INSTRUCTIONS FOR USE
STERILE STITCH CUTTER

DESCRIPTION:
Stitch Cutters are made of Carbon steel / Stainless Steel. They are packed in Peel Apart foil pouches. Each blade is individually packed to prevent the edge from getting damaged in contact with another blade. Carbon steel have a protective VCI liner. Device is intended for single use and is sterilized by Gamma Irradiation.

Labelling and Marking of blades is fully compliant with the requirements of MDD/93/42/EEC, EU MDR 2017/745, EN ISO 20417:2021, BS 2982:1992 & EN ISO 15223-1:2021.

INTENDED USE:
These are used to cut the surgery stiches.

INDICATION:
Wound stitches

INTENDED USER
This device must be used by surgeons/paramedical staff who are trained and qualified, nurses or other medical professionals as per hospital norms for cutting of stitches.

PATIENT TARGET GROUP
Device can be used for all age patients group based on decision by surgeon, doctor or paramedic staff.

CONTRAINDICATIONS:
- Re-use of blade can work as carrier for communicable disease to patient and/or user
- Adverse event may happen if cutter blades are used after expiry date of product sterility

STORAGE CONDITION:
- Keep away from direct sun light.
- Keep away from rain
- Storage temperature should be 5°C to 45°C
- Keep away from children
- Store in cool and dry place.

SHELF-LIFE:
5 Years (60 months) from the date of manufacturing.

PRECAUTIONS:
- Care must be taken so that the pouch is not opened in an unsterile area otherwise the blade which has already been sterilized by Gamma radiation will become unsterile.
- Don't use if product or pouch appear to be damaged
- For single patient use only content supplied sterile
- During use avoid twisting, bending or putting excessive force or strain on the blade in order to prevent breakage.
- Always open the pouch from peel apart direction to avoid injury.
- Devices are extremely sharp, use care while handling.
- 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 fitment of blade 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

USE
- It is recommended that the foil pouch is peeled apart half in a sterile area allowing the blade to be exposed. There is no need to drop the blade from the pack.
- Mini Stitch Cutter Blade may be used with Fitment# 3 handles conforming to EN ISO 27740.

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DISPOSAL:
Discard the Surgical Blades 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

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
- ADPPL is not responsible for any possible consequences resulting from improper use.
- ADPPL do not hold any responsibility if device re-used or re-sterile.
- Sterility of product is not guaranteed if packet is broken/torn.
- Keep out of reach of children.
- After use of products must be disposed off as per country law of bio-waste handling rule
- The device does not include any measuring function. The scale provided on the handle of the device is only for indicative purpose and device is not measuring function

KNOWN CHARACTERISTICS OF DEVICE & TECHNICAL FACTOR FOR THE RISK IN CASE OF RE-USE

- Difficult to cut at incision site during reuse.
- Any infectious disease can transfer.
- In case of reuse of device may cause communicable and transferable disease from the device.

RETURN OF DEVICE
The documents & papers required for return of defective device and in compliance of law of the land for origin and destination shall be provided to ADPPL within a week (subject to any natural calamity) of receipt of the product along with the photograph & inspection report as an evidence of damaged product and the product shall not be used under any circumstances & it should be separately kept with proper identification of damaged goods.

NOTICE TO THE USER
Any serious incident that occurs 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. The details for the notice to the manufacturer of any serious incident can be reported through our web site www.adityadispomed.com and customer complaint contact T: +91 124 4764900.
In case of reporting to regulatory authority/competent authority of the member state as per law of the land for reporting of such incidents as per the regulation where the user is established.

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SYMBOLS

LOT	Batch code	REF	Catalogue number		Use by date
	Do not re-use		Caution, consult instruction for use		Do not use if package is damaged and consult instructions for use
	Keep dry		Keep away from sunlight	STERILIZE	Do not resterilize
STERILE R	Sterilized using Irradiation	5 °C 45 °C	Temperature Limitation		Manufacturer
	Consult instruction for use	EC REP	Authorized representative in the European community	CE 2460	CE Mark with NB Number
	Non-pyrogenic	MD	Medical Device	IN	Country of Manufacturer

The same IFU is available on our web site

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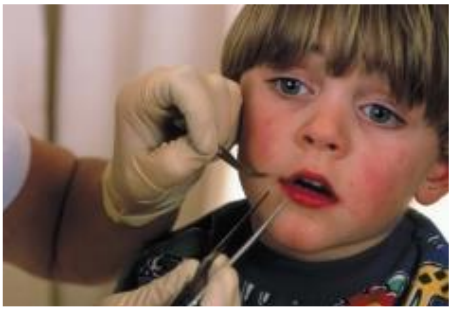
Reference/Model Nos.: Standard Stitch Cutter, Long Stitch Cutter, Mini Stitch Cutter

1. 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.



2. 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.

3. Gently pull the suture out ensuring that the section which has been exposed to the atmosphere is not drawn through the wound thus introducing potential contamination and an increased risk of post infection.