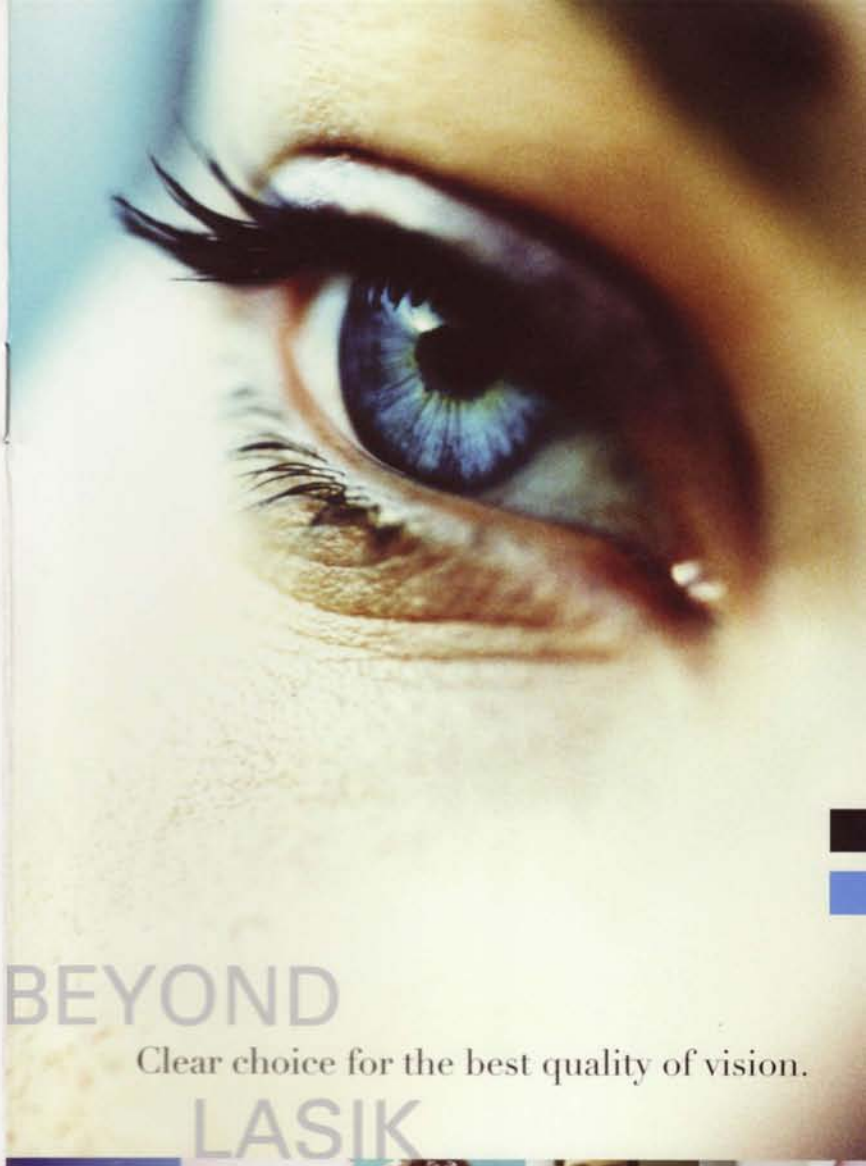
Visian ICL™

See what you've been missing.



BEYOND LASIK

Clear choice for the best quality of vision.

STAAR™ SURGICAL

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Vision of the future
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Visian ICL™

See what you've been missing.

Introducing the Implantable Collamer® Lens Visian ICL™

Imagine the luxury of taking perfect vision* for granted. Now, with the Visian ICL, you are finally able to do just that. The Visian ICL is an implantable contact lens that works with the eye to correct vision. Unlike traditional contact lenses that go on the surface of the eye, Visian ICL is surgically inserted into the eye where it provides excellent quality of vision for a wide range of correction needs.

*Individual results may vary

Visian ICL™

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 of the eye, where it continues to focus light accurately without any maintenance required.

Safety

The Visian ICL is inserted into the eye by an ophthalmologist through a small, micro incision. The lens unfolds in the eye and is positioned between the iris and the natural lens where it stays indefintely. The procedure takes approximately 15 minutes and is performed on an outpatient basis.

Advanced lens material

The Visian ICL is made of Collamer, an advanced lens material that has unique properties. Collamer transmits light and reduces reflections that can interfere with vision, so you see clearly. Made of a copolymer and collagen, Collamer is also highly biocompatible. It allows the Visian ICL to rest quietly in position while accurately correcting vision. Collamer is the only lens material made with collagen—the best choice for a lens that is going to remain inside your body for a lifetime.

Removable

The Visian ICL does not alter any structures within the eye or on the cornea. If necessary, it can be removed from the eye by a simple surgical procedure.

Invisible and undetectable

You won't be able to see the Visian ICL in your eye, and neither will anybody else. Exceptional quality of vision will be the only reminder that you have had 21st century vision correction.

Excellent for a wide range of vision correction needs

Extreme refractive error

Anyone seeking clear vision may be a candidate for the Visian ICL, including patients with extreme or special vision correction needs.

Thin corneas

The cornea is the curved surface on the front of the eye. The Visian ICL does not have any effect on the cornea and may be appropriate if you have thin corneas.

Dry eyes

Visian ICL does not cause or contribute to dry eyes.

Is the Visian ICL right for you? Consult with your eye care specialist and ask about the unique advantages of the Visian ICL. More than 40,000 patients now have this lens, and it may be just right for you.

Established technology, worldwide acceptance

The Visian ICL is the first lens of its kind to receive FDA approval for use in the US. It is based on many years of research and development in adapting the proven technology of the IOL (intraocular lens) used for cataract surgery. The IOL cataract procedure is familiar to ophthalmologists and is performed safely on millions of patients each year.

While the technology is similar, the Visian ICL procedure differs from cataract surgery as the natural lens is not removed from the eye. Instead, Visian ICL is placed in front of the natural lens and works with it to correct vision.

Studies have shown that the Visian ICL provides one of the best postoperative results of all refractive procedures available. Patients report a very high level of satisfaction with the Visian ICL procedure. In the rigorous US clinical trial, 99.4% of patients said they were satisfied three years after the procedure.

The Visian ICL was developed by STAAR Surgical Company, a pioneer in ophthalmic surgical technologies with a long history of successful innovations.

The ultimate choice, even for doctors themselves

Surgeons around the world have made the Visian ICL their procedure of choice more than 40,000 times – not only for their patients, staff and family, but even for themselves.

Göran Helgason, ICL surgeon and patient, Sweden

"After years of implanting ICLs into the eyes of my patients, I became awkward talking to them about this vision correction, wearing spectacles myself. Gradually, my patients convinced me that the ICL works so well that I thought: Why shouldn't I use it for myself, even with only low myopia? In summer 2004 I had bilateral surgery which only took 30 minutes and went perfectly. I didn't feel anything. The only thing that disturbed me during surgery was the bright light from the microscope. I am thrilled with the result. As a surgeon, I rely on an excellent quality of vision in my daily work. My sight now is even better than I expected.

Frequently Asked Questions

Who are candidates for Visian ICL?

If you are between 21 and 45 and nearsighted, you are an excellent candidate for Visian ICL. It is preferable that you have had no previous ophthalmic surgery or history of ophthalmic disease such as glaucoma, iritis, or diabetic retinopathy.

Exactly where is Visian ICL placed in the eye?

Visian ICL is placed in the "posterior chamber," behind the iris and in front of the eye's crystalline lens. The lens does not touch any internal eye structures and stays in position.

What is the track record of Visian ICL?

Extensive research and development preceded the introduction of Visian ICL. It is now being used by more than 40,000 patients worldwide. The satisfaction rate among patients is extremely high—above 99%. Visian ICL provides excellent and stable outcomes.

What if your vision changes?

Visian ICL offers treatment flexibility. If your vision changes dramatically, the lens can be removed and replaced, or another procedure can be performed at any time. With Visian ICL, you can wear glasses or contact lenses if necessary. Visian ICL does not help presbyopia (difficulty with reading in people over 40), but you can add reading glasses if needed.

Can they dry out or get dirty like a contact lens?

No. Visian ICL avoids problems experienced with traditional contact lenses. It is designed to remain in place inside your eye, without maintenance. A routine, annual visit with your eye doctor is recommended to make sure everything is fine.

Can Visian ICL be seen by the naked eye?

No. The lens is positioned behind the iris where it is invisible to both you and observers. You enjoy a cosmetic appearance that is natural. Only your doctor will be able to tell that vision correction has taken place.

What is Visian ICL made of?

The Visian ICL is made of Collamer, an advanced lens material that is highly biocompatible. Collamer does not cause a reaction inside the eye and contains an ultraviolet filter that provides protection to the eye.

What is involved in the Visian ICL procedure?

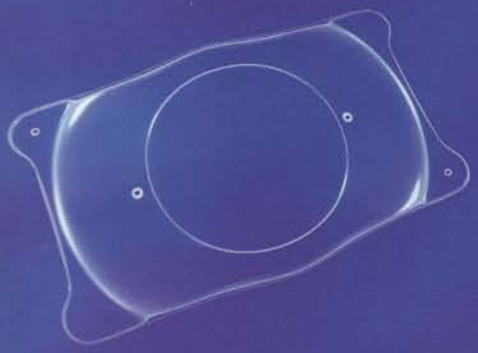
One to two weeks prior to surgery, your doctor will make a small opening with a laser to allow fluid to pass between the lens and the front chamber of the eye. The actual Visian ICL procedure typically takes approximately 15 minutes and is performed on an outpatient basis. (Please note that someone will have to drive you to and from surgery.) Normally, very little discomfort is associated with this procedure. A light topical or local anesthetic is administered and a mild sedative may be given. Eye drops or oral medication may be prescribed. You will come back the next day for a follow-up visit.

How long does Visian ICL stay in my eye?

The Visian ICL is intended to remain in place in the eye without maintenance. Should it become necessary, the lens can be removed by a certified ophthalmologist.

Can Visian ICL be felt once it is in place?

The lens is not noticeable after it is put in place. It does not attach to any structures within the eye and stays in position.



What are the advantages of the Visian ICL?

There are many unique advantages to the Visian ICL, including:

1. **Performance** – Provides excellent quality of vision with predictable and stable results
2. **Simplicity** – Inserted through a micro incision utilizing a procedure that is familiar to the surgeon. The lens is invisible to both you and observers. It requires no maintenance
3. **Versatility** – Capable of correcting a wide range of nearsightedness and is removable if necessary
4. **Biocompatibility** – Collamer, an exceptional lens material offering unparalleled biocompatibility
5. **Safety** – Safe, proven procedure that is familiar to ophthalmologists

15 Minutes That Will Change Your Life.

Prior to the implantation of the Visian ICL, you will receive topical anesthetic drops. Your surgeon may also administer a sedative.

First, a microscopic incision will be made where the white of your eye meets the colored part.

Second, a gel-like substance will be injected into your eye and the Visian ICL will be inserted in front of your iris.

Finally, the Visian ICL is carefully placed behind the iris and the gel is removed from your eye.

That's it! Because the incision made is microscopic, it will heal naturally in a very short period of time without needing any sutures.

Implanting the Visian ICL is an outpatient procedure, and takes about 15 minutes. A few hours after the procedure you will be able to leave the clinic.

Harry H. Huang, M.D., P.A.
5630 Shields Drive
Bethesda, MD 20817

INFORMED CONSENT FOR
PHAKIC IMPLANT SURGERY

INTRODUCTION
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 ophthalmologist can determine if you should have phakic implant 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 any procedure before agreeing to have it.

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 or distorted. 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 steep 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^{TM} phakic implantable collamer lens (IOL) has been approved by the Food and Drug Administration (FDA) for the treatment of patients with moderate to high myopia between the ranges of -5 diopters to -20 diopters, with up to 2.5 diopters of astigmatism.

Surgical implantation of a phakic intraocular lens (phakic implant surgery) is one of a number of alternatives for correcting nearsightedness. In phakic implant surgery, an artificial lens (such as the Visian^{TM} phakic implantable collamer lens (ICL)) is surgically placed inside your eye. The lens is made from material similar to the type used for intraocular lenses currently being implanted in the eye to correct vision after cataract surgery. The difference between phakic implant surgery and other intraocular lens implants is that your natural lens is not removed during phakic implant surgery. The phakic lens is inserted in addition to your natural lens.

Phakic implant 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, the result might be affected even to the extent of making your vision worse.

ALTERNATIVES TO PHAKIC IMPLANT SURGERY
You are under no obligation to have phakic implant surgery. If you decide not to have phakic implant 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 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. PRK and LASIK do not require an incision into the inside of the eye as does phakic implant surgery.
1. Photorefractive Keratectomy (PRK) uses an excimer laser to reshape the cornea to refocus light rays on the cornea. PRK may be used to correct low to higher amounts of myopia (generally -1 D to -12 D).
2. LASIK is an operation which combines the creation of a flap using a device called a microkeratome and the removal of tissue with the excimer laser. During LASIK, a thin layer of cornea is surgically cut with the microkeratome, the exposed surface of the cornea is reshaped with the 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 an "accommodating" lens that also helps improve near vision for reading. Because of the increased risk of retinal detachment, refractive lens exchange is most appropriate for patients who are extremely nearsighted (-10 D and above).
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 PHAKIC IMPLANT 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 before the placement of the phakic implant by using a laser (YAG-laser iridotomy).

Before phakic implant surgery begins, you will be given an anesthetic to minimize your pain during surgery. You may undergo light sedation administered by an anesthesiologist or nurse anesthetist while your eye is made numb by your surgeon with either drops or an injection (local anesthesia); 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 or other qualified health care professional 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 or health care professional 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^{TM} phakic ICL is inserted between your cornea and your iris. The incision required to perform this operation is at times self-sealing but it may require closure with very fine stitches (sutures) which will gradually dissolve over time or may 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 observed under a slit lamp biomicroscope 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 phakic implant surgery may take several weeks to stabilize. Patients are generally able to return to their normal activities within 2 or 3 days following phakic implant surgery.

Only one eye will be treated at a time. If you decide to have the second eye treated with phakic implant surgery, you will need to wait until your ophthalmologist has determined that the first eye has healed sufficiently. You will be required to wait a minimum of one week and possibly as much as three months following surgery on your first eye before receiving an implant in the second eye.

BENEFITS OF PHAKIC IMPLANT SURGERY
If you have moderate to high myopia, phakic implant surgery may improve your natural distance vision without the use of glasses or contacts.

LIMITATIONS OF PHAKIC IMPLANT 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 accommodate, or 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. Moreover, 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.
3. With increasing age, patients are likely to develop cataracts. If the cataracts are significant enough to cause visual problems, the phakic implant may need to be removed so that the eye can undergo cataract removal with or without implantation of a suitable artificial intraocular lens.

PATIENT RESPONSIBILITY FOR COSTS
Health insurance generally does not pay for elective phakic implant surgery for the purpose of correcting natural vision. Therefore, the patient is responsible for the cost of the surgery, including the surgeon's fee, anesthesiologist's fee (if any), and the surgical center's or hospital's fee. In the event of a complication, it may be possible that other surgery, eye drops, or even hospitalization may be required. Some or even all of these costs may be covered by health insurance. The patient is responsible for the costs of any uncovered surgery-related injuries.

PATIENT CONSENT
I give my ophthalmologist permission to perform either a YAG-laser iridotomy AND phakic implant surgery, and acknowledge that I understand the following: the foreseeable risks of phakic implant 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 are very rare but include damage to the natural lens; inflammation inside the eye; temporary increases in the pressure in the front part of the eye; cataract formation; bleeding (usually a small amount but can be a large amount); scar formation between the iris and lens of the eye (synechia) that prevents the pupil from moving correctly; corneal damage; and vision disturbances such as double vision (diplopia), glare, or halos.

VISION-THREATENING COMPLICATIONS
In most cases, the surgery will be accomplished with numbing drops, but in some cases the eye surgeon may elect to use an injection around the eye for anesthesia. Very rare complications from injections include damage to the eye muscles, perforation of the eye, and damage to the retina or optic nerve leading to loss of vision.
1. 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 treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation, blindness, or even loss of the eye.
2. I understand that I could experience damage to the iris (the colored portion of the eye) or develop a rise in the pressure in the front of my eye (secondary glaucoma). I may require another iridotomy if this occurs or eye drops to control the pressure.
3. I understand that I could develop a retinal detachment, a separation of the retina from its adhesion at the back 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 phakic IOL.
4. I understand that 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 phakic implant, 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 phakic IOL.
5. I understand that 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 long the endothelial cell loss will continue and what effect the cell loss and phakic implant will have on the long-term health of the cornea. If too many cells are lost over time, I may need a corneal transplant.

6. I understand that I may develop glaucoma, which is an increase in the pressure of the eye caused by slowed 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^{TM} Phakic ICL on the future risk of glaucoma is not known.
7. I understand that other complications could threaten my vision, including, but not limited to, iritis or inflammation of the iris (immediate and 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 SIDE EFFECTS
I understand that 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.
I understand that 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.
I understand that an overcorrection or undercorrection could occur, causing me to become farsighted, remain nearsighted, or increase my astigmatism and that this could be either permanent or treatable with either glasses, contact lenses, or additional surgery.
I understand that 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.
I understand that there may be a difference in vision between my two eyes after the phakic implant 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 phakic implant or consider another type of surgery for that eye.
I understand that, after phakic implant surgery, the eye may be more fragile to trauma from impact. Evidence has shown that, as with any scar, a 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 phakic implant surgery. 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.
I understand that 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 phakic implant surgery are unknown and that unforeseen complications or side effects could possibly occur.
I understand that the correction that I can expect to gain from phakic implant 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.
I understand that 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.
I understand that, 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 may not be complete.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING
The details of phakic implant surgery have been presented to me in detail in this document 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, AND phakic implant surgery, I am stating that I have read this informed consent, I fully understand the possible risks, complications, and benefits that can result from the surgery and the alternatives available to me, and I hereby give my consent to have phakic implant surgery performed on my:

Left Eye Right Eye

My personal reason(s) for choosing to have phakic implant surgery are as follows:

_____

_____

_____

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 phakic implant 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 phakic implant surgery will be performed.

_____ _____
Patient Name Date

_____ _____
Witness Name Date

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

Revised 2/2009/RAS