

## Instructions for use

## **Microsurgery Knife**

### 1. Purpose

- This product is a knife for ophthalmic surgery.
- This product is for single use only.

#### 2. Contraindications and Prohibitions Application (Applicable Patierits)

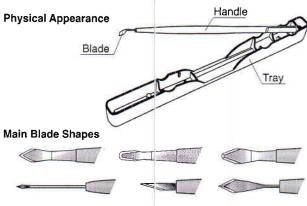
• Do not use the product on any patients who are sensitive or allergic to metal.

#### Prohibitions

- Re-use prohibited, because of performance characteristics, no re-sterilization, possible infections.
- Re-sterilize prohibited.
- Do not use the product when the aseptic condition of the products is considered to be lost due to damage or breakage of package.

#### 3. Shape and Structure

 This product is a disposable surgical knife for ophthalmic surgery which consists of blade and handle.



#### Material

- Blade: Stainless Steel (Chrom um contained)
- · Coating: Silicone (the corresponding products only)
- Handle: Polybutylene Terephthalate
- Tray: Polycarbonate

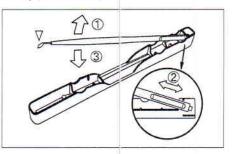
## 4. Handling and Use

This knife is used for general incision in ophthalmic surgery. Before Use

- Confirm there is no damage on the sterilized pouch, open the pouch up and remove the product.
- Confirm there is no damage / breakage of the product and use it without intermission.

## Removing and storing the knile

- In order to remove the knife from the tray, hold the handle upward from the tray (Illustration<sup>①</sup>).
- In order to use the knife, follow the established surgical method.
- In order to store the knife to the tray, put the blade downward and insert the end of the handle into the tray (Illustration②). Hold the handle downward to the tray with the care of not hitting the blade into the tray (Illustration③).



\* Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent

## 5. Precautions for Use

## Important Precautions

- Do not use the product if the package is damaged / broken (The aseptic condition cannot be assured even though the product is within their expiration date).
- When removing the product from the package, do this procedure with care of the blade. If the blade gets contact with anything else, do not use the product and replace it with a new one.
- Do not use the product if any abnormality such as damage / breakage is recognized.
- Handle the products with care in order to avoid being injured by the blades (The blade is so sharp that it would injure).
- After the usage of the products, be aware of the risk of infections and dispose them properly as medical waste with the perspective of preventing infection.

### Precautions for using "Arch Knife"

- In clear cornea incision, avoid the blade from reaching to conjunctiva. Otherwise, it would lead to conjunctival chemosis.
- In sclerocornea incision, avoid the incision part of clear cornea too close to sclera. Otherwise, the iris would be incarcerated to the incised wound.
- Do not add too much pressure to the intraocular after surgeries.
- Do not expand the incision wound.
- When injecting an intraocular lens in the eye, use an injector.

## 6. Storage and Expiration Date

Storage

- Avoid exposing the product to high temperature, high humidity, direct sunlight and water.
- Store the product at the ambient temperature.
- Store the product in a clean and dry place without loading anything on the products.
- Do not store the product together with chemical products or in an area where gas occurs.
- Avoid damaging or making pinholes to package materials.

## **Expiration Date**

• Check the expiration date, which is indicated on the primary and sales packaging.

# **C€** 0197



## Manufacturer

Kai Industries Co., Ltd. 1110, Oyana, Seki City, Gifu Prefecture, 501-3992, Japan

## EC REP Authorized Representative

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Do not use if package is damaged

Do not reuse

STERILEEO

Ethylene oxide sterilization

ке К

Keep dry