

Ophthalmic Hand Instruments Instructions for Use

IMPORTANT NOTICE

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

DEVICE DESCRIPTION

Surgistar's ophthalmic hand instruments are standard ophthalmic devices consisting of a small 400-series stainless steel tip that is formed or otherwise machined to specified dimensions, and mounted on a polycarbonate or Delrin® handle. The shape of the tip determines the type and the intended use of the device. None of the tips of Surgistar's hand instruments contain sharp edges. They are delivered sterile to the end user and are intended for single patient use.

Materials

Tip: stainless steel
Handle: polypropylene or Delrin®

INTENDED USE

Ophthalmic hand instruments are intended for use by ophthalmic surgeons to perform various functions during ophthalmic surgery (see definition of each variant below). The specific nature of the disease will determine the physician's choice of product and the techniques used.

Spatula: Typically used in glaucoma and cataract surgery, spatulas are normally used to scrape the corneal stroma and epithelium for taking cell samples for histological examination. They are also used to move and manipulate tissue such as corneal flaps. Stainless steel tip, polycarbonate handle..

Manipulator: Manipulators are typically used to manipulate and rotate the lens nucleus, the iris, and other tissues during ophthalmic surgery. Stainless steel tip, polycarbonate handle.

Chopper: Choppers are used for chopping the lens nucleus into fragments before emulsification and aspiration during cataract surgery. Stainless steel tip, polycarbonate handle.

Manipulator/Chopper: A single handle consisting of a manipulator tip on one end and a chopper tip on the other end. Stainless steel tips, Delrin® handle.

Manipulator/Spatula: A single handle consisting of a manipulator tip on one end and a spatula tip on the other end. Stainless steel tips, Delrin® handle.

Non-Irrigating Micro Pick: Non-irrigating micro picks are used to manipulate tissue in vitreoretinal surgery. Stainless steel tip, polycarbonate handle.

Intubation Set Retrieval Device: Retrieval devices are used for removal of intubation set probes from the inferior meatus.

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 hand instruments 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 hand 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 ophthalmic hand instruments are gamma sterilized to SAL 10⁻⁶ and must be opened under aseptic conditions.

CONDITIONS OF STORAGE

Surgistar's ophthalmic hand instruments should be stored in a cool (60°F – 70°F), 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 hand instrument held after the expiration date should not be used.

RETURN GOODS POLICY

Surgistar accepts returned hand instruments 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

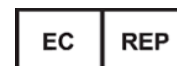
1. Carefully remove product from sterile packaging. Care should be taken when removing product from packaging, in handling, and in disposal.
2. Physician to perform procedure as necessary.
3. Discard product in its original packaging or into approved sharps container.

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		



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