

 **INSTRUCTION FOR USE**

PRODUCT

Ophthalmic Blades/ Knife (Sterile)

(Sizes: Keratome, Crescent, Lance Tip, MVR, Spoon, Scleral)

(Stainless Steel, ABS plastic/ Acrylic)

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 in ophthalmic surgery for making precise incisions.

The device is surgically invasive device and for transient use.

MODE OF ACTION

The grip of handle and angled cut ophthalmic blade

facilitates a clean cut during the incision. It can directly

use for incision after open the primary pack.

INDICATIONS

- Dissection Incision.
- Different size for different operating part of eye.
- Removal of extra tissue from operating area.

CONTRAINDICATIONS

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

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 of ophthalmic blade as per Different part of eyes to operate.
- Incision has to place as per the desired length.

 **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 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.



Caution/ Warning (Read IFU before use)



Product reference/Art. No.



Do Not Reuse



Lot Number/Batch Number



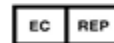
Date of Manufacturing



Use By / Expiry Date



Sterilized by gamma radiation



European Authorized Representative



Manufactured by



Do not re-sterilize



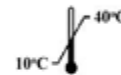
Keep dry



Keep away from sunlight



Moisture limitation



Temperature limitation



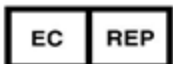
Do not use if package is damaged



Consult for IFU



Non-Pyrogenic



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INSTRUCTION FOR USE

- 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 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 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 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 Device 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

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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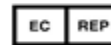
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Manufactured by



Do not re-sterilize



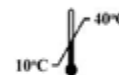
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Temperature limitation



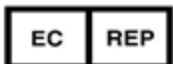
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