



**Visian® Toric ICL™ (Implantable Collamer® Lens)
For Nearsightedness with Astigmatism**

For Nearsightedness (Myopia) between -3.0 to -20.0 Diopters with Astigmatism between 1.0 to 4.0 Diopters

**Facts You Need to Know About STAAR Surgical's
Visian Toric ICL Surgery**

PATIENT INFORMATION BOOKLET

Please read this entire booklet. Discuss its contents with your doctor so that you have all of your questions answered to your satisfaction. Ask any questions you may have before you agree to this surgery.

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1.0 Glossary

This section summarizes important terms used in this information booklet or that your eye doctor may discuss with you. Please discuss any related questions with your doctor.

Acute: Of sudden, rapid onset, usually with notable symptoms.

Acute Corneal Decompensation: A sudden swelling of the usually clear front surface of the eye (*cornea*).

Anisocoria: Unequal *pupil* size.

Anterior Chamber: Front chamber of the eye; *anterior chamber* depth is the space between the back of the *cornea* to the front part of the *crystalline lens*. *Anterior chamber* angle is the location where the *cornea* and *iris* meet.

Antibiotic Medication: A drug used to treat or prevent infection. Your doctor may prescribe this medication after Visian Toric ICL surgery.

Anti-inflammatory Medication: A drug that reduces inflammation or the body's reaction to injury or disease. Any eye surgery can cause inflammation. Your doctor may prescribe the medication after *Visian Toric ICL* surgery.

Astigmatism: A focusing error that results in blurred distant and/or near vision. The *cornea* is more curved in some directions than others, and causes light rays to focus at different points inside the eye. Parts of objects appear clearer than other parts.

Cataract: Opacity, or clouding, of the *crystalline lens* inside the eye that can blur vision.

Collagen: A gel-like supporting substance found in the *cornea*, skin and other connective tissue of the body.

Collamer: Hydroxyethyl methacrylate (HEMA)/porcine-*collagen* based polymer material (STAAR proprietary product).

Conjunctival Irritation: A reddening of the observable, white portion of the eyeball and inner eyelid.

Contraindications: Any special conditions that result in the treatment not being recommended.

Cornea: The clear front layer of the eye. Surgery such as PRK, LASIK and RK reshape the front surface of the *cornea* to improve distant vision.

Corneal Edema: Abnormal fluid build-up/swelling in the *cornea*. The condition is usually temporary after surgery with no significant effect on vision. Persistent *corneal swelling* may cause a loss of vision.

Corneal Endothelium: A thin, single layer of cells on the innermost surface of the *cornea*, responsible for keeping the *cornea* clear. These cells do not reproduce and decrease in number with age.

Corneal Flap: A thin slice of tissue on the surface of the *cornea* made with a microkeratome at the beginning of a LASIK procedure. This flap is folded back before the laser shapes the inner layer of the *cornea*.

Corneal Transplant: Removal and replacement of the *cornea*.

Crystalline Lens: A structure inside the eye that helps to focus light onto the back surface (*retina*) of the eye.

Cystoid Macular Edema: Swelling of the *macula*, located in the center of the *retina*.

Diabetic Retinopathy: Damage to the back surface of the eyes responsible for sensing light due to diabetes.

Diopter: A unit of focusing power, used to describe the amount of *nearsightedness* and *astigmatism* of an eye. Abbreviated as "D".

Double Vision: Seeing multiple images of the object being looked at.

Endophthalmitis: Severe infection or inflammation of the entire eyeball.

Endothelial Cell Loss: A thin, single layer of cells (*endothelial cells*) on the innermost surface of the *cornea* keeps the *cornea* clear by pumping water out of it. Normally, these cells slowly decrease in number as you age. Additional loss of these cells beyond the normal amount can occur following many kinds of eye surgery. If too many cells are lost, the *cornea* can become cloudy, which can decrease vision.

Endothelium: See *Corneal Endothelium*.

Glare: A harsh or uncomfortable bright light. *Glare* symptoms are usually caused by a distortion of light that would otherwise be tolerable without the distortion.

Glaucoma: An eye disease usually associated with high eye pressure. *Glaucoma* damages the optic nerve of the eye and usually causes a progressive loss of vision.

Halos: Circular flares or rings of light that may appear around a headlight or other lighted object. This symptom may occur after surgery.

Hyphema: Blood in the front (*anterior*) chamber of the eye.

Hypopyon: Discharge in the front (*anterior*) chamber of the eye.

Implantable Collamer Lens (ICL): A *lens* made of *collagen* containing polymer which is implanted in the eye behind the *iris* and in front of the *crystalline lens* in order to correct or reduce *nearsightedness*. The Visian ICL can be replaced or removed.

Implantable Toric Collamer Lens (TICL): A *lens* made of *collagen* containing polymer which is implanted in the eye behind the *iris* and in front of the *crystalline lens* in order to correct or reduce *nearsightedness* and *astigmatism*. The *Visian Toric ICL* can be replaced or removed.

Inflammation of the Eye: The eye's response to injury, infection or irritation which can cause redness of the eye, pain, blurred vision and/or light sensitivity.

Intraocular Lenses: An artificial *lens* that is placed in the eye to correct refractive errors such as *nearsightedness*.

Intraocular Pressure (IOP): The amount of pressure of the fluid inside your eye.

Iris: Colored part of the eye.

Iris Prolapse: A movement of the colored portion of the eye through a surgical wound to a position outside the eye.

Iritis: Inflammation in the front (anterior) chamber or another portion of the eye.

Laser Assisted In-Situ Keratomileusis (LASIK): A type of eye surgery that uses a device to create a thin, hinged flap of tissue on the *cornea* which is then folded back. A laser then reshapes the tissue under the flap and the flap is put back on the eye so the tissue heals.

Lens: Natural *crystalline lens* in the eye which helps focus light properly into the back of the eye.

Macular Degeneration: A reduction in your central vision due to the thinning of a part of your *retina* responsible for fine (reading) vision.

Macular Edema: Swelling in the area responsible for fine (reading) vision on the back surface of the eye (*retina*).

Macular Hemorrhage: Bleeding in the area responsible for fine (reading) vision on the back surface of the eye (*retina*).

Myopia: A focusing error that results in blurrier vision at distance than near. *Myopia* is also called *nearsightedness*.

Narrow Anterior Chamber Angle: A decrease in the size of the front chamber of the eye which could block the flow of fluid from inside to outside of the eye resulting in a raised eye pressure (*glaucoma*).

Nearsighted/Nearsightedness: A focusing error that results in blurrier vision at distance than near. *Nearsightedness* is also called *myopia*.

Non-reactive Pupil: A condition where the *pupil* of the eye does not get larger or smaller when light is shined in the eye or removed.

Ocular Hypertension: Increased eye pressure.

Peripheral Anterior Synechiae: Scar tissue at the outer edges of the front chamber of the eye.

Peripheral Iridotomy: A small hole placed at the outer edge of the colored portion of the eye, usually using an Yttrium Aluminum Garnet (YAG) laser beam.

Persistent: Lasts for a period of time during the study follow-up usually at least until the end of the study.

Phakic Intraocular Lens: A thin man-made *lens* that is placed in an eye that still has its natural *crystalline lens*.

Photorefractive Keratectomy (PRK): A type of eye surgery that uses a laser to reshape the front surface of the eye to improve vision. After the epithelium (outermost layer) of the *cornea* is first scraped away, the laser removes tissue from the exposed surface. After the surgery, the epithelium grows back.

Pigment Dispersion: An abnormal release of pigment particles from cells in the eye that could block drainage of fluid from the inside to the outside of the eye.

Pseudoexfoliation: A condition where flakes of material can come off the surface of the crystalline lens and block the drainage of fluid from the inside to the outside of the eye.

Pupil: The opening in the middle of the colored portion (*iris*) of the eye; fluctuates in size allowing varying degrees of light into the eye.

Pupillary Block Glaucoma: The inability of *fluid* to flow from the back chamber of the eye to the front chamber frequently blocking drainage of fluid out of the eye and raising the pressure in the eye (*glaucoma*).

Radial Keratotomy (RK): A type of eye surgery that changes the shape of the front surface of the eye by making a special pattern of cuts in the *cornea* to correct *nearsightedness* and/or *astigmatism*.

Retina: The layer of nerve tissue at the back of the eye that captures images, similar to film in a camera, and sends information about these images to the brain. Light must be focused correctly on the *retina* to form clear images.

Retinal Detachment: Separation of the *retina* from its natural position on the back surface of the eyeball.

Subretinal Hemorrhage: Bleeding under the *retina*.

Uveitis: Inflammation of the middle layer of tissue in the eye.

Viscoelastic Fluid: Gel-like fluid placed inside the eye during eye surgery to help maintain the shape of the eye.

Visian ICL for Myopia (MCL): *Implantable Collamer Lens* for the correction of *nearsightedness*. This *lens* is similar in design to the *Visian Toric ICL* except that it does not correct astigmatism.

Visian Toric ICL (TICL): *Implantable Collamer Lens* for the correction of *nearsightedness* with *astigmatism*.

Visual Acuity: A measure of the sharpness of vision using a letter chart. Best Corrected *Visual Acuity* (BCVA) is the best vision with eyeglasses. Uncorrected *Visual Acuity* (UCVA) is the best vision without eyeglasses or contact lenses.

Vitreous Loss: The loss of a clear gel like material from the farthest back chamber of the eye during a surgical procedure.

YAG Laser: Yttrium Aluminum Garnet laser beam used in ophthalmology to create a small hole at the outer edge of the colored portion of the eye (*peripheral iridotomy*).

2.0 Introduction

The purpose of this booklet is to help you decide if you want to have the *Visian Toric Implantable Collamer Lens (TICL)* placed in one or both of your eyes to treat your *nearsightedness* (or *myopia*) and *astigmatism*. It is important for you to understand both the benefits and risks of this surgery before you make a decision. The "Glossary" in this booklet explains the meaning of all words printed in *italics*. Please read this entire booklet carefully and discuss your questions with a doctor who is trained in *Visian Toric ICL* surgery.

3.0 What Is Nearsightedness with Astigmatism

Your eye works like a camera. You see objects because your eye focuses light into images. Both the clear front layer of your eye, called the *cornea*, and your natural *crystalline lens* focuses rays of light onto the back surface of the eye, called the *retina*. **Diagram 1** shows how an eye with normal vision focuses rays of light onto the *retina* at the back of the eye.

DIAGRAM 1: NORMAL EYE
Light focuses on the *retina*. Vision is clear.

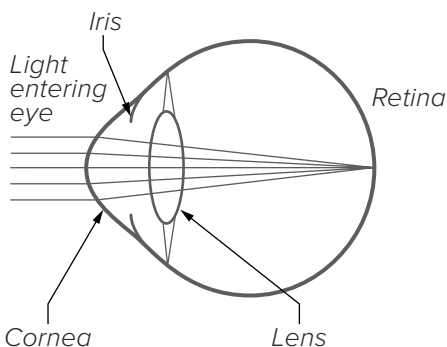
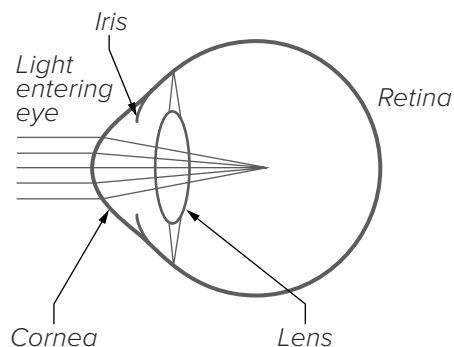


DIAGRAM 2: NEARSIGHTED EYE
Light focuses in front of the *retina*. Vision is blurry



You may have *nearsightedness* with *astigmatism* if you have trouble seeing objects clearly when they are far away.

Nearsightedness, which is also called *myopia*, is a focusing error that causes blurrier vision at distance than at near. Light from an object in the distance focuses in front of the back surface of your eye (*retina*) responsible for capturing images, rather than directly on the *retina*. **Diagram 2** shows how a *nearsighted* eye with blurry vision focuses light at a point in front of the *retina*.

Astigmatism can cause similar symptoms. In eyes with *astigmatism*, the clear front layer of the eye that lets light enter (*cornea*) is more curved in some directions than others. This causes light rays to focus at different points inside the eye and some parts of objects will appear clearer than other parts. **Diagram 3** shows how an eye with *nearsightedness* and *astigmatism* may focus light.

DIAGRAM 3:
NEARSIGHTED EYE with ASTIGMATISM

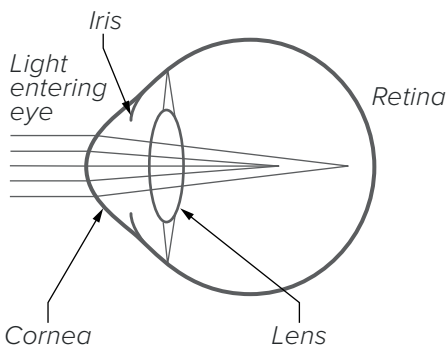
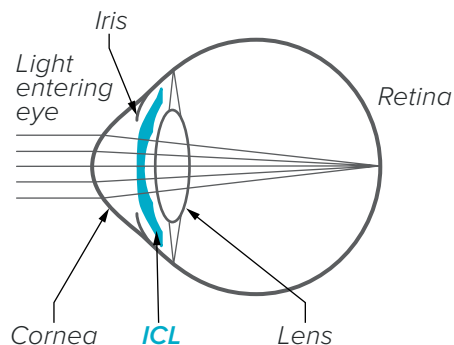


DIAGRAM 4:
CORRECTION OF VISION AFTER EVO ICL SURGERY
Light focuses on the *retina* after surgery. Vision is clearer.



Your eyeglass prescription tells your doctor how *nearsighted* you are and how much *astigmatism* your eyes have. Glasses, contact *lenses* or eye surgery can help your eye focus light properly on the *retina*. This will correct *nearsightedness* and *astigmatism* and help you see distant objects more clearly. The *Visian Toric ICL* can also help your eye focus light properly on the *retina*.

How Does *Visian Toric ICL* Correct *Nearsightedness* with *Astigmatism*?

The *Visian Toric ICL* is made from a soft plastic and natural *collagen-based* material called *collamer*. It is similar to *lenses* that are placed in the eye (*intraocular lenses*) to correct vision after *cataract* surgery.

The *Visian Toric ICL* is placed in the eye through a small cut, and is placed behind the colored part of the eye (*iris*) and in front of the natural *lens* (*crystalline lens*). When placed correctly, the *Visian Toric ICL* focuses light properly on the back surface of your eye (*retina*). **Diagram 4** shows how light is focused in a *nearsighted* eye with *astigmatism* that has been implanted with a *Visian Toric ICL*.

A *diopter* (D) is a unit of focusing power used to describe the amount of *nearsightedness* or focusing error (*astigmatism*) in the eye. Your eyeglass prescription is the usual way to tell how *nearsighted* you are and how much *astigmatism* you have. *Visian Toric ICL* surgery is designed to treat *nearsightedness* between -3.0 D to -15.0 D, and *astigmatism* between 1.0 and 4.0 D. *Visian Toric ICL* surgery is designed to reduce *nearsightedness* greater than -15.0 D up to -20.0 D, and *astigmatism* between 1.0 D and 4.0 D. If you have *nearsightedness* with *astigmatism* within these ranges, *Visian Toric ICL* surgery may improve your distance vision without eyeglasses or contact lenses.

Your doctor will use your eyeglass prescription with a thorough eye examination to determine if you are a candidate for *Visian Toric ICL* surgery. Discuss with your doctor whether you are a good candidate for surgery with the *Visian Toric ICL*.

Visian Toric ICL surgery is permanent as long as the *lens* stays in your eye. The *Visian Toric ICL* can be removed at a future date. However, the residual effect of the *Visian Toric ICL* on your eye after it is removed is not known. If your physician removes the *Visian Toric ICL*, you will lose the benefit of your *nearsightedness* with *astigmatism* correction. This means that your vision may not return to what it was like before the *Visian Toric ICL* surgery.

4.0 Other Treatments to Correct Nearsightedness with Astigmatism

Other treatments for *nearsightedness* include eyeglasses, contact *lenses* or other eye surgeries. Eye surgeries available to correct *nearsightedness* with *astigmatism* include *Radial Keratotomy (RK)*, *Photorefractive Keratectomy (PRK)*, *Laser Assisted in situ Keratomileusis (LASIK)* and *Phakic Intraocular Lens* implantation (the *Visian Toric ICL* is a *phakic intraocular lens*). These surgeries may not meet the vision requirements for some careers, such as military service.

Eye surgeries can either change the shape of the front surface of the clear layer at the front of your eye (*cornea*), including *RK*, *PRK*, and *LASIK*, or require the insertion of a *lens* into the eye. *RK* uses a surgical instrument to make fine cuts in the *cornea*. *PRK* and *LASIK* use a laser to reshape the *cornea*. For *LASIK*, an instrument cuts a thin flap of tissue from the front of your *cornea*. This *corneal flap* is folded back and a laser removes tissue under the flap to change the shape of the *cornea*. The flap is then put back in place for the eye to heal.

5.0 Benefits and Risks of Visian Toric ICL for Nearsightedness with Astigmatism

Benefits

Visian Toric ICL surgery can safely correct *nearsightedness* between -3D to -15D with between 1.0 D to 4.0 D of *astigmatism*, and can partially correct *nearsightedness* in eyes with greater than -15D up to -20D of *myopia* and between 1.0 to 4.0 D of *astigmatism*.

If your eyeglass prescription is in these ranges, the *Visian Toric ICL* may make your distance vision without eyeglasses or contact *lens* correction better. Placing the *Visian Toric ICL* into the eye requires surgery, and all eye surgery carries potentially serious risks. Please review this booklet and discuss the risks with your doctor.

Risks

This part of the booklet explains the risks of *Visian Toric ICL* surgery. The *Toric ICL* is a modification of an earlier model of *ICL*, which corrected *nearsightedness (myopia)* but not *astigmatism*. The risks associated with this earlier *ICL* model all apply to the *Toric ICL* as well. Information concerning risks was collected in the following clinical studies for the FDA:

1. FDA Safety and Effectiveness Study of the Visian Toric ICL (TICL)

This study collected information on the benefits and risks of the *TICL*. The study followed 210 eyes of 124 patients through 12 months (1 year) after surgery.

2. FDA Post-Approval Study of the Visian Toric ICL (TICL)

This study collected information on the long-term performance of the *TICL*. The study followed 232 eyes of 125 patients through 24 months (2 years) after surgery.

3. Safety and Effectiveness Study of the Visian ICL

In an earlier study for the *Visian ICL for Myopia (MICL)*, 526 eyes of 294 patients were followed through 36 months (3 years) after surgery; a smaller set of these patients (335 eyes of 192 patients) were followed through approximately 5 years (or longer) after surgery. The study doctors collected information on the items listed below:

- Additional surgeries;
- *Cataract* formation;
- Loss of best corrected vision (BCVA)
- Raised pressure inside the eye (*intraocular pressure*) and damage to the optic nerve caused by increased pressure in the eye (*glaucoma*);
- Loss of cells on the innermost surface of the *cornea* (endothelial cells);
- Other complications.

4. Patient Survey Study for the Visian ICL

A patient survey study for the *Visian ICL for Myopia* collected information on adverse events and complications reported by 1547 patients (2999 eyes) up to 5 years after surgery (2125 eyes).

Please see section **13.0 Clinical Studies**, for more information about these FDA studies.

The major risks that were identified are discussed below.

- **Additional (Secondary) Surgery.** Another surgery to take out, replace or adjust the position of the *Visian Toric ICL* may be necessary. You may also need another surgery if you develop a *cataract* or to lower increased pressure inside your eye.
- FDA Safety and Effectiveness study for the *Visian Toric ICL (TICL)*
 - 8 out of 210 eyes (3.8%) implanted with a *Visian Toric ICL* needed another surgery:
 - one eye (0.5%) had a second surgery to change the position of the lens,
 - one eye (0.5%) had a second surgery to replace a *Visian Toric ICL*,
 - 3 eyes (1.4%) had a second surgery to remove the *Visian Toric ICL*,
 - 3 eyes (1.4%) needed another surgery to treat or prevent raised pressure inside the eye (*intraocular pressure* or *IOP*)
 - 2 eyes (1.0%) had another hole placed in the extreme outer edge of the colored portion of the eye (*peripheral iridotomy*) to prevent an increase in eye pressure,
 - one eye (0.5%) needed another surgery to remove the remaining gel-like fluid used during eye surgery (*viscoelastic* fluid) that caused an increase in pressure inside the eye.
- FDA Post-Approval Study of the *Visian Toric ICL (TICL)*
 - 28 out of 232 eyes (12.1%) implanted with a *Visian Toric ICL* needed another surgery:
 - seven eyes (3.0%) had a second surgery to remove the *Visian Toric ICL*, including two eyes that had a second surgery to treat pupillary block and one eye that had the *TICL* lens removed at the start of *cataract* surgery,
 - six eyes (2.6%) had a second surgery to treat pupillary block or narrowing of the *anterior chamber*. Four (1.7%) of these eyes had another hole placed in the extreme outer edge of the colored portion of the eye (*peripheral iridotomy*) and the other two eyes (0.9%) had another surgery to enlarge the *peripheral iridotomy* created before *TICL* surgery.
 - five eyes (2.2%) had a second surgery to change the position of the *Visian Toric ICL*. Two of these eyes also had a third surgery to correct leftover *nearsightedness* or *nearsightedness* with *astigmatism*.
 - two eyes (0.9%) had a second surgery to exchange the *Visian Toric ICL* lens for a different *TICL* lens,
 - one eye (0.4%) that underwent *TICL* lens removal also had *cataract* surgery,
 - thirteen eyes (5.6%) had a second surgery to correct leftover *nearsightedness* or *nearsightedness* with *astigmatism* that remained after the *Visian Toric ICL* surgery.
- FDA Safety and Effectiveness Study of the *Visian ICL for Myopia*
 - 43 out of 526 implanted eyes (8.2%) had another surgery related to the *Visian ICL* through 5 to 7 years after implantation:
 - 4 eyes (0.8%) had a second surgery to change the position of the *Visian ICL*,
 - 8 eyes (1.5%) had a second surgery to replace the *Visian ICL*,
 - 10 eyes (1.9%) had a second surgery to remove the *Visian ICL*,
 - one eye (0.2%), had both a replacement and removal of the *Visian ICL*.
 - In the cases of *Visian ICL* removal, the reason for removal was associated with *cataract* surgery.
 - 20 out of 526 implanted eyes (3.8%) had a second surgery to treat raised pressure inside the eye:
 - 17 eyes (3.2%) had another hole placed in the extreme outer edge of the colored portion of the eye (*peripheral iridotomy*) to reduce the pressure,
 - 3 eyes (0.6%) had another surgery to remove the remaining gel-like fluid used during eye surgery (*viscoelastic* fluid).

Patient Survey Study for the *Visian ICL*

126 out of 2999 implanted eyes (4.2%) had another surgery to reposition, replace or remove the *MICL* through 5 years after implantation.

Cataract Formation

A *cataract* is a clouding of the natural lens inside the eye that can decrease vision. Because the *Visian Toric ICL* is placed inside the eye near the natural lens, there is a risk of developing a *cataract* that may need surgery. Older age and higher levels of *nearsightedness* before surgery also increase the risk for *cataract* after surgery with *Visian Toric ICL*. The risk of a *cataract* continues to rise with each year that the *Visian Toric ICL* is in the eye. Because of this, you should see your doctor regularly for an eye exam to check you for *cataracts*.

Cataracts that affect vision may require surgery to remove the *cataract*.

FDA Safety and Effectiveness study for the *Visian Toric ICL (TICL)*

6 eyes (2.9%) developed some form of *cataract* by 12 months after surgery.

FDA Post-Approval Study of the *Visian Toric ICL (TICL)*

1 eye (0.4%) developed some form of *cataract* up to 2 years after *Visian Toric ICL* surgery.

FDA Safety and Effectiveness Study of the *Visian ICL*

45 out of 334 eyes (13.5%) that were seen at 5-7 years after surgery, developed some form of *cataract*.

Patient Survey Study for the *Visian ICL*

154 out of 2999 eyes (5.1%) reported *cataract* development up to 5 years after *Visian ICL* surgery.

The long-term risk of *cataract* beyond 7 years is unknown. If your doctor recommends *cataract* surgery, both the *Visian Toric ICL* and the *cataract* is removed and another intraocular lens is implanted, just as is done in any routine *cataract* surgery.

Loss of best corrected vision (BCVA)

FDA Safety and Effectiveness study for the *Visian Toric ICL (TICL)*

- three eyes (1.4%) in the FDA study of the *Visian Toric ICL* lost two or more lines of vision:
 - one eye (0.5%) lost vision due to clouding of the natural lens (*cataract*),
 - one eye (0.5%) lost vision without a reason given. This vision loss was not due to *cataract* and the patient reported being very satisfied with her vision.
 - one eye (0.5%) lost two lines of vision compared to before surgery at 6 months and 12 months after surgery but vision improved by one line at 17 months after surgery.

FDA Post-Approval Study of the *Visian Toric ICL (TICL)*

- two eyes (0.9%) lost two or more lines of corrected distance visual acuity as measured on an eye chart:
 - one eye (0.4%) lost two lines of corrected distance vision at 1 month after surgery because the *Visian Toric ICL* lens dislocated from its original position and remained unstable. Corrected vision measured 20/32 at one month compared to 20/20 before surgery. The *Visian Toric ICL* was removed and the vision improved and stabilized by one month after removal surgery to 20/25 before the subject was exited from the study.
 - one eye (0.4%) was reported to have lost two lines of vision at the 3 month visit associated with misalignment of the lens. Vision measured 20/26 at 3 months after surgery compared to 20/16 before surgery, but improved on its own to 20/20 by 12 months, and to 20/17 by 24 months after surgery. The lens misalignment in this case did not require treatment.

FDA Safety and Effectiveness Study of the *Visian ICL*

- 18 out of 526 eyes (3.4%) in the study lost vision of two or more lines as measured on an eye chart:
 - 9 eyes (1.7%) lost vision because of clouding of the natural lens (*cataract*),
 - one eye (0.2%) lost vision due to stretching of the eye,
 - one eye (0.2%) lost vision due to pulling of the *retina* from its natural position (*retinal detachment*),
 - reasons could not be determined for vision loss for 4 eyes (0.8%),
 - in 3 eyes (0.6%), vision loss was temporary and improved without treatment.

Vision got better in eyes that lost vision due to clouding of the natural lens after *cataract* surgery. In 7 of the 18 eyes (1.3% of all 526 eyes in the study) that lost vision of two or more lines in the study, vision did not get better after 5 or more years after surgery.

Raised *intraocular pressure (IOP)* and *glaucoma* development

Normal eye pressure (*intraocular pressure* or *IOP*) can vary, but is often considered to be from 10-21 millimeters of mercury (mmHg). An *IOP* higher than normal is called *ocular hypertension* and if left untreated, can cause damage to the optic nerve (*glaucoma*) and cause permanent vision loss. Patients with high levels of *near-sightedness* are also at increased risk of developing *glaucoma*.

FDA Safety and Effectiveness study for the *Visian Toric ICL (TICL)*

- 2 eyes (1.0%) had an increase in *IOP* to values greater than 10mmHg higher than before *Visian Toric ICL* surgery,
- one eye (0.5%) had an increase in *IOP* to higher than 25mmHg at 6 months after surgery, which dropped to 17mmHg at 12 months,
- one eye (0.5%) experienced raised *IOP* due to the inability of fluid to flow from the back chamber of the eye to the front chamber (*pupillary block glaucoma*). The patient received another surgery (*Peripheral Iridotomy*) which resolved the problem.

No patients in the *Visian Toric ICL* study developed damage to the optic nerve (*glaucoma*).

FDA Post-Approval Study of the *Visian Toric ICL (TICL)*

A total of 40 out of 232 implanted eyes (17.2%) had an increase in *IOP* to values greater than 10mmHg higher than before *Visian Toric ICL* surgery. In 14 eyes (6.0%), the increased *IOP* returned to normal levels without any treatment.

- seventeen eyes (7.3%) were treated with medication and the increased *IOP* resolved,
- eight eyes (3.4%) were treated with both medication and another surgery to resolve the increased *IOP*,
- two eyes (0.9%) were treated with both a surgery to resolve the increased *IOP* and to remove the *Visian Toric ICL*,
- five eyes (2.2%) were treated with only a surgery to resolve the increased *IOP*,
- two eyes (0.9%) were treated with only a surgery to remove the *Visian Toric ICL*,

No patients in the post-approval *Visian Toric ICL* study developed damage to the optic nerve (*glaucoma*).

FDA Safety and Effectiveness Study of the *Visian ICL*

- 20 out of 526 implanted eyes (3.8%) experienced an increase in eye pressure requiring treatment beyond just the use of medicine, most often at 1 to 2 days after surgery:
 - 17 eyes (3.2%) had another hole placed in the extreme outer edge of the colored portion of the eye (*peripheral iridotomy*) to reduce the pressure.
 - 3 eyes (0.6%) had another surgery to remove the remaining gel-like fluid used during eye surgery (*viscoelastic fluid*).
- 14 eyes (2.7%) had an increase in *IOP* to values greater than 10mmHg higher than before *Visian ICL* surgery or to higher than 25mmHg through 5 years or more after surgery.
- 7 eyes (1.3%) in 4 patients developed damage to the optic nerve (*glaucoma*) through 5 or more years after *ICL* surgery. The first case of *glaucoma* was diagnosed at 5 months after *Visian ICL* surgery and the last case happened at over 6 years (73 months) after surgery.

Patient Survey Study for the *Visian ICL*

- 47 of the 2999 implanted eyes (1.6%) had reports of being treated for increased *IOP* or *glaucoma* up to 5 years after surgery.

Endothelial Cell Loss

A thin, single layer of cells (endothelial cells) on the surface of the *cornea* closest to the inside of your eye, keeps the *cornea* clear by pumping water out of it. Normally, these cells slowly decrease in number as you age. Additional loss of these cells beyond the normal amount can happen after many kinds of eye surgery. If too many cells are lost, the *cornea* can become cloudy, which can decrease vision.

Loss of endothelial cells can happen after *Visian Toric ICL* surgery. Before your surgery, you will have an eye exam that will help your doctor decide if you are a candidate for *Visian Toric ICL* surgery. Patients implanted with the *Visian Toric ICL* experience some loss of endothelial cells and a continuing loss of endothelial cells over time that is greater than that expected from aging.

FDA Safety and Effectiveness Study of the *Visian ICL*

- 13 eyes (11%) of those checked at 5 -7 years from surgery had more than 30% *endothelial cell loss*:
 - 3 of these eyes (2.6%) reported this loss within the first year after surgery. The timing of the loss for the 3 eyes suggest that the loss may have been caused by the surgical procedure used to insert the *Visian ICL* into the eye.
 - 10 eyes (8.7%) had *endothelial cell loss* 5 years or more after surgery.

Patient Survey Study for the *Visian ICL*

- corneal problems were reported for 5 of the 2999 implanted eyes (0.3%) up to 5 years after surgery.

Amount of loss can vary, but if loss reaches a critical level, there could be a build-up of fluid or swelling of the *cornea* (*corneal edema*). *Corneal edema* may require that your *cornea* be removed and replaced (corneal transplantation).

Glare and Halos

Glare and *halos* are common in patients with *astigmatism* even if they never had any ocular surgery. They may be more bothersome in low light conditions when the *pupil* is dilated. Even if patients don't have *glare* and *halos* before *Visian Toric ICL* surgery, they may develop *glare* and *halos* after surgery. If you currently experience *glare* and *halos*, there is a chance that they may be more severe after *Visian Toric ICL* surgery.

FDA Safety and Effectiveness study for the *Visian Toric ICL (TICL)*

Glare

- 29 out of 210 eyes (13.8%) of patients reported *glare* before surgery. At 1 year after surgery, 37 out of 185 eyes (20%) of patients reported *glare*.
- 28 of 185 eyes (15.1%) of patients noted increased *glare* symptoms at 1 year after surgery compared to before surgery.

Halos

- 28 of 210 eyes (13.3%) of patients reported *halos* before surgery. At 1 year after surgery, 37 out of 185 eyes (20%) of patients reported *halos*.
- 33 of 185 eyes (17.8 %) of patients noted increased *halos* at 1 year after surgery compared to before surgery.

FDA Safety and Effectiveness Study of the *Visian ICL*

Glare

- 76 out of 526 eyes (14.4%) of patients reported *glare* before surgery. At 3 years after surgery, 41 out of 351 eyes (11.7%) of patients reported *glare*.
- 34 of 351 eyes (9.7%) of patients noted increased *glare* symptoms at 3 years after surgery compared to before surgery.

Halos

- 59 out of 526 eyes (11.2%) of patients reported *halos* before surgery. At 3 years after surgery, 49 out of 350 eyes (14%) of patients reported *halos*.
- 40 of 350 eyes (11.4 %) of patients noted increased *halos* at 3 years after surgery compared to before surgery.

Patient Survey Study for the *Visian ICL*

This study did not collect surveys from patients before their surgery. It is not known how many of the patients that reported *glare* and *halos* before *Visian ICL* surgery.

- *glare* was reported for 85 out of 2999 (2.8%) implanted eyes up to 5 years after surgery.
- *halos* were reported for 156 out of 2999 (5.2%) implanted eyes up to 5 years after surgery.

Other Complications

Other risks associated with *Visian Toric ICL* surgery may include:

- movement of the colored portion of the eye (*iris*) through a surgical wound to a position outside the eye (*iris prolapse*),
- bleeding in the area on the *retina* responsible for reading vision (*macular hemorrhage*),
- bleeding under the *retina* (*subretinal hemorrhage*),
- increase in focusing error (*astigmatism*),
- lifting or pulling of the *retina* from its natural position (*retinal detachment*),
- the inability of fluid to flow from the back chamber of the eye to the front chamber, frequently blocking drainage of fluid out of the eye and raising the pressure in the eye (*pupillary block glaucoma*),
- unequal *pupil* size (*anisocoria*).

Potential complications are not limited to those reported during the clinical studies. The following represent potential complications/adverse events reported with refractive surgery in general:

- irritation of the white portion of the eyeball and inner eyelid (*conjunctival irritation*),
- temporary severe abnormal fluid build-up/swelling in the *cornea* (*acute corneal decompensation*) after surgery that does not cause a loss of vision,

- continuing abnormal fluid build-up/swelling in the *cornea* (*persistent corneal edema*) that may cause a loss of vision,
- partial or total eye infection (*endophthalmitis*),
- significant harsh or uncomfortable bright light (*glare*) or circular flares or rings of light that may appear around a headlight or other lighted object (*halos*),
- blood in the eye (*hyphema*),
- discharge in the eye (*hypopyon*),
- *Visian Toric ICL* dislocation,
- cyst-like swelling of the center of the *retina* with fluid (*cystoid macular edema*),
- condition where the colored portion of the eye does not get larger or smaller when light is shined in the eye (*non-reactive pupil*),
- severe *inflammation of the eye*,
- inflammation in the front part of the eye (*iritis*),
- inflammation in the middle layer of tissue in the eye (*uveitis*),
- loss of clear gel-like material from the farthest back chamber of the eye during surgery (*vitreous loss*) and,
- removal and replacement of the *cornea* (*corneal transplant*).

6.0 Contraindications

You should **NOT** have *Visian Toric ICL* surgery if you:

- are less than 21 years of age;
- have a narrow front (anterior) chamber as measured by a special test by your doctor, or if your doctor finds that the shape of your eye is not adequate to fit the *Visian Toric ICL* (anterior chamber depth less than 3.0 millimeters)
- are pregnant or nursing;
- do **not** meet the minimum *endothelial cell density* for your age at the time of surgery as determined by your eye doctor.

7.0 Warnings

- Two holes in the extreme outer edge of the colored portion of the eye (peripheral iridotomies) must be performed 90° apart using a laser at between 2 to 3 weeks before implantation of the *Visian Toric ICL*.
- The long-term effects of the *Visian Toric ICL* on the thin, single layer of cells on the surface of the *cornea* closest to the inside of your eye, that keep the *cornea* clear (*corneal endothelium*) are not known. In the FDA clinical study with the *Visian ICL* for *Myopia* (for *nearsightedness*), some patients had 30% or greater loss of *corneal endothelial* cells. You should be aware that a greater than normal build-up of fluid or swelling of the *cornea* (*corneal edema*) can happen. The *corneal edema* may even require that your *cornea* be removed and replaced (*corneal transplantation*). You should see your doctor regularly for an exam to check your *endothelium* as long as you have the *Visian Toric ICL* in your eye(s). This will help your doctor monitor the long-term health of your *cornea*.
- After *Visian Toric ICL* surgery, patients have increased risk of developing cloudiness of the natural lens (*cataract*), including risk of a *cataract* that may need surgery. The risk of *cataract* continues to rise with each year that the *Visian Toric ICL* is in the eye. Because of this, you should see your doctor regularly for an eye exam to check you for *cataracts*. The long-term risk of a *cataract* and additional surgery may be higher in older patients and those with higher degrees of *nearsightedness* (*myopia*). The long-term risk of a *cataract* beyond 7 years is unknown.
- When the *Visian Toric ICL* is placed in the eye, there is an increased risk of an early increase in pressure inside your eye (*intraocular pressure* or *IOP*). This is usually caused by blockage of fluid flow in the eye that requires treatment with a second surgery. The long-term risks of the following *types of complications* are not well established:
 - damage to the optic nerve caused by increased pressure (*glaucoma*),
 - scar tissue at the outer edges of the front chamber of the eye (*peripheral anterior synechiae*), and
 - abnormal release of pigment particles from cells in the eye that could block the drainage of fluid from the inside to the outside of the eye (*pigment dispersion*).
- There is a part of the eye that fluid flows through when draining from the inside of the eye. After *Visian TICL* surgery, this drainage area may get narrower and should be monitored by your doctor. It is important that you return to the doctor after surgery, according to the schedule that he provides.
- Patients may develop *glare* and *halos* after *Visian Toric ICL* and patients with *glare* and *halos* prior to surgery may have more severe symptoms after surgery. If your *pupil* in medium light conditions is larger than the optic of the *Visian Toric ICL*, you may experience *glare* or *halos* after surgery. Discuss with your surgeon whether the size of your *pupil* might affect the quality of vision achieved with *Visian Toric ICL*. See **Diagrams 5, 6, and 7** for examples of the appearance of *glare*, starburst, and *halos*.

DIAGRAM 5 – EXAMPLE OF GLARE



DIAGRAM 6 – EXAMPLE OF STARBURST



DIAGRAM 7 – EXAMPLE OF HALOS



8.0 Precautions

1. Patients with higher amounts of *nearsightedness* with stigmatism had worse results. The *Visian Toric ICL* was less effective in correcting *nearsightedness* and there was a higher risk of complications in these patients.
2. The relationship between the *Visian Toric ICL* and lifting or pulling of the *retina* from its natural position (*retinal detachment*) is not known.
3. The ability of ultraviolet absorbing *lenses* to reduce the incidence of *retinal* disorders has not been established. Examples of *retinal* disorders include damage to your eye caused by sun gazing or reduction in your central vision due to the thinning of a part of your *retina* (*macular degeneration*).
4. The safety of and ability of the *Visian Toric ICL* to correct moderate to high *nearsightedness* with *astigmatism* has **NOT** been established in patients with:
 - unstable or worsening *nearsightedness* with *astigmatism*;
 - history or clinical signs of inflammation inside the eye (*iritis/uveitis*);
 - damage to the layer of the nerve tissue at the back of the eye that captures images (*retina*) caused by diabetes (*diabetic retinopathy*);
 - damage to the optic nerve caused by increased pressure in the eye (*glaucoma*);
 - history of previous eye surgery such as removal and replacement of the *cornea* (*corneal transplant*) or surgery to repair the layer of the nerve tissue at the back of the eye that captures images (*retina*) after it has separated from its natural position on the back surface of the eyeball (*retinal detachment*);
 - life-threatening non-ocular disease (e.g., end-stage heart failure or kidney disease);
 - progressive sight-threatening disease other than *nearsightedness*;
 - a diagnosis of high pressure inside the eye (*ocular hypertension*);
 - insulin-dependent diabetes;
 - flakes of material blocking normal fluid drainage from the eye (*pseudoexfoliation*);
 - abnormal release of pigment inside the eye (*pigment dispersion*);
 - greater than -20.0 D or lower than -3.0 D of *nearsightedness*; greater than 4.0 D or lower than 1.0 D of *astigmatism*.

9.0 Are You a Good Candidate for *Visian Toric ICL* Surgery?

Your doctor will conduct a thorough eye examination to determine if you are a candidate for *Visian Toric ICL* surgery. In addition, if you are considering *Visian Toric ICL* surgery for *nearsightedness* with *astigmatism* you must:

- be between the ages of 21 and 45;
- have between -3.0 D and -20.0 D of *nearsightedness* and between 1.0 D and 4.0 D of *astigmatism*;
- understand that the *Visian Toric ICL* is indicated for the correction of *nearsightedness* with *astigmatism* between -3.0 D and ≤ -15.0 D and between 1.0 D and 4.0 D of *astigmatism*, and the reduction of *nearsightedness* with *astigmatism* between > -15.0 D and -20.0 D and between 1.0 D and 4.0 D of *astigmatism*;
- have the shape of your eye able to fit the *Visian Toric ICL* (have an *anterior chamber* depth of 3.0 millimeters or greater);
- have a minimally acceptable density of the thin, single layer of cells (*endothelial cells*) on the innermost surface of the *cornea*, responsible for keeping the *cornea* clear. If your doctor determines that your *endothelial cell density* is below the minimum level, you will be at greater risk of swelling of your *cornea* (*corneal edema*), possibly requiring removal and replacement of your *cornea* (*corneal transplantation*);
- have written evidence that your *nearsightedness* has been stable for at least 1 year;
- understand the risks and benefits of surgery with *Visian Toric ICL* for *nearsightedness* with *astigmatism* compared to other available treatments for *nearsightedness with astigmatism*;
- be able to lie flat on your back;
- have no known allergies to any of the medications that your physician may discuss will be used before, during and after your surgery;
- **not** be pregnant or nursing.
- understand that at between 2 to 3 weeks before *Visian Toric ICL* surgery you will need to have holes made in the extreme outer edge of the colored portion of the eye (*peripheral iridotomy*) using a laser;
- be willing to sign an Informed Consent Form provided by your doctor.

You and your doctor will determine if you are a suitable candidate for the *Visian Toric ICL* and the frequency of follow-up required to monitor the health of your eye.

10.0 What Should You Expect During *Visian Toric ICL* Surgery?

Before the Surgery

Before surgery, your doctor needs to determine your complete medical and eye history and check the health of both your eyes. This exam will determine if your eyes are healthy and if you are a good candidate for *Visian Toric ICL* surgery. This examination will include a measurement of the inner layer of your *cornea* (*endothelium*).

If you wear contact lenses, it is very important that you stop wearing them 2 to 4 weeks before your eye examination and surgery for the doctor to obtain a stable eye measurement. Failure to do this may lead to suboptimal results of your surgery.

Tell your doctor if you take any medications, have any eye conditions, have undergone previous eye surgery, have any medical conditions or have any allergies. Ask your doctor if you should eat or drink right before the surgery. **You should also arrange for transportation since you must not drive immediately after surgery.** Your doctor will let you know when your vision is good enough to drive again.

Two to Three Weeks before Surgery

Two to three weeks before your *Visian Toric ICL* surgery, your doctor will make two holes in the extreme outer edge of the colored portion of the eye (peripheral iridotomies) to prepare your eye for implantation of the *Visian Toric ICL*. This is necessary to make sure that the fluid flows properly from the back chamber to the front chamber of the eye to prevent a buildup of pressure within the eye after *Visian Toric ICL* surgery. The doctor will usually apply numbing drops to the eye and make tiny openings in the colored portion of the eye (*iris*) with a laser beam. Usually this doesn't affect your ability to drive home after this procedure, but check with your doctor.

After the *peripheral iridotomy* procedure, you will be prescribed eye drops for you to use. It is important that you follow all medication instructions. Your doctor will instruct you to discontinue the use of these medications before the day of surgery.

The Day of Surgery

On the day of surgery, eye drops will be placed in your eye to enlarge (dilate) the black part of your eye (*pupil*).

Once your *pupil* is fully dilated, your doctor will put numbing eye drops in your eye and/or inject a needle with numbing medication into your eye and ask you to lie on your back on the treatment table/chair in the treatment room. Your doctor may discuss alternative anesthetic/sedation options with you before surgery.

A small incision is made into the clear front layer of the eye that lets light enter (*cornea*) and the *Visian Toric ICL* is inserted and positioned in its proper position in the eye as illustrated in **Diagram 4** at the beginning of this booklet. The entire procedure will usually take approximately 20 to 30 minutes or less.

After the surgery is complete, your doctor will place some eye drops/ointment in your eye. For your eye protection and comfort, your doctor may apply a patch or shield over your eye. The procedure is painless because of the numbing medication.

It is important that you do not drive yourself home and make arrangements before the day of surgery for transportation home.

The First Days after Surgery

Your physician will need to see you the day after surgery for a checkup which will include monitoring the pressure in your eye.

You may be sensitive to light and have a feeling that something is in your eye. Sunglasses may make you more comfortable. Also, your eye may hurt. Your doctor can prescribe pain medication to make you more comfortable during the first few days after the surgery. If you experience severe pain in the eye, please contact your doctor immediately. You will need to use eye drop/ointment drugs in the first week to treat or prevent infection (*antibiotic*) and reduce inflammation in the eye (*anti-inflammatory*) in the first week.

IMPORTANT: Use the eye medications as directed by your eye doctor. (Your results may depend upon your following your doctor's instructions).

DO NOT rub your eyes, especially for the first 3 to 5 days after surgery. If you notice any sudden decrease in your vision, you should contact your doctor immediately.

Long Term Care: In a small number of cases, *Visian Toric ICL* repositioning, replacement and/or removal may become necessary. *Visian Toric ICL* repositioning may be performed if your doctor finds the *Visian Toric ICL* is not properly aligned in the direction of *astigmatism*. *Visian Toric ICL* replacement may be performed if your doctor believes a different lens may either fit your eye better or provide you better vision. *Visian Toric ICL* removal may be necessary if you develop a *cataract* and your doctor recommends surgery. If you need to have *cataract* surgery, the *intraocular lens* used to replace your natural *crystalline lens* can often correct your *nearsightedness with astigmatism*. If your doctor removes the *Visian Toric ICL*, you will lose the benefit of your *nearsightedness with astigmatism* correction. This means that your vision may not return to what it was like before the *Visian Toric ICL* surgery. After *Visian Toric ICL* surgery it is important that you follow your physician's recommendations for eye care and follow-up visits.

11.0 Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if *Visian Toric ICL* surgery for *nearsightedness with astigmatism* is right for you:

- What are my other options to correct my *nearsightedness with astigmatism*?
- Will I have to limit my activities after surgery and for how long?
- What are the benefits of *Visian Toric ICL* surgery for my amount of *nearsightedness with astigmatism*?
- What quality of vision can I expect in the first few months after surgery?
- If *Visian Toric ICL* surgery does not correct my vision, what is the possibility that my eyeglasses would need to be stronger than before? Could my need for eyeglasses increase over time? Could I undergo a different type of eye surgery for the correction of my vision?
- How is *Visian Toric ICL* surgery likely to affect my need to wear eyeglasses or contact *lenses* as I get older?
- Will my eye heal differently, if injured after implantation of the *Visian Toric ICL*?
- Should I have *Visian Toric ICL* surgery in my other eye?
- How long will I have to wait before I can have surgery in my other eye?
- What vision problems might I experience if I have a *Visian Toric ICL* only in one eye?

Discuss the cost of surgery and follow-up care needs with your doctor. Most health insurance policies do not cover eye surgery for the correction of *nearsightedness with astigmatism*.

12.0 Self-Test

Are You an Informed and Educated Patient?

Take the test below to see if you can answer the following questions after reading this booklet.

	True	False
1. <i>Visian Toric ICL</i> surgery for <i>nearsightedness with astigmatism</i> is the same as laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
2. <i>Visian Toric ICL</i> surgery is risk-free.	<input type="checkbox"/>	<input type="checkbox"/>
3. It does <u>not</u> matter if I wear my contact <i>lenses</i> before <i>Visian Toric ICL</i> surgery when my doctor told me <u>not</u> to wear them.	<input type="checkbox"/>	<input type="checkbox"/>
4. After the surgery, there is a good chance that I will depend less on eyeglasses or contact <i>lenses</i> to see distant objects.	<input type="checkbox"/>	<input type="checkbox"/>
5. There is a risk I may lose some best corrected vision after <i>Visian Toric ICL</i> surgery.	<input type="checkbox"/>	<input type="checkbox"/>
6. It does not matter if I am pregnant or nursing.	<input type="checkbox"/>	<input type="checkbox"/>
7. If my doctor finds that I have decreased size of the front chamber of the eye (<i>narrow anterior chamber angles</i>) which could block the flow of fluid from the inside to the outside of the eye, I am still a good candidate for <i>Visian Toric ICL</i> surgery.	<input type="checkbox"/>	<input type="checkbox"/>
8. The <i>Visian Toric ICL</i> will correct my <i>astigmatism and my nearsightedness</i> .	<input type="checkbox"/>	<input type="checkbox"/>
9. It is important I follow my eye doctor's specific instructions concerning medications.	<input type="checkbox"/>	<input type="checkbox"/>
10. My doctor does not need to know about my full medical history (conditions not dealing with the eye).	<input type="checkbox"/>	<input type="checkbox"/>

You can find the answers to Self-Test at the end of **Section 15 – Summary of Important Information**.

13.0 Clinical Studies

Safety and Effectiveness FDA Study of the *Visian Toric ICL* for Nearsightedness with *Astigmatism (TICL)*.

A clinical study was conducted to evaluate the benefits and risks of *Visian Toric ICL* surgery.

Description of the Study Patient Group:

- 210 eyes of 124 patients were implanted with a *Visian Toric ICL*
- Most patients were white (Caucasian) and over half of the patients were female
- Patients ranged from 21 to 45 years of age at time of surgery
- *Nearsightedness* before surgery ranged between -2.38 D and -19.5 D. The average was -9.37 D.
- *Astigmatism* before surgery ranged between 1.0 D and 4.0 D. The average was 1.95 D

The clinical study was conducted to study the following:

- *Visual Acuity* without glasses after surgery
- Ability to the *Visian Toric ICL* to correct *nearsightedness and astigmatism*
- Patient satisfaction after *Visian Toric ICL* Surgery
- Quality of Vision after *Visian Toric ICL* Surgery

Visual Acuity Without Glasses after Surgery:

Visual acuity measures the sharpness of vision using a letter chart. In the United States, a *visual acuity* of 20/40 or better measured on an eye chart is required in most states to drive a car without glasses or contact lenses. One year after insertion of the *Visian ICL*, 100% of eyes in the *Visian Toric ICL* study saw 20/40 or better without glasses or contact lenses.

- **Table 1** shows the percent of patients in the study that had 20/20 or better and 20/40 or better vision without glasses, measured using an eye chart. The table shows vision at time points after surgery, either for all patients (All Study Patients row) or based on their degree of *nearsightedness* before *Visian Toric ICL* surgery.

Table 1: *Visual Acuity Without Glasses, After Surgery by Range of *Nearsightedness (Myopia)* Before Surgery**

Lens Group	Exam Interval	20/20 or Better	20/40 or Better
All Study Patients	1 Week	76.6%	99.4%
	1 Month	83.7%	98.8%
	3 Months	87.0%	100%
	6 Months	90.3%	100%
	12 Months	89.3%	100%
≤ -7.0 D of <i>myopia</i> before surgery	12 Months	93.9%	97.0%
> -7.0 D to -10.0 D <i>myopia</i> before surgery	12 Months	83.9%	97.8%
> -10.0 D to -15.0 D <i>myopia</i> before surgery	12 Months	77.0%	96.7%
> -15.0 D <i>myopia</i> before surgery	12 Months	33.3%	33.3%

*Eyes with range of *nearsightedness (myopia)* with glasses 20/20 or better before surgery and targeted for complete correction

Patient Satisfaction after *Visian Toric ICL* Surgery:

Patients in the clinical study were asked to report their satisfaction with the *Visian Toric ICL* procedure. One year (12 months) after *Visian Toric ICL* surgery, 97.8% of patients were very/extremely satisfied and 2.2% were moderately/fairly satisfied with their vision. No patients (0.0%) reported being unsatisfied.

Quality of Vision after *Visian Toric ICL* Surgery:

Quality of vision reported by patients as very good/excellent improved from 64.3% before the *Visian Toric ICL* to 94.6% at 12 months after the *Visian Toric ICL* procedure. Patients reporting poor/very poor vision dropped to 0% at 12 months compared to 10.5% before the *Visian Toric ICL*.

Patients in the clinical study were asked on a questionnaire to report on vision symptoms before and 12 months after the *Visian Toric ICL* procedure. Responses are shown in **Table 2**. Percentages of patients reporting *Glare*, *Halos*, *Double Vision*, Night Vision and Night Driving Difficulties were similar before and after surgery.

Table 2: Vision Symptoms Reported by Patients

Symptom	Improved at 12 Months	No Change at 12 Months	Worsened at 12 Months
Harsh or uncomfortable bright light (<i>Glare</i>)	10.3%	74.6%	15.1%
Circular flares/rings of light around lighted objects (<i>Halos</i>)	11.4%	70.8%	17.8%
Seeing multiple images of the object being looked at (<i>Double Vision</i>)	1.6%	96.8%	1.6%
Night Vision	12.5%	75.5%	11.9%
Night Driving Difficulties	11.0%	75.8%	13.2%

The results of the FDA study showed that the *Visian Toric ICL* was able to correct *nearsightedness* with *astigmatism* in study patients. At 12 months after surgery, 89.1% of patients could read 20/20 without glasses and 95.3% could read 20/40 without glasses. At 12 months after surgery, 97.8% of patients reporting being “Very/Extremely Satisfied” with their vision and no patients reported being unsatisfied.

Detailed information regarding the adverse events observed in the *Visian Toric ICL* Clinical Study can be found in Section 5 – Benefits and Risks.

FDA Post-Approval Study of the *Visian Toric Implantable Collamer Lens (TICL)*

When the FDA approved the *TICL*, they asked STAAR to conduct a new study to collect long-term data on the performance of the *TICL*.

Description of Study Patient Group:

- 232 eyes of 125 patients were implanted with *TICL lenses*.
- Most patients were white (Caucasian) and over half of the patients were female.
- Patients ranged from 21 to 45 years of age at time of surgery.
- *Nearsightedness* before surgery ranged between -2.00 D and -13.75 D. *Astigmatism* before surgery ranged between -1.00 and -4.00 D.

The goals of the clinical study were to measure the following in new patients after *TICL* surgery:

- Stability of the *TICL* in its position in the eye after surgery
- Ability of the *TICL* lens to correct *nearsightedness* with *astigmatism*
- Ongoing safety of the *TICL* up to 2 years after surgery

***TICL* Rotational Stability:**

The main goal of the *TICL* study was to determine if between 18 and 24 months after surgery, any *TICL* lenses rotated more than 5 degrees from where the surgeon placed them during surgery. The *TICL* study showed that no eyes (0/232) rotated greater than 5 degrees during these timepoints.

Visual Acuity:

Visual Acuity without Glasses after Surgery

Visual acuity measures the sharpness of vision using a letter chart. In the US, a *visual acuity* of 20/40 or better measured on an eye chart is required in most states to drive a car without glasses or contact lenses.

At least 98% of eyes had vision without glasses of 20/40 or better at each follow-up doctor visit from 6 months to 2 years after surgery. **Table 3** shows the percent of all eyes of patients in the study that had 20/40 or better and 20/20 or better vision without glasses after *TICL* surgery. The table includes data for all patients who were available to be measured using an eye chart at the specified time points.

Table 3: Visual Acuity* Without Glasses Between 6 Months and Two Years After Surgery

Exam Interval	20/20 or Better	20/40 or Better
6 Months	110/148 (74.3%)	147/148 (99.3%)
1 Year	119/152 (78.3%)	150/152 (98.7%)
2 Years	105/144 (72.9%)	143/144 (99.3%)

*Eyes with range of *nearsightedness (myopia)* shown, visual acuity with glasses 20/20 or better before surgery and targeted for complete correction

Two eyes (0.9%) lost two or more lines of corrected distance visual acuity as measured on an eye chart:

- one eye (0.4%) lost two lines of corrected distance vision at 1 month after surgery because the Visian Toric ICL lens dislocated from its original position and remained unstable. Corrected vision measured 20/32 at one month compared to 20/20 before surgery. The Visian Toric ICL was removed and the vision improved and stabilized by one month after removal surgery to 20/25 before the subject was exited from the study.
- one eye (0.4%) was reported to have lost two lines of vision at the 3 month visit associated with misalignment of the lens. Vision measured 20/26 at 3 months after surgery compared to 20/16 before surgery, but improved on its own to 20/20 by 12 months, and to 20/17 by 24 months after surgery. The lens misalignment in this case did not require treatment.

Adverse Events

Increased IOP was the most common reported complication/adverse event after surgery, reported for 17.2% (40/232 eyes). Most of these events were caused by the remaining residual gel-like fluid used in the eye during surgery (*viscoelastic* fluid). In 14 (6.0%) eyes, the pressure in the eye returned to normal levels without any treatment. In 2 subjects, cases of increased pressure in both eyes were reported as serious because they were caused by a blockage of flow of fluid from inside to outside of the eye (*narrowing of anterior chamber angle*) and the *TICL* lenses were removed. The remaining events were treated either by stopping or tapering the eyedrops given after surgery, by adding a new medication or by a second surgery (see Additional Surgery in this section). No patients in the post-approval *TICL* study developed damage to the optic nerve (*glaucoma*).

Other Adverse Events:

- dry eye was reported in 10 eyes (4.3%) of 5 subjects
- 2 eyes (0.9%) lost two or more lines of best corrected distance vision due to dislocation/misalignment of the *TICL* lens from its intended position.
- Additional surgery to resolve an adverse event was reported in 28 (12.1%) eyes:
 - 7 eyes (3.0%) had surgery to remove the lens, including one eye that had a second surgery to treat *pupillary block*, one eye that had the *TICL* lens removed at the start of *cataract* surgery, and one eye that had the *TICL* lens removed after it became dislocated from its original position
 - 6 eyes (2.6%) had a second surgery to treat *pupillary block* or narrowing of the *anterior chamber*. Four (1.7%) of these eyes had another hole placed in the extreme outer edge of the colored portion of the eye (*peripheral iridotomy*) and the other two eyes (0.9%) had another surgery to enlarge the *peripheral iridotomy* created before *TICL* surgery.
 - 5 eyes (2.2%) had a second surgery to change the position of the *TICL* lens. Two of these eyes also had a third surgery to correct leftover *nearsightedness* or *nearsightedness with astigmatism*.
 - 2 eyes (0.9%) had a second surgery to exchange the *TICL* lens for a different *TICL* lens
 - 1 eye (0.4%) that underwent *TICL* lens removal also had *cataract* surgery
 - 13 eyes (5.6%) had a second surgery to correct leftover *nearsightedness* or *nearsightedness with astigmatism* that remained after *TICL* surgery.

Safety and Effectiveness Study of the Visian ICL for Nearsightedness

A previous clinical study was conducted to evaluate the benefits and risks of *Visian ICL for Myopia (nearsightedness)*. The *Visian ICL for Myopia (MICL)* is similar to the *Visian Toric ICL* except that it does not correct *astigmatism*.

The *Visian MICL* study was conducted in two phases: the first phase lasted three years after surgery to collect effectiveness and safety information. The second phase involved collection of more safety data to at least five years after *Visian MICL* surgery.

Description of the Study Patient Group:

- 526 eyes of 294 patients were implanted with the *Visian MICL*
- Most patients were white (Caucasian) and over half of the patients were female
- Patients ranged from 21 to 45 years of age at time of surgery
- *Nearsightedness* before surgery ranged between -3.0 D and -20.0 D. The average was -10.06 D.

The safety follow-up of study patients included the following events:

- Additional surgeries;
- *Cataract* formation;
- Loss of best corrected vision with eyeglasses (BCVA);
- Raised pressure inside the eye (*intraocular pressure*) and damage to the optic nerve caused by increased pressure in the eye (*glaucoma*);
- Loss of cells on the innermost surface of the *cornea* (endothelial cells);
- Other complications.

In the clinical study of the *Visian ICL*, vision without glasses improved for all eyes except in those eyes with the most extreme amount of *nearsightedness*. The strongest *Visian ICL* could not completely correct the vision in those eyes and some patients still needed glasses or contact lenses after surgery to view distant objects. At 3 years after surgery, 94.7% of eyes saw 20/40 or better without glasses or contact lenses. A total of 92.1% of patients reported being "Very/Extremely Satisfied" and only 2 patients reported being unsatisfied with their vision at 3 years after surgery.

Detailed information regarding the adverse events observed in the *Visian ICL* Clinical Study can be found in Section 5 – Benefits and Risks.

Visian ICL for Myopia Adverse Event Patient Survey Study

A survey study was conducted in the US after *Visian ICL for Myopia* was approved by the FDA. The goal of this study was to collect safety information from patients who had *ICL* surgery in the general population. All patients who consented to participate were asked to complete surveys at scheduled times up to 5 years after their *Visian MICL* surgery. The surveys asked patients to report any complications or additional eye surgeries because of the *MICL*.

Description of the Study Patient Group:

- 2999 eyes of 1547 patients implanted with the *Visian MICL* participated
- Most patients were white (Caucasian) and over half of the patients were female
- Patients ranged from 17 to 77 years of age at time of surgery

The surveys asked for information about the following adverse events:

- Problems with cells on the innermost surface of the *cornea* (*endothelial cells*);
- *Cataract* formation;
- Medical treatment for inflammation inside the eye;
- Medical treatment for raised pressure inside the eye (*intraocular pressure*) and damage to the optic nerve caused by increased pressure in the eye (*glaucoma*);
- Surgery because of separation of the layer of nerve tissue at the back of the eye (*retinal detachment*) that captures images;
- Surgery to remove, replace or reposition the *ICL*;
- Other complications in the eye.

Overall, patient responses to surveys provided similar information to what was found in the FDA safety and effectiveness clinical study of 526 eyes of 294 patients. This study included patients over 45 years of age. This age group was not included in the FDA studies for *TICL* or *MICL*. These older patients reported a higher rate of *cataract formation* or need for a second surgery than patients who were 45 or younger at the time of initial *MICL* surgery.

Detailed information regarding the adverse events observed in the *Visian ICL* Adverse Event Patient Survey Study can be found in Section 5 – Benefits and Risks.

14.0 Summary of Important Information

- *Visian Toric ICL* surgery provides a permanent correction of your *nearsightedness with astigmatism* as long as the *Visian Toric ICL* remains in the eye. The *Visian Toric ICL* may be removed. If your physician removes the *Visian Toric ICL*, you will lose the benefit of your *nearsightedness with astigmatism* correction. This means that your vision may not return to what it was like before the *Visian Toric ICL* surgery.
- *Visian Toric ICL* surgery does not eliminate the need for reading glasses, even if you have never worn them before.
- Your vision must be stable before *Visian Toric ICL* surgery. You must provide written evidence that your *nearsightedness with astigmatism* has changed no more than 0.50 D each year for at least 1 year.
- Pregnant and nursing women should wait until they are not pregnant and not nursing to have *Visian Toric ICL* surgery.
- *Visian Toric ICL* surgery has some risks. Please read and understand this entire booklet before you agree to the surgery. The sections on **Risks (Section 5.0)** **Warnings (Section 7.0)** and **Precautions (Section 8.0)** are especially important to read carefully.
- Some other options to correct *nearsightedness with astigmatism* include glasses, contact lenses, *RK*, *PRK* and *LASIK*.
- Before considering *Visian Toric ICL* surgery you should:
 - a) have a complete eye examination,
 - b) talk with at least one eye care professional about *Visian Toric ICL* surgery, especially the potential benefits, risks, and complications. You should discuss the time needed for healing after surgery.
- Certain eye diseases, eye conditions, previous eye surgery, systemic medical conditions may have an impact on the results after *Visian Toric ICL* surgery. It is important that you provide your doctor with your complete medical history so your doctor may determine if you are a good candidate for the *Visian Toric ICL* for correction of *nearsightedness with astigmatism*.
- The *Visian Toric ICL* is intended to improve your vision. However, because you are *nearsighted*, you should consult with your eye doctor on a regular basis (i.e., once a year) to verify the overall health of your eye.

Answers to Self-Test Questions:

- | | |
|------|-------|
| 5. F | 10. F |
| 6. F | 11. F |
| 7. F | 12. T |
| 8. T | 13. T |
| 9. T | 14. F |

15.0 Patient Assistance Information

To be completed by you or your Primary Eye Care Professional as a reference.

Primary Eye Care Professional

Name:

Address:

Phone:

Visian Toric ICL Doctor

Name:

Address:

Phone:

Treatment Location

Name:

Address:

Phone:

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