

PRODUCT- Biopsy Punch

- Size : 1mm, 1.5mm, 2mm, 2.5mm, 3mm, 3.5mm, 4mm, 5mm, 6mm, 7mm, 8mm,
- Sterilised By Ethylene Oxide

MATERIALS USED

- Stainless Steel, ABS, PP

INDICATIONS

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

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 use after expiry date as expiry of product is expiry date of sterility.

INSTRUCTION FOR USE

- Select proper type and size of Biopsy Punch as per skin of specimen.
- After selection clean and sight with proper disinfectant.
- Inspect package of Biopsy Punch for its intactness expiring and then remove blade from package.
- With group on handle choose the skin for cutting skin specimen.
- Punching has to be done by rotating punch on skin with the gentle pressure.
- Remove the Biopsy Punch after cutting the desire dept. of skin.
- Take the sample of specimen.

WARNINGS :

- Read instructions for use
- The product should be use only by a qualified surgeon, doctor or a 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 disease to patient and / or user
- Use product immediately after opening the pack.
- Disposafe is not responsible for any possible consequences resulting from improper use.
- Do not hold any responsibility if device re-used or re-

INSTRUCTION FOR USE :

- sterile.
- Sterility of product is not guaranteed if packed is broken.
- Re-sterilization and re-use of blade cause to change in mechanical properties and material used
- Re-sterilization and re-used of blade may not meet the intended use as blade may be blunt

STORAGE CONDITION

- Keep away from direct sunlight.
- Keep away from rain.
- Storage temperature should be 10 to 40 Degree Celsius. Humidity of storage area should be 35 % RH to 65% RH.

DISPOSE OF USED POUCH AND BIOPSY PUNCH

- After use Biopsy Punch and pouches shall be disposed of in compliance with the local regulatory requirement of handling used medical device as per country Norms / Hospital guideline.

PRECAUTIONS

- Always open the pouch from peel a part direction to avoid injury.
- Device are extremely sharp, use care while handling.
- Care must be taken so that the pouch is not opened in an unsterile area otherwise blade which has already been sterilized by Ethylene Oxide will become unsterile. Proper procedure must be used as applicable for handling any sterile product.
- Care must be taken during dispose of device to avoid any contact or injury due to the sharp nature of the device.
- In case of changes in the performance of device for intended use replace the defective device by new to full fill the required application.

Disposafe Health And Life Care Limited

Plot No. 1 & 2, Phase-II, Sector-59, Ballabhgarh,

Faridabad - 121004, Haryana, INDIA

E-mail : Info@disposafe.com, Web : www.disposafe.com

Customer Care No. +91-129-4170201

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REF

Product reference / Art. No.



Do Not Reuse

LOT

Lot Number / Batch Number



Date of Manufacturing



Use By / Expiry Date



Sterilised By Ethylene Oxide
Single Sterile Barrier System



Manufactured by



Do not re-sterilize



Keep dry



Keep away from sunlight



Moisture limitation



Temperature Limitation



Do not use if package is damaged



Consult for IFU



Non-Pyrogenic



Authorised Representative
In The European Community

MD

Medical Device

EC REP

Cepartner4U B.V.,
ESDOORNLAAN 13,
3951 DB MAARN,
THE NETHERLANDS

E-mail : office@cepartner4u.com

