INFORMED CONSENT

STRIAE SMOOTHING

INTRODUCTION

This document is provided to obtain your informed consent for striae smoothing. It contains important information detailing the risks and benefits as well as alternative treatments available.

It is important that you thoroughly read and understand everything, and only sign once you have read, understood, and have had all questions answered to your satisfaction enabling you to make an informed decision.

INSTRUCTIONS

- You must review this entire document prior to treatment.
- Take as much time as needed to read and understand this document prior to signing.
- Your doctor is available to answer any questions or concerns you have regarding this consent.
- This document must be signed prior to any treatment.
- You will sign this document in-person at Laser Eye Institute.
- You may request a copy of this document at any time.

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INFORMED CONSENT FOR STRIAE SMOOTHING

INDICATIONS AND PROCEDURE

During LASIK treatment the initial step requires the generation of a flap. After treatment this flap is repositioned to act as a bandage, promoting healing and fast visual recovery. In some instances the flap my slip, dislodge, or wrinkles. Most typically this occurs as a result of trauma to the eye, specifically, the LASIK flap. While healing a LASIK flap is very susceptible to trauma, this trauma could be as minimal as rubbing the eye or eye squeezing. This condition is commonly called a wrinkled flap, or dislocated flap post-LASIK. The amount of dislocation can only be measured by your ophthalmologist with a slit-lamp examination. Depending on the severity and impact to vision surgical correction may be required. This surgical correction is known as striae smoothing or repositioning of dislocated flap. Surgical treatment involves placing a topical anesthesia on the eye, then lifting the LASIK flap, hydrating it with fluid, and stretching and smoothing it before returning it back into place.

Post-operative instructions after LASIK should be followed carefully to avoid trauma which may result in flap wrinkling. If left untreated, the condition will worse and may become permanent resulting in poorer or loss of vision.

Clinically significant striae requiring treatment is rare and is typically a direct result to trauma or failing to ahead to post-operative instructions. Striae smoothing requires additional surgical treatment to correct that is not included in the global LASIK fee or post-operative care period.

ALTERNATIVES

Stria smoothing is recognized as the preferred initial treatment to correct flap striae. More serve cases may require additional treatment including suturing, ironing, or phototherapeutic keratectomy (PTK). If left untreated striae folds may become permanent resulting in poorer or loss of vision.

RISKS AND COMPLICATIONS

Despite the best of care complications and side effects may occur; should this happen in your case, the result might be affected event to the extent of making your vision worse or total loss of vision. The long-term risks and effects are unknown. I have received no guarantee as to the success of my particular case. I understand the associated risks.

I understand that additional treatment may be required, including suturing, ironing, or phototherapeutic keratectomy.

I understand that even after successful treatment vision may not improve to levels it was prior to striae folds.

I understand that after treatment epithelium ingrowth may occur, where the surface layer grows under the flap requiring additional surgical treatment.

Corneal scaring or corneal swelling may occur after treatment, this may cause vision to worsen.

I understand that if left untreated, my condition will worsen resulting in poorer, or even loss of vision.

I understand that after treatment my vision could worsen, or I could lose contrast sensitivity.

It is possible that the introduction or spread of infection may occur which may lead to visual impairment.

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.

I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body.

I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

INFORMED CONSENT

By signing the below, I certify the following to the best of my knowledge:

All 3 pages of this document have been given to me in its entirety. I have been given this document in advance of being asked to sign it.

All of my questions regarding treatment have been answered to my satisfaction allowing me to give my informed consent.

I have read, understand, and hereby consent to: *Stria Smoothing*

I understand that during the proposed procedure(s) unforeseen conditions may be revealed requiring the performance of additional procedures, and I authorize such procedures to be performed at my physician's discretion. These additional procedures may carry additional risks in addition to the risks outlined above.

I understand that no warranty or guarantee has been made to me regarding the result, cure, or safety.

I give my permission for Laser Eye Institute to videotape or photograph my procedure for purposes of documentation, education, research, or training. Additionally, I give my permission for Laser Eye Institute to use data about my treatment to advance the field of laser vision correction. I understand that my name, or any other personally identifiable information will remain confidential unless I give subsequent written permission for my identity to be disclosed.

MY SIGNATURE BELOW FURTHER CERTIFIES:

TO THE BEST OF MY KNOWLEDGE I AM NOT CURRENTLY PREGNANT.

I AM NOT UNDER THE INFLUENCE OF ANY NARCOTIC, ALCOHOL OR ANY OTHER DRUG, OR SUBSTANCE THAT MAY IMPAIR MY JUDGEMENT OR MY ABILITY TO UNDERSTAND THIS CONSENT.

I WAS ABLE TO READ AND UNDERSTAND THIS INFORMED CONSENT. ANY QUESTIONS I HAD REGARDING THE ABOVE PROCEDURE(S), RISKS, BENEFITS, AND ALTERNATE PROCEDURES HAVE BEEN EXPLAINED TO MY SATISFACTION ALLOWING ME TO GIVE MY INFORMED CONSENT FOR THE ABOVE PROCEDURE(S).

Patient Name	Patient MRN	Date

Patient Email Address	Surgical Coordinator

Patient Signature