIL 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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Peters SURGICAL

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