

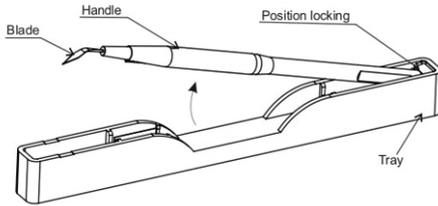
IFU FOR OPHTHALMIC MICRO SURGICAL KNIVES

INTENDED USE

Ophthalmic microsurgical knives are used to make precise incisions for ophthalmic surgery; the precise incisions achievable with these knives are among the preconditions for application in delicate ophthalmic surgical interventions.

FURTHER INFORMATION

1) Construction



a) Handling of the case

I. **Taking out the knife:** Take special care to prevent the blade from coming into contact with any part of the packaging. Gently pick up the device and lift the knife from the locking position.
Note: The knife may lose its sharpness if the blade touches any object.

II. **Replacing the knife:** Hold the knife with the blade edge facing downward. Align it properly with the locking position in the tray. Press down gently until the handle clicks into place, ensuring the knife is securely locked.

2) Material

Blade: Stainless steel
Handle: Polycarbonate
Tray: Polycarbonate

3) Each ophthalmic knife is individually packed and sealed in a pouch to ensure sterility. These products are sold in boxes.

4) The device is intended to be used by a trained ophthalmic surgeon.

INSTRUCTIONS FOR USE

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

WARNINGS/PRECAUTIONS FOR SAFE HANDLING

- Read, follow, and retain the Instructions for Use.
- Use the product only for its intended purpose. Refer to the *Intended Use* section.
- Store products in a dry, clean and secure environment.
- Avoid exposure to high temperatures, high humidity, direct sunlight, or moisture. Store at room temperature.
- Do not store near chemicals or in areas where gas emissions may occur.
- Preserve the product under conditions where the packaging remains undamaged and free from any breaks or pinholes. Do not use if the packaging is broken or contains pinholes.
- Always check the expiration date on each package and box.
- Dispose of any product that has exceeded its expiration date.
- Prior to each use, inspect the product for signs of damage, such as looseness, bending, breakage, cracking, wear, or fracture.
- Do not use the product if it is damaged or defective. Set it aside and do not attempt to repair or reuse it.
- Ensure the blade does not come into contact with any surface or object before use.
- Dispose of the used knife with medical waste disposal protocols.
- Use the knife immediately after unpacking. Dispose of the used knife carefully to prevent infection.

CONTRAINDICATION-PROHIBITION

- Do Not Reuse**
 This device is supplied sterile and intended for single use only. It must be disposed of after use in accordance with hospital policy. Reusing the device may lead to serious infections and other complications.
- Do Not Re-sterilize**
 If the sterile barrier is compromised, the device is no longer sterile and must not be re-sterilized. Using such a device may result in infection or other adverse outcomes for the patient.
- Do Not Use After Expiry Date**
 Always verify the expiration date before use. Do not use the product if the date has passed.
- Do Not Use if Package Integrity is Compromised**
 If the packaging is damaged or suspected to be non-aseptic, do not use the product.

SYMBOLS AND EXPLANATIONS

Sl. No.	Symbol	Description
1		Date of manufacture
2		Use-by date
3		Sterilized using Ethylene Oxide
4		Do not reuse
5		Do not re-sterilize
6		Batch code
7		Keep away from sunlight
8		Keep dry
9		Caution
10		Do not use if the package is damaged
11		Temperature limit : Lower limit : 15 °C Upper limit : 25 °C
12		Caution: Federal (U.S.A.) law restricts this device to sale and use by or on the order of, a physician.
13		Medical Device