

**Ophthalmic Safety Knife Instructions for Use**

**IMPORTANT NOTICE**

It is highly recommended that the surgeon adhere to the cautions outlined in these instructions.

**DEVICE DESCRIPTION**

Specifically designed, integrated retractable shield that protects the stainless steel blade during handling. The plastic shield is activated by the user through a push button sliding mechanism that provides tactile and audible feedback in both the shielded and unshielded position.

**Materials**

- Stainless steel blade
- Plastic handle

**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.

**CAUTION**

- Care should be taken at all times to avoid unintentional sticks to healthcare providers or patient. If unintentional stick occurs, do not use the device.
- 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.
- To prevent injury or damage, avoid contact between the blade edge and any surfaces prior to use.
- 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 and remember to dispose of in a safe and environmentally friendly manner.
- Federal (USA) law restricts this device to sale by, or on the order of a physician.

**METHOD OF STERILIZATION**



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

**CONDITIONS OF STORAGE**

Surgistar's safety knives should be stored in a cool (60oF – 70oF), dry place, away from sources of heat or sunlight, and possible contamination from biohazards and water damage.

**EXPIRATION DATE**

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

**RETURN GOODS POLICY**

Surgistar accepts returned safety knives for exchanges or account credit only. No cash refunds will be issued. To return safety knives, you must first obtain a return authorization number from our customer service department. No returned goods will be accepted without proper authorization number. Returned goods should be shipped by traceable method. No credit will be given for lost or damaged safety knives in shipment. Safety knives will be replaced or your account credited as long as they are returned within six months of their original invoice date.

**INSTRUCTIONS**

- Select the style and size of Surgistar ophthalmic surgical safety knife indicated for the patient and procedure to be performed.
- 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.
- Physician to perform procedure as necessary taking precautions to avoid accidental cuts to self, medical personnel and patient.
- After use, discard the knife into an approved sharps container.

**SYMBOLS**

	Lot Code		Product Code
	Sterilized Using Gamma		Use by date
	Do not use if package is damaged		Manufacturer
	Do not reuse		CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of a Physician
	Consult instructions for use		Do Not Resterilize
	Caution		



Surgistar, Inc.  
2310 La Mirada Drive  
Vista, California 92081 USA  
Telephone: (760) 598-2480  
Fax: (760) 598-2481  
Email: customerservice@surgistar.com  
www.surgistar.com

Wellkang, Ltd.  
Address The Black Church,  
St. Mary's Place  
Dublin 7, Ireland  
Tel: +353(1)4433560

