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IntraLASIK Correction of Nearsightedness, Farsightedness, and Astigmatism Using IntraLase™ Technology

Indications and Procedure

This information is being provided to you so that you can make an informed decision about IntraLASIK, or "all-laser" LASIK.

The iLASIK surgery also involves two procedures. First, it uses the FDA-approved IntraLase™ laser to create a flap with laser energy. The IntraLase laser is capable of creating extremely precise flaps by producing tiny bubbles inside the cornea that are 1/10,000 of an inch in diameter. The laser beam cannot penetrate into the eye beyond the cornea. After the flap is created, the excimer laser is used to reshape the eye by removing ultra-thin layers from the cornea in order to reduce farsightedness, nearsightedness, or astigmatism. The flap is returned to its original position, without sutures.

Take as much time as you wish to make a decision about signing this form. You are encouraged to ask any questions and have them answered to your satisfaction before you give your permission for surgery. Every surgery has risks as well as benefits, and each person must evaluate this risk/benefit ratio for himself/herself in light of the information presented in the information that follows.

ALTERNATIVES

IntraLASIK is an elective procedure: there is no emergency condition or other reason that requires or demands that you have it preformed. There are alternatives to this surgery: you could continue wearing contact lenses or glasses and have adequate visual acuity. There are also other types of refractive surgery, including LASIK with a microkeratome.

RISKS AND COMPLICATION

This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur: should this happen in your case, the result might be affected even to the extent of making your vision worse. In giving my permission for

IntraLASIK, I understand the following: The surgeon will use the FDA-approved IntraLase™ laser to create a flap, and the FDA-approved excimer laser to reshape the eye. The long-term risks and effects of IntraLASIK, are unknown. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure.

Spectacles and contact lenses are the most common methods of correcting nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. When tolerated well, they are likely to be a good alternative to LASIK surgery. Refractive surgery is continually evolving and other refractive procedures may be available as an alternative to LASIK. You should also be aware that having any refractive procedure could potentially disqualify you from some professions, including the military and certain law enforcement agencies.

LASIK permanently changes the shape of the cornea. The surgery is performed under a topical anesthetic (drops in the eye). The procedure involves folding back a thin layer of corneal tissue (corneal flap) and then removing a thin layer of corneal tissue with the light from an excimer laser. After removal, the flap (corneal flap) is replaced and bonds back into place without the need for stitches. The result of removing thin layers of tissue causes the center of the cornea to flatten in the case of nearsightedness, or steepen in the case of farsightedness, or become more rounded in the case of astigmatism, which changes the focusing power of the cornea. Although the goal of LASIK is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (or weaker) glasses, this result is not guaranteed.

You should understand that LASIK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment. After the procedure, you should avoid rubbing the eye.

Your eyes may be more susceptible to traumatic injury after LASIK and protective eye wear is recommended for all contact and racquet sports where a direct blow to the eye could occur. Also, LASIK does not correct the condition known as presbyopia (or aging of the eye) which occurs to most people around age 40 and may require them to wear reading glasses for close-up work. People over 40 that have their nearsightedness corrected may find that they need reading glasses for clear, close vision.

During pregnancy, your refractive error can fluctuate, which could influence your results. If you know you are pregnant or attempting to become pregnant within the next three months, it is important that you advise your doctor immediately. You should also tell your doctor about any medications that you are taking such as hormone replacement therapy or antihistamines as they may influence healing.

POTENTIAL RISKS OF LASIK INCLUDE:

1. **LOSS OF VISION.** LASIK surgery can possibly cause loss of vision or loss of best corrected vision. This can be due to infection, irregular scarring or other causes, and unless successfully controlled by antibiotics, steroids or other necessary treatment, could even cause loss of the infected eye. Vision loss can be due to the cornea healing irregularly which could add astigmatism and make wearing glasses or contact lenses necessary, and useful vision could be lost. It is also possible that you may not be able to successfully wear contacts after LASIK.

2. **VISUAL SIDE EFFECTS.** Other complications and conditions that can occur with LASIK surgery include: anisometropia (difference in power between the two eyes), aniseikonia (difference in image size between the two eyes, double vision, hazy vision, fluctuating vision during the day and from day to day, increased sensitivity to light which may be incapacitating for some time and may not completely go away, and glare and halos around lights which may not completely go away. Some of these conditions may affect your ability to drive and judge distances, and driving should only be done when you are certain your vision is adequate.
3. **OVER-CORRECTION AND UNDER-CORRECTION.** LASIK surgery may not give you the result you desired. If after the procedure you are either under-corrected or over-corrected, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. If you were nearsighted, over-correction could result in farsightedness. If you were farsighted, over-correction could result in nearsightedness. Over-corrections, especially when treating farsightedness, often diminish with time but could be permanent. It is also possible that your initial favorable results could regress over time, as the eyes naturally age.
4. **OTHER RISKS.** Additional reported complications include: corneal ulcer formation, endothelial cell loss, epithelial healing defects, ptosis (droopy eye lid), corneal swelling, retinal detachment and hemorrhage. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full thickness corneal transplant using a donor cornea. These complications include: loss of corneal disc, damage to the corneal disc, disc decentration and progressive corneal thinning (ectasia). Sutures may also be required, which could induce astigmatism. There are also potential complications due to anesthesia and medications which may involve other parts of your body. It is also possible that the IntraLase or the excimer laser could malfunction and the procedure could be stopped. Since it is impossible to state all potential risks of any surgery, this form is incomplete.
5. **FUTURE COMPLICATIONS.** You should also be aware that there are other complications that could occur that have not been reported before the creation of this consent form as LASIK surgery has been performed only since the early 1990s and longer term results may reveal additional risks and complications.
6. **DRY EYE.** Many patients having LASIK already have dry eyes, especially those who are contact lens intolerant or who are older than their mid 30s. In some people, LASIK can make dry eyes temporarily worse. In these cases, the eye usually returns to its pre-LASIK state within several months. In some cases, the worsening of dry eye may be permanent necessitating the placement of punctal plugs and/or the permanent use of artificial tears.

POST-OPERATIVE INSTRUCTIONS:

After your surgery you will be given medications and instructions to help prevent infection and control healing. It is imperative that you follow ALL instructions exactly as they are given to you. It is also imperative that all follow-up visits be kept as directed.

CONSENT:

In signing this form, you are stating that you have read this consent form and although it contains medical terms which you may not completely understand, you have had the opportunity to ask questions and had them answered to your satisfaction.

You also give your permission for medical data concerning your operation and related treatment, and any video recordings of your surgery to be released to physicians and others demonstrating a “need-to-know” for clinical study.

I am making an informed decision in giving my permission to have Laser Assisted In-Situ Keratomileusis (LASIK) surgery performed on my:

right eye **left eye** **both eyes** by Richard S. Hoffman M. D. at Oregon iLasik & Refractive Center

Signature of Patient _____ Date _____ Time of Day _____

Signature of Witness _____ Date _____ Time of Day _____

Signature of Surgeon _____ Date _____ Time of Day _____