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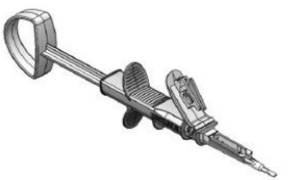
Click Injector

Instructions for Use



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IMPORTANT NOTICE

This product is intended for use by a qualified ophthalmic surgeon in a sterile medical setting. It is recommended that the surgeon adheres to the warnings outlined in these instructions.

DEVICE DESCRIPTION

The single-use sterile Click Injector system is made of high-quality materials and has been designed exclusively for foldable intraocular lens (IOL) implantation. The injector system is used with a separately packed IOL in a lens holder unit with separate instructions for use. The Click Injector allows the ophthalmic surgeon to safely inject both hydrophilic and hydrophobic lenses, of many sizes and designs, into the eye through a minimal invasive incision. Validation of compatibility between Click injector system and intraocular lens according to ISO 11979 performed by the lens manufacturer is required for qualification of lens.

INTENDED USE

The single-use Click Injector system is intended to be used for implantation of qualified foldable intraocular lenses into the eye following cataract removal. Validation of compatibility between Click Injector system and intraocular lens according to ISO 11979 performed by the lens manufacturer is required for qualification of lens.

INDICATIONS

Implantation of qualified foldable intraocular lenses into the eye following cataract removal.

CLINICAL BENEFITS

Quick and easy handling, reliable results and safe intraocular lens delivery.

UNWANTED SIDE EFFECTS

PATIENT TARGET GROUP, INTENDED USER AND USE ENVIRONMENT

Patients indicated for implantation of qualified foldable intraocular lenses into the eye following cataract removal. The intended user is the qualified ophthalmic surgeon. The device shall be used in a controlled environment (hospital environment) at controlled room temperature.

GUARANTEE AND LIABILITY LIMITATION

The manufacturer guarantees that this device has been produced under appropriate conditions with reasonable care, and assumes no liability for any direct or consequential unwanted side effects or resulting damages, losses or costs that may arise as a result of the direct or indirect use of this product. Manufacturer's liability is restricted to the performance of repairs resulting from product defects, which are clearly not the result of incorrect handling or use of lenses that have not been subject to successful validation according to ISO 11979 performed by the lens manufacturer.

WARNINGS

1. The device is meant for single use only. It must not be reused or resterilized. Reuse and/or resterilization may compromise device performance and could cause serious harm to the patient's health and safety.
2. Make sure that the sterile packaging is not damaged prior to use. Do not use a device from a packaging that is damaged. Do not use after expiry date has passed. Outer side of the packaging is not sterile.
3. Inject IOL within 3 minutes after loading to avoid lubrication issues or dehydration when viscoelastic is exposed to air for too long.
4. Do not continue implantation if device does not 'CLICK' or if the lens does not fold correctly as this could lead to damaged IOL or injector malfunction.
5. Be careful and precise during implantation of the lens into the eye. Inserting the cartridge tip with inappropriate force or using inappropriate small incisions could lead to wound damage or stretch, injector malfunction or IOL damage during injection.
6. All serious incidents relating to the device must be reported to the supplier and the competent authority of the country in which the user and/or patient is located.

COMPATIBLE FLUIDS

The Click Injector system is equipped with a highly efficient coating that significantly reduces friction when viscoelastic or balanced saline solution (BSS) is used.

DIRECTIONS FOR USE

The Click Injector is used to fold and implant foldable IOLs in the eye. The appropriate surgical technique is the responsibility of the surgeon. He or she must assess the suitability of the given procedure based on his or her education and experience.

Follow the steps as described below to ensure safe handling:

1. Check before use: the sterile blister must be undamaged and the content in sterile condition.Attention: Outer side of the packaging is not sterile.
2. Open blister containing sterile injector and place it in the sterile field.
3. Follow instructions for use of lens holder unit to unpack lens holder and IOL.
4. Follow instructions for use of lens holder to lubricate the injector and IOL without exerting any pressure on the plunger.
   Attention: In case of conflicting directions stated in the instructions of the IOL manufacturer, always follow the instructions of the IOL manufacturer. Avoid insufficient application of fluid or overfilling the loading chamber, as this could lead to damaged IOL or injector malfunction.
5. Follow instructions for use of lens holder unit to load lens holder on injector.
6. Slowly (>3 seconds) push folding element into lens holder until a 'CLICK' is heard. This signals that the Click Injector is securely 'loaded' and ready for injection.
7. Remove the activation lock safety feature from the plunger by pressing on the arrow mark.
8. Once loaded, the IOL should be injected within 3 minutes, as the viscoelastic may lose lubricity if allowed to stand too long while exposed to air.
9. Slowly (>5 seconds) advance the plunger in a gentle, even, and controlled manner, while ensuring the IOL haptics are correctly folded onto the IOL optic. If haptics are caught between plunger and injector nozzle, slacken pressure on plunger until IOL retraction is observed.

11. Depending on the surgical technique either (1) position the cartridge tip on the appropriately sized incision or (2) insert the cartridge tip up to 4mm into an appropriately sized incision. Selection of the appropriate surgical technique and selection and combination of medical products is subject to the respective surgeon based on experience and education.
    Attention: Inserting the cartridge tip with inappropriate force or using inappropriate small incisions could lead to wound damage or stretch, injector malfunction or IOL damage during injection.
12. Advance the IOL carefully until it fully left the cartridge tip including trailing haptic. Do not advance the plunger further after IOL fully exited the cartridge. Slight injector rotation during IOL injection could support the positioning of the IOL during insertion into the eye. Stop pressing plunger when IOL exits injector. Do not let the injector soft tip exit the nozzle. Withdraw injector from eye.
    Attention: Additional advancement of plunger after IOL exited cartridge could lead to unwanted expansion of silicon cushion at the cartridge tip end.
13. Thoroughly remove viscoelastic material from eye and IOL with standard irrigation and aspiration techniques.

DISPOSAL

After use, the Click Injector system must be disposed in accordance with your clinical guidance for disposal of single-use surgical instruments.

CONTACT INFORMATION

Please use the contact information below for reporting of serious incidents:
Email: lenstecbarbados@lenstec.com
Telephone: +1 (246) 420-6795