# Informed Consent

## Custom Lens Replacement (CLR)

**Introduction**

This information is given to you so that you can make an informed decision about having eye surgery to correct your farsightedness (hyperopia), nearsightedness (myopia), astigmatism, or presbyopia. Take as much time as you wish to make your decision about signing this informed consent. You have the right to ask questions about any procedure before agreeing to have the operation. Please be sure that all your questions are answered to your satisfaction prior to having your operation.

This surgery, called a custom lens replacement or CLR, involves the removal of the clear lens of your eye, even though there is no cataract. 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. The eye surgeon, known as an ophthalmologist, surgically removes the natural lens of the eye and replaces it with an intraocular lens implant (IOL) in order to restore vision. This is an artificial lens, usually made of plastic, silicone, or acrylic material, surgically and permanently placed inside the eye. You must remember that the natural lens within your own eye with a slight cataract, although not perfect, has some advantages over any man-made lens.

**Benefits of Surgery**

Benefits include better vision than you presently have without glasses. The farsighted (hyperopic) eye is out of focus because the length of the eye is too short for the curvature of the outer lens of the eye (cornea), which causes light rays to focus behind the retina. The nearsighted (myopic) eye is out of focus because the length of the eye is too long for the curvature of the outer lens of the eye (cornea), which causes light rays to focus in front of the retina. The light rays can theoretically be brought to a clearer focus on the retina by substituting an artificial IOL that has the proper power, thereby improving the natural focus of the eye. Although this can theoretically improve your natural distance vision, you will lose the natural focusing power of the eye (accommodation). As a result, you will need to have near vision restored. Alternatives for near vision are discussed later in this document.

**Non-surgical Alternatives to CLR**

Non-surgical alternatives to custom lens replacement are to continue to wear spectacle lenses or contact lenses. Contact lenses or glasses are nonsurgical, extremely accurate, permit easy changes in prescription, and also allow the eye to retain its focusing power for near vision.

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 (farsighted) or reduced (nearsighted) image size and a slight decrease in peripheral vision caused by the thickness of the lenses.

Although contact lenses provide higher quality and more normal vision than glasses, 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.

**Surgical Alternatives to CLR**

There are several other procedures for the correction of farsightedness and nearsightedness. The advantage of the procedures described below is that you retain your natural focusing power and do not require an incision into the inside of your eye, which is needed for CLR surgery. You may choose not to have this surgery at all and either continue wearing your glasses or contact lenses, or you may elect to have one of the other procedures discussed in this section.

1. Conductive keratoplasty (CK) is capable of reshaping the cornea, but is only indicated for low degrees of hyperopia.

2. The excimer laser can be used to correct low to moderate amounts of hyperopia (generally +1 to +3 D or diopters) and low to higher amounts of myopia (generally -1 D to –10D) through either PRK (photorefractive keratectomy) or LASIK (laser in situ keratomileusis). LASIK is an operation which combines the creation of a flap with the microkeratome or a laser and the removal of tissue with the excimer laser. PRK involves removing the surface cells on the cornea (“epithelium”) and using the excimer laser to remove tissue from the exposed tissue on the corneal surface.

3. In phakic implant surgery, an artificial intraocular lens is surgically placed inside your eye. The lens is made from material similar to the type used for the intraocular lenses currently being implanted in the eye to correct vision after cataract or custom lens replacement surgery. The difference between phakic implant surgery and other intraocular lens implants is that your natural lens is not removed during phakic implant surgery. The phakic lens is inserted in front of your natural lens.

**No Treatment**

If you decide not to have surgery, this will result in no improvement in your vision and may result in further decrease of vision.

**Need to Stop Wearing Contact Lenses Prior to IOL Measurements**

If you wear contact lenses, you will be required to leave them out of the eyes for a period of time prior to having your intraocular lens (IOL) measurements. This is done because the contact lens rests on the cornea, distorting its shape, and this distortion will have an effect on the accuracy of the doctor's measurements of the power of surgical correction needed. Discontinuing contact lens use allows the corneas to return to their natural shape. Soft contact lens wearers should leave lenses out of the eyes for at least 3 days. Rigid (including gas permeable and standard hard lenses) contact lens wearers should leave lenses out of the eyes for at least one month. Rigid contact lens wearers usually experience fluctuating vision once their lenses have been discontinued due to changes in the shape of the cornea. Although the cornea usually returns to its natural state within one month, this process may take longer, and you will need to remain contact lens free until stabilization is complete.

**Release of Responsibility**

You agree to release all liability and responsibility from Brinton Vision and its surgeons, knowing you are not to drive following the procedure until cleared to do so (generally at your 1 day, post-operative visit)

## More Information About Intraocular Lens Biometry

While biometry, the method used to calculate the power of the IOL, is very accurate in the majority of patients, the final result may be different from what was planned. As the eye heals, the IOL can shift very slightly toward the front or the back of the eye. The amount of this shift is not the same in everyone, and it may cause different vision than predicted.

Patients who are highly nearsighted or highly farsighted have the greatest risk of differences between planned and actual outcomes. Patients who have had LASIK, PRK, radial keratotomy (RK), astigmatic keratotomy, CK or other refractive surgeries are especially difficult to measure precisely.

If the eye's visual power after surgery is considerably different than what was planned, surgical replacement of the IOL or other corneal refractive procedures might be considered to improve vision.

**Presbyopia and Alternatives for Near Vision After CLR**

Patients who qualify for CLR surgery may have, or will eventually develop, an age-related condition known as presbyopia. Presbyopia is the reason that reading glasses become necessary, typically after age 40, even for people who have excellent distance and near vision without glasses. Presbyopic individuals require bifocals or separate (different prescription) reading glasses in order to see clearly at close range. There are several other options available to you to achieve distance and near vision after CLR surgery:

Glasses: You can choose to have a monofocal (single focus) IOL implanted for distance vision and wear separate reading glasses, or have an IOL implanted for near vision and wear separate glasses for distance.

Monovision/Blended Vision: The ophthalmologist could implant IOLs with two different powers, one eye for near vision, and the other eye for distance vision. This combination of a distance eye and a reading eye is called monovision or blended vision, and reduces the need for reading glasses. It has been employed quite successfully in many contact lens and refractive surgery patients.

Presbyopia-Correcting IOL: The ophthalmologist could implant a "presbyopia-correcting" IOL. These IOLs, more recently approved by the Food and Drug Administration (FDA), provide distance vision AND restore some of the near focusing ability of the eye. Depending upon the technological features of the IOLs, they may be described as "accommodating", "apodized diffractive", "zonal refractive", or "multifocal". All of these lenses are "presbyopia-correcting", meaning they correct for both distance vision and other ranges, such as near or intermediate to reduce the need for reading glasses.

**FDA Status of IOLs Implanted During CLR**

When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a "label" to explain its use. Once a device/medication is approved by the FDA, physicians may use it "off-label" for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects. All IOLs were approved for use in patients with cataracts. Their use in patients having custom lens replacement is considered an "off-label" use of the IOL.

**Anesthesia, Procedure, and Postoperative Care**

Either the ophthalmologist or the anesthesiologist/nurse anesthetist will make your eye numb with either drops or an injection (local anesthesia). You may also undergo light sedation administered by an anesthesiologist or nurse anesthetist, or elect to have the surgery with only local anesthesia.

An incision, or openings, are then made in the eye. These are usually self-sealing, but may require closure with very fine stitches (sutures). The natural lens in your eye will then be removed by a type of surgery called phacoemulsification, which uses a vibrating probe to break the lens up into small pieces. These pieces are gently suctioned out of your eye through a small, hollow tube inserted through a small incision into your eye. After your natural lens is removed, the IOL is placed inside your eye. In rare cases if complications occur at the time of surgery, it may not be possible to implant the IOL you have chosen, or any IOL at all.

After the surgery, your eye will be examined the next day, and then at intervals determined by your surgeon. During the immediate recovery period, you will place drops in your eyes for about 4 weeks, depending on your individual rate of healing. If you have chosen monovision or a multifocal IOL to reduce your dependency on glasses or contacts, they may still be required either for further improvement in your distance vision, reading vision, or both. You should be able to resume your normal activities within 2 or 3 days, and your eye will usually be stable within 4 to 6 weeks.

**Risks of Custom Lens Replacement Surgery**

The goal of CLR surgery is to correct your hyperopia (farsightedness) or myopia (nearsightedness). Depending upon the type of IOL chosen, the goal may also be to restore some of the near (and intermediate, depending upon the IOL) focusing ability of your eye or to reduce your dependency upon glasses or contact lenses. CLR surgery is usually quite comfortable. Mild discomfort for the first 24 hours is typical, but severe pain would be extremely unusual and should be reported immediately to your surgeon.

Since this surgery is essentially the same as cataract surgery, the same risks apply. As a result of the surgery and local anesthesia injections around the eye, 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 and respiratory problems, and, in rare cases, death. Although all of these complications can occur, their incidence following CLR surgery is exceptionally low.

**Complications of Surgery**

These risks of CLR include, but are not limited to: 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 lens of the eye (corneal edema), which can be corrected with a corneal transplant; swelling in the central area of the retina (called cystoid macular edema), which usually improves with time and treatment; retained pieces of the natural lens in the eye, which may need to be removed surgically; infection; detachment of the retina, which is definitely an increased risk for highly nearsighted patients, but which can usually be repaired; uncomfortable or painful eye; 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. Additional surgery may be required to treat these complications.

Complications of Intraocular Lens Implantation: Insertion of an intraocular lens may produce complications that develop during surgery or develop days, weeks, months, or even years later from implanting the lens. Complications may include, but are not limited to, increased night glare and/or halos (multifocal IOLs may increase the likelihood of these problems), distortion, double vision, ghost images, increased/decreased intraocular pressure (fluid pressure inside the eye), loss of corneal clarity, infection, uveitis (inflammation of the iris or colored portion of the eye), iris atrophy (thinning of the iris), glaucoma, bleeding in the eye, inability to dilate the pupil, dislocation of the lens, retinal detachment, total loss of vision and/or loss of the eye. Despite the best/proper care, complications can arise and possibly result in the loss of vision. At some future time, the lens implanted in the eye may have to be repositioned, replaced, or removed surgically. The repositioning, removal or replacement of an intraocular lens has similar potential complications as the primary lens implantation surgery.

Complications associated with anesthesia: You will be given anesthesia as determined by the surgeon, anesthesiologist and/or certified registered nurse anesthetist. Complications from local anesthesia injections around the eye include perforation of the eye, destruction of the optic nerve, interference with the circulation of the retina, allergic reaction, droopy eyelid, respiratory depression, hypotension, cardiac problems, and, in rare situations, brain damage or death.

Complications of Surgery in General: As with all types of surgery there is the possibility of other complications due to anesthesia, drug reactions (allergic) or other factors which may involve other parts of the body, including, although rare, the possibility of cardiac arrest, brain damage or even death. Since it is impossible to state every complication that may occur as a result of surgery, the list of complications in this form are incomplete.

If a monofocal IOL is implanted, either distance or reading glasses or contacts will be needed after CLR for adequate vision.

Complications associated with mono-vision: Mono-vision may result in problems with impaired depth perception. Complications associated with multifocal IOLs. While a multifocal 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. Driving at night may be affected. If you drive a considerable amount at night, or perform delicate, detailed, "up-close" work requiring closer focus than just reading, a monofocal lens in conjunction with eyeglasses may be a better choice for you. If complications occur at the time of surgery, a monofocal IOL may need to be implanted instead of a multifocal IOL.

If an IOL is implanted, it is done by a surgical method. It is intended that the small plastic, silicone, or acrylic IOL will be left in the eye permanently.

If there are complications at the time of surgery, the doctor may decide not to implant an IOL in your eye even though you may have given prior permission to do so.

Other factors may affect the visual outcome of CLR surgery, including eye diseases such as glaucoma, diabetic retinopathy, and age-related macular degeneration; the power of the IOL; your individual healing ability; and, if certain IOLs are implanted, the function of the ciliary (focusing) muscles in your eyes.

The selection of the proper IOL, while based upon sophisticated equipment and computer formulas, is not an exact science. After your eye heals, its visual power may be different from what was predicted by preoperative testing. You may need to wear glasses or contact lenses after surgery to obtain your best vision. Additional surgeries such as IOL exchange, placement of an additional IOL, or refractive laser surgery may be needed to improve your vision after CLR.

The results of surgery cannot be guaranteed. If you chose a multifocal IOL, it is possible that not all of the near (and intermediate) focusing ability of your eye will be restored. Additional treatment and/or surgery may be necessary. Regardless of the IOL chosen, you may need laser surgery to correct clouding of vision. At some future time, the IOL implanted in your eye may have to be repositioned, removed surgically, or exchanged for another IOL.

If your ophthalmologist has informed you that you have a high degree of hyperopia (farsightedness) and/or that the axial length of your eye is short, your risk for a 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 your ophthalmologist has informed you that you have a high degree of myopia (nearsightedness) and/or that the axial length of your eye is long, your risk for a complication called a retinal detachment is increased. Retinal detachments can lead to vision loss or blindness.

In certain circumstances, your doctor may recommend separating each eye surgery by a period of time. If this is the case, you may experience a period of imbalance between the two eyes (anisometropia). 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 you will function with only one clear eye for distance vision. In the absence of complications, surgery in the second eye can usually be accomplished within 1 to 4 weeks, once the first eye is stabilized.

**Financial Implications of Custom Lens Replacement Surgery**

I have requested that my physician perform a non-covered procedure, "Custom lens replacement with implantation of Intra-ocular lens". This procedure is elective. I understand that I am responsible for the cost of the surgery and the IOL, including the surgeon's fee, the anesthesiologist's fee, if any, and the surgical center's or hospital's fee. This is because health insurance 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 that is not visually disabling. I understand the purpose of this procedure is to reduce dependence on spectacle correction.

I understand that I will be responsible for the costs of any 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 CLR, 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 as well.

Patient initials: _____

**<u>Items specific to the Light Adjustable Lens</u>**

The RxSight Light Adjustable Lens (RxLAL™) is similar to other intraocular lenses (IOLs) that can be implanted in your eye to replace the natural lens that is removed during Custom Lens Replacement. The RxLAL™ reduces the need for glasses or contact lenses by being able to change its focusing power after it is implanted in the eye. The focusing power of the RxLAL™ is adjusted by a specific patterns of ultraviolet (UV) light produced by the RxSight Light Delivery Device (LDD), an instrument that your doctor uses in the office beginning 4-6 weeks after CLR surgery. Up to three light adjustment treatments can be performed to adjust your vision, with a separation of 7-14 days between treatments. Following your final light adjustment, the same LDD is used to lock in the RxLAL™ and make the prescription permanent. From immediately after surgery until 24 hours after the

completion of the lock-in treatment, you will need to protect the RxLAL™ from UV light in the environment by wearing protective eyewear during all waking hours.

**Prior to implantation**

It is important to tell you doctor of any eye diseases, surgery or any other problems with your vision that you may have experienced in the past.

Because some medicines and supplements can increase your eye's sensitivity to the UV light used in the LDD (and put you at risk of damage to the eye during the LDD light treatments), it is very important that you tell your doctor about all the medications and supplements that you are taking. If your medications change any time before surgery, or between surgery and the last light treatment, you must let your doctor know as soon as possible as one of the new medicines may put you at risk.

**Risk during implantation**

As with other IOLs, if the RxLAL™ is scratched or incorrectly placed in the eye at the time of surgery, it may need to be removed with another surgery prior to light treatments.

**RxSight UV Protective Eyewear**

Immediately after surgery, you must wear the special UV protective eyewear provided to you. The protective eyewear will protect the RxLAL™ from UV light from the sun and other UV sources that are common both indoors and outside. Before the RxLAL™ is locked in, you can experience a loss in vision if you are exposed to daylight or any other UV light source when you are not wearing protective eyewear.

Two pairs of UV protective eyewear will be provided to you, a clear pair and a dark tinted pair. When indoors, the clear pair must be worn at all times as it is not always possible to know which light sources may affect the lens. Before moving outside, the clear eyewear must be changed to the dark tinted eyewear as sunlight carries a greater risk of changing the shape of the lens in an uncontrolled manner. You do not have to wear the dark tinted pair outside at night, as there is no sunlight. The clear pair may be worn at night to protect the RxLAL™ from other UV light sources. The UV protective eyewear must be worn until your doctor tells you that you no longer need to wear them (usually 24 hours after final light treatment).

If you do not wear the required protective eyewear, the light treatments may not improve vision or may make your vision worse. If this happens, the RxLAL™ may have to be removed and replaced with a new lens to improve vision. This can lead to other complications from the additional surgery.

**Risk associated with RxSight Light Delivery Device (LDD) Treatments**

To perform the light treatments, your pupil needs to be large enough for the entire lens to be seen. If it is not possible to enlarge the pupil enough, additional eye drops, injections into the eye, or surgery may be needed to further enlarge the pupil. If the pupil cannot be sufficiently enlarged after these types of treatments, the lens may need to be removed.

There is a possible risk of UV-induced damage to the eye, including the cornea and retina, which may be permanent.

UV light can sometimes cause a reactivation of previous herpes virus infection in the eye, which is why it is very important to tell your doctor about all previous eye history. A reactivation of herpes virus can cause scarring of the cornea, blurred vision, eye pain, extreme light sensitivity, permanent loss of vision, and possible need for corneal transplant.

Erythropsia is a pink to red tinge to the vision and may occur temporarily or for longer following a light treatment due to the type of light used by the LDD.

A temporary or long-term color vision deficiency may also occur.

Corneal dryness and corneal abrasions from the contact lens used during light treatments, can occur.

If a light treatment is performed to correct astigmatism, it is possible that vision may be affected if the lens rotates after light treatment, or if the light treatment is not performed correctly.

It is also possible that the desired results of the surgery may not be obtained or may not last. Since it is impossible to identify every complication that may occur as a result of any surgery, there may be risks that have not been described here.

**Consent for Operation**

In giving my permission for a CLR with the possible implantation of an intraocular lens in my eye, I declare that I understand the following information.

Custom Lens Replacement (CLR), 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 CLR surgery performed either at the time of the lens implantation or before lens implantation.

If an intraocular lens is implanted, it is done by a surgical method. It is intended that the small artificial lens will be left in my eye permanently.

**The results of my surgery are not guaranteed.**

At the time of surgery, if unforeseen problems occur, my doctor may not be able to safely implant an intraocular lens in my eye, even though I have given prior permission to do so.

I understand that a film of cloudiness of the lens capsule may occur behind my implant several weeks or years after surgery, which may necessitate the use of a laser (YAG) to clear my vision.

I understand that macular or retinal degeneration, glaucoma, diabetes or other eye diseases that I might have could keep me from seeing as clearly as I would like following surgery.

I understand that I also have the option to choose not to have surgery.

I understand that some of the complications of CLR and/ or intraocular lens implantations may result in the need for further surgical or laser procedures.

I understand that my surgeon is not providing the equipment, technical support and staff support to be used in performing this procedure, but these services and equipment will be provided by another facility or entity. If my procedure is performed in an ambulatory surgery center (ASC), I understand that the professional services provided in performing this procedure will be supplied by physicians who are not employees of the ASC but who have been granted privileges by the ASC to perform this procedure at the ASC. I understand that the physician identified below will be assisted by others as he or she considers necessary to my care.

I have not taken any pre-operative medications prior to reading, understanding and signing this Informed Consent form. I have informed my physician of any medications that I may be taking in order to account for the risk of allergic reactions, drug reactions, and other potential complications during cataract surgery and/or intraocular lens implantation and any subsequent treatment.

I authorize the physicians and other health care personnel involved in performing my CLR surgery and in providing my pre and post-procedure care to share with one another any information relating to my health, my vision, or my CLR that they deem relevant to providing me with care.

I agree to arrange for someone to drive me home after my surgery and to refrain from driving myself until I am comfortable with both my day and night vision.

Neither my operating physician nor any of his/her employees or representatives have made any oral statements to me that are inconsistent with the information stated in this consent form.

I authorize and direct Jason P. Brinton, M.D., my surgeon, and/or associate or assistants of his choice to perform the indicated procedure(s) on me, using topical/local anesthetics and/or any therapeutic procedure which he may deem advisable for my well-being, whether or not arising from presently unforeseen conditions.

In signing this informed consent for custom lens replacement with implantation of an intraocular lens, I am stating I have read all ten (10) pages of this informed consent (or it has been read to me). I also understand that I have the right to choose “NO TREATMENT” at all. If I choose no treatment, my vision may stay the same or gradually become worse resulting in loss of my eyesight.

The basic procedures of custom lens replacement (CLR) surgery, the reasons for the type of IOL chosen for me, and the advantages, disadvantages, risks, and possible complications and 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, I have been given the opportunity to ask questions and the doctor and staff have satisfactorily answered all of my questions.

In signing this informed consent for CLR surgery and implantation of an IOL, I am stating that I have been offered a copy, I fully understand the possible risks, benefits, alternatives and complications of CLR surgery and

I have read this informed consent _____ (patient initials)

OR

The consent form was read to me by_____ (name)

I wish to have a custom lens replacement operation with an intraocular lens on my

RIGHT / LEFT Eye

Patient Signature: _____

Patient Name (Please Print):_____

Date:_____ Time: _____

Facility: _____

Witness' Signature: _____