Surgistar, Inc.

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

An ISO 13485 and CE certified company

CE 2797

Ophthalmic Needles, Cannulas, Cystotomes
Instructions for Use

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

DEVICE DESCRIPTION
These devices are slender, hollow hand-held instruments consisting of a stainless steel tube connected to a polypropylene hub. The polypropylene hubs of these devices are designed to industry standard configurations for fitting the nozzle of a syringe, which is a device that consists of a calibrated hollow barrel and a movable plunger. At one end of the syringe's barrel is a male connector (nozzle) for fitting the female connector (hub) of a needle, cannula or cystotome. These two components work in tandem during use.

Materials
- Needle: stainless steel
- Hub: polypropylene

INTENDED USE
Surgistar ophthalmic needles, cannulas and cystotomes are intended to inject fluids into, or withdraw fluids from, the body. They are used in the surgical treatment of various diseases of the eye such as cataracts, refractive corrections, lacrimal duct issues, and others. 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.

Needle: A cannula that has been sharpened to create an orifice in the eye.

Cannula: A blunt needle used for irrigating or aspirating during ophthalmic surgery.

Cystotome: A needle that has been physically formed (bent) to conform with the convexity of the crystalline lens to access the cataract.

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.
- Surgistar's ophthalmic needles, cannulas and cystotomes are sold sterile. 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's ophthalmic needles, cannulas and cystotomes responsibly and remember to dispose of in a safe and environmentally friendly manner.
- 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.
- To avoid infection, microbial hazard or physical hazard from sharp blade, please discard the knife into an approved sharps container after use.

METHOD OF STERILIZATION
STERILE R

Surgistar's ophthalmic needles, cannulas and cystotomes are gamma sterilized to SAL 10^{-6} and must be opened under aseptic conditions.

CONDITIONS OF STORAGE
Surgistar's ophthalmic needles, cannulas and cystotomes should be stored in a dry place at room temperature, 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 needle, cannula or cystotome held after the expiration date should not be used.

Manufacturing Date
The manufacturing date is lot number (YYMMDD) indicated on the packaging.

INSTRUCTIONS
1. Remove product from sterile packaging carefully, as many of these devices are surgically sharp. Care should be taken when removing product from packaging, in handling, and in disposal.
2. Surgistar Ophthalmic needles, cannulas and cystotomes come on standard luer-lock plastic hubs. As needed, these may be attached to any standard mal luer slip or male luer lock syringe for use in irrigation, aspiration, or delivery of saline solution, medications, etc.
3. Physician to perform procedure as necessary.
4. Discard product in its original packaging or into approved sharps container.

SYMBOLS



MD
Medical Device

Single Sterile Barrier



Storage Conditions

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