



## ADDENDUM

### KAMRA™ PRESBYOPIC CORNEAL INLAY INFORMED CONSENT

**Informed Consent.** This KAMRA™ Presbyopic Corneal Inlay Informed Consent is intended to supplement the Vision Correction Surgery Patient Information Form to provide you with additional information concerning KAMRA™ corneal inlay surgery so that you can make an informed decision whether to undergo KAMRA™ corneal inlay surgery. You should carefully read both the Vision Correction Surgery Patient Information Form and this KAMRA™ corneal inlay Informed Consent and discuss all your questions and concerns with your surgeon or personal eye care provider.

**Alternatives to KAMRA corneal inlay.** The safest alternative to the KAMRA corneal inlay is to continue to wear your eyeglasses or contact lenses and not have the corneal inlay. Other surgical alternatives to the KAMRA corneal inlay include Monovision LASIK, bifocal contact lenses or intraocular lenses. Be sure to ask your surgeon or personal eye care provider to learn more about these procedures.

**You May Not Be a Candidate for KAMRA Corneal Inlay If You:**

- Have eye inflammation or infection, severely dry eyes, excessive corneal scarring, certain degenerations or dystrophies of the cornea, amblyopia (lazy eye), strabismus (muscle imbalance) or previous strabismus surgery, keratoconus or any recurrent, residual or active eye condition that may affect healing.
- Have a history of herpes simplex eye infections, uncontrolled vascular disease, uncontrolled diabetes, an autoimmune disease or rheumatologic condition, such as lupus or rheumatoid arthritis.
- Are immunocompromised or take medications that may suppress your immune system.
- Have an implanted electronic device such as a pacemaker or defibrillator.
- Have progressive nearsightedness or farsightedness.
- Have previously undergone corneal surgery.
- Have corneal blood vessel growth within 1 mm of the ablation zone.
- Have a history of keloid formation.
- Take certain medications, such as Accutane, Cordarone or Imitrex.

**Risks and Complications of KAMRA Corneal Inlay.** This KAMRA Informed Consent summarizes possible risks and complications associated with KAMRA; however, it is impossible to list all the potential risks and complications of KAMRA. Because KAMRA is a relatively new procedure, certain risks and complications associated with it may be unforeseeable at this time. As a result, it is important to be aware that the long-term studies and results of KAMRA may reveal additional risks and complications not described in this KAMRA Informed Consent.

**Vision-threatening complications.** Certain complications of KAMRA may seriously affect your vision and may not be correctable with eyeglasses or contact lenses. The most serious complication can result in loss of vision or require a corneal transplant. These complications include:

- Pulsion-FS laser (IntraLase) malfunction, causing an abnormal corneal pocket and leading to loss of vision not correctable by eyeglasses or contact lenses.
- Displaced inlay causing permanent irregularity of the cornea and leading to loss of vision not correctable with eyeglasses or contact lenses.
- Irregular corneal healing, causing distortion, ghost images or scarring.
- Epithelial (protective outer layer of the cornea) healing defects, resulting in delayed healing, pain, light sensitivity, infection or growth of epithelium under the corneal pocket.
- Corneal infection, resulting in permanent scarring or perforation of the cornea.
- Corneal inflammation, which may result in scarring, farsightedness and irregular corneal healing.
- Intractable glare and inability to function in a dark environment due to small aperture of the KAMRA corneal inlay.
- Retinal detachment, venous or arterial blockage of the retina, hemorrhage (bleeding) of the retina, cataract formation, total blindness or loss of the eye.
- Complications due to the anesthetic drops or other medications used in conjunction with KAMRA.

**Other complications.** KAMRA may result in additional complications, including:

- Loss of corneal endothelial cells
- Astigmatism, creating a need for eyeglasses.
- Worsening of your uncorrected distance vision while improving your distance vision.
- Dry eye, which generally is treatable with artificial tears and resolves in 1-3 months, but which on rare occasions, may be permanent.
- Alteration in your night vision, which for some patients means poorer quality night vision.

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**Other Complications - Continued**

- The following common side effects which are usually temporary but which may be permanent: pain or discomfort, foreign body sensation, increased sensitivity to light, glare and halos around lights, haze (clouding of the cornea sometimes causing blurred vision) or fluctuating vision.
- Diminished contrast sensitivity.
- Difference in the perceived pupil size in each eye (cosmesis)
- Ptosis (droopy eyelids).
- Increased vulnerability of your eyes to trauma from impact for the first year or longer after KAMRA; it is recommended that you wear protective eyewear when engaging in activities where the possibility of trauma to the eye exists.
- Difficulty identifying necessary intraocular lens power for cataract surgery lens calculations and predicting refractive outcome.
- Death.

**Additional risks.** Because of the potential risks associated with KAMRA, it is very important to provide complete and accurate medical information to your surgeon. If you fail to provide complete and accurate information, you may be subject to additional risks and complications, or the risk of complications may increase.

**Patient Agreement**

By signing this KAMRA Informed Consent, you understand and agree as follows (check all that apply):

- The information contained in this KAMRA Informed Consent has been explained to me using terms I could understand, and all my questions and concerns have been addressed.
- I have received and reviewed the Vision Correction Surgery Patient Information Form, and the information contained therein has been explained to me using terms I could understand, and all my questions and concerns have been addressed. (For more information regarding the KAMRA procedure, please consult the Vision Correction Surgery Patient Information Form, page 2.)
- I understand that, during the KAMRA procedure, the corneal pocket will be created using an instrument called a Pulsion-FS laser.
- My clinical findings in relation to the risks of keratectasia (corneal ectasia) have been thoroughly explained to me and I am fully aware of the possible risks and complications associated with vision correction surgery. I understand that there is no absolute test to ensure that I will not develop keratectasia following vision correction surgery, and that while severe keratectasia may need to be treated with a corneal transplant, mild keratectasia can be corrected with the use of glasses or contact lenses. (For more information regarding keratectasia, please consult the Vision Correction Surgery Patient Information Form, page 6.)
- I understand that KAMRA is an elective procedure and hereby freely accept all possible risks, complications and side effects that may result from KAMRA.
- I understand that no guarantees have been made to me regarding the outcome of KAMRA, and that I remain financially responsible for all costs associated with the surgery.

**Patient's Signature:** \_\_\_\_\_

**Patient's Name: (Print)** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Witness's Signature:** \_\_\_\_\_

**Witness's Name: (Print)** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Surgeon's Signature:** \_\_\_\_\_

**Surgeon's Name: (Print)** \_\_\_\_\_

**Date:** \_\_\_\_\_