IOLMATIC: Instructions for use - hydrophobic lenses

Description
The sterile-packed, single-use IOLMATIC injector is made of high-grade materials and exclusively designed for implanting foldable intraocular lenses (IOL). The IOLMATIC safely injects hydrophilic and hydrophobic lenses of any size and design into the eye e.g. through of 2,2 mm incisions and smaller.

Application
Folding and injection of one-piece foldable lenses (IOL) in the capsular bag or ciliary sulcus after extra-capsular cataract extraction. The device is meant for single use only. Re-use and/or re-sterilization compromise device performance and could cause serious harm to the patient's health and safety. Implementation of the appropriate surgical techniques are the responsibility of the respective surgeon. He or she must assess the appropriateness of the relevant procedure based on his or her education and experience.

Instructions for use

01. Prior to use, always check that the blister containing the IOLMATIC preloaded injector is undamaged and in sterile condition. Warning: the outer packaging of the blister is not sterile.

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

02. Hold the injector body by its central part without exerting any pressure on the plunger. Rinse the injector nozzle with sufficient BSS. Then fill the nozzle of the injector with sufficient viscoelastic material: either from above or through the nozzle from the front side of the injector. Make sure the inner nozzle surface is completely lubricated with viscoelastic. Also lubricate both sides of the folding element with viscoelastic.
03. By exerting a gentle steady force, push the folding element into the lens holder until a ‘CLICK’ is heard. This signals IOLMATIC is securely ‘loaded’ and ready for injection.

04. The lens should be injected immediately after loading as viscoelastic materials may lose lubricity if allowed to stand too long while exposed to air.

05. Gently advance the plunger in a slow, regular and controlled manner. In case of C-loop lenses, please check that the IOL haptics are correctly folded onto the lens. If haptics are caught between the plunger and the injector nozzle, slacken the pressure on the plunger in such a way that a retraction movement can be performed. Do not continue implantation before haptics are correctly folded onto the lens.

06. Proceed to IOL injection by guiding the tip of the injector through the incision and pushing it over the iris to the near edge of the pupil. Stop pressing the plunger when the IOL exits the injector nozzle. Do not let the injector soft tip exit the nozzle. Withdraw the injector from the eye.
07. Remove the viscoelastic material thoroughly from the eye and lens with the standard irrigation and aspiration techniques.

Guarantee and Liability Limitation
The manufacturer guarantees that this product has been manufactured with the appropriate care and assumes no liability for 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.