INFORMED CONSENT FOR ARTIFICIAL CORNEAL TRANSPLANT
(KERATOPROSTHESIS SURGERY)

WHAT IS AN ARTIFICIAL CORNEAL TRANSPLANT AND WHY DO I NEED ONE?

The cornea is the clear front window of your eye. It functions like a watch crystal. Many corneal diseases, infections, postoperative complications, and trauma can injure your cornea and make it scarred or cloudy and reduce your level of vision. Your eye surgeon has determined that you need to have a new cornea to replace the unhealthy cornea that is currently in place. There are several reasons why you may need a new cornea:

- Complications from LASIK or PRK surgery
- Degenerative eye conditions called corneal dystrophies which affect the clarity of the cornea.
- Scarring from previous infections, such bacterial, fungal, and viral (e.g. Herpes simplex) infections.
- Excessive swelling (edema) of the cornea.
- Keratoconus, a condition associated with thinning of the cornea and an irregular shape.
- Corneal problems from previous surgeries
- Chemical burns on the cornea
- Previous ocular trauma.

Patients who need a new cornea often have a surgical procedure called a penetrating keratoplasty (PK), which involves removing a full thickness piece of the patient’s cornea and replacing it with a new full thickness piece of corneal tissue. Sometimes, a DSAEK (Descemet’s stripping automated endothelial keratoplasty) is performed which involves attaching a thin piece of transplanted cornea to the back of the patient’s existing cornea. Cornea transplants may fail or cause a rejection.

An artificial cornea transplant, or keratoprosthesis, is an option for patients who are not good candidates for a traditional corneal transplant surgery. The artificial cornea replaces the damaged central cornea with a clear man-made material that your body is unlikely to reject.

The keratoprosthesis resembles a miniature telescope that is inserted into a corneal transplant and stitched into the patient’s own cornea. The natural lens, if still present, is removed. If the patient has already had cataract surgery, the lens implant is left alone. A soft contact lens is then placed onto the eye for comfort and must be worn every day. If desired, the lens can be colored to match the color of your other eye. The surgery usually takes about an hour and a half to perform.

ALTERNATIVES TO ARTIFICIAL CORNEA TRANSPLANT SURGERY:

The alternatives are traditional corneal transplants, such as PK or DSAEK, or Phototherapeutic Keratectomy (PTK) performed with the excimer laser.
COMPLICATIONS AND SIDE EFFECTS

There is no guarantee that the surgery will improve your condition. It may fail to improve your vision or even make it worse. In addition, surgery is risky. Sometimes it can make the original problem worse, cause an injury, or create a new problem; if it does, this is called a complication. Complications can happen right away or not until days, months, or years later. You may need more treatment or surgery to treat the complications. In some instances, keratoprosthesis surgery can be repeated.

The risks of artificial corneal transplant surgery with a keratoprosthesis include:

- Vitreous hemorrhage- bleeding inside the eye
- Endophthalmitis- infection inside the eye
- Glaucoma- elevated intraocular pressure
- Retroprosthetic Membrane- scar tissue forming behind the keratoprosthesis blocking the vision
- Vitritis- sterile inflammation inside the eye
- Retinal Detachment- separation of the retina from the wall of the eye resulting in loss of vision
- Stromal Melting- thinning or melting of the corneal transplant tissue that holds the keratoprosthesis in place, resulting in loosening or loss of the keratoprosthesis
- Ptosis- a droopy eyelid
- Loss of vision
- Blindness
- Injury to other nearby body parts

This document lists the major risks of artificial corneal transplant surgery with a keratoprosthesis to help you decide whether you are ready to accept the risks.

THIS IS AN ELECTIVE PROCEDURE

You do not have to undergo keratoprosthesis surgery. Alternatives to this surgery have been explained to me.

HOW WILL THE KERATOPROSTHESIS PROCEDURE AFFECT MY VISION AND/OR CONDITION?

The goal of this surgery is to restore clarity and refractive function of the cornea and improve vision.

WHAT TYPE OF ANESTHESIA IS USED? WHAT ARE ITS MAJOR RISKS?

The surgery is performed as an ambulatory procedure under local anesthesia, although general anesthesia may be used on infants and children. There are some risks associated with anesthesia, whether general or local. Complications of anesthesia injections around the eye may include: perforation of the eyeball, injury to the optic nerve resulting in loss of vision, hemorrhage, retinal detachment, interference with retinal circulation resulting in possible vision loss, drooping of the upper eyelid, hypotension or lowering of the blood pressure, and respiratory depression. General anesthesia can result in heart and breathing problems, and in a very unusual and rare instances, death or diminished brain function can occur.
PATIENT’S ACCEPTANCE OF RISKS

I have read the above information (or it was read to me) and have discussed it with my physician. I understand that it is impossible for the physician to inform me of every possible complication that may occur. My physician has told me that the results cannot be guaranteed and that more treatment or surgery may be necessary. By signing below, I agree that my physician has answered all of my questions and that I understand and accept the risks, benefits, and alternatives of artificial corneal transplant surgery with a keratoprosthesis. I have been offered a copy of this document.

I wish to have an artificial cornea placed in my _____ Right eye _____ Left eye

__________________________________________________________
Patient Signature (or Person Authorized to Sign for Patient) Date