FACTS YOU NEED TO KNOW ABOUT *ADVANCED CUSTOMVUE* LASER ASSISTED IN-SITU KERATOMILEUSIS (LASIK) LASER TREATMENT

Patient Information Booklet

For mixed astigmatism from 1 to 5 diopters

Please read this entire booklet. Discuss its contents with your doctor so that all your questions are answered to your satisfaction. Ask any questions you may have before you agree to the surgery.

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GLOSSARY

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions you may have about these terms.

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

Anti-inflammatory Medication: a drug that reduces redness and swelling associated with inflammation. May be a corticosteroid, or a nonsteroidal anti-inflammatory drug.

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

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

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

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

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

Cornea: the clear front surface of the eye. Surgery such as PRK and LASIK reshape or flatten this surface to correct vision.

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

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

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

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

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

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

iDesign Advanced WaveScan Studio* System:** the ***iDesign Advanced WaveScan Studio System is a diagnostic instrument to objectively measure the refractive errors of the eye.

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

Intraocular Pressure (IOP): fluid pressure inside the eye. Your doctor measures the pressure inside the eye with a tonometer.

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

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

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

Microkeratome: an automated surgical tool that cuts a flap of tissue from the front surface of the eye with a blade.

Myopia: a refractive error in which the cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Nearsightedness is another term for myopia.

Nearsightedness: a refractive error in which the cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Myopia is another term for nearsightedness.

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

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

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

Refract: to bend or focus rays of light.

Refractive Error: a focusing error of the eye, in which parallel light rays are not brought to a sharp focus precisely on the retina, producing a blurred image. Refractive errors can be myopic, astigmatic, or hyperopic.

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

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

Wavefront error: simple and complex focusing errors in the eye that are revealed by differences in the paths of light rays as they are bent by the eye.

Wavefront Error Maps: a color map that displays wavefront errors measured by the ***iDesign Advanced WaveScan Studio*** System.

INTRODUCTION

Your doctor and Abbott Medical Optics Inc. (***AMO***) provide the information in this booklet to help you decide whether to have an ***Advanced CustomVue*** LASIK treatment. ***Advanced CustomVue*** LASIK (laser assisted *in situ* keratomileusis) may be used to correct, or reduce mixed astigmatism.

Some other ways to correct your vision include wearing glasses or contact lenses. Other surgical methods include implantable lens surgery and other types of LASIK that do not use wavefront technology. These include LASIK using traditional eye prescriptions or corneal topography. Additional alternatives include photorefractive keratectomy (PRK) and other corneal incision procedures to reshape the curvature of the cornea.

Please read this booklet completely. Discuss any questions with your doctor before you decide if ***Advanced CustomVue*** LASIK is right for you. Only an eye care professional trained in laser vision correction can determine whether you are a suitable candidate.

How Refractive (Wavefront) Errors Affect Your Vision

The cornea and lens of the eye focus rays of light by bending (or refracting) them to focus an image on the retina at the back of the eye, much like a camera focuses images onto film.

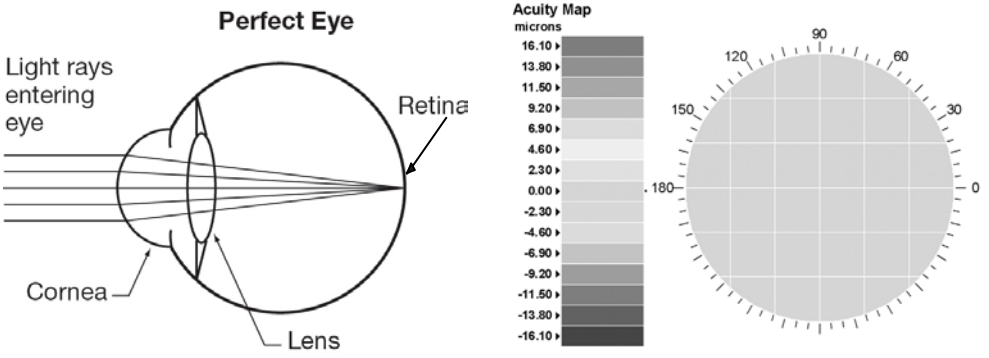


Figure 1 Perfect Eye

Figure 1: On the left is a diagram showing how the eye focuses light rays to create a sharp image on the retina. The corresponding wavefront map of an ideal eye is displayed on the right.

The above figure shows an ideal eye with no focusing imperfections. All of the rays of light traveling through the eye focus to a single point on the retina at the back of the eye.

In reality, all eyes have some degree of imperfections. One way to measure the focusing errors of an eye is to measure the *wavefront* of the eye. This can be done with an instrument like the ***iDesign Advanced WaveScan Studio*** System. The wavefront map shows the imperfections of the eye. The ***iDesign Advanced WaveScan Studio*** System measures the wavefront errors by measuring light as it reflects out of the eye with a camera sensor.

The wavefront of a perfect eye has a flat surface because all of the light rays travel uniformly through the eye, as shown in **Figure 1**. The wavefront of an eye with imperfections is curved or wavy because some light rays reach the retina before others, and some rays strike different locations on the retina

than others. Wavefront errors include both simple and complex focusing errors. The simple wavefront errors, which can be corrected with curved lenses (e.g., glasses or contact lenses,) are also called *refractive errors* and include *mixed astigmatism*.

Astigmatism is usually caused by a misshapen cornea. Instead of being perfectly spherical, like a basketball, a cornea with astigmatism more sharply curved in one direction than the other, like a football. The different curvatures of the cornea focus the light unequally so that the light does not ever come to a single point. Things look blurry because images are not ever focused clearly on the retina (the back of the eye).

There are two types of astigmatism. Hyperopic (farsighted) astigmatism causes some rays to focus behind the retina and myopic (nearsighted) astigmatism causes some rays to focus in front of the retina. Mixed astigmatism is when an eye has both types of astigmatism at the same time.

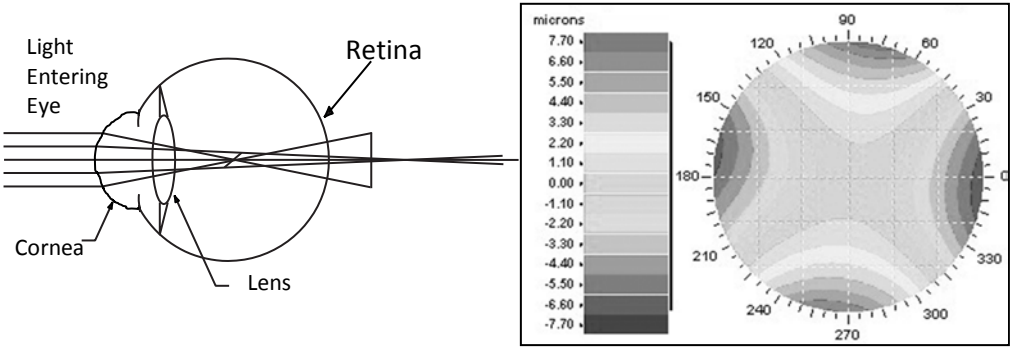


Figure 2: On the left is a diagram of an eye with mixed astigmatism showing that the light entering the eye through different regions of the cornea focuses in two points, but neither point is on the retina. The corresponding wavefront of a mixed astigmatism eye shows a surface that curves forward in one direction, and backward in the other, much like the shape of a saddle.

The ***iDesign Advanced WaveScan Studio*** System can also measure complex

focusing errors. In **Figure 3** is a map of all wavefront errors and on the right is a map showing just the complex errors. The combination of simple and complex wavefront errors in any eye is unique. The ***Advanced CustomVue*** treatment is "custom" because it includes information from the ***iDesign Advanced WaveScan Studio*** System that is more individualized than what a doctor uses to program a non-custom treatment.

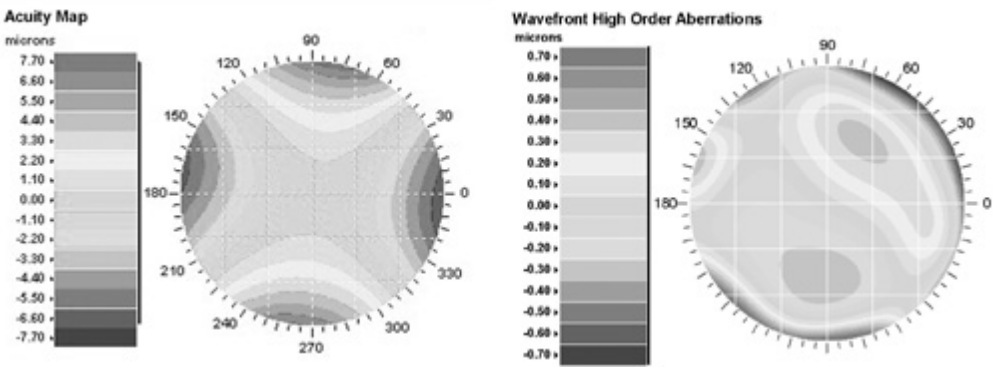


Figure 3: On the left is a wavefront map of all wavefront errors and on the right is a wavefront map showing only the complex errors.

The *AMO STAR S4 IR* Excimer Laser

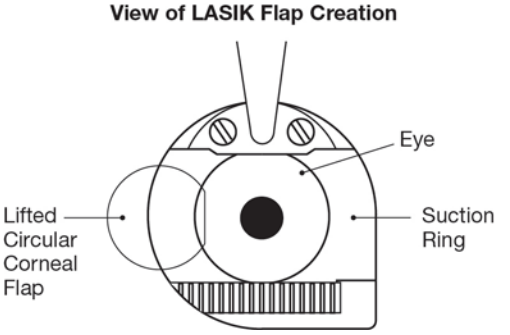
The excimer laser system produces a beam of cool ultraviolet light. The doctor transfers the information from the ***iDesign Advanced WaveScan Studio*** System into a computer that controls the laser. The laser produces a series of rapid pulses that remove small and precise amounts of corneal tissue. Excimer laser light does not penetrate into the eye and leaves other eye structures (iris, lens, retina) untouched.

The laser system also contains an auto-centering eye tracking system which will align the treatment and automatically compensate for many of your eye movements during the ***Advanced CustomVue*** treatment. And the Iris Registration feature of the ***STAR S4 IR*** system adjusts for rotation (twisting) of your eye between time of wavefront measurement and start of the treatment.

How the *Advanced CustomVue* LASIK Procedure Works

LASIK is a laser surgery technique used to correct refractive errors of the eye

including astigmatism. Before starting the laser, the doctor creates a flap on your cornea using either a different type of laser or an automatic cutting device that uses a blade (microkeratome). A suction ring is placed on the eye and then a circular flap of tissue is created from the surface of the cornea. After the flap is cut, the doctor lifts the flap and folds it out of the way of the laser. After the laser finishes, the doctor repositions the flap.



View (from above) of suction ring on the eye.

Figure 4

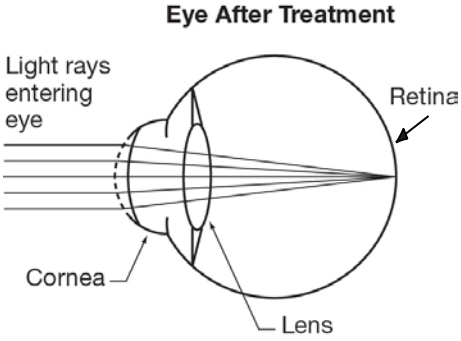


Diagram of an eye after treatment showing where tissue is removed

Figure 5

To correct mixed astigmatism, the cornea needs to be flatter in one direction and steeper in another direction. The laser will remove more tissue from the center than the edge in one direction (for example, the horizontal direction) and remove more tissue from the edge than the center in the other direction (for example, the vertical direction). The doctor creates a treatment plan, unique to your eye, from the ***iDesign Advanced WaveScan Studio*** system to guide the laser. The laser removes tissue from the eye according to the treatment plan.

The iDesign Advanced WaveScan Studio System

Before your ***Advanced CustomVue*** LASIK treatment is programmed into the laser, you must have one or more measurements taken by the ***iDesign Advanced WaveScan Studio (AWS)*** System. The ***iDesign AWS*** System is a tabletop system that measures your eyes with specialized cameras. You will sit in front of the ***iDesign AWS*** System and look at a light through an opening in the system while it scans your eye. Your doctor may take more than one

measurement and then choose the most appropriate measurement to use as the basis for the ***Advanced CustomVue*** LASIK treatment. The doctor will also take other routine measurements of your vision to help design your treatment.

BENEFITS

Advanced CustomVue LASIK can correct between 1 and 5 diopters (D) of mixed astigmatism. If you have mixed astigmatism within this range, ***Advanced CustomVue*** LASIK treatment may help you to see clearly distant objects without eyeglasses or contact lenses or with reduced prescription.

Clinical Study to Evaluate Benefits

A clinical study was conducted to evaluate the benefits and risks of ***Advanced CustomVue*** LASIK for mixed astigmatism. This study involved 149 treated eyes of 84 patients. This study was conducted at 7 U.S. centers, starting in December 2012. The study results shown in this booklet include all the available reported outcomes on these patients through June 2016. Each table lists the number of eyes or study patients (n) for which data was available at the reported time point.

STUDY PATIENT DEMOGRAPHICS

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

Table 1: Demographics of 84 Patients

Age	Average	36.3 ± 10.4 years	
	Range	18 to 58 years	
Gender	Male	45	54%
	Female	39	46%
Race	Caucasian	73	87%
	African American	5	6%
	Other*	3	4%
	Asian	2	2%
	Native American/Inuit	1	1%
	Pacific Islander	0	0%
Contact Lens History	None	67	80%
	Soft	0	0%
	Rigid/ Toric	17	20%
*"Other" classifications of race include: Part Filipino, Middle Eastern and Hispanic.			

VISUAL ACUITY WITHOUT GLASSES AFTER TREATMENT

Visual acuity measures the sharpness of vision using a letter or other appropriate charts. **Table 2** shows that three months after the treatment, 92% of study patients saw 20/20 or better *without* glasses while 100% of study patients saw 20/40 or better. A visual acuity of 20/20 is considered normal vision and 20/16 and 20/12.5 are considered better than normal vision.

A visual acuity of 20/40 or better usually allows you to drive without any glasses or contact lenses.

Table 2: Visual Acuity Without Glasses After Treatment

Time After Treatment	1 Month (n=146)	3 Months (n=149)	6 Months (n=96)	9 Months (n=89)	12 Months (n=88)	24 Months (n=69)
20/12.5 or better	11%	13%	15%	22%	13%	10%
20/16 or better	51%	57%	64%	62%	63%	65%
20/20 or better	92%	92%	92%	92%	92%	87%
20/25 or better	98%	98%	94%	97%	98%	94%
20/40 or better	99%	100%	100%	100%	100%	97%

VISUAL ACUITY WITHOUT GLASSES AFTER TREATMENT AND WITH GLASSES BEFORE TREATMENT

Table 3 shows the number of lines on the eye chart that patients could see before and after surgery. At three months, 84% of the eyes saw as well as or better *without* glasses after ***Advanced CustomVue*** LASIK treatment as *with* glasses before treatment.

Table 3: Visual Acuity Without Glasses After Treatment Compared to With Glasses Before Treatment, N = 149 Eyes

Change in Lines of Vision	1 Month	3 Months	6 Months	9 Months	12 Months	24 Months
	(n=146)	(n=149)	(n=96)	(n=89)	(n=88)	(n=69)
More than 2 lines better	0%	0%	0%	0%	0%	0%
2 lines better	1%	4%	8%	11%	3%	3%
1 line better	26%	31%	28%	34%	39%	32%
No change	59%	49%	45%	35%	38%	42%
1 line worse	10%	13%	13%	16%	17%	16%
2 lines worse	3%	3%	5%	1%	1%	3%
More than 2 lines worse	1%	0%	1%	3%	2%	4%

RISKS

As with any surgical procedure there are risks associated with ***Advanced CustomVue*** treatments. It is important to discuss these risks with your doctor before you make the decision to have the surgery. If the results of the surgery are not satisfactory, you may need to have additional laser treatment in the same eye. Your doctor may perform ***Advanced CustomVue*** LASIK for both eyes. However, sometimes it is better to have this procedure done on only one eye.

Talk with your doctor about whether it would be better to treat one or both of your eyes.

Some risks are related to the creation of the corneal flap. Corneal flap complications include but are not limited to: cutting an incomplete, irregular flap or free flap; misalignment of the flap; and perforation of the cornea. Corneal flap complications range in severity from those that simply require the treatment to be postponed for several months, to those which create corneal irregularities resulting in permanently blurred vision.

IMPORTANT:

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

CONTRAINDICATIONS — When Can't You Have LASIK?

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, because these conditions may cause temporary and unpredictable changes in your cornea and a LASIK treatment may improperly change the shape of your cornea.
- You have collagen vascular (e.g., rheumatoid arthritis), autoimmune (e.g., lupus), or immunodeficiency diseases (e.g., AIDS), because these conditions affect the body's ability to heal.
- You show signs of corneal abnormalities including keratoconus, abnormal corneal topography, epithelial basement membrane disease (EBMD) or degenerations of the structure of the 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.
- Your corneas are thin. If your corneas are too thin to allow your doctor to cut a proper flap in the LASIK procedure, you can't have LASIK because it is necessary to have a flap.
- You have symptoms of significant dry eye. If you have severely dry eyes, LASIK may increase the dryness. This may or may not go away. Severe eye dryness may delay healing of the flap or interfere with the surface of the eye after surgery. It may result in poor vision after LASIK.
- You have advanced glaucoma or uncontrolled diabetes. Talk to your eye care doctor before considering LASIK.

What Warnings and Other Information Do You Need to Know About?

WARNINGS

If you have any of the following conditions, you may have LASIK if your doctor evaluates the seriousness of your condition and believes the benefit of having LASIK is greater than the risk.

- Taking isotretinoin (Accutane[1]) treatment because this medication may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.

- Diabetes. If you have diabetes, 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 LASIK is more risky for you.

- Glaucoma, increased pressure inside your eye, ocular hypertension or being followed by your doctor as a possible case of glaucoma (i.e., glaucoma suspect)

- Conditions or taking medications that affects your immune system

- Taking antimetabolites for any medical conditions.

- Autoimmune connective tissue disease (e.g., scleroderma)

- Severe allergies. If you have severe allergies and take medicines for them, LASIK is more risky for you. In addition, please discuss with your surgeon if you rub your eyes often in association with an allergy as this may cause problems with the healing of the flap created during LASIK procedure.

- An eyeglass or contact lens prescription that has changed by more than 1.0 diopter in the last 12-months. If your refractive error is unstable, the right amount of treatment cannot be determined. This may result in poor vision after LASIK or the need for retreatment.

PRECAUTIONS

The safety and effectiveness of wavefront-guided LASIK with the ***STAR S4 IR*** Laser for mixed astigmatism has not been established in patients:

- With the systemic use of amiodarone hydrochloride (Cordarone[2] - used for normalizing heart rhythm) because it may affect the accuracy of the LASIK

[1] Accutane is a trademark of Hoffmann-La Roche, Inc.
[2] Cordarone is a trademark of Sanofi-Synthelabo, Inc.

treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK. With history of any eye diseases or abnormalities such as:

- Corneal scars may affect the accuracy of the LASIK treatment or the way your corneal heals after LASIK resulting in poor vision outcomes.
- If your eyes have an active disease, it is unknown whether LASIK is safe and effective under this condition.
- History of glaucoma or have had pressure greater than 21 mmHg inside your eyes, because it is unknown whether LASIK is safe and effective for you.

- With 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 LASIK will weaken the cornea too much. This may result in poor vision after LASIK.
- Who use medicines that might make it harder for wounds to heal, such as Sumatriptan (Imitrex[3]) used for migraine headaches, because it is unknown whether LASIK is safe and effective for this condition.
- Who take other medications. Let your doctor know if you are taking any prescription medicines or any medicines you bought without a prescription as some of these medications (even over-the-counter medications) can affect the eye and the ability to accurately measure the refraction of your eye.
- Who take any medications that could affect the eye's ability to heal (e.g., steroids either orally, injected or inhaled).
- Who take medications and have medical conditions that were excluded from the clinical trial on LASIK (e.g., diabetes, rheumatoid arthritis, lupus, etc....)
- Who are not within the studied age groups: Patients who are younger than 18 years of age, because it is unknown whether LASIK is safe and

[3] Imitrex is a registered trademark of GlaxoSmithKline, Inc.

effective for you.

- Who have mixed astigmatism less than 1 diopter or worse than 5 diopters, because it is unknown whether LASIK is safe and effective for you.
- Over the long term (more than 2 years), because it is unknown whether LASIK is safe and effective for periods longer than 2 years.
- Prior LASIK or Refractive Surgery: it is unknown whether LASIK is safe and effective for repeating the LASIK procedure on the same eye.
- With undiagnosed dry eyes. Your doctor should also evaluate you for dry eyes before surgery. You may have dry eyes after LASIK surgery even if you did not have dry eyes before surgery.
- Who have a family history of degenerative corneal disease.
- Who have a history of inflammation of the iris or other structures in the eye (i.e., iritis, uveitis, or chronic inflammation the eye).
- Who have a history of crossed eyes (strabismus) or surgery for crossed eyes.
- Future measurements of your eye pressure can be affected by Advanced CustomVue LASIK. Tell your future eye doctor you've had LASIK surgery.
- Future cataract surgery can be affected by Advanced CustomVue LASIK. Tell your future eye doctor you've had LASIK surgery.
- Who engage in activities that could potentially damage the LASIK flap such as contact sports (e.g., football, soccer, boxing) or any sport involving a projectile (e.g., baseball, tennis, volleyball) for at least two weeks.
- Who have naturally occurring pupils smaller than 4.0 mm, as they are not eligible for treatment with Advanced CustomVue LASIK. The maximum pupil size allowed for treatment is 9.5 mm and there are no safety or effectiveness data for eyes with pupils larger than 8.6 mm.

Clinical Study Results to Evaluate Risks

In the clinical study on ***Advanced CustomVue*** LASIK for mixed astigmatism, visual acuity *with* glasses was the same or better for 97% of eyes treated at 3 months.

VISUAL ACUITY WITH GLASSES AFTER TREATMENT

Table 4 shows that all patients in the clinical study saw 20/20 or better *with* glasses at all-time points after treatment.

Table 4: Visual Acuity With Glasses (Best Vision) After Treatment

Visual Acuity	1 Month (n=146)	3 Months (n=149)	6 Months (n=96)	9 Months (n=89)	12 Months (n=88)	24 Months (n=69)
20/12.5 or better	23%	21%	29%	33%	28%	28%
20/16 or better	60%	68%	79%	85%	80%	88%
20/20 or better	100%	100%	100%	100%	100%	100%

CHANGE IN VISUAL ACUITY WITH GLASSES AFTER TREATMENT

Table 5 shows the change in visual acuity *with* glasses at 1, 3, 6, 9, 12 and 24 months after treatment for the patients in the clinical study.

Table 5: Change in Visual Acuity With Glasses After Treatment Compared to Before Treatment

Time After Treatment	1 Month (n=146)	3 Months (n=149)	6 Months (n=96)	9 Months (n=89)	12 Months (n=88)	24 Months (n=69)
Eyes with gain of >2	0%	0%	0%	0%	0%	1%
Eyes with gain of 2	4%	9%	12%	18%	9%	7%
Eyes with gain of 1	37%	34%	45%	44%	50%	52%
Eyes with no change	55%	55%	40%	36%	38%	35%
Eyes with loss of 1	3%	3%	4%	2%	3%	4%
Eyes with loss of 2	1%	0%	0%	0%	0%	0%
Eyes with loss of >2	0%	0%	0%	0%	0%	0%

Contrast Sensitivity

Unlike normal vision tests that measure the ability to see a black and white eye chart, contrast sensitivity measures how well one sees in low contrast conditions such as driving in rain or fog. Most eyes (91-96%) in the study had the same or improved contrast sensitivity 3 months after surgery as they did before surgery. However some eyes (5-9%) had a significant loss in contrast sensitivity after surgery.

Table 6 shows the change in contrast sensitivity 3 months after treatment.

Table 6: Change in Contrast Sensitivity 3 Months after Treatment

N = 149 Eyes

Condition	% of Eyes with a loss	% of Eyes with no change	% of Eyes with a gain
Bright conditions with no glare	5%	81%	15%
Dim conditions with no glare	9%	61%	30%
Dim conditions with glare	7%	68%	25%

PATIENT REPORTED VISUAL WELLBEING

Patients were asked to complete a questionnaire that was designed to assess vision-related functioning and well-being before surgery and 3-months after surgery. Patients did not report poorer vision-related functioning on this questionnaire following surgery.

Adverse Events and Complications

The overall percentage of eyes in the clinical study that experienced adverse events and complications after ***Advanced CustomVue*** LASIK treatment, as shown in **Table 7.**

Table 7: Adverse Events and Complications

N = 149 Eyes

Greater than or equal to 1% of eyes had:	
Feeling of something in the eye	15 %
Pain	11%
Cells growing under the flap	5%
Inflammation of the cornea under the flap	2%
Procedure to remove cells under the flap	1%
Inflammation of the cornea requiring treatment	1%
Temporary severe light sensitivity	1%

PATIENT SYMPTOMS AFTER *ADVANCED CUSTOMVUE* TREATMENT

Patients were asked to rank the severity of their symptoms both before and after the ***Advanced CustomVue*** treatment.

Table 8 lists the patient symptoms reported as "Mild", "Moderate", "Marked" or "Severe" before treatment (Preop) on 149 eyes and at 3 months after treatment on 149 eyes.

Table 8: Severity of Eye Symptoms Before and 3-Months After Surgery
Treatment N = 149 Eyes

Symptom	Before Surgery				3-Months After Surgery			
	Mild	Moderate	Marked	Severe	Mild	Moderate	Marked	Severe
Pain	7%	0%	0%	0%	1%	1%	0%	0%
Tearing	15%	0%	0%	0%	5%	1%	0%	0%
Photophobia (light sensitivity)*	9%	2%	1%	0%	17%	3%	1%	0%
Foreign Body Sensation (feeling that something is in your eye)*	1%	0%	0%	0%	8%	0%	0%	0%
Dryness	30%	3%	0%	0%	38%	9%	1%	0%
Fluctuation of vision (changes in clarity)*	17%	2%	0%	0%	26%	3%	0%	0%
Day Glare (harsh bright light at day)*	20%	4%	1%	0%	8%	0%	0%	0%
Night Glare (harsh bright light at night)*	29%	11%	1%	1%	27%	2%	0%	0%
Binocular Diplopia (double vision both eyes)*	0%	1%	0%	0%	3%	0%	0%	0%
Monocular Diplopia (double vision one eye)*	1%	0%	0%	0%	1%	0%	0%	0%
Ghosting (faint second image)*	3%	1%	0%	0%	4%	1%	0%	0%
Halos (hazy ring around lights)*	37%	12%	1%	1%	40%	3%	0%	0%
Difficulty Driving at Night	31%	17%	1%	1%	15%	3%	0%	0%

*Note: The wording in parentheses () were not part of the questionnaire. These terms were added to the table to clarify the meaning of the terms.

What to Expect Following Surgery

The First Week:

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

Two To Six Months

- Your vision may fluctuate during this time period. You may also experience some dryness.

Are You A Good Candidate For Advanced CustomVue LASIK?

If you are considering ***Advanced CustomVue*** LASIK, you must:

- Be at least 18 years of age and have mixed astigmatism.
- Have healthy eyes that are free from eye disease or corneal abnormality (e.g., scar, infection, significant dry eyes, etc.).
- Have documented evidence that your vision did not change by more than 1.0 diopter during the year before your preoperative examination.
- Be informed of LASIK risks and benefits as compared to other available treatments for mixed astigmatism.
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be willing to sign an informed consent form as provided by your eye care professional.
- Be able to keep your eye accurately on the fixation light for the entire laser surgical procedure.

If you are considering ***Advanced CustomVue*** LASIK, you must **NOT**:

- Have advanced glaucoma, uncontrolled diabetes, collagen vascular, autoimmune or immunodeficiency diseases as the surgery may lead to poor outcomes and possible vision loss.
- Be pregnant or nursing as your refraction is unstable and could result in a poor outcome.

Before Surgery

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

WARNING:

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

Before the surgery, please tell your doctor whether you take any medications or have any allergies. Also, talk with your doctor about eating or drinking immediately before the surgery. You should also arrange for transportation, since you must not drive immediately after the surgery. You may resume driving only after receiving permission from your doctor.

The Day of Surgery

Before the surgery, local anesthetic (numbing) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up. An instrument will be placed between your eyelids to hold them open during the surgery. There will also be a temporary shield covering the eye not having surgery. You will be asked to listen to the sounds of the treatment so that you will be prepared for the noise

the laser makes during the surgery.

The surgery begins with the placement of a suction ring that elevates the pressure in the eye. The vision in the eye will go black as the suction increases the pressure in the eye. The femtosecond laser or microkeratome creates a circular corneal flap. Vision will return to the eye after the suction is released.

The doctor will then reposition your head in the chair and refocus the microscope. The doctor will lift this flap of tissue. You will be asked to look directly at a blinking light while the laser is running. It is important to fix your gaze on the light for the entire laser procedure. Try to keep both eyes open without squinting, as this makes it easier to keep looking at the light. Small amounts of tissue will then be removed from your cornea using the ***AMO STAR S4 IR*** Excimer Laser system.

PRECAUTION:

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

Typically, the laser beam will be applied to your eye less than 3 minutes and, overall, the surgery may last about 10 minutes.

After the laser surgery is complete, some eye drops may be placed on your eye. The surgery is painless because of the anesthetic drop. When the anesthetic drops wear off (about 30 to 60 minutes), your eye may hurt moderately for 1 to 2 days. The discomfort is typically described as “a sandy sensation.” Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. To promote healing and lessen the risk of infection, do **NOT** rub your eye after surgery.

After Surgery

You may experience mild to moderate pain, discomfort, blurred vision, tearing and sensitivity to light during the first week following surgery.

IMPORTANT:

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

WARNING:

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

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

Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if

Advanced CustomVue LASIK is right for you:

- What other options are available for correcting my vision?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of ***Advanced CustomVue*** LASIK for my amount of refractive error?
- What vision can I expect in the first few months after surgery?
- If ***Advanced CustomVue*** LASIK does not correct my vision, what is the possibility that my glasses will need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after laser surgery if I need them?
- How is ***Advanced CustomVue*** LASIK likely to affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having laser surgery?
- Should I have ***Advanced CustomVue*** LASIK in my other eye?
- How long will I have to wait before I can have surgery on my other eye?
- What vision problems might I experience if I have ***Advanced CustomVue*** LASIK only on one eye?

Discuss the cost of surgery and follow-up care requirements with your doctor, as ***Advanced CustomVue*** LASIK is not covered by most health insurance policies.

Self-Test

Are You an Informed and Educated Patient?

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

Number	Question	TRUE	FALSE
1.	***Advanced CustomVue*** LASIK surgery is risk free.		
2.	It doesn't matter if I wear my contact lenses when my doctor told me not to.		
3.	The laser does all the work; I just have to lie on the chair.		
4.	After the surgery, there is a good chance that I will be less dependent on eyeglasses		
5.	I may need reading glasses after laser surgery.		
6.	There is a risk that I may lose some vision after ***Advanced CustomVue*** LASIK surgery.		
7.	It doesn't matter if I am pregnant.		
8.	If I have an autoimmune disease, I am still a good candidate for laser vision correction.		

Answers to SELF-TEST are found on page 30.

Summary of Important Information

- ***Advanced CustomVue*** LASIK is a permanent operation to the cornea and is irreversible.
- ***Advanced CustomVue*** LASIK may not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least one year before ***Advanced CustomVue*** LASIK. You will need written evidence that your mixed astigmatism has changed less than 1.0 diopters.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- ***Advanced CustomVue*** LASIK may result in some discomfort. The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks before you agree to the surgery.
- Alternatives to ***Advanced CustomVue*** LASIK include, but are not limited to, glasses, contact lenses, non-custom LASIK and PRK, RK, and Automated Lamellar Keratectomy (ALK).
- Some people have job-related vision requirements that cannot be met by having ***Advanced CustomVue*** LASIK.
- Before considering laser vision correction you should:

  a. Have a complete eye examination.

  b. Talk with one or more eye care professionals about the potential benefits of laser refractive surgery, and the complications, risks, and time required for healing.

Answers to Self-Test Questions

1. False (see **'Risks'** on page 14);
2. False (see **'Before Surgery'** on page 24);
3. False (see **'The Day of Surgery'** on page 24);
4. True (see **'Benefits'** on page 10);
5. True (see **'Risks'** on page 14);
6. True (see **'Risks'** on page 14);
7. False (see **'Contraindications'** on page 15);
8. False (see **'Contraindications'** on page 15).

PATIENT ASSISTANCE INFORMATION

PRIMARY EYE CARE PROFESSIONAL

NAME:

ADDRESS:

PHONE:

LASER VISION CORRECTION DOCTOR

NAME:

ADDRESS:

PHONE:

TREATMENT LOCATION

NAME:

ADDRESS:

PHONE:

LASER MANUFACTURER:

AMO Manufacturing USA, LLC
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Milpitas, CA, USA 95035 USA
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www.amo-inc.com
Product of USA

Abbott