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INFORMED CONSENT FOR USE OF A FEMTOSECOND LASER DURING CATARACT SURGERY WHEN A PREMIUM IOL IS IMPLANTED, DURING REFRACTIVE LENS EXCHANGE SURGERY, OR TO TREAT ASTIGMATISM

WHAT IS THE FEMTOSECOND LASER?

The femtosecond laser is a medical device that can be used for many purposes; it was recently approved by the Food and Drug Administration to perform some of the steps of surgery to remove a cataract or cloudy lens (approved use). It is also being used to perform some of the steps of surgery to remove a clear lens or refractive lens exchange (RLE), and to make arcuate incisions in the cornea (AK) to reduce astigmatism. There are benefits and risks associated with the use of the laser, and there may be additional costs. This section of the consent document will provide information to help you decide if you would like your eye surgeon (ophthalmologist) to use the laser to perform parts of the cataract/refractive lens surgery or to reduce astigmatism.

HOW DOES SURGERY WITH THE LASER DIFFER FROM TRADITIONAL SURGERY TO REMOVE THE LENS? WHAT ARE THE POSSIBLE BENEFITS?

Traditionally, the eye surgeon uses blades to create the incisions in the cornea (the front window of the eye), and other special instruments to create the capsulotomy (the circular incision in the outer layer of the cataract or clear lens). The surgeon also uses a phacoemulsification device that utilizes ultrasound power to break up the lens and remove it from the eye. The femtosecond laser can be used to perform some or all of these steps. The possible benefits of the laser include the ability to make more precise and consistent incisions in the cornea, a more circular and centered capsulotomy, and to pre-soften the cataract so less ultrasound energy is necessary with the phacoemulsification device.

HOW IS THE LASER USED TO TREAT ASTIGMATISM?

Patients with astigmatism have several choices for the reduction of astigmatism. Nonsurgical options for astigmatism correction include glasses and contact lenses. Surgical correction of astigmatism can be achieved through a toric intraocular lens, a limbal relaxing incision (LRI) made manually with a blade, or an arcuate incision made with the femtosecond laser (AK). Refractive surgery such as LASIK or PRK can also treat astigmatism. The shape and size of incisions made with the laser may be more precise.

WHAT ARE THE COMPLICATIONS ASSOCIATED WITH THE FEMTOSECOND LASER?

Use of the laser could increase the time needed to perform the surgery, and you may need to have the procedure performed in two different locations or two different rooms at the surgery center. It could also lead to complications, which include but are not limited to: decentration of the corneal or capsulotomy incisions; incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure; anterior capsular tear; posterior capsular tear with lens/lens fragment dislocation into the



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vitreous; corneal abrasion or defect; pain; infection; bleeding; damage to intraocular structures; anterior chamber fluid leakage; anterior chamber collapse; and elevated eye pressure.

In the case of an interrupted or incomplete corneal incision, the laser can be recentered and the incisions repeated at a different location, or the incisions can be completed using hand-held blades. In the case of an incomplete or interrupted capsulotomy, the procedure may be immediately repeated with a slightly larger diameter to complete the capsulotomy or the surgeon may elect to complete the procedure using traditional manual capsulotomy methods. In the case of an incomplete or interrupted fragmentation, the procedure can be repeated after recenteration or the surgeon may elect to complete fragmentation using conventional phacoemulsification treatment. In the case of loss of lens fragments into the vitreous, a separate procedure called a vitrectomy may be necessary to remove the vitreous and lens fragments.

PATIENT'S ACCEPTANCE OF RISKS

I understand that it is impossible for the doctor to inform me of every possible complication that may occur. By signing below, I agree that my doctor has answered all of my questions, that I have been offered a copy of this consent form, and that I understand and accept the risks, benefits, and alternatives of _____ surgery with a femtosecond laser.

I wish to have a _____ operation with a femtosecond laser on my _____ Right eye _____ Left eye

Patient Signature (or Person Authorized to Sign for Patient)

Date