



## WHAT YOU NEED TO KNOW ABOUT THE RAINDROP® NEAR VISION INLAY

### AN IMPLANT TO IMPROVE NEAR VISION IN PRESBYOPIC PATIENTS

## Patient Information Brochure

**CAUTION:** The safety and effectiveness of implantation of the Raindrop Near Vision Inlay before, during, or after LASIK or other procedures to change the power of the eye have not been evaluated.

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

This brochure has been provided to assist in your understanding of the Raindrop Near Vision Inlay procedure. Read the brochure in full and discuss the benefits and risks with your eye care provider. Prior to any type of surgery, it is important to make sure all your questions are addressed.



**ReVision Optics, Inc.**

25651 Atlantic Ocean Drive, Suite A1

Lake Forest, CA 92630 USA

T +1.949.707.2740

info@revisionoptics.com • www.raindropinlay.com



## **TABLE OF CONTENTS**

<b>Glossary</b>	01
<b>Introduction</b>	03
<b>Understanding The Eye</b>	03
<b>What Is Presbyopia?</b>	04
<b>Treating Presbyopia</b>	05
<b>Raindrop® Near Vision Inlay</b>	06
<b>When Is The Raindrop Near Vision Inlay Used?</b>	06
<b>What To Expect With The Raindrop Near Vision Inlay Procedure</b>	07
<b>Potential Risks, Contraindications, Warnings, And Precautions</b>	09
<b>Summary Of Important Information</b>	14
<b>Clinical Study Findings</b>	15
<b>Patient Assistance Information</b>	27

## **INDEX OF FIGURES**

<b>FIGURE 1:</b> Anatomy Of The Eye.....	03
<b>FIGURE 2:</b> Normal Vision.....	04
<b>FIGURE 3:</b> Presbyopic Vision.....	04
<b>FIGURE 4:</b> Raindrop Near Vision Inlay.....	04
<b>FIGURE 5:</b> The Raindrop Near Vision Inlay Is Less Than $\frac{1}{10}$ Of An Inch In Size, Only 2 mm In Diameter, Smaller Than The Eye Of A Needle. ....	06
<b>FIGURE 6:</b> Lifting The Corneal Flap For Implantation Of The Inlay.....	07
<b>FIGURE 7:</b> Placing The Inlay In The Middle Of The Cornea.....	07
<b>FIGURE 8:</b> Replacing The Corneal Flap Over The Inlay.....	07
<b>FIGURE 9:</b> Follow Your Eye Care Providers Instructions On Medications And Follow Up Appointments.....	08

## **INDEX OF TABLES**

<b>TABLE 1:</b> Incidence Of Ocular Adverse Events For All Patients.....	18
<b>TABLE 2:</b> Incidence Of Complications For All Patients.....	19
<b>TABLE 3:</b> Eye Symptoms Before Surgery And At The 24 Month Visit.....	22
<b>TABLE 4:</b> Visual Symptoms Before Surgery And At The 24 Month Visit.....	23
<b>TABLE 5:</b> Eye Symptoms Before Surgery And At The 24 Month Visit For Surgical Subgroup.....	25
<b>TABLE 6:</b> Visual Symptoms Before Surgery And At The 24 Month Visit For Surgical Subgroup.....	26

## GLOSSARY

### **Acuity**

Clearness, or sharpness of vision.

### **Artificial Tears**

Lubricant eye drops used to treat the dryness and irritation associated with dry eyes.

### **Astigmatism**

A distortion of the image on the retina caused by irregularities in the cornea or lens.

### **Best-Corrected Distance Vision**

The best distance vision which can be achieved with the aid of eyeglasses or contact lenses. Distance visual acuity is typically measured at twenty feet (six meters).

### **Contrast Sensitivity**

The ability of the visual system to distinguish between an object and its background.

### **Cornea**

The clear, front part of the eye. The cornea is the first part of the eye that bends (or refracts) the light and provides most of the focusing power.

### **Diopter**

The unit of power for bending light.

### **Dry Eye**

A common condition that occurs when the eyes do not produce enough tears to keep the eye moist and comfortable. Common symptoms of dry eye include pain, stinging, burning, scratchiness, and intermittent blurring of vision.

### **Glare**

Scatter from bright light that decreases vision.

### **Halos**

Rings around lights due to imperfections in or on the surface of the eye.

### **Haze**

Corneal clouding that may cause the sensation of looking through smoke or fog.

### **Inflammation**

The body's reaction to trauma, infection, or a foreign substance, often associated with pain, redness, swelling, and/or loss of function.

### **Inlay**

A tiny device inserted into the cornea to improve vision. The primary purpose of this type of device is to improve near vision in adults who have presbyopia.

### **In Situ**

A Latin term meaning "in place" or not removed.

### **Intermediate Vision**

Range of visual focus between approximately 14 inches to 36 inches, e.g., seeing the dashboard or computer screen.

### **Kerato**

Prefix indicating relationship to the cornea.

### **Keratoconus**

Disorder characterized by an irregular corneal surface (cone-shaped) resulting in blurred and distorted images.

### **Laser**

The acronym for light amplification by stimulated emission of radiation. A laser is an instrument that produces a powerful beam of light that can vaporize tissue.

**Laser Keratome**

A laser device used to create a corneal flap.

**LASIK**

The acronym for laser assisted in situ keratomileusis which refers a procedure where a flap is created in the cornea using a mechanical or laser keratome and then the underlying cornea is reshaped using a different laser device.

**Lens**

A part of the eye that provides some focusing power. The lens is able to change shape allowing the eye to focus at different distances.

**Manifest Refraction**

The testing done to determine the lens power to enable you to see far away objects most clearly.

**Monovision**

The purposeful adjustment of one eye for near vision and the other eye for distance vision.

**Presbyopia**

The inability to see clearly as objects are moved closer or to read fine print. Presbyopia is due to reduced elasticity of the natural lens with increasing age.

**Pupil**

The round opening in the center of the colored part of the eye, the iris, that changes size in response to changes in lighting. It gets larger in dim lighting conditions and gets smaller in brighter lighting conditions.

**Refraction**

Measurement of the light-bending power of the eye; also, the bending of light as it passes from one medium into another.

**Retina**

A layer of fine sensory tissue that lines the inside wall of the eye. The retina acts like the film in a camera to capture images, transforms the images into electrical signals, and sends the signals to the brain.

**Stroma**

The middle tissue layer of the cornea.

**Visual Acuity**

The clearness of vision; the ability to distinguish details and shapes.

## INTRODUCTION

### Do You Have Presbyopia?

- Do you increase the font size on your cell phone and e-reader to extra-large?
- Do you wish you had longer arms so you could hold the menu out farther in the restaurant?

If you are over the age of 40 and answered “yes” to either of these questions, you may be experiencing presbyopia. Presbyopia is an age-related condition in which your near vision is blurry. It results from the gradual loss of flexibility in your eyes’ natural lenses.

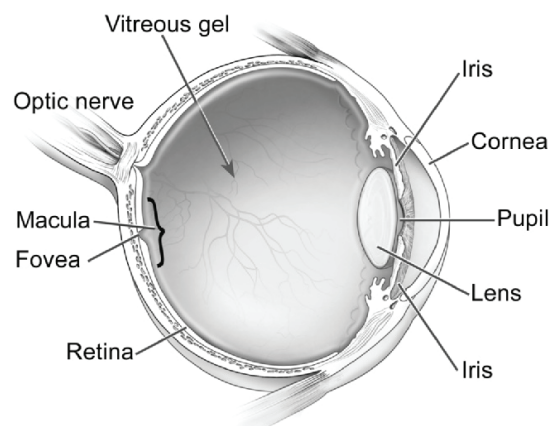
This brochure contains information to help you decide if the Raindrop Near Vision Inlay is right for you. Please read this brochure completely and discuss the risks and benefits with your eye care professional. Only he/she can determine if you are a candidate for this new sight-changing inlay.

### Understanding the Eye

The eye is one of the most unique parts of your body. It never stops working, continually sending signals about the visual world around you to your brain, which translates images into information, enabling you to “see.”

Your eye is the original camera. Light bounces off objects then enters the eye through the cornea, a “clear window” that helps your eye focus. The light then enters the pupil (the dark part in the center of the colored part of your eye) and passes through the lens, which shifts to bend the light as needed to direct it towards the back of the eye. There lies the most important player in your sight: the retina, composed of 130 million light-sensitive cells that transmit the light from your eye to your brain for translation into an image you “see.” See **Figure 1** below.

**Figure 1: Anatomy Of The Eye**



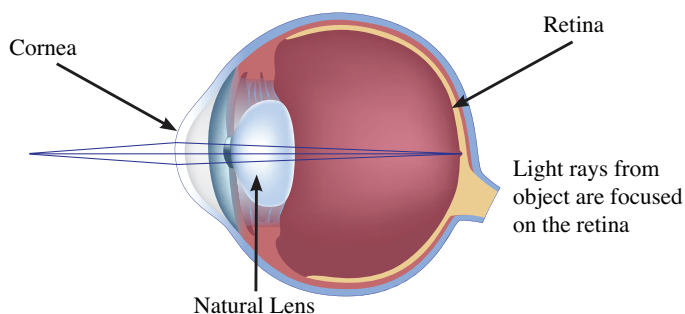
## What is Presbyopia?

As you age, the lens becomes stiffer, less flexible, and so less able to bend the light onto the retina. The result is that light focuses behind the retina and your eye loses its ability to focus on near objects. **Figure 2** demonstrates how your eye worked prior to presbyopia and **Figure 3** shows the loss of flexibility in the lens and onset of presbyopia.

The Raindrop Near Vision Inlay increases the curvature of your cornea in the center region to focus light rays back on your retina (**Figure 4**). The bottom image demonstrates vision with the Raindrop Near Vision Inlay. Most of the light rays are focused on the retina, to improve near vision. There is a slight loss in distance vision in the Raindrop Near Vision Inlay treated eye only.

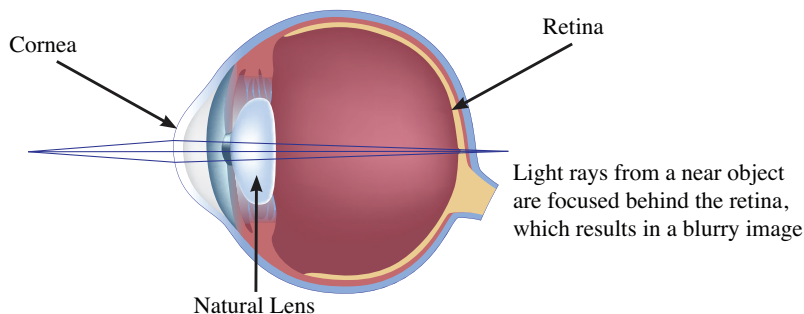
**Figure 2: Normal Vision**

Your natural lens changes shape to focus on objects at various distances.



**Figure 3: Presbyopic Vision**

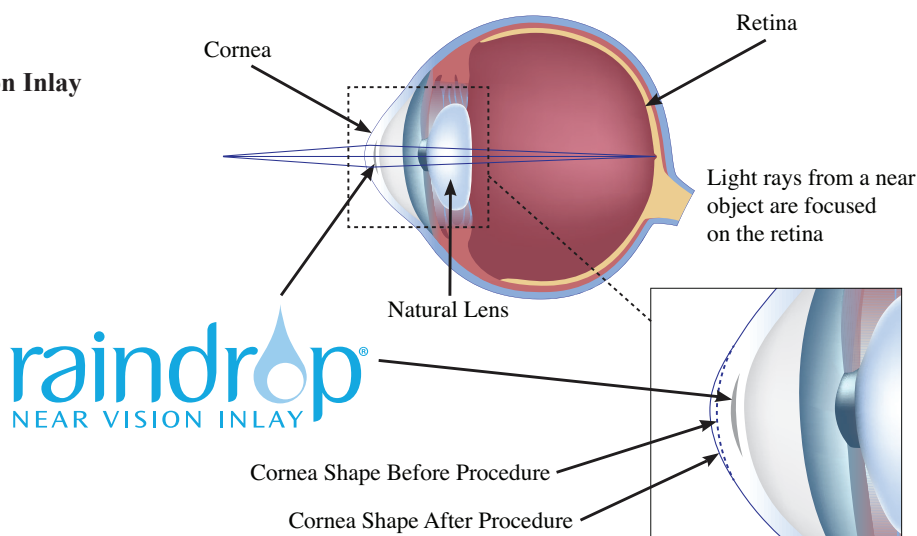
Normal aging causes hardening of your lens, preventing your lens from changing shape and focusing on near objects.



**Figure 4: Raindrop Near Vision Inlay**

Raindrop Near Vision Inlay changes the shape of the cornea to provide an improvement in near vision.

Further explanation of the Raindrop Near Vision Inlay can be found on page 6.



## Treating Presbyopia

The Raindrop Near Vision Inlay procedure is an elective procedure. You may decide not to have the Raindrop Near Vision Inlay, so other possible alternative treatments for presbyopia include:

**Glasses:** Bifocal, trifocal, “reader,” and/or progressives glasses have prescription for one, two, or more distances (a range from near to far) in the same lens. Glasses can be worn, removed, and replaced easily. If the power or the fitting of the glasses is incorrect, it can lead to inadequate vision correction, headaches, and eyestrain.

**Contact Lenses (monovision, bifocal, trifocal, and multifocal):** In monovision, one eye is corrected for distance vision (or no contact lens is used if the uncorrected distance vision is good) and the other eye is corrected for near vision. Often, patients do well with monovision, but in some cases patients may have difficulties adjusting to the eyes’ inability to focus on the same visual distance. In addition, there are monofocal, or multifocal contact lenses that have powers to correct for one, two, or more distances (a range from near to far) in the same contact lens. Contact lenses offer cosmetic benefits, but they have to be cleaned and replaced frequently to avoid redness, irritation, and eye infections.

**Laser Correction (monovision LASIK [Laser-Assisted in Situ Keratomileusis]):**

Monovision LASIK uses an excimer laser to correct one eye for near vision and the other eye for distance vision. Monovision LASIK treatment may help patients to see clearly both far away and close up without glasses or contact lenses. If a patient sees well for far distance without glasses or contact lenses, only one eye will be treated with LASIK to enable your near vision. Patients may require another treatment if results are not satisfactory. Other common risks involved with the LASIK procedure include dry eyes and visual symptoms.

**Conductive Keratoplasty:** Conductive keratoplasty is a treatment to reshape the corneal curvature to improve near vision in one eye. Radio wave energy is used to heat and shrink small spots of tissue in a circle around the peripheral cornea tightening the tissue in a band like a belt and making the cornea steeper. However, this effect can decrease over time.

**Other Corneal Inlays:** Corneal inlays are designed to correct presbyopia by implanting a small device in the cornea of one eye. Inlays are only intended to be used with patients who have good distance vision. Another commercially marketed inlay has a different mechanism of action than the Raindrop Near Vision Inlay. It is a black film-like ring that increases the depth of focus by blocking peripheral light rays entering the pupil from reaching the sensory back of the eye (the retina). The following adverse events have been reported for this corneal inlay: inlay removal, a decrease in more than two lines of distance vision, and an increase in eye pressure.

## **RAINDROP® NEAR VISION INLAY**

The Raindrop Near Vision Inlay is a transparent curved disc smaller than the eye of a needle. It is made from a gel-like material that is 80% water and has similar light bending properties as the clear front part of eye, the cornea. The Raindrop Near Vision Inlay is inserted into the cornea of one eye only during a surgical procedure.

Study results found the Raindrop Near Vision Inlay improves near vision. It works by reshaping the central region of the cornea, increasing the steepness in the very center of the cornea, and then tapering off in steepness.

### **When is the Raindrop Near Vision Inlay Used?**

The Raindrop Near Vision Inlay is indicated for placement in the non-dominant eye (usually the eye you close when aiming) to improve near vision of patients, 41 to 65 years of age, who are unable to focus clearly on near objects or small print, who have not had cataract surgery, and who do not require correction for clear distance vision, but who do require reading glasses with +1.50 to +2.50 units of power (diopters).



**Figure 5: The Raindrop Near Vision Inlay Is Less Than  $\frac{1}{10}$  Of An Inch In Size, Only 2 mm In Diameter, Smaller Than The Eye Of A Needle.**

## What to Expect with the Raindrop Near Vision Inlay Procedure

### Before the Procedure

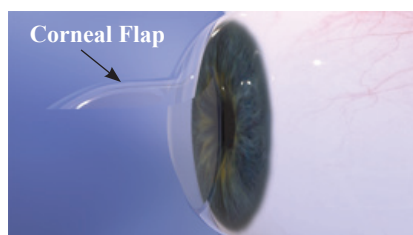
Your eye care provider will perform a complete eye exam to help determine whether you may be a good candidate for the Raindrop Near Vision Inlay. He/she will assess your general health and consider any medications you are taking. Make sure you tell your eye care professional about all medical and eye conditions, and all medications you are taking, including over-the-counter items like vitamins and supplements.

If you decide to move forward with the Raindrop Near Vision Inlay, your eye care provider will have you try a contact lens in the eye to be implanted for five (5) days to see if you will be able to get used to the difference in your vision between two eyes once the Raindrop Near Vision Inlay is implanted.

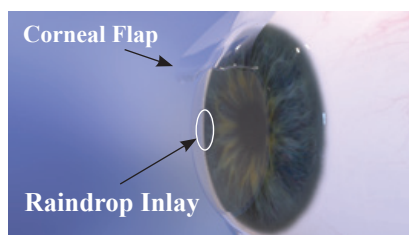
Two (2) days prior to your surgery you will start using a steroid eye drop prescribed by your doctor. In addition, you will need to make arrangements to be driven home after surgery, and your eye care provider will let you know when you can resume driving.

### During the Procedure

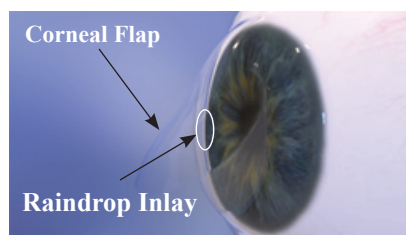
Your surgeon will numb your eye with drops so you won't feel any pain. During the short surgical procedure, you will lie on your back and focus on a light so your eye remains as still as possible. The surgeon creates a flap in the cornea using a laser cutting device (laser keratome), which is also a technique used in the first step of LASIK surgery (**Figure 6**). The surgeon will then insert the Raindrop Near Vision Inlay into the middle layer of the cornea, called the stroma (**Figure 7**). The flap is replaced and the procedure is done (**Figure 8**). You don't need any stitches; the eye heals on its own.



**Figure 6: Lifting The Corneal Flap For Implantation Of The Inlay**



**Figure 7: Placing The Inlay In The Middle Of The Cornea**



**Figure 8: Replacing The Corneal Flap Over The Inlay**

After the Raindrop Near Vision Inlay is inserted and the flap closed, the surgeon uses a special microscope to check the position of the Raindrop Near Vision Inlay in the cornea and, if necessary, reposition it.

### **After the Procedure**

After the procedure, you will need to wear an eye shield at night for up to four (4) weeks so you don't rub your eye in your sleep. You will also need to use steroid and antibiotic drops and artificial tears in the eye with the Raindrop Near Vision Inlay to minimize the risk of inflammation, infection, and dry eye.

You should avoid rubbing your eyes, wearing eye make-up, playing contact sports, exercising, swimming, gardening, smoking, and being in dusty environments for at least the first week after surgery. Please check with your eye care provider for when you can resume these and other activities he or she may have asked you to stop after surgery.

If you feel any pain, see any discharge or redness in the eye with the Raindrop Near Vision Inlay, or have a decrease in your vision, or flashing lights or floating spots, then call your eye care provider immediately.

You will typically see your eye care provider after the procedure, at one (1) day, one (1) week, one (1) month, and then every six (6) months. After that, you should be seen for an annual eye exam each year, at minimum, or sooner if you experience any problems in the inlay implanted eye.

Most health insurance policies do not cover the Raindrop Near Vision Inlay procedure.



**Figure 9: Follow Your Eye Care Providers Instructions On Medications  
And Follow Up Appointments.**

## POTENTIAL RISKS, CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

### Potential Risks

It is possible the Raindrop Near Vision Inlay implantation may make your best-corrected distance vision with glasses or contact lenses and/or uncorrected distance vision worse than it was before surgery.

**Caution:** In some cases, after receiving the Raindrop Near Vision Inlay, you may still require glasses or contact lenses for some activities, such as reading small print.

**Vision and Eye Symptoms.** Raindrop Near Vision Inlay implantation may cause or worsen problems with glare, halos, blurred vision, double vision, fluctuation of vision, dryness, foreign body sensation, and pain. Some of these symptoms may be improved with additional treatment, including artificial tears and plugs to stop tears from draining from the surface of the eye (punctal plugs). However, these symptoms may not resolve, even with treatment.

**Contrast Sensitivity.** Contrast sensitivity refers to the ability of your visual system to distinguish between an object and its background. Raindrop Near Vision Inlay implantation may cause decreased contrast sensitivity most noticeable in the inlay implanted eye and under certain lighting conditions, like when driving at night or in very bright light. There could be a further reduction in contrast if the inlay implanted eye were to develop corneal clouding (see below) and/or either eye were to develop clouding of the natural lens (cataract), too-high pressure resulting in vision loss (glaucoma), age-related degeneration of the light-sensitive retinal tissue (macular degeneration) or were to be implanted with an artificial lens that focuses for multiple distances (multifocal intraocular lens) after removal of a cataract.

**Eye Infections.** There is a risk of infection and/or inflammation to the front part of the eye, as a result of Raindrop Near Vision Inlay implantation.

**Dry Eyes.** There is a risk of developing a new dry eye condition or worsening of an existing dry eye condition after the implantation procedure. A patient experiencing dry eye symptoms may require treatment with artificial tears, punctal plugs, and/or other therapy depending on the severity of the dry eye condition.

**Corneal Complications.** Risks of complications to the cornea include, but are not limited to:

- clouding (corneal haze);
  - in low light conditions greater losses of contrast sensitivity may be experienced
  - vision may decrease
  - additional steroid therapy may be needed to treat this condition, which may result in an increase in eye pressure and faster cataract development than with normal
  - aging (see **Increased Eye Pressure**)
- thinning and bulging;
  - in a severe case, a corneal transplant might be necessary
- scarring;

- surface cells growing through the surgical wound into the middle layer of tissues in the cornea (stroma) requiring a second surgery to remove them;
- the inlay comes out of the eye, shifts in position, or tissue over it shifts in position;
- surface defects or recurring loss of the surface cells of the cornea causing pain;
- inflammation;
- melting of the corneal tissue or swelling and breakdown of the cornea that can cause loss of vision and may require transplant of healthy tissue from a donor.

**Cataract Formation.** Clouding of the eye's natural lens that occurs with normal aging, "cataract formation," and its symptoms could be worsened and occur sooner with the Raindrop Near Vision Inlay.

**Decreased Uncorrected Distance Vision.** Roughly half of the patients implanted with the inlay in the clinical trial to study the safety and effectiveness of the inlay had a decrease in distance vision in the implanted eye, when the distance vision was measured without correction (e.g., glasses or contact lens). In some cases, removal of the inlay will improve your vision but the improvement may take many months. In other cases, removal of the inlay will not improve your vision and the decreased vision could become permanent.

**Increased Eye Pressure.** There is a potential risk for eye pressure to increase as a result of using steroid eye drops needed to suppress inflammation from inlay implantation, the body's natural reaction to surgery. If your pressure increases as a result of the eye drops, your doctor will treat it by prescribing you another eye drop to decrease the eye pressure. This will usually control the eye pressure, but in some cases, further treatment may be needed. In most cases treatment to lower eye pressure is no longer needed once the steroids are stopped. In a few cases, long-term treatment for high eye pressure may be needed, even after the steroids are stopped.

**Need for Inlay Removal or Additional Surgery.** After Raindrop Near Vision Inlay implantation, more surgery may be needed to remove the inlay permanently or to exchange the inlay for a new one in order to treat a complication. Other types of surgery may also be needed to treat complications, such as lifting the corneal flap under which the inlay is implanted. Each of these additional surgeries has its own risks, and may or may not completely resolve the problem.

**Complications of the Back Part of the Eye.** There is a rare chance for the sensory tissue lining the back of the eye (the retina) to detach or the vessels supplying the nerve of the eye that transmits the signals to the brain not to work properly as a result of the surgery to implant the inlay which could result in permanent loss of vision.

**Vision Loss.** You may experience a loss in best-corrected distance vision with glasses or contact lens after the surgery. In some cases, removal of the inlay will improve your vision but the improvement may take many months. In other cases, removal of the inlay will not improve your vision and the decreased vision could become permanent.

**Managing Eye Problems.** Cataract removal with artificial lens implantation to replace the cloudy natural lens, usually needed at some point later in life, may be possible with the inlay in place. However, your surgeon may choose to remove the inlay before such surgery. The presence of the inlay may affect eye pressure measurements, making it difficult for your eye doctor to detect

changes in your eye pressure compared to before surgery that may be important for your eye health, for example, if you are at risk for developing glaucoma. Even though the inlay is transparent, your eye care provider may also have difficulty viewing, imaging, and treating other eye conditions or structures due to the presence of the inlay.

## Contraindications

You should NOT have the Raindrop Near Vision Inlay implanted if you:

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

## Warnings

The Raindrop Near Vision Inlay may not be suitable for you if you:

- have dry eyes, which may worsen following Raindrop Near Vision Inlay implantation;
- have past herpes eye infection, which might increase the risk of infection of the outer part of the eye (cornea);
- have controlled build-up of high pressure in the eye (glaucoma), which may worsen with eye drop (steroid) use following Raindrop Near Vision Inlay implantation;
- have controlled connective tissue disease or abnormal immune response (autoimmune disease), which may alter the effect that the Raindrop Near Vision Inlay has on the cornea or healing of the corneal wound (the flap) after surgery;
- have controlled high blood sugar (diabetes), which may affect wound healing following Raindrop Near Vision Inlay implantation;
- have a weakened immune system due to medications (e.g., steroids) or medical conditions (e.g., Acquired Immunodeficiency Syndrome), which may make you more prone to infection after surgery. Such medications and conditions may increase the risk for other complications, such as dry eye or abnormal wound healing;
- are taking Accutane (isotretinoin), for example, for severe acne, which may cause changes to your vision following Raindrop Near Vision Inlay implantation;
- are taking chronic medications known to worsen or cause severe dry eye. These medications may include anti-histamines, beta-blockers, birth control pills, diuretics, drugs for the treatment of cardiac arrhythmia, or other medications which may worsen dryness symptoms and signs after implantation of the Raindrop Near Vision Inlay;

- have any abnormal material accumulating in the clear outer layer of the eye (corneal dystrophy) or break down of the outer layer of the eye (corneal degeneration) that may worsen and decrease vision following Raindrop Near Vision Inlay implantation;
- have age-related degeneration of the light-sensitive retinal issue (macular degeneration), detachment of the light-sensitive issue from the back of the eye (retinal detachment), clouding of the natural lens (cataract), or any other disease that would compromise vision and prevent you from experiencing an improvement in near vision following implantation of the Raindrop Near Vision Inlay;
- have an irreversible decrease in vision in either eye, e.g., resulting from “lazy eye”; when the vision in one of your eyes is reduced because the eye and the brain are not working together (amblyopia), injury, disease, or other abnormality, which might prevent you from experiencing an improvement in near vision following implantation of the Raindrop Near Vision Inlay;
- have a significant change in distance vision in the previous 12 months;
- have very good or very poor near vision without glasses or contact lenses in the eye to be implanted, do not have good distance vision without glasses or contact lenses in each eye, and do not have excellent distance and near vision with glasses or contact lenses in each eye;
- cannot demonstrate imbalanced vision (monovision) tolerance, where one eye is for near vision and the other eye is for distance vision, by contact lens trial in the eye to be implanted for at least five (5) days;
- have a cornea that is too thin (less than 500 micrometers thick);
- have a pupil size of less than or equal to 3.0 mm in bright light or greater than or equal to 7.0 mm in dim light, as distance vision may be adversely compromised;
- participate in activities that could damage the flap or dislodge the inlay, such as contact sports, like football or martial arts;
- have a habit of extreme and frequent eye rubbing which may cause the Raindrop Near Vision Inlay or flap to misalign.

## Precautions

- Recovery of your vision after surgery may be delayed. This may be helped by using preservative-free artificial tears frequently.
- The safety and effectiveness of Raindrop Near Vision Inlay implantation before, during, or after LASIK or other procedures to change the power of the eye have not been evaluated.
- The safety and effectiveness of removal of clouding natural lens with artificial lens implantation after Raindrop Near Vision Inlay implantation is not known.
- Removal of the inlay may be necessary prior to certain eye procedures (such as laser treatment of the back of the eye) should you need them, since your eye doctor may have trouble treating your eye with the inlay in place. In addition, the safety and effectiveness of such procedures with the inlay in place has not been studied in humans.

If you have any of the conditions below, talk to your doctor before you get the Raindrop Near Vision Inlay. It is not known whether the Raindrop Near Vision Inlay is safe and effective in patients that have any of the following conditions, as these were not specifically studied:

- patients who are pregnant or currently nursing;
- patients with active/recurrent inflammation of the eyelid (blepharitis);
- patients with clinically significant dry eye;
- patients who have worn hard contact lenses in the last three (3) weeks or soft contact lenses within one (1) week prior to preoperative examination and the stability of the power of the eye is not confirmed;
- patients with too low counts of the cells lining the back of the cornea (endothelial cell counts of less than 2000 cells per millimeter squared) determined by using a special high-powered microscope;
- patients with previous eye surgeries, including surgery to correct error in the power of the eye (refractive surgery), for example to improve distance vision, such as PRK, RK, LASIK, LASEK, or another type of refractive procedure, and cataract surgery;
- patients requiring a cut to enlarge the space between the eyelids (canthotomy) to generate a flap in the eye to be treated;
- patients with flat or steep curvature of the outer part of the eye (cornea);
- patients who have a difference of 1.00 unit (diopter) or more between measurements of the power of the eye before and after using special medicated eye drops to temporarily block any remaining ability of the natural lens to change shape;
- patients with build-up of high pressure in the eye (glaucoma suspect);
- patients taking Cordarone (amiodarone hydrochloride), for example, for heart arrhythmia;
- patients taking Alsuma (sumatriptan), for example, for migraine or cluster headaches;
- patients who have a family history or signs of corneal disease characterized by general thinning and cone-shaped protrusion in the center of the cornea (keratoconus) or any other condition that may cause thinning of the cornea;
- patients with a history of eye injury;
- patients with a past history of eye infection or inflammation; and
- patients not within the ages of 41 to 65 years old.

While the following is a potential risk, it is also not known whether the Raindrop Near Vision Inlay may result in the following, as it was not studied:

- It is unknown whether your eyes working together in stereo is affected by implantation of the Raindrop Near Vision Inlay, since it was not investigated in the clinical study.

In order to help lessen some of the risks of Raindrop Near Vision Inlay implantation, you should avoid rubbing your eyes, wearing eye make-up, playing contact sports, exercising, swimming, gardening, smoking and being in dusty environments for at least the first week after surgery. Please check with your eye care provider for when you can resume these and other activities he or she may have asked you to stop after surgery.

It is important to keep your follow-up appointments with your eye care provider and contact her/ him if you experience any decrease in vision, near or distance, or have increased halos or glare.

## Is Raindrop Near Vision Inlay Right for Me?

You may be a good candidate if you:

- Are between the ages of 41 and 65 years old
- Are unable to focus clearly on near objects or small print, but still have good distance vision
- Need reading glasses with +1.50 to +2.50 diopters of power
- Have not had any changes in your distance vision in the last year
- Have healthy eyes, including your eye surface
- Have not had any other eye surgeries

Your eye care provider can help you determine whether Raindrop Near Vision Inlay is right for you.

## SUMMARY OF IMPORTANT INFORMATION

- The Raindrop Near Vision Inlay procedure is not risk-free. Read this entire booklet, most importantly the section on Potential Risks before your elect to have this procedure.
- 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;
  - have an active eye infection or active inflammation;
  - have signs of corneal disease characterized by general thinning and cone-shaped protrusion in the center of the cornea (keratoconus) or keratoconus suspect;
  - have abnormal features of the outer part of the eye (cornea) to be implanted;
  - have active abnormal immune response (autoimmune) or connective tissue diseases;
  - do not have enough corneal thickness to safely have the procedure performed;
  - have a recent herpes eye infection or problems resulting from a previous infection;
  - have uncontrolled build-up of high pressure in the eye (glaucoma);
  - have uncontrolled high blood sugar (diabetes).
- There are non-surgical alternatives to the Raindrop Near Vision Inlay, which include reading glasses or contact lenses.
- Before having the Raindrop Near Vision Inlay procedure you should:
  - have a complete eye examination.

- 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.

## **CLINICAL STUDY FINDINGS**

The clinical study was designed to support the approval of the Raindrop Near Vision Inlay for the improvement of near vision in patients 41 to 65 years old who are unable to focus clearly on near objects or small print. The study has a total of 373 Raindrop Near Vision Inlay patients who did not require glasses for distance vision, but required additional correction to read at near before the inlay surgery. Patients in the study have not had prior eye surgery to change the power of the eye, such as LASIK, or an artificial lens for the replacement of a clouding natural lens (cataract surgery). Patients were implanted with the inlay in one eye under a flap created in the outer layer of the eye (cornea). The flap is created using a laser cutting device (laser keratome), which is also a technique used in the first step of LASIK.

During this 3-year study, patients returned for the following visits after surgery: 1 day, 1 week, 1, 2, 3, 4, 6, 8, 9, 12, 24, 30, and 36 months. Safety and effectiveness results are presented for the 344 patients that completed the study visit at 24 months after surgery. The rates of adverse events and complications that occurred at any time during the study through 36-months after surgery are presented for all 373 patients that participated in the study and had surgery. Patients continue to be followed in the study at the time of reporting these study results. Two hundred nine (209) patients still have not been seen for the 36 month visit after surgery.

The vast majority of the patients were Caucasian and a little over half of them were females. The average age was 51 years old.

### **Raindrop Near Vision Inlay Effectiveness**

Results of the clinical study of the Raindrop Near Vision Inlay showed that, on average, implantation of the inlay improved near vision, while distance vision in the inlay eye was somewhat decreased

#### **Near Vision With The Raindrop Near Vision Inlay Without Correction Before and After Surgery**

The goal of the study was to have 75% of patients achieve 20/40 or better near vision in their Raindrop Near Vision Inlay eye without corrective lenses at 24 months. This goal was achieved; the primary analysis (inlay removals before 24 months counted as failures) of this goal revealed that 92% (336/364) of patients at the 24 month visit after surgery were able to see 20/40 or better at near at the target measurement of 16 inches (40 cm) without corrective lenses.

Prior to surgery one (1) patient was able to see at 20/40, but 24 months after surgery 98% of available eyes (336/344) were able to see at near at the targeted measurement distance of 16 inches. Over 87% (301/344) of patients were able to see 20/25 or better at near.

Using both eyes together, before surgery, 20% (75/373) of all patients had near vision without lenses of 20/40 or better. Twenty-four (24) months after surgery, 99% (342/344) of all patients were 20/40 or better for near vision.

### **Intermediate Vision With The Raindrop Near Vision Inlay Without Correction Before and After Surgery**

Although intermediate vision was not a goal of the study, information on intermediate vision was collected. Prior to surgery 180 patients were able to see at 20/40 or better, but 24 months after surgery 333 (97%) were able to see at intermediate at the targeted measurement distance of 31 inches (80 cm) with the Raindrop eye. Over 76% (262/344) of patients were able to see 20/25 or better at intermediate.

Using both eyes together, before surgery, 73% (271/373) of all patients had intermediate vision without lenses of 20/40 or better. Twenty-four months after surgery, 99% (341/344) of all patients were 20/40 or better for intermediate vision.

### **Distance Vision With the Raindrop Near Vision Inlay Without Correction Before and After Surgery**

On average, distance vision without correction was 20/20. After surgery, it was a little worse than 20/25, which is a little worse than before surgery, but still good vision. On average, patients lost a little over one (1) line of distance vision.

Using both eyes together, patients did not experience a decrease in distance vision without correction.

## **Safety**

The safety of the Raindrop Near Vision Inlay was assessed through evaluation of changes in vision with correction (best-corrected visual acuity), stability of the power of the eye, induced irregular curvature of the outer layer of the eye (corneal astigmatism), and adverse events.

The safety goals were assessed as follows:

- Preserving vision with correction: less than 5% of eyes should have a loss of two (2) or more lines of distance or near vision with correction at all follow-up visits after surgery from six (6) months onward. Less than 1% of eyes with distance and near vision with correction of 20/20 before surgery should have distance and near vision with correction worse than 20/40 at all follow-up visits after surgery from six (6) months onward.
- Stability of the power of the eye: at least 95% of treated eyes have a change within 1.00 unit (diopter) of eye power (manifest refraction) between two refractions, and at least 50% of treated eyes have a change within 0.50 diopter of eye power between two (2) refractions.
- Induced astigmatism: less than 5% of eyes should have postoperative irregular eye power (manifest refractive astigmatism) at all follow-up visits after surgery from six (6) months onward that increases from before surgery by greater than 2.00 diopters.
- Adverse events and complications: adverse events should occur in no more than 5% of eyes. Any single adverse event should occur in no more than 1% of eyes.

Additional assessments of safety covered in this section include eye pressure, contrast sensitivity, and endothelial cell density. Visual and eye symptoms results are also summarized.

### **Preserving Vision With Correction**

All patients had 20/20 or better distance vision with lenses prior to surgery in their Raindrop Near Vision Inlay eye. There were no patients at the 12-month (0/361) and 24-month (0/344) visits that had a best-distance vision corrected with lenses worse than 20/40.

At all follow-up visits after surgery from six (6) months onward, 98% of the patients had 20/25 or better best-corrected distance vision with lenses in their Raindrop Near Vision Inlay eye.

- 99% (357/361) at 12 months
- 99% (340/344) at 24 months

At all follow-up visits after surgery from six (6) months onward, 85% of the patients had 20/20 or better best-corrected distance vision, similar to their preoperative values, with lenses in their Raindrop Near Vision Inlay.

- 88% (316/361) at 12 months
- 86% (297/344) at 24 months

At all follow-up visits after surgery from 1 month onward, 0% to 2% of patients experienced a loss of greater than or equal to 2 lines of distance vision with correction at each follow-up visit, which supports the safety goal that fewer than 5% of eyes should lose 2 or more lines of distance vision without correction at all follow-up visits after surgery from six (6) months onward.

Near vision with correction is similar to the results of the distance vision with correction. After surgery, one (1) patient reported near vision with correction worse than 20/40 (i.e., 20/50) at any scheduled follow-up visit after 1 month (i.e., 9 months). This resolved at a visit 5 days later, where the patient had 20/20 near vision with correction. A total of 0% to 3% of patients experienced a loss of 2 or more lines of near vision with correction at all follow-up visits after surgery from six (6) months onward, which met the safety goal.

### **Stability Of The Power Of The Eye (Manifest Refraction)**

Manifest refraction is the measure of the lens power the eye needs in order to see at its best. The stability of the refraction was measured by evaluating the change in the refraction from visit to visit to see if implanting the Raindrop Near Vision Inlay affected the constancy of vision. The manifest refraction was found to be stable by six (6) months.

### **Induced Astigmatism**

There were no eyes with irregular eye power (manifest refractive astigmatism) that increased by greater than 2.00 diopters at one (1) month and later.

### **Adverse Events And Complications**

Some patients from the clinical study experienced adverse events and complications that may be related to the inlay implantation procedure or to the inlay in the eye (**Tables 1 and 2**).

**Table 1: Incidence Of Eye Adverse Events For All Patients**

	Through 12 Months N = 373		Through 24 Months N = 373		Through 36 Months N = 373	
	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects	# of Events	# (%) of Subjects
Surface defect on the cornea involving the flap	2	2 (0.5%)	2	2 (0.5%)	2	2 (0.5%)
Melting of the flap of the cornea	0	0 (0.0%)	1	1 (0.3%)	1	1 (0.3%)
Infection of the eye	5	4 (1.1%)	6	5 (1.3%)	8	7 (1.9%)
Growth of surface cells under the flap of the cornea	11	10 (2.7%)	11	10 (2.7%)	11	10 (2.7%)
Lost, misaligned, or misplaced flap	1	1 (0.3%)	1	1 (0.3%)	1	1 (0.3%)
Decrease of > 2 lines of distance vision from before surgery to 3 months or later after surgery	10	8 (2.1%)	13	10 (2.7%)	14	11 (2.9%)
Clouding of the cornea at beyond 6 months with $\geq 2$ line loss in vision after surgery	4	4 (1.1%)	4	4 (1.1%)	4	4 (1.1%)
Hospitalization	1	1 (0.3%)	1	1 (0.3%)	1	1 (0.3%)
Clouding of the lens inside the eye with $\geq 2$ line loss in distance vision at any time after surgery	0	0 (0.0%)	1	1 (0.3%)	1	1 (0.3%)
Eye pressure increase	8	5 (1.3%)	9	6 (1.6%)	9	6 (1.6%)
Inflammation in the cornea	6	6 (1.6%)	6	6 (1.6%)	6	6 (1.6%)
Additional surgery	35	32 (8.6%)	45	41 (11.0%)	48	44 (11.8%)
Replace the inlay	19	18 (4.8%)	19	18 (4.8%)	19	18 (4.8%)
Remove the inlay	14	14 (3.8%)	24	24 (6.4%)	27	27 (7.2%)
Flap lift	2	2 (0.5%)	2	2 (0.5%)	2	2 (0.5%)
Separation of the eye's gel-like filling from the retina	0	0 (0.0%)	0	0 (0.0%)	1	1 (0.3%)
Broken bone around the eye	1	1 (0.3%)	1	1 (0.3%)	1	1 (0.3%)
Inflammation of the iris	1	1 (0.3%)	1	1 (0.3%)	1	1 (0.3%)
Short-term visual disturbance	1	1 (0.3%)	1	1 (0.3%)	1	1 (0.3%)

**Table 2: Incidence Of Complications For All Patients**

	All Eyes N=373 n (%)
Surface defect of the cornea near the edge of the flap at 1 month or later	2 (1%)
Swelling of the cornea between 1 week and 1 month after the procedure	13 (3%)
Central clouding of the cornea	62 (17%)
Feeling like something is rubbing against the eye after blinking (foreign body sensation) at 1 month or later	33 (9%)
Pain at 1 month or later	9 (2%)
Overlapping images (double vision)	1 (less than 1%)
Glare (scatter from bright light that decreases vision) or halos (rings around lights)	3 (1%)
Dryness of the eye beyond 6 months after procedure	1 (less than 1%)
Other*	7 (2%)

\*Other: surface defect of the cornea at flap hinge (n=2), scratch on the cornea, redness of the eye due to inflammation due to allergies, eye infections from the virus that causes chicken pox (Herpes zoster), plugged tear gland, and redness of the eye due to inflammation caused by a virus ("pink eye").

### Clouding Of The Cornea (Haze)

Haze is clouding of the cornea in the eye. In most cases the haze does not result in visual symptoms and may be treated with eye drops like steroids. There were 62 patients (17%) in the study that developed haze, with 40 (11%) patients experiencing a single incidence of haze and 22 (6%) patients experiencing haze two or more times.

### Removals

The Raindrop Near Vision Inlay can be removed. Twenty-seven (7.2%; 27/373) patients during the clinical study had their inlay removed. The reasons for the removal were as follows:

- Patient Dissatisfied With Vision Three (3) Months After Surgery: 10 Patients (37%)
- Raindrop Not Centered Over The Pupil (Decentration): 2 Patients (7%)
- Growth of Surface Cells Under The Flap (Epithelial Ingrowth): 2 Patients (7%)
- Clouding Of The Cornea (Haze): 10 Patients (37%)
- Patient's Request: 3 Patients (11%)

### After Removal

After Raindrop Near Vision Inlay removal, patients were followed one (1) day (26 patients seen), one (1) week (24 patients seen), one (1) month (23 patients seen), three (3) months (19 patients seen), and six (6) months (18 patients seen) after removal.

Information about best-corrected vision with lenses at distance and near after removal was available for 25 of the 27 patients that had removal. All 25 had 20/25 or better vision at distance and near at their last visit after removal.

Most patients, without lenses, were within a line of their distance vision prior to surgery. At the last available visit after removal, three (3) patients had a loss of two (2) or more lines of distance vision without lenses. Twenty-three (23) patients in the removal group had a loss or gain of less than two (2) lines of distance vision without correction at the last available visit after removal.

Only two (2) adverse events occurred after removal and these were observed in a single patient. This patient developed growth of surface cells under the corneal flap (epithelial ingrowth) at one (1) week after removal. To treat this condition, the surgeon lifted the flap (additional surgery) at the three (3) month after removal visit.

Central clouding of the cornea was reported in ten (10) patients after removal. These complications resolved in nine (9) of the patients. Central clouding of the cornea (haze) was unresolved in one (1) patient at the last after removal visit (6 months).

### **Inlay Replacement**

Eighteen (18) patients had their inlays replaced in the study. The data collected after inlay replacement is included in the analyses with the data from the rest of the study patients.

The reasons for the replacements were as follows:

- Raindrop Not Centered Over The Pupil: 12 patients (67%)
- Growth of Surface Cells Under The Flap (Epithelial Ingrowth): 1 patient (6%)
- Other\*: 5 patients (28%)

\*Other includes surface cell (epithelial) nest, inlay not present after surgery, foreign matter under the flap, wrinkles in the flap, and wrinkled inlay.

### **Contrast Sensitivity**

Contrast sensitivity refers to the ability of your visual system to distinguish between an object and its background. Patients were evaluated with best correction in the inlay eye and with both eyes together in low lighting conditions with and without glare and in good lighting conditions without glare. At 24 months, on average, patients did not experience a significant decrease in contrast sensitivity in the Raindrop Near Vision Inlay eye or with both eyes together compared to before surgery. Patients that developed clouding of the cornea (haze) after surgery generally had greater losses of contrast sensitivity in dim light conditions with glare than patients who did not develop haze.

### **Endothelial Cell Counts**

The endothelium is a single layer of tissue cells lining the undersurface of the cornea, where it regulates the hydration of the cornea. Typically, endothelial cells are lost very slowly as you age at a rate of 0.6% per year. On average, patients lost 0.6% of endothelial cells from before surgery to 24 months after surgery.

## **Eye Pressure**

The eye has a measurable pressure due to the force of fluid inside of it. Eye drops called steroids can cause an increase in the eye pressure, which has to be monitored for and possibly treated with other eye drops. In addition, the presence of the inlay can result in an incorrect change in the measurement of the eye pressure. In the study, during the period after surgery when all patients were on steroid drops to prevent inflammation in the eye, the pressure went up by a little over one unit (1 millimeter of mercury) on average from before surgery. After this period, the eye pressure went down by about one unit on average compared to eye pressure before surgery, which may mean that the presence of the inlay may cause very slight incorrect lowering of the eye pressure measurements. This degree of difference is not important in most patients. Some patients had much greater changes in eye pressure from before surgery to after surgery both in the higher and lower directions.

## **Eye and Visual Symptoms**

Eye and visual symptoms were reported and rated by the following five (5) categories: Absent, Mild, Marked, Moderate, and Severe. Because the questionnaire used was not developed with patient input, the true symptom rates and their severity may be different than the study rates. However, the estimates from the study patients are shown in **Tables 3** and **4** for all patients by category before surgery and 24 months after surgery.

**Table 3: Eye Symptoms Before Surgery And At The 24 Month Visit**

	Pain		Foreign Body Sensation		Light Sensitivity	
	Before Surgery N=373	Month 24 N=344	Before Surgery N=373	Month 24 N=344	Before Surgery N=373	Month 24 N=344
Absent	371 (99%)	342 (99%)	366 (98%)	343 (100%)	349 (94%)	313 (91%)
Mild	2 (1%)	2 (1%)	7 (2%)	1 (less than 1%)	22 (6%)	29 (8%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)	2 (1%)
Marked	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Reported	0	0	0	0	0	0

	Tired Eyes		Dryness		Discomfort	
	Before Surgery N=373	Month 24 N=344	Before Surgery N=373	Month 24 N=344	Before Surgery N=373	Month 24 N=344
Absent	293 (79%)	302 (88%)	321 (86%)	201 (59%)	327 (88%)	315 (92%)
Mild	75 (20%)	37 (11%)	51 (14%)	119 (35%)	43 (12%)	28 (8%)
Moderate	5 (1%)	5 (1%)	1 (less than 1%)	23 (7%)	3 (1%)	1 (less than 1%)
Marked	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Reported	0	0	0	1	0	0

**Table 4: Visual Symptoms Before Surgery And At The 24 Month Visit**

	Glare		Halos	
	Before Surgery N=373	Month 24 N=344	Before Surgery N=373	Month 24 N=344
Absent	351 (94%)	235 (68%)	356 (95%)	234 (68%)
Mild	19 (5%)	101 (29%)	17 (5%)	99 (29%)
Moderate	3 (1%)	6 (2%)	0 (0%)	10 (3%)
Marked	0 (0%)	2 (1%)	0 (0%)	1 (less than 1%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Reported	0	0	0	0

	Blurred Vision		Double Vision		Fluctuation of Vision	
	Before Surgery N=373	Month 24 N=344	Before Surgery N=373	Month 24 N=344	Before Surgery N=373	Month 24 N=344
Absent	361 (97%)	253 (74%)	373 (100%)	310 (90%)	360 (97%)	253 (74%)
Mild	9 (2%)	80 (23%)	0 (0%)	28 (8%)	12 (3%)	85 (25%)
Moderate	3 (1%)	7 (2%)	0 (0%)	5 (1%)	1 (less than 1%)	5 (1%)
Marked	0 (0%)	3 (1%)	0 (0%)	1 (less than 1%)	0 (0%)	1 (less than 1%)
Severe	0 (0%)	1 (less than 1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Reported	0	0	0	0	0	0

## Surgical Procedure

When comparing the results of the different ways surgery was performed, one way appeared somewhat better than the others and is included in the instructions for use for the Raindrop Near Vision Inlay. There were 135 out of 373 patients who had surgery done this way and their results are presented below.

There were 133/133 (100%) Surgical Subgroup patients who could see without lenses at 20/40 or better at 12 months and 128/128 (100%) with this level of vision at 24 months.

No patients in this subgroup experienced worse than 20/40 best distance vision with lenses after surgery from 1 month onward. After surgery, 0% to 2% of patients experienced loss of two (2) or more lines of a best distance vision with lenses at all follow-up visits from one month onward, which supports fewer than 5% of eyes should lose two (2) lines or more of best distance vision with lenses at all follow-up visits after surgery from six (6) months onward.

No patients in this subgroup experienced worse than 20/40 best near vision with lenses at any follow-up visits after surgery from 1 month onward. After surgery, no patient experienced loss of two (2) or more lines of a best near vision with lenses at any follow-up visits from one month onward, which supports fewer than 5% of eyes should lose two (2) or more lines of best distance vision with lenses at all follow-up visits after surgery from six (6) months onward.

Stability of the focusing power of the eye for distance was not worse in this subgroup of patients. The manifest refraction was found to be stable by six (6) months.

The numbers of patients, out of the 135 patients in the subgroup, that experienced each of the adverse events that occurred in this group at any time during the study are as follows:

- Infection of the Eye: 1 patient (0.7%)
- Lost, Misaligned, or Misplaced Flap: 1 patient (0.7%)
- Eye Pressure Increase: 2 patients (1.5%)
- Inflammation in the Cornea: 1 patient (0.7%)
- Replace the Inlay: 5 patients (3.7%)
- Inlay Removal: 5 patients (3.7%)
- Inflammation of the Colored Part of the Eye (Iris): 1 patient (0.7%)

The numbers of patients, out of the 135 patients in the subgroup, that experienced each of the complications that occurred in this group at any time during the study are as follows:

- Surface Defect of the Cornea Near the Edge of the Flap at 1 Month or Later: 1 patient (0.7%)
- Swelling of the Cornea Between 1 Week and 1 Month After Procedure : 3 patients (2.2%)
- Central Clouding of the Cornea (Haze): 12 patients total (8.9%; 8 with one episode and 4 with more than one episode)
- Feeling Like Something is Rubbing Against the Eye after Blinking (Foreign Body Sensation) at 1 Month or Later: 5 patients (3.7%)
- Pain at 1 Month or Later: 1 patient (0.7%)
- Dryness of the Eye Beyond 6 Months After Procedure: 1 patient (0.7%)
- Eye Infections from the Virus that Causes Chicken Pox (Herpes Zoster): 1 patient (0.7%)

The subgroup had fewer patients that had their inlays removed. There were 3.7% (5/135) removals in this subgroup. The reasons for removals (number of patients = 5) were:

- Dissatisfied With Vision After 3 Months Postoperative: 2 patients (40%, 2/5)
- Growth of Surface Cells Under The Flap (Epithelial Ingrowth): 1 patient (20%, 1/5)
- Clouding of the Cornea (Haze): 1 patient (20%, 1/5)
- Patient's Request: 1 patient (20%, 1/5)

All patients in this subgroup who had the inlay removed had 20/20 or better best distance vision corrected with lenses after removal.

Lastly, a summary of eye and visual symptoms reported before surgery and 24 months after surgery for this surgical parameter subgroup are presented in **Tables 5** and **6**.

**Table 5: Eye Symptoms Before Surgery And At The 24 Month Visit For Surgical Subgroup**

	Pain		Foreign Body Sensation		Light Sensitivity	
	Before Surgery N=135	Month 24 N=128	Before Surgery N=135	Month 24 N=128	Before Surgery N=135	Month 24 N=128
Absent	135 (100%)	128 (100%)	135 (100%)	128 (100%)	131 (97%)	122 (95%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (3%)	6 (5%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Marked	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Reported	0	0	0	0	0	0

	Tired Eyes		Dryness		Discomfort	
	Before Surgery N=135	Month 24 N=128	Before Surgery N=135	Month 24 N=128	Before Surgery N=135	Month 24 N=128
Absent	111 (82%)	115 (90%)	117 (87%)	78 (61%)	122 (90%)	122 (95%)
Mild	24 (18%)	12 (9%)	18 (13%)	44 (35%)	13 (10%)	5 (4%)
Moderate	0 (0%)	1 (1%)	0 (0%)	5 (4%)	0 (0%)	1 (1%)
Marked	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Reported	0	0	0	1	0	0

**Table 6: Visual Symptoms Before Surgery And At The 24 Month Visit For Surgical Subgroup**

	Glare		Halos	
	Before Surgery N=135	Month 24 N=128	Before Surgery N=135	Month 24 N=128
Absent	127 (94%)	90 (70%)	131 (97%)	89 (70%)
Mild	8 (6%)	38 (30%)	4 (3%)	38 (30%)
Moderate	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Marked	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Reported	0	0	0	0

	Blurred Vision		Double Vision		Fluctuation of Vision	
	Before Surgery N=135	Month 24 N=128	Before Surgery N=135	Month 24 N=128	Before Surgery N=135	Month 24 N=128
Absent	134 (99%)	95 (74%)	135 (100%)	120 (94%)	133 (99%)	91 (71%)
Mild	1 (1%)	30 (23%)	0 (0%)	6 (5%)	2 (1%)	36 (28%)
Moderate	0 (0%)	3 (2%)	0 (0%)	2 (2%)	0 (0%)	1 (1%)
Marked	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Not Reported	0	0	0	0	0	0

## PATIENT ASSISTANCE INFORMATION

### **EYE CARE PROVIDER**

**Name:**

**Address:**

**Telephone Number:**

### **LOCATION OF TREATMENT**

**Name:**

**Address:**

**Telephone Number:**

---

**RAINDROP® NEAR VISION INLAY**  
Manufacturer and Customer Service

---



**ReVision Optics, Inc.**  
25651 Atlantic Ocean Drive, Suite A1  
Lake Forest, CA 92630 USA  
T +1.949.707.2740  
info@revisionoptics.com • www.raindropinlay.com

