



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

**Facts You Need To Know About STAAR Surgical's Visian Toric ICL
SURGERY**

PATIENT INFORMATION BOOKLET

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

**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 reshapes 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*.

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* based 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 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 other 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.

Visian ICL for Myopia (MICL): *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: *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.

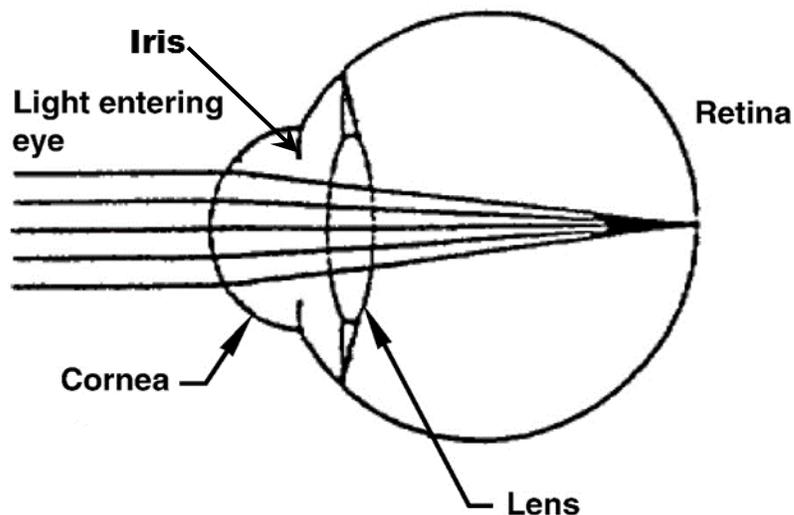
3.0 What Is Nearsightedness with Astigmatism

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.

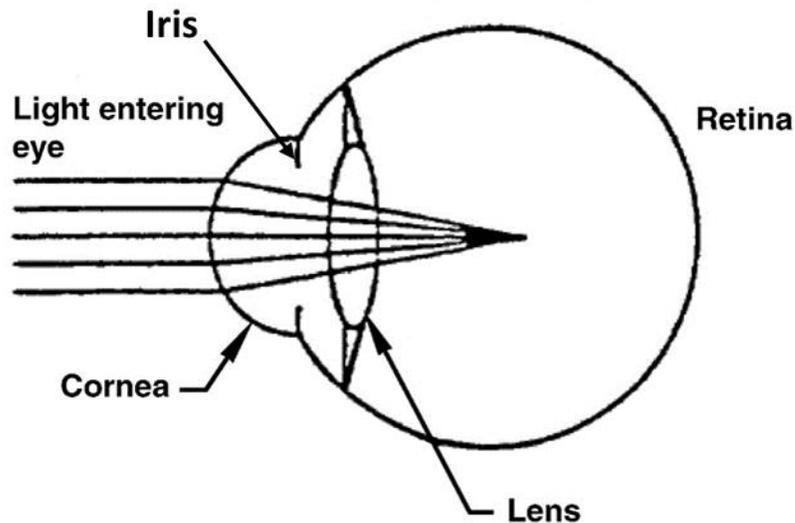


You may have *nearsightedness with astigmatism* if you have trouble seeing objects clearly when they are far away.

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*.

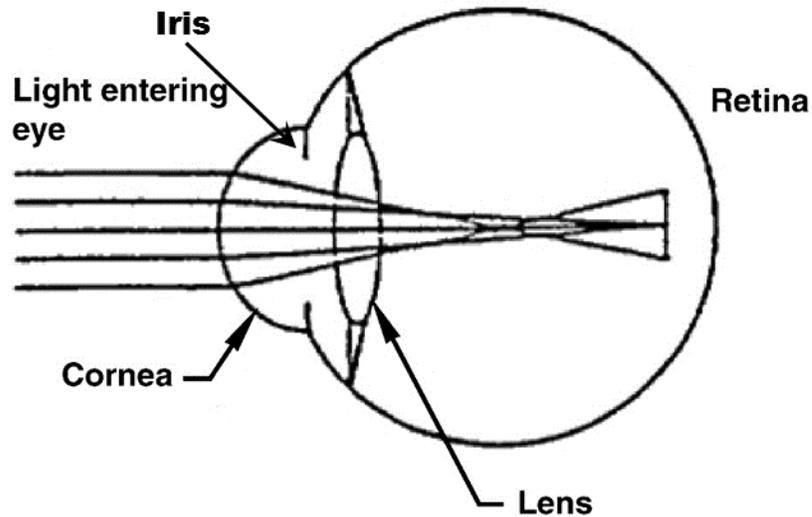
DIAGRAM 2: NEARSIGHTED EYE

Light focuses in front of the retina.
Vision is blurry.



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 and ASTIGMATIC EYE



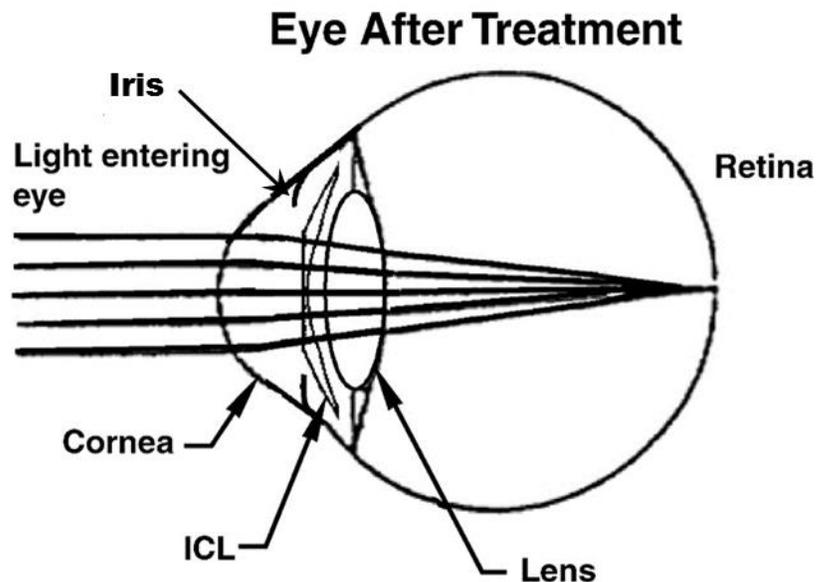
Your eyeglass prescription tells your doctor how *nearsighted* you are and how much *astigmatism* your eyes have. Glasses, contact lenses or eye surgery can help your eye focus light properly on the *retina*. This will correct *nearsightedness* and *astigmatism* and help you see distant objects more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

DIAGRAM 4: CORRECTION OF VISION AFTER VISIAN TORIC ICL SURGERY

Light focuses on the retina after surgery.
Vision is clearer.



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 -3.0D to -15.0D , and *astigmatism* between 1.0 and 4.0D . *Visian Toric ICL* surgery is designed to **reduce** *nearsightedness* greater than -15.0D up to -20.0D , and *astigmatism* between 1.0D and 4.0D . 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 $1.0D$ to $4.0D$ of *astigmatism*, and can partially correct *nearsightedness* in eyes with greater than $-15D$ up to $-20D$ of *myopia* and between 1.0 to $4.0D$ 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:

- For the *Toric ICL*, 210 eyes of 124 patients had the lens implanted and were followed through 12 months (1 year) after surgery.
- 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.

Please see section **13.0 Clinical Study of the *Visian Toric ICL***, and section **14.0 Adverse Events Observed in the Previous *Visian ICL* 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. In the FDA clinical study for the *Visian Toric ICL*, eight out of 210 eyes implanted with a *Visian Toric ICL* needed another surgery. *The Visian Toric ICL* was removed in three of the 210 eyes. One patient had a *Visian Toric ICL* replaced in one eye and one eye of a different patient required surgery to adjust the position of the lens. Another three eyes had another surgery to treat or prevent raised pressure inside the eye (*intraocular pressure* or *IOP*). In two eyes, another hole was placed in the extreme outer edge of the colored portion of the eye (*peripheral iridotomy*) to prevent an increase in eye pressure. In the third eye, the surgeon had to perform another surgery to remove the remaining gel-like fluid used during eye surgery (*viscoelastic fluid*) that caused an increase in pressure inside the eye.

In the FDA study of the *Visian ICL for Myopia*, 43 out of 526 implanted eyes (8.2%) had another surgery related to the *MICL* through 5 to 7 years after implantation. Of these 43 eyes, 22 eyes had another surgery to remove (10 eyes), replace (8 eyes), or adjust the position (4 eyes) of the *MICL*. One eye had surgery to replace and then another surgery to remove the *MICL*. Another 20 eyes in the *MICL* study had another surgery to treat raised pressure inside the eye (*intraocular pressure* or *IOP*).

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*. In the *Visian Toric ICL* FDA clinical study, 6 eyes developed some form of *cataract* by 12 months after surgery. In the FDA Clinical study of the *Visian ICL* for Myopia, 45 out of 334 eyes that were seen at 5-7 years after surgery, developed some form of *cataract*. 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)

Three eyes in the FDA study of the *Visian Toric ICL* lost vision of two or more lines as measured on an eye chart. In one eye, the loss of vision was due to clouding of the natural lens (*cataract*). In another eye, there was recorded loss of vision of two lines as measured on an eye chart compared to before surgery. This loss was not due to *cataract* and the patient reported being very satisfied with her vision. In the third eye, the loss of vision of two lines was measured at 6 months and 12 months after surgery but was found to improve by one line at 17 months after surgery.

In the FDA Clinical study of the *Visian ICL* for *Myopia*, 18 eyes lost vision of two or more lines as measured on an eye chart. The most common reason was clouding of the natural lens (*cataract*). Vision got better in these eyes after *cataract* surgery. In other eyes, vision improved without treatment. In 7 of the 18 eyes, however, vision did not get better after 5 or more years.

Raised *intraocular pressure* (IOP)

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 *nearsightedness* are also at increased risk of developing *glaucoma*.

In the clinical study of the *Visian Toric ICL*, two eyes of two patients had an increase in *IOP* to values greater than 10mmHg higher than before *Visian Toric ICL* surgery. One patient had an increase in *IOP* to higher than 25mmHg at 6 months after surgery, which dropped to 17mmHg at 12 months. One patient experienced raised *IOP* due 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*).

In the FDA clinical trial of the *Visian ICL for myopia*, 20 eyes (out of 526 implanted) experienced an increase in eye pressure requiring treatment beyond just the use of medicine, most often at 1 to 2 days after surgery. In most of these eyes, another hole was placed in the extreme outer edge of the colored portion of the eye (*peripheral iridotomy*) to reduce the pressure. A few patients in the *Visian ICL for myopia* study developed damage to the optic nerve (*glaucoma*). 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.

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. Amount of loss varies, but in the FDA study for the Visian ICL for Myopia, 11% of patients checked at 5 -7 years from surgery had more than 30% endothelial cell loss. 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*. In the *Visian Toric ICL* FDA study, 15.1% of patients noted increased *glare* symptoms compared to before surgery, and 17.8% noted increased severity of *halos*.

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*),
- 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*),
- 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*),
- 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 more narrow 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 *astigmatism* 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 -20D or lower than -3.0D of *nearsightedness*; greater than 4.0D or lower than 1.0D 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 -3D and -20D of *nearsightedness* and between 1.0D and 4.0D of *astigmatism*
- understand that the *Visian Toric ICL* is indicated for the correction of *nearsightedness* with *astigmatism* between -3D and $\leq -15D$ and between 1.0D and 4.0D of *astigmatism* , and the reduction of *nearsightedness* with *astigmatism* between $> -15D$ and -20D and between 1.0D and 4.0D 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.

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

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* replacement and/or removal may become necessary. *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*.

If your doctor removes the *Visian Toric ICL*, you will lose the benefit of your *nearsightedness* 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.

	<u>True</u>	<u>False</u>
1. <i>Visian Toric ICL</i> surgery for <i>nearsightedness</i> with <i>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 not matter if I wear my contact lenses before <i>Visian Toric ICL</i> surgery when my doctor told me not 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 lenses 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</i> and my <i>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 Study of the Visian Toric ICL

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 -2.38D and -19.5D . The average was -9.37D .
- *Astigmatism* before surgery ranged between 1.0D and 4.0D . The average was 1.95D

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%
≤ -7D of myopia before surgery	12 Months	93.9%	97.0%
> -7D to -10D myopia before surgery	12 Months	83.9%	97.8%
> -10D to -15D myopia before surgery	12 Months	77.0%	96.7%
> -15D myopia 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%

14.0 Adverse Events Observed in the Previous *Visian ICL* Clinical Studies

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 $-3D$ and $-20D$. The average was $-10.06D$.

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.

Additional (Secondary) Surgery

A total of 8.2% of eyes in the *MICL* FDA clinical study had a secondary surgery to change the position of, remove or replace the *Visian MICL*, or to treat raised pressure inside the eye (*intraocular pressure* or *IOP*).

A second surgery to change the position of the *Visian MICL* was done in 0.8% of eyes while 1.5% of eyes had a second surgery to replace the *Visian MICL*, and 1.9% of eyes had a second surgery to remove the *Visian MICL*. One eye (0.2%), had both a replacement and removal of the *Visian MICL*. In all cases, the reason for *Visian MICL* removal was associated with *cataract* surgery.

A second surgery to treat raised pressure inside the eye was done in (3.8%) of eyes in the study. Of these, 3.2% of eyes underwent an additional *YAG laser* treatment. In the other 0.6% of eyes, the surgeon had to perform another surgery to remove the remaining gel-like fluid used during eye surgery (*viscoelastic* fluid).

Cataract Formation

Long-term follow up of patients in the FDA *MICL* clinical study suggests that older age and higher levels of *nearsightedness* increase the risk for *cataract* after *Visian ICL* surgery. In the FDA *MICL* clinical study, 45 out of 334 eyes that were seen at 5-7 years after surgery, developed some form of *cataract*. The long-term risk of *cataract* beyond 7 years is unknown.

Loss of best corrected vision with eyeglasses (BCVA)

Eighteen eyes of 16 patients in the FDA *MICL* study lost vision of two or more lines as measured on an eye chart. The most common reason was clouding of the natural lens (*cataract*). Vision got better in these eyes after *cataract* surgery. In other eyes, vision improved without treatment. In 7 of the 18 eyes, however, vision did not get better after 5 or more years.

Raised intraocular pressure (IOP) requiring medication or surgery

A total of 27 eyes (out of 526 implanted) in the FDA clinical study of the *MICL* required either medication or surgical treatment to lower the raised *IOP*.

Twenty of the 27 eyes developed an early (most often 1 to 2 days after surgery) increase in *IOP* which required treatment of a second surgery. In most of these eyes another hole was placed in the extreme outer edge of the colored portion of the eye (*peripheral iridotomy*) to reduce the pressure. The remaining 7 eyes were diagnosed with *glaucoma*. In these eyes, medication was used to reduce the pressure and no additional surgery was required. The first case of *glaucoma* was diagnosed at 5 months after *MICL* surgery and the last case happened over 6 years (73 months) after surgery.

Endothelial Cell Loss

Loss of *endothelial cells* has been reported after *MICL* surgery. Amount of loss varies, but in the *MICL* FDA study, 13 eyes of 10 of patients (11.3% of those available for evaluation 5 years or more after surgery) reported more than 30% *endothelial cell* loss. Three of the 13 eyes reported this loss within the first year after surgery. The timing of the loss for these 3 eyes suggests that the loss may have been caused by the surgical procedure used to insert the *MICL* into the eye. The remaining 10 eyes had *endothelial cell* loss 5 years or more after surgery.

Other Complications

One case each of the following complications were reported in the *MICL* FDA study:

- movement of the colored portion of the eye (*iris*) through a surgical wound to a position outside the eye (*iris prolapse*) at 1 day after surgery,

- bleeding in the area on the *retina* responsible for reading vision (*macular hemorrhage*) at 1 week after surgery and,
- bleeding under the *retina* (*subretinal hemorrhage*) at 3 months after surgery.

A >2 diopter increase in focusing error (*astigmatism*) caused by a change in the curvature of the *cornea* was seen in 2 eyes at 3 years after *MICL* surgery. Lifting or pulling of the *retina* from its natural position (*retinal detachment*) was reported in 3 eyes at 4, 22 and 31 months after *MICL* implantation.

15.0 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 0.50D 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:

- | | |
|------|-------|
| 1. F | 6. F |
| 2. F | 7. F |
| 3. F | 8. F |
| 4. T | 9. T |
| 5. T | 10. F |

16.0 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: _____

Visian Toric ICL Manufacturer and Distributor:

<p>STAAR Surgical Company 1911 Walker Avenue Monrovia, CA 91016 USA Tel: (800) 352-7842 FAX: (800) 952-4923</p>

10000141/New