

Instructions for use - hydrophilic lenses

Description

The single-use IOLMATIC sterile injector system is made of high-quality materials and has been designed exclusively for foldable intraocular lens (IOL) implantation. The injector system is supplied with a preloaded IOL. The IOLMATIC allows the ophthalmic surgeon to safely inject both hydrophilic and hydrophobic lenses, of any size and design, into the eye through ≤ 2.2 mm incisions.

Application

The IOLMATIC injector is used to fold and implant foldable IOLs in the capsular bag or sulcus. The device is meant for single use only - it should 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. 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.

Instructions for use

01. Check before use: the sterile blisters containing tray, lens holder, and injector must be undamaged and in sterile condition. Warning: outer packaging of blisters is not sterile.



02. Open blister containing sterile injector and place it in the sterile field.



03. Open outer packaging of tray containing preloaded lens holder. Keep tray in a vertical position while peeling off aluminum tab, and place it standing upright in the sterile field. Keep lens holder in tray and do not remove liquid from tray.



04. Hold injector around its midsection without exerting any pressure on the plunger. Rinse the injector nozzle with BSS. Next, fill injector nozzle with viscoelastic material either from above or through the nozzle tip, ensuring complete lubrication of inner nozzle surface. Lubricate both sides of the folding element with viscoelastic.



05. Guide injector into lens holder. Gently increase pressure until a 'CLICK' is heard. This first 'CLICK' ensures that the two pieces have locked.



06. The injector should remain in a vertical position in the tray for a minimum of 30 seconds and a maximum of 30 minutes.



07. Retrieve injector from tray without exerting pressure on plunger. Check that lens or haptics are not tilted within lens holder.



08. Gently push folding element into lens holder until a second 'CLICK' is heard. This signals that IOLMATIC is securely 'loaded' and ready for injection.



09. Once loaded, the lens should be injected immediately, as the viscoelastic may lose lubricity if allowed to stand too long while exposed to air.



10. Gently advance the plunger in a slow, even, and controlled manner, while ensuring the IOL haptics are correctly folded onto the lens. If haptics are caught between plunger and injector nozzle, slacken pressure on plunger until lens retraction is observed. Do not continue implantation until haptics are correctly folded onto the lens.



11. To proceed inject IOL by guiding injector tip through the incision. Stop pressing plunger when IOL exits injector. Do not let the injector soft tip exit the nozzle. Withdraw injector from eye.



12. Thoroughly remove viscoelastic material from eye and lens with standard irrigation and aspiration techniques.



Guarantee and Liability Limitation

The manufacturer guarantees that this device has been produced with appropriate care, and assumes no liability for 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.