INFORMED CONSENT FORM

THIS DOCUMENT CONTAINS IMPORTANT INFORMATION ABOUT YOUR CUSTOM LENS REPLACEMENT SURGERY; PLEASE READ IT CAREFULLY BEFORE YOU SIGN IT.

You are entitled to receive information about the Custom Lens Replacement (CLR) procedure you intend to undergo with Dr. Jason Brinton at Brinton Vision, whether it be for myopia, (nearsightedness), hyperopia (farsightedness), astigmatism, and/or presbyopia (the need for near-vision glasses due to age-related loss of flexibility in the eye's natural lens, impairing its ability to change shape and focus clearly from far to near objects). It is important that you understand the risks of the treatment and lens options and carefully weigh the alternatives prior to having CLR surgery.

Patients Initials

If you have any questions regarding your procedure, please discuss them fully with your doctor prior to surgery. You may also want to seek a second opinion before undergoing this procedure. Whether or not you have CLR, you should continue to have a yearly comprehensive eye exam with dilated pupils to maintain eye health.

PROCEDURE AND IOL OPTIONS

The eye's focusing system is comprised of two lenses – one is fixed (the cornea, where LASIK is performed) and one is flexible (the crystalline lens, beneath the surface of the eye, where CLR is performed). In your forties, the crystalline lens gradually loses flexibility and function as it goes through predictable aging changes, which are divided into the three stages of *Dysfunctional Lens Syndrome* or DLS (ages are approximate).

1) DLS Stage 1, age 40+. The crystalline lens begins to stiffen and harden, leading to a loss of focusing power, near vision changes, and need for reading glasses.
2) DLS Stage 2, age 50+. The inner portion of the crystalline lens further degrades and discolors, causing reduced contrast and night vision.
3) DLS Stage 3, age 70+. The inner portion of the crystalline lens clouds over, leading to significant vision loss and in some cases, visual disability. At Stage 3, the clouded inner portion of the crystalline lens is referred to as a cataract. Cataracts are a normal part of the aging process of the eye; everyone who lives long enough will get a cataract.

In Custom Lens Replacement (CLR), the eye is numbed with drops. An opening (incision) is made to the side of the cornea. The inner portion of the crystalline lens – what stiffens and hardens in Stage 1, degrades and discolors in Stage 2, and eventually clouds over, leading to significant vision loss in Stage 3 – is separated, emulsified by ultrasound *(phacoemulsification)*, and rinsed from the eye. A clear intraocular lens implant (IOL) made of silicone or acrylic material is placed in the eye. The inner IOL and natural outer portion of the lens (capsule) join together, providing power to meet the eye's focusing needs and eliminating future cataract development.

Dr. Brinton selects IOLs for implant based on your medical history, diagnostic testing, and vision goals. Monofocal (single focus) IOL options provide the highest quality of vision but will focus only for far vision or near vision, not both. Multifocal (far and near), extended depth of focus, and other similar IOL options provide a greater range of vision but compromise vision quality.

PATIENT ACKNOWLEDGEMENTS

I acknowledge, understand, and agree, by my initials and signatures below, to the following:

1. BENEFITS AND OUTCOME NOT GUARANTEED.

The benefits of CLR procedures cannot be guaranteed. The goal of CLR is to reduce or eliminate blurred vision from myopia, hyperopia, presbyopia, astigmatism, or a combination of those. There are no guarantees that I will completely eliminate my reliance on eyeglasses and/or contact lenses or that my eyesight will be improved at all.

Patients Initials

2. SURGICAL RISKS AND POSSIBLE SIDE EFFECTS:

OVER-RESPONSE OR UNDER-RESPONSE TO TREATMENT. It is possible that my treatment could result in an unintended under-response or over-response that may require the continued use of glasses or contact lenses after my surgery has been performed.

By initialing here, I acknowledge I have read, understand, and agree with the information on this page: _____

CHANGE IN OR INDUCING ASTIGMATISM. The surgical procedure I am undergoing may also change my astigmatism or induce astigmatism even if I did not have astigmatism prior to the procedure.

INFECTION OR INFLAMMATION. Although infrequent, I understand another risk is the possibility of infection or inflammation during healing of the eye. In rare circumstances this or another complication may result in loss of vision, loss of eye, or death. I understand that to achieve good results from the procedure, I must follow my doctor's recommendations regarding postoperative antibiotic eye drops and other medications, activities, and restrictions, and attend all scheduled postoperative visits.

Patients Initials

NIGHT GLARE. I may experience night glare, such as a *starburst,* a *halo effect,* or haze around lights in the nighttime. Some degree of night glare can be expected in all patients. It usually is tolerable and resolves in time, but on occasion could be permanent. Patients with high myopia, high astigmatism, high hyperopia, or large pupils are at a greater risk of experiencing these problems on a permanent basis. Dry eyes, multifocal IOLs, and over or under response may also increase night glare.

Patients Initials

NIGHT VISION. Vision may not seem as sharp at night as during the day. In some cases, corrective lenses may help me see more clearly at night, particularly with monovision. Corrective lenses may not be able to compensate for some loss of night vision.

INCREASED SENSITIVITY. There may be an increased sensitivity to light or glare.

BLURRINESS. Blurriness is common in the healing process. While blurriness generally clears in several days, it may take longer to clear, and could remain permanently.

LOSS OF BEST-CORRECTED VISUAL ACUITY. I understand there is a risk of loss of the best vision I can get with the assistance of corrective lenses, also known as my *best corrected visual acuity*. For most patients, visual acuity will have stabilized in about 3 months following their procedure, although neuroadaptation (brain adjusting to the new vision) can take longer. A small percentage of patients develop irregular corneas that reduce the sharpness, clarity and crispness of their vision. I understand that if this happens, I may not be able to read the last few lines of the eye chart, regardless of corrective lens assistance.

Patients Initials

POSTERIOR CAPSULAR OPACIFICATION (PCO). All lens implants develop PCO sometime between 3 months and 33 years after lens replacement surgery when natural cells in the eye obscure the clarity of the IOL. When this happens, I understand that I will need a YAG laser procedure to restore visual clarity.

READING GLASSES. I understand that if I have CLR to correct both eyes for distance vision, I will need reading glasses in order to see objects approximately 3 feet and closer. I understand that Monovision and multifocal IOLs, like reading glasses, are among several treatments for Presbyopia.

DRYNESS. I may experience dryness of my eyes and this dryness may cause severe irritation, discomfort, and blurring of vision for several weeks, or longer, and in some cases could be permanent. I understand that if this happens I may need to use artificial tears, eye ointments, prescription medication, or punctal plugs for an indefinite period of time. Post-menopausal women are at higher risk for developing dry eyes. Some medications may also cause dry eyes.

Patients Initials

DOUBLE VISION. I may experience double or ghosted vision, which may or may not go away with time. If it does not go away, I may need re-treatments, glasses or rigid contact lenses after my procedure, which may or may not help this issue.

FURTHER TREATMENT. I understand that further treatment may be necessary. Further treatment could include a variety of eye drops, the wearing of glasses and/or contact lenses (hard or soft), exchange of my IOL for a different IOL, or additional eye surgery or laser correction. Follow-up visits will be required. If I do not follow my doctor's orders regarding follow-up care, I may be jeopardizing the healing process or long-term health of my eye(s).

RISK TO BOTH EYES. If I have both eyes treated on the same day, complications could develop in both eyes at the same time. As a patient, it is my choice for treatment of one eye at a time or both eyes on the same day.

Patients Initials

CONVERSION TO MONOFOCAL IOL. Even if a multifocal IOL is planned, Dr. Brinton may determine during my procedure that implanting a monofocal IOL targeted for monovision is in my best interest due to my eye anatomy or other factors.

OTHER COMPLICATIONS. Eye complications of CLR surgery may include hemorrhage (bleeding); rent of the capsule that supports the IOL; vitreous loss; swelling of the cornea, sometimes requiring corneal transplant; cystoid macular edema or swelling of the retina; retained crystalline lens material in the eye; dislocation of the IOL; incision leak; decreased function or altered shape of the iris; detachment of the retina, which is an increased risk for highly myopic (nearsighted) patients; nanophthalmic choroidal effusion, which is an increased risk for highly hyperopic (farsighted) patients; painful eye; miodesopsia (floaters); droopy eyelid; and glaucoma. As with all types of surgery, there is a possibility I may experience the complications above or other complications, including those due to anesthesia or drug reactions that may involve other parts of the

Patients Initials

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body. I have discussed this possibility with my doctor and the staff and understand that it is impossible to be informed of all potential risks of any surgery, including CLR procedures. I have provided my surgeon and the staff with complete and up-to-date information regarding prescription and over-the-counter medications I take, any drug allergies and my pre-existing medical conditions, including prior surgeries, degenerative conditions, active or pre-existing eye disorders and any previous eye treatments. I understand that postoperative complications may occur that require additional medical care, treatments, tests, medicines or surgery and this care or surgery will be at my expense.

3. CONTRAINDICATIONS. *Treatment may not be indicated in every person. The situations in which treatment may be contraindicated include the following:*

Patients Initials

Contraindications*:

- Certain abnormalities of the cornea (e.g., keratoconus or other corneal ectasias, thinning, edema, interstitial or neurotrophic keratitis, extensive vascularization)
- Uncontrolled glaucoma
- Uncontrolled external disease (e.g., blepharitis, dry eye, atopy/allergy)
- Uncontrolled autoimmune or other immune-mediated disease
- Unrealistic patient expectations

Relative Contraindications* - those conditions that are evaluated individually by the doctor and include the patient's history, current clinical situation and pre-existing health conditions. I understand that the following factors may increase my risk of complications:

Patients Initials

- Functional monocularity
- Ocular conditions that limit visual function
- Excessively steep or flat corneas
- Abnormal corneal topography indicating suspect keratoconus
- Significant irregular astigmatism
- Visually significant corneal stromal or endothelial dystrophies
- History of herpes simplex virus (HSV) or varicella zoster virus (VZV) keratitis
- Inadequately controlled dry eye
- Glaucoma
- History of uveitis
- Diabetes mellitus
- Pregnancy or lactation
- Autoimmune or other immune-mediated diseases
- Certain systemic medications (e.g., isotretinoin, amiodarone, sumatriptan, levonorgestrel implants, colchicine)

Other Possible Contraindications - These conditions are patient-specific and should be addressed individually with your surgeon. I understand that these conditions or situations may increase my risk of complications.

Patients Initials

- Corneal stromal or endothelial dystrophies
- Poor epithelial adherence, epithelial basement membrane dystrophy, or recurrent erosion syndrome
- Dry eye syndrome - includes, but is not limited to, the rare patient who has dry eyes without contact lenses and must use artificial tears daily. (Patients with difficulty wearing contact lenses due to dry eye should inform their surgeon.)
- Prior incisional or lamellar keratorefractive surgery
- Use of anti-depressants
- Significant occupational or recreational risk for eye trauma
- History of severe eye infection or active eye infection

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- High refractive errors (high myopia, high hyperopia, or high astigmatism)
- Very thick corneas may indicate the presence of Fuchs Endothelial Dystrophy and may require corneal transplants
- Occupations with specific vision requirements

4. FDA APPROVAL.

All IOLs were approved for use in patients with cataracts. In consultation with my doctor, I understand that IOLs may be implanted outside of the FDA guidelines, including when treatment may be otherwise contraindicated, as explained above. IOL implantation for the correction of eye prescription, rather than for the correction of cataract, is considered an *off-label* use of an IOL. This is routinely done both internationally and in the United States.

5. FDA APPROVAL FOR MEDICATIONS.

In consultation with my doctor, medications such as antibiotics and steroid eye drops may be used and prescribed in a regimen not approved by the FDA in order to help reduce the risk of infections, swelling or other complications. This is routinely done both internationally and in the United States.

6. COMMUNICATION AND MEDICAL DATA.

My physicians, medical technicians, and other health care personnel involved in performing my surgery and in providing my medical care may share with one another, by regular email, text, phone, voicemail, or postal mail, any information relating to my health, vision, or vision correction procedure. I understand that my eye and health information will be entered into an electronic medical record database system. My physician may use this database to analyze preoperative and postoperative information and aid in the development of optimized outcomes. I give permission for medical data concerning my operation and subsequent treatment to be used in clinical teaching.

PATIENT TREATMENT STATEMENT

CHECK ALL APPROPRIATE BOXES:

☐ I have MYOPIA (nearsightedness) or HYPEROPIA (farsightedness), with or without astigmatism, which requires me to wear corrective lenses in order to see clearly for my daily activities. I have been informed of the alternatives to undergoing the surgical option I have chosen, including eyeglasses, contact lenses, and other types of refractive surgery.

☐ I have PRESBYOPIA (the need for near-vision glasses due to age-related loss of flexibility in the eye's natural lens, impairing its ability to change shape and focus clearly from far to near objects). I have been informed of the alternatives to undergoing the surgical option I have chosen, including eyeglasses, contact lenses, and other types of refractive surgery.

☐ I have elected to undergo and give permission for the following procedure(s) to be performed on me:

Primary Treatment:

Right Eye (OD): ☐ Custom Lens Replacement

Left Eye (OS): ☐ Custom Lens Replacement

Patient Name (Please Type or Print) _____ Date _____

Patient Signature _____ Physician Signature _____

By initialing here, I acknowledge I have read, understand, and agree with the information on this page: _____

PATIENT STATEMENT OF INFORMED CONSENT

I have carefully read this Informed Consent document (or it has been read to me) and I understand the information presented in it.

I have been given adequate time to thoroughly review and understand this Informed Consent prior to my procedure(s) and acknowledge that although these documents contain medical terms, I fully understand all the potential risks and complications discussed in this Informed Consent, including but not limited to those I may have failed to specifically initial. If English is not my preferred language for discussion of medical information, Brinton Vision has offered me the services of a professional medical interpreter. I understand that there are alternatives to all surgical procedures, including the option of not having surgery, and these alternatives have been explained to me in detail. I understand that if I choose not to have surgery my condition is expected to stay the same or slowly progress as I age. I understand that my risk of complications may be increased with a retreatment procedure, now or in the future. I understand that it is not possible for my doctor to inform me of every conceivable complication that may occur during my procedure. I have had the opportunity to have all my questions answered regarding the procedure, its risks and my other options. I have made my decision without threat or coercion of any kind. I am satisfied and ready to proceed with the procedure.

I have been given the opportunity to meet with my surgeon, Dr. Brinton, in addition to my examining doctor prior to the procedure if I so request.

If I have selected a monovision treatment, I have been given the opportunity to experience a *contact lens trial* of monovision prior to the procedure if I so request.

I consent to the administration of anesthesia and other medications as recommended by Dr. Brinton and understand that certain risks attend all anesthetics and medications. I understand and accept the risks and potential complications associated with the procedure (including but not limited to any contraindications I may have to achieving a successful outcome) and understand that my doctor may be treating me beyond the FDA-approved guidelines for the IOL or medications being used. I agree to arrange for someone to drive me home after my procedure and to refrain from driving myself until I am certain that my day and night vision are adequate.

I authorize any assistants and observers approved by my surgeon to be present during my procedure and I understand that I may be video recorded or photographed and included in online marketing materials. I have been given the opportunity to receive a copy of my signed Informed Consent document if I so request.

I understand that my surgeon and the staff must rely on statements and information I have provided to him regarding my family, eye and medical history, current eye and medical conditions, and current prescription and non-prescription drugs, and I hereby certify that all information I have provided is complete, true and correct. I understand that if I withhold information, I may have a higher risk of complications or even have an inappropriate treatment. Neither Dr. Brinton nor any of his employees or representatives have made oral statements to me that are inconsistent with the information stated in this Informed Consent. I hereby attest that I am of sound mind and am not under the effects of any medication which may impair my ability to consent to the procedures explained herein.

Patient Name (Please Type or Print)	Date of Birth
Patient Signature	Date
Examining Doctor Signature	Date
Physician Signature	Date
Witness Signature	Date

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