

 **INSTRUCTION FOR USE**

**PRODUCT**

**Skin Graft (Sterile)**

(Sizes: Simplex and Duplex)

(Carbon Steel and Stainless Steel)

Sterilized by Gamma radiation of minimum 25 kGy and not more than 32 kGy (2.5 M Rads to 3.2 M.Rads)

**INSTRUCTION FOR USE (IFU)**

**INTENDED USE**

The device is used for removal of skin from body for transplantation on other part of body.

The device is for transient use.

**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 for 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 open the pouch.

**INDICATIONS**

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

**CONTRAINDICATIONS**

- Re-used of blades can work as carrier for communicable disease to patient and/or user.
- Adverse event may be happen if blades are used after expiry date as expiry date of product is expiry date of sterility.
- Do not use in cardiac/ ophthalmic surgery.

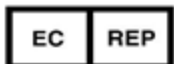
**INSTRUCTIONS**

- Inspect package of Skin Graft Blades for its intactness expiring and then remove blade from package
- Peel off the device from the individual packing.
- Select proper type and size of Skin Graft as per the sight, always use bigger size for larger size of skin
- 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 paramedic.



MDSS GmbH, Schiffgraben 41,  
D-30175 Hannover, Germany  
Tel. +49 511 6262 8630  
Fax. +49 511 6262 8633  
[Email:info@mdss.com](mailto:Email:info@mdss.com)



PARAMOUNT SURGIMED LIMITED  
A-106, RIICO Industrial Area,  
Bhiwadi - 301 019, Distt. Alwar, Rajasthan  
India  
Customer care no. +91-11-46436600  
Email: [sales@paramountblades.com](mailto:sales@paramountblades.com)



Caution/ Warning (Read IFU before use)



Product reference/Art. No.



Do Not Reuse



Lot Number/Batch Number



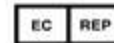
Date of Manufacturing



Use By / Expiry Date



Sterilized by gamma radiation



European Authorized Representative



Manufactured by



Do not resterilize



Keep dry



Keep away from sunlight



Moisture limitation



Temperature limitation



Do not use if package is damaged



Consult for IFU



Non-Pyrogenic

**ADMN. OFF.**

1, L.S.C., Okhla Industrial Area,  
Phase-II, New Delhi-20 (INDIA)  
Tel. +91-11- 46436601,  
46436666, 26389812,13  
Fax. +91-11-26389815, 41616555 Email:  
[sales@paramountblades.com](mailto:sales@paramountblades.com) Website:  
[www.paramountblades.com](http://www.paramountblades.com)

**INSTRUCTION FOR USE**

- 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
- 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 of products must be disposed off 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 removal of skin from body during reuse.
- Any infectious disease can transfer.

**STORAGE CONDITION:**

- Keep away from direct sun light.
- Keep away from rain
- Storage temperature should be 10 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 off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste



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Lot Number/Batch Number



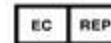
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Use By / Expiry Date



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Manufactured by



Do not resterilize



Keep dry



Keep away from sunlight



Moisture limitation



Temperature limitation



Do not use if package is damaged



Consult for IFU



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Fax. +49 511 6262 8633  
[Email:info@mdss.com](mailto:Email:info@mdss.com)



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Bhiwadi - 301 019, Distt. Alwar, Rajasthan  
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




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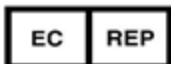
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 **INSTRUCTION FOR USE**

**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.

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-  Product reference/Art. No.
-  Do Not Reuse
-  Lot Number/Batch Number
-  Date of Manufacturing
-  Use By / Expiry Date
-  Sterilized by gamma radiation
-  European Authorized Representative
-  Manufactured by
-  Do not resterilize
-  Keep dry
-  Keep away from sunlight
-  Moisture limitation  
35% RH - 65% RH
-  Temperature limitation  
10°C - 40°C
-  Do not use if package is damaged
-  Consult for IFU
-  Non-Pyrogenic



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