

(English)

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)

DEVICE DESCRIPTION

The device is used for scraping lesions from the surface of a patient's skin. It is made of Stainless-steel curette blade (SUS 304) mounted on ABS handles and protected by LDPE guard. It is supplied sterile conditions.

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. The device is contact with intact skin and mucosal membrane.

MODE OF ACTION:

A Dermal curette is a single handed medical instrument. This Curette has a round ended tip, which is sharp. The curette is held pressed firmly against the skin and remove the desired 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.

CONTRAINDICATIONS

- ❖ Re-used of device can work as carrier for communicable disease to patient and/or user.
- ❖ Adverse event may be happened if device is 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 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:

										
Caution/Warning (Read IFU before use)	Product Reference/ Art. No.	Lot Number/ Batch Number	Date of Manufacturing	Use By/Expiry Date	Manufactured By	European Authorized Representative	Do not use if package is damaged	Do Not Reuse	Consult Mth IFU	Size
										
Keep away from sunlight	Keep Dry	Moisture Limitations	Temperature Limitations	Non Pyrogenic	Don't Resterilized	Single Sterile Barrier System Sterilized by Gamma Radiation	Medical Device	Country Code	CE 2460	

No disinfection required.

MAINTENANCE:

No requirement

INSPECTION & FUNCTION TESTING:

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

DESCRIPTION OF COMPONENT PARTS:

None

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

- ❖ 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
- ❖ Indication on the handle is given which indicate the sharp edge of curette.
- ❖ The curette is held between the thumb, index, and middle finger, while the skin should be stretched with the fingers of the other hand.
- ❖ The curette is pressed firmly against the skin and remove the desired skin with a steady to and for motion. The desired thickness can be obtained by adjusting the angle depth of the curette.
- ❖ This holding method enables precise guiding of the device, so that the piece of tissue can be removed in one well-targeted incision.



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 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 as curette 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

										
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Mfg. Lic. No. MFG/MD/2023/000291

EU REP

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- ❖ 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 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 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 use. Any serious incident that has occurred in relation to the device, should be reported to the Paramount 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.paramountsurgimed.com.

										
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