CONSENT FOR TREATMENT USING THE CUSTOM-CONTOURED ABLATION PATTERNS (CUSTOM-CAP)

You and your ophthalmologist have been discussing various methods that could be used to repair problems from your previous surgery. One very new method is called Custom-CAP. This form has some information about the Custom-CAP Method to assist you. It is being used together with your doctors standard consent document(s) and some other required information.

This document may contain words that you do not understand. Please ask the doctor to explain any words or information that you do not clearly understand. You may home an unsigned copy of this consent form to think about it or discuss it with family and friends before making your decision.

INTRODUCTION

Occasionally laser eye surgery (ablation) produces an off-center (decentered) result that causes vision problems. Sometimes vision is worse than before surgery. Some patients experience severe glare, ghosting, halos, and double vision.

VISX, Incorporated, the company that makes eye surgery lasers, and Carl Zeiss Ophthalmic Systems (Humphrey division), the company that makes a device that makes computerized maps of corneas (topographer), have worked together to develop a new method to treat patients with decentered results.

This method uses a new software program. The program helps a doctor create a customized treatment plan based on information obtained from the topographer. Using the output from this software program to direct the laser is called the Custom-CAP Method.

Custom-CAP is reserved for patients who have already had at least one prior laser refractive procedure (either PRK or LASIK) that was off-center.

The Food and Drug Administration (FDA) approved the Custom-CAP Method as a Humanitarian Device. A Humanitarian Device is a device intended to help treat a condition that affects less than 4000 patients in the United States per year. It is thought that decentered ablations affect fewer than 4000 people in the United States per year. To grant a humanitarian device request there must be enough safety information but effectiveness may not have been shown.

PROCEDURES

If your ophthalmologist believes that the custom-CAP treatment plan could help normalize your eye, and if you consent, he or she will map your cornea using the software program and input this information into the laser. Then he or she will use the laser -- with the programmed information -- to treat your eye.
If both of your eyes are suffering from an off-centered result, you may be a candidate for a Custom-CAP treatment in both eyes. However, because of the complicated nature of this surgery, and because it is still quite new, both the company and the reviewers advise the ophthalmologist to do one eye at a time.

BENEFITS

This treatment may correct the off-center ablation produced from your prior laser surgery and restore your cornea to a more ideal shape. Note that the Custom-CAP treatment is not meant to reduce your dependence on glasses, or to correct your refractive error. **Should you desire correction of the refractive error with LASIK/PRK later, this will be at additional cost equal to that of routine refractive surgery at WVI.** You should also carefully consider that the effectiveness of a Custom-CAP procedure has not been studied carefully.

- Possible correction of symptoms of glare, ghosting, halos, and/or double vision.
- Possible improved vision either with or without corrective lenses.

RISKS

The laser procedure is still a laser ablation such as you had before. The usual risks of laser vision correction are still possible. Presumably you have discussed these with the doctor.

In addition, a custom-CAP procedure could also result in a further decrease in vision, corneal scarring and increase in corneal irregularity. A Custom-CAP retreatment could also cause your cornea to be thinned so much that it may be necessary to have a corneal transplant. There may be other risks that cannot be foreseen.

**Do not sign this consent form unless you have had a chance to ask questions and have received a satisfactory answer to all of your questions.**

**PATIENT STATEMENT**

The Custom-CAP procedure has been explained to me. I have had an adequate chance to ask questions. I consent to have my decentered ablation treated with the Custom-CAP and realize the refractive error will not be corrected with this surgery. A copy of this signed consent form will be given to me.

__Patient Signature__

__Date__

__Patient Name (printed)__