Surgistar, Inc.

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

An ISO 13485 and CE certified company

CE 2797

Lacrimal Intubation Set Instructions for Use

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

DEVICE DESCRIPTION
Two small stainless steel probes attached to a length of medical grade silicone tubing.

Materials
Probe: stainless steel
Tubing: medical grade silicone

INTENDED USE
Indications: Surgistar Lacrimal Intubation Sets and DCR Sets are used in the surgical treatment of diseases of the eye, and specifically lacrimal ducts. As such, they are only to be used by licensed, trained physicians. The specific nature of the disease and treatment prescribes will determine the physician's choice of product and the techniques used.

⚠

- The silicone tubing used in Surgistar's Lacrimal Intubation Sets and DCR Sets is intended to remain in the body for up to 29 days.
- 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.
- Do not use if there is evidence of malfunction of the device or changes in its performance that may affect safety,
- Do not re-sterilize or reuse to prevent cross-contamination and infection. Surgistar, Inc. assumes no liability for devices that have been altered, dismantled, reassembled, re-sterilized and/or reused.
- Please use Surgistar Lacrimal Intubation Sets 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 lacrimal intubation sets and DCR sets are gamma sterilized to SAL 10^{-6} and must be opened under aseptic conditions.

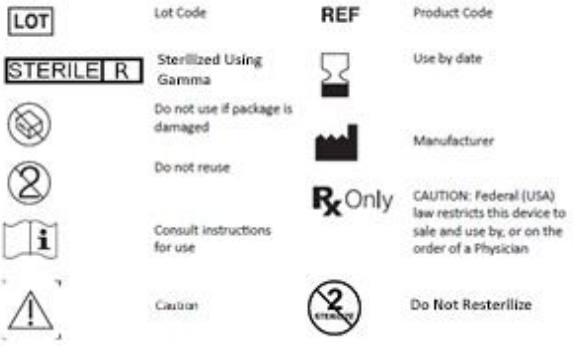
CONDITIONS OF STORAGE
Surgistar's lacrimal intubation sets and DCR sets should be stored in a cool (60ºF – 70ºF), dry place, away from sources of heat or sunlight, and possible contamination from biohazards and water damage.

EXPIRATION DATE
The expiration date is clearly indicated on the packaging. Any ophthalmic lacrimal intubation set or DCR set held after the expiration date should not be used.

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

INSTRUCTIONS
1. Remove product from sterile packaging carefully. Care should be taken when removing product from packaging, in handling, and in disposal.
2. Surgistar Ophthalmic Lacrimal Intubation Sets and DCR Sets are made from malleable and semi-malleable stainless steel and may be bent to suit the patient anatomy
3. Physician to perform procedure as necessary, taking into consideration that the maximum implant time for the silicone tubing is 29 days.
4. Discard product in its original packaging or into approved sharps container.

SYMBOLS



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

EC REP

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