INFORMED CONSENT

EPITHELIUM INGROWTH REMOVAL

INTRODUCTION

This document is provided to obtain your informed consent for removal of epithelium ingrowth. 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.

ID: CF REV: E-20201014

INFORMED CONSENT FOR REMOVAL OF EPITHELIUM INGROWTH / SMILE INTERFACE

INDICATIONS AND PROCEDURE

This information is being provided to you so that you can make an informed decision about surgically removing growth from the stromal bed or the flap undersurface, also known as "EPI-Ingrowth". Ingrowth of epithelium into the corneal flap interface is a potential complication of laser vision correction. Ingrowth of these cells into the corneal stromal interface is usually asymptomatic, however, these cells may lead to decreased vision due to irregular corneal astigmatism, direct intrusion of cells into the visual axis, or lead to melting of the overlying flap. Treatment is generally needed in instances where there is decreased vision or threat for a flap melt.

Treatment involves surgically removing the invading epithelial cells from the interface and achieving closure of the flap edge to prevent recurrent invasion of epithelium into the flap stromal interface space. Afterwards topical antibiotics and steroids are given, a bandage contact lens may be placed to improve comfort. The chance of recurrence afterwards is approximately 20%.

ALTERNATIVES

Suturing or gluing the flap after removal of the epithelial cells to create a tight apposition between the flap and the stromal bed has been shown to reduce the recurrence rate without the adverse effects of the listed adjunctive treatments. Adjunctive gluing of the flap after epithelial debridement in recurrent ingrowth cases to improve flap adhesion to the stromal bed has also been reported to have favorable outcomes. Additionally, YAG laser is another method used to destroy epithelial cells. This option may be especially useful when cells are located in a small area (<1mm). There may be treatments unknown at this time now or in the future for treatment of ingrowth not listed here.

RISKS AND COMPLICATIONS

There may be other risks not know at this time, which may become known later. 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. I have received no guarantee as to the success of my particular case. I understand that the associated risks.

Epithelial ingrowth that has been persistent in the flap interface for weeks to months may lead to flap melting. Flap melt usually begins at the flap edge overlying the area of epithelial invading cells. Flap melting has been described as secondary to collagenase release from hypoxic epithelial cells underneath the flap. The patient may be asymptomatic, however, flap melts can lead to a distortion of the corneal surface with possible astigmatic changes and secondary tear film disruption leading to dry eye problems.

Haze and scarring from inactive or treated epithelial ingrowth may be associated with glare, haloes, ghosting, and decreased vision.

It is possible that ingrowth will reoccur requiring further or alternate treatment.

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

It is possible that flap striae, or wrinkling, may occur requiring further treatment, which may lead to visual impairment.

Corneal scaring 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 there is approximately a 20% chance or reoccurrence.

I understand that the creation of a flap may be susceptible to trauma. It is important to follow instructions carefully to avoid wrinkling of the flap. Correcting a flap issue caused by failure to follow instructions is subject to a surgical and facility fee.

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: *Epithelial Ingrowth Removal*

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