

# INFORMED CONSENT ADDENDUM

## MONOVISION ADDENDUM

### INTRODUCTION

This document is provided to obtain your informed consent for laser vision correction using a treatment method known as monovision. Monovision treatment is applied during laser vision correction (LASIK, PRK/LASEK, SMILE) to reduce your dependence on both distance and reading glasses. This addendum contains important information detailing the risks and benefits as well as alternative treatments available. Laser vision correction is an elective procedure and you are choosing it because you want to, not because you must.

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.
- This document is an addendum to your LASIK, PRK/LASEK, or SMILE consent. It reviews the additional risks associated with a monovision treatment.
- Monovision adjusts the amount of treatment applied during LASIK, PRK/LASEK, or SMILE. It is important you also review the consent documents for your specific laser vision correction treatment.
- You have the opportunity to try Monovision through a Monovision contact lens trial.

## INFORMED CONSENT ADDENDUM FOR MONOVISION / MENUVISION (MV)

### INDICATIONS AND PROCEDURE

Laser vision correction can precisely correct fixed focal errors of the eye such as nearsightedness, farsightedness, and astigmatism. These optical conditions are fundamentally different than presbyopia, the loss of adjustability of focus for near viewing. Presbyopia is the reason that reading glasses (magnifiers) become necessary, typically in the 40's; even for people who have excellent distance vision. A person that is presbyopic will use bifocal lenses, progressive lenses, or two sets of glasses to correct their distance and near vision.

### **AT THIS TIME THERE IS NO PERFECT TREATMENT OR CURE FOR PRESBYOPIA, MONOVISION IS A COMPROMISE.**

For some individuals, correcting one eye for distance vision, and the other eye for reading, affords a reasonable solution. This is called monovision (one eye for distance, one eye for near vision). If a person functions well with monovision in lenses (either glasses, or contacts), the same option can be created on a more permanent basis with laser vision correction. If you are contemplating such correction for yourself, it is important to understand the advantages and drawbacks of selecting monovision.

### ALTERNATIVES

There are several options available to those who are presbyopic, besides monovision including: wearing bifocals, separate distance and reading glasses, or contacts. For example, contact lenses can be worn for distance correction in both eyes, and reading glasses can be put on to read. Similarly, during laser vision correction both eyes can be fully corrected for distance and reading glasses can be used to read.

### RISKS AND COMPLICATIONS

In deciding to have monovision laser vision correction, you should understand the potential risks and complications that are associated with this type of treatment. Additionally, you should fully understand the visual **compromise** you make when selecting monovision.

### INABILITY TO TOLERATE VISUAL IMBALANCE

Rarely, some individuals are unable to tolerate an imbalance in their vision. This imbalance may cause headaches, trouble focusing, and may impair routine activities. Individuals who are unable to tolerate an imbalance in vision should not have a monovision treatment. Trying monovision with either trial lenses or contact lenses is an appropriate method to determine if you will tolerate monovision. Even if you are able to tolerate monovision with trial lenses (glasses) or contact lenses, you may be unable to tolerate monovision once applied permanently.

### REDUCED DEPTH PERCEPTION

For most people, depth perception is best when viewing with both eyes optimally corrected and balanced for distance (called binocular vision). Monovision can reduce depth perception to some extent, because the eyes are not focused at the same distance point. Monovision can reduce optimum depth perception, thus it is recommended that this option be tried with trial lenses or contact lenses prior to contemplating a surgical correction which will be permanent.

### OCULAR DOMINANCE, AND CHOOSING THE DISTANCE EYE CORRECTLY

Ocular dominance is similar to right- or left-handedness. Typically, eye care professionals believe that for most individuals, one eye is the dominant eye for viewing. Several tests can be performed to determine which eye, right or left, is dominant in a person. Conventional wisdom holds that if contemplating monovision, the dominant eye should be corrected for distance, and the non-dominant eye corrected for near. While this is a good guideline, it should not be construed as an absolute rule. A very small percentage of persons may be co-dominant, and in rare circumstances a person may actually prefer using the dominant eye for near viewing. The methods for testing and determining ocular dominance are not always 100% accurate; and there is some subjective component in the measurement process. Be sure you understand this and have discussed with your surgeon which eye should be corrected for distance, and which for near. If you have any doubts or uncertainty whatsoever, treatment should be delayed until a very solid comfort level is attained. Under no circumstances should you consider undertaking monovision surgical correction before you are convinced it will be right for you. Once surgery is performed, it is not always possible to undo what is done, or to reverse the distance and near eye. Additionally, patients that perform one-eye tasks (such as looking through the scope of a rifle, or using a video camera viewfinder) must be especially aware of their ocular dominance and discuss such one-eye tasks with their doctor prior to treatment.

### SELECTION OF NEAR EYE POWER

Just as important as selecting the eye which will be corrected for distance, selecting the amount of correction (called power) for the near eye is extremely important. When having a monovision treatment different amounts of correction can be applied to the near eye to adjust the point at which the eye will naturally focus. All monovision patients are encouraged to try different near-eye-powers with many of their daily activities to determine the most appropriate near-eye-power. Near eye power selection is subjective, a patient reading contracts held a few inches away will prefer a different near eye power than a patient who uses a computer monitor placed further away. The most effective way to determine near-eye-power is through the use of contact lenses, in which the near eye contact lens can be easily switched.

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## VISUAL CONSTRAINTS AFTER TREATMENT, MONOVISION COMPROMISE

**Monovision is a compromise.** You will need glasses at times for distance vision since both eyes are not fully corrected for distance. Some examples of this may include driving while it is dark and raining or watching a movie from the back row. Conversely since both eyes are not fully corrected for near vision there will be times where you will need reading glasses. Some examples of this would be reading an entire newspaper or reading a contract with small print. For most patients, these strenuous visual activities make up a small percentage of their waking time and they are satisfied by not requiring any corrective glasses for much of their day. In selecting a monovision treatment you should fully understand this compromise, be satisfied with the risks and benefits, and understand you will need corrective glasses for some visual activities.

## REVERSAL

A small percentage of patients are not satisfied with monovision. Most monovision treatments may be reversed. This is accomplished by treating the monovision eye fully for distance. Once reversed both eyes will be corrected for distance and you will require reading glasses. Even patients who did not routinely use reading glasses prior to Monovision may require them after a Monovision reversal. Monovision may only be reversed after the initial treatment has stabilized and you have allowed a period of time to adjust to monovision correction. This time period will be determined by your surgeon, typically six months. Reversal of monovision carries all the risks of the original procedure. Since a reversal of monovision requires correcting both eyes fully for distance once reversed it will be permanent and you will need reading glasses to correct your near vision.

## OFF LABEL TREATMENT

The Food and Drug Administration (FDA) approves medical devices for specific treatment profiles (Indications), and laser vision correction has not been indicated by the FDA for monovision or monovision treatments. FDA approval for the excimer lasers were based upon specific treatment constraints and monovision treatments were not included as part of the FDA study or approval. I understand that this is considered an off-label procedure and there may be both short term and long term risks either now, or in the future, not studied by the FDA that may be related or unrelated to an off-label treatment.

## TRYING MONOVISION WITH TRIAL LENSES OR CONTACT LENSES

It is the policy of Laser Eye Institute for every patient to try monovision through either trial lenses in office, or through contact lenses. You are encouraged to spend as much time as possible to determine if monovision is right for you, selection of the distance eye, and selection of reading power. A Monovision contact lens trial allows you to try monovision for an extended period of time during daily activities, on a semi-permanent basis.

**A Monovision contact lens trial is strongly suggested for all patients. If you declined to complete a monovision contact lens trial you understand that Monovision may result in headaches, imbalance in vision, and reduction in depth perception which may only become evident when trying monovision for an extended period with contact lenses. Despite these risks and the opportunity to complete a monovision contact lens trial, you elect to have a monovision treatment.**

**In consenting to Monovision treatment you certify that you were given the option to try monovision through either: trial lenses (glasses), or a monovision contact lens trial. You successfully completed a trial of Monovision and are satisfied to apply Monovision permanently.**

## INFORMED CONSENT

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

All 4 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: *Monovision / Menuvision*

I understand at this time there is no perfect treatment or cure for presbyopia (aging of the eye) and that my presbyopia, or need for reading glasses, will worsen with age. **I understand monovision is a compromise that may require glasses for some near, intermediate, or distance activities.**

I understand the importance of selecting my near vision eye, as well as the correct near vision power.

**I have been given the opportunity to try monovision contact lenses.**

**I have successfully tried monovision through trial lenses (glasses) or contact lenses.**

I understand if unable to tolerate monovision it may be reversed, and I will be responsible for any additional fees incurred. If reversed, both eyes will be fully corrected for distance requiring the full-time use of near-vision or reading glasses to correct my presbyopia.

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	Monovision Near/Reading Eye
	Near Vision Eye:    RIGHT (OD)    LEFT (OS)