

LIPSTOCK

LASIK & CATARACT CENTER

LASIK AND ENHANCEMENT CONSENT FORM

General Information

The following information is intended to help you make an informed decision about having Laser Assisted In-Situ Keratomileusis (LASIK) to correct your vision. Please read this document carefully and completely. This consent form may contain terminology that you do not understand. If you have any questions, do not hesitate to ask Dr. Lipstock, one of our ophthalmic technicians or our refractive surgical coordinator to explain any terminology or information that you do not clearly understand.

Patient name: _____ DOB: _____

Date of Procedure: _____ Age: _____ Sex: _____

Proposed Procedure: LASIK(intralase)/(microkeratome)/ Enhancement (circle one)

Surgeon: Kenneth D. Lipstock, M.D.

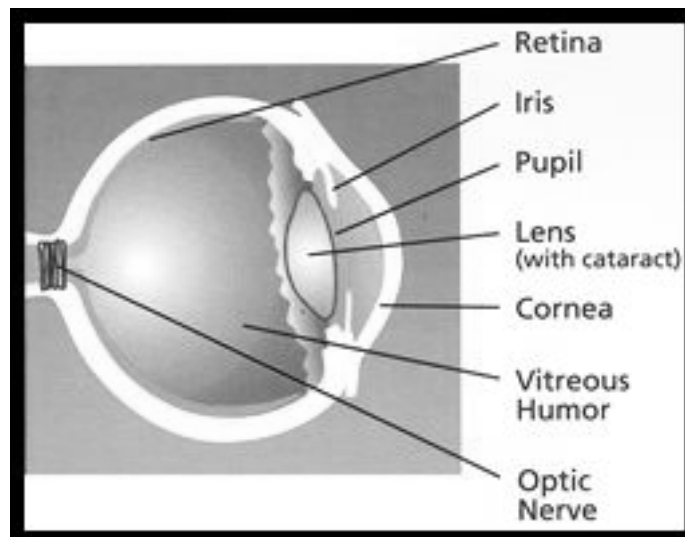
It is impossible to list all of the possible risks and complications associated with this proposed procedure or any other treatment. Risks and complications that are considered to be unforeseeable or very remote are not discussed.

Patient initial here: _____

Anatomy and Diagnosis:

The cornea is the clear, dome-shaped tissue that covers the front surface of your eye (Figure 1.) Light rays enter your eye through the cornea, which is the main focusing element of the eye. The cornea bends the light rays through the pupil. A healthy cornea is clear and brings light into a sharp focus inside the eye on the retina.

Figure 1. Human Eye Anatomy



Nearsightedness (myopia) is a condition of the eye where light is focused in front of the retina creating a distorted image. This is due to the corneal curvature being too steep or the length of the eye too long. Farsightedness (hyperopia) occurs when the cornea is not steep enough or the eye is too short, so light is focused behind the retina creating a distorted image. Astigmatism occurs when the corneal curvature is oval

so two focal points are created causing distorted vision; astigmatism usually accompanies some myopia or hyperopia. Myopia, hyperopia and astigmatism are known as "refractive errors".

Procedure:

You are planning to have your myopia, hyperopia and/or astigmatism corrected by a laser vision correction procedure known as LASIK. Dr. Lipstock will be using the FOOD AND DRUG ADMINISTRATION (FDA) approved VISX Star S4 ActiveTrak excimer laser to change your corneal curvature in order to correct your refractive error. Lipstock LASIK & Cataract Center is constantly updating our technology to offer our patients the most advanced procedures and treatment available.

In LASIK, a thin flap of surface corneal tissue is created using either the FDA approved IntraLase ultrahigh speed infrared laser or a hand held mechanical device with an oscillating blade known as a microkeratome. The flap is created to allow access to the underlying corneal tissue known as stroma. After moving the flap aside the stroma is exposed, and multiple pulses of excimer light from the VISX laser are applied to the corneal stroma. The cornea is thereby reshaped, flattening the central curvature for myopia, steepening for hyperopia and making it more spherical for astigmatism. The flap is then replaced over the front surface of the cornea. The excimer laser light could also be applied to the front surface of the cornea without creating a flap. The purpose of creating the flap and allowing treatment to the underlying stroma is to minimize post operative discomfort, increase the speed of visual recovery, and avoid the risk of corneal haze or scarring.

LASIK is performed as an outpatient procedure at Lipstock LASIK & Cataract Center. Anesthetic (numbing) eye drops are placed in the eye immediately prior to the procedure. A mild sedative pill is administered to reduce apprehension prior to the procedure. The eyelids are held open using an eyelid opener. The other eye is covered during the treatment.

During the LASIK procedure, the surface cells on the cornea are left generally intact. The first step of the procedure involves creating the corneal flap. In order to do this accurately, the pressure inside the eye needs to be raised to a high level. This is accomplished using a ring placed on the white of the eye. This suction ring is then activated, the pressure inside the eye is confirmed to be sufficiently elevated, and either the FDA approved IntraLase FS, a femtosecond infrared laser or a mechanical microkeratome is used to create a corneal flap. The pain nerves have been anesthetized with eye drops prior to elevating the eye pressure so no pain creating the flap itself is felt either with the IntraLase laser or the microkeratome. However, pressure sensing nerves cannot be anesthetized, so most patients will feel a pressure sensation during this time. The flap created is usually less than 1/3 of the total corneal thickness (achieving the desired thickness of the flap has been reported to be 400 times more accurate with the computer driven IntraLase laser than with the mechanical, handheld microkeratome).

If a mechanical microkeratome is used, in the vast majority of cases, it is stopped before it completely goes across the cornea creating the desired flap with a hinge at one end; in rare cases there is no hinge and a full round disc (called a "free cap") is created. The use of the IntraLase laser to make the flap essentially eliminates the risk of creating a free cap.

After the flap is created, it is retracted exposing the underlying stroma. With the corneal stroma exposed, the VISX laser application begins. This excimer laser does not burn or cut, it actually breaks apart individual chemical bonds of the corneal tissue. This usually takes 15 to 60 seconds, depending on the amount of the refractive error being corrected. The laser's computer calculates the exact number of pulses delivered by the laser. During the procedure, the patient will hear a snapping sound from the VISX laser and may detect a slight odor (resulting from the interaction of the excimer laser light and the individual atoms of the cornea).

After the laser treatment, the flap is put back in its original position without the need for sutures. Antibiotic and anti-inflammatory eye drops are placed in the treated eye. In this immediate postoperative period, the patient may notice his/her vision to be significantly improved compared to before the procedure; best vision, however, may take several days or weeks to achieve. Because of this, and also because of potential effects of any sedatives administered, the patient will not be allowed to drive home. The procedure will not be performed unless a driver is present.

Post-Operative Course:

The LASIK patient is examined in the office the next day. Many patients can see well enough to drive the next day, but that is not always the case, so arrangements must be made in advance to have a driver for the first postop day visit.

For the first few hours after the LASIK procedure the vision is usually blurry; it may seem like you are looking through a foggy window. This is from both dryness on the surface of the cornea as well as edema fluid (water molecules) within the cornea. This "fog" usually begins to decrease within several hours, and by the next morning the vision is usually much clearer. It is also common to feel a burning or foreign body sensation soon after procedure. The patient is advised to go home immediately after the procedure and take a nap. The oral sedative given will make sleeping easier. Usually this postoperative irritation subsides after about a three hour nap. It is not uncommon to see some red areas on the white of the eye. These areas are equivalent to small black and blue marks, and they are secondary to the suction ring pressing on small blood vessels on the white of the eye; they are clinically insignificant.

A major concern in the early postoperative phase following LASIK is dislodging the flap or cap. Although it is rare for the flap to be displaced, it is generally believed that this is most likely to occur in the first 1-2 weeks after the procedure and can be caused by vigorous eye rubbing or to other injuries to the eye. If the injury is bad enough the flap can be displaced months after the procedure. It is very rare to have a flap displaced after one year. Patients will be asked to consciously avoid rubbing their eyes for the first three months and to wear protective eye shields when they sleep for the first five nights after the procedure, and to wear protective eyewear during activities during which eye injuries can occur. It appears that flap displacement occurs less frequently with Intralase initiated LASIK than when LASIK is initiated with a microkeratome.

The postoperative medication regimen is reviewed with the patient both before and after the procedure and additionally with the patient's driver prior to discharge on the day of the procedure. Follow up visits are scheduled for one day after the procedure, then approximately one to two weeks and two to three months later. Additional visits may be scheduled according to your doctor's determination. Dr. Lipstock will be examining you carefully the day after the procedure. Dr. Lipstock is almost always available during regular office hours as well as at night and on weekends (an on-call doctor will be available for the occasional times Dr. Lipstock is not available).

In order to minimize the risk of infection and postoperative discomfort, as well as maximize the visual results of the LASIK procedure, it is important for the patient to comply faithfully with the medication dosage and schedule. Medications are usually necessary for the first week after LASIK although, in some cases, they may be required for up to several months.

Although in the vast majority of patients markedly improved uncorrected vision is generally noted within 24 hours after LASIK, an individual patient's best vision may not be realized for several weeks or months after the procedure.

Patients who do not have all of their vision corrected by LASIK can elect to wear glasses or contact lenses or could possibly have additional refractive procedures (either LASIK or other procedures). Re-operation rates in our experience with LASIK have been less than 5%. Generally, re-operation, which could involve LASIK or other types of refractive procedures, will not be performed for at least four months following the original procedure.

The LASIK procedure as presently performed in the USA may involve one or both eyes at a time, although the majority of the time both eyes are done at the same time. Because vision in the early postoperative period may be somewhat blurry, performing LASIK on both eyes simultaneously could interfere with a patient's ability to drive, work, and function effectively during the early postoperative period. As you will read later in this consent form, side effects and complications can occur with LASIK. If LASIK is performed in one eye at a time you avoid the chance of any of these problems occurring in both eyes at the same time. After reading the following information you will be better able to determine if the extra convenience of bilateral surgery is suitable for you.

NEED FOR READING GLASSES:

After LASIK patients may need to wear eyeglasses or contact lenses for reading. The need for reading glasses is age related and generally begins around age 42 and progresses over the years requiring stronger and stronger

reading glasses. This usually stops increasing at about age 65. This condition, known as "presbyopia, occurs as a result of the natural aging process of the lens (which is located inside the eye). As the lens gets denser with age it becomes more difficult for the focusing muscle to change the shape of the lens to focus up close, so near vision becomes blurry. Nearsighted people over age 42 (the presbyopic age) can see up close without their glasses, although their distance vision is blurry (they are nearsighted presbyopes). Farsighted presbyopes (farsighted people over age 42) have difficulty seeing both near and far without their glasses. People who only need reading glasses have simple presbyopia without nearsightedness or farsightedness. When we correct nearsighted presbyopes or farsighted presbyopes with LASIK so both eyes see clearly at a distance then they have simple presbyopia only. They no longer need glasses for driving but they need reading glasses for near tasks.

One approach to address the issue of presbyopia is called "blended vision" and involves intentionally setting the dominant eye for distance and the nondominant eye is made a little nearsighted to allow for near vision tasks without glasses; this is done by undercorrecting the nearsighted eye or overcorrecting the farsighted eye. The result is for this nondominant eye to have good uncorrected near vision (and somewhat blurred distance vision) while the fully corrected dominant eye will have good distance vision (and somewhat blurred near vision). With both eyes open the patient can see both near and far. This is because the brain is able to blend the two images together. The greater the difference between the two eyes the more difficult it becomes for the brain to do this. Therefore, the nondominant eye is not aimed for so much nearsightedness that all small print can be seen even at age 60. But enough nearsightedness is aimed for so that significantly useful near vision is retained for all ages. Some reading glasses may still be required for smaller print or in dimmer light depending on the age of the patient. For most patients they can at least see their computer print without reading glasses. The goal is to make you better than normal, since the normal presbyopic patient sees well at distance but cannot see near objects well at all.

At Lipstock LASIK & Cataract Center we highly recommend blended vision for our nearsighted and farsighted patients, because they have done so well with it. For those rare patients who cannot adapt, a reoperation (commonly referred to as an "enhancement" procedure) can be done to adjust the amount of blended vision or to eliminate it so that both eyes are set for distance vision.

SIDE EFFECTS OF LASIK

It is impossible to cover all conceivable side effects, risks, and complications associated with any surgical procedure. The following side effects of LASIK are usually mild and/or temporary.

Tearing: Tearing commonly occurs after LASIK, but is usually limited to the first 12-24 hours following the procedure.

Pain: It is common to experience some burning or a mild to moderate foreign body sensation for at least the first 3 to 6 hours after the procedure. This is due to the fact that there is always a narrow corneal abrasion around the edge of the flap. Fortunately this usually heals very quickly so that after a few hours of sleep (sleep is recommended immediately after the procedure so the eyelids are not blinking and rubbing over the area where it needs to heal) the discomfort is usually much less. If at the time of the procedure it appears that there is an abrasion right on top of the surface of the flap itself (sometimes occurring because of the microkeratome rubbing over the surface of the cornea and rarely ever seen when Intralase is used) an extended wear contact lens is placed on the eye to act as a bandage; the eyelids will then blink over the contact and not the abrasion thereby providing more comfort for the patient. The contact is slept in and is easily removed by the doctor with sterile forceps in the exam room the next day or a few days later.

Dry Eyes: Dryness of the eyes presents as a burning, gritty sensation with intermittent blurring of vision. It is a common condition as we age or can be caused by medications or other medical conditions (e.g. rheumatoid arthritis, lupus). At your pre-operative exam, symptoms and signs of dry eyes will be assessed. If a dry eye condition is diagnosed treatment will be started prior to LASIK, because after LASIK there is usually a temporary worsening of dry eyes that gradually improves by itself over 6 to 12 months. Occasionally some patients will experience some increase in dryness that persists for greater than one year. Typically artificial tear drops are used as needed for dry eyes. For those with a worse dry eye condition than average other drops are sometimes used, and sometimes temporary punctual occlusion (closure of the tear drains with tiny plastic plugs) is done. It

appears that eyes may not be as dry after LASIK when done with Intralase than with a microkeratome, although Intralase LASIK will cause some dryness as well.

Light Sensitivity: Rarely a very mild degree of light sensitivity may persist for prolonged periods after LASIK. A mild degree of light sensitivity soon after LASIK may necessitate the temporary use of sunglasses for comfort. Also rarely an intense light sensitivity may occur a few weeks after routine LASIK that was performed with IntraLase. This has been called "transient light sensitivity". This usually responds very quickly to the temporary use of steroid eye drops. It responds best when treated soon after its onset. So those few patients experiencing this delayed onset light sensitivity after routine LASIK with IntraLase should notify our office so the eye drop treatment can be started soon.

Blurred Vision: Here we are talking about blurred vision in the early postoperative period, particularly in the first 24-78 hours, and this may interfere with functions such as driving, work, and hobbies. The actual level of vision necessary for people to comfortably function varies from patient to patient and thus, it is impossible to presently predict when your vision will be good enough for you to feel comfortable. In general the vast majority of patients can function well enough to go to work the day after the procedure. Nearsighted presbyopic patients may have some difficulty reading without reading glasses in this early period even if monovision was given (this usually gradually improves over the first month or two). Farsighted patients usually read well the first day after procedure but their distance vision is somewhat blurry and this usually gradually improves over the first several weeks and months).

Sedation Related: You will receive a mild degree of oral sedation prior to the LASIK procedure. This will help you to sleep after the procedure. You should not drive or operate machinery for 12-24 hours after the procedure.

Glare, Haloes, and Visual Symptoms: Mild glare and/or haloes at nighttime are not uncommon right after LASIK. In most patients, these symptoms are mild and will dissipate over the first one to two months.

Under-correction or Over-Correction and Regression: The introduction of the excimer laser improved the accuracy of refractive procedures. We have the latest generation, state of the art Visx excimer laser and it has become incredibly accurate for the treatment of nearsightedness, farsightedness and astigmatism. If the human eye was made out of plastic then LASIK would be 100% accurate. However, the individual biology of wound healing (as well as other factors) varies from patient to patient, and this means that LASIK is not a 100% accurate procedure. Furthermore, the higher your prescription the less accurate the LASIK treatment becomes. Undercorrection is the most commonly noted inaccuracy and generally is very mild. Nearsighted patients undercorrected will have some residual nearsightedness, farsighted patients will have some residual farsightedness, and patients with astigmatism will have some residual astigmatism if they are undercorrected. Overcorrected nearsighted patients will have some farsightedness and overcorrected farsighted patients will have some nearsightedness. It should be stressed that this is not a safety issue, but an accuracy issue, since with eyeglasses the vision is still perfectly clear. Fortunately most patients who are under or overcorrected can have a repeat LASIK procedure, commonly called an "enhancement" that can fine tune the result. Usually the enhancement procedure is exquisitely accurate, because the residual prescription being treated is generally quite small.

In several independent studies, the percentage of patients seeing 20/20 or better one week and one month after LASIK has been shown to be greater in those who had LASIK with Intralase than those who had LASIK with a microkeratome. Nevertheless, enhancements are sometimes required after both procedures.

Usually there is some regression of effect after LASIK that eventually stabilizes after a few months. Most of the change takes place the first few days and weeks, and it then tapers off and the result becomes very stable. Rarely some patients may have a very slight regression of effect some years later. In these rare instances, an enhancement procedure can usually be done. Presbyopia increases with time and the ability to see near objects decreases as you age, even if blended vision is given (but blended vision should continue to be very helpful at least for intermediate range).

Enhancement procedures for under or overcorrected patients are performed at least four months after the LASIK procedure to allow time for the result to stabilize. Many of those patients who require an enhancement function fine without eyeglasses prior to the enhancement. Those who do require glasses to function well will be

given a prescription (usually much less than they started with) to take to an eyeglass store; usually their old frames are used.

Enhancement procedures are performed by surgically lifting the previously made flap. Occasionally there is not enough thickness of the residual cornea to perform an enhancement. In some cases the flap is too strongly adhered to the stroma to attempt a lift to enhance. In these situations either another refractive procedure is performed (most commonly performing the excimer laser ablation on the surface of the flap without lifting it and this is called PRK) or eyeglasses or contacts may be worn.

COMPLICATIONS OF LASIK

Fortunately with LASIK in general the worse the complication the rarer it occurs. Over the years LASIK has become safer and safer. Now with the IntraLase laser to make the flap and Visx CustomVue excimer laser technology to correct the shape of the cornea, LASIK has become amazingly safe. It is not, however, risk free. Below we will talk about complications that can lead to a mild distortion of vision all the way to total blindness. Again some of these complications should hardly ever be seen now with the latest technology that is available at Lipstock LASIK & Cataract Center; however, some are still possible, and we provide this information so you are fully informed of the potential safety issues associated with LASIK.

Loss of Best-Corrected Vision: LASIK can possibly cause loss of vision even if eyeglasses are worn; this is referred to as loss of "best corrected vision". Sometimes a patient may still be 20/20 but see ghosting of images and loss of contrast sensitivity. Any loss of vision or quality of vision is a safety issue and not an accuracy issue. Such loss of vision can be due to various causes. There is a less than 1% risk of a significant loss (2 lines or more on the eye chart) of vision with LASIK. Although our safety rate has been excellent to date at Lipstock LASIK & Cataract Center, it is still theoretically possible, albeit very rare (less than .1%), to have a very serious loss of vision. Such rare problems have been reported in the medical literature. This could require a gas permeable contact lens to be worn to see clearly, or a corneal transplant to solve the problem, or both. Very rarely even these treatments may not solve the entire problem.

Visual Side Effects: Other visual problems that can occur with LASIK include: anisometropia (difference in power between the two eyes that is disturbing); this can usually be solved with an enhancement. Increased sensitivity to light can occur that may be incapacitating for some time and may not completely go away (this is rare, and is usually easily treated). Other visual disturbances that can occur are ghosting of images, decreased vision in dim light situations and haloes and glare. In routine LASIK cases such visual disturbances become more common as the prescriptions become very high. Visx CustomVue wavefront technology is making such occurrences rarer; however for those with extreme prescriptions other refractive procedure options may offer a better quality of vision than LASIK. Dr. Lipstock will help guide you to the safest and clearest choice for your individual refractive error.

Irregular Astigmatism: Typical astigmatism that most people have is "regular astigmatism" and it is corrected by eyeglasses or contacts. Irregular astigmatism is due to an irregularity in the shape of the cornea that causes decreased best corrected vision and visual disturbances such as ghosting of images, decreased vision in dim light and persistent haloes and glare. Eyeglasses do not fully correct this, and soft contacts don't either. In the past either a gas permeable hard contact lens or a corneal transplant could give clear vision for those with irregular astigmatism. Now the wavefront guided customized laser technology available in excimer lasers (including Visx CustomVue used at Lipstock LASIK & Cataract Center) can decrease or eliminate irregular astigmatism in some (but not all) patients. This is a welcome addition to our treatment options for those with irregular astigmatism.

At Lipstock LASIK & Cataract Center we are very pleased to offer our patients IntraLase to make their flap for LASIK (step one of LASIK) and Visx CustomVue wavefront guided technology to change the shape of the cornea underneath the flap (step two of LASIK). The making of the flap is the most complex part of the LASIK procedure. The advantage of the IntraLase is that there is no cutting blade. A computer controlled laser is used to create the flap and no blade touches the eye. CustomVue wavefront-guided technology corrects not just nearsightedness, farsightedness, and regular astigmatism, but also individual imperfections in each person's visual system that could not previously be measured let alone corrected. Now many patients can actually be made to see better than they ever did with glasses or soft contacts. Also now for the first time irregular astigmatism can sometimes be corrected.

Not all patients are candidates for Intralase or CustomVue treatment. For some we may recommend a microkeratome and conventional excimer laser software for the treatment. And some may still have a loss of best corrected vision despite the use of Intralase and CustomVue technology.

Corneal Abrasions: Corneal abrasions are usually caused by the mechanical microkeratome rubbing over the surface of the cornea while creating the flap. Corneal abrasions occur when the microkeratome disturbs the most superficial layer of cells (epithelial cells) on the surface of the cornea. When an area of these cells on the surface of the flap are rubbed off we call that an abrasion. The rest of the flap may be perfect, but the abrasion causes a foreign body sensation and blurred vision.

Corneal abrasions or other small surface defects are reported to occur with microkeratomes from 1 to 25% of the time. They more commonly occur in patients over age 40. Corneal abrasions occur less frequently with use of the Intralase laser in place of a microkeratome, since there is nothing rubbing over the surface of the cornea when Intralase is used. Some epithelial disturbances can occasionally be seen after the flap is created with Intralase when the surgeon lifts the flap aside, but the incidence of abrasions is significantly less than when a microkeratome is used.

A corneal abrasion on the surface of a flap is treated with an extended wear contact lens that the patient sleeps in. The contact lens acts like a band aide, so the eyelids rub over the contact and not the abrasion. This provides comfort for the patient and also enables quicker healing of the abrasion. The corneal abrasion usually heals in several days to a few weeks. Sometimes it leads to residual nearsightedness or astigmatism that may require an enhancement procedure later. Occasionally an abrasion can lead to the eyelids sticking to the healed abrasion site while asleep, and upon awakening those cells can be once again disturbed. This is called recurrent corneal erosion. This is usually treated with an ointment placed in the eye at bedtime to prevent sticking to the epithelial cells.

Rarely a healed corneal abrasion can lead to an irregular shape of the cornea because of the way the superficial epithelial cells healed over the abrasion site. This causes irregular astigmatism (usually relatively mild) with a decrease in best corrected vision and visual quality. Rarely, this may require treatment with the excimer laser on the surface of the flap to decrease the superficial irregularities, mechanical removal of the epithelial cells so they regrow smooth or a gas permeable contact lens.

Corneal Scarring: Corneal scarring may rarely occur after LASIK. Significant corneal scarring that can lead to a decrease in best corrected vision, ghosting or glare is rare but can occur. Corneal scarring can be due to problems with things such as creating the flap, lifting the flap, displacement of the flap, infections, or sterile inflammation. Steroid eye drops are often used to prevent scarring (sometimes oral steroids are used). Steroid drops may result in elevated pressure inside the eye, which may require treatment with additional eye drops. Prolonged use of steroid eye drops may also increase the risk of cataract formation. Severe corneal scarring may require prolonged medical treatment and/or further eye procedures.

Kerataconus: Some people, never having had any eye procedure, are born with a genetic predisposition to develop a thin area in the cornea that becomes weak and develops a bulge outward. This may also occur as a result of chronic eye rubbing. This can be mild and never effect the vision at all, or it can progress and lead to severe irregular astigmatism. Gas permeable contact lenses are used to treat the irregular astigmatism, and sometimes a corneal transplant is required. This disease usually manifests itself in one's early adult years.

LASIK will make the cornea thinner. If one has an early form of kerataconus, any thinning of the cornea can cause a worsening of the kerataconus. At the time of the LASIK exam we screen out patients very carefully for signs of early kerataconus. Even in normal patients we can create a syndrome similar to kerataconus if we make the cornea too thin. The standard is to leave behind at least 250 microns of untouched cornea. We make very careful measurements of corneal thickness before and during procedure to assure that more than 250 microns will be left behind.

Even though the flap is replaced during LASIK, it does not count for structural integrity anymore. It is the underlying cornea that must remain greater than 250 microns. The excimer laser treatment of the underlying cornea will make it thinner. The higher the refractive error the thinner the cornea is made. We know exactly how much thinner the excimer laser will make it. What we don't know is how thick the flap will be. The thicker

the flap the thinner the underlying cornea. Comparative studies have shown that the ability to create a flap the exact thickness aimed for is significantly greater when the flap is made with the Intralase laser than with a mechanical microkeratome. This is very important. This decreases the chance of inducing kerataconus. We have a good idea of whether or not a patient has enough corneal thickness to precede with LASIK, because of the corneal thickness measurements taken before the procedure. However, since the flap thickness can vary we take this measurement again during procedure right after the flap is made. In the rare occasion where the flap is too thick and not enough corneal stroma remains to treat with the excimer laser, we will abort the case and simply replace the flap. Needless to say, this is quite inconvenient for the patient. Such incidents, although already rare, should be significantly less when the flap is made with Intralase. Also when the Intralase is used, fewer patients will need to be screened out prior to LASIK because of corneas that are too thin; this is because the surgeon is able to create a thinner flap safer with Intralase than with a microkeratome (see below). At the time of the LASIK exam, some patients' corneas will be noted to be too thin to create a flap with either Intralase or a microkeratome. Many of these patients can undergo surface laser vision correction (PRK).

The incidence of kerataconus caused by LASIK is rare, but it has been reported to occasionally occur even after the best screening efforts. As with naturally occurring kerataconus it is treated with a gas permeable contact lens and sometimes a corneal transplant.

Partial and Too Thin Flaps: Creating a flap for LASIK requires a balance by the surgeon of not making the flap too thick (to avoid kerataconus), and not making it too thin. A flap can be so thin that it can have an actual hole in its thinnest part. This is rare, but it does occasionally occur. If the excimer laser treatment is performed with such a thin flap, significant corneal scarring can occur that can decrease best corrected vision. Even if the thin flap is replaced and no excimer laser treatment is done, corneal scarring can also occur, but the scarring is less and it is usually visually insignificant. Such eyes can be retreated with the excimer laser on the surface of the flap; this can be done several days or weeks later. Such treatment is usually very successful; however some loss of best corrected vision can occur. Again, creating a flap with the more accurate Intralase laser makes less likely the occurrence of a flap that's too thin. But even with the Intralase, a flap that is too thin can occur. However, such incidents have not been shown to cause the kind of central hole in a flap that can occur when the microkeratome is used, thereby avoiding significant secondary scarring. If a thin flap occurs with the Intralase, the case may need to be aborted and no eximer laser treatment done. Surface laser treatment may be recommended a few days or weeks later.

Suction is required to elevate the eye pressure while making the flap with both the Intralase and a microkeratome. If suction is lost while creating the flap, a partial flap may be created. This can be a serious complication leading to significant scarring of the cornea when it occurs with the use of a microkeratome. It is rare but it can occur. Intralase adds further safety to the procedure, because if suction is lost while making the flap with Intralase, the microscopic bubbles within the cornea (created by the Intralase) will simply dissipate. The next day it is as if nothing was done to the cornea and vision is clear with the old eyeglasses. If there was difficulty getting suction it can be repeated again or alternatively PRK (Laser Vision Correction on the cornea's surface without a flap) can be safely performed instead.

Torn Flaps: Rarely while lifting an Intralase flap to get ready for step two of the procedure, there can be a tear in the flap. Usually the procedure can be completed with no significant problem. Very rarely the case may be aborted and the flap replaced without the excimer laser treatment. Significant scarring could rarely occur.

Infection: Infection is a very rare but serious potential complication. In order to minimize the risk of postoperative infection, it is critical for you to follow precisely the prescribed postoperative medication regimen, as well as recommendations to avoid placing non-sterile material in the eye for at least the first two weeks after the procedure. Should infection occur in the cornea after LASIK, a potentially lengthy course of treatment may be necessary. Although most corneal infections can be successfully treated without significant loss of vision, potential consequences of corneal infections include corneal scarring, corneal perforation, and spread of the infection inside the eye. Any of these conditions, if severe enough, may result in partial loss of vision or even blindness. If you have had any type of eye infection in the past, you need to report this to the staff of Lipstock LASIK & Cataract Center prior to the procedure. Those in the health care industry, especially those working in hospitals, should be especially careful to their exposure to infectious contaminants the first few weeks after the procedure.

Flap Wrinkles: Flap wrinkles are rare. They usually occur as a result of flap displacement which most often occurs within the first few weeks of LASIK (the highest risk occurring in the first 12 to 48 hours). It is important not to rub your eyes and avoid injury especially during the first few weeks and months after LASIK. If the flap is displaced there is usually a severe foreign body sensation and the vision is usually very blurry. You should call our office immediately if you experience this. The sooner the flap is replaced (preferably within the first few hours) the easier it is to smooth out the wrinkles created in the flap. At Lipstock LASIK & Cataract Center, in the last 13 years after thousands of LASIK procedures, we have seen about 10 displaced flaps. Fortunately all were replaced by Dr. Lipstock and smoothed free of wrinkles with no loss of vision. However, it has been reported elsewhere that wrinkles were difficult to remove and sutures were required; and, sometimes that did not help and best corrected vision was decreased permanently, so this is a possibility. It appears that flaps adhere significantly stronger and faster when they are made with Intralase than with a microkeratome. This again adds safety, although flap displacement has been reported with flaps made with Intralase also. For those concerned about flap displacement, especially those prone to getting hit in the eye for whatever reason, we should discuss the pros and cons of PRK. (Excimer laser treatment on the surface of the cornea without a flap).

Epithelial Ingrowth: LASIK involves the creation of an interface between two layers of corneal tissue. It has been observed that surface (epithelial) cells can grow into the interface. Although not very rare, epithelial ingrowth into the corneal interface generally is mild, not progressive and causes no problem. In most cases, it is something that the surgeon will observe but will not be noticeable by the patient nor will it affect their vision. In rare cases, these cells may continue to grow within the interface, and since they are not transparent, they can threaten vision and/or cause irregularities or other problems with the overlying flap. In these situations the epithelial cells may need to be mechanically removed. This procedure requires that the flap be retracted and ingrowing epithelial cells mechanically removed. Significant epithelial ingrowth rarely recurs enough to require the flap to be lifted more than once. It has been reported that sutures at the flap edge may rarely be needed to prevent recurring epithelial ingrowth, and although rarely needed, it has been reported to be very effective in preventing recurring epithelial ingrowth.

Ptoxis: Ptoxis, or drooping of the upper eyelid, has been noted to be an uncommon occurrence following LASIK. It is reported to be mild in degree and will resolve spontaneously over several months. If it is severe and/ or persistent, an eyelid surgical procedure may be necessary.

Cataract, Retinal Detachment, Retinal Hemorrhage: LASIK has not been directly and conclusively associated with disorders inside the eye such as cataract or retinal detachment or hemorrhage. Everyone develops at least a minor cataract (clouding of the lens) by age 60, but it doesn't usually blur the vision significantly until one's 70's. However sometimes cataracts develop in younger patients. Also very nearsighted patients tend to develop cataracts at a younger age. As noted above, prolonged postoperative medications can possibly increase the risk of cataract formation. Additionally, nearsighted individuals are statistically at greater risk for spontaneous retinal detachment (and other retinal problems) than the general population. A retinal detachment could occur at anytime and be completely unrelated to the LASIK procedure (although LASIK flattens the nearsighted cornea to resolve the refractive error, the nearsighted eye also is usually longer, and this remains so after LASIK and continues to pose some extra risk of retinal detachment throughout the nearsighted patient's life). There have been a few very rare reported cases of retinal hemorrhage noted after LASIK, and again there is no evidence that this was directly related to the LASIK procedure. If somehow there is an association of LASIK with retinal hemorrhage it is at the very least very rare.

Elevated Eye Pressure: As noted above, part of the LASIK procedure involves temporarily (from 10 to 60 seconds) elevating the pressure inside the eye to a high level. During this time the vision in the eye becomes dim or may completely disappear; this is to be expected. It is felt that this is due to the pressure closing small blood vessels inside the eye. Once the pressure is normalized, these vessels re-open and vision fully returns. Although there are no cases in the reported annals of refractive procedure, there is a concern among refractive surgeons that this blood vessel closure could conceivably cause some damage to the nerves inside the eye. Studies looking for this have not been able to document this, but in some susceptible patients (such as those with advanced nerve damage from glaucoma) it may be preferable to choose a refractive procedure technique other than LASIK.

It is very important to have a very comprehensive, dilated eye exam prior to LASIK looking for such things as glaucoma, cataracts, dry eyes, corneal disorders and retinal disorders so the best refractive procedure

approach can be used for each individual patient. At Lipstock LASIK & Cataract Center you can expect a 2-3 hour exam to help us determine what is best for you.

Other: Having LASIK or any other type of refractive procedure could conceivably disqualify you from some professions (particularly military or law enforcement). It is your responsibility to investigate any requirements and/or exclusion criteria for any profession and/or sport or hobby in which you may be interested.

Pregnancy is a relative contraindication to LASIK because of the variable healing response, and the unknown response of the fetus to the eye medications especially during the first trimester. If you are female and able to become pregnant, you should use adequate birth control during and for at least 3 months following the procedure(s).

In addition to the above, it is possible to experience unknown or as yet unreported complications following LASIK, in spite of the fact that we have over 50 years of experience with lamellar (corneal flap) refractive procedures. As noted above, complications can occur after LASIK and it is conceivable that, if severe enough, these may cause partial loss of vision or even blindness or may require prolonged treatment and/or further procedures.

EXPECTED BENEFITS OF LASIK PROCEDURE:

The purpose of LASIK is to reduce your level of nearsightedness, farsightedness, and/or astigmatism and to improve your ability to see at a distance and/or near without glasses or contact lenses. Although the vast majority of the time after primary LASIK and/or a repeat LASIK procedure (enhancement) you can obtain clear vision without glasses or contacts, at least for distance vision, no guarantee is being made that you will not have to wear glasses or contact lenses either some or all of the time to achieve your best vision. Even if your uncorrected vision is significantly better than it was before the procedure, you may require glasses or contact lenses to see well for distance tasks (e.g., driving or playing sports) either part-time or full-time. Additionally, you may, depending upon your age, need to wear reading glasses after LASIK.

ALTERNATIVE TREATMENTS TO LASIK:

LASIK is a procedure which in consultation with your physician you may elect to undergo. There are alternatives to LASIK for reducing nearsightedness, farsightedness, and astigmatism. These include non-surgical and surgical options. Non-surgical corrections include wearing eyeglasses or contact lenses. Orthokeratology is a technique that warps the corneal shape with contact lenses to temporarily decrease nearsightedness. Surgical alternatives to LASIK include PRK, a procedure that involves applying the same excimer laser energy to the most superficial layers of the corneal stroma (like LASIK without a flap). PRK has been determined by the FDA to be safe and effective for the treatment of nearsightedness, farsightedness, and astigmatism. Another alternative is Intacs corneal rings for very mild degrees of nearsightedness. This does not correct any astigmatism or farsightedness. It is rarely performed anymore for routine nearsighted patients. Radial keratotomy (RK) is another older refractive procedure technique that utilizes radial incisions in the cornea made by a diamond scalpel. This technique is rarely ever used today for nearsightedness. A variant of RK, called astigmatic keratotomy, or AK, is still sometimes used for the treatment of astigmatism. CK (conductive keratoplasty) is an alternative to LASIK for mild amounts of farsightedness without astigmatism. A phakic intraocular lens is an alternative to LASIK for very high nearsighted prescriptions. In fact it is the preferred choice for extreme amounts of nearsightedness. This involves placing a lens within the eye. A clear lensectomy (or cataract procedure for those with cloudy internal lenses) is another alternative to LASIK. This involves removing your natural lens and replacing it with an intraocular lens.

LASIK ENHANCEMENT:

A LASIK enhancement is performed by lifting the flap that had already been made during the first LASIK procedure. Complication secondary to creating a flap will not occur during an enhancement. All other risks are the same as for the primary procedure. One difference between lifting a flap and making one for the first time is that lifting the flap creates a somewhat wider abrasion around the edge of the flap. If it appears that there will be too much of a foreign body sensation, an extended wear soft contact lens will be placed in the eye to act like a band aide. This will provide for more comfortable and quicker healing. The contact is usually

removed with sterile instruments in the exam room the next day. Also, the wider abrasions from lifting the flap cause a somewhat higher incidence of epithelial in-growth. (see epithelial in-growth section).

CONSENT:

Do not sign this form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

In signing this consent form for LASIK, I am stating that I have read this completely or that it has been read in full to me and that I understand its content and purpose. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur. I understand that no warranty or guarantee has been made to me regarding the effectiveness or safety of the LASIK procedure. I understand that LASIK is "approved" by the FOOD AND DRUG ADMINISTRATION as an indication for the use of the excimer laser for myopia, hyperopia, and/or astigmatism. Furthermore, I am stating that all questions regarding my procedure have been answered to my satisfaction.

I hereby give permission to Kenneth Lipstock, M.D. to perform **(circle one)**:

- 1.) Laser-Assisted in Situ Keratomileusis (LASIK) on my eye(s) using Intralase/microkeratome
- OR
- 2.) LASIK enhancement

If during the course of the procedure any unforeseen condition(s) arise calling for, in Dr. Lipstock's judgment, procedure(s) in addition to or different from that contemplated, I authorize him to do whatever he deems appropriate such as, but not limited to, performing PRK.

I authorize the physicians and other healthcare personnel involved in performing my LASIK procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my LASIK procedure that they deem relevant to providing me with care.

I authorize the photography and recording of the procedure performed upon me for professional use by my physicians. I hereby grant permission to have the procedure observed by third parties.

I understand that I will receive a copy of this consent form.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a patient.

_____ I choose to have the LASIK procedure on only one eye at a time

_____ I choose to have the LASIK procedure on both eyes on the same day, if possible.

_____ I choose to have the PRK procedure if LASIK is unable to be performed.

Patient's Signature

Date

Witness's Signature

Date

Kenneth D. Lipstock, M.D.

Date