

Name: \_\_\_\_\_ Date: \_\_\_\_\_

## **INFORMED CONSENT FOR LASIK, CUSTOM LASIK, LASIK ENHANCEMENT, AND CUSTOM LASIK ENHANCEMENT**

This information is to help you make an informed decision about having Laser Assisted in-Situ Keratomileusis (LASIK) surgery to treat your nearsightedness, farsightedness, and/or astigmatism. You are encouraged to ask any questions and have them answered to your satisfaction. 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 by the doctor and the information that follows. For a successful experience you must accept responsibility for this decision. Read this document carefully. When all your questions and concerns have been adequately addressed and you have fully understood the information presented, please initial by the following statements:

- \_\_\_\_\_(Initial) 1) Spectacles and contact lenses are the most common method of correcting nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. When tolerated well, they are likely to be good alternatives to LASIK surgery. Other alternatives may include PRK (Photorefractive Keratectomy), intra-corneal rings, clear lensectomy (lens removal before cataract development) with intraocular lens insertion, intraocular lens insertion without lensectomy, conductive keratoplasty, thermal keratoplasty, incisional keratotomy, orthokeratology, or simply tolerating vision without correction. You should be aware that having any refractive procedure could potentially disqualify you from some professions, including some branches of the military and certain law enforcement agencies.
- \_\_\_\_\_(Initial) 2) LASIK permanently changes the shape of the cornea. The surgery is performed under a topical anesthetic (drops in the eye). The procedure involves creating and folding back a thin layer of corneal tissue (corneal flap) using a microkeratome, and then removing a thin layer of corneal tissue with the light from an Excimer laser. After removal, the flap is replaced and bonds back into place without the need for stitches. The result of removing thin layers of tissue changes the focusing power of the cornea allowing you to see clearer. 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. In some cases additional procedures, spectacles, or contact lenses may be required to achieve adequate vision.
- \_\_\_\_\_(Initial) 3) You should understand that LASIK surgery would not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration, retinal detachment, and progressive myopia. LASIK does not decrease, and may increase your need for periodic ocular health evaluation and management. A complete eye exam is recommended at least yearly.
- \_\_\_\_\_(Initial) 4) After the procedure, you should avoid rubbing the eyes. Any trauma to the eye, especially during the first 2 weeks following your surgery, can severely compromise your long-term visual results. Caution around small children is emphasized. Protective eyewear is always recommended for all contact and racquet sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye exists.

- \_\_\_\_\_(Initial) 5) LASIK does not correct the condition known as PRESBYOPIA. Presbyopia is a natural aging process inside the eye that leads to a progressive loss of up-close focusing ability, making it more difficult to see near objects, despite a clear view of distance objects. While this does not usually become problematic before the age of 40, it WILL occur and warrants consideration before having LASIK. **People over 40 that have their distance vision fully corrected with LASIK will find that they need reading glasses for clear, up-close vision. If you demand clear vision in both eyes both at far and near regardless of age and will not wear reading glasses, then LASIK is not for you!** Alternatives exist such as monovision, purposeful undercorrection, and clear lensectomy with multifocal intraocular lens insertion. These options should be discussed during your consultation. Since LASIK does not correct presbyopia, you may be required to wear reading glasses for all close up work such as reading.
- \_\_\_\_\_(Initial) 6) Understand that if you currently do not require reading glasses and are over age 40, you will very likely require reading glasses immediately or soon after LASIK (even if you currently take your glasses off to read).
- \_\_\_\_\_(Initial) 7) Female patients only: During pregnancy and nursing, 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, or if you are nursing, it is important that you notify your doctor immediately. If you feel you could be pregnant at the time of surgery, postpone your procedure and consult with your gynecologist or family physician. You should also tell your doctor about any medications that you are taking, such as hormone replacement therapy, as they may influence healing.

### **POTENTIAL RISKS OF LASIK:**

- \_\_\_\_\_(Initial) 8) LOSS OF VISION. Although rare, LASIK surgery can possibly cause loss of vision or loss of best-corrected vision. This can be due to infection, severe inflammation, 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 require wearing glasses or contact lenses to obtain useful vision. Rarely, it is also possible that you may not be able to successfully wear contacts after LASIK.
- \_\_\_\_\_(Initial) 9) LOSS OF BEST-CORRECTED VISION: Understand that irregular healing of the flap could result in a distorted cornea. This would mean that even glasses or contact lenses might not correct the vision to the level that was possible before undergoing LASIK. In other words, it is possible that the vision may not be correctable to 20/20 after the procedure, even though it was before the procedure. This is called loss of best-corrected vision. If not improved with hard contact lens wear, and if the visual distortion is sufficiently severe, a partial or complete corneal transplant may be necessary to repair the cornea and/or restore useful vision.
- \_\_\_\_\_(Initial) 10) VISUAL SIDE EFFECTS. Other complications and conditions that can occur with LASIK surgery include: double vision, image ghosting, hazy vision, fluctuating vision throughout the day, increased sensitivity to light which may be incapacitating for some time and may not completely go away, dryness, glare, and halos around lights which may not completely go away. Some of these conditions may affect your ability to drive and judge distances. Driving should only be done when you are certain your vision is adequate.

- \_\_\_\_\_ (Initial) 11) **OVERCORRECTION AND UNDERCORRECTION.** There is a small chance that LASIK surgery may not give you the result you desired. As a result of the surgery, it is possible that your vision may not be fully corrected to 20/20 vision. If you have previously worn hard contact lenses, the shape of your eyes may have been altered, which can present more difficulty and more than one procedure may be required. If after the procedure you are either undercorrected or overcorrected, it may be possible to have additional surgery to fine-tune or enhance the initial result. However, the enhancement outcome cannot be guaranteed. Understand that temporary glasses for distance may be necessary while awaiting an enhancement. It is also possible that your initial favorable results could regress over time. **If both you and your physician decide that an enhancement is warranted, the enhancement will be performed at a discounted fee of \$250 per eye for up to one year from the time of original LASIK surgery.** In some cases, it may not be possible to have any additional laser surgery due to insufficient residual corneal thickness. In such cases, it may be necessary to return to glasses or contact lens wear.
- \_\_\_\_\_ (Initial) 12) **DRY EYE SYNDROME:** LASIK can exacerbate or induce a temporary and rarely a permanent dry eye state. This may cause discomfort and blurred vision. Effective interventions exist and can be utilized to maintain ocular health and comfort.
- \_\_\_\_\_ (Initial) 13) **NIGHT VISION DIFFICULTY:** LASIK can cause a “starbursting” or “halo” effect around lights, usually seen at night or in darkened environments. This condition usually occurs within the first 3-6 months and diminishes with time, but in some cases can be permanent. Patients with large pupils and/or severe myopia are at greatest risk for these symptoms. Understand that your vision may not seem as sharp at night as during the day, and that you may need to wear glasses during these times.
- \_\_\_\_\_ (Initial) 14) **EPITHELIAL INGROWTH:** During the first 24 hours, the epithelial protective layer grows over the flap. There is a small risk that epithelial cells may grow underneath the flap after the initial LASIK procedure. There is an increased risk of epithelial ingrowth in retreatment LASIK procedures (i.e. a second treatment) or enhancement procedures. Treatment of this condition usually involves lifting the flap and clearing the cells. Untreated epithelial ingrowth, if severe and progressive, may distort vision and may actually damage the flap. Small ingrowths do not usually present any visual problems and often can be monitored.
- \_\_\_\_\_ (Initial) 15) **CORNEAL FLAP COMPLICATIONS:** It is possible that an irregular or partial flap can occur during the initial stages of the procedure. This can occur secondary to excessive squeezing, a Microkeratome malfunction, or for some unknown reason, leading to a premature halt to the procedure before completion. In this case, the eye would need to heal for 3-6 months before the entire LASIK or PRK procedure could be considered again. Furthermore, there may be an increased risk of epithelial ingrowth, visual side effects, loss of best corrected visual acuity, or corneal scarring associated with repeated LASIK/PRK in patients with this complication. Depending on the type of malfunction, this may or may not be accompanied by temporary or permanent visual loss.
- \_\_\_\_\_ (Initial) 16) **CORNEAL ABRASION:** In some instances, the corneal surface (epithelium) can be abraded during the LASIK procedure. This can lead to discomfort and associated blurred vision for one or more days. A corneal abrasion can increase the likelihood of epithelial ingrowth under the flap, infection, inflammation, and/or astigmatism. It can also lead to recurrent corneal erosion, with episodes of a sharp gritty feeling in the eye and blurry vision noticed upon awakening. Effective medical and/or surgical interventions exist to treat corneal erosion, should it occur.

- \_\_\_\_\_ (Initial) 17) Occasionally a soft contact lens may be placed on the eye just after surgery for therapeutic purposes. There should not be any removal of this lens without the assistance of a physician. If for some reason, the contact lens is removed, place the contact lens in contact lens or artificial tear solution in a clean container and call your physician as soon as possible. Do not discard the lens as there may be corneal tissue attached.
- \_\_\_\_\_ (Initial) 18) OTHER RISKS: Additional reported complications include, but are not limited to: corneal ulcer formation, corneal swelling, corneal haze, corneal ectasia (bulging), corneal melt, endothelial cell loss, chronic epithelial healing defects, flap wrinkles, dislocated flap, trapping of debris under the flap, decentered laser ablation, central islands, ptosis (droopy eyelid), optic nerve injury, chronic eye pain, retinal detachment or damage, retinal tears and/or vitreous detachment, hemorrhage, arterial or venous blockage, and cataract formation. These risks and potential complications may result in the need for additional surgery and/or the loss of visual acuity or best-corrected acuity. Although rare, complications could also arise requiring further corrective procedures including either a partial (lamellar) or full thickness corneal transplant using donor cornea tissue. These complications include, but are not limited to: corneal perforation, chronic corneal swelling, corneal scarring, severe corneal thinning, loss of the corneal flap, displacement, amputation or damage to the flap, severe flap wrinkles, progressive corneal thinning (keratoectasia), and severe infectious or inflammatory keratitis. Sutures may also be required which could induce astigmatism. Since it is impossible to state all potential risks of any surgery, this form is incomplete.
- \_\_\_\_\_ (Initial) 19) Understand that there are also potential complications due to anesthesia, drug reactions, or other factors that may involve other parts of the body. Medication will be offered to facilitate the LASIK procedure. This includes anti-anxiety medications and pain-relievers. If you take these medications, it is your responsibility to exercise appropriate precautions afterwards (avoid driving, operating dangerous equipment, etc.) Understand that the use of these medications while pregnant or nursing could seriously jeopardize the fetus (child). It is your responsibility to notify your doctor immediately if you feel you could be pregnant.
- \_\_\_\_\_ (Initial) 20) 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. Failure to comply can jeopardize your final visual result and/or your ocular health. Patients are advised to avoid business or travel plans that would require them to leave the area for the first week after LASIK. (In the unusual event that you have a post-operative problem, close follow-up with frequent office visits may be required).
- \_\_\_\_\_ (Initial) 21) 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.
- \_\_\_\_\_ (Initial) 22) The F.D.A. has approved our laser for LASIK in a wide range of refractive errors. Some refractive errors, however, are still in F.D.A.-sponsored clinical trials. We prefer to use our surgical judgement and expertise in the interim. Your treatment plan may include **off-label** (non F.D.A.-sanctioned) techniques.
- \_\_\_\_\_ (Initial) 23) I understand that LASIK treatment should not be performed on patients with uncontrolled vascular disease, autoimmune diseases, uncontrolled diabetes, or on those who are on medication or therapy that suppresses the immune system.

- \_\_\_\_\_ (Initial) 24) I do not have keratoconus, which is a cone-shaped distortion of the cornea. LASIK treatment should not be performed on patients with signs of keratoconus (patients with this condition have unstable corneas).
- \_\_\_\_\_ (Initial) 25) I do not have a history of Herpes Simplex or Herpes Zoster virus affecting my eyes. LASIK treatment is not recommended to patients with history of Herpes Simplex Virus or Herpes Zoster infection affecting the eye (cases of Herpes reactivation have been reported after LASIK).
- \_\_\_\_\_ (Initial) 26) I understand that LASIK should not be performed in patients taking Isotretione (Accutane) or Amiodarone hydrochloride (Cardarone).
- \_\_\_\_\_ (Initial) 27) I understand that LASIK should not be performed in patients with uncontrolled diabetes.
- \_\_\_\_\_ (Initial) 28) I understand that my routine post-operative follow-ups at Global Laser Vision are included in the cost of the original LASIK procedure for up to one year from the original LASIK. Should I wish to receive any further care past this period, there will be an additional fee.
- \_\_\_\_\_ (Initial) 29) I understand that Global Laser Vision and/or its doctors are in no way responsible for any physical or mental requirements that may be requested of me by any present or future place of employment or educational facility.
- \_\_\_\_\_ (Initial) 30) I agree that in the event of any litigation or arbitration between the Patient and the Doctor/s, and/or the professional corporation and/or any of the employees of the professional corporation with respect to this agreement, all costs and expenses, including without limitation, actual professional fees such as experts', accountants', and attorneys' fees, incurring by the prevailing party therein shall be paid for by the opposing party. Accordingly, the prevailing party shall be entitled to an award of reasonable attorney's fees, experts' fees, and Accountants' fees and all costs and expenses involving the enforcement of this agreement in a Court of Law or in a binding Arbitration.

I acknowledge by signing this document, that I have read the foregoing information consisting of 5 pages including this page. It is my intention in affixing my signature below as well as initializing by the preceding paragraphs, to acknowledge that I have understood all of the information in the foregoing paragraphs, that as to any paragraphs containing any medical terms or information which I did not completely understand, I had the opportunity to ask questions and did ask questions, that such questions were answered to my satisfaction and that I therefore understood such information as set forth in such paragraphs. I further acknowledge that no representations have been made regarding the success of this surgery, except as set forth in this consent form. Furthermore, I am willing to accept the fact that I may need glasses or contact lenses or further surgery following LASIK to achieve my best possible level of vision.

By signing below, I hereby give my permission to have Standard or Custom Laser Assisted in-Situ Keratomileusis (LASIK) or Lasik Enhancement surgery performed by Dr. Chris Blanton on:

- both eyes."                       ----- my right eye."                       ----- my left eye."

Signature of Patient: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of Witness: \_\_\_\_\_ Date: \_\_\_\_\_