Surgistar, Inc.

MFG of Single-Use Ophthalmic, ENT, and Other Surgical Cutting Instruments

An ISO 13485 and CE certified company

CE 2797

Surgical Blades Instructions for Use

IMPORTANT NOTICE
It is highly recommended that the surgeon adheres to the cautions outlined in these instructions.

DEVICE DESCRIPTION
A stainless steel part with a cutting edge, sold with or without a handle.

INTENDED USE
Indications: Surgistar blades are used in the surgical treatment of various diseases. 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 blade 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 blades 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.
- 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.

METHOD OF STERILIZATION
STERILE R

Surgistar's surgical blades are gamma sterilized to SAL 10^{-6} and must be opened under aseptic conditions.

CONDITIONS OF STORAGE
Surgistar blades 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 blades held after the expiration date should not be used.

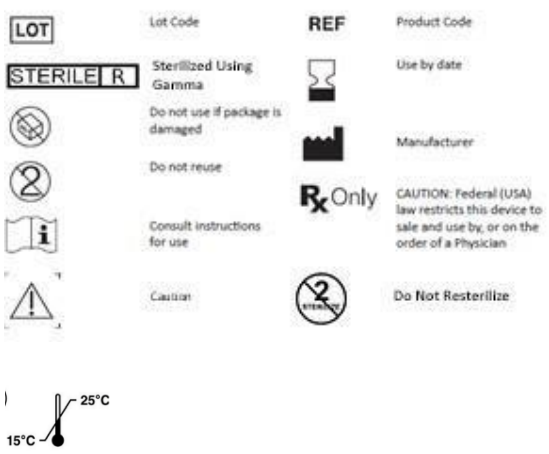
Manufacturing Date

The manufacturing date is lot number indicated on the packaging.

RETURN GOODS POLICY
Surgistar accepts returned surgical blades for exchanges or account credit only. No cash refunds will be issued. To return blades, 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 blades in shipment. Surgical blades will be replaced or your account credited as long as they are returned within six months of their original invoice date.

INSTRUCTIONS
1. Select the style and size of Surgistar blade indicated for the patient and procedure to be performed.
2. Remove product from sterile packaging carefully. Surgistar blades are surgically sharp. Care should be taken when removing blades from packaging, in handling, and in disposal.
3. Physicians to perform procedure as necessary taking precautions toavoid accidental cuts to self, medical personnel and patient.
4. To avoid infection, microbial hazard or physical hazard from sharp blades, please discard the knife into an approved sharps container after use.

SYMBOLS



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