FRONT

BACK

250 mm

90 mm

i Medical®

GB

Injector - Cartridge set
Instructions for Use

Cartridge Model : I GLIDE TUBE - 2.8 mm - 45° Medium
I GLIDE TUBE - 2.2 mm - 45° Small

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.

INDICATION
Lens Delivery Device acts as a support Device for IOL implantation and does not have a primary role in the clinical outcome.

CONTRAINDICATIONS
There are no known contraindications for the use of Lens Delivery Device system during the implantation of a foldable IOL.

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

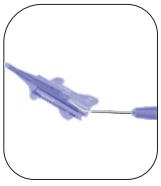
USE ENVIRONMENT
The device can be used in hospital or clinic.

PATIENT POPULATION
Cataract patients 18 years of age or above

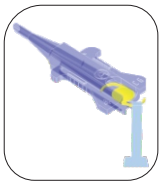
CLINICAL BENEFIT
Lens delivery system enables implantation of foldable intraocular lens during cataract to minimize incision size

DIRECTIONS FOR USE

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

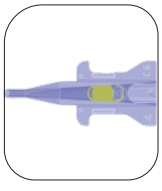


- Grasp the lens with forceps by the optic edge only. Hold the cartridge with the IOL diagram facing upwards. Engage the lead haptic with the canopy and sweep the lead haptic over the optic body in one motion leaving half the optic inside the cartridge. Ensure that the lead haptic is fully tucked over 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.
- The lens should be injected immediately after being introduced into the cartridge as viscoelastic solution may lose its lubricating properties when exposed to air for a long period of time.
- Forcing an implant through an inadequately enlarged incision results in traumatization of the wound and potentially compromises its ability to self-seal. Additionally, there is a risk of premature release of the implant with subsequent ocular injury and/or damage to the implant.
- 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.

EXPIRATION DATE
The expiration date on the packing box is sterility expiration date. Do not use IOL delivery system after this 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 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 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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