

Informed Consent
KAMRA Corneal Inlay for Correction of Presbyopia



PATIENT NAME: _____ **RM:** _____

This information sheet has been created to provide you with information about surgery to restore near vision with the KAMRA™ inlay.

In addition to the general information sheet about refractive surgery, this paper provides you with more details about the surgical procedure, benefits and potential complications.

Before your surgery you will be asked about your medical history and medications. Afterward several diagnostic assessments will be performed. The results will be explained by your surgeon.

▪ **What's the KAMRA Corneal Inlay?**

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.

▪ **How is the Surgery performed?**

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 standard LASIK (laser eye surgery). The KAMRA inlay will be placed centrally in the cornea. If you are in addition to your presbyopic also myopic or hyperopic 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. You will receive drops to anaesthetize your eye to minimize discomfort during the procedure. The surgeon will describe the procedure to you step-by-step, which takes 10-20 minutes to perform.

After the procedure is complete, a patch or protective cover may be placed over your eye and you will be able to go home. When the implant is in place, your pupil may look slightly larger than it might otherwise appear in daylight if you have light colored Iris.

You may be administered treatment for dry eyes including punctual plugs. These are inserted into the tear ducts to reduce the drainage of tears in people who have a tendency for dry eyes. They are tiny tubes made of a material that might or might not be absorbed by the body over time.

Eye drops will be required for a period of 4 to 6 months after the procedure. Some patients benefit from using eye drops beyond this initial period. Your doctor will advise you.

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

▪ **What is the benefit of the Inlay?**

Implanting the KAMRA Inlay™ restores your intermediate and near vision in your implanted eye which should reduce your dependency of glasses or contacts. After surgery you should notice that you don't need glasses or contacts in most circumstances.

As described above, the inlay blocks unfocused light and allows only focused light rays to enter the eye which gives you a greater depth of field, similar to a small camera aperture. It can take several weeks or even months (in a small amount of patients) to get the full result.

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

▪ **Are there possible risks or side effects?**

It is possible that you will experience some side effects (blurry vision, dry eye syndromes). 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:
 - o Infections
 - o Epithelial Ingrowth
 - o Flap Displacement
 - o Flap Melt
 - o Corneal Edema
 - o Corneal Haze
 - o Ocular Hypertension
 - o Decrease of Vision
 - o Cataract
 - o Retinal Detachment
 - o 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.

Patient’s Declaration

I received a copy of this information sheet: “Kamra Inlay for Correction of Presbyopia”.

I was given enough time to read this information and to decide for or against this procedure.

I discussed each section with the doctor and/or surgeon and understood them. Alternative solutions were discussed as well.

I do not have any question and I agree with the procedure.

_____ Right Eye _____ Left Eye

Patient Signature

Date

Witness Signature

Date

Surgeon Signature

Date

I have been offered a copy of this consent form (please initial) _____