PARAMOUNT

INSTRUCTION FOR USE

Ref. No.: PSL-QSP-7.5-09 IFU07/ Issue No 06/ Rev. No.- :04/ Date: 20/11/2024

(English)

PRODUCT

Biopsy Punch (Sterile); GMDN Code: 63166

(Sizes: 1mm, 1.5mm, 2mm, 2.5mm, 3.0mm, 3.5mm, 4mm, 5mm, 6mm, 7mm, 8mm, 10mm, 12mm, 15mm)
(Stainless Steel tube, ABS plastic, LDPE) Sterilized by Gamma radiation of minimum 25 kGy

DEVICE DESCRIPTION

The device is used for obtaining full-thickness skin specimen. It is made of Stainless-steel tube (SUS 304) mounted on ABS handles and protected by LDPE guard. The device is sterilized by Gamma Radiation & Expiry is 5 years from the date of manufacturing.

INTENDED USE

The device is used for obtaining full-thickness skin specimen. The device is invasive device and for transient use. The device is contact with intact skin and mucosal membrane.

MODE OF ACTION

Biopsy punch is rotated down through the epidermis and dermis, and into the subcutaneous fat, sharp angle cut tube facilitates to take the sample from the human body for the examination. It can be used directly after opening of the pouch.

INDICATIONS

- For obtaining diagnostic full-thickness skin specimen.
- Different size for different skin area of body
- Removal of skin specimen from operating area.

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:

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

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

No disinfection required.

MAINTENANCE:
No requirement

INSPECTION & FUNCTION TESTING:
Check for smooth functioning of medical device. Visually inspect for damage.

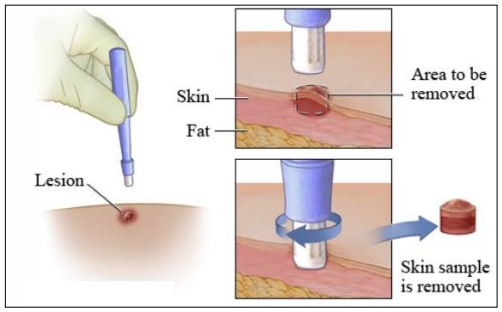
ADDITIONAL INFORMATION:
NA

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

- 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 as per skin area and size of specimen.
- After selection clean the sight with proper disinfectant
- With grip on handle choose the skin for cutting skin specimen.
- Punching must be done by rotating punch on skin with the gentle pressure.
- Remove the Biopsy Punch after cutting the desire depth of skin.
- Take the sample of specimen.



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 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 sharpness 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, use care while handling.

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- 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 obtaining full-thickness skin specimen 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^{o}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 peel pouches with external identification on the box.

RETURN OF DEVICE

The return of defective devices 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.**