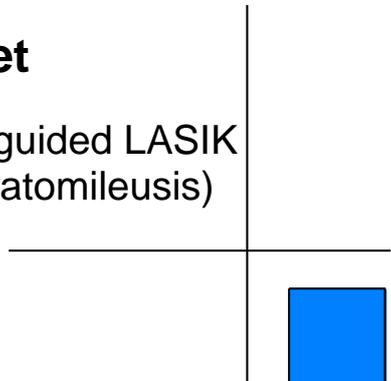


# **ALLEGRETTO WAVE EYE-Q**

**Scanning Spot LASIK Laser System**

## **Patient Information Booklet**

Facts You Need to Know About Topography-guided LASIK  
Laser Treatment (Laser Assisted In Situ-Keratomileusis)



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

The WaveLight ALLEGRETTO WAVE<sup>®</sup> Eye-Q Excimer Laser System, when used with the WaveLight ALLEGRO Topolyzer (topographer) and T-CAT treatment planning software, is indicated for performing topography-guided laser assisted in-situ keratomileusis (Topo-guided LASIK):

- for the reduction or elimination of up to -9.00 diopters (D) of nearsightedness with astigmatism, up to -8.00 D of nearsightedness, and up to -3.00 D of astigmatism;
- in patients who are 18 years of age or older; and
- in patients whose amount of nearsightedness with or without astigmatism has changed by 0.50 D or less in the year before surgery.

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## 1. GLOSSARY

<b>Ablation</b>	Removal of tissue with an excimer laser.
<b>ALLEGRETTO WAVE® EYE-Q Laser System</b>	Trade name for modern, high speed excimer laser system with eye-tracker for treatment of refractive errors, manufactured by WaveLight GmbH in Germany.
<b>ALLEGRO Topolyzer</b>	Trade name for a topographer device, manufactured by WaveLight GmbH in Germany.
<b>Anesthetic Eye Drops</b>	Medication used to numb the eye.
<b>Antibiotic Eye Drops</b>	Medication used to prevent or treat infections of the eye.
<b>Anti-inflammatory Eye Drops</b>	Medication used to prevent or treat inflammation of the eye.
<b>Astigmatism</b>	A type of refractive error occurring 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), resulting in images that are focused at two different distances from the retina. The amount of astigmatism is measured in diopters.
<b>Autoimmune Disease</b>	Condition in which the body attacks itself that may lead to inflammation or swelling of parts of the body. An example is multiple sclerosis.
<b>Bandage Contact Lens</b>	Soft contact lens temporarily used to cover the cornea after surgery.
<b>Best Corrected Visual Acuity</b>	The best vision that can be obtained with glasses.
<b>Cataract</b>	Clouding of the lens inside the eye that may cause loss of vision.
<b>Collagen Vascular Disease</b>	Condition that alters the way the body creates or metabolizes connective tissue, like collagen. The cornea is made up of collagen. Examples are lupus or rheumatoid arthritis.
<b>Cornea</b>	The clear front surface of the eye, which bends rays of light to focus an image of objects on the retina.
<b>Custom or Customized Surgery</b>	Refractive surgery that is based on more information than just the amount of nearsightedness, farsightedness, and astigmatism.
<b>Diffuse Lamellar Keratitis</b>	Inflammation under the flap.

<b>Diopter</b>	Unit used to measure the amount of nearsightedness, farsightedness and astigmatism. Nearsightedness is measured in terms of negative diopters. Farsightedness is measured in terms of positive diopters. Astigmatism can be measured in either positive or negative diopters.
<b>Epithelial Ingrowth</b>	A condition in which cells from the surface of the cornea (the corneal epithelium) start growing underneath the corneal flap that's produced in the LASIK procedure.
<b>Excimer Laser</b>	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.
<b>Eye-tracker</b>	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.
<b>Farsightedness (Hyperopia)</b>	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.
<b>FDA</b>	Food and Drug Administration. This is the governmental agency that approves medical technology for use in the U.S.A.
<b>Femtosecond Laser</b>	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.
<b>Flap</b>	Thin slice of corneal tissue created on the surface of the cornea with a microkeratome or femtosecond laser as part of the LASIK procedure.
<b>Glaucoma</b>	A group of diseases that cause increased pressure in the eye, and can result in vision loss by damaging the optic nerve.
<b>Halo</b>	Circular flares of light around bright lights in dim lighting conditions.
<b>Haze</b>	Cloudiness of the cornea.
<b>Herpes Simplex</b>	A virus that can cause cold sores and eye infections.
<b>Herpes Zoster</b>	A virus that can cause an infection with blisters on one side of the body.
<b>Hyperopia</b>	Medical term for farsightedness.
<b>Immunodeficiency Disease</b>	A condition that alters the body's ability to fight infection. An example is AIDS.

<b>Iris</b>	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.
<b>Keratoconus</b>	Condition of the cornea that results in progressive thinning and steeping of the cornea with a reduction in visual acuity.
<b>Keratomileusis</b>	Sculpting of the cornea by removing tissue.
<b>Laser in-situ Keratomileusis (LASIK)</b>	Refractive surgery that changes corneal curvature by removing corneal tissue beneath a flap.
<b>Laser Microkeratome</b>	Precision laser instrument used to create a flap during LASIK surgery. Also referred to as femtosecond laser.
<b>LASIK</b>	Acronym for laser in-situ keratomileusis.
<b>Lens</b>	A clear structure behind the iris that helps focus rays of light, or an image, on the retina.
<b>Mechanical Microkeratome</b>	A precision instrument that is used to create the flap during LASIK surgery.
<b>Mixed Astigmatism</b>	A type of astigmatism in which the cornea is too flat in one direction and too steep in the other direction, resulting in blurred vision, double images, or ghost images from images that are focused both in front of the retina and behind the retina.
<b>Myopia</b>	Medical term for nearsightedness.
<b>Nearsightedness (Myopia)</b>	A type of refractive error in which the cornea is too steep and/or the eye is too long, resulting 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.
<b>Optic Nerve</b>	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.
<b>Optical</b>	Of or pertaining to sight; applying optics or the principles of optics to assist sight or correct vision. Optics is the branch of science that deals with light and vision.
<b>Photorefractive Keratectomy (PRK)</b>	Refractive surgery that changes corneal curvature by removing corneal tissue after the top layer of cells (corneal epithelium) is removed without making a flap.
<b>Presbyopia</b>	A condition where, with age, the lens loses its ability to change shape and the eye exhibits a progressively diminished ability to focus on near objects.
<b>PRK</b>	Acronym for photorefractive keratectomy.

<b>Ptosis</b>	Drooping of the upper eye lid.
<b>Pupil</b>	The opening in the center of the iris. The iris changes the size of the pupil and controls how much light enters the eye.
<b>Radial Keratotomy (RK)</b>	Refractive surgery that changes corneal curvature by using a knife to make pie-shaped cuts in the cornea.
<b>Refractive Error</b>	A condition of the eye that occurs when light does not focus perfectly on the retina and distant images become blurry.
<b>Refractive Surgery</b>	Eye surgery that aims to change the shape of the cornea permanently to correct refractive errors. This change in eye shape restores the focusing power of the eye by allowing the light rays to focus precisely on the retina for improved vision.
<b>Retina</b>	The light-sensitive and color-sensitive membrane inside the eye that transforms light images into nerve signals.
<b>RK</b>	Acronym for radial keratotomy.
<b>Standard LASIK</b>	LASIK refractive surgery that uses only the amount of nearsightedness, farsightedness, and/or astigmatism (refractive error) to calculate the LASIK treatment plan.
<b>Steroids</b>	Medications used to reduce inflammation or the body's healing response after injury or disease.
<b>Suction Ring</b>	The part of the microkeratome that attaches it to the eye and holds the eye in position as the corneal flap is made.
<b>T-CAT</b>	Acronym for topography-guided custom ablation treatment. Topo-guided (T-CAT) LASIK is the trade name for the topography-guided LASIK procedure performed with the ALLEGRETTO WAVE® Eye-Q Excimer laser system, the T-CAT software, and the topography from the ALLEGRO Topolyzer topographer.
<b>Topography</b>	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.
<b>Topography-guided (Topo-guided) LASIK</b>	LASIK treatment based on topographic measurements.
<b>Topographer</b>	The diagnostic measurement device designed to perform topography measurements and topography maps.
<b>Traditional LASIK</b>	LASIK refractive surgery that uses the amount of nearsightedness, farsightedness, and/or astigmatism to calculate the LASIK treatment plan.
<b>Vitreous</b>	Gel-like fluid that fills the inside of the eye.



**Wavefront Optimized  
LASIK**

The trade name for LASIK that is performed with the ALLEGRETTO WAVE® Eye-Q Excimer laser system. This procedure uses the amount of nearsightedness, farsightedness, and/or astigmatism and some corneal shape information to calculate the LASIK treatment plan.

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## 2. INTRODUCTION

Please read this entire booklet before you decide to have this surgery. Your doctor can help you decide if a Topo-guided LASIK treatment is suitable for you. Make sure your doctor answers all your questions to your satisfaction before you agree to have Topo-guided LASIK treatment. All terms printed in bold can be found in the glossary at the beginning of the booklet. The glossary defines each of these terms for you.

Some occupations may have certain vision requirements that cannot be met with a refractive surgical procedure. Some jobs in the military (e.g. aviation pilots, deep sea divers) and some other professions may not be available if you have **refractive surgery**, including Topo-guided LASIK. Check with your employer or military for any job-related requirements that apply to you before you have LASIK surgery.

This booklet contains important information that should help you decide whether to have **topography-guided LASIK (Topo-guided LASIK)** surgery to correct your **nearsightedness** or nearsightedness with **astigmatism**. **LASIK** stands for **Laser *in situ* Keratomileusis**. In topography-guided LASIK, detailed information obtained from the shape (**topography**) of your **cornea** is used to help plan the LASIK treatment. Topography-guided LASIK that is performed with the **ALLEGRETTO WAVE® Eye-Q Excimer Laser** is also known as Topo-guided LASIK or **T-CAT**. T-CAT is an abbreviation for Topography-guided **Custom Ablation** Treatment.

Your doctor can perform Topo-guided LASIK with the ALLEGRETTO WAVE® EYE-Q Excimer Laser System to help eliminate or reduce your nearsightedness and astigmatism. After treatment, you may no longer need to wear glasses or contact lenses for seeing at a distance.

### 3. COMMON VISION PROBLEMS

The human eye, shown in Figure 1 below, is very much like a camera, shown in Figure 2. Light enters the eye through the **cornea** (clear front covering of the eye) and the **pupil** (opening of the eye) and then passes through the **lens**. The cornea and lens work together to bend rays of light and focus an image on the **retina**, the back surface of the eye, in the same way that a camera lens focuses light to form a clear image onto film.

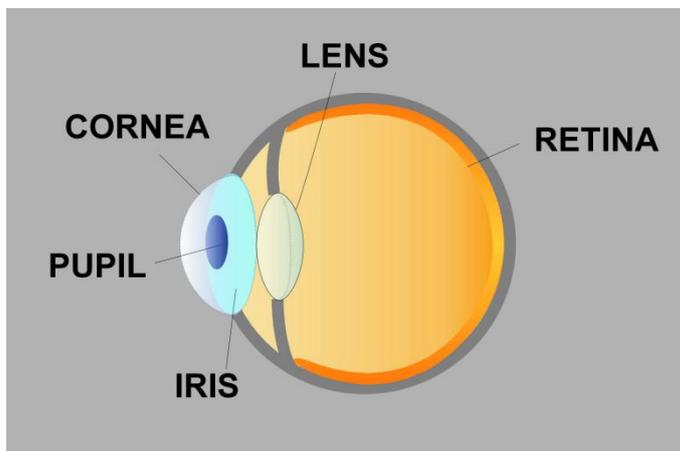


Figure 1: The Human Eye

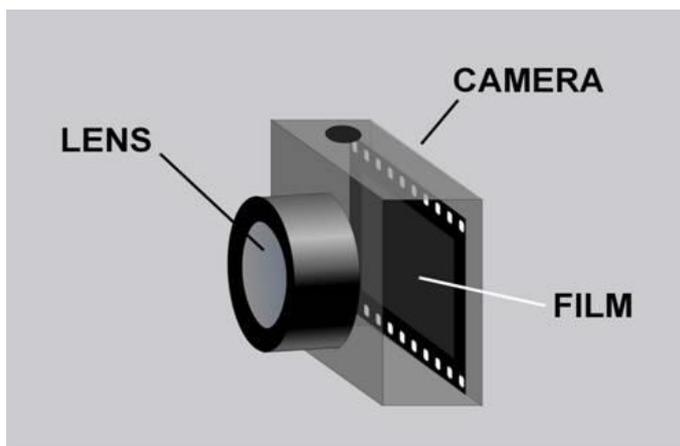


Figure 2: Camera

A **refractive error** is a common vision problem that occurs when light does not focus perfectly on the retina. There are three types of refractive errors:

(1) **nearsightedness**, (2) **farsightedness**, and (3) **astigmatism**.

Nearsightedness (**myopia**) is a type of focusing error that results when light focuses in front of the retina, rather than on the retina, as shown in Figure 3 below. A nearsighted eye can see close objects clearly, but objects farther away in the distance are blurry.

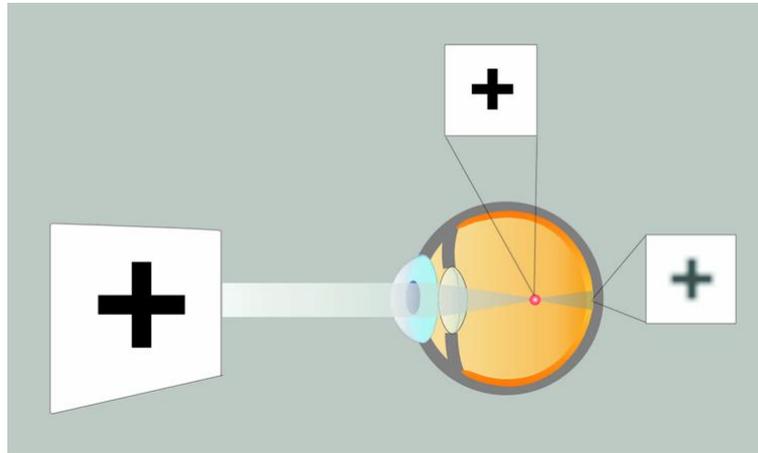


Figure 3: Nearsighted Eye Looking at a Black Cross at Distance

Farsightedness (**hyperopia**) is a type of focusing error in which distant objects are blurry and near objects are even more blurry. In farsightedness, the light focuses beyond the retina, as shown in Figure 4 below. Farsightedness commonly becomes evident later in life because eyes of young people are often able to compensate for this condition by changing the shape of the lens in the eye. This ability to compensate for farsightedness is lost as the person ages and the lens in the eye loses its flexibility (see **presbyopia** below).

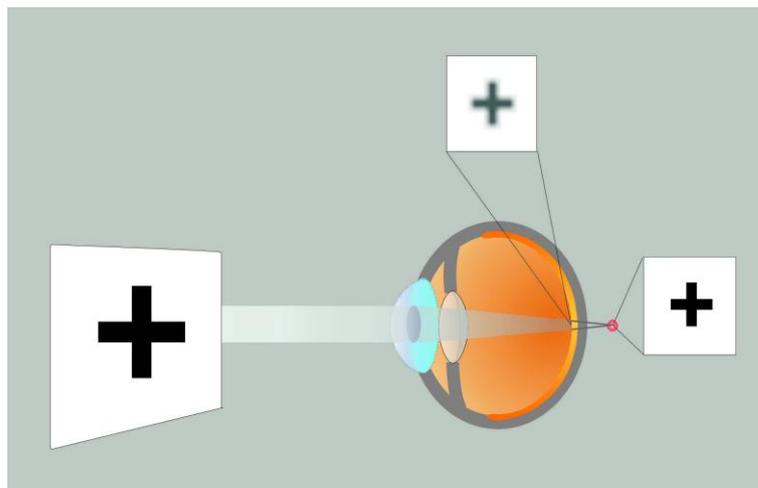


Figure 4: Farsighted Eye Looking at a Black Cross at Distance

Astigmatism occurs when the cornea or lens is not equally curved in all directions. The irregular shape causes the light to focus at two different focal points, depending on the location that the rays of light enter the eye, instead of on a single point on the retina, as shown in Figure 5 below. Astigmatism causes images to be blurred at all distances.

Astigmatism commonly occurs along with nearsightedness (myopic astigmatism) or farsightedness (hyperopic astigmatism). Some eyes have a combination of nearsightedness and farsightedness with the astigmatism (**mixed astigmatism**).

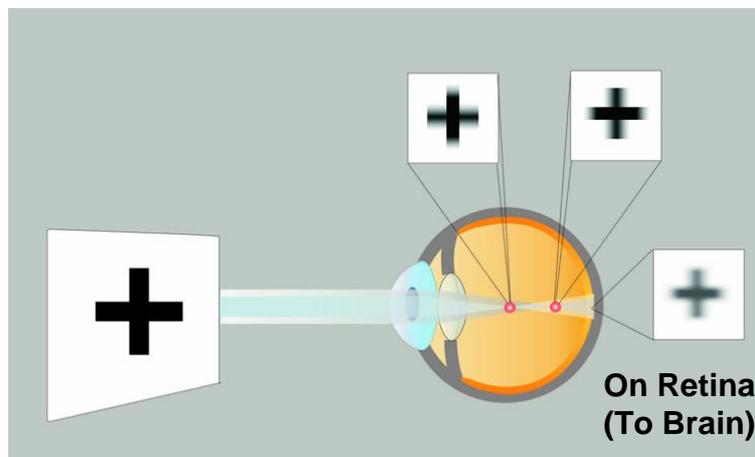


Figure 5: Nearsighted Eye With Astigmatism Looking At A Black Cross

**Presbyopia** is a common type of vision problem that occurs as you age. As people age, the lens becomes stiff, so its focusing power will no longer change. When this occurs, the lens is no longer able to focus light rays on the retina and the light rays become focused behind the retina (similar to farsightedness in Figure 4). Near objects are blurred, even for eyes with perfect distance vision, and reading glasses may be required to see objects that are close.

Refractive errors are easily diagnosed during a comprehensive eye examination. As part of the eye examination, your doctor checks your vision to see how your eyes focus light and how much correction with an **optical** lens is needed to compensate for the amount and type of refractive error in your eye. The amount of refractive error in your eye is described by a unit of measure called a **diopter**.

Refractive errors may be treated with glasses, contact lenses, refractive surgery. When refractive surgery is performed, the shape of the cornea is changed so that the light rays will focus directly on the retina after the surgery. For an eye with nearsightedness, the cornea is too steep; and the cornea must be flattened by removing more tissue from the center of the cornea than from the outer area of the cornea. Eyes with farsightedness have a cornea that is too flat, and the surgery is performed to make the cornea steeper by removing more tissue from the outer areas of the cornea than from the center of the

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cornea. To treat astigmatism, the shape of the cornea is changed to make it more regular.

Refractive surgery changes the curvature of the cornea to move the focal point to the retina so that distant images are clear. It does not affect accommodation or cure presbyopia. Older people who are used to taking their glasses off to see near objects clearly might have to wear reading glasses to see near objects clearly after they have refractive surgery,

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#### 4. WHAT IS TOPOGRAPHY-GUIDED LASIK

Glasses and contact lenses correct nearsightedness, farsightedness and astigmatism by helping your eye focus light on the retina.

Topography-guided LASIK (also called Topo-guided LASIK or T-CAT) is a surgical procedure that corrects nearsightedness and astigmatism by reshaping the front surface of the eye, which enables light to focus properly on the retina.

An **excimer laser** is used to perform LASIK surgery. This excimer laser will remove tiny amounts of tissue from the cornea. It does not change any other parts of the eye.

When the excimer laser is used to perform Topo-guided LASIK, information from a topography map of the cornea is used to help plan the treatment.

Topo-guided LASIK is a highly **customized surgery** compared to **standard LASIK** or **traditional LASIK**, (“standard” or “traditional”) LASIK does not use individual topography measurements to help plan the standard LASIK treatment.

Topo-guided LASIK treatment is permanent because a small portion of your cornea was removed by the laser.

The change in your ability to see after you have Topo-guided LASIK may or may not be permanent because LASIK does not prevent future changes in the focusing power of your eye that can sometimes occur, such as the development of presbyopia that occurs naturally due to aging. You may need to wear reading glasses after the surgery, even though you did not need to wear reading glasses before Topo-guided LASIK.

## 5. WHAT IS THE ALLEGRO TOPOLYZER

### 5.1. Topography Measurement

A corneal topography system (**topographer**) is a device that makes detailed measurements of the shape of the corneal surface. It works by shining light onto the surface of the eye, then measuring the reflected light to create a color-coded map of the cornea's curvature. The map is used for evaluations related to **refractive surgery**, contact lens fitting, and the diagnosis and management of corneal diseases. The topography is especially useful for measuring astigmatism. These maps provide a visual “picture” of the shape of the cornea (Fig. 6). This information is unique to each eye and is used to help plan the custom Topo-guided LASIK treatment.

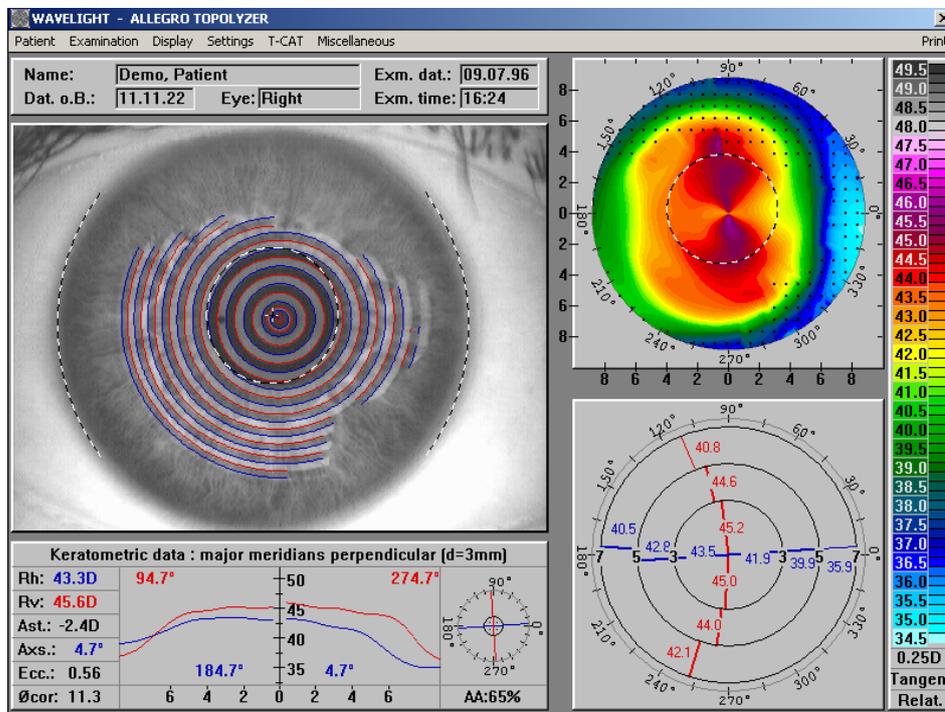


Figure 6: Examples of Topography Maps from the ALLEGRO Topolyzer Topography Device

The **ALLEGRO Topolyzer**, shown in Figure 7 below, is a topographer with special features that allow it to send topography measurements to the EYE-Q laser system to perform Topo-guided LASIK.



Figure 7: ALLEGRO Topolyzer

## 6. WHAT IS THE ALLEGRETTO WAVE® EYE-Q LASER SYSTEM

The ALLEGRETTO WAVE® EYE-Q laser system, shown in Figure 8 below, consists of the laser and all control systems necessary for the surgeon to perform Topo-guided LASIK, such as computerized control panels, monitors for the computer systems, and a microscope to view the eye during the surgery. The system is equipped with an **eye-tracker** that follows the movement of the eye during surgery. The eye-tracker helps assure that the laser pulses are placed in the correct position on the eye, even if the eye moves during treatment. The eye-tracker will stop the treatment if the eye moves too much.

The ALLEGRETTO WAVE® EYE-Q laser system uses a very small laser beam to shape the cornea precisely to correct irregularities in corneal shape, as well as nearsightedness, farsightedness, and astigmatism.

The ALLEGRETTO WAVE® EYE-Q laser system also has a movable bed. When you are prepared for Topo-guided LASIK, you will lie down on the bed. This bed is then moved under the laser to properly position your eye for the Topo-guided LASIK treatment.



Figure 8: ALLEGRETTO WAVE EYE-Q

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## 7. HOW DOES TOPO-GUIDED LASIK CORRECT REFRACTIVE ERRORS

The focal point of the nearsighted eye falls in front of the retina. Refractive surgery flattens 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. The focal point of the farsighted eye is behind the retina. Refractive surgery steepens the cornea so that light is bent more and the focal point moves forward to fall on the retina. To treat astigmatism, the shape of the cornea is changed in a way that creates a sharp focal point on the retina.

The amount of tissue that must be removed from the cornea to change its shape depends on the amount (diopters) of nearsightedness, farsightedness, and/or astigmatism that the eye has. The greater the refractive error, the more the shape of the cornea must be changed and the greater the amount of tissue that must be removed. Topo-guided LASIK uses the measured amount of nearsightedness and astigmatism to calculate the shape change needed to correct the eye's optical system; and also corrects any irregularities in the shape of the cornea that are measured by the Topolyzer.

The shaping procedure uses an excimer laser. The light of this laser is invisible ultraviolet (UV) light.

The system applies very short laser light pulses to create very precise and smooth shapes on the cornea. Each pulse removes tissue with a diameter of less than 1 millimeter (0.04 inch). In order to keep treatment times short, the laser has to deliver many pulses in a short time. The ALLEGRETTO WAVE EYE-Q laser system delivers 400 pulses per second. This rapid delivery of multiple light pulses makes a buzzing sound when the laser operates.

Every laser pulse has to be directed precisely onto your cornea; however, the eye can move, even when you are trying to keep your eye steady. Therefore, prior to the release of each laser pulse, a built in eye-tracker detects the current position of your eye and aligns the laser pulse with your cornea.

### 7.1. Are you a good candidate for LASIK?

The ALLEGRETTO WAVE® EYE-Q laser system is approved for use in performing Topo-guided LASIK treatments in patients who have nearsightedness with or without astigmatism. You would be a good candidate for Topo-guided LASIK if you are 18 years of age or older and your vision is:

- Up to - 8.0 diopters of nearsightedness, or
- Up to -3.0 diopters of astigmatism, or
- Up to -9.0 diopters nearsightedness with astigmatism; and,

- The amount of nearsightedness with or without astigmatism in your eye did not change by more than 0.5 diopters during the year before your preoperative examination.

The information presented in the following sections of this booklet will help you determine if Topo-guided LASIK is advisable for you. It reviews the potential risks and benefits of the procedures, reports the outcomes of the clinical study that was completed to evaluate Topo-guided LASIK, and describes what to expect if you decide to undergo Topo-guided LASIK.

Surgical alternatives to LASIK surgery include **radial keratotomy (RK)** and **photorefractive keratectomy (PRK)**. RK is an older procedure in which a knife is used to weaken the cornea by making deep cuts in it. It is rarely, if ever, used today. Like LASIK, PRK uses an excimer laser to shape the cornea, but the laser energy is applied to the surface of the cornea, without a **flap** having been made. It is typically recommended for eyes in which a flap might lead to problems. Ask your physician whether you might be a better candidate for PRK than LASIK.

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## 8. RISKS OF TOPO-GUIDED LASIK SURGERY

### 1. Will my vision be perfect after Topo-guided LASIK surgery?

Although the Wavelight excimer laser is a precision instrument, patients may not all respond identically to treatment, and complications can occur. As a result vision may not be perfect after Topo-guided LASIK. It is important to discuss all risks with your doctor before making the decision to have the surgery:

- *Your eye may be either undercorrected or overcorrected after the surgery.* Undercorrection or overcorrection may be well tolerated or result in the need to wear glasses or contact lenses or have additional LASIK surgery in the same eye to improve vision.
- *Irregular astigmatism* may occur when the cornea does not heal smoothly and may require wearing of hard gas permeable contact lenses to achieve the best vision. Irregular astigmatism may lessen over several weeks or months.
- 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.
- *Glare and halos* may occur and interfere with night driving. The frequency and severity of glare and halos is reduced, on average, by Topo-guided LASIK. In rare cases, glare and halos may increase in severity enough to interfere with normal vision, and eye drops may be required to reduce the size of the pupil.
- *Infection of the eye* is a potential complication following Topo-guided LASIK surgery that could require a long course of treatment. Although rare, a corneal infection could lead to corneal scarring, corneal perforation, or the spread of the infection inside the eye. Any of these complications of a corneal infection, if severe enough, could result in partial or complete loss of vision (blindness).
- *The cornea may become inflamed*, leading to cloudiness of the cornea (**diffuse lamellar keratitis**) in the flap area that typically shows up 1 to 3 days after surgery. Treatment of the corneal inflammation will involve the use of **steroid** eye drops. If the inflammation becomes worse, the corneal flap may need to be lifted to clean the area under the flap. Lifting the flap may require additional healing time and, although uncommon, could lead to worse vision or visual symptoms, such as glare and halo.
- *The pressure inside the eye (intraocular pressure) may increase* in the treated eye, due to the prescribed medication to reduce swelling.
- *Long term use of the **anti-inflammatory eye drops** after surgery can lead to a possible increased risk of cataract formation.* Topo-guided LASIK itself has not been proven to cause problems inside the eye such as cataract or retinal detachment.

## 2. What risks are associated with the surgical procedure?

- Many patients feel more comfortable with a mild degree of oral sedation before the Topo-guided 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 vision in the eye become dim, or even completely disappear temporarily. This reduced vision is caused by increased pressure from the suction, preventing the flow of blood into the eye. Once the suction ring is removed and the pressure returns to normal blood flows again and vision fully returns. There is a concern among refractive surgeons that blood flow to 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 mechanical microkeratome or laser used to create the flap. In this case, the surgeon may not perform Topo-guided LASIK at that time. A new flap may be created 3 months after the first attempt and the surgery can be completed then or the surgeon may choose to perform photorefractive keratectomy (PRK) instead of LASIK.
- Patients with very large pupils (larger than 6 mm) are advised of the potential for a poor visual result after Topo-guided LASIK surgery including glare, halos, and nighttime driving difficulties.
- The effects of the ALLEGRETTO WAVE EYE-Q laser device on implantable medical devices (such as a heart pacemaker) are unknown.
- You may experience the following side effects which are part of the normal healing process. These symptoms are temporary and occur in many patients:
  - Do NOT rub your eye, even if it feels itchy. Rubbing the eye could damage the flap or move it out of place. If the flap moves, you may notice a sudden decrease in the quality of your vision. If this happens, you should contact your doctor immediately.
  - You might experience eye irritation related to drying of the corneal surface following Topo-guided LASIK surgery. The symptoms may be temporary or, in rare cases permanent, and may require frequent application of artificial tears or instillation of prescription eye drops.
  - You might feel moderate pain, discomfort and a feeling of something in the eye for several days after surgery. Pain medication may be necessary.
  - You may experience tearing, usually limited to the first 72 hours after surgery. In rare cases tearing can be so bad as to blur vision and interfere with functions such as driving. Follow your doctor's instruction regarding when to resume driving activities.
  - You may experience blurry or double vision as the cornea heals, particularly in the first 72 hours. Double vision can also occur as a long-term complication of the surgery.
  - You may experience glare and increased sensitivity to bright light. Light sensitivity is usually most intense for the first 48 hours after surgery,

although it may persist for prolonged periods after Topo-guided LASIK. Your eyes may remain slightly more sensitive to light than they were before surgery. You may have difficulties with night driving.

- You may experience swelling of the eye or cornea. Swelling usually resolves within 48 hours after surgery.

### 3. What side effects could follow after having Topo-guided LASIK surgery?

You may experience side effects that are less common after LASIK surgery.

- Although visual symptoms, like glare, halos, starbursts, and difficulty driving at night tend to be less frequent and less severe after Topo-guided LASIK, some patients may notice an increase in these symptoms after Topo-guided LASIK. If you have these visual symptoms, they may be worse under poor lighting conditions than under normal lighting conditions.
- Drooping of the upper eyelid (**ptosis**), has been noted as an uncommon occurrence following Topo-guided LASIK. The cause is not yet fully understood. Generally, ptosis after LASIK is mild in degree and will resolve by itself over several months.
- Although it is rare, corneal scarring (or **haze**) may occur after Topo-guided LASIK surgery. Scarring or haze may cause partial vision loss or cloudiness of vision.
- Cells from the surface of the cornea may grow under the flap (**epithelial** ingrowth). This condition is uncommon, usually does not affect vision, and typically does not require treatment. Occasionally, it will affect vision and may require removal by surgically lifting the flap and removing the cells.
- Prolonged abnormal surface healing may occur. During the process of using the microkeratome, defects on the flap surface may be created. These generally respond well to patching of the eye and/or the use of a soft contact lens. The defects may take several days or weeks to fully heal, and could - while active - reduce visual acuity.
- The development of dry eye symptoms may be a complication of Topo-guided LASIK surgery.

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## 9. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Discuss with your doctor if you have any of the following conditions to determine if Topo-guided LASIK surgery is right for you.

### 9.1. Contraindications - When It is NOT Advisable to Have Topo-guided LASIK?

If you have any of the following situations or conditions, you should NOT have Topo-guided LASIK because the risk is greater than the benefit:

- You are pregnant or nursing, because these conditions may cause temporary and unpredictable changes in your cornea; and a Topo-guided LASIK treatment would improperly change the shape of your cornea.
- You have a weakened immune system from **collagen vascular, autoimmune or immunodeficiency disease**, such as rheumatoid arthritis, multiple sclerosis, lupus or AIDS, because these conditions affect the body's ability to heal.
- You show signs of degenerations of structure of the cornea, including **keratoconus** or any other condition that causes thinning of your cornea. These conditions can lead to serious corneal problems after Topo-guided LASIK surgery. It may result in the need for additional surgery and may result in poor vision after Topo-guided LASIK.
- You show symptoms of severe dry eye. If you have severely dry eyes, Topo-guided LASIK may increase dryness. This may or may not go away. This dryness may delay healing of the flap or interfere with the surface of the eye after surgery.
- Your corneas are too thin. If your corneas will be too thin after your doctor has cut a flap and performed the LASIK treatment, you can't have LASIK.
- You have recurrent corneal erosion. This condition can lead to serious corneal problems during and after Topo-guided LASIK surgery.
- You have an advanced **glaucoma**. It is unknown whether Topo-guided LASIK is safe and effective for you.
- You have uncontrolled diabetes. Topo-guided LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.

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## 9.2. Warnings

Discuss with your doctor if you have any of the following conditions. You may be able to have Topo-guided LASIK if your doctor evaluates the seriousness of your condition and believes the benefit of having LASIK is greater than the risk.

- Systemic diseases likely to affect wound healing. If you have a systemic disease such as a connective tissue disease, insulin-dependent diabetes, severe atopic disease or are immunocompromised, Topo-guided 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, Topo-guided LASIK is more risky for you.
- Significant dry eyes that have not responded to treatment. If your eyes have not responded to treatment for significant dry eyes, Topo-guided LASIK is more risky for you.
- Severe allergies. If you have severe allergies and take medicines for them, your medications may have to change before or after your eye surgery. These medications may change the wetness (moisture level) in your eye. If the medication changes the moisture of your eye, the accuracy of your refractive results may be affected, and Topo-guided LASIK is more risky for you.
- History of glaucoma, increased pressure inside your eyes, have been diagnosed with ocular hypertension, or are being followed for possible glaucoma (glaucoma suspect), because it is unknown whether Topo-guided LASIK is safe and effective for you.
- Your doctor is unable to obtain preoperative topography maps that are of good enough quality to use for planning the Topo-guided LASIK treatment. Poor quality topography maps may affect the accuracy of the Topo-guided LASIK treatment and may result in poor vision after Topo-guided LASIK.
- Taking the medications isotretinoin (Accutane®<sup>1</sup>) for acne treatment, because this may affect the accuracy of the Topo-guided LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after Topo-guided LASIK.

## 9.3. Precautions:

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

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<sup>1</sup> Accutane® is a registered trademark of Hoffmann-La Roche Inc.

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- Progressive nearsightedness, or unstable eyes, with nearsightedness or astigmatism that has changed by more than 0.5 diopters in the last 12 months. This may result in poor vision after Topo-guided LASIK.
  - If you have an eye disease, it is unknown whether Topo-guided 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 Topo-guided LASIK will weaken the cornea too much. This may result in poor vision after Topo-guided LASIK.
  - Corneal abnormality (e.g., scar, irregular astigmatism, infection, contact lens warpage, etc.). If you have an abnormal corneal condition, such as corneal scars, it may affect the accuracy of the Topo-guided LASIK treatment or the way your cornea heals after Topo-guided LASIK. This may result in poor vision after Topo-guided LASIK.
  - Your corneas are too thin. If your corneas are too thin to allow your doctor to cut a proper flap during the Topo-guided LASIK procedure, you can't have 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 (e.g. Imitrex®<sup>2</sup>) used for migraine headaches, because it is unknown whether Topo-guided LASIK is safe and effective under this condition.
  - You take the medication Amiodarone hydrochloride (Cordarone®<sup>3</sup>) for normalizing heart rhythm because it has side effects to the eye that may affect the accuracy of the Topo-guided LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after Topo-guided LASIK.
  - You are younger than 18 years of age because it is unknown whether Topo-guided LASIK is safe and effective for you.
  - Over the long term (more than 12 months), it is unknown whether Topo-guided LASIK is safe and effective.
  - You should discuss the risks with your doctor for any 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 Topo-guided LASIK is safe and effective under this condition.

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<sup>2</sup> Imitrex® is a registered trademark of GlaxoSmithKline Inc.

<sup>3</sup> Cordarone® is a registered trademark of Wyeth Inc.



- 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 eye-tracker on the laser may not work properly; and Topo-guided LASIK may not be safe and 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 certain types of cancer drugs (antimetabolites), may affect the ability of your eye to heal after surgery.
- Large pupils. Before surgery, your doctor should measure 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 and drive in conditions such as dim light, rain, fog, snow and glare from bright lights.
- Undiagnosed dry eyes. Your doctor should also evaluate you for dry eyes before surgery. You may have dry eyes after Topo-guided LASIK surgery even if you did not have dry eyes before surgery.
- Treatment that is not within the **FDA**-approved treatment range. The safety and effectiveness of treatments that are more than -9.0 diopter of nearsightedness with astigmatism, or have more than -8.0 diopters of nearsightedness or more than -3.0 diopters of astigmatism are not known. LASIK treatments provided outside the FDA-approved treatment range may be risky. Please ask your doctor if your treatment range is approved.
- Any other medical condition that is likely to increase the risk of LASIK surgery or make you an unsuitable candidate for LASIK surgery. Your doctor should know your medical conditions.
- History of crossed eyes (strabismus). It is unknown whether Topo-guided LASIK is safe and effective under this condition.
- If you have a decreased vision in one eye, it is unknown whether Topo-guided 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 will be affected if both eyes are 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 Topo-guided LASIK or by wearing glasses or contact lenses that compensate for the difference.

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## 10. WHAT WILL HAPPEN BEFORE, DURING AND AFTER LASIK

The following section provides important information you need to know about what will happen and the care that is needed, before, during, and after Topo-guided LASIK surgery.

Topo-guided LASIK surgery 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 Topo-guided LASIK surgery, you will have a complete examination of your eyes before surgery to make sure your eyes are healthy and that you are able to have Topo-guided LASIK surgery safely. The examination will include your complete medical history and computerized mapping of your corneal surface with a topography machine. This topography examination is used to evaluate the smoothness and shape of the cornea, and to plan the treatment.



### **CAUTION**

- Patients must stop wearing their contact lenses:
  - 3 days or longer before the preoperative examination for soft contact lenses.
  - 3 weeks or longer before the preoperative examination for gas permeable or hard contact lenses.Failure to do so might produce poor results after surgery, as your treatment parameters cannot be determined precisely.
- Tell your doctor about:
  - All medications you take. Medications you take could affect the outcome of your treatment.
  - Allergies. If you have any allergies, tell your doctor so you will not receive any treatment that could cause 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

- On the day of surgery, do NOT wear:
  - Eye make-up or other make-up around your eyes since your eye area should be as clean as possible during the surgery to help avoid infection or irritation.
  - Perfume or cologne during the surgery. It may interfere with the laser and result in poor vision.

Numbing (**anesthetic eye drops**) will be placed into the eye that will be treated before the surgery. When the surgery is performed, you will be asked to lie flat on your back on a cushioned bed. This bed has headrest with a ring cushion. The back of your head should be comfortably centered in the ring to minimize movement of your head during treatment. If your head is properly positioned in the headrest, head movement will be difficult. Once you are positioned on the bed, the bed is moved to properly center your eye under the laser.

When you are under the laser, you will be asked to look up at the lights. There are red and white lights, which your doctor uses, and a green blinking light. You must stare at this green blinking light in the center of the black opening in the cover above your head. The doctor may change the brightness of the white lights for different steps of the procedure. This is normal and should not distract you.



#### CAUTION

- Do NOT let the red and white lights distract you during the LASIK surgery. Stare only at the green blinking light 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.

The doctor will place an instrument between your eyelids to hold them open during surgery. A temporary cover will be placed over the other eye for your comfort. For the whole procedure, relax and try to keep your eye open without squinting.

As shown in Figure 9 below, your doctor will use a **microkeratome** to cut a thin flap of tissue. You may feel a mild aching sensation and/or temporary loss of vision during creation of the flap. After the flap is created, vision will return, but it will be blurry.

The microkeratome may be either a **laser or mechanical** type of microkeratome. With either microkeratome, a device is attached to the eye with **suction**. Mechanical microkeratomes usually make a weak buzzing sound. Laser microkeratomes are usually noiseless.

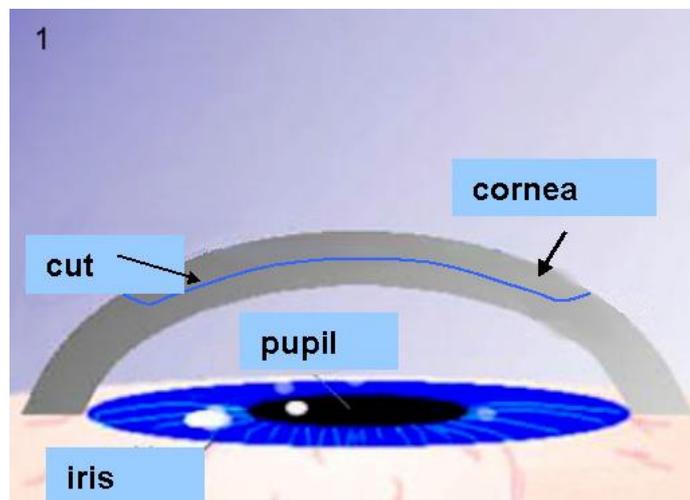


Figure 9: Cross Section Of A Cornea

Your doctor will fold the flap back to expose the inner layers of your cornea (see Figure 10 below). Your vision will be blurry at that time, but you should try to keep your eye locked on the green blinking light during the Topo-guided LASIK procedure.

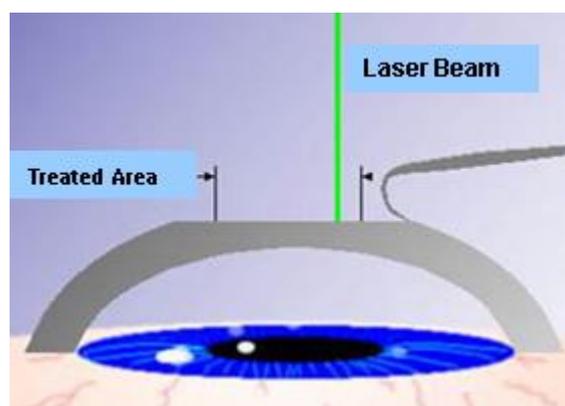


Figure 10: Flap Being Opened

The doctor will center your eye below the laser and start the eye-tracker. You will need to look steadily at the green blinking light to keep your eye from moving as the laser shapes your cornea. When the laser operates, you will hear a buzzing sound. It is important not to move any part of your body or look away from the green light during treatment.

When your surgeon starts the laser treatment, a bright red light will flash; and the laser pulses will begin. The laser will remove tiny amounts of tissue from the inner layers of the cornea under the flap, as shown in Figure 11 below.

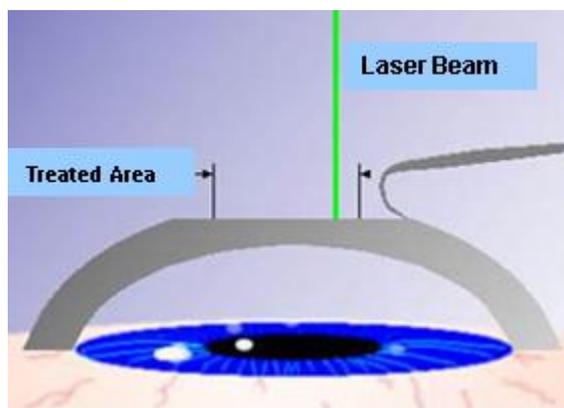


Figure 11: Cornea Being Shaped By Laser

You will hear the buzzing sound of the laser treatment on your cornea and a suction noise above your head. This is created by a suction device, used to keep the air above your eye clean and remove any waste materials from the laser surgery. Although the eye-tracker will follow small movements of your eye, you should do your best to hold your eye perfectly still by staring at the blinking green light throughout the treatment. If you move your eye too far, the tracker will stop the laser treatment, and your doctor will remind you to stare at the green blinking light. Your doctor will use the laser for about one minute. The entire Topo-guided LASIK procedure will take about 10 minutes from start to finish.

After the laser treatment is finished, the surgeon will return the flap to its original position, rinse your eye, and check to be sure that the flap is in the correct position (see Figure 12).

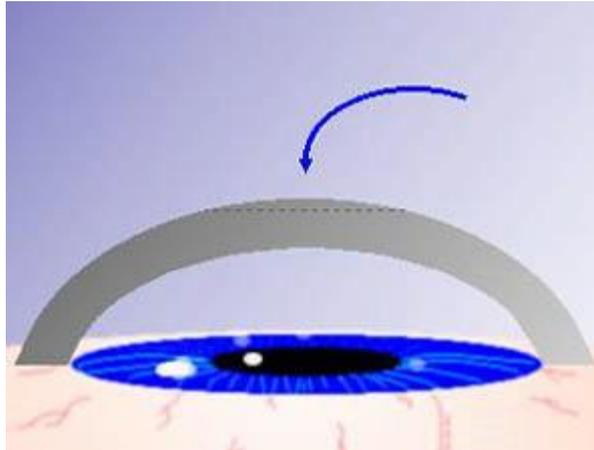


Figure 12: Flap Being Folded Back Into Position

Your vision will improve immediately, but it will not be perfectly clear. Your doctor will wait a few seconds to allow the flap to stick into position, then remove the device holding your eyelids open. Your doctor may add some eye drops on your eye before moving you out from under the laser.

Some doctors may choose to treat the second eye right away. If you have decided to have your second eye treated on the same day and the procedure has gone well in the first eye, your doctor will treat the second eye immediately after the first. Even if you have agreed to have both eyes treated on the same day, your doctor may decide to treat your other eye at a later date.

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. There may be mild discomfort for 1-3 days, but severe pain is unusual. You should call your doctor if you experience severe pain after Topo-guided LASIK.

### First Days after Surgery:

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 and using artificial tears should make you feel more comfortable during this time.

You can begin to use lotions, creams, or make-up around the eye area 2 weeks after the surgery, or as instructed by your doctor. You should wait 1 to 3 days after the surgery before participating in any non-contact sports, depending on how you feel and any instructions from your doctor. You should also avoid swimming or using hot tubs for 1 to 2 months after the surgery to avoid the possibility of infection. You should not participate in contact sports, such as karate, football, boxing, soccer, etc. for at least 4 weeks after the surgery. Wearing protective eyewear is recommended when participating in any activity during which your eyes could get bumped or hit.

It may take 3 to 6 months before your vision becomes stable. During this time, you may experience small changes in your visual acuity.

### CAUTION



- Do NOT rub your eye for any reason during the first 3 to 5 days after surgery. Rubbing the eye could damage the flap or move it out of place and cause your vision to worsen. Your doctor may provide a plastic shield to protect your eye during this period. If so, you should wear the shield.
- Use the **antibiotic eye drops**, anti-inflammatory eye drops and lubricants as directed by your doctor. Your results depend upon your following your doctor's directions. Not following your doctor's directions might lead to poor treatment results.
- If you need to use topical **steroids**, you may have side effects from them. Some possible side effects are elevated pressure in the eye, glaucoma or a cataract. Read the patient information that comes with your medication to learn more about it.
- Contact your doctor immediately if you notice more than just mild pain, or if you notice a sudden change or loss of vision in your eye. Eye pain or sudden loss of vision can be a sign of a serious problem.

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## 11. WHAT SHOULD YOU ASK YOUR DOCTOR

You may want to ask your doctor the following questions to help you decide if Topo-guided LASIK surgery 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 if yes, for how long?
- What are the benefits of Topo-guided LASIK for my amount of nearsightedness?
- What vision can I expect the first few months after surgery?
- If Topo-guided LASIK does not correct my vision, can I wear the same glasses or contact lenses that I wore before surgery?
- Will I be able to wear contact lenses after Topo-guided LASIK if I need them?
- Is it likely that I will need reading glasses as I get older?
- If injured after having Topo-guided LASIK, will my cornea heal differently?
- Should I have Topo-guided LASIK in both eyes?
- How long will I have to wait until I get Topo-guided LASIK on the second eye?
- If I have Topo-guided LASIK only on one eye, what vision problems may I experience?

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

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## 12. SUMMARY OF IMPORTANT INFORMATION

- Topo-guided LASIK is a permanent operation to the cornea and cannot be reversed.
- Topo-guided 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 Topo-guided LASIK surgery.
- Your vision must be stable at least one year before the pre-operative examination.
- Pregnant or nursing women do not qualify for Topo-guided LASIK surgery.
- You are not a good candidate for Topo-guided LASIK surgery if you have a condition that makes wound healing difficult.
- Topo-guided LASIK surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery.
- Topo-guided LASIK is not a laser version of RK; these surgeries are completely different from each other.
- Alternatives to Topo-guided LASIK include, but are not limited to, glasses, contact lenses, PRK and RK.
- The military (e.g. aviation pilots, deep sea divers) and some other employers may prohibit refractive surgery, including Topo-guided LASIK. Before you have LASIK surgery, check with your employer, professional organizations or military for any job-related requirements.
- Before considering Topo-guided LASIK surgery, you should
  - a) Have a complete eye exam.
  - b) Talk with one or more eye care professionals about the potential benefits, risks and complications of Topo-guided LASIK. You should also discuss the time needed for healing, the discomfort you may experience or problems that may occur during this time.

## 13. 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) Topo-guided LASIK is a permanent procedure	<input type="checkbox"/>	<input type="checkbox"/>
b) Topo-guided LASIK is free of risks	<input type="checkbox"/>	<input type="checkbox"/>
c) Topo-guided LASIK is the same as RK	<input type="checkbox"/>	<input type="checkbox"/>
d) It doesn't matter if I wear my contact lenses when my doctor told me not to wear them	<input type="checkbox"/>	<input type="checkbox"/>
e) I may need reading glasses after Topo-guided LASIK	<input type="checkbox"/>	<input type="checkbox"/>
f) There is a risk that I may lose some vision after Topo-guided LASIK	<input type="checkbox"/>	<input type="checkbox"/>
g) It's OK to have Topo-guided LASIK if I am pregnant	<input type="checkbox"/>	<input type="checkbox"/>
h) It matters if I take medication with ocular or healing side effects, such as Cordarone®, Imitrex® or Accutane®	<input type="checkbox"/>	<input type="checkbox"/>
i) After surgery there is a very good chance that I will be less dependent on eye glasses	<input type="checkbox"/>	<input type="checkbox"/>
j) Since the ALLEGRETTO WAVE® EYE-Q uses an eye-tracker, I do not have to focus on the blinking light during laser treatment	<input type="checkbox"/>	<input type="checkbox"/>
k) Even if my refraction was changing a lot over the last year, I am still a good candidate for Topo-guided LASIK	<input type="checkbox"/>	<input type="checkbox"/>
l) Topo-guided LASIK is the same as Wavefront Optimized LASIK	<input type="checkbox"/>	<input type="checkbox"/>

You can find the answers in chapter 16 "Answers To Self-Test Questions" on page 39.



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## 14. WHERE CAN YOU GET MORE INFORMATION

### **Primary Eye Care Professional:**

Name:  
Address:  
Phone:  
Email:

### **LASIK Doctor:**

Name:  
Address:  
Phone:  
Email:

### **Treatment Location:**

Name:  
Address:  
Phone:

### **Laser Manufacturer:**

WaveLight GmbH  
Am Wolfsmantel 5  
91058 Erlangen  
Germany

### **Distribution and Support in the U.S.A.:**

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

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## 15. ANSWERS TO SELF-TEST QUESTIONS

- a) True (see page 36)
- b) False (see page 25, page 26, and page 36)
- c) False (see page 36)
- d) False (see page 29)
- e) True (see page 16, and page 36)
- f) True (see page 27)
- g) False (see page 25 and page 36)
- h) True (see page 27)
- i) True (see pages 36)
- j) False (see page 19)
- k) False (see page 27 and page 36)
- l) False (see page 10 and 16)



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## 16. CLINICAL STUDY INFORMATION

A clinical study was done to evaluate the safety and effectiveness of Topo-guided LASIK with the ALLEGRETTO WAVE EYE-Q Excimer Laser System. The study included 249 eyes of 212 patients treated with Topo-guided LASIK for nearsightedness with or without astigmatism. At the time the Topo-guided LASIK treatment was performed, the youngest patients in the study were 18 years old; and the oldest patients were 65 years old.

For your information, a summary of the results from the clinical study are provided below to help you evaluate the risks and benefits of Topo-guided LASIK surgery.

### 16.1. What Are The Potential Benefits Of Topo-guided LASIK?

One of the potential benefits of Topo-guided LASIK is your visual acuity may improve; and you may no longer need to wear glasses or contact lenses after the treatment.

Visual acuity measures the sharpness of vision using a letter chart that displays rows of letters that get progressively smaller in size from the top to the bottom of the chart. Each row of letters on the eye chart is known as one line of vision. 20/20 vision is “normal” vision. This means that a person can see the same line of letters on an eye chart at 20 feet that a normal person can see at 20 feet.

20/40 vision is worse than 20/20 vision, and 20/15 vision is better than 20/20 vision. A person with 20/15 vision can see objects at 20 feet that a person with 20/20 vision can only see at 15 feet. A person with 20/40 vision can see objects at 20 feet that a normal person can see at 40 feet; or in other words, a person with 20/40 vision must stand at half the distance from an object to see it as clearly as a person with 20/20 vision.

To obtain a driver’s license, all states require that your vision be 20/40-20/70 or better without correction, or with glasses or contact lenses if you need them.

#### **Visual Acuity *Without* Glasses Before And After Topo-guided LASIK For Nearsightedness**

The doctors in the clinical study measured visual acuity without glasses (uncorrected visual acuity; UCVA) before the Topo-guided LASIK treatment and at 1, 3, 6, 9, and 12 months after the procedure.

Three months after the Topo-guided LASIK treatment for nearsightedness, vision without correction (UCVA) improved with:

- Nearly one-third (31.6%) of the eyes achieved a UCVA of 20/12.5 or better.
- Over two-thirds (68.9%) of the eyes had an UCVA of 20/16 or better.
- A total of 92.7% of the Topo-guided LASIK eyes had an UCVA of 20/20 or better.

- 99.2% of the eyes in the study were seeing 20/40 or better at 3 months after the Topo-guided LASIK surgery, which is good enough to drive without glasses or contact lenses in all states.

Vision without glasses tended to continue to improve slightly between 3 and 12 months after Topo-guided LASIK.

### **Vision Without Glasses After Surgery Compared To Vision With Glasses Before Surgery**

How well eyes treated with Topo-guided LASIK were able to see without glasses after surgery compared to their vision with glasses before having surgery is presented below. At 3 months after Topo-guided LASIK:

- Nearly one-third (29.6%) of the eyes saw 1, 2, or more than 2 lines of vision better *without* correction after surgery compared to their vision *with* glasses before treatment.
- Nearly two-thirds (60.3%) of the eyes had vision *without* glasses after Topo-guided LASIK that was equal to their vision *with* glasses before treatment.
- In total, 9 out of every 10 eyes (90%) treated with Topo-guided LASIK saw as well, or better, *without* glasses after surgery as *with* glasses before surgery.

## **16.2. What Are The Risks Of Topo-guided LASIK?**

The doctors in the clinical study evaluated the risks of having Topo-guided LASIK, including worse vision, by measuring visual acuity with correction (**best corrected visual acuity**) before and after the Topo-guided LASIK treatment. The doctors also performed other safety measurements at several visits throughout the study and evaluated any adverse events that occurred.

### **Visual Acuity With Glasses After Topo-guided LASIK For Nearsightedness**

The doctors in the clinical study measured visual acuity with glasses before the Topo-guided LASIK treatment and at 1, 3, 6, 9, and 12 months after the procedure.

Three months after the Topo-guided LASIK treatment:

- None of the eyes (0.0%) had vision with glasses that was worse than 20/40.
- None of the eyes (0%) that had 20/20 or better vision with glasses *before* the surgery, had 20/25 or worse vision with glasses *after* the Topo-guided LASIK treatment.

How well the eyes treated with Topo-guided LASIK were able to see *with* glasses after surgery compared to their vision *with* glasses before having surgery is provided below.

At 3 months after Topo-guided LASIK:



- 11.0% of the eyes gained 2 or more lines of vision with glasses after Topo-guided LASIK.
- Nearly one-third (29.2%) of the eyes saw 1 line of vision better with glasses compared to their vision with glasses before treatment.
- Almost two-thirds (59.1%) of the eyes saw the same with glasses before and after the Topo-guided treatment.
- None of the eyes lost 2 or more lines of vision with glasses.

Three eyes had a 2 or more line loss of best vision with glasses at a visit other than the month 3 visit. Each of these occurrences of visual acuity loss was observed at only a single visit, and each eye had another event going on at the same time that affected visual acuity. At 1 month, one of the eyes had inflammation of the LASIK flap area that affected visual acuity; at 6 months, one eye had significant eye dryness that affected visual acuity; and, at 12 months, the patient was taking allergy medicine that affected visual acuity. Each of these occurrences of visual acuity loss was temporary and resolved with treatment for the concomitant event.

### **Adverse Events**

Adverse events that occurred during the study for all eyes treated with Topo-guided LASIK were as follows:

- Decrease of 2 or more lines of vision with glasses at 3 months or after the Topo-guided LASIK treatment
  - 1 eye (0.4%) at 6 months
  - 1 eye (0.4%) at 12 months
  - 2 eyes at unscheduled visits
- Retinal detachment
  - 2 eyes (0.8%) at 6 months, both of which occurred in the same patient

### **Complications**

Complications that occurred during the study for all eyes treated were as follows:<sup>4</sup>

- Corneal edema between 1 week and 1 month after the procedure
  - 1 eye (0.4%) at 1 week
- Foreign body sensation at 1 month or later
  - 7 eyes (2.8%) at 1 month
  - 5 eyes (2.0%) at 3 months
  - 3 eyes (1.2%) at 6 months

<sup>4</sup> Includes eyes that had new reports, plus eyes with ongoing or recurring events reported at the visit.

- 
- Pain at 1 month or later
    - 2 eyes (0.8%) at 1 month
    - 2 eyes (0.8%) at 9 months
  
  - Double images
    - 2 eyes (0.8%) at 1 month
    - 1 eye (0.4%) at 3 months
    - 1 eye (0.4%) at 6 months
    - 2 eyes (0.8%) at 9 months
    - 1 eye at an unscheduled visit
  
  - Ghost images
    - 1 eye (0.4%) at 1 week
    - 2 eyes (0.8%) at 1 months
    - 2 eyes (0.8%) at 3 months
    - 2 eyes at unscheduled visits
  
  - Misaligned LASIK flap
    - 2 eyes (0.8%) at 1 day
  
  - Corneal inflammation
    - 5 eyes (2.0%) at 1 day
    - 2 eyes (0.8%) at 1 week
    - 1 eye (0.4%) at 1 month
    - 4 eyes at unscheduled visits
  
  - Dry eyes requiring prescribed use of artificial tears eye drops or punctal plugs at 3 months or later
    - 10 eyes (4.0%) at 3 months
    - 8 eyes (3.3%) at 6 months
    - 6 eyes (2.5%) at 9 months
    - 3 eyes (1.3%) at 12 months
    - 6 eyes at unscheduled visits

### **Other Safety Observations**

Other observations occurring with a 1% or greater incidence 3 and 12 months after Topo-guided LASIK are as follows:

- Blurred vision
  - 5 eyes (2.0%) at 3 months
  - 6 eyes (2.6%) at 12 months
  
- Dry eye, requiring no treatment or eye drops as needed
  - 25 eyes (10.1%) at 3 months
  - 20 eyes (8.7%) at 12 months

- Fluctuation in vision
  - 0 eyes (0.0%) at 3 months
  - 3 eyes (1.3%) at 12 months
- Halo
  - 3 eyes (1.2%) at 3 months
  - 0 eyes (0.0%) at 12 months
- Irritation
  - 0 eyes (0.0%) at 3 months
  - 4 eyes (1.7%) at 12 months
- Night driving difficulty
  - 3 eyes (1.2%) at 3 months
  - 1 eyes (0.4%) at 12 months
- Photophobia
  - 5 eyes (2.0%) at 3 months
  - 0 eyes (0.0%) at 12 months
- Mild corneal inflammation associated with eye dryness
  - 2 eyes (0.8%) at 3 months
  - 4 eyes (1.7%) at 12 months
- Starburst
  - 1 eye (0.4%) at 3 months
  - 3 eyes (1.3%) at 12 months

### **Contrast Sensitivity**

Contrast sensitivity measures the ability to see conditions with decreased contrast with or without bright lights. Contrast vision is important for seeing in dusk, rain, fog, snow fall, and at night; when performing tasks involving similar colors, such as pouring coffee into a dark cup; or, seeing low contrast forms, such as sidewalk curbs or stairs. A person with poor contrast sensitivity may see well in normal lighting conditions but can become visually impaired in low contrast lighting conditions or in situations involving bright lights, such as the glare from headlights of oncoming cars when driving in low contrast conditions.

Best vision with glasses was measured before surgery and at 3 and 6 months after Topo-guided LASIK using special eye charts that compared changes in contrast sensitivity. Contrast sensitivity was measured in daylight and dim lighting conditions, without glare and with a glare light source. At 3 and 6 months after Topo-guided LASIK surgery, on average:

- 
- The eyes had better contrast vision, in both daylight and dim light without and with glare conditions, *after* the Topo-guided LASIK treatment than *before* the surgery.

### 16.3. Patient Self-Evaluation Before And After Topo-guided LASIK

Study patients were given a questionnaire to fill out to rate whether they had any of the eleven commonly reported visual symptoms in their Topo-guided LASIK treated eye before the Topo-guided LASIK treatment and at each visit from 1 to 12 months after the surgery. The absence of a visual complaint was rated as “*none*”, and the presence of a visual complaint was rated as “*mild*”, “*moderate*”, “*marked*” or “*severe*”.

Study patients were also given the Refractive Status and Vision Profile (RSVP) questionnaire to evaluate the quality of their vision. The RSVP is a validated questionnaire that measures a patient’s self-evaluation of his or her vision-related health status as it relates to refractive surgery. The scales are designed such that higher scores indicate greater dissatisfaction or a greater negative outcome, except expectations, where a lower score represents an improvement. The clinical outcomes measured by the RSVP are a range of visual, functional, and psychological impacts of **refractive error** that are likely to be important to patients. Published literature indicates that a difference of 6 points or more on the total RSVP score is a clinically significant change.<sup>5</sup>

The self-evaluation of visual symptoms and the RSVP questionnaires were completed by each study patient before the Topo-guided LASIK treatment and at each study visit, beginning at 1 month after the treatment.

#### **Moderate To Severe Visual Symptoms**

Changes in the degree of severity of the visual symptoms reported via the self-administered visual symptoms questionnaire at 3 months compared to baseline are summarized below. All categories of complaints showed a reduction in severity of complaints after the Topo-guided LASIK procedure compared to baseline, except double vision and foreign body sensation.

Symptoms commonly associated with LASIK that improved in severity at 3 months after Topo-guided LASIK treatment were as follows:

- 6.4% decrease in severity of reading difficulty
- 4.4% decrease in severity of complaints of difficulty driving at night
- 4.0% decrease in severity of glare complaints
- 3.6% decrease in severity of light sensitivity
- 2.4% decrease in severity of halos
- 2.0% decrease in severity of starbursts

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<sup>5</sup> Schein OD, Vitale S, Cassard SD, Steinberg EP. Patient outcomes of refractive surgery: The refractive status and vision profile. J Cataract Refract Surg. 2001 May;27(5):665-73.

- 1.6% decrease in severity of dryness
- 1.2% decrease in severity of fluctuation of vision
- 0.4% decrease in severity of pain

Symptoms that had a minimal increase in severity after Topo-guided LASIK were:

- 0.8% increase in severity of double vision
- 0.4% increase in severity of foreign body sensation

### **Quality Of Vision**

As shown below, the differences between the scores before Topo-guided LASIK and at 3 months after the treatment demonstrate:

- There is an overall improvement in quality of vision.
- The average improvement in total RSVP score (-15.97 points) is nearly three times the minimum threshold (6 points) for clinically significant and meaningful improvement.
- The study of Topo-guided LASIK treatment showed improvement in physical/social functioning, driving, visual symptoms, optical problems, and problems with corrective lenses compared to the patient's normal method of vision correction (glasses or contact lenses) before surgery.

### **Satisfaction With Topo-guided LASIK**

A question to evaluate the study patients self-reported satisfaction with the Topo-guided LASIK procedure was added during the course of the study. Of the 124 patients who were polled:

- Nearly all of the study patients (98.4%) were satisfied with their outcomes and would have the Topo-guided LASIK treatment again.





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