



CHRISTENBURY EYE CENTER

Patient Name: _____ **MR #** _____

Lensectomy Informed Consent for the Correction of Hyperopia (Farsightedness), Myopia (Nearsightedness) or Presbyopia with Implantation of an AcrySof® ReSTOR® Intra-Ocular Lens, with or without a Cataract

INTRODUCTION

This surgery involves the removal of the crystalline lens of my eye, even though a cataract may or may not be present. The natural lens will be replaced with an artificial implant called an intra-ocular lens, in order to attempt to correct my farsightedness or nearsightedness and an attempt to correct Presbyopia (the need for reading glasses), so that my natural vision will be improved, thereby reducing my dependency on glasses or contact lens as a method of correcting vision. Lens implant / replacement surgery (i.e.: Cataract or ReSTOR surgery) is one of the most commonly performed procedures in the United States, with over 1 million of these types of procedures performed each year. In some cases, the lens may have an early cataract which does not significantly interfere with corrected vision, and which would normally not require surgical removal. This intra-ocular lens can also be inserted at the time of cataract surgery. The AcrySof® ReSTOR® IOL is FDA-approved for the correction of Cataracts, with or without Presbyopia. If physicians use a product for an indication not in the approved labeling, this is considered "Off-Label" Use of an approved medical device. The use of the AcrySof® ReSTOR® IOL to correct Presbyopia without the presence of a Cataract is allowed by the FDA and is considered "Off-Label".

Based on the clinical trials, Alcon, the lens manufacturer, has indicated the following types of patients possibly should not have the AcrySof® ReSTOR® Apodized Diffractive Optic IOL:

- Patients that 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

EXAMINATIONS PRIOR TO SURGERY

If I agree to have the surgery, I will undergo a complete eye examination by my surgeon. This will include an examination to determine my glasses prescription (refraction) both with and without dilating drops, measurement of my vision with and without glasses (visual acuity), measurement of the pressures inside my eye (tonometry), measurement of the curvature of my cornea (keratometry), ultrasonic measurement of the length of my eye (axial length), intra-ocular lens calculation (biometry) to determine the best estimate of the proper power of the implanted lens, microscopic examination of the front part of my eye (slit-lamp examination), and examination of the retina of my eye with my pupils dilated (indirect ophthalmoscopy).

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

If I decide to proceed with the surgery, I may undergo light sedation administered while my eye is made numb by my surgeon with either drops or an injection (local anesthesia) or I may elect to have the surgery with local anesthesia only, without sedation. The natural lens in my eye will then be removed by breaking it up into small pieces with a vibrating needle. These pieces are gently vacuumed out of my eye through a small, hollow tube inserted through a small incision into my eye. This type of surgery is called phacoemulsification. After my natural lens is removed, the artificial lens of the power determined during my pre-operative examination will then be placed inside my eye. The incision required to perform this operation is at times self-sealing but it may require closure with very fine stitches (sutures). After the surgery, my eye will be examined as necessary. During the immediate recovery period, I will place drops in my eyes as instructed. The success of any procedure is often dependent on compliance with the specified medication regimen post-operatively. After 4 to 6 weeks, glasses or contact lenses may still be required either for further improvement in my distance vision, reading vision, or both. I should be able to resume my normal activities within 2 or 3 days, and my eye will usually be stable within 3 to 6 weeks, at which time glasses or contact lenses could be prescribed if necessary.

BENEFITS OF SURGERY

The potential benefits to me will be clearer vision with less dependence on spectacles or contact lens. The limitations include any astigmatism, farsightedness, or myopia not corrected by the intra-ocular lens or how my individual eye responds to the surgery, lens implant and healing process.

The Apodized Diffractive Intra-Ocular Lens, known as AcrySof® ReSTOR® is FDA approved for the correction of cataracts in adults with or without Presbyopia. This new lens has the ability to focus at near and far by allocating appropriate light energy according to activity and light levels. This means the ReSTOR can potentially provide vision, without corrective lenses, for near vision (i.e.: reading) and for distance vision (i.e.: driving). Intermediate Vision is generally good and patients report that intermediate vision improves over weeks and months, once both eyes are implanted with the ReSTOR IOL. The ReSTOR lens has 2 optics – one for distance vision and one for near vision. There is no optic specifically for intermediate vision. In spite of this, very few patients seem to report that they require glasses for intermediate or computer distance. Some individuals may find it more comfortable to sit closer to their desk top computers or prefer using a laptop at closer range. You may find that rather than holding reading material farther away to read, you'll actually bring it in closer. Age-related Presbyopia requires you hold things farther out in order to read, while ReSTOR allows you to bring things in. Other Multifocal IOL's that attempt to provide an intermediate optic tend to degrade the quality of vision at distance and near, and that is why we prefer the better distance and near optics of the ReSTOR IOL.

ADVANTAGES OF LENSECTOMY IN PATIENTS OVER 40 WHO HAVE NO CATARACT:

- 1. A wide range of correction options are available**
- 2. Reduced healing issues**
- 3. Decreased incidences of glaucoma, when compared with the natural lens**
- 4. Improved uncorrected and best corrected vision for most patients**
- 5. No further need for cataract surgery in the future because the natural lens has been removed**
- 6. Potential to regain some degree of near vision**

RISKS

This type of surgery itself is usually quite comfortable for the patient. Mild discomfort for the first 24 hours is typical, but severe pain would be extremely unusual. This surgery is essentially the same as cataract surgery, and the risks include, but are not limited to:

- 1. Infection, which is the most serious risk and can lead to complete loss of vision. The incidence of infection are rare, at less than 1%.**
- 2. Swelling in the central area of the retina (called cystoid macular edema) which usually improves with time**
- 3. Clouding of the outer lens of the eye (corneal edema) which can be corrected with a corneal transplant**
- 4. Detachment of the retina even though the retinal detachment can usually be repaired. The incidence of Retinal detachment in the general population is approximately 12 in 100,000 and may be slightly higher if one undergoes Cataract / Lens replacement / Lens implant surgery. Other risk factors include, but are not limited to, high Myopia (i.e.: Myopia of greater than 8 Diopters), undergoing a YAG procedure following Cataract / Lens replacement / Lens Implant Surgery, long eye length (i.e.: Axial Length greater than 23mm). The total incidence of Retinal Detachment in these types of patients is approximately 1%.**
- 5. Damage to the retina or nerve during the administration of the anesthesia if an injection is performed**
- 6. Increased astigmatism**
- 7. Inaccuracy of the intra-ocular lens power, resulting in an under or over-correction (3 to 5% probability). Some patients may require glasses, additional ocular surgery or laser vision correction after this procedure.**
- 8. Decentration of the intra-ocular lens, which may provide unwanted images and increased glare**
- 9. Development of increased pressure in the eye (glaucoma).**
- 10. Inflammation, acute or chronic.**
- 11. Opacification of the posterior capsule requiring YAG laser capsulotomy, an in-office, outpatient procedure.**
- 12. There is a slightly greater chance of having severe difficulty with halos (5%) and glare (5%) compared to someone with a Monofocal IOL (3%). Some patients may notice temporarily an increase in glare and halos, but they typically improve with time. You may grow accustomed to them or continue to notice them. In rare instances (less than 1%), patients have requested that their IOL be removed.**
- 13. Need for further ocular surgery.**
- 14. I understand that in order to implant any intra-ocular lens, the lens itself must be folded using forceps or other mechanical means and loaded into an injector or "shooter". Once the lens is loaded, it can then be gently injected into the eye in a controlled fashion through a small, self-sealing incision.**

Occasionally, even with proper care and technique, there can be small defects introduced into the lens due to the mechanical process of folding the lens. If this does happen, it is usually not detectable or visible at the time of surgery, only during examination post-operatively (only seen with magnification). We know of no instances where the lens had to be removed or replaced due to this, as it generally has no noticeable affect on the vision.

DISADVANTAGES OF SURGERY

1. In some cases, it may not be possible to implant the AcrySof® ReSTOR® Apodized Diffractive IOL, which would require a standard Intra-Ocular Lens to be implanted. One definite disadvantage or side effect of having the clear lens removed and then having a standard IOL implanted, especially in a patient less than 40 years of age, is the loss of the near focusing power of the eye (accommodation) with implantation of a standard IOL. Thus, it must be clearly understood that even with a successful surgery and an accurate standard intra-ocular lens calculation targeted to correct the eye's distance vision, close vision will usually remain blurred, requiring a separate pair of glasses for close and intermediate vision. It may be possible to deliberately correct one of the eyes for close vision instead of distance, which would allow the patient to read without glasses, even though this eye would then be nearsighted and require a corrective lens for distance vision. This combination of a distance eye and a reading eye is called monovision. It has been employed quite successfully in selected patients. Alcon, the lens manufacturer, recommends that both eyes receive the ReSTOR IOL for optimum visual results.
2. Another possible disadvantage, compared to normal cataract surgery, is that although the accuracy of the intra-ocular lens calculations is quite satisfactory for normal sized eyes, these calculations can be more inaccurate for unusually long or short eyes. The latest formula available will be used to evaluate your eye measurements and calculate the power of the lens to be implanted. In the event of an under- or over-correction, the vision can usually be corrected by a glasses prescription, which should be considerably weaker than the patient's original prescription. A large error in the lens calculation could be corrected by a stronger pair of glasses, contact lenses, or the potential exchange of the implant or the insertion of a second implant in another operation, or possibly laser vision correction surgery.
3. One eye will undergo surgery at a time, usually a day apart. The purpose is to allow a one day post-operative visit for the first eye to ensure there is no infection or intra-ocular pressure rise before proceeding to the second eye. Also, with this routine patients experience a shorter period of time of visual imbalance.

NON-SURGICAL ALTERNATIVES

Non-surgical alternatives to clear lens extraction are to continue to wear spectacle lenses or contact lenses. Although there are essentially no risks to wearing glasses, the quality of vision with strong farsighted or nearsighted glasses is not normal because of an enlarged image and a slight decrease in peripheral vision caused by the thickness of the lenses. Although contact lenses provide higher quality and more normal vision, they have a slight risk of complications, especially if they are worn overnight. The risks of contact lenses include: infection, which can rarely cause loss of vision if the infection involves the cornea; allergies (giant papillary conjunctivitis, GPC) which can make wearing the lenses difficult; mild irritation; and discomfort. There is also evidence that some damage occurs to the important internal layer of cells that are responsible for keeping the cornea clear. This damage could cause harm if the contact lenses are worn for many years. Whether this damage will eventually lead to serious long term complications such as corneal clouding is unknown. Contact lenses or glasses are non-surgical, extremely accurate, permit easy changes in prescription, and also allow the eye to retain its focusing power for near vision.

SURGICAL ALTERNATIVES, INCLUDING LASER

There are several other procedures for the correction of farsightedness and nearsightedness:

1. The excimer laser is capable of reshaping the cornea and can be used to correct low to moderate amounts of hyperopia (generally +1 to +5 D) through either PRK (Photorefractive keratectomy) or LASIK (laser in situ keratomileusis) and low to higher amounts of myopia (generally -1 D to -12D). PRK does not correct Presbyopia.
2. LASIK is an operation which combines the creation of a flap with the microkeratome and the removal of tissue with the excimer laser to correct distance vision. LASIK has been found to be quite successful and relatively safe for the correction of moderate and high myopia up to about -12.00, depending on the patient. Above 12 diopters, LASIK may be complicated by problems with accuracy and by a high incidence of complications involving the quality of vision, especially at night, and many surgeons have stopped performing LASIK for these extremely near-sighted eyes. LASIK does not correct Presbyopia.

The advantage of all the above procedures is that they do not affect the patient's natural focusing power and do not require an incision into the inside of the eye as does clear lens extraction. Although laser vision correction can correct for distance vision, for patients over 40, they will still need reading glasses or bifocals for near vision. Of these surgical options, only the ReSTOR® IOL procedure has been shown to offer both good distance and near vision. There are no other surgical alternatives to correct Presbyopia except for other intraocular lenses, such as the Array®, Crystalens™ and ReZOOM® Intraocular lenses. However, clinical data has demonstrated that these other lens designs are not as successful as the ReSTOR®, and we do not recommend them.

I understand that I may choose not to have this surgery at all and either continue wearing my glasses or contact lenses or I may elect to have one of the other procedures discussed in this section.

Need for Temporary Glasses or Laser Vision Correction after the ReSTOR Procedure due to Residual Refractive Error (Astigmatism, Myopia, Hyperopia)

The ReSTOR procedure is designed to correct Nearsightedness, Farsightedness and Presbyopia. However, it does not correct corneal Astigmatism, and sometimes a small residual of myopia or farsightedness occurs. We term this “residual refractive error”. It is important to realize that “residual refractive error” may affect both distance and near vision after the ReSTOR procedure. Therefore, we try to identify these patients preoperatively so we can properly advise them on what to expect after their procedure, and if they are likely to need a laser vision correction following the ReSTOR procedure. A good estimate for residual Astigmatism is a Corneal Toricity measurement of greater than 1 Diopter, which can often be detected by our tests before surgery. If you have a Corneal Toricity greater than 1 Diopter, within the week following your ReSTOR procedure, you may need temporary glasses in the interim to correct for the residual Astigmatism. It is not possible to predict any residual myopia or farsightedness – this is dependent on how each patient responds to the ReSTOR procedure. The cost for these temporary spectacle lens is typically less than \$30 (*with your own spectacle frame*) when purchased through the Christenbury Eye Center’s optical department.

Some patients may find that they don’t mind these spectacles, or rarely use them, are happy with their vision, and do not wish to undergo any additional procedures. However, if indicated and recommended by Dr. Christenbury, you may choose to have an IntraLASIK procedure to correct your residual refractive error. Approximately 10 -15% of patients would choose a laser vision correction procedure to allow them to be less dependent on any spectacles. This is typically performed 2 to 6 months following your ReSTOR procedure, and the fee for this additional procedure will be covered in the initial cost of the ReSTOR procedure for one year. Patients will be responsible for the cost of medications that you need to fill at a pharmacy of your choice

Scheduling your second eye

If your post operative medical eye exam is stable it is advisable to proceed with the ReSTOR procedure on the second eye, even if you are not yet 20/20 without glasses. Both distance and near vision is better when the ReSTOR is placed bilaterally (in both eyes). It is easier as a patient to have both eyes healing together, whether you are totally spectacle free, or even if you require temporary spectacles for “residual refractive error” and are waiting for a follow up laser vision correction procedure after the ReSTOR procedure.

PATIENT RESPONSIBILITY FOR COSTS

I understand that I am responsible for the cost of the surgery, both the surgeon's fee, anesthesiologist's fee if any, and the surgical center's or hospital's fee must be borne by the patient. Health insurance typically does not pay for removal of the clear lens of the eye for the purposes of correcting natural vision or for removal of an early cataract which is not visually disabling.

I understand that I will be responsible for the costs of the surgery-related injuries. I also understand that no compensation is being offered to me in the event of an injury or complication. In the event of a complication for the clear lens extraction, it might be possible that other surgery, eye drops, or even hospitalization may be required. Although some or even all of these costs may be covered by my health insurance policy, if they are not, I understand that I will be responsible for these costs.

If I need a second surgical procedure, such as replacement or repositioning of my intra-ocular lens, I understand that although my surgeon will not charge me a surgical fee, there will be additional fees for supplies and medications or from the surgery center and from the anesthesiologist if one is required.

ASTIGMATISM

Patients with nearsightedness and farsightedness often also have astigmatism. An astigmatism is caused by an irregularly shaped cornea; instead of being round like a basketball, the cornea is shaped like a football. This can make your vision blurry. In addition to toric IOLs, astigmatism can be reduced by glasses, contact lenses, and refractive surgery(LASIK or PRK). There is also a procedure called a Astigmatic Keratotomy incision, which can be done at the same time as the cataract operation, or as a separate procedure. An Astigmatic Keratotomy incision is a small cut or incision the ophthalmologist makes into your cornea to make its shape rounder. Any attempt at astigmatism reduction could result in over or under-correction, in which case glasses, contact lenses, or another procedure may be needed.

YAG Laser after ReSTOR for Posterior Capsule Opacification:

The ReSTOR IOL is usually placed in the capsular "bag", and this clear membrane "shrink wraps" itself around the IOL and holds it in place. This action takes 4-6 weeks to happen in most cases. The membrane or bag can become hazy or opacify in up to 50% of ReSTOR patients. This is called posterior capsule opacification (PCO). The PCO can occur early - weeks or months, or late - years after surgery. Treatment for a (PCO) involves a simple laser treatment called a YAG laser posterior capsulotomy, and is usually performed anytime after the 3 month post-operative visit.

A YAG laser is generally an office-based, outpatient procedure that is painless, requires dilation of the pupil, a topical numbing drop, and takes literally just a few minutes. The vision is generally blurred the day of the procedure, but most patients notice improved vision by the next day. If the Medical Director of Christenbury Eye Center determines that a YAG Laser procedure is needed after the ReSTOR IOL procedure due to posterior capsule opacification, the Christenbury Eye Center will bill the cost of the procedure to your medical insurance in accordance with the Center's managed care contract with your insurance carrier. In the event that you do not have medical insurance, the Center will discuss fees at the time of the YAG procedure. The cost of medications is the patient's responsibility. Post-operative visits related to the YAG laser procedure will be provided free of charge for 1 month after your procedure. Any visits to our office after the 1 month post operative period for your YAG laser are billable visits.

Patient Statement of Understanding about the Risks and Benefits of Clear Lens Extraction Surgery:

In giving my permission for a clear lens extraction and/or for the possible implantation of an intraocular lens in my eye, I declare I understand the following: (please initial each item)

_____ 1. I have read and understand this Informed Consent (or it has been read to me). I have also read and understand the handout entitled "Understanding The ReSTOR Presbyopia Correction".

Cataract/Lensectomy surgery, by itself, means the removal of the natural lens of the eye by a surgical technique. In order for an intraocular lens to be implanted in my eye, I understand I must have cataract/lensectomy surgery performed either at the time of the lens implantation or before lens implantation.

_____ 2. **Complications of surgery to remove the cataract/crystalline lens:** As a result of the surgery and local anesthesia injections around the eye, it is possible that my vision could be made worse. In some cases, complications may occur weeks, months or even years later. Complications may include hemorrhage (bleeding), perforation of the eye, loss of corneal clarity, retained pieces of cataract in the eye, infection, detachment of the retina, uncomfortable or painful eye, droopy eyelid, glaucoma and/or double vision. These and other complications may occur whether or not a lens is implanted and may result in poor vision, total loss of vision or even loss of the eye in rare situations.

_____ 3. **Specific complications of lens implantation:** Insertion of an intraocular lens may induce complications which otherwise might not occur. In some cases, complications may develop during surgery from implanting the lens or days, weeks, months, or even years later. Complications may include loss of corneal clarity, infection, uveitis, iris atrophy, glaucoma, bleeding in the eye, inability to dilate the pupil, increased night glare and/or halo, double or ghost images, dislocation of the lens and retinal detachment. In rare instances, lens power measurements may significantly vary resulting in the need for corrective lenses or surgical replacement of the intraocular lens.

_____ 4. If an intraocular lens is implanted, it is done by surgical method. It is intended that the small plastic, silicone or acrylic lens will be left in my eye permanently.

_____ 5. At the time of surgery, my doctor may decide not to implant an intraocular lens in my eye even though I may have given prior permission to do so.

_____ 6. The results of surgery in my case cannot be guaranteed. Glasses, Additional treatment and/or surgery may be necessary to provide my best level of vision after the procedure. I may need YAG laser surgery to correct clouding of vision. At some future time, the lens implanted in my eye may have to be repositioned, replaced or removed surgically.

_____ 7. I authorize Christenbury Eye Center to release information regarding my surgery to my family physician and / or insurance company. I consent to observers of my procedure for education or regulatory / accreditation purposes.

- _____ 8. I understand that if I have had previous corneal or refractive surgery (RK, PRK, LASIK for example), there may be some inaccuracy in measuring the cornea power (K Reading) which is necessary to calculate the lens implant power for cataract surgery. This means there is a slightly higher risk of residual refractive error (residual nearsightedness or farsightedness) from your clear lens extraction / cataract surgery and a possible need for future LASIK or PRK enhancement, increased dependence on glasses/contact lens, or in some cases a intra-ocular lens implant exchange. If pre-operative eye medical records (refraction, K readings) are available, our experience is the IOL calculation is more accurate, but if these medical records are not available the IOL calculation is not as accurate and one is more likely to have residual refractive error.
- _____ 9. I have been provided a copy of Alcon's *PATIENT INFORMATION BROCHURE – Alcon AcrySof® ReSTOR® Apodized Diffractive Optic Posterior Chamber Intraocular Lens(IOL)*. I have read and understand this brochure and had my questions answered to my satisfaction.
- _____ 10. I have been made aware that I may require punctal plugs before, during or after my ReSTOR procedure, for any signs or symptoms of dry eye. I authorize the physicians and/or medical technicians of Christenbury Eye Center to perform this minor procedure.
- _____ 11. I authorize the physicians of Christenbury Eye Center to perform an Aqueous Release of fluid if the eye pressure is elevated postoperatively following the ReSTOR procedure.
- _____ 12. I authorize the physicians of Christenbury Eye Center to perform a **Astigmatic Keratotomy Incision** if needed for Astigmatism Reduction (may still need glasses)

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING, CONSENT FOR SURGERY

The details of the clear lens extraction procedure (refractive lensectomy) have been presented to me in detail in this document and explained to me by my ophthalmologist. My ophthalmologist has answered all my questions to my satisfaction. I therefore consent to undergoing clear lens extraction (refractive lensectomy). I have been fully informed of my right to receive a copy of this signed and dated consent form.

I consent to have a Lensectomy procedure with an AcrySof® ReSTOR® Apodized Diffractive Optic Intra-Ocular Lens Implant performed by Jonathan D. Christenbury, MD on my:

Right eye

Left eye

Patient Signature

Time and Date

Patient Account Number

Witness Signature

Date

AGREEMENT TO ARBITRATE/ALTERNATIVE DISPUTE RESOLUTION

In accordance with the terms of the United States Arbitration Act, I agree that any dispute, controversy, claim or disagreement arising out of or relating to the provision of healthcare services to me by Christenbury Eye Center and its agents, employees, physicians, nurses, staff and other healthcare providers shall be subject to and exclusively resolved by and through **final and binding arbitration**, which shall be conducted in Charlotte, Mecklenburg County, North Carolina before a panel of three arbitrators and in accordance with the Commercial Arbitration Rules of the American Arbitration Association, a copy of which is available to me upon request. I understand that this agreement to submit any controversy, dispute, claim or disagreement to final and binding arbitration includes all healthcare services which previously have been or will in the future be provided to me and that this agreement is not restricted to those health care services rendered in connection with this admission or visit. I further understand that this agreement to arbitrate, and the decision of any arbitrators with respect to the subject matter of the arbitration, is and shall be binding on any individual or entity claiming by or through me or on my behalf. I further acknowledge that the judgment on the award rendered by the arbitrators may be entered in any court having jurisdiction thereof.

I further declare and agree that:

- (1) I have completely read and fully understood the terms of this agreement;**
- (2) I have been given an opportunity to review this Agreement and I have been offered a copy of the Commercial Arbitration Rules of the American Arbitration Association;**
- (3) This Agreement is being sought in connection with the performance of an elective procedure which is being sought on a non-emergency basis; and**
- (4) There are other healthcare providers of the elective procedure in the community from whom I could receive the same treatment.**

ACKNOWLEDGED AND AGREED this ____ day of _____, 20 ____.

Printed Name of Patient

Patient Signature

Date

Witness Signature

Date

IntraLASIK Enhancement Policy for our ReSTOR patients:

If the Medical Director determines that an IntraLASIK procedure is needed after the AcrySof® ReSTOR® IOL procedure due to residual Myopia, Hyperopia or uncorrected Astigmatism, Christenbury Eye Center will perform the IntraLASIK enhancement at no additional charge within 1 year from the date of the ReSTOR procedure. Patients will be responsible for the cost of any medications. Post-operative visits related to the IntraLASIK enhancement procedure will be provided free of charge for 6 months after your procedure. **Any visits** to our office after the 6 month post operative period for your ReSTOR® IOL procedure (Yearly Eye Exams) or unrelated to your procedure (eye infections, pink eye, injury) will be billable, charged visits.

Patient Signature

Date

Witness Signature

Date

YAG Procedure after the ReSTOR Procedure

The ReSTOR IOL, is usually placed in or in front of the capsular “bag” inside your eye, and this clear membrane “shrink wraps” itself around the IOL and holds it in place. This action generally takes 4-6 weeks to happen in most cases. The membrane or bag can become hazy or opacify in up to 50% of ReSTOR patients. This is called posterior capsule opacification (PCO). The PCO can occur weeks, months or years after IOL surgery. Occasionally, the posterior capsule is hazy at the time of IOL surgery, or develops haze early post-operatively, especially in younger patients, and an early treatment is necessary. Treatment for PCO involves a simple laser treatment called a YAG laser posterior capsulotomy. A YAG laser is generally an office-based, outpatient procedure that is painless, requires dilation of the pupil, a topical numbing drop, and takes literally just a few minutes.

The YAG procedure can often be performed 3 months after the ReSTOR procedure (90 days or more), and we can only perform the YAG treatment on 1 eye at a time (must be done on different days). If the Medical Director determines that you require a YAG procedure, we will bill the cost of the procedure to your medical insurance in accordance with the Center's managed care contract with your insurance carrier. In the event that you do not have medical insurance, the Center will discuss fees at the time of the YAG procedure. The cost of medications is the patient's responsibility. We require a 1 week and a 1 month post-operative visits after the YAG procedure, the cost of which is covered in the fee for the procedure. If a patient needs both a YAG procedure followed by an IntraLASIK Enhancement, the YAG must be scheduled first and the LASIK procedure must be scheduled at least 1 month after the YAG procedure.

Patient Signature

Date

Witness Signature

Date