(**English)**

PRODUCT

Stitch Cutter (Sterile), GMDN Code: 16224

(Sizes: Long, Short, Mini)

(Carbon Steel and Stainless Steel) Sterilized by Gamma radiation of minimum 25 kGy.

DEVICE DESCRIPTION

Stitch Cutter is made of Stainless steel (Grade F) and Carbon steel (As per BS 2982). The device is packed in peel apart Aluminum Pouch with VCI liner to protect the blade from corrosion. The device is sterilized by Gamma Radiation & Expiry is 5 years from the date of manufacturing.

INTENDED USE

The device is used for cutting the stitches. The device is for transient use. Stitch Cutter is used for general suture removal.

MODE OF ACTION

Stitch cutter blade is made of Stainless-steel / Carbon steel strip with specific shaft long, short, mini and consistently sharp, angled cut blade facilitates for cutting the stitches easily. The slightly curved, flat, tip slides under the suture and when rotated, gently removes the suture from the site. It can directly use after open the aluminium pouch. The stitch cutter is manufactured by paramount variant short and long will be use directly without any fitment and in case of mini stitch cutter shall be use with fitment # 3 handle as per ISO 7740.

INDICATIONS

- To Cut the Stitches

CONTRAINDICATIONS/ RESIDUAL RISK

- Re-used of device can work as carrier for communicable disease to patient and/or user.
- Adverse event may be happened if device are used after expiry date as expiry date of product is expiry date of sterility.
- The Selection and size other than required may affect the intended application of device.
- Do not use if patient is allergic with metal.
- Do not use in cardiovascular and neurovascular surgeries.

PATEINT TARGET GROUP

The device can be used on all group of patients.

INTENDED USERS

The device shall be used by qualified surgeon, doctor, or paramedical staff.

PREPARATION FOR DECONTAMINATION:

No requirement

APPLICATION ON THE BODY:

Intact Skin

CLEANING AUTOMATED:

No cleaning is required before use of the device.

CLEANING MANUAL:

No cleaning is required before use of device.

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DISINFECTION:
No disinfection required.

MAINTENANCE:
No requirement

INSPECTION & FUNCTION TESTING:
Check for smooth functioning of medical device. Visually inspect for damage.

ADDITIONAL INFORMATION:
NA

DESCRIPTION OF COMPONENT PARTS
None

SYSTEM PREPARATION:
Check the label for manufacturing and expiry dates (do not use the medical device after expiry). Make sure the package is not damaged. Visually examine the pouch to see if there are any damages.

INSTRUCTIONS FOR USE

- Inspect package of for its intactness & expiration date.
- Peel off the pouch to take out the stitch cutter.
- Mini Stitch cutter must attach on corresponding pre sterile B P handle conforming the BS EN 27740 for the size slot and check the grip of blade on slot. Other sizes can be use without handle.
- If necessary, clean the area thoroughly with an appropriate solution. Hold the free end of the suture then slide under the Stitch Cutter so it lies flat to the patient's skin as shown in image.
- Rotate the stitch cutter gently upwards so that the cutting edge contacts with the suture material as close as possible to where it enters the skin.
- Gently pull the suture out ensuring that the section which has been exposed to the outside is not drawn through the wound thus introducing potential contamination and an increased risk of post infection.
- After use of stitch cutter, it should be discarded and dispose.

WARNING

- Read instruction for use.
- The product should be used only by a qualified surgeon, Doctor or paramedic.
- Before use always check integrity of product and packing along with expiry date.

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- For single use only, if re-used this can work as carrier for communicable disease, HIV, Hepatitis, contagious dieses, undue diseases to patient and/or user.
- Use product immediately after opening the pack.
- PARAMOUNT is not responsible for any possible consequences resulting from improper use.
- PARAMOUNT do not hold any responsibility if device re-used or re-sterile.
- Sterility of product is not guaranteed if packet is broken/torn.
- Re-sterilization and re-use of stitch cutter cause to change in mechanical properties and material used.
- Re-sterilization and re-use of stitch cutter may not meet the intended use as stitch cutter may be blunt.
- Keep out of reach of children.
- After use, products must be disposed of as per country law of bio-waste handling rule.

PRECAUTIONS

- Always open the pouch from peel apart direction to avoid injury.
- Devices are extremely sharp, Take care while handling.
- Care must be taken so that the pouch is not opened in an unsterile area, otherwise, the device which has already been sterilized by Gamma radiation will become unsterile. Proper procedures must be used as applicable for handling any sterile product.
- Care must be taken during disposal of device to avoid any contact or injury due to the sharp nature of the device.
- Proper care must be taken while getting Blade from the tray to avoid any injury or Accident.
- In case of changes in the performance of device for intended use, replace the device by new to full fill the required application.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

- Difficult to cut at incision site during reuse.
- Any infectious disease can transfer.

STORAGE CONDITION:

- Keep away from direct sun light.
- Keep away from rain.
- Storage temperature should be 10^{o}C to 40^{o}C.
- Humidity of storage area should be 35% RH to 65 % RH.
- Keep away from children.
- Store in cool and dry place.

DISPOSAL SYSTEM

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

PACKAGING:

The device is supplied in box of 100. The box contained heat-sealed Aluminum peel pouches with external identification on the box.

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.

ADVERSE EVENT:

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The improper use / misuse of device may occur adverse event to patient or user. e.g., deep cut, injury to user during fitment of blade. Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

ELECTRONIC VERSION OF IFU:

Available on the website **www.paramountblades.com.**

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