Surgistar, Inc.

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

An ISO 13485 and CE certified company

CE 2797

DONOR CORNEAL TREPHINE
Instructions for Use

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

DEVICE DESCRIPTION
Surgistar's donor corneal trephines are standard ophthalmic devices consisting of a small, round 400-series stainless steel blade that is formed or otherwise machined to specified dimensions for preparing a variety of tissue sizes. They are delivered sterile to the end user and are intended for single patient use.

Materials

Blade: 400-series stainless steel

INTENDED USE
Donor trephines are intended to be used in the preparation of donor graft tissue for corneal surgery.

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 donor trephines 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 donor trephines 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

STERILE R

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

CONDITIONS OF STORAGE
Surgistar's donor trephines should be stored 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 donor trephine held after the expiration date should not be used.

RETURN GOODS POLICY
Surgistar accepts returned donor trephines 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	Lot Code	REF	Product Code
STERILE R	Sterilized using gamma		Use by date
	Do not use if package is damaged		Manufacturer
	Do not reuse	Rx Only	CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of a Physician
	Consult instructions for use		

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