



EVO and EVO+ Visian Implantable Collamer® Lens (EVO ICL™)

For Nearsightedness

**For Nearsightedness (Myopia) between –3.0 to –20.0 Diopters
with 2.5 Diopters or less of Astigmatism**

AND

EVO and EVO+ Visian Toric Implantable Collamer® Lens

(EVO TICL™)

For Nearsightedness with Astigmatism

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

**Facts You Need to Know About STAAR Surgical’s
EVO ICL and EVO TICL SURGERY**

PATIENT INFORMATION BOOKLET

Please read this entire booklet. Discuss its contents with your doctor so that you may 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 *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 this medication after *ICL* surgery.

Aqueous Fluid: The fluid which flows from the back chamber of the eye through the *pupil* and into the *anterior chamber*. The fluid flows out of the eye through the *anterior chamber* angle.

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.

Central Port: A 0.36 mm hole in the center of the optic that allows *aqueous fluid* to circulate to the *anterior chamber* of the eye (also referred to as *KS- AquaPort®*).

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

Collamer: Hydroxyethyl methacrylate (HEMA)/porcine-collagen containing 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. Surgeries such as PRK, LASIK, SMILE 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 *retina*, the back surface of the eye 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*.

EVO ICL: *Implantable Collamer Lens* for the correction of *nearsightedness* with a 0.36 mm *central port* (also referred to as *EVO Visian ICL lens* and *EVO+ Visian ICL lens*).

EVO TICL: *Implantable Collamer Lens* for the correction of *nearsightedness and astigmatism* with a 0.36 mm *central port* (also referred to as *EVO Visian Toric ICL* lens and *EVO+ Visian Toric ICL* lens).

EVO Visian ICL for Myopia: *Implantable Collamer Lens* for the correction of *nearsightedness*. This lens is similar in design to the *Visian ICL* lens except that it has a 0.36 mm *central port* (also referred to as *EVO ICL* lens).

EVO Visian Toric ICL: *Implantable Collamer Lens* for the correction of *nearsightedness with astigmatism*. This lens is similar in design to the *Visian Toric ICL* lens except that it has a 0.36 mm *central port* (also referred to as *EVO TICL* lens).

EVO+ Visian ICL for Myopia: *Implantable Collamer Lens* for the correction of *nearsightedness*. This lens is similar in design to the *Visian ICL* lens except that it has a 0.36 mm *central port* (also referred to as *EVO+ ICL* lens).

EVO+ Visian Toric ICL for Myopia: *Implantable Collamer Lens* for the correction of *nearsightedness*. This lens is similar in design to the *Visian Toric ICL* lens for Myopia except that it has a 0.36 mm *central port* (also referred to as *EVO+ TICL* lens).

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 or nearsightedness with astigmatism*. The ICL lens 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.

KS-AquaPort®: A 0.36 mm port in the center of the optic that allows *aqueous fluid* to circulate to the *anterior chamber* of the eye (also referred to as the *central port*).

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. The term is also used to refer to a contact *lens* worn on the surface of the eye and an implantable *lens* such as the *EVO* and *EVO+ ICL*.

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 smaller or larger 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 made in the outer edge of the *iris* with a *YAG Laser*. The *Visian MICL* lens and *Visian TICL* lens without the 0.36 mm *central port* require a *peripheral iridotomy* to prevent *pupillary block glaucoma*. The *EVO ICL* and

EVO TICL lenses do not require a *peripheral iridotomy* because they have the 0.36 mm *central port* to allow the flow of aqueous fluid.

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 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 *aqueous 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*.

Refractive Lens Exchange (RLE): Eye surgery that removes the eye's natural lens and replaces it with an artificial *intraocular lens*.

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.

Small Incision Lenticule Extraction (SMILE): Eye surgery that uses a laser to cut a small incision into the *cornea* and then create a disc-shaped piece of tissue. The tissue is then removed from the small incision, which causes the shape of the *cornea* to change.

Subretinal Hemorrhage: Bleeding under the *retina*.

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

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

Visian ICL for Myopia (MICL): *Implantable Collamer Lens* for the correction of *nearsightedness*. This *lens* is similar in design to the *EVO* and *EVO+ ICL lens* except that it does not have a 0.36 mm *central port*.

Visian ICL for Myopia (TICL) with astigmatism: *Implantable Collamer Lens* for the correction of *nearsightedness* with *astigmatism*. This *lens* is similar in design to the *EVO* and *EVO+ Toric ICL lens* except that it does not have a 0.36 mm central port.

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 *EVO* or *EVO+* *Visian Implantable Collamer Lens (EVO ICL)* placed in one or both of your eyes to treat your *nearsightedness (myopia)* or *nearsightedness with 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 *EVO ICL* surgery.

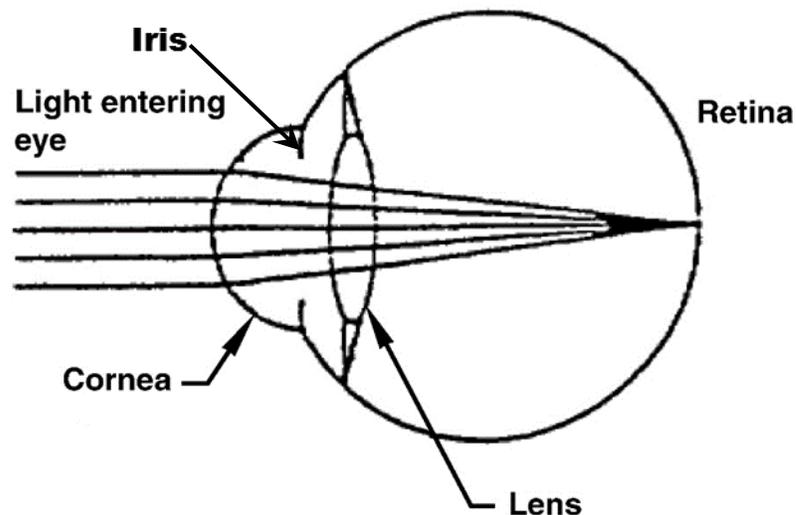
3.0 What Is Nearsightedness and Nearsightedness with Astigmatism

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

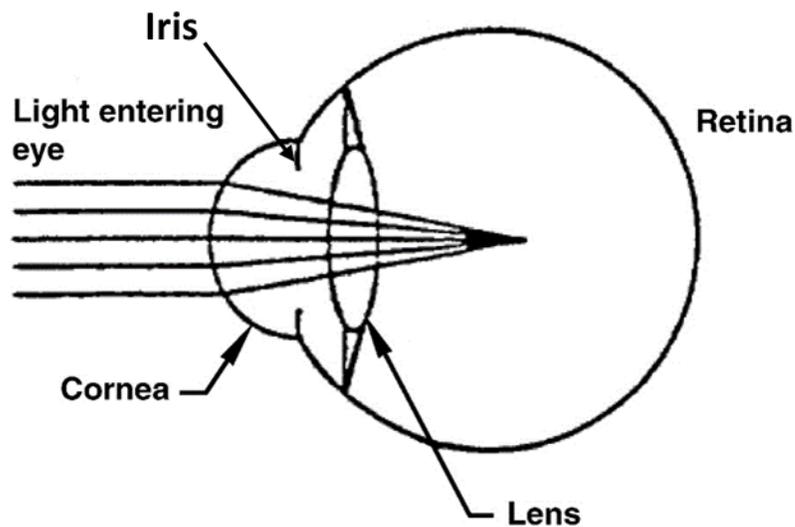
Light focuses on the retina.
Vision is clear.



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*.

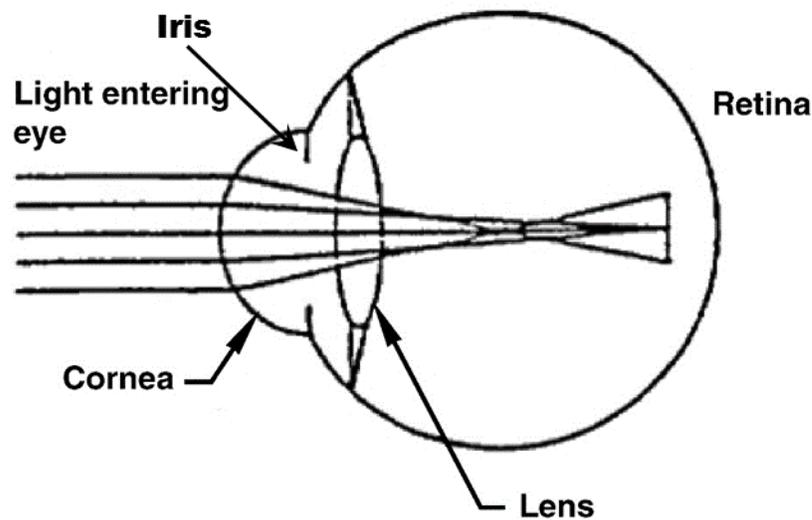
DIAGRAM 2: NEARSIGHTED EYE

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 EYE with ASTIGMATISM



Glasses and contact *lenses* can help your eye focus light properly on the *retina*. The *EVO ICL lens* can also help your eye focus light properly on the *retina*. 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 layer of nerve tissue at the back of the eye that captures images (*retina*). This will correct *nearsightedness* and *astigmatism* and help you see distant objects more clearly.

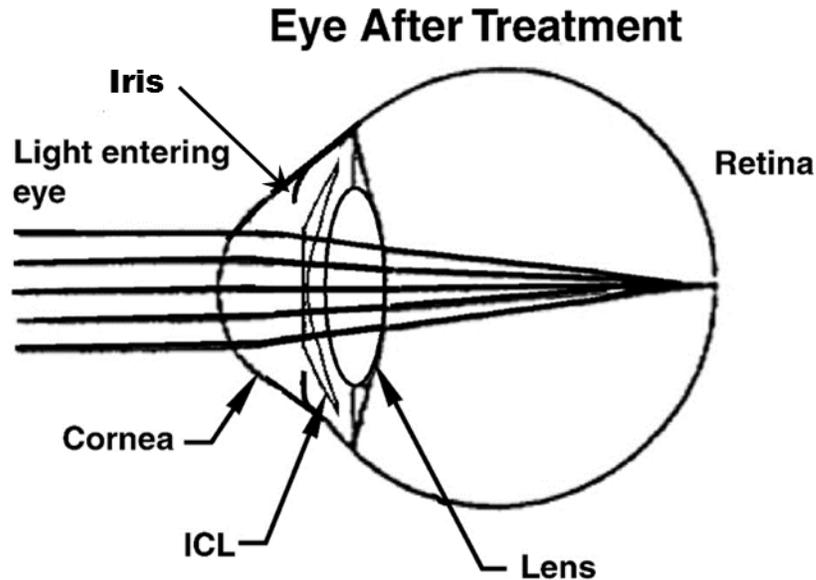
How Do *EVO ICL* and *EVO TICL Lenses* Correct *Nearsightedness* and *Nearsightedness with Astigmatism*?

EVO ICL lenses are made from a soft plastic and natural *collagen* containing material called *Collamer*. It is similar to *lenses* that are placed in the eye (*intraocular lenses*) to correct vision after *cataract* surgery. *EVO ICL lenses* are similar to *Visian ICL lenses* that have been available in the US since 2005. They correct *nearsightedness (myopia)* except that a small hole (*central port*) has been added to the center of the lens. In *Visian ICL lens* models without the *central port*, patients must have another surgery between 2 to 3 weeks before *ICL* surgery to create two holes (*peripheral iridotomies*) in the extreme outer edge of the colored portion of the eye (*iris*). This additional surgery is not needed with the *EVO ICL lens* because it has a hole in the center of the optic. *EVO ICL lenses* have been available outside of the United States since 2011. As of 2021, more than 1 million *ICL lenses* have been implanted worldwide and over 750,000 of those are *EVO ICL lenses*.

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

DIAGRAM 4: CORRECTION OF VISION AFTER *EVO 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 *astigmatism* in the eye. Your eyeglass prescription is the usual way to tell how *nearsighted* you are and how much *astigmatism* you have.

If you have *nearsightedness*, *EVO ICL* surgeries are designed to treat *nearsightedness* between -3.0 D to -15.0 D and reduce *nearsightedness* up to -20.0 D in eyes with up to 2.5 D of *astigmatism*.

If you have *nearsightedness* with *astigmatism*, *EVO TICL* surgeries are designed to treat *nearsightedness* between -3.0 D to -15.0 D, and *astigmatism* between 1.0 and 4.0 D, and

reduce *nearsightedness* greater than $-15.0D$ up to $-20.0D$, and *astigmatism* between $1.0D$ and $4.0D$.

Your doctor will use your eyeglass prescription and a thorough eye examination to determine if you are a candidate for *EVO ICL* surgery. *EVO ICL* surgery may improve your distance vision without eyeglasses or contact *lenses*. Discuss with your doctor whether you are a good candidate for surgery with the *EVO ICL*.

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

4.0 Other Treatments to Correct Nearsightedness

Other treatments for *nearsightedness* include eyeglasses, contact lenses or other eye surgeries. Eye surgeries available to correct *nearsightedness* include *Radial Keratotomy (RK)*, *Photorefractive Keratectomy (PRK)*, *Laser Assisted in situ Keratomileusis (LASIK)*, *Small Incision Lenticule Extraction (SMILE)*, and *Phakic Intraocular Lens* implantation (*EVO ICL lenses* are *phakic intraocular lenses* but other types of *phakic intraocular lenses* are also available).

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*, *LASIK*, and *SMILE*, or require the insertion of a lens into the eye. *RK* uses a surgical instrument to make fine cuts in the *cornea*. *PRK*, *LASIK* and *SMILE* 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. In *SMILE* surgery, a laser is used to cut into the *cornea* and create a disc-shaped piece of tissue that is then removed.

5.0 Benefits and Risks of *EVO ICL Lenses* for *Nearsightedness* and *Nearsightedness* with *Astigmatism*

Benefits

EVO ICL surgery can safely correct *nearsightedness* between -3.0 D to -15.0 D, and partially correct *nearsightedness* up to -20.0 D in eyes with up to 2.5 D of *astigmatism*.

EVO TICL surgery can safely correct *nearsightedness* between -3.0 D to -15.0 D and *astigmatism* between 1.0 D and 4.0 D, and partially correct *nearsightedness* greater than -15.0 D up to -20.0 D, and *astigmatism* between 1.0 D and 4.0 D.

If your eyeglass prescription is in these ranges, the *EVO ICL* may make your distance vision without eyeglasses or contact lens correction better. Placing the *EVO ICL* lens 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 *EVO ICL* surgery. *EVO ICL lenses* are modifications of earlier models without a *central port*. The *Visian ICL lens (MICL)* corrects *nearsightedness (myopia)* but not *astigmatism* and the *Visian Toric ICL lens (TICL)* corrects *nearsightedness (myopia)* with *astigmatism*. The risks associated with these earlier *ICL lens* models all apply to the *EVO ICL lenses* as well.

Risks associated with the *EVO ICL lenses* include the following:

- **Additional (Secondary) Surgery.** Another surgery to take out, replace or adjust the position of the *EVO ICL lens* may be necessary. You may also need another surgery if you develop a *cataract* or to lower increased pressure inside your eye.
- **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 *nearsightedness* are also at increased risk of developing *glaucoma*.

- **Cataract Formation.** A *cataract* is a clouding of the *crystalline* lens inside the eye that can decrease vision. Because *EVO ICL lenses* are placed inside the eye near the *crystalline* 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 *EVO ICL lenses*. The risk of a *cataract* continues to rise with each year that the *EVO ICL lens* is in the eye. *Cataracts* that affect vision may require surgery to remove the *cataract*. Because of this, you should see your doctor regularly for an eye exam to check you for *cataracts*.

The long-term risk of *cataract* beyond 7 years is unknown. If your doctor recommends *cataract* surgery, both the *ICL lens* 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.** Your vision may become worse after surgery (i.e., lost vision of two or more lines as measured on an eye chart).
- **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 *EVO ICL* surgery. Before your surgery, you will have an eye exam that will help your doctor decide if you are a candidate for *EVO ICL* surgery. Patients implanted with the *EVO ICL lens* 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 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* may be more bothersome in low light conditions when the *pupil* is dilated. Even if patients don't have *glare* and *halos* before *EVO 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 *EVO ICL surgery*.

Other risks associated with *EVO 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*),
- 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 (*pigment dispersion*),
- scar tissue at the outer edges of the front chamber of the eye (*peripheral anterior synechiae*).

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*),
- *EVO ICL* lens 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*).

Summaries of the most serious/frequent risk data collected from each clinical study of the *EVO ICL lenses* and earlier *ICL lens* models are provided in Section 13.0, Clinical Studies.

6.0 Contraindications

You should **NOT** have *EVO 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 *EVO ICL lens* (*anterior chamber* depth less than 3.0 millimeters)
- are pregnant or nursing;
- have moderate to severe damage to the optic nerve caused by increased pressure (*glaucoma*);
- 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

- The long-term effects of the *EVO ICL lens* 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 *Visian ICL lenses* 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 *EVO ICL lens* in your eye(s). This will help your doctor monitor the long-term health of your *cornea*.
- After *EVO 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 *EVO ICL lens* 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 *EVO ICL lens* 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 residual *viscoelastic*, but could be caused by blockage of fluid flow in the eye that requires treatment with a second surgery. The potential long-term risk of the *EVO ICL lens* to raise the pressure inside your eye (*intraocular pressure*) and the long-term risks of the following are unknown:
 - 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*).

Due to this increased risk, your doctor will need to check the pressure in your eye between 1-6 hours after surgery. Possible symptoms that may be related to an increase in the pressure in your eye may include eye pain, redness, and/or cloudy vision. If you experience any of these symptoms, you should contact your doctor right away.

- There is a part of the eye that fluid flows through when draining from the inside of the eye. After *EVO ICL* 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 your doctor provides.
- Patients may develop *glare* and *halos* after *EVO ICL* surgery 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 *EVO ICL lens*, 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 *EVO ICL lenses*. 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* may have worse results. The *Visian ICL* and the *Visian TICL lenses* were less effective in correcting *nearsightedness* and there was a higher risk of complications in these patients in the FDA clinical studies.
2. The relationship between the *EVO ICL lens* 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 *EVO ICL lens* to correct moderate to high *nearsightedness* has **NOT** been established in patients with:
 - unstable or worsening *nearsightedness* with or without *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 of *astigmatism*.

9.0 Are You a Good Candidate for *EVO ICL* Surgery?

Your doctor will conduct a thorough eye examination to determine if you are a candidate for *EVO ICL* surgery. In addition, if you are considering *EVO ICL* surgery for *nearsightedness* with or without *astigmatism* you must:

- be between the ages of 21 and 45;
- have between -3.0 D and -20.0 D of *nearsightedness* and no more than 4.0D of *astigmatism*;
- understand that:
 - the *EVO ICL lens* is indicated for the correction of *nearsightedness* between -3.0 D and \leq -15.0 D and the reduction of *nearsightedness* between $>$ -15.0 D and -20.0 D; and
 - the *EVO TICL lens* is indicated for the correction of *nearsightedness* with *astigmatism* between -3.0 D and \leq -15.0 D of *nearsightedness* 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 of *nearsightedness* and between 1.0 D and 4.0 D of *astigmatism*;
- have the shape of your eye able to fit the *EVO ICL lens* (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 *EVO ICL lens* for *nearsightedness* compared to other available treatments for *nearsightedness*;
- 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.

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

10.0 What Should You Expect During *EVO 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 *EVO 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.

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 *EVO ICL lens* 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.

Your doctor will need to check the pressure in your eye between 1-6 hours after surgery. This is important because if you have higher than normal eye pressure, it needs to be treated as quickly as possible, to reduce the risk of possible damage to the optic nerve (*glaucoma*) and permanent vision loss.

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 and one week 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, *EVO ICL lens* repositioning, replacement and/or removal may become necessary. *EVO TICL lens* repositioning may be performed if your doctor finds the *EVO TICL lens* is not properly aligned in the direction of *astigmatism*. *EVO ICL lens* replacement may be performed if your doctor believes a different lens may either fit your eye better or provide you better vision. *EVO ICL lens* 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 *EVO ICL lens*, you will lose the benefit of your *nearsightedness* or *nearsightedness* and *astigmatism* correction. This means that your vision may not return to what it was like before *EVO ICL* surgery.

After *EVO ICL* surgery it is important that you follow your physician's recommendations for eye care and follow-up visits. You should see your doctor regularly for an eye exam to check for *cataracts*, to check the pressure inside your eye (*intraocular pressure* or *IOP*), and to check your *endothelium* as long as you have the *EVO ICL lens* in your eye(s).

11.0 Questions To Ask Your Doctor

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

- What are my other options to correct my *nearsightedness* or *nearsightedness with astigmatism*?
- Will I have to limit my activities after surgery and for how long?
- What are the benefits of *EVO ICL* surgery for my amount of *nearsightedness* or *nearsightedness with astigmatism*?
- What quality of vision can I expect in the first few months after surgery?
- If *EVO 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 *EVO 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 *EVO ICL lens*?
- Should I have *EVO 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 an *EVO ICL lens* 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* or *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>EVO ICL</i> surgery for <i>nearsightedness</i> or <i>nearsightedness</i> with <i>astigmatism</i> is the same as laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
2. <i>EVO 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>EVO 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>EVO 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>EVO ICL</i> surgery.	<input type="checkbox"/>	<input type="checkbox"/>
8. The <i>EVO ICL</i> lens will correct my <i>nearsightedness</i> or <i>nearsightedness</i> with <i>astigmatism</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 14 – Summary of Important Information**.

13.0 Clinical Studies

Clinical Study of EVO ICL Lenses with Central Port

The *EVO ICL lens* is similar to the *Visian ICL lens for Myopia (MICL)* except that the *EVO ICL lens* has a *central port* (hole). The *EVO Toric ICL lens (EVO TICL)* is similar to the *Visian Toric ICL lens for Myopia with Astigmatism (TICL)* except that the *EVO Toric ICL lens* has a *central port*.

Surgery in the United States (US) with *Visian MICL* or *TICL lenses* requires that you have another surgery up to two weeks before *ICL* surgery to place a hole (*peripheral iridotomy*) in the colored portion of your eye (*iris*). This surgery (*peripheral iridotomies*) performed before implantation of the *Visian MICL* or *TICL lenses* is done to reduce the risk of a high increase in eye pressure that could cause permanent loss of vision if not treated quickly. This pressure increase is due to the blockage of flow of fluid from the back of the eye to the front of the eye. In some countries outside of the US, there has been successful use of *EVO ICL* lenses without having this prior surgery.

The FDA asked STAAR to conduct a study to scientifically evaluate whether use of *EVO ICL lenses* without making a hole in the *iris* is reasonably safe and effective. Patients treated in the study were examined by the study doctor through at least 6 months after surgery and will continue to be examined by the study doctor until 3 years after surgery.

Description of Study Patient Group:

- 629 eyes of 327 patients were implanted with *EVO ICL lenses*
 - 404 eyes were implanted with an *EVO ICL lens* for *nearsightedness* and 225 eyes were implanted with an *EVO TICL lens* for *nearsightedness* with *astigmatism*.
- Most patients were white (Caucasian) and over half of the patients were female.
- Patients ranged from 22 to 45 years of age at time of surgery.
- *Nearsightedness* before surgery ranged between -3.0 D and -16.0 D.
Astigmatism before surgery ranged between -0.25 and -4.00 D.

Study Results

Rate of treatment of raised intraocular pressure (IOP) with a second surgery:

One specific goal of the *EVO ICL* study was to determine the rate of treatment of high *intraocular pressure (IOP)* due to blockage of fluid flow in the eye (*pupillary block*). In the *EVO ICL* study, no eyes (0/629) have experienced a blockage of fluid flow and no eyes have required a second surgery for the treatment of raised *intraocular pressure*.

Other cases of raised intraocular pressure (IOP) in the EVO ICL study:

In the *EVO ICL* study, increases in eye pressure were reported only if they required treatment by the doctor, or were increases of ≥ 10 mmHg to at least 25 mmHg.

Starting 1 – 6 hours after surgery, 125 of 629 (19.9%) implanted eyes experienced an increase in eye pressure that returned to normal levels by 1 day after surgery. These events were caused by the remaining residual gel-like fluid used in the eye during surgery (*viscoelastic* fluid). Ninety-seven of these eyes required treatment with medication and/or release of fluid from the eye by paracentesis/aqueous tap, a procedure in which the surgeon uses an instrument to drain a small amount of fluid from the eye through a corneal incision that was constructed during *EVO ICL* implantation. Table 2 shows the number of eyes that required each kind of treatment.

Table 2: Treatment for Increase in Eye Pressure in EVO ICL Study 1-6 hours after Surgery

	All Eyes (N=629)
Number of eyes with elevated IOP	125/629 (19.9%)
Number of eyes with elevated IOP requiring treatment	97/629 (15.4%)
Eyes treated with medication(s)	94/629 (14.9%)
Eyes treated with paracentesis/aqueous tap	70/629 (11.1%)

A total of 15 of 629 (2.4%) implanted eyes experienced an increase in eye pressure starting 6 – 31 days after surgery that was caused by a side effect of anti-inflammatory steroid eyedrops.

Another 3 of the 629 (0.5%) implanted eyes experienced an increase in eye pressure after another eye surgery during the study.

Endothelial Cell Loss:

Another specific goal of the *EVO ICL* study was to measure the rate of loss of the thin, single layer of cells (*endothelial cells*) on the surface of the *cornea* closest to the inside of your eye. The average rate of loss of eyes in the *EVO ICL* study at 6 months after surgery was 2.3% (4.0%), which is similar to the rate seen in the *MICL* study. Three eyes (0.5%) of those seen at 6 months after surgery had more than 30% endothelial cell loss. The timing of the loss for the 3 eyes suggest that the loss was caused by the surgical procedure used to insert the *EVO ICL* lens into the eye.

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.

Table 3 shows the percent of all eyes of all 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 Eyes row) or based on their degree of *nearsightedness* before *EVO ICL* surgery.

Table 3: Visual Acuity* Without Glasses, After Surgery by Range of *Nearsightedness* (Myopia) Before Surgery

<u>Lens Group</u>	Exam Interval	20/20 or Better	20/40 or Better
All Study Eyes	3 Month	503/624 (80.6)	623/624 (99.8)
	6 Month	432/569 (75.9)	565/569 (99.3)
≤ -7 D of myopia before surgery	3 Month	243/287 (84.7)	287/287 (100.0)
	6 Month	203/257 (79.0)	257/257 (100.0)
> -7 D to -10 D myopia before surgery	3 Month	169/219 (77.2)	219/219 (100.0)
	6 Month	156/205 (76.1)	204/205 (99.5)
> -10 D to -15 D myopia before surgery	3 Month	90/116 (77.6)	115/116 (99.1)
	6 Month	72/105 (68.6)	102/105 (97.1)
> -15 D myopia before surgery	3 Month	1/2 (50.0)	2/2 (100.0)
	6 Month	1/2 (50.0)	2/2 (100.0)

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

In the clinical study of *EVO ICL lenses*, vision without glasses was 20/40 or better for all but 4 eyes of 4 patients (4/569, 0.7%). The vision in two eyes with high levels of *nearsightedness* was not completely corrected with the *EVO ICL lens*. The third eye showed improvement at the 1 Month and 3 Month vision tests. By the 6 Month visit, the vision decreased due to the development of clouding of the natural lens (*cataract*). The fourth eye experienced a *retinal detachment* which was successfully repaired but resulted in mild *nearsightedness*. The vision with glasses in this eye was the same at the 6 Month visit as it had been before surgery.

Other Adverse Events:

Additional (Secondary) Surgery:

6 out of 629 implanted eyes (1.0%) had another surgery related to the *EVO ICL lens* through 6 months after surgery:

- 3 eyes (0.5%) had a second surgery to change the position of the *EVO ICL lens*
- 2 eyes (0.3%), had a second surgery to change the position and then a third surgery to replace the *EVO ICL lens*
- 1 eye (0.2%) had a second surgery to remove the *EVO ICL lens*. In this case, the patient complained of *halo* and *glare* and requested the lens be removed. The *glare* and *halo* went away after the lens was removed.

Glaucoma Development:

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

Cataract Formation:

1 out of 629 eyes (0.2%) implanted in the study have reported a *cataract*.

Loss of Best Corrected Vision:

Loss of best corrected vision was not reported if it only occurred and resolved within one week after surgery or if the loss was less than two lines of vision as measured on an eye chart. One (0.2%) eye experienced a temporary loss of two lines of vision as measured on an eye chart during the first month after surgery. No other eyes have lost two or more lines of vision through at least the 6 month visit.

Glare and Halos:

This study did not collect surveys from patients before or after their surgery. Therefore, it is not known how many of the patients experienced *glare* and/or *halos* in this study. One patient reported *glare* and *halos* in their first treated eye and requested surgery to remove

the *EVO ICL* lens. On the day after lens removal surgery, the patient reported that the *glare* and *halos* were gone. There have been no other reports of *glare* and *halo* in the study.

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

A clinical study was conducted to evaluate the benefits and risks of *Visian TICL* surgery. The *Visian Toric ICL lens* for *Myopia with astigmatism (Visian TICL)* is similar to *EVO TICL* lens except that *EVO TICL lens* has a *central port*.

Description of the Study Patient Group:

- 210 eyes of 124 patients were implanted with a *Visian 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 -2.38 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 of the *Visian TICL lens* to correct *nearsightedness* and *astigmatism*
- Patient satisfaction after *Visian T ICL Surgery*
- Quality of Vision after *Visian TICL Surgery*

Visual Acuity Without Glasses after Surgery:

- Table 4 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 eyes of all patients (All

Study Patients row) or based on their degree of *nearsightedness* before *Visian TICL* surgery.

Table 4: *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 Eyes	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 TICL Surgery:

Patients in the clinical study were asked to report their satisfaction with the *Visian TICL* procedure. One year (12 months) after *Visian TICL* 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 TICL Surgery:

Quality of vision reported by patients as very good/excellent improved from 64.3% before the *Visian TICL lens* to 94.6% at 12 months after the *Visian TICL* procedure.

Patients reporting poor/very poor vision dropped to 0% at 12 months compared to 10.5% before the *Visian TICL lens*.

Patients in the clinical study were asked on a questionnaire to report on vision symptoms before and 12 months after the *Visian TICL* procedure. Responses are shown in Table 5. Percentages of patients reporting *Glare*, *Halos*, *Double Vision*, Night Vision and Night Driving Difficulties were similar before and after surgery.

Table 5: 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 TICL lens* 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.

A summary of the most serious/frequent risk data collected from this study is provided below.

Additional (Secondary) Surgery:

- 8 out of 210 eyes (3.8%) implanted with a *Visian TICL lens* 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 the a *Visian TICL lens*,
 - 3 eyes (1.4%) had a second surgery to remove the *Visian TICL lens*,
 - 3 eyes (1.4%) needed another surgery to treat or prevent raised pressure inside the eye (*intraocular pressure* or *IOP*):
 - 3 eyes (1.4%) 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.

Cataract Formation:

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

Loss of Best Corrected Vision:

- Three eyes (1.4%) in the FDA study of the *Visian TICL lenses* 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.

Raised intraocular pressure (IOP) and glaucoma development:

- 2 eyes (1.0%) had an increase in IOP to values greater than 10mmHg higher than before *Visian TICL* 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 TICL* study developed damage to the optic nerve (*glaucoma*).

Glare and Halos:

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.

Safety and Effectiveness Study of *Visian ICL Lenses (MICL)*

A clinical study was conducted to evaluate the benefits and risks of *Visian ICL* lenses (MICL) surgery. The *Visian ICL lens for Myopia (MICL)* is similar to the *EVO ICL lens* except that the *EVO ICL lens* has a *central port*.

The 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 Study Patient Group:

- 526 eyes of 294 patients were implanted with a *Visian MICL lens*
- 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.

Visual Acuity without Glasses after Surgery:

Three years after insertion of *Visian MICL lenses*, 94.7% of eyes in the *Visian MICL* study saw 20/40 or better without glasses or contact lenses.

Table 6 shows the percent of all eyes of all 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 MICL* surgery.

Table 6: Visual Acuity* Without Glasses, After Surgery by Range of Nearsightedness (Myopia) Before Surgery

<u>Lens Group</u>	Exam Interval	20/20 or Better	20/40 or Better
All Study Eyes	1 Year	65.4%	96.7%
	2 Year	59.6%	93.4%
	3 Year	59.3%	94.7%

<u>Lens Group</u>	Exam Interval	20/20 or Better	20/40 or Better
≤ -7.0 D of myopia before surgery	1 Year	76.3%	98.8%
	2 Year	70.3%	97.3%
	3 Year	72.4%	98.3%
> -7.0 D to -10.0 D myopia before surgery	1 Year	70.0%	96.0%
	2 Year	64.3%	94.9%
	3 Year	62.7%	92.8%
> -10.0 D to -15.0 D myopia before surgery	1 Year	43.3%	93.7%
	2 Year	37.5%	95.0%
	3 Year	37.5%	93.8%
> -15.0 D myopia before surgery	1 Year	NA%**	NA%**
	2 Year	NA%**	NA%**
	3 Year	NA%**	NA%**

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

** No Eyes > -15.0 D group with this preoperative vision or targeted correction

In the clinical study of *Visian MICL lenses*, vision **without** glasses improved for all eyes except in those eyes with the most extreme amount of *nearsightedness*. The strongest *Visian MICL lens* could not completely correct the vision in those eyes. Also, in one eye, the *retina* separated from its natural position on the back surface of the eyeball (*retinal detachment*) and this eye had no change in uncorrected vision compared to before surgery. Some patients still needed glasses or contact lenses after surgery to view distant objects.

Patient Satisfaction after Visian MICL Surgery:

Patients in the clinical study were asked to report their satisfaction with the *Visian MICL* procedure. Three years after *Visian MICL* surgery, 92.1% of patients were very/extremely satisfied and 7.3% were moderately/fairly satisfied with their vision. Only 0.6% of patients were unsatisfied.

Quality of Vision after Visian MICL Surgery:

Quality of vision reported by patients as very good/excellent improved from 55% before the *Visian MICL* procedure to 77% at 3 years after the *Visian MICL* procedure. Patients reporting poor/very poor vision dropped in half at 3 years (5.8%) compared to before the *Visian MICL* procedure (11.6%).

Patients in the clinical study were asked on a questionnaire to report on the following symptoms before and 3 years after the *Visian MICL* procedure. Responses are shown in Table 7. More patients rated the following symptoms absent or mild at 3 years compared to before the *Visian MICL*: harsh or uncomfortable bright light (*glare*), night vision difficulties and night driving difficulties. Percentages of patients reporting circular flares or rings of light around lighted objects (*halos*) and seeing multiple images of the object being looked at (*double vision*) were similar before the *Visian MICL* and at 3 years after surgery.

The clinical study results showed that patients with higher levels of *nearsightedness* before the *Visian MICL* procedure reported more frequent and more severe symptoms both **before** and **after** the *Visian MICL* procedure.

Table 7: Subjective Patient Symptoms- Compared to Before Surgery

Symptom	Improved at 3 Years	No Change at 3 years	Worsened at 3 Years
Harsh or uncomfortable bright light (Glare)	12.0%	78.3%	9.7%
Circular flares/rings of light around lighted objects (Halos)	9.1%	79.4%	11.4%
Seeing multiple images of the object being looked at (Double Vision)	1.1%	97.2%	1.7%
Night Vision	12.0%	76.0%	12.0%
Night Driving Difficulties	13.7%	76.1%	10.1%

Patients in the *Visian MICL lens* safety and effectiveness clinical study were followed for 36 months (3 years) after surgery in the first phase of the study and up to 60 months (5 years) or longer in the second phase of the study.

A summary of the most serious/frequent risk data collected from this study is provided below.

Additional (Secondary) Surgery:

- 43 out of 526 implanted eyes (8.2%) had another surgery related to the *Visian MICL lens* through 5 to 7 years after implantation:
 - 4 eyes (0.8%) had a second surgery to change the position of the *Visian MICL lens*,
 - 8 eyes (1.5%) had a second surgery to replace the *Visian MICL lens*,
 - 10 eyes (1.9%) had a second surgery to remove the *Visian MICL lens*,
 - one eye (0.2%), had both a replacement and removal of the *Visian MICL lens*.

In the cases of *Visian MICL lens* 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*).

Cataract Formation:

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

Loss of Best Corrected Vision:

- 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:

- 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 MICL* 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 MICL* surgery and the last case happened at over 6 years (73 months) after surgery.

Endothelial Cell Loss:

- 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 MICL* lens into the eye.
 - 10 eyes (8.7%) had *endothelial cell* loss 5 years or more after surgery.

Glare and Halos:

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.

Visian ICL for Myopia Adverse Event Patient Survey Study

A survey study was conducted in the US after *Visian ICL lens for Myopia* (MICL) 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 lens*.

Description of the Study Patient Group:

- 2999 eyes of 1547 patients implanted with the *Visian MICL lens* 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 *Visian ICL lens*;
- 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 safety and effectiveness study of *Visian MICL* lenses. These older patients reported a higher rate of *cataracts* and need for a second surgery than patients who were 45 or younger at the time of initial *Visian MICL* surgery.

A summary of the most serious/frequent risk data collected from this study is provided below.

Additional (Secondary) Surgery:

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

Cataract Formation:

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

Raised intraocular pressure (IOP) and glaucoma development:

- 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:

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

Glare and Halos:

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

14.0 Summary of Important Information

- *EVO ICL* surgery provides a correction of your *nearsightedness* or *nearsightedness* with *astigmatism* as long as the *EVO ICL lens* remains in the eye. The *EVO ICL lens* may be removed. If your physician removes the *EVO ICL lens*, you will lose the benefit of your *nearsightedness* or *nearsightedness* with

astigmatism correction. This means that your vision may not return to what it was like before the *EVO ICL* surgery.

- *EVO ICL* surgery does not eliminate the need for reading glasses, even if you have never worn them before.
- Your vision must be stable before *EVO ICL* surgery. You must provide written evidence that your *nearsightedness* 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 *EVO ICL* surgery.
- *EVO 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* include glasses, contact lenses, *RK*, *PRK*, *LASIK*, and *SMILE*, as described in **Section 4.0**.
- Before considering *EVO ICL* surgery you should:
 - a. have a complete eye examination,
 - b. talk with at least one eye care professional about *EVO 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 *EVO 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 *EVO ICL lens* for correction of *nearsightedness* or *nearsightedness* with *astigmatism*.
- The *EVO ICL lens* 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. T |
| 4. T | 9. T |
| 5. T | 10. 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: _____

EVO ICL Doctor

Name: _____

Address: _____

Phone: _____

Treatment Location

Name: _____

Address: _____

Phone: _____

EVO ICL Manufacturer and Distributor:

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