PRODUCT

Dermal Blade (Sterile) GMDN- 63028

(Stainless Steel, Plastic)

Sterilized by Gamma radiation of minimum 25 kGy

DEVICE DESCRIPTION

Dermal blades are made of stainless-steel blade mounted on flexible PP holder. The device is packed in a soft blister pouch. The device is sterilized by Gamma Radiation & Expiry 5 years from the date of manufacturing.

INTENDED USE

The device is intended for cutaneous surgery giving smooth clean excisions with less tissue trauma. It is Used to remove surface protuberances, flat lesions, or deep lesions by saucer-shaped incision. Dermal blade is made of stainless-steel blade mounted on flexible plastic holder. The device is under the category of surgically invasive device and for transient use. It is covered under surface device (nature of body contact) and contact with intact skin and mucosal membrane. The device is an invasive device and for transient use.

MODE OF ACTION

Hold plastic teeth with tension applied to both sides to create curvature shape of blade. The sharp surface is brought beneath the lesion or any protuberances for removal. It can directly use after opening from the primary pack

INDICATIONS

- Raised lesion removal
- Lesions that separate easily from deeper skin
- Removal/shave of extra tissue from body surface

CONTRAINDICATIONS

- Re-used blades can work as carrier for communicable disease to patient and/or user.
- Adverse events may happen if blades are used after expiry date as expiry date of product is expiry date of sterility.
- 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 in all groups of patients.

INTENDED USERS

The device shall be used by qualified surgeons, doctors, 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.

PARAMOUNT SURGIMED LIMITED
A-106, RIICO Industrial Area, Bhiwadi-301019, Alwar, Rajasthan, India
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.

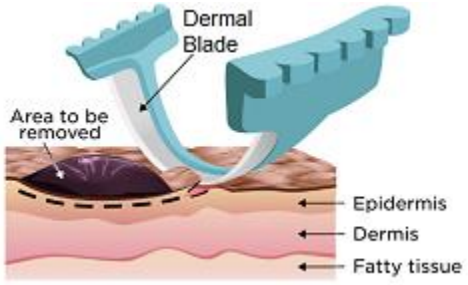
ADDITIONAL INFORMATION:
NA

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 is any damage.

INSTRUCTIONS FOR USE

- Inspect package for its intactness, expiration date.
- Peel off the device from the soft blister individual packing from pouch peel open side.
- To use, hold the plastic teeth, one side with thumb & other side with forefinger with tension applied to both sides to create curvature shape of blade as per given image.
- Brought the sharp surface beneath the lesion or any protuberances.
- Slightly pressure on the skin with blade and remove the desired tissue
- Incision must place as per the desired length preferably measured and marked.
- After use, products must be disposed of as per country law of bio-waste handling rule.



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
- 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 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 must not open 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.

PARAMOUNT SURGIMED LIMITED
A-106, RIICO Industrial Area, Bhiwadi-301019, Alwar, Rajasthan, India
Customer Care No. : +91 11 46436600
Mfg. Lic. No. MFG/MD/2023/000291

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

- 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 sunlight.
- Keep away from the rain.
- The storage temperature should be 10^{o}C to 40^{o}C.
- The humidity of storage area should be 35% RH to 65 % RH.
- Keep away from children.
- Store in a 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 bio-medical waste

PACKAGING

The device is supplied in box of 20. 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.

PARAMOUNT SURGIMED LIMITED
A-106, RIICO Industrial Area, Bhiwadi-301019, Alwar, Rajasthan, India
Customer Care No. : +91 11 46436600
Mfg. Lic. No. MFG/MD/2023/000291

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