**Instructions for use**

Remove this section.

This consent form is for on-label use of the Kamra inlay. It was approved for a very narrow range of indications.

Remove the two sentences in [yellow] if you are using the femtosecond laser to create a pocket.

Add your letterhead to the first page of the consent form.

Keep each section together on the same page: move it as needed.

Change font size for large print.

**Informed consent for the KAMRA inlay to treat presbyopia**

Presbyopia makes it hard for you to see things close up (near vision). This happens to most people as they age. People with presbyopia hold a book at arm’s length to see it more clearly. Some remove their eyeglasses to see more clearly.

There are treatments to correct presbyopia and improve your near vision.Your eye surgeon will talk to you about your choices. Most people wear reading glasses or contact lenses to treat presbyopia. There are several different surgeries you can have to correct presbyopia. These include refractive surgery (LASIK, PRK, or CK). The Kamra inlay is another type of surgery you can choose.

The KAMRA inlay is a round, plastic disc that is placed inside one of your eyes. It is smaller and thinner than a contact lens. The eye surgeon uses a laser to make a pocket over the pupil in the clear part of your eye called the cornea. The eye surgeon then places the inlay in this pocket. [Or the eye surgeon could use a blade to make a flap. The eye surgeon then places the inlay under the flap.]

The Kamra inlay may help you to see close-up objects more clearly.It does this by changing the way that light enters your eye. You may be able to read without wearing glasses or contact lenses.

There are risks (problems) that can happen if you have any surgery. Sometimes surgery can make the problem worse, cause an injury, or create a new problem. If it does, this is called a complication. Complications can happen right away or not until days, months, or years later. You may need more treatment or surgery to treat the complication. If the complication happens during surgery, your surgeon may need to perform another surgery right away to treat it. Your surgeon may discover a new condition or problem for the first time during the surgery. The surgeon may need to change the plan for surgery to treat this problem or condition right away.

**There are risks that can happen with the Kamra inlay.** Your eye surgeon cannot tell you about every risk. Here are some of the serious or common ones.

* **The Kamra inlay surgery could harm your vision or your eye**
  + You could lose some or all of your vision in that eye
  + You could get an eye infection
  + Your cornea could get damaged. Your cornea could become scarred, cloudy, or swollen. This could make it hard to see clearly. Your cornea could weaken and start to bulge out. You might need a cornea transplant if the damage is severe or if your eye won’t heal.
  + Your eye pressure could get high or cause glaucoma. This happens to some patients when they take steroid drops. Steroid drops are taken to decrease swelling after the surgery.
  + Your inlay could get dislocated and move out of position. If it does, the eye surgeon might need to put it back in place.
  + [The flap could get dislocated and move out of position. If it does, the eye surgeon might need to put it back in place.]
  + You may not be able to have refractive surgery if you have an inlay.
  + You may need to have the Kamra inlay removed if you are not happy with the result. Your vision might not go back to what it was before surgery.
  + It might be difficult for your eye surgeon to examine your eyes, do some eye tests, or treat eye diseases. The inlay may need to be removed to treat your eye.
* **The Kamra inlay could cause problems with your vision or your eye**
* You may get a condition called dry eye. If you already have dry eye, it could get worse. Dry eye can make your eye burn, tear, or feel scratchy.
* You may still need to wear glasses or contact lenses to read small print or in low light.
* You may still need to wear glasses or contact lenses to use your computer.
* You may have changes in your vision. You can have double vision, glare, halos, blurry vision, ghosting, or color changes. Your glasses prescription may change. Your distance vision may change.
* You may have decreased contrast sensitivity. This means that it may be hard to see well in the early evening (at dusk) or to read in a poorly-lit room.
* Your pupils may appear to be different sizes.

**Consent**. By signing below, you consent (agree) that:

* You read this informed consent form, or someone read it to you.
* You understand the information in this informed consent form.
* The eye surgeon or staff offered you a copy of this informed consent form.
* The eye surgeon or staff offered you a copy of the Kamra patient information booklet.
* The eye surgeon or staff answered your questions about the Kamra inlay.
* You understand that you may need to wear glasses or contact lenses after the surgery.
* You understand that the inlay may need to be removed.

**I consent to have a Kamra inlay in my \_\_\_\_\_\_\_\_\_\_ (state “right” or “left”) eye.**

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