INSTRUCTION FOR USE:

DISPOSAFE Standard Stitch Cutter

PRODUCT: Standard Stitch Cutter Sterilized by Gamma radiation of minimum 25kGv and not more than 40 kGy (2.5 M Rads to 4.0 M. Rads)

MATERIALS USED

Stainless Steel

INDICATIONS:

To cut the stitches.

- CONTRAINDICATIONS:
- · Re-use of device can work as carrier for communicable disease to patient and /or user.
- Adverse event may happen if device is 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.

INSTRUCTION FOR USE:

- Always open the pouch from peel apart direction to avoid injury.
- Devices are extremely sharp, use carefully while handling.
- Care must be taken so that the pouch is not opened in an unsterile area otherwise the Standard Stitch Cutter which has already been sterilized by Gamma radiation will become unsterile. Proper procedure must be used as applicable for handling any sterile product
- Care must be taken during of device to avoid any contact or injury due to the sharp nature of the device.
- · Proper care must be taken while Stitch Cutter with respective handle to avoid any injury or accident
- In case of changes in the performance of device for intended use replace the defective device by new to full fill the required application
- · Standard Stitch cutter did not need to attach on pre B P 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
- 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 of in compliance with the local regulatory requirements of handling medical use.

CAUTION/WARNINGS:

- 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.
- For single use only. If re-used this can work as carrier for communicable disease, HIV Hepatitis contagious dies, undue diseases to patient and/or user
- Use product immediately after opening the pack
- **DISPOSAFE** is not responsible for any possible consequences resulting from improper use.
- · DISPOSAFE do not hold any responsibility if device reused or re-sterile.
- Sterility of product is not guaranteed if pack is broken/torn.
- Re-steriliztion and re-use of Standard Stitch Cutter cause to change in mechanical properties and material used.
- Re-sterilization and re-use of Standard Stitch Cutter may not meet the intended use, the edge may be blunt.
- Keep away from children.

STORAGE CONDITION:

· Store In Cool & Dry Place.



Caution/Warning (Read IFU before use)



Reference No.



Do Not Reuse



Lot Number / Batch Number



Date of Manufacturing Use By / Expiry Date



Sterilized by gamma radiation



Single Sterile Barrier System



Manufactured by



Do not resterilize



Keep dry



Keep away from sunglight



Temperature Limitation



Do not use if package is damaged and consult IFU



Consult for IFU



Non-Pyrogenic





Medical Device



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EC REP

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