

PATIENT INFORMATION BROCHURE

IC-8[®] Athera[™] IOL Small Aperture Intraocular Lens

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Introduction

This brochure has been written to help you and your eye doctor make an informed decision about the best intraocular lens (IOL) for your cataract surgery. Your doctor will advise you about the potential risks and benefits of the surgical procedure to remove the cataract and implant an IOL. This brochure will help you decide if the **IC-8 Aphaera** small aperture IOL from AcuFocus, Inc. is an appropriate choice for you. Please see the section “What types of IOLs are available for this procedure” to learn about other options you may have.

What is a Cataract?

To understand what a cataract is, it is helpful to understand how the human eye works¹. As shown in **Figure 1** below, the front of the eye is made of the cornea, iris, pupil and a natural lens which is contained in the lens capsule. The back of the eye is the retina, where images are focused. When you look at an object, light reflected from the object enters the eyes through the cornea. The cornea focuses the light before it passes through the pupil. The amount of light that can reach the retina is controlled by the iris which automatically adjusts the size of the pupil to allow light through. Located directly behind the pupil, the natural lens further focuses light onto the retina, the light-sensitive inner lining of the back of the eye. When light reaches the retina, the retina converts optical images into signals, then the optic nerve transmits these signals to the part of brain that controls our sense of sight.

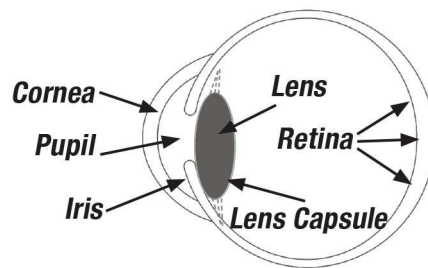


Figure 1 – Drawing of the Human Eye

When the natural lens of your eye is clear, it helps focus images onto the back of your eye so you can see objects and text clearly. Over time, the natural lens of your eye may start to become “cloudy.” When this happens, it is called a cataract. Most cataracts are related to the natural aging process. Cataracts can also be caused by certain medical conditions, medications or eye injuries. While cataracts may start out small at first and have little effect on vision, as they grow larger, they may cloud more of the lens and

¹ <https://www.allaboutvision.com/resources/anatomy.htm>

distort the light passing through. If left untreated, cataracts can result in complete loss of vision. Early noticeable symptoms of cataracts include:

- Cloudy, blurry, foggy, or filmy vision
- Glare from lamps, the sun, or headlights
- Frequent changes in eyeglass prescription
- Double vision

Cataracts can only be removed with cataract surgery. You should consider cataract surgery when vision loss is interfering with your daily activities. It is typically performed as an outpatient procedure under local or topical anesthesia. The natural lens of the eye is removed and replaced with a permanent IOL implant.

Please see “*What to Expect During Cataract Surgery*” for more detailed information about this surgical procedure, and “*Types of IOLs*” for more details about the various IOL options available today. There are also other options for restoring your functional vision, such as glasses and contact lenses, which don’t involve surgery. You should discuss these options fully with your eye doctor to select the option that best meets your expectations and lifestyle.

What is Corneal Astigmatism?

Astigmatism is a common eye condition that causes blurry far and/or near vision. In a normal eye, the cornea (the clear front part of the eye) has a round shape. It allows the light rays coming into the eye to focus at a single point on the back of the eye (retina) to form a clear image. In an eye with corneal astigmatism, the cornea has an oval shape and as a result, the light rays do not focus at the same point on the retina. This may cause some parts of an object to be unclear. This may also lead to eye discomfort and headaches. During a comprehensive eye exam, your eye doctor will be able to tell you if you have corneal astigmatism.

What is an Intraocular Lens (IOL)?

During cataract surgery, the cloudy natural lens of the eye is removed and replaced with a clear artificial lens known as an intraocular lens or IOL.

Figure 2 shows the basic parts of the human eye with an implanted IOL.

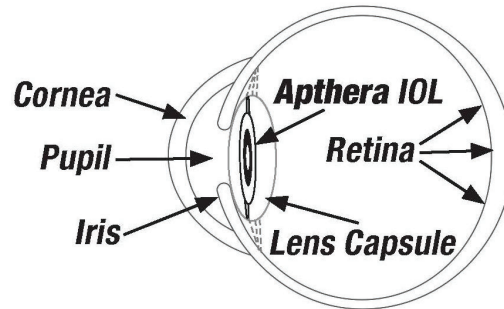


Figure 2 – Drawing of the Human Eye with an Implanted IOL

What to Expect Before Cataract Surgery

After completing a comprehensive eye exam and determining you have a cataract, you and your eye doctor will discuss cataract surgery. Before surgery, your doctor will measure your eye. This will help determine which IOL will be suitable for you.

What to Expect During Cataract Surgery

Cataract surgery is typically an outpatient procedure performed under local anesthesia. Local anesthesia is typically applied in the form of eyedrops. Sometimes patients may also receive additional medicine intravenously to ensure the best possible experience. Typically, you will be awake during the surgery and lying down. You should feel little or no discomfort. Your eye doctor will use a microscope to look at your eye close up. To access your eye's natural lens, which sits in a bag-like structure inside your eye called the lens capsule, your eye doctor will need to make a small incision in the outer surface of the eye. The lens capsule is located just behind the colored part of your eye known as the iris. Through this opening, the eye doctor will create a small opening in the front of the lens capsule and then insert a tiny instrument to break up and remove the cataract. Your doctor will then place an IOL into the empty capsule replacing your natural lens. The IOL will help focus light inside the eye to allow you to see more clearly. Please see "What types of IOLs are available for this procedure" for information about IOL options.

What to Expect After Cataract Surgery

Your surgeon will usually place a shield over your eye after surgery. You will be ready to go home after a short stay in the outpatient recovery area. It is possible that after the medicine wears off you might feel some itching or minor eye discomfort. Most people report that they can easily manage minor eye discomfort with short-term use of over-the-counter pain medication. Plan to have someone else drive you home.

Your eye doctor should give you a patient implant identification card to keep in your wallet. This card shows the type of implant in your eye and some other general information. Present this card to any eye doctor who examines your eyes after surgery.

Potential Risks Associated with Cataract Surgery

As with any surgery, there are risks and potential complications associated with routine cataract surgery and IOL implantation. This is unrelated to the lens you choose.

Cataract surgery complications are rare, but may include inflammation, infection, bleeding, swelling, drooping eyelid, dislocation of the artificial lens, retinal detachment, increased eye pressure (glaucoma), secondary cataract, and injury to the eye. The problems could be minor, temporary, or they could last permanently. There is a small chance that your vision could be made worse by the operation. Please discuss these general risks associated with cataract surgery with your eye doctor.

Types of IOLs

There are many different IOLs to choose from. Your eye doctor will discuss your options with you based on your specific needs. These include the **IC-8 Athera** IOL. Other IOL types are also available such as monofocal IOLs, multifocal IOLs, extended depth of focus IOLs, accommodating IOLs, and toric IOLs. Each option has its own advantages and disadvantages. Discuss all your IOL options with your eye doctor so you may choose the IOL that best meets your expectations and lifestyle.

Monofocal IOLs

Monofocal IOLs are single-focus lenses designed to provide far vision. This means you will usually be able to see objects far away, but you will most likely need glasses for near vision activities such as reading, sewing, and writing, as well as intermediate vision activities such as working on a computer, putting on make-up, or shaving.

Multifocal IOLs

Multifocal IOLs provide vision at two or more distances to treat presbyopia, the loss of near vision. There are two types of multifocal IOLs, bifocal IOLs and trifocal IOLs. Bifocals offer far and intermediate or near vision at specific distances, at the same time. Trifocals offer vision at three distinct distances: near, intermediate and far. The goal of these lenses is to reduce the need for glasses or contact lenses. However, multifocal IOLs also can create problems with night vision, such as glare and/or halos around lights. They may also decrease the sharpness of your vision compared to a monofocal lens.

Extended Depth of Focus IOLs

Extended depth of focus (EDF) IOLs are the newest type of IOL for the treatment of presbyopia. Unlike multifocal IOLs, EDF IOLs provide a continuous range of vision from far to intermediate, with some lens designs also providing functional near vision.

Reading glasses may still be needed to see fine details and small print. The **IC-8 Athera** IOL is an extended depth of focus IOL – see “*The IC-8 Athera Small Aperture IOL*” section for more details.

Accommodating IOLs

Accommodating IOLs are designed to mimic the natural focusing process of the eye. These lenses provide far vision and may change focus, enabling you to see up close (near). You may still need reading glasses to see fine details and small print.

Toric IOLs

Toric IOLs are designed for people with astigmatism. There are three types of toric IOLs – monofocal toric IOLs, multifocal toric IOLs, and EDF toric IOLs. Toric IOLs can correct the refractive error caused by a cornea with an oval shape due to astigmatism. Like the other types of IOLs, there is a chance you may still need glasses for far, intermediate, and/or near vision.

The IC-8 Athera Small Aperture IOL

The **IC-8 Athera** IOL is a first-of-its-kind small aperture lens designed for patients with cataracts. The **IC-8 Athera** IOL is indicated to be implanted in one eye after the natural lens is removed in cataract surgery, in eyes with up to 1.5 diopters (D) of preoperative corneal astigmatism. The other eye should be implanted with a monofocal or monofocal toric IOL. The **IC-8 Athera** IOL provides an extended depth of focus from far through intermediate and near and is intended for adult patients to reduce the effects of presbyopia.

The **IC-8 Athera** lens is designed to focus light that enters your eye using small aperture technology. When light passes through the small aperture (created by the **FilterRing™** component inside the lens), only focused light reaches the retina. Defocused light that can cause blurry vision is filtered out. This seamlessly expands your range of vision by bringing objects and text into focus from far to near.

The **IC-8 Athera** IOL, when working together with a monofocal or monofocal toric IOL provides many key benefits, including:

- Delivering reliable, continuous range of vision from near (such as reading) to intermediate (such as computer work) to far (such as looking at a street sign), without any blurry zones
- Helping patients with astigmatism up to 1.5 D
- Providing high-quality optics²

Please discuss with your eye doctor whether this IOL is the right option for you.

Potential Risks and Side Effects Associated with the IC-8 Aphera IOL

Cataracts affect your vision by causing unwanted visual effects such as glare, appearance of rings around lights, starburst, faded colors, blurry or double vision and trouble seeing at night. After cataract surgery, most patients experience a significant reduction in those visual effects. Patients treated with a monofocal lens, which only provide clear vision at one distance, typically experience a low level of side effects after cataract surgery. For lens designs that provide a broader range of vision, clear vision at many distances, some visual effects may be experienced after surgery that can make it more difficult to see in some situations.

In the U.S. clinical study of the **IC-8 Aphera** IOL (referred to as **IC-8 IOL**), reports of visual effects (disturbances) were captured for the **IC-8 IOL** group and the monofocal IOL group. While most patients experienced low levels of visual effects, some patients did experience higher levels of visual effects. **Table 1** below shows the summary of severity of visual effects experienced by **IC-8 IOL** group and monofocal IOL group after surgery. **Table 2** shows the summary of how bothersome the visual effects experienced by the **IC-8 IOL** group and monofocal IOL group were after surgery. Rates after surgery above 1% for “severe” and/or “very bothersome” visual effects are included in both tables.

Overall, the majority of **IC-8 IOL** patients experienced low levels of visual effects after surgery rating severity and bothersomeness as either “not at all” or “mild”.

² Through focus image quality bench test data, measured from +1.00 diopter to -2.50 diopters in 0.50 diopter increments to establish depth of focus

Table 1: Visual Effect Severity Ratings for the IC-8 IOL Group and Monofocal IOL Group at 12 Months After Surgery

Visual Effect	Severity Rating	IC-8 IOL Group Rating After Surgery (N=331)	Monofocal IOL Group Rating After Surgery (N=100)
Glare	Not at all	42.3%	49.0%
	Mild	39.9%	43.0%
	Moderate	14.8%	8.0%
	Severe	3.0%	0.0%
Halos	Not at all	45.6%	73.0%
	Mild	36.0%	23.0%
	Moderate	14.8%	4.0%
	Severe	3.6%	0.0%
Starbursts	Not at all	48.9%	73.0%
	Mild	36.9%	25.0%
	Moderate	10.6%	1.0%
	Severe	3.6%	1.0%
Hazy Vision	Not at all	64.4%	75.0%
	Mild	25.1%	23.0%
	Moderate	9.1%	2.0%
	Severe	1.5%	0.0%
Blurred Vision	Not at all	54.7%	66.0%
	Mild	34.1%	31.0%
	Moderate	9.7%	3.0%
	Severe	1.5%	0.0%
Vision Fluctuation	Not at all	54.1%	71.7%
	Mild	36.9%	23.2%
	Moderate	7.6%	5.1%
	Severe	1.5%	0.0%
Focusing Difficulties	Not at all	36.9%	51.5%
	Mild	50.8%	45.5%
	Moderate	10.6%	3.0%
	Severe	1.8%	0.0%
Difficulty Judging Distance or Depth Perception	Not at all	75.5%	78.8%
	Mild	19.0%	18.2%
	Moderate	5.1%	3.0%
	Severe	0.3%	0.0%
Problem Seeing when Light Conditions Change	Not at all	61.3%	68.0%
	Mild	29.3%	29.0%
	Moderate	6.9%	1.0%
	Severe	2.4%	2.0%

Table 2: Bothersomeness Ratings of Visual Effects for the IC-8 IOL Group and Monofocal IOL Group at 12 Months After Surgery

Visual Effect	Bothersomeness Rating	IC-8 IOL Group Rating After Surgery (N=331)	Monofocal IOL Group Rating After Surgery (N=100)
Glare	Not at all	48.9%	57.0%
	A little	38.1%	38.0%
	Quite	9.4%	5.0%
	Very	3.6%	0.0%
Halos	Not at all	52.6%	79.0%
	A little	34.1%	17.0%
	Quite	8.8%	4.0%
	Very	4.5%	0.0%
Starbursts	Not at all	58.0%	75.0%
	A little	31.4%	23.0%
	Quite	6.9%	1.0%
	Very	3.6%	1.0%
Hazy Vision	Not at all	67.4%	80.0%
	A little	24.5%	19.0%
	Quite	6.3%	0.0%
	Very	1.8%	1.0%
Blurred Vision	Not at all	57.7%	67.0%
	A little	32.3%	30.0%
	Quite	7.9%	3.0%
	Very	2.1%	0.0%
Vision Fluctuation	Not at all	57.7%	72.7%
	A little	33.2%	25.3%
	Quite	6.9%	2.0%
	Very	2.1%	0.0%
Focusing Difficulties	Not at all	42.3%	60.6%
	A little	46.8%	36.4%
	Quite	7.9%	3.0%
	Very	3.0%	0.0%
Difficulty Judging Distance or Depth Perception	Not at all	76.4%	79.8%
	A little	18.4%	18.2%
	Quite	3.9%	2.0%
	Very	1.2%	0.0%
Problem Seeing when Light Conditions Change	Not at all	64.4%	70.0%
	A little	28.7%	27.0%
	Quite	4.2%	2.0%
	Very	2.7%	1.0%

Some serious ocular adverse events were observed throughout the 12-month clinical study. Out of the 343 eyes treated with the **IC-8** IOL, five (5) eyes experienced cystoid macular edema (swelling of the central part of the retina at the back of the eye); one (1) eye experienced endophthalmitis (severe infection of the eye); ten (10) eyes had secondary procedures; two (2) eyes experienced iritis (intraocular inflammation); and one (1) eye experienced retinal vein occlusion (blocked vein in the retina at the back of the eye).

At 12 Months, all serious ocular adverse events were resolved, except one (1) event of cystoid macular edema, two (2) events of iritis (intraocular inflammation), and one (1) event of retinal vein occlusion.

Table 3 provides details of the ten (10) secondary surgical procedures reported in **IC-8** IOL eyes. No **IC-8** IOLs were removed during the clinical study. In the monofocal group, one patient required removal and replacement of the monofocal IOLs in both of the patient’s eyes during the study. Following exit from the clinical study but within a year of surgery, one patient treated in the monofocal group had one of the patient’s monofocal IOLs removed and replaced, and two patients treated in the **IC-8** IOL group had their **IC-8** IOLs removed. All subjects requested removals due to unwanted visual effects.

Table 3. Details of the Secondary Surgical Procedures

IC-8 IOL Eyes
<p>Ten (10) out of 343 patients having secondary surgical procedures in IC-8 IOL eyes:</p> <p>Secondary surgical procedures reported as not related to cataract surgery or the IC-8 IOL:</p> <ul style="list-style-type: none"> - One (1) patient received a secondary surgical procedure (vitrectomy) to remove the floaters, which appear as specks or dust in the eye. <p>Secondary surgical procedures reported as related to cataract surgery and possibly related to the IC-8 IOL:</p> <ul style="list-style-type: none"> - One (1) patient received a secondary surgical procedure (vitrectomy) to remove a floater (which appear as specks or dust in the eye). - One (1) patient received a secondary surgical procedure (vitrectomy) to remove anterior vitreous debris (similar to floaters, which appear as specks or dust in the eye). <p>Secondary surgical procedures reported as related to cataract surgery but not to the IC-8 IOL:</p>

- One (1) patient received a secondary procedure (vitrectomy concurrent with intravitreal injection) to treat endophthalmitis (inflammation in the eye).
- One (1) patient received a secondary procedure (intravitreal injections) to treat cystoid macular edema (swelling of the central part of the retina at the back of the eye). This patient also had a secondary procedure to treat floaters as stated above.
- Two (2) patients received a secondary procedure to remove the remaining cataract material left in their eye after cataract surgery.
- One (1) patient received a secondary procedure to reposition the IOL.
- Four (4) patients received a modified paracentesis procedure to lower their intraocular pressure following cataract removal surgery (one of these patients is a patient who also had a secondary procedure to remove the remaining cataract material left in their eye after cataract surgery as stated above).

Following treatment, all of these adverse events were resolved.

U.S. Clinical Study Vision Results

The **IC-8 Aphthera** IOL has been well studied in the United States. The clinical study tested two groups of patients with up to 1.5 D of astigmatism. The first group, the **IC-8** IOL Group, consisted of patients that had an **IC-8 Aphthera** IOL (referred to as **IC-8** IOL) implanted in one eye and a monofocal or monofocal toric IOL implanted in the other eye. The second group, the Monofocal IOL Group, consisted of patients with a monofocal or monofocal toric IOL implanted in both eyes. The test results of both groups were compared to determine the effectiveness and safety of the **IC-8** IOL. Additionally, the **IC-8** IOL eyes were compared to monofocal or monofocal toric IOL eyes.

Vision was tested using an eye chart. Each line on the eye chart is labeled using numbers on the right, such as 20/20, 20/25, 20/30, 20/40 and so on. Your vision is defined as the smallest line on the eye chart that you are able to read at least three or more letters on. For example, if you are able to read at least three letters on the line labeled 20/25, your vision is 20/25. An example of an eyechart can be found in **Figure 3**. This chart can be used as a reference when discussing the increased number of lines you can read with the **IC-8** IOL.

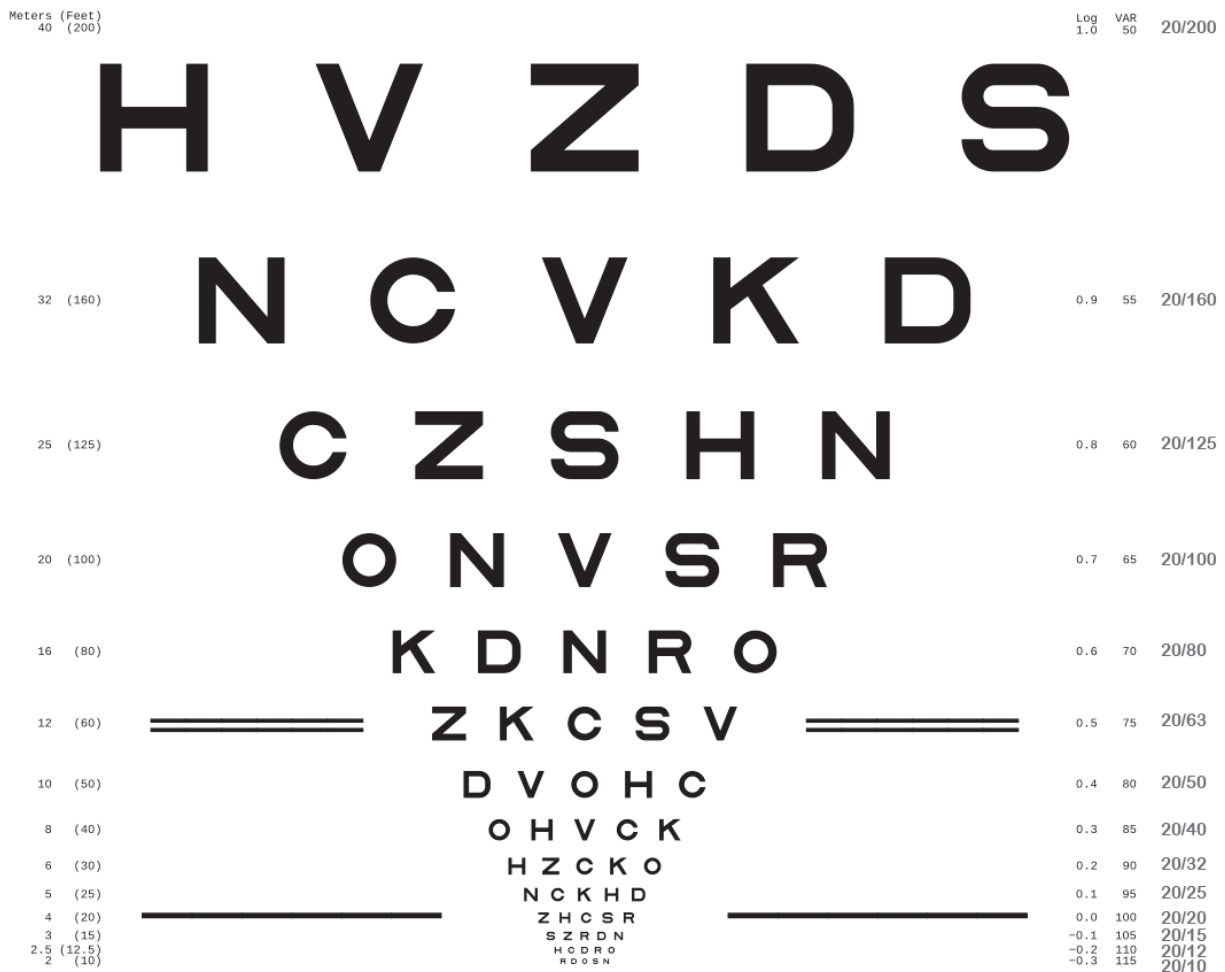


Figure 3 – Example Eye Chart (not the real size)

Table 4 compares far, intermediate and near vision results for the **IC-8** IOL eye versus the monofocal or monofocal toric IOL eye with and without glasses. It also compares vision for both eyes in the **IC-8** IOL group versus the Monofocal IOL Group with and without glasses. When comparing the two groups with glasses, patients achieved the following for far, intermediate and near vision:

- Far Vision: **IC-8** IOL Group and Monofocal IOL Group patients saw the same excellent far vision – reading the same line on the eye chart.
- Intermediate Vision: **IC-8** IOL Group patients saw approximately two (2) lines smaller (better) on the eye chart.
- Near Vision: Patients in the **IC-8** IOL Group saw approximately two (2) lines smaller (better) on the eye chart compared to the Monofocal IOL Group patients.

Table 4: Comparison of Monocular (One Eye) and Binocular (Both Eyes) Range of Vision Results Between the IC-8 IOL Eye, Monofocal IOL Eye, the IC-8 IOL Group, and the Monofocal IOL Group at 6 Months After Surgery

	Monocular (One Eye)		Binocular (Both Eyes)	
	IC-8 IOL Eye	Monofocal IOL Eye ¹	IC-8 IOL Group ²	Monofocal IOL Group ³
Far Vision 20/25^{-2*} or better without glasses (driving, reading street signs, etc.)	60.0% of patients	70.0% of patients	93.1% of patients	94.0% of patients
Far Vision 20/25^{-2*} or better with glasses (driving, reading street signs, etc.)	91.0% of patients	96.0% of patients	99.1% of patients	99.0% of patients
Intermediate Vision 20/25^{-2*} or better without glasses (computer work, cooking, etc.) at approximately 26 inches	78.8% of patients	22.0% of patients	85.7% of patients	39.0% of patients
Intermediate Vision 20/25^{-2*} or better with glasses (computer work, cooking, etc.) at approximately 26 inches	64.8% of patients	7.0% of patients	73.7% of patients	15.0% of patients
Near Vision 20/40^{-2*} or better without glasses for far (reading, sewing, etc.) at approximately 16 inches	83.3% of patients	19.0% of patients	87.5% of patients	44.0% of patients
Near Vision 20/40^{-2*} or better with glasses for far (reading, sewing, etc.) at approximately 16 inches	66.6% of patients	14.0% of patients	75.2% of patients	33.0% of patients

¹Monofocal IOL eye refers to the second eye in the Monofocal IOL Group.

²The **IC-8** IOL Group consists of patients who were implanted with an **IC-8** IOL in one eye and a monofocal or monofocal toric IOL in their other eye.

³The Monofocal IOL Group consists of patients who had a monofocal or monofocal toric IOL implanted in both eyes.

*On an eye chart, reading all letters on a line, for example 20/25, with no mistakes, means you have 20/25 vision. If you read the majority of the 20/25 line, missing two (2) letters, written as 20/25⁻², means you have approximately 20/25 vision.

Additional Data Points

- Patients in the **IC-8** IOL Group achieved the same visual benefit of 20/25 or better for far vision whether they had no corneal astigmatism or as much as 1.5 D.
- Vision in eyes with an **IC-8** IOL exceeded international standards:
 - 99.1% of patients achieved 20/40 or better far vision with glasses at 12 months after surgery
 - 99.4% of best-case patients achieved 20/40 or better far vision with glasses at 12 months after surgery
- When looking at the two groups overall range of vision, from near to far, the **IC-8** IOL Group experienced a significant increase in range of vision versus the Monofocal IOL Group.

Contrast Sensitivity and Contrast Acuity

Contrast sensitivity testing is used to evaluate your ability to distinguish objects from a background in different lighting conditions. In the **IC-8 Aphthera** IOL clinical study, contrast sensitivity was evaluated monocularly (in one eye) and binocularly (with both eyes) in the **IC-8** IOL Group and compared to contrast sensitivity scores for the Monofocal IOL Group. Eyes treated with the **IC-8** IOL experience lower contrast sensitivity in bright and dim light conditions versus eyes treated with a monofocal or monofocal toric IOL when tested monocularly. However, when using both eyes, patients in the **IC-8** IOL Group achieved comparable binocular contrast sensitivity scores as patients in the Monofocal IOL Group in both bright and dim light conditions.

Contrast acuity testing evaluates your ability to distinguish text from a background in decreased contrast (for example, gray letters on a light gray background). In the **IC-8** IOL clinical study, patients in the **IC-8** IOL Group achieved comparable contrast acuity scores in far vision to Monofocal IOL Group patients and better contrast acuity scores in near vision (reading) and intermediate vision (computer work, cooking, etc.).

Contraindications

1. Before surgery, your eye doctor will take your medical history and perform a complete eye exam to determine if you are a candidate for the **IC-8 Aphthera** IOL. Your doctor will use dilating drops to dilate your pupil during your eye exam. Patients whose pupils do not dilate widely should not have the **IC-8 Aphthera** IOL implanted in their eye.
2. The **IC-8 Aphthera** IOL is contraindicated for patients with any retinal disease or for patients who may be at risk for getting retinal diseases in the future.

Warnings

1. Some visual effects may be expected, such as halos or glare, issues in dim light conditions, and other visual symptoms regardless of lighting conditions. As with all IOLs, there is a possibility that visual symptoms may be significant enough that a patient may request removal of the lens.
2. Contact your eye doctor immediately if you have any of the following symptoms after surgery: a significant decrease in vision; double vision persisting more than a few days; a significant increase in pain in the implanted eye; significant itching, redness, and/or watering of your eye; significant eye discharge; or increased sensitivity to light. These symptoms could indicate postoperative complications including a potentially serious eye infection.
3. While most patients, in the clinical study, experienced good vision in dim or low-contrast conditions, after surgery, vision with the **IC-8 Aphera** IOL eye may be poorer in dim or low-contrast conditions than in the other eye treated with a monofocal or monofocal toric IOL. As a precaution, extra care should be taken 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. Implantation of the **IC-8 Aphera** IOL in both eyes has not been studied and could result in compromised vision. The **IC-8 Aphera** IOL should not be implanted in both eyes.
5. Vision with the **IC-8 Aphera** IOL in eyes with corneal astigmatism greater than 1.5 D has not been studied and may result in poor vision after surgery.
6. As part of routine eye health monitoring, the eye doctor may perform certain diagnostic tests that may take longer to perform and require some additional effort to complete in the **IC-8 Aphera** IOL treated eye. If glaucoma or retinal conditions develop, some difficulty with conducting examinations and/or administering treatments is possible. In rare cases, the eye doctor may decide to remove the lens.
7. Although cataracts do not grow back, some patients may experience blurry vision after cataract surgery due to the membrane behind the lens becoming cloudy. In those instances, a secondary procedure may be necessary to improve vision. Damage to the lens is possible during the procedure which may result in increased visual effects, and in rare cases, the lens may need to be exchanged.

Precautions

1. Prior to surgery, your eye doctor will check if you have any eye diseases. You should tell your eye doctor of any eye problems or if you have been diagnosed

with any eye conditions. If your eye is not healthy, you may not get the full benefit of the **IC-8 Aphthera** IOL.

2. If you wear contact lenses, your eye doctor may ask you to stop wearing contact lenses for a certain period of time before the surgery so the doctor can choose the right lens power for you.
3. If you are expected to have 1.0 to 1.5 D of astigmatism after surgery, you may not experience as much improvement in intermediate vision compared to patients who have smaller amounts of astigmatism.
4. After surgery, you may need eyeglasses when reading small print or looking at small objects.
5. Inform your eye doctor before getting any retinal laser procedure that you have the **IC-8 Aphthera** IOL in your eye. The **IC-8 Aphthera** IOL may be damaged by lasers used to treat eye conditions. Damage to the **IC-8 Aphthera** IOL might affect vision, may lead to potential release of carbon black color pigment from the **FilterRing** component, and in rare cases may require lens removal.
6. The **IC-8 Aphthera** IOL has not been studied for use in children or in pregnant/nursing women.
7. As with other IOLs, if there are unexpected results, you may need another surgical procedure to adjust the position of the IOL.
8. Pre-existing diseases or conditions may place you at higher risk of experiencing complications during and after routine cataract surgery. Examples of pre-existing diseases or conditions are diabetes, heart disease, and previous trauma to your eye. Examples of complications include not being able to implant the **IC-8 Aphthera** IOL into your eye, poorer visual outcome, and more difficult recovery.
9. It is possible you may experience visual symptoms such as glare, halos, and starbursts which can make it difficult to see clearly when there are bright lights at night.

MRI Safety Information

If you need to receive a Magnetic Resonance Imaging (MRI) scan, the following table provides important safety information. Make sure to show your patient implant card and the following information to the MRI technician/MRI imaging center before you receive a MRI scan. This information can also be obtained by contacting AcuFocus at 844-895-3363.



The **IC-8 Aphthera** 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	1.5T or 3T
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Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Maximum Whole Body SAR	2.0 W/kg (Normal Operating Mode)
Scan Duration	60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact

Postoperative Care Instructions

You will return home after surgery. Your vision should improve within four (4) to six (6) weeks after cataract surgery. Many patients may see better within one (1) to two (2) weeks. Recovery time varies, but full healing can take up to three (3) months. During the healing process, your vision may fluctuate. You will need to take eye drops as prescribed by your doctor to help control inflammation and prevent the risk of infection. Avoid activities that could harm your eye while you are recovering from surgery, such as playing sports, bending down, or any activities where objects can put pressure on the eye or come in contact with the eye. Typically, your eye doctor will examine you the following day.

Be sure to talk with your eye doctor so you can fully understand the recovery process after your cataract surgery. It may take you some time to get used to your new IOL(s). Always talk with your eye doctor if you have any questions or concerns.

After your cataract surgery, maintaining regular eye exams is important.

Key Points to Remember About Your Choice

- It is important to discuss your lifestyle and/or visual needs with your eye doctor to help select the best IOL for you.
- If being able to see a continuous range of vision (far, intermediate, and near) is important for your lifestyle, the **IC-8 Aphthera** IOL may be a good option for you.
- Review the advantages and disadvantages with your doctor before deciding which IOL is right for you.

Thank you for considering the **IC-8 Aphthera** IOL.

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