GB

i-Cushion

Instructions for Use

DESCRIPTION
The package consists of individual sterile disposable i-Cushion for single use only.

INDICATION
- Only to be used with I-medical's Lens delivery system.

CONTRAINDICATION
- Patient with a known allergy or intolerance to device material

INTENDED USER
The Device is intended to be used by qualified ophthalmic surgeon.

USE ENVIRONMENT
The device can be used in hospital or clinic.

PATIENT POPULATION
To prevent IOL surface quality during injection of intraocular lens in patients with cataract.

CLINICAL BENEFIT
i-Cushion enables implantation of foldable intraocular lens during cataract.

MODE OF ACTION
- Acts as a cushion between lens and plunger to prevent the surface quality of intraocular lens

DIRECTION FOR USE

- Prior to opening the pouch, verify the label for correct model and expiration date
- Inspect the pouch carefully before opening
- In case tears, cuts, punctures, or other similar sign is observed, chances are that the pouch is opened or damaged
- To remove the i-Cushion, open the pouch and transfer it to a sterile environment. Carefully fit the i-Cushion on the tip of the plunger

PRECAUTIONS

- Contents are sterile unless the package is opened or damaged.
- The package is ETO sterilized and must be opened only under aseptic conditions.
- Do not reuse the cushion
- Always ensure that the i-Cushion is fully fitted on the plunger tip
- Do not autoclave this product
- This product should be stored at room temperature
- Use of this product other then intended purpose is not recommended

HOW SUPPLIED
i-Cushion is supplied sterile in a dry heat sealed package. The package is sterilized with ethylene oxide. The content is sterile unless the package is opened or damaged.

EXPIRATION DATE
The expiration date on the package is the sterility expiration date.

REPORTING
Adverse reactions and potentially sight threatening complications that may reasonably be regarded as device related, need to be reported to the manufacture or local distributor

RETURN OF DAMAGED i-Cushion

Return the i-Cushion in its original package identified with the lot number and reason for returning. Do not attempt to re-sterilize the i-Cushion.

See instruction for use
Do not resterilise
Do not reuse
Do not store below 0°C & above 45°C
Store away from sunlight
Do not use if package damaged
Store in dry place

STERILE EO

CE 2460

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250 mm

90 mm