

# OptiLASIK™

Laser Vision Correction\*

LEADS WHILE DOING THE WALTZ.  
ONCE WON A  
PIE-EATING  
CONTEST.

STARTED WRITING HER  
NOVEL, AGAIN.

STILL DOES  
CARTWHEELS  
ON OCCASION.

karen }

Chose a **LASIK**  
procedure  
optimized for *her*  
unique vision.



Your eyes are as  
unique as you are.

**Make sure they're treated that way.**

Learn the facts about **OptiLASIK™** Laser Vision Correction  
and why it was made for you.

\* With WaveLight® technology.

Allegretto  
Wave®  
Eye-Q Laser

Realize your unique  
vision potential.

LOVES 50s  
SCI-FI FLICKS.  
STILL SLEEPS WITH  
A SOCK MONKEY.  
GOES ROCK CLIMBING  
MOST WEEKENDS.  
CAN'T STAND THE TASTE  
OF CHOCOLATE.

lynn }

Chose a **LASIK** procedure  
optimized for *her* unique needs.

## the facts:

- More than **17 million** people worldwide have had some form of laser vision correction.
- Every year, **1.3 million** Americans have LASIK surgery performed.
- **93%** of patients see at least 20/20 or better following LASIK surgery.<sup>1</sup>
- **97%** of LASIK patients recommend LASIK to their friends.<sup>1</sup>

## They're your eyes – they deserve special treatment.

You're unique. No surprises there, right? You have special qualities – quirks and characteristics that set you apart, that make you different from everyone else.

But did you know that your eyes are just as unique? It's true – your eyes have their *own* special attributes – traits that make them yours and yours alone. Some can be wonderful: Maybe your eyes are spectacularly blue. Maybe you can see well in the dark. Sometimes, though, the quirks of your eyes can lead to vision problems – and we all know what *that* leads to...

### TIRED OF GLASSES AND CONTACTS?

If you're looking into LASIK vision correction, it's probably because you know how much of a pain glasses and contacts can be.

Sure, glasses can be a fashion statement, but they can also just get in the way. They're a hassle during your favorite activities, and they block your beautiful eyes from the world. If they're not getting smudged, they're getting knocked off – *enough already!*

Contacts show your eyes off, but they've got their own set of problems. All the supplies you have to buy, the constant cleaning procedures and checkups, lost lenses and allergies – *enough!*

Now, imagine life without contacts and glasses – the simplicity, the freedom to do what you want without worry. That's what LASIK surgery can give you.

### OPTILASIK™ FOR OPTIMIZED VISION.

We know, LASIK can seem a bit scary at first – a *laser* pointed at your *eye?!* – but laser surgery is one of the safest and most common elective procedures. And, once you've had LASIK, your results may make you wish you'd gotten the procedure even sooner!

The question is, though, if your eyes are as unique as you are, why should they be treated with the *exact same procedure* everyone else gets? If you're thinking about laser vision correction, choose the procedure that was designed to work with your eyes' unique attributes. You have options – you have **OptiLASIK™**.

# Laser vision correction. Changing the way you see the world.

You've had vision problems for what? Most, maybe *all* of your life? So, you've paid your dues – it's time for a brand new outlook! **OptiLASIK™** Laser Vision Correction can make it happen, giving you the vision you've always wanted. But, before you dive in, you need to know the basics: your eyes, the conditions that affect them, and how laser vision correction gets the job done.



## Myopia (Nearsightedness)

Light rays bend more than they should, so they focus in front of the retina. Far away images seem blurry.



## Hyperopia (Farsightedness)

Light rays bend less than they should, so they focus behind the retina. Close-up images seem blurry.



## Astigmatism

Light rays bend at different angles, so they're not all focused at the same spot. All images seem blurry.

GOES BUNGEE JUMPING ON HIS BIRTHDAY.  
**NEVER FORGETS  
A FACE.**  
COLLECTS  
VINTAGE  
RAT PACK  
RECORDS.  
MAKES A  
MEAN MANGO  
MOJITO.

jeff }

Chose a **LASIK** procedure optimized for *his* ideal perspective.

## Your vision: A refresher course.

At its most basic, your eye works like a camera, bending light to focus it onto the **retina** (the back of your eye) for a crisp, clear image.

Now, although the **lens** inside your eye certainly *helps* to focus light, the majority of focusing power actually comes from a different part of your eye. The **cornea** – the clear, protective coating on the surface of your eye – does most of the heavy lifting, making it the main focus of laser vision correction, as you'll see in a moment.

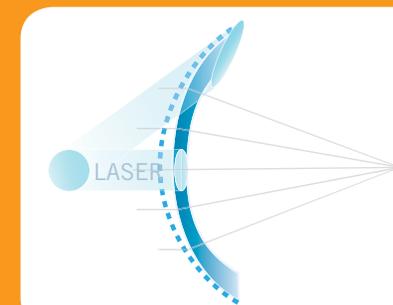
## WHAT'S GOT YOUR EYES BENT OUT OF SHAPE?

If your eye is the *exact, perfectly ideal shape*, light will focus precisely where it should on the retina, and you'll

have great vision. However, if the shape of your eye is even a *little* off, it can result in light focusing at the wrong spot, leading to distorted eyesight.

## HOW CAN LASER VISION CORRECTION HELP YOU?

While the specifics may vary (as you'll see on the next page), at its core, every form of laser vision correction follows the same basic routine: Using a laser beam, your surgeon will *reshape* the cornea so that it's closer to its ideal shape.



A laser beam is used to remove small amounts of tissue from the cornea, making your eye a more ideal shape for focusing light.

It sounds like something out of science fiction, but don't worry – the procedure is quick, safe and virtually painless. Plus, almost immediately, your reshaped eyes will be able to focus more accurately, for vastly improved vision (and a considerably happier you).

KNOWS EVERY CONSTELLATION BY HEART.

COULDN'T LIVE WITHOUT  
HIS POTTERS' WHEEL.

LOVES KARAOKE,  
EVEN IF HE CAN'T SING.

ALWAYS BRINGS FLOWERS ON THE FIRST DATE.

mark }

Chose a **LASIK** procedure  
optimized for *his* optimal outlook.



## Consider the possibilities.

Now that you've got the basics of laser vision correction down, it's time to start thinking about your options. Laser surgery is a proven procedure that can give you *life-changing* results, but that doesn't mean it's right for everybody. Your surgeon will help you decide if surgery is right for you, and, if so, which type of procedure will work best with your eyes. In the end, though, it's up to *you* to decide if the time is right.

### IS LASER VISION CORRECTION RIGHT FOR YOU?

First things first – before you even *think* about surgery, you'll need to have an initial consultation with your surgeon, just to make sure you (and your eyes) are ideal for laser vision correction. In addition to testing your vision, to verify that it's actually within the range that laser surgery can help, your doctor also will check that your prescription has been stable for

at least the past year. If your vision is still changing, you might have to wait on surgery. (And speaking of waiting, you have to be at least 18 – and sometimes 21 – to consent to surgery. *Hang in there, minors!*)

Certain eye conditions can affect your surgical options – thin corneas, Dry Eye Syndrome, etc. – so your doctor may test for them, just in case. Don't forget to mention any *other* medical conditions you have, or any medications you might be taking, as they can affect surgery as well.

Finally, and most importantly, your surgeon will make sure you're comfortable and knowledgeable about laser vision correction, answering any questions you might have and helping you understand what you can expect from the procedure. After all, if *you're* not ready for surgery, it doesn't matter if your eyes are!

### WHICH TYPE OF LASER VISION CORRECTION IS RIGHT FOR ME?

Although LASIK surgery is probably the type of laser vision correction you've heard the most about, there are actually a number of different procedures that can help improve your vision. While each technique works on the same basic foundation – using a laser to reshape the surface of your eye (the **cornea**) – they each vary slightly in their execution, and their results:

#### LASIK (laser-assisted in-situ keratomileusis)

The most common type of laser vision correction. With LASIK surgery, a thin layer of tissue is pulled back from the cornea. A laser then works *inside* the cornea to reshape it for vision correction. Once your cornea has been reshaped, the outer layer of tissue is put back into place and serves as a natural bandage, allowing your eye to heal quickly, and with minimal discomfort.

#### PRK\* (photorefractive keratectomy)

Another common form of laser vision correction. In PRK, the top layer of your cornea (the **epithelium**) is removed, so that the cornea can be reshaped. After surgery, the epithelium must heal on its own; contact lenses are often used as a bandage. Although the results are the same as LASIK, healing takes slightly longer with PRK, and more discomfort can be associated with the procedure.

#### LASEK\* (laser-assisted sub-epithelial keratectomy)

A new type of laser vision correction, similar to PRK. With LASEK surgery, the epithelium is *temporarily* loosened from the cornea. Once your eye has been reshaped, the epithelium is then replaced over the exposed cornea to help aid in healing. Some surgeons feel that recovery is faster and less uncomfortable than with PRK, but there isn't universal agreement on this yet.

Based upon your unique needs, your surgeon will recommend the laser eye correction procedure that's right for you. Keep in mind, though, that no matter which procedure you choose, each type of laser vision correction is safe, effective and can give you the results you've always dreamed of.

\*The Allegretto Wave® Eye-Q Laser Vision System is not approved for this type of procedure.

CAN'T WHISTLE TO SAVE HER LIFE.

DESIGNS  
HER  
OWN  
DRESSES.

STILL CATCHES  
FIREFLIES IN THE  
SUMMER.

ADORES  
HER PET  
PYTHON.

## THE TECHNOLOGY YOUR SURGEON TRUSTS:

**OptiLASIK™** is backed by the power of the advanced Allegretto Wave® Eye-Q Laser System from Alcon, the world leader in eye care technology. Alcon knows eyes, so you can rest assured that the Allegretto Wave® system offers the innovation you need for outstanding results.

To learn more about Alcon and the Allegretto Wave® System, visit [alconrefractive.com](http://alconrefractive.com)

{april

Chose a **LASIK** procedure optimized for *her* best visual potential.

## OptiLASIK™ for *optimized* vision.

Okay, so you've decided on LASIK surgery – it's safe, it's proven, it's the right decision. So, you're all set, right? *Wrong*. LASIK has a number – sometimes a *bewildering* number – of options and alternatives for you to consider. Custom LASIK, bladeless LASIK, this system, that system – how can you tell which is right for you?

**Look no further. You have options – now, you have OptiLASIK™.**

### WHAT MAKES OPTILASIK™ UNIQUE?

**OptiLASIK™** Laser Vision Correction combines today's most advanced surgical technologies into a procedure optimized for *your* ideal vision. You see, in the past, some LASIK procedures simply reshaped your eye based on your current glasses or contact lens prescription – as a result, everyone with the *same prescription* received *the same treatment*, without taking into account the unique attributes that make your eyes special.

**OptiLASIK™** is different. Utilizing the advanced diagnostic technology of the Allegretto Wave® Eye-Q Laser System, **OptiLASIK™** actually creates a “map” of your eyes. This “map” is your own personal vision profile, capturing your eyes' one-of-a-kind quirks and characteristics. By using your “map” as a guide, your surgeon is better able to personalize the LASIK procedure, for *your* best results.

Now, it's true – custom procedures have existed in the past. **OptiLASIK™** is special, though, in that it actually accommodates for the *natural shape* of your eye. Earlier procedures reshaped the cornea with little regard for

the way your eyes curve naturally – as a result, LASIK surgery could result in tiny errors in your vision: glare, trouble seeing at night, etc.

**OptiLASIK™** Laser Vision Correction is designed to adapt to the unique curvature of your eye, reshaping it more closely to the curve of an ideal, natural eye. As a result, **OptiLASIK™** helps preserve the quality of your vision, ensuring your eyes are at their most natural *and* their most useful.

They're your eyes – make sure they're at their very best, with **OptiLASIK™**.

# What to expect with OptiLASIK™:

Get the confidence that comes with knowing the facts.

If you're at your surgeon's office, reading this brochure, you've already taken the hardest step in the entire LASIK procedure: *overcoming your fear*. We know that surgery can seem like this big, scary ordeal, but with **OptiLASIK™**, it doesn't have to be. While it's still a surgical procedure, the entire **OptiLASIK™** process is fast, safe and – in almost no time at all – you can finally have the vision you've always wanted.

## PREPPING FOR THE PROCEDURE.

Once you've decided that **OptiLASIK™** is right for you, your surgeon will run a series of tests to evaluate your vision, much like you would at a normal eye exam. This isn't just eye charts and "Can you read the top line?" – your surgeon will use a highly advanced scanning tool to create a personalized "map" of your eyes.

This "map" reflects the unique attributes that make your eyes special, *including* those annoying irregularities that led to vision problems all these years. Your surgeon will use your "map" to determine exactly *how* your eyes will need to be reshaped for ideal vision.

## OPTILASIK™ – THE BIG DAY AT LAST!

Start to finish, **OptiLASIK™** only takes a few minutes. Here's the rundown:

- Before **OptiLASIK™** begins, you'll receive a series of anesthetic drops in each eye. These drops will numb your eyes and help ensure that **OptiLASIK™** is virtually painless – at most, you may feel some light pressure.
- Once your eyes are numb, you'll be asked to lie down on a table under the laser equipment. Throughout the procedure, you'll be asked to focus on a small blinking light above you. Don't worry if your eyes move a tiny bit – the Allegretto Wave® Eye-Q Laser uses sophisticated eye-tracking technology, so it can keep up.
- Your surgeon will begin **OptiLASIK™** by pulling back a thin layer of tissue from your cornea, exposing the underlying tissue so your surgeon can more easily reshape it.
- From there, your surgeon will apply small, rapid "bursts" of the laser to carefully reshape your cornea – flat areas may be made rounder, curved areas may be flattened, etc.
- The personalized "map" of your eyes will help guide the laser, making sure you receive the precise treatment you need, while still maintaining an ideal, natural shape.
- Once your eye has been reshaped, the doctor will put the outer layer of tissue back into place, where it acts as a natural "bandage." No need for stitches here!

And that's it! All you have to do now is rest up, and get ready to enjoy the benefits of your improved vision!

## Listen up, lens wearers!

If you currently have contacts, your surgeon will probably ask you to stop wearing them 2 to 4 weeks before the procedure, as they can affect the shape of your eyes. We know, you don't want to be back in glasses, but think of it as a goodbye party!

SWIMS IN THE OCEAN EVERY MORNING.

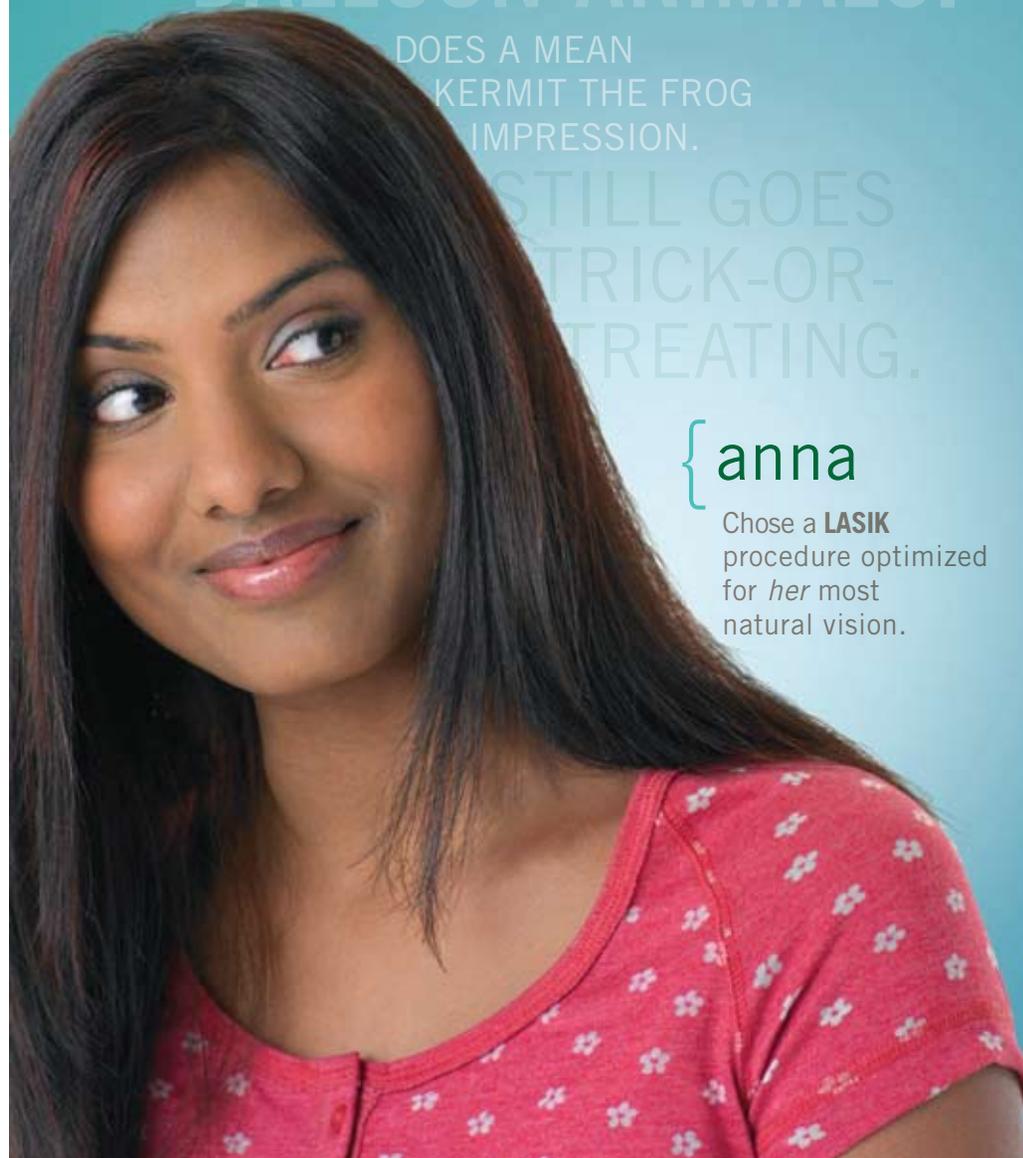
LOVES MAKING  
BALLOON ANIMALS.

DOES A MEAN  
KERMIT THE FROG  
IMPRESSION.

STILL GOES  
TRICK-OR-  
TREATING.

{anna

Chose a **LASIK** procedure optimized for *her* most natural vision.



# The results you want— OptiLASIK™ and your new outlook on life.



Within a matter of minutes, **OptiLASIK™** Laser Vision Correction can completely change the way you see the world. Many people sit up *right after surgery* and notice dramatically better vision.\* Still, complete recovery can take time – weeks, or months even – and much of the responsibility will be in *your* hands. So, to get the most out of **OptiLASIK™**, you need to know what to expect after surgery.

\*Results may vary.

## THE ROAD TO RECOVERY.

Although we'd *love* to claim all the credit for your rapid recovery, most of it falls on you, and the amazing resilience of your eyes. Your eyes heal and adapt with *surprising* speed, but you can help the process along by closely following your surgeon's instructions.

As part of the recovery process, your surgeon may ask that you:

- Use **prescription eye drops** to prevent infection and reduce any swelling or irritation.
- Use an **over-the-counter lubricant eye drop** to keep your eyes moist and comfortable.
- **Wear eye shields**, particularly during sleep, to prevent irritation.
- **Wear dark eyeglasses** if you experience sensitivity to bright lights.
- **Avoid rubbing your eyes** for a few weeks after surgery.

A week or so after surgery, you'll probably also have a follow-up visit with your doctor, just to make sure your eyes are healing nicely.

Immediately after **OptiLASIK™**, you may experience a few slight side effects from the procedure, including watery eyes, a burning, scratchy sensation, or mild discomfort. These symptoms usually pass within the first few days. If you experience any severe pain, however, or vision that gets worse rather than better, contact your doctor immediately.

Many people notice clearer vision right after **OptiLASIK™** – everyone responds differently, though. During your first week of recovery, your vision may seem slightly hazy or blurry – you may also be sensitive to light, or have trouble seeing at night. These symptoms usually clear up as your eyes heal, but you may continue to experience slight fluctuations in your vision for up to 6 months after surgery.

## THE RESULTS ARE IN!

As your eyes heal and your vision stabilizes, you can wind up with some pretty impressive results, thanks to **OptiLASIK™**. Most people are able to see as well as – or even better than – they did with their glasses and contact lenses.

Imagine being able to enjoy a concert or baseball game, even if you're in the back row. Having the confidence you need on a job interview or first date, without glasses getting in the way. Enjoying the summertime – playing sports, swimming – without itchy, irritating contacts. With **OptiLASIK™** Laser Vision Correction, you'll finally have the freedom to do all the things you want, with nothing standing in your way.

**Your freedom. Your confidence. Your eyes.  
You have options – you have OptiLASIK™.**

## The facts about **OptiLASIK™** with WaveLight® technology:

- **93%** of nearsighted patients see 20/20 or better.<sup>1</sup>
- **83%** of farsighted patients see 20/25 or better.<sup>2</sup>
- **92%** of patients described their vision as “good” or “excellent.”<sup>1</sup>
- *Think 20/20 vision is impressive?* **3/4** of nearsighted patients actually see better than 20/20!<sup>1</sup>

# Product Information

## (Brief Statement of Intended Use):

### Myopia:

- a. Approval of the premarket approval application is for the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System to perform LASIK treatments in patients 18 years of age or older for the reduction or elimination of myopic refractive errors up to -12.0 diopters (D) of sphere with and without astigmatic refractive errors up to -6.0 D; and in patients with documented evidence of a stable manifest refraction defined as less than or equal to 0.50 D of preoperative spherical equivalent shift over one year prior to surgery.
- b. LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), and other refractive surgeries.
- c. Approval of the application is based on clinical trials in the United States with 901 eyes treated, of which 813 of 866 eligible eyes were followed for 12 months. Accountability at 3 months was 93.8%, at 6 months was 91.9%, and at 12 months was 93.9%.
- d. The studies found that of the 844 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 3-month stability time point, 98.0% were corrected to 20/40 or better, and 84.4% were corrected to 20/20 or better without spectacles or contact lenses.
- e. The clinical trials showed that the following subjective patient adverse events were reported as “moderate to severe” at a level at least 1% higher than baseline of the subjects at 3 months post-treatment: visual fluctuations (12.8% at baseline versus 28.6% at 3 months).
- f. Long-term risks of LASIK for myopia with and without astigmatism beyond 12 months have not been studied.
- g. Note that the complete name for this ophthalmic laser is “WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System for laser-assisted *in-situ* keratomileusis (LASIK) treatments of myopic refractive errors up to -12.0 diopters (D) of sphere with and without astigmatic refractive errors up to -6.00 D at the spectacle plane.”

### Hyperopia:

- a. Approval of the premarket approval application is for the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System to perform LASIK treatments in patients 18 years of age or older for the reduction or elimination of hyperopic refractive errors up to +6.0 diopters (D) of sphere with and without astigmatic refractive errors up to 5.0 D at the spectacle plane, with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D; and in patients with documented evidence of a stable manifest refraction defined as less than or equal to 0.50 D of preoperative spherical equivalent shift over one year prior to surgery, exclusive of changes due to unmasking latent hyperopia.
- b. LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), and other refractive surgeries.
- c. Approval of the application is based on clinical trials in the United States with 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 69.9%.
- d. The studies found that of the 212 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 6-month stability time point, 95.3% were corrected to 20/40 or better, and 67.5% were corrected to 20/20 or better without spectacles or contact lenses.
- e. The study showed that the following subjective patient adverse events were reported as “much worse” by at least 1% of the subjects (in order of increasing frequency) at 6 months post final treatment: glare from bright lights (3.0%); night driving glare (4.2%) light sensitivity (4.9%); visual fluctuations (6.1%); and halos (6.4%).
- f. Long term risks of LASIK for hyperopia with and without astigmatism beyond 12 months have not been studied.
- g. Note that the complete name for this ophthalmic laser is “WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System for laser-assisted *in-situ* keratomileusis (LASIK) treatments of hyperopic refractive errors up to +6.0 diopters (D) of sphere with and without astigmatic refractive errors up to 5.0 D with a maximum manifest refraction spherical equivalent (MRSE) of +6.00 D.”

### Mixed Astigmatism:

- a. Approval of the premarket approval application is for the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System to perform LASIK treatments in patients 21 years of age or older for the reduction or elimination of naturally occurring mixed astigmatism of up to 6.00 D at the spectacle plane; and in patients with documentation of a stable manifest refraction defined as less than or equal to 0.50 D of preoperative spherical equivalent shift over one year prior to surgery.
- b. LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), and other refractive surgeries.

- c. Approval of the application is based on clinical trials in the United States with 162 eyes treated, of which 111 were eligible to be followed at 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%.
- d. The studies found that of the 142 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 3-month stability time point, 95.8% achieved acuity of 20/40 or better, and 67.6% achieved acuity of 20/20 or better without spectacles or contact lenses.
- e. The clinical trials showed that the following subjective patient adverse events were reported as “moderate to severe” at a level at least 1% higher than baseline of the subjects at 3 months post-treatment: sensitivity to light (43.3% at baseline versus 52.9% at 3 months); visual fluctuations (32.1% at baseline versus 43.0% at 3 months); and halos (37.0% at baseline versus 42.3% at 3 months).
- f. Long term risks of LASIK for mixed astigmatism beyond 6 months have not been studied.
- g. The safety and effectiveness of LASIK surgery has ONLY been established with an optical zone of 6.0 - 7.0 mm and an ablation zone of 9.0 mm.
- h. Note that the complete name for this ophthalmic laser is “WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System for laser-assisted *in-situ* keratomileusis (LASIK) treatments of naturally occurring mixed astigmatism of up to 6.00 D at the spectacle plane.”

### Wavefront-Guided Treatment of Myopia:

- a. Approval of the premarket approval application is for the WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System used in conjunction with the WaveLight® ALLEGRO Analyzer® device. The device uses a 6.5 mm optical zone, a 9.0 mm ablation/treatment zone, and is indicated for wavefront-guided (WFG) laser-assisted *in-situ* keratomileusis (LASIK): 1) for the reduction or elimination of up to -7.00 diopters (D) of spherical equivalent myopia or myopia with astigmatism, with up to -7.00 D of spherical component and up to 3.00 D of astigmatic component at the spectacle plane; 2) in patients who are 18 years of age or older; and 3) in patients with documentation of a stable manifest refraction defined as ≤0.50 D of preoperative spherical equivalent shift over one year prior to surgery.
- b. LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), traditional LASIK and other refractive surgeries.
- c. Approval of the application is based on a randomized clinical trial in the United States with 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized® LASIK (Control Cohort). 178 of the Study Cohort and 180 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.2%.
- d. The studies found that of the 180 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 6-month stability time point in the Study Cohort, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better without spectacles or contact lenses. In the Control Cohort, of the 176 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20 or better without spectacles or contact lenses.
- e. The clinical trials showed that the following subjective patient adverse events were reported as “moderate to severe” at a level at least 1% higher than baseline of the subjects at 3 months post-treatment in the Study Cohort, light sensitivity (37.2% at baseline versus 47.8% at 3 months) and visual fluctuations (13.8% at baseline versus 20.0% at 3 months). In the Control Cohort, halos (36.6% at baseline versus 45.4% at 3 months) and visual fluctuations (18.3% at baseline versus 21.9% at 3 months).
- f. Long term risks of wavefront-guided LASIK for myopia with and without astigmatism beyond 6 months have not been studied.
- g. Note that the complete name for this ophthalmic laser is “WaveLight® ALLEGRETTO WAVE® / ALLEGRETTO WAVE® Eye-Q Excimer Laser System used in conjunction with the WaveLight® ALLEGRO Analyzer® device. The device uses a 6.5 mm optical zone, a 9.0 mm ablation/treatment zone, and is indicated for wavefront-guided (WFG) laser-assisted *in-situ* keratomileusis (LASIK): 1) for the reduction or elimination of up to -7.00 diopters (D) of spherical equivalent myopia or myopia with astigmatism, with up to -7.00 D of spherical component and up to 3.00 D of astigmatic component at the spectacle plane; 2) in patients who are 18 years of age or older; and 3) in patients with documentation of a stable manifest refraction defined as ≤0.50 D of preoperative spherical equivalent shift over one year prior to surgery.”

### References:

1. WaveLight® FDA Clinical Trials: *Wavefront Optimized®* and Wavefront-Guided for Myopia plus Astigmatism. <http://www.fda.gov/cdrh/PDF2/P020050S004b.pdf>
2. WaveLight® FDA Clinical Trials: *Wavefront Optimized®* for Hyperopia. <http://www.fda.gov/cdrh/pdf3/P030008.html>

NEVER WINS AT POKER.

STUDIED  
BALLET, BUT  
DENIES IT.

RESTORES  
VINTAGE ELECTRIC  
GUITARS.

ALWAYS CARRIES  
A 4-LEAF CLOVER.

OptiLASIK™

Laser Vision Correction

**ABC Eye Center Name**  
1234 Anystreet  
Anytown, USA 12346-6789

 **WaveLight**®  
Brought to you by  
**Alcon**®

Allegretto  
Wave®  
Eye-Q Laser

Realize your unique  
vision potential.



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