

# DISPOCUT

# INSTRUCTION FOR USE :

## STERILE SURGICAL BLADE CARBON STEEL

### PRODUCT (Surgical Blade (Sterile)

(Size 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 11A, 12, 13, 14 15B, 15C, 15D, 15S, 16, 17, 19, 20, 21, 22, 22A, 23, 24, 25, 36, 40,

40B, 60, 60B, 61, 62) Carbon Steel

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

### MATERIALS USED - Carbon Steel

#### INDICATIONS :

- Dissection Incision. - Different size for different thickness of issues & sight.
- Removal of extra tissue 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 used after expiry date as expiry date of product is expiry date of sterility.

#### INSTRUCTIONS FOR USE :

- Select proper type and size of Blade as per the sight, always use bigger size for thick tissue and smaller for fine soft tissue.
- After selection clean the sight with proper disinfectant
- Inspect package of blade for its inaptness expiring and then remove blade from package
- Blade has to attached on corresponding pre sterile B P handle as per the size slot and check the grip of blade on slot.
- With grip on metal handle choose the sight for incision.
- Incision has to place as per the desired length preferably measured and marked.

#### CAUTION / WARNINGS:

- 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 dies, undue diseases to patient and/or user
- Use product immediately after opening the pack
- DISPOSAFE is not responsible for any possible consequences resulting from improper use.
- DISPOSAFE do not hold any responsibility if device re-used or re-sterile.
- Sterility of product is not guaranteed if pack is broken/torn.
- Re-sterilization and re-use of blade cause to change in mechanical properties and material used
- Re-sterilization and re-use of blade may not meet the intended use is blade may be blunt.

#### STORAGE CONDITION:

- Keep away from direct sun light. \*Keep away from rain \*Storage temperature should be 10 to 40 degree celcius
- Humidity of storage area should be RH 35% to 65 %.

#### DISPOSAL OF USED POUCH AND BLADES:

- After use blade pieces and pouches shall be disposed off in compliance with the local regulatory requirements of handling medical use.

#### PRECAUTIONS:

- Always open the pouch from peel apart direction to avoid injury.
- Devices are extremely sharp, use carefully while handling.
- Care must be taken so that the pouch is not opened in an unsterile area otherwise the blade which has already been sterilized by Gamma radiation will become unsterile. Proper procedure must be used as applicable for handling any sterile product
- Care must be taken during of device to avoid any contact or injury due to the sharp nature of the device.
- Proper care must be taken while Firmment blade with respective handle 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



Medical Device



Caution/Warning  
(Read IFU before use)



Product reference



Do Not Reuse



Lot Number/Batch Number



Date of Manufacturing



Use By / Expiry Date



Sterilized by gamma radiation  
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



CEpartner4U B.V.,  
ESDOORNLAAN 13, 3951 DB MAARN,  
THE NETHERLANDS,  
E-MAIL: office@cepartner4u.com



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  
Mfg. Lie. No.: MFG/MD/2019/000106