

## Ophthalmic Knife Instructions for Use

### WARNINGS

- The user must be fully acquainted with surgical procedures and techniques.
- Select the appropriate type of knife for each surgical purpose. Use in accordance with normal surgical procedures.
- Do not use the knife if its packaging is damaged or if there is evidence of any other abnormalities.

### CONTRAINDICATIONS AND PROHIBITIONS

- Do not use on patients who are sensitive or allergic to metals.
- Do not use for any other purpose than ophthalmic surgery.
- Do not use if the blade has been hit against or been in contact with anything other than the eye, as the blade's sharpness might be compromised.
- 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 safety 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.
2. Main materials:
  - a. Handle: Polycarbonate or Polysulfone
  - b. Blade: 400 Series Stainless steel

### INTENDED USE

Indications: Surgistar Ophthalmic Surgical Safety Knives are used in the surgical treatment of various diseases of the eye. E.g., cataract, retinal, glaucoma and other procedures to create an incision in the eye. As such, they are only to be used by licensed, trained physicians. The specific nature of the disease will determine the physician's choice of product and the techniques used.

### PERFORMANCE, PURPOSE AND EFFECT

To make surgical incisions.

### OPERATION AND USE

- Use in accordance with ordinary incision procedures.
- To expose the blade on a safety knife, hold the rear end of the cover to release the lock. Next, hold onto the cover and slide it towards the rear. Slide the cover until it stops and then release it to lock it.
- To stow 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 to the end to stow the blade inside the cover.

### CAUTION

- Use the knife as soon as it is unpacked.
- Do not use deformed or fractured knives.
- Do not disassemble or distort the shape of the knife before use.
- This knife has a very sharp blade. Take extreme care when handling to avoid unintentional sticks to healthcare providers or patients. External injury caused by a contaminated blade can lead to pathogenic infection linked to blood disorders. If unintentional stick occurs, do not use the device.
- To prevent injury or damage, avoid contact between the blade edge and any surfaces prior to use.
- Do not use excessive force, or use with inappropriate equipment.
- Sterility is guaranteed unless opened or damaged. Do not use if the sterile pack has been opened or damaged.
- Do not re-sterilize or reuse. Surgistar, Inc. assumes no liability for devices that have been altered, dismantled, reassembled, re-sterilized and/or reused.
- Please use Surgistar Ophthalmic Surgical Safety Knives and other instruments responsibly. To prevent infection, dispose of with care in a safe and environmentally friendly manner, such as in a medical waste basket.
- Federal (USA) law restricts this device to sale by, or on the order of a physician.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Surgistar's ophthalmic safety knives are gamma sterilized to SAL 10-6 and must be opened under aseptic conditions.

### CONDITIONS OF STORAGE

Surgistar knives should be stored at ambient temperature away from possible contamination from biohazards and water damage.

### EXPIRATION DATE

The expiration date is clearly indicated on the packaging. Any ophthalmic knives held after the expiration date should not be used.

### INSTRUCTIONS

1. Select the style and size of Surgistar ophthalmic surgical knife indicated for the patient and procedure to be performed.
2. Remove product from sterile packaging carefully. Surgistar knives are surgically sharp. Care should be taken when removing knives from packaging, in handling, and in disposal.
3. Physician to perform procedure as necessary taking precautions to avoid accidental cuts to self, medical personnel and patient.
4. After use, discard the knife into an approved sharps container.

## SYMBOLS



Lot Code

REF

Product Code



Sterilized Using Gamma



Use by date



Do not use if package is damaged



Manufacturer



Do not reuse

Rx Only

CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of a Physician



Consult instructions for use



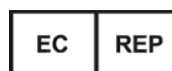
Caution



Do Not Resterilize



Surgistar, Inc.  
2310 La Mirada Drive  
Vista, California 92081 USA  
Telephone: (760) 598-2480  
Fax: (760) 598-2481



Wellkang Ltd  
Enterprise Hub, NW Business Complex,  
1 Beraghmore Rd, Derry, BT48 8SE  
Northern Ireland

### METHOD OF STERILIZATION

**STERILE R**