(English)

PRODUCT

Skin Graft (Sterile), GMDN code: 35134

(Sizes: Simplex and Duplex)

(Carbon Steel and Stainless Steel) Sterilized by Gamma radiation of minimum 25 kGy

DEVICE DESCRIPTION

The device is used to removal of skin from body for transplantation on other part of body. It is made of Stainless steel (Grade F) and Carbon steel (As per BS 2982). It is supplied sterile.

INTENDED USE

The device is used for removal of skin from body for transplantation on other part of body. 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 knife blade is held pressed firmly against the skin and the roller of the knife. Graft skin with the help of sharp straight cutting blade with a steady to and from sawing motion. The desired thickness of the graft can be obtained by adjusting the depth of the knife blade. The skin graft blade shall be use directly after mounting on appropriate handle.

INDICATIONS

- Removal of skin from body for transplantation on other part of body

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.
- Do not use if patient is allergic with metal.
- Do not use in cardiovascular and 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.

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:

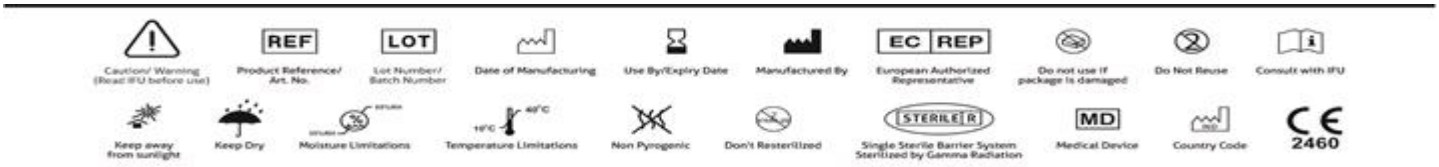
No disinfection required.

MAINTENANCE:

No requirement

INSPECTION & FUNCTION TESTING:

Check for smooth functioning of medical device. Visually inspect for damage.



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

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.

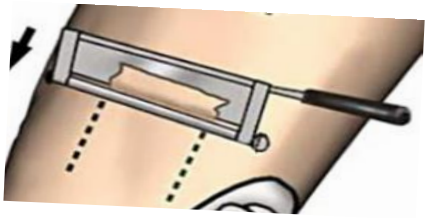
PARAMOUNT SURGIMED LIMITED
A-106, RIICO Industrial Area, Bhiwadi-301019,
Alwar, Rajasthan, India
Customer Care No. : +91 11 46436600
Email : sales@paramountblades.com

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

INSTRUCTIONS FOR USE

- Select proper type and size of Skin Graft as per the sight, always use bigger size for larger size of skin.
- Inspect package of Skin Graft Blades for its intactness expiring and then remove blade from package.
- If necessary, clean the area thoroughly with an appropriate solution.
- Skin Graft must attach on corresponding pre sterile handle as per the size slot and check the grip of blade on slot with grip on metal handle choose the sight for skin removing by marking area.
- Removal of skin has to be done as per the desired length and thickness.



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 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, Take care while handling.
- 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. 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 getting Blade from the tray to avoid any injury or Accident.
- In case of changes in the performance of device for intended use, replace the 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.

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

DISPOSAL SYSTEM

Discard the blade in proper 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 contained soft blister peel 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.**

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