IC-8™ Apthera™ IOL Technical Specifications

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	Single 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	Ultrasound
A-Constant: Surgeon Factor: Anterior Chamber Depth (ACD):	120.5 2.64 6.42	120.15 2.44 6.22

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 contact ultrasound 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.

*Refer to **Directions for Use** for complete specifications.

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IC-8® Apthera™ IOL
Important Safety Information

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

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 monofocal toric IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity.

Contraindications/Warnings/Precautions: Patients with dilated pupil size less than 7.0 mm and 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, are contraindicated for use of the **IC-8 Apthera** IOL. 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. 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. Diagnostic tests in patients implanted with the lens may take longer and require some additional effort from the patient and the physician to perform. Specific training (related to YAG capsulotomy) from AcuFocus, Inc. or an authorized representative of AcuFocus is required before a surgeon is authorized to implant the **IC-8 Apthera** IOL. 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. 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.

Attention: Reference the Directions for Use labeling for each IOL for a complete listing of warnings and precautions.

Access educational resources at **AcuFocusUniversity.com** and talk to your local AcuFocus representative for more information.

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