DEER EYE CLINIC

INFORMED CONSENT FOR CATARACT SURGERY USING THE CRYSTALENS INTRAOCULAR LENS

INTRODUCTION

Cataract surgery involves the removal of the cloudy lens of my eye, and usually the natural lens will be replaced with an artificial implant called an intra-ocular lens. This reduces or eliminates the need for strong eyeglasses after surgery

Traditional intraocular lenses correct vision at one distance only, far or near (usually far vision is chosen). Advanced lens designs allow a patient to elect a correction that improves both far and reading vision. The advance Crystalens accommodating lens is available at an extra cost. I understand that I have alternatives and that any surgery has inherent risks. Ultimately, only I can make the decision that the potential benefits outweigh the risks.

EXAMINATION BEFORE Surgery

If I agree to have surgery using the advance accommodating IOL, more extensive measurements of the eye are required including: measurement of the curvature of the cornea (keratomety); measurement of the length of the eye (axial length); and specific intra-ocular lens calculation (biometry) to determine the best estimate for the proper power of the implanted lens. As with any measurements, there is an associated degree of accuracy. Due to measurement and individual healing variability, there is no guarantee as to achieving the desired refractive (prescription) goal.

PROCEDURE AND POST OPERATIVE CARE

The surgery is performed using light sedation administered by an anesthesiologist while the eye is made numb by my surgeon with either drops or a local anesthetic injection. The natural lens will then be removed by breaking it up into small pieces using an ultrasound probe and the pieces are gently vacuumed away. This type of surgery is called phacoemulsification. Afther the natural lens is removed, an artifical lens of the power determined during my pre-operative examination is placed inside my eye. In rare cases, it may not be possible to implant a lens. The incision is required to perform this operation is usually self-sealing, but it may require closure with very fine stitches that will be removed weeks after the procedure.

Several follow-up examinations are required after surgery. It is necessary to use prescribed eye drops to assist in healing during the immediate recovery period. Even though the goal is to reduce dependencey on glasses or contacts, they still may be requried for further improvement in my distnace vision, reading vision, or both. I should be able to resume my normal activities within several days, and my vision will usually be stable within several weeks.

BENEFITS OF SURGERY

Benefits to me should be a clearer, natural vision than I presently have. Using standard implant with cataract surgery improves natural distanc evision, but most patients require additonal glasses for reading.

If one desires to have uncorrected clear vision for both distant and near tasks, an accommodative implant is required. The Crystalens accommodating intra-ocualr lens is an advanced design that makes it possible to focus for far and near with the eye's natural focusing effort. Best results are obtained wihen used it both eyes, but it may be used in one eye only.

RISKS

The surgery is usually quite comfortable for the patient. Mild discomfort for the first 24 hours may occur, but severe pain would be extremely unusual.

Risks include but are not limited to:

1. Infection, which can lead to complete loss of vision
2. Swelling in the central area of the retina, called cystoid macular edema, which usually improves with time
3. Clouding of the outer surface of the eye (corneal edema) that can be corrected with corneal transplant
4. Detachment of the retina (an increased risk in highly near-sighted eyes). A retinal detachment can usually be repaired.

5. Damage to the retina or nerve during the administration of the anesthesia if an injection is performed. This is very rare.
6. Inaccuracy of the intra-ocular lens power
7. Decentration of the intra-ocular lens, which may provide unwanted images and increased glare
8. The general risks of anesthesia, despite the fact that only mild sedation will be used.

SURGICAL ALTERNATIVES AND SHORTCOMINGS

If a standard monofocal implant (not a Crystalens) is used, close vision will usually remain blurred, requiring a separate pair of glasses for near and intermediate vision. In contrast, the Crystalens accommodates to provide near vision along with the distance correction. There is no guarantee that reading glasses may not be needed even with the Crystalens.

An alternative to an accommodative lens, if both corrected distance and near vision is desired, it is to deliberately correct one eye for distance and one for near. The combination of a distance eye and a reading eye is called monovision. With monovision one eye requires a corrective lens for best distance vision and one may have problems with depth perception.

The latest lens measurement techniques and formulas are used before surgery to predict the power of the implanted lens. In the event that a patient's individual healing results in the prescription being other than predicted, the vision can usually be corrected by an eyeglass prescription, which should be weaker than the patient's original prescription. If the results are further from predicted values, a stronger pair of glasses, contact lenses, or surgical exchange of the implant of the insertion of a second implant in other operation, corneal relaxing incisions, or laser refractive surgery may be necessary for the optimum outcome.

Since only one eye will undergo the surgery at a time, one may experience a period of imbalance between the two eyes (anisometropia). Once may need to function with only one clear eye for vision until the second eye is operated. In the absence of complications, surgery in the second eye can usually be accomplished within a few weeks.

NON-SURGICAL ALTERNATIVES

The only alternative to cataract surgery is to have stronger eyeglasses prescribed and to accept the vision blur. One may need to modify their life style as required by less acute vision. No medicine has been found to correct a cloudy cataract lens.

PATIENT RESPONSIBILITY FOR COSTS

I understand that I am responsible for the additional cost of the surgery using a Crystalens. Medicare (and any secondary coverage) does pay for removal of the cataract, but recognizes the extra expenses associated with the use of the advanced implant as billable directly to the patient and not a covered Medicare benefit.

If I need a second surgical procedure, such a removal, replacement, or repositioning of my intra-ocular lens, I understand that there will be additional fees from the surgeon, the surgery center, and the anesthesiologist, although these are usually covered by health insurance. If I need an additional refractive surgery such as LASIK or PRK to attain a more desirable prescription, there will be an additional fee not covered by insurance.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the Crystalens has been presented to me in detail in this document and explained to me by my ophthalmologist. I have had ample time to read this and ask questions, and my ophthalmologist has answered all of my questions to my satisfaction. I therefore consent to cataract surgery and implantation of the Crystalens. I have been fully informed of my right to receive a copy of the signed and dated consent form.

_____	_____	_____
Patient's Name (Printed)	Signature	Date
_____	_____	
Witness Signature	Date	
_____	_____	
Physician Signature	Date	

Advance Beneficiary Notice (ABN)
For Cataract Surgery with Implantation of Crystalens (IOL) Estimate

Patient Name: _____ Account #:_____

Surgery Date: _____ Surgery Location: _____ Physician: _____

The purpose of this form is to help you make an informed decision about whether or not you want to receive this surgical procedure, knowing that you will have to pay for a portion of the service yourself.

Before You Make Any Decision, You Should:

- Read this notice carefully.
- Ask us to explain, if you do not understand, why your insurance or Medicare will not cover this surgical procedure.

I understand that I am requesting cataract surgery including the Crystalens to reduce my dependency from glasses for distance and near vision. This procedure involves me receiving a special intraocular lens called a Crystalens. The total cost for this procedure and the Crystalens IOL is $2,050.00 per eye. This is because my private insurance or Medicare will only cover the cost of the cataract surgery and the usual and medically necessary cataract related consultation and diagnostic testing services. All fees will be paid in advance of my surgery day.

The Charges Included in the $2,050.00 Are:

- The additional cost of the Crystalens Intraocular Lens
- Extended testing and preoperative care necessary related to the Crystalens IOL.

This fee **does not** include any copay, deductible, or coinsurance applicable to the cataract surgery. This fee also **does not** include laser services that may be required for treatment of posterior capsule opacification, which is a common even following cataract surgery. This fee also does not include anesthesia expenses. This fee **does not** include corneal relaxing incisions or refractive enhancements. I will receive a separate bill from Anesthesia Group Practice regarding anesthesia expenses for the portion that my insurance or Medicare does not cover.

Please Choose One Option:

Option 1. _____ Yes I want to receive this surgical procedure on my ____ right eye ____ left eye.

I understand that this additional procedure and the Crystalens are not medically necessary and therefore will not be covered by my insurance carrier or Medicare. I understand that I must pay the full amount of the portion not covered by my insurance carrier or Medicare prior to surgery. I understand that I am personally fully responsible for payment including any estimated amount not covered by my insurance carrier or Medicare.

Option 2. _____ No. I have decided not to receive this surgical procedure.

I have read and understand the above options and cost to me of any additional refractive procedures.

_____ _____

Patient Signature **Date**

____ Payment received in full Date:_____ By:_____

Amount Received: _____ Check____ Cash____ Credit Card ____

DEER EYE CLINIC

Philip J. Deer, Jr., M.D.
Philip J. Deer, III, M.D.

INFORMED CONSENT FOR CATARACT OPERATION AND/OR IMPLANTATION OF INTRAOCULAR LENS

Consent for Operation

In giving my permission for a cataract extraction and/or for the possible implantation of an intraocular lens In my eye, I declare I understand the following:

1. Cataract surgery, by itself, means the removal of the natural lens of the eye by a surgical technique. In order for an intraocular lens to be implanted In my eye, I understand I must have cataract surgery performed either at the time of the lens implantation or before lens implantation

2. Alternative: Do nothing.

3. **Complications of surgery to remove the cataract and insert the intraocular lens:** As a result of the surgery and the local anesthesia injections around the eye, it is possible that my vision could be made worse. In some cases, complications may occur weeks, months, or even years later. These and other complications may result in poor vision, total loss of vision, or even loss of the eye in rare situations.
    a. Complications of removing the cataract may include hemorrhage (bleeding), lossof corneal clarity, retained pieces of cataract in the eye, infection, detachment of retina, uncomfortable or painful eye, droopy eyelid, glaucoma, and/or double vision. These and other complications may occur wheterh or not a lens is implanted and may result in poor vision, total loss of vision, or even loss of the eye in rare situations
    b. Uncommon complications associated with the intraocular lens may include increased night glare and/or halo, double or ghost images, and dislocation of the lens. In some instances, corrective lenses or surgical replacement of the Intraocular lens may be necessary for adequate visual function following cataract surgery.

4. If an intraocular lens is implanted, it is done by surgical method. It is intended that the small plastic, silicone, or acrylic lens will be left in my eye permanently.

5. At the time of surgery, my doctor may decide not to implant an intraocular lens in my eye even though I may have given prior permission to do so.

6. The results of surgery in my case cannot be guaranteed. Additional treatment and/or surgery may be necessary. I may need laser surgery to correct clouding of vision. At some future time, the lens implanted in my eye may have to be repositioned, removed surgically, or exchanged for another lens implant.

7. I understand that cataract surgery and the calculations for intraocular implants are not “an exact science.” I accept that I might need to wear glasses or contact lenses subsequent to surgery to obtain my best vision. There is also the possibility of the need for subsequent surgeries such as lens exchange, placement of an additional lens, or refractive laser surgery if I am not satisfied with my vision after cataract removal.

The basic procedures of cataract surgery, and the advantages and disadvantages, risks and possible complications of alternative treatments have been explained to me by the doctor. Although it is impossible for the doctor to inform me of every possible complication that may occur, the doctor has answered all my questions to my satisfaction. In signing this informed consent for cataract operation, and/or implantation of intraocular lens, I am stating I have read this informed consent (or it has been read to me) and I fully understand it and the possible risks, complications, and benefits that can result from the surgery.

If I decide to have an operation, I agree to have the type of operation listed below which I have indicated by my signature:

I wish to have a cataract operation **WITH** an intraocular lens implant on my _____ (state “right,” “left,” or “both” eye(s).

_____ _____
Patient (or person authorized to sign for patient) Date

_____ _____ _____
Patient’s Name (Print) Age Date

_____ _____
Witness’ Signature Date

_____ _____
Doctor’s Signature Date

Patient's Rights

You have the right to:

- Ask to see and get a copy of your health records.
- Have corrections added to your health information.
- Receive a notice that tells you how your health information may be used and shared.
- Decide if you want to give your permission before your health information can be used or shared for certain purposes, such as marketing.
- Get a report on when and why your health information was shared for certain purposes.
- If you believe your rights are being denied or your health information isn't being protected you can: File a complaint with your provider or health insurer, or file a complaint with the U.S. Government. You also have the right to ask your provider or health insurer questions about your rights. You can also learn more about your rights, including how to file a complaint from the website at www.hhs.gov/ocr/hipaa or by calling 1-866-627-7748

A patient's **Statement of Rights** is established with the expectation that the observance of these rights will contribute to more effective patient care and greater satisfaction of the patient, his family, his physician, and the facility caring for the patient. These written policies shall be established and made available to the patient, his family, and the public. Such policies shall have the following rights without regards to age, race, sex, national origin, religion, or physical handicap.

That the patient will receive the care necessary to help regain or maintain his maximum state of health and if necessary cope with death. The Facility personnel who care for the patient are qualified through education and experience to perform the services for which they are responsible. The patient will be treated with consideration, respect and full recognition of individuality, including privacy in treatment and in care. The patient is provided to the extent know by the physician, complete information regarding diagnosis, treatment, and the progress. If medically inadvisable to disclose the patient such information, the information is given to a person designated by the patient or to a legally authorized individual. Within the limits of the facility service policy, the patient and family will be instructed in appropriate care techniques.

That the patient or responsible person will be fully informed of services available in the facility, provisions for after-hours and emergency care and related fees for services rendered. Information will be given to the patient on a timely basis. Financial incentive will be made available to patients upon request. That the patient will be a participant in decisions regarding his/her care plant. That the patient will have the right to refuse treatment to the extent permitted by law and to be informed of the medical consequences of such refusal. The patient will be requested to sign a release of responsibility form and if refused a registered letter will be sent. When the patient is not legally responsible, the surrogate decision maker, as allowed by law, has the right to refuse care, treatment, and services on the patient's behalf. That plans will be made with the patient and family so that continuing services will be available to the patient throughout the period of need. The plans should be timely and involve the use of all appropriate personnel and community resources. The facility personnel will keep adequate records and will treat with confidence all personal matters that relate to the patient. The patient has the right to be notified, and approve and/or refuse the release of protected health information (PHI) to any individual outside the facility, except when this information is used to facilitate health care procedures for their treatment, as required by law or a third party payment contract. That the patient has the right to be informed of any human experimentation or other research/educational projects affecting his/her care or treatment and to refuse participation in such experimentation or research. Ethical principles guide the business practices of the center. The center will provide for and welcome the expression of grievances/complaints and suggestion by the patient or the patient's family at all times. The patient has a right to have an advance directive, such as a living will or healthcare proxy. These documents express the patient's choices about future care or name someone to decide if the patient cannot speak for him or herself. The patient who has an advance care directive should provide a copy to the center and to their physician for their wishes to be made known and honored. Upon request, the organization helps patients formulate medical advance directives or refers them for assistance. The patient has a right to be fully informed before any transfer to another facility or organization. The patient has a responsibility to observe prescribed rules of the center for their stay and treatment and that the patient forfeits the right to care at the center if printed instructions are not followed. The patient is responsible for promptly fulfilling his or her financial obligations to the center, and the right to request information on billing practices. Every attempt will be made to contact the patient prior to their scheduled procedure to advise them

of the financial responsibility. The patent has a responsibility for being considerate of other patients and personnel and for assisting in the control of noise, smoking, and the number of visitors. The patient has the right to accept medical care or to refuse treatment, to the extent permitted by law, and to be informed of the medical consequences of such refusal. The patient also has the responsibility for his/her action should he/she refuse treatment or does not follow the physician or center instructions. The patient is responsible for reporting whether he/she clearly understands the planned course of treatment and what is expected of him/her. Impairments may include but are not limited to vision, speech, hearing, or cognitive impairments. If interpretive services are required, those necessary will be provided to assure an understanding of the planned course of treatment. The patient is responsible for keeping appointments and when unable to do so for any reason, must notify the center and physician.

The patient care rendered reflects consideration of the patient as an individual with personal value and belief systems that affect his/her attitude toward and response for the care provided by the center. Patients are allowed to express those spiritual beliefs and cultural practices that do not harm others or interfere with the planned course of medical therapy for the patient. The patient of the patient's designated representative to participate in the consideration of ethical issues that arise in the care of the patient. The patient has the right to be free from mental, physical, sexual, and verbal abuse, neglect, and exploitation.

The patient has the right to pain management. The patient will be provided the name of the physician or other practitioner primarily responsible for their care, treatment, and services and the name of the physician or other practitioner primarily responsible for their care, treatment, and services. Decisions regarding the provision of ongoing care, treatment, services, discharge, or transfer are based on the assessed needs of the patient, regardless of the recommendations of any internal or external review. The organization will inform the patient or surrogate decision maker about the unanticipated outcomes of care, treatment, or services that relate to sentinel events considered reviewable to accrediting organizations. The patient has a right to report complaints to the Arkansas Department of Health, www.healthyarkansas.com, 501-661-2201, 5800 West 10th, Suite 400, Little Rock, AR 72204 and/or to Medicare www.cmshhs.gov/center/ombudsman.asp or 1-800-Medicare, Office of Inspector General, PO Box 23489, Washington, DC 20026, without regard to retaliatory retribution.

Introduction to Your Arkansas Advance Directive

It is the policy of the Surgery Center that advanced directives will not be honored as all scheduled procedures are elective in nature. Therefore every effort will be made to sustain life. However, and Advanced Directive form will be provided if requested, as required by law.

1. The **Arkansas Declaration** is your state's living will. It allows you to state your wishes about medical care in the event that you either: (1) develop a terminal condition and are unable to make your own medical decision; or (2) you are in a permanently unconscious state. The Declaration becomes effective when you are in either of these states, your doctor and one other doctor has determined you are in such a state, and the Declaration has been communicated to your Doctor. The Declaration lets you name a Health Care Proxy to make decisions about your medical care- including decisions about life support- if you become terminally ill or permanently unconscious.
2. The **Arkansas Durable Power of Attorney for Healthcare** lets you name someone to make decisions about your medical care any time you lose the ability to make medical decisions for yourself. Note: These documents will be legally binding only if the person completing them is a competent adult (at least 18 years old).

Physician Interest- Your physician may have a financial interest in the center. Information will be provided at your request.

_____ _____

Patient's Signature Date