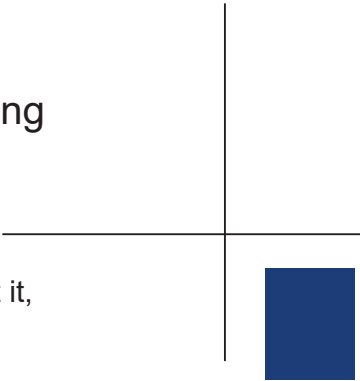


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WaveLight[®] EX500

Patient Information Booklet

Information for patients considering
INNOVEYES[™] LASIK

A decorative element in the middle right consisting of a solid blue rectangle and a black crosshair that extends to the left and upwards.

Please read this entire booklet. If you have any questions about it, discuss them with your doctor before you agree to the surgery.

Information for patients considering:

- INNOVEYES[™] LASIK surgery for reduction or elimination of myopia (**nearsightedness**) or myopia with astigmatism (**nearsightedness** with **astigmatism**) in eyes with spherical equivalent (SE) more than - 1.00 diopters (D) and up to - 9.00 D, with up to - 8.00 D of sphere component and up to - 3.00 D of astigmatic component at the spectacle plane, as shown from the **INNOVEYES[™] Sightmap Measured Refraction**,
- with magnitude of the SE difference between the Manifest Refraction and the Sightmap Measured Refraction being less than 0.75 D,
- who are 18 years of age or older, and
- who have documented evidence that their refraction did not change by more than 0.5 D during the year before the preoperative examination (**stable manifest refraction** spherical equivalent, MRSE).



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1. GLOSSARY

Ablation, Ablate	Removal of tissue with an excimer laser.
Ametropic Eye	An eye abnormality, such as nearsightedness, farsightedness, or astigmatism, resulting from faulty refractive ability of the eye.
Analgesic Medication	Pain relieving medication.
Anesthetic Eye Drops	Medication used to numb the eye.
Antibiotic Eye Drops	Medication used to prevent or treat infections of the eye.
Anti-inflammatory Eye Drops	Medication used to prevent or treat inflammation of the eye.
Astigmatism	A common vision condition that causes blurred vision. It occurs when the cornea or lens is flatter or steeper in one direction than it is in the other direction (much like the shape of a football). This results in images that are focused at two different distances from the retina. The amount of astigmatism is measured in diopters.
Autoimmune Disease	Condition in which the body attacks itself that may lead to inflammation or swelling of parts of the body. An example is multiple sclerosis.
Bandage Contact Lens	Soft contact lens temporarily used to cover the cornea after surgery.
BCDVA	Abbreviation of Best Corrected Distant Visual Acuity
Best Corrected Visual Acuity	The best vision that can be obtained with glasses or contact lenses.
BSCVA	Abbreviation of Best Spectacle Corrected Visual Acuity. Best visual acuity with glasses.
Blepharitis	An inflammation of the eyelids.
Cataract	Clouding of the lens inside the eye that may cause loss of vision.
Cataract Surgery	A procedure where the lens inside your eye that has become cloudy is removed and replaced with an artificial lens (called an intraocular lens, or IOL) to restore clear vision.
Chalazion	A chronic bump on the eyelid.

Clear Lens Exchange	Refractive surgery similar to cataract surgery where the clear lens of the eye is removed and then replaced with an artificial lens.
Collagen Vascular Disease	Condition that changes the way the body creates or processes connective tissue, like collagen. The cornea is made up of collagen. Examples are lupus or rheumatoid arthritis.
Conjunctivitis	Inflammation of the tissue covering the white part of the eye.
Cornea	The clear front surface of the eye, which bends rays of light to focus an image of objects on the retina.
Corneal Edema	Swelling of the cornea
Corneal Epithelium / Tissue	Surface cells, forming the top layer of the cornea.
Corneal Epithelial Defect	Damage in the top layer of the cornea that may result in pain or discomfort. The damage is temporary and usually heals quickly.
Corneal Erosion	When the outer layer (epithelial cells) of the cornea fail to attach to the underlying layer of the cornea (stromal tissue.)
Custom or Customized Surgery	Refractive surgery that is based on more information than just the amount of nearsightedness, farsightedness and astigmatism.
Cylinder	Value that describes the amount of astigmatism.
Diffuse Lamellar Keratitis	Inflammation under the flap.
Diopter (D)	Unit of measurement of the amount of nearsightedness, farsightedness and astigmatism of the eye.
Diffuse Lamellar Keratitis	Inflammation of the cornea underneath the flap.
Epithelial Ingrowth	A condition in which cells from the surface of the cornea (the corneal epithelium) start growing underneath the corneal flap that is produced in the LASIK procedure.
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.

Eyetracker	Device that detects and tracks the position of the eye or pupil. Such a tracker may enable laser systems to follow movements of the eye with the laser beam.
Farsightedness (Hyperopia)	A type of refractive error in which the cornea is too flat and/or the eye is too short, resulting in images that are focused behind the retina. Near objects seem blurry, distant objects may be seen more clearly than near objects, although objects in the distance may also be blurry.
FDA	Food and Drug Administration. This is the governmental agency that approves medical technology for use in the U.S.A.
Femtosecond Laser	Infrared laser that can divide corneal tissue without heat or impact to the surrounding cornea. This can be used to create a corneal flap for LASIK.
Flap	Thin slice of corneal tissue created on the surface of the cornea with a microkeratome or femtosecond laser as part of the LASIK procedure.
Floaters	Cloudy structures in the fluid in the center of the eyeball causing “floating” structures in the image.
Glaucoma	A group of diseases that cause increased pressure in the eye. This can result in vision loss by damaging the optic nerve.
Halo	Circular flares of light around bright lights in dim lighting conditions.
Haze	Cloudiness of the cornea.
Herpes Simplex	A virus that can cause cold sores and eye infections.
Herpes Zoster	A virus that can cause an infection with blisters on one side of the body.
Hordeolum	An infection of the glands at the base of the eyelashes.
Hyperopia	Medical term for farsightedness.
Immunodeficiency Disease	A condition that alters the body’s ability to fight infection. An example is AIDS.
INNOVEYES™ Sightmap Measured Refraction	The amount of refractive error measured by the INNOVEYES™ Sightmap device.

Interface	Interface layer between the flap and the remaining corneal tissue.
IOL	Artificial lens used to replace the natural lens of the eye.
Iris	The colored part of the eye, between the cornea and the lens that controls the amount of light reaching the retina by changing the size of the pupil.
Keratitis	An inflammation of the cornea.
Keratoconus	An eye disease where the normally round, dome shaped cornea becomes thin and begins to bulge into a cone-like shape.
Keratomileusis	Sculpting of the cornea by removing tissue.
Lamellar Keratitis	Inflammation under the flap.
Laser Microkeratome	Precision laser instrument used to create a flap during LASIK surgery. Also referred to as femtosecond laser.
LASIK	Laser-assisted in situ keratomileusis. Eye surgery that corrects/improves vision by reshaping the cornea after a flap is created.
Lens	A clear structure behind the iris that helps focus rays of light, or an image, on the retina.
Manifest Refraction	Subjective Refraction. Examination of these measure refractive error based on reading an eye chart.
Mechanical Microkeratome	A precision instrument that is used to create the flap during LASIK surgery.
Micron	1/1000 of a millimeter or 4/10000 inch. The symbol is "µm".
Mixed Astigmatism	A type of astigmatism in which the cornea is too flat in one direction and too steep in the other direction. This results in blurred vision, double images, or ghost images from images that are focused both in front of the retina and behind the retina.
Myopia	Medical term for nearsightedness.
Nearsightedness	A type of refractive error in which the cornea is too steep and/or the eye is too long. This results in images that are focused in front of the retina. Distant objects are blurry but near objects are clear. The amount of nearsightedness is measured in diopters.

Optic Nerve	A bundle of more than 1 million nerve fibers in the back of the eye that carry visual messages from the retina to the brain.
Optical	A term that means something to do with the ability to see. For example, glasses are an <i>optical aid</i> .
Optical Aberrations	Imperfections of the eye that cause the light to focus ineffectively onto the back of your eye, resulting in blurry images.
Optical Power	Ability of an object such as the eye to bend light rays as they pass through.
Optical Zone	Part of the treatment area in which the refractive laser treatment shall be effective.
Photorefractive Keratectomy (PRK)	A type of eye surgery that changes the curvature of the cornea. This is done by removing corneal tissue after the top layer of cells (corneal epithelium) is removed without making a flap.
Placido Imaging	Placido Topography is the classical form of mapping the surface of the cornea.
Presbyopia	A condition where, with age, the lens loses its ability to change shape and the eye slowly loses its ability to focus on near objects.
Ptosis	Drooping of the upper eye lid.
Punctate keratitis	Punctate keratitis is death of small groups of cells on the surface of the cornea (the clear layer in front of the iris and pupil). The eyes become red, watery, and sensitive to light, and vision may decrease somewhat. Most people recover fully. Symptoms can be relieved.
Pupil	The opening in the center of the iris. The iris changes the size of the pupil and controls how much light enters the eye.
Radial Keratotomy (RK)	Eye surgery that changes the curvature of the cornea by using a knife to make spoke-like cuts in the cornea.
Refractive Error	A condition of the eye that occurs when light does not focus perfectly on the retina and distant images become blurry.
Refractive Surgery	Eye surgery that aims to fix refractive errors of the eye.
Retina	The light-sensitive and color-sensitive membrane in the back of the eye that transforms light images into nerve signals.

Spherical Equivalent	An estimate of an eyes' refractive error, calculated by merging the spherical (nearsightedness or farsightedness) and cylindrical (astigmatism) components: It is the sum of spherical component (S) plus half of the cylindrical component (C).
Standard LASIK	WAVEFRONT OPTIMIZED™ LASIK refractive surgery that uses only the amount of nearsightedness, farsightedness, and/or astigmatism (refractive error) to calculate the LASIK treatment plan.
Starbursts	The appearance of rays of light coming out from lighted objects, such as car headlights
Steroids	Medications used to reduce inflammation or the body's healing response after injury or disease.
Striae	Minute groove/lines of a parallel series on the cornea.
Suction Ring	The part of the microkeratome that attaches it to the eye and holds the eye in position as the corneal flap is made.
Topography	A method of computer-assisted examination of the cornea. It creates a detailed map of the cornea and any variations in the smoothness of the cornea.
Traditional LASIK	WAVEFRONT OPTIMIZED™ LASIK refractive surgery that uses only the amount of nearsightedness, farsightedness, and/or astigmatism (refractive error) to calculate the LASIK treatment plan.
Treatment Zone	Area on the cornea where tissue is removed during laser treatment.
UCDVA	Abbreviation of Uncorrected Distant Visual Acuity
Uncorrected Visual Acuity	Vision acuity without wearing glasses or contact lenses
Visual acuity	Sharpness of vision, assessed using eye charts to measure how well you see in the distance.
Vitreous, Vitreous body	Gel-like fluid that fills the space between the lens and the retina within the eye.
Wavefront	Image of light waves. Can be used to determine errors of an eye.

Table 1: Glossary

2. INTRODUCTION

This booklet contains important information that should help you decide whether to have INNOVEYES™ LASIK to correct low to moderate **nearsightedness** with or without low **astigmatism**. With this procedure, an **excimer laser** is used to reshape the **cornea**, the clear structure at the front of the eye, by removing small amounts of tissue from the cornea. The **excimer laser** that will be used is the **WaveLight® EX500** excimer laser system.

Please read this entire booklet and ask your doctor any questions you may have. All terms printed in **bold** can be found in the glossary at the beginning of the booklet.

Please read this entire booklet before you decide to have this surgery. Your doctor can help you decide if a LASIK treatment is suitable for you. Make sure your doctor answers all your questions to your satisfaction before you agree to have a LASIK treatment.

Discuss the content of this booklet and any questions you may have with your doctor. Your doctor can help you decide if a LASIK treatment is right for you.

Contraindications, warnings and precautions of the procedure are listed in this booklet. Check with your doctor possible contraindications, warnings and precautions that may apply to you. Make sure your doctor answers all your questions to your satisfaction before you agree to have LASIK treatment.

Some occupations may have certain vision requirements that cannot be met with a refractive surgical procedure. Please check details before making the decision to have surgery.

3. COMMON VISION PROBLEMS

The human eye (see figure 1 below) is very much like a camera. The camera lens focuses light to form clear images onto film. Similarly, the **cornea** and crystalline **lens** of the eye focus light onto the **retina**, the back surface of the eye.

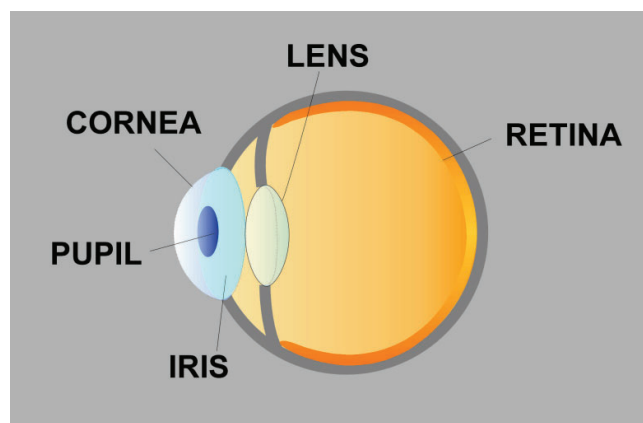


Figure 1: The Human Eye

In some people, the focusing of light doesn't occur perfectly. People encounter **refractive errors** such as **nearsightedness** and **astigmatism**.

Nearsightedness results in blurry distant vision. Light from a distant object focuses in front of the retina, rather than on the retina. As a result, images of distant objects appear blurry on the retina.

Nearsightedness is not a disease but it is a variation of the human eye that tends to be genetic. In the US, half of the people between 20 and 59 years of age are nearsighted¹. Reasons for the nearsighted condition can be that light rays focus at a point in front of the retina rather than directly on its surface, because your eye is longer than normal.

Nearsightedness also can be caused by the cornea and/or the lens inside the eye being too curved for the length of the eyeball. Sometimes the reason for nearsightedness is the combination of the two. This condition starts developing usually during childhood and stabilizes in the late teens or early adulthood.

¹ Vitale S, Ellwein L, Cotch MF, Ferris FL, Sperduto R. Prevalence of Refractive Error in the United States, 1999-2004. Arch Ophthalmol 2008;126(8):1111-1119.

Figure 2 shows that distant vision is blurry when light focuses incorrectly in nearsighted eyes.

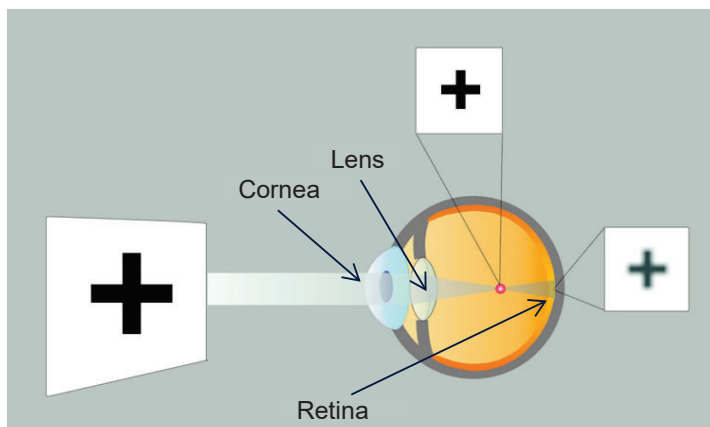


Figure 2: Nearsighted Eye Looking At A Black Cross

Astigmatism may occur alone or along with nearsightedness (myopic **astigmatism**). It causes a person to see blurry edges on some objects, but not in others. The reason for this condition is differing **optical powers** of the eye. This leads to different focal points in the eye as shown in figure 3 below. As a result, the image on the retina is blurry and distorted.

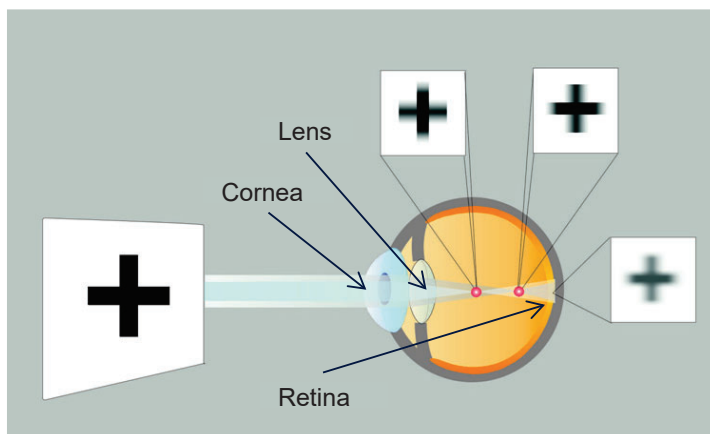


Figure 3: Nearsighted Eye With Astigmatism Looking At A Black Cross And Sending Images to The Brain.

Presbyopia is a common type of vision problem that first occurs as you age (around the age of 40). It occurs because the crystalline lens becomes stiff and is no longer able to focus light rays on the retina. Instead, the light rays become focused behind the retina. Near objects are blurred, even for eyes with perfect distance vision, and reading glasses may be required for clear near vision.

Laser-assisted in situ keratomileusis (LASIK) is a surgical procedure that uses an excimer laser to permanently change the shape of the cornea. To correct **nearsightedness**, the optical power of the eye must be decreased. Therefore, the surface of the cornea is flattened by removing tissue mainly from the center of the cornea. To correct myopic astigmatism, the eye's optical power must be reduced more in one axis than in the other axis. The cornea is flattened in the entire area of the treatment zone to achieve the spherical correction, while in a specific direction - defined by the axis of astigmatism - the surface of the cornea is flattened even further. LASIK involves the creation of a thin **flap** on the surface of the cornea to expose the part of the cornea that will be changed by the laser. The **flap** is repositioned at the end of the procedure.

4. WHAT IS THE WVELIGHT® EX500 LASER SYSTEM?

The WaveLight® EX500 laser system (see figure 4) consists of the laser and all control systems necessary for the surgeon to perform LASIK, such as control panels, monitors and a microscope. The WaveLight® EX500 laser system uses a specially shaped light beam profile and a small spot diameter to achieve the desired shape of the treated surface. The WaveLight® EX500 laser system applies very short laser light pulses which provide precision in reshaping the cornea and creates a smooth surface. This rapid delivery of multiple light pulses makes a buzzing sound when the laser operates. The system is equipped with an **eyetracker** to help ensure that it places the laser pulses in the correct position on the eye. The eyetracker will interrupt the treatment if your eye moves too much. When you are prepared for INNOVEYES™ LASIK, you will lie down on a bed. This bed is then moved under the laser and the INNOVEYES™ LASIK procedure will be started.



Figure 4: Example WaveLight® EX500 Device

5. WHAT IS INNOVEYES™ LASIK?

INNOVEYES™ or alternatively “wavelight plus” is the tradename of the software used for the surgical procedure that is used for correcting low to moderate nearsightedness with or without low astigmatism. The software for the INNOVEYES™ LASIK treatment is programmed in the WaveLight® EX500 laser system. The INNOVEYES™ LASIK treatment plan uses eye measurements captured by the INNOVEYES™ Sightmap device (figure 5) to create a treatment plan personalized for your eyes.

The INNOVEYES™ Sightmap is designed to measure the length of your eyeball, the shape of your cornea, and optical aberrations of your eye. Optical aberrations are imperfections of the eye that cause the light to focus ineffectively onto the back of your eye, resulting in blurry images. The INNOVEYES™ Sightmap device will provide an INNOVEYES™ Sightmap Measured Refraction which will be used for treatment.

A health care professional will take several measurements of your eyes with the INNOVEYES™ Sightmap. Accurate measurements are needed to produce an accurate treatment plan.



Figure 5: INNOVEYES™ Sightmap Device

6. HOW DOES INNOVEYES™ LASIK CORRECT NEARSIGHTEDNESS AND ASTIGMATISM?

INNOVEYES™ LASIK corrects nearsightedness and astigmatism by using measurements from your eye to create a personalized LASIK treatment. In the case of **nearsightedness**, the focal point of the eye falls in front of the retina. INNOVEYES™ LASIK will flatten the cornea so that light is not bent so much and the focal point moves back to the retina, creating a clear image of distant objects. With **astigmatism**, two focal points exist. To treat **astigmatism**, the shape of the cornea is changed in a way that both focal points are focused on the retina, for a clear image. INNOVEYES™ LASIK is also designed to correct optical aberrations measured by the INNOVEYES™ Sightmap device.

INNOVEYES™ LASIK does not prevent future changes in the focusing power of your eye that occurs with **presbyopia**, a condition that occurs naturally with aging. You may need to wear reading glasses after INNOVEYES™ LASIK to correct blurry near vision.

7. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Contraindications - When is it not possible to have INNOVEYES™ LASIK?

If you have any of the following situations or conditions you should NOT have INNOVEYES™ LASIK because the risk is greater than the benefit:

- you show symptoms of **severe dry eye**. INNOVEYES™ LASIK may worsen this problem, even if successfully treated before INNOVEYES™ LASIK, and increase your risk of infection and/or scarring. Symptoms of dry eye may include a scratchy or sandy feeling in the eye, stinging, burning, episodes of excessive tearing, a stringy discharge from the eye, pain, redness, eye fatigue, light sensitivity, and blurred vision. If you are not able to tolerate wearing contact lenses, this may be a sign that you have dry eyes. Make sure your INNOVEYES™ LASIK doctor checks you for dry eyes before having INNOVEYES™ LASIK.
- your corneas are too thin. If your corneas will be too thin after your doctor has cut a flap and performed the INNOVEYES™ LASIK treatment, you cannot have INNOVEYES™ LASIK. The surgeon will have to calculate if the residual stromal bed thickness is less than 250 microns. Residual stromal thickness less than 250 microns puts you at risk for a condition called ectasia.
- you are **pregnant** or **nursing**, because these conditions may cause temporary and unpredictable changes in your cornea and an INNOVEYES™ LASIK treatment would improperly change the shape of your cornea.
- you have a weakened immune system, collagen vascular, autoimmune or immunodeficiency disease, such as rheumatoid arthritis, multiple sclerosis, lupus or AIDS, and atopic syndrome such as allergic conjunctivitis, hypersensitivity, eczema, or connective tissue disease, which can cause corneal melting etc. because these conditions affect the body's ability to heal. INNOVEYES™ LASIK will increase your risk of severe damage to your cornea and vision loss.
- you have degeneration of structures of the cornea, show signs of **keratoconus** or any other condition that causes a thinning of your cornea. If you have a cone-shaped cornea (keratoconus), thinning of the bottom part of the cornea along the edges (pellucid marginal degeneration), or any other condition that may cause a thinning or bulging of your cornea, INNOVEYES™ LASIK can worsen these conditions and cause a permanent reduction in your vision. This may result in the need for additional surgery (such as a corneal transplant) after INNOVEYES™ LASIK. Your INNOVEYES™ LASIK doctor should map the shape of your cornea before INNOVEYES™ LASIK to make sure you do not have any thinning.
- you have **uncontrolled diabetes** and depend on insulin. If your blood sugar is uncontrolled, your eyeglass prescription can fluctuate and your doctor will not be able to accurately determine what degree of INNOVEYES™ LASIK treatment is appropriate. Uncontrolled diabetes can also negatively affect wound healing after INNOVEYES™ LASIK. Let your INNOVEYES™ LASIK doctor know if you have diabetes.

- you have recurrent corneal erosion. This condition can lead to serious corneal problems during and after INNOVEYES™ LASIK surgery.
- you have an **uncontrolled glaucoma**. If you have uncontrolled glaucoma, the increased eye pressure associated with cutting the INNOVEYES™ LASIK flap puts you at greater risk for loss of vision. Let your INNOVEYES™ LASIK doctor know if you have been diagnosed with glaucoma.
- You have an **active eye infection or active inflammation**. If you have an active infection or inflammation of the eye (such as keratitis, iritis, or uveitis), INNOVEYES™ LASIK will likely make your condition worse, resulting in permanent eye damage. Let your INNOVEYES™ LASIK doctor know if you are currently being treated, or if you have ever been treated, for such a condition.
- You had a **recent herpes eye infection or problems resulting from past infection**. If you have had herpes (simplex or zoster) eye infection within the past year or you have had corneal damage from prior herpes infections, you are at higher risk for further corneal damage after INNOVEYES™ LASIK. Let your INNOVEYES™ LASIK doctor know if you have ever had a herpes.

Warnings – When You Should Consider NOT Having LASIK

INNOVEYES™ LASIK is NOT recommended in patients who have any of the following conditions.

- Systemic diseases likely to affect wound **healing**. If you have a systemic disease such as a connective tissue disease, severe atopic disease, diabetes or are immunocompromised, INNOVEYES™ LASIK may be risky for you because it may affect the ability of your eyes to heal.
- History of **Herpes simplex** or **Herpes zoster** infection that has affected your eyes. If you have had a Herpes simplex or a Herpes zoster infection that affected your eyes, or have an infection now, INNOVEYES™ LASIK is more risky for you.
- Severe **allergies**. If you have severe allergies and take medicines for them, INNOVEYES™ LASIK is more risky for you.
- History of **glaucoma** or have had pressure greater than 23 mmHg inside your eyes, because it is unknown whether INNOVEYES™ LASIK is safe and effective for you.
- Taking **medications** with ocular side effects, e.g. Isotretinoin (Accutane®²) for acne treatment, because this may affect the accuracy of the INNOVEYES™ LASIK treatment or the way your cornea heals after INNOVEYES™ LASIK. This may result in poor vision after INNOVEYES™ LASIK.
- Moderate or Mild Dry Eyes. If you have dry eyes, LASIK can worsen dryness, discomfort, and blurred vision. This may or may not get better. If you take certain medications, such as nasal decongestants, you are at greater risk of having dry eyes. If you have a condition that can cause dry eye, such as thyroid disease, Sjögren's syndrome, lupus, or rheumatoid arthritis, you are also at greater risk. Make sure your doctor checks you for dry eyes before having LASIK.
- Activities that could damage the LASIK flap. The flap is corneal tissue that is cut and lifted up during LASIK and which can wrinkle, move out of place, or break off even years after surgery. Participation in contact sports, like football or martial arts, increases your risk for dislocation, or even, loss of the flap. You should discuss your work activities and hobbies with your doctor prior to surgery to help determine whether LASIK is right for you. You should ask your LASIK doctor how long you should refrain from participating in certain activities following surgery. You should also discuss with your doctor steps you can take to decrease these risks.
- Controlled Diabetes. Even if your diabetes is well controlled, you may have poor healing of your eye following LASIK.
- History of crossed eyes (strabismus). If you have a history of “crossed eyes” (strabismus), it is unknown whether INNOVEYES™ LASIK is safe and effective under this condition. You may be at an increased risk of having double vision after surgery. Tell your doctor if you have ever had “crossed eyes” or double vision.

² Accutane® is a registered trademark of Hoffmann-La Roche Inc.

- Decreased vision in one eye. If you have one eye that does not see clearly, even with glasses, you should discuss this with your doctor. This condition can be due to amblyopia, a “lazy eye,” or damage from an injury or disease. With decreased vision in one eye, complications that might result from LASIK in your better seeing eye could more severely impact your functioning.
- Epithelial basement membrane dystrophy (repeated attacks of sharp eye pain). In this condition, the outer layer of corneal cells does not stick well to the other corneal layers causing the outer cells to rub off easily. These recurring “scratches” (recurrent erosions) on the eye surface often cause blurred vision, pain, light sensitivity, and tearing. LASIK is likely to worsen this condition. Tell your doctor if you have had these symptoms in the past and ask if any signs of this condition are noted on your eye exam.
- Unreliable preoperative INNOVEYES™ Sightmap examination. INNOVEYES™ LASIK procedures require accurate and reliable data from the INNOVEYES™ Sightmap device. Inaccurate or unreliable data will lead to inaccurate treatment. Please ask your doctor if you have a reliable Sightmap exam.

Precautions:

It is unknown whether INNOVEYES™ LASIK is safe and effective for the following conditions. You should discuss these issues with your doctor.

- **Unstable** eyes that have changed by more than 0.5 diopter in nearsightedness, or astigmatism in the last 12 months, and your nearsightedness or astigmatism is getting better or worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may result in poor vision after INNOVEYES™ LASIK.
- If you have an eye **disease**, it is unknown whether INNOVEYES™ LASIK is safe and effective under this condition.
- History of **injury or surgery** to the center of the cornea (for example, surgery to correct vision such as RK, PRK, LASIK), or other surgery on the eye. If your eyes are injured or you have had surgery, it is unknown whether INNOVEYES™ LASIK will weaken the cornea too much. This may result in poor vision after INNOVEYES™ LASIK.
- **Corneal abnormality** (e.g., scar, irregular astigmatism, infection, etc.). If you have an abnormal corneal condition, such as corneal scars, because it may affect the accuracy of the INNOVEYES™ LASIK treatment or the way your cornea heals after INNOVEYES™ LASIK. This may result in poor vision after INNOVEYES™ LASIK.
- Your **corneas** are **too thin**. If your corneas are too thin to allow your doctor to cut a proper flap during the INNOVEYES™ LASIK procedure, you cannot have INNOVEYES™ LASIK because it is necessary to have a flap.
- You take **medicines** that might make it harder for wounds to heal, such as Sumatriptan succinate (Imitrex®³) used for **migraine** headaches, because it is unknown whether INNOVEYES™ LASIK is safe and effective for this condition.
- You take medications with ocular side effects, e.g. Amiodarone hydrochloride (Cordarone®⁴) for normalizing heart rhythm, because this may affect the accuracy of the INNOVEYES™ LASIK treatment or the way your cornea heals after INNOVEYES™ LASIK. This may result in poor vision after INNOVEYES™ LASIK.
- Over the **long term** (more than 12 months), because it is unknown whether INNOVEYES™ LASIK is safe and effective for periods longer than 12 months.

Over the long term (more than 12 months) because safety and effectiveness data beyond 12 months following INNOVEYES™ LASIK has not been collected. However, long-term refractive stability after LASIK is generally good for most people, but it can vary depending on individual factors.

³ Imitrex® is a registered trademark of GlaxoSmithKline Inc.

⁴ Cordarone® is a registered trademark of Wyeth Inc.

After the procedure, many patients experience stable vision for years, but there are a few considerations to keep in mind:

1) Age: As people age, their eyes naturally change, and conditions like presbyopia (the loss of near vision) or cataracts may affect vision, even after LASIK. This is more likely to occur later in life, typically in the 40s or 50s.

2) Refractive regression: Some patients may experience a slight shift in their vision months or years after the procedure, where their vision might regress towards their pre-LASIK prescription. However, this is typically minor and can sometimes be corrected with a touch-up procedure.

- **Physician Adjustments.** Your doctor may modify the INNOVEYES™-calculated ablation program in order to give you a treatment that does not fully correct distance vision. You should discuss the risks in depth with your doctor for any INNOVEYES™ LASIK corrections that do not fully correct for distance vision, especially if performed only in one eye.
- If you have a **cataract** or other problem with the lens or **vitreous** of your eye, it is unknown whether INNOVEYES™ LASIK is safe and effective under this condition.
- If you have any problems with the **iris** (colored part) of your eye or have had **previous surgery** on this part of your eye, then the eyetracker on the laser may not work properly and INNOVEYES™ LASIK may not be safe effective for you.
- **Any other medications** you are taking. Let your doctor know if you are taking prescription medicines or any medications you bought without a prescription because certain medications including **antimetabolites** may affect the ability of your eye to heal after surgery.
- **Large pupils.** Before surgery your doctor should analyze your pupil size under dim lighting conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see in conditions such as dim light, rain, fog, snow and glare from bright lights. This has been shown to occur more frequently when the entire prescription has not been fully corrected and perhaps in patients with pupil sizes larger than the treatment area.
- **Activities under poor lighting conditions.** LASIK may decrease your ability to see well in poor lighting conditions, such as in dim lighting, rain, snow, and fog, when contrast (difference in how bright an object is compared to its background) is low, or when there is glare from bright lights, especially at night. You should discuss these potential problems with your LASIK doctor. After LASIK, you should be careful while driving when you are in poor lighting conditions until you can determine whether you have any difficulties.

- **Undiagnosed dry eyes.** Your doctor should also evaluate you for dry eyes before surgery. You may have dry eyes after INNOVEYES™ LASIK surgery even if you did not have dry eyes before surgery.
- **Medical Conditions.** Your doctor should know your medical conditions. Some medical conditions might make you an unsuitable candidate for INNOVEYES™ LASIK treatment.
- If you have a decreased vision in one eye, it is unknown whether INNOVEYES™ LASIK is safe and effective under this condition.
- If there is an infection or problem with healing after the surgery, it is more likely that both eyes are affected if they are both treated at the same session.
- If only one eye is treated the difference in vision between the treated eye and the one without treatment might make vision difficult. In such a case you might not have functional vision unless the second eye is treated with INNOVEYES™ LASIK or by wearing glasses or contact lenses that compensate for the difference.
- **Family History of Thinning of the Cornea.** Eye diseases like a cone-shaped cornea (*keratoconus*), thinning of the inferior part of the cornea (*pellucid marginal degeneration*), and other conditions that may cause a thinning or bulging of the cornea can run in families. You may not be aware that you have such a condition if it is in the early stage. If you have one of these conditions and it has not been diagnosed, LASIK may cause more rapid progression of the disease. You should tell your LASIK doctor about any family history of these or any other eye problems.
- **Allergies or Eye Rubbing.** If you rub your eyes after LASIK, you are at a greater risk for dislodging the LASIK flap. This is because the strength of the attachment of the flap to the underlying corneal layers is permanently reduced after surgery. Additionally, some allergy medications cause dry eye symptoms. If you take these medicines, you are at greater risk for severe dry eye after LASIK. Tell your doctor about all your allergies and medications (even over-the-counter medications) and if you tend to rub your eyes frequently.
- **Elevated eye pressure (ocular hypertension) or being followed for possible glaucoma.** If you have either of these conditions related to eye pressure, there are several ways LASIK can cause problems for you. It is more difficult to accurately monitor your eye pressure after LASIK, which may delay the detection of glaucoma. You may be at greater risk for damage to your vision associated with cutting the LASIK flap, due to a brief but significant rise in eye pressure. Additionally, steroid drops used after surgery may raise the eye pressure and cause glaucoma to worsen. Tell your LASIK doctor if you have any of these conditions.
- **Irregular astigmatism.** Patients with irregular astigmatism may not be good candidates because of an increased risk for visual symptoms after LASIK.

8. ARE YOU A GOOD CANDIDATE FOR INNOVEYES™ LASIK?

You are a good candidate for INNOVEYES™ LASIK if you:

- Are at least 18 years of age and have nearsightedness with or without **astigmatism**
- Are **nearsighted (myopia) with or without astigmatism** with spherical equivalent more than – 1.00 diopters (D) and up to - 9.00 D, with up to - 8.00 D of sphere component and up to - 3.0 D of astigmatic component at the spectacle plane, as shown from the **INNOVEYES™ Sightmap Measured Refraction**, and with magnitude of the SE difference between the Manifest Refraction and the Sightmap Measured Refraction being less than 0.75 D.
- Have healthy eyes that are free from eye disease or corneal abnormality (e.g., scar, infection, etc.; see Contraindications)
- Have documented evidence that our refraction did not change by more than 0.5 diopters during the year before your pre-operative examination
- Are informed of risks and benefits as compared to other available treatments for nearsightedness with or without **astigmatism**
- Are able to lie flat without difficulty
- Are able to tolerate local or topical anesthesia
- Are willing to sign an informed consent form as provided by your eye care professional
- Are able to keep your eye accurately on the fixation light for the entire laser surgical procedure.

Surgical alternatives to INNOVEYES™ LASIK include other **LASIK** treatments, **Photorefractive Keratectomy (PRK)**, radial keratotomy (RK), automated lamellar keratoplasty (ALK) and Refractive lens exchange (RLE), Lenticule Extraction surgery (LE) and phakic lens implantation. Non-surgical alternatives to LASIK are wearing glasses or contact lenses.

PRK is a laser eye surgery like LASIK, but instead of creating a flap in the cornea, it removes the outer layer of the cornea (epithelium) and reshapes the underlying tissue. Benefits include no risk of flap complications and being suitable for people with thinner corneas. Risks include longer recovery time compared to LASIK (usually 3–5 days for the epithelium to heal), more discomfort and pain during the recovery period, and vision potentially being blurry for a few days to weeks after surgery.

RK is a type of eye surgery that was once commonly used to treat nearsightedness (myopia). It involves making radial incisions in the cornea to reshape it and improve vision. Although it has largely been replaced by more advanced procedures like LASIK and PRK, it is still important to understand the potential risks and benefits. Benefits include improved vision and quick recovery. Risks include fluctuating vision, under or overcorrection, corneal scarring, loss of visual acuity and weakened cornea. Additionally, the procedure is not reversible and may have post-surgical complications such as infections or issues with healing.

ALK is a surgical procedure used to correct refractive vision problems, specifically for patients with high myopia (nearsightedness) or astigmatism. In ALK, the surgeon uses an automated device to create a precise, thin flap on the cornea. Then, a portion of the underlying corneal tissue is removed to flatten the cornea. After the procedure, the flap is repositioned, and it typically heals quickly. Benefits of ALK include improved vision and a relatively quick recovery. Risks of ALK include the possibility of infection, corneal scarring, increased intraocular pressure, visual disturbances, incomplete correction and the potential need for further surgeries.

RLE is essentially cataract surgery but done to correct refractive errors (nearsightedness, farsightedness, astigmatism) rather than to remove a cataract. The natural lens is replaced with an artificial intraocular lens (IOL). This procedure is effective for people with presbyopia (age-related farsightedness) or those over 40. As with any eye surgery, there's a risk of infection, bleeding, or retinal detachment, there is also the potential for glare or halos at night with certain types of IOLs. Additionally, the procedure may not be suitable for younger individuals.

LE involves using a femtosecond laser to create a small lens-shaped piece of tissue inside the cornea, which is then removed through a tiny incision. Benefits include no flap related complications, faster recovery time and less discomfort than PRK. Risks include that it is still a relatively new procedure with less long-term data compared to LASIK.

A **phakic lens** is a surgically implanted lens placed inside the eye, between the iris and the natural lens. It is primarily used for those with high refractive errors who are not good candidates for LASIK. Benefits of phakic lenses include that the procedure is reversible, as the lens can be removed if necessary. Since the procedure does not involve reshaping the cornea it a good choice for those with thin corneas or dry eyes. The risks of phakic IOL implantation include infection or complications related to the implant, the potential for cataract formation and increased eye pressure (glaucoma).

Glasses correct vision problems such as nearsightedness, farsightedness, astigmatism, and presbyopia, allowing you to see clearly. Glasses can shield your eyes from dust, wind, and environmental factors. Some glasses have UV protection that helps guard against harmful rays. Poorly fitted glasses can cause discomfort, including pressure on the nose or ears, headaches, or irritation. Eyeglasses often fog up when transitioning between different environments. Glasses may slightly restrict peripheral vision, especially if the frames are large, affecting your field of view. Glasses can break if dropped, and lenses can get scratched over time leading to diminished visual clarity.

Benefits of **contact lenses** include improved vision and convenience. Unlike glasses, contacts will not fog up in the rain or with temperature changes, and they do not cause glare in bright lighting. Risks of contact lenses include the potential of eye infections, dry eyes, injuries or damage to the eye, decreased oxygen to the eye and the potential of allergic reactions.

9. WHAT ARE THE BENEFITS OF HAVING INNOVEYES™ LASIK?

The medical benefit of the INNOVEYES™ Sightmap is in its collection of diagnostic data and data of the optical properties of the whole eye to facilitate treatment planning for refractive surgery. The diagnostic data may be used to screen out patients that are not eligible for surgery or for planning treatment with the intent of improving outcomes with INNOVEYES™ LASIK.

INNOVEYES™ LASIK, as performed with the WaveLight® EX500 excimer laser system, is effective in reducing **nearsightedness (myopia) with or without astigmatism**, with spherical equivalent more than – 1.00 diopters (D) and up to - 9.00 D, with up to - 8.00 D of sphere component and up to - 3.00 D of astigmatic component at the spectacle plane, as shown from the **INNOVEYES™ Sightmap Measured Refraction**, and with the magnitude of the SE difference between the Manifest Refraction and the Sightmap Measured Refraction being less than 0.75 D.

10. WHAT ARE THE RISKS OF HAVING INNOVEYES™ LASIK?

The risks of INNOVEYES™ LASIK include complications that can be observed by the doctor, and those that may be directly experienced by the patient.

The risks of INNOVEYES™ LASIK that may be **observed by the doctor** include, but are not limited to, the following:

- **Loss of vision.** This means that vision becomes unclear (blurry or hazy vision) even with glasses or contact lenses. Your doctor may be able to measure this loss using a vision chart. The loss may be mild or, in rare cases, severe. In extremely rare cases, people can experience a total loss of vision. Vision loss is usually temporary, but there are complications of INNOVEYES™ LASIK that can cause permanent loss of vision. How clearly you can see may change from day-to-day or even from minute-to-minute (fluctuating vision). Some of the potential causes of vision loss following INNOVEYES™ LASIK are discussed below.
- **Corneal complications.** The following corneal complications may lead to permanent vision loss, for example, due to loss of corneal clarity from scarring or swelling, and may require corneal transplant surgery for treatment:
 - **Infection.** The cornea may get infected right after surgery. This can be treated with topical medication, which may or may not successfully control the infection. On rare occasions, an infection may cause a hole in the clear covering of the eye (perforation of the cornea).
 - **Inflammation.** Excessive inflammation is the body's reaction to tissue disruption, for example, from surgery or infection. Inflammation of the cornea can cause scarring or swelling resulting in cloudiness or haziness (loss of corneal clarity) depending on the severity and response to steroid treatment.
 - **Treatment or healing results in irregular corneal shape or loss of corneal clarity.**
 - **Bulging of the cornea** is probably the most extreme irregularity. This complication is uncommon, but can cause permanent and significantly blurry vision, sometimes requiring corneal transplant.
 - **Smaller irregularities in the shape of the cornea** can be measured by the doctor using special instruments. These can cause blurry vision or unwanted images.
- **Retinal detachment.** The retina is the light-sensitive tissue that lines the interior back of the eye and captures images transmitted to the brain, much like the film of a camera. If the retina detaches, or comes unglued from its attachments within the eyeball, it will lose its function and need to be reattached through surgery. This may result in permanent loss of vision in some instances even if the retina is successfully reattached. Retinal detachment after INNOVEYES™ LASIK is rare, and usually only occurs in people who are very nearsighted and are prone to this type of retinal problem.

- **Desired correction not achieved or doesn't last.** INNOVEYES™ LASIK may not result in the desired amount of vision correction, or the level of vision correction may decrease over time. Additional corrective surgery may not always be possible, and when it is possible may again not result in the desired correction. Even if your vision results are generally good, you may still need glasses or contact lenses to perform certain tasks, such as reading.
- **Drooping eyelid.** The lid of the eye(s) that had surgery may droop. This can be a temporary, in rare instances permanent complication from an instrument used to hold the lid during surgery. Besides the appearance of unevenness in the height of the eyelids, this may result in a feeling of the eyes getting tired during the course of the day or difficulty seeing, and may require eyelid surgery in extreme cases.

The risks of INNOVEYES™ LASIK that are directly related to the **patient's experience and perceptions** include, but are not limited to, the following:

- **Dry eyes.** INNOVEYES™ LASIK may cause or increase eye dryness, which may also cause discomfort and visual problems in severe untreated cases. The doctor may see dry spots on the normally moist portions of the cornea, or surface damage caused by dryness. These problems usually improve within 3 to 6 months, but in rare cases never go away and may require additional treatment/intervention.

If you have dry eye before surgery, INNOVEYES™ LASIK may increase dry eye symptoms and related problems after surgery. Your doctor should test you for pre-existing dry eye prior to surgery. However, even if dry eye tests before surgery are normal, there is no test to guarantee that you will not get a dry eye problem after INNOVEYES™ LASIK. Lubricating drops are usually necessary immediately after surgery to help with dryness. Symptoms of dry eye may include a scratchy or sandy feeling as if something is in the eye, stinging, burning, episodes of excessive tearing, a stringy discharge from the eye, pain, redness, light sensitivity, and blurred vision. The sensation of dryness can vary from mild to severe, but in most cases the feelings are a minor annoyance. Eye drops such as artificial tears, or other treatments, such as plugs in the tear drainage system of the eye, may reduce these symptoms, but may not completely resolve them. A small number of patients experience extreme discomfort that interferes with their ability to do daily tasks.

- **Visual Symptoms.** INNOVEYES™ LASIK may cause or worsen visual symptoms such as glare, halos, starbursts, and ghost images/double images, most commonly experienced in dim lighting conditions, and blurred and fluctuating vision. These problems usually improve within 3 to 6 months after surgery, but in some cases never go away, even when glasses are worn. Visual symptoms can be mild, but can also be severe enough to cause difficulties in performing daily tasks. **A common complaint is difficulty with driving at night.** Specific visual symptoms are described below.
 - **Glare.** Glare is *difficulty seeing well when there are bright lights like headlights or sunlight.*
 - **Halos.** You may see halos. By halos, we mean *seeing a fuzzy cloud of light around lighted objects.*
 - **Starbursts.** You may see *rays of light coming from lighted objects.*

- **Double images.** Double images, which some people call “ghost” or “shadow” images, are *distorted or blurry visual images*. If you experience such images, close one eye and then the other to determine if you only see the double images with both eyes open. If you still have double images with one eye closed, note in which eye you are experiencing the double images. This information is important to report back to your doctor to help him or her determine the cause of the problem.
- **Decreased ability to see under low lighting conditions.** You may have more difficulty seeing in low lighting conditions after surgery than before surgery. For example, some patients describe having more trouble reading the menu in a dimly lit restaurant or climbing down stairs in a theater. Driving during certain periods of the day, such as dusk and dawn, may become difficult, because of trouble reading signs, distinguishing the curb from the road, and being able to see people crossing the street. Some people have reported having so much difficulty seeing under these types of conditions that they avoid doing certain activities they used to enjoy.
- **Permanent difficulty seeing in dim lighting, rain, snow, fog, or bright glare.** Visual impairment under these conditions (seeing in dim lighting, rain, snow, fog, or bright glare) was not studied; hence it is difficult to predict the possibility and severity of visual impairment in these conditions.
- **Discomfort or pain.** It is not unusual for patients to have some discomfort right after INNOVEYES™ LASIK, but it usually goes away within a few weeks or months. Complications like dry eye, inflammation, or infection may cause severe, constant pain in some patients, preventing them from doing their normal activities.
- **Unintentional imbalance between two eyes.** INNOVEYES™ LASIK may cause a visual imbalance between the two eyes if the desired correction is not achieved, or one eye is treated with INNOVEYES™ LASIK but the other eye cannot undergo treatment. Imbalances between the two eyes may cause headaches, eyestrain, double vision, and reduced depth perception, if both eyes are not able to focus at the same time at the same distance.
- **Need for glasses for close work.** Almost all people in their 40s or older lose their ability to focus from far to near. INNOVEYES™ LASIK does not treat this condition (called “presbyopia”). After surgery, patients who are already over 40 years old (or once they reach their 40’s) usually need to wear glasses for close work, such as reading, even if they did not need to wear them before surgery.
- **intraocular infection/endophthalmitis,**
- **cataract or elevated intraocular pressure (glaucoma), and**

- corneal flap complications:
 - **Corneal flap complications.** LASIK requires the cutting of a flap of the front-most part of the cornea. The flap is swung out of the way so the laser can treat underlying tissue, and is returned to its original position after the treatment. Flap complications include irregular cutting of the flap, the flap not properly returning to its original position, the flap coming off and even getting lost, and irregular healing. If a flap complication occurs during surgery, the surgery may need to be interrupted and rescheduled. A flap complication can result in the need for additional surgery or, rarely, permanent loss of vision. In almost all LASIK cases, the strength of the flap's re-attachment to the underlying tissue is significantly and permanently weaker than before LASIK. There are reports of the flap being torn off, even many months after surgery. It may be necessary to wear protective eyewear during certain physical activities like contact sports.
- Many patients feel more comfortable with a mild degree of oral sedation before the LASIK procedure. If you receive sedation, you should not drive or operate machinery for 24 to 48 hours after surgery.
- Application of the suction ring used with the mechanical or laser microkeratome will increase the pressure inside the eye. It is very common for patients to have the vision in the eye to become dim or even temporarily completely disappear. It is felt the pressure may cause closing of small blood vessels inside the eye. Once the Suction Ring is removed and the pressure is normalized, the vessels re-open and vision fully returns. There is a concern among refractive surgeons that blood vessel closure in the eye may be permanent, although, this has never occurred. Should this occur, the result could be a permanent, partial, or even total loss of vision, which would be apparent at the time of surgery.
- An unsatisfactory flap related to the use of the microkeratome. In this case the surgeon will not perform LASIK at that time. A new flap can usually be created 3 months after the first attempt and the surgery can be completed then.
- Patients with very large pupils (larger than 6 mm) are advised of potential for negative effects of vision after LASIK surgery including glare, halos, and nighttime driving difficulties.
- The effects of the WaveLight EX500 laser device on implantable medical devices are unknown (e.g. pacemaker, insulin pump).
- Ingrowth of the corneal epithelium may first be noted within the first few weeks after surgery. LASIK involves cutting between two layers of corneal tissue. It has been observed that surface cells can grow into the space between the two layers. Although not uncommon, epithelial ingrowth is generally mild and not progressive. In most cases it is something the surgeon will observe but will not be noticeable to the patient nor will it affect their vision. In rare cases cells will continue to grow and affect vision. This will require re-opening of the flap and mechanical removal of the epithelial cells. If it is not treated epithelial ingrowth can lead to loss of the flap.

Some problems that patients experience commonly occur during the early period following INNOVEYES™ LASIK and are usually greatly reduced within 3 to 6 months. However, in some patients these problems can be permanent and, in rare cases, may impact their ability to perform daily tasks.

See the chapter 15 “Summary Of The Clinical Study Results” on page 42, to find out how often specific problems occurred in those treated with INNOVEYES™ LASIK in the study for FDA approval.

11. WHAT WILL HAPPEN BEFORE, DURING AND AFTER INNOVEYES™ LASIK?

The following section lists all issues you need to know about pre-operative, operative and postoperative procedures and care.

INNOVEYES™ LASIK can be performed on one eye at a time or on both eyes during the same surgical session if you and your doctor agree.

Before Surgery:

If you are interested in having INNOVEYES™ LASIK, you will have a complete examination of your eyes before surgery. This will determine if your eyes are healthy and suitable for the surgery.



CAUTION

- If you wear contact lenses, it is very important to stop wearing lenses before the pre-operative examination. Patients wearing soft contact lenses must stop wearing them 1 week before the preoperative examination as well as prior to surgery and patients wearing gas permeable or hard contact lenses must stop wearing lenses 3 weeks before the preoperative examination as well as prior to surgery. Failure to do so might produce poor results after surgery, as your treatment parameters cannot be determined precisely.
- Tell your doctor about medications you take. Medications you take could affect the outcome of your surgery.
- If you have any allergies, tell your doctor so you will not receive any treatment that could cause you problems with your allergies.

You should arrange for transportation since you must not drive immediately after surgery. You may resume driving only after receiving permission to do so from your doctor.

Day of Surgery:

Eat and drink according to your doctor's recommendation.



CAUTION

- Do not wear make-up at and around your eyes during the surgery since your eye area should be as clean as possible during the surgery to help avoid infection or irritation.
- Do not wear perfume or cologne during the surgery, it may interfere with the laser and result in poor vision.

At the clinic, numbing (**anesthetic eye drops**) drops will be placed into the eye that is about to-be treated. You will be asked to lie flat on your back on a cushioned bed. This bed has a special headrest with a ring cushion. The back of your head should lie properly in the ring to minimize movement of your head. If your head is properly seated in the headrest, head movement will be difficult.

The doctor will place an instrument between your eyelids to hold them open during the procedure. Your doctor may use a mechanical microkeratome or a Femtosecond Laser to create a **flap** of tissue from the upper layer of your cornea. You will feel slight pressure on your eye and your vision may get dark. Vision will reappear when your doctor removes the microkeratome. After the **flap** is created, you will be moved with the bed under the **WaveLight® EX500** excimer laser. There are red, green and white lights under the laser (see figure 6). You must continuously look at the green blinking light in the center of the laser aperture.

Your doctor will fold the flap back to expose the inner layers of your cornea. Your vision will be blurry at that time, but you should try to keep your attention on the green blinking light during the LASIK procedure.



CAUTION

- Do not let the red and white lights distract you during the INNOVEYES™ LASIK. Focus on the green blinking light only to ensure that the treatment occurs in the correct location on your eye.
- Do not move your head during the surgery to ensure that the treatment occurs in the correct location on your eye.



Figure 6: Examples Of Patients View Under The Laser (Crisp (left) And Blurred (right))

A temporary cover will be placed over the other eye for your comfort. Relax and try to keep your eye open without squinting for the whole procedure.

The eyetracker will be started and your doctor will rearrange the position of you (and your eye) for the laser treatment. Your doctor will ask you to look steadily at the green blinking light. A bright red light will flash and the laser pulses will begin. The laser will remove tiny amounts of tissue from your cornea. You will hear a buzzing sound when the laser removes tissue and you will also hear a suction noise at a close distance. Although the eyetracker will follow movements of your eye you should always keep your attention at the blinking green light throughout the treatment. If you move your eye too far, the tracker will interrupt the procedure and your doctor will remind you to focus on the green blinking light. Your doctor will use the laser for about one minute. Your entire INNOVEYES™ LASIK will take about 5-10 minutes per eye.

After the laser treatment is finished, the surgeon will fold back the flap and check the correct position. Your vision will improve immediately, but it will be blurry or cloudy.

Your doctor will then remove the device holding your eyelid. A bandage contact lens and eye drops may be applied to your eye.

Some doctors may choose to treat the second eye right away. In this case the same procedure is performed on your other eye.

The surgery is usually painless due to the use of numbing (**anesthetic**) drops. The numbing effect will fade 45 to 60 minutes after the surgery. The eye may hurt for approximately the first 4 days following the surgery. Your doctor may prescribe pain medication to make you feel more comfortable during this time

First Days after Surgery:

You will need to use eye drops after surgery. The eye drops include **antibiotics**, eye drops or oral medication for pain, ocular **steroids** and lubricant eye drops. Use each medication as directed by your doctor.

You can begin to use lotions, creams, or make-up around the eye area after the surgery as instructed by your doctor. You should wait after the surgery before participating in any sports, depending on how you feel and any instructions from your doctor. You should also avoid swimming or using hot tubs after the surgery to avoid the possibility of infection.



CAUTION

- Do NOT rub your eye during the first week after surgery even if it feels itchy. Your doctor may provide a plastic shield to protect your eye during this period. If so, you should wear the shield.
- Some possible side effects of ocular steroids are eye pressure, glaucoma or cataract. Read the patient information that comes with your medication to learn more about it.
- Your results depend upon following your doctor's directions for using all medications. Not following your doctor's directions might lead to poor treatment results.
- Severe eye pain or sudden loss of vision can be a sign of a serious problem. Contact your doctor immediately if you notice any severe pain, sudden change, or loss of vision in your eye.

If your doctor fixed an **eye patch** on your eye, your doctor or his/her staff will remove it the next day. If your doctor applied a **bandage contact lens**, your doctor will remove it when the surface of your eye has healed.

Your treated eye(s) will be mildly **sensitive to light**, and you may have the feeling that something is in your eye for the first few days. Wearing **sunglasses** should make you feel more comfortable during this time.

Your vision should become stable within the first few weeks after surgery. However, you may experience small improvement or deterioration of your vision over time. This is quite normal and may occur for up to 3 months or more after surgery.

12. WHAT SHOULD YOU ASK YOUR DOCTOR?

You may want to ask your doctor the following questions to help you decide if INNOVEYES™ LASIK is the best option for you:

- What other options are available to correct my vision?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of INNOVEYES™ LASIK for my amount of nearsightedness with or without astigmatism?
- What vision can I expect the first few months after surgery?
- If INNOVEYES™ LASIK does not correct my vision, what is the possibility that my glasses will be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after INNOVEYES™ LASIK if I need them?
- Is it likely that I will need reading glasses, as I get older?
- Will my cornea heal differently, if injured after having INNOVEYES™ LASIK?
- Should I have INNOVEYES™ LASIK in both eyes?
- How long will I have to wait until I get INNOVEYES™ LASIK on the second eye?
- What vision problems may I experience, if I have INNOVEYES™ LASIK only on one eye?

You should discuss the cost of surgery and follow-up care with your doctor. Most health insurance policies do not cover **refractive surgery**.

13. SUMMARY OF IMPORTANT INFORMATION

- INNOVEYES™ LASIK is a permanent operation to the cornea and cannot be reversed.
- INNOVEYES™ LASIK involves the use of a laser to permanently remove corneal tissue to correct low to moderate nearsightedness with or without low astigmatism.
- INNOVEYES™ LASIK may not eliminate the need for glasses or contact lenses. In addition, you may need reading glasses, even if you did not wear them prior to the INNOVEYES™ LASIK.
- Some alternatives to INNOVEYES™ surgery include, but are not limited to glasses, contact lenses and LASIK.
- Your vision must be stable at least one year before the pre-op examination to be eligible for INNOVEYES™ LASIK. You will need written evidence that your nearsightedness and astigmatism have changed only 0.5 diopters or less.
- Pregnant or nursing women do not qualify for INNOVEYES™ LASIK.
- You are not a good candidate for INNOVEYES™ LASIK if you have a **collagen vascular disease** (such as rheumatoid arthritis) or **autoimmune disease** (such as lupus) or have a condition that makes wound healing difficult.
- INNOVEYES™ LASIK may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery.
- Before considering INNOVEYES™ LASIK, you should
 - a) Have a complete eye exam.
 - b) Have your eye(s) measured with the INNOVEYES™ Sightmap device.
 - c) Talk with one or more eye care professionals about the potential benefits, risks and complications of INNOVEYES™ LASIK. You should also discuss the time needed for healing, the discomfort you may experience or problems that may occur during this time.
- A potential benefit of INNOVEYES™ LASIK is to have normal vision (20/20 visual acuity) without glasses after surgery. Your nearsightedness with or without astigmatism may not be fully corrected and you may still need to wear glasses or contact lenses. In addition, you may need reading glasses, even if you did not wear them prior to the INNOVEYES™ LASIK.
- The risks of INNOVEYES™ LASIK include corneal **haze**, dry eye, glare, halos, starbursts, eye pain, burning feeling in eyes, eyes sensitive to light, blurry vision, fluctuation of vision, difficulty focusing in dim or low light, watery eyes and feeling like something is in your eyes. Corneal infiltrates and corneal edema are also possible risks but occur very infrequently.
- Refer to chapter 10 “What Are The Risks Of Having INNOVEYES™ LASIK?” for a description of other risks including, but not limited to, loss of vision, corneal or intraocular infection, corneal bulging or irregular shape, retinal detachment, incomplete correction, drooping eyelid, double images, and difficulty seeing in dim lighting, rain, snow, fog, or bright glare.

14. FREQUENTLY ASKED QUESTIONS

Is INNOVEYES™ LASIK treatment permanent?

- The portion of your cornea removed by INNOVEYES™ LASIK does not regrow at this layer of your cornea.
- The level of vision correction may decrease over time; the effectiveness of INNOVEYES™ LASIK with WaveLight® EX500 beyond 12 months has not been investigated.

Will I be able to see sharply at a distance (visual acuity) without glasses after INNOVEYES™ LASIK?

The goal of INNOVEYES™ LASIK in the correction of low to moderate nearsightedness with or without low astigmatism is to reduce or eliminate the need for glasses or contact lenses to see at distance. In the clinical study of the WaveLight® EX500 Laser System using INNOVEYES™ LASIK for nearsightedness with or without **astigmatism**, 94.4% of eyes had normal vision (visual acuity of 20/20 or better) without glasses one year after surgery. There is a chance that your nearsightedness with or without **astigmatism** may not be fully eliminated and you may need to wear glasses or contact lenses to see sharply at distance.

Will I need reading glasses after INNOVEYES™ LASIK?

You may need to wear reading glasses after INNOVEYES™ LASIK to correct presbyopia even though you did not need to wear reading glasses before INNOVEYES™ LASIK. INNOVEYES™ LASIK does not prevent future changes in the focusing power of your eye that occurs with presbyopia, a condition that occurs naturally due to aging.

Will my vision be perfect after INNOVEYES™ LASIK?

As with any surgical procedure, there are risks associated with INNOVEYES™ LASIK. Below are some conditions that may prevent you from having perfect vision after the INNOVEYES™ LASIK:

- It is not possible to predict how your eyes will respond to the treatment. Your eye may be either undercorrected or overcorrected after the surgery. A mild degree of either may be perfectly well tolerated. If the result of the surgery is not satisfactory, you may need to wear glasses or contact lenses. In the clinical study, three (0.9%) eyes were overcorrected by more than 1 diopter and two (0.6%) eyes were undercorrected by more than 1 diopter. No eyes were over- or undercorrected by more than two diopters.
- A special type of astigmatism - known as irregular astigmatism - may occur after INNOVEYES™ LASIK that may affect your vision. In this condition, the cornea does not heal smoothly and you may need to wear hard (gas permeable) contact lenses to achieve best vision. Irregular astigmatism may lessen over several weeks or months.
- Glare, halos and starbursts are not uncommon after INNOVEYES™ LASIK. As seen in the clinical study, in most patients, these symptoms are mild and will lessen over time. In rare cases they may be severe and last long enough to require the use of eye drops to reduce the size of the eye's pupil. Glare and halos may interfere with night driving.
- Infection of the eye is a potential complication following INNOVEYES™ LASIK that could lead to vision problems. Potential consequences of corneal infections include corneal scarring, corneal perforation and spread of the infection inside the eye. Any of these conditions, if severe enough, may result in partial loss of vision or even blindness. A potentially lengthy course of treatment may be necessary. Potential consequences of corneal infections include corneal scarring, corneal perforation and spread of the infection inside the eye. Any of these conditions, if severe enough, may result in partial loss of vision or even blindness.
- **Cataracts**, which may affect your vision, could form because of the long term use of steroids after the INNOVEYES™ procedure.
- You may need reading glasses, even if you did not wear them before the surgery. This will occur due to the normal aging process called presbyopia. If you are in the presbyopic age range, any method to correct your nearsightedness will likely necessitate the need for reading glasses.
- Diffuse haziness (lamellar keratitis) in the corneal flap bed (typically at 1 to 3 days after surgery) occurs in 1 of 1000 eyes. Treatment involves steroid-type eye drops. In some cases the surgeon might have to lift the flap again.
- Intraocular pressure of the eye may rise, possibly due to prescribed medication to reduce swelling (inflammation) or diffuse lamellar keratitis. The increased pressure usually does not cause noticeable symptoms. A severe increase in pressure may cause pain or nausea.

What risks are associated with the surgical procedure?

A summary of the risks as observed in the clinical study are described in chapter 10 "What Are The Risks Of Having INNOVEYES™ LASIK?" on page 27.

Should I have both eyes treated during the same session?

You and your surgeon must decide whether to treat the second eye immediately after the first eye or at a later date. Even if you decide to have both eyes treated at the same time, it is the doctor's decision at the time of surgery whether this will actually occur.

- If there is an infection or problem with healing after the surgery, it is more likely that both eyes are affected if they are both treated at the same session.
- If only one eye is treated, the difference in vision between the treated eye and the one without treatment might make vision difficult. In such a case you might not have functional vision unless the second eye is treated with INNOVEYES™ LASIK or by wearing glasses or contact lenses that compensate for the difference.

15. SUMMARY OF THE CLINAL STUDY RESULTS

Clinical Study Information:

A clinical study was conducted at 9 clinical sites in the US to evaluate the benefits and risks of the WaveLight® EX500 excimer laser system used for INNOVEYES™ LASIK. A total of 336 eyes from 168 patients with low to moderate **nearsightedness**, with or without low **astigmatism** had INNOVEYES™ LASIK. Assessments performed during the study included distance vision testing with and without glasses, measurement of the errors of the eye, evaluation of the health of the eyes patients. Study visits occurred before and after INNOVEYES™ LASIK at scheduled times up to 12 months. The results are shown in percentages, which is the number of people out of 100 who experienced the symptom.

Patients who agreed to be involved in the clinical study provided informed consent and completed the required screening procedures to determine study eligibility. Patients had at least one eye with nearsightedness up to - 8.00 diopters with or without **astigmatism** of up to - 3.00 diopters.

The results of the study showed that it takes 3 months for the eye to be stable after INNOVEYES™ LASIK for low to moderate **nearsightedness** with or without low **astigmatism**.

Clinical Study Results:

Vision without Glasses after INNOVEYES™ LASIK

The doctors in the clinical study measured distance vision without glasses (**uncorrected distance visual acuity** [UCDVA]) before and after INNOVEYES™ LASIK.

Three months after INNOVEYES™ LASIK, UCDVA was as follows:

- 326 of 326 (100%) eyes tested had UCDVA of 20/40 or better.
- 301 of 326 (92.3%) eyes tested had UCDVA of 20/20 or better.
- 218 of 326 (66.9%) eyes tested had UCDVA of 20/16 or better.

The UCDVA results at 3 months were consistent with the results at 12 months.

Vision Without Glasses after INNOVEYES™ LASIK Compared to Vision With Glasses Before INNOVEYES™ LASIK

How well patients were able to see distance without glasses after INNOVEYES™ LASIK compared to their vision with glasses before INNOVEYES™ LASIK is presented below. At 3 months after INNOVEYES™ LASIK:

- 278 of the 326 (85.3%) of eyes tested had vision without glasses that was equal to or better than their vision with glasses prior to INNOVEYES™ LASIK.

The doctors in the clinical study evaluated the risks of having INNOVEYES™ LASIK by measuring distance vision with glasses (**best corrected distance visual acuity** [BCDVA]) and **astigmatism** before and after INNOVEYES™ LASIK for low to moderate nearsightedness with or without low **astigmatism**.

Vision with Glasses after INNOVEYES™ LASIK

At 3 months after INNOVEYES™ LASIK:

- None of the eyes had vision with glasses that was worse than 20/40.
- None of the eyes lost 2 or more lines of vision with glasses compared to before INNOVEYES™ LASIK.
- None of the eyes had induced astigmatism of greater than 2 D as compared to before INNOVEYES™ LASIK.

The BCDVA results at 3 months were consistent with the results at 6 months.

Adverse Events:

An adverse event is defined as unexpected medical occurrence, unintended disease or injury, or unexpected clinical signs whether or not related to INNOVEYES™ LASIK or the WaveLight® EX500 excimer laser system.

Adverse events were classified as serious and non-serious depending on how they affected the patient's health. No unanticipated adverse events were observed in this study.

All adverse events reported by the doctor are listed below.

11 eyes with corneal flap complication	2 eyes with had retinal laser coagulation
4 eyes with blepharitis	2 eyes had retinal tears
3 eyes with conjunctivitis	2 eyes had blurred vision
3 eyes with allergic conjunctivitis	1 eye had an abscess drainage
3 eyes with corneal operation	1 eye had an abscess of the eyelid
3 eyes with diffuse lamellar keratitis	1 eye had a chalazion
3 eyes with dry eye	1 eye chorioretinal atrophy
3 eyes with punctate keratitis	1 eye had a corneal abrasion
3 eyes with reduced visual acuity	1 eye with corneal disorder
2 eyes with corneal opacity	1 eye had a hordeolum
2 eyes with allergy	1 eye with vitreous disorder
2 eyes with needed punctal plug insertion	

Bolded words can be found in the glossary

Five adverse events from the list above were classified as serious (Serious Adverse Event SAE). These events occurred in four eyes of three patients:

- 2 events occurred in both eyes of one patient who had retinal tears at approximately 167 days after INNOVEYES™ LASIK. The eyes were treated with **retinal laser coagulation**.
- 1 event of corneal opacity occurred at 213 days after INNOVEYES™ LASIK followed by 1 event of **visual acuity** reduced at 250 days after INNOVEYES™ LASIK in the same eye. This eye recovered with treatment.
- 1 event of **visual acuity** reduced at 336 days after INNOVEYES™ LASIK due to dry eye. This eye recovered without treatment.

These 5 events were reported as unrelated to the WaveLight® EX500 excimer laser or the INNOVEYES™ LASIK procedure and all patients recovered.

Contrast sensitivity (the ability to see objects that may not be outlined clearly or that do not stand out from their background) is usually tested under dim lights with and without a source of glare. Below are the results of contrast sensitivity for patients in the study:

- At 3 months after INNOVEYES™ LASIK:
 - 132 out of 330 (40.0%) eyes had clinically meaningful increase in contrast sensitivity in dim light with a glare source
 - 83 of 330 (25.2%) eyes had clinically meaningful increase in contrast sensitivity in dim light without a glare source
 - 52 out of 330 (15.8%) eyes had clinically meaningful decrease in significantly worse contrast sensitivity in dim light with a glare source
 - 33 of 330 (10.0%) eyes had clinically meaningful decrease in contrast sensitivity in dim light without a glare source
 - 147 out of 330 (44.5%) eyes had no significant change in contrast sensitivity in dim light with a glare source
 - 216 of 330 (65.5%) eyes had no significant change in contrast sensitivity in dim light without a glare source

Patient reported outcomes:

Visual disturbances, eye symptoms and satisfaction with the surgery were assessed based on patients' responses to a questionnaire that evaluates symptoms associated with INNOVEYES™ LASIK. The questionnaire is called the Patient Reported Outcomes with LASIK (PROWL). The rates shown below are based on responses at 12 months.

Reported Visual Symptoms	Patient Responses from PROWL
Double Image	• 4 out of 163 (2.5%) patients who completed the PROWL at 12 months reported Double Image. • 71 out of 74 (95.9%) patients who reported Double Image before the procedure reported the symptom to be resolved at 12 months. • 1 out of 88 (1.1%) patients who completed the PROWL at 12 months developed Double Images.
Glare	• 22 out of 163 (13.5%) patients who completed the PROWL at 12 months reported Glare. • 57 out of 76 (75.0%) patients who reported Glare before the procedure reported the symptom to be resolved at 12 months. • 3 out of 86 (2.5%) patients who completed the PROWL at 12 months developed Glare.
Halos	• 39 out of 163 (23.9%) patients who completed the PROWL at 12 months reported Halos. • 58 out of 90 (64.4%) patients who reported Halos before the procedure reported the symptom to be resolved at 12 months. • 7 out of 72 (9.7%) patients who completed the PROWL at 12 months developed Halos.
Starbursts	• 49 out of 163 (30.1%) patients who completed the PROWL at 12 months reported Starbursts. • 66 out of 107 (61.7%) patients who reported Starbursts before the procedure reported the symptom to be resolved at 12 months. • 8 out of 55 (14.5%) patients who completed the PROWL at 12 months developed Starbursts.

The PROWL questionnaire also collected data on dry eye symptoms using the Ocular Surface Disease Index (OSDI). At 12 months of 163 patients, 133 (81.6%) did not report dry eye symptoms, 7 (4.3%) reported moderate dry eye symptoms, and 2 (1.2%) reported severe dry eye symptoms.

Questions to evaluate the study patients self-reported satisfaction with the INNOVEYES™ LASIK procedure were also included. At one year following INNOVEYES™ LASIK of the 163 patients who were polled:

- Most patients were either very satisfied (30, 18.4%) or completely satisfied (129, 79.1%) with their vision. Some patients (4, 2.4%) were somewhat satisfied with their vision.
- Preoperatively, 2 (1.2%) patients reported not using glasses or contact lenses for vision in a typical day; following INNOVEYES™ LASIK, 149 (91.4%) patients reported not using glasses or contacts lenses.
- Of the 161 patients who drove, 158 (98.1%) reported no difficulty and 3 (1.9%) reported little difficulty in driving during the daytime in familiar places. Throughout the postoperative period, no patients reported giving up driving due to their vision.

16. PATIENTS SELF TEST

Are you an informed and educated patient?

Take the test below and see if you can correctly answer the questions after reading this booklet.

	TRUE	FALSE
a) INNOVEYES™ LASIK is a permanent procedure.	☐	☐
b) INNOVEYES™ LASIK is free of risks.	☐	☐
c) It doesn't matter if I wear my contact lenses when my doctor told me not to wear them.	☐	☐
d) I may need reading glasses after INNOVEYES™ LASIK.	☐	☐
e) There is a risk that I may lose some vision after INNOVEYES™ LASIK.	☐	☐
f) It's ok to have INNOVEYES™ LASIK if I am pregnant.	☐	☐
g) It matters if I take medication with ocular or healing side effects like Cordarone®, Imitrex® or Accutane®.	☐	☐
h) After surgery there is a very good chance that I am less dependent on eye glasses.	☐	☐
i) Since the WaveLight® EX500 uses an eyetracker, I do not have to fixate the blinking light during laser treatment.	☐	☐
j) Even if my refraction was changing a lot over the last year, I am still a good candidate for INNOVEYES™ LASIK.	☐	☐

You can find the answers in chapter 18 "Answers To Self-Test Questions" on page 49.

17. WHERE CAN YOU GET MORE INFORMATION?**Primary Eye Care Professional:**

Name:
Address:
Phone:
Email:

INNOVEYES™ Doctor:

Name:
Address:
Phone:
Email:

Treatment Location:

Name:
Address:
Phone:

Laser Manufacturer:**Legal Manufacturer:**

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134 U.S.A.
Telephone: 800-TO-ALCON
(800-862-5266)
Internet: ALCON.COM

Manufacturing Site:

WaveLight GmbH
Am Wolfsmantel 5
91058 Erlangen
Germany

18. ANSWERS TO SELF-TEST QUESTIONS

- a) True (see page 38 and page 39)
- b) False (see page 27, page 38 and page 41)
- c) False (see page 32)
- d) True (see page 39 and page 40)
- e) True (see page 40 and page 42)
- f) False (see page 38)
- g) True (see page 32)
- h) True (see page 26, page 38 and page 39)
- i) False (see pages 33-34)
- j) False (see page 38)

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- End -
