(English)

PRODUCT

Safety Scalpel (Sterile) GMDN Code: 47569

(Sizes: 10, 10A, 11, 11K,13, 15 ,15B, 15C, 15D, 17, 18, 19, 20, 21, 22, 23, 24, 24D, 25, 26, 36,)

(Stainless Steel, ABS Plastic, Polycarbonate) Sterilized by Gamma radiation of minimum 25 kGy

DEVICE DESCRIPTION

The device is made of stainless-steel blade fitted on the ABS handle and guarded with polycarbonate sheath. The scalpel is packed in soft blister pouch. The device is sterilized by Gamma Radiation & Expiry is 5 years from the date of manufacturing.

INTENDED USE

The device is used for incision/ cuts during surgery. The device is under category of surgically invasive device and for transient use.
It is covering under surface device (nature of body contact) and contact with intact skin and mucosal membrane. Scalpel blade is retracted inside the inbuilt protection body and does not need to remove any protection cap before used by Surgeon reduce the risk of blood borne and sharp edge injury. The device is invasive device and for transient use.

MODE OF ACTION:

Scalpel blade is retracted inside the inbuilt protection body and does not need to remove any protection cap before used by Surgeon reduce the risk of blood borne and sharp edge injury.
The grip of handle and angled cut blade facilitates a clean cut during the incision. It can directly use for incision after opening from the primary pack.

INDICATIONS

- Dissection Incision.
- Different size for different thickness of tissue & sight.
- Removal of extra tissue from operating area

.CONTRAINDICATIONS/ RESIDUAL RISK

- Re-used of blades can work as carrier for communicable disease to patient and/or user.
- Adverse event may be happened 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 affect the intended application of device
- Do not use other than surgical surgery.
- Do not use if patient is allergic with metal.
- Do not use in cardiovascular, ophthalmic surgery & 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 & Mucosal membrane.

CLEANING AUTOMATED

No cleaning is required before use of the device.

CLEANING MANUAL

No cleaning is required before use of device.

PARAMOUNT SURGIMED LIMITED
A-106, RIICO Industrial Area, Bhiwadi-301019,
Alwar, Rajasthan, India
Customer Care No. : +91 11 46436600
Email : sales@paramountblades.com

ADMN. OFF.
1, L.S.C., Okhla Industrial Area, Phase-II,
New Delhi-110020, India
Tel. +91-11- 46436601,
46436666, 26389812,13
Fax. +91-11-26389815, 41616555
Email: sales@paramountblades.com
Website : www.paramountblades.com

EC REP
MDSS GmbH, Schiffgraben 41,
D-30175 Hannover, Germany
Tel. +49 511 6262 8630
Fax. +49 511 6262 8633
Email : info@mdss.com

DISINFECTION
No disinfection required.

MAINTENANCE
No requirement

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

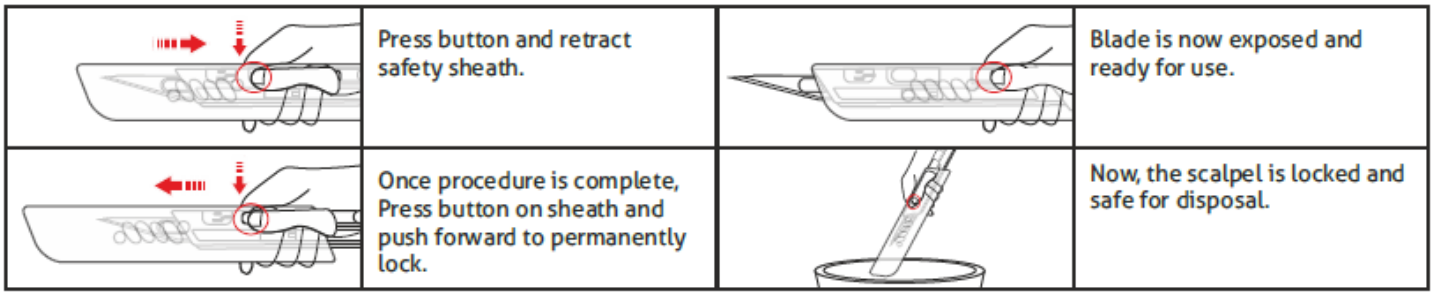
ADDITIONAL INFORMATION:
NA

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

- Inspect package for its intactness, expiration date.
- Peel off the device from the soft blister individual packing from pouch peel open side.
- To open for use, place thumb on button of sheath and retract backward until blade is exposed and shield is secured with click sound.
- To close, but not permanently lock, place thumb on button of sheath and push forward to the first catch. At this position, Scalpel may be reopened and closed again.
- Incision must place as per the desired length preferably measured and marked.
- After Use to dispose of the scalpel, press the sheath button with thumb and fully retract forward and then push the button. It will give a click sound and will permanently lock. At this position, Safety scalpel is safely covered and permanently locked for disposal.



WARNING

- Read instruction for use.
- The product should be used only by a qualified surgeon, Doctor or paramedical staff.
- 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 dieses, undue diseases to patient and/or user.
- Use product immediately after opening the pack.
- Do not use excessive force or use with inappropriate equipment.
- 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.

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- Re-sterilization and re-use of device cause to change in mechanical properties and material used.
- Re-sterilization and re-use of device may not meet the intended use as blade 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, 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^{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 sharp 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 10. The box contains soft blister pouches with external identification on the box.

RETURN OF DEVICE

The return of defective device 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

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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