(English)

PRODUCT

Ophthalmic Knife (Sterile)

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

(Stainless Steel Blade, ABS plastic handle and ABS Plastic tray) Sterilized by Gamma radiation of minimum 25 kGy.

DEVICE DESCRIPTION

Ophthalmic Knife are made of stainless-steel blades mounted on the ABS plastic handle. The knife is Placed in ABS plastic tray and packed in peel apart soft blister Pouch pack in combination of soft blister poly with medical grade paper to maintain the sterility. The device is sterilized by Gamma Radiation & Expiry is 5 years from the date of manufacturing.

INTENDED USE

The device is intended to make self-sealing micro incision and side port incision in the ophthalmic surgical procedures. The device is under category of surgically invasive device and for transient use. The device is contact with eyeball and mucosal membrane.

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.
- Incision in the upper layer to reach the internal part of the eye.

CONTRAINDICATIONS

- Re-used of blades can work as carrier for communicable disease to patient and/or user.
- Adverse event may be happened 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 affect the intended application of device
- Do not use other than ophthalmic surgery
- A patient who will be operate should not be allergic to metal.
- Do not use in cardiovascular surgeries and neurovascular surgeries

PATEINT TARGET GROUP

The device can be used on all group of patients.

INTENDED USERS

The device shall be used by qualified ophthalmic surgeon.

PREPARATION FOR DECONTAMINATION:

No requirement

APPLICATION OF THE BODY:

Mucosal membrane of eyeball.

CLEANING AUTOMATED:

No cleaning is required before used of the device.

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CLEANING MANUAL:
No cleaning is required before used of device.

DISINFECTION:
No disinfection required

MAINTENANCE:
No requirement

INSPECTION & FUNCTION TESTING:
Check for smooth functioning of medical device. Visually inspect for damage.

ADDITIONAL INFORMATION:
Read instructions carefully before use.

DESCRIPTION OF COMPONENT PARTS:
None

SYSTEM PREPARATION:
Check the label for manufacturing and expiry dates (do not use the medical device after expiry). Check for UDI number.
Make sure the package is not damaged. Visually examine the pouch to see if there are any damages.

INSTRUCTIONS FOR USE

- Select proper type and size of knife as per the requirement.
- Inspect package of knife for its intactness & expiration date and then peel apart the
- Pouch to get tray from Package as shown in Figure 1.
- Now take out the knife from tray by gripping on handle as given in Figure 2.
- Sharpness may be effective if sharp edge touches any article. If required, Place the knife at a non-metal surface to prevent the blade becoming blunt.
- Grip handle like pen, or similar way, avoiding contact with cutting edge and make incision as per intended use.
- During the surgical procedure, use a containment method of choice, to protect surgical team from any sharp's injuries, such as a plastic kidney dish.
- After use, safely dispose of the knife into a sharp's container.

Figure 1

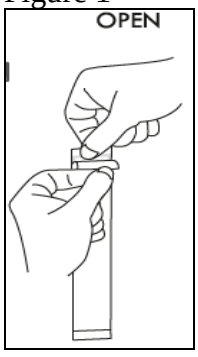
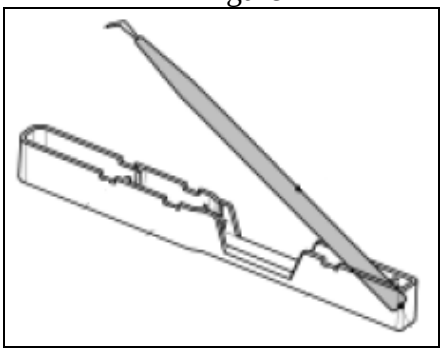


Figure 2



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WARNING

- Read instruction for use.
- The product should be used only by a qualified surgeon, Ophthalmologist.
- 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 dieses, undue diseases to patient and/or user
- Use product immediately after opening the pack.
- Do not use excessive force or use with inappropriate equipment
- 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 of 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, take care while handling.
- Care must be taken so that the pouch is not opened in an unsterile area, otherwise, the knife which has already been sterilized by Gamm 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 getting knife from the tray 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:

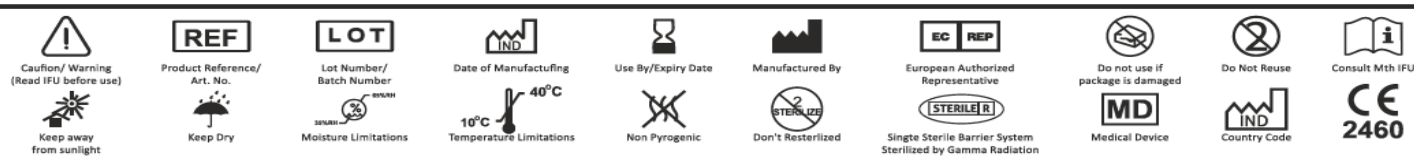
- Keep away from direct sun light.
- Keep away from rain
- Storage temperature should be 10 to 40^{o}C
- Humidity of storage area should be 35% RH to 65 % RH.
- Keep away from children.
- Store in cool and dry place.

DISPOSAL SYSTEM

Discard the Ophthalmic Knife in proper waste container & dispose of the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste.

PACKAGING:

The device is supplied in box of 6. The box contained heat-sealed soft blister peel pouches with external identification on the box.



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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.

ADVERSE EVENT:

The improper use / misuse of device may occur adverse event to patient or user e.g. deep cut in eyeball.

ELECTRONIC VERSION OF IFU:

Available on the website **www.paramountblades.com.**

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