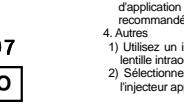


# Product Name: MANI® OPHTHALMIC KNIFE



Read instructions before use

Do not reuse  
1 Box / 6 Pieces, 1 Bag / 1-100 Piece (s)

**ENG**

## English

[Warnings]  
1) The user must be fully acquainted with the surgical procedures and techniques.

2) Select the appropriate type of knife for each surgical purpose. Use in accordance with the usual surgical procedures.

3) Avoid using a knife if its packaging is damaged or if there is evidence of any other abnormalities.

[Contraindications and Prohibitions]

1) Do not use on any patients who are sensitive or allergic to metals.

2) Do not use for other purpose than ophthalmic surgery.

3) Do not use a blade if it has been hit against or been in contact with anything else other than the eye.

[The edge might be damaged and lose its sharpness.]

Do not reuse or re-sterilize. Reuse or re-sterilization could seriously compromise the structural integrity and/or might lead to damage or infection to patients.

[As far as the concerned knife is concerned, re-sterilization may lead to the deformation or breakage of the handle, which would result in a change of the length of the blade]

[Shape and Structure]

1. The product is a sterile knife with handle.

Two types are available. One type comes stowed inside a case and the other type is the standard type with the blade protected by a cover.

2. Main material

A. UHMWPE (Polyethylene terephthalate (PBT))

Polycarbonate (only for the guarded knife)

B. Blade: Stainless steel (containing nickel and chromium)

Coating: Silicone (except Gof / Scleral Knife & Guarded knife)

C. Handle: High-strength thermoplastic resin

D. Cover: High-strength thermoplastic resin

[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 of the case

1) Take out the knife  
When you take 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 blades touch another object.

2) Replacing the knife

Holding the knife with its blade edge facing 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.

3. Handling of safety type

a. Holding the cover to release the lock.

b. Hold onto the cover and slide it towards the rear.

c. Slide the cover until it stops and then releases it to lock it.

2) Stowing the blade

Hold the cover lock release at the back of the cover with your fingers and with the lock released, slide the cover forward till the end to stow the blade inside the cover. (Follow the steps above in reverse to stow the blade.)

[Precautions for Use]

1) Precautions for use

This knife might cause sensitization and allergy to metals.

2. Important basic precautions

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 very sharp blade. Take extreme care when handling. External injury caused by a contaminated blade can lead to pathogenic infection linked to blood disorders.

3) Do not damage or distort the shape of the blade before use.

4) Do not disassemble or distort the shape of the blade before use.

5) Dispose of the used knife in a medical waste basket and follow the instructions thereof.

6) The knife can be placed on the rests after the knife is taken out of the case to avoid damage of the blade when coming into contact with anything. Note that the knife may lose its sharpness once its blade touches something.

7) The knife should be placed in a case upon delivery and receipt.

8) Do not use the safety type with the safety lock.

9) Take care not to allow the blade that is exposed from the cover of the safety type to come into contact with anything. The sharpness of the knife will be blunted and degraded when the blade comes into contact with anything.

10) Grip the handle well when using the safety type. Fine operation is difficult due to rattling when you grip the cover.

11) Handover of the safety type must be carried out with the blade stowed inside the cover.

12) After use, the safety type must be discarded with the blade stowed inside the cover.

[Precautions for use of the arched blade]

1. Location of the wound

The location of creating the incision is different from that of normal flat blade use because the arched blade is a 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. Pay attention in keeping 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.

2. Misalignment of the incision wound

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After

