

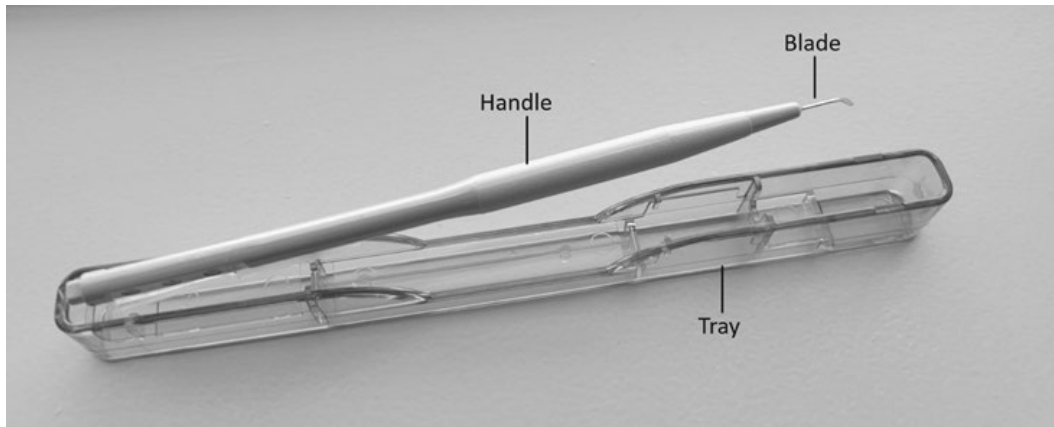
IFU FOR OPHTHALMIC KNIVES

Intended use

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

Further information

1. Construction



2. Handling of the case

- Taking out the knife: with special care to keep the blade off any other part of the case, pick up device and raise the knife. Note that the knife may lose its sharpness once its blade touches an object.
- Replacing the knife: Holding the knife with its blade edge facing downward, fully press in part 1 then lightly press handle until you hear a click.

3. Material

Blade: Stainless steel

Handle: Polycarbonate

Tray: Polycarbonate

- Each ophthalmic knife is individually packed sealed in a pouch to ensure sterility. These products are sold in boxes.
- The device is intended to be used by trained ophthalmic surgeon

Instruction 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 keep the instruction for use.
- Use the product only in accordance with its intended use, see intended use.
- Store any new products in a dry, clean and safe place.
- Avoid high temperature, high humidity, direct sunlight, soaking and preserve at room temperature
- Do not preserve at the chemical products place and gas occurrence place
- Preserve at the status of non-break to package material and non-pinhole
- It is necessary to confirm the use period on each package and box
- By confirming the use period on each package and box, dispose the products which expire the use period.
- Prior to each use, inspect the product for: loose, bent, broken, cracked, worn or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged. Avoid contact of the delicate blades at tips with hard surfaces or other instruments.
- Dispose of the used knife in a medical waste basket and follow the instructions thereof.
- Use the knife as soon as it is unpacked. Dispose of the used knife with care to prevent infection.

Contraindication-Prohibition

- Re-use prohibited
The device is supplied sterile and is supposed to be disposed of, as per hospital policy, after each use. However, if the doctor or hospital reuses the device, it can cause severe infections apart from other complications.
- Re-sterilization prohibited
A device with broken sterile barrier may be non-sterile and it should not be re-sterilized. This may cause infection and other complications to the patient, if still used by the doctor/ hospital.
- Do not use after expiration date
- Do not use if it is considered that the products aseptic condition is spoiled by broken package.

Symbols and Explanations

| | Symbol | Explanation |
|----|---|---|
| 1 |  | Manufacturer |
| 2 |  | Date of manufacture |
| 3 |  | Non Latex |
| 4 |  | Sterilized using ethylene oxide |
| 5 |  | Do not re-use |
| 6 |  | Keep away from sunlight |
| 7 |  | Product should be kept dry |
| 8 |  | Do not use if the package is damaged |
| 9 |  | Manufactured in the USA and/or applies to medical devices sold in the USA |
| 10 |  | Prescription use only |
| 11 |  | Catalog number |
| 12 |  | Batch code |
| 13 |  | Exp date |
| 14 |  | Quantity |
| 15 |  | Carrier contains unique device identifier information |