bioli™ IOL Delivery System

Loading Guide

IC-8™ Apthera™ IOL with the bioli™ Delivery System

Use sterile garments and work in a sterile field when preparing Bausch + Lomb delivery systems and delivering IOLs.

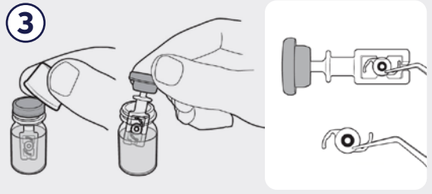
1

- Take the blister-pack containing the lens vial out of the box.
- Confirm that the model, power, and expiration date on the blister-pack and lens vial match the information on the box.
- Do not use if it has passed the expiration date.
- In a sterile environment, open the blister-pack by peeling open the lid (made of Tyvek® material) and remove the lens vial.

2

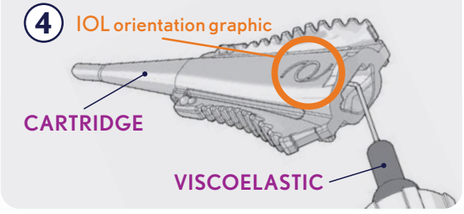
- Before opening the vial, confirm that the fluid is completely covering the lens when the vial is in the upright position.

3



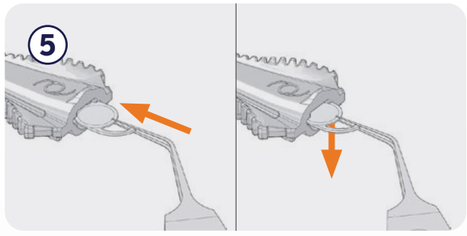
- Remove cap from the vial and expose the twist-cap lens holder.
- Take the lens holder out of the vial and, with a pair of sterile, smooth (non-toothed) forceps, remove the lens from the holder by gently grasping the lens haptic and optic edge, ensuring the anterior side is up (haptics pointing counter-clockwise).
- Do not grasp the optic body.

4



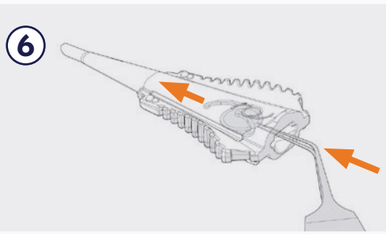
- Ensure IOL orientation graphic faces user.
- Fill cartridge with viscoelastic prior to loading.

5



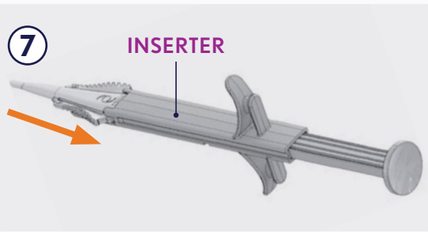
- Insert lens halfway into the cartridge.
- Gently push lens down on the optic edge with the forceps.
- Verify that the lens is on the bottom surface of the cartridge.

6



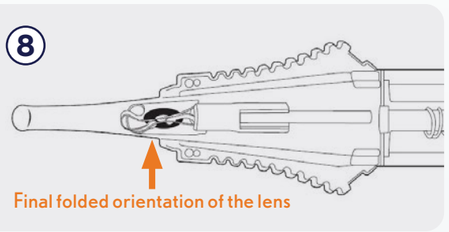
- Gently fold trailing haptic onto anterior side of the optic.
- Push to position lens as far into cartridge as forceps will permit.
- Ensure trailing haptic remains tucked.

7



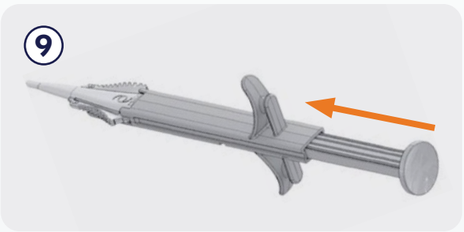
- Attach the cartridge to the inserter body.
- Align the cartridge (IOL graphic up) and slide it into the inserter slot.
- Apply inward force until you hear an audible “click” sound.

8



- Advance the plunger tip onto the IOL for preparation of implantation.
- Back the plunger tip off 1mm before the delivery step.
- This picture shows the haptics folded within the “taco” shape the lens will assume as it progresses through the cartridge.
- Verify that the plunger tip is behind the optic.
- Ensure the leading and trailing haptics are looped between the folded halves of the optic.

9



- Insert the cartridge tip into the eye bevel down.
- Position the tip of the cartridge at the anterior capsule opening.
- Advance plunger in one, slow motion.
- Insert the lens carefully into the eye capsular bag.
- Place and center the lens using a suitable positioning instrument.

Learn more about IC-8™ Apthera™ IOL with the bioli™ Delivery System at **bauschsurgical.com**

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bioli™ IOL Delivery System

bioli-A1

bioli™ IOL Delivery System

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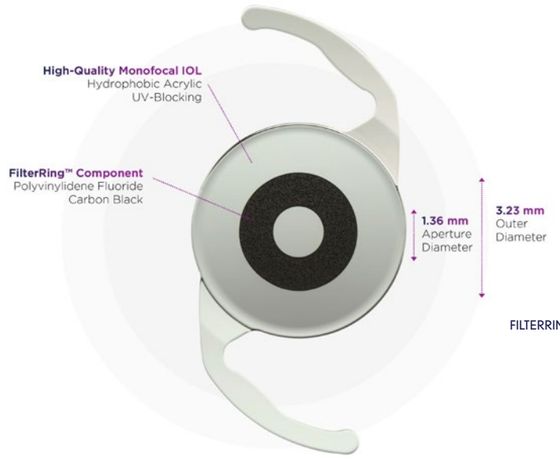
FOR INSERTING LENS MODEL IC-8 Apthera
RECOMMENDED INCISION SIZE 3.2mm
TYPE OF ACTION Push-type
COMMENTS Single-handed delivery. Disposable.

IC-8™ Apthera™ IOL

IC8APT order number IC8APT-XXX



MODEL	IC-8™ Apthera™ IOL
MATERIAL (OPTIC AND HAPTIC)	Hydrophobic Acrylic UV-blocking
POWERS	+10.0 D through +30.0 D in 0.5 D increments
OPTIC TYPE	One-piece Biconvex, anterior aspheric surface
OPTIC DIAMETER (ØB)	6.0 mm
OVERALL DIAMETER (ØT)	12.5 mm
OPTIC EDGE DESIGN	360° posterior square edge
HAPTIC DESIGN	Modified C-loop haptic with 5° angulation
REFRACTIVE INDEX	1.483 at 35°C and 589 nm
FILTERRING™ COMPONENT MATERIAL	Polyvinylidene fluoride (PVDF) with carbon black
FILTERRING COMPONENT OUTER DIAMETER	3.23 mm
FILTERRING COMPONENT INNER DIAMETER (APERTURE)	1.36 mm
BIOMETRY	Optical
A-CONSTANT SURGEON FACTOR ANTERIOR CHAMBER DEPTH (ACD)	120.5 2.64 6.42

Optical biometry A-constant values are presented as a guideline.
Physicians should calculate the lens power based on their experience and preference.

LEARN MORE AT bauschsurgical.com

1. IC-8 Apthera Directions for Use, Bausch + Lomb, Inc.

Indications and Important Safety Information for IC-8 Apthera IOL

INDICATIONS: The IC-8 Apthera IOL is indicated for unilateral implantation for the visual correction of aphakia and to create monovision in patients of age 22 or older who have been diagnosed with bilateral operable cataract, who have up to 1.5 D of astigmatism in the implanted eye, and who do not have a history of retinal disease and who are not predisposed to experiencing retinal disease in the future. The device is intended for primary implantation in the capsular bag, in the non-dominant eye, after the fellow eye has already undergone successful implantation (uncorrected distance visual acuity 20/32 or better and best-corrected distance visual acuity 20/25 or better) of a monofocal or monofocal toric IOL that is targeted for emmetropia. The refractive target for the IC-8 Apthera IOL should be -0.75 D. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal or monofocaltoric IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity.

CONTRAINDICATIONS: (1) Patients with dilated pupil size less than 7.0 mm. (2) Patients with a history of retinal disease including but not limited to, high myopia, diabetes, macular disease, sickle cell disease, retinal tear, retinal detachment, retinal vein occlusion, ocular tumor, uveitis, and patients who are predisposed to experiencing retinal disease in the future.

WARNINGS: The lens should not be implanted if appropriate intraocular support of the lens is not possible. Severe subjective visual disturbances (e.g., glare, halo, starburst, hazy vision) may occur after device implantation. There is a possibility that these visual disturbances may be significant enough that a patient may request removal of the lens. Contrast sensitivity in eyes implanted with this lens is significantly reduced when compared to the fellow eye implanted with a monofocal or monofocal toric IOL. Although there was no significant reduction in binocular contrast sensitivity in the IDE clinical study, it is essential that prospective patients be fully informed of this visual effect in the implanted eye before giving their consent for unilateral implantation of the lens. Patients should be informed that they may need to exercise caution when engaging in activities that require good vision in dimly lit environments (such as driving at night or in poor visibility conditions). There is a possibility that visual symptoms due to reduced contrast sensitivity may be significant enough that a patient may request removal of the lens. This lens should not be implanted bilaterally because bilateral implantation is expected to cause significant reduction in contrast sensitivity under all lighting conditions. The use of this lens in patients with corneal astigmatism greater than 1.5 D is not recommended. Diagnostic tests in patients implanted with the lens may take longer and require some additional effort from the patient and the physician to perform. Use of some medical lasers to treat certain eye conditions may present potential risks of damaging the FilterRing component of the lens. Removal of the lens may be necessary prior to retinal or vitreal procedures. Surgeons should perform a careful benefit-risk assessment based on individual patient characteristics, weighing all the risks disclosed in the Directions for Use labeling against the benefit of extended depth of focus. Nd:YAG laser capsulotomy treatments may be more difficult to perform and may be less effective in an IC-8 Apthera IOL implanted eye. Specific training from Bausch + Lomb or an authorized representative of Bausch + Lomb related to YAG capsulotomy is required before a surgeon is authorized to implant the IC-8 Apthera IOL.

PRECAUTIONS: Prior to surgery, prospective patients should be informed of the possible risks and benefits associated with this lens and a Patient Information Brochure should be provided to the patient. Patients with a predicted postoperative astigmatism between 1.0 D and 1.5 D may not obtain as great an amount of improvement in intermediate vision compared to patients with lower amounts of astigmatism.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician.

ATTENTION: Reference the Directions for Use labeling for a complete listing of important safety information.

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