Loading Instructions for the Bausch + Lomb Crystalsert® CI-26 – Crystalens® and TRULIGN™ Toric IOL Delivery System

with the Crystalens AO1UV and AO2UV or the TRULIGN Toric IOL BL1UT

Crystalens® AO
Accommodating Posterior Chamber IOL

TRULIGN® TORIC
POSTERIOR CHAMBER INTRAOCULAR LENS

1. Begin with a Crystalens or TRULIGN Toric IOL of appropriate model and dioptric power, a Crystalsert® delivery system, Amvisc® Plus viscoelastic, and a pair of nontoothed forceps. Remove the lid from the IOL case.

2. Inspect the Crystalsert to ensure that the drawer is fully retracted and the plunger is in the starting position as evidenced by the location of the stop at the rear detent of the syringe.

3. Keeping the Crystalsert level, apply Amvisc Plus viscoelastic to the area extending under the lens track edge as well as to the floor of the loading area as shown. Using nontoothed forceps, carefully remove the IOL from its case and confirm that the right loop of the leading haptic is round, to ensure that the lens is anterior side up.

4. Place the IOL onto the loading area so that the leading plate haptic is tangent to the body, and position the leading right loop under the lens track edge as shown. Then actuate the drawer by pressing up on the drawer stop arm...

5. ...and slowly close the drawer until the snap-closure mechanism has engaged. The right trailing loop should be visible, but not protruding from the opening, as shown above.

6. Slowly advance the plunger, which will move the IOL forward and up into the tip of the Crystalsert®, then stop when the plunger hits the forward detent position of the syringe. Then fill the cavity of the tip with Amvisc® Plus to avoid introducing air bubbles during the insertion process.

CRYSTALENS® POSTERIOR CHAMBER ACCOMMODATING INTRAOCULAR LENS (IOL):

INDICATIONS FOR USE: The Crystalens® posterior chamber accommodating intraocular lens (IOL) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia secondary to the removal of a cataractous lens in adult patients with and without presbyopia. Crystalens provides approximately one diopter of monocular accommodation which allows for near, intermediate, and distance vision without spectacles. WARNINGS: Careful preoperative evaluation and sound clinical judgement should be used by the surgeon to decide the risk / benefit ratio before implanting a lens in a patient. Unlike most other IOLs, theCrystalens AO IOL optic has hinges connecting it to the haptic; please see adverse events section below for more information.PRECAUTIONS: Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 45°C (113°F). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with conditions as outlined in the Crystalens AO IOL Directions for Use. ADVERSE EVENTS: The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ("FDA grid") population. As with any surgical procedure, risk is involved. Vaulting is a post-operative adverse event where the Crystalens AO IOL optic hinges move into and remain in a displaced configuration. If vaulting occurs, please see Directions for Use for a detailed listing of symptoms, information regarding diagnosis, potential causes, and sequelae. Physicians should consider the characteristics of each individual vaulting case prior to determining the appropriate treatment. Data on long-term follow-up after treatment of vaulting is not available. ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.
CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

TRULIGN® TORIC POSTERIOR CHAMBER INTRAOCULAR LENS (IOL):

The TRULIGN® Toric posterior chamber intraocular lens (IOL) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia who desire reduction of residual refractive cylinder with increased spectacle independence and improved uncorrected near, intermediate and distance vision. WARNINGS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk / benefit ration before implanting a lens in a patient. Rotation of toric lenses away from their intended axis can reduce their effectiveness, and misalignment can increase postoperative refractive cylinder. The TRULIGN® Toric IOL should only be repositioned when the refractive needs of the patient outweigh the potential risks inherent in any surgical reintervention into the eye. Unlike most other IOLs, the Trulign Toric optic has hinges connecting it to the haptic; please see adverse events section below for more information. PRECAUTIONS: The safety and effectiveness of the TRULIGN® Toric intraocular lenses have not been substantiated in patients with preexisting ocular conditions and intraoperative complications. Long-term stability in the human eye has not been established; therefore postoperative monitoring after implant should be performed on a regular basis. Lens rotation less than 5° may not warrant reorientation. Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 45°C (113°F). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with conditions as outlined in the TRULIGN® Toric IOL directions for use. ADVERSE EVENTS: The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ("FDA grid") population. As with any surgical procedure, risk is involved. Vaulting is a post-operative adverse event where the TRULIGN® Toric IOL optic hinges move into and remain in a displaced configuration. If vaulting occurs, please see Directions for Use for a detailed listing of symptoms, information regarding diagnosis, potential causes, and sequelae. Physicians should consider the characteristics of each individual vaulting case prior to determining the appropriate treatment. Data on long-term follow-up after treatment of vaulting is not available. ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.
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