

**Facts You Need to Know About  
*IDESIGN*<sup>®</sup> Refractive Studio-Driven  
Wavefront-Guided Photorefractive  
Keratectomy (PRK) Procedure using the  
*STAR S4 IR*<sup>®</sup> Excimer Laser System**

**Patient Information Booklet**

**For the reduction or elimination of myopia (nearsightedness) up to -8.00 D, with astigmatism up to -3.00 D**

**Please read this entire booklet. Discuss its contents with your doctor. Make sure your doctor answers all your questions to your satisfaction. Ask all questions you may have before you agree to the surgery.**

**RESTRICTED DEVICE:** U.S. Federal Law restricts these devices to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of these devices to practitioners who have been trained in its calibration and operation and who have experience in the surgical treatment and management of refractive errors.

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# GLOSSARY

**Please discuss with your doctor any questions you may have about these terms.**

**Aberration:** a complex visual distortion not corrected by glasses

**Adverse Event:** undesirable experience associated with the use of a medical product in a patient.

**Antibiotic Medication:** a drug used to treat or prevent infection.

**Anti-inflammatory Medication:** a drug that reduces redness and swelling associated with inflammation. They may be a corticosteroid, or a non-steroidal anti-inflammatory drug.

**Astigmatism:** The cornea and lens focus light rays from horizontal and vertical lines at different distances from the retina. The multiple focal distances result in blurred vision. Astigmatism may occur alone or along with nearsightedness and other refractive errors.

**Automated Lamellar Keratectomy (ALK):** a type of surgery used to correct vision by removing a small piece of cornea using a microkeratome (an automated instrument), reshaping or flattening the cap of cornea, and then replacing the cap on the corneal bed.

**Cataract:** opacity or clouding of the lens inside the eye that can cause a loss of vision.

**Coma:** a complex visual focusing error of the eye that can cause lights to look like a comet tail

**Connective Tissue Disease:** a condition that may result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis.

**Contraindications:** any special condition that results in the treatment being inadvisable.

**Cornea:** the clear front surface of the eye.

**Corneal Haze:** a cloudiness of the cornea that may occur after PRK.

**Corneal Refractive Surgery:** vision correction surgery that aims to reshape the cornea permanently to correct refractive errors. This change in eye shape restores the focusing power of the eye so light rays focus on the retina for improved vision.

**Corneal Topography:** measurement of the shape of the surface of the eye.

**Corneal Ulcer:** an infection of the cornea that may result in a loss of vision.

**Diopter (D):** a unit used to measure the amount of myopia, hyperopia, or astigmatism of any eye.

**Excimer Laser:** a type of laser emitting UV light that is used in PRK or LASIK to remove corneal tissue precisely and without damage to surrounding tissue.

**Femtosecond Laser:** a laser that cuts a flap of tissue from the front surface of the eye.

**Glaucoma:** a condition usually associated with high eye pressure. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

**Halos:** circular flares or rings of light that may appear around a headlight or other lighted object.

**Herpes Simplex:** a type of infection caused by a virus that can recur. This virus typically causes cold sores and/or blisters to appear on the face or other parts of the body.

**Herpes Zoster:** a type of infection caused by a virus that can recur. Blisters typically appear on only one side of the body.

**Immunodeficiency Disease:** a condition that alters the body's ability to fight infection. An example is AIDS.

**Intraocular Pressure (IOP):** fluid pressure inside the eye.

**iDESIGN® Refractive Studio:** the **iDESIGN® Refractive Studio** is a diagnostic instrument to objectively measure the refractive errors of the eye. The **iDESIGN® Refractive Studio** also measures the surface of your eye (topography) as well as other eye data.

**Keratomileusis:** sculpting of the cornea by removing tissue to correct refractive error

**Keratoconus:** a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs.

**Keratometry:** is a measurement of the corneal curvature to determine the power of the cornea

**LASIK (laser-assisted *in situ* keratomileusis):** a type of surgery used to correct vision by creating a flap in the cornea using a femtosecond laser or a microkeratome (an automated instrument), then reshaping the cornea underneath using an excimer laser, and then replacing the flap on the corneal bed.

**Lens:** a structure inside the eye that helps to focus light onto the back of the eye. Also, an optical instrument for forming an image by focusing rays of light.

**Microkeratome:** an automated surgical tool that cuts a flap of tissue from the front surface of the cornea with a blade or laser.

**Myopia:** a refractive error in which the eye focuses light rays from distant objects in front of the retina. This causes images of distant objects to appear blurry. Nearsightedness is another term for myopia.

**Nearsightedness:** another term for myopia.

**Ocular Hypertension:** an increase in the pressure inside the eye.

**Photorefractive Keratectomy (PRK):** a type of surgery used to correct vision by reshaping the top surface of the cornea using an excimer laser.

**Presbyopia:** is the normal age-related loss of ability to focus on near objects.

**Pupillometry:** the measurement of the diameter or width of the pupil of the eye

**Radial Keratotomy (RK):** a type of surgery used to correct vision by flattening the cornea with a scalpel.

**Refract:** to bend or focus rays of light.

**Refraction:** the focusing power of a lens or eye.

**Refractive Error:** a focusing error of the eye. The eye does not bring light rays to a sharp focus precisely on the retina, producing a blurred image. Refractive errors can be myopic, astigmatic, or hyperopic.

**Refractive Lenticule Extraction:** Refractive lenticule extraction is a flapless and minimally invasive form of laser vision correction. The surgeon uses a laser to cut a small lens-shaped piece of corneal tissue (lenticule), which is removed through a tiny incision, to reshape the cornea used to treat myopia and myopic astigmatism.

**Regression:** a decrease in the amount of vision correction after PRK surgery.

**Retina:** the back surface of the eye. The retina senses focused light. It transfers signals to the brain.

**Spherical Aberration:** a complex focusing error of the eye that can make lights have a halo around them.

**Trefoil:** a complex focusing error of the eye that can make lights appear to have a triangle shape.

**Wavefront:** a surface representing the cross-section of the paths that light rays follow as they travel through the eye.

**Wavefront error:** simple and complex focusing errors in the eye that reveal differences in the paths of light rays as the eye bends them.

**Wavefront Error Maps:** a color map that displays wavefront errors measured by the *iDESIGN*® Refractive Studio.

# INTRODUCTION

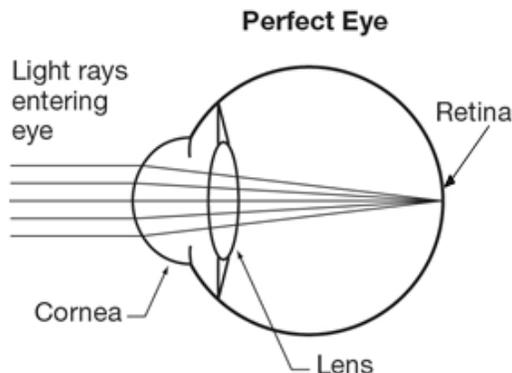
**iDESIGN®** Refractive Studio (**iDESIGN®** System) wavefront-guided PRK (photorefractive keratectomy) treatments may help nearsighted patients with and without astigmatism.

Your doctor and Johnson & Johnson Vision provide the information in this booklet to help you decide if you should have an **iDESIGN®** System-driven wavefront-guided PRK treatment to reduce your need for glasses or contact lenses. There are other non-surgical ways to correct your vision. You can wear glasses or contact lenses. There are other surgical options. These include implantable lens surgery, wavefront-guided LASIK and other types of LASIK that do not use wavefront technology (LASIK using traditional eye prescriptions or corneal topography).

Please read this booklet completely. Ask your doctor any questions before you decide if **iDESIGN®** System-driven wavefront-guided PRK treatments of myopia is right for you. Only an eye care professional trained in laser vision correction can decide if you are a good candidate.

## How Refractive (Wavefront) Errors Affect Your Vision

The eye works like a camera that focuses images onto film. The cornea and lens of the eye bend light rays to focus on the retina at the back of the eye.



**Figure 1:** A diagram showing how the eye focuses light rays to create a sharp image on the retina.

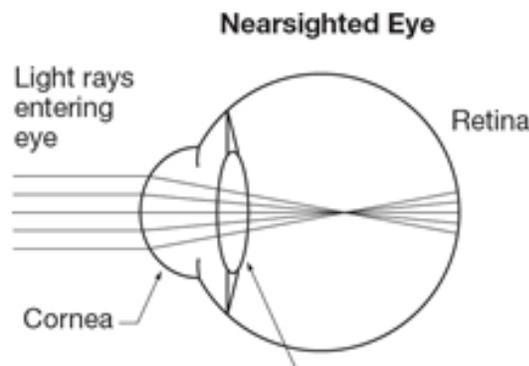
All eyes have some focusing imperfections. One way to measure them is to measure the *wavefront* of the eye. The **iDESIGN®** Refractive Studio is a tool to measure the wavefront of an eye.

The wavefront of a perfect eye is uniform because all the light ray's travel evenly through the eye, as shown in **Figure 1**. The wavefront of an eye with imperfections is curved or wavy because some light rays reach the retina before others. Some rays strike different locations on the retina than others.

Wavefront errors include both simple and complex errors. Lenses can correct the simple wavefront errors, which are called *refractive errors*. Refractive errors include *myopia and astigmatism*. Other refractive errors include hyperopia and mixed astigmatism. These are not approved for use in PRK with the **iDesign®** Refractive Studio.

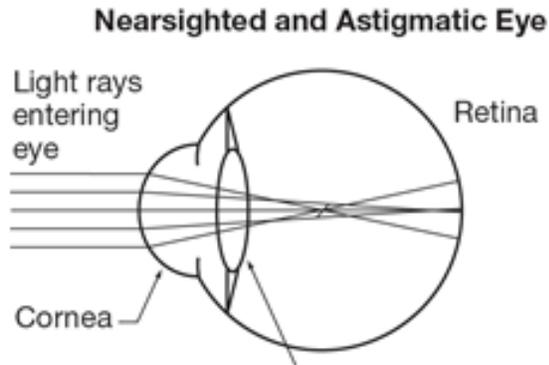
Myopia (nearsightedness) usually starts in childhood and can get worse through your teens. It usually stops changing by your late teens but sometimes nearsightedness may worsen with age.

As shown in **Figure 2**, nearsighted eyes bend light too much, so that light rays focus to a single spot in front of the retina. Things that are faraway look blurry because the rays spread apart instead of focus sharply when they strike the retina. This occurs when the eyeball becomes too long and prevents incoming light from focusing directly on the retina. It may also be caused by an abnormal shape of the cornea or lens.



**Figure 2:** A diagram of a nearsighted eye showing the light rays focusing in front of the retina.

As shown in **Figure 3**, astigmatism causes the rays of light entering through different parts of the eye to focus unequally on the retina. Some rays may focus on the retina, but other rays focus in front of it. Things look blurry because images never focus clearly on the retina.



**Figure 3:** A diagram of an eye with astigmatism showing light rays that do not ever come to a focus at one point.

## WHAT IS PRK?

PRK, an abbreviation for Photo Refractive Keratectomy, is a type of laser eye surgery. With this procedure the outer layer of the cornea (corneal epithelium) is removed as part of the surgery. Typically, this outer layer or epithelial removal is done manually without the use of the laser. Then the laser reshapes the cornea through removal of a small amount of corneal tissue. The amount of corneal tissue removed by the laser depends on the amount of nearsightedness and/or astigmatism that is present in the eye.

## What are the Devices used for the PRK Procedure?

### The *iDESIGN*® Refractive Studio

Before the doctor can program the laser for your *iDESIGN*® System-driven PRK treatments, the *iDESIGN*® Refractive Studio must measure your eyes. The *iDESIGN*® Refractive Studio is a tabletop system that measures your eyes with special cameras. You will sit in front of the *iDESIGN*® Refractive Studio and look into it at a light through an opening in the system while it scans your eye. Your doctor may take more than one measurement and then choose the most appropriate measurement to use as the basis for the *iDESIGN*® System-driven PRK treatment. Your doctor will also take other routine measurements of your vision to help design your treatment.

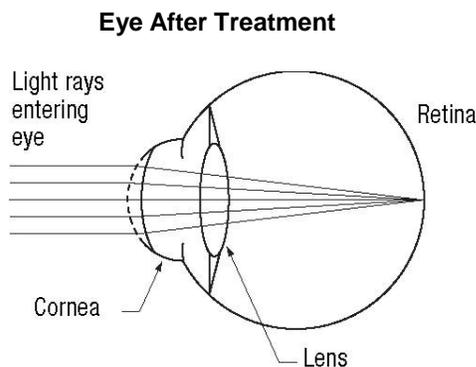
The *iDESIGN*® Refractive Studio can measure simple and complex focusing errors. The combination of simple and complex wavefront errors in any eye is unique. *iDESIGN*® System-driven PRK treatments are “custom” because it includes information from the *iDESIGN*® Refractive Studio that is more individualized than what a doctor uses to program a non-custom treatment. The doctor uses information from the *iDESIGN*® Refractive Studio, as well as other measurements of how you see, to design your *iDESIGN*® System-driven PRK treatments.

## The **STAR S4 IR®** Excimer Laser

The excimer laser system, which delivers a beam of ultraviolet light, is used to precisely remove corneal tissue. The doctor transfers the information from the **iDESIGN®** Refractive Studio into a computer that controls the laser. The laser produces a series of rapid pulses that remove small and precise amounts of corneal tissue. Excimer laser light does not penetrate into the eye and leaves other eye structures (iris, lens, retina) untouched.

The laser system also contains an auto-centering eye tracking system which will align the treatment and automatically compensate for many of your eye movements during the **iDESIGN®** System-driven PRK treatments. In addition, the Iris Registration feature of the **STAR S4 IR®** Excimer Laser System adjusts for rotation (twisting) of your eye between time of wavefront measurement and start of the treatment.

As shown in **Figure 4**, the laser changes your vision by changing the shape of the cornea. To correct nearsightedness the laser removes more from the center of the cornea. When there is astigmatism, the laser sculpts the eye vertically or horizontally. The doctor creates a unique treatment plan using the **iDESIGN®** Refractive Studio to guide the laser. The laser removes tissue from the eye according to the treatment plan.



**Figure 4:** A diagram of an eye after treatment showing where tissue is removed

## Purpose of the Devices

The STAR S4 IR® Excimer Laser System and the iDESIGN® Refractive Studio is used for wavefront-guided photorefractive keratectomy (PRK) for reduction or elimination of nearsightedness (myopia) in patients:

- With powers from 0.00 to -8.00 units of focusing power (diopters or D) of nearsightedness and from 0.00 to -3.00 D of astigmatism (eye shaped more like a football than a basketball), as measured by **iDESIGN®** Refractive Studio System in the treated eye;
- Whose doctor-measured and **iDESIGN®** Refractive Studio System - measured prescriptions agree within 0.625 D for total myopia, and within 0.5 D for astigmatism;
- Who are 18 years of age or older
- Who showed no change in nearsightedness by more than 1.00 D during the year before surgery, and
- Who have pupil measurements by **iDESIGN®** Refractive Studio System of at least 4 millimeters.

## Alternatives to PRK Procedure

There are several other alternatives for the correction of myopia and myopic astigmatism:

- Glasses or contact lenses.
- Artificial lens implanted inside the eye.
- Wavefront-guided or corneal topography-assisted LASIK.
- LASIK, PRK, or refractive lenticule extraction using standard eye measurements.

Each alternative has its own advantages and disadvantages. You should fully discuss these alternatives with your physician to select the method that best meets your expectations and lifestyle. Please refer to the BENEFITS and RISKS sections below.

## Important Things to Consider Regarding PRK

- You should be aware that there are advantages and disadvantages to PRK. You will need to tolerate hazy vision and pain which may be severe in the first few days after surgery. Pain medications are often prescribed for this period of healing and during this time your vision may be blurry preventing you from participating in your daily activities (driving, reading, computer work, etc.).
- You may have a soft contact lens “bandage” placed on your eye to help protect it during this early healing period which will be removed by your doctor.

- There is also a longer period for your vision to improve and to become stable when compared to LASIK.
- The benefits over LASIK may include a removal of risk of a flap complication, including subsequent dislocation of the flap after trauma as no flap is created. In addition, in patients who have normal but thin corneas PRK may be preferable to LASIK.
- If either your job or your recreational activities such as contact sports involve a significant risk of eye injury, PRK may be a better choice than LASIK.
- After considering your vision needs and your specific lifestyle, the information in this booklet and your doctor's recommendations, remember that the decision whether to undergo an **iDESIGN**® PRK treatment is yours alone. Please make sure that all your questions regarding your treatment are answered prior to undergoing surgery. **iDESIGN**® System-driven PRK treatments can correct up to -8.0 diopters (D) of nearsightedness with up to -3.0 D of astigmatism. If you have nearsightedness within this range, **iDESIGN**® System-driven PRK treatments may help you to see clearly distant objects without glasses or contact lenses.

## RISKS

As with any surgery, **iDESIGN**® System-driven PRK treatments have risks. It is important to discuss the risks with your doctor before you decide to have surgery. If the results of the surgery are not satisfactory, you may need to have another laser treatment. Usually, your doctor will perform **iDESIGN**® System-driven PRK treatments on both eyes. Sometimes it is better to have this treatment only on one eye. Ask your doctor if it would be better to treat one or both of your eyes.

### Risks of PRK include:

- Loss of best vision, even when corrected with glasses or contact lenses (called loss of best corrected vision)
- Over-correction (too strong) or under-correction (too weak) that may need eyeglasses or contact lens wear
- Increase in astigmatism (irregular shape of the front part of your eye)
- Partial loss of the treatment effect over time (regression)
- Unintended imbalance between the two eyes (anisometropia) that may cause headaches, eye strain, double vision and/or difficulty judging distance or depth perception
- At around 40 years of age or older you may need glasses for close work such as reading.
- Difficulty with future eye measurements (see discussion in PRECAUTIONS).

**Symptoms include:**

- Eye soreness or pain (including chronic eye pain that is resistant to therapy referred to as neuropathic pain)
- Dry eyes
- Halos, glare, starbursts, hazy vision
- Blurred vision, distortion, double or multiple images (ghost images, images that appear to have a shadow)
- Changes in quality of vision (fluctuating vision), difficulty focusing, difficulty with night driving
- Feeling of something in the eye, grittiness
- Light sensitivity, decreased ability to see in low-light conditions (e.g., reading a street sign at dusk or at night)

**Other complications that can result in decreased vision and may require surgery or other treatment include:**

- Corneal damage (scarring, swelling, cloudiness, haziness)
- Bulging of the cornea (ectasia), irregular corneal shape
- Loss of outermost corneal layer (Corneal epithelial defect), break or loss of cornea's outer layer (corneal erosion), corneal hole (perforation), opacity/cloudiness of the cornea (corneal decompensation), and persistent corneal swelling (edema)
- Corneal infection (corneal ulceration) and corneal inflammation/swelling
- Drooping eyelid (ptosis)
- Increased pressure in the eye
- Cataract (lens cloudiness)
- Retinal detachment (retina lifted off the back of the eye)

**IMPORTANT:**

**You may need reading glasses after laser surgery even if you did not wear them before. Your vision may not be perfect, and you may need to wear glasses or contact lenses for some activities even after laser vision correction.**

**BENEFITS**

*iDESIGN*® System-driven PRK treatments can correct up to -8 diopters (D) of nearsightedness with up to -3 diopters of astigmatism. If you have nearsightedness within this range, *iDESIGN*® system-driven PRK treatments may help you see distant objects clearly without glasses or contact lenses.

## CONTRAINDICATIONS — When Can't You Have PRK?

If you have any of the following situations or conditions you should not have PRK because the risk is greater than the benefit:

- You have any type of active connective tissue disease (e.g., rheumatoid arthritis), or active autoimmune disease (e.g., lupus). These conditions affect the body's ability to heal.
- You have significant dry eye. If you have severely dry eyes, PRK may increase the dryness. This may or may not go away. Severe eye dryness may delay healing or interfere with the surface of the eye after surgery. It may result in poor vision after PRK, which may be permanent.
- You show signs of keratoconus (cone-shaped cornea) or another condition that causes a thinning of your cornea. These conditions can lead to serious corneal problems during and after PRK surgery. They may result in need for additional surgery. They may result in poor vision after PRK.
- You have uncontrolled diabetes. This condition may interfere with the healing of your eyes after PRK. It may result in poorer vision and refractive outcomes.
- Active eye infection or inflammation of the eye, recent herpes eye infections or problems from past infections of the eye.
- Corneas are too thin. Your doctor will examine your cornea before your procedure to make sure that your cornea is not too thin because treating a thin cornea could result in serious damage to your eye.

## WARNINGS

If you have any of the following conditions, discuss the seriousness of your condition with your doctor.

- You have a systemic disease that may affect wound healing, such as controlled autoimmune or connective tissue disease, or controlled diabetes
- You have an immunocompromised status or take medications that may result in a weakened immune system, such as antimetabolites, which can increase the risk of infection.
- You are taking Isotretinoin (Accutane), which can increase the risk of dry eye and may affect wound healing.
- You have a history of *Herpes simplex* or *Herpes zoster* infection that has affected your eyes. If you have ever had *Herpes simplex* or a *Herpes zoster* in your eyes, PRK may be riskier for you because it may affect your eyes.

- You have glaucoma.
- You have a cardiac pacemaker, implanted defibrillator or other implanted electronic device.
- You have mild to moderate dry eye as this may increase the risk of worsening dry eye.
- You have decreased vision in one eye (e.g., amblyopia). If complications occur in your "strong" eye from PRK this could severely affect your functioning.

Additional warnings you need to consider:

- Eye movement during treatment. Even though the **STAR S4 IR®** Laser System has an eye tracker, you will be asked to look at a blinking light while the laser is running. It is important to stare at the light for the entire laser procedure. The treatment may not be positioned correctly on your eye if your eye moved too much during treatment. This may result in blurry vision after PRK.
- If your contact lenses were worn too close to the exam time for the doctor to obtain a stable measurement, your **iDESIGN®** Refractive Studio measurements, as well as other measurements may be inaccurate. This may result in poor vision after PRK.

## PRECAUTIONS

You may be at increased risk for complications following PRK if you have the following conditions:

- You have severe allergies or a tendency to rub your eyes. If you have severe allergies and take medicines for them, PRK may be riskier for you. You may have problems healing.
- You have a history of high eye pressure or are being followed for possible glaucoma (glaucoma suspect)
- You are pregnant or nursing. These conditions may cause temporary and unpredictable changes in your cornea. PRK treatment may improperly change the shape of your cornea.

You should discuss these conditions with your doctor.

The safety and effectiveness of the **STAR S4 IR®** Excimer Laser and the **iDESIGN®** Refractive Studio have NOT been established for wavefront- guided PRK surgery in the following conditions. You should discuss these with your doctor:

- Your vision has not been stable and have signs of increasing or unstable nearsightedness, eye disease; eye abnormality; previous eye surgery; or injury in the treatment area of your eye.

- You are taking the medication Sumatriptan (Imitrex<sup>®1</sup>) used for migraine headaches. It is not known if PRK is safe and effective for this condition.
- You are taking the medication Amiodarone hydrochloride (Cordarone<sup>®2</sup>) for normalizing heart rhythm. They may affect the accuracy of the PRK treatment or the way your cornea heals after PRK. This may result in poor vision after PRK.
- You have a pupil size of more than 8.0 millimeters in dim light conditions
- Nearsightedness is worse than 8 diopters or astigmatism is worse than 3 diopters. It is not known if PRK is safe and effective for you.
- For retreatment with this laser for PRK. It is not known if PRK is safe and effective for repeating the PRK procedure on the same eye.
- Undiagnosed dry eyes. Your doctor should also evaluate you for dry eyes before surgery. You may have dry eyes after PRK surgery even if you did not have dry eyes before surgery. Dry eyes may cause some fluctuation in your vision.
- You have more than 6 diopters of nearsightedness you may be at increased risk for the development of visual symptoms and less accurate results.

Additional considerations that could affect your eye health:

- It is possible, following PRK treatment that you will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.
- You have a family history of thinning of the cornea and other degenerative corneal disease (such as keratoconus, pellucid marginal degeneration, Fuchs' Corneal Dystrophy, Granular Corneal Dystrophy (Types 1 and 2), Lattice Corneal Dystrophy) you may not be good candidates for PRK treatment as they might increase risks associated with PRK.
- You have vessel growth into the cornea (corneal neovascularization) that is within 1.0 mm of the treatment area
- You are under 18 years of age
- Over the long term (more than 6 months after surgery) have not been established
- You had prior intraocular or corneal surgery of any kind
- You have an error in focusing power outside the specified range in the indications for use;
- Your visual acuity (a measure for the clarity of your vision) with glasses or contact lenses is worse than 20/20 in the eye to be treated.
- Your visual acuity with glasses or contact lenses is less than 2 lines on the eye chart better than your vision without glasses or contact lenses.

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<sup>2</sup> Cordarone<sup>®</sup> is a registered trademark of Sanofi-Synthelabo, Inc.

- You have a greater than 0.75 D difference of total focusing power of your eye as measured by your doctor when your pupils are dilated compared to when your pupils are not dilated
- Your wavefront measurement is less than 4 millimeters in size.
- You were wearing contact lenses unless there is evidence that your prescription is stable after not wearing your contact lenses for the time period recommended by your eye doctor.
- You have a history of inflammation of the iris or other structures in the eye (iritis, uveitis or chronic inflammation of the eye).
- You have naturally occurring pupils smaller than 4.0 mm, as they are not eligible for treatment with **iDESIGN®** System-driven PRK treatments. The maximum pupil size allowed for treatment is 9.5 mm and there are no safety or effectiveness data for eyes with pupils larger than 8.7 mm<sup>3</sup>
- You have a history of crossed eyes (strabismus) or you have undergone strabismus surgery.
- The ability to accurately measure and interpret eye pressure measurements. Thinning of the cornea due to PRK surgery will affect the accuracy of your eye pressure measurements (used as part of the exam for glaucoma) and more difficult to interpret glaucoma treatment response. You should inform eye doctors that you have had a procedure to correct myopia.
- The ability to obtain accurate measurements for the appropriate artificial lens power for future cataract surgery. You should be provided with a Patient Information Card with all your eye measurements from before the procedure. You should keep this card for when you need to have cataract surgery in the future.
- You are not within the studied age groups: If you are younger than 18 years of age or older than 47 years of age
- The effects of medications and medical conditions that were excluded from the clinical trial on PRK are unknown (e.g. the use of inhaled or systemic corticosteroids).
- If you had prior LASIK or Refractive Surgery.
- With history of any eye diseases or abnormalities, such as, corneal scars and history of glaucoma or high eye pressure measurement.

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<sup>3</sup> Effectiveness data for eyes that were treated with myopia as measured by iDesign System up to -10.00 D spherical equivalent, with up to -4.00 D cylinder.

# WHAT TO EXPECT

## Before Surgery

If you are interested in having laser vision correction, you will need to have a pre-surgical exam to determine if your eye is healthy and suitable for surgery. This will include a complete medical and eye history, and thorough examination of both eyes, including wavefront-based refractive errors and computerized mapping of your cornea.

### **WARNING:**

If you wear contact lenses, it is very important to stop wearing them 2 to 4 weeks before your pre-surgical exam and treatment for the doctor to obtain a stable eye measurement. Failure to do this might produce poor surgical results.

Before the surgery, please tell your doctor if you take any medications or have any allergies. Also, ask your doctor about eating or drinking immediately before surgery. You should also plan a ride home from your doctor's office. You must not drive immediately after the surgery. You may start driving again only when you receive permission from your doctor.

## The Day of Surgery

Before the surgery, the doctor places local anesthetic (numbing) drops into the eye to be treated and escorts you into the room with the laser. You will lie on your back in a reclining chair and look up. An instrument will hold your eyelids open during the surgery.

The surgery begins with removal of the outermost layer of the cornea. This is done manually.

There will also be a temporary shield covering the eye not having surgery. Listen to the sounds that the laser makes to prepare you for the surgery.

The doctor will then reposition your head in the chair and refocus the microscope. You will need to look directly at a blinking light while the laser is running. It is important to fix your gaze on the light for the entire laser procedure. Try to keep both eyes open without squinting, as this makes it easier to keep looking at the light. The **STAR S4 IR®** Excimer Laser System then quickly removes small amounts of your cornea.

### **PRECAUTION:**

It is very important that you keep looking at the flashing fixation light during the procedure, even if the light fades, blurs or becomes dim. You need to concentrate on looking at this light throughout the treatment to ensure the best results possible.

Typically, the laser beam will be applied to your eye for less than 3 minutes and, overall, the surgery may last about 10 minutes. The doctor will place some eye drops on your eye when the laser pulses are finished. The surgery is painless because of the numbing drop. When the numbness wears off (about 30 to 60 minutes), your eye may hurt moderately for 1 to 2 days. The discomfort is typically described as “a sandy sensation.”

Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. To promote healing and lessen the risk of infection, do **NOT** rub your eye after surgery until your doctor tells you it is safe to do so.

### **After Surgery**

You will be mildly sensitive to light and have the feeling that something is in your eye for 1 to 2 days. The doctor may apply a bandage contact lens that you will wear for 3 to 5 days to assist the surface of your eye in healing. Sunglasses may make you more comfortable during this time. You will need to instill eye drops that your doctor recommends.

### **The First Week Following Surgery**

- Mild to moderate pain and discomfort may last for up to 3 days after surgery.
- Blurred vision and tearing may occur as the cornea heals.
- You may be sensitive to bright lights.

During the early stages, especially during the first week, your eyesight may not have fully adjusted to new changes. It may take several weeks for your eyes to adjust.

You may want to avoid or decrease your participation in strenuous activities and contact sports.

You should avoid swimming, hot tubs and spas for the first three weeks.

## **The First Two to Six Months Following Surgery**

Your vision may change during this period. You may also have some eye dryness. Your doctor may prescribe eye drops to help resolve your dry eyes. Use the drops as prescribed.

### **IMPORTANT:**

**Use lubricants and eye medications as directed by your doctor. Your results depend upon you following your doctor's instructions.**

### **WARNING:**

**Your doctor will monitor you for any side effects if you need to use a topical steroid medication. Possible side effects of prolonged topical steroid use are:**

- **Glaucoma (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision).**
- **Cataract formation (an opacity or clouding of the lens inside the eye that can cause a loss of vision).**

## Are You A Good Candidate For *iDESIGN*® System-Driven PRK Treatments?

If you are considering *iDESIGN*® System-driven PRK treatments, you must:

- Be at least 18 years of age.
- Have healthy eyes that are free from eye disease or corneal abnormality such as scars and infections.
- Have documented evidence of a change in manifest refraction of no more than 1.0 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.
- Have had no change in nearsightedness of more than 1.00 D during the year before surgery
- Be informed of PRK risks and benefits as compared to other available treatments for nearsightedness with or without astigmatism.
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be willing to sign the informed consent form provided by your doctor.
- Be able to fix your gaze on the blinking light for the entire laser procedure.

If you are considering *iDESIGN*® System-driven PRK treatments, you must NOT:

- Have severe dry eye, a thin cornea, uncontrolled diabetes, active connective tissue disease or autoimmune disease as the surgery may lead to poor outcomes and possible vision loss.

# SUMMARY of CLINICAL STUDY RESULTS

## Study Purpose

A clinical study was conducted to evaluate the safety and effectiveness of wavefront-guided photorefractive keratectomy (PRK) for the correction of nearsightedness with the **iDesign Advanced Wavescan® Studio** System and **STAR S4 IR®** Excimer Laser System. A summary of the clinical study is presented below.

## Summary of Study Design

This study was a 1-year study, conducted at seven sites, and both eyes were treated. This study involved 334 treated eyes of 167 patients treated with nearsightedness with or without astigmatism. This study started in February 2016. The last patient in this study was treated in August 2017. Safety measures included change in best vision with glasses (BSCVA), changes in astigmatism, refractive errors of the eyes, and eye health including adverse events. Effectiveness measures included vision testing without glasses or contact lenses, time taken for eye to reach stable state (refractive stability), and accuracy of treatment. Additional safety measures included: contrast testing (contrast sensitivity) and patient symptoms (including severity of dry eye symptoms).

After signing the informed consent and meeting all criteria to participate in the study, patients were offered the study treatment. Patients had to have at least one eye with nearsightedness up to -10.00 D of nearsightedness with or without astigmatism up to -4.00 D, as measured using the **iDESIGN®** system to participate in the study. The study results shown in this booklet were collected on the treated patients through November 2017. Analyses of results were performed at 1, 3, 6, 9, and 12 months after treatment. Each table lists the number of eyes or study patients for whom data were available at the reported time point.

It was determined that refractive stability (the time it takes the eye to be stable after PRK surgery) was reached at 6 months. The key effectiveness and safety targets were evaluated at 6 months as the primary study analyses:

- The primary effectiveness measures include percent of treated eyes with: (1) uncorrected vision (UCVA) of 20/40 or better, (2) an accurate correction, and (3) a stable correction (refractive stability) percent of eyes with.
- The primary safety measures include the percentages of eyes with: (1) losses of more than 2 lines of best vision with glasses (best vision, best corrected vision, or BSCVA), (2) an increase in astigmatism of more than 2.00 D and each type of serious, device-related adverse event.

## Clinical Study Results

One hundred sixty-seven (167) study patients (or 334 eyes) were enrolled in the trial. Of those, 161 study patients (322 eyes) were examined 6 months after PRK treatment, the key timepoint of the study, and 184 eyes of 92 study patients were examined one year after PRK treatment.

### Study Patient Characteristics

**Table 1** lists the age, gender, race, and contact lens history of patients in this study.

- Patient's ages ranged from 19 to 47 years, with an average of 27 years of age.
- The study patient population consisted of more males (114) than females (53).
- The majority of study patients were White (110), 22 were Black or African American, 12 were Asian, 3 were American Indian/Alaska Native and 20 were of any other racial group.

**Table 1 – Characteristics of 167 Patients**

Category	Classification	Total Study Patients
Gender	Male	114 (68%)
	Female	53 (32%)
Race	American Indian/Alaska Native	3 (2%)
	Asian (Includes Indian)	12 (7%)
	Black or African American	22 (13%)
	White	110 (66%)
	Other <sup>a</sup>	20 (12%)
Age (Years)	Mean ± SD	27 ± 5
	Range	19-47
Preoperative CL Wear <sup>b</sup>	No	162 (97%)
	Soft	5 (3%)
	Rigid/Toric	0 (0%)
	Soft/Toric	0 (0%)
<sup>a</sup> Other includes Hispanic and Mixed.		
<sup>b</sup> Contact lens wear within the 4 weeks (28 days) prior to the screening visit.		

Note: The participants in this trial tended to be younger and composed of more males than has been the case for the refractive surgery population in general.

Before surgery the *iDESIGN*<sup>®</sup> system measured amount of nearsightedness ranged from -0.64 D to -8.99 D with up to -3.98 D of astigmatism.

## Safety Results

### Vision with Glasses After Treatment

**Table 2** shows the percent of patient's eyes with a change in vision *while wearing glasses* at 1, 3, 6, 9, and 12 months after treatment. At 6 months, 313/322 (97%) of eyes after surgery saw with glasses as well as or better as than before surgery. There was only one eye (0.3%) that had a decrease in vision of more than 2 lines at 6 months compared to before surgery. This was due to corneal damage (haziness). The safety target of less than 5% of eyes with a loss of more than 2 lines of best vision with glasses (BSCVA) was met. No eyes had BSCVA worse than 20/40.

**Table 2 - Change in Vision with Glasses from Before to After Treatment**  
(Number of eyes out of total number examined at each visit, and percent of 100 eyes)

Acuity Line Change)	1 Month	3 Months	6 Months	9 Months	12 Months
<b>Eyes with gain of more than 2 lines</b>	0/322 (0%)	0/328 (0%)	0/322 (0%)	0/228 (0%)	0/184 (0%)
<b>Eyes with gain of 2 lines</b>	1/322 (0.3%)	6/328 (2%)	10/322 (3%)	10/228 (4%)	18/184 (10%)
<b>Eyes with gain of 1 line</b>	40/332 (12%)	134/328 (41%)	151/322 (47%)	124/228 (54%)	108/184 (59%)
<b>No Change</b>	195/332 (59%)	174/328 (53%)	152/322 (47%)	90/228 (39%)	56/184 (30%)
<b>Eyes with loss of 1 line</b>	77/332 (23%)	13/328 (4%)	8/322 (2%)	4/228 (2%)	2/184 (1%)
<b>Eyes with loss of 2 lines</b>	15/332 (4%)	1/328 (0.3%)	0/322 (0%)	0/228 (0%)	0/184 (0%)
<b>Eyes with loss of more than 2 lines</b>	3/332 (1%)	0/328 (0%)	1/322 (0.3%)	0/228 (0%)	0/184 (0%)

### Increase in Astigmatism following surgery

At 6 months, no eyes (0%; 0/322) had an increase in astigmatism of more than 2.00 D, meeting the safety target of less than 5% of eyes.

### Contrast Sensitivity (Contrast Testing)

Contrast sensitivity is the visual ability to distinguish an object from its background; it is not the same as visual acuity. It measures your ability to distinguish between finer and finer increments of light versus dark (contrast). Contrast sensitivity was measured under lighting conditions: dim light without producing glare, dim with glare, and in bright light without glare. On average, contrast sensitivity was not negatively affected.

### Patient Symptoms

The symptoms questionnaire asked patients before treatment and 6 months after treatment to rank how often they experienced symptoms (never, rarely, sometimes, often, always), how bothersome they were, and how much difficulty they caused. **Table 3** lists the results. At 6 months, of the patients who did experience a visual symptom, a low percentage of patients (less than 9%) often or always experienced the visual symptom. Most patients (90% - 99.4%) were either not bothered or slightly bothered by symptoms or did not experience the visual symptoms. Few patients (less than 4%) reported difficulty or limitation due to symptoms at 6 months.

**Table 3 - Patient Symptoms After Treatment**

(Percentage of 100 patients, number of patients at each visit out of 161 total number of study patients)

Symptom	Study patients who reported they were experiencing symptom <sup>b</sup>	Study patients who reported often or always experiencing symptom	Study patients who did not experience <sup>c</sup> or were not or slightly bothered by symptom	Highest rating of bother by symptoms, and percentage of study patients	Study patients with limitation or difficulty due to symptom
Halos	26.7% (43/161)	3.1% (5/161)	99.4% (160/161)	Moderate 0.6% (1/161)	0.6% (1/161)
Glare	33.5% (54/161)	2.5% (4/161)	96.3% (155/161)	Moderate 3.7% (6/161)	0.6% (1/161)
Starbursts <sup>d</sup>	35.4% (57/161)	4.9% (8/161)	96.3% (155/161)	Moderate 3.7% (6/161)	0.0% (0/161)
Sensitivity to Light	55.9% (90/161)	8.7% (14/161)	90.0% (145/161)	Very 1.9% (3/161)	3.7% (6/161)
Multiple/ Double Vision	4.3% (7/161)	0% (0/161)	99.4% (160/161)	Moderate 0.6% (1/161)	0.0% (0/161)
Fluctuating Vision	18.0% (29/161)	1.2% (2/161)	98.1% (158/161)	Moderate 1.9% (3/161)	2.5% (4/161)

<sup>a</sup> The questionnaire asked study patients to rank the frequency and level of bother of their visual symptoms over the last 7 days both before and at 6 months after treatment

<sup>b</sup> Total study patients indicating rarely, sometimes, often and always experiencing the given symptom.

<sup>c</sup> Includes study patients that did not experience the symptom or not reported.

<sup>d</sup> One subject not reported

**Table 4** presents the results of a patient questionnaire that measured severity of dry eye symptoms. The dry eye symptom questionnaire scores before and after treatment were categorized as normal, mild, moderate and severe. The numbers of patients in each dry eye symptom severity category at 6 months after treatment were similar to those before treatment.

**Table 4 - Dry Eye Symptoms Severity Over Time** (Number of patients at each visit, and percentage of 100 patients)

Severity	Before Treatment (167 total patients)	6 Months After Treatment (161 total patients)
Normal	138 (83%)	140 (87%)
Mild	13 (8%)	13 (8%)
Moderate	6 (4%)	5 (3%)
Severe	10 (6%)	3 (2%)

**Table 5** presents each patient's change in dry eye severity category from before surgery to 6 months after surgery. The majority of patients that were normal before surgery remained normal at 6 months.

**Table 5 Subject's change in severity of dry eye score from before surgery to 6 months after surgery** (Number of patients at each visit out of 161 total number of patients, and percentage of 100 patients)

Before surgery dry eye status	Normal		Mild		Moderate		Severe		Total	
	Number of patients	%	Number of patients	%	Number of patients	%	Number of Patients	%	Number of patients	%
	<b>Normal</b>	123	90	9	7	3	2	1	1	136
<b>Mild</b>	8	67	4	33	0	0	0	0	12	100
<b>Moderate</b>	4	80	0	0	0	0	1	20	5	100
<b>Severe</b>	6	67	0	0	2	22	1	11	9	100

Unexpectedly, twenty patients showed improvement in dry eye severity. Since the questionnaire asks about vision, eye comfort and visual symptoms, some patients may have improved scores due to improved vision and reduced contact lens wear after treatment.

### Satisfaction with Vision

Patients rated their satisfaction with their vision before treatment with glasses or contact lenses. They rated their satisfaction with vision after **iDESIGN®** PRK with and without glasses or contact lenses and overall. The results are shown in **Table 6**. When asked to rate their satisfaction wearing glasses or contacts 6 months after treatment, 89% of patients indicated "Not applicable, I never wear glasses or contacts".

**Table 6 - Summary of Satisfaction with Vision Before and After Treatment**

		Preop (Total patients=167) <sup>a</sup>		1 Month (Total patients=166)		3 Months (Total patients=164)		6 Months (Total patients=161)		9 Months (Total patients=114) <sup>b</sup>		12 Months (Total patients=92)	
Category	Satisfaction	Number of patients	%	Number of patients	%	Number of patients	%	Number of patients	%	Number of patients	%	Number of patients	%
		satisfaction with present vision when not wearing glasses or contacts	Completely satisfied	0	0.0	59	35.5	117	71.3	127	78.9	91	79.8
Very satisfied	0		0.0	77	46.4	42	25.6	32	19.9	22	19.3	9	9.8
Somewhat satisfied	0		0.0	24	14.5	4	2.4	1	0.6	0	0.0	2	2.2
Neither satisfied or dissatisfied	2		1.2	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0
Somewhat dissatisfied	14		8.4	4	2.4	0	0.0	0	0.0	0	0.0	0	0.0
Very dissatisfied	57		34.1	1	0.6	0	0.0	0	0.0	1	0.9	1	1.1
Completely dissatisfied	94		56.3	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0
satisfaction with present vision when wearing glasses or contacts	Completely satisfied	22	13.2	7	4.2	7	4.3	10	6.2	9	7.9	4	4.3
	Very satisfied	64	38.3	9	5.4	1	0.6	4	2.5	4	3.5	1	1.1
	Somewhat satisfied	61	36.5	6	3.6	5	3.0	0	0.0	1	0.9	1	1.1
	Neither satisfied or dissatisfied	10	6.0	1	0.6	2	1.2	1	0.6	0	0.0	0	0.0
	Somewhat dissatisfied	8	4.8	2	1.2	1	0.6	0	0.0	0	0.0	0	0.0
	Very dissatisfied	3	1.8	4	2.4	1	0.6	2	1.2	1	0.9	2	2.2
	Completely dissatisfied	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1
Not applicable, I never wear glasses or contacts	0	0.0	137	82.5	147	89.6	144	89.4	98	86.0	83	90.2	
OVERALL satisfaction with your present vision	Completely satisfied	6	3.6	59	35.5	116	70.7	128	79.5	94	82.5	79	85.9
	Very satisfied	21	12.6	79	47.6	44	26.8	31	19.3	19	16.7	11	12.0
	Somewhat satisfied	59	35.3	24	14.5	3	1.8	1	0.6	0	0.0	1	1.1
	Neither satisfied or dissatisfied	20	12.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0
	Somewhat dissatisfied	32	19.2	3	1.8	0	0.0	0	0.0	0	0.0	0	0.0
	Very dissatisfied	15	9.0	0	0.0	0	0.0	1	0.6	1	0.9	1	1.1
	Completely dissatisfied	14	8.4	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0

<sup>a</sup> At the preoperative visit, one subject marked two answers for Question 2: "Neither satisfied or dissatisfied" and "Somewhat dissatisfied"

<sup>b</sup> At the 9-month visit, one subject did not mark an answer for Question 2.

## Adverse Events and Complications

**Table 7** shows the overall percentages of eyes in the clinical study that had adverse events and complications after *iDESIGN*® system PRK treatment. A total of 27 eye adverse events (AE) were reported in 19 patients over the course of the study. The results of this study support the safety and effectiveness of *iDESIGN*® system wavefront-guided PRK treatment. During the study, the most frequently reported AEs were corneal swelling at 1 month (rate of 3%; 10/334); and all resolved by 3 months. At the stability time point of 6 months, AEs included corneal damage (haziness) beyond 6 months with loss of 2 eye chart lines or greater of best vision with glasses and decrease in best vision with glasses of greater than or equal to 2 eye chart lines not caused by irregular corneal shape (both 0.3%, 1/322; same eye), corneal damage (haziness) potentially affecting vision (0.6%, 2/322; both eyes of same patients), break in the top layer of the eye (0.3%; 1/322), and swelling in the middle of the eye (0.3%; 1/322).

A total of 11 serious AEs occurred in 10 patients:

- Four serious, adverse events determined to be unrelated to the device occurred in 4 eyes of 4 patients: retina coming away from the back of the eye (n = 1), inflammation inside the eye (n = 1), and corneal scratch (n = 2).
- Seven serious, adverse events determined to be related to the device occurred in 7 eyes of 6 patients: corneal infection (n = 2 eyes), corneal damage (haziness) (n = 3 eyes), and loss of outer layer of cornea (n = 2 eyes).

The rate of each type of serious, device-related adverse event was <1% meeting the safety target for serious, device-related AEs. One eye (0.3%, 1/322 eyes) had corneal haze beyond 6 months and lost more than 2 lines of BSCVA, meeting the safety target of <1%. Each type of serious adverse event determined by the eye doctor to be related to the device occurred in less than 1% of eyes, meeting the safety target of <1%.

The highest rates of reports of complications occurred between 1 week and 1 month after surgery. Corneal swelling was reported in 34.7% of eyes (116/334); most reports were rated as a trace amount (82.8%; 96/116). Ghosting or double images was reported by 44.3% of patients (74/167) prior to 1 month; rates decreased over time. During the study, other complications included eye pain (highest rate at 6 months: 3.4%, 11/322), feeling like something is inside the eye (highest rate at 3 months: 1.5%, 5/328), loss of outer layer of cornea (total rate of 0.9%; 3/334) and damage to the outer layer of the cornea (total rate of 0.9%; 3/334).

**Table 7 - Summary of Adverse Events and Complications Over Time**  
(Number of eyes out of total number examined at each visit, and percent of 100 eyes)

<b>Adverse Event</b>	<b>&lt;1 Month (334 total eyes)</b>	<b>1 Month (332 total eyes)</b>	<b>3 Months (328 total eyes)</b>	<b>6 Months (322 total eyes)</b>	<b>9 Months (228 total eyes)</b>	<b>12 Months (184 total eyes)</b>	<b>Cumulative<sup>a</sup> (334 total eyes)</b>
Corneal infection	2/334 (0.6%)	0/332 (0.0%)	1/328 (0.3%)	0/322 (0.0%)	0/228 (0.0%)	0/184 (0.0%)	3/334 (0.9%)
Corneal swelling at 1 month or later	n/a	10/332 (3.0%)	0/328 (0.0%)	0/322 (0.0%)	0/228 (0.0%)	0/184 (0.0%)	1/334 (0.3%)
Corneal damage (haziness) after 6 months that reduces best vision by 2 lines or more	n/a	n/a	n/a	1/322 (0.3%)	0/228 (0.0%)	0/184 (0.0%)	1/334 (0.3%)
Decreased best vision of more than 2 eye chart lines not caused by irregular cornea shape, at 3 months or later	n/a	n/a	0/328 (0.0%)	1/322 (0.3%)	0/228 (0.0%)	0/184 (0.0%)	1/334 (0.3%)
Retina lifted off the back of the eye	0/334 (0.0%)	0/332 (0.0%)	0/328 (0.0%)	0/322 (0.0%)	0/228 (0.0%)	1/184 (0.5%)	1/334 (0.3%)
<b>Any other vision-threatening event (Serious)</b>							
Corneal damage (haziness) potentially affecting vision	0/334 (0.0%)	0/332 (0.0%)	0/328 (0.0%)	2/322 (0.6%)	0/228 (0.0%)	0/184 (0.0%)	2/334 (0.6%)
Corneal scratch	0/334 (0.0%)	0/332 (0.0%)	0/328 (0.0%)	0/322 (0.0%)	0/228 (0.0%)	0/184 (0.0%)	2/334 (0.6%)
Loss of cornea's outer layer	0/334 (0.0%)	0/332 (0.0%)	0/328 (0.0%)	1/322 (0.3%)	0/228 (0.0%)	0/184 (0.0%)	2/334 (0.6%)
Inflammation inside the eye	0/334 (0.0%)	0/332 (0.0%)	0/328 (0.0%)	1/322 (0.3%)	0/228 (0.0%)	0/184 (0.0%)	1/334 (0.3%)
<b>Other adverse events (Non-serious)</b>							
Loss of cornea's outer layer	0/334 (0.0%)	0/332 (0.0%)	0/328 (0.0%)	0/322 (0.0%)	0/228 (0.0%)	0/184 (0.0%)	1/334 (0.3%)
Long term dry eye	0/334 (0.0%)	0/332 (0.0%)	0/328 (0.0%)	0/322 (0.0%)	0/228 (0.0%)	0/184 (0.0%)	2/334 (0.6%)
Headaches	0/334 (0.0%)	0/332 (0.0%)	2/328 (0.6%)	0/322 (0.0%)	0/228 (0.0%)	0/184 (0.0%)	2/334 (0.6%)
<b>Complication</b>							
Corneal swelling between 1 week and 1 month after the procedure	116/334 (34.7%)	n/a	n/a	n/a	n/a	n/a	n/a
Damage to the top layer of cells at the edge of the cornea at 1 month or later	n/a	0/332 (0.0%)	0/328 (0.0%)	1/322 (0.3%)	0/228 (0.0%)	0/184 (0.0%)	3/334 (0.9%)
Loss of cornea's outer layer at 1 month or later	n/a	0/332 (0.0%)	0/328 (0.0%)	1/322 (0.3%)	0/228 (0.0%)	0/184 (0.0%)	3/334 (0.9%)
Feeling like something is inside the eye at 1 month or later	n/a	0/332 (0.0%)	5/328 (1.5%)	2/322 (0.6%)	1/228 (0.4%)	0/184 (0.0%)	1/334 (3.0%)
Pain at 1 month or later	n/a	5/332 (1.5%)	9/328 (2.7%)	11/322 (3.4%)	1/228 (0.4%)	0/184 (0.0%)	28/334 (8.4%)
Ghosting or double images	74/334 (44.3%)	47/332 (28.3%)	15/328 (9.1%)	7/322 (4.3%)	4/228 (3.5%)	2/184 (2.2%)	96/334 (57.5%)

<sup>a</sup> Cumulative includes unscheduled visits.

## Additional Eye Evaluation Findings

The cornea was evaluated for clearness before surgery and at each visit after surgery (**Table 8**). At 6 months, most corneas were clear (90.1%; 290/322), 7.8% of eyes (25/322) had faint or trace haziness, 1.9% (6/322) of eyes had mild haziness, and 1 eye (0.3%) had moderate haziness. No eyes had dense or very dense haziness.

**Table 8 Corneal Clearness Over Time**  
(Number of eyes at each visit, and percentage of 100 eyes)

Corneal Clearness	Before Surgery 334 total eyes		1 Day After 334 total eyes		1 Week After 334 total eyes		1 Month After 332 total eyes		3 Month After 328 total eyes		6 Month After 322 total eyes		9 Month After 228 total eyes		12 Month After 184 total eyes		All Visits After 334 total eyes	
	number of eyes	%	number of eyes	%	number of eyes	%	number of eyes	%	number of eyes	%	number of eyes	%	number of eyes	%	number of eyes	%	number of eyes	%
Clear	332	99.4	321	96.1	311	93.1	295	88.9	275	83.8	290	90.1	212	93.0	176	95.7	334	100.0
Faint/ Trace Haziness	2	0.6	13	3.9	21	6.3	35	10.5	51	15.5	25	7.8	12	5.3	8	4.3	90	26.9
Mild Haziness	0	0.0	0	0.0	2	0.6	2	0.6	2	0.6	6	1.9	4	1.8	0	0.0	11	3.3
Moderate Haziness	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1 <sup>a</sup>	0.3	0	0.0	0	0.0	1	0.3
Dense Haziness	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Very Dense Haziness	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

## Effectiveness Results

### Vision Without Glasses Before and After Treatment

A letter chart was used to test the sharpness of vision (acuity). Monocular (each eye separately) and binocular vision (both eyes open to look at the chart) were tested without glasses or contact lenses over time. **Table 9** shows that 6 months after treatment, 100% of eyes separately (monocular) were able to see 20/40 or better, meeting the target of 85%, and 99% of eyes were 20/20 or better.

**Table 9- Monocular (with Single Eye Open) Vision Without Glasses Before and After Treatment** (Number of eyes at each visit, and percent of 100 eyes)

Eye Chart Line	Preoperative (334 total eyes)	1 Month (332 total eyes)	3 Month (328 total eyes)	6 Month (322 total eyes)	9 Month (228 total eyes)	12 Month (184 total eyes)
20/16 or better	0 0.0%	171 51.5%	290 88.4%	296 91.9%	208 91.2%	175 95.1%
20/20 or better	2 0.6%	265 79.8%	325 99.1%	320 99.4%	226 99.1%	184 100%
20/25 or better	3 0.9%	314 94.6%	328 100%	320 99.4%	227 99.6%	184 100%
20/40 or better	19 5.7%	328 98.8%	328 100%	322 100%	228 100%	184 100%
20/100 or better	96 28.7%	332 100%	328 100%	322 100%	228 100%	184 100%
Worse than 20/100	238 71.3%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%

**Table 10** shows that 6 months after treatment, 100% of study patients were able to see 20/20 or better with both eyes open (binocularly).

**Table 10 - Binocular (with Both Eyes Open) Vision Without Glasses Over Time** (Number of study patients at each visit, and percent of 100 patients)

Eye Chart Line	Preoperative (167 total patients)	1 Month (166 total patients)	3 Month (164 total patients)	6 Month (161 total patients)	9 Month (114 total patients)	12 Month (92 total patient)
20/16 or better	1 0.6%	128 77.1%	161 98.2%	160 99.4%	112 98.2%	92 100%
20/20 or better	3 1.8%	155 93.4%	164 100%	161 100%	114 100%	92 100%
20/25 or better	8 4.8%	165 99.4%	164 100%	161 100%	114 100%	92 100%
20/40 or better	27 16.2%	166 100%	164 100%	161 100%	114 100%	92 100%
20/100 or better	72 43.1%	166 100%	164 100%	161 100%	114 100%	92 100%
Worse than 20/100	95 56.9%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%

## Vision Without Glasses After Treatment and With Glasses Before Treatment

The study compared eye chart scores before treatment with glasses or contact lenses to the eye chart scores after treatment with no glasses or contact lenses.

**Table 11** shows the number of lines on the eye chart that patients could see (greater or fewer) after surgery without glasses compared to before surgery with glasses. At six months, 261 (81%) of the eyes saw as well as or better *without* glasses after *iDESIGN*® system PRK treatment as *with* glasses before treatment.

**Table 11 - Vision Without Glasses After Treatment Compared to Vision With Glasses Before Treatment (Number of eyes at each visit, and percent of 100 eyes)**

Eye Chart Line Change	1 Month (332 total eyes)	3 Month (328 total eyes)	6 Month (322 total eyes)	9 Month (228 total eyes)	12 Month (184 total eyes)
>2 lines better	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
2 lines better	0 0.0%	1 0.3%	5 1.6%	3 1.3%	6 3.3%
1 line better	16 4.8%	62 18.9%	88 27.3%	76 33.3%	70 38.0%
Equal	91 27.4%	197 60.1%	169 52.5%	117 51.3%	91 49.5%
1 line worse	131 39.5%	61 18.6%	55 17.1%	27 11.8%	14 7.6%
2 lines worse	56 16.9%	7 2.1%	3 0.9%	3 1.3%	3 1.6%
>2 lines worse	38 11.4%	0 0.0%	2 0.6%	2 0.9%	0 0.0%

## Accuracy and Stability of Correction

To determine the accuracy of the wavefront-guided PRK procedure with the *iDESIGN*® system, the amount of correction that was measured from patients after treatment was compared to the amount of correction they were supposed to receive. The accuracy was within  $\pm 1.00$  D of intended correction in 310 out of 322 eyes (96.3%) and within 0.50 D in 275 out of 322 eyes (85.4%) at 6 months after surgery.

Stable vision corrections for both overall nearsightedness and astigmatism were achieved at 6 months after surgery, and therefore 6 months is the key timepoint for evaluating study targets.

## Summary of Key Safety and Effectiveness Measures

All key safety and effectiveness targets were met at 6 months for the correction of nearsighted eyes with the wavefront-guided PRK procedure using the *iDESIGN*<sup>®</sup> System and *STAR S4 IR*<sup>®</sup> Excimer Laser System.

The main safety and effectiveness measures 6 months after surgery were sorted for the following patient characteristics: patient age, gender, amounts of overall nearsightedness and astigmatism before surgery. Although some measures varied by subgroup, all subgroups met the effectiveness targets. The number of safety events in any subgroup was not more than two. **Table 12** shows how the results sorted based on age. **Table 13** shows how the results sorted based on gender. **Table 14** shows how the results sorted based on overall nearsightedness, and **Table 15** shows how the results sorted based on astigmatism.

**Table 12 Key Safety and Effectiveness Measures at 6 Months Sorted by Patient Age (Number of eyes, and percent of 100 eyes)**

Study Measures	Age Group (Years)				Total (322 eyes total)
	≥18 to ≤21 (54 eyes total)	>21 to ≤25 (108 eyes total)	>25 to ≤30 (110 eyes total)	>30 to ≤47 (50 eyes total)	
Accuracy of outcome within 1/2 D	48 88.9%	81 75.0%	103 93.6%	43 86.0%	275 85.4%
Accuracy of outcome within 1.0 D	52 96.3%	99 91.7%	109 99.1%	50 100%	310 96.3%
Vision without glasses of 20/40 or Better	54 100%	108 100%	110 100%	50 100%	322 100%
Vision with glasses worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Vision with glasses more than two eye chart lines worse than before treatment	0 0.0%	0 0.0%	1 0.9%	0 0.0%	1 0.3%
Vision with glasses more than two eye chart lines worse than before treatment caused by eye haziness	0 0.0%	0 0.0%	1 0.9%	0 0.0%	1 0.3%
Increase in astigmatism more than 2.0 D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Corneal infection	0 0.0%	0 0.0%	1 0.9%	0 0.0%	1 0.3%
Loss of top layer of eye	0 0.0%	1 0.9%	1 0.9%	0 0.0%	2 0.6%
Corneal Haziness	0 0.0%	2 1.9%	1 0.9%	0 0.0%	3 0.9%

**Table 13 Key Safety and Effectiveness Measures at 6 Months  
Sorted by Gender (Number of eyes, and percent of 100 eyes)**

<b>Gender</b>			
<b>Safety/Effectiveness Measures</b>	<b>Male 222 eyes total</b>	<b>Female 100 eyes total</b>	<b>Total 322 eyes total</b>
Accuracy of outcome within 1/2 D	188 84.7%	87 87.0%	275 85.4%
Accuracy of outcome within 1.0 D	210 94.6%	100 100%	310 96.3%
Vision without glasses of 20/40 or Better	222 100%	100 100%	322 100%
Vision with glasses worse than 20/40	0 0.0%	0 0.0%	0 0.0%
Vision with glasses more than two eye chart lines worse than before treatment	1 0.5%	0 0.0%	1 0.3%
Vision with glasses more than two eye chart lines worse than before treatment caused by eye haziness	1 0.5%	0 0.0%	1 0.3%
Increase in astigmatism more than 2.0 D	0 0.0%	0 0.0%	0 0.0%
Corneal infection	1 0.5%	0 0.0%	1 0.3%
Loss of top layer of eye	1 0.5%	1 1.0%	2 0.6%
Corneal Haziness	1 0.5%	2 2.0%	3 0.9%

**Table 14 Key Safety and Effectiveness Measures at 6 Months  
Sorted by Overall Nearsightedness Before Surgery**  
(Number of eyes, and percent of 100 eyes)

Safety/Effectiveness Measures	≥-1.0 D to ≤0.0 D (5 eyes total)	≥-2.0 D to <-1.0 D (46 eyes total)	≥-3.0 D to <-2.0 D (54 eyes total)	≥-4.0 D to <-3.0 D (74 eyes total)	≥-5.0 D to <-4.0 D (36 eyes total)	≥-6.0 D to <-5.0 D (44 eyes total)	≥-7.0 D to <-6.0 D (33 eyes total)	≥-8.0 D to <-7.0 D (19eyes total)	≥-9.0 D to <-8.0 D (11 eyes total)	Total (322 eyes total)
	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %
Accuracy of outcome within 1/2 D	5 100%	46 100%	54 100%	74 100%	36 100%	44 100%	33 100%	19 100%	11 100%	322 100%
Accuracy of outcome within 1.0 D	5 100%	42 91.3%	52 96.3%	66 89.2%	36 100%	34 77.3%	22 66.7%	12 63.2%	6 54.5%	275 85.4%
Vision without glasses of 20/40 or Better	5 100%	46 100%	54 100%	73 98.6%	36 100%	39 88.6%	32 97.0%	16 84.2%	9 81.8%	310 96.3%
Vision with glasses worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Vision with glasses more than two eye chart lines worse than before treatment	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 3.0%	0 0.0%	0 0.0%	1 0.3%
Vision with glasses more than two eye chart lines worse than before treatment caused by eye haziness	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 3.0%	0 0.0%	0 0.0%	1 0.3%
Increase in astigmatism more than 2.0 D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Corneal infection	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.8%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.3%
Loss of top layer of eye	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 2.3%	1 3.0%	0 0.0%	0 0.0%	2 0.6%
Corneal Haziness	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 3.0%	0 0.0%	2 18.2%	3 0.9%

**Table 15 Key Safety and Effectiveness Measures at 6 Months  
Sorted by Overall Astigmatism Before Surgery**  
(Number of eyes, and percent of 100 eyes)

Safety/Effectiveness Measures	≥-0.5 D to ≤0.0 D (n=99)	≥-1.0 D to <-0.5 D (n=94)	≥-2.0 D to <-1.0 D (n=86)	≥-3.0 D to <-2.0 D (n=29)	≥-4.0 D to <-3.0 D (n=14)	Total (n=322)
	n %	n %	n %	n %	n %	n %
Accuracy of outcome within 1/2 D	99 100%	94 100%	86 100%	29 100%	14 100%	322 100%
Accuracy of outcome within 1.0 D	85 85.9%	85 90.4%	71 82.6%	24 82.8%	10 71.4%	275 85.4%
Vision without glasses of 20/40 or Better	97 98.0%	91 96.8%	82 95.3%	28 96.6%	12 85.7%	310 96.3%
Vision with glasses worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Vision with glasses more than two eye chart lines worse than before treatment	1 1.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.3%
Vision with glasses more than two eye chart lines worse than before treatment caused by eye haziness	1 1.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.3%
Increase in astigmatism more than 2.0 D	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Corneal infection	0 0.0%	1 1.1%	0 0.0%	0 0.0%	0 0.0%	10.3%
Loss of top layer of eye	1 1.0%	1 1.1%	0 0.0%	0 0.0%	0 0.0%	20.6%
Corneal Haziness	1 1.0%	0 0.0%	2 2.3%	0 0.0%	0 0.0%	30.9%

## SUMMARY OF IMPORTANT INFORMATION

### Please read this entire booklet before you agree to the surgery

- Before considering laser vision correction for nearsightedness you should:
  - Have a complete eye exam. It is very important to stop wearing contact lenses before the pre-surgical eye exam.
  - Talk with one or more eye care professionals about the potential risks and benefits of PRK.
- Your vision must be stable for at least one year before the **iDESIGN®** System-driven PRK treatment.
- **iDESIGN®** System-driven PRK treatments may result in some discomfort. The surgery is not risk-free.
- You will need to tolerate hazy vision and pain which may be severe in the first few days after surgery.
- During recovery your vision may be blurry preventing you from participating in your daily activities (driving, reading, computer work, etc.).
- There is a longer period for your vision to improve and to become stable when compared to LASIK.
- The **iDESIGN®** System-driven PRK treatment is a permanent operation to the cornea and cannot be reversed.
- If either your job or your recreational activities such as contact sports involve a significant risk of eye injury, PRK may be a better choice than LASIK.
- Your vision may not be perfect, and you may need to wear glasses or contact lenses for some activities even after laser vision correction.

# PATIENT ASSISTANCE INFORMATION

To be filled out by your surgeon

Patient name: \_\_\_\_\_

Date of surgery or retreatment: \_\_\_\_\_

Refractive surgeon name: \_\_\_\_\_

Surgeon phone: \_\_\_\_\_

Date of pre-operative readings: \_\_\_\_\_

Right eye pre-operative refraction: \_\_\_\_\_ sphere \_\_\_\_\_ cylinder \_\_\_\_\_ axis  
at vertex distance \_\_\_\_\_ mm

Left eye pre-operative refraction: \_\_\_\_\_ sphere \_\_\_\_\_ cylinder \_\_\_\_\_ axis  
at vertex distance \_\_\_\_\_ mm

Right eye pre-operative keratometry: \_\_\_\_\_ (D)K1 \_\_\_\_\_ (D)K2

Left eye pre-operative keratometry: \_\_\_\_\_ (D)K1 \_\_\_\_\_ (D)K2

Intended refractive outcome: \_\_\_\_\_ right eye \_\_\_\_\_ left eye

Date of post-operative readings: \_\_\_\_\_

Right eye post-operative refraction: \_\_\_\_\_ sphere \_\_\_\_\_ cylinder \_\_\_\_\_ axis

Left eye post-operative refraction: \_\_\_\_\_ sphere \_\_\_\_\_ cylinder \_\_\_\_\_ axis

## Primary Eye Care Professional

Name:

Address:

Phone:

## Laser Vision Correction Doctor

Name:

Address:

Phone:

## Treatment Location

Name:

Address:

Phone:

## Laser Manufacturer:

AMO Manufacturing USA, LLC  
510 Cottonwood Drive  
Milpitas, CA USA 95035  
1-877-266-4543 (USA)

Product of USA

*Johnson & Johnson* VISION