GENERAL INFORMATION

This informed consent has been created to provide you with information about surgery to improve near vision with the KAMRA™ inlay. It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. Risks and complications that are considered to be unforeseeable, remote or uncommonly known are not discussed.

AN OVERVIEW OF THE KAMRA™ PROCEDURE

The implant measures 3.8mm in diameter with a central opening of 1.6mm and is 5 microns thick. Tiny holes throughout the KAMRA inlay help assist the natural nutrient flow and waste transport system in your cornea. It is made from polyvinylidene fluoride (PVDF), which is a material that has a long history of use in medical devices. Carbon black is used to create the opaque feature of the KAMRA inlay.

The KAMRA inlay is placed within the corneal stroma (the body of the cornea), directly in front of the pupil. The central light rays entering your eye are more focused than peripheral light rays, which can blur your vision. The KAMRA inlay blocks these peripheral light rays allowing only the focused central rays to enter your eye. By blocking the light rays that can blur your vision, the KAMRA inlay can provide a clearer image at a much wider range of distances providing you including improvement in your near vision.

SURGERY: To implant the KAMRA inlay, a flap or pocket will be created in your cornea using a type of laser called a femtosecond laser, which is used in LASIK (laser eye surgery). The KAMRA inlay will be placed centrally in the cornea. If in addition to your presbyopia you also have myopia or hyperopia or have astigmatism, a second laser, (the excimer laser) will be used to reshape your cornea to allow for the best visual effect to be achieved.

During the procedure you will be lying on your back and asked to focus on a light above your eye. The surgery is performed using a topical anesthetic (drops in the eye). The surgeon will describe the procedure to you step-by-step, which takes 10-20 minutes to perform.

When the implant is in place, your pupil may look slightly larger than it might otherwise appear in daylight.

You may be administered treatment for dry eyes including punctal plugs. These are inserted into the tear ducts to reduce the drainage of tears in people who have a tendency for dry eyes.

Usage of eye drops will be required post-operatively. A small group of patients may develop a reversible rise in intraocular eye pressure as a result of the use of a steroid eye drop. In this case, the eye drop may be changed and/or a pressure reducing drop be prescribed.

BENEFIT

I understand this procedure may reduce my dependency on glasses or contact lens for near and intermediate vision in my implanted eye. It can take several weeks or even months to get the full result.

RISKS AND SIDE EFFECTS

It is possible that you will experience some side effects (blurry vision, dry eye syndromes, night glare). There might be an adaptation period where you will not see the maximum effect of the inlay, this period takes a few days or weeks in most patients, but can take longer if there are special conditions, e.g. a very dry surface of the cornea.

• It is possible that your distance vision in the implanted eye decreases.
• The KAMRA Inlay can induce refractive changes in the implanted eye. It is possible but not guaranteed that this change can be corrected by glasses or contacts. It is possible that you might need to use glasses or contacts after surgery.
• It is possible that the expected results are not achieved or over a long period of time you experience a gradual natural loss of vision.
Another risk is a loss of endothelial cells. The function of those cells in the cornea is to control metabolism and nutrition. If there is a severe loss of cells, the clarity of your cornea can worsen resulting in a decrease of visual acuity. In the worst case scenario, a corneal transplantation might be needed. In the worldwide clinical trials there was no evidence found for a greater loss of endothelial cells.

Because of the small aperture of the KAMRA inlay, night vision in the implanted eye may be decreased. It is also possible that you will recognize symptoms like Glare or Halos, esp. while driving at night.

Other risks are:
- Infections
- Epithelial Ingrowth
- Flap Displacement
- Flap Melt
- Corneal Edema
- Corneal Haze
- Ocular Hypertension
- Decrease of Vision
- Cataract
- Retinal Detachment
- Retinal Bleeding
- Infections
- Epithelial Ingrowth
- Flap Displacement
- Flap Melt
- Corneal Edema
- Corneal Haze
- Ocular Hypertension
- Decrease of Vision
- Cataract
- Retinal Detachment
- Retinal Bleeding

Most of those risks are similar to other laser vision correcting procedures (LASIK, PRK, etc.) that are approved and performed worldwide for about 25 years in millions of patients. If one of the above complications occur, your surgeon might need to perform an additional surgery (including removal of the inlay) to ensure the health of the eye and best functional result for you.

It is also possible that the inlay has to be removed later on to ensure optimal treatment of other eye diseases.

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

Since it is impossible to identify every complication that may occur as a result of any surgery, you should understand that this list of risks may not be complete. Risks may exist that are unforeseeable at this time.

**ALTERNATIVE TREATMENTS**

Implantation of a corneal KAMRA inlay is not the only means of improving your near vision. The following is a list of currently approved alternatives for improvement of near vision in presbyopic eyes:

- Spectacles
- Contact Lenses
- Monovision
- Bifocal Contact Lenses
- Laser Refractive Surgery
- Intraocular Lenses

**PATIENT STATEMENT**

I have read this Informed Consent (or it has been read to me). The KAMRA procedure has been explained to me in terms that I understand. I have been informed about the possible benefit and possible complications, risks, consequences and contraindications associated with KAMRA. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur. I have been given the opportunity to ask questions and have received satisfactory answers to any questions that I have asked. I understand that no guarantee of a particular outcome was given and that my vision could become better or worse following the procedure.

I consent to have implantation of the KAMRA inlay to my ___________________________.

(state “left” or “right” eye)

____________________________________________________________   _________________________
Patient’s Signature (or person authorized to sign for patient)  Date

____________________________________________________________
Print Patient’s Name

____________________________________________________________   _________________________
Witness’ Signature  Date
POST-OPERATIVE CARE INFORMED CONSENT

I understand that I have the option of where I would like my postoperative care to occur. I understand that I have the option to continue my postoperative care with Vance Thompson Vision or I have the option to have my postoperative care handled with my eyecare provider. I understand that at any point in time I have the option of returning for follow-up care with my own eye doctor. At this point in time, having a clear understanding of all that is involved in the postoperative care and the need to keep up with all postoperative appointments as an integral part of the success of my refractive surgery procedure.

I have chosen to do my postoperative care with ____________________________________________.

Patient’s Signature (or person authorized to sign for patient) ________________________________ Date ________________

Print Patient’s Name ________________________________________________________________

Witness’ Signature ________________________________ Date ________________