

# INSTRUCTION FOR USE

## PRODUCT

**Curette Dermal (Sterile)**, GMDN Code: 63259

(Sizes: 2mm, 3mm, 4mm, 5mm, 7mm)

(Stainless Steel, ABS plastic/ LDPE)

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 scraping lesions from the surface of a patient's skin. The device is under category of surgically invasive device and for transient use.

### Mode of action:

A **Dermal curette** is a single ended medical instrument. This Curette has a round ended tip, which is sharp outside. The **curette** is held pressed firmly against the **skin** and the round outside cut of the curette **remove the die skin** with a steady to and for sawing motion. The desired thickness can be obtained by adjusting the angle depth of the **curette**. The Curette blade shall be use directly after open the pouch

### INDICATIONS

- Different size for different thickness of tissue & sight.
- Removal of skin from operating area for test specimen.
- The curette is extremely sharp and thus gives precise and gentle tissue removal, which also facilitates its deployment in the treatment of superficial malign tumours.

### CONTRAINDICATIONS

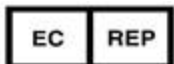
- Re-used of device can work as carrier for communicable disease to patient and/or user.
- Adverse event may be happen if device are used after expiry date as expiry date of product is expiry date of sterility.
- Do not use in cardiac / ophthalmic surgery.

### INSTRUCTIONS

- Inspect package of device for its intactness expiring and then remove from package
- Peel off the device from the individual packing.
- Select proper type and size of Curette dermal as per skin area.
- After selection clean the sight with proper disinfectant
- To do this, the curette is held between the thumb, index and middle finger, while the skin should be stretched with the fingers of the other hand.
- This holding method enables precise guiding of the device, so that the piece of tissue can be removed in one well-targeted incision.



**WARNING**



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)



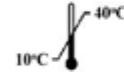
PARAMOUNT SURGIMED LIMITED  
A-106, RIICO Industrial Area,  
Bhiwadi - 301 019, Distt. Alwar, Rajasthan  
India  
Customer care no. +91-11-46436600  
Email: [sales@paramountblades.com](mailto:sales@paramountblades.com)



Keep away from sunlight



Moisture limitation



Temperature limitation



Do not use if package is damaged



Consult for IFU



Non-Pyrogenic



Caution/ Warning (Read IFU before use)



Product reference/Art. No.



Do Not Reuse



Lot Number/Batch Number



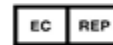
Date of Manufacturing



Use By / Expiry Date



Single sterile barrier sterilized by gamma radiation



European Authorized Representative



Manufactured by



Do not resterilize



Keep dry



Medical Device symbol

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)

- 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 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 sharpness 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 scraping lesions from the surface of a patient's skin.
- Any infectious disease can transfer.

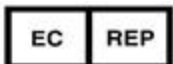
**STORAGE CONDITION:**

- 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

	Keep away from sunlight
	Moisture limitation
	Temperature limitation
	Do not use if package is damaged
	Consult for IFU
	Non-Pyrogenic
	Caution/ Warning (Read IFU before use)
	Product reference/Art. No.
	Do Not Reuse
	Lot Number/Batch Number
	Date of Manufacturing
	Use By / Expiry Date
	Single sterile barrier sterilized by gamma radiation
	European Authorized Representative
	Manufactured by
	Do not resterilize
	Keep dry
	Medical Device symbol



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)

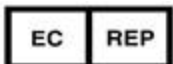
1, L.S.C., Okhla Industrial Area,  
Phase-II, New Delhi-20 (INDIA)  
Tel. +91-11- 46436601,  
46436666, 26389812,13  
Fax. +91-11-26389815, 41616555 Email:  
[sales@paramountblades.com](mailto:sales@paramountblades.com) Website:  
[www.paramountblades.com](http://www.paramountblades.com)

product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste

**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.

-  Keep away from sunlight
-  Moisture limitation
-  Temperature limitation
-  Do not use if package is damaged
-  Consult for IFU
-  Non-Pyrogenic
-  Caution/ Warning (Read IFU before use)
-  Product reference/Art. No.
-  Do Not Reuse
-  Lot Number/Batch Number
-  Date of Manufacturing
-  Use By / Expiry Date
-  Single sterile barrier sterilized by gamma radiation
-  European Authorized Representative
-  Manufactured by
-  Do not resterilize
-  Keep dry
-  Medical Device symbol



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

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)