AcuFocus™

IC-8™ Apthera™ IOL

Hydrophobic Acrylic Small Aperture Intraocular Lens

DIRECTIONS FOR USE

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.
Warning: Specific training from AcuFocus, Inc. or an authorized representative of AcuFocus is required before a surgeon is authorized to implant the **IC-8 Apthera** IOL.

DEVICE DESCRIPTION: The **IC-8 Apthera** intraocular lens (IOL) is a one-piece, UV blocking intraocular lens made from an implantable medical grade hydrophobic acrylic material with ≤ 4% water content, which is folded to enable placement through an incision smaller than the optic diameter of the lens. The **IC-8 Apthera** IOL is designed to be surgically implanted into the human eye (placed into the capsular bag) to replace a cataractous crystalline lens and is intended to provide an extended depth of focus from far through near.

The **IC-8 Apthera** IOL is an aspheric monofocal lens that features an embedded **FilterRing™** component with a small central aperture. This unique, wavefront-filtering design mitigates the reduction in visual acuity caused by unfocused peripheral light by allowing only central light rays to focus on the retina. The anterior optic surface is aspheric, incorporating negative spherical aberration. The posterior surface of the **IC-8 Apthera** IOL is designed with a 360° square edge. The **IC-8 Apthera** IOL is supplied sterile for single-use only. **Figures 1 to 3**, as well as **Table 1** provide detailed physical characteristics of the **IC-8 Apthera** IOL.

Figure 1: Physical Characteristics of the IC-8 Apthera IOL

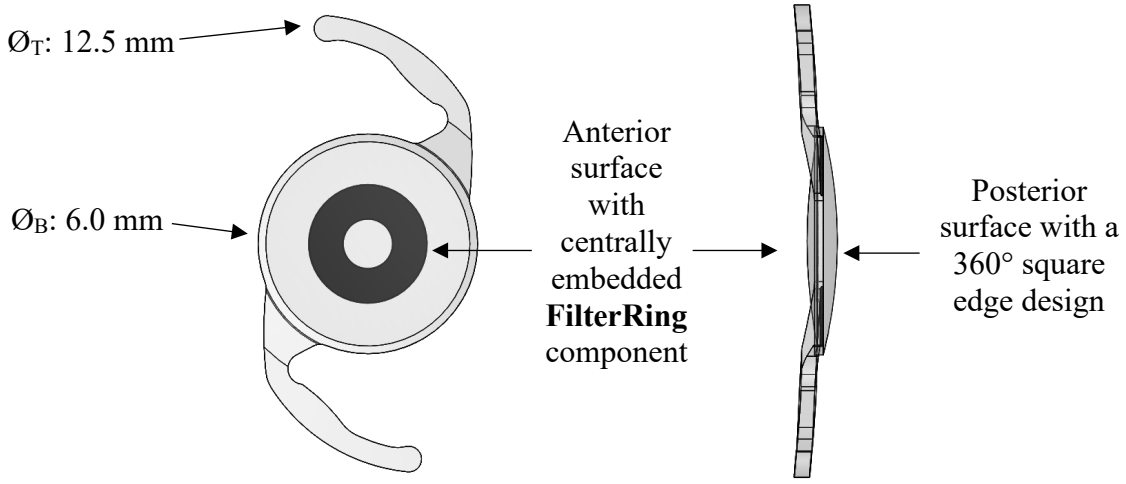
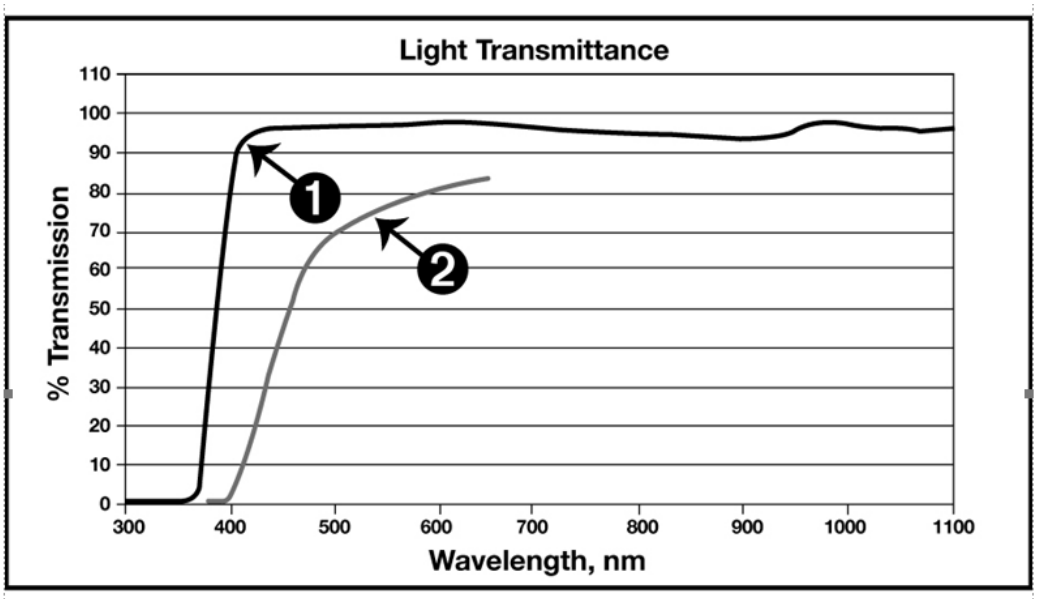


Table 1: Device Design Characteristics

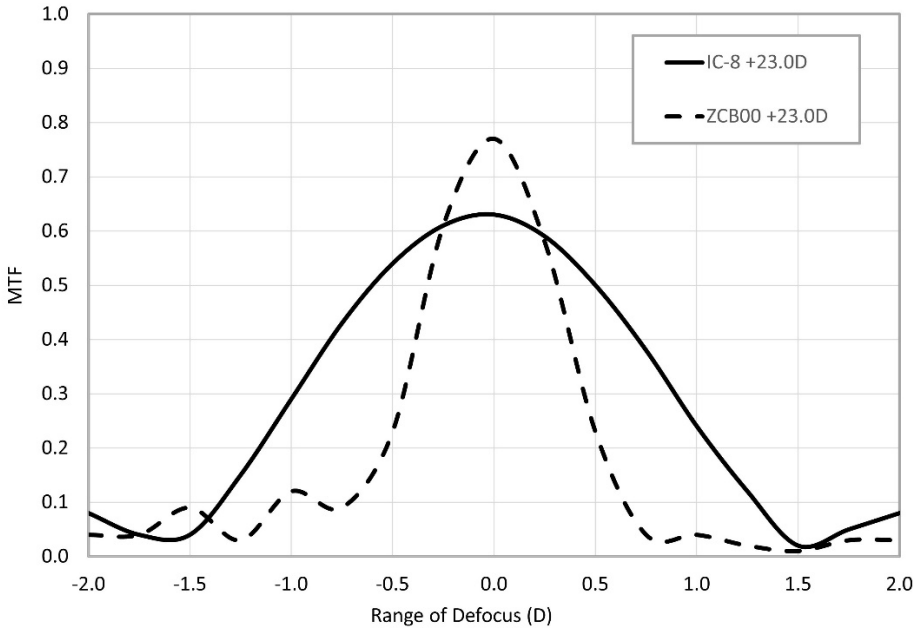
Material	UV-blocking hydrophobic acrylic
Power	+10.0 D through +30.0 D in 0.5 D increments
Optic diameter ($Ø_B$)	6.0 mm
Overall diameter ($Ø_T$)	12.5 mm
Optic design	Biconvex, aspheric anterior surface, and 360° posterior square edge
Haptic design	Modified C-loop haptic with 5° angulation
Refractive index	1.483 at 35ºC and 589 nm
Spherical Aberration	-0.22 mm
Light transmission	UV cut-off at 10% Transmittance (T) for a typical 20.0 diopter **IC-8 Apthera** IOL is shown in **Figure 2**
FilterRing component material	Polyvinylidene fluoride (PVDF) with carbon nanoparticles
FilterRing component outer diameter	3.23 mm
FilterRing component aperture diameter	1.36 mm
Number of micro-perforations	3,200
FilterRing component Thickness	5 mm
A-Constant for Ultrasound Biometry:	120.15
Optical Surgeon Factor	2.64
Ultrasound Surgeon Factor	2.44

Figure 2: Spectral Transmittance



Legend:
Curve 1: Spectral Transmittance (T) curve of a typical 20.0 diopter **IC-8 Apthera** IOL, UV cut-off at 10% T is 375 nm.
Curve 2: Spectral Transmittance (T) curve corresponding to a 53-year-old phakic eye (Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962; 1:776-783.)

Figure 3: Modulation Transfer Function (MTF) Through-Focus Response of +23.0 D IOLs in a Model Eye (Green Light, 50 lp/mm, 3 mm Aperture)



MECHANISM OF ACTION: The **IC-8 Apthera** IOL's distinctive design is based on the well-established concept of small aperture optics that reduces defocus and optical aberrations by decreasing the size of the blur circle to achieve extended depth of focus. The small central aperture of the **IC-8 Apthera** IOL mitigates the reduction in visual acuity caused by unfocused peripheral light rays, allowing only central light rays to focus on the retina. Peripheral light rays entering the eye at a larger angle create a large blur circle at the retinal image plane. Eliminating these peripheral light rays reduces the size of the blur circle, improving image resolution and increasing depth of focus to alleviate presbyopic symptoms at intermediate and near while maintaining far vision.

INDICATIONS FOR USE: 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:

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:

1. The lens should not be implanted if appropriate intraocular support of the lens is not possible, e.g., the posterior capsule is ruptured, the zonules are damaged, or an eye is compromised due to developmental defects.
2. Severe subjective visual disturbances (e.g., glare, halo, starburst, hazy vision) may occur after device implantation, regardless of lighting conditions. There is a possibility that visual symptoms (i.e., severe subjective visual disturbance) may be significant enough that a patient may request removal of the lens.
3. Contrast sensitivity in eyes implanted with the **IC-8 Apthera** IOL 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.

4. The **IC-8 Apthera** IOL should not be implanted bilaterally because bilateral implantation is expected to cause significant reduction in contrast sensitivity under all lighting conditions.
5. The use of **IC-8 Apthera** IOL in patients with corneal astigmatism greater than 1.5 D is not recommended.
6. Diagnostic tests such as visual fields, fluorescein angiography, optical coherence tomography, binocular indirect ophthalmoscopy, and fundus photography in patients with the **IC-8 Apthera** IOL may take longer and require some additional effort from the patient and the physician to perform. If the patient develops glaucoma or a retinal condition, some difficulty with conducting the ophthalmic examination and/or administering treatment is possible, and the **IC-8 Apthera** IOL may need to be removed.
7. Nd:YAG laser capsulotomy treatments may be more difficult to perform and may be less effective in an **IC-8 Apthera** IOL implanted eye resulting in need for a secondary YAG procedure, or in rare cases, a pars plana vitrectomy to remove residual posterior capsular remnant. Damage to the lens can occur (observed in the IDE clinical trial) and may result in increased subjective visual disturbances, and in rare cases, device explant.
8. Use of some medical lasers to treat certain eye conditions may present potential risks of damaging the **IC-8 Apthera** IOL. In general, lasers with longer wavelengths (650 nm or more) and the lasers in the infrared spectrum are most likely to cause thermal damage to the embedded **FilterRing** component. As such, physicians should avoid focusing the laser beam directly on the embedded **FilterRing** component to avoid damage and potential release of carbon black.
9. Removal of the **IC-8 Apthera** IOL may be necessary prior to retinal or vitreal procedures.
10. Surgeons should perform a careful benefit-risk assessment based on individual patient characteristics, weighing the risks of device damage, repeat YAG procedures, vitrectomy, and device explant, against the benefit of extended depth of focus.
11. The lens is for single-use only. Do not reuse the lens. A used lens should be considered as biomedical waste and disposed in accordance with healthcare facility protocol and local requirements. Reuse may lead to biological reactions including but not limited to inflammation, infection, injury, or other clinical conditions.
12. Do not resterilize the lens by any method. Do not autoclave the lens.

PRECAUTIONS:

1. Prior to surgery, prospective patients should be informed of the possible risks and benefits associated with the **IC-8 Apthera** IOL. A Patient Information Brochure should be provided to the patient.
2. Recent contact lens wear may affect the patient's refraction; therefore, surgeons should establish corneal stability following the discontinuation of contact lens use prior to determining the lens power.
3. Care should be taken to achieve IOL centration as significant lens decentration, where the **FilterRing** component either partially or fully occludes the visual axis, would be expected to result in reduced visual acuity/quality.

4. 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.
5. It is recommended that in the event that a Nd:YAG capsulotomy is necessary to treat PCO in an eye implanted with an **IC-8 Apthera** IOL, a hinged circular YAG capsulotomy be performed around the **FilterRing** component(i.e. a capsule opening of approximately 10 clock hours around the outside of the **FilterRing** component from 5 to 7 o'clock leaving an inferior hinge), ensuring that the capsulotomy flap retracts inferiorly. Care should be taken to ensure sufficient pupil dilation (minimum of 7 mm) is achieved to perform the capsulotomy around the periphery of the **FilterRing** component.
6. The safety and effectiveness of the **IC-8 Apthera** IOL have not been established in patients with pre-existing ocular conditions and intraoperative complications listed in **Table 2**. Careful preoperative evaluation and sound clinical judgment should be used by the physician to determine the benefits and risks before implanting a lens in a patient with one or more of these conditions:

Table 2: Conditions with No Safety and Effectiveness Data

Preoperative corneal astigmatism greater than 1.5 D	Irregular corneal astigmatism or other corneal abnormalities
Acute, chronic, or uncontrolled systemic disease that would increase the operative risk	Ocular disease or pathology, other than cataract, that is predicted to cause future visual acuity loss
Pupil abnormalities	Patients < 22 years of age
Strabismus or amblyopia	Zonular or capsular abnormalities
Glaucoma or uncontrollable high intraocular pressure	Previous corneal refractive or intraocular surgery
Significant anterior chamber hyphema	Congenital bilateral cataracts
Pregnancy, lactation, or other conditions associated with hormonal fluctuation	Extremely shallow anterior chamber not due to cataract
Active or recurrent severe anterior or posterior segment inflammation or any disease producing an inflammatory reaction in the eye	**IC-8 Apthera** IOL placement in the ciliary sulcus
IC-8 Apthera IOL implantation in the dominant eye	

7. Potential adverse effects (e.g., complications) during or following cataract surgery with implantation of an intraocular lens may include but are not limited to:
    - The presence of capsular rupture or radial capsular tears known or suspected at the time of surgery
    - Surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss)
    - Zonular damage
    - Endophthalmitis/intraocular infection

- Secondary surgical intervention (including implant repositioning, removal, AC tap, or other surgical procedure)
- Raised intraocular pressure requiring treatment
- Iritis
- Corneal stromal edema
- Hypopyon
- Retinal detachment
- Cystoid macular edema
- IOL dislocation
- Pupillary block

8. The lens is sterile until the blister-pack is opened or damaged. Inspect the blister-pack carefully for tears, punctures, or other signs that the blister-pack has been damaged or opened (e.g., wet packaging, cracked glass vial). Do not implant the lens if the sterility has been compromised.
9. Do not implant the lens if the fluid does not completely cover the lens when the vial is in its upright position.
10. Do not use the lens if it has passed the expiration date on the packaging.
11. Handle the lens carefully to avoid damage to the lens surface or haptics.
12. Do not use injector systems and ophthalmic viscosurgical devices (OVDs) that have not been validated for use with the **IC-8 Apthera** IOL.
13. Do not soak or rinse the lens with any solution other than sterile balanced salt solution or sterile normal saline.
14. Do not store the lens in direct sunlight, at a temperature greater than 104°F (40°C), or below 41°F (5°C). Do not freeze.

IOL IMPLANTATION: An AcuFocus validated injector system and ophthalmic viscosurgical device (OVD) combination should be used for implantation of the **IC-8 Apthera** IOL. AcuFocus recommends using the qualified AST Products, Inc. bioli™ IOL Delivery System (Model BIOLI-A1) or any other AcuFocus qualified injector systems. Validated OVDs that can be used with the **IC-8 Apthera** IOL and AST bioli™ IOL Delivery System combination are listed in **Table 3**. Contact AcuFocus for further information on qualified combinations.

Table 3: Ophthalmic Viscosurgical Devices (OVDs) Validated for Use with the IC-8 Apthera IOL

Lens	Diopter	Validated OVDs	
		Sodium hyaluronate (NaHy) concentration	Zero-shear viscosity
IC-8 Apthera IOL	+10.0 D to +30.0 D	1.0% -1.6%	30,000 -562,000 mPas

CALCULATION OF LENS POWER: Accurate keratometry and biometry are essential to successful postoperative visual outcomes. The surgeon should preoperatively determine the power of the lens to be implanted. The **IC-8 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 no 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 described in the following references:

- Roberts TV, Hodge C, Sutton G, Lawless M; contributors to the Vision Eye Institute IOL outcomes registry. Comparison of Hill-radial basis function, Barrett Universal and current third generation formulas for the calculation of intraocular lens power during cataract surgery. Clin Exp Ophthalmol. 2018 Apr;46(3):240-246.
- Ijima K, Kamiya K, Iida Y, Shoji N. Comparison of Predictability Using Barrett Universal II and SRK/T Formulas according to Keratometry. J Ophthalmol. 2020 Jun 19;2020:7625725.
- Teshigawara T, Meguro A, Mizuki N. Influence of pupil dilation on the Barrett universal II (new generation), Haigis (4th generation), and SRK/T (3rd generation) intraocular lens calculation formulas: a retrospective study. BMC Ophthalmol. 2020 Jul 20;20(1):299.
- Kane JX, Van Heerden A, Atik A, Petsoglou C. Intraocular lens power formula accuracy: Comparison of 7 formulas. J Cataract Refract Surg. 2016 Oct;42(10):1490-1500.
- Melles RB, Holladay JT, Chang WJ. Accuracy of Intraocular Lens Calculation Formulas. Ophthalmology. 2018 Feb;125(2):169-178.
- Muniz Castro H, Tai AX, Sampson SJ, Wade M, Farid M, Garg S. Accuracy of Intraocular Lens Power Calculation Using Anterior Chamber Depth from Two Devices with Barrett Universal II Formula. J Ophthalmol. 2019 Sep 23;2019:8172615.
- Holladay JT. Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations. J Cataract Refract Surg. 1997 Nov;23(9):1356-70.

SUGGESTED A-CONSTANT: The A-constant values for optical biometry and contact ultrasound biometry are presented as a guideline (**Table 4**), and 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.

Table 4: Suggested A-Constant

	Optical Biometry	**Ultrasound Biometry**
A-constant	120.5	120.15
Anterior Chamber Depth (ACD)	6.42	6.22
Surgeon Factor	2.64	2.44

Note: Ultrasound lens ACD 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.

DIRECTIONS FOR USE: (Read the entire directions before using this device.)

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.
2. In a sterile environment, open the blister-pack by peeling open the lid (made of DuPont™ Tyvek® material) and remove the lens vial.

CAUTION: Content is sterile until the blister-pack is damaged or opened. Inspect the blister-pack carefully for tears, punctures, or other signs that the blister-pack has been damaged or opened (e.g., wet packaging, cracked glass vial). Do not implant the lens if the sterility has been compromised.

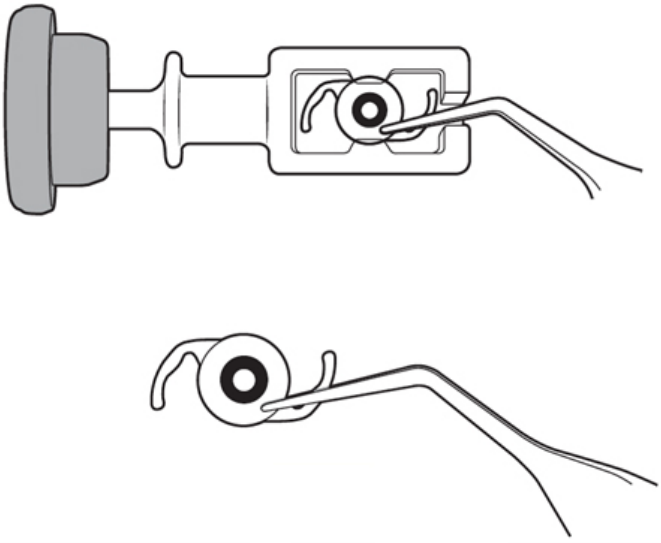
3. Before opening the vial, confirm that the fluid is completely covering the lens when the vial is in the upright position (**Figure 4**).

Figure 4

Figure 5a

Figure 5b

4. Remove cap from the vial and expose the twist-cap lens holder (Figures 5a & 5b). 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) as shown in (Figures 6a & 6b). Do not grasp the optic body. Inspect the lens for any defects.



5. Prior to insertion, carefully ensure the lens is properly loaded into the cartridge and the cartridge is locked into the injector.
   IMPORTANT: Only use the AST bioli™ IOL Delivery System (Model BIOLI-A1) and ophthalmic viscosurgical devices (OVDs) with a sodium hyaluronate (NaHy) concentration of 1.0% -1.6% and zero-shear viscosity of 30,000 -562,000 mPas, as they have been validated for use with the **IC-8 Apthera** IOL.* Follow the instructions for use provided with those devices by their respective manufacturers (not supplied with the **IC-8 Apthera** IOL.)
6. Insert the lens carefully into the eye capsular bag. Place and center the lens using a suitable positioning instrument.

*Data on file, AcuFocus, Inc.

CLINICAL STUDY OF THE IC-8 APTHERA IOL

The clinical study of the **IC-8 Apthera** IOL (referred to as the **IC-8** IOL) was a prospective, multi-center, open-label, parallel-group, non-randomized, examiner-masked, one-year clinical study conducted at 21 investigational sites in the United States. The study compared binocular performance of subjects in the **IC-8** IOL group, implanted with the **IC-8** IOL in one eye (**IC-8** IOL eye) with a monofocal or monofocal toric IOL in the fellow eye, to the binocular performance of subjects in the Control group, implanted bilaterally with monofocal or monofocal toric IOLs. The monocular performance of the eyes implanted with the **IC-8** IOL was compared to the monocular performance of the fellow eyes implanted with a monofocal or monofocal toric IOL.

The clinical study results achieved through 12 Months postoperatively demonstrate that the **IC-8** IOL is safe and effective for the visual correction of aphakia in eyes with up to 1.5 D of preoperative corneal astigmatism and provides continuous extended depth of focus from far through intermediate and near to mitigate the effects of presbyopia.

Clinical Study Population

A total of 453 subjects were implanted in this clinical study. In the **IC-8** IOL group, 343 subjects received implantation of the **IC-8** IOL in one eye and a monofocal (AcrySof® IQ SA60WF or TECNIS® ZCB00) or monofocal toric (AcrySof® IQ SA6AT3/ SA6AT4 or TECNIS® ZCT150/ ZCT225) IOL in their fellow eye. In the Control group, 110 subjects received bilateral implantation of the monofocal or monofocal toric IOLs. At the conclusion of the 12-month study, accountability was 98.8% (331/335) for the IC-8 group (**Table 5**) and 95.3% (101/106) for the Control group (**Table 6**).

Table 5 IC-8 Group Subject Accountability (N=343) (n/N, %)

	Day 1 (1st Eye)	Week 1 (1st Eye)	Month 1 (1st Eye)	Day 1 (2nd Eye)	Week 1 (2nd Eye)	Month 1 (2nd Eye)	Month 3	Month 6	Month 12
Active	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%
Available for Analysis	343/343 100.0%	343/343 100.0%	342/343 99.7%	342/343 99.7%	343/343 100.0%	341/343 99.4%	340/343 99.1%	335/343 97.7%	331/343 96.5%
Missing Subjects	0/343 0.0%	0/343 0.0%	1/343 0.3%	1/343 0.3%	0/343 0.0%	2/343 0.6%	3/343 0.9%	8/343 2.3%	12/343 3.5%

Discontinued*	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	3/343 0.9%	3/343 0.9%	8/343 2.3%**
Lost to follow-up	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	0/343 0.0%	3/343 0.9%†	4/343 1.2%†
Missed Visit	0/343 0.0%	0/343 0.0%	1/343 0.3%	1/343 0.3%	0/343 0.0%	2/343 0.6%	0/343 0.0%	2/343 0.6%	0/343 0.0%
Accountability	343/343 100.0%	343/343 100.0%	342/343 99.7%	342/343 99.7%	343/343 100.0%	341/343 99.4%	340/340 100.0%	335/340 98.5%	331/335 98.8%

*Discontinued includes subjects that were discontinued due to reasons other than lost to follow-up. Discontinued counts and Lost to follow-up (LTFU) counts are cumulative from the first visit interval onward to each respective column.
**For Discontinued counts in Month 12 column, subjects who missed Month 12 visit and were subsequently exited after the visit window closed (3 withdrew consents) are included with the subjects who were exited cumulative through the Month 12 visit window (5 discontinued due to other reasons).
†For LTFU counts, subjects were counted as lost to follow-up after the last visit at which they were seen, regardless of when they were subsequently exited.
Note: The early study visits (Day 1, Week 1, Month 1) are presented by eye; the order of these visits listed for accountability does not necessarily represent the actual order of the visits.
Accountability = Available for Analysis / (N – Discontinued – Active). Other percentages were calculated as (n / N) * 100%.

Table 6 Control Group Subject Accountability (N=110) (n/N, %)

	Day 1 (1st Eye)	**Week 1 (1st Eye)**	**Month 1 (1st Eye)**	**Day 1 (2nd Eye)**	**Week 1 (2nd Eye)**	**Month 1 (2nd Eye)**	**Month 3**	**Month 6**	**Month 12**
Active	0/110 0.0%	0/110 0.0%	0/110 0.0%	0/110 0.0%	0/110 0.0%	0/110 0.0%	0/110 0.0%	0/110 0.0%	0/110 0.0%
Available for Analysis	110/110 100.0%	110/110 100.0%	109/110 99.1%	110/110 100.0%	109/110 99.1%	108/110 98.2%	106/110 96.4%	100/110 90.9%	101/110 91.8%
Missing Subjects	0/110 0.0%	0/110 0.0%	1/110 0.9%	0/110 0.0%	1/110 0.9%	2/110 1.8%	4/110 3.6%	10/110 9.1%	9/110 8.2%
Discontinued*	0/110 0.0%	0/110 0.0%	1/110 0.9%	0/110 0.0%	0/110 0.0%	1/110 0.9%	1/110 0.9%	3/110 2.7%	4/110 3.6%
Lost to follow-up	0/110 0.0%	0/110 0.0%	0/110 0.0%	0/110 0.0%	0/110 0.0%	1/110 0.9%†	3/110 2.7%†	5/110 4.5%†	5/110 4.5%†
Missed Visit	0/110 0.0%	0/110 0.0%	0/110 0.0%	0/110 0.0%	1/110 0.9%	0/110 0.0%	0/110 0.0%	2/110 1.8%	0/110 0.0%
Accountability	110/110 100.0%	110/110 100.0%	109/109 100.0%	110/110 100.0%	109/110 99.1%	108/109 99.1%	106/109 97.2%	100/107 93.5%	101/106 95.3%

*Discontinued includes subjects that were discontinued due to reasons other than lost to follow-up. Discontinued counts and Lost to follow-up (LTFU) counts are cumulative from the first visit interval onward to each respective column.
†For LTFU counts, subjects were counted as lost to follow-up after the last visit at which they were seen, regardless of when they were subsequently exited.
Note: The early study visits (Day 1, Week 1, Month 1) are presented by eye; the order of these visits listed for accountability does not necessarily represent the actual order of the visits.
Accountability = Available for Analysis / (N – Discontinued – Active). Other percentages were calculated as (n / N) * 100%.

Allocation of treatment groups was based on subject preference and was confirmed by the Investigator prior to enrollment into each treatment group and subsequent IOL implantation. The Investigator determined the monofocal eye and the **IC-8** eye based on the following factors: sighting dominance, patient's occupational and/or recreational needs, history of monovision contact lens wear, habitual spectacle prescription, worst cataract eye, or available lens powers, so as to achieve the best predicted overall outcome for the subject. In 91.5% (314/343) of **IC-8** subjects, the **IC-8** IOLs were implanted in the non-dominant eye.

The study population demographics were similar between the two groups, except the control group enrolled more subjects aged 80 years and older (**Table 7**).

Table 7 Demographics

Parameters	**IC-8 Group (N=343)**		**Control Group (N=110)**		**Overall (N=453)**	
Age (years)						
Mean (SD)	66.1 (7.96)		69.1 (8.63)		66.8 (8.22)	
Median	67.0		70.0		67.0	
Q1, Q3	61.0, 71.0		64.0, 75.0		62.0, 72.0	
Min, Max	36, 85		45, 90		36, 90	
95% CI	65.2, 66.9		67.5, 70.8		66.1, 67.6	
Age Group (n/N, %)						
< 60	70/343	20.4%	12/110	10.9%	82/453	18.1%
60-69	152/343	44.3%	42/110	38.2%	194/453	42.8%
70-79	108/343	31.5%	42/110	38.2%	150/453	33.1%
≥ 80	13/343	3.8%	14/110	12.7%	27/453	6.0%
Sex (n/N, %)						
Male	132/343	38.5%	34/110	30.9%	166/453	36.6%
Female	211/343	61.5%	76/110	69.1%	287/453	63.4%
Race (n/N, %)						
American Indian/Alaska Native	1/343	0.3%	1/110	0.9%	2/453	0.4%
Asian	3/343	0.9%	3/110	2.7%	6/453	1.3%
Black/African American	22/343	6.4%	6/110	5.5%	28/453	6.2%
White	311/343	90.7%	99/110	90.0%	410/453	90.5%
Other	6/343	1.7%	1/110	0.9%	7/453	1.5%
Ethnicity (n/N, %)						
Hispanic/Latino	22/343	6.4%	10/110	9.1%	32/453	7.1%
Not Hispanic/Latino	320/343	93.3%	100/110	90.9%	420/453	92.7%
Unknown	1/343	0.3%	0/110	0.0%	1/453	0.2%
Iris Color (n/N, %)						
Blue	105/343	30.6%	43/110	39.1%	148/453	32.7%
Brown	153/343	44.6%	49/110	44.5%	202/453	44.6%
Gray	1/343	0.3%	0/110	0.0%	1/453	0.2%
Green	28/343	8.2%	6/110	5.5%	34/453	7.5%
Other	56/343	6.3%	12/110	10.9%	68/453	15.0%

N = Total # in the Analysis population. n = # subjects with data in the respective category. % = n /N *100%.
Abbreviations: Q1, Q3=First and third quartile; SD=Standard Deviation.
IC-8 and Control Groups were compared with Fisher's exact tests for binary variables, Chi-square tests for categorical variables, and a t-test for continuous variables.

Manifest Refraction

In both the **IC-8** IOL and Control groups, the first eyes were implanted with a monofocal or monofocal toric IOL targeted for emmetropia (plano to -0.50 D MRSE) and had to achieve the qualification criteria within the 1-week to 1-month visit of: 20/32 or better UCDVA and 20/25 or better BCDVA; no ongoing ocular adverse events; and normal corneal health as assessed by slit lamp biomicroscopy (Grade 1+ or less edema and Grade 1 or less SPK).

In the **IC-8** IOL group, subjects were implanted with the **IC-8** IOL in the second eye with a target MRSE of -0.75 D (no more plus than -0.75 D and not more minus than -1.00 D). In the Control group, subjects were implanted with a monofocal or monofocal toric IOL in the second eye, which was targeted for emmetropia (plano to -0.50 D MRSE).

If the predicted residual refractive cylinder was ≥ 0.75 D and a monofocal toric IOL was not indicated, limbal relaxing incisions (LRIs) were allowed for minimization of residual astigmatism during initial surgery for all monofocal IOL eyes in the **IC-8** IOL and Control groups.

Table 8 provides the mean intended target spherical equivalent refraction for the chosen IOL power implanted in the IDE clinical trial, showing -0.852 D mean target refraction for the **IC-8** IOL and -0.112 to -0.146 D mean target refraction for monofocal or monofocal toric IOLs.

Manifest refraction was conducted using the duochrome technique in the study with a computerized test system (CTS, M&S® Technologies, Niles, IL). Mean ± SD manifest spherical equivalent (MRSE) at 6 Months in the **IC-8** IOL eyes was -0.314 ±0.4637, and -0.021 ±0.3815 in the second eyes of the Control group. In the first monofocal or monofocal toric eyes, mean ± SD MRSE was 0.073 ±0.3679 for the **IC-8** IOL group and 0.003 ±0.3589 for the Control group subjects.

Table 9 shows the percentages of absolute MRSE at 6 Months by treatment groups compared to the intended target spherical equivalent manifest refraction, indicating over 85% of eyes were within ≤ 1.00 D in both groups.

Table 8
Mean Intended Target Spherical Equivalent (for IOL Implantation)

Target Spherical Equivalent (D)	IC-8 Group		Control Group	
	IC-8 Eyes (N=343)	Fellow Eyes (N=343)	Second Eyes (N=110)	First Eyes (N=110)
Mean (SD)	-0.852 (0.1351)	-0.112 (0.1553)	-0.146 (0.1296)	-0.145 (0.1309)
Median	-0.860	-0.110	-0.140	-0.150
Min, Max	-1.30, -0.20	-0.62, 0.37	-0.52, 0.16	-0.51, 0.23
95% CI	-0.867, -0.838	-0.129, -0.096	-0.171, -0.122	-0.169, -0.120

Table 9
Percentage of Absolute MRSE vs. Intended Target at 6 Months

	IC-8 Group		Control Group	
MRSE vs. Target	**IC-8 Eyes n/N (%)**	**Fellow Eyes n/N (%)**	**Second Eyes n/N (%)**	**First Eyes n/N (%)**
≤ 0.25 D	62/334 (18.6%)	162/334 (48.5%)	47/100 (47.0%)	46/100 (46.0%)
≤ 0.50 D	139/334 (41.6%)	258/334 (77.2%)	82/100 (82.0%)	76/100 (76.0%)
≤ 1.00	287/334 (85.9%)	327/334 (97.9%)	99/100 (99.0%)	99/100 (99.0%)
> 1.00 D	47/334 (14.1%)	7/334 (2.1%)	1/100 (1.0%)	1/100 (1.0%)

Clinical Study Results

All co-primary effectiveness objectives were exceeded in the study, demonstrating statistical superiority of the **IC-8** IOL group to the Control group in mean binocular uncorrected intermediate and near visual acuities, as well as statistical non-inferiority in mean binocular uncorrected distance visual acuity. Monocularly, the **IC-8** IOL eyes demonstrated statistical superiority to the fellow monofocal/monofocal toric IOL implanted eyes in distance-corrected intermediate visual acuity in the **IC-8** IOL group. The monocular negative defocus range for the **IC-8** IOL eyes at the 0.2 logMAR visual acuity threshold was approximately 1 D greater when compared to the monofocal/monofocal toric IOL eyes, exceeding the > 0.5 D criterion for success. All co-primary effectiveness results were evaluated for the Intent-to-Treat (ITT) population of all subjects who completed enrollment and were bilaterally implanted in the study.

The secondary effectiveness endpoint was achieved in the assessment of vision in **IC-8** IOL eyes with up to 1.5 D of preoperative corneal astigmatism, demonstrated by statistical non-inferiority in monocular uncorrected distance visual acuity in eyes with 1 to 1.5 D of preoperative corneal astigmatism to eyes with < 1.0 D of preoperative corneal astigmatism. The secondary effectiveness endpoint was evaluated in the modified Intent-to-Treat (mITT) population, which included all eyes implanted with the **IC-8** IOL that achieved BCDVA 20/25 or better.

The safety objectives included a comparison of best-corrected distance visual acuity and adverse event rates for the **IC-8** IOL eyes to the ISO 11979-7:2014 Safety and Performance Endpoint (SPE) rates. Monocular and binocular photopic and mesopic contrast sensitivity (with and without glare) were also evaluated. The safety analyses were conducted using the Safety population, which was identical to the ITT population in this study.

Overall, the results of the clinical study demonstrate that at 12 Months post implantation, the **IC-8** IOL is safe and effective for the visual correction of aphakia in eyes with up to 1.5 D of preoperative corneal astigmatism, and provided statistical superiority for mean binocular uncorrected intermediate and near visual acuity, statistical superiority for monocular distance-corrected intermediate visual acuity, statistical non-inferiority for monocular best-corrected distance visual acuity, and increased monocular depth of focus when compared with a monofocal or monofocal toric IOL.

Primary Effectiveness Study Results

Measurements of the co-primary effectiveness endpoints of binocular uncorrected intermediate visual acuity (UCIVA), binocular uncorrected near visual acuity (UCNVA), binocular uncorrected distance visual acuity (UCDVA), monocular distance-corrected intermediate visual acuity (DCIVA) and defocus curves were conducted under photopic conditions using ETDRS charts produced in a computerized test system (CTS, M&S® Technologies, Niles, IL). Monocular and binocular visual acuity data were collected at distance (4 m), intermediate (66 cm), and near (40 cm).

Binocular Visual Acuity

Results of the co-primary endpoints of binocular photopic uncorrected distance (4 m) visual acuity (UCDVA), intermediate (66 cm) visual acuity (UCIVA), and near (40 cm) visual acuity (UCNVA) for the **IC-8** IOL group and Control group are presented in **Table 10** and **Table 11**. Overall, the **IC-8** IOL group was statistically superior to the Control group in binocular uncorrected intermediate and near visual acuities, and statistically non-inferior in uncorrected distance visual acuity, exceeding all pre-defined success criteria:

- The **IC-8** IOL group provided mean binocular photopic UCDVA statistically non-inferior to the Control group with a 0.1 logMAR margin (p-value <.0001) (**Table 10**), and also met the clinical performance co-primary endpoint with 89.6% (300/335) of **IC-8** IOL subjects achieving UCDVA of 0.1 logMAR or better at 6 Months (exceeding the 50% clinical success criterion) (**Table 11**).
- The **IC-8** IOL group provided mean binocular photopic UCIVA statistically superior to the Control group with a difference of 1.8 lines (p-value <.0001) (**Table 10**).
- The **IC-8** IOL group met the clinical performance co-primary endpoint with 79.1% (265/335) of **IC-8** IOL subjects achieving UCIVA of 0.1 logMAR or better (exceeding the 50% clinical success criterion), which was 57.1% higher than the Control group subjects at 6 Months (exceeding the 25% clinical success criterion) (**Table 11**).
- The **IC-8** IOL group provided mean binocular photopic UCNVA statistically superior to the Control group with a difference of 1.9 lines (p-value <.0001) (**Table 10**).
- The **IC-8** IOL group met the clinical performance co-primary endpoint with 83.6% (280/335) of **IC-8** IOL subjects achieving UCNVA of 0.3 logMAR or better (exceeding the 50% clinical success criterion), and 50.6% higher than the Control group subjects at 6 Months (exceeding the 25% clinical success criterion) (**Table 11**).

Table 10
Mean Binocular Photopic UCDVA, UCIVA and UCNVA, 6 Months

Mean Binocular Visual Acuity	IC-8 IOL Group			Control Group			p-value	Difference in Means IC-8 IOL Group vs. Control Group (logMAR)
	N	Mean (logMAR)	Std. Dev.	N	Mean (logMAR)	Std. Dev.		
UCDVA	335	-0.010	0.1063	100	0.002	0.0992	<.0001	-0.012
UCIVA	335	0.051	0.1629	100	0.228	0.1646	<.0001	-0.177

UCNVA	335	0.186	0.1425	100	0.377	0.1576	<.0001	-0.191

Table 11
Proportion of Subjects Achieving logMAR VA Thresholds for Binocular Photopic UCDVA, UCIVA and UCNVA, 6 Months

Binocular Visual Acuity (logMAR)	**UCDVA**				**UCIVA**				**UCNVA**			
	IC-8 IOL Group		**Control Group**		**IC-8 IOL Group**		**Control Group**		**IC-8 IOL Group**		**Control Group**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**	**n/N**	**%**	**n/N**	**%**	**n/N**	**%**
0.00 or better	217/335	64.8%	55/110	55.0%	154/335	46.0%	7/110	7.0%	27/335	8.1%	2/110	2.0%
0.10 or better	300/335	89.6%	92/110	92.0%	265/335	79.1%	22/110	22.0%	111/335	33.1%	5/110	5.0%
0.20 or better	321/335	95.8%	96/110	96.0%	299/335	89.3%	55/110	55.0%	219/335	65.4%	15/110	15.0%
0.30 or better	333/335	99.4%	99/110	99.0%	313/335	93.4%	79/110	79.0%	280/335	83.6%	33/110	33.0%
Worse than 0.30	2/335	0.6%	1/110	1.0%	22/335*	6.6%	21/110 **	21.0%	55/335*	16.4%	67/110 **	67.0%
*There were 19 and 17 **IC-8** IOL subjects whose binocular UCIVA and UCNVA scores were erroneously recorded to be worse than 0.3 logMAR, respectively, due to incorrect viewing distance used during testing. **There were 11 Control group subjects whose binocular UCIVA and UCNVA scores were erroneously recorded to be worse than 0.3 logMAR, due to incorrect viewing distance used during testing.												

Monocular Visual Acuity

Results of the co-primary endpoint of monocular photopic distance-corrected intermediate (66 cm) visual acuity (DCIVA) for the **IC-8** IOL eyes and the fellow monofocal/monofocal toric IOL eyes at 6 Months post implantation demonstrate that:

- The **IC-8** IOL eyes met the clinical performance co-primary endpoint with mean photopic monocular DCIVA statistically superior to the monofocal/monofocal toric IOL eyes with a mean difference of 1.8 lines (favoring the **IC-8** IOL) (p-value <.0001).
- 73.4% (246/335) of **IC-8** IOL eyes achieved DCIVA of 0.2 logMAR or better (**Table 12**), exceeding the 50% clinical success criterion.

Table 12
LogMAR Levels of Monocular Distance-corrected Intermediate Visual Acuity, 6 Months (IC-8 IOL Group)

DCIVA (logMAR)	**IC-8 IOL Eyes**		**Fellow Eyes**	
	n/N	**%**	**n/N**	**%**
0.00 or better	63/335	18.8%	4/335	1.2%
0.10 or better	172/335	51.3%	28/335	8.4%
0.20 or better	246/335	73.4%	90/335	26.9%

0.30 or better	299/335	89.3%	165/335	49.3%
Worse than 0.30	36/335*	10.7%	170/335*	50.7%
% = n /N *100%. * There were 20 subjects whose monocular DCIVA scores were erroneously recorded to be worse than 0.30 log MAR for **IC-8** IOL eyes and fellow eyes, due to incorrect viewing distance used during testing.				

Monocular Defocus Curve

Monocular photopic distance-corrected depth of focus curves were obtained at 3 Months for the **IC-8** IOL eyes and the fellow monofocal/monofocal toric IOL eyes (**Figures 7, 8, 9, 10, and 11**). Data were collected using a computerized visual acuity test system (CTS, M&S® Technologies, Niles, IL). The **IC-8** IOL eyes demonstrated visual acuity of 0.2 logMAR or better at the defocus range of +1 D to approximately -2 D, and the fellow eyes at the range of +1 D to approximately -1 D. The negative intercepts of the defocus curves on the 0.2 logMAR threshold line are -1.99 D for **IC-8** eyes and -1.08 D for fellow eyes, yielding a difference of 0.91 D favoring **IC-8** eyes. The approximately 1 D difference between the **IC-8** IOL eyes and fellow eyes over the negative defocus range exceeded the protocol-defined threshold of 0.5 D in favor of the **IC--8** IOL eyes, exceeding the clinical success criterion of 0.5 D for this endpoint.

Figure 7
Monocular Defocus Curves at 3 Months (IC-8 IOL Group) (Mean, 95% CI)
IC-8 IOL and Fellow Eyes

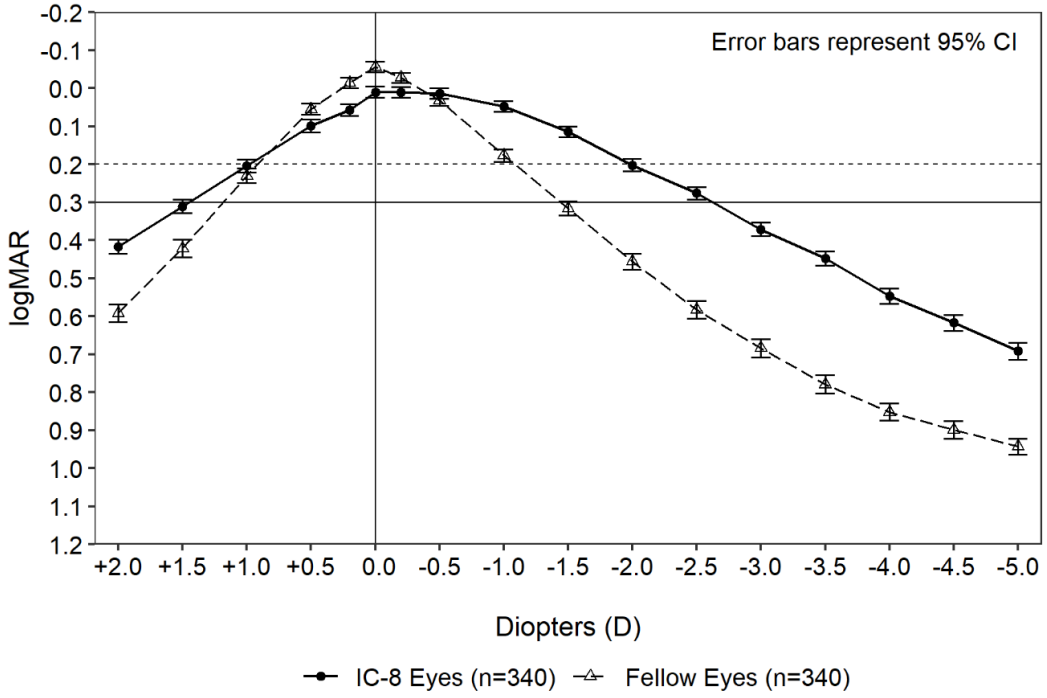


Figure 8
Monocular Defocus Curves at 3 Months (IC-8 IOL Group) (Mean, 1 SD)
IC-8 IOL and Fellow Eyes

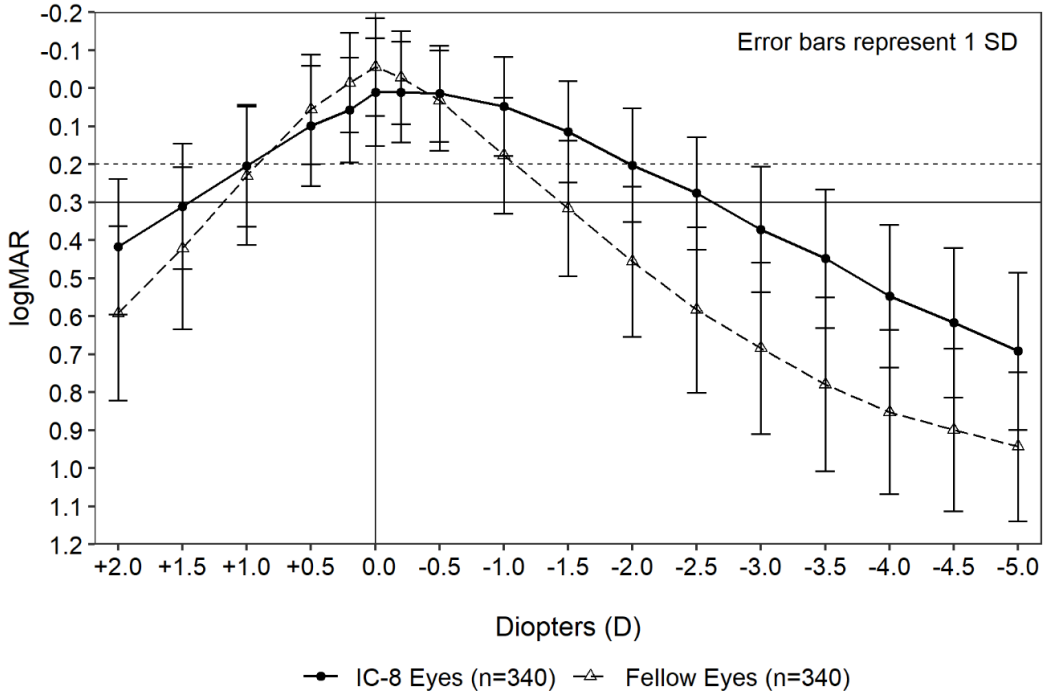


Figure 9
Monocular Defocus Curves at 3 Months (Mean, 95% CI)
IC-8 IOL Eyes vs. the Second Eyes in the Control IOL Group

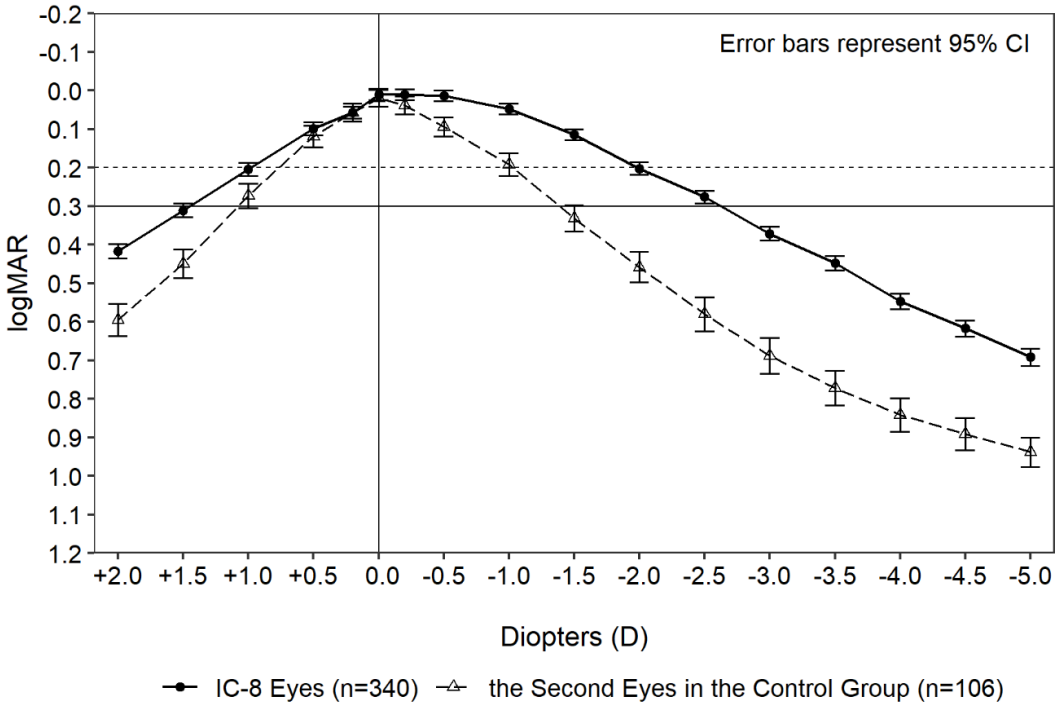


Figure 10
Mean Monocular Defocus Curves in IC-8 IOL Eyes at 3 Months
By Pupil Size Groups

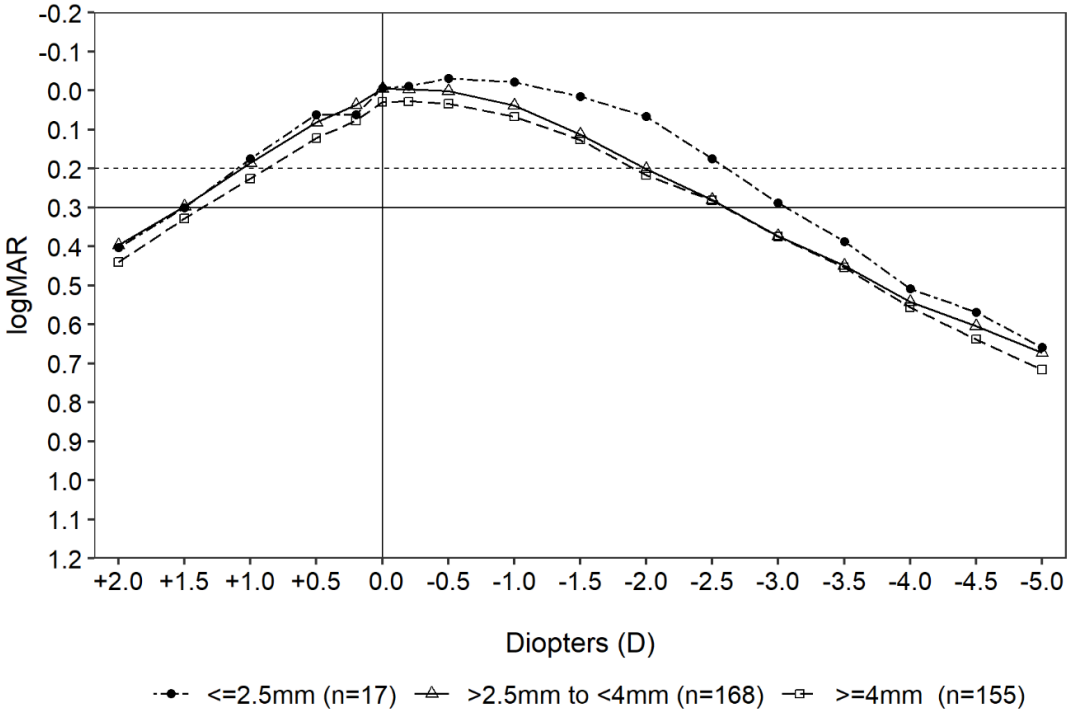
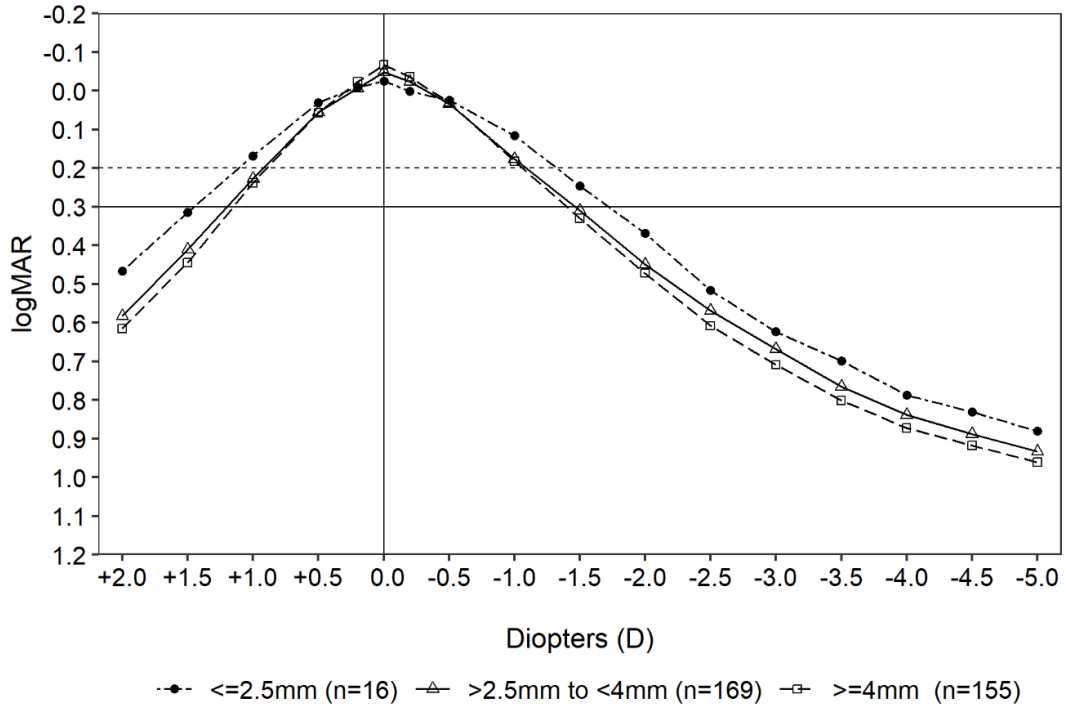


Figure 11
Mean Monocular Defocus Curves in Fellow Eyes (IC-8 IOL Group) at 3 Months
By Pupil Size Groups



Secondary Effectiveness Study Results

The measurement of the secondary effectiveness endpoint of monocular UCDVA was conducted under photopic conditions using ETDRS charts produced in a computerized test system (CTS, M&S® Technologies, Niles, IL). Visual acuity data were collected at far distance (4m).

Assessment of Astigmatism

Monocular uncorrected distance visual acuity was assessed in **IC-8** IOL eyes with < 1 D of preoperative corneal astigmatism (Astigmatism Group 1) and compared with **IC-8** IOL eyes with 1 D to 1.5 D of preoperative corneal astigmatism (Astigmatism Group 2). As shown in **Table 13**, Astigmatism Group 2 was statistically non-inferior to Astigmatism Group 1 in monocular UCDVA (mean difference of 0.023 logMAR; p <0.0001), supporting that the **IC-8** IOL provides consistent correction of aphakia with 20/25 average uncorrected distance vision for patients with up to 1.5 D of preoperative corneal astigmatism. Additionally, as shown in **Table 13**, the difference in UCIVA and UCNVA between Astigmatism Group 1 and Astigmatism Group 2 was within 0.1 logMAR. The results were calculated in the mITT population, including all eyes implanted with the **IC-8** IOL that achieved BCDVA 20/25 or better.

Table 13
Mean logMAR Monocular UCDVA, UCIVA, and UCNVA by Preoperative Corneal Astigmatism Group in IC-8 IOL Eyes with BCDVA 20/25 or better at 3 Months

Mean Monocular Visual Acuity	UCDVA		UCIVA		UCNVA	
	ASTG Group 1 (N=244)	ASTG Group 2 (N=65)	ASTG Group 1 (N=244)	ASTG Group 2 (N=65)	ASTG Group 1 (N=244)	ASTG Group 2 (N=65)
Mean	0.085	0.108	0.057	0.134	0.186	0.217
SD	0.1269	0.1208	0.1762	0.2302	0.1281	0.1487
Snellen	20/24	20/26	20/23	20/27	20/31	20/33
Mean Diff. in logMAR	--	0.023	--	0.077	--	0.031
p-value	--	<.0001	--	N/A	--	N/A

ASTG Group = Preoperative Corneal Astigmatism Group

Other Study Results

Binocular Visual Accuity

Mean binocular best-corrected distance and distance-corrected intermediate and near visual acuities for the **IC-8** IOL group and Control group are presented in **Table 14**, and categorical Snellen and logMAR visual acuities are presented in **Table 15** and **Table 16**, respectively.

Table 14
Mean Binocular Photopic BCDVA, DCIVA and DCNVA, 6 Months

Mean Binocular Visual Acuity	IC-8 IOL Group			Control Group		
	N	Mean (logMAR)	Std. Dev.	N	Mean (logMAR)	Std. Dev.
BCDVA	335	-0.084	0.0902	100	-0.068	0.0778
DCIVA	335	0.113	0.1534	100	0.288	0.1611
DCNVA	335	0.265	0.1416	100	0.427	0.1503

Table 15
Proportion of Subjects Achieving Snellen Visual Acuity Thresholds for Binocular Photopic BCDVA, DCIVA and DCNVA, 6 Months

Binocular Distance-corrected Visual Acuity (Snellen)	IC-8 Group		Control Group	
	n/N	%	n/N	%
BCDVA				
$20/20^{-2}$ or better	318/335	94.9%	93/100	93.0%
$20/25^{-2}$ or better	332/335	99.1%	99/100	99.0%
$20/32^{-2}$ or better	334/335	99.7%	100/100	100.0%
$20/40^{-2}$ or better	334/335	99.7%	100/100	100.0%
Worse than $20/40^{-2}$	1/335	0.3%	0/100	0.0%
DCIVA				
$20/20^{-2}$ or better	134/335	40.0%	2/100	2.0%
$20/25^{-2}$ or better	247/335	73.7%	15/100	15.0%
$20/32^{-2}$ or better	292/335	87.2%	45/100	45.0%
$20/40^{-2}$ or better	307/335	91.6%	72/100	72.0%
Worse than $20/40^{-2}$	28/335*	8.4%	28/100**	28.0%
DCNVA				
$20/20^{-2}$ or better	15/335	4.5%	0/100	0.0%
$20/25^{-2}$ or better	74/335	22.1%	1/100	1.0%
$20/32^{-2}$ or better	164/335	49.0%	10/100	10.0%
$20/40^{-2}$ or better	252/335	75.2%	33/100	33.0%
Worse than $20/40^{-2}$	83/335*	24.8%	67/100**	67.0%

Binocular Distance-corrected Visual Acuity (Snellen)	IC-8 Group		Control Group	
	n/N	%	n/N	%
Snellen VA was converted from logMAR VA. A Snellen notation of $20/20^{-2}$ or better is equivalent to a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly. *There were 19 and 18 **IC-8** IOL subjects whose binocular DCIVA and DCNVA scores were erroneously recorded to be worse than $20/40^{-2}$, respectively, due to incorrect viewing distance used during testing. **There were 11 Control group subjects whose binocular DCIVA and DCNVA scores were erroneously recorded to be worse than $20/40^{-2}$, due to incorrect viewing distance used during testing.				

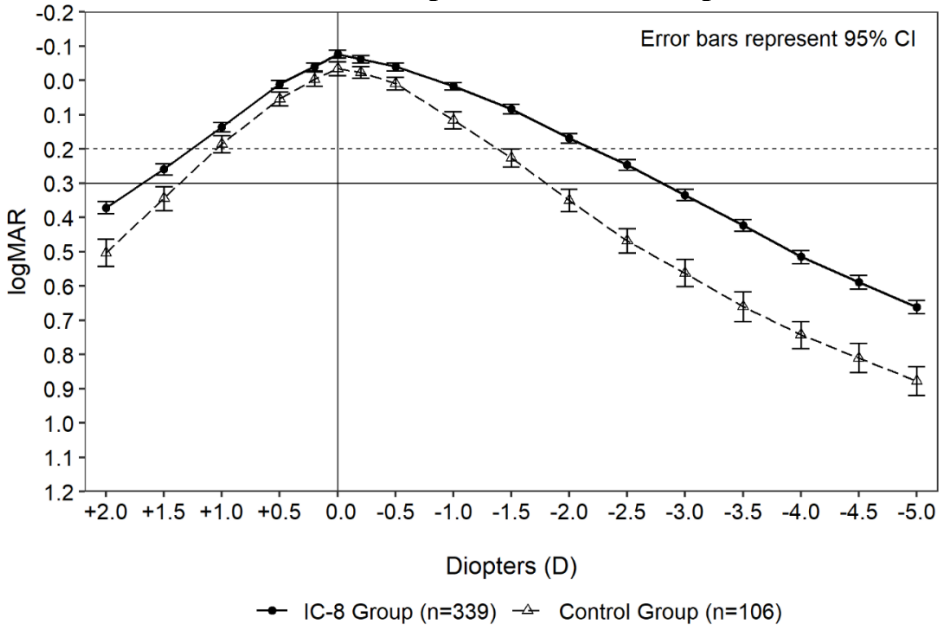
Table 16
Proportion of Subjects Achieving logMAR Visual Acuity Thresholds for Binocular Photopic BCDVA, DCIVA and DCNVA at 6 Months

Binocular Distance-Corrected Visual Acuity (logMAR)	IC-8 Group		Control Group	
	n/N	%	n/N	%
BCDVA				
0.00 or better	297/335	88.7%	87/100	87.0%
0.10 or better	330/335	98.5%	98/100	98.0%
0.20 or better	333/335	99.4%	100/100	100.0%
0.30 or better	334/335	99.7%	100/100	100.0%
Worse than 0.30	1/335	0.3%	0/100	0.0%
DCIVA				
0.00 or better	81/335	24.2%	1/100	1.0%
0.10 or better	207/335	61.8%	11/100	11.0%
0.20 or better	272/335	81.2%	40/100	40.0%
0.30 or better	306/335	91.3%	60/100	60.0%
Worse than 0.30	29/335*	8.7%	40/100**	40.0%
DCNVA				
0.00 or better	5/335	1.5%	0 /100	0.0%
0.10 or better	48/335	14.3%	1/100	1.0%
0.20 or better	130/335	38.8%	7/100	7.0%
0.30 or better	225/335	67.2%	27/100	27.0%
Worse than 0.30	110/335*	32.8%	73/100**	73.0%
*There were 19 and 20 **IC-8** IOL subjects whose binocular DCIVA and DCNVA scores were erroneously recorded to be logMAR worse than 0.30, respectively, due to incorrect viewing distance used during testing. **There were 11 Control group subjects whose binocular DCIVA and DCNVA scores were erroneously recorded to be logMAR worse than 0.30, due to incorrect viewing distance used during testing.				

Binocular Defocus Curves

Binocular photopic distance-corrected depth of focus curves were obtained at 3 months for the **IC-8** IOL group and the Control group (**Figure 12**). Data were collected using ETDRS charts in a computerized visual acuity test system (CTS, M&S® Technologies, Niles, IL). The negative intercepts of the defocus curves on the 0.2 logMAR threshold line are -2.21 D for **IC-8** group and -1.38 D for the Control group, yielding a difference of 0.82 D favoring the **IC-8** IOL group.

Figure 12
Binocular Defocus Curves at 3 Months (Mean, 95% CI)
IC-8 IOL Group and Control Group



Monocular Visual Accuity

Results of the monocular photopic BCDVA, DCIVA, and DCNVA for the **IC-8** IOL eyes and the fellow monofocal/monofocal toric IOL eyes at 6 Months post implantation are presented in **Table 14**. The **IC-8** IOL eyes achieved mean monocular photopic DCNVA with a difference of 0.217 lines over the fellow monofocal/monofocal toric IOL eyes (**Table 17**).

Table 17
Mean Monocular Photopic BCDVA, DCIVA and DCNVA, 6 Months (IC-8 IOL Group)

Mean Monocular Visual Acuity	IC-8 IOL Eyes			Fellow Eyes			p-value	Mean Difference IC-8 IOL Eyes vs. Fellow Eyes (logMAR)
	N	Mean (logMAR)	Std. Dev.	N	Mean (logMAR)	Std. Dev.		
BCDVA	335	0.008	0.1130	335	-0.066	0.1006	N/A	0.074

DCIVA	335	0.144	0.1709	335	0.325	0.1687	<.0001	-0.180
DCNVA	335	0.302	0.1441	335	0.519	0.1621	N/A	-0.217

Monocular photopic uncorrected acuity results (**Table 18**) at 6 Months demonstrate that the **IC-8** IOL eyes achieved comparable distance visual acuity to the fellow monofocal/monofocal toric IOL eyes, and better intermediate and near visual acuities by at least 2 lines (0.2 logMAR).

Table 18
Mean Monocular Photopic UCDVA, UCIVA and UCNVA, 6 Months (IC-8 IOL Group)

Mean Monocular Visual Acuity	IC-8 IOL Eyes			Fellow Eyes		
	N	Mean (logMAR)	Std. Dev.	N	Mean (logMAR)	Std. Dev.
UCDVA	335	0.128	0.1420	335	0.034	0.1259
UCIVA	335	0.081	0.1881	335	0.292	0.1801
UCNVA	335	0.206	0.1569	335	0.483	0.1689

Table 19
Proportion of Subjects Achieving Snellen Visual Acuity Thresholds for Monocular Photopic UCDVA, UCIVA and UCNVA, 6 Months (IC-8 IOL Group)

Monocular Uncorrected Visual Acuity (Snellen)	IC-8 Eyes		Fellow Eyes	
	n/N	%	n/N	%
UCDVA				
$20/20^{-2}$ or better	97/335	29.0%	192/335	57.3%
$20/25^{-2}$ or better	201/335	60.0%	279/335	83.3%
$20/32^{-2}$ or better	282/335	84.2%	316/335	94.3%
$20/40^{-2}$ or better	318/335	94.9%	331/335	98.8%
Worse than $20/40^{-2}$	17/335	5.1%	4/335	1.2%
UCIVA				
$20/20^{-2}$ or better	177/335	52.8%	18/335	5.4%
$20/25^{-2}$ or better	264/335	78.8%	72/335	21.5%
$20/32^{-2}$ or better	299/335	89.3%	167/335	49.9%
$20/40^{-2}$ or better	310/335	92.5%	222/335	66.3%
Worse than $20/40^{-2}$	25/335*	7.5%	113/335**	33.7%
UCNVA				
$20/20^{-2}$ or better	52/335	15.5%	0/335	0.0%
$20/25^{-2}$ or better	137/335	40.9%	3/335	0.9%
$20/32^{-2}$ or better	225/335	67.2%	31/335	9.3%

20/40^{-2} or better	279/335	83.3%	74/335	22.1%
Worse than 20/40^{-2}	56/335*	16.7%	261/335**	77.9%

Snellen VA was converted from logMAR VA. A Snellen notation of 20/20^{-2} or better is equivalent to a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
*There were 20 and 18 **IC-8** IOL eyes whose monocular UCIVA and UCNVA scores were erroneously recorded to be worse than 20/40^{-2}, respectively, due to incorrect viewing distance used during testing.
**There were 20 fellow eyes whose monocular UCIVA and UCNVA scores were erroneously recorded to be worse than 20/40^{-2}, due to incorrect viewing distance used during testing.

Table 20
Proportion of Subjects Achieving logMAR Visual Acuity Thresholds for Monocular Photopic UCDVA, UCIVA and UCNVA at 6 Months (IC-8 IOL Group)

Monocular Uncorrected Visual Acuity (logMAR)	**IC-8 Eyes**		**Fellow Eyes**	
	n/N	**%**	**n/N**	**%**
UCDVA				
0.00 or better	68/335	20.3%	155/335	46.3%
0.10 or better	159/335	47.5%	261/335	77.9%
0.20 or better	264/335	78.8%	307/335	91.6%
0.30 or better	307/335	91.6%	327/335	97.6
Worse than 0.30	28/335	8.4%	8/335	2.4%
UCIVA				
0.00 or better	135/335	40.3%	9/335	2.7%
0.10 or better	234/335	69.9%	48/335	14.3%
0.20 or better	291/335	86.9%	129/335	38.5%
0.30 or better	308/335	91.9%	206/335	61.5%
Worse than 0.30	27/335*	8.1%	129/335**	38.5%
UCNVA				
0.00 or better	22/335	6.6%	0/335	0.0%
0.10 or better	98/335	29.3%	1/335	0.3%
0.20 or better	192/335	57.3%	16/335	4.8%
0.30 or better	263/335	78.5%	57/335	17.0%
Worse than 0.30	72/335*	21.5%	278/335**	83.0%

*There were 20 **IC-8** IOL eyes whose monocular UCIVA and UCNVA scores were erroneously recorded to be logMAR worse than 0.30, due to incorrect viewing distance used during testing.
There were 20 fellow eyes in the **IC-8 Group whose monocular UCIVA and UCNVA scores were erroneously recorded to be logMAR worse than 0.30, due to incorrect viewing distance used during testing.

+0.75D Distance-Corrected Visual Acuity

This assessment was performed at 6 Months with the best distance manifest refraction (infinity adjusted for each testing distance) in place for both eyes in each group, and a +0.75 D lens added in front of the **IC-8** eyes in the **IC-8** IOL group and in front of the second eyes in the Control group. The intention of this comparison was to simulate the intended target of -0.75 D for the **IC-8** IOL eye in the **IC-8** IOL group and to compare visual acuity results if the Control group had the same refractive mini-monovision target. Mean monocular and binocular +0.75D DCIVA, +0.75D DCNVA and +0.75D DCDVA were measured at 6 Months. The mean comparisons demonstrated that:

- **IC-8** IOL eyes and the **IC-8** IOL group achieved better monocular and binocular +0.75 D target-corrected visual acuity (1-2 lines better at intermediate and near, ≤ 0.5 lines better at distance) compared to the Control group.
- Mean +0.75D DCDVA, +0.75D DCIVA and +0.75D DCNVA in **IC-8** IOL eyes were 0.133, 0.071, and 0.183 logMAR, respectively, demonstrating visual outcomes better than 20/32 across far, intermediate, and near distances for **IC-8** IOL eyes.

All monocular and binocular +0.75D distance-corrected visual acuity results in **IC-8** IOL eyes and the **IC-8** IOL group met the pre-specified performance targets at each whole-line Snellen equivalent visual acuity category (**Tables 21-23**).

Table 21
Snellen Levels of Monocular and Binocular +0.75D Distance-Corrected Intermediate Visual Acuity at 6 Months

+0.75D DCIVA (Snellen)	**Monocular†**				**Binocular††**			
	IC-8 Group IC-8 Eyes		**Control Group Second Eyes**		**IC-8 Group**		**Control Group**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**	**n/N**	**%**
20/20 or better	147/335	43.9%	6/100	6.0%	188/335	56.1%	18/100	18.0%
20/25 or better	**240/335**	**71.6%**	**24/100**	**24.0%**	**278/335**	**83.0%**	**56/100**	**56.0%**
20/32 or better	286/335	85.4%	56/100	56.0%	307/335	91.6%	74/100	74.0%
20/40 or better	301/335	89.9%	76/100	76.0%	310/335	92.5%	85/100	85.0%
Worse than 20/40	34/335*	10.1%	24/100**	24.0%	25/335*	7.5%	15/100**	15.0%
Difference in percentage of eyes/subjects achieving 20/25 or better (%)	47.6		--		27.0		--	

*There were 20 **IC-8** IOL subjects whose monocular and binocular +0.75D DCIVA scores were erroneously recorded to be worse than 20/40, due to incorrect viewing distance used during testing.
**There were 11 Control group subjects whose monocular and binocular +0.75D DCIVA scores were erroneously recorded to be worse than 20/40, due to incorrect viewing distance used during testing.

† Monocular performance target: 25% more **IC-8** IOL eyes achieving 20/25 or better +0.75D DCIVA versus control eyes.
†† Binocular performance target: 25% more **IC-8** group subjects achieving 20/25 or better +0.75D DCIVA versus control group.
Snellen equivalent visual acuity categories in this analysis are defined with whole-line binning, e.g., Snellen 20/20 or better is equivalent to logMAR 0.00 or better.

Table 22
Snellen Levels of Monocular and Binocular +0.75D Distance-Corrected Near Visual Acuity at 6 Months

+0.75D DCNVA (Snellen)	**Monocular†**				**Binocular††**			
	IC-8 Group IC-8 Eyes		**Control Group Second Eyes**		**IC-8 Group**		**Control Group**	
	n/N	**%**	**n/N**	**%**	**n/N**	**%**	**n/N**	**%**
20/20 or better	33/335	9.9%	0/100	0.0%	37/335	11.0%	1/100	1.0%
20/25 or better	116/335	34.6%	3/100	3.0%	141/335	42.1%	6/100	6.0%
20/32 or better	210/335	62.7%	10/100	10.0%	246/335	73.4%	30/100	30.0%
20/40 or better	**280/335**	**83.6%**	**30/100**	**30.0%**	**300/335**	**89.6%**	**58/100**	**58.0%**
Worse than 20/40	55/335*	16.4%	70/100**	70.0%	35/335*	10.4%	42/100**	42.0%
Difference in percentage of eyes/subjects achieving 20/40 or better (%)	53.6		--		31.6		--	

*There were 15 **IC-8** IOL subjects whose monocular and binocular +0.75D DCNVA scores were erroneously recorded to be worse than 20/40, due to incorrect viewing distance used during testing.
**There were 9 Control group subjects whose monocular and binocular +0.75D DCNVA scores were erroneously recorded to be worse than 20/40, due to incorrect viewing distance used during testing.
† Monocular performance target: 25% more **IC-8** IOL eyes achieving 20/40 or better +0.75D DCNVA versus control eyes.
†† Binocular performance target: 25% more **IC-8** group subjects achieving 20/40 or better +0.75D DCNVA versus control group.
Snellen equivalent visual acuity categories in this analysis are defined with whole-line binning, e.g., Snellen 20/20 or better is equivalent to logMAR 0.00 or better.

Table 23
Snellen Levels of Monocular and Binocular +0.75D Distance-Corrected Distance Visual Acuity at 6 Months

	Monocular†	**Binocular††**

+0.75D DCDVA (Snellen)	IC-8 Group IC-8 Eyes		Control Group Second Eyes		IC-8 Group		Control Group	
	n/N	%	n/N	%	n/N	%	n/N	%
20/20 or better	67/335	20.0%	10/100	10.0%	125/335	37.3%	14/100	14.0%
20/25 or better	**156/335**	**46.6%**	**36/100**	**36.0%**	**239/335**	**71.3%**	**56/100**	**56.0%**
20/32 or better	263/335	78.5%	71/100	71.0%	316/335	94.3%	81/100	81.0%
20/40 or better	309/335	92.2%	91/100	91.0%	331/335	98.8%	99/100	99.0%
Worse than 20/40	26/335	7.8%	9/100	9.0%	4/335	1.2%	1/100	1.0%
Difference in percentage of eyes/subjects achieving 20/25 or better (%)	10.6		--		15.3		--	
† Monocular performance target: the percentage of **IC-8** IOL eyes achieving 20/25 or better +0.75D DCDVA not less than control eyes by more than 10%. †† Binocular performance target: the percentage of **IC-8** group subjects achieving 20/25 or better +0.75D DCDVA not less than control group by more than 10%.								

Safety Study Results

The safety of the **IC-8** IOL was established through the co-primary safety endpoints of monocular best-corrected distance visual acuity (BCDVA), rates of cumulative and persistent ocular adverse events, as well as the rate of **IC-8** IOL removals due to visual/optical reasons at 12 Months post implantation. The study results demonstrated that:

- **IC-8** IOL eyes were statistically non-inferior to the fellow eyes in monocular BCDVA.
- Proportion of **IC-8** IOL eyes with BCDVA of 0.3 logMAR or better met the ISO 11979-7:2014 SPE threshold rates.
- Rates of cumulative adverse events (AEs) were statistically significantly below the ISO 11979-7:2014 SPE rates, except for total secondary surgical interventions (SSIs).
- Rates of persistent AEs were statistically significantly below the ISO 11979-7:2014 SPE rates.
- There were no removals of the **IC-8** IOL reported during the study.[1]

[1] In the Control group, one subject was reported with bilateral IOL removal during the study, and replacement of both of their monofocal IOLs with different monofocal lenses due to visual complaints of dysphotopsia. Following exit from the IDE study but prior to completion of the 12-months post-operative period, one subject previously enrolled in the Control group had their monofocal IOL removed in one eye due to visual complaints of double vision and a "yellow tint", and two subjects previously enrolled in the **IC-8** IOL group had their **IC-8** IOLs removed. One subject had their **IC-8** IOL removed due to visual complaints of a "hinged blob". The Investigator believed that the cause may be one of three things: 1) Posterior Vitreous Detachment (PVD) or Vitreous consolidation, 2) A remnant of capsule in the subject's visual axis, 3) The YAG laser capsulotomy resulted in a "spot" (direct quote from Investigator) on the inner portion of the aperture resulting in a "little refractive spot change" (direct quote from Investigator). The other subject had their **IC-8** IOL removed due to subjective complaints of starburst, glare, and halo.

As shown in **Table 24**, the **IC-8** IOL eyes were statistically non-inferior to the fellow eyes in monocular BCDVA based on a difference in means of 0.068 logMAR, with 95% UCL of 0.082 logMAR that was lower than the statistical non-inferiority margin of 0.1 logMAR ($p<0.0001$).

Table 24
Mean logMAR Monocular Best-Corrected Distance Visual Acuity, 12 Months
(IC-8 IOL Group)

BCDVA	**IC-8 IOL Eyes (N=331)**	**Fellow Eyes (N=331)**
Mean (SD)	0.009 (0.1131)	-0.059 (0.0928)
Snellen equiv. of Mean	20/20	20/17
Mean Difference[a]	0.068	--
Mean Difference in Lines	0.7	--
p-value[b]	<.0001	--
95% Upper CL[c]	0.082	--

N = # subjects with available data for the respective parameter.
[a] Mean difference in logMAR was compared within subjects between **IC-8** eyes and fellow eyes in the **IC-8** Group.
[b] p-value based on mean logMAR difference using one-sided one-sample t-test with non-inferiority margin of 0.1 logMAR.
[c] One-sided 95% upper CL for mean difference less than the margin of 0.1 logMAR demonstrated noninferiority of **IC-8** eyes vs. the fellow eyes.

The proportion of **IC-8** IOL eyes that achieved BCDVA of 0.3 logMAR or better was 98.5% (326/331) and 98.7% (315/319) in the ITT (**Table 25**) and Best-Case (**Table 26**) analysis populations, respectively, and their corresponding 95% upper confidence limits exceeded the ISO 11979-7:2014 Safety and Performance Endpoint (SPE) threshold rates of 92.5% and 96.7%, respectively.

Table 25
LogMAR Levels of Monocular Best-Corrected Distance Visual Acuity at 12 Months
(IC-8 IOL Group)

Monocular BCDVA (logMAR)	**IC-8 IOL Eyes**		**Fellow Eyes**	
	n/N	**%**	**n/N**	**%**
0.00 or better	197/331	59.5%	265/331	80.1%
0.10 or better	277/331	83.7%	322/331	97.3%
0.20 or better	314/331	94.9%	329/331	99.4%
0.30 or better	326/331	98.5%	330/331	99.7%
Worse than 0.30	5/331	1.5%	1/331	0.3%
Not Reported	0		0	
p-value of logMAR 0.3 or better category percentage vs. SPE rate[a]	>0.999			
95% Upper CL of logMAR 0.3 or better category percentage[b]	99.4%			

% = n/N *100%.
[a] The proportion of **IC-8** eyes achieving BCDVA logMAR 0.3 or better compared to the SPE rate (92.5%) in ISO 11979-7:2014 using one-sided exact test based on binomial distribution. P-value > 0.05 indicates statistical success demonstrating the proportion was not less than the SPE rate.
[b] One-sided 95% upper CL for the proportion of **IC-8** eyes achieving BCDVA logMAR 0.3 or better based on exact binomial distribution.

Table 26
LogMAR Levels of Monocular Best-Corrected Distance Visual Acuity at 12 Months (IC-8 IOL Group, Best-Case Population)

Monocular BCDVA (logMAR)	IC-8 IOL Eyes		Fellow Eyes	
	n/N	%	n/N	%
0.00 or better	194/319	(60.8%)	258/319	80.9%
0.10 or better	268/319	(84.0%)	311/319	97.5%
0.20 or better	304/319	(95.3%)	317/319	99.4%
0.30 or better	315/319	(98.7%)	318/319	99.7%
Worse than 0.30	4/319	(1.3%)	1/319	0.3%
Not Reported	0		0	
p-value of logMAR 0.3 or better category percentage vs. SPE rate[a]	>0.999			
95% Upper CL of logMAR 0.3 or better category percentage[b]	99.6%			

% = n/N *100%.
[a] The proportion of best-case **IC-8** IOL eyes achieving BCDVA logMAR 0.3 or better compared to the SPE rate (96.7%) in ISO 11979-7:2014 using one-sided exact test based on binomial distribution. P-value > 0.05 indicates statistical success demonstrating the proportion was not less than the SPE rate.
[b] One-sided 95% upper CL for the proportion of **IC-8** IOL eyes achieving BCDVA logMAR 0.3 or better based on exact binomial distribution.
Note: The best-case population includes subjects with both eyes meeting the best-case criteria (no preoperative ocular pathology, no macular degeneration or pathology at any time, and no previous refractive surgery).

The rates of cumulative adverse events (AEs) for **IC-8** IOL eyes and fellow monofocal/monofocal toric IOL eyes, as compared to the ISO 11979-7:2014 Safety and Performance Endpoint (SPE) rates, are provided in **Table 27**.

The rates of cumulative AEs for the **IC-8** IOL eyes and their corresponding 95% lower confidence limits met (i.e., were lower than) the ISO 11979-7:2014 Safety and Performance Endpoint (SPE) rates for all AE categories except for total SSIs. The rate of SSIs (related and unrelated to the **IC-8** IOL) was statistically higher than the ISO 11979-7:2014 SPE rate. There were 10 **IC-8** IOL eyes with SSIs/procedures reported, and only 1 of which had an IOL intervention. The remaining **IC-8** IOL eyes had non-IOL interventions including 3 eyes with modified paracentesis procedures only, 1 eye with modified paracentesis procedures and a retained cortex removal procedure, 1 eye with a retained cortex removal procedure only, and 4 eyes with vitrectomies (2 eyes with vitrectomy

procedures only, 1 eye with a vitrectomy procedure and intravitreal injection procedures, 1 eye with a modified vitrectomy procedure concurrent with intravitreal injection) (**Table 27**). The one IOL-related intervention was a repositioning procedure due to vaulting of the IOL.

Table 27
Cumulative Ocular Serious Adverse Events in IC-8 IOL Eyes and Fellow Eyes through 12 Months (IC-8 IOL Group)

Cumulative SAE	SPE Rate	IC-8 Eyes				Fellow Eyes			
		n/N	%	95% LCL	p-value	n/N	%	95% LCL	p-value
Cystoid macular edema	3.0%	5/343	1.5%	0.6%	0.977	4/343	1.2%	0.4%	0.992
Hypopyon	0.3%	0/343	0.0%	0.0%	>0.999	0/343	0.0%	0.0%	>0.999
Endophthalmitis	0.1%	1/343	0.3%	0.0%	0.290	0/343	0.0%	0.0%	>0.999
Lens dislocated from posterior chamber	0.1%	0/343	0.0%	0.0%	>0.999	0/343	0.0%	0.0%	>0.999
Pupillary block	0.1%	0/343	0.0%	0.0%	>0.999	0/343	0.0%	0.0%	>0.999
Retinal detachment	0.3%	0/343	0.0%	0.0%	>0.999	0/343	0.0%	0.0%	>0.999
Secondary surgical intervention‡	0.8%	10/343	2.9%	1.6%	<.001	6/343	1.7%	0.8%	0.060
IOL repositioning	N/A	1/343	0.3%	0.0%	--	1/343	0.3%	0.0%	--
Removal of retained cortex	N/A	2/343	0.6%	0.1%	--	0/343	0.0%	0.0%	--
Vitrectomy	N/A	4/343	1.2%	0.4%	--	1/343	0.3%	0.0%	--
Modified paracentesis*	N/A	4/343	1.2%	0.4%	--	3/343	0.9%	0.2%	--
Intravitreal injection**	N/A	1/343	0.3%	0.0%	--	1/343	0.3%	0.0%	--
Laser retinopexy†	N/A	0/343	0.0%	0.0%	--	1/343	0.3%	0.0%	--
Other: Retinal vein occlusion	N/A	1/343	0.3%	0.0%	--	0/343	0.0%	0.0%	--

N = Total # in the Analysis population; n = # eyes with events in the respective AE category.
The rate of adverse event is based on the proportion of eyes with events, % = (n / N) * 100.
SPE = Safety and Performance Endpoints (SPE) rates per ISO 11979-7:2014 Table B.2 for posterior chamber IOL.
95% LCL = one-sided 95% lower confidence limit (based on exact binomial distribution). The SPE rate is considered not exceeded if the one-sided 95% lower CL for an AE is less than the SPE rate, equivalent to p-value greater than 0.05.
- Cystoid macular edema: Macular edema diagnosed by clinical examination and adjunct testing (e.g., OCT, FA) resulting in BCDVA of 20/40 or worse at 1 month or later.
- Endophthalmitis: Intraocular inflammation leading to diagnostic vitreous tap and intraocular antibiotics
- Any other AEs that were standard medical diagnoses were coded per MedDRA.
* Modified paracentesis procedure (also known as 'burping the wound') in the study were all performed in an exam room via the slit-lamp as an outpatient procedure to expel excess aqueous

from the eye via the original incision (paracentesis) site to lower intraocular pressure. No procedure involved the creation of a new incision or disruption of the original incision site to release the aqueous. There were 6 modified paracentesis procedures in 4 **IC-8** Eyes, with 3 procedures in 1 **IC-8** Eye (which also had a removal of retained cortex). There were 3 modified paracentesis procedures in 3 Fellow Eyes.
** Intravitreal injection as treatment for cystoid macular edema.
† Laser retinopexy as treatment for operculated tear.
‡ No **IC-8** IOL removals were reported during the study. In the Control group, one subject was reported with bilateral IOL removal during the study, and replacement of both of their monofocal IOLs with different monofocal lenses due to visual complaints of dysphotopsia. Following exit from the IDE study but prior to completion of the 12-months post-operative period, one subject previously enrolled in the Control group had their monofocal IOL removed in one eye due to visual complaints of double vision and a "yellow tint", and two subjects previously enrolled in the **IC-8** IOL group had their **IC-8** IOLs removed. One subject had their **IC-8** IOL removed due to visual complaints of a "hinged blob". The Investigator believed that the cause may be one of three things: 1) Posterior Vitreous Detachment (PVD) or Vitreous consolidation, 2) A remnant of capsule in the subject's visual axis, 3) The YAG laser capsulotomy resulted in a "spot" (direct quote from Investigator) on the inner portion of the aperture resulting in a "little refractive spot change" (direct quote from Investigator). The other subject had their **IC-8** IOL removed due to subjective complaints of starburst, glare, and halo.

As presented in **Table 28**, two of the vitrectomies were pars-planar vitrectomies performed to treat posterior capsular remnants following YAG laser capsulotomies; both related to difficulty the Investigator experienced when performing the YAG laser capsulotomies in the **IC-8** IOL eyes. One vitrectomy was performed to treat visually significant floaters that were also present preoperatively and assessed by the Investigator as not related to the study device; a vitrectomy was also performed in the fellow eye of this subject to treat visually significant floaters that were present preoperatively. One vitrectomy was a modified vitrectomy concurrent with intravitreal injection performed to treat a case of endophthalmitis, assessed by the Investigator as unlikely related to the study device and possibly related to the procedure.

Table 28
Postoperative Ocular Adverse Events through 12 Months:
Secondary Surgical Interventions

SSI	IC-8 Group				Control Group			
	IC-8 Eyes		Fellow Eyes		Second Eyes		First Eyes	
	n/N	%	n/N	%	n/N	%	n/N	%
	90% CI		90% CI		90% CI		90% CI	
Intravitreal injection	1/343	0.3%	1/343	0.3%	0/110	0.0%	1/110	0.9%
	0.0%, 1.4%		0.0%, 1.4%		0.0%, 2.7%		0.0%, 4.2%	
IOL exchange*	0/343	0.0%	0/343	0.0%	1/110	0.9%	1/110	0.9%
	0.0%, 0.9%		0.0%, 0.9%		0.0%, 4.2%		0.0%, 4.2%	
IOL repositioning	1/343	0.3%	1/343	0.3%	0/110	0.0%	1/110	0.9%
	0.0%, 1.4%		0.0%, 1.4%		0.0%, 2.7%		0.0%, 4.2%	

Iris reposition	0/343	0.0%	0/343	0.0%	0/110	0.0%	1/110	0.9%
	0.0%, 0.9%		0.0%, 0.9%		0.0%, 2.7%		0.0%, 4.2%	
Laser retinopexy	0/343	0.0%	1/343	0.3%	0/110	0.0%	0/110	0.0%
	0.0%, 0.9%		0.0%, 1.4%		0.0%, 2.7%		0.0%, 2.7%	
Laser Vitreolysis	0/343	0.0%	0/343	0.0%	1/110	0.9%	0/110	0.0%
	0.0%, 0.9%		0.0%, 0.9%		0.0%, 4.2%		0.0%, 2.7%	
Modified paracentesis**	4/343	1.2%	3/343	0.9%	0/110	0.0%	1/110	0.9%
	0.4%, 2.6%		0.2%, 2.2%		0.0%, 2.7%		0.0%, 4.2%	
Removal of retained cortex	2/343	0.6%	0/343	0.0%	0/110	0.0%	0/110	0.0%
	0.1%, 1.8%		0.0%, 0.9%		0.0%, 2.7%		0.0%, 2.7%	
Vitrectomy	4/343	1.2%	1/343	0.3%	0/110	0.0%	0/110	0.0%
	0.4%, 2.6%		0.0%, 1.4%		0.0%, 2.7%		0.0%, 2.7%	
– to remove posterior capsular remnant	2/343	0.6%	0/343	0.0%	0/110	0.0%	0/110	0.0%
	0.1%, 1.8%		0.0%, 0.9%		0.0%, 2.7%		0.0%, 2.7%	
– to treat endophthalmitis	1/343	0.3%	0/343	0.0%	0/110	0.0%	0/110	0.0%
	0.0%, 1.4%		0.0%, 0.9%		0.0%, 2.7%		0.0%, 2.7%	
– to remove bilateral vitreous floaters	1/343	0.3%	1/343	0.3%	0/110	0.0%	0/110	0.0%
	0.0%, 1.4%		0.0%, 1.4%		0.0%, 2.7%		0.0%, 2.7%	

N = Total # in the Analysis population; n = # eyes with events in the respective AE category.
The rate of adverse event is based on the proportion of eyes with events, % = (n / N) * 100.
90% CI = two-sided 90% confidence interval (based on exact binomial distribution).
*No **IC-8** IOL removals were reported during the study. In the Control group, one subject was reported with bilateral IOL removal during the study, and replacement of both of their monofocal IOLs with different monofocal lenses due to visual complaints of dysphotopsia. Following exit from the IDE study but prior to completion of the 12-months post-operative period, one subject previously enrolled in the Control group had their monofocal IOL removed in one eye due to visual complaints of double vision and a “yellow tint”, and two subjects previously enrolled in the **IC-8** IOL group had their **IC-8** IOLs removed. One subject had their **IC-8** IOL removed due to visual complaints of a “hinged blob”. The Investigator believed that the cause may be one of three things: 1) Posterior Vitreous Detachment (PVD) or Vitreous consolidation, 2) A remnant of capsule in the subject’s visual axis, 3) The YAG laser capsulotomy resulted in a “spot” (direct quote from Investigator) on the inner portion of the aperture resulting in a “little refractive spot change” (direct quote from Investigator). The other subject had their **IC-8** IOL removed due to subjective complaints of starburst, glare, and halo.
Modified paracentesis procedure (also known as 'burping the wound') in the study were all performed in an exam room via the slit-lamp as an outpatient procedure to expel excess aqueous from the eye via the original incision (paracentesis) site to lower intraocular pressure. No procedure involved the creation of a new incision or disruption of the original incision site to release the aqueous. There was 1 eye/subject (IC-8** eye in a Test Group

subject) with 3 modified paracentesis procedures in the same eye; other eyes/subjects had 1 paracentesis procedure each.

The rates of persistent adverse events for the **IC-8** IOL eyes and fellow eyes in the **IC-8** IOL group (**Table 29**) met the ISO 11979-7:2014 SPE rates.

Table 29
Persistent Ocular Serious Adverse Events in IC-8 IOL Eyes and Fellow Eyes through 12 Months (IC-8 IOL Group)

Persistent SAE	SPE Rate	IC-8 Eyes				Fellow Eyes			
		n/N	%	95% LCL	p-value	n/N	%	95% LCL	p-value
Corneal stromal edema	0.3%	0/331	0.0%	0.0%	>0.999	0/331	0.0%	0.0%	>0.999
Cystoid macular edema	0.5%	1/331	0.3%	0.0%	0.810	1/331	0.3%	0.0%	0.810
Iritis	0.3%	2/331	0.6%	0.1%	0.262	1/331	0.3%	0.0%	0.630
Raised IOP requiring treatment	0.4%	0/331	0.0%	0.0%	>0.999	0/331	0.0%	0.0%	>0.999
Other: Retinal vein occlusion	N/A	1/331	0.3%	0.0%	--	0/331	0.0%	0.0%	--

N = # eyes available at 12 Months; n = # eyes with events in the respective AE category.
The rate of adverse event is based on the proportion of eyes with events, % = (n / N) * 100.
SPE = Safety and Performance Endpoints (SPE) rates per ISO 11979-7:2014 Table B.2 for posterior chamber IOL.
95% LCL = one-sided 95% lower confidence limit (based on exact binomial distribution). The SPE rate is considered not exceeded if the one-sided 95% lower CL for an AE is less than the SPE rate, equivalent to p-value greater than 0.05.
- Corneal stromal edema: Corneal swelling (stromal) resulting in BCDVA of 20/40 or worse at 1 month or later.
- Cystoid macular edema: Macular edema diagnosed by clinical examination and adjunct testing (e.g., OCT, FA) resulting in BCDVA of 20/40 or worse at 1 month or later.
- Raised IOP requiring treatment: Elevation of IOP greater than or equal to 10 mmHg above baseline to a minimum of 25mmHg.
- Any other AEs that were standard medical diagnoses were coded per MedDRA.

Table 30
IOL Removals in the IC-8 IOL Group and Control Group through 12 Months

	IC-8 IOL Group				Control Group			
	IC-8 IOL Eyes		Fellow Eyes		Second Eyes		First Eyes	
	n/N	%	n/N	%	n/N	%	n/N	%
IOL Removals Total	0/343	0.0%	0/343	0.0%	1/110	0.9%	1/110	0.9%
Due to Visual/Optical Reasons*	0/343	0.0%	0/343	0.0%	1/110	0.9%	1/110	0.9%
Due to Other Reasons	0/343	0.0%	0/343	0.0%	0/110	0.0%	0/110	0.0%

N = Total # in the Analysis population; n = # eyes with events in the respective AE category.
The rate of adverse events is based on the proportion of eyes with events, % = (n / N) * 100.
95% UCL = one-sided 95% upper confidence limit (based on exact binomial distribution).
The one-sided 95% upper CL of **IC-8** IOL removal rate due to visual/optical reasons less than 3.1% claimed statistical success.
*Following exit from the IDE study but prior to completion of the 12-months post-operative period, two subjects previously enrolled in the **IC-8** IOL group had their **IC-8** IOLs removed, and one subject previously enrolled in the Control group had their monofocal IOL removed in one eye, due to visual/optical reasons.

Ocular adverse events, based on a modified version of the American Academy of Ophthalmology Task Force Consensus Statement on Adverse Events with Intraocular Lenses (Masket et al., 2017) are presented in **Table 31.** The results demonstrate ≤ 0.6% of almost all adverse event types in **IC-8** IOL eyes and ≤ 0.9% in fellow eyes in the **IC-8** IOL group and the first and second eyes in the Control group.

Table 31
Ocular Adverse Events Based on a Modified Version of AAO Consensus (Masket et al., 2017) through 12 Months

	IC-8 IOL Group		**Control Group**	
	IC-8 IOL Eyes	**Fellow Eyes**	**Second Eyes**	**First Eyes**
	n/N (%)	**n/N (%)**	**n/N (%)**	**n/N (%)**
Cumulative AE	**90% CI**	**90% CI**	**90% CI**	**90% CI**
Chronic anterior uveitis	1/343 (0.3%)	0/343 (0.0%)	0/110 (0.0%)	0/110 (0.0%)
	0.0%, 1.4%	0.0%, 0.9%	0.0%, 2.7%	0.0%, 2.7%
Clinically significant cystoid macular edema	2/343 (0.6%)	0/343 (0.0%)	0/110 (0.0%)	1/110 (0.9%)
	0.1%, 1.8%	0.0%, 0.9%	0.0%, 2.7%	0.0%, 4.2%
Visually significant corneal edema	1/343 (0.3%)	1/343 (0.3%)	0/110 (0.0%)	0/110 (0.0%)
	0.0%, 1.4%	0.0%, 1.4%	0.0%, 2.7%	0.0%, 2.7%
Endophthalmitis	1/343 (0.3%)	0/343 (0.0%)	0/110 (0.0%)	0/110 (0.0%)
	0.0%, 1.4%	0.0%, 0.9%	0.0%, 2.7%	0.0%, 2.7%
Mechanical pupillary block	0/343 (0.0%)	0/343 (0.0%)	0/110 (0.0%)	0/110 (0.0%)
	0.0%, 0.9%	0.0%, 0.9%	0.0%, 2.7%	0.0%, 2.7%
Intraocular pressure increased	20/343 (5.8%)	16/343 (4.7%)	10/110 (9.1%)	7/110 (6.4%)
	3.9%, 8.4%	2.9%, 7.0%	5.0%, 14.9%	3.0%, 11.6%
Rhegmatogenous RD	0/343 (0.0%)	0/343 (0.0%)	0/110 (0.0%)	0/110 (0.0%)
	0.0%, 0.9%	0.0%, 0.9%	0.0%, 2.7%	0.0%, 2.7%
Toxic anterior segment syndrome (TASS)	0/343 (0.0%)	0/343 (0.0%)	0/110 (0.0%)	0/110 (0.0%)
	0.0%, 0.9%	0.0%, 0.9%	0.0%, 2.7%	0.0%, 2.7%
Secondary IOL intervention*				
IOL exchange	0/343 (0.0%)	0/343 (0.0%)	1/110 (0.9%)	1/110 (0.9%)
	0.0%, 0.9%	0.0%, 0.9%	0.0%, 4.2%	0.0%, 4.2%
IOL removal	0/343 (0.0%)	0/343 (0.0%)	0/110 (0.0%)	0/110 (0.0%)
	0.0%, 0.9%	0.0%, 0.9%	0.0%, 2.7%	0.0%, 2.7%
IOL reposition	1/343 (0.3%)	1/343 (0.3%)	0/110 (0.0%)	1/110 (0.9%)

	0.0%, 1.4%	0.0%, 1.4%	0.0%, 2.7%	0.0%, 4.2%

N = Total # in the Analysis population; n = # subjects with events in the respective AE category.
The rate of adverse event is based on the proportion of eyes with events, % = (n / N) * 100.
90% CI = two-sided 90% confidence interval (based on exact binomial distribution).
- Chronic anterior uveitis: Anterior segment inflammation characterized by grade 1+ cell or greater using Standardization of Uveitis Nomenclature (SUN) criteria that persists for greater than 3 months after surgery, or relapses in less than 3 months after discontinuation of therapy, or the subject is maintained on therapy for more than 3 months to control inflammation.
- Clinically significant cystoid macular edema: Macular edema diagnosed by clinical examination and adjunct testing(e.g., OCT, FA) resulting in BCDVA of <=20/40 at >=1 month.
- (Visually significant) corneal edema: Corneal swelling (stromal or epithelial) resulting in BCDVA of <=20/40 at >=1 month.
- Endophthalmitis: Intraocular inflammation leading to diagnostic vitreous tap and intraocular antibiotics
- Mechanical pupillary block: Shallowing of anterior chamber due to obstruction of aqueous humor flow from the posterior to anterior chamber through the pupil by the crystalline lens, vitreous face, or implanted device.
- Intraocular pressure increased (Increased IOP): Elevation of IOP by >=10 mmHg above baseline to a minimum of 25 mmHg.
- Rhegmatogenous RD: Partial or complete RD associated with retinal tear.
- Toxic anterior segment syndrome (TASS): Acute, non-infectious inflammation of the anterior segment that starts within 24 to 48 hours after surgery, usually resulting in hypopyon and commonly presenting with corneal edema, and that improves with steroid treatment.
- IOL Exchange: The investigational device is replaced with the same lens model.
- IOL Removal: The investigational device is removed and replaced with a non-investigational lens or no lens is implanted.
- IOL Reposition: The existing IOL is surgically moved to another location or rotated.
* No **IC-8** IOL removals were reported during the study. In the Control group, one subject was reported with bilateral IOL removal during the study, and replacement of both of their monofocal IOLs with different monofocal lenses due to visual complaints of dysphotopsia. Following exit from the IDE study but prior to completion of the 12-months post-operative period, one subject previously enrolled in the Control group had their monofocal IOL removed in one eye due to visual complaints of double vision and a "yellow tint", and two subjects previously enrolled in the **IC-8** IOL group had their **IC-8** IOLs removed. One subject had their **IC-8** IOL removed due to visual complaints of a "hinged blob". The Investigator believed that the cause may be one of three things: 1) Posterior Vitreous Detachment (PVD) or Vitreous consolidation, 2) A remnant of capsule in the subject's visual axis, 3) The YAG laser capsulotomy resulted in a "spot" (direct quote from Investigator) on the inner portion of the aperture resulting in a "little refractive spot change" (direct quote from Investigator). The other subject had their **IC-8** IOL removed due to subjective complaints of starburst, glare, and halo.

Contrast Sensitivity

Monocular and binocular mesopic and photopic contrast sensitivity (with and without glare) was assessed at 6 Months in the contrast sensitivity subgroup for the **IC-8** IOL eyes and the monofocal/monofocal toric IOL eyes and **IC-8** IOL and Control groups. Data were obtained from

260 and 67 subjects in the **IC-8** IOL and Control groups, respectively, using a computerized test system (CTS, M&S Technologies, Niles, IL).

A summary of mean contrast sensitivity results is presented for the binocular condition in **Table 32** and the monocular condition in **Table 33**. In the binocular natural viewing condition, in both mesopic and photopic conditions with and without a glare source, the **IC-8** IOL subjects achieved similar mean contrast sensitivity compared to the monofocal/monofocal toric IOL subjects. In the monocular condition, as expected, the **IC-8** IOL subjects had a reduction in mean monocular mesopic and photopic contrast sensitivity with and without glare compared to the monofocal/monofocal toric IOL subjects.

Table 32
Binocular Photopic and Mesopic With and Without Glare Contrast Sensitivity (logCS) at 6 Months

Spatial Frequency	IOL	N	Photopic		Mesopic	
			No Glare	Glare	No Glare	Glare
			Mean (log units)	Mean (log units)	Mean (log units)	Mean (log units)
1.5 Cycles Per Degree (CPD)	**IC-8** IOL Group	260	N/A	N/A	1.936	1.395
	Control Group	67	N/A	N/A	1.969	1.559
3 Cycles Per Degree (CPD)	**IC-8** IOL Group	260	2.233	1.866	2.030	1.602
	Control Group	67	2.287	1.983	2.079	1.714
6 Cycles Per Degree (CPD)	**IC-8** IOL Group	260	2.119	1.856	1.688	1.382
	Control Group	67	2.141	1.891	1.723	1.403
12 Cycles Per Degree (CPD)	**IC-8** IOL Group	260	1.689	1.431	0.995	0.797
	Control Group	67	1.654	1.476	0.986	0.756
18 Cycles Per Degree (CPD)	**IC-8** IOL Group	260	1.164	0.957	N/A	N/A
	Control Group	67	1.090	0.970	N/A	N/A

Table 33
Monocular Photopic and Mesopic With and Without Glare Contrast Sensitivity (logCS) at 6 Months (IC-8 IOL Group)

Spatial Frequency	IOL (Eyes)	N	Photopic		Mesopic	
			No Glare	Glare	No Glare	Glare

			Mean (log units)	Mean (log units)	Mean (log units)	Mean (log units)
1.5 Cycles Per Degree (CPD)	**IC-8** IOL Eyes	260	N/A	N/A	1.385	1.044
	Fellow Eyes	260	N/A	N/A	1.850	1.338
3 Cycles Per Degree (CPD)	**IC-8** IOL Eyes	260	1.935	1.620	1.475	1.201
	Fellow Eyes	260	2.202	1.822	1.964	1.552
6 Cycles Per Degree (CPD)	**IC-8** IOL Eyes	260	1.795	1.513	1.217	1.035
	Fellow Eyes	260	2.055	1.747	1.609	1.353
12 Cycles Per Degree (CPD)	**IC-8** IOL Eyes	260	1.308	1.106	0.620	0.496
	Fellow Eyes	260	1.554	1.345	0.913	0.749
18 Cycles Per Degree (CPD)	**IC-8** IOL Eyes	260	0.832	0.659	N/A	N/A
	Fellow Eyes	260	1.072	0.887	N/A	N/A

Low Contrast (10%) Visual Acuity

Photopic low contrast (10% contrast) uncorrected and distance-corrected visual acuities was assessed monocularly in **IC-8** eyes and the second eyes in the Control group and binocularly in the contrast sensitivity subgroup of subjects with BCDVA 20/25 or better in each eye at 6 Months. Low contrast visual acuity assessment demonstrated that all monocular and binocular intermediate and near mean low contrast visual acuities (uncorrected and distance-corrected) were approximately 1-2 lines better for the **IC-8** group compared with the Control group (**Tables 34** and **35**). While monocular distance low contrast visual acuity was better for the eyes with monofocal or monofocal toric IOL, binocular distance mean low contrast visual acuity (uncorrected and distance-corrected) was comparable (within half a line) between the **IC-8** group and the Control group.

Table 34
Mean logMAR Monocular 10% Contrast Uncorrected and Distance-corrected Visual Acuities (in CS Subgroup with BCDVA 20/25 or Better in Each Eye), 6 Months

Monocular 10% Contrast Visual Acuity (logMAR)	IC-8 Group IC-8 Eyes			Control Group Second Eyes		
	N	Mean	Std. Dev.	N	Mean	Std. Dev.
UCDVA	244	0.828	0.4755	66	0.431	0.1536
UCIVA	244	0.510	0.2272	66	0.699	0.1980

UCNVA	244	0.619	0.1692	66	0.882	0.1530
DCDVA	244	0.588	0.2494	66	0.318	0.1281
DCIVA	244	0.561	0.2001	66	0.754	0.1602
DCNVA	244	0.702	0.1420	66	0.927	0.1173

Table 35
Mean logMAR Binocular 10% Contrast Uncorrected and Distance-corrected Visual Acuities (in CS Subgroup with BCDVA 20/25 or Better in Each Eye), 6 Months

Binocular 10% Contrast Visual Acuity (logMAR)	**IC-8 Group**			**Control Group**		
	N	**Mean**	**Std. Dev.**	**N**	**Mean**	**Std. Dev.**
UCDVA	259	0.364	0.1915	67	0.323	0.1196
UCIVA	259	0.426	0.1920	67	0.580	0.1817
UCNVA	259	0.571	0.1464	67	0.774	0.1351
DCDVA	259	0.267	0.1516	67	0.245	0.1150
DCIVA	259	0.498	0.1712	67	0.651	0.1657
DCNVA	259	0.661	0.1329	67	0.822	0.1339

Patient Reported Outcomes

A Patient Reported Outcome (PRO) instrument (questionnaire) was developed for use in this clinical study to assess subjective visual symptoms in conjunction with the Quality of Vision (QoV) questionnaire. Subjects reported the frequency, severity, and bothersomeness of the visual symptoms that they experienced. Questionnaires were administered to both groups preoperatively and postoperatively at the beginning of the subject visit before all other testing or assessments.

The majority of subjects in both the **IC-8** IOL and Control groups reported ‘never’ or ‘occasionally’ in frequency, ‘not at all’ or ‘mild’ in severity, and ‘not at all’ or ‘a little’ in bothersomeness for all the visual symptoms. An overall summary of visual symptoms experience/bothersomeness showed approximately more than 80% of subjects reported ‘never experienced’, ‘experienced symptom but not bothered at all’ or ‘a little bothered’ for all visual symptoms at 12 Months in both the **IC-8** IOL and Control groups.

At 12 Months, the most common visual disturbances with severe ratings in the **IC-8** IOL group were starbursts (**IC-8** IOL: 3.6% [12/331], Control: 1.0% [1/100]), halos (**IC-8** IOL: 3.6% [12/331], Control: 0.0% [0/100]), and glare (**IC-8** IOL: 3.0% [10/331], Control: 0.0% [0/100]) (**Table 36**). The other visual symptoms reported by more than 1% of subjects as ‘severe’ in the **IC-8** IOL group included: hazy vision, blurred vision, vision fluctuation, focusing difficulties, problem seeing when light conditions change, and the ocular symptom of eye dryness. All other visual symptoms were reported by less than 1% of subjects as ‘severe’ in the **IC-8** IOL group,

including distortion, double or multiple images, difficulty judging distance or depth perception, problem judging distance of moving objects, surroundings seem dimmer, and negative dysphotopsia. For bothersomeness, the observed trends are similar to the results for severity (**Table 37**). Only the visual symptoms reported by more than 1% of subjects as either 'severe' or 'very bothered' are presented in **Tables 36** and **37**.

Stratification of mean visual symptoms experience/bothersomeness rating by preoperative mesopic pupil size in the **IC-8** IOL group indicates minimal worsening of visual symptoms with increasing pupil size at 12 Months and the mean rating is < 1.0 (on a scale of 0 to 3, with 0=Never experience/Not at all bothered, 1=A little bothered, 2=Quite bothered, 3=Very bothered) in all visual symptoms for all three mesopic pupil size groups.

Table 36
Distribution of Visual Symptoms Severity Rating in IC-8 Group at 12 Months Compared with Control Group at 12 Months

Visual Symptoms	Severity Rating	IC-8 Group 12 Months (N=331)		Control Group 12 Months (N=100)	
		n/N	%	n/N	%
Glare	Not at all	140/331	42.3%	49/100	49.0%
	Mild	132/331	39.9%	43/100	43.0%
	Moderate	49/331	14.8%	8/100	8.0%
	Severe	10/331	3.0%	0/100	0.0%
Halos	Not at all	151/331	45.6%	73/100	73.0%
	Mild	119/331	36.0%	23/100	23.0%
	Moderate	49/331	14.8%	4/100	4.0%
	Severe	12/331	3.6%	0/100	0.0%
Starbursts	Not at all	162/331	48.9%	73/100	73.0%
	Mild	122/331	36.9%	25/100	25.0%
	Moderate	35/331	10.6%	1/100	1.0%
	Severe	12/331	3.6%	1/100	1.0%
Hazy Vision	Not at all	213/331	64.4%	75/100	75.0%
	Mild	83/331	25.1%	23/100	23.0%
	Moderate	30/331	9.1%	2/100	2.0%
	Severe	5/331	1.5%	0/100	0.0%
Blurred Vision	Not at all	181/331	54.7%	66/100	66.0%
	Mild	113/331	34.1%	31/100	31.0%
	Moderate	32/331	9.7%	3/100	3.0%
	Severe	5/331	1.5%	0/100	0.0%
Vision Fluctuation	Not at all	179/331	54.1%	71/99	71.7%
	Mild	122/331	36.9%	23/99	23.2%
	Moderate	25/331	7.6%	5/99	5.1%
	Severe	5/331	1.5%	0/99	0.0%
	Not at all	122/331	36.9%	51/99	51.5%

Focusing Difficulties	Mild	168/331	50.8%	45/99	45.5%
	Moderate	35/331	10.6%	3/99	3.0%
	Severe	6/331	1.8%	0/99	0.0%
Difficulty Judging Distance or Depth Perception	Not at all	250/331	75.5%	78/99	78.8%
	Mild	63/331	19.0%	18/99	18.2%
	Moderate	17/331	5.1%	3/99	3.0%
	Severe	1/331	0.3%	0/99	0.0%
Problem Seeing when Light Conditions Change	Not at all	203/331	61.3%	68/100	68.0%
	Mild	97/331	29.3%	29/100	29.0%
	Moderate	23/331	6.9%	1/100	1.0%
	Severe	8/331	2.4%	2/100	2.0%
Eye Dryness	Not at all	110/331	33.2%	35/100	35.0%
	Mild	136/331	41.1%	48/100	48.0%
	Moderate	69/331	20.8%	15/100	15.0%
	Severe	16/331	4.8%	2/100	2.0%

Table 37
Distribution of Visual Symptoms Bothersomeness Rating in IC-8 Group at 12 Months Compared with Control Group at 12 Months

Visual Symptoms	Bothersomeness Rating	IC-8 Group 12 Months (N=331)		Control Group 12 Months (N=100)	
		n/N	%	n/N	%
Glare	Not at all	162/331	48.9%	57/100	57.0%
	A little	126/331	38.1%	38/100	38.0%
	Quite	31/331	9.4%	5/100	5.0%
	Very	12/331	3.6%	0/100	0.0%
Halos	Not at all	174/331	52.6%	79/100	79.0%
	A little	113/331	34.1%	17/100	17.0%
	Quite	29/331	8.8%	4/100	4.0%
	Very	15/331	4.5%	0/100	0.0%
Starbursts	Not at all	192/331	58.0%	75/100	75.0%
	A little	104/331	31.4%	23/100	23.0%
	Quite	23/331	6.9%	1/100	1.0%
	Very	12/331	3.6%	1/100	1.0%
Hazy Vision	Not at all	223/331	67.4%	80/100	80.0%
	A little	81/331	24.5%	19/100	19.0%
	Quite	21/331	6.3%	0/100	0.0%
	Very	6/331	1.8%	1/100	1.0%
Blurred Vision	Not at all	191/331	57.7%	67/100	67.0%
	A little	107/331	32.3%	30/100	30.0%
	Quite	26/331	7.9%	3/100	3.0%
	Very	7/331	2.1%	0/100	0.0%

Vision Fluctuation	Not at all	191/331	57.7%	72/99	72.7%
	A little	110/331	33.2%	25/99	25.3%
	Quite	23/331	6.9%	2/99	2.0%
	Very	7/331	2.1%	0/99	0.0%
Focusing Difficulties	Not at all	140/331	42.3%	60/99	60.6%
	A little	155/331	46.8%	36/99	36.4%
	Quite	26/331	7.9%	3/99	3.0%
	Very	10/331	3.0%	0/99	0.0%
Difficulty Judging Distance or Depth Perception	Not at all	253/331	76.4%	79/99	79.8%
	A little	61/331	18.4%	18/99	18.2%
	Quite	13/331	3.9%	2/99	2.0%
	Very	4/331	1.2%	0/99	0.0%
Problem Seeing when Light Conditions Change	Not at all	213/331	64.4%	70/100	70.0%
	A little	95/331	28.7%	27/100	27.0%
	Quite	14/331	4.2%	2/100	2.0%
	Very	9/331	2.7%	1/100	1.0%
Eye Dryness	Not at all	115/331	34.7%	38/100	38.0%
	Mild	152/331	45.9%	51/100	51.0%
	Moderate	40/331	12.1%	10/100	10.0%
	Severe	24/331	7.3%	1/100	1.0%

Retinal Visualization

Dilated fundus examinations were performed preoperatively and at 12 Months using binocular indirect ophthalmoscopy (BIO) and slit-lamp fundus exam (SLE).

At 12 Months**,** Investigators reported little to no difficulty in 99.4% to 100% (329 to 331 of 331) of **IC-8** IOL eyes, moderate difficulty in 0 to 0.6% (0 to 2 of 331) eyes when performing retinal evaluation of the optical disc, macula, mid-periphery, or periphery during dilated fundus examination using BIO. No Investigator reported extreme or a lot of difficulty in performing retinal evaluation during dilated fundus examination (using BIO) in any **IC-8** IOL eyes (**Table 38**).

The Investigator ratings of the level of difficulty in performing retinal evaluation using dilated SLE were similar between **IC-8** IOL eyes and monofocal/monofocal toric IOL implanted eyes. At 12 Months**,** Investigators reported little to no difficulty in 99.7% (330/331) of **IC-8** IOL eyes when performing retinal evaluation of optic disc and macula during dilated fundus examination using SLE. No Investigator reported extreme or a lot of difficulty during dilated fundus examination using SLE in any **IC-8** IOL eyes (**Table 39**).

Investigators reported being able to achieve a stereoscopic view of the posterior pole using both BIO and dilated SLE in 100% (331/331) of the eyes in both the **IC-8** IOL and Control groups at 12 Months post implantation.

Table 38
Distribution of Investigator Survey Regarding Level of Difficulty in Performing Retinal Evaluation during Dilated Fundus Exam (BIO) at 12 Months (IC-8 IOL group)

Investigator Survey on BIO	IC-8 Eyes n/N (%)	Fellow Eyes n/N (%)
Optic Disc		
No difficulty	311/331 (94.0%)	330/331 (99.7%)
A little difficulty	20/331 (6.0%)	1/331 (0.3%)
Moderate difficulty	0/331 (0.0%)	0/331 (0.0%)
A lot of difficulty	0/331 (0.0%)	0/331 (0.0%)
Extreme difficulty	0/331 (0.0%)	0/331 (0.0%)
Macula		
No difficulty	312/331 (94.3%)	331/331 (100.0%)
A little difficulty	19/331 (5.7%)	0/331 (0.0%)
Moderate difficulty	0/331 (0.0%)	0/331 (0.0%)
A lot of difficulty	0/331 (0.0%)	0/331 (0.0%)
Extreme difficulty	0/331 (0.0%)	0/331 (0.0%)
Mid-Periphery		
No difficulty	244/331 (73.7%)	330/331 (99.7%)
A little difficulty	85/331 (25.7%)	1/331 (0.3%)
Moderate difficulty	2/331 (0.6%)	0/331 (0.0%)
A lot of difficulty	0/331 (0.0%)	0/331 (0.0%)
Extreme difficulty	0/331 (0.0%)	0/331 (0.0%)
Periphery		
No difficulty	251/331 (75.8%)	331/331 (100.0%)
A little difficulty	79/331 (23.9%)	0/331 (0.0%)
Moderate difficulty	1/331 (0.3%)	0/331 (0.0%)
A lot of difficulty	0/331 (0.0%)	0/331 (0.0%)
Extreme difficulty	0/331 (0.0%)	0/331 (0.0%)

Table 39
Distribution of Investigator Survey Regarding Level of Difficulty in Performing Retinal Evaluation during Dilated Slit-lamp Exam (SLE) at 12 Months (IC-8 IOL group)

Investigator Survey on Dilated SLE	IC-8 Eyes n/N (%)	Fellow Eyes n/N (%)
Optic Disc		
No difficulty	312/331 (94.3%)	331/331 (100.0%)
A little difficulty	18/331 (5.4%)	0/331 (0.0%)
Moderate difficulty	1/331 (0.3%)	0/331 (0.0%)
A lot of difficulty	0/331 (0.0%)	0/331 (0.0%)
Extreme difficulty	0/331 (0.0%)	0/331 (0.0%)
Macula		

No difficulty	311/331 (94.0%)	330/331 (99.7%)
A little difficulty	19/331 (5.7%)	1/331 (0.3%)
Moderate difficulty	1/331 (0.3%)	0/331 (0.0%)
A lot of difficulty	0/331 (0.0%)	0/331 (0.0%)
Extreme difficulty	0/331 (0.0%)	0/331 (0.0%)

Retinal diagnostic testing was performed for all 49 patients at two investigational sites participating in the retinal diagnostic testing subgroup using fundus photography, SD-OCT and visual field testing conducted both preoperatively and at 3 Months in both eyes of **IC-8** IOL group subjects. The image quality of the SD-OCT images and fundus photos were independently graded by a Fundus Photography Reading Center (FPRC) and by the two Investigators. Three image quality scores were assigned to images in the subgroup: CS1 indicates grading confidence is high with no significant problem caused by image quality. No blurring or obstruction of retinal details. CS2 indicates grading confidence is adequate but suboptimal image quality noticeably interfered. Some blurring or obstruction of the retinal details. CS3 indicates grading confidence is inadequate to determine major disease parameters. Marked blurring or obstruction of the retinal details. The majority of the final dilated fundus photography and SD-OCT quality scores for images obtained from **IC-8** eyes at 3 Months were rated by the FPRC as CS2 (87.8% [43/49] and 63.3% [31/49] for dilated fundus photography and SD-OCT respectively) or CS1 (4.1% [2/49] and 28.6% [14/49] for dilated fundus photography and SD-OCT respectively), indicating that the graders had been able to perform the evaluation with sufficient level of confidence needed for the task in both of these categories for **IC-8** IOL eyes. Additionally, the percentage of CS3 was below 10% for **IC-8** eyes for both dilated fundus photography and OCT imaging at Month 3 and was comparable between **IC-8** eyes and fellow eyes (6.1% [3/49], 2.0% [1/49], 8.2% [4/49], and 6.1% [3/49], respectively). The Investigators rated 100% of the dilated fundus photography and dilated SD-OCT macular scan and disc scan image quality as excellent or adequate preoperatively and at 3 Months, regardless of dilated pupil size.

Visual field testing was performed preoperatively and at 3 Months for all 49 patients. Testing was performed with the Humphrey Visual Filed Analyzer and the results were evaluated by the Fundus Photography Reading Center. In the **IC-8** eyes, 75.5% (37/49) had no change from baseline to 3 Months while 69.4% (34/49) of the fellow monofocal eyes had no change from baseline. When looking at the Mean Deviation (MD) scores, the **IC-8** eyes had a change in MD of 0.207 and the fellow monofocal eyes had a MD change of 0.791. The change in Pattern Standard Deviation (PSD) scores were 0.369 in the **IC-8** eyes and 0.308 in the fellow monofocal eyes.

IOL Centration

The presence or absence of decentration and/or tilt were evaluated by slit lamp examination at each postoperative visit. At 12 Months, decentered IOLs were reported in 4 **IC-8** IOL eyes. Monocular distance-corrected and uncorrected visual acuities at far, intermediate, and near distances at 6 and 12 Months were compared between **IC-8** IOL eyes with decentered IOLs and those without decentered IOLs. All 4 subjects with reports of decentered IOLs achieved 20/25 or better BCDVA, 20/20 or better UCIVA, and 20/32 or better UCDVA and UCNVA (20/25 at 12 Months) and had better mean logMAR visual acuity at these visits, outperforming the subjects without decentered IOLs, suggesting that small amounts (0.5 mm or less) decentration of the **IC-8** IOL did not adversely affect vision outcomes.

PCO and Performing YAG

The slit lamp results in the study showed that there were 46.6% (160/343) of **IC-8** eyes with clinically non-significant posterior capsule opacification (PCO), compared with 53.4% (183/343) in fellow eyes and 50.9% to 51.8% (56 to 57 of 110) in the eyes of control group subjects. The rate of clinically significant PCO needing treatment was 32.4% (111/343) in **IC-8** eyes compared with 14.0% (48/343) in fellow eyes and 16.4% to 17.3% (18 to 19 of 110) in the eyes of control group subjects. During the study, 107/343 **IC-8** eyes received posterior capsulotomies (Nd:YAG) as treatment for PCO affecting vision. In 13 of these 107 capsulotomy procedures, the Investigators reported some difficulty in performing the procedure in an **IC-8** IOL treated eye. A correlation between reporting some difficulty performing a capsulotomy procedure and reports of resultant issues or laser damage to the IOL was noted. In 17 of these 107 YAG procedures, 5 eyes required a second capsulotomy treatment (the **IC-8** IOL in 1 eye was damaged); 2 eyes had a pars plana vitrectomy (PPV) to remove a residual posterior capsular remnant (the **IC-8** IOL in 1 eye was damaged); and another 10 eyes implanted with the IC-8 IOL had pits or damage on the device. Of the 11 subjects with reported YAG laser damage at the final study visit, 1 reported severe glare, 1 reported severe halo, and 1 reported severe starburst at 12 Months. Training on appropriate capsulotomy technique will be provided by AcuFocus to mitigate the risk of YAG damage to the **IC-8** IOL.

HOW SUPPLIED: Each **IC-8 Apthera** IOL is supplied sterile in a twist-cap lens holder contained in a 5 mL glass vial filled with water for injection and secured by a rubber stopper and a screw cap. The vial is placed in a blister-pack and sealed with a lid made of DuPont™ Tyvek® material. The lens is gamma sterilized and the blister-pack and vial shall be opened only under sterile conditions.

EXPIRATION DATE: The expiration date on the lens package is the sterility expiration date. The **IC-8 Apthera** IOL must not be implanted after the indicated sterility expiration date.

METHOD OF STERILIZATION: The **IC-8 Apthera** IOL is gamma sterilized.

CONDITIONS OF STORAGE AND TRANSPORT: Minimum temperature 41°F (5°C) / Maximum temperature 104°F (40°C). Keep dry. Do not freeze.

PATIENT INFORMATION: Each patient should receive information regarding the **IC-8 Apthera** IOL prior to the decision to implant the intraocular lens. A patient information brochure can be obtained by contacting AcuFocus, toll free at 844-895-3363.

MRI SAFETY INFORMATION

The **IC-8 Apthera** IOL is non-metallic and non-magnetic.
A patient implanted with this device can be safely scanned in an MR system meeting the following conditions: Static Magnetic Field of 1.5T or 3T; Maximum Spatial Field

Gradient of 40 T/m (4,000 gauss/cm); RF Excitation - Circularly Polarized (CP); No Transmit Coil restrictions; Maximum Whole Body SAR of 2.0 W/kg (normal operating mode); Scan Duration of 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks); The presence of this implant may produce an image artifact.

PATIENT IMPLANT CARD: A Patient Implant Card is included in the **IC-8 Apthera** IOL box. Take the patient identification label from the label sheet provided in the box and apply it to the back side of the patient implant card. This card is to be given to the patient with instructions to keep it as a permanent record to be shown to any healthcare practitioner that the patient consults in the future.

IMPLANT NOTIFICATION CARD: An Implant Notification Card is enclosed in the **IC-8 Apthera** IOL box. Each patient must be registered with the manufacturer, AcuFocus, Inc. Immediately following implantation of the **IC-8 Apthera** IOL, complete and mail the Implant Notification Card to AcuFocus at the address below. Implant registration is essential for the long-term patient follow-up program and will assist AcuFocus in responding to reports of adverse events.

ADVERSE EVENT REPORTING: Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as IOL-related and that were not previously expected in nature, severity, or rate of occurrence must be reported to AcuFocus by the contact methods below. This information is being requested from all physicians in order to identify emerging or potential long-term problems with posterior chamber intraocular lens implantation.

AcuFocus, Inc.
32 Discovery, Suite 200
Irvine, CA 92618, U.S.A.
Toll Free: 844-895-3363
www.acufocus.com
customerservice@acufocus.com

SYMBOL GLOSSARY:

The symbols used in the product labeling are in accordance with ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, unless specified otherwise.

Symbol	Standard Reference	Symbol Title/ Explanation
	#5.1.4	Use-by date
	#5.1.5	Batch code

	#5.4.2	Do not re-use
	#5.1.6	Catalogue number
	#5.2.6	Do not resterilize
	#5.3.4	Keep dry
	#5.2.8	Do not use if package is damaged
	#5.4.3	Consult Instructions for Use
	#5.1.1	Manufacturer
	#5.2.4	Sterilized using irradiation
	#5.3.7	Temperature limit
	#5.1.7	Serial Number
	ASTM F2503, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Magnetic Resonance (MR) Conditional

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Patent Information: www.acufocus.com/us/patents.

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