



STERILE EO

Read instructions before use

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

Product Name: MANI OPHTHALMIC KNIFE

en

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 the blade if it has been hit against or been in contact with anything other than the blade itself.

[The edge might be damaged and loses 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 Guarded 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 a safety type with the blade protected by a cover.

2) Main material

A. Handle: Polybutylene terephthalate (PBT)

Polycarbonate (only for the guarded knife)

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

Coating: Silicone (except / Golf / Scleral / 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) 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 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 test the knife.

3) Handling of safety type

1) Exposing the blade

a. Hold the rear end of 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 fingertips 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 blade dislocation.

3) Do not deform or fractured knives.

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

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

6) This knife can be placed in the rest after the knife taken out of the case to avoid damage of the edge by coming into contact with anything. Note that the knife may lose its sharpness once its blade touches an object.

7) Do not use the safety type if it is not closed.

8) Slide the cover of the safety type all the way to the rear and lock it.

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 the grip 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 could catch the conjunctiva, which might cause conjunctival edema. Pay attention in keeping the incision of the conjunctiva.

In clear cornea incision, place the wound construction at a little distance towards the center of the cornea from the corneal limbus.

[Arched blade]
Height: Regular standard of location to create incision.

1.8 mm 0.3 mm The incision should be created 0.3 to 0.6 mm centrally away from the corneal limbus

2.0 mm ~ 0.4 mm The incision should be created 0.4 to 0.7 mm centrally away from the corneal limbus

2.8 mm 0.5 mm The incision should be created 0.5 to 0.8 mm centrally away from the corneal limbus

3.0 mm 0.6 mm The incision should be created 0.6 to 0.9 mm centrally away from the corneal limbus

3.2 mm 0.6 mm The incision should be created 0.6 to 0.9 mm centrally away from the corneal limbus

3.4 mm 0.6 mm The incision should be created 0.6 to 0.9 mm centrally away from the corneal limbus

Marking of the planned area of the incision would give a guide for incision.

In sclera cornea incision, the incisio

n can be incarcerated in the incision wound.

Therefore the corneal incision plane should not be too close to the sclera.

Dissection and suturing of the conjunctiva will be necessary in sclera cornea incision procedure.

2) Misalignment of the incision wound

After the surgery, the intraocular pressure should be adjusted through the 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 the water from the incision wound, then treat the wound for re-adjustment of IOP.

Hydration is seldom necessary due to better self-sealing. Just straightening up the incision wound is enough.

3) Enlarging incision

1) Enlarging incision with the arch knife, if enlarging the incision is required

For the reason of changing surgical application, another wound construction is recommended.

4) Others

1) Use an IOL injector for Intraocular Lens Implantation to avoid any damage to the incision wound.

11) Die Übergabe des Sicherheitstyps muss mit in der Kappe verstaubter Klinge erfolgen.

12) Nach der Verwendung muss der Sicherheitstyp mit in der Kappe verstaubter Klinge entsorgt werden.

[Precautions when using Marking Straight Knife]
Marking Straight Knife is a Straight knife with lines that can be used as guides for the width of the incision when creating a side port. There are two lines of 1.0 and 1.2 mm in length marked on the blade.

[Precautions when using Marking Silt Knife]
Marking Silt Knife is a Silt Knife that has lines to be used as guides for creating a tunnel. Two lines are marked at 1.5 and 2.0 mm from the blade tip.

[Precautions when using Double-Step Knife]
Double-Step Knife has a reference line on the blade which can be used as a guide to prevent inserting the knife deeper than intended (past the line). The distance between the line and the tip of the blade is 4.5 mm.

[Storage and Expiration Date]
1. Storage

Avoid exposure to high temperatures and humidity, direct sunlight and water. Store at room temperature.

2. Expiration date

The expiry date is indicated on the individual package or external packaging, so long as it is maintained in accordance with an appropriate storage procedure.

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