



**Visian ICL™ (Implantable Collamer Lens)
For Nearsightedness**

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

PATIENT INFORMATION BOOKLET

**For Nearsightedness (Myopia) between -3 to -20 Diopters
with 2.5 Diopters or less of Astigmatism**

Please read this entire booklet. Discuss its contents with your eye 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 doctor may discuss with you. Please discuss any related questions with your doctor.

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

Acute Corneal Swelling: 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 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 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: An irritation of the 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 that lets light enter. Surgery such as PRK, LASIK and RK reshapes 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 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 *cornea*.

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

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

Diabetic Retinopathy: Damage to the back surface of the 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*.

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 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 ICL* can be 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 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.

Lens Opacities: A cloudiness of the *crystalline lens*.

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 of the eye to the outside 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 colored portion of the eye does not get larger or smaller when light is shined in the eye.

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: Placement of a man-made lens 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 the 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 black part 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*.

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

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

Subretinal Hemorrhage: Bleeding under the *retina*.

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

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

Visian ICL: see *Implantable Collamer Lens*

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 produce a small hole at the outer edge of the colored portion of the eye (*peripheral iridotomy*).

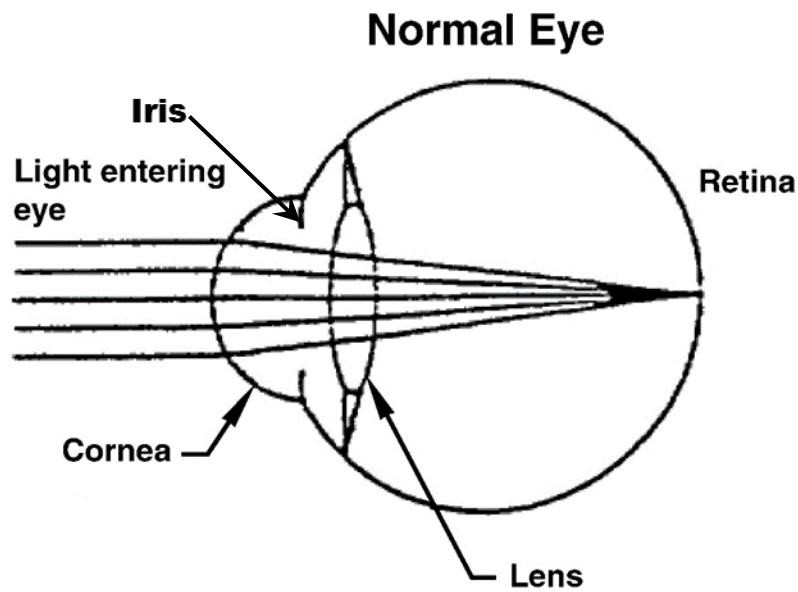
2.0 Introduction

The purpose of this booklet is to help you decide if you want to have the *Visian Implantable Collamer Lens (ICL)* placed in one or both of your eyes to treat your *nearsightedness* (or *myopia*). 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 ICL* surgery.

3.0 What Is Nearsightedness?

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.

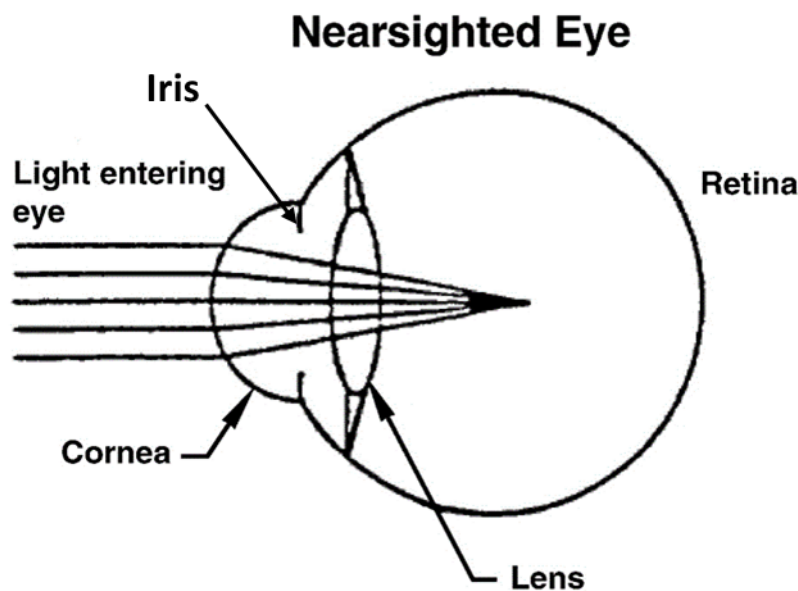
DIAGRAM 1: NORMAL EYE
Light focuses on the retina.
Vision is clear.



Nearsightedness 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*. Your eyeglass prescription tells your doctor how *nearsighted* you are. **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.



Glasses and contact lenses can help your eye focus light properly on the *retina*.
The *Visian ICL* can also help your eye focus light properly on the *retina*.

4.0 How Does Visian ICL Correct Nearsightedness?

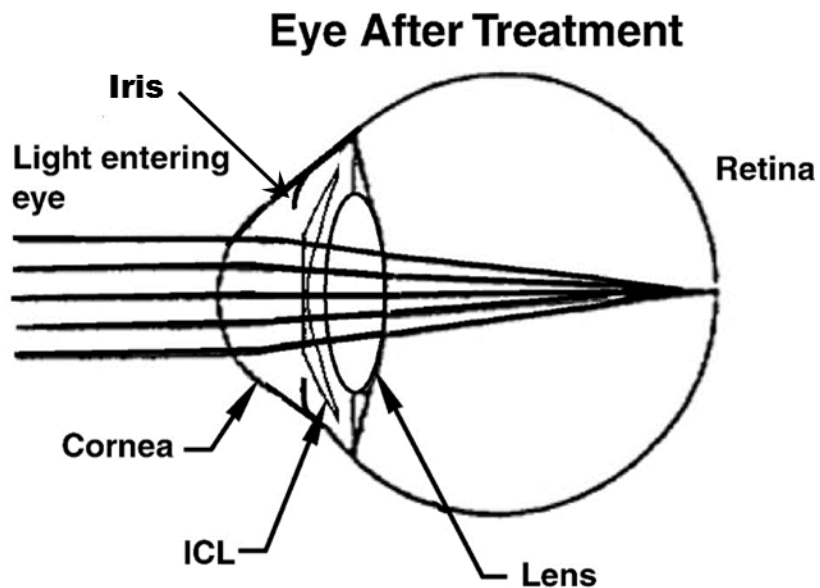
The *Visian ICL* is a lens made from a soft plastic and natural *collagen*-based material called *collamer*. It is similar to lenses that are placed in the eye (*intraocular lenses*) to correct vision after *cataract* surgery. The *Visian ICL* is placed in the eye through a small cut, and is placed

behind the colored part of the eye (*iris*) and in front of the natural lens (*crystalline lens*). When placed correctly, the *Visian ICL* focuses light properly on the back surface of your eye (*retina*).

Diagram 3 shows how light is focused in a *nearsighted* eye that has been implanted with a *Visian ICL*.

DIAGRAM 3: CORRECTION OF VISION AFTER VISIAN ICL SURGERY

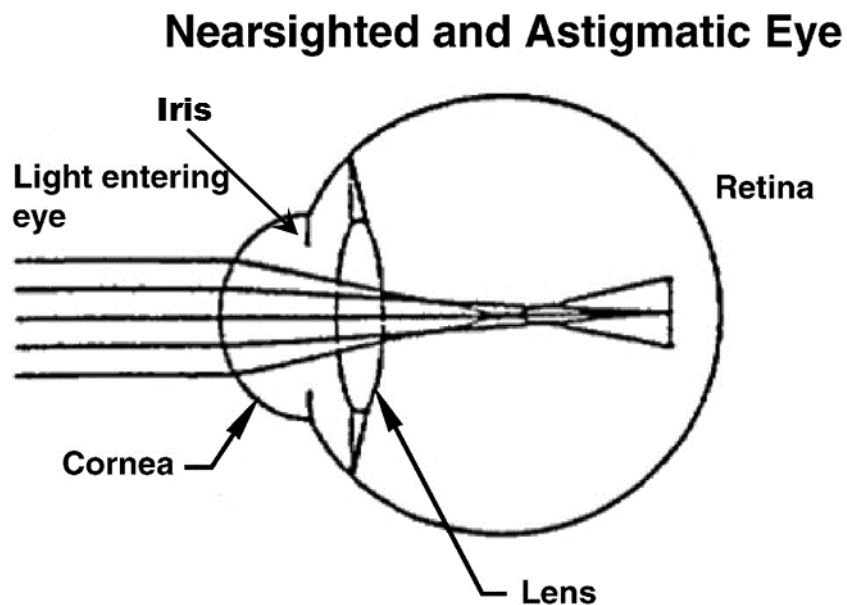
Light focuses on the retina after surgery.
Vision is clearer.



A *diopter* (D) is a unit of focusing power used to describe the amount of *nearsightedness* or focusing error (*astigmatism*) in the eye. *Visian ICL* surgery is designed to treat *nearsightedness* between -3D to -15D , and reduce *nearsightedness* up to -20D in eyes with up to 2.5D of *astigmatism*. If you have *nearsightedness* within these ranges, *Visian ICL* surgery may improve your distance vision without eyeglasses or contact lenses.

The *Visian ICL* will not correct any *astigmatism* you may have. *Astigmatism* is a focusing error of the eye that results in blurred vision. 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 4** shows how an eye with *astigmatism* may focus light.

DIAGRAM 4: NEARSIGHTED and ASTIGMATIC EYE



Visian ICL surgery is permanent as long as the *Visian ICL* stays in your eye. The *Visian ICL* can be removed at a future date. However, the residual effect of the *Visian ICL* on your eye after it is removed is not known. If your physician removes the *Visian 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 ICL* surgery.

5.0 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)* and *Phakic Intraocular Lens* implantation (the *Visian 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.

6.0 Benefits And Risks Of The Visian ICL for Nearsightedness

Benefits

Visian ICL surgery can safely correct *nearsightedness* between $-3D$ to $-15D$, and partially correct *nearsightedness* up to $-20D$ in eyes with up to $2.5D$ of *astigmatism*.

If your eyeglass prescription is in these ranges, the *Visian ICL* may make your distance vision without eyeglasses or contact lens correction better. Placing the *Visian 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 ICL* surgery. Please see 14.0 Clinical Studies of the *Visian ICL* for more information about the FDA Clinical Study.

In a clinical study of the *Visian ICL*, patients were examined by the study doctor until 36 months (3 years) after surgery in the first part of the study. In the second part of the study, patients returned for visits until 60 months (5 years) or longer after *Visian ICL* surgery. The study doctors collected information on the below items:

- Additional surgeries;

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

Additional (Secondary) Surgery

Another surgery to take out, replace or adjust the position of the *Visian ICL* may be necessary. In the FDA clinical study, the *Visian ICL* was removed most often because of *cataract* surgery. Additional (secondary) surgery may also be necessary to lower eye pressure. Please see the section on “*Raised intraocular pressure (IOP) and Glaucoma Development*” below.

Cataract Formation

After *Visian 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 a *cataract* continues to rise with each year that the *Visian 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 levels of *nearsightedness* (*myopia*). The long-term risk of *cataract* beyond 7 years is unknown. If your doctor recommends *cataract* surgery, both the *Visian 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

Eighteen eyes in the FDA 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) 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*. In the clinical study, some patients had an increase in IOP to values greater than 10mmHg higher than before *Visian ICL* surgery or to higher than 25mmHg. Other patients 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 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 ICL* surgery. Before your surgery, you will have an eye exam that will help your doctor decide if you are a candidate for *Visian ICL* surgery. Patients implanted with the *Visian 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 11% of those 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*).

Other Complications

Other risks associated with *Visian 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 study. 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 swelling*) after surgery that does not cause a loss of vision,
- continuing abnormal fluid build-up/swelling in the cornea (*persistent corneal swelling*) 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 ICL* dislocation,
- cyst-like swelling with 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*).

7.0 Contraindications

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

- are less than 21 years of age;
- have a narrow front (*anterior*) chamber as measured by a special eye test by your doctor, or if your doctor finds that the shape of your eye is not adequate to fit the *Visian 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 implantation as determined by your eye doctor

8.0 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 ICL*.
- The long-term effects of the *Visian 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*, 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 ICL* in your eye(s). This will help your doctor monitor the long-term health of your *cornea*.

- After *Visian 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 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.
- The potential of the *Visian ICL* 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*).

9.0 Precautions

1. Patients with higher amounts of *nearsightedness* had worse results. The *Visian ICL* was less effective in correcting *nearsightedness* and there was a higher risk of complications in these patients.
2. The effect of *pupil* size on visual symptoms is not known.
3. The relationship between the *Visian ICL* and future cloudiness of the lens (*cataract*) and lifting or pulling of the *retina* from its natural position (*retinal detachment*) is not known.
4. 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*).

5. The safety of and ability of the *Visian ICL* to correct moderate to high *nearsightedness* has **NOT** been established in patients with:

- unstable or worsening *nearsightedness*;
- 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*);
- with 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 of *nearsightedness*; greater than 2.5D of *astigmatism*.

10.0 Are You A Good Candidate For Visian ICL Surgery?

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

- be between the ages of 21 and 45;
- have between $-3D$ and $-20D$ of *nearsightedness* and no more than $2.5D$ of *astigmatism*;
- understand that the *Visian ICL* is indicated for the correction of *nearsightedness* between $-3D$ and $\leq -15D$ and the reduction of *nearsightedness* between $> -15D$ and $-20D$;
- have the shape of your eye able to fit the *Visian 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 *Visian ICL* for *nearsightedness* surgery 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 doctor 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 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 ICL* and the frequency of follow-up required to monitor the health of your eye.

11.0 What Should You Expect During Visian 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 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 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 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 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 ICL* is inserted and positioned in its proper position in the eye as illustrated in **Diagram 3** 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 doctor will need to see you the day after surgery to conduct an eye exam which will include monitoring the pressure in your eye.

You may be sensitive to light and have a feeling that something is in your eye. Sunglasses may make you more comfortable. Also, your eye may hurt. Your doctor can prescribe pain medication to make you more comfortable during the first few days after the surgery. If you

experience severe pain in the eye, please contact your doctor immediately. You will need to use eye drop/ointment drugs in the first week to treat or prevent infection (*antibiotic*) and reduce inflammation in the eye (*anti-inflammatory*) in the first week.

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

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

Long Term Care: In a small number of cases, *Visian ICL* replacement and/or removal may become necessary. *Visian ICL* replacement may be performed if your doctor believes a different lens may either fit your eye better or provide you better vision. *Visian 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 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 ICL* surgery. After *Visian ICL* surgery it is important that you follow your doctor's recommendations for eye care and follow-up visits.

12.0 Questions To Ask Your Doctor

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

- What are my other options to correct my *nearsightedness*?
- Will I have to limit my activities after surgery and for how long?
- What are the benefits of *Visian ICL* surgery for my amount of *nearsightedness*?
- What quality of vision can I expect in the first few months after surgery?

- If *Visian 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 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 ICL*?
- Should I have *Visian 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 n *Visian ICL* only in 1 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*.

13.0 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 ICL</i> surgery for <i>nearsightedness</i> is the same as laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
2. <i>Visian 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 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 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 ICL</i> surgery.	<input type="checkbox"/>	<input type="checkbox"/>
8.	The <i>Visian ICL</i> will correct my <i>astigmatism</i> .	<input type="checkbox"/>	<input type="checkbox"/>
9.	It is important I follow my 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 16- Summary of Important Information.**

14.0 Clinical Studies

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

- **Description of Study Patient Group:**

- 526 eyes of 294 patients were implanted with a *Visian 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 $-3D$ and $-20D$. The average was $-10.06D$.

- **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. Three years after insertion of the *Visian ICL*, 94.7% of eyes in the *Visian 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 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 Year	65.4%	96.7%
	2 Year	59.6%	93.4%
	3 Year	59.3%	94.7%
≤ -7D of myopia before surgery	1 Year	76.3%	98.8%
	2 Year	70.3%	97.3%
	3 Year	72.4%	98.3%
> -7D to -10D myopia before surgery	1 Year	70.0%	96.0%
	2 Year	64.3%	94.9%
	3 Year	62.7%	92.8%
> -10D to -15D myopia before surgery	1 Year	43.3%	93.7%
	2 Year	37.5%	95.0%
	3 Year	37.5%	93.8%
> -15D 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 D group with this preoperative vision or targeted correction

In the clinical study of the *Visian ICL*, vision **without** glasses improved for all eyes except in those eyes with the most extreme amount of *nearsightedness*. The strongest *Visian ICL* could not completely correct the vision in those eyes. 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 ICL* Surgery:

Patients in the clinical study were asked to report their satisfaction with the *Visian ICL* procedure. Three years after *Visian ICL* 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 ICL* Surgery:

Quality of vision reported by patients as very good/excellent improved from 55% before the *Visian ICL* to 77% at 3 years after the *Visian ICL* procedure. Patients reporting poor/very poor vision dropped in half at 3 years (5.8%) compared to before the *Visian ICL* (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 ICL* procedure. Responses are shown in **Table 2**. More patients rated the following symptoms absent or mild at 3 years compared to before the *Visian ICL*: 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 ICL* and at 3 years after surgery.

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

Table 2: 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 (<i>Glare</i>)	12.0%	78.3%	9.7%
Circular flares/rings of light around lighted objects (<i>Halos</i>)	9.1%	79.4%	11.4%
Seeing multiple images of the object being looked at (<i>Double Vision</i>)	1.1%	97.2%	1.7%
Night Vision	12.0%	76.0%	12.0%
Night Driving Difficulties	13.7%	76.1%	10.1%

15.0 Adverse Events Observed In The Visian ICL Clinical Studies

Patients in the *Visian ICL* 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. 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 FDA clinical study had a secondary surgery to change the position of, remove or replace the *Visian ICL*, or to treat raised pressure inside the eye (*intraocular pressure* or IOP).

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

A *cataract* is a clouding of the natural lens inside the eye that can decrease vision. Because the *Visian ICL* is placed inside the eye near the natural lens, there is a risk of developing a *cataract*. Long-term follow up of patients in the FDA clinical study suggests that older age and higher

levels of *nearsightedness* increase the risk for *cataract* after *Visian ICL* surgery. *Cataracts* that affect vision may require surgery to remove the *cataract*. In this case, both the *Visian ICL* and the *cataract* is removed and another *intraocular lens* is implanted, just as is done in any routine *cataract* surgical procedure. In the FDA clinical study, 45 eyes developed some form of *cataract*, out of 526 eyes implanted with the *Visian ICL*, with 334 eyes followed for 5 – 7 years.

Loss of best corrected vision with eyeglasses (BCVA)

Eighteen eyes of 16 patients in the 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) 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*.

In the early days after surgery, an increase in eye pressure requiring treatment beyond just the use of medicine was reported for 3.8% of eyes in the FDA clinical study of the *Visian ICL*, 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.

An increase in IOP to values greater than 10mmHg higher than before *Visian ICL* surgery or to higher than 25mmHg was reported in 2.7% of eyes through 5 years or more after surgery. A total of 7 eyes in 4 patients developed damage to the optic nerve (*glaucoma*) through 5 or more years after ICL surgery. The first case of *glaucoma* was diagnosed at 5 months after *Visian ICL* surgery and the last case happened at over 6 years (73 months) after surgery.

Endothelial Cell Loss

A thin, single layer of cells on the innermost surface of the *cornea* (*endothelial cells*) keep the *cornea* clear by pumping water out of the *cornea*. 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 cause decreased vision.

Loss of *endothelial cells* has been reported after surgery to implant the *Visian ICL*. Before your surgery, your doctor will evaluate the health of your corneal *endothelium* to aid in determining whether you are a candidate for *Visian ICL* surgery. It is important to note that while most patients in the study reported no significant *endothelial cell* loss, 13 eyes of 10 patients reported more than 30% *endothelial cell* loss (11.3% of those available for evaluation 5 years or more after surgery). 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 *Visian ICL* 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 *Visian ICL* 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 *Visian ICL* 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 *Visian ICL* implantation.

A case of unequal pupil size (*anisocoria*) was reported for a patient implanted with an ICL in another clinical study.

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

- An irritation of the white portion of the eyeball and inner eyelid (*conjunctival irritation*)

- Severe abnormal fluid build-up/swelling in the cornea (*acute corneal swelling*). The condition is usually temporary after surgery with no significant effect on vision.
- Continuing abnormal fluid build-up/swelling in the cornea (*persistent corneal swelling*). Persistent *corneal swelling* may cause a loss of vision.
- 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*). These are usually caused by a distortion of light that would normally be tolerable without the distortion.
- Blood in the eye (*hyphema*),
- Discharge in the eye (*hypopyon*),
- Eye infection,
- *Visian ICL* dislocation,
- Cyst-like swelling with of the center of the retina with fluid (*cystoid macular edema*),
- A 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*).

16.0 Summary of Important Information

- *Visian ICL* Surgery provides a permanent correction of your *nearsightedness* as long as the *Visian ICL* remains in the eye. The *Visian ICL* may be removed. If your physician removes the *Visian 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 ICL* surgery.

- *Visian 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 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 the *Visian ICL* surgery.
- *Visian ICL* surgery has some risks. Please read and understand this entire booklet before you agree to the surgery. The sections on **Risks (Section 6.0)**, **Warnings (Section 8.0)** and **Precautions (Section 9.0)** are especially important to read carefully.
- Some other options to correct *nearsightedness* include glasses, contact lenses, *RK*, *PRK* and *LASIK*.
- Before considering *Visian ICL* surgery you should:
 - a. have a complete eye examination.
 - b. talk with at least one eye care professional about *Visian 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 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 ICL* for correction of *nearsightedness*..

- The *Visian 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 |

17.0 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 ICL Doctor

Name: _____

Address: _____

Phone: _____

Treatment Location

Name: _____

Address: _____

Phone: _____

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