IC·8™ Apthera™ IOL

CLINICAL PEARLS

BAUSCH + LOMB

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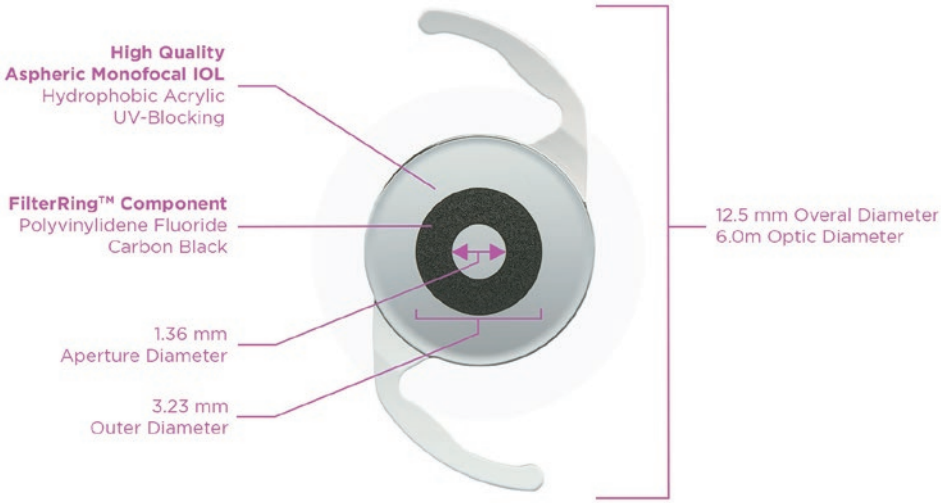
METHOD OF ACTION

- The IC-8® **Apthera**™ IOL is a single-piece, hydrophobic acrylic intraocular lens with an embedded FilterRing™ component with a central aperture of 1.36 mm.
- Using small aperture technology, the **Apthera** IOL provides patients with greater than 2.0 D of continuous range of vision.[1]

Data on file, Bausch & Lomb, Incorporated.

Apthera™ IOL Features



Diopter Range: +10.0 D to +30.0 D (0.50 D increment steps)
Edge Design: 360° posterior square edge
Optic Design: Biconvex, anterior aspheric surface
Haptic Design: Modified C with 5° angulation
Single Use Injector System

PATIENT POPULATION

- Scheduled to undergo intraocular lens implantation in both eyes
- Adults age 22 or older
- Do not have a history of retinal disease and who are not predisposed to experiencing retinal disease in the future

CONTRAINDICATIONS

- Patients with dilated pupil size less than 7.0 mm.
- 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.

PRE-OP TESTING

- Standard pre-op cataract patient testing
- Corneal astigmatism of ≤ 1.50 D
- Dilated Pupil size ≥ 7.0 mm

Biometry	Optical	Applanation
A-Constant:	120.5	120.15
Surgeon Factor:	2.64	2.44
ACD:	6.42	6.22

Manufacturer: AcuFocus, Inc.
Type: Posterior Chamber
Model: **IC-8® Apthera™** IOL
Material: Acrylic (Optic and Haptic)

Note: *Ultrasound lens ACD (Anterior Chamber Depth) was generated by subtracting 0.2 mm from the optical lens ACD. Ultrasound A-constant and surgeon factors were calculated from the ultrasound lens ACD.*

These A-constant values for optical biometry and applanation biometry are presented as a guideline. Physicians should calculate the lens power based on their experience and preference. As surgical instrumentation and techniques may differ, surgeons must personalize their A-constant.

CALCULATION OF LENS POWER:

The **Apthera** IOL eye should be targeted for a residual refraction of -0.75 D. It is recommended to choose the lens power that will result in a refractive target that is:

- Not more plus than -0.75 D and
- Not more minus than -1.00 D.

This can be calculated from the corneal radius of curvature, anterior chamber depth (ACD), and axial length of the eye according to the Barrett Universal II formula.

SETTING PATIENT EXPECTATIONS

For maximum patient satisfaction, set appropriate expectations for a patient considering the **Apthera**™ IOL.

1 Explain the Goal

The **Apthera** IOL, when working together with a monofocal or monofocal toric IOL, provides many key benefits, including:

- Delivers reliable, continuous range of vision from near to far, without any blurry zones
- Provide examples such as:
  - Reading magazines (near)
  - Working on the computer (intermediate)
  - Looking at street signs (far)
- Helps patients with a low amount of corneal astigmatism (as much as 1.5 D)
- Provides high-quality optics

2 May Need Magnification

- Dim light conditions
- Prolonged near vision activities
- Tiny print

3 Set Realistic Expectations

- Recovery takes time
  - Days, weeks, sometimes a little longer
- Avoid reading glasses
- Follow all postoperative care instructions as given by your doctor

PROCEDURE OVERVIEW

- Perform cataract surgery per surgeon's normal standard of care

- First Eye:

  Monofocal / monofocal toric IOL should be implanted first in the dominant eye.

  – Target emmetropia and post-oprefraction of plano +/- 0.25 D
- Successful first eye treatment defined as:

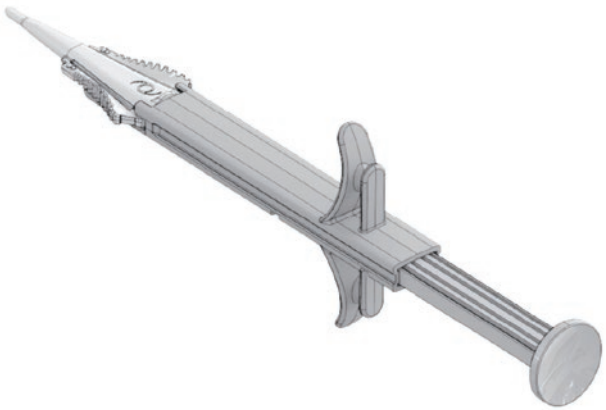
  – UCDVA 20/32 or better and BCDVA 20/25 or better

- Second Eye/**Apthera**™ IOL:

  Apthera IOL should be placed in the non-dominant eye after successful monofocal IOL treatment.

  – Achieve a target refraction of -0.75 D
- **Apthera** IOL corneal incision size: 3.2 mm
- Capsulorhexis: 5.0 to 5.5 mm in diameter
- Polish posterior & anterior capsule

SINGLE-USE INJECTOR



POST-OPERATIVE CARE

Use surgeon's normal standard of care

- **Apthera**™ IOL specific requirements:
  - Auto refractor and retinoscopy measurements are unreliable, or unattainable postoperatively, due to the small aperture opening in the **FilterRing**™ component.
    - Do not use to determine the manifest refraction
    - Maximum plus refraction
    - Patients with the **Apthera** IOL may not detect small changes in power because of the small aperture
  - Use good light on reading card and for acuity testing
- Dry eye management and testing as usual for cataract

EXAMPLES OF TECHNIQUES FOR POST-OP REFRACTIONS

Due to the small aperture design, refractions can be more challenging in the implanted eye.

- The refraction end points are usually softer.
- The patient will tolerate a larger range of introduced lenses without experiencing blur.
- A "mid-point" refraction will provide the most accurate result. Alternatively, a "red/green" balance test can be used.
- NOTE: Auto refractors and retinoscopy are unreliable or unattainable postoperatively.

REFRACTION TECHNIQUE

Performing a Mid-Point Refraction

Step 1: Perform a normal manifest refraction, then instruct the patient to fixate and maintain clarity on a distance optotype 2 lines above best corrected vision.

Step 2: Add plus lenses until first blur, record their endpoint.

Step 3: Starting from the baseline manifest refraction, now add minus lenses until first blur, record endpoint.

Step 4: Calculate the mid-point refraction using the following equation:
[(Endpoint plus blur) + (Endpoint minus blur)] / 2 =(rounded to nearest max plus 0.25 D)

Step 5: Add figure from Step 4 to the spherical component of the manifest refraction from Step 1; this represents the calculated mid-point.

Performing a Mid-Point Refraction

Step 1: Initial manifest Rx: +1.00 – 0.75 X 090

Step 2: Plus lenses to blur: +0.50 D (2 lenses)

Step 3: Minus lenses to blur: -1.75 D (7 lenses)

Step 4: [(+0.50 D) + (-1.75 D)] / 2 = -0.62 D (Rounded to -0.50 D)

Step 5: -0.50 D + 1.00 D = +0.50 D

Final midpoint refraction: +0.50 -0.75 X 090

ALTERNATE REFRACTION TECHNIQUE

Red/Green Balance Test

To help you find the mid-point refraction the Red/Green balance test may alternatively be utilized.

1. Complete the initial manifest refraction and dim the room illumination completely.

2. Select the projector's Red/Green filter with the appropriate target. This can be the 20/40 line or 2 lines above best corrected vision.

3. Have the patient compare the letters in the red/green sides and state which letters appear sharper, clearer or better focused or if both sides appear equally clear. (DO NOT ask if the letters are "better", "darker" or "brighter")

NOTE: If the patient is R/G colorblind this test may still be utilized because it is based on the principles of chromatic aberration and not color discrimination. The patient can still make a comparison. They should be asked to compare the "left" side with the "right" side rather than red vs. green.

- RED IS CLEARER:
  Place an additional 0.25 D of MINUS spherical power. Continue this until the patient reports equal clarity between sides or until the "green" side appears clearer.

- GREEN IS CLEARER:
  Place an additional 0.25 D of PLUS spherical power. Continue this until the patient reports equal clarity between sides or until the "red" side appears clearer.

- MID-POINT REFRACTION:
  The letters on both red and green sides appear equally clear. Remove the Red/Green filter and recheck BVA.

LASER USE AFTER **Apthera**™ IOL IMPLANTATION

IMPORTANT:

Nd: YAG Capsulotomy

Hinged circular capsulotomy pattern is to be used for the Nd:YAG procedure. This method creates an opening around the outside of the **FilterRing**™ component from 5 to 7 o'clock, leaving an inferior hinge.

- The resulting tissue flap should naturally fall back out of the visual axis and remain connected to the capsular bag, maintaining an inferior hinge.
- For first cases, allow extra time to perfect this technique.

- Titrate Nd: YAG laser energy to the lowest level possible to produce a capsular opening.
- Avoid direct laser hits to the **FilterRing** component. Testing did not show loss of integrity and there were no chemicals released. Should contact be made with the **FilterRing** component:
  - Lens integrity is maintained.
  - No toxic chemicals are released.

Hinged Circular Yag Laser Pattern

The red dotted line on this IOL diagram refers to the location of the laser shots

Data on file, Bausch & Lomb, Incorporated.

HINGED CIRCULAR CAPSULOTOMY TECHNIQUE

Hinged Circular Capsulotomy Steps

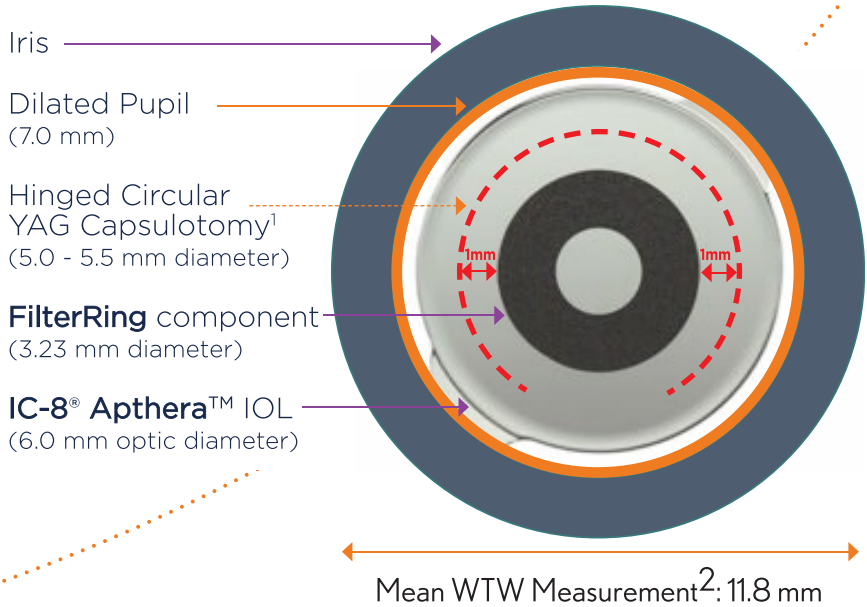
Step 1: Dilate the pupil to at least 7.0 mm.

Step 2: Identify the halfway point between the outer edge of the **FilterRing**™ component and the IOL optic edge.

Step 3: Place laser shots slightly peripheral to this halfway point (approximately 1 mm away from the outer edge of the FilterRing component). The result is a 5.0 to 5.5 mm posterior capsular opening.

Step 4: Create a continuous posterior capsular opening from 5 to 7 o'clock (10 clock hours) using the lowest effective energy level necessary to efficiently open the capsule.

Step 5: Leave the posterior capsular flap connected, maintaining an inferior hinge between 5 and 7 o'clock.



[1] Zeki S. Inverted U Strategy for Short Pulsed Laser Posterior Capsulotomy. ACTA Ophthalmol. Scand. 1999: 77: 575-577.
[2] Hashemi at al. White-to-white corneal diameter distribution in an adult population. Journal of Current Ophthalmology 27 (2015) 21-24.

CAPSULOTOMY PEARLS - LASER

- Fire laser shots peripheral to and away from the outer edge of the **FilterRing**™ component. Avoid direct laser hits to the FilterRing component. Testing did not show loss of integrity and there were no chemicals released.
  - Should contact be made with the **FilterRing** component:
    - Lens integrity is maintained.
    - No toxic chemicals are released.
- Use a posterior laser offset to mitigate lens pitting
- Use the lowest effective energy level necessary to ensure successful posterior capsular opening

CAPSULOTOMY PEARLS - VISUALIZATION

Maximize visualization to mitigate complications

- Care should be taken to ensure sufficient pupildilation (minimum of 7.0 mm) is achieved to perform the capsulotomy around the periphery of the **FilterRing** component.[1]
- A capsulotomy contact lens (e.g., Peyman or central Abraham) may be used to stabilize the eye, improve the laser beam optics, and facilitate accurate focusing.[2]

[1]Data on file, Bausch & Lomb, Incorporated.

[2]Steinert RF. Nd:YAG Laser Posterior Capsulotomy. American Academy of Ophthalmology. 2013.

CAPSULOTOMY PEARLS - FLAP RETRACTION

- Ensure the flap is completely separated from the surrounding area of the posterior capsule except inferiorly. This can be achieved by[1]:
  - Ensuring that the laser shots created in the posterior capsule are contiguous, otherwise retraction of the flap may not be complete.
- Monitor the flap to ensure it begins to retract.
  - Retrace your steps and place additional shots to break any remaining tissue bridges.
  - Ensure that the laser treatment extends below the level of the visual axis from the 5 to 7 o'clock location maintaining an inferior hinge.
- If the capsule is still not retracting after performing the previous procedures, carefully place a lasershot through the center aperture.
  - Take care to not damage the lens andthe **FilterRing**™ component
  - Use a posterior laser offset
  - Use a capsulotomy contact lens

[1]Zeki S. Inverted U Strategy for Short Pulsed Laser Posterior Capsulotomy. ACTA Ophthalmol. Scand. 1999: 77: 575-577

IC-8™ Apthera™ IOL

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.