FRONT

i Medical®

GB

Injector - Cartridge set
Instructions for Use

Cartridge Model : i-GLIDE 1.85 mm Small, i-GLIDE 2.20 mm Medium
Injector Model : i-JECT Injector, Disposable Injector
Injector Cartridge Set : i-JECT Set Medium, i-JECT Set Small

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

- Hold the cartridge as shown in the image in such a way that the IOL design is found at

the top. Open the cartridge and inject Viscoelastic Solution

- Open the cartridge as shown in the image. Place lens into the cartridge ensuring that

the anterior side of the lens is on the top. Make sure that the lens is seated in the grove created by the open wings of the cartridge.

- Close the wings as shown in the image by taking care that no part of the lens becomes trapped between the wings, visually confirm this.

250 mm

90 mm

BACK

- Once the cartridge is locked in place, visually check whether the silicone tip of the plunger is aligned with the opening of the cartridge. A port has been provided to visualize it.

- Press the plunger in a smooth slow motion until the lens is inside the tip. Check that no excess force is required as this may be an indication that the lens is trapped between the wings of the plunger tip or has overridden the lens. If this is the case, do not proceed further. Now insert the cartridge into the eye and press the plunger until the lens comes out fully & disengages from the cartridge.

PRECAUTIONS
- Contents are sterile unless the package is opened or damaged.
- The package is ETO sterilized and must be opened only under aseptic conditions.
- The injector & cartridge system should only be used with the **i-Medical** 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 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 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

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MFG/MD/2020/000163
i-Medical® Ophthalmic International Heidelberg GmbH
Markircher Straße 7 · D-68229 Mannheim · Germany
Fax: +49(0)621-48 44 90-20 · www.imedical.de

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