INFORMED CONSENT FOR CORNEAL INLAY
FOR CORRECTION OF PRESBYOPIA

This informed consent has been created to provide you with information about surgery with a corneal inlay. Any questions you have regarding refractive surgery or other alternative therapies for your case should be directed to your doctor.

An inlay is considered presbyopic refractive surgery. Refractive surgery for vision correction is a choice. Please be aware that the practice of medicine and surgery is not an exact science and no guarantees can be made as to the results of the operation. There are other methods of obtaining useful vision without surgery.

Alternatives to refractive surgery: Refractive surgery is an elective procedure, and you may decide not to have this procedure at all. Alternative methods for correcting your vision include:
- Eyeglasses/Spectacles/Contact lenses
- Bifocal Contact Lenses
- Clear Lens Extraction/Refractive Lens Exchange
- Monovision

Risks: Like all surgical procedures, refractive surgery has risks that should be considered. The risks of refractive surgery include, but are not limited to:

Loss of Vision: Refractive surgery can rarely cause loss of best-corrected vision. This can be due to infection, inflammation, irregular healing, irregular laser treatment, scarring or other complications. These rare complications can often, but not always, be corrected with glasses or contact lenses.

Visual Side Effects: Other visual aberrations that can occur with refractive surgery include; double or “ghosting” of vision, hazy vision, decreased contrast sensitivity, fluctuating vision during the day and from day to day, increased or decreased light sensitivity, glare and halos around lights or starburst from lights. Many of these side effects improve over time, but may not completely go away. In rare instances, some of these could affect your night driving. If your occupation depends on night vision, you should consider this potential risk carefully.

Implantation of the inlay and/or any secondary procedures may cause problems with the cornea such as: foreign body sensation, corneal perforation, corneal scarring, recurrent corneal erosions, (cells that do not adhere to the cornea), or ulceration (wound caused by injury or foreign body to the epithelium), corneal melting (irreparable damage to the cornea or corneal tissue softening), corneal haze (cloudiness or opacity in the cornea as a reaction to the inlay), intra-corneal deposits, or corneal opacities.

Other possible risks include corneal decompensation (swelling and cloudiness of the cornea), glare, cataract formation and endothelial cell density loss.

As with many treatments for presbyopia, there might be a trade off in your vision quality. The possible decrease in use of reading glasses may come at the cost of losing some of the sharpness of your vision. Even with glasses, this loss of sharpness may become worse in dim light.

It may be necessary for you to wear a contact lens or eyeglasses to have useful vision and there is a possibility this may not restore useful vision. Further, it is possible that the desired results of surgery may
not be obtained and that, at a later date, it may become necessary to remove the inlay. If it is recommended by your surgeon that the inlay be removed, you may be asked to cover the cost of removal.

After removal of the inlay, full visual recovery of the eye cannot be guaranteed. It is also possible that the loss of vision may not fully be corrected with glasses or contacts or additional surgical procedures.

**How is surgery performed?**

The inlay is surgically placed under a flap or into a pocket that is created in your cornea using a femtosecond laser, which is commonly used in LASIK procedures. During the procedure you will be lying on your back and asked to focus on the light above your eye. You will receive drops to anesthetize your eye to minimize discomfort during the procedure. The surgeon will describe the procedure to you step-by-step, which takes approximately 10-15 minute to perform. You may be administered treatment for dry eyes including temporary punctal plugs. These are inserted into the tear ducts to reduce the drainage of tears. They are tiny absorbable tubes made of material that the body slowly breaks down over time.

**After the inlay surgery, the physician will ask you to:**

- Instill steroid eye drops that will be required for a period of months after the procedure. (A small group of patients may develop a reversible rise in intraocular eye pressure as a result of the steroid drops. In this case, the eye drop may be changed and/or pressure reducing drop may be prescribed).
- Do not rub your eyes.
- Always wash your hands before administering your eye drops.
- Use sunglasses while outdoors.
- Restrict the use of eye makeup for up to one month.
- Do not participate in contact sports, such as boxing, martial arts, or other activities where a blow to the face and/or eye may occur for up to one month after surgery.

If the eye that was treated becomes red, irritated or painful, you should immediately contact your physician and schedule to come in for an examination within 12 to 24 hours.

**What is the benefit of the corneal inlay?**

The main benefit which may result from your surgery to implant the corneal inlay is the potential to reduce your need for reading glasses; however, this cannot be guaranteed. You may still need reading glasses in certain circumstances (dim lighting and very small print). You may also see well enough that you will not require any corrective lenses.

Because the inlay is only implanted in one eye, you may experience an imbalance in the vision between your eyes (stereopsis). This imbalance may cause headaches or problems in judging distances and depth perception. You may also experience ghost or double images. It is important that you undergo a trial of imbalanced vision (monovision contact lens trial) before you decide to undergo treatment with the inlay. The contact lens trial is designed to evaluate your ability to tolerate imbalanced vision. It is not intended to simulate the effect of the inlay on your vision. Your vision after implantation may be better or worse than the vision you experienced during the contact lens trial. If you are not satisfied with your vision during the contact lens trial, you should not undergo implantation.

**Based on the recommendation made to me by my surgeon, I authorize**
to perform the planned surgical implantation of the corneal inlay.

The procedure I have chosen:

☐ KAMRA Corneal Inlay ☐ RAINDROP Corneal Inlay

I am making an informed decision in giving my permission to have the above procedure performed on my:

__________Right Eye __________ Left Eye

Patient Declaration:

I was given enough time to read this informed consent and to decide for or against this procedure. I discussed each section with the physician and understood them. Alternative solutions were discussed as well. I do not have any questions.

☐ For women only: I am not pregnant or nursing.

In the event of an accidental exposure of my blood or bodily fluids to a physician, employee or contractor of the facility, I consent to testing for HIV and Hepatitis.

I permit one or more observers to be present in the operating room and release The Eye Institute of Utah and my surgeon from all or any liability that may result from their presence.

Patient’s Signature ___________________________ Date __________________

Patient’s Name (Print) ___________________________

Witness’ Signature ___________________________ Date __________________