

## Product Name: MANI OPHTHALMIC KNIFE

### ② Do not reuse



### Read instructions before use

#### [Warnings]

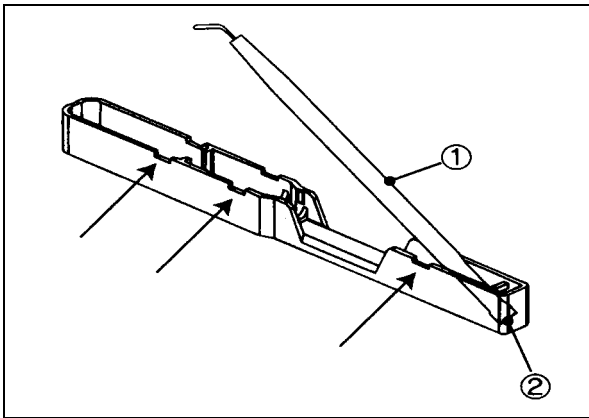
- 1) The user must be fully acquainted with surgical procedures and techniques.
- 2) Select an appropriate type of knife for each surgical purpose. Use in accordance with ordinary surgical procedures.
- 3) Avoid using a knife if it is in fractured or tainted package or if it suffers fracture or any other abnormality.

#### [Contraindications and Prohibitions]

- 1) Do not use on patient who is too sensitive or allergic to metals.
- 2) Do not use for other purpose than ophthalmic surgery.
- 3) Do not use a knife if it has been hit against or in contact with other parts than the eyeball. [The blade might be damaged and lose its sharpness.]
- 4) Do not reuse or re-sterilize. Reuse or re-sterilization could compromise seriously the structural integrity and/or might lead to damage or infection to patients. \* \*

#### [Shape and Structure]

1. This knife is sterilized and has a grip.
  - 1) Main material
    - ① Grip: Polybutylene terephthalate (PBT)
    - ② Blade: Stainless steel (containing nickel and chromium)
  - Coating: Silicone (except Golf / Scleral Knife) \*



#### [Performance, Purpose and Effect]

This knife is to be used to incise and penetrate into eyeballs.

#### [Specification of the Item]

Vickers hardness is 500Hv or more for the blade made of stainless steel.

#### [Operation and Use]

1. Use in accordance with ordinary incision procedures.
2. Handling the case
  - 1) Taking out the knife  
With special care to keep the blade off any other part of the case, pick up part ① and raise the knife. Note that the knife may lose its sharpness once its blade touches an object.
  - 2) Replacing the knife  
Holding the knife with its blade edge downward, fully press in part ②. Then lightly press part ① until you hear a click. The three notches shown with arrows can be used to rest the knife.

#### [Precautions for Use]

1. Precautions for use
  - 1) This knife might cause sensitization and allergy to metals.
2. Important basic cautions
  - 1) Use the knife as soon as it is unpacked. Dispose of the used knife with care to prevent infection.

- 2) This knife has a highly sharp blade. Take extreme care in handling. External injury caused by contaminated blade can lead to pathogenic infection linked to blood disorders.
- 3) Do not use deformed or fractured knives.
- 4) Do not disassemble or distort shape of the knife before use.
- 5) Dispose of the used knife in a case with a description of its content.
- 6) Knife can be placed on the knife rests after the knife taken out of the case to avoid damage of the edge by touching anything. Note that the knife may lose its sharpness once its blade touches an object.

#### [Precautions for use of arched blade] \* \*

1. Location of the wound \* \*
  - 1) Location of creating the incision is different from that of normal flat blade because arched blade is three dimensional blade.  
If the arched blade places the incision at the same location as flat blade does, the end of the edge could catch the conjunctiva, which might cause conjunctival edema. Paying attention to keep the incision off the conjunctiva.  
In clear cornea incision, place the wound construction at a little distance towards the center of the cornea from the corneal limbus. The distance is for the height of the arch of the blade. A rough standard for the distance would be:  
MSL32AB – height of the arch:0.6mm – the incision should be created 0.6mm to 0.9mm centrally away from the corneal limbus.  
MSL28AB & MSL30AB – height of the arch:0.5mm – the incision should be created 0.5mm to 0.8mm centrally away from the corneal limbus.  
MSL25AB & MSL26AB - height of the arch:0.4mm – the incision should be created 0.4mm to 0.7mm centrally away from the corneal limbus.  
Marking the planned area of the incision would give a guide for incision.  
In sclera cornea incision, iris can be incarcerated in the incision wound. Therefore the corneal incision plane should not be too close to the sclera. Dissection and suturing of conjunctiva will be necessary in sclera cornea incision procedure. \* \*
2. Misalignment of the incision wound \* \*
  - 1) After the surgery, intraocular pressure should be adjusted through side port, observing the condition of the incision wound. Misalignment of the incision wound can be caused by a short tunnel or exerting excessive IOP. When the misalignment is recognized, remove water from the incision wound, then treat the wound for re-adjustment of IOL.  
Hydration is seldom necessary due to better self-sealing. Straightening up the incision wound would be enough. \* \*
3. Enlarging incision \* \*
  - 1) Enlarging incision with arched blade is impossible. Do not use Implant knife \* \*
  - 2) After making incision with arched knife, if enlarging the incision is required for the reason of changing surgical application, another wound construction is recommended. \* \*
4. Others \* \*
  - 1) Use IOL injector for Intraocular Lens Implantation to avoid any damage to the incision wound. \* \*
  - 2) Select an appropriate size of arched knife that will fit the size of the injector applied. \* \*

#### [Storage and Expiration Date]

1. Storage
  - 1) Avoid exposure to high temperature, high humidity, direct sunlight and water.
  - 2) Avoid scars and pinholes on the packing material.
  - 3) This product is subject to specification change. Use these knives on a first-in first-out basis.
  - 4) Check the expiration date on the product. Discard if it is overdue. Also discard knives left unused long after they are unpacked.

2. Expiration date

- 1) This product may be used up to 5 years after date of production, as indicated on the package label, so long as it is maintained in accordance with an appropriate storage procedure.

**[Packaging]**

6 pieces per box

**[Manufacturer]**



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