

# **Clear Advantage Vision Correction Center**

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## **INFORMED CONSENT FOR LASIK AND FEMTOSECOND LASER**

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**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 of 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 surgery without the patient accepting a certain degree of risk and responsibility. This consent form, in combination with the 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 complications 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.

### **SECTION 2: LASER VISION CORRECTION BACKGROUND SUMMARY**

Laser-Assisted 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 sculpts the surface layer of the cornea, while LASIK reshapes 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. LASIK is performed on an out patient basis and takes 10 – 20 minutes to complete. Although patients sometimes feel some pressure sensation, the procedure is generally painless. Topical anesthetic drops are used to numb the eye and an eyelid holder is used to prevent blinking. Patients focus on a red target light throughout the procedure. In LASIK, a protective corneal flap is created by the use of a Femtosecond “bladeless” laser. The protective flap is about 30% of the corneal thickness and is hinged beneath the upper eyelid. A suction ring holds the eye in position while the corneal flap is created. The femtosecond laser creates the flap by using tiny rapid pulses of laser light. Each pulse of light passes harmlessly through the cornea and forms a microscopic bubble at a specific depth and position. Patients are unable to see the corneal flap being made as the vision becomes dark when the suction is applied and the red target light disappears until the flap is completed. Most patients sense some pressure, but the femtosecond laser technique is considered 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. Although rare, a bandage contact lens may be required, and a protective eye shield or protective goggles will be used. Although the vision is blurry immediately following LASIK, patients are able to blink normally and there is rapid overnight visual improvement.

### **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 years of age.
- Candidates must have a stable refraction with no more than a 0.50 diopter change within the previous year, as the procedure will not change the natural growth or aging of the eye and certain retinal and optic nerve diseases.
- Candidates must be free of certain health problems including uncontrolled diabetes, autoimmune or collagen vascular disease, any medication or condition that renders the patient immunocompromised.
- Candidates must make their surgeon aware of certain eye problems including amblyopia (lazy eye), strabismus (muscle imbalance), severe dry eyes, or any recurrent, residual or active eye condition that may affect healing.
- Candidates must make their surgeon aware of certain general health conditions including keloid scarring with previous surgery healing, back problems which may prohibit the ability to lie down (particularly during the procedure), claustrophobia or other psychological problems which may affect the surgery or recovery.
- Candidates must make their surgeon aware of implants including a cardiac pacemaker, insulin pump or other electronic implanted device.

**Patient Initials** \_\_\_\_\_

- Patients must also make their surgeon aware of any medication allergies and any medications they are taking to avoid any possible drug interactions and allergic reactions.
- The FDA considers pregnancy and nursing contraindications, although their effects 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 in the next six months.

#### PRE-PROCEDURE and POST-PROCEDURE CARE

The screening examination is intended to assess your candidacy for refractive surgery based upon the corneal shape, thickness, 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 the surgery, but it is unrelated to laser surgery. Refractive surgery will not treat ocular disease. You should have a complete eye exam 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 problems, 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 LASIK to allow the cornea to return to its natural contour. Soft contacts must be removed *at least* five days prior to surgery. Toric lenses, soft toric lenses, or astigmatism correcting contact lenses must be removed 10 to 14 days prior to surgery. Candidates with rigid gas permeable lenses must discontinue their use for several weeks, and sometimes several months, prior to LASIK.

Post-operative follow-up care with an eye care professional is recommended for one year to monitor LASIK healing, and yearly examinations are recommended thereafter. Occasionally an enhancement procedure (an attempt to refine the initial laser procedure) is requested, and usually this can be done at no additional charge in the first year. However, if a later enhancement is required or if a complication occurs, the patient may incur a fee and may be required to travel to another laser center or be seen by another surgeon at the patient's own expense. The final clinical results are dependent, in part, upon properly following your post-operative care instructions.

#### SECTION 4: PRESBYOPIA AND THE MONOVISION OPTION:

Presbyopia, the normal aging change of the internal near focusing structures of the eye, naturally causes people to need reading glasses for near vision and intermediate glasses for arms length vision (computer screen) in their 40's or 50's. If you need bifocals or reading glasses now, and do not opt for monovision, you will still need reading glasses and/or intermediate glasses after LASIK. If you do not wear reading glasses and/or intermediate glasses now, you will most likely need them as you age, whether or not you have LASIK. LASIK does not stop the natural aging process of the eye. Although farsighted patients usually improve their reading ability with LASIK, it is possible that nearsighted patients who are already in their 40's or 50's, may require reading glasses and/or intermediate glasses sooner than if they did not have LASIK, often immediately after surgery.

One possible option is monovision. In monovision, the aim is to have the non-dominant eye slightly under-corrected (i.e. not fully corrected for distance vision) in order to help reading and intermediate vision. This involves giving up a little distance sharpness. Glasses for night-time (i.e. driving) are more common with patients with monovision, and reading glasses and/or intermediate glasses may still be required for fine print or prolonged reading or computer work; HOWEVER, overall dependence upon glasses and contacts is usually reduced. Monovision helps with simple near tasks such as opening mail, reading price tags, or looking at one's wristwatch. Patients, who desire or require the best distance or night vision unaided, such as golfers or airline pilots, should avoid monovision. If you desire laser vision correction and are under the age of 40, monovision is not generally recommended.

Initial next to the statement that accurately describes your goal for vision correction:

**I would like to correct my distance vision.** \_\_\_\_\_

I may need to wear reading glasses and/or intermediate glasses after the age of 40. \_\_\_\_\_

**I would like to have monovision (one eye distance / one eye near).** \_\_\_\_\_

I am over the age of 40 and I want one eye corrected for distance vision and one eye corrected for near vision. \_\_\_\_\_

#### SECTION 5: LEGAL RESPONSIBILITIES

##### CONFIDENTIALITY

By initialing below, you give permission for the medical data concerning your surgery and subsequent treatment to be submitted to Clear Advantage Vision Correction Center, Eyesight Ophthalmic Services, the laser manufacturer and the government regulatory authorities. The data will be utilized for statistical analysis, record keeping, marketing, and 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, Clear Advantage Vision Correction Center, and your surgeon shall be governed by and construed in accordance with the laws of New Hampshire. You also acknowledge with your initials that courts of the state of New Hampshire 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 New Hampshire and you irrevocably submit to the exclusive jurisdiction of the courts of New Hampshire.

## SECTION 6: 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 corrective contact lenses. The risk of a severe complication is not only dependent upon the functioning of the femtosecond laser and surgical technique, but upon a number of other factors including the prescription, orbital structure, cornea shape, and healing characteristics of the individual treated. In general, there is a small risk in the range of 1 – 5 % of experiencing a complication and a very small risk, probably less than 1 in 5000, of a severe sight-threatening complication. Please read this section carefully for a better understanding and initial below

The risks of LASIK revolve around 6 primary areas:

1. Post-operative Side Effects, Adverse Effects and Complications
2. Refractive Complications
3. Corneal Flap Complications
4. Corneal Healing Complications
5. Corneal Ectasia
6. Other Miscellaneous Complications

### 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 but very serious 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 Sand of the Sahara) is an inflammatory reaction that can produce corneal hazing, blurred vision, farsightedness, or astigmatism which 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. The most important long-term side effects are night glare, starbursts, 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 common when only one eye has been treated. Night visual disturbances may be 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 night 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.

### 2. Refractive Complications

Refractive problems that may be encountered include too much correction, too little correction, asymmetric correction, a prescription imbalance between eyes, aggravation of muscle imbalance problems, or a loss of effect from regression. LASIK may result in over corrections and under corrections due to 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 typically achieved. Patients may also heal differently between eyes, based upon differences between eyes in pre-operative prescriptions, corneal curvature, variation in healing, or other surgical variables. Differences in refraction between eyes is termed anisometropia; this is most severe when only one eye is treated, and may result in a loss of depth perception, eyestrain, headache, double vision and the need for contact lenses. Both farsightedness and anisometropia may 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.

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### 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 to 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 only a few dozen times worldwide. Corneal flap complications that occur after the LASIK procedure during recovery period include displacement and wrinkling of the corneal flap and epithelial ingrowth. Overall, corneal flap complications are rare, with a reported incidence between 0.3 – 14%, depending on the type of device used. The highest incidences of flap complications are associated with microkeratome (bladed) procedures. It is for this reason that most surgeons prefer utilizing a femtosecond laser for flap creation unless there is a medical condition that would make the femtosecond less ideal.

Corneal flap complications using the **FEMTOSECOND LASER** (bladeless laser) include but are not limited to:

- Corneal flaps of inadequate thickness, may or may not be adequate for laser treatment, and may result in the procedure being stopped and repeated at a later date. A thin corneal flap may result in slow visual recovery over weeks to months and possibly permanently blurred vision with or without laser treatment.
- 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 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 of the corneal cap may result in scarring, and permanent corneal irregularity and the need for more invasive surgery.
- 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 (squeeze blinking) 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.
- 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 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.

### 4. Corneal Healing Complication

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 could potentially slow visual recovery and increase the need for enhancement procedures and/or for over- and under-corrections. Corneal healing may not 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 that 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 decentrations, that 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 limitations of healing problems are that further surgical intervention does not guarantee better healing and may, in fact, result in a further reduction in 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

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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.

#### 5. Corneal Ectasia

It is possible that the thinning of a cornea with LASIK may lead to gradual bulging of the tissue, or 'ectasia.' Mild corneal ectasia may have minimal impact on a person's vision other than leading to a return of mild myopia. More significant corneal ectasia may result in progressive distortion of vision and, in severe cases, may require corneal transplant surgery. People with higher myopic prescriptions and naturally thinner corneas are felt to be at a higher risk for developing post-LASIK ectasia. Pre-operatively, surgeons calculate the presumed residual corneal thickness following LASIK to estimate the risk of future corneal ectasia. However, we do not fully understand all the factors that place someone at risk for ectasia. What we currently feel is a "safe" residual thickness may later be determined to be inadequate to prevent ectasia. There have been reports of corneal ectasia following LASIK, but most of these older cases would not have been performed under modern screening protocols. It should be noted that the overwhelming majority of LASIK patients already treated have not subsequently demonstrated corneal ectasia.

#### 6. Increased Risk of Severe Damage with Eye Injury

The corneal flap normally heals so that patients are able to resume active lifestyles without damaging their LASIK flaps. However, it is possible to dislodge the corneal flap years after surgery. An eye injury, which may not have caused serious damage to a non-LASIK eye, could potentially cause a serious sight-threatening injury in an eye with a LASIK flap. As a precaution, we recommend that patients wear protective eyewear (approved by the Protective Eyewear Certification Council) when participating in sports or activities in which they may be struck in the eye.

#### 7. 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.

### SECTION 7: 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 may still be needed for certain activities that require fine or detailed vision.

Enhancement procedures can be performed when a patient's healing appears 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 or residual hyperopia, myopia, or astigmatism or unaided vision of 20/40 or worse. Enhancement procedures are usually not performed until after 3 months, once adequate corneal healing and stability is achieved. Enhancement procedures are typically performed by lifting the original flap during 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. The laser manufacturer also has a Patient Information Booklet that is available to patients at Clear Advantage and Eyesight Ophthalmic Services, which describes, among other things, the results of clinical trials for the laser.

### SECTION 8: 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 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 find 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.

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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 treatment. 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 check the appropriate response to indicate the treatment you choose:

I would like to have ☐ my RIGHT eye ☐ my LEFT eye ☐ BOTH of my eyes treated

#### SECTION 9: WRITTEN CONFIRMATION

**PLEASE WRITE or TYPE IN THE FOLLOWING TWO STATEMENTS IN THE SPACE PROVIDED BELOW** 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 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.”**

#### SECTION 10: VOLUNTARY CONSENT

Please sign below indicating that you have carefully reviewed this informed consent document and that you have had an opportunity to ask any questions. By signing below, you also indicate that you 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.

**Patient Full Name (PRINT):** \_\_\_\_\_

**Patient Signature:** \_\_\_\_\_

**Witness Full Name (PRINT):** \_\_\_\_\_

**Witness Signature:** \_\_\_\_\_

**Surgeon Name:** N. Timothy Peters, M.D. Jennifer Ling, M.D.

**Surgeon Signature:** \_\_\_\_\_

**Date of Procedure:** \_\_\_\_\_