(English)

PRODUCT

Disposable Scalpel (Sterile) GMDN Code: 47569

(Sizes: 9, 10, 10A, 11, 11K, 12, 13, 14, 15, 15B, 15C, 15D, 15S, 16, 17, 18, 19, 20, 21, 22, 22A, 23, 24, 25, 26, 36, 11P, 12D, 24D, 34, 36D)

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

DEVICE DESCRIPTION

Disposable Scalpel is made of stainless-steel blade fitted on the ABS handle and guarded with LDPE cap. 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.The device is contact with intact skin and mucosal membrane.

MODE OF ACTION:

The grip of handle and angled cut blade facilitates a clean cut during the incision. It can directly use for incision after opening of 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 stainless steel 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:

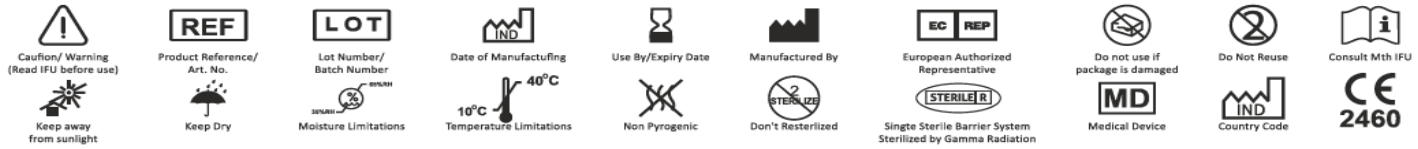
No cleaning is required before use of the device.

CLEANING MANUAL:

No cleaning is required before use of device.

DISINFECTION

No disinfection required.



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Customer Care No. : +91 11 46436600
Mfg. Lic. No. MFG/MD/2023/000291

EC REP
MDSS GmbH, Schiffgraben 41,
D-30175 Hannover, Germany

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

- Select proper type and size of scalpel as per the sight, always use bigger size for thick tissue and smaller for fine soft tissue.
- After selection clean the sight with proper disinfectant
- Inspect package for its intactness & expiring and then remove scalpel from package.
- With grip on handle choose the sight for incision.
- Incision must place as per the desired length preferably measured and marked.

WARNING

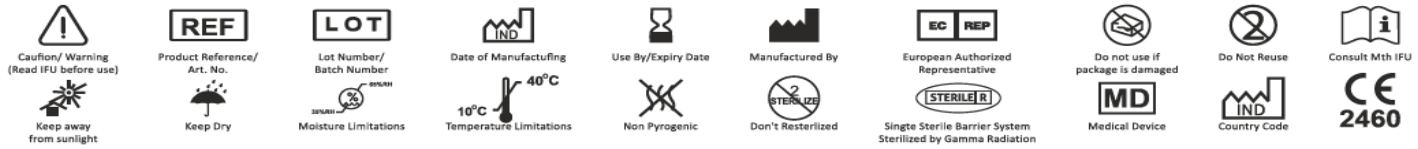
- Read instruction for use.
- The product should be used only by a qualified surgeon, Doctor or paramedic.
- Before use always check integrity of product and packing along with expiry date.
- For single use only, if re-used this can work as carrier for Communicable disease, HIV, Hepatitis, contagious 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.
- Re-sterilization and re-use of blade cause to change in mechanical properties and material used.
- Re-sterilization and re-use of blade may not meet the intended use as blade may be blunt.
- Keep out of reach of children.
- After use of 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.



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- Any infectious disease can transfer.

STORAGE CONDITION:

- Keep away from direct sun light.
- Keep away from rain.
- Storage temperature should be 10°C 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 of the Product in accordance with accepted medical practice and applicable local,state and country laws and regulations or 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 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:

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.