

PATIENT INFORMATION BROCHURE

ALCON AcrySof™ Aspheric Toric
Intraocular Lenses

(Models SN6AT3, SN6AT4, SN6AT5, SN6AT7, SN6AT8, SN6AT9)

ALCON AcrySof™ Aspheric UV-absorbing Toric
Intraocular Lenses

(Models SA6AT3, SA6AT4, SA6AT5, SA6AT6, SA6AT7, SA6AT8, SA6AT9)

ALCON Clareon™ Toric Aspheric Hydrophobic Acrylic
Intraocular Lenses

*(Models CNW0T3, CNW0T4, CNW0T5, CNW0T6, CNW0T7, CNW0T8,
CNW0T9 and*

Models CNA0T3, CNA0T4, CNA0T5, CNA0T6, CNA0T7, CNA0T8, CNA0T9)

PATIENT INFORMATION BROCHURE
ALCON Toric Intraocular Lenses

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Glossary

| | |
|--------------------------------|---|
| Aspheric IOL: | An artificial lens with an optic surface designed to enhance distance vision particularly under low light conditions when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape. |
| Astigmatism: | Astigmatism is a focusing error in the eye that results in blurred distance and/or near vision. |
| Cataract: | A clouding of the natural crystalline lens of the eye that interferes with vision. |
| Cornea: | The clear front part of the eye that focuses light into the eye. |
| Corneal Astigmatism: | The inability of the eye to focus clearly at any distance because of different curvatures on the cornea. |
| Crystalline lens: | The clear natural structure in the eye that helps to focus light on the back of the eye. The crystalline lens functions like the lens of a camera. |
| Intraocular Lens (IOL): | An artificial lens that replaces the natural crystalline lens of the eye after cataract surgery. |
| Iris: | The colored membrane in front of the natural crystalline lens that controls the size of the pupil and the amount of light entering the eye. |
| Monofocal IOL: | An artificial lens designed to restore only distance vision. |
| Retina: | The light-sensitive layer in the back part of the eye that receives images (light) and sends them to the brain for interpretation. |
| Toric IOL: | An artificial lens with an optic surface designed to correct corneal astigmatism. |

Introduction

This brochure provides information about the ALCON Toric Intraocular Lenses (IOLs). These IOLs are designed to correct corneal astigmatism, and restore distance vision after cataract surgery. Please read this entire brochure carefully and discuss the information with your eye doctor.

Your eye doctor will advise you about the potential risks and benefits of cataract removal and IOL implantation. You should make sure that all of your questions are answered to your satisfaction. Please discuss with your eye doctor to determine if an ALCON Toric IOL would be the right lens for you.

What is corneal astigmatism?

Astigmatism is a focusing error in the eye that results in blurred distance and/ or near vision. In a normal eye, the cornea has a round shape (like a basketball); therefore, the light rays entering the eye 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 oblong shape (like an American football). As a result, the light rays do not focus at the same point on the retina and parts of an object may not appear clear. High levels of corneal astigmatism may also be associated with visual distortions (e.g. objects appear tilted or misshapen or floors appear curved). During your eye examination, your eye doctor will be able to tell you if you have corneal astigmatism.

What is a cataract?

Your eye functions much like a camera. Your natural crystalline lens focuses light onto the retina so you can see clearly, much like the lens of a camera focusing light onto film for a clear picture. At birth, your natural lens is clear. However, as you age, the lens becomes “cloudy” and eventually affects your ability to see clearly. This condition is called a cataract, and usually gets worse over time.

Surgery is the only way that a cataract can be removed. You should consider surgery when a cataract affects your vision enough to interfere with your daily activities.

What types of IOLs are available for cataract surgery?

The ALCON Toric IOL is one option for correcting corneal astigmatism and distance vision after cataract surgery. There are other IOLs to choose from for distance vision, but some are not designed to correct astigmatism. Your eye doctor will discuss the IOL options available to you.

ALCON Toric IOL

The ALCON Toric IOL is designed to optically correct corneal astigmatism and restore distance vision. There are different models of ALCON Toric IOL for varying levels of corneal astigmatism. This Toric IOL, also, incorporates an aspheric surface designed to enhance distance vision under low light conditions, when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape.

ALCON Aspheric Monofocal IOL

The ALCON **Aspheric** Monofocal IOL is designed to restore distance vision but does not optically correct corneal astigmatism. This IOL also has an aspheric surface designed to enhance distance vision under low light conditions, when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape.

Monofocal IOL

A monofocal IOL is designed to restore distance vision but does not optically correct corneal astigmatism.

IOL Performance Expectations

Performance expectations of each IOL are described in Table 1 below:

Table 1: Expected IOL Performance for Patients with Astigmatism

| Characteristic | Spherical Monofocal IOL | ALCON Aspheric Monofocal IOL | ALCON Toric IOL |
|----------------------------------|---|---|---|
| Pre-existing Corneal Astigmatism | Is not designed to correct your pre-existing corneal astigmatism | Is not designed to correct your pre-existing corneal astigmatism | Designed to optically correct your pre-existing corneal astigmatism |
| Distance Vision | Your uncorrected distance vision will likely be blurred due to your uncorrected corneal astigmatism. You will likely need prescription glasses or contact lens correction to see clearly at distance. | Your uncorrected distance vision will likely be blurred due to your uncorrected corneal astigmatism. You will likely need prescription glasses or contact lens correction to see clearly at distance. | Your uncorrected distance vision will likely be clearer if your astigmatism is corrected. |
| Near Vision | A monofocal IOL is not designed to provide near vision. | An aspheric monofocal IOL is not designed to provide near vision. | An aspheric toric IOL is not designed to provide near vision. |
| Near Vision continued... | You will need astigmatism correcting prescription reading glasses to clearly see objects up close or to read. | You will need astigmatism correcting prescription reading glasses to clearly see objects up close or to read. | You are less likely to need astigmatism correcting prescription glasses, but will still need reading glasses to clearly see objects up close or to read. |
| Enhanced Distance Vision | A monofocal IOL is not designed to provide the additional benefit of enhanced distance vision in low light environments. | An aspheric monofocal IOL is designed to provide the additional benefit of enhanced distance vision in low light environments, when a person wears full correction glasses. The lens is designed | An aspheric toric IOL is designed to provide the additional benefit of enhanced distance vision in low light environments, when a person wears full correction glasses. The lens is |

| Characteristic | Spherical Monofocal IOL | ALCON Aspheric Monofocal IOL | ALCON Toric IOL |
|--|---|---|--|
| | | <p>to benefit a person with an average corneal shape.</p> <p>However, you will need glasses or contact lens correction for your corneal astigmatism to obtain this benefit.</p> | <p>designed to benefit a person with an average corneal shape.</p> <p>However, if you still need glasses for distance vision you will need to wear them to obtain this benefit.</p> |
| <p>Visual Distortions (i.e. straight lines look tilted and / or flat surfaces look curved)</p> | <p>You may experience visual distortions due to the optical correction of high astigmatism with glasses or contact lenses.</p> | <p>You may experience visual distortions due to the optical correction of high astigmatism with glasses or contact lenses.</p> | <p>You may experience visual distortions in the event that the toric IOL rotates, is improperly positioned, or if you require distant vision glasses for uncorrected astigmatism.</p> |
| <p>Glasses Use</p> | <p>You will likely need prescription glasses or contact lenses for most daily tasks due to uncorrected corneal astigmatism.</p> <p>You will likely also need prescription glasses to clearly see objects up close or to read.</p> | <p>You will likely need prescription glasses or contact lenses for most daily tasks due to uncorrected corneal astigmatism.</p> <p>You will likely also need prescription glasses to clearly see objects up close or to read.</p> | <p>You may be able to function without glasses or contact lens correction for many daily tasks requiring distance vision.</p> <p>You will likely still need prescription glasses to clearly see objects up close or to read.</p> |

Please discuss the IOL options with your eye doctor to determine which type is right for you.

Cataract surgery is one of the most common surgical procedures performed; however, as with all surgeries there are warnings, precautions, and risk that you should be aware of.

Clinical Studies

Alcon provides the IOLs described here with two different lens materials: AcrySof™ and Clareon™. Bench studies have demonstrated equivalent optical performance between AcrySof™ Toric IOLs and Clareon™ Toric IOLs. Therefore, the data presented in this section are applicable to both AcrySof™ and Clareon™ Toric IOLs.

A clinical study compared the AcrySof™ Toric IOL to a monofocal IOL. Table 2 shows the uncorrected distance visual acuity that is, far vision without wearing any prescription glasses obtained for subjects implanted with toric and non-toric lenses.

Table 2: Far Vision Without Glasses at 6 months after surgery

| | Sample size | Acuity | | | | | | | | | | 20/40* or better | |
|-----------|-------------|------------------|------|--------|------|--------|------|--------|------|-------------------|------|------------------|------|
| | | 20/20* or better | | 20/25* | | 20/32* | | 20/40* | | Worse than 20/40* | | | |
| | | N | n | % | n | % | n | % | n | % | n | % | n |
| Toric | 211 | 81 | 38.4 | 59 | 28.0 | 36 | 17.1 | 22 | 10.4 | 13 | 6.2 | 198 | 93.8 |
| Non-toric | 210 | 40 | 19.0 | 46 | 21.9 | 37 | 17.6 | 39 | 18.6 | 48 | 22.9 | 162 | 77.1 |

* On an eye chart, reading all the letters on the 20/40 line with no mistakes means you have 20/40 or better vision. Reading the majority of the 20/40 line correctly means you have approximately 20/40 or better vision. Similarly, reading all the letters on the 20/20 line with no mistakes means you have 20/20 or better vision

Far vision results will vary from person to person. Far vision without glasses after surgery will generally be better for people with low astigmatism before surgery compared to people with high astigmatism before surgery.

The clinical study also assessed the safety profile of the AcrySof Toric IOL. The safety events from the clinical trial are described below in **Table 3**.

Table 3: Clinical Study Safety Events

| Safety Events | AcrySof Toric IOL N=244 | |
|---------------------------------|----------------------------|-----|
| | N | % |
| Retinal Detachment/Repair | 1 | 0.4 |
| Surgical Reintervention | 4 [*] | 1.6 |
| IOL Reposition Due to Rotation | 1 | 0.4 |
| IOL Replacement Due to Rotation | 1 | 0.4 |
| Laser Treatment | 2 | 0.8 |
| Paracentesis | 1 | 0.4 |

*A single subject had two surgical interventions in the same eye.

In this study, two of the secondary Surgical Reinterventions were specifically related to use of a toric lens. See the Warnings section below related to this type of specific risk associated with toric lenses.

Rate of Visual Distortions

During another study, a visual distortion questionnaire was given to subjects before surgery and six months after to evaluate the rate of visual distortions before and after surgery with the Alcon Toric IOLs. The overall rate of visual distortions decreased after surgery (**Table 4**). Responses to questions related to spectacle wear, frequency of experiencing distortion, and degree of bother are presented in **Tables 4 through 7**.

Table 4: Visual Distortion Questionnaire Results by Visit

| During the past 4 weeks, have you had | | Before Surgery (N = 14) | | 6 months after surgery (N = 14) | |
|---|-----|----------------------------|------|------------------------------------|------|
| | | n | % | n | % |
| 1) ...trouble with things appearing distorted? | No | 3 | 21.4 | 12 | 85.7 |
| | Yes | 11 | 78.6 | 2 ^{a,b} | 14.3 |
| 2) ...trouble with flat surfaces (like floors) appearing curved? | No | 12 | 85.7 | 13 | 92.9 |
| | Yes | 2 | 14.3 | 1 ^c | 7.1 |
| 3) ...trouble with straight lines (like door or window frames) appearing tilted? | No | 10 | 71.4 | 14 | 100 |
| | Yes | 4 | 28.6 | 0 | 0.0 |
| 4) ...trouble with feeling sick to your stomach due to distortion of your vision? | No | 14 | 100 | 14 | 100 |
| | Yes | 0 | 0.0 | 0 | 0.0 |

^aReported with or without glasses.

^bReported with or without glasses before surgery but only with glasses at 6 months.

^cSame subject as in (b). Reported only with glasses (progressive lenses) at 6 months. Not reported before surgery.

Table 5: Visual Distortion Questionnaire Results – Subjects who reported having Trouble with Things Appearing Distorted

| 1) For subjects who had trouble with things appearing distorted in the last 4 weeks: | | Before Surgery (N = 11) | | 6 months after surgery (N = 2) | |
|--|--------------|-------------------------|------|--------------------------------|------|
| | | n | % | n | % |
| Do you notice this only when you wear your glasses? | No | 10 | 90.9 | 1 | 50.0 |
| | Yes | 1 | 9.1 | 1 | 50.0 |
| How often have you noticed this? | Rarely | 2 | 18.2 | 0 | 0.0 |
| | Sometimes | 2 | 18.2 | 0 | 0.0 |
| | Frequently | 3 | 27.3 | 1 | 50.0 |
| | All the time | 4 | 36.4 | 1 | 50.0 |
| How much does it bother you? | None | 1 | 9.1 | 1 | 50.0 |
| | A Little | 4 | 36.4 | 0 | 0.0 |
| | A Lot | 6 | 54.5 | 1 | 50.0 |

Table 6: Visual Distortion Questionnaire Results – Subjects who reported having Trouble with Flat Surfaces Appearing Curved

| 2) For subjects who had trouble with flat surfaces (like floors) appearing curved in the last 4 weeks: | | Before Surgery (N = 2) | | 6 months after surgery (N = 1) | |
|--|--------------|------------------------|------|--------------------------------|-----|
| | | n | % | n | % |
| Do you notice this only when you wear your glasses? | No | 2 | 100 | 0 | 0.0 |
| | Yes | 0 | 0.0 | 1 | 100 |
| How often have you noticed this? | Rarely | 0 | 0.0 | 0 | 0.0 |
| | Sometimes | 0 | 0.0 | 0 | 0.0 |
| | Frequently | 1 | 50.0 | 1 | 100 |
| | All the time | 1 | 50.0 | 0 | 0.0 |
| How much does it bother you? | None | 0 | 0.0 | 0 | 0.0 |
| | A Little | 0 | 0.0 | 0 | 0.0 |
| | A Lot | 2 | 100 | 1 | 100 |

Table 7: Visual Distortion Questionnaire Results – Subjects who reported having Trouble with Straight Lines Appearing Tilted

| 3) For subjects who had trouble with straight lines (like door or window frames) appearing tilted in the last 4 weeks: | | Before Surgery (N = 4) | | 6 months (N = 0) | |
|--|--------------|------------------------|------|------------------|-----|
| | | n | % | n | % |
| Do you notice this only when you wear your glasses? | No | 3 | 75.0 | 0 | 0.0 |
| | Yes | 1 | 25.0 | 0 | 0.0 |
| How often have you noticed this? | Rarely | 0 | 0.0 | 0 | 0.0 |
| | Sometimes | 2 | 50.0 | 0 | 0.0 |
| | Frequently | 0 | 0.0 | 0 | 0.0 |
| | All the time | 2 | 50.0 | 0 | 0.0 |
| How much does it bother you? | None | 0 | 0.0 | 0 | 0.0 |
| | A Little | 1 | 25.0 | 0 | 0.0 |
| | A Lot | 3 | 75.0 | 0 | 0.0 |

Warnings

1. Your eye doctor may not be able to implant the ALCON Toric IOL into your eye if you have complications during surgery (e.g. tissue damage that may cause the lens to rotate after surgery). Depending on your specific surgical complications your doctor may or may not be able to implant a different IOL during the same surgical procedure.
2. Contact your eye doctor immediately if you have any of the following symptoms while using the antibiotic eye drops prescribed by your doctor: itching, redness, watering of your eye, sensitivity to light. These symptoms could indicate a potential serious eye infection.
3. Sometimes the ALCON Toric IOL may be placed incorrectly, move, or rotate. If this happens and if vision is poor, then a second surgery will be needed to properly position the lens.

Precautions

1. As with any surgical procedure, there is risk involved. Possible complications from cataract surgery include infection, damage to the lining of the cornea, separation of the retina from the layer of tissue at the back of the eye (retinal detachment), inflammation or swelling inside or outside the eye, damage to the iris (the colored part of your eye), and an increase in eye pressure. You may need additional surgery to reposition or replace the IOL, or to treat other surgery complications. Toric IOLs require surgical repositioning more often than non- toric IOLs.
2. Tell your eye doctor if you have been diagnosed with any eye disease. The safety and effectiveness of the ALCON Toric IOL has not been established in patients with pre-existing eye conditions and complications during surgery, such as an increase in eye pressure (glaucoma) or complications of diabetes in the eye (diabetic retinopathy). The

outcome of cataract surgery will depend on the health of your eye before surgery.

3. You may need to wear glasses to benefit from an aspheric IOL designed to enhance distance vision under low light conditions, if you have any of the following:
 - a) *Nearsightedness or farsightedness after surgery*: These conditions may result from errors in measurements before surgery, wrong lens power, or changes in the cornea in response to the surgery;
 - b) *Uncorrected astigmatism after surgery*: This condition may result from the same reasons as stated above. In addition, uncorrected astigmatism could also result from improper position of the IOL or if your corneal astigmatism is greater than the amount that can be corrected with the IOL.
4. A toric IOL corrects astigmatism only when it is placed in the correct position in the eye. There is a possibility that the toric IOL could be placed incorrectly or could move within the eye. If the toric lens is not positioned correctly following surgery, the change in your astigmatism correction by the IOL, along with any necessary correction with glasses, may cause visual distortions.
5. Avoid any activity that could harm your eye while you are recovering from surgery.

Potential Risks

There are risks associated with cataract surgery. You may have reactions to medicines, and side effects include redness, scratchiness of the eye, and sensitivity to light. Possible complications from cataract surgery include infection, bleeding, inflammation, tissue damage, tissue swelling of the front or back of the eye, or an increase in eye pressure. If your lens is not in the correct position, your vision may also be affected and the normal flow of fluid within the eye may be blocked. Your vision may not improve or may get worse if these complications occur. You may require additional surgery to treat these side effects.

If you have high corneal astigmatism, you may notice that some objects appear tilted or misshapen or floors appear curved. These visual distortions may be present before cataract surgery but may remain after surgery if your astigmatism is not fully corrected or if the IOL is not in the proper position in your eye. It may take some time to adapt to your new IOL(s) and any changes in your astigmatism. Please discuss with your eye doctor about your vision and any symptoms after surgery.

Your eye doctor may advise that you have a second surgery if the toric IOL is not properly positioned in your eye.

The overall risks associated with cataract surgery, compared to other types of surgeries, is relatively low. Toric IOLs require surgical repositioning more often than non-toric IOLs. Discuss any questions about the possible risks and benefits of cataract surgery and the ALCON Toric IOL with your eye doctor.

What to expect during cataract surgery?

Cataract surgery is a procedure to replace your cloudy natural crystalline lens with an intraocular lens implant. You should expect the following before, during, and after surgery.

Before Surgery

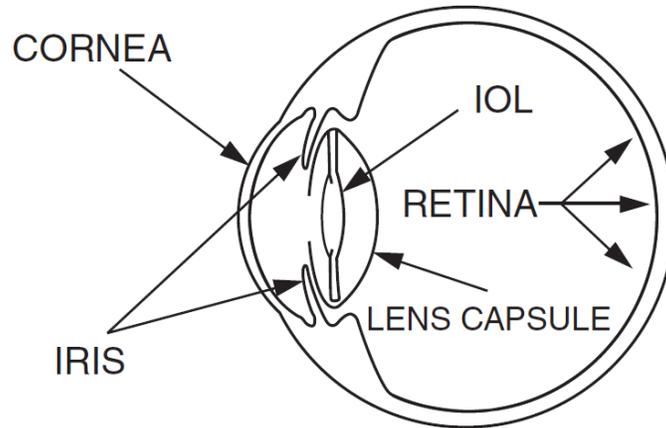
You will need a thorough eye examination. Be sure to tell your eye doctor about any problems about your vision or general health. Your eye will be measured after you and your eye doctor have decided that you will have your cataract removed. This will determine your amount of corneal astigmatism and the IOL power that will be right for you. You should plan to have someone else drive you home.

Day of Surgery

Cataract surgery techniques vary widely. However, the eye is always numbed to make the operation painless. To perform surgery, your doctor will use a microscope to have a magnified view of your eye to properly position the toric IOL. Your natural lens sits in a bag-like structure called the capsule. The capsule is located just behind the colored part of your eye (iris). A small incision is made on the clear front part of your eye (Cornea) to reach and remove the cataract. An IOL is then placed into the capsule to replace your natural lens. The IOL will act in the same way as your natural lens to restore your distance vision. The eye doctor will usually place a shield over your eye to protect it after surgery. After a short stay in the outpatient recovery area you will be ready to go home. Your eye doctor will let you know when your vision is good enough to drive again.

Below in Figure 1 shows the basic parts of the eye with an implanted IOL.

Figure 1 – Drawing of Eye with an Implanted IOL



After Surgery

After surgery, your eye doctor should give you a wallet card that identifies the type of implant in your eye. Typically, your eye doctor will examine you the following day. Many patients may see better within 1 to 2 days, most are stable at 10 to 14 days, but some may take 4 to 6 weeks to fully recover from the surgery. Improvements in vision are different for each individual.

Take all prescribed medicines and apply antibiotic eye drops as instructed by your eye doctor. Be sure to consult your eye doctor if you have any questions or concerns as a result of cataract surgery.

Key points to remember regarding your choice

1. Both the ALCON Aspheric Monofocal IOL and ALCON Toric IOLs restore distance vision following cataract surgery. However, the ALCON Toric IOL is designed to also optically correct your corneal astigmatism.
2. If reduced dependence on glasses or enhanced distance vision is your desired outcome, you should consider the ALCON Toric IOL to correct corneal astigmatism during cataract surgery.
3. Discussing your lifestyle or visual needs with your eye doctor can help determine which IOL is best for you.

Thank you for considering the ALCON Toric IOL.

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134-2099

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