

Trulign™ Toric Intraocular Lenses

PATIENT INFORMATION BROCHURE

(Inside of Cover Page)

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Glossary

Anesthesia For Cataract Surgery - The standard cataract surgery anesthetic are eye drops. The patient is awake during surgery, but may be given relaxing medication.

Aphakia - The absence of the eye's natural crystalline lens, after cataract removal.

Aphakic Spectacles - Thick, eyeglasses that were once the standard correction following removal of a cataract. The glasses were cumbersome and greatly distorted peripheral vision. Today, an intraocular lens (IOL) is implanted in the eye after the lens with a cataract is removed.

Astigmatism - Astigmatism is blurry vision produced by light in focusing at two different places in the eye, making both near and distance vision a problem.

Aspheric IOL - An artificial lens with an optic surface designed to enhance 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.

Capsular Bag - The clear, thin, elastic membrane that holds the lens. When a cataract is removed, the replacement IOL is implanted into the capsular bag.

Cataract - An opacity or clouding and hardening of the crystalline lens that may prevent a clear image from forming on the retina. The cataractous lens may require surgical removal and replacement with an intraocular lens if visual loss becomes significant.

Eye Muscle - Controls the focusing of the natural or artificial lens. When the muscle relaxes, the lens rests in the backwards position for distance vision. When it contracts, it increases the pressure in the vitreous which gently pushes the lens forward for near vision. As the lens enlarges and hardens, the eye muscle is unable to work as well.

Cornea - The transparent front segment of the eye that covers the iris and pupil, providing most of the eye's focusing power.

Crystalline Lens - The clear natural structure in the eye which is the primary focusing mechanism that helps to focus light on the back of the eye. The crystalline lens functions like the lens of a camera, made up of protein and water, located behind the iris, it changes shape and moves forward and back to focus images from various distances onto the retina.

Corneal Astigmatism - Different curvatures on the cornea which causes blurred vision by focusing the light at two different places in the eye.

Diopter - A measurement of the degree to which light focuses; which relates to the power or strength of the lens.

Haptics - The two plates and/or tiny loops located on opposite sides of an intraocular lens that hold the lens securely in place. Trulign Toric IOL has patented hinges built into the haptics to allow gentle movement forward and backward to focus.

Hyperopia - Also known as farsightedness, is a refractive error caused by the eye being too short. Light focuses behind the retina and therefore strikes the retina before it can come to a sharp focus.

Intermediate Vision - Range of visual focus between 14" - 36", e.g., seeing the dashboard, prices in the supermarket, computer screen.

Intraocular Lens (IOL) - An artificial lens that replaces the natural crystalline lens of the eye after cataract surgery. The Trulign Toric IOL is a flexible IOL made of a proprietary advanced generation solid silicone.

Iris - The colored membrane in front of the natural crystalline lens that gives color to the eye (e.g., brown eyes) and controls the amount of light entering the eye by varying the size of the black opening (pupil). The iris constricts for near vision.

Monofocal IOL - An artificial lens designed to restore only one distance of vision.

Myopia - Also known as nearsightedness, is a refractive error caused by the eye being too long. In these cases light focuses in front of the retina.

Near Vision - Range of visual focus up to 14", e.g., reading, sewing, etc.

Ophthalmologist - A physician and surgeon specializing in refractive, medical, and surgical treatment of eye diseases and disorders.

Optic Nerve - Carries the visual information captured on the retina to the visual cortex of the brain for recognition and interpretation.

Optometrist - A primary eye care provider who diagnoses and treats disorders of the visual system, and manages and treats eye diseases.

Point Size - A relative measure of the size of a font in type. 20/40 vision is equivalent to reading 6-point type, the size of the stock quotes in the newspaper or print in the telephone book. Most computers are set to 12-point type.

Pupil - The variable-sized, black circular opening in the center of the iris that controls the amount of light that enters the eye.

Retina - The light-sensitive layer in the back part of the eye that receives images (light) from the sensitive rods and cones that capture the visual images and sends them along the optic nerve to the brain for interpretation. The thin lining at the back of the eye that converts images from the eye's optical system into electronic impulses sent along the optic nerve for transmission to the brain.

Toric IOL - An artificial lens with an optic surface designed to correct corneal astigmatism.

Vitreous Humor - A transparent jelly and fluid that fills the section of the eye between the retina and the lens. When the eye muscle contracts, it increases the pressure in the vitreous which then gently pushes the lens forward.

Introducing Trulign™ Toric IOL

This brochure provides information about the Trulign Toric Intraocular Lens (IOL). Unlike many other mono or multifocal IOLs, this IOL is intended for use in patients who desire reduction of postoperative astigmatism with increased spectacle independence and improved uncorrected near, intermediate and distance vision. Your eye doctor will advise you about the potential risks and benefits of cataract removal and IOL implantation.

Please read this entire brochure carefully and consult with your doctor concerning any questions you have about the Trulign Toric IOL or the surgery. You can also obtain additional information by calling the manufacturer, Bausch + Lomb, toll-free at 866-393-6642 (USA).

What is a cataract?

Cataracts are a natural part of the aging process. More than 20 million Americans have cataracts. A cataract is a progressive thickening, and clouding of the eye's lens. Because cataracts develop very slowly, the decline in vision can be difficult to detect.

You use your **distance vision** when taking a walk or window-shopping.

Intermediate vision encompasses most daily activities, such as working on your computer or checking the instruments on your dashboard when driving.

Near vision is utilized for images such as reading, sewing or putting on makeup.

If you have a cataract, your physician may have recommended cataract surgery, the most common and one of the safest procedures performed in the U.S. Removal of the cloudy lens and replacement with an artificial lens (an intraocular lens implant) is the primary treatment for cataracts.

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.

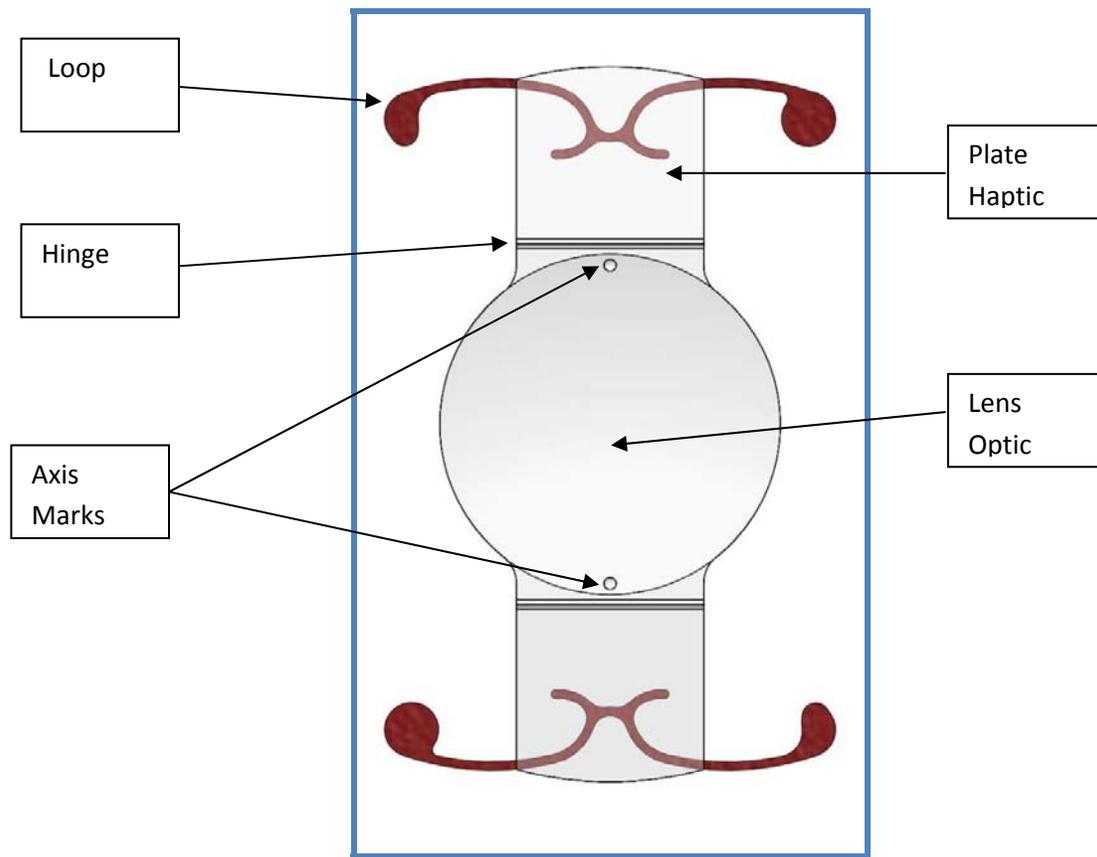
What types of IOLs are available for treatment of corneal astigmatism?

The vast majority of available IOLs are monofocal. It is a technology that has been used successfully for decades. Monofocal toric IOLs are one option for correcting corneal astigmatism and distance vision after cataract surgery to provide clear vision at one focal point, usually distance vision. In most cases, however, the patient still needs to wear glasses or contact lenses to see images within their near field of vision and sometimes for those in the intermediate field of vision, as well. 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. The Trulign Toric IOL is intended for use in patients who desire reduction of postoperative astigmatism with increased spectacle independence and improved uncorrected near, intermediate and distance vision.

In Figure 1 the Trulign Toric intraocular lens has:

- Plate Haptics and loops that hold the lens in place (Haptics are the two plates and/or tiny loops located on opposite sides of an intraocular lens that hold the lens securely in place.)
- Hinges that allow lens to move gently forward and back
- An optic that focuses the image on the retina

Figure 1: Trulign Toric Intraocular Lens



The Trulign Toric IOL may allow many patients to do intermediate distance tasks and some near distance tasks without glasses patients often need reading glasses for fine near work.

Clinical study results

The Trulign Toric IOL clinical study for the United States Food and Drug Administration involved 229 eyes in 229 adult patients (227 eyes in 227 patients were implanted). Results of the study demonstrated that the Trulign Toric IOL effectively corrects astigmatism.

- 85% of the cases involving astigmatism that the surgeon intended to correct were remedied.
- Only 46.5% of the patients receiving a non-toric lens achieved the intended reduction in astigmatism.
- 100% of patients implanted with Trulign Toric IOL could pass a drivers' test without glasses.

- Only 75% of patients who were implanted with a non-toric lens could pass a drivers' test.

Benefits of Trulign Toric IOL:

- Effectively treat corneal astigmatism,
- Provide clear distance and intermediate vision (you will be able to see objects that are far away and about arm's length),
- Provide improved near vision, and
- Reduce the need for a secondary surgical procedure for residual astigmatism.

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

Warnings

1. Your eye doctor may not be able to implant the Trulign 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.

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 Trulign Toric IOL has not been established in patients with preexisting 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. Tell your eye doctor if you have had prior refractive surgery, such as LASIK. The safety and effectiveness of the Trulign Toric IOL has not been studied in patients with prior refractive surgery.
4. You will need to wear glasses 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.
 - c. If you must do prolonged reading or read small print, you are likely to need to wear reading glasses.
5. 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.
 6. Avoid any activity that could harm your eye while you are recovering from surgery. For example, avoid any activities where objects can come in contact with or put pressure on the eye, such as Tennis or Scuba Diving.

Potential Risks

There are risks associated with cataract surgery and IOL implantation. The complications and side effects experienced during the clinical study were similar to those experienced with other intraocular lenses and with routine cataract surgery. Because it is surgery it is not completely risk-free. Complications may occur as a result of the removal of your cataract whether or not an intraocular lens is implanted. Complications of cataract surgery range from minor, usually temporary side effects, to sight-threatening complications. Fortunately, significant sight-threatening complications are extremely rare and include, but are not limited to infection, hemorrhage, and retinal detachment. People with existing medical conditions such as diabetes and chronic eye infections are at a higher risk of developing complications.

You may have reactions to medicines that may be prescribed to you after your eye surgery, 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.

The risks of implantation with the Trulign Toric IOL are the same risks that exist for all intraocular lenses. However, because the Trulign Toric IOL contains a hinge, there is a risk of the lens becoming stuck in an undesired position. If the lens becomes stuck in the forward position, giving you only good near vision, and you will need glasses or contact lenses to see at distance. If the lens becomes stuck in the backward position, it will give you good distance vision, like a standard intraocular lens, but you will need glasses to read or to see near objects. If the lens becomes stuck at an angle, you might need to have the lens removed.

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 Trulign Toric IOL with your eye doctor.

Are you a candidate for the Trulign Toric IOL?

Your doctor will perform a thorough examination to determine if you have a cataract, and advise you of the most appropriate option for correcting your vision. Depending upon your expectations, lifestyle and the presence of any pre-existing visual conditions, your ophthalmologist will determine whether you can benefit from the implantation of a Trulign Toric IOL.

Virtually everyone with good general health is a candidate for implant surgery. Individuals with chronic eye infections, uncontrolled diabetes, or other health problems may have to wait until these conditions are managed before they have surgery.

Only you and your doctor can determine if Trulign Toric IOL is right for you.

What to expect

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 after your surgery.

Once selected as a candidate for the Trulign Toric IOL, be certain that you are comfortable with all aspects of your cataract surgery. Ask questions and inform your eye doctor of any medications you are currently taking. Prior to surgery, you can expect:

- Pre-op visit- physician evaluations of your eye and vision needs
This is your chance to ask questions of your eye doctor and share any specific visual needs you might have. For example, if you have a hobby or pastime, such as oil painting, golfing, playing the piano or gardening.
- Precise pre-op measurements
Prior to surgery, your eye doctor will perform three tests that will measure your vision and help to ensure the results achieved by your Trulign Toric IOL are consistent with your expectations.
 - Refraction-measures what you see compared to a standard scale, i.e. 20/20.
 - Biometry-measures the length of the eye and tells the eye doctor the power of the lens to be placed in the eye.
 - Keratometry-measures the amount your cornea is curved, bending light toward your lens.

During Surgery

Cataract surgery techniques vary widely. However, the eye is always numbed to make the operation painless. A few things to know for your day of surgery:

- Surgery with the Trulign Toric IOL is an outpatient procedure.
- Surgery is usually performed as an outpatient procedure and typically takes less than 20 minutes. However, you will need a friend or family member to take you home.
- Your surgeon will use eye drops to anesthetize your eye and dilate your pupil.
- Your nurse will cleanse and drape your eye.
- You will be awake during the short procedure.
- You will experience no pain, but there will be a slight pressure.

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.

After Surgery

After surgery, your eye doctor should give you a wallet card that identifies the type of implant in your eye. It is important to carry your wallet card with you at all times as the information that is on this card is useful for future reference or if asked at subsequent eye appointments with your current eye doctor or any other eye doctor you may see. 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.

It is important that you closely follow your doctor's instructions after surgery. During the first two weeks it is important to remember:

- Do not rub your eye since this could impair its healing.
- Limit your activity on the day after your surgery and avoid showering or swimming.
- On the second day after your surgery you may resume your normal activities, including showering and swimming.

- Your pupils will be dilated, so you will not be able to focus near and you may experience glare.
- Your intermediate vision will be slightly diminished, but will improve.
- Your distance vision will not significantly diminish and will improve.
- You may experience halos around bright lights because of the eye drops your doctor has given you. These side effects will quickly dissipate.

Thank you for considering the Trulign Toric IOL.