IC-8® Apthera™ Small Aperture IOL for Patients with Healthy Corneas

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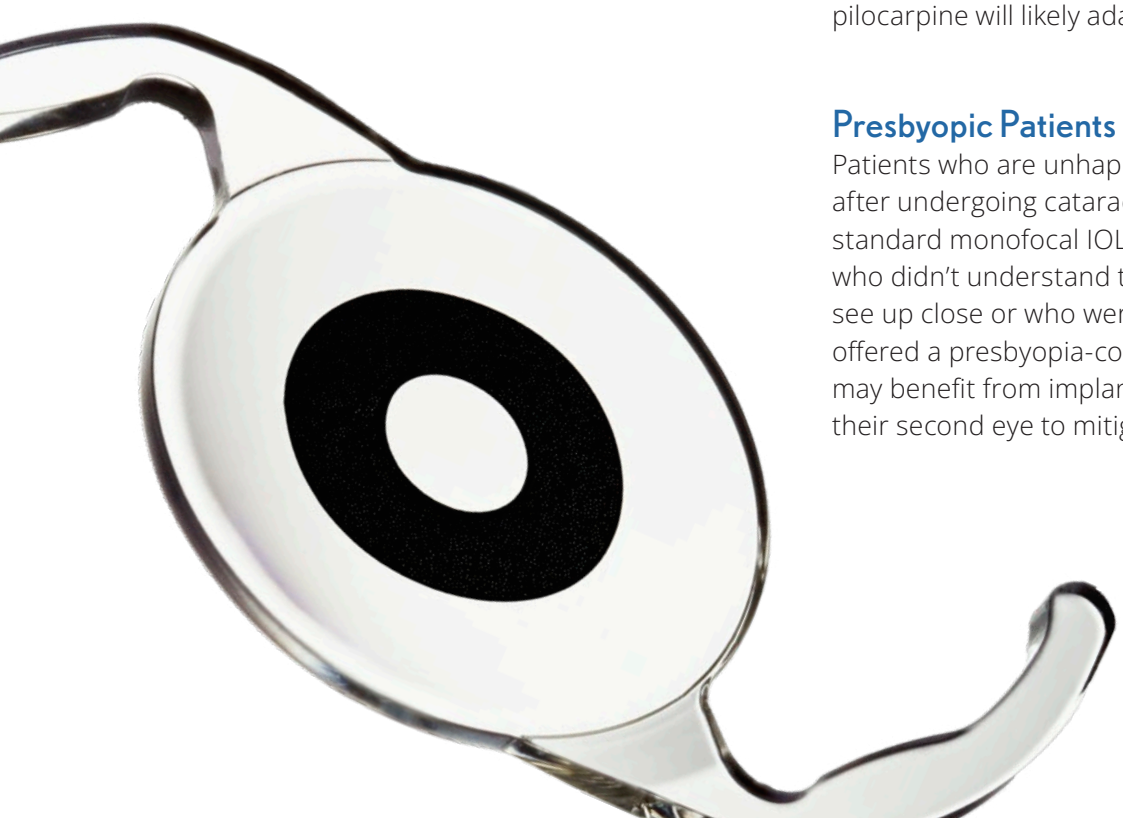
PATIENT SELECTION

What types of patients are great candidates for my first Apthera lens implantations?

For your initial cases, consider choosing patients who have otherwise healthy eyes, with no ocular surface disease. Here are six types of patients that are good candidates for the Apthera lens:



Previous or Current Monovision Patients

Patients who have enjoyed success with phakic monovision. These patients already understand the concept of monovision, reducing the need for extensive preoperative counseling of monovision effects. However, they are often disappointed by the thought of conventional pseudophakic monovision because it may not duplicate their prior experience with contact lenses. The Apthera IOL can deliver a premium monovision experience that maintains stereopsis and depth perception while minimizing loss of distance vision.

Pharmaceutically Induced Small Aperture Optic Patients

Patients who have already tried and enjoyed small aperture optics with topical miotic drops such as pilocarpine will likely adapt very easily to the Apthera lens.

Presbyopic Patients

Patients who are unhappy with their range of vision after undergoing cataract surgery in one eye with a standard monofocal IOL. We all have those patients who didn't understand that they would need glasses to see up close or who were treated elsewhere and not offered a presbyopia-correcting IOL. These patients may benefit from implantation of the Apthera lens in their second eye to mitigate the effects of presbyopia.

Low Astigmatic Patients

Low astigmats who don't have sufficient corneal astigmatism to qualify for a toric lens. The IC-8 lens is indicated for patients with up to 1.5 D of astigmatism correction, without relaxing incisions and without the requirements for axis marking and alignment. In the U.S. clinical trial, even patients at the higher end of this range—those with 1.0 to 1.5 D of cylinder—achieved similar distance, near, and intermediate vision to those with <1.0 D of cylinder, which tells us that the small aperture mechanism of action provides an excellent range of vision improvement for eyes with low levels of astigmatism.

Unstable Preoperative Measurements

Astigmatic eyes for which your diagnostic devices provide varying or inconsistent axes. Thanks to the small aperture, the Apthera lens will provide consistent outcomes (up to 1.5 D of astigmatism) no matter which axis is the correct one.

Blended Vision Patients

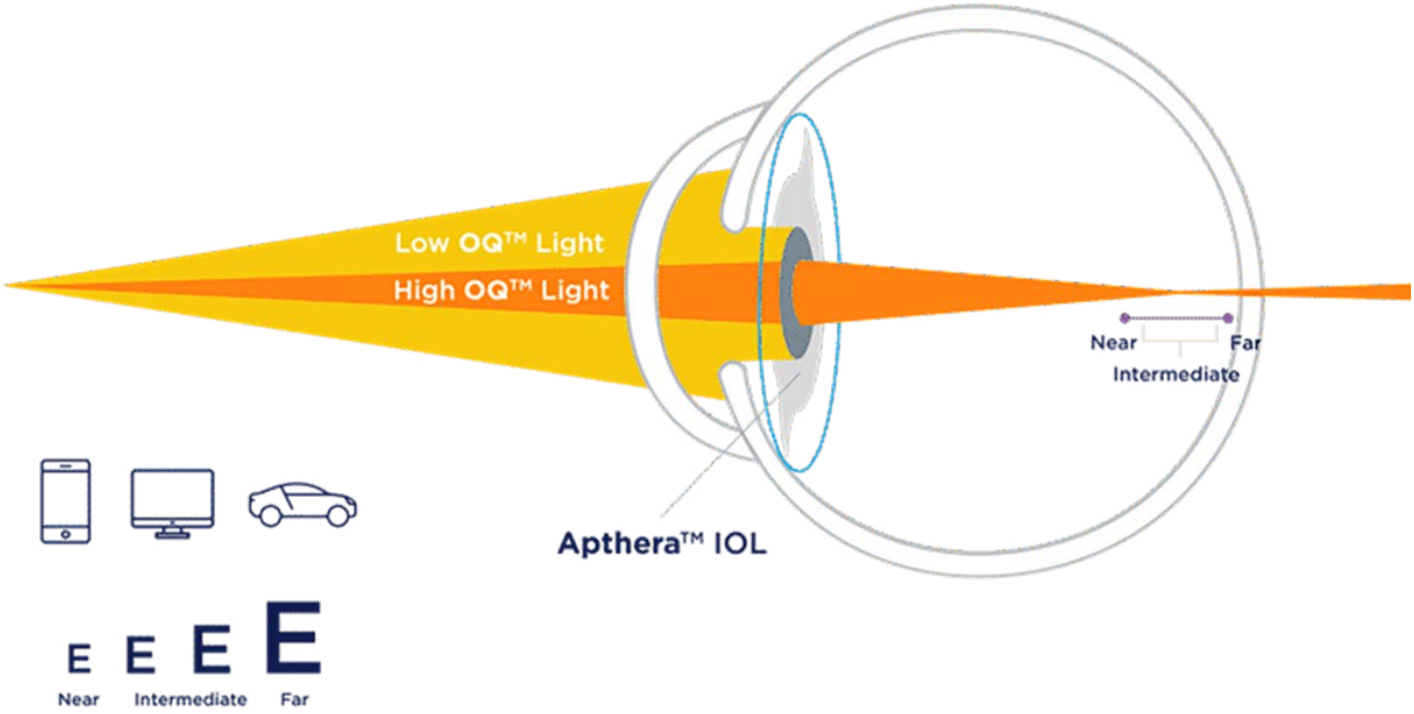
Patients who desire reduced dependence on glasses but are not interested in bilateral advanced IOLs—whether due to symptoms, contrast sensitivity concerns, or cost, and are interested in the premium blended vision Apthera provides.

Apthera IOL Procedure Overview

Order	First Eye	Second Eye
Eye	Dominant Eye	Non Dominant Eye
Recommended IOL	enVista or Aspire Monofocal or Monofocal Toric	IC-8 Apthera
Target Refraction	Emmetropia and post op refraction of plano (+/- 0.25 D)	-0.75 D
Criteria	Successful treatment as determined by UCDVA 20/32 or BCDVA 20/25	No ocular underlying conditions Mesopic < 5.0mm
Range of Vision	Distance vision correction	Extended depth of focus/ Blended vision
Surgical Considerations	Standard IOL surgery	Capsulorhexis 5.5 mm Corneal incision increased to 3.2 mm for lens insertion
		Polish posterior and anterior capsule

Advantages of the IC-8 Small Aperture lens

The IC-8 small aperture lens, achieves increased depth of focus by incorporating an annular opaque mask with a central 1.36 mm aperture. The increased depth of focus makes it potentially forgiving in the case of refractive misses and the small aperture increases tolerance of up to 1.5 D of astigmatism. The ability of the small aperture to block defocused peripheral light also provides an opportunity to reduce the impact of aberrations. Previous studies of small-aperture IOL implantation in patients with virgin corneas have documented good uncorrected vision at all distances, minimal photic phenomena, and good contrast sensitivity.



*Simulated Image

Which patients should I avoid?

Patients with amblyopia, high angle kappa/alpha, floppy iris, central corneal scars, or pseudoexfoliation should be avoided. Also, patients with central corneal scarring are considered not good candidates due to the small aperture design of the implant.

As with other presbyopia-correcting IOLs, the Apthera lens is not a good option for patients with retinal diseases. Particularly in their early experience with this lens, surgeons should avoid implanting it in patients with conditions such as myopic macular degeneration, diabetes, macular disease, sickle cell disease, retinal tear, retinal detachment, retinal vein occlusion, ocular tumor, uveitis, and those predisposed to these or other retinal diseases. The reason to avoid such patients is not that retinal conditions cannot be managed in an Apthera eye, but rather, that we don't want to knowingly implant a lens that might compound any impact the underlying disease might have on contrast sensitivity. In the Apthera IDE trial and commercially outside the U.S., patients have successfully undergone pars plana vitrectomy and other retinal procedures, and surgeons have reported that high-quality retinal imaging was easy to accomplish with the Apthera lens in place.[2-4,6]

Patients should have a dilated exam preoperatively to ensure they can be pharmacologically dilated to a pupil size of at least 7.0 mm or greater. This will ensure sufficient visibility to perform a Nd:YAG capsulotomy around the outside of the FilterRing component, if needed. It is important to note that in the U.S. IDE trial, the size of the natural (undilated) pupil did not adversely affect distance acuity in the Apthera eye or correlate with visual symptoms, regardless of lighting conditions. Patients with smaller pupils had better near vision, as we see with any IOL, but in no case was a smaller natural pupil size a liability. A large mesopic pupil (larger than 5.5 mm) could provoke some nighttime visual symptoms—again, as one would expect with any premium IOL—if the pupil dilated beyond the edge of the FilterRing. Pilocarpine once or twice weekly may be helpful if this occurs.

It is important to make sure the ocular surface and tear film are optimized and there is no staining in the central 3.0 mm. This is important with any premium IOL—and especially so for a small aperture lens. If ocular surface problems cannot be resolved, we recommend against implanting the Apthera lens.

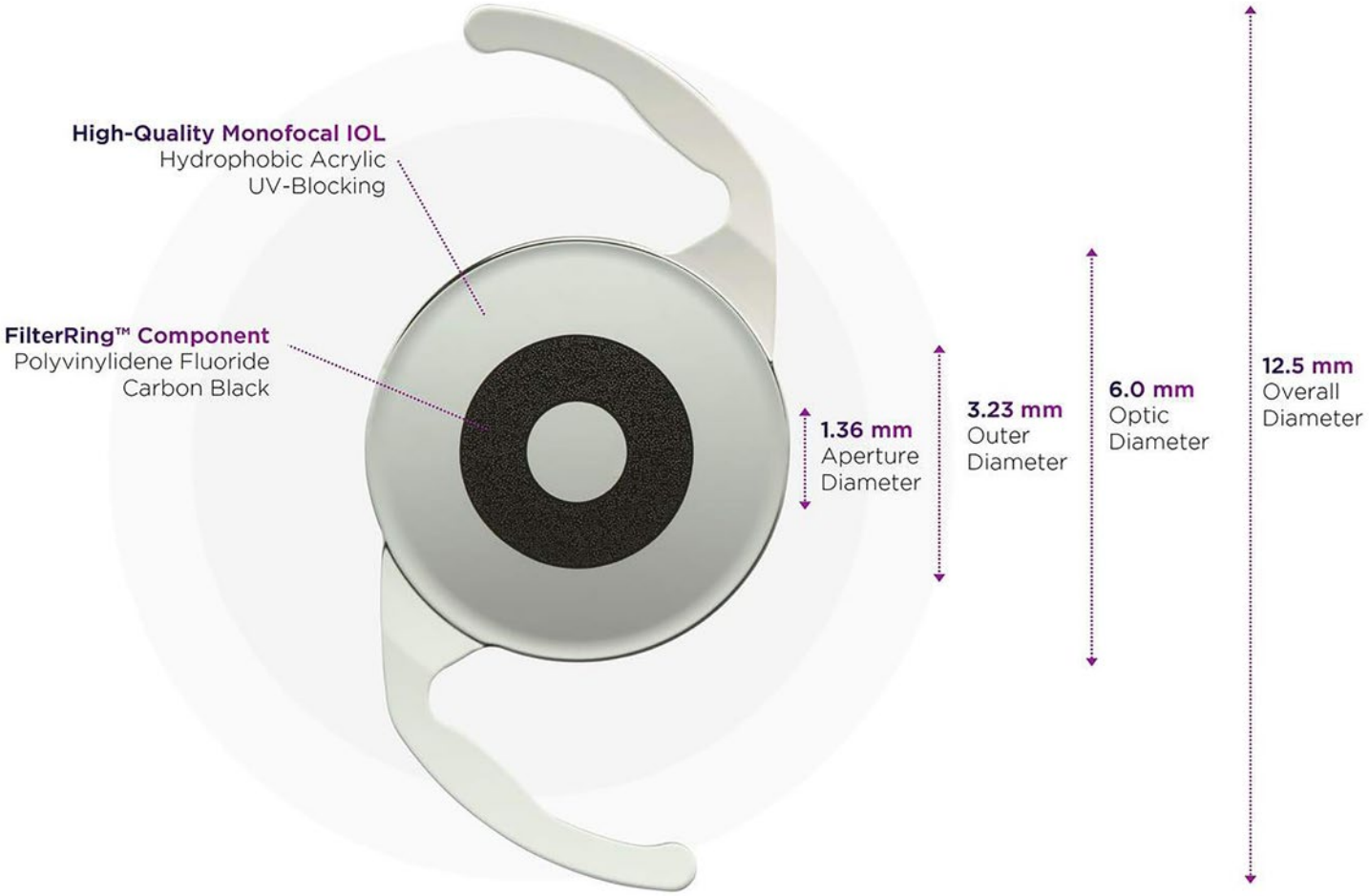
Tear osmolarity is the main diagnostic factor of DED and tear film instability for a variety of reasons, first, it is a more objective method than other tests as it does not include the subjective component of the doctor. Other diagnostic measures, such as TBUT and staining with fluorescein, always include a subjective view of the doctor and if tests are performed by another person could result in different results. Second, increased tear osmolarity is a known mechanism in the development of DED. Thirdly, with the ScoutPro system determination of tear osmolarity is a safe, quick, and convenient process that can be completed within the physician's office.[8]

Finally, consider the patient's visual demands and expectations. Avoid implanting the Apthera lens in a -3.00-D myope who is expecting a very well-defined near point of focus. If they expect to see J1 at 12 inches like they do when removing their glasses, they will be disappointed.

Should I counsel patients to expect dimness or night vision problems with this lens?

The visual disturbance profile with this lens is quite good. Patients may notice a difference between the two eyes, especially in the early postoperative period. However, in the U.S. IDE trial (n=453), patients were specifically asked about dimness and the overall rating score was 0.3 [0 = none, 1=mild, 2=moderate and 3=severe]. Overall, most patients in both the Apthera group (n=343) and a bilateral monofocal control group (n=110) reported "never" or "occasionally" experiencing visual symptoms and being bothered by them only "a little" or "not at all" at all study visits. For driving, >95% of patients reported no trouble or only a little trouble during the day and >80% reported no trouble or a little trouble at night. In the Apthera group, only 3.0%, 3.6% and 3.6%, respectively, reported experiencing severe glare, halos, or starbursts. This was comparable to the control group. There were no removals of Apthera IOLs during the study. [2,3,5]

In our clinical experience, dissatisfaction requiring explantation is very rare, but the possibility of dimness and other quality-of-vision problems should be disclosed preoperatively, as with any presbyopia-correcting IOL. Patients should be counselled to use both eyes and not to compare one versus the other as this is a blended vision solution. With both eyes working together, patients experience monofocal-like binocular photopic and mesopic contrast performance with or without glare.



IC-8® Apthera™ IOL Features

Setting Patient Expectations

For maximum patient satisfaction, and to help ensure patient satisfaction, set appropriate expectations for patients considering the Apthera IOL.

Explain the Goal

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

- Delivers reliable, continuous range of vision from near to far, without any blurry zones.
  - Reading magazines (near)
  - Working on computer (intermediate)
  - Looking at street signs (far)
- Helps patients with lower amounts of astigmatism (up to 1.5 D)
- Provides high-quality optics

Magnification may be needed

- In dim light conditions
- For prolonged near vision activities
- For tiny print

Set Realistic Expectations

- Recovery takes time
  - Days, weeks, sometimes even longer
- Avoid reading glasses
- Use artificial tears
- Not recommended for patients that drive at night

PREOPERATIVE MANAGEMENT

Which eye should I plan to treat first?

Labelling in the U.S. directs surgeons to implant the Apthera lens after successful implantation of a monofocal or monofocal toric in the first eye.

Which IOL power calculation formulas should I use?

In the U.S. IDE trial, the Barrett Universal II formula was used for all Apthera IOL power calculations. For normal eyes, surgeons can feel comfortable using their preferred power calculation method.

What refraction should I target?

The ideal refractive target for the Apthera eye is -0.75 D. This slight degree of myopia shifts the defocus curve, further enhancing the depth of focus provided by the small aperture. In the U.S. IDE trial, a mean MRSE of -0.31 ± 0.46 D, was achieved, which was within 0.50 D of the target. Given this, we recommend targeting -0.75 to -1.00 D in the Apthera eye, always with a bias towards more myopic rather than a bias towards emmetropia. In other words, if the Barrett formula predicts an MRSE of -0.65 D, we suggest selecting the next minus power. This will maximize the range of vision without sacrificing distance acuity.

Can I implant this lens through my usual 2.4 mm incision?

For surgeons who might typically prefer a smaller incision, we recommend making an architecturally sound, self-sealing, 3.0- to 3.2-mm incision that can accommodate the 3.2-mm injector provided with the lens, rather than attempting to stretch or enlarge a smaller incision. Although some surgeons do implant the lens through an incision smaller than 3.0 mm, attempting to use a smaller inserter could jeopardize the speed of visual recovery or even induce a material power shift.

Do I need to take extra steps pre- or intra-operatively to ensure good centration of the small aperture?

Good IOL centration is always desirable, but it is no more important with the Apthera lens than with any other presbyopia-correcting IOL. In the clinical trial, slight temporal decentration (≤0.5 mm) was reported in 4 of 343 eyes in the Apthera group, with no visual impact. In our experience, if the lens is in the capsular bag, it will center well and essentially become the new pupil. Many surgeons prefer a femtosecond laser-created capsulotomy for Apthera procedures, but it is not essential. Utilizing additional preoperative measurements looking for low Angle Kappa and Purkinje Images will aid in proper centration of the IC-8 small aperture IOL.

Can I implant the lens bilaterally?

The Apthera lens is not approved for bilateral implantation in normal eyes.[7]

Could the mask inside the lens become damaged during insertion?

It is theoretically possible to damage the FilterRing during insertion with aggressive handling or attempting to use a smaller-than-recommended injector, to further reduce this risk it is recommended that surgeons only use the approved injector. Should there be any damage during insertion, the lens can be cut right through the FilterRing for removal, as with any other IOL.

IC-8® Apthera™ Inserter

POSTOPERATIVE MANAGEMENT

How should Apthera patients be refracted postoperatively?

Due to the small aperture and the continuous depth of focus, refraction can be a little more challenging in an Apthera eye. As is the case with most presbyopia-correcting IOLs, autorefraction and retinoscopy may be unreliable or unattainable. Based on experience, the "mid-point" refraction technique provides the most accurate refractive endpoint. Referring clinicians and staff should be trained to "push plus" and perform a mid-point refraction if they are not already familiar with the technique. **(Table 1)**

How do you counsel patients postoperatively?

Early complaints about "glare" may be from the incision itself. We find that the negative dysphotopsia or edge glare that patients experience with diffractive IOLs is not at all common with the Apthera IOL. Remind patients to use good light and discourage them from comparing one eye against the other. If they have never had monovision before, explain that the two eyes are purposefully different and work best together; while they may notice a difference in brightness or near vision if they keep comparing the two eyes, these issues should resolve when using both eyes. Some patients may take 3 to 6 months to fully neuroadapt.

Step	Instruction	Example
1	Perform a normal manifest refraction, then instruct the patient to fixate and maintain clarity on a distance optotype 2 lines above best corrected vision	+1.00 -0.75 x 090 20/20
2	Add plus lenses until first blur, record their endpoint	+0.50 D (2 lenses)
3	Starting from the baseline manifest refraction, now add minus lenses until first blur, record endpoint	-1.75 D (7 lenses)
4	Calculate the mid-point refraction using the following equation: [(endpoint plus blur) + (endpoint minus blur)] / 2 = midpoint (rounded to nearest max plus 0.25 D)	[(+0.50) + (-1.75)] / 2 = -0.625 D (rounded to -0.50 D)
5	Add figure from Step 4 to the spherical component of the manifest refraction from Step 1: this represents the final mid-point refraction	+0.50 -0.75 x 090

Table 1: *Steps for performing a mid-point refraction*

Is it advisable to perform a Nd:YAG capsulotomy in eyes implanted with the Apthera lens?

Yes, if posterior capsular opacification (PCO) develops, as it will in a percentage of eyes. The Apthera IOL is no more prone to PCO than other IOLs, but Apthera patients may be more bothered by it. Even mild PCO, if centrally located, can affect visual quality through the small aperture. The recommended technique involves performing a hinged, circular capsulotomy at a diameter of 5.0 to 5.5 mm, outside the FilterRing component. With a 7.0-mm dilated pupil, the surgeon will have a clear view of the FilterRing component edge, the edge of the IOL optic, and the recommended location for the capsulotomy.

Using a contact lens for the Nd:YAG procedure is more important than in routine cases, in our experience, but is not required. Try to avoid directly hitting the FilterRing with the laser, but in our experience, accidental laser shots to the FilterRing have discolored but not significantly damaged it or affected it optically. If the hinged capsulotomy does not fall back as intended, the surgeon may need to apply some laser shots through the aperture of the FilterRing. It is recommended that for first cases additional time is scheduled to perfect this technique.

The DFU states that a specific course is required. Why is that?

The Apthera lens is the first lens to incorporate a small aperture in its design. As a result, specific product training for performing routine procedures will be provided. Training on appropriate capsulotomy technique will be required for surgeons implanting the Apthera IOL to mitigate the risk of a secondary YAG and potential YAG damage to the Apthera IOL. Nd-YAG lasers have the potential to damage IOL's of all designs. Surgeons must complete an FDA-mandated online course in this technique prior to implanting Apthera IOLs commercially in the U.S. Go to **acufocusuniversity.com/registration/** to access the course.

My patient had good near vision initially with the Apthera IOL, but it has declined, and the patient is no longer satisfied. What should I do?

With a small aperture, every optical interface within the central zone is important. Deterioration in near vision is an early sign of PCO; surgeons should not be afraid to perform a Nd:YAG capsulotomy using the company's guidance for doing so, as described in the DFU.

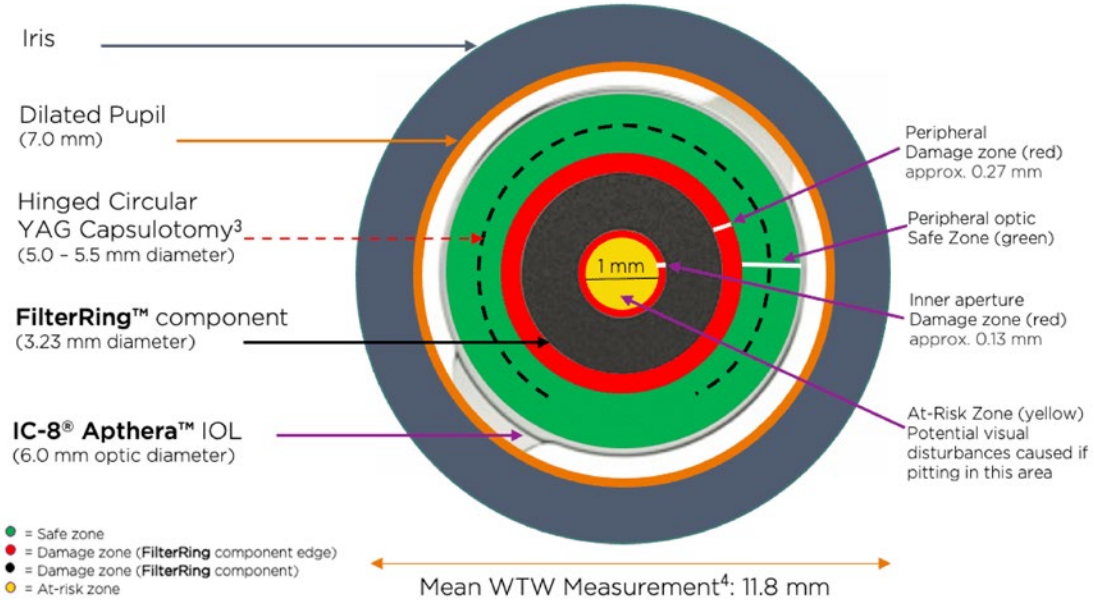


Figure 1: *As demonstrated by the distance-corrected monocular defocus curves, Apthera IOL treated eyes maintained 1.99 D of extended depth of focus and demonstrated 0.91 D of additional range of vision benefit over monofocal IOL eyes at 0.2 logMAR threshold.*[2,3]

Will I be able to examine the retina in an eye with an IC-8 Apthera?

In the IDE clinical trial for the Apthera lens, retinal diagnostic testing was performed in a subgroup of 49 subjects, with images evaluated by an independent reading center. Visual field (VF) testing was found to be unaffected by the Apthera IOL. Mean VF pattern deviation from baseline to 3 months was equivalent (<1 dB) in Apthera and control eyes, indicating that the embedded FilterRing component does not induce VF defects.[4] Nearly all of the clinical investigators (99.4%) reported no difficulty in visualization of the central retinal features and the remainder reported only a "little difficulty." The independent reading center verified that the image quality of fundus photos and OCT imaging of the optic disc and macula was excellent to adequate in 100% of cases.[4] Additionally, in a published prospective case series, Srinivasan et al reported no difficulty imaging the posterior segment with the IC-8 IOL implanted.[6]

What retinal procedures can be performed in an eye with an Apthera lens?

The Apthera lens does not prevent the performance of common retinal procedures. Vitrectomy, membrane peel, air fluid exchange, cryotherapy, and retinal laser are among the retinal procedures that have successfully been performed after implantation of an IC-8 lens.

There were four pars plana vitrectomies performed in Apthera eyes in the clinical trial. In some cases, these were to eliminate posterior capsular remnants, and in others to address vitreous opacities unrelated to the posterior capsule. Following the restoration of sharp vision with cataract surgery, some patients become quite bothered by floaters. We advocate for pseudophakic vitrectomy to address this problem when it occurs following implantation of any presbyopia-correcting IOL, including the Apthera IOL.

Caution should be taken to avoid focusing any laser directly on the FilterRing component. In general, lasers with longer wavelengths (≥650 nm) are more likely to cause thermal damage. Although there is a labeled warning referencing the potential release of carbon black material should this happen, no such release of material has been observed during extensive R&D testing.

When should I explant the lens?

If the patient is very unhappy and this dissatisfaction persists even after several months of neuroadaptation, explantation should be considered. However, several expert Apthera surgeons in this group have never explanted a single Apthera IOL. Proper preoperative patient selection and counseling as described above, reduces probability of explants. If explanted, replacement with a high-quality monofocal IOL is recommended.

RECENT PUBLISHED MANUSCRIPTS

Manuscript #1: Clinical comparison of a small-aperture intraocular lens versus a monofocal control.

This manuscript evaluated the visual acuity (VA), visual quality, and safety of the IC-8 small aperture (SA) intraocular lens (IOL), in patients with cataract. This prospective, multicenter, open-label, parallel-group, non-randomized, examiner-masked, 12-month clinical study was conducted at 21 sites in the United States. At 6 months, the SA IOL Group achieved superior binocular uncorrected intermediate and near VA (UIVA and UNVA; P<0.0001) and equivalent binocular uncorrected distance VA (UDVA) versus the Control Group. In SA IOL eyes, 99.1% achieved monocular corrected distance VA of 0.3 logMAR or better. The SA IOL and Control Groups had comparable binocular photopic and mesopic contrast sensitivities at 6 months both with and without glare. The SA IOL Group reported few visual symptoms overall, though at higher rates than in the Control Group. The SA IOL Group exhibited improved intermediate and near vision, comparable distance vision and binocular contrast sensitivities, and few visual symptoms or adverse events versus the bilateral monofocal/monofocal toric IOL Group, suggesting that the SA IOL is an effective option for presbyopia correction at the time of cataract surgery.

Manuscript #2: Evaluating the small aperture intraocular lens: depth of focus and the role of refraction and preoperative corneal astigmatism on visual performance.

This manuscript evaluated the depth of focus (DOF) and visual acuities (VAs) by manifest refractive spherical equivalent (MRSE) and degree of preoperative corneal astigmatism with the IC-8 small aperture intraocular lens (SA IOL). This prospective, multi-center, open-label, parallel-group, non-randomized, examiner-masked, one-year clinical study included patients that had cataract and ≤1.5D preoperative corneal astigmatism and was conducted at 21 sites in the United States. Patients received either the SA IOL in one eye targeted to -0.75D and a monofocal or monofocal toric IOL in the other targeted to plano (SA IOL Group) or bilateral monofocal/monofocal toric IOLs targeted to plano (Control Group). Monocular and binocular assessments included defocus curves and uncorrected VAs (distance, intermediate, and near) by postoperative MRSE; monocular VAs were assessed by degree of preoperative corneal astigmatism. The SA IOL Group (n=343) achieved 0.82D additional binocular DOF versus the Control Group (n=110), and SA IOL eyes achieved 0.91D additional monocular DOF over fellow eyes. Across all MRSEs, the SA IOL Group achieved monocular uncorrected VAs of 20/40 or better and binocular uncorrected VAs of 20/32 or better across all distances. The SA IOL provides increased DOF versus monofocal/monofocal toric IOLs and consistent monocular and binocular vision across several postoperative MRSEs and up to 1.5D of preoperative corneal astigmatism, giving patients with cataract and mild astigmatism the potential for an extended range of vision and reliable visual outcomes.

We welcome additional questions from users of the IC-8 Apthera IOL and may update this document as new questions arise, and new study data become available.

INIDCATIONS FOR USE STATEMENT

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.[1]

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