

## Verisyse™ Phakic Implant Surgery

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### DISCLAIMER

*Recommendations presented here should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. The ultimate judgment regarding the propriety of any specific procedure or treatment must be made by the ophthalmic in light of the individual circumstances presented by the patient. This information is intended solely to provide risk management recommendations. It is not intended to constitute legal advice and should not be relied upon as a source for legal advice. If legal advice is desired or needed, an attorney should be consulted. This information is not intended to be a modification of the terms and conditions of your OMIC policy of insurance. Please refer to your OMIC policy for these terms and conditions.*

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### NOTICE TO PHYSICIANS

- INFORMED CONSENT
- This consent form is provided as a sample form only. Carefully review it and change it as needed to reflect your practice.
- OMIC encourages its insureds to inform their patients of their limited experience performing new surgical techniques. For additional information regarding this informed consent issue, please refer to OMIC's Hotline article, "Informing Patients About Your Surgical Experience," featured in the Spring 2004 Digest, and available at [www.omic.com](http://www.omic.com).
- APPROVED USES
- The Verisyse™ Phakic IOL was approved by the FDA to reduce or eliminate myopia in adult patients who have:
  - Myopia ranging from -5 to -20D with  $\leq 2.5D$  of astigmatism at the spectacle plane
  - An anterior chamber depth  $\geq 3.2$  mm
  - Stable refraction ( $< 0.5D$  change for six months)
    - **Any use outside these parameters constitutes "off-label" use of the device.** The ophthalmologist should weigh the risk/benefit ratio and inform the patient of the "off-label" status. The "off-label" status should be added to the procedure-specific consent form.
- POSSIBLE CONTRAINDICATIONS
- Patients less than 21 years of age
- Anterior chamber depth  $< 3.2$  mm as determined by the eye doctor

- Abnormal iris or cornea
- Patients who are pregnant or nursing
- Endothelial cell density less than specified in the labeling
- OMIC COVERAGE INFORMATION.
- OMIC insured ophthalmologists must apply for, and be granted, an endorsement to their OMIC policy in order to obtain coverage for phakic IOLs.
- Coverage is granted for on-label use.
- Please contact the Underwriting Department at 800.562-6642, extension 639 for questions about coverage or off-label use.
- The application form and refractive requirements are available at <http://www.omic.com/>

**OMIC policyholders who have additional questions or concerns about this issue should call our Risk Management Department at 800-562-6642, extension 651 or 662.**

## Informed Consent for Verisyse™ Phakic IOL Implant Surgery

### INTRODUCTION

This information and the *Patient Information Booklet* are 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 this 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 Verisyse™ phakic intraocular 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 Verisyse™ phakic intraocular lens) 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 a two-phase operation. First, a thin layer of cornea is either surgically cut with the microkeratome or a flap is created using a laser. The exposed surface of the cornea is then 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 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 either at the time of surgery by using an instrument (a surgical

iridotomy) or within two weeks 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 constricted, and your eye has been anesthetized, the surgeon will make a small incision in your cornea to allow insertion of the lens. The Verisyse™ phakic IOL is inserted in the front part of your eye (anterior chamber) between your cornea and your iris. The incision required to perform this operation is usually 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.

**OMIC policyholders who have additional questions or concerns about practice changes are invited to call OMIC's confidential Risk Management Hotline at (800) 562-6642, extension 641.**

## PATIENT CONSENT

I give my ophthalmologist permission to perform either a YAG-laser iridotomy or a surgical 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 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 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 of Phakic IOL Surgery

1. 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.
2. 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.
3. 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 or eye drops to control the pressure if this occurs.
4. I understand that 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 phakic IOL.
5. 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.
6. 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 much endothelial cell loss will occur 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.

7. 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 IC<sup>L</sup>™ Phakic IOL on the future risk of glaucoma is not known.
8. 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 Complications

1. 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.
2. 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.
3. 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.
4. 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.
5. 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 a phakic implant or another type of surgery for that eye.
6. 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.

7. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.
8. I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
9. I understand that the long-term effects of phakic implant surgery are unknown and that unforeseen complications or side effects could possibly occur.
10. 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.
11. 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.
12. 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 is not 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 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 phakic implant surgery, I am stating that I have read this informed consent and *Patient Information Booklet* (or they have been read to me), fully 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 phakic implant surgery performed on my:

Left Eye

Right Eye

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

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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.

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_____	_____	_____	_____
Patient Name	Date	Witness Name	Date

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