



Clear Advantage Vision Correction Center

INFORMED CONSENT FOR RAINDROP NEAR VISION INLAY

**PLEASE READ THE FOLLOWING PAGES CAREFULLY AND INITIAL AND SIGN WHERE INDICATED.
PLEASE DO NOT SIGN ANY SECTION THAT YOU HAVE NOT READ OR DO NOT UNDERSTAND.**

SECTION 1: GENERAL INFORMATION ON INFORMED CONSENT

It is our hope to fully inform you of the side effects, limitations and complications of refractive surgery. We continually strive to balance the benefits of refractive surgery with the known and unknown risks. It is important to understand that it is impossible to perform any surgery without the patient accepting a certain degree of risk and responsibility. This consent form, in combination with the educational materials provided and the entire consultation process, is designed to enhance your understanding of the potential for difficulties that may be encountered during both the procedure and the healing process.

Many of our patients are surprised and some are upset by the extent to which we attempt to inform them of the potential for complications. It is not our intention to frighten or dissuade someone from pursuing refractive surgery, as most of our patients will never encounter any serious complications, and the vast majority are thrilled with the improvement they achieve. It is our intention to accurately outline the associated risks to all candidates so that they may either elect not to accept the risks associated, or be better prepared to deal with any unexpected complications or side effects which may arise. The Raindrop near vision inlay is a purely elective procedure, and you may decide not to have this operation at all. The only way to avoid all surgical risk is by not proceeding with surgery.

SECTION 2: WHAT IS RAINDROP® NEAR VISION INLAY?

Raindrop is a small, transparent, curved disc called a corneal inlay. It's made of approximately 80% water and from similar material to a soft contact lens. It is similar to the clear front part of the eye and it is the size of a pinhead and extremely thin. Raindrop® Near Vision Inlay offers a long term solution to near vision loss caused by aging. Raindrop® Near Vision Inlay helps reshape the front of the eye, restoring near vision. The inlay is placed just below the surface of the eye during a simple ten minute procedure. It is placed in the non-dominant eye, offering a long term solution to presbyopia.

SECTION 3: INDICATIONS FOR USE:

The Raindrop Near Vision Inlay is indicated for intrastromal implantation to improve near vision in the non-dominant eye of phakic, presbyopic patients, 41 to 65 years of age, who have manifest refractive spherical equivalent (MRSE) of +1.00 diopters (D) to -0.50 D with less than or equal to 0.75 D of refractive cylinder, who do not require correction for clear distance vision, but who do require near correction of +1.50 D to +2.50 D of reading add.

SECTION 4: SUMMARY OF IMPORTANT INFORMATION

The Raindrop Near Vision Inlay may not eliminate the need for reading glasses. Implantation of the Raindrop Near Vision Inlay has the potential to cause vision and eye symptoms; dry eyes; decreased vision; decreased contrast sensitivity; problems with the cornea, such as clouding, thinning, scarring, and inflammation; eye infection; increased eye pressure; and the need for another eye surgery, such as removal or replacement of the inlay, or other treatment.

You should not have the Raindrop Near Vision Inlay implanted if you have

- severe dry eye;
- an active eye infection or active inflammation;
- signs of corneal disease characterized by general thinning and cone-shaped protrusion in the center of the cornea (keratoconus) or keratoconus suspect;
- abnormal features of the outer part of the eye (cornea) to be implanted;
- active abnormal immune response (autoimmune) or connective tissue diseases;
- thin corneas or do not have enough corneal thickness to safely have the procedure performed;
- a recent herpes eye infection or problems resulting from a previous infection;
- an uncontrolled buildup of high pressure in the eye (glaucoma);
- uncontrolled high blood sugar (diabetes).
- had previous eye surgery, such as LASIK or cataract surgery

Before having the Raindrop Near Vision Inlay procedure you should have a complete eye examination and talk with your eye care provider about alternative treatments, potential benefits, complications, risks, healing time, and any other concerns you have about having the procedure.

Patient Initials _____

SECTION 5: PRE-PROCEDURE and POST-PROCEDURE CARE

Prior to Surgery

If you are interested in pursuing Raindrop® Near Vision Inlay your eye doctor will prescribe a steroid eye drop to start two days before surgery. Other eyedrops will be prescribed and the staff will provide you instructions on the frequency and use of the eyedrops.

It's also critical to have travel arrangements scheduled before your procedure as you will not be able to drive home following your surgery.

Day Of Surgery

On the day of your procedure you will be administered a numbing eye drop by your doctor, so you won't feel any pain. During the 10 minute procedure you will be laying on your back and focusing on a light, allowing your eye to remain as still as possible. Your surgeon will create flap in the cornea with a laser flap creation device, similar to the first step in LASIK. Your surgeon will then insert the Raindrop® Near Vision Inlay into the middle layer of the cornea. Your surgeon will then replace the flap, and the procedure is done. The eye heals itself, with no need for stitches.

There are some simple post procedure guidelines to assure your eye heals safely and as quickly as possible.

- You will be required to wear an eye shield at night for up to one week to help prevent you from rubbing your eye while you sleep.
- You will also be prescribed steroid and antibiotic eyedrops and will also need to use artificial tears in the eye with the Raindrop® Near Vision Inlay to help minimize the risk of infection, inflammation and dry eye.

Aftercare

You will be able to resume normal activities the day after your procedure, including driving.

After your surgery you should avoid rubbing your eyes, playing sports, wearing makeup, exercising, smoking, swimming, gardening, and being in dusty environments for at least one week after your procedure. It's best to check with your eye care provider to determine when you can resume these activities.

You will likely see your doctor at one day, one week, one month, three months and six months post procedure. An annual eye exam should be performed following the post-op check ups, and sooner if you experience an issues with your inlay implanted eye.

SECTION 6: LEGAL RESPONSIBILITIES

CONFIDENTIALITY

By initialing below, you give permission for the medical data concerning your surgery and subsequent treatment to be submitted to Clear Advantage Vision Correction Center, Eyesight Ophthalmic Services, the laser manufacturer and the government regulatory authorities. The data will be utilized for statistical analysis, record keeping, marketing, and quality control. Patient identity will be strictly confidential in any dissemination of data.

GOVERNING LAW / JURISDICTION

By initialing below, you agree that the relationship and resolution of any and all disputes between yourself, Clear Advantage Vision Correction Center, and your surgeon shall be governed by and construed in accordance with the laws of New Hampshire. You also acknowledge with your initials that courts of the state of New Hampshire shall have jurisdiction to entertain any complaint, demand, claim or cause of action whether based on alleged breach of contract or alleged negligence arising out of treatment. You hereby agree that you will commence any such legal proceedings in New Hampshire and you irrevocably submit to the exclusive jurisdiction of the courts of New Hampshire.

SECTION 7: RISKS AND COMPLICATIONS

As discussed earlier, all forms of surgery carry a certain degree of risk for adverse effects and complications. Problems can be related to the surgical component or the healing component. Most surgical problems are related to the creation of the corneal flap and most healing problems develop within the first few months following the Raindrop inlay. Most complications improve or resolve within 6 – 12 months or with retreatment, but some surgical or healing complications may result in permanent visual blurring, glare, discomfort or

need for corrective contact lenses. The risk of a severe complication is not only dependent upon the functioning of the femtosecond laser and surgical technique, but upon a number of other factors including the prescription, orbital structure, cornea shape, and healing characteristics of the individual treated. In general, there is a small risk in the range of 1 – 5 % of experiencing a complication and a very small risk, probably less than 1 in 1,000, of a severe sight-threatening complication. Please read this section carefully for a better understanding and initial below.

Patient Initials _____

The risks of refractive surgery revolve around 6 primary areas:

1. Post-operative Side Effects, Adverse Effects and Complications
2. Refractive Complications
3. Corneal Flap Complications
4. Corneal Healing Complications
5. Corneal Ectasia
6. Other Miscellaneous Complications

1. Post-operative Side Effects, Adverse Effects and Complications

There are several adverse effects which may be encountered early in the post-operative period, which include foreign body sensation, pain or discomfort, sensitivity to bright lights, blurred vision, dryness of the eyes, tearing and fluctuation in vision. Persistent pain is uncommon following the inlay procedure and may indicate a disturbance of the epithelial protective layer, displacement of the corneal flap or possible infection and should be evaluated promptly by your doctor. Corneal infection is rare but very serious and can potentially result in corneal scarring requiring a corneal transplant and in very severe cases, infections can even result in blindness. Corneal inflammation can also be produced from medication, the inlay itself, or healing reactions, which may be allergic, toxic or immune in nature. This inflammation can come many months after implantation. This often can be treated with eye drops but in rare cases, may require the removal of the Raindrop inlay.

Diffuse interface keratitis (also known as Sand of the Sahara) is an inflammatory reaction that can produce corneal hazing, blurred vision, farsightedness, or astigmatism which may result in permanent corneal irregularities. Treatment may involve topical steroids or further surgery and may or may not restore vision fully. The most common long-term side effect is dryness of the eyes, which often precedes corneal flap creation but may be exacerbated. The most important long-term side effects are night glare, starbursts, haloes, or simply reduced visual quality under low light conditions. It is very common to have night glare early during the recovery course and night glare is common when only one eye has been treated. Night visual disturbances may be produced by the pupil size exceeding the inlay area. In a small percentage of patients night glare may be permanent and affect your night driving abilities.

2. Corneal Flap Complications

The primary benefits of the inlay are related to the creation of the protective corneal flap. The corneal flap must be of clinically adequate quality, thickness and size to proceed with the implant. Corneal flap complications range in severity from those that simply require the procedure to be postponed by 3 to 6 months, to those that create permanent corneal irregularities resulting in blurred vision. Corneal flap complications that occur after the inlay procedure during recovery period include displacement and wrinkling of the corneal flap and epithelial ingrowth. Overall, corneal flap complications are rare, with a reported incidence between 0.3 – 14%, depending on the type of device used. The highest incidences of flap complications are associated with microkeratome (bladed) procedures. It is for this reason that the femtosecond laser is used for flap creation.

Corneal flap complications using the **FEMTOSECOND LASER** (bladeless laser) include but are not limited to:

- Corneal flaps of inadequate thickness, may or may not be adequate for the inlay placement, and may result in the procedure being stopped and repeated at a later date. A thin corneal flap may result in slow visual recovery over weeks to months and possibly permanently blurred vision with or without laser treatment.
- Corneal flaps are routinely hinged either nasally or superiorly beneath the upper eyelid. A corneal hinge is not required for a good visual result, but a hinged corneal flap is more secure and typically heals faster and more smoothly. It is possible that a free corneal cap may be produced which is not hinged to the cornea. Although the inlay may still be performed, if any irregularities in flap quality or thickness are noted, the corneal disc is immediately replaced and allowed to heal. If the free corneal cap is of excellent quality then the procedure is completed, but special care must be taken during the first 24 – 48 hours not to displace or lose the corneal cap. Loss of the corneal cap may result in scarring, and permanent corneal irregularity and the need for more invasive surgery.
- Corneal flap displacement, partial or complete, occurs during the early post-operative period, typically during the first 12 – 24 hours, but may occur days to weeks later with trauma. Care should be taken to protect the eyes from trauma, as well as avoiding rubbing the eyes or forcefully closing the eyes (squeeze blinking) during the first week following the inlay. Partial displacement of the corneal flap may result in corneal striae or wrinkles, which blurs vision both qualitatively and quantitatively. Most corneal striae are treatable but some may be resistant to treatment especially in highly nearsighted patients. Complete displacement of the corneal flap is often painful and requires urgent replacement. There is a higher risk of epithelial ingrowth and infection with corneal flap displacement.

Patient Initials _____

- Epithelial ingrowth occurs during the first month following flap creation and is more likely to occur in patients with an abnormal or weakly adherent protective layer, for which age is a factor. Epithelial ingrowth is produced when epithelial surface cells grow underneath the corneal flap incision. Epithelial ingrowth is more common with any trauma or breakdown of the epithelium, which is more common in LASIK enhancement procedures and long-term contact lens wearers. Treatment of this condition involves lifting the flap and clearing the cells away. Although most small areas of epithelial ingrowth need only be monitored, untreated large areas of epithelial ingrowth may distort vision and may actually damage the flap integrity if severe and progressive.

3. Increased Risk of Severe Damage with Eye Injury

The corneal flap normally heals so that patients are able to resume active lifestyles without damaging their LASIK flaps. However, it is possible to dislodge the corneal flap years after surgery. An eye injury, which may not have caused serious damage to a non-LASIK eye, could potentially cause a serious sight-threatening injury in an eye with a flap. As a precaution, we recommend that patients wear protective eyewear (approved by the Protective Eyewear Certification Council) when participating in sports or activities in which they may be struck in the eye.

4. Other Miscellaneous Complications

It is important to note that it is impossible to list every conceivable complication that is not listed above. Risks and complications that are considered to be unforeseeable, remote or not commonly known are not discussed. In addition, there may be long-term effects not yet known or anticipated at the present time. The most severe possible complications would necessitate more invasive or repeated corneal surgery, including corneal transplantation and could potentially produce partial or complete loss of vision.

SECTION 8: FREQUENTLY ASKED QUESTIONS

Who should consider the Raindrop Near Vision Inlay?

- Age related near vision loss or presbyopia is the condition that leaves many of us reaching for reading glasses in our 40s and early 50s. Anybody who needs reading glasses for daily tasks such as using a mobile phone, reading a menu, fine print or doing close-up work may be a candidate.

What causes this condition?

- Presbyopia, or age related loss of near vision, happens when your lens loses elasticity, making it difficult to change your focus to see objects up close. Everyone -- yes, everyone -- will eventually develop presbyopia.

How effective is the Raindrop Near Vision Inlay procedure?

- Most people who have had the Raindrop implanted see an improvement in their near vision by one week and it continues to improve for several weeks. Patients need to use eye drops for several months for comfort and healing.

What is the inlay, exactly?

- It is a tiny disc, about the size of a pinhead. It is comprised of approximately 80 percent water and is placed just beneath the surface of the eye. It works by gently changing the central curvature of the cornea, the clear front part of the eye.

How long does it take?

- The procedure is complete in 10 minutes, usually.

Is it painful?

- Numbing drops are given for the procedure, so most patients do not experience any pain.

What is the Raindrop Near Vision Inlay made of?

- It is a soft, biocompatible material, similar to a soft contact lens, which has similar properties and water content as the cornea.

Does it interfere with far vision?

- One Raindrop Near Vision Inlay is placed in the cornea of the non-dominant eye. Both eyes work together to create one image. The near vision is improved in the Raindrop eye, while the distance is slightly affected. With both eyes working together there typically is minimal to no compromise for distance vision and patients still have a significant improvement in near vision.

Is it safe for the eye?

- Extensive trials and usage show that it is safe. This was confirmed by the US FDA. Raindrop is bioengineered to facilitate the transport of nutrients and fluid to the eye.

Patient Initials _____

Will people know I am wearing one?

- No. It is transparent, so no one will realize there is a Raindrop® in your eye.

How does it work in low light?

- Very well. Since Raindrop is transparent 99.7% of light passes through the inlay reaches the back of the eye where the image is processed. Raindrop offers patients good performance in all lighting conditions.

Can the inlay ever be removed

- Yes, the Raindrop can be removed and most patients go back to their vision before Raindrop.

Please FILL IN the blank below with the appropriate response to indicate the treatment you choose to have:

I would like to have _____ treated
Write in one of the following - (the right eye / the left eye)

SECTION 9: WRITTEN CONFIRMATION

PLEASE WRITE IN THE FOLLOWING TWO STATEMENTS IN THE SPACE PROVIDED BELOW to confirm that you have understood and accept that the Raindrop inlay is an elective surgical procedure and, as with all surgical procedures, the result cannot be guaranteed; that you acknowledge that although vision-threatening complications are quite rare, it is possible that partial or complete loss of vision may be produced as a result of a surgical or healing complication; that the procedure may not eliminate all of your presbyopia and that additional correction with glasses, contact lenses or further surgery may be required.

“I understand that there are risks and no guarantees.”

“I understand that I may still need to wear glasses.”

SECTION 10: VOLUNTARY CONSENT

Please sign below indicating that you have carefully reviewed this informed consent document and that you have had an opportunity to ask any questions. By signing below you also indicate that you are aware that the Raindrop inlay is an elective procedure, that you do not need to have this procedure, and that you understand your other surgical and non-surgical alternatives for vision correction.

Patient Full Name (PRINT): _____

Patient Signature: _____

Witness Full Name (PRINT): _____

Witness Signature: _____

Surgeon Name: N. Timothy Peters, M.D.

Surgeon Signature _____ **Procedure date:** ____/____/____