



INSTRUCTION FOR USE

PRODUCT

Stitch Cutter (Sterile), GMDN Code: 16224

(Sizes: Long, Short, Mini)

(Carbon Steel and Stainless Steel)

Sterilized by Gamma radiation of minimum 25 kGy and not more than 32 kGy (2.5 M Rads to 3.2 M.Rads)

INSTRUCTION FOR USE (IFU)

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 as per ISO 7740.

INDICATIONS

– To Cut the Stitches

CONTRAINDICATIONS

- Re-used of blades can work as carrier for communicable disease to patient and/or user.
- Adverse event may be happen if blades are used after expiry date as expiry date of product is expiry date of sterility.
- The Selection and size other than required may effect the intended Application of device
- Do not use in cardiac/ ophthalmic surgery.

INSTRUCTIONS

- Peel off the device from the individual packing.
- 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.
- 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 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.



Caution/ Warning (Read IFU before use)



Product reference/Art. No.



Do Not Reuse



Lot Number/Batch Number



Date of Manufacturing



Use By / Expiry Date



Sterilized by gamma radiation



European Authorized Representative



Manufactured by



Do not resterilize



Keep dry



Keep away from sunlight



Moisture limitation



Temperature limitation



Do not use if package is damaged



Consult for IFU



Non-Pyrogenic



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 **INSTRUCTION FOR USE**

 **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.
- For single use only, If re-used this can work as carrier for communicable disease, HIV, Hepatitis, contagious diseases, 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 of products must be disposed off 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, use 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 use of the device 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

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 to 40°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 off the



Caution/ Warning (Read IFU before use)



Product reference/Art. No.



Do Not Reuse



Lot Number/Batch Number



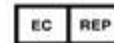
Date of Manufacturing



Use By / Expiry Date



Sterilized by gamma radiation



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Manufactured by



Do not resterilize



Keep dry



Keep away from sunlight



Moisture limitation



Temperature limitation



Do not use if package is damaged



Consult for IFU



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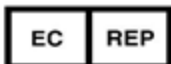
 **INSTRUCTION FOR USE**

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.

-  Caution/ Warning (Read IFU before use)
-  Product reference/Art. No.
-  Do Not Reuse
-  Lot Number/Batch Number
-  Date of Manufacturing
-  Use By / Expiry Date
-  Sterilized by gamma radiation
-  European Authorized Representative
-  Manufactured by
-  Do not resterilize
-  Keep dry
-  Keep away from sunlight
-  Moisture limitation
35% RH - 65% RH
-  Temperature limitation
10°C - 40°C
-  Do not use if package is damaged
-  Consult for IFU
-  Non-Pyrogenic



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