

Consent for EPI-LASIK

This information must be reviewed so you can make an informed decision regarding EPI-LASIK surgery to attempt to improve the uncorrected visual acuity in the operative eye. Only you and your doctor can determine if you should have EPI-LASIK surgery based upon your own visual needs and medical considerations. Any questions you have regarding EPI-LASIK or other alternative therapies for your case should be directed to your doctor.

In giving my permission for EPI-LASIK surgery, I declare that I understand the following information:

The long term risks and effects of EPI-LASIK surgery are unknown.

The goal of EPI-LASIK with the excimer laser is to reduce or eliminate dependence upon or need for eyeglasses and/ or contact lenses; however, I understand that, as with all forms of treatment, the result in my case cannot be guaranteed. For example:

1. There is no guarantee that I will completely eliminate my reliance on eyeglasses and/ or contact lenses. It is possible that the treatment could result in undercorrection, where some degree of nearsightedness may remain, requiring the use of glasses or contact lenses.
2. The treatment may also result in overcorrection, causing hyperopia (farsightedness) which may or may not require the use of contact lenses or glasses.
3. If I currently need reading glasses, I will likely still need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have EPI-LASIK surgery.
4. The treatment may also result in a change in my astigmatism that could require the use of glasses and/ or contact lenses.
5. Further treatment may be necessary, including a variety of eyedrops, the wearing of eyeglasses or contact lenses (hard or soft) or additional EPI-LASIK surgery.
6. My best vision, even with glasses or contacts, may become worse.
7. There may be a difference in spectacle correction between eyes, making the wearing of glasses difficult or impossible. Fitting and wearing contact lenses may be more difficult.

Alternatives to EPI-LASIK surgery:

The alternatives to EPI-LASIK surgery include eyeglasses, contact lenses or a different refractive procedure. Each of these alternatives to EPI-LASIK has been explained to me.

I have been informed, and I understand, that certain complications and side effects have been reported in the post-treatment period and are associated with the normal post-treatment healing process: mild discomfort or pain (first 24 to 48 hours), corneal swelling, double vision, feeling something is in the eye (foreign body sensation), ghost images, light sensitivity and tearing.

Possible long-term complications of EPI-LASIK surgery:

1. Haze: Loss of perfect clarity of the cornea, usually not affecting vision, which usually resolves over time.
2. Glare: Sensation produced by bright lights that are greater than normal and can cause discomfort and annoyance.
3. Halo: Hazy rings surrounding lights may be seen, particularly at night.
4. Loss of Best Vision: A decrease in my best vision even with glasses or contacts.
5. Intraocular Pressure (IOP) Elevation: An increase in the inner eye pressure due to post-treatment medication, which is usually resolved by drug therapy or discontinuation of post-treatment medications (i.e. topical steroid eyedrops).

The following complications have been reported infrequently by those who have had EPI-LASIK surgery: itching, dryness of the eye or foreign body feeling in the eye; double or ghost images; patient discomfort; inflammation of the cornea or iris; persistent corneal surface defect; irregular astigmatism (warped corneal surface which causes distorted images); cataract; drooping of the eyelid, corneal scarring; and a slight risk of possible infection due to the use of a bandage contact lens in the immediate post operative period.

I understand there is a remote chance of a partial or complete loss of vision in the eye that had the EPI-LASIK surgery. _____(initial)

I understand that EPI-LASIK is a relatively new procedure first introduced in the United States in 2003. Therefore, all of the possible long term side effects may not be known_ _____(initial)

I understand that it is not possible to state every complication that may occur as a result of EPI-LASIK surgery. I also understand that complications or a poor outcome may manifest weeks, months or even years after EPI-LASIK surgery. _____(initial)

I understand this is an elective procedure and EPI-LASIK surgery is not reversible. _____(initial)

OFF-LABEL PROCEDURES:

Some of the procedures that are performed as part of modern LASER Vision Correction operations may not be approved by the FDA and are considered to be “off-label” uses of a particular device, drug or technique. For example, if you and your surgeon have decided to have a Wavefront (Custom) LASER Vision Correction procedure performed as part of your epi-LASIK procedure, that is an “off-label” (non-FDA-approved) procedure. The FDA has only approved Wavefront (Custom) treatments as part of a LASIK procedure. However, your doctor may be of the opinion that combining the Wavefront (Custom) LASER technology with the epi-LASIK procedure may be the best procedure for certain situations.

Mitomycin: The drug Mitomycin was originally approved by the FDA for the treatment of certain types of cancer. However, eye surgeons have been using the drug Mitomycin for years as part of certain eye surgeries for the purpose of preventing and/or treating unwanted scarring. The use of Mitomycin for this purpose can be highly effective, but this particular use of the drug is not FDA-approved for this purpose, and is considered to be an “off-label” use. The long-term safety of this drug has not been established.

I have read and understand the above statements regarding “off-label” uses and agree to proceed with the treatment my doctor has recommended.

_____ (initials) or _____ (N/A)

FOR WOMEN ONLY: I am not pregnant or nursing. I understand that pregnancy could adversely affect my treatment result and could increase the chances of over- corrections or under-corrections.

Patient initials

My personal reasons for choosing to have EPI-LASIK surgery are as follows:

I have read and understand the information that has been discussed with me. I have spoken with my physician, who has explained EPI-LASIK, its risks and alternatives, and answered my questions about EPI-LASIK surgery. I therefore consent to having EPI-LASIK surgery.

Patient Signature

Date

Physician Signature

Date

Witness Signature

Date

I have been offered a copy of this consent form:

Patient Initials