

**Informed Consent for Lens Extraction
With Implantation of an
Accommodative Intraocular Lens**

This surgery involves the removal of the natural lens of my eye. I may have a cataract or clouded lens, or I may have chosen to have my clear, natural lens removed in order to improve my uncorrected vision. The natural lens will be replaced with an artificial implant called an accommodative intra-ocular lens in order to attempt to correct my presbyopia, and my hyperopia or myopia, so that my natural vision will be improved thereby reducing my dependency on corrective glasses or contact lenses. I understand that my ability to perform distance, near and intermediate tasks without glasses or contact lenses is not guaranteed.

Benefits to me will be more clear, natural vision than I presently have. The **farsighted (hyperopic)** eye is out of focus because the length of the eye is too short for the curvature of the outer lens of the eye (cornea). Light rays, therefore, focus behind the retina. The **nearsighted (myopic)** eye is out of focus because the length of the eye is too long for the curvature of the outer lens of the eye (cornea). Light rays, therefore, focus in front of the retina. Light rays from distant objects can theoretically be brought to a clearer focus on the retina by utilizing an artificial lens that has the proper power, thereby improving the natural focus of the eye.

Loss of accommodation, or **presbyopia**, means the eye is no longer able to automatically focus images from various distances onto the retina. The accommodative lens implant is designed to work with the focusing muscles in the eye and move backward and forward as you continuously change focus on objects around you.

Initials: _____

Witness: _____

Astigmatism occurs when the curvature of the cornea is oval like a football instead of spherical like a basketball. This causes light to focus on more than one point in the eye, resulting in blurred, distorted vision at distance and near. I understand that I may have astigmatism along with my presbyopia, hyperopia or myopia, and that astigmatism correction may be necessary for me to reduce my dependency on corrective glasses or contact lenses for distance, near and intermediate tasks. Limbal relaxing incisions (LRI), PRK, or LASIK are all procedures to correct astigmatism. Depending on the amount of correction that would be required, the surgeon will determine which procedure will be appropriate.

In some cases, the lens may have an early cataract ("incipient cataract") which does not significantly interfere with corrected vision and functioning, and which would normally not require surgical removal. The cost of the surgery, the surgeon's fee, anesthesiologist's fee if any, and the surgical center's or hospital's fee must be borne by the patient. Health insurance does not pay for removal of the clear lens of the eye for the purposes of correcting natural vision or the removal of an early cataract which is not visually disabling.

Should I agree to have the surgery, I will undergo a complete eye examination by my surgeon. This will include measurement of my vision with and without glasses (visual acuity), a determination and measurement of my best-corrected vision, or how well I can see through my correct prescription (refraction), measurement of the pressures inside my eye (tonometry), measurement of the curvature of my cornea (keratometry), mapping of the curvature and power of my cornea to determine the amount and type of astigmatism (corneal topography), laser or ultrasonic measurement of the axial length of my eye (ocular biometry), intra-ocular lens calculation to determine the best estimate of the proper power for the implanted lens, microscopic examination of the back segment of my eye with my pupils dilated (bio-microscopic indirect ophthalmoscopy).

Initials: _____

Should I decide to proceed with the surgery, I may undergo light sedation prior to or during my procedure, or I may elect to have the surgery without sedation. My eye and the back of my eyelids will be numbed with a topical anesthetic, and anesthetic medication may be infused inside my eye during surgery. I understand that a local anesthetic injection may be needed to supplement the topical and intra-ocular anesthetic. The natural lens in my eye will then be removed by breaking it up into small pieces with a vibrating needle. These pieces are gently suctioned out of my eye through a small, hollow tube inserted through a small incision into my eye. This type of surgery is called phacoemulsification. After my natural lens is removed, the artificial accommodative lens of the power determined during my pre-operative examination will then be placed inside my eye. In rare cases of highly far-sighted (hyperopic) or near-sighted (myopic) eyes, it may be necessary to implant 2 lenses. The incision required to perform the operation is constructed to be self-sealing, but it may require closure with vary fine stitches (sutures). After the surgery, my eye will be examined the next day, and then at intervals determined by my eye doctors. I understand that I will need to be available to be seen at the prescribed intervals. I should be able to resume most of my normal activities within 1 to 3 days.

Eye drops will be applied to my eye after surgery to paralyze my eye's ability to change focus from far to near for 1-2 weeks, during which time my near and intermediate vision will be somewhat blurred. I may need to use reading glasses for near tasks. This is done to ensure that the accommodative lens implant is correctly positioned as my eye heals. These drops also dilate my pupil and may make me sensitive to light. I will also be using eye drops for 3-4 weeks following surgery to prevent infection and reduce inflammation as my eye heals.

In order to maximize my ability to perform near and intermediate tasks without glasses or contact lenses, I will need to begin retraining the ciliary muscles of my eyes that control accommodation. My ciliary muscles have become dormant from lack of use, and after 2 weeks have passed following my surgery, I will begin reading small print without glasses at least twice a day for a minimum of 10 minutes a session, as well as any other eye exercises or vision therapy that my doctors may prescribe. It is important that I discontinue the use of reading glasses at this time so that I use and strengthen the focusing muscles of my eyes. I understand that it may take up to a year, or longer, to achieve full accommodative potential following implantation of an accommodative lens.

Please *handwrite* and initial the following statement:

"I understand that is important to discontinue the use of reading glasses to strengthen the focusing muscles of my eyes. It may take a 12 months or longer to achieve my full reading potential."

Initials: _____

Witness: _____

I understand the requirements of my follow-up care and am willing, if circumstances require, to see a doctor other than my operating surgeon for my follow up visits. I understand and permit information derived from these visits to be shared among my eye care professionals.

I understand the potential benefit, which may be derived from my surgery, is a reduction or correction of my nearsightedness, farsightedness, and/or astigmatism. I may see well enough after surgery that I will not require corrective lenses for many or all tasks.

Initials: _____

Description of risks, side effects, and discomforts:

This type of surgery itself is usually quite comfortable for the patient. Mild discomfort for the first 24 hours is typical, but severe pain would be extremely unusual. Since this surgery is essentially the same as cataract surgery, the same risks apply. Complications of cataract surgery include: infection, which if serious can lead to complete loss of vision or loss of the eye; swelling in the central area of the retina (called cystoid macular edema which usually improves with time); clouding of the outer lens of the eye (corneal swelling which may need to be treated with a corneal transplant); detachment of the retina (definitely an increased risk in highly near-sighted, myopic eyes) which can cause permanent vision loss even though the retinal detachment can usually be repaired; damage to the retina or nerve during the administration of the anesthesia if an injection is performed: increased astigmatism; inaccuracy of the intra-ocular lens power; decentration of the intra-ocular lens, which may produce unwanted images and increased glare; and development of increased pressure in the eye (glaucoma). Although all the complications can occur, their incidence following cataract surgery is exceptionally low. I understand that I will also receive a standard list of cataract surgery risks in addition to this list.

I understand under certain conditions, my surgeon may decide that is in my best interest to implant a standard lens. I understand the difference between the two lens implants, and acknowledge the potential need.

Initials: _____

Witness: _____

Another possible disadvantage compared to normal cataract surgery is that although the accuracy of the intra-ocular lens calculations is quite satisfactory for normal sized eyes, these calculations can be more inaccurate for unusually long or short eyes. The latest formula will be used to evaluate the power of the lens to be implanted. In the event of a minor error in the calculations, the vision can usually be corrected by an eyeglass prescription, which should be considerably weaker than your original prescription. A large error in the lens calculation could be corrected by a stronger pair of glasses, contact lenses, the exchange of the lens implant, the insertion of a second implant in another operation, or possibly corneal surgery including LASIK or PRK.

I understand that there is a possibility of needing to return to the surgery suite to exchange the lens implant for another power or the insertion of a second implant in another operation.

Initials: _____

Witness: _____

As with normal cataract surgery, the lens capsule that supports the intraocular lens (the "implant") may become cloudy or hazy. This may cause my visual acuity to decrease. The capsule can be opened using a laser to partly or completely restore my distance vision, and the laser may partly or completely restore my reading vision as well.

Since only one eye will undergo surgery at a time, I may experience a period of imbalance between the surgery on the two eyes (anisometropia). This may not be corrected with spectacle glasses because of the marked difference in the prescriptions, so I may either temporarily have to wear a contact lens in the non-operated eye or will need to function with only one clear eye. I understand that it is not always possible to predict how I will feel between surgery on my two eyes.

Initials: _____

Non-Surgical Alternatives:

Non-surgical alternatives to natural lens extraction (with or without a cataract present) are to continue to wear spectacle lenses or contact lenses. Although there are essentially no risks to wearing glasses, the quality of vision with strong farsighted or nearsighted glasses is often poor because of an enlarged image and a slight decrease in peripheral vision caused by the thickness of the lenses. If I have a cataract my vision will be poor due to the clouded lens. Although 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, which can rarely cause loss of vision if the infection involves the cornea; allergies (giant papillary conjunctivitis, GPC) which can make wearing the lenses difficult; mild irritation; and discomfort. There is also evidence that some damage occurs to the important internal layer of cells that are responsible for keeping the cornea clear. This damage could cause harm if the contact lenses are worn for many years. Whether this damage will eventually lead to serious long term complications such as corneal clouding is unknown. Contact lenses or glasses are non-surgical, extremely accurate, permit easy changes in prescription, and also allow the eye to retain its age-appropriate focusing power for near vision.

Surgical alternatives (including lasers):

There are several other procedures for the correction of farsightedness and nearsightedness. The excimer and holmium lasers are capable of reshaping the cornea. The holmium laser is only indicated for low degrees of hyperopia. The excimer laser can be used to correct low to moderate amounts of hyperopia (generally +1 to +3D) through either PRK (Photorefractive keratectomy) or LASIK (laser in-situ keratomileusis) and low to higher amounts of myopia (generally minus 1D to minus 8D)

LASIK is an operation which combines the creation of a flap with the microkeratome and the removal of tissue with the excimer laser. LASIK has been found to be quite successful and relatively safe for correction of moderate and high myopia up to about -8D. Above 8 to 10D diopters LASIK may be complicated by problems with accuracy and by issues involving the quality of vision, especially at night. Many surgeons have stopped performing LASIK for these extremely near-sighted eyes.

The advantage of all the above procedures is they retain the patient's natural focusing power and do not require an incision into the inside of the eye as does natural lens extraction. I understand that I may choose not to have this surgery at all and either continue wearing my glasses or contact lenses, or I may elect to have one of the other procedures discussed in this section.

I understand that I may be responsible for the costs of the surgery-related injuries. I also understand that no compensation is being offered to me in the event of an injury or complication. In the event of a complication for the natural lens extraction, it might be possible that other surgery, eye drops, or even hospitalization may be required. Although some or even all of the costs may be covered by my health insurance policy, if they are not, I understand that I will be responsible for these costs.

Should a second surgical procedure be required, for example, replacement or repositioning of my intra-ocular lens or a laser capsulotomy, I understand that although my surgeon will not charge me a surgical fee, there may be additional fees from the surgery center and from the anesthesiologist if one is required.

Initials: _____

Please handwrite and initial the following statements:

"I understand I may not achieve the quality of vision I had hoped for. There are no guarantees."

"I understand I may still need reading glasses. I may require glasses for distance and intermediate vision."

"I feel all of my questions have been answered."

Initials: _____

Witness: _____

I have carefully read and understand the information presented in this form and consent to undergoing a natural lens extraction (with or without a cataract present), with accommodative intraocular lens implantation. I have been fully informed of my right to receive a copy of this signed and dated consent form.

Patient Signature

Date

Witness Signature

Date

Physician Signature

Date

RESPONSIBILITY FOR PAYMENT:

I understand that my fee for the surgery will be \$_____ for my right eye and \$_____ for my left eye, for a total of \$_____ for both surgeries. I agree to remit payment to SkyVision Centers for each eye prior to the date of the surgery.

Patient Signature

Date

Initial