




# WaveLight<sup>®</sup>

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Workstation

Choose a **LASIK**  
procedure  
optimized for *your*  
unique vision.



Your eyes are as  
unique as you are.

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

Learn the facts about LASIK surgery with WaveLight<sup>®</sup>  
refractive technology, and see why it was made for you.

Consult with your doctor about the  
risks associated with LASIK surgery.

*Realize your unique  
vision potential.*

## the facts:

- More than **17 million** people worldwide have had some form of laser vision correction.<sup>1</sup>
- Every year, **nearly 400,000** Americans have LASIK surgery.<sup>2</sup>
- **93%** of nearsighted patients see at least 20/20 or better following LASIK surgery.<sup>3</sup>
- **87%** of LASIK patients recommend LASIK to their friends.<sup>3</sup>

Choose a **LASIK** procedure optimized for *your* unique needs.

## 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 lost lenses – *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.

### **WAVELIGHT® TECHNOLOGY FOR PERSONALIZED LASIK.**

We know, LASIK can seem a bit scary at first – a *laser* pointed at your *eye?! –* but laser surgery has been extensively evaluated by the FDA, who have found it to be both

safe *and* effective. In fact, 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 the *exact same way* as everyone else's? If you're thinking about laser vision correction, choose the innovative LASIK technology that was designed to work *with* your eyes' unique attributes. It's time to see the light, with **WaveLight®** refractive technology.

**Remember:** Just the thought of a laser pointed at your eye can seem a bit scary! But laser surgery has been studied and approved by the FDA as a safe and effective way of reducing the dependency of glasses or contact lens. Laser assisted in-situ keratomileusis (LASIK) can only be performed by a trained physician and is cleared for the reduction or elimination of myopia, hyperopia, and astigmatism as indicated within the product labeling. Potential side effects to laser refractive surgery may include glare, dry eye, as well as other visual anomalies.

# Your vision: A refresher course.

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! LASIK surgery with **WaveLight®** refractive technology can make it happen, potentially 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 what you can do about it.



## Myopia (Nearsightedness)

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

## EYE ANATOMY 101

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.



Choose a **LASIK** procedure optimized for *your* ideal perspective.

### Important Information About the WaveLight® Excimer Lasers

WaveLight® Excimer Lasers are prescription medical devices that are approved for use in performing laser assisted in-situ keratomileusis (LASIK) to correct certain kinds of near-sightedness (myopia), far-sightedness (hyperopia), and astigmatism. Only doctors who have been trained in laser refractive surgery (including laser calibration and operation) should use an WaveLight® Excimer Laser.

You should not undergo LASIK surgery if you are pregnant or nursing; if you have a collagen vascular, autoimmune or immunodeficiency disease; if you show signs of keratoconus or any other condition that causes a thinning of your cornea; or if you are taking isotretinoin (Accutane®)



## 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.

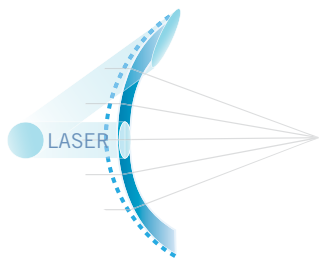
### WHAT'S GOT YOUR EYES BENT OUT OF SHAPE?

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.

### QUICK FIXES – AND A NEW SOLUTION.

Glasses and contact lenses work by compensating for the shape of your eyes, adjusting how light bends so that it will focus in the correct spot on the retina and provide clear vision. The problem is, of course, they only work as long as you're wearing them.

Luckily, patients with vision problems now have options *beyond* contacts and glasses. Now, your doctor can actually *reshape* your cornea, essentially changing your eyes so they permanently focus light how they should. The result? The clear vision you'd have if your eyes were their ideal shape. And that's where LASIK enters the picture.



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

or amiodarone hydrochloride (Cordarone®). The most common risks of LASIK vision correction surgery with refractive lasers include dry eye syndrome; the possible need for glasses or contact lenses after surgery; visual symptoms including halos, glare, starbursts, and double vision; and loss of vision.

Talk to your doctor and review the appropriate WaveLight® Excimer Laser Patient Information Booklet for your condition to learn more about the potential risks and benefits for laser refractive surgery. For further information, please refer to the additional Important Safety Information on this site, or FDA's web page on LASIK surgery.

\* Trademarks are property of their respective owners.

### What does LASIK mean, anyway?

LASIK is an acronym for *laser-assisted in-situ keratomileusis*, which is just a fancy way of describing the process of creating a flap before reshaping the cornea with a laser.

Choose a **LASIK** procedure optimized for *your* optimal outlook.

## LASIK basics. Changing the way you see the world.

OK, so you know what's causing your vision problems. Now, let's talk solutions – LASIK, to be precise.

LASIK surgery is the most common form of **laser vision correction**, a surgical procedure in which a laser is used to reshape the eyes, so that they're closer to their ideal shape for focusing light.

At its core, LASIK is basically a 2-step process:



### Step 1: Flap Creation

A thin flap, like a door, is created in the surface of the cornea and opened, exposing the underlying tissue so your surgeon can reshape the cornea from within. These flaps were originally made by hand, but new laser technology actually allows for *bladeless* flap creation.



### Step 2: Eye Reshaping

Your surgeon will work *in* the cornea to carefully reshape the eye, removing small amounts of tissue with tiny, rapid bursts from a laser. Once the eye is a more ideal shape for clear, focused vision, the flap is put back into place, where it acts as a natural bandage.

**Remember:** Although LASIK surgery has been shown to be safe and effective, it's still surgery, and like any surgical procedure, there can be complications or side effects. Make sure to discuss the risks and benefits with your doctor, so you can make an informed decision about surgery.

To learn more about **WaveLight**<sup>®</sup> refractive technology, see the Important Safety Information at the back of this brochure.



It sounds like something out of science fiction, but don't worry – the procedure is fast and effective, with minimal discomfort. Plus, almost immediately, your reshaped eyes will very likely be able to focus more accurately, for considerably improved vision (and a considerably happier you).

### **IS LASIK RIGHT FOR YOU?**

Now, LASIK is a trusted procedure that can give you *life-changing results*, but that doesn't mean it's right for *everybody*. Before you even *think* about surgery, you'll need to have an initial consultation with your doctor, just to make sure you (and your eyes) are ideal for LASIK.

In addition to testing your vision, to verify that it falls within the range that LASIK can actually help, your doctor will make sure 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 qualify for surgery with the WaveLight® Laser System. *Hang in there, minors!*)

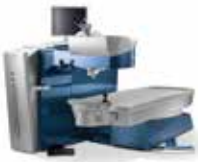
Certain eye conditions can also affect your surgical options – thin corneas, dry eye, etc. – so your doctor may test for them, just in case. Don't forget to mention any *other* medical conditions you have, or any medications you might be taking, as they can affect surgery as well.

Finally, and most importantly, your surgeon will make sure you're comfortable and knowledgeable about LASIK, answering any questions you might have and helping you understand what you can expect from the procedure. As with any surgical procedure, there can be risks, complications and side effects that come with LASIK surgery; your surgeon will discuss these concerns with you and help you decide if surgery makes sense for you. After all, if *you're* not ready for surgery, it doesn't matter if your eyes are!

Choose a **LASIK** procedure optimized for *your* best visual potential.

## THE TECHNOLOGY YOUR SURGEON TRUSTS:

Alcon, the world leader in eye care technology, is the mind behind the **WaveLight® Workstation**, a one-two punch of LASIK performance:



### The WaveLight® FS200 Femtosecond Laser

If we had to guess, there's one aspect of LASIK that may still be freaking you out a little: *The flap*. Creating the flap is a standard step in LASIK – performed hundreds of times by your surgeon – but we know it can still be a concern. The **WaveLight® FS200 Laser** was developed to make this process just a little more convenient. Specially designed for fast, precise custom flap creation, the **WaveLight® FS200 Laser** is the first step in delivering excellent results.

## WaveLight® Technology for *personalized* LASIK.

So you've decided to have LASIK surgery. 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.** It's time to see the light, with **WaveLight®** refractive technology.

### WHAT MAKES Wavelight® REFRACTIVE TECHNOLOGY UNIQUE?

**WaveLight®** refractive technology combines the latest surgical advancements into a LASIK procedure personalized for *your* ideal vision. In the past, every LASIK patient received the same basic procedure every single time, without accounting for all

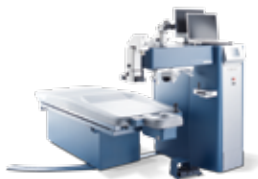
the unique attributes that make your eyes special.

**WaveLight®** refractive technology is different. **WaveLight®** technology allows your surgeon to create a personalized treatment plan, with treatment options that take into account *your* unique visual needs, for *your* best results.

You and your surgeon will work together to develop a treatment plan that works best with your eyes, your goals, your lifestyle. Then, utilizing the advanced technology of both the **WaveLight® FS200 Laser** and the **WaveLight® ALLEGRETTO WAVE® Eye-Q Laser**, your doctor will perform the LASIK treatment that's right for you.

For example: In rare cases, some





### The WaveLight® ALLEGRETTO WAVE® Eye-Q Laser

Flap creation is important, but it's reshaping the eye that provides the clear vision you've been looking for – and for that, you need the right combination of speed, precision and personalization. Designed to provide outstanding results, the **WaveLight® ALLEGRETTO WAVE® Eye-Q Laser** combines high-speed laser technology, precise beam positioning and the flexibility of personalized treatment paths.

To learn more about Alcon and the **WaveLight® Workstation**, visit [ReclaimYourVision.com](http://ReclaimYourVision.com)

people's eyes are prone to a certain type of quirk (called higher order aberrations) that can affect night vision and cause you to see glare around lights. With the **WaveLight® ALLEGRETTO WAVE® Eye-Q Laser**, your surgeon has the option to perform a custom treatment to correct these aberrations as needed.

Most people don't have enough higher order aberrations to require this custom treatment, however. Instead, for most patients, the **WaveLight®** system offers a unique procedure that actually accounts for the *natural shape* of your eye. You see, earlier LASIK 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.

The **WaveLight® ALLEGRETTO WAVE® Eye-Q Laser** was designed to preserve the natural curvature of your eye. As a result, LASIK with **WaveLight®** refractive technology can help preserve the quality of your vision, ensuring your eyes are at their most natural *and* their most useful.

Finally, with the **WaveLight® FS200 Laser**, there's no need to flip out over flaps! With traditional LASIK, your surgeon had to create the flap by hand with a surgical blade. Now, **WaveLight®** refractive technology features a *second* laser, specially designed for fast, precise flap creation. This bladeless, all-laser technology only adds to the already-excellent outcomes of the **WaveLight® ALLEGRETTO WAVE® Eye-Q Laser**.

They're your eyes – make sure they're at their very best, with **WaveLight®** refractive technology.

# What to expect with LASIK with WaveLight® technology:

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 a big, scary ordeal, but with **WaveLight®** refractive technology, it doesn't have to be. While LASIK is still a surgical procedure, thanks to the advanced technology of the **WaveLight®** system, the entire LASIK process is fast, safe and

precise. Plus, in just a matter of minutes, you'll finally have the opportunity for the vision you've always wanted.

## 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!*

### **PREPPING FOR THE PROCEDURE.**

Once you've decided that LASIK surgery is right for you, your doctor 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?", though – your surgeon will work with you to decide the treatment path that's best for your eyes.

You'll discuss your vision problems, your goals, and your lifestyle, hobbies and interests. Your surgeon may even use a special scanning tool to create a personalized map of your eyes. Your doctor will then use all of this information to determine a personalized treatment plan, including exactly how your eyes will need to be reshaped for your best vision.

## LASIK SURGERY – THE BIG DAY AT LAST!

Start to finish, the LASIK procedure only takes a few minutes. Here's the rundown:

- **Before surgery begins, you'll receive a series of anesthetic drops in each eye. These drops will numb your eyes and help ensure you're comfortable throughout the procedure – most patients only feel some light pressure during surgery.**
- **Once your eyes are numb, you'll be asked to lie down on a bed under the WaveLight® Workstation.**
- **The first step is flap creation – using the innovative WaveLight® FS200 Femtosecond Laser, your surgeon will create a precise flap, or door, in each cornea, exposing the underlying tissue so your surgeon can correct your vision.**
- **Once the flaps have been made, you'll be shifted over to the other half of the WaveLight® Workstation – the advanced WaveLight® ALLEGRETTO WAVE® Eye-Q Laser – to begin the process of reshaping your eyes for better vision.**
- **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. – making it that much closer to its ideal shape for clear, focused vision.**
- **Throughout this part of the procedure, you'll be asked to focus on a small blinking light above you. Don't worry if your eyes move a little bit – the ALLEGRETTO WAVE® Eye-Q Laser uses sophisticated eye-tracking technology, so it can keep up.**
- **Once your eye has been properly reshaped, your doctor will put the flap back into place, where it will act as a natural bandage. No need for stitches here!**

**And** that's it! In a matter of minutes, you're good to go! All you have to do now is rest up, and get ready to enjoy the benefits of improved vision!

**Remember:** Just the thought of a laser pointed at your eye can seem a bit scary! But laser surgery has been studied and approved by the FDA as a safe and effective way of reducing the dependency of glasses or contact lens. Laser assisted in-situ keratomileusis (LASIK) can only be performed by a trained physician and is cleared for the reduction or elimination of myopia, hyperopia, and astigmatism as indicated within the product labeling. Potential side effects to laser refractive surgery may include glare, dry eye, as well as other visual anomalies.

# The results you want—

Enjoy your new outlook on life, with **WaveLight®** technology.



Within a matter of minutes, LASIK surgery with WaveLight® refractive technology 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 LASIK surgery, you need to know what to expect after the procedure.

## 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.

\* Results may vary.

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.

## The facts about LASIK with **WaveLight**® refractive technology:

- **93%** of nearsighted patients see 20/20 or better.<sup>3</sup>
- **83%** of farsighted patients see 20/25 or better.<sup>3</sup>
- **92%** of patients described their vision as “good” or “excellent.”<sup>3</sup>
- *Think 20/20 vision is impressive? **75%** of Wavefront Optimized® treated nearsighted patients and **64%** of Wavefront-Guided nearsighted patients actually see better than 20/20.<sup>3</sup>*

Immediately after LASIK surgery, 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 LASIK with **WaveLight**® refractive technology – 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 **WaveLight**® refractive technology. 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 LASIK surgery – and **WaveLight**® refractive technology – you'll have the freedom to do more of the things you want, with nothing standing in your way.

**Your freedom. Your confidence. Your eyes.**  
**It's time to see the light, with WaveLight**®  
**refractive technology.**

# Important Safety Information about the WaveLight® Excimer Laser Systems

This information pertains to all WaveLight® Excimer Laser Systems, including the WaveLight® ALLEGRETTO WAVE®, the ALLEGRETTO WAVE® Eye-Q, and the WaveLight® EX500.

**CAUTION:** Federal (U.S.) law restricts the WaveLight® Excimer Laser Systems to sale by or on the order of a physician. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery (including laser calibration and operation) should use a WaveLight® Excimer Laser System.

**INDICATIONS:** FDA has approved the WaveLight® Excimer Laser Systems for use in laser-assisted in situ keratomileusis (LASIK) treatments for nearsightedness (myopia), farsightedness (hyperopia), and astigmatism, including mixed astigmatism. Astigmatism occurs if the shape of your eye causes light to bend and distort as it passes through your lens. With astigmatism, objects tend to appear blurry or unfocused. Mixed astigmatism occurs if you have symptoms or nearsightedness and farsightedness at the same time.

The WaveLight® Excimer Laser Systems are approved for the following specific LASIK treatments and ranges:

- Reduction or elimination of nearsightedness of up to - 12.00 diopters of sphere and up to 6.00 diopters of astigmatism at the spectacle plane.
- Reduction or elimination of farsightedness up to + 6.00 diopters of sphere and up to 5.00 diopters of astigmatism at the spectacle plane, with a maximum manifest refraction spherical equivalent of + 6.00 diopters.
- Reduction or elimination of naturally occurring mixed astigmatism of up to 6.00 diopters at the spectacle plane.
- Wavefront-guided reduction or elimination of nearsightedness of up to -7.00 diopters of sphere and up to 3.00 diopters of astigmatism at the spectacle plane. Wavefront-guided LASIK treatment takes into account small, complex imperfections in the shape of your eye that can affect your vision. Wavefront-guided LASIK is more highly customized than traditional LASIK procedures.

The WaveLight® Excimer Laser Systems are only indicated for use in patients who are 18 years of age or older (21 years of age or older for mixed astigmatism), who have documented evidence that their refraction did not change by more than 0.50 diopters during the year before their preoperative examination.

**Alternatives to LASIK:** LASIK is just one option for correcting your vision. Alternative options include eyeglasses, contact lenses, photorefractive keratectomy surgery (PRK), and other refractive surgeries. Be sure to talk to your doctor to find out if LASIK is appropriate for your condition.

**CONTRAINDICATIONS:** If you have any of the following situations or conditions, you should not have LASIK because the risk is greater than the benefit:

- You are pregnant or nursing. These conditions may cause temporary and unpredictable changes in your cornea and a LASIK treatment would improperly change the shape of your cornea.
- You have a collagen vascular, autoimmune or immunodeficiency disease, such as rheumatoid arthritis, multiple sclerosis, lupus or AIDS. These conditions affect the body's ability to heal.
- You show signs of keratoconus or any other condition that causes a thinning of your cornea. This condition can lead to serious corneal problems during and after LASIK surgery. It may result in need for additional surgery and may result in poor vision after LASIK.
- You are taking medications with ocular side effects, such as Isotretinoin (Accutane®) for acne treatment or Amiodarone hydrochloride (Cordarone®) for normalizing heart rhythm, because they may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.

**WARNINGS:** If you have any of the following conditions, you should have LASIK only 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, severe atopic disease or are immunocompromised, LASIK may be risky for you because it may affect the ability of your eyes to heal.
- Diabetes. If you have diabetes and depend on insulin, LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.
- 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, LASIK is more risky for you.
- Symptoms of significant dry eye. If you have severely dry eyes, 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.
- Severe allergies. If you have severe allergies and take medicines for them, LASIK is more risky for you.

**Precautions:** If any of the following conditions or situations apply to you, you should discuss them with your doctor:

- Your nearsightedness, farsightedness, astigmatism or mixed astigmatism is getting better or worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may

result in poor vision after LASIK.

- You have an eye disease. It is unknown whether LASIK is safe and effective under this condition.
- You have had a prior eye injury or eye surgery. If your eyes are injured or you have had surgery, it is unknown whether LASIK will weaken the cornea too much. This may result in poor vision after LASIK.
- You have a corneal abnormality (e.g., scar, irregular astigmatism, infection, etc.). An abnormal corneal condition may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.
- Your corneas are too thin. If your corneas are too thin to allow your doctor to cut a proper flap during the LASIK procedure, you can't have LASIK because it is necessary to have a flap.
- You have a history of glaucoma or high eye pressure. It is unknown whether LASIK is safe and effective for you.
- You take medicines that might make it harder for wounds to heal, such as sumatriptan succinate (Imitrex®) for migraine headaches. It is unknown whether LASIK is safe and effective for people who take these medicines.
- You are younger than 18 years of age (21 years for mixed astigmatism). It is unknown whether LASIK is safe and effective for you.
- Your doctor may modify the wavefront-calculated ablation program in order to give you a treatment that does not fully correct distance vision. You should discuss the risks in depth with your doctor for any LASIK corrections that do not fully correct for distance vision, especially if performed only in one eye.
- You have a cataract or other problem with the lens or vitreous of your eye. It is unknown whether LASIK is safe and effective under this condition.
- You have any problems with the iris (colored part) of your eye or have had previous surgery on this part of your eye. The eyetracker on the laser may not work properly and LASIK may not be safe and effective for you.
- You are taking prescription or over-the-counter medications that may affect the ability of your eye to heal after surgery, including antimetabolites.
- Your doctor plans to use a treatment zone with the laser < 6.0 millimeters or > 6.5 millimeters in diameter. It is unknown whether LASIK with these treatment zones is safe and effective for you.
- Your nearsightedness is worse than - 12.00 diopters, or with astigmatism that is worse than 6.00 diopters. It is unknown whether LASIK is safe and effective for you.
- Your farsightedness is worse than + 6.00 diopters, or with astigmatism that is worse than 5.00 diopters. It is unknown whether LASIK is safe and effective for you.
- Your mixed astigmatism is worse than 6.00 diopters. It is unknown whether LASIK is safe and effective for you. Your mixed astigmatism is > 4.00 diopters to ≤ 6.00 diopters. Due to the lack of large numbers of patients in the general population, there are few subjects with cylinder amounts in this range to be studied. Not all complications, adverse events, and levels of effectiveness may have been determined.
- You have 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 in conditions such as dim light, rain, fog, snow and glare from bright lights. This has been shown to occur more frequently when the entire prescription has not been fully corrected and perhaps in patients with pupil sizes larger than the treatment area.

Your doctor should evaluate you for dry eye before surgery. You may have dry eye after LASIK surgery even if you did not have dry eye before surgery.

It is not known whether LASIK with a WaveLight® Excimer Laser System is effective over the long term (more than 12 months).

## ADVERSE EVENTS AND COMPLICATIONS

Common risks of LASIK procedures include:

- developing dry eye syndrome, which can be severe;
- the possible need for glasses or contact lenses after surgery;
- visual symptoms including halos, glare, starbursts, and double vision, which can be debilitating; and
- the loss of vision.

The following adverse events and complications were reported in the clinical studies for the WaveLight® Excimer Laser Systems:

- **Nearsightedness Study:** In the myopia (nearsightedness) clinical study, 0.2% (2/876) of the eyes had a lost, misplaced, or misaligned flap reported at the 1 month examination. The following complications were reported 6 months after LASIK: 0.9% (7/818) had ghosting or double images in the operative eye; 0.1% (1/818) of the eyes had a corneal epithelial defect.
- **Farsightedness Study:** In the hyperopia (farsightedness) clinical study, 0.4% (1/276) of the eyes had a retinal detachment or retinal vascular accident reported at the 3 month examination. The following complications were reported 6 months after LASIK: 0.8% (2/262) of the eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface.
- **Mixed Astigmatism Study:** In the mixed astigmatism clinical study, two adverse events were

reported. One patient suffered from decreased vision in the treated eye, following blunt trauma to the eye 6 days after surgery. The second event involved the treatment of an incorrect axis of astigmatism. The following complications were reported 6 months after LASIK: 1.8% (2/111) of the eyes had ghosting or double images in the operative eye.

- **Wavefront-Guided Nearsightedness Study:** No adverse events occurred during the postoperative period of the wavefront-guided LASIK procedures. One subject undergoing traditional LASIK treatment was treated on the incorrect axis of astigmatism. The following complications were reported 6 months after wavefront-guided LASIK in the Study Cohort: 1.2% (2/166) of the eyes had a corneal epithelial defect; 1.2% (2/166) had foreign body sensation; and 0.6% (1/166) had pain. No complications were reported in the Control Cohort.

## CLINICAL DATA

**Nearsightedness Study:** Of the 782 eyes in the myopia (nearsightedness) study that were included in the analysis of effectiveness without wearing glasses, at 6 months after surgery, 98.3% were corrected to 20/40 or better, and 87.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher 3 months after surgery than at baseline: visual fluctuations (28.6% vs. 12.8% at baseline).

**Farsightedness Study:** Of the 212 eyes in the hyperopia (farsightedness) study that were included in the analysis of effectiveness without wearing glasses, at 6 months after surgery, 95.3% were corrected to 20/40 or better, and 67.5% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms as "much worse" 6 months after surgery: halos (6.4%); visual fluctuations (6.1%); light sensitivity (4.9%); night driving glare (4.2%); and glare from bright lights (3.0%).

**Mixed Astigmatism Study:** Of the 111 eyes in the mixed astigmatism study that were eligible for the analysis of effectiveness without wearing glasses, at 6 months after surgery, 97.3% were corrected to 20/40 or better, and 69.4% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher 6 months after surgery than at baseline: sensitivity to light (52.9% vs. 43.3% at baseline); visual fluctuations (43.0% vs. 32.1% at baseline); and halos (42.3% vs. 37.0% at baseline).

**Wavefront-Guided Nearsightedness Study:** The wavefront-guided myopia (nearsightedness) clinical study compared patients treated with wavefront-guided LASIK (Study Cohort) to patients treated with traditional LASIK (Control Cohort). Of the 166 eyes in the Study Cohort that were eligible for the analysis of effectiveness without wearing glasses, at 6 months after surgery, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better. Of the 166 eyes in the Control Cohort, at 6 months after surgery, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20.

In the Study Cohort, subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher 3 months after surgery than at baseline: light sensitivity (47.8% vs. 37.2% at baseline) and visual fluctuations (20.0% vs. 13.8% at baseline). In the Control Cohort, the following visual symptoms were reported at a "moderate" or "severe" level at least 1% higher 3 months after surgery than at baseline: halos (45.4% vs. 36.6% at baseline) and visual fluctuations (21.9% vs. 18.3% at baseline).

**ATTENTION:** Please refer to a current WaveLight® Excimer Laser System Patient Information Booklet for a complete listing of the indications, complications, warnings, precautions, and side effects. Ask your doctor for a copy of the current Patient Information Booklet.

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## References:

1. Market Scope Annual Report, 2007.
2. Approximately 391,376 (2010 estimate) reference / based on Market Scope data for 2010. Accessed November 2, 2010.
3. Data on file. Alcon, Inc.



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