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Informed Consent for Cataract Surgery and/or Implantation of an Intra-Ocular Lens

NAME: _____

DOB: _____

This information is given to you so that you can make an informed decision about having eye surgery. Take as much time as you wish to make your decision about signing this informed consent document. You have the right to have all your questions answered before you sign this document. You are welcome to contact Dr Devgan to answer any questions at any time before or after signing this document. His personal email is devgan@gmail.com

I understand and agree to the following:

Nature of the Procedure

A cataract is an opacity or cloudiness in the natural lens. Cloudiness in the natural lens impairs its ability to focus light, causing blurred vision. Vision can be restored by removing the hazy natural lens and replacing it with a clear artificial lens called an intra-ocular lens (IOL). The surgery is called cataract surgery. Your eye will be numbed, and you may also be given sedation through an IV. An incision, or opening, is made in the eye. A tiny vibrating probe is inserted through the incision to break the natural lens up into small pieces. These pieces are gently suctioned out of your eye through the probe. After your natural lens is removed, the IOL is placed inside your eye.

Potential Benefit

Removing the cloudy lens may restore crisp, clear vision, allowing you to function better in your normal activities. Except for unusual situations, a cataract surgery is indicated only when you cannot function satisfactorily due to decreased vision caused by the cataract. You may decide not to have a cataract surgery at this time. Cataract surgery will not correct other causes of decreased vision, such as glaucoma, diabetes, or age-related macular degeneration.

Alternative Treatments

The alternative to cataract surgery now is to do nothing or delay the surgery. Your vision may get worse over time, but cataract surgery can be done in the future if your vision worsens. In the great majority of patients, no harm comes to the eye from delaying cataract surgery. There is no pressure or urgency in performing cataract surgery now; you may wait until you feel that you are ready.

Risks, Limitations and Side Effects of Cataract Surgery

Like all surgical procedures, cataract surgery is not absolutely 100% guaranteed safe. The following paragraphs list possible risks, limitations, and side effects of this procedure.

As a result of the surgery or associated anesthesia, it is possible that your vision could be made worse. In some cases, complications may occur weeks, months or even years later. These and other complications may result in poor vision, total loss of vision, or even loss of the eye in rare situations. Depending upon the type of anesthesia, other risks are possible, including cardiac, stroke or respiratory problems, and, in very rare cases, death. Although all of these complications can occur, their incidence following cataract surgery is low.

Complications of removing the natural lens may include hemorrhage (bleeding); rupture of the capsule that supports the IOL; perforation of the eye; clouding of the outer layer of the eye (corneal edema), which may require correction with a corneal transplant; swelling in the central area of the retina (called cystoid macular edema); retained pieces of lens in the eye, which may need to be removed surgically; infection; detachment of the retina (which occurs more commonly if you are highly nearsighted); droopy eyelid; increased astigmatism; glaucoma; and double vision. These and other complications may occur whether or not an IOL is implanted and may result in poor vision, total loss of vision, or even loss of the eye in rare situations. There may be unknown complications of cataract surgery. Additional surgery may be required to treat these complications.

Complications associated with the IOL may include increased night glare and/or halo, double or ghost images, and slippage of the IOL inside the eye. In some instances, corrective lenses or surgical replacement of the IOL may be necessary for adequate visual function following cataract surgery.

Complications associated with local anesthesia injections around the eye include perforation of the eye, destruction of the eye nerve, interference with the circulation of blood flow in the retina, droopy eyelid, respiratory depression, hypotension, cardiac problems, and in rare situations, brain damage or death. For most patients, the eye can be anesthetized with eye-drops or other solutions without the need for anesthetic injections around the eye.

The selection of the proper IOL, while based upon sophisticated equipment and computer formulas, is not an exact science. After your eye heals, you may be more nearsighted or more farsighted than was intended. Patients who are highly nearsighted or farsighted before surgery have a greater risk that the eye's prescription is different than planned. Patients who have had LASIK or other refractive surgeries are also difficult to predict precisely. Additional surgeries such as IOL exchange, placement of an additional IOL, or vision correction surgery may be needed if you are not satisfied with your vision after cataract surgery. You may need to wear glasses or contact lenses after surgery to obtain your best vision. While cataract surgery has the potential to restore excellent vision, perfect vision is not a realistic expectation since nothing is as good as youthful, healthy eyes. You should be able to resume your normal activities within 2 or 3 days, and your eye will usually be stable within 2 to 6 weeks, at which time glasses or contact lenses can be prescribed if needed.

In rare cases, it may not be possible to implant the IOL you have chosen, or any IOL at all. In this situation, the surgeon will select the best option for you as dictated by the surgical situation, which may be different than your selection prior to surgery. The results of surgery cannot be guaranteed. Additional treatment and/or surgery may be necessary. You may need laser surgery after cataract surgery to correct clouding of vision.

If you have a high degree of hyperopia (farsightedness) and/or your eye is smaller than average, your risk for a rare complication known as nanophthalmic choroidal effusion is increased. This complication could result in difficulties completing the surgery and implanting a lens, or even loss of the eye. If you have a high degree of myopia (nearsightedness) and/or your eye is larger than average, your risk for a retinal detachment is increased. Retinal detachments can usually be repaired but may lead to vision loss or blindness. Other factors may reduce the visual outcome of cataract surgery, including other eye diseases such as glaucoma, diabetic retinopathy, age-related macular degeneration, or your individual healing ability.

Since only one eye will undergo surgery at a time, you may experience a period of imbalance between the two eyes. This usually cannot be corrected with spectacle glasses because of the marked difference in the prescriptions, so you will either temporarily have to wear a contact lens in the non-operated eye or will function with only one clear eye for distance vision. In the absence of complications, surgery in the second eye can usually be done one or two weeks later.

Off-label use: While all products that we use, including the lens implants, are FDA approved, many possible applications of these lens implants are not specifically FDA approved. These are called "off-label" uses. Implanting an FDA approved lens implant in a patient without significant cataracts is an "off-label" use while implanting the same lens in a patient with significant cataracts is usually an FDA "on-label" indication. Many of the

treatments that we do are off-label. The physician will use the most appropriate treatment for my condition, regardless of its FDA label status.

My vision will be foggy after the procedure and I may be sedated, so I agree not to drive a car until my vision is safe for driving. Postoperative care is important to a good outcome. I agree to attend all recommended aftercare visits. I may be video recorded and/or audiotaped during the procedure. These videos will be used for teaching purposes only, and my identity will not be disclosed.

Concurrent Treatment of Pre-Existing Astigmatism

Astigmatism is a condition where the outer focusing portion of the eye, the cornea, is somewhat oval shaped instead of being round or spherical, resulting in blurring of the vision. Large degrees of astigmatism are usually best treated with special toric IOLs, but mild or moderate astigmatism can often be treated at the time of cataract surgery with a technique called a Limbal Relaxing Incisions ("LRI") or even by how the cataract surgery is done.

Limbal Relaxing Incision is a surgical procedure which consists of making fine microscopic arcuate (curved) incisions at the limbus, which is the junction of the clear part of the eye (cornea) with the white (sclera) of the eye. These are made with a specialized diamond or laser for the purpose of flattening the steepest part of the cornea to obtain a more spherical cornea. LRI permanently changes the shape of the cornea. Although the goal of LRI is to improve vision to the point of not wearing glasses, this result is not guaranteed. LRI is an elective procedure and its only purpose is to sharpen your vision. If you decide not to have LRI, there are other methods of correcting your astigmatism. These alternatives include, among others, eyeglasses, contact lenses, and other refractive surgical procedures such as PRK or LASIK which are at an extra cost.

While it is not common, I understand that I may experience incapacitating glare or halos from oncoming headlights or other bright light sources, particularly in the evening or nighttime, for a varying length of time or possibly permanently. I am aware that this may interfere with driving for an indefinite period both day and night, and I understand that I am not to drive until I am certain that my vision is adequate both day and night.

I understand that fluctuations or variation in vision may occur during the day during the initial stabilization period (up to three months or longer). As occurs in all surgical procedures, scarring is the result of making incisions in living tissue. This particular surgery is no exception. My eye will be more susceptible to a blow to the eye during the healing phase and possibly somewhat after healing as the microscopic scar tissue may not be as strong as the normal tissue. Protective eyewear is recommended for all contact and racquet sports where a direct blow to the eye could cause permanent injury to the eye.

Additional reported complications include corneal perforation, which could possibly require sutures; incisional inclusions, corneal vascularization, corneal ulcer formation, endothelial cell loss, epithelial healing defects

Choice of Intra-Ocular Lens (IOL) Implant for Cataract Surgery

There are several options available to you with regards to the intra-ocular lens (IOL) that will be implanted permanently in the eye at the time of surgery.

- **PREMIUM SINGLE FOCUS IOL WITH READING GLASSES:** You can choose to have a premium, aspheric, single focus IOL implanted and have refractive vision correction at the same sitting in order to give good distance vision without glasses. This option gives the highest quality distance vision and only requires the use of glasses for intermediate and near tasks like computer use, reading, cell phone use, applying make-up, and more.
- **PREMIUM TORIC IOL:** The Premium Toric IOL is designed for patients who have higher degrees of astigmatism. If astigmatism is left uncorrected, it affects all types of vision, including near vision, intermediate vision, and distance vision, and then glasses would be required for essentially all activities, day and night. While smaller amounts of astigmatism can be corrected with Limbal Relaxing Incisions (LRI) at the time of surgery with other types of lens implants, larger degrees of astigmatism are often better addressed with Toric IOLs. The Premium Toric IOL has the same high optical qualities of the Premium Single Focus IOL but with the addition of the ability to address astigmatism in order to provide sharper vision for the patients with less reliance on glasses.
- **PREMIUM MULTI-FOCAL IOL:** These lenses are “multi-focal,” meaning they correct for both distance vision and other ranges, such as near or intermediate. These multi-focal IOLs have multiple zones on the lens surface which look like concentric rings. These IOLs provide distance vision and restore some or all of the near focusing ability of the eye. However, additional prescription glasses may be needed at times to enhance either distance, intermediate or near vision. A multi-focal IOL may allow you to read and see far away without glasses. If you chose a multi-focal IOL, it is possible that not all of the near (and intermediate) focusing ability of your eye will be restored. However, it may reduce your clarity of vision somewhat, and will cause some night glare. While a multi-focal IOL can reduce dependency on glasses, it might result in less sharp vision, which may become worse in dim light or fog. It may also cause some visual side effects such as rings or circles around lights at night. It may be difficult to distinguish an object from a dark background, which will be more noticeable in areas with less light. Driving at night may be affected.

- **MONOVISION OPTION:** To further increase the range of good vision without glasses, the eyes can have different IOLs implanted so that one eye is more distance dominant and the other is more near dominant. This option can be done with any of the IOLs. You can choose to have two IOLs with two different powers, with one eye for better near vision, and other eye for better distance vision. This combination of a distance eye and a reading eye is called monovision and will allow you to read with less dependency on reading glasses. It has been employed quite successfully in many contact lens and refractive surgery patients. However, the imbalance between your eyes may be disturbing. Monovision may result in problems with impaired depth perception or balance between the eyes. Once surgery is performed, it is not always possible to undo what is done, or to reverse the distance and near eye without some loss of visual quality.
- **STANDARD SINGLE-FOCUS IOL AND FULL-TIME GLASSES:** For patients not wanting to pay for vision correction at the same time as cataract surgery, you can choose to have a standard single focus IOL implanted and then be required to wear glasses for all activities, day and night, including, distance vision, intermediate (computer) vision, and reading vision. This type of lens is not intended to provide freedom from glasses, rather it is simply used as a replacement lens after the cataract is removed. With this standard lens, you will need full-time glasses, for near and far, after cataract surgery.

Even if you have chosen monovision or a multi-focal IOL, glasses or contacts may still be required for further improvement in your distance vision, reading vision, or both.

Patient Consent

The basic procedures of cataract surgery, the reasons for the type of IOL chosen for me, and the advantages and disadvantages, risks, and possible complications of alternative treatments have been explained to me by my ophthalmologist. Although it is impossible for the doctor to inform me of every possible complication that may occur, the doctor has answered all my questions to my satisfaction. If my cataract was previously removed, I have been informed that my eye is medically acceptable for IOL implantation.

In signing this informed consent for cataract surgery and/or implantation of an IOL, I am stating that I have read this informed consent (or it has been read to me), and I fully understand it and the nature and possible complications of a cataract surgery and/or implantation of an IOL. Furthermore, I have had all my questions answered to my satisfaction.

Choose only one of these 4 options by initialing it, and then cross out the others:

(1) Premium Single Focus IOL Option

I wish to have a cataract surgery with a premium, single focus IOL and I will then need to wear reading glasses for optimum near and intermediate vision, on:

My RIGHT EYE / LEFT EYE << circle one and initial here: _____

(2) Premium Toric IOL Option

I wish to have a cataract surgery with the premium Toric IOL implanted in order to address much of my pre-existing astigmatism. The goal is to have good vision without glasses for some activities, but I will likely be required to use glasses for others, such as reading, on:

My RIGHT EYE / LEFT EYE << circle one and initial here: _____

(3) Premium Multi-focal IOL Option

I wish to have a cataract surgery with a premium multi-focal IOL implant, which may cause glare and halos, in order to give distance and near vision without glasses, on:

My RIGHT EYE / LEFT EYE << circle one and initial here: _____

(4) Standard Single Focus IOL with Full-Time Glasses Option

I wish to have a cataract surgery with a standard, single focus IOL and I will then need to wear glasses full time, day and night, for all ranges of vision, on:

My RIGHT EYE / LEFT EYE << circle one and initial here: _____

I give permission to Dr. Uday Devgan to perform a cataract surgery, limbal relaxing incisions, and/or implantation of an IOL as indicated above:

Patient's Signature _____ **Date** _____

Witness' Signature _____ **Date** _____