



GB

Injector - Cartridge set Instructions for Use

Cartridge Model : I GLIDE TUBE - 2.8 mm

Injector Model : Injector F

DESCRIPTION

The package consists of individual sterile disposable injector and cartridge for single use only and it is intended to be used by qualified ophthalmic surgeon.

CLINICAL BENEFIT

The summary of safety and clinical performance will be added in IFU, Once the SSCP is reviewed by notified body and uploaded in EUDAMED.

DIRECTIONS FOR USE

- Remove cartridge from the inner pouch and fill completely with viscoelastic.



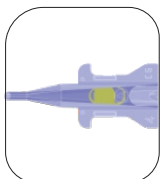
- Grasp the lens with forceps by the optic edge only. Hold the cartridge with the IOL diagram facing upwards. Engage the lead haptic with the canopy and sweep the lead haptic over the optic body in one motion leaving half the optic inside the cartridge. Ensure that the lead haptic is fully tucked over the optic body.



- Grasp the trailing with forceps and tuck it over the optic body.



- Using forceps, advance the lens past the line marked on the cartridge. Ensure that the lens and haptics remain folded in place after removing forceps.



- Align the cartridge with injector. Insert the cartridge bevel tip to with given cartridge slots. Slide the cartridge in forward direction.



- Push down the back end of the cartridge to ensure the alignment with injector. If the rod tip makes contact with the cartridge, the cartridge has not been inserted correctly. Retract the rod and ensure that the cartridge is fully snapped into the handpiece before moving forward.



PRECAUTIONS

- Contents are sterile unless the package is opened or damaged.
- The package is ETO sterilized and must be opened only under aseptic conditions.
- Use Viscoelastic Solution before loading the IOL in the cartridge.
- The injector & cartridge system should only be used with the I MEDICAL OPHTHALMIC INTERNATIONAL HEIDELBERG GMBH Manufactured lenses.
- Do not use this device or any of its components with any other lens.
- Do not use if the cartridge tip is cracked or split prior to implantation.
- Never release the plunger until the optic body has been completely released.
- Always ensure that the silicone tip is fully fitted on the plunger tip.
- Unused medical device waste and consumables should be sent to local waste management regulatory body for disposal

HOW SUPPLIED

Injector and cartridge are supplied sterile in a dry heat sealed package. The inner package is sterilized with ethylene oxide. The content is sterile unless the package is opened or damaged.

DISCLAIMER OF LIABILITY

The manufacture will not be liable for any injury suffered to patient as a result of:

- Any implantation method or technique used by a surgeon to implant the lens
- Any prescription selection and use of the lens for any individual patient or patient's condition

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 INJECTOR & CARTRIDGE

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

See instruction for use

Do not re-sterilise

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

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