



NV EYE  
SURGERY

**A comprehensive guide for our Patients**

# Refractive Surgery

LASIK, PRK, and Visian ICL

Peter W. DeBry, M.D.

[www.NVeyeSurgery.com](http://www.NVeyeSurgery.com)

*Thank you for considering Dr. DeBry and the NV Eye Surgery team for your vision correction procedure. We have prepared this book to help you have all of the information you need to make this important decision, and guide you through the process from beginning to end. Please read through it carefully and write down any notes you may want to ask the doctor or your surgical counselor.*

## Overview

The eye is an amazing optical device. Like a camera, the eye focuses light into a clear image, which is then changed into electrical signals and sent to the brain for interpretation. Abnormalities in the size and shape of the eye lead to poor vision, which requires glasses or contact lenses for improved clarity.

Scientists and engineers have been working for years, trying to perfect the options for restoring vision without glasses or contact lenses. Currently the two major categories of vision enhancement include LASIK/PRK and ICL lens implant procedures. LASIK and PRK work externally by reshaping the cornea, ICL implants are placed inside the eye to help focus light rays without glasses or contact lenses. Each procedure has specific benefits and minor risks. Our job is to help educate you on your options and guide your decision making so that you end up with the best possible vision with the safest and highest technology procedure.

*Dr. DeBry will work with each patient to make sure they get the best technology for their vision-correction surgery.*

### **Are you an ideal candidate for vision correction procedures:**

- People who don't see well without glasses and are motivated to be less dependent on glasses or contact lenses
- A healthy eye with no significant eye diseases
- A stable refraction with no big changes in the power of your glasses or contact lenses for a few years
- Willing to accept some risk to achieve better vision

## **About your surgeon – Peter W. DeBry, M.D.**

Success in vision-correction surgery requires high quality standards and attention to fine details. Dr. Peter W. DeBry brings these qualities to Las Vegas with his extensive training in eye surgery and lens implantation. Dr. DeBry completed medical school at the University of Utah in 1996. At that time he was honored with induction into the prestigious Alpha Omega Alpha medical honor society, reserved for the top physicians in each graduating class.



Next he spent three years of residency focused on medical and surgical eye care in Madison, Wisconsin, where he was chosen to help coordinate resident training as the chief resident. After this he was one of only four doctors nationally selected to attend one of the country's top fellowships in eye surgery techniques, and spent the next year at the Bascom Palmer Eye Institute in Miami, Florida. After working with top doctors learning the most up-to-date surgical techniques, he moved to Kansas City, Missouri where he taught these techniques to new eye surgeons as Associate Clinic Professor at the University of Missouri. Finally, he relocated in 2003 to help provide cataract, and vision correction surgery for the residents of Las Vegas.

Dr. DeBry is one of the most experienced eye surgeons in Las Vegas. From performing a corneal transplant in a 90 year-old to a vision-saving glaucoma surgery in a baby, he does more complex surgeries than any other local eye surgeon. Dr. DeBry was invited to be among the first few groups of eye surgeons in the United States trained in the surgical techniques for Verisyse and Staar Visian ICL Lens implantation. He has been doing these procedures since 2005, longer than any other full time surgeon in Las Vegas. He has presented research at local and national meetings and has published articles in national ophthalmology journals.

# Basic Information About the Eye and Vision

## How does the eye focus light?

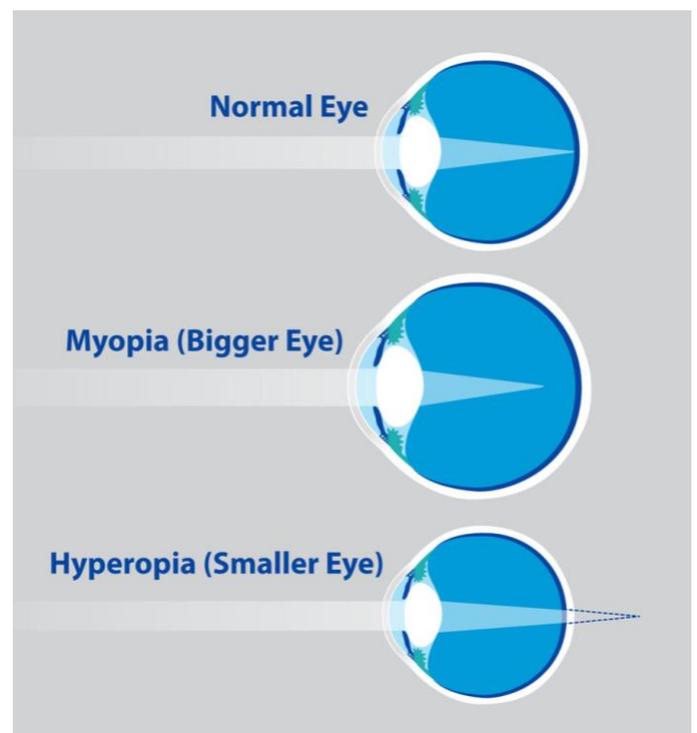
The eye works like a camera to focus light and create a clear image. There are two main eye structures that share the job of providing good focus, the cornea and the lens. The cornea is the window of the eye, much like your car windshield. It is made of living tissue (cells and collagen) that is perfectly clear, and shaped with a curved surface. As the light rays enter this curved surface the rays are bent (or refracted), directing the rays closer together and towards the lens. The next structure that light rays encounter is the lens. The lens of the eye is shaped like an M&M candy and is also composed of perfectly clear cells and collagen. The lens also bends the light rays, refracting them towards the posterior surface in the eye, the retina.

## Why can't you see well without glasses?

The eye is amazing! Your body has its own auto-focusing camera system with 3-D technology. Clear vision without glasses requires the eye to be a perfect shape and size with each component of the eye doing its job in the focusing process. Looking around the world at the people you see every day it is easy to realize that we all aren't born with a perfect shape and size. If your eye is bigger or smaller than average, or if each component of the eye (cornea and lens) doesn't focus perfectly, your vision will be out of focus. Blurry vision due to focusing problems is called **Refractive Error**. There are three main categories of refractive error: myopia, hyperopia, and astigmatism.

## What causes people to be nearsighted (myopia)?

Myopia, or nearsightedness, is a condition of the eye where the focusing power of the eye does not match the size and shape of the eyeball. People who are myopic generally have an eye that is bigger than average or a cornea that has a higher curvature than average. This results in the image being focused in front of the retina, which causes blurred vision for distant objects. One benefit to being myopic is the ability to see things up close without your glasses or contact lenses.



## **What causes people to be hyperopic?**

Hyperopia is caused by an eye that is smaller than average, or a cornea that is flatter than it should be. In many people the auto-focusing ability of the eye is able to help keep an image in focus when the eye is young and healthy. Because of this many hyperopic people don't need to wear glasses when they are children and young adults. Eventually the auto-focus mechanism ages and blurry vision results, leading to the need for glasses. A hyperopic person can't see well in the distance or up close without glasses or contact lenses.

## **What is astigmatism?**

Astigmatism is a focusing problem of the eye related to the shape of the cornea. A normal cornea is perfectly round like a basketball. With astigmatism the eye develops with a slight oval shape like a football. Astigmatism is corrected with glasses or contact lenses. Almost everyone has a small amount of astigmatism. Astigmatism can be treated with LASIK/PRK and the Visian ICL lens.

## **Other than glasses or contact lenses how is refractive error treated?**

There are three main methods of surgically treating refractive error. Since the cornea and lens are the two eye structures that focus the light, they are the main structures commonly treated to improve vision. Laser technology can be used to reshape the cornea (LASIK and PRK), and surgical procedures can be done to replace the existing lens (Refractive lens exchange) or simply insert a new lens (Visian ICL).

## **What is monovision and who should consider it?**

Monovision is an option to help people in their 40's and older to avoid wearing reading glasses. As the eye ages it loses its ability to focus on items within 18-24 inches. This aging change is called presbyopia. One method to treat presbyopia, monovision, is to use your dominant eye for distance activities (driving, TV) and the other eye for close activities (reading, computer). This is commonly done with contact lenses for people in the mid-40's and older. If you are in your 40's and are considering LASIK, PRK, or an ICL implant, monovision may be beneficial for you. If you have not tried monovision, before having a permanent surgery we recommend working with your optometrist in a monovision contact lens trial to make sure you can adjust to it. Benefits of monovision include less need for reading glasses. Some people have difficulty tolerating the different focus between the two eyes and reduced depth perception.

## What is co-management?

Dr. DeBry often works closely with your optometrist planning your refractive surgery. Your optometrist may help make some of the initial measurements on your eye to achieve an accurate power selection. The optometrist may also see you for some of the post-operative visits. You have the choice to decide which doctors will participate in your pre- and post-operative care. If your optometrist provides some of these services they will be paid accordingly based on the services they provide. We may elect to have you pay separate payments to our clinic and the optometrist. Please see the co-management consent form located later in this book for more information.



# LASIK and PRK

## How do lasers used in LASIK or PRK treat Refractive Error?

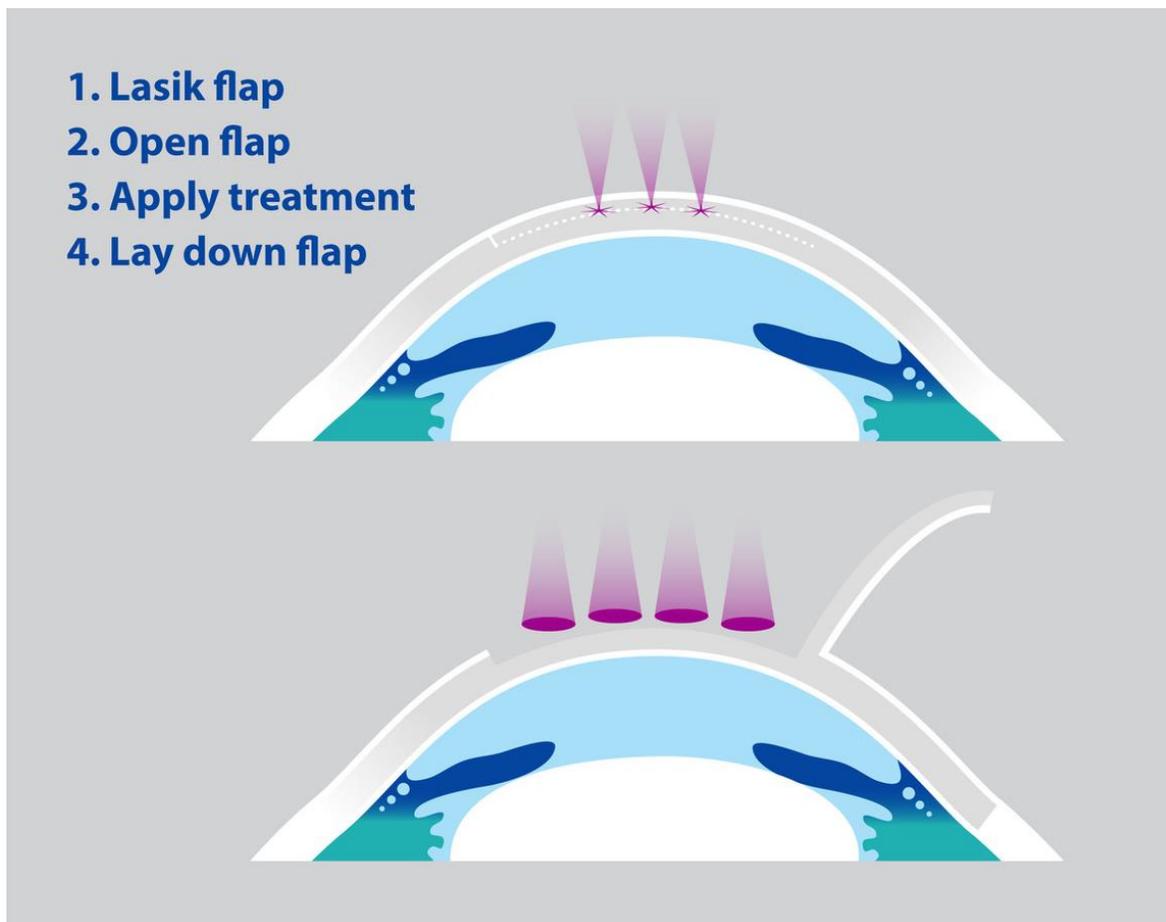
To improve vision the focusing problems of the eye need to be corrected. Laser technology is used to reshape the cornea. By making the cornea more flat or more curved, the light rays are bent differently and focusing can be improved. The Excimer (excited-dimer) laser uses light energy to break chemical bonds in the cornea. The ultraviolet light energy (wavelength of 193 nm) comes from an Argon-Fluoride laser, which produces very short pulses of energy (10 nanoseconds). These pulses of light energy actually dissolve or ablate the collagen fibers. By using a computer to guide the location of each laser application into a complex pattern of overlapping spots, the shape of the cornea is sculpted to a new and improved shape, resulting in better focus and clearer vision.

## What is PRK? Photorefractive keratectomy

With PRK the cornea is sculpted with an Excimer laser. The thin skin that covers the cornea must first be removed. The laser is then applied. Over the next 3-4 days the skin (epithelium) grows back over the cornea. PRK is a simpler procedure than LASIK. PRK has a longer visual recovery than LASIK because the vision will not be fully improved until the epithelium has completely healed and become smooth again. There is also more discomfort with PRK as the nerves in the cornea are exposed when the thin skin is removed. Because PRK is a simpler procedure there is less potential for some complications that can happen with a LASIK flap (see below). Because nerves are not cut, there may be less dry eye problems after the procedure.

## What is LASIK?

LASIK also uses an Excimer laser to sculpt the cornea. However, before treating the eye with the laser a few layers of the cornea are removed as a thin flap. The laser is then applied to the cornea below the flap and the flap is placed back into position. By cutting the flap and applying the laser to the internal collagen fibers of the cornea there is less pain and a quicker visual recovery. The presence of a flap may lead to complications in rare cases such as an eye injury, or an excessively thin cornea leading to ectasia.



## What are the risks associated with LASIK and PRK?

LASIK and PRK are very safe procedures with a track record of success over 25 years. Treatments and technology improve each year, bringing the opportunity to achieve better vision with minimal risk. However, each person responds differently to surgeries, and any surgical procedure can have risks involved. Some of the main risks include...

Night Vision Problems. Following LASIK surgery some patients will be aware of increased glare or halos at night. This tends to occur in patients with night vision symptoms before the surgery, in patients with a larger correction, and patients with larger pupils. The glare is related to

light rays coming into the eye from the edges of the cornea where the normal cornea meets with the ablated cornea.

Dry Eye. Because the nerves are damaged with the flap creation and corneal ablation it is common to have some dry eye symptoms for up to 3 months after the procedure. If you have a dry eye problem before surgery, LASIK may not be the best option and PRK or ICL should be considered. You will likely need to use artificial tears during the day until your corneal nerves recover.

Infection. Because the protective surface of the eye is removed with either PRK or LASIK there is a chance that bacteria get into the cornea and cause an infection. Antibiotic eye drops are used to prevent an infection, but even with this protection rare infections can develop. The risk of an infection is less than 1 in 1,000.

Corneal Ectasia. LASIK and PRK make the cornea thinner, which in some people can weaken the structure of the cornea. If the cornea becomes weak it can change shape, leading to worsening vision. Pre-operative testing and good decision-making can usually help prevent this complication.

Flap Complications (LASIK). Using a flap allows for faster vision recovery with LASIK, but the process of creating a flap does lead to some other risks. With a simple trauma to the eye the flap can dislodge, requiring a procedure to replace it. Small cells from the epithelium (thin skin that covers the eye) can grow underneath the flap requiring a procedure to lift the flap. If there are problems when the flap is cut you may have to postpone your LASIK procedure for another day.

Stromal Haze (PRK). The cornea is amazing clear tissue. An injury to the cornea can lead to scar tissue formation, which causes the cornea to become cloudy in the area of the scar. PRK is a very mild trauma to the eye and therefore some people develop a slight haze to the cornea. In most cases this does not have a significant impact on the quality of the vision, but if haze is extensive it may make your vision less clear. Severe scarring would be unusual. In the case of severe scarring a corneal transplant surgery may be necessary.

Over-correction or Under-correction. Your eye is a living organ. Very precise measurements need to be made and then appropriate treatments applied to achieve the best possible vision. In some cases it is difficult to get accurate measurements and different people can respond differently to the treatments. Because of this some treatments will lead to over-correction or under-correction, meaning that the vision does not turn out to be 20/20 after the procedure. If this occurs an enhancement procedure can be completed. Usually the eye is allowed to heal for at least 3 months before an enhancement is initiated. You may need to wear glasses or contact lenses for a few months during this time.

## **How do I know if I am a good candidate for LASIK/PRK?**

Not everyone is an ideal candidate for refractive surgery. We get terrific results because we are careful to select patients who are good candidates for each procedure. For LASIK and PRK there are several items necessary to achieve good results. They include...

- A generally healthy eye and cornea
- No uncontrolled dry eye symptoms
- Adequate corneal thickness – measured at your pre-op with a safe and simple test (pachymetry)
- Eyelid and facial structures that allow the laser to get near the eye
- Dissatisfaction with glasses and/or contact lenses
- A desire to have improved vision with a willingness to accept some risk to achieve this goal

All of these items are assessed at your refractive surgery screening visit. After a thorough review Dr. DeBry and/or Dr. Mu will help you to understand your options and make recommendations for the procedure that will help you achieve your best vision.

## **What is All-Laser LASIK?**

As described previously, LASIK treatments require a thin flap to be made on the cornea. In the past this flap was created with a very sharp blade called a microkeratome. In a small percentage of people the microkeratome created unique problems as the flap was cut with imperfections or centering issues. To lower the risk of irregular flaps a laser was developed for flap creation. This Femto-second laser cuts tissue with an accuracy of 0.01 mm and makes perfectly circular flaps with a very consistent thickness. The use of all-laser LASIK has made LASIK a safer procedure. It has also added a little more cost to the procedure because now 2 lasers are used instead of one. An interesting side note, the femto-second laser fires a laser pulse 0.00000000000001 seconds in duration. This rapid burst of energy causes a microscopic explosion in the tissue, breaking bonds

## What is Custom LASIK?

### What Makes LASIK Surgery “Custom”?

In the past, LASIK surgeons relied on eyeglass prescription information to determine which areas of the cornea needed reshaping. However, your prescription doesn't tell the whole story. In order to achieve a truly custom LASIK procedure, your surgeon needs a detailed map of the surface of the cornea, as well as information on how well your cornea and lens refract light.

Customizing your LASIK surgery means tailoring the surgery to suit your specific vision needs – not just leaving it up to an educated guess. At the very pinnacle of modern custom LASIK technology is the iDesign system.

### What Is the iDesign System?

The iDesign system utilizes wavefront aberrometry to create an entirely custom map of your cornea. The iDesign system scans your cornea to provide information on both your “lower order aberrations” (which make up 90% of your visual imperfections such as myopia, hyperopia and astigmatism) and your “higher order aberrations” (the last 10% of your visual imperfections that cause problems such as halos, glare and poor night vision). This means that your surgeon has the full spectrum of your visual imperfections, not just the lower order aberrations that your prescription provides.



This system and method of laser eye surgery is also known as wavefront-guided LASIK. There are many different machines that allow for wavefront-guided LASIK, but iDesign is among the best. This is because the iDesign system collects over 1,200 data points, which is significantly more than some other wavefront systems. This makes iDesign 25 times more accurate than normal measurements for standard prescriptions.

After your surgeon uses iDesign technology to create this detailed map, the information integrates seamlessly into the STAR S4 IR Excimer Laser System – which is the laser that does the corneal reshaping. Because the excimer laser has been programmed with your corneal information in mind, it knows exactly where and how to adjust the shape of the cornea for the best visual outcome.

Your eyes are completely unique to you. Tiny little imperfections in your cornea create your own distinct visual problems, and all of those abnormalities are impossible to detect without this special equipment. A more accurate system means less risk involved, less recovery time after the surgery, and more time seeing life the way it's meant to be seen.

### **What happens on the day of the surgery?**

Having eye surgery is a bit like a trip to the dentist. It is a little uncomfortable, takes about 15 minutes to have it done, and has great benefits. It can be scary as some people don't like things coming up close to their eyes. To help relax you we will provide a prescription for Triazolam, a sleeping pill commonly used to relax anxious nerves.

During the procedure you will lie down on a comfortable bed with a firm headrest. Get comfortable, as it is very important to hold still once the procedure starts. The eyelids are cleansed and sticky tape is put around the eyelashes to keep them out. A small wire is used to gently hold open the eyelids. During the treatment there are several steps...

- The Femtosecond laser will cut the flap. A suction ring is placed on the eye during this step. It takes only 15 seconds but is a bit uncomfortable due to the pressure from the suction ring. Your vision will fade to black during this time.
- Next the flap will be lifted and the corneal tissue prepared for the excimer laser. During this step your vision will be blurry.
- The excimer laser treatment is next. This takes between 15 and 45 seconds depending on the degree of correction being treated. There will be a red or green light during this time and it is important that you focus on the colored light to keep the laser treatment centered on the cornea.
- After the laser the flap will be irrigated. You will feel some cold water around the eye. Then the flap will be placed back into position and allowed to seal for

a few minutes. The wire holding the lids will be removed and the treatment repeated on the other eye.

After the procedure we encourage you to go home and take a nap. You will be sleepy from the relaxing medication and it is helpful to keep your eyes closed for a few hours to start the healing process. The vision will be a little blurry for the first 24 hours, but will improve even more over the next several days as the cornea starts to heal.

PRK treatments are even easier as there is no Femtosecond flap created. You will simply lie under the laser table for a few minutes as the lids are prepared, and the corneal epithelium is removed. The excimer laser application is done right on the surface of the cornea and takes 15-45 seconds. A bandage contact lens is placed on the eye after the procedure to help with comfort and healing of the epithelium.

### **Choosing Bilateral Surgery**

You have the choice to do PRK/LASIK in both eyes on the same day, or separate the two surgeries into two different days. The safest option is to do the eyes on two different days. This allows Dr. DeBry the opportunity to assess the outcome of the first surgery before the second procedure. Based on the first procedure, small adjustments in laser power can be made prior to the second eye being done. However, many people have scheduling constraints with work or family responsibilities that make it difficult to take extra days off to do the surgeries on different days. If you choose to have the surgeries done on the same day we will have you sign an extra consent form acknowledging this choice. The risk of a severe bilateral problem such as an infection is very rare. Plan on your vision being blurry for the first day or two while the eye is healing from the procedure. We recommend you don't plan any important meetings or travel for at least a few days after the procedure to allow your vision time to improve.

### **Are there any restrictions after the procedure?**

The most important thing to avoid after the procedure is rubbing your eyes. This can displace the flap if you had LASIK or the bandage contact lens if you had PRK. Otherwise there are very few restrictions. You can bathe and shower like normal, just avoid getting soap and water in your eyes. It would be a good idea to avoid visually

demanding tasks for a few days after the procedure. You should stay out of the swimming pool or hot tub for a few weeks after the procedure.

### **What if I need an enhancement?**

LASIK and PRK change the shape of the cornea, but there can be regression over time. Also, some people don't achieve perfect results after the first treatment and a second treatment needs to be applied. Some people require an enhancement procedure years after LASIK/PRK. Our policy is that enhancements are included with the original surgery fee for the first year. If an enhancement is needed years later there will be a new fee for those services.

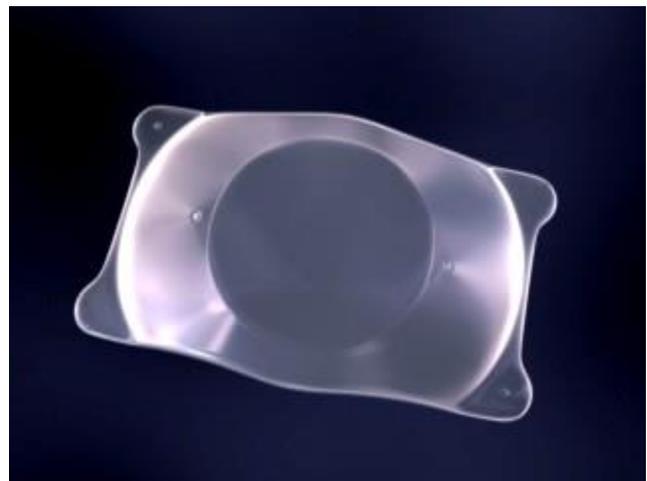
## **Visian ICL Surgery**

### **What is the ICL?**

Another option for vision correction is an ICL implant. The ICL is a lens implant developed to correct myopia. Although the Visian ICL is often informally named an "implantable contact lens," in the United States, the acronym ICL stands for "Implantable Collamer Lens." Collamer is the unique material that the lens is made of. The ICL surgery has some benefits when compared to LASIK or PRK, but also has its own unique set of risks.

### **Quality of Vision**

The Visian ICL offers unparalleled quality of vision, providing excellent contrast. Two unique factors help explain this superior optical performance. First, the Visian ICL is made of Collamer – a soft, flexible lens material that contains a small amount of collagen – making the lens extremely biocompatible for a lifetime of clear vision. Second, the lens is placed inside the eye, where it continues to focus light accurately without any maintenance required.



## Safe, Proven Procedure

The safety and effectiveness of the Visian ICL surgery implantation procedure has been proven with over 1,000,000 implants worldwide. Unlike corneal refractive surgery (LASIK and PRK), the Visian ICL does not permanently alter the structure of the eye. Instead, the Visian ICL is placed in the eye's posterior chamber, where it works with the natural lens to correct vision.

## Small Incision

Unlike other phakic IOLs, the Visian ICL is foldable. This feature allows physicians to implant the lens using a smaller incision. The small incision procedure is a technique that is familiar to eye surgeons. The Visian ICL requires a 3.0mm (1/8 inch) incision as opposed to the 6.0mm incision required by other FDA-approved phakic IOLs. This smaller incision is seen as less invasive, does not require sutures, and is less likely to cause astigmatism (change the corneal shape).

## Removable, if Necessary

Although the Visian ICL is meant to stay in the eye indefinitely, it is easily removed by a trained ophthalmic surgeon, leaving the patient's options open for future treatments. LASIK and PRK permanently alter the eye structures and cannot be reversed if the recipient is dissatisfied or if there are complications.

## How will my vision change with the procedure?

One amazing aspect of the ICL implant is that many people report that they see better after the procedure than they had ever seen before with glasses or contact lenses. This is related to the quality of the implant material and the location of placement within the eye. The lens actually makes the image a little larger than glasses or contact lenses, which can help you to see small details even clearer. 49% of lens recipients gained one or more lines of best-corrected vision. In other words, if they could see 20/30 with their glasses or contact lenses before the procedure, they improved to 20/20 after the procedure.



## Will I be happy with my decision to have the ICL surgery

Most patients who have had the ICL implant are happy with their decision and feel they had a good outcome from the surgery. In the FDA study of 341 patients, only 1% claimed that they were dissatisfied with the procedure. 97% of patients said they would have the surgery again

## Risks of the procedure

The Visian ICL has been studied in FDA trials and successfully implanted in over 1,000,000 eyes over the last 15 years. This experience has shown the implant to be very safe and effective. Nevertheless, all medical treatments have potential side effects and complications. Before choosing an elective procedure it is important that you understand these possible problems. Potential problems from the ICL procedure include:

**Infection** – because an incision is made in the eye and the ICL is implanted through this incision, there is a risk that bacteria could enter the eye and cause an infection. This can occur even with the antibiotic medications used before and after the procedure. The risk of a severe infection is less than 1:1,000.

**Cataract** – a cataract or cloudy lens usually develops with ageing. You may have heard of older people having cataract surgery. Trauma can also cause cataract development. The ICL surgery is a minor trauma to the eye. In the FDA study the rate of cataract developing that required surgery was only 0.6%. Patients who developed a cataract eventually required another surgery to fix this condition. Most people still end up with good vision without glasses after a successful cataract procedure.

**High eye pressure** – during the ICL procedure a thick gel is placed inside the eye to protect the delicate eye structures. This thick gel can block the fluid circulation and cause a short-term elevation in the eye pressure. This can usually be treated successfully with eye drops. It is also possible that the ICL can push the iris forward and block the drain of the eye. This may require medications or laser surgery to treat the condition. Your eye pressure will need to be checked after the procedure to make sure there are no pressure problems developing.

**Retinal Detachment** – the retina is the thin film that covers the inside of the eye like wallpaper covers a wall. A retinal detachment means the retina peels away from the eye. A retinal detachment usually requires surgery to repair the detachment. Eyes that are myopic or nearsighted usually are larger than normal, which leads to a thinner retina. Being nearsighted is a risk factor for developing a retinal detachment. In the FDA study 3 patients (less than 1%) developed a retinal detachment in the months after the surgery. Because these myopic eyes had risk factors for retinal detachment, it is difficult to tell whether the surgery was a contributing factor in these cases. As a nearsighted person you should have a good retinal exam at least once each year.

**Lens sizing problems** – Although several sets of measurements are made prior to ICL surgery, it is possible that the lens selected is smaller or larger than an ideal size. This occurs because of variability within biological systems that is difficult to measure. Problems of this nature that are severe enough to lead to an ICL exchange occur less than 5% of procedures.

### **Glare and nighttime vision issues**

A lens implant has the potential to cause glare and halos at night. The normal eye response to darkness is to make the pupil get larger to let in more light. A healthy young person may have a very large pupil in dim illumination. If the pupil gets larger than the implanted lens, some light can hit the lens edge and bounce into the eye causing glare or halos. This same process can also happen with glasses, contact lenses, and LASIK procedures. In the FDA study, some patients reported symptoms of glare and halos related to their vision correction with glasses or contact lenses. After the procedure a few patients noted more noticeable symptoms of glare and halos. It was rare that this was considered severe or bothersome. For example 11% reported noticing moderate or severe glare before the procedure and 14% reported this symptom after the procedure. 20% of patients reported night driving difficulties before the procedure and 16% reported this after the procedure.

### **Astigmatism correction**

Astigmatism means that the cornea, or front window of the eye is shaped more like a football than a basketball. The curvature in one direction is different than the curvature 90 degrees away (perpendicular). Astigmatism causes the vision to be slightly blurry. This can be corrected with glasses or special contact lenses (toric lens). Astigmatism correction is available in the newest model of the Visian ICL. Some lenses may need to be specially ordered which can take weeks or months to be produced.



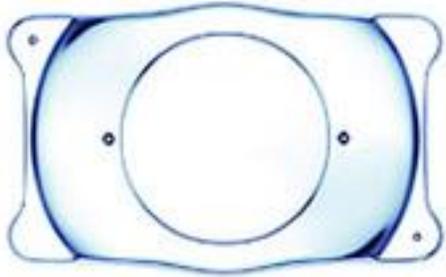
### **Is the ICL material safe?**

The ICL is made of a high tech material known as collamer. Collamer is a revolutionary material used exclusively in making STAAR Surgical corrective lenses, including several models of the Visian ICL. Its name comes from the combination of “collagen” and “polymer”. Because it is made with collagen, Collamer is compatible with your body’s natural chemistry. Collamer is easy to implant because it unfolds gently and predictably in the eye. Collamer transmits light very similarly to your natural lens because the material’s characteristics are nearly identical to the human crystalline lens. Collamer offers numerous advantages over other lens materials:

**Quality of Vision** - Due to its unique anti-reflective properties and high water content, Collamer helps transmit light nearly identically to the human crystalline lens. This means less light is reflected

within the eye, leading to sharper, clearer vision; and far fewer occurrences of glare, halos, or poor night vision associated with other lenses or corrective procedures.

**Biocompatibility** - Meaning “compatible with your body’s natural chemistry,” biocompatibility is a key advantage of Collamer. The collagen in the Collamer



attracts fibronectin, a substance found naturally in the eye. A layer of fibronectin forms around the lens, inhibiting white cell adhesion to the lens. This coating prevents the lens from being identified as a foreign object, and the lens remains unnoticed and “quiet in the eye” indefinitely. What’s more, like the collagen it contains, Collamer carries a slight negative ionic charge. Proteins in the eye also carry a negative charge. As these two

negative forces meet each other along the border of the Visian ICL, the charge repulsion pushes away the proteins from the lens, naturally keeping it clean and clear.

**UV Protection** - Long-term exposure to UV radiation can damage the eyes; longer term or more intense exposure increase the chance of eye disorders including the development of cataracts and some retinal problems. As an added feature, the Visian ICL advanced lens material contains a UV blocker that actually prevents harmful UVA and UVB rays from entering the eye, possibly preventing the development of UV related eye disorders.

## Pre-operative testing

The best visual results from an ICL procedure require accurate measurements to determine the perfect size and power of lens implant. The FDA also has specific criteria that must be met to ensure good results from the procedure. To complete all of these tests more than one visit to the office may be required. Your optometrist may also help collect the required measurements for the procedure. The following tests are typically required

- Refraction – measuring the correct lenses to achieve your best vision
- Cycloplegic refraction – same measurement done after dilating drops are applied
- Contact lens over-refraction – same measurement done with a contact lens in place
- Topography – map of the corneal surface, measures for astigmatism and any irregularities in the surface shape
- Corneal cell count – measures the health of the corneal cells that keep the cornea clear



- Size and shape of the eye – you must have 3.0 mm of open space to allow adequate lens placement
- Pachymetry – measures the thickness of the cornea

It is best that these measurements be done without a contact lens being worn for at least several weeks. Contact lenses worn for many years can actually change the shape of the cornea. If you wear contact lenses we recommend that you stay out of them for a few weeks and wear only glasses until the measurements can be completed. If it is very difficult to go without contact lenses, then the surgery can still be done, however, there is a slightly higher chance that the lens implanted will not be the right size and strength for your eye. Since you will have this lens for 30 years or more, it is probably worth a few weeks of inconvenience without your contacts to get the best eye measurements.

### **Choosing Bilateral Surgery**

You have the choice to do both ICL implants on one day, or separate the two surgeries into two different days. The safest option is to do the eyes on two different days. This allows Dr. DeBry the opportunity to assess the outcome of the first surgery before the second procedure. Based on the first procedure, small adjustments in lens size or power can be made prior to the second eye being done. However, many people have scheduling constraints with work or family responsibilities that make it difficult to take extra days off to do the surgeries on different days. If you choose to have the surgeries done on the same day we will have you sign an extra consent form acknowledging this choice. The risk of a severe bilateral problem such as an infection is very rare. Plan on your vision being blurry for the first day or two while the eye is healing from the procedure. We recommend you don't plan any important meetings or travel for at least a few days after the procedure to allow your vision time to improve.

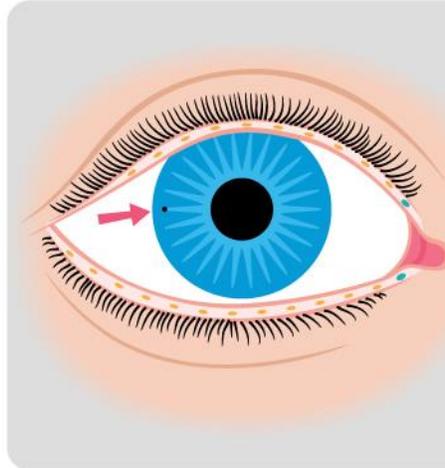
### **Where to have the surgery**

An ICL implant can be done in our in-office surgery suite or in the operating room at an outpatient surgery center (ASC). An ICL surgery is similar to a trip to the dentist to have a cavity filled, it takes around 15 minutes and there is mild discomfort. Most patients can tolerate this just fine with a mild sedating pill (Triazolam) and anesthetic eye drops. If you do not have a high level of anxiety we recommend the surgery be done in the office. This option will save you \$1500 per eye compared to the ASC. If you have significant anxiety that might require an anesthesiologist and IV sedation, we are happy to arrange the procedure in the outpatient surgery center. The final results of the surgery will be the same at either location.

## What is a peripheral iridotomy, and why is it required with the Visian ICL implant?

The Visian ICL implant is placed behind the iris, the colored portion of the eye. The eye is filled with fluid, and this fluid is continuously circulating within the eye. This fluid must move through the pupil, passing through the area that is now occupied by the lens implant. It is possible that the lens implant blocks the flow of

fluid. The peripheral iridotomy creates a very small opening in the iris, allowing fluid to easily pass around the lens implant. This prevents a blockage in fluid flow, which could lead to dangerously high eye pressures. The iridotomy can be done before the



The small hole in the iris from the laser is very small. Most iridotomies can't even be seen without a special microscope. The actual opening may not be much bigger than the tip of your pencil or the period at the end of this sentence.

surgery using a laser or during the surgery making small incisions. For most people this small opening in the iris has no visual symptoms. A small percentage of people may notice a line of light or glare coming through the new iridotomy opening.

## What to expect on the surgery day for in-office surgery

When you arrive at the office you will be given a sedating pill (Triazolam) and several sets of eye drops that dilate the pupils. Once the dilation has set in, an anesthetic gel will be applied. This whole process takes around one hour. During this time we will also check your blood pressure and a quick urine pregnancy test if you are a female of childbearing potential. Once the pill has started to relax you and the eyes are dilated and anesthetized, you will be brought back to the surgery room. We have a very comfortable bed to lie on. A few monitors will be applied to help us monitor your pulse rate and blood pressure. The skin around the eye will be cleansed with an antiseptic (Povidone Iodine) and a thin drape applied over your face to keep the surgical area sterile. You don't have to worry about blinking because a small wire is used to keep the eyelids open. During the procedure you will be asked to stare straight ahead into the fairly bright microscope light. You will likely feel some burning and pressure for short times during the procedure, which takes around 10 minutes. After the procedure your eye will be covered with a clear plastic shield.

If you have chosen to have bilateral surgery, the second eye treatment is done as a completely separate procedure. You will leave the operating room, the room will be wiped down, and all new sterile supplies opened. Once the equipment is set up and ready, you will go back into the OR and have the second eye done. Treating each eye as a completely separate procedure lowers the risk of a rare but severe event such as an infection affecting both of your eyes

## **What is different with a procedure in the ASC?**

For a procedure done in the ambulatory surgery center there are a few minor differences. Because you will be getting a stronger sedating medication you will need to be fasting. This means no food or drink for at least 8 hours before your procedure. You will also need to have an IV placed in your arm to allow the anesthesiologist to give you the sedating medications in your vein. As mentioned previously, there is an extra cost for these services.

## **What will the vision be like for the first 24 hours?**

Once the lens is implanted you will no longer be nearsighted, but the best vision may take up to a week to achieve. For the first day you should plan on the vision in your surgical eye being blurry. This is due to the medications used before and during the procedure, the bright microscope light, and the post-operative eye drops. The next day the vision should be improved and over the next few days you will notice additional clarity as the eye heals.

## **Why do I need to take eye drops after the procedure?**

There are two different eye drops that are used to help give you the best outcome from the procedure; a mild anti-inflammatory (Prednisolone) and an antibiotic (Moxifloxacin). We ask that you start the drops a few days before the procedure to prepare the eye for the treatment, and continue them for a few weeks after. The detailed dosing schedule is included in the back of this book. Please let us know if you have difficulty buying them or run out of drops after the procedure. Your best results may depend on adequate dosing of the eye drops after the procedure.



## **Are there any restrictions after the procedure?**

Because of the sedating medications used, you will need a driver to take you home from the office or surgery center. You shouldn't drive the rest of the day until the medications have worn off. If you have bilateral surgery you shouldn't drive until the vision has cleared to the point where you feel comfortable driving. We ask that you take it easy the first 24 hours and don't plan any important meetings or events. You should be gentle with your eyes and avoid rubbing them if possible. Dr. DeBry also recommends that you avoid vigorous activity for a few days as you adjust to your new vision. Finally, no swimming with your head under the water is allowed for one week after the procedure. All of your normal daily activities are fine, including showering and bathing.

***The following pages contain important information and sample copies of all of the forms you will be given to read and sign in preparation for your LASIK/PRK/ICL procedure.***

# **INFORMED CONSENT FOR LASER IN-SITU KERATOMILEUSIS (LASIK)**

This information is being provided to you so that you can make an informed decision about the use of a device known as a Femtosecond laser, combined with the use of a device known as an excimer laser, to perform LASIK. LASIK is one of a number of alternatives for correcting nearsightedness, farsightedness and astigmatism. In LASIK, the Femtosecond is used to create a flap in the cornea. The flap then is opened like the page of a book to expose tissue just below the cornea's surface. Next, the excimer laser is used to remove ultra-thin layers from the cornea to reshape it and change the refractive power of the eye reducing your need for glasses or contact lenses. Finally, the flap is returned to its original position, without sutures.

LASIK is an elective procedure: There is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur; should this happen in your case, the quality of vision might be affected even to the extent of making your vision worse.

## **ALTERNATIVES TO LASIK**

If you decide not to have LASIK, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. These alternatives include eyeglasses, contact lenses and other refractive surgical procedures.

In giving my permission for LASIK, I understand the following: The long-term risks and effects of LASIK are unknown. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure:

## **VISION THREATENING COMPLICATIONS**

1. I understand that the Femtosecond laser or the excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.
2. I understand that the flap incision could result in an incomplete flap, or a flap that is too thin or irregular. If this happens, it is likely that the excimer laser part of the procedure will have to be postponed until the cornea has a chance to heal sufficiently to try to create the flap again.
3. I understand that any irregular healing of the flap could result in a distorted cornea. This would mean that glasses or contact lenses may not correct my vision to the level possible before undergoing LASIK. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.

4. I understand that mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye.
5. I understand that I could develop keratoconus. Keratoconus is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement) . Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.
6. I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, corneal thinning (ectasia), appearance of “floaters” and retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

## **NON-VISION THREATENING SIDE EFFECTS**

1. I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent.
2. I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the LASIK procedure. These symptoms may be temporary or, on rare occasions, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.
3. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or undercorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
4. After refractive surgery, a certain number of patients experience glare, a “starbursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. The exact cause of these visual problems is not currently known; some ophthalmologists theorize that the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye

drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate.

5. I understand that I may not get a full correction from my LASIK procedure and this may require future enhancement procedures, such as more laser treatment or the use of glasses or contact lenses.
6. I understand that there may be a “balance” problem between my two eyes after LASIK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. I understand that my first eye may take longer to heal than is usual, prolonging the time I could experience anisometropia.
7. I understand that, after LASIK, the eye may be more fragile to trauma from impact. Evidence has shown that, as with any scar, the corneal incision will not be as strong as the cornea originally was at that site. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following LASIK. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.
8. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.
9. I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
10. I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.
11. I understand that the long-term effects of LASIK are unknown and that unforeseen complications or side effects could possibly occur.
12. I understand that visual acuity I initially gain from LASIK could regress, and that my vision may go partially back to a level that may require glasses or contact lens use to see clearly.
13. I understand that the correction that I can expect to gain from LASIK may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.
14. I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward. I therefore, understand that I must not drive the day of surgery and not until I am certain that my vision is adequate for driving.



# INFORMED CONSENT FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

PRK is a laser treatment to the eye designed to reshape the cornea and reduce your dependence on glasses or contact lenses. This information must be reviewed so you can make an informed decision regarding Photorefractive Keratectomy (PRK) surgery to reduce your nearsightedness, farsightedness, or astigmatism. Only you and your doctor can determine if you should have PRK surgery based upon your own visual needs and medical considerations. Any questions you have regarding PRK or other alternative therapies for your case should be directed to your doctor.

## ALTERNATIVES TO PRK SURGERY:

The alternatives to PRK include eyeglasses, contact lenses, and other refractive surgical procedures. Each of these alternatives to PRK has been explained to me.

## COMPLICATIONS AND SIDE EFFECTS

I have been informed, and I understand, that certain complications and side effects have been reported by patients who have had PRK, including the following:

**Possible short-term effects of PRK surgery:** The following have been reported in the short-term post treatment period and are associated with the normal post-treatment healing process: mild discomfort or pain (first 72 to 96 hours), corneal swelling, double vision, feeling something is in the eye, ghost images, light sensitivity, and tearing.

### **Possible long-term complications of PRK surgery:**

Haze: Loss of perfect clarity of the cornea, usually not affecting vision, which usually resolves over time.

Starbursting. After refractive surgery, a certain number of patients experience glare, a “starbursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. Although there are several possible causes for these difficulties, the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate. These risks in relation to my particular pupil size and amount of correction have been discussed with me.

Loss of Best Vision: A decrease in my best vision even with glasses or contacts.

IOP Elevation: An increase in the inner eye pressure due to post-treatment medications, which is usually resolved by drug therapy or discontinuation of post-treatment medications.

Mild or severe infection: Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation.

Keratoconus: Some patients develop keratoconus, a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.

**Infrequent complications.** The following complications have been reported infrequently by those who have had PRK surgery: itching, dryness of the eye, or foreign body feeling in the eye; double or ghost images; eye discomfort; inflammation of the cornea or iris; persistent corneal surface defect; persistent corneal scarring severe enough to affect vision; ulceration/infection; irregular astigmatism (warped corneal surface which causes distorted images); cataract; drooping of the eyelid; and a slight increase of possible infection due to use of a bandage contact lens in the immediate post-operative period.

#### **IN GIVING MY PERMISSION FOR PRK SURGERY, I DECLARE THAT I UNDERSTAND THE FOLLOWING INFORMATION:**

The long-term risks and effects of PRK surgery are unknown. The goal of PRK with the excimer laser is to reduce dependence upon or need for contact lenses and/or eyeglasses; however, I understand that as with all forms of treatment, the results in my case cannot be guaranteed. For example:

1. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or undercorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
2. If I currently need reading glasses, I will likely still need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have PRK surgery.
3. Further treatment may be necessary, including a variety of eye drops, the wearing of eyeglasses or contact lenses (hard or soft), or additional PRK or other refractive surgery.
4. My best vision, even with glasses or contacts, may become worse.
5. There may be a difference in spectacle correction between eyes, making the wearing of glasses difficult or impossible. Fitting and wearing contact lenses may be more difficult.



# Visian ICL Consent Form

*This information is being provided to you so that you can make an informed decision about having eye surgery to reduce or eliminate your nearsightedness. Only you and your eye surgeon can determine if you should have Visian ICL surgery based upon your own visual needs and medical considerations. Take as much time as you wish to make your decision before signing this consent form. You have the right and are encouraged to ask your doctor questions about this procedure before agreeing to have it.*

The Visian ICL (Implantable Collamer Lens) is a lens that is permanently implanted in the eye behind the iris and in front of the natural lens. It is called a phakic intraocular lens (IOL) because the eye still has its natural lens. The Visian ICL has been approved by the Food and Drug Administration (FDA) for the treatment of patients with moderate to severe nearsightedness (myopia). Myopia, the clinical term for nearsightedness, is a condition that causes light rays to focus in front of the retina, causing distant objects to look blurry. It can be caused by an eyeball that is too long for its optical power or by curvature of the cornea or lens that is too high for the actual length of the eyeball. The amount of myopia is measured in “diopters,” a technical term used to describe the power of a lens. The Visian ICL is approved for treatment of myopia between the ranges of -3 diopters to -20 diopters, with up to 2.5 diopters of astigmatism.

Visian ICL surgery is an elective procedure: there is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur. Should this happen in your case, your vision could be affected, and might even be worse than before surgery.

## **ALTERNATIVES TO VISIAN ICL SURGERY**

You are under no obligation to have Visian ICL surgery. If you decide not to have Visian ICL surgery, there are other methods of correcting your nearsightedness:

### Non-Surgical Alternatives

Contact lenses or glasses are non-surgical, extremely accurate, permit easy changes in prescription, and also allow the eye to retain its focusing power for near vision.

1. **Spectacles (glasses).** Although there are essentially no risks to wearing glasses, the quality of vision with strong nearsighted glasses is not normal because of the smaller appearance of images (“minification”) and the slight decrease in peripheral vision caused by the thickness of the lenses.
2. **Contact Lens.** While contact lenses provide higher quality and more normal vision, they have a slight risk

of complications, especially if they are worn overnight. The risks of contact lenses include infection, allergies, irritation, and discomfort.

### Surgical Alternatives, Including Laser

There are several other procedures for the correction of moderate to high myopia. Unlike Visian ICL surgery, PRK and LASIK do not require an incision into the inside of the eye.

1. Photorefractive Keratectomy (PRK) uses an excimer laser to reshape the cornea which changes its focusing power. PRK may be used to correct low to higher amounts of myopia (generally -1 D to -12 D).
2. LASIK is a two-phase operation. First, a thin layer of cornea is either surgically cut with a microkeratome (special cutting tool) or a flap is created using a laser. Then the exposed surface of the cornea is reshaped with an excimer laser, and the flap is returned to its original position. LASIK has been found to be quite successful and relatively safe for the correction of moderate and high myopia up to -12 D. Above 12 diopters, LASIK is known to have a high incidence of complications involving the quality of vision, especially at night, and has proven to be less accurate than it is with the treatment of lower levels of nearsightedness. For these reasons, many surgeons have stopped performing LASIK for extremely nearsighted eyes.
3. Refractive Lens Exchange (RLE) is an intraocular procedure in which the natural lens is removed and replaced with a synthetic lens of a more accurate power. Patients age 40 or over may request a multifocal lens that corrects for both near and distance vision. There is an increased risk of retinal detachment with lens exchange surgery in very nearsighted eyes.
4. Other Refractive Surgery Procedures include keratomileusis, corneal inlays, and radial keratotomy (RK). These procedures are rarely performed, and RK is generally effective only for patients with low to moderate degrees of myopia.

### **GENERAL DESCRIPTION OF TREATMENT WITH VISIAN ICL SURGERY**

If you wear contact lenses, you will be required to leave them out of the eyes for a period of time prior to having your preoperative eye examination and before your surgery. This is done because the contact lens rests on the cornea, distorting its shape, and this distortion will have an effect on the accuracy of the doctor's measurements of the power of surgical correction needed. Discontinuing contact lens use allows the corneas to return to their natural shape. Soft contact lens wearers should leave lenses out of the eyes for at least one week. Rigid (including gas permeable and standard hard lenses) contact lens wearers should leave lenses out of the eyes for at least three weeks. Rigid contact lens wearers usually experience fluctuating vision once their lenses have been discontinued due to changes in the shape of the cornea. Although the cornea usually returns to its natural state within three weeks, this process may take longer, and you will need to remain contact lens free until stabilization is complete.

The surgeon will make two small holes in the colored portion of your eye (the iris) to help ensure that intraocular fluid does not build up behind the phakic lens; this procedure is called an iridotomy. It will take place either at the time of surgery (a surgical iridotomy) or a few weeks before the placement of the Visian ICL by using a laser (YAG-laser iridotomy).

Before Visian ICL surgery begins, your pupils will be dilated and you will be given an anesthetic to minimize your pain during surgery. You may undergo sedation administered by your doctor, or an anesthesiologist while your eye is made numb with eye drops; you may elect to have the surgery with local anesthesia only, without sedation; or, if your surgeon determines that it is in your best interest, you may undergo general anesthesia, in which case you will not be awake during the operation. All methods of anesthesia have risks, and although not common, may include the risk of serious bodily injury or death. Your ophthalmologist will explain the method of anesthesia that has been selected for you as well as the associated risks. You have the right and are encouraged to ask your doctor any questions you have related to the anesthesia.

After your pupil has been dilated, and your eye has been anesthetized, the surgeon will make a small incision in your cornea to allow insertion of the lens. The Visian ICL phakic IOL is inserted in the posterior chamber of the eye, behind the iris and in front of the natural lens. The incision required to perform this operation is usually self-sealing but it may require closure with very fine stitches (sutures) that require removal later in the office. A temporary shield may be placed over the eye to protect it during the immediate postoperative period.

You will return to your ophthalmologist the next day for an examination. The shield will be removed and your eye will be examined with a microscope to make sure the lens is positioned correctly and that there are no complications. You will return for additional postoperative exams as instructed by your ophthalmologist. Although you may see some improvement in your vision as early as the first postoperative day, the visual effects of Visian ICL surgery may take several weeks to stabilize. Patients are generally able to return to their normal activities within 2 or 3 days following Visian ICL surgery.

### **BENEFITS OF VISIAN ICL SURGERY**

If you have moderate to high myopia, Visian ICL surgery is designed to improve your natural distance vision without the use of glasses or contacts.

### **LIMITATIONS OF VISIAN ICL SURGERY**

1. This procedure does not treat presbyopia, a condition common in patients age 40 or older in which the eye loses its ability to change power to allow focusing of both near and distant objects. Even with a successful surgery and an accurate intraocular lens calculation targeted to correct the eye's distance vision, close vision will usually remain blurred for presbyopic patients. Patients age 40 or older are likely to require bifocals or reading glasses to improve their near vision.
2. The phakic lens does not correct astigmatism.
3. The results of this surgery cannot be guaranteed, and glasses may still be required for sharpest vision for distance, for night driving or other activities performed in low light, for reading or, for all of these activities.
4. With increasing age, patients are likely to develop cataracts. If the cataracts are significant enough to cause visual problems, the Visian ICL may need to be removed so that the eye can undergo cataract removal.

## **PATIENT RESPONSIBILITY FOR COSTS**

Health insurance generally does not pay for elective Visian ICL surgery for the purpose of correcting your vision. Therefore, you are responsible for the cost of the surgery, including the surgeon's fee, anesthesiologist's fee, (if any), and the surgical center. In the event of a complication, it may be possible that other surgery, or eye drops, may be required. Some or even all of these costs may be covered by health insurance. You would be responsible for the costs of any uncovered surgery-related injuries.

## **PATIENT CONSENT**

I give my ophthalmologist permission to perform either a YAG-laser iridotomy or a surgical iridotomy AND Visian ICL surgery, and acknowledge that I understand the following: the foreseeable risks of Visian ICL surgery are not fully known. I have received no guarantee as to the success of my particular case and I understand that I may still need glasses, contact lenses, or a laser procedure such as LASIK for further improvement of my vision. I understand that during the surgical procedure, the doctor may decide not to implant the lens even though I have given permission to do so. Furthermore, I understand that the following risks are associated with the procedure:

### **Complications of Iridotomy**

Potential complications of either a YAG-laser iridotomy or a surgical iridotomy are very rare but include damage to the natural lens; inflammation inside the eye; temporary increases in the pressure in the eye; cataract formation; bleeding (usually a small amount but can be a large amount); scar formation between the iris and Visian ICL (synechia) that prevents the pupil from moving correctly; corneal damage; and vision disturbances such as double vision (diplopia), glare, or halos.

### **Vision-Threatening Complications**

Mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective surgery or, if very severe, corneal transplantation, blindness, or even loss of the eye.

I could experience damage to the iris (the colored portion of the eye) or develop a rise in the pressure in the eye (secondary glaucoma). I may require another iridotomy or eye drops to control the pressure if this occurs.

I could develop a retinal detachment, a separation of the retina from the inside wall of the eye, which usually results from a tear in the retina and could lead to vision loss. Patients with moderate to high levels of nearsightedness have a higher risk of retinal detachment when compared to the general population. This risk level may be increased with implantation of the Visian ICL.

I may develop a cataract, or a clouding of the eye's natural lens, which impairs normal vision, and may require removal of the lens, the Visian ICL, and insertion of an artificial lens. Patients with high levels of

nearsightedness are at higher risk for cataract development, and that risk may be increased with implantation of the Visian ICL.

I may develop corneal swelling (edema) and/or ongoing loss of cells lining the inner surface of my cornea (endothelial cells). These cells play a role in keeping the cornea healthy and clear. Corneal edema and loss of endothelial cells may result in a hazy and opaque appearance of the cornea, which could reduce vision. It is not yet known how much endothelial cell loss will occur from the Visian ICL, and what affect the cell loss and Visian ICL will have on the long-term health of the cornea. If too many cells are lost over time, I may need a corneal transplant.

I may develop glaucoma, which is an increase in the pressure of the eye caused by decreased fluid drainage. Glaucoma can lead to vision loss, and may require treatment with long-term medications or surgery. Patients with high levels of nearsightedness are at an increased risk for the development of glaucoma, and that risk may be increased by implantation of the lens. The effect of the Visian ICL on the future risk of glaucoma is not known.

Other complications could threaten my vision, including, but not limited to, iritis or inflammation of the iris (immediate or persistent), uveitis, bleeding, swelling in the retina (macular edema), and other visual complications. Though rare, certain complications may result in total loss of vision or even loss of the eye. Complications may develop days, weeks, months, or even years later.

### **Non Vision-Threatening Complications**

I may be given sedation in conjunction with the procedure and that my eye may be patched afterward. I have been advised not to drive immediately after receiving sedation and for a period of eight hours thereafter. I understand that my life and health and the life of others will be at risk if I drive during this period. This is because I may be impaired by the sedative. I also understand that driving while impaired may violate traffic laws.

There may be increased sensitivity to light or night glare. I also understand that at night there may be a “starbursting” or halo effect around lights. The risk of this side effect may be related to the size of my pupil, and larger pupils may put me at increased risk.

An over-correction or under-correction could occur, causing me to become farsighted, remain nearsighted, or increase my astigmatism and that this could be either permanent or treatable with glasses, contact lenses, or additional surgery.

The phakic lens may need to be repositioned, removed surgically, or exchanged for another lens implant. The lens may change position (decentration), or I may require a different size or power of lens than

that of the implanted lens. In rare instances, lens power measurements may significantly vary, resulting in the need for corrective lenses or surgical replacement of the phakic lens. Potential complications of additional surgery include all of the complications possible from the original surgery.

There may be a difference in vision between my two eyes if the Visian ICL surgery has been performed on one eye but not the other. This imbalance is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. Because of the marked difference in the prescriptions, vision correction using glasses most likely would not be comfortable or provide good vision. In order to have balanced vision in both eyes, I may need to wear a contact lens in the eye without the Visian ICL or consider a Visian ICL or another type of surgery for that eye.

After Visian ICL surgery, the eye may be more fragile to trauma. Evidence has shown that, as with any scar, a corneal incision will not be as strong as the cornea originally was at that site. The treated eye, therefore, is somewhat more vulnerable to all varieties of injury. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.

There is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process. I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery. I understand that the long-term effects of Visian ICL surgery are unknown and that unforeseen complications or side effects could possibly occur.

The correction that I can expect to gain from Visian ICL surgery may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.

If I currently need reading glasses, I will still likely need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have this surgery.

As with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form is not complete.

## PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of Visian ICL surgery have been presented to me in detail in this document and in the Patient Information Booklet and have been explained to me by my ophthalmologist. Although it is impossible for the doctor to inform me of every possible complication that may occur, my ophthalmologist has answered all my questions to my satisfaction. In signing this informed consent for YAG-laser iridotomy or surgical iridotomy, AND Visian ICL surgery, I am stating that I have read this informed consent and Patient Information Booklet (or they have been read to me), understand the possible risks, complications, and benefits that can result from the surgery and the alternatives available to me, and hereby give my consent to have Visian ICL surgery performed on my:

\_\_\_\_\_ Right Eye    \_\_\_\_\_ Left Eye    \_\_\_\_\_ Both Eyes    (Patient to initial which eye)

I give permission for my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for my ophthalmologist to use data about my procedure and subsequent treatment to further understand Visian ICL surgery. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my ophthalmologist's office or the center where my Visian ICL surgery will be performed.

\_\_\_\_\_

Patient Signature

\_\_\_\_\_

Date

\_\_\_\_\_

Witness Signature

\_\_\_\_\_

Date

I have been offered a copy of this consent form (please initial) \_\_\_\_\_

## Visian ICL Summary of Risks, Benefits, and Alternatives

**Purpose:** The Visian ICL is designed to improve the vision in patients who are myopic (nearsighted) by decreasing the requirement for glasses or contact lenses.

**Risks:** There is generally less than a 2% chance of a severe problem that might cause visual problems after the surgery. Main risks include:

- Infection
- High Eye Pressure
- Cataract
- Glare
- Over correction or Under correction
- Retinal Detachment
- Corneal Edema
- Retinal Edema
- Poor position or lens sizing problems

**Alternatives:** Visian ICL implantation is an elective procedure. Other methods of vision correction include glasses, contact lenses, PRK, and LASIK.

*It is not possible to anticipate all possible complications or outcomes from a surgery.*

*No guarantees can be made regarding the success of the planned procedure.*

*Glasses or contact lenses may still be required to achieve good vision at certain distances.*

# Addendum for same day bilateral Visian ICL implantation

This addendum is to be used in conjunction with the consent form “Informed Consent for Visian ICL Implant Surgery”. Do not sign this addendum without first reading and signing “Informed Consent for Visian ICL Implant Surgery.”

## Risks:

Having both Visian ICL surgeries done on the same day may increase the consequences of having vision-threatening complications such as infection, swollen corneas, swollen retinas, or retinal detachment. Instead of vision impairment or loss in one eye, it could lead to loss of vision or even blindness in both eyes. In addition, the planned visual outcome may not be as precise since my doctor won’t have the advantage of knowing the results from the first eye Visian ICL surgery, and altering the surgical approach or lens power accordingly.

## Benefits:

Having both Visian ICL surgeries done on the same day reduces the risks for me of having anesthesia twice and the inconvenience and problems associated with anisometropia, which can make it hard to see well between surgeries scheduled days or weeks apart.

## Discussion:

My doctor has determined that I am a candidate to have Visian ICL surgeries in both eyes. If I choose to have bilateral same day Visian ICL surgeries, my doctor has discussed certain steps he will take to reduce the risk of complications, especially infection, in each eye.

My personal reason(s) for choosing to have bilateral same day Visian ICL surgeries are as follows:

By signing below, I am indicating my willingness to accept the possible increased risk of eye complications of bilateral Visian ICL surgery.

\_\_\_\_\_

Patient Signature

\_\_\_\_\_

Date

By signing below, I am confirming that I have discussed with this patient the risks and benefits related to bilateral same day Visian ICL surgery.

\_\_\_\_\_

Physician Signature

\_\_\_\_\_

Date

# Patient Acknowledgement In-Office surgery and anesthesia care plan

Eye surgery is one of the most precise and technically demanding procedures. Patients expect the best possible outcome from their procedure. Advances in technology now allow for most eye surgeries to be completed in less than 30 minutes with minimal discomfort, not much different than a trip to the dentist. With this continued advancement in technology many eye surgeries can safely be done in an office-based surgical suite. There are some benefits and some potential drawbacks to office-based surgery. The purpose of this form is to educate you about your options and obtain your consent to have office-based eye surgery.

An office-based surgical suite is required to provide a sterile environment and is subject to many of the same regulations as a hospital or surgery center. Our patient safety protocols and equipment are reviewed and inspected to make sure they meet local and national guidelines. Lifesaving equipment and medications are available if necessary. Your surgeon will monitor your vital signs and medical status during the procedure. In the event you develop a severe medical problem you may need to be transferred to a local hospital.

## Potential Benefits

Convenient location  
No need to fast  
No IV required  
Less costly out-of-pocket expenses

## Potential Drawbacks

Only light sedation available  
No Anesthesiologist  
Only certain procedures available

## **Anesthesia Care Plan**

You will be prescribed an oral sedative or provided a dose in the office prior to your procedure. This will help you to not feel anxious during the procedure. For a cataract procedure topical eye drops of anesthetic will be given. For other surgeries small injections of local anesthesia will be given. To safely have surgery in an office-based setting you should not have any uncontrolled medical conditions. These might include heart disease with active chest pain or an implanted defibrillator, high blood pressure with very high readings, diabetes with uncontrolled blood sugars, or breathing problems that require multiple medications or oxygen as treatment. Please let your surgeon know if you have any of these conditions.

## **Acknowledgement and Consent**

I have read this document and understand the potential risks and benefits of having my eye surgery done in an office-based setting. I also understand my anesthesia care plan which will be administered by my surgeon. I have no severe or uncontrolled medical conditions that might interfere with a successful surgery.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Surgeon

\_\_\_\_\_  
Date



## ICL Medication Schedule

- Always wait 5 minutes between drops
- If you run out of drops before the schedule indicates they should be stopped, call the office for instructions

### Pre-operative Drops – start 3 days before the procedure

Prednisolone	Twice Daily (morning and evening)
Moxifloxacin	

### Surgery Day Drops

Prednisolone	Every 2 hours until bedtime
Moxifloxacin	

### First Week After Surgery Drops

Prednisolone	Four times daily
Moxifloxacin	

### Weeks 2 and 3

Prednisolone	Two times daily
Moxifloxacin	Stop

# Visian ICL Surgery

## Post - Operative Instructions

ICL surgery is one of our most successful and technologically advanced surgeries. However, even the best surgery can have problems when post-operative instructions are not followed or medications are not used appropriately. Please read through this sheet carefully, it tells you specific instructions for the first 24 hours after your cataract surgery.

- Keep the plastic shield or glasses covering the eye at all times for the first 24 hours. You may carefully lift it when drops need to be applied.
- Do not rub or put any pressure against your eye.
- Use both of your eye drops every 2 hours until bedtime.
- Use Tylenol for any pain or discomfort. The usual dose is two 500 mg pills every 4 hours.
- If you experience severe pain, severe headache, nausea, or vomiting within the first 24 hours call Dr. DeBry immediately (702-825-2085 office, or 702-219-8770 cell), even if it is a weekend or late at night.
- Keep your activity to a low level. No strenuous exercise or heavy lifting.
- Because sedating medications may still be in your system avoid driving, alcohol, operating equipment or machinery, and making important decisions for 24 hours after your procedure.
- You may bathe or shower tomorrow. Be careful to not get soap or water in the operated eye. You may remove the shield during this time, but avoid rubbing the eye.

Your appointment tomorrow will be at \_\_\_\_\_.

Please call if you have a problem with this time or location.

Most importantly, if you have any question or problems CALL US IMMEDIATELY.

Office – 702-825-2085

Dr. DeBry cell – 702-219-8770