PREMIER VISION CONSULTANTS, LLC

INFORMED CONSENT FOR CATARACT SURGERY

This information is being provided to you so that you can make an informed decision about the choices you have in cataract surgery. These choices will influence your vision for your lifetime. Take as much time as you wish to make your decision before signing this consent form. You have the right and are encouraged to ask your doctor questions about this procedure before agreeing to have it.

What is a cataract and how is it treated?

The lens in the eye can become cloudy and hard, resulting in a cataract. Cataracts can develop from normal aging, from an eye injury, or if you have taken certain medications, such as steroids. Cataracts may cause blurred vision, dulled vision, loss of color perception, sensitivity to light and glare, and/or ghost images. If the cataract changes vision so much that it interferes with your daily life, the cataract may need to be removed. Surgery is the only way to remove a cataract. You can decide not to have the cataract removed. If you don't have the surgery, your loss of vision from the cataract will continue to worsen.

How will removing the cataract affect my vision?

The goal of cataract surgery is to correct the decreased vision that was caused by the cataract. During the surgery, the eye surgeon removes the cataract and puts in a new artificial lens called an intraocular lens or IOL. Cataract surgery will not correct other causes of decreased vision or visual problems, such as glaucoma, diabetes, age-related macular degeneration, amblyopia, tearing, burning, dry eye, tired eyes, or droopy lids. In some instances, certain conditions can be worsened by cataract surgery. Most patients may still need to wear glasses or contact lenses after cataract surgery for either near and/or distance vision and/or astigmatism.

What types of IOLs are available?

The choice of IOL is important, as this will affect your visual function for a lifetime. Changing lenses once they are implanted, carries significant risk. As with any elective surgery decision, you are well-advised to make your decision based upon multiple factors. Speak to your surgeon; do your research; consult the websites of the implant lens manufacturers and the FDA; and satisfy your own curiosity before making a determination.

There are Monofocal IOLs available to treat nearsightedness (myopia) and farsightedness (hyperopia). Monofocal IOL is covered by insurance when a medically necessary cataract is removed. A Monofocal IOL can provide either near OR distance vision, though many patients sometimes still need both distance and near glasses, especially if the patient has astigmatism.

Newer Multifocal IOLs can provide both near and distance vision (ReSTOR IOL). IOLs that treat astigmatism are called Toric IOLs. You can also have one eye corrected for near vision, and the other for distance vision, a choice called monovision. Only patients who have previously tolerated the compromises of monovision should consider this option.

What is astigmatism? What are the treatment options?

Patients with myopia and hyperopia often also have astigmatism. Astigmatism is caused by a cornea shaped like a football instead of being round like a baseball. This can make your vision blurry without glasses or contacts. The TORIC IOL can reduce the astigmatism enough so that most patients do not need astigmatism correction. However, they will need near vision glasses and some may still need distance glasses. The ReSTOR lens does not correct for astigmatism. Refractive surgery such as LASIK, PRK, LRI (limbal relaxing incisions) can also be done as a separate procedure to help reduce astigmatism.

What are the major risks of cataract surgery?

Even though cataract surgery is one of the most frequently performed surgeries and is among the most successful, all surgery has risks and can result in complications, injury, or even death, from both known and unknown causes. The major risks of cataract surgery include, but are not limited to:

- Bleeding.
- Mild or severe infection. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if treated with antibiotics, could lead to permanent visual loss that may require further surgeries and may result in blindness and even total loss of the eye.
- Blindness or total loss of the eye.
- Injury to parts of the eye and nearby structures from the anesthesia, the operation itself, or pieces of the lens that cannot be removed.
- High eye pressure- glaucoma.
- Retinal swelling, retinal hole, detached retina, or macular hole (requiring treatment by a retina doctor).
- Vitreous detachment, increased floaters, or increased awareness of old floaters
- Chronic inflammation- uveitis.
- Failure of the wound to heal needing suturing
- Droopy eyelid. There is a natural tendency of the eyelids to droop with age. Eye surgery may hasten this process.
- Inability to remove the whole cataract, requiring another procedure to remove the cataract by a retinal doctor.
- Opening of the clear posterior capsule requiring a vitrectomy to remove vitreous coming forward.
- Irregular pupil; sluggish pupil; inability to dilate the pupil.
- Loss of corneal clarity, possibly needing a corneal transplant.
- Irritation, redness, light sensitivity.
- Current or past use of certain medications such as FLOMAX (Tamsulosin), alpha blockers, and others may increase risk of complications. Certain medications may permanently make your iris floppy.
- Residual prescription. We custom calculate the power and size of your implant depending on the corneal curvature and length of the eye. Certain conditions (such as high myopia, high hyperopia, or after refractive surgery) can decrease the accuracy of the calculation resulting in still needing glasses, contacts, or refractive surgery to correct the residual prescription.
- Anisometropia (imbalance between the eyes) usually corrected when the second eye surgery is performed.
- Glare/haloes. Risk with all IOLs. Depending upon your eye and the type of IOL used, you may have increased night glare or halos, double vision, ghost images, impaired depth perception, blurry vision, and trouble driving at night.
- Inability to place IOL chosen. Even though you may have given permission to place a Multifocal or Toric IOL, it may be necessary to substitute a Monofocal IOL in its place, and possibly no lens.
- Further surgery to reposition or replace the IOL.
- The eye may be more vulnerable to injury. A corneal incision will not be as strong as the cornea originally was at that site. Patients should wear eye protection when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object may be high.
- Depending upon the type of anesthesia, other risks are possible, including cardiac and respiratory problems, and in rare cases, death.

There is no guarantee that cataract surgery will improve your vision. As a result of the surgery and/or 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. You may need additional treatment or surgery to treat these complications. Additional treatments may not be included in the fee for this procedure.

What is an after-cataract?

The IOL is usually placed in the capsular "bag" to hold the IOL in place. The membrane or bag can become hazy or opacified months or years later. Treatment for this posterior capsule opacification involves a laser treatment called a YAG laser posterior capsulotomy. This is an outpatient procedure which may be needed as early as 3 months after the initial cataract surgery. Insurance typically covers the procedure when visually significant.

Patient responsibility for costs

Health insurance generally does not cover elective procedures such as ReSTOR IOL or refractive surgery. They typically cover the costs related to the cataract surgery, when there is a medical necessity. Therefore, the patient is responsible for the elective portion of the surgery. In the event of a complication, it may be possible that other surgery, eye drops, or even hospitalization may be required. Some or even all of these costs may be covered by health insurance. The patient is responsible for the costs of any uncovered surgery-related injuries. There will be additional costs to the patient for refractive surgery to treat any residual myopia, hyperopia, or astigmatism.

I give permission for my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give permission for my ophthalmologist to use data about my procedure and subsequent treatment to further improve cataract surgery. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my ophthalmologist's office or the center where my implant surgery will be performed.

Please list the activities that are being impaired by the cataract:_____

_____

Patient's acceptance of risks

I understand that it is impossible for the doctor to inform me of every possible complication that may occur. Despite the best of care, complications and side effects may occur. By signing below, I agree that my doctor has answered all of my questions, and that I understand and accept the risks, benefits, and alternative of cataract surgery. I understand that I will need to purchase and use eye drops before and after surgery and I agree to follow the recommended protocol.

☐ I wish to have cataract surgery with an intraocular lens implant.

☐ **LEFT** Eye _____Patient's Initials ☐ **RIGHT** Eye _____Patient's Initials

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☐ I am a candidate for the Multifocal IOL, but have chosen the ☐ **Monofocal** IOL ☐ **TORIC** IOL option.
I want my implant aimed more for _____ (near/distance).

☐ I have chosen the option for the **Multifocal** IOL.

☐ I will receive ☐ **Monofocal** IOL ☐ **TORIC** IOL as I have been informed by my surgeon that I am NOT an appropriate candidate for the Multifocal IOL.
I want my implant aimed more for _____ (near/distance)

☐ I have read the informed consent and it has been explained to me in a manner I can understand. All my questions and concerns have been addressed. The doctor has reviewed the consent with me. I have received the ASC patient bill of rights in the office.

☐ I understand that no guarantees have been made to me regarding the outcome of the surgery, and that I remain financially responsible for all costs associated with the surgery.

Patient's Signature: _____ Date: _____

Patient's Name: _____

Witness's Signature: _____ Date: _____

Witness's Name: _____

Surgeon's Signature: _____ Date: _____
Surgeon's Name: Santiago Villazon, M.D.

Revised 5/13

INFORMED CONSENT FOR USE OF A FEMTOSECOND LASER DURING CATARACT/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 (off-label uses). 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 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 BENEFITS AND COST?

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.

Medicare and insurance typically covers visually significant cataract surgery, but not elective portions of the surgery such as refractive surgery (astigmatic keratectomy) nor elective lenses such as the toric or ReSTOR IOL (nor specialized technology such as specialized imaging of the femtosecond laser for better placement of elective lenses).

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. Medicare does not pay for the surgical correction of astigmatism. If you choose a toric IOL, you will be responsible for the difference between the cost of a standard monofocal IOL and a toric IOL. If you choose LRI, AK, or refractive surgery, you will be responsible for paying the fees associated with it.

WHAT ARE THE COMPLICATIONS ASSOCIATED WITH THE FEMTOSECOND LASER?

Use of the laser could increase the time needed to perform the surgery. 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 vitreous; corneal abrasion or defect; pain; infection; bleeding; damage to intraocular structures; anterior chamber fluid leakage; anterior chamber collapse; and elevated eye pressure. All of the risks listed under cataract surgery major risks may also occur.

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 recentration 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. Further surgery by either the surgeon or a retina specialist may be necessary.

Any attempt at astigmatism reduction could result in over- or under-corrections, in which case glasses, contact lenses, or another procedure may be needed. Other risks of Astigmatic Keratotomy include foreign body sensation, dry eye, need for further surgical opening of the Keratotomy for more effect or laser vision correction, infection, light sensitivity, scarring, corneal perforation, weakening of the cornea leading to susceptibility to injury, irregular astigmatism, glare, or haloes.

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 ☐**Cataract/lens removal** ☐**Astigmatic Keratotomy** with a femtosecond laser on my:

☐ **LEFT** Eye _____Patient's Initials ☐ **RIGHT** Eye _____Patient's Initials

Patient's Signature: _____ Date: _____

Patient's Name: _____

Witness's Signature: _____ Date: _____

Witness's Name: _____

Surgeon's Signature: _____ Date: _____
Surgeon's Name: Santiago Villazon, M.D.

INFORMED CONSENT FOR ReSTOR Multifocal IOL

How does a ReSTOR lens work?

The ReSTOR lens is an FDA approved IOL, at an extra patient cost. It has the ability to focus both near and far by allocating appropriate light energy for each function. The ReSTOR lens is different than a Monofocal IOL as it has two optics- one for distance and one for near (Multifocal). You may find that rather than holding reading material farther away to read, you'll actually bring it in closer. The lens is designed to restore distance and near vision, but may not completely eliminate your need for glasses, especially with fine print. The goal is to reduce your dependence on glasses, though it may not completely eliminate it.

The ReSTOR lens does not correct for astigmatism. Refractive surgery such as LASIK, PRK, LRI (limbal relaxing incisions) can also be done as a separate procedure to help reduce astigmatism.

Who should not have a ReSTOR lens?

-Patients who are hypercritical with unrealistic expectations
-Patients with excessive complaints about their prescription
-Patients who drive at night for a living or whose occupation or hobbies depend on good night vision
-Patients who are commercial airline or amateur pilots
-Patients who have life-long complaints about glare
-Patients who are happy wearing glasses
-Patients who want guarantees on surgical outcomes
-Patients with eye diseases such as glaucoma or macular degeneration that decrease visual function

What are some of the complications specific to the ReSTOR lens?

ReSTOR IOL does not guarantee that no glasses are needed. 20% of the patients in the FDA study still required some assistance from glasses following surgery. Especially if there is pre-existing corneal astigmatism or if there is a residual prescription, other refractive procedures such as LASIK, PRK, or LRI may be necessary to help decrease the need for glasses. The patient is responsible for the cost of any additional refractive surgery.

During the healing, most patients experience some blurred vision, glare, and halos. As the eye heals, these symptoms typically improve, especially when the second eye surgery is performed. As with many things, there may be a trade off. The possible decrease in use of glasses may come at a cost of losing some of the sharpness of your vision. Even with glasses, this loss of sharpness may become worse in dim light or fog. Seeing rings or circles around lights at night may be permanent. Multifocal IOLs may increase the likelihood of these problems. 5% of the patients in the FDA study reported severe difficulty with halos and 5% reported severe difficulty with glare. About 19% of patients had moderate halos and 21% of patients had moderate glare.

- Residual prescription. We custom calculate the power and size of your implant depending on the corneal curvature and length of the eye. Certain conditions (such as high myopia, high hyperopia, or after refractive surgery) can decrease the accuracy of the calculation resulting in still needing glasses, contacts, or refractive surgery to correct the residual prescription. .
- Glare/haloes. Risk with all IOLs. Depending upon your eye and the type of IOL used, you may have increased night glare or halos, double vision, ghost images, impaired depth perception, blurry vision, and trouble driving at night.
- Inability to place IOL chosen. Even though you may have given permission to place a Multifocal IOL, it may be necessary to substitute a Monofocal IOL in its place, and possibly no lens.
- Further surgery to reposition or replace the IOL.

☐ I choose Multifocal IOL as my treatment choice. _____ Patient's Initials

Patient name: _____

CONSENT FOR TORIC INTRAOCULAR LENS IMPLANT

The Toric intraocular lens implant is available to correct up to 4 diopters of regular astigmatism. The goal is to help reduce the dependence on glasses; it may not eliminate the need for glasses. If the Toric implant is calculated for you to see at distance, glasses will still be needed to read. If more astigmatism correction is needed, further correction of astigmatism can be done with glasses, a limbal relaxing incision, or a corneal refractive procedure. The Toric intraocular lens, limbal relaxing incisions and corneal refractive procedures are not covered by Medicare or insurance.

INDICATIONS AND ALTERNATIVES: "Standard" or "conventional" cataract surgery involves implanting a spherical intraocular lens (IOL) that does not correct astigmatism (unequal focusing power on different parts of the cornea). Glasses or contact lenses are then required to correct the residual astigmatism. In late 2005, the FDA approved the latest generation implant lenses, known as Toric IOL's or astigmatism-correcting implant lenses. These lenses may allow less dependence on glasses for vision. Further refinements will undoubtedly occur over time with future generation toric lenses.

NON-CANDIDATES FOR TORIC IOL: Patients who prefer glasses for cosmetic or safety reasons, or patients who do not care about being independent of glasses are not optimal candidates. The presence of pre-existing refractive surgery or ocular pathology, such as macular degeneration, diabetic retinopathy, or corneal disease or scarring, may result in a less than optimal outcome.

POSSIBLE ADVANTAGES AND BENEFITS OF THE TORIC IOL: Based on a study submitted to obtain FDA approval, the advantages of Toric IOL implantation included (patients with less than 2.5D astigmatism):

- A 3-fold better chance of under 0.5D residual astigmatism than with non-toric IOL.
- A 60% chance of distance spectacle independence (97% with bilateral implantation).
- A 66% chance of 20/25 or better vision without glasses (vs. 41% with conventional IOL).

POSSIBLE RISKS OF TORIC IOL: There are some potential disadvantages of the Toric IOL implantation. These include (but are not limited to) the following:

- Improper alignment or rotation of the IOL after surgery may result in more residual astigmatism than predicted. This can result in the need for glasses or contact lenses, or even the need for subsequent refractive surgery correction (such as Limbal Relaxing Incision (LRI), Astigmatic Keratotomy (AK), or laser vision correction). Some patients may require surgical realignment or even explantation (removal) of the Toric IOL and replacement with a conventional lens. There are additional fees is refractive surgery is needed.
- Patients who have Toric IOLs have a greater chance of spectacle independence when both eyes have had cataract surgery.
- The Toric IOL can rotate and lose some of its effectiveness. A second procedure may rarely be needed to rotate the Toric implant for maximum effect.
- Patients with severe astigmatism (greater than 2.5D) have increased risk of residual astigmatism
- Problems encountered during surgery (including, but not limited to pupil damage, vitreous loss, poor IOL centration, or discovery of capsular bag instability) may prevent implantation of a Toric IOL in one or both eyes, or result in a less than optimal outcome. A monofocal IOL or no lens may need to be placed.

☐ I choose TORIC IOL as my treatment choice. _____ Patient's Initials

Patient name: _____

I want my implant aimed more for _____ (near/distance)

Monovision Addendum

Monovision is an option for patients over 40 who have difficulty reading due to the natural aging process of the lens. Monovision is an option in which one eye is corrected for distance vision while the other eye is corrected for near or intermediate vision. Monovision is not tolerated by everyone and a contact lens trial must be done prior to considering monovision surgery. Even with monovision, reading glasses may still be needed for fine print and distance vision may not be as crisp for night driving (increasing glare/haloes) and certain sporting activities. Depth perception may be compromised. Monovision may increase your chances of still needing distance correction to help improve these symptoms. I understand monovision is not FDA approved and is an "off-label" use of the device.

☐ I choose monovision as my treatment choice. _____ Patient's Initials

☐ I choose to have my _____ eye targeted for near vision

_____

Patient's Name