

INSTRUCTION FOR USE:

DISPOSABLE-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 tissues & sight.
- Removal of extra tissue from operating area.

CONTRAINDICATIONS:

- Re-use of blades can work as carrier for communicable disease to patient and /or user.
- Adverse event may happen if blades are used after expiry date as expiry date of product is expiry date of sterility.

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 Fitment 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

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
- DISPOSABLE is not responsible for any possible consequences resulting from improper use.
- DISPOSABLE 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, the edge may be blunt.
- Keep away from children.

STORAGE CONDITION:

- 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.



Medical Device



Caution/Warning (Read IFU before use)



Product reference



Do Not Reuse



Lot Number / Batch Number



Date of Manufacture



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
and consult instruction for use.



Consult for IFU



Non-Pyrogenic

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



Cepartner4U B.V.,
ESDOORNLAAN 13, 3951 DB MAARN
THE NETHERLANDS
E-mail : office@cepartner4u.com

CE
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