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

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

- 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.

- Remove injector from the pouch and visually inspect it. Ensure smooth movement of the plunger.

- Align the back of the cartridge with the injector mouth and press it firmly.

- 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.

250 mm

90 mm

BACK

- 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.
- 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.

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

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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