

Informed Consent for Cataract Surgery using LensX Laser Device

DESCRIPTION LENSX PROCEDURE:

The eye's lens is the organ that focuses light and forms an image on the retina. The lens is held inside a bag-like membrane, called the capsule. As the lens ages, opacities and other defects, known as cataracts, forms within the lens degrading the focusing power of the lens. Cataract surgery is the removal of a lens and, typically, replacing the lens with an artificial lens (IOL) to restore vision.

In traditional cataract surgery, a metal blade is used to create an incision on the eye to gain access to the internal eye. A capsulotomy is an opening in the lens capsule to allow access to the lens contained inside. This is created using a sharp needle (cystotome) or a manual (hand-held) scalpel. Lens removal is typically done with an ultrasound device or a mechanical probe to break up and remove the cloudy lens. The purpose of the LenSx laser device is to replace the manual instruments with an automated laser device.

The LenSx laser device used in this procedure is FDA-cleared for this purpose. The device requires a way to hold the eye while it is working. There is a lens and ring system that is approved for this use. Along with assistance of lens replacement the LenSx laser device may also help alleviate a condition known as astigmatism by creating one or two precise incisions in the cornea. Astigmatism is a condition in which the surface of the eye has a more oval shape rather than a round shape. Once the laser has created the capsule opening, broken up the lens and created the astigmatism incisions (if necessary), you will be transported to the surgery suite. Here, after the conclusion of lens removal, an IOL is inserted inside the capsule.

An eye doctor will evaluate you during a preoperative exam before the cataract surgery, as well as during your surgery. You will also be evaluated at 1 day following your surgery. Further follow-ups can be requested according to the findings of the doctor. At these visits, the condition of your eye will be checked using standard procedures, including measurement of your ability to see clearly.

You will lie on your back throughout the surgical procedure. In addition to a mild

sedative, you will have an anesthetic placed on the surface of each eye so that they are numb during the entire treatment procedure. An instrument (called a speculum) will be used to keep your eyelids from closing. The contact lens and ring system will be applied to your eye using mild suction and the lasers delivery system will be lowered onto your eye. It is not expected that you will feel any pain during the procedure but you may feel pressure on your eye during the creation of the capsule incision. Once the laser capsule procedure is complete, the laser delivery system and the disposable contact lens are removed and the normal cataract surgery will proceed.

POTENTIAL RISKS AND DISCOMFORTS

You may experience complications related to the cataract surgery. The surgeon will discuss these risks with you. The risks from the device include damage to the surface of your eye, increased pressure to your eye during its use or an infection. Steps are taken to reduce these risks.

After cataract surgery, you may be prescribed post-operative medications including antibiotics or steroids. These may continue for several weeks at the discretion of the surgeon. Certain activities may also be restricted until adequate wound healing occurs.

There may be risks associated with research that are currently unknown.

The risks to an embryo, fetus or infant from exposure to this device are unknown.

Pregnant women or nursing mothers may not participate.

CONSENT

I (we) voluntarily request Dr. _____ as my physician, and such associates, technical assistants and other health care providers as they may deem necessary to treat my condition with the above described LenSx Laser System which has been explained.

I (we) understand that the following surgical, medical, and/or diagnostic procedures are planned for me and I (we) voluntarily consent to and authorize these procedures.

I have read the information in this consent form (or it has been read to me). I have been given an opportunity to ask any questions concerning my surgery, and my eye doctor has answered my questions. I freely consent to undergo the LenSx procedure.

By signing this consent form, I have not waived any of my legal rights.

I can receive a copy of this form at my request.

Subject's Signature

Date

Printed Name of Subject

Witness's Signature

Date

Printed Name of Witness

Surgeon's Signature

Date

Printed Name of Surgeon