

INSTRUCTION FOR USE

PRODUCT

Surgical Blade (Sterile), GMDN Code: 37445

(Sizes: 1, 2, 3, 4, 5, 6, 8, 9, 10, 10A, 11, 11K, 12, 13, 14, 15, 15B, 15C, 15D, 15S, 16, 17, 18, 19, 20, 21, 22, 22A, 23, 24, 25, 36, 40, 40B, 60, 60B, 61, 62, 1R, 2R, 3R, 1V, 2V, 3V, 11P, 12D, 24D, 34, 36D, 61V, 62V, 63, 64, 65, 66, 67, 68, 69, 69B)

(Carbon Steel and Stainless Steel)

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

INSTRUCTION FOR USE (IFU)

INTENDED USE

The device is used for incision/ cuts during surgery for all blade sizes. 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:

Surgical blade is made of Stainless-steel / Carbon steel strip with specific shaft of fitment 3 & 4 and consistently sharp, angled cut blade facilitates a clean cut .

It can directly use after opening of the Aluminium pouch.

INDICATIONS

- Dissection Incision.
- Different size for different thickness of tissue & 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.
- The Selection and size other than required may effect the intended Application of device
 - Do not use in cardiac / ophthalmic surgery

INSTRUCTIONS

- 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 intactness expiring and then remove blade from package
- Blade must attach on corresponding pre sterile B P handle conforming the BS EN 27740 for the size slot and check the grip of blade on slot.
- with grip on metal handle choose the sight for incision.
- Incision must place as per the desired length preferably measured and marked.



- Read instruction for use
- The product should be used only by a qualified surgeon,



Caution/ Warning (Read IFU before use)



Product reference/Art. No.



Do Not Reuse



Lot Number/Batch Number



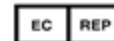
Date of Manufacturing



Use By / Expiry Date



Sterilized by gamma radiation



European Authorized Representative



Manufactured by



Do not resterilize



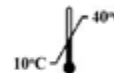
Keep dry



Keep away from sunlight



Moisture limitation



Temperature limitation



Do not use if package is damaged



Consult for IFU



Non-Pyrogenic



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 **INSTRUCTION FOR USE**

- 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 blade cause to change in mechanical properties and material used
- Re-sterilization and re-use of blade may not meet the intended use as blade 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:

- 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 blade 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 fitment of 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

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

- Difficult to cut at incision site 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°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 Surgical Blades in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste



Caution/ Warning (Read IFU before use)



Product reference/Art. No.



Do Not Reuse



Lot Number/Batch Number



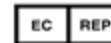
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Use By / Expiry Date



Sterilized by gamma radiation



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Manufactured by



Do not resterilize



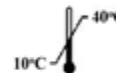
Keep dry



Keep away from sunlight



Moisture limitation



Temperature limitation



Do not use if package is damaged



Consult for IFU



Non-Pyrogenic



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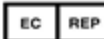





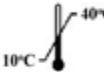



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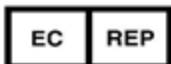
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 **INSTRUCTION FOR USE**

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.

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-  Do Not Reuse
-  Lot Number/Batch Number
-  Date of Manufacturing
-  Use By / Expiry Date
-  Sterilized by gamma radiation
-  European Authorized Representative
-  Manufactured by
-  Do not resterilize
-  Keep dry
-  Keep away from sunlight
-  Moisture limitation
35% RH - 65% RH
-  Temperature limitation
10°C - 40°C
-  Do not use if package is damaged
-  Consult for IFU
-  Non-Pyrogenic



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