LASIK INFORMED CONSENT
INITIAL TREATMENT

PLEASE READ THE FOLLOWING PAGES CAREFULLY AND INITIAL AND SIGN WHERE INDICATED. PLEASE DO NOT SIGN ANY SECTION THAT YOU HAVE NOT READ OR DO NOT UNDERSTAND.

SECTION 1: **GENERAL INFORMATION ON INFORMED CONSENT**

It is our hope to fully inform you concerning the side effects, limitations and complications of LASIK surgery. We continually strive to balance the benefits of laser surgery with the known and unknown risks. It is important to understand that it is impossible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility. This consent form in combination with the extensive educational materials provided and the entire consultation process is designed to enhance your understanding of the potential for difficulties that may be encountered during both the procedure and the healing process.

Many of our patients are surprised and some are upset by the extent to which we attempt to inform them of the potential for complications. It is not our intention to frighten or dissuade someone from pursuing laser surgery, as most of our patients will never encounter any serious complications, and the vast majority are thrilled with the improvement they achieve. It is our intention, to accurately outline the associated risks to all candidates so that they may either elect not to accept the risks associated or be better prepared to deal with any unexpected complication or side effects which may arise. LASIK is a purely elective procedure, and you may decide not to have this operation at all. The only way to avoid all surgical risk is by not proceeding with surgery. Most refractive conditions are approved for LASIK treatment by the United States Food and Drug Administration (FDA) using several excimer lasers. The excimer laser is not indicated by the FDA to correct certain refractive conditions. However, it is legal to treat these certain refractive conditions **OFF LABEL** on a case by case basis when judged by your surgeon to be the best course of action for the treatment of your particular eye condition using the excimer laser. Your Doctor can provide you with the exact refractive conditions that have been approved by the FDA for LASIK treatment and those that are off label.

Patient Initials_____

SECTION 2: LASER VISION CORRECTION BACKGROUND SUMMARY:

TRADITIONAL LASIK:

Laser in situ Keratomileusis (LASIK), a form of laser vision correction, reshapes the part of the eye known as the cornea to possibly reduce or eliminate the need for glasses or contact lenses in cases of myopia(nearsightedness), hyperopia(farsightedness) and astigmatism (ovalness). There are two primary techniques for reshaping the cornea with laser surgery, PRK and LASIK. Both procedures are able to treat myopia, hyperopia and astigmatism but have benefits, limitations and risks. In both forms of laser vision correction, the transparent cornea at the front of the eye is reshaped with your prescription. PRK or photorefractive keratectomy reshapes the surface layers of the cornea while LASIK, fine tunes the inner corneal layers with the Excimer laser. The excimer laser produces a cool beam of ultraviolet light energy, capable of removing very precise amounts of corneal tissue to change the shape or curvature of the cornea and potentially improve your vision. The LASIK procedure is a newer more advanced form of keratomileusis, a procedure that has been practiced in South America and Europe for over 30 years.

Both PRK and LASIK are performed on an outpatient basis and take only 5-15 minutes to complete. Although patients often feel some pressure sensation, both procedures are painless. In both the PRK and LASIK procedures, topical anesthetic drops are used to thoroughly numb the eye and an eyelid holder is used to prevent blinking. Patients focus on a red target light throughout both procedures. In the PRK procedure, the surgeon first removes the corneal epithelium or protective surface layer of the cornea. The Excimer laser then applies computer-controlled pulses of light energy to the corneal surface to reshape the eye. A bandage contact lens is typically inserted or the surgeon may patch the eye closed following PRK for a few days. The epithelium grows back over 3-4 days and the vision gradually improves once the protective layer is healed.

In the LASIK procedure, a protective corneal flap is created using a very sophisticated surgical instrument known as a microkeratome. The protective flap is about 30% of the corneal thickness and is hinged either along the nasal or inside edge of the cornea or beneath the upper eyelid. A LASIK suction ring holds the eye in position while the automated microkeratome creates the corneal flap. Patients are unable to see the corneal flap being made as the vision becomes gray when the suction is applied and the red target light disappears until the flap is completed. Most patients sense some vibrating pressure, but the microkeratome incision is completely painless. When the laser pulses are completed, the corneal flap is replaced and the natural suction within the cornea seals the corneal flap within 1-5 minutes. No sutures are needed as the corneal flap seals rapidly. A bandage contact lens is not typically required with LASIK and a protective eyeshield rather than a patch may be needed. This should be used as your doctor advises but certainly is recommended while sleeping for a minimum of 4 nights, but only while sleeping. Although the vision is blurry immediately following LASIK, patients are able to blink normally and there is rapid overnight visual improvement.

In PRK, the removal of the surface protective layer increases the risk of pain, infection and corneal haze. The creation of the corneal flap with LASIK allows the protective layer to be preserved and provides for a more rapid and comfortable visual recovery. The surface corneal layers are more sensitive than the layers treated with LASIK, therefore healing time is reduced compared to PRK. The intra-operative risks with LASIK however are greater with LASIK than PRK, primarily because of possible complications with the creation of the protective corneal flap with the microkeratome. For patients with higher degrees of myopia, hyperopia and astigmatism where more healing complications are encountered, or for patients who desire a more rapid visual recovery, LASIK may be the treatment of choice.

Patient Initials_____

ALL LASER LASIK:

Instead of a microkeratome blade, All Laser LASIK uses the FDA-approved Ziemer femtosecond laser to create a flap with laser energy. This is the **only difference** between Traditional LASIK and All Laser LASIK. The femtosecond laser is capable of creating extremely precise flaps by producing tiny bubbles inside the cornea that are 1/30,000 of an inch in diameter. The laser beam cannot penetrate into the eye beyond the cornea. After the flap is created using the femtosecond laser, an Excimer laser is used, exactly as in traditional LASIK, to reshape the eye by removing ultra-thin layers from the cornea in order to reduce farsightedness, nearsightedness, or astigmatism. The flap is then returned to its original position, without sutures. All potential flap complications with a blade microkeratome can also happen with a femtosecond laser

It may be rarely possible that the Ziemer laser **or** the Excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss. As is true with Traditional LASIK using bladed microkeratome technology, I understand that my vision after surgery using the Ziemer femtosecond technology may not be clear immediately and that I might not notice improvement for several days to several weeks.

As is true with Traditional LASIK using bladed microkeratome technology, I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of my vision. I understand these conditions usually occur during the normal stabilization period of from one to three months, but they may very rarely also be permanent.

As is true with Traditional LASIK using bladed microkeratome technology, I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the LASIK procedure. These symptoms may be temporary or, on rare occasions, permanent, and may require frequent application of artificial tears, other related dry eye products and/or closure of the tear duct openings in the eyelids.

Patient Initials_____

SECTION 3: LASIK INDICATIONS, CONTRAINDICATIONS and PERI-OPERATIVE CARE

. LASIK is indicated for the treatment of myopia (nearsightedness), hyperopia (farsightedness) and astigmatism.

. Candidates must be over 18-21 years of age depending upon the laser used.
. Candidates must have a stable refraction with no more than 0.50 diopter change within the previous year as the procedure will not change the natural growth or aging of the eye
. Candidates must be aware that this is an elective procedure and that there are alternative forms of vision correction that are both non-surgical and surgical including eyeglasses, contact lenses, orthokeratology (OK), radial keratotomy(RK), intracorneal ring segments (ICRS), automated lamellar keratoplasty(ALK), laser thermokeratoplasty (L TK), refractive phakic lens implants, laser assisted sub-epithelial keratomileusis(LASEK), photorefractive keratectomy (PRK) or Epi-LASIK.
. Candidates must be free of certain eye diseases including keratoconus, glaucoma, cataracts, retinal and optic nerve diseases. Corneal ectasia is a steepening of the cornea that can worsen with time and can lead to a reduction in visual acuity. In some cases, ectasia may be associated with keratoconus or related corneal disorder. Keratoconus is a relatively rare degenerative corneal disease affecting vision. that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement) testing. Since keratoconus and related disorders may occur naturally, there is no absolute test that will ensure a patient will not develop ectasia following laser vision correction. Severe ectasia may need to be treated with a corneal transplant while mild ectasia can be corrected by glasses, contact lenses, intacts or collagen cross linking.
. Candidates must be free of certain eye viruses including herpes simplex and herpes zoster
. Candidates must be free of certain health problems including uncontrolled diabetes, autoimmune vascular disease, any medication or condition which renders the patient immunocompromised
. Candidates must make their surgeon aware of certain eye problems including amblyopia (lazy eye), strabismus (muscle imbalance), dry eyes, or any recurrent, residual or active eye condition which may affect healing .
. Candidates must make their surgeon aware of certain general health conditions including keloid scarring with previous surgical healing, back problems, claustrophobia or other psychological problems, which may affect the surgery or recovery
. Candidates must make their surgeon aware of any implants including a cardiac pacemaker, insulin implant or any other electronic implanted device
. Patients must also make their surgeon aware of any medication allergies and any medications they are taking to avoid potential drug interactions and allergic reactions
. The FDA considers pregnancy and nursing contraindications, although their affects on LASIK have not been studied. Female patients agree to disclose to their surgeon if they are pregnant, could potentially be pregnant or plan to become pregnant within the next 6 months.

Patient Initials_____

PRE-PROCEDURE and POST -PROCEDURE CARE:

The screening examination performed by your eye doctor is intended to assess candidacy for refractive surgery based upon the corneal shape, prescription and other ocular and visual findings, but not to identify or treat eye disease. Ocular disease may be present prior to refractive surgery or may develop after surgery, but it is unrelated to laser surgery. Refractive surgery will not treat ocular disease. You should have a complete eye examination with retinal evaluation prior to refractive surgery and annually thereafter to identify and treat ocular disease. In general, patients with higher degrees of myopia have a higher risk of retinal problem and reducing the degree of myopia with laser vision correction does not lower the risk. Patients who wear contact lenses must discontinue their use prior to laser vision correction to allow the cornea to return to its natural contour.

Soft contact lenses must be removed at least 3-5 days prior to surgery and overnight use requires the lenses to be discontinued one to two weeks prior to the procedure date. Candidates with rigid gas permeable lenses must discontinue their use 1-3 months prior to LASIK. Post-operative follow-up care with an eye care professional is required for 1 year to monitor LASIK healing and then yearly for routine eye care. If an additional or "enhancement" procedure is needed or a complication occurs, a patient may be required to return to the surgery center. The final clinical results are dependent upon how your body heals in response to the laser effect on your eye and upon proper post-operative care instructions. Due to individual healing patterns, it is impossible to guarantee exact results in individual cases even though the laser is calibrated and tested on plastic plates prior to treatment. Some patients either over or under respond to the laser and thus may have some residual optical error as a final result.

Patient Initials:_____

SECTION 4: PRESBYOPIA AND THE MONOVISION OPTION:

Monovision may allow for improved reading ability in both nearsighted and farsighted patients after age 40. Many people around the age of 40 begin to have trouble reading up close due to the natural weakening of their focusing muscles, which is known as 'presbyopia'. LASIK will not prevent the natural aging of the eyes and the need for reading glasses as you age, even if you do not require them now. Although farsighted patients usually improve their reading ability with LASIK, it is possible that nearsighted patients may need reading glasses sooner. The monovision option is usually only selected by candidates over 39 years of age, and simply means that we leave one eye a little nearsighted after LASIK. For nearsighted patients, your myopia is undercorrected in one eye, and for farsighted patients, your hyperopia is a little overcorrected to provide you with some reading ability as you age. Monovision will not eliminate your need for reading glasses for fine print, but is useful for reading your watch, opening your mail or reading price tags without readers. The disadvantage is that your distance sharpness will not be as good and you will have more difficulty with activities such as driving at night or with sports such as golf or tennis. Night driving glasses may be needed with monovision to reduce night glare. If you are in monovision contact lenses already, then the monovision option may be ideal for you. A trial of monovision contact lenses by your own eye doctor is beneficial and must be done before laser vision correction , if this is what you desire. In our experience, 15% of patients over age 40 still prefer distance vision possible in both eyes and wear reading glasses when needed, declining the monovision option. Please INITIAL the appropriate statement below:

PLEASE INITIAL ONE OF THE FOLLOWING:

I would like to have the best distance vision in both eyes_____

I would like to have monovision and I have tried it and like it _____

SECTION 5: RISKS AND COMPLICATIONS

As discussed earlier, all forms of surgery carry a certain degree of risk for adverse effects and complications. Problems can be related to the surgical component of LASIK or the healing component. Most surgical problems are related to the creation of the corneal flap and most healing problems develop within the first month following LASIK. Most complications improve or resolve within 6-12 months or with retreatment, but some surgical or healing complications may result in permanent visual blurring, glare, discomfort or need for contact lenses. The risk of a severe complication is not only dependent upon the functioning of the microkeratome, blade and surgical technique but upon a number of other factors including the prescription, orbital structure and corneal shape. In general, there is a small risk in the range of 1-5% of experiencing a complication and a very small risk, less than 1 %, of a severe sight-threatening complication. Please read this section carefully for a better understanding and initial below.

The risks of LASIK revolve around 5 primary areas:

1. Post-operative side effects, adverse effects and complications
2. Refractive complications
3. Corneal Flap Complications
4. Corneal Healing Complications
5. Other Miscellaneous Complications

Patient Initials:_____

1. Post-operative Side Effects, Adverse Effects and Complications

There are several adverse effects which may be encountered early in the post-operative period, which include foreign body sensation, pain or discomfort, sensitivity to bright lights, blurred vision, dryness of the eyes, tearing and fluctuation in vision. Persistent pain is uncommon following LASIK and may indicate a disturbance of the epithelial protective layer, displacement of the corneal flap or possible infection and should be evaluated promptly by your doctor. Corneal infection following LASIK is rare and can potentially result in corneal scarring requiring a corneal transplant and in very severe cases, infections can even result in blindness. Corneal inflammation can also be produced from medication or healing reactions, which may be allergic, toxic or immune in nature. Diffuse interface keratitis (also known as Sands of the Sahara) is the most important reaction and can produce corneal hazing, blurred vision, farsightedness and astigmatism that may result in permanent corneal irregularities. Treatment may involve topical steroids or further surgery and may or may not restore vision fully. The most common long-term side effect is dryness of the eyes, which often precedes LASIK but may be exacerbated. This may continue for several months to a year after the procedure, and in a few cases may be permanent. Patients may need to use moisturizing eye drops during this period. There are cases where patients have significant dry eye symptoms following surgery that require additional treatments or procedures beyond lubricant drops. In rare cases this may include punctual plugs or similar therapies. These 'techniques have been used for years for patients who have not had any laser vision correction procedures but who have chronic dry eyes or dryness from contact lenses. The most important long-term side effect is night glare, starbursting, haloes or simply reduced visual quality under low light conditions. It is very common to have night glare early during the recovery course and night glare is more common when only one eye has been treated. Night visual disturbances are typically produced by the pupil size exceeding the laser treatment area. It is more common in nearsighted patients with severe prescriptions and large pupils. Some patients benefit from driving glasses and most, but not all patients, improve substantially over 6-12 months. In a small percentage of patients night glare may be permanent and affect your night driving abilities.

Patient Initials:_____

2. Refractive Complications

Refractive problems that may be encountered include too much correction, too little correction, a prescription imbalance between eyes, aggravation of muscle imbalance problems or a loss of effect from regression. LASIK may result in overcorrrections and undercorrections due to the variability in patient healing patterns and other surgical variables, leaving patients nearsighted, farsighted or with astigmatism. This may or may not require patients to wear spectacles, contact lenses or undergo further surgery. Further surgery entails additional risk and is not guaranteed to provide an ideal visual outcome, although improvement is usually achieved. Patients may also heal differently between eyes based upon differences between eyes in preoperative prescriptions, corneal curvature variation in healing and other surgical variables. Differences in refractions between eyes is known as anisometropia; this is most severe when only one eye is treated, and may result in a loss of depth perception, eye strain, headache, double vision and the need for contact lenses. Both farsightedness and anisometropia result in worsening of pre-existing muscle balance problems, causing an eye to wander more or produce eye fatigue. Lastly, depending upon the severity of the original prescription, the individual healing pattern of the patient, and other surgical variables, regression may occur causing the eyes to return toward their original prescription, partially or very rarely, completely. Further enhancement surgery may be performed when medically stable if adequate corneal tissue is available and no other medical contraindications are present.

Patient Initials:_____

3. Corneal Flap Complications

The primary benefits of LASIK are related to the creation of the protective corneal flap. The corneal flap must be of clinically adequate quality, thickness and size to proceed with laser treatment. Corneal flap complications range in severity from those that simply require the procedure to be postponed by 3-6 months, to those that create permanent corneal irregularities resulting in blurred vision. The most severe LASIK complication is that of corneal perforation which has been reported several dozen times worldwide. Corneal flap complications that occur after the LASIK procedure during the recovery period include displacement and wrinkling of the corneal flap and epithelial ingrowth.

Corneal flap problems include but are not limited to:

Corneal flaps of inadequate size, typically too short, preventing laser treatment, and requiring the LASIK procedure to be repeated in 3-6 months. Typically, there is no serious visual disturbance although glare and shadowing may occasionally be produced. Corneal flaps of inadequate thickness, may or may not be adequate for laser treatment, and may result in the procedure being stopped and repeated after 3-6 months. A thin corneal flap may result in a slow visual recovery over weeks to months and possibly permanently blurred vision with or without laser treatment.

Corneal flaps of inadequate quality or smoothness, include a variety of corneal flap problems which may produce serious permanent corneal irregularities and significant visual blurring. Corneal flap irregularities may be produced because of inadequate suction pressure, inadequate orbital size, inadequate patient cooperation, malfunction or problems with the microkeratome, blade or suction apparatus.

Corneal flaps are routinely hinged either nasally or superiorly beneath the upper eyelid. A corneal hinge is not required for a good visual result, but a hinged corneal flap is more secure and typically heals faster and more smoothly. It is possible depending upon the corneal shape, the suction ring alignment and the microkeratome, that a free corneal cap may be produced which is not hinged to the cornea. Although the laser treatment can still be performed, if any irregularities in flap quality or thickness are noted, the corneal disc is immediately replaced and allowed to heal. If the free corneal cap is of excellent quality then the procedure is completed, but special care must be taken during the first 24-48 hours not to displace or lose the corneal cap. Loss *o*f the corneal cap may result in scarring, and permanent corneal irregularity and the need for more invasive surgery.

Corneal perforation is the most serious LASIK complication. Corneal perforation is prevented by the microkeratome depth plate, which is checked before each and every procedure. Some microkeratomes have fixed corneal depth plates. Perforation *of* the cornea requires corneal suturing, and the need *for* an intraocular lens implant as the natural lens is usually lost or damaged. It should be appreciated that corneal perforation may also potentially result in infection, the need f*or* a corneal transplant or even rarely blindness.

Corneal flap displacement, partial or complete, occurs during the early post-operative period, typically during the first 12-24 hours, but may occur days to weeks later with trauma. Care should be taken to protect the eyes from trauma, as well as, avoiding rubbing the eyes or forcefully closing the eyes during the first week following LASIK. Partial displacement *of* the corneal flap may result in corneal striae or wrinkles, which blurs vision both qualitatively and quantitatively. Most corneal striae are treatable but some may be resistant to treatment especially in highly nearsighted patients. Complete displacement *of* the corneal flap is often painful and requires urgent replacement. There is a higher risk *of* epithelial ingrowth and infection with corneal flap displacement. Evidence has shown that, as with any scar, the corneal incision will not be as strong as the cornea originally was at that site. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following LASIK. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.

Epithelial ingrowth occurs during the first month following LASIK and is more likely to occur in patients with an abnormal or weakly adherent protective layer, for which age is a factor. Epithelial ingrowth is produced when epithelial surface cells grow underneath the corneal flap during the healing *of* the corneal flap incision. Epithelial ingrowth is more common with any trauma or breakdown *of* the epithelium, which is more common in LASIK enhancement procedures and long-term contact lens wearers. Treatment *of* this condition involves lifting the flap and clearing the cells away. Although most small areas *of* epithelial ingrowth need only be monitored, untreated large areas *of* epithelial ingrowth may distort vision and may actually damage the flap integrity *if* severe and progressive.

Patient Initials:_____

4. Corneal Healing Complications

The protective corneal flap of LASIK reduces the healing component *of* LASIK refractive surgery compared to PRK, but significant healing is still required which can affect the quality and vision of the final result. Corneal healing problems with LASIK are more likely to be experienced by patients corrected for higher degrees *of* nearsightedness, farsightedness and astigmatism, which may potentially slow visual recovery and increase the need for enhancement procedures for over and under-corrections. Corneal healing may not only affect the speed *of* visual recovery but the smoothness, and may produce visual blurring. Rarely, corneal scarring may be produced with LASIK. The most important aspect *of* corneal healing following LASIK or any other form *of* refractive surgery, is the development *of* corneal irregularities which may permanently affect the quality, crispness and sharpness of the final visual result. Corneal irregularities or irregular astigmatism is produced when the cornea heals in an irregular pattern, which may or may not follow a surgical flap complication. Corneal irregularity may also be produced from abnormalities and complications of the laser treatment, including central islands and decentration which may produce blurring, shadowing, glare and doubling of vision. Some corneal irregularity is commonly expected for the first several weeks following an uncomplicated LASIK, however if it persists beyond six months it is considered abnormal and may be permanent. Most corneal irregularity improves over 6-12 months and some causes of corneal irregularity may be surgically managed but other causes are permanent. The greatest limitation of healing problems are that further surgical intervention does not guarantee better healing and may in fact, result in a further reduction of visual quality. Irregular astigmatism from both healing and surgical complications may result in a loss of best corrected vision, which means that a patient may be unable to read the bottom few lines of the eye chart even with spectacle or contact lens correction. Specifically, the best vision a patient measures after surgery even with lens correction may not be as good as the patient enjoyed before refractive surgery. In some cases, patients will actually gain best corrected vision.
In certain cases, the vision may be severely impaired and affect the ability of a patient to drive legally, this is most important in patients who already have reduced visual acuity from other causes. LASIK is not intended to increase the visual potential of a patient and many candidates with high prescriptions often are unable to read 20/20 before surgery and should not expect to read 20/20 after surgery. Furthermore, a patient who is best corrected before surgery to 20/40 is already borderline for legally driving and any loss of best corrected vision from healing or surgical complications may prevent legal driving.

Patient Initials:_____

5. Other Miscellaneous Complications

It is important to note that it is impossible to list every conceivable complication that is not listed above. Risks and complications that are considered to be unforeseeable, remote or not commonly known are not discussed. In addition, there may be long-term effects not yet known or anticipated at the present time. The most severe possible complications would necessitate more invasive or repeated corneal surgery, including **corneal transplantation** and could potentially produce partial or complete loss of vision or loss of an eye. Although retinal detachment is probably not caused by LASIK, any moderately myopic or highly myopic (near sighted) patient with or without prior LASIK surgery is more likely to get a retinal detachment than someone who is not near sighted. In the general population, the incidence of retinal detachment is approximately 0.03% or three per 10,000 eyes per year. In nearsighted people, the average incidence of retinal detachment is approximately 0.07% or seven per 10,000 eyes.

I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward. I, therefore, understand that I must not drive the day of surgery and should not drive until I am certain that my vision is adequate for driving.

Patient Initials:_____

SECTION 6: EXPECTATIONS OF THE PROCEDURE

The goal of LASIK is to achieve the best visual result the safest way. The goal is not to eliminate glasses and contacts completely but to dramatically reduce your dependence upon them in an attempt to help improve your quality of life. Night driving glasses and reading glasses may always be needed even when an excellent visual result is achieved. It is also important to recognize that even 90% clarity of vision is still 10% blurry and glasses or contact lenses may still be needed for certain activities that require fine or detailed vision. Enhancement procedures can be performed when stable unless medically unwise or unsafe. Adequate corneal tissue must be available to proceed with an enhancement procedure and a repeat measurement of the residual corneal thickness will be taken. Typically patients considered for an enhancement procedure should have at least 1.00 diopter of residual hyperopia, myopia or astigmatism or unaided vision of 20/40 or worse. Enhancement procedures are performed after 3-6 months, once adequate corneal healing and stability is achieved. Enhancement procedures are typically performed by lifting the original flap after the first few months before full healing occurs, or by creating a new corneal flap. There are always risks which must be balanced against the benefits of performing further surgery.

Complications are an inherent part of surgery and despite our best efforts, training and skill, we recognize that some patients will experience problems. It is simply our hope to educate you as to what those problems may be so that you can make an informed decision whether or not to proceed. No one ever believes that they will be in the small percentage of people that develops a significant complication, so it is important for all candidates to appreciate that there are truly no guarantees.

In this document, we have tried to inform you of all the potential complications of LASIK and Laser Vision Correction Surgery. We realize that this document can be scary to you, the patient. We are not trying to scare you, but rather to inform you so that you can make an educated decision about whether to do or not do Laser Vision Correction Surgery. However, the flip side is that LASIK and Laser Vision Correction Surgery can be extremely rewarding and give great results when successful. Using the LadarVision® Excimer Laser using Wavefront CustomCornea® treatments, which is the Laser that we use, in recent peer reviewed studies with no enhancements:

• After one month, 93% of CustomCornea® eyes were 20/20, 100% 20/40 *(Journal of Refractive Surgery Sept/Oct 2004 Pg 614-618)*

• After one month, 80% of CustomCornea® eyes had 20/16 or better *(Journal of Refractive Surgery Sept/Oct 2004 Pg 614-618)*

• After three months, 94% of CustomCornea® eyes had 20/20 or better *(Journal of Refractive Surgery Jan 2007, Pg 26-38)*

The studies also showed that more people were satisfied or very satisfied with their night vision after their LadarVision® CustomCornea® LASIK as compared to the prior level of satisfaction using glasses or contact lenses at night. Although no individual surgical outcome can be guaranteed, these clinical studies nevertheless, show the extraordinary effectiveness of this exciting new technology.

Patient Initials:_____

SECTION 6.5: REFRACTIVE SURGERY'S IMPACT ON FUTURE CATARACT SURGERY

As we age, many people develop visually significant cataracts as a natural result of the aging process. Laser vision correction does not cause cataract formation. Refractive procedures impact and change the shape of the cornea and may make it more difficult for an ophthalmologist to determine the correct lens implant to be used if cataract surgery is required in the future. As such, we strongly recommend that Refractive Surgery patients keep their pre-operative paperwork in a safe place. These pre-operative numbers will assist your future cataract surgeon in selecting the most appropriate lens implant for your eye. You will be given a copy of this paperwork for safekeeping and a copy will be kept at the Braverman Eye Center, however, in case we forget to give it to you, please ask us for the information.

Patient Initials:_____

SECTION 7: TREATMENT OF ONE OR BOTH EYES

There are both advantages and disadvantages of having LASIK on both eyes on the same day. The benefits of surgery on both eyes during the same session begin with the simple fact that patients often prefer this option as it is more convenient, with respect to either work or home life. Patients may also feel that their vision feels more balanced, with improved depth perception and night glare may dissipate more rapidly. Some patients find they have less anxiety, while others prefer the safety of treating only one eye at a time to allow visual recovery of the first eye prior to proceeding with the second eye.

The primary risks of treating both eyes on the same day are related to unrecognized surgical complications or more commonly, unexpected healing complications, which can produce either temporary or permanent visual blurring. Adequate visual recovery from laser vision correction for activities such as driving, as well as returning to work, may take 1 day or 1 month, or even longer in patients who respond abnormally, whether one or both eyes are treated. If both eyes are treated, then visual recovery may be prolonged and there is no way to predict who will take longer to heal. There is also no opportunity to learn from the healing pattern of the first eye. If there is an undercorrection or overcorrection in one eye, this is likely to occur in both eyes and both eyes will require retreatment. Other healing complications may also affect both eyes, most importantly the risk of infection may result in severe scarring, corneal transplantation and even complete loss of vision in both eyes.

Please **FILL IN the blank** below to indicate the treatment you choose to have on surgery day.

I would like to have my _____ treated.
(right eye/left eye/both eyes)

SECTION 8: LEGAL RESPONSIBILITIES and DISCLOSURES

CONFIDENTIALITY
By initialing below, you give permission for the medical data concerning your surgery and subsequent treatment to be submitted to Dr. Braverman and all doctors concerned with pre and post operative care, the excimer laser manufacturer and the governmental regulatory authorities. You give permission to record on video or photographic equipment your procedure, for purposes of education, research, or training of other health care professionals. The data will be utilized for statistical analysis, record keeping, marketing and/or quality control. Patient identity will be strictly confidential in any dissemination of data.

Patient Initials:_____

GOVERNING LAW \ JURISDICTION
By initialing below, you agree that the relationship and resolution of any and all disputes between yourself and the Stanley Braverman MD, PA shall be governed by and construed in accordance with the laws of the state of Florida. You also acknowledge with your initials that courts of Florida shall have jurisdiction to entertain any complaint, demand, claim or cause of action, whether based on alleged breach of contract or alleged negligence arising out of treatment. You hereby agree that you will commence any such legal proceedings in the state of Florida and you irrevocably submit to the exclusive jurisdiction of the courts of Florida.

Patient Signature: _____

SECTION 9: WRITTEN CONFIRMATION

Please write in your own handwriting the following two statements to confirm that you have understood and accept that LASIK is an elective surgical procedure and as with all surgical procedures, the result cannot be guaranteed. That you acknowledge that although vision-threatening complications are quite rare, it is possible that partial or complete loss of vision may be produced as a result of a surgical or healing complication. That the procedure may not eliminate all of your myopia, hyperopia or astigmatism and that additional correction with glasses, contact lenses or further surgery may be required.

I understand that "there are risks and* no *guarantees"

I understand that "I may still need* to *wear glasses or contact lenses"

SECTION 10: VOLUNTARY CONSENT

Please sign below that you have carefully reviewed this informed consent document and that you have had opportunity to have any questions that you may have had answered. By signing below you also are aware that **LASIK** is an elective procedure, that you do not need to have this procedure, and that you understand your other surgical and non-surgical alternatives for vision correction. **You have been offered a copy of this consent form.**

Patient Full Name (print): _____

Patient Signature: _____

Date: _____

Witness Name (print): _____

Witness Signature: _____

_____ **I HAVE DISCUSSED AND ANSWERED ALL QUESTIONS ASKED BY PATIENT.**

_____ **I HAVE DISCUSSED ALL POTENTIAL RISKS AND COMPLICATIONS THAT APPLY TO PATIENT'S PROFESSION.**

Surgeon Name (print): Stanley D. Braverman M.D.

Surgeon Signature: _____

Co-managing Doctor: _____

Date of Procedure: _____

LASIK Primary Treatment Form Revision 9/03/2008