Facts You Need to Know About the VisuMax SMILE Procedure for the Correction of Myopia

A Surgery to Reduce or Eliminate Myopia
Using the Carl Zeiss VisuMax Femtosecond Laser

Patient Information Booklet

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

The VisuMax Femtosecond Laser is indicated for use in the small-incision lenticule extraction (SMILE) procedure for the reduction or elimination of nearsightedness (myopia) from -1.00 to -8.00 units of power (diopters or D) in patients:

- With -1.00 to -8.00 D of nearsightedness and -0.50 diopter of astigmatism (eye shaped more like a football than a basketball) or less in the eye to be treated,
- Whose nearsightedness has changed by no more 0.50 diopter in the year before surgery,
- Who are 22 years of age or older.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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Carl Zeiss Meditec
VisuMax Femtosecond Laser
Patient Information Booklet

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Glossary

This section explains important terms in this booklet. Please discuss any related questions with your doctor.

Astigmatism: A type of error in the focusing power of the eye caused by the eye being shaped more like a football than a basketball.

Cataract: Cloudiness that develops (usually with the natural aging process) in the clear, natural lens of the eye that reduces vision.

Cornea: Clear tissue located in the front of the eye covering the colored portion. It's shape determines most of the focusing power of the eye.

Diopter (D): Unit of focusing power

Ectasia: A condition where the tissue of the cornea is too thin, leading to bulging in the central portion. This is a possible risk after a laser vision correction procedure is performed.

Excimer Laser: A medical device used to remove tissue from the cornea with short pulses of ultraviolet light. It re-shapes the cornea to correct nearsightedness, farsightedness, and astigmatism.

Femtosecond Laser: A medical device used to make cuts within the cornea with short pulses of near-infrared light. It is also used to re-shape the cornea to correct nearsightedness.

Farsightedness or Hyperopia: A vision condition where distant objects can be seen clearly, but ones that are up close may appear blurry. This is caused by a cornea that is too flat or an eye that is too short.

Glare: When bright light interferes with the ability to see. An example of the effect of glare would be driving at night and looking at oncoming headlights, resulting in difficulty seeing road signs or other vehicles.

Glaucoma: A disease marked by increased pressure in the eye that may lead to damage of the optic nerve, the nerve that allows you to see.

Halos: A fuzzy cloud or hazy ring seen around bright lights. Some patients with may see halos when they do not wear their glasses or contact lenses and look at bright lights.

Keratoconus: Gradual thinning of the cornea resulting in a cone-shaped bulge in the center. This condition tends to run in families.

LASIK: LASIK stands for "laser in situ keratomileusis." LASIK is a type of surgery to treat nearsightedness, farsightedness, and astigmatism. A device called a microkeratome, which is like a carpenter's plane, cuts a thin flap of tissue from the front of the cornea (clear part on the front of the eye). This same procedure can be performed with a femtosecond laser. The flap is then folded out of the way. Next, an excimer laser removes tissue from the front surface of the cornea to alter the shape and power. After the laser treatment, the flap is folded back over the cornea.

Lens: A clear structure located behind the colored part of the eye. It helps to focus light on the thin layer of nerve cells in the back of the eye (the retina) to create a visible image.

Lenticule: A small piece of tissue that is removed from the cornea during the SMILE procedure to correct your nearsightedness.

Nearsightedness or Myopia: A vision condition where objects far away appear blurry because the cornea is too steep or the eye is too long.

Pupil: The dark center of the colored part of the eye (iris) that allows light into the eye. It shrinks in bright light and enlarges in dim light.

PRK: PRK stands for "photorefractive keratectomy." In this surgery, the top layer of the cornea is removed, then an excimer laser removes tissue from the middle surface of the cornea to correct refractive error.

Refractive error: Error in the focusing power of the eye.

Refractive Surgery: A surgical procedure to reduce or eliminate an error in the focusing power of the eye.

Retina: The thin layer of nerve cells in the back of the eye, responsible for converting light images into signals sent to the brain.

SMILE: The abbreviation for Small Incision Lenticule Extraction, the vision correction procedure performed with the VisuMax femtosecond laser.

Starbursts: Light rays coming from lighted objects, such as from car headlights.

Vitreous: A clear, jelly-like substance that fills the inside of the eye.

Visual acuity: A measure of the clarity of your vision using a standard letter chart.

Introduction

This booklet is written to help you decide whether to have small incision lenticule extraction (SMILE) surgery to eliminate or reduce your nearsightedness (an error in the focusing power of the eye causing distant objects to appear blurred). Glasses and contact lenses also correct nearsightedness, as do the surgeries known as LASIK (Laser *in situ* Keratomileusis) and PRK (photorefractive keratectomy). This booklet refers to the VisuMax SMILE procedure using the Carl Zeiss Meditec VisuMax femtosecond laser.

If you are nearsighted in both eyes, both eyes may qualify for the procedure. Talk with your doctor about whether it would be better to treat one eye or both eyes.

Please read this whole booklet. Discuss your questions with your doctor. Your doctor can determine whether or not you are a good candidate for the VisuMax SMILE procedure. You can then consider the expected benefits versus the risks and make an informed decision. Please keep in mind that some jobs have vision requirements which may or may not allow for PRK, LASIK, or the VisuMax SMILE procedure.

How The Eye Functions

Your eye focuses light on the retina (the thin layer of nerve cells at the back of the eye) to form images, similar to how a camera creates pictures on film. Your eye takes the focused light, changes them into nerve signals, then sends them to the brain for processing. If your eye is out of focus, the image you see will also be blurred.

The cornea (clear front portion of the eye) bends the light toward your retina and accounts for two-thirds of the focusing power of the eye. The lens (a clear structure inside your eye) accounts for the other one-third of the focusing power of the eye.

Focusing With Your Eye

The eye focuses light by bending all light rays to meet at a single point. If the light focuses in front of or behind the retina, the image you see will be blurred. If you have perfect vision or are using the proper glasses or contact lens prescription, the object will be focused on the retina (Figure 1). If you have nearsightedness and/or astigmatism (Figures 2 and 3), the point of focus will be off the retina, resulting in blurry vision. With the VisuMax SMILE procedure, the goal is to sharpen the blurred image on the retina caused by nearsightedness by changing the shape of the cornea (Figure 4) so you can see more clearly without glasses.

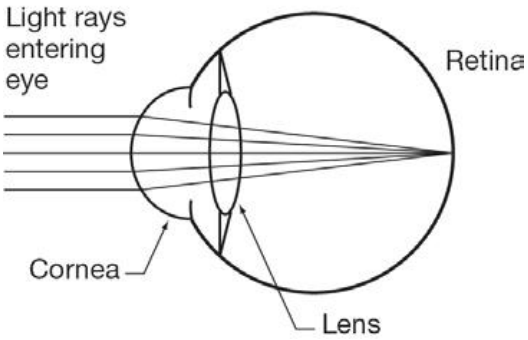

Figure 1: Normal Eye

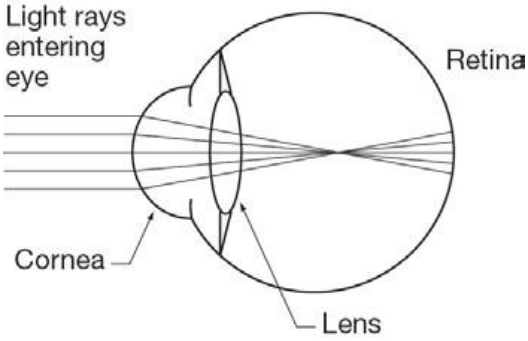

Figure 2: Nearsighted Eye

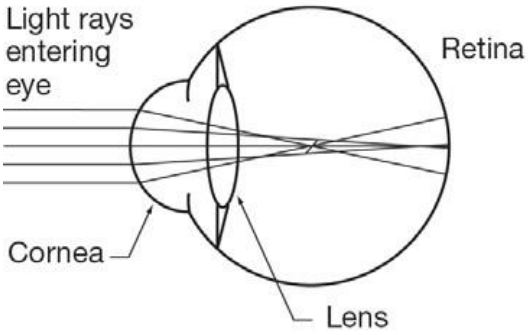

Figure 3: Nearsighted and Astigmatic Eye

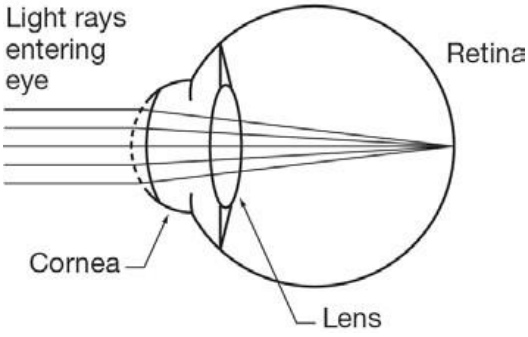

Figure 4: Nearsighted Eye Corrected

The Nearsighted Eye

Myopia, also referred to as nearsightedness, is a common vision condition in which close objects are seen clearly but objects farther away are blurred. A common sign of myopia is difficulty seeing distant objects, like a TV or movie screen or street signs. Because the eye continues to change and grow throughout childhood, myopia typically progresses until about age 20. Myopia occurs when the eye focuses light in front of the retina. This can be due to the shape of the cornea being too steep and/or the length of the eyeball being too long. Glasses or contact lenses can correct nearsightedness by correctly focusing the light right at the retina. Surgery options for changing the shape of the cornea, like LASIK, PRK, and the VisuMax SMILE procedure, involve a laser to remove a small amount of tissue to permanently reshape the cornea. You will find more information about the differences between SMILE, LASIK, and PRK in the sections 'What is The VisuMax SMILE Procedure?' and 'Alternatives to the VisuMax SMILE Procedure'.

What is the VisuMax SMILE Procedure?

The VisuMax SMILE procedure is a surgical treatment for nearsightedness. A femtosecond (very fast, short-pulsed) laser makes cuts within the cornea, creating a disc-shaped piece of tissue within the cornea and a small incision in the surface of the cornea. The surgeon removes the piece of tissue through the small incision. This removal of tissue causes the shape of the cornea to change which corrects your nearsightedness.

Doctors perform the SMILE procedure one eye at a time. In most cases, the doctor does the second eye on the same day. The doctor can also do this on a separate day, depending on your particular case.

What is the VisuMax Femtosecond Laser?

The VisuMax femtosecond laser is a precision ophthalmic surgical laser designed for the creation of incisions in the cornea. The VisuMax accomplishes this by scanning tightly focused patterns of short (femtosecond) pulses of near-infrared light (laser) in the cornea at precise and predefined positions and depths. Administration of continuous, focused laser pulses results in the creation of smoothly and precisely cut surfaces within the cornea.

How does the VisuMax Femtosecond Laser Eliminate or Reduce Your Myopia?

To correct nearsightedness, the cornea needs to be flattened in the center. The VisuMax femtosecond laser eliminates or reduces your myopia by cutting a disc-shaped piece of tissue within the cornea, which is thicker in the center and thinner at the edge. The tissue is then removed through a small incision in the surface of the cornea that was also cut by the VisuMax femtosecond laser.

You will be required to lie flat on your back for the procedure. The laser system uses a disposable, single-use Treatment Pack to apply the laser treatment and place the cuts precisely in your cornea. The Treatment Pack is a plastic cone that holds a curved lens that fits your cornea. The Treatment Pack will be attached to your cornea by light suction on the eye. At the same time it is attached to the VisuMax femtosecond laser. While the Treatment Pack is placed on your eye, the doctor will ask you to keep looking right at a blinking light. Looking at the blinking light ensures that the Treatment Pack and consequently the laser cuts will be placed in the right position. The light will be visible throughout the entire procedure, though at times it could get slightly blurry. The doctor will then start the laser portion of the procedure which typically takes less than 60 seconds. Once the laser has created the disc-shaped piece of tissue, the doctor will then utilize surgical instruments to safely remove this tissue. You may feel some sensation during this part of the procedure, but you should not feel pain due to the numbing drops applied prior to and during the procedure.

Alternatives to the VisuMax SMILE Procedure

Alternatives to the VisuMax SMILE procedure to have your nearsightedness corrected might include glasses, contact lenses, surgery with another FDA approved laser using PRK or LASIK, or a lens implant surgically placed inside the eye.

Glasses or contact lenses can correct nearsightedness by correctly focusing the light right at the retina. Surgery options like PRK, LASIK, and the VisuMax SMILE procedure, permanently reshape the cornea since a laser is used to remove a small amount of tissue from your cornea. PRK requires the removal of the thin outer layer of the cornea and then a laser is used to sculpt the underlying tissue. LASIK is similar to PRK, except instead of removal of the thin outer layer of the cornea, a flap is created and after the sculpting of the underlying tissue, the flap is positioned to cover the treatment area. The sculpting of the underlying tissue in PRK and LASIK is done with an excimer laser, a type of laser that uses short pulses of ultraviolet light. The flap in LASIK is cut either with a blade, or a femtosecond laser such as the VisuMax, which uses short pulses of infrared light. Also a lens implant is another surgical alternative to treat nearsightedness. During this procedure, an artificial lens is permanently implanted inside the eye to change the focusing power of the eye. The natural lens is not removed during this procedure and remains inside the eye..

You should consult with your physician to determine if you are a candidate for these procedures as well as to discuss the risks/benefits of each alternative. Furthermore, important information about these alternative procedures is available at the following websites (accessed August, 2016):

- ***FDA***:*http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/default.htm*
- ***NEI***: *https://nei.nih.gov/health/errors/myopia*
- ***AAO***: *http://www.aao.org/eye-health/treatments/lasik*
- ***FTC***: https://www.consumer.ftc.gov/articles/0062-basics-lasik-eye-surgery#lasikbasics

Potential Benefits of the VisuMax SMILE Procedure

Clarity of vision is measured using a standard letter chart (visual acuity). After the SMILE procedure, your visual acuity without glasses may improve, which means you may read smaller lines of letters on the eye chart. Your visual acuity without glasses after the SMILE procedure may be comparable or even better than your visual acuity with glasses before the procedure.

Please refer to the Clinical Study Information section, for additional information about the benefits of this procedure.

Potential Risks of the VisuMax Femtosecond Laser SMILE Procedure?

What risks are associated with the surgical procedure?

Although the VisuMax Femtosecond Laser is a precision instrument, patients may not all respond identically to treatment, and complications can occur. As a result vision may not be perfect after the VisuMax SMILE procedure. Patients around 40 years of age or older may need glasses for close work such as reading, even if they did not need them before surgery. This is related to a condition called presbyopia, where the focusing ability of the eye to adjust for near vision undergoes an age-related decline.

The VisuMax SMILE procedure may result in vision problems or symptoms that you did not have before or cause worsening of some vision problems or symptoms, which you may have already been experiencing. These symptoms may range from mild and annoying to severe and affecting ability to perform tasks, and include:

- Best vision (corrected with glasses or contact lenses) worse after procedure
- Over-correction or under-correction that may require eyeglasses or contact lenses
- Increase in astigmatism
- Difficulty judging distance or depth perception
- Dry eye
- Halos
- Glare
- Starbursts
- Hazy vision
- Blurred vision
- Distortion
- Double or multiple images (ghost images, images that appear to have a shadow)
- Fluctuating vision
- Difficulty focusing
- Difficulty with night driving
- Eye pain or soreness
- Feeling of something in the eye
- Grittiness
- Light sensitivity
- Decreased ability to see in low-light conditions (e.g. reading a street sign at dusk)
- Unintentional imbalance between the two eyes causing headaches and eye strain

Rare complications of the VisuMax SMILE procedure include ocular conditions or abnormalities that may cause vision loss that cannot be corrected by glasses, contact lenses, or further surgical treatment. Some examples are:

- Corneal risks (scarring, swelling, cloudiness, haziness, irregular shape, bulging cornea (ectasia))
- Infection and inflammation of the eye
- Detachment of the retina (light sensitive part of the eye)
- Detachment of the vitreous (clear, jelly like substance inside the eye)

- Drooping eyelid
- Cloudiness of natural lens in the eye
- Increase in eye pressure

Some uncommon risks related to the surgical portion of the VisuMax SMILE procedure include, but are not limited to:

- Laser penetration through the cornea during the laser portion of the procedure
- Perforation of the cornea during the manual portion of the SMILE procedure
- Interruption during the procedure which may lead to tissue damage during the manual portion of the SMILE procedure. Cells from the front of the cornea trapped in the treatment area
- Debris or cells trapped in the area where corneal tissue was removed

These complications range in severity from simply requiring the treatment to be postponed temporarily to permanent corneal irregularities and blurred vision.

Please refer to the Adverse Events portion of the Clinical Study Information section for additional information of risks that this procedure may pose.

Will my vision be perfect after surgery?

Although the VisuMax femtosecond laser provides precise treatments, there is no guarantee of perfect vision after surgery and the effect of treatment may decrease over time. You may need to wear glasses or contact lenses to perform certain tasks, even if your vision results are generally good.

Indications For Use

The VisuMax Femtosecond Laser is indicated for use in the small-incision lenticule extraction (SMILE) procedure for the reduction or elimination of nearsightedness (myopia) from -1.00 to -8.00 units of power (diopters or D) in patients:

- With -1.00 to -8.00 D of nearsightedness and -0.50 diopter of astigmatism or less in the eye to be treated,
- Whose nearsightedness has changed by no more 0.50 diopter in the year before surgery,
- Who are 22 years of age or older.

Contraindications, Warnings, and Precautions

Contraindications - When is it not advisable to have the VisuMax SMILE procedure?

In the circumstances described below, the risk of the procedure may be greater than the potential benefits. You should **NOT** have the VisuMax SMILE procedure if:

- You have an insufficient corneal tissue thickness for the amount of correction needed;
- You have abnormal findings on the map of the surface curvature of your cornea that indicate general thinning of the cornea and/or a cone-shaped bulge in the center of cornea (keratoconus);
- You have signs of increasing or unstable nearsightedness or signs of corneal conditions that can lead to a thinning and bulging of the cornea;
- You have a distorted or unfocused image mirrored on the eye during measurements that may indicate an irregular or unstable corneal surface;
- You have severe dry eye;
- You have an active eye infection or inflammation;
- You have recently had a Herpes infection that affected your eyes or problems with your eyes resulting from a past infection;
- You have an active autoimmune disease or connective tissue disease (e.g. rheumatoid arthritis, systemic lupus erythematosus);
- You have uncontrolled diabetes;
- You have uncontrolled glaucoma (a disease marked by increased pressure in the eye causing damage to the optic nerve, the nerve that allows you to see).

Warnings

If you have any of the conditions below, talk to your doctor before you have the VisuMax SMILE procedure. In these cases, your doctor must judge whether the benefits of the procedure outweigh the risks. The following convey risk for serious adverse consequences if the VisuMax SMILE procedure is performed in the following patients:

- You have a controlled autoimmune disease or connective tissue disease. In these cases, the VisuMax SMILE procedure may be risky for you due to a delay in healing of your eyes and less predictable outcomes after LASIK. Depending upon your disease, its severity, and the medication(s) you are taking, there may be additional risks. These may include severe dry eye, infection, inflammation, poor healing, and corneal melt;
- You have controlled diabetes;
- You have a compromised immune system due to a disease condition (e.g. AIDS) or immunosuppressive therapy (e.g. systemic steroids);

- You have a history of Herpes simplex or Herpes zoster infection that affected your eyes. The procedure might reactivate the infection;
- You have controlled glaucoma;
- You have been or are currently taking isotretinoin (Accutane®) as it can increase the risk of dry eye and abnormal wound healing;
- You have repeated attacks of sharp eye pain due to the outer layer of corneal cells rubbing off easily, often during sleep, (recurrent corneal erosions), because the outer cells do not stick well to the other corneal layers (epithelial basement membrane dystrophy). This procedure may worsen the condition;
- You have amblyopia, a condition in which vision is compromised in one or both eyes (even with glasses), due to the communication between the eyes and the nervous system;
- You have deep eye sockets, a strong blink reflex, anxiety, pterygium (a growth on the white part of your eye), or any other condition that may prevent maintenance of proper alignment of the treatment laser with your eye;
- Your eyelids do not close completely;
- You have difficulty following directions or are unable to constantly focus on a target.

Precautions

If you have the following conditions, it is not known whether the VisuMax SMILE procedure is safe and effective for you. You should discuss these issues with your doctor.

- You have an error in the focusing power of your eye outside the range in the approved indications for use;
- You have a difference of 0.75 D or more of total focusing power of your eye as measured by your doctor when your pupils are dilated compared to when your pupils are not dilated.
- You have a central corneal thickness of less than 500 microns (the minimum limit allowed in our clinical study) in the eye to be treated;
- You have a known family history of a condition involving thinning of the cornea which can be worsened by any corneal procedure;
- You have a visual acuity (a measure for the clarity of your vision) without glasses better than or equal to 20/40 in the eye to be treated;
- You have a visual acuity with glasses worse than 20/20 in the eye to be treated;
- You have a visual acuity with glasses worse than 20/40 in the eye NOT to be treated;
- You wear contact lenses and have not discontinued the use of contact lenses for at least 2 weeks (for hard lenses) or 3 days (for soft lenses) prior to the preoperative examination, and through the day of surgery;

- Your vision has not been stable in the last 12 months, as seen by a prescription change of 0.50 diopter or more. In this case, your doctor will not know the correct prescription to treat, and this may result in poor vision after the VisuMax SMILE procedure;
- You have a pupil diameter of more than 8.0 millimeters in dim light conditions;
- You want a treatment which will correct one eye for distance vision and one eye for near vision;
- You previously had an injury or surgery performed on your eye. In these cases, it is not known whether the VisuMax SMILE procedure will weaken the cornea. This may result in poor vision after the VisuMax SMILE procedure;
- You have abnormalities on your cornea (e.g. scars, irregular shape, warpage) which can lead to unpredictable results with the procedure;
- You have any condition leading to large amounts of eyelid debris (e.g. severe blepharitis or rosacea);
- You now have or previously had high pressure in your eyes or possibly have glaucoma.;
- You have an atopic condition, also known as atopic syndrome or disease, which is a tendency to have strong allergic reactions including conditions like eczema (rash), asthma (trouble breathing), and hay fever (runny nose and itchy eyes);
- You have severe allergies requiring medication. This may prolong the healing time after he VisuMax SMILE procedure and along with allergy medications can often increase dryness in the eyes. Allergies also increase the risk of eye rubbing which should not be done after this procedure;
- You take medicines that may affect wound healing. Cordarone® (amiodarone hydrochloride) and Imitrex® (sumatriptan succinate), are examples which have known effects on the eye. ;
- You are less than 22 years of age;
- The structures of your eye in the path of vision are not completely clear. For example, things like corneal scars may affect the accuracy of the VisuMax SMILE procedure or the way your eye heals. This may result in poor visual results after the VisuMax SMILE procedure;
- You have had inflammation inside your eye (uveitis/iritis). Such diseases are often treated with medications that that can affect wound healing, like steroids;
- You are pregnant or nursing. During these times, a refractive procedure may cause over- or under-correction of your vision, or even regression (reduction or loss of the correction over time);

Note: The safety and effectiveness of the VisuMax SMILE procedure has NOT been established over the long term (more than 12 months after surgery). Additionally, the following may also be affected by the VisuMax SMILE procedure:

- Your ability to distinguish between between an object and its background, especially in low light conditions.
- The ability to accurately measure and interpret eye pressure measurements (you should inform eye doctors that you have had a procedure to correct myopia);
- The ability to obtain accurate measurements for future cataract surgery (you should be provided with a patient information card with all your eye measurements from before the procedure).

Are You a Good Candidate for the VisuMax SMILE Procedure?

To have the VisuMax SMILE procedure, you must:

- Be 22 years of age or older;
- Have healthy eyes free from retinal problems, corneal scars, and any eye disease;
- Have nearsightedness within the approved range of -1.00 to -8.00 D and -0.50 D or less of astigmatism (eye shaped more like a football than a basketball) in the eye to be treated;
- Have stable nearsightedness, which has changed by no more than 0.50 D in the year before surgery;
- Be fully informed about the risks and benefits of the VisuMax SMILE procedure as compared to other treatments for nearsightedness;
- Be able to lie flat without difficulty;
- Be able to look directly at a blinking light during the whole VisuMax SMILE procedure;
- Be willing to sign an Informed Consent Form provided by your doctor;
- Be able to tolerate eye drops to numb your eye.

What can You Expect Before the VisuMax SMILE Procedure?

Before the Surgery

If you are interested in the VisuMax SMILE procedure, you will need a comprehensive eye exam. This is to make sure your eyes are healthy and suitable for this procedure the VisuMax SMILE procedure. The exam will include a thorough medical and eye history, and an examination of both eyes, including specific diagnostic tests to determine your eligibility.

WARNING: If you wear contact lenses, the doctor will ask you to stop wearing them before your exam. You must stop wearing hard/soft contact lenses for a time determined by your doctor so that a stable eye measurement can be obtained. Failure to do this may lead to poor results from the VisuMax SMILE procedure.

Before the VisuMax SMILE procedure, talk to your doctor if you take any medications or if you have any allergies. These may cause healing problems. Also discuss whether you should eat and drink just before surgery. You should arrange to have someone drive you home after surgery. You should not drive after surgery until your doctor gives you permission.

Unrealistic Expectations about Surgery

Before the VisuMax SMILE procedure, speak with your doctor about your expectations from this procedure. Unrealistic expectations may lead you to be disappointed or cause you to make the wrong decision about whether to have surgery. You should discuss with your doctor whether your expectations are realistic, particularly about how the VisuMax SMILE procedure will change your quality of life.

If you expect “perfect vision” and believe that you will never need to wear glasses again, this is an unrealistic expectation. You should consider whether you will be satisfied with less than "perfect vision" or will be able to perform activities sufficiently. You should also consider whether you would be willing to wear glasses for certain activities such as driving at night or for reading, if necessary.

The surgery does not correct presbyopia, a condition in which the eye begins to lose the ability to adjust for near vision. This is a natural part of the aging process of the eye, which becomes noticeable in your early to mid-40s and affects everyone. Presbyopia may seem to come on suddenly, but the actual decline in focusing ability occurs over many years. Even if you could see clearly up close without reading glasses prior to the surgery, you may experience the need for reading glasses immediately following the procedure if you are in this age group or older.

What Happens During the VisuMax SMILE Procedure?

The Day of Surgery

On the actual day of surgery, you will be given some numbing drops in your eye(s). Upon entering the surgery room, you will be asked to lie down on the laser bed. You will lay facing up toward the laser's microscope and the ceiling. An instrument will be placed between your eyelids to hold them open during the procedure. The eye not having surgery may be covered with a temporary shield.

The surgery starts with the placement of the Treatment Pack on your eye. There will be light suction applied, but you will be able to see the blinking light throughout the entire procedure. Keeping both eyes open without squinting will make it easier to maintain focus on the blinking light throughout the surgery. The laser portion of the surgery takes about 30 to 60 seconds. The entire procedure, including the removal of the corneal tissue, generally takes 10 to 20 minutes in total.

WARNING: It is important to keep looking right at the blinking light when the Treatment Pack is placed on your eye. Otherwise the reshaping of your cornea will be off-center, which could affect your vision after surgery.

What Can You Expect After the VisuMax SMILE Procedure?

Immediately After the Surgery

After the surgery, your doctor will put some medication drops into your eye. Your doctor may apply a patch or shield to your eye for protection and comfort.

When the numbing drops administered during the surgery wear off, your eye may experience some discomfort or pain. If necessary, your doctor may prescribe oral pain medicine for use as necessary.

WARNING: You should never rub or touch your treated eye after surgery. Rubbing your eyes may increase the risk of blurred vision, infection, inflammation, swelling or epithelial in-growth (a condition where cells grow abnormally within the cornea, which can decrease the quality of vision).

First Days after Surgery

You may be mildly sensitive to light and glare. Wear sunglasses to ease your discomfort. You may also have the feeling that something is in your eye. Do not rub your eye if you feel this sensation.

Your vision should stabilize within a few weeks. Your doctor may see a haze or cloudiness in the cornea after the VisuMax SMILE procedure. It usually will not affect your vision. In most cases, the haze will clear up over time.

Use all medication eye drops and lubricants your doctor prescribes as directed. These are necessary for the proper healing of your eye(s). One of the medication eye drops prescribed after surgery is topical steroids. One side effect, particularly with long-term use of topical steroids, may be increased eye pressure. Extended use of topical steroids may lead further to glaucoma, and cataract formation (cloudiness of the clear natural lens of the eye that reduces vision).

You will be asked to return for follow-up examinations by your doctor following the procedure. It is important for you to keep these appointments to monitor your healing process.

WARNING: You should contact your doctor if you notice any pain, change in vision, or loss of vision in the eye. These may be signs of a serious medical condition.

Questions to Ask Your Doctor

You may want to ask the questions below to help you decide if the VisuMax SMILE procedure is right for you.

- What are the other options to correct nearsightedness?
- Will I have to limit what I do after the VisuMax SMILE procedure? If yes, for how long?
- What are the benefits of the VisuMax SMILE procedure for my level of nearsightedness?
- What vision can I expect in the first few months after the VisuMax SMILE procedure?
- If the VisuMax SMILE procedure does not correct my vision, could my vision be worse than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses if I still need them after the VisuMax SMILE procedure?
- How is the VisuMax SMILE procedure likely to affect my need to use glasses or contact lenses as I get older?
- Will my cornea heal differently if I injure it after the VisuMax SMILE procedure?
- Should I have the VisuMax SMILE procedure surgery on my other eye?
- How long will I have to wait before I can have the VisuMax SMILE procedure surgery on my other eye?
- What vision problems will I have if I have the VisuMax SMILE procedure in only one eye?

Discuss the cost of surgery and follow-up care with your doctor. Most health insurances do not cover the VisuMax SMILE procedure for vision correction.

Self-Test

Are you an informed and educated patient regarding the VisuMax SMILE procedure?

You should be able to answer the following true/false statements after reading this booklet.

1. The VisuMax SMILE procedure is risk-free.
2. I can wear my contacts as much as I want up to the time I have the procedure.
3. I don’t have to do anything during the procedure, except show up on time.
4. I will have perfect vision after the procedure.
5. I may need reading glasses after the VisuMax SMILE procedure.
6. There is a risk that I may lose some vision due to the VisuMax SMILE procedure.
7. Pregnant women can proceed with the procedure without any precautions.

8. If I have an active autoimmune disease, I am still a good candidate for the VisuMax SMILE procedure.
9. I only need to tell my doctor about medications prescribed for my eyes.

Summary of Important Information

- The VisuMax SMILE procedure is permanent. Once done, it cannot be reversed.
- The VisuMax SMILE procedure does NOT end the need for reading glasses, even if you have never needed glasses to read before.
- The VisuMax SMILE procedure is used to treat nearsightedness.
- Your nearsightedness must be stable and not have changed by more than 0.50 D in the year before surgery.
- You should not have the VisuMax SMILE procedure if you have any of the following conditions:
    - Severe dry eye;
    - An active eye infection or inflammation;
    - A recent Herpes infection that affected your eyes or problems with your eyes resulting from a past infection;
    - An active autoimmune disease or connective tissue disease;
    - Uncontrolled diabetes;
    - Uncontrolled glaucoma.
- You may experience discomfort following the VisuMax SMILE procedure. The VisuMax SMILE procedure is not risk-free. Please read this entire booklet before you agree to have the treatment. Pay special attention to the sections on Benefits and Risks.
- Some alternatives to the VisuMax SMILE procedure are glasses, contact lenses, LASIK, PRK, and lens implant surgery.
- Before you decide to have the VisuMax SMILE procedure you should do as follows:
    - Have a complete eye exam.
    - Talk with one or more doctors about the VisuMax SMILE procedure. Discuss its benefits, risks, potential complications, postoperative healing, and alternative procedures.

Answers to Self-Test Questions

1. False (see Section Potential Risks of the VisuMax Femtosecond Laser SMILE Procedure?)
2. False (see Section Before the Surgery)
3. False (see Section The Day of Surgery)
4. False (see Section Unrealistic Expectations about Surgery)

5. True (see Section Unrealistic Expectations about Surgery)
6. True (see Section Potential Risks of the VisuMax Femtosecond Laser SMILE Procedure?)
7. False (see Section Precautions)
8. False (see Section Contraindications)
9. False (see Section Before the Surgery)

Clinical Study Information

A clinical study was conducted to evaluate the safety and effectiveness of the VisuMax SMILE procedure for the correction of nearsightedness. The study included 336 treated eyes of 336 patients from 5 U.S. centers and was started in July, 2012.

The study results presented in this booklet include all available outcomes through March, 2015.

Patient Characteristics

- Patients' ages ranged from 22 to 58 years, with an average of 33 years of age.
- 196 of the patients were female and 140 were male.
- 309 of the patients were white, 10 were black, 6 were Asian and 11 were of any other racial/ethnic group.
- Treatments ranged from -1.00 D to -10.00 D of myopia, with an average preoperative myopia of about -4.75 D.

Results to Evaluate Risks

Distance Vision with Glasses (Best Vision) After Treatment

In the clinical study, distance vision corrected with glasses (distance vision with glasses, or best vision) was measured using a standard letter chart before the procedure, and then at each of the follow up visits (1 day, 1 week, 3, 6, 9 and 12 month) after treatment. Table 1 presents the change in best distance vision at 6 and 12 months after the surgery, the key visits for analyzing the results of the study. The large majority of patients experienced no change or an improvement of at least one line on the vision chart. However, 11 patients at 6 months and 8 patients at 12 months (from the total patients listed) showed a one line decrease in best distance vision.

Table 1
Change in Distance Vision with Glasses
(Best Vision) after Surgery

Change in Best Vision	Month 6	Month 12
	number of patients of 329 total	number of patients of 311 total
More than 2 Lines Better	3	5
2 Lines Better	6	3
1 Line Better	66	71
No Change	243	224
1 Line Worse	11	8
2 Lines Worse	0	0
More than 2 Lines Worse	0	0

Key safety events

In Table 2, key safety results are presented for all 329 patients at 6 months and also for all 336 patients at their last available visit. These key safety events include; best vision after surgery which was 2 lines worse on the vision chart compared to best vision before surgery, best vision after surgery that was 20/40 or worse when best vision before surgery was at least 20/20, and glasses prescription after surgery had more than 2.0 D of astigmatism. There were no patients that presented with any of the key safety events from the study at these time points.

Table 2
Change in Distance Vision with Glasses
(Best Vision) after Surgery

Key Safety Event	Month 6	Last Available Visit
	number of patients of 329 total	number of patients of 336 total
Best vision 2 lines worse	0	0
Best Vision worse than 20/40	0	0
More than 2.0 D of astigmatism after surgery	0	0

Adverse Events

A total of 15 eye adverse events were reported in 14 patients over the course of the study. Table 3 shows the number of patients in the study that experienced adverse events during surgery. All four eyes completed the study with vision better than 20/20. Table 4 shows the number of patients that had adverse events after surgery. Other than one subject whose vision without glasses was 20/25, all other patients completed the study with at least 20/20 vision without glasses. Other possible adverse events and complications are also described in the previous section of this document titled "What Are The Risks of VisuMax SMILE Procedure?"

Table 3
Adverse Events During Surgery

Adverse Events During Surgery	Number of Patients out of 336 total
Difficult removal of corneal tissue with damage	2
Tear in cornea located in treatment area	1
Small piece of corneal tissue intended for removal remaining after procedure	1

Table 4
Adverse Events After Surgery

Adverse Events After Surgery	Number of Patients out of 336 total
Small piece of corneal tissue intended for removal remaining after procedure	2*
Decrease in vision of 2 or more lines on the visual acuity chart even with the use of glasses/contact lenses	1
Inflammation of a blood vessel in the back of the eye	1
Early cancerous growth of the conjunctiva (the clear tissue covering the white part of the eye and lining the eyelids)	1
Inflammation of the surface of the eye due to allergy	1
Inflammation of the surface of the eye due to viral infection	1
Herpes eyeinfection	1
Inflammation inside the eye	1
Separation of the vitreous gel in the back of the eye	1
Conjunctival growth	1

*One of these patients is also included in Table 3, as this adverse event was noted both during and after surgery.

Complications

Table 5 shows the number of patients in the study that experienced complications during or after the procedure. The largest majority of these reports involved symptoms of moderate or severe glare or halos, at 35 patients and 20 patients, respectively. The peak incidence of these reports occurred earlier in the healing process at 3 and 6 months, with a significant reduction by the ensuing 9 and 12 month visits. At month 12, in fact, there were only four residual reports of moderate or severe glare and one report of moderate or severe halos.
For 3 patients with complications, another surgical procedure was needed to treat the complication. One patient had to have debris flushed from the area where corneal tissue was removed. Two patients had to have cells from the front of the cornea flushed from the treatment area.

Table 5
Complications

Complications	Number of Patients out of 336 total
Difficult removal of corneal tissue with no damage	8
Interruption of suction during procedure, but completed	4
Interruption of suction during procedure, discontinued treatment	2
Treatment area not centered	1
Dry Eye	9
Inflammatory cells (e.g. white blood cells) in cornea	3
Cells from the front of the cornea trapped in treatment area	3
Debris in the area where corneal tissue was removed	9
Feeling of something in the eye occurring 1 month or later after surgery	1
Moderate or severe glare symptoms	35
Moderate or severe halos symptoms	20
Pain occurring 1 month or later	1
Wrinkling of the corneal tissue	1
Light sensitivity that may be debilitating at times	1

Patient Symptoms Before and After the VisuMax SMILE Procedure

At the visit before surgery and 3, 6, 9, and 12 months visits after surgery, patients were asked to complete a questionnaire on visual symptoms that they may have experienced. The specific symptoms included on the questionnaire are listed below.

- Glare
- Halos
- Starbursts
- Hazy vision
- Blurred vision
- Distortion

- Double or multiple images
- Fluctuation of vision
- Focusing difficulties
- Judging distance or depth perception

Table 6 shows the summary of visual symptoms reported at 3, 6, 9 and 12 months following the procedure, compared to before the procedure, in terms of the frequency, severity, and degree of bothersome-ness of these symptoms combined. On average, there were more patients reporting worsening of symptoms over improvement, at 6 months. By 12 months, however, there were more patients reporting improvement compared to worsening of symptoms.

Table 6
Change in Visual Symptoms from Before to After Surgery

Summary of Visual Symptoms		Month 3	Month 6	Month 9	Month 12
		number of patients of 332 total	number of patients of 328 total	number of patients of 319 total	number of patients of 309 total
Frequency	Worse	176	150	133	116
	Same	70	74	74	71
	Improved	86	104	112	122
Severity	Worse	160	131	108	93
	Same	81	97	93	95
	Improved	91	100	118	121
Bothersome	Worse	138	106	95	79
	Same	102	123	119	119
	Improved	92	99	105	111

Table 7 presents the worsening, as well as improvement, of 2-grades or more at 12 months, in terms of how frequent, how severe, and how bothersome each symptom was, compared to before the surgery. Starbursts (5 reports out of 309) and blurred vision (8 reports out of 309) were the symptoms with the most cases of worsening of 2-grades or more at 12 months after surgery. With respect to severity, double/multiple images and blurred vision had the highest numbers (with 4 reports each out of 309) of worsening of 2-grades or more at 12 months. Starbursts, blurred vision, and judging distance or depth perception (also with 4 reports each out of 309) were the symptoms that had the most reports of worsening of 2-grade or more at 12 months in terms of bothersome-ness. However, there were more reports overall of an improvement (39) than a worsening (27) of 2-grades or more 12 months after the surgery, compared to before the surgery.

Table 7
Changes of 2 or More Grades in Visual Symptoms 12 Months after Surgery

Summary of Visual Symptom		N = 309	
		Better	Worse
Glare	Frequency	5	3
	Severity	11	3
	Bothersome	7	2
	# of Subjects	17	7
Halos	Frequency	7	4
	Severity	4	0
	Bothersome	2	0
	# of Subjects	8	4
Starbursts	Frequency	1	5
	Severity	2	3
	Bothersome	0	4
	# of Subjects	3	7
Hazy Vision	Frequency	4	1
	Severity	2	0
	Bothersome	2	0
	# of Subjects	5	1
Blurred Vision	Frequency	3	8
	Severity	4	4
	Bothersome	5	4
	# of Subjects	5	8
Distortion	Frequency	1	0
	Severity	0	0
	Bothersome	1	0
	# of Subjects	1	0
Double or Multiple Images	Frequency	0	4
	Severity	0	4
	Bothersome	0	3
	# of Subjects	0	5
Fluctuation	Frequency	0	2
	Severity	2	1
	Bothersome	1	1
	# of Subjects	2	2
Focusing	Frequency	0	2
	Severity	7	2
	Bothersome	5	2
	# of Subjects	11	3
Judging Distance Depth Perception	Frequency	6	0
	Severity	5	1
	Bothersome	4	4
	# of Subjects	9	4
	# of Subjects	39	27

N = Number of eyes with non-missing values the 12-Month visit.
The symptoms with the two highest rates of 2-grades of worsening or more within each subscale are shaded.

In terms of how bothersome or severe a particular symptom was at 12 months following the surgery, Table 8 shows the number of patients (from a total of 310 that responded at 12 months) who replied that it was "quite" or "very" bothersome, as well as those that replied the severity was "moderate" or "severe". The table does not, however, represent how bothersome the symptoms were before the surgery. As presented in the table, there were very few reports overall, mostly limited to "quite" bothersome and "moderate" for severity. There was a single report each of "very" bothersome and "severe" involving the symptom of double or multiple images, and there was one report of "severe" for the symptom of difficulty focusing.

Table 8
Two Highest Categories of Bothersome and Severity for Each Visual Symptom at 12 Months

Visual Symptom	Number of patients out of 310 Total			
	Bothersome		Severity	
Glare	Quite	3	Moderate	4
	Very	0	Severe	0
	Total	3	**Total**	4
Halos	Quite	1	Moderate	1
	Very	0	Severe	0
	Total	1	**Total**	1
Starbursts	Quite	6	Moderate	6
	Very	0	Severe	0
	Total	6	**Total**	6
Hazy vision	Quite	0	Moderate	0
	Very	0	Severe	0
	Total	0	**Total**	0
Blurred vision	Quite	4	Moderate	4
	Very	0	Severe	0
	Total	4	**Total**	4
Distortion	Quite	0	Moderate	0
	Very	0	Severe	0
	Total	0	**Total**	0
Double or Multiple Images	Quite	2	Moderate	3
	Very	1	Severe	1
	Total	3	**Total**	4
Fluctuation	Quite	1	Moderate	1
	Very	0	Severe	0
	Total	1	**Total**	1
Focusing	Quite	3	Moderate	2
	Very	0	Severe	1
	Total	3	**Total**	3
Judging Distance or Depth Perception	Quite	5	Moderate	2
	Very	0	Severe	0
	Total	5	**Total**	2

There were minor differences in instructions, method of choosing the response option formatting, and directions associated with choosing the responses for the Quality of Vision (QoV) questionnaire used in this trial compared to the original QoV questionnaire. The impact of these differences on the reported frequency, bothersomeness, and severity of symptoms is unknown.

Patients were also asked to assess some symptoms associated with dryness and how those symptoms change in windy conditions, low humidity, and air conditioning, specifically:

- Light sensitivity
- Grittiness
- Eye pain or soreness

Table 9 shows a summary categorizing these dryness-related symptoms as worse, the same, or improved (compared to before surgery) at 3, 6, 9 and 12 months following the procedure. The 12-month outcomes once again show a greater number of patients reporting 'improved' symptoms, compared to the 6 month outcomes. This improvement is also shown in the lower number of reports of 'worse' dryness-related symptoms at 12 months, compared to 6 months. However, the reports of feeling uncomfortable in situations (i.e. windy conditions, low humidity and air conditioning) during the last week showed more patients with worsening compared to those reporting improvement.

Table 9
Change in Dryness-Related Symptoms from Before to After Surgery

Dryness-related Symptom	Month 3	Month 6	Month 9	Month 12
Experienced Symptoms during the Last Week	number of patients of 332 total	number of patients of 328 total	number of patients of 319 total	number of patients of 308 total
Worse	128	92	76	73
Same	130	145	151	144
Improved	74	91	92	91
Felt Uncomfortable in Situations during the Last Week	number of patients of 310 total	number of patients of 307 total	number of patients of 300 total	number of patients of 332 total
Worse	134	119	88	87
Same	121	127	144	138
Improved	55	61	68	63

Table 10 presents the number of patients with moderate and severe dry eye symptoms (based on the Ocular Surface Disease Index or OSDI scoring system) before surgery, compared to 6 and 12 months after surgery. As shown, there was a total of 26 patients with total scores ≥ 23 before surgery, placing them in the "moderate" or "severe" categories. Six months after surgery, this remained consistent with 27 total patients with

total scores in these ranges. However, 12 months after surgery, as well as at the last available visit, there was a reduction in the number of patients (to 15 and 19, respectively) with total scores reflective of these two categories.

Table 10
Number of Patients with Moderate or Severe Dry Eye Symptoms Before Surgery and 6 and 12 Months After Surgery

Severity of Dry Eye Symptoms	Preop	Month 6	Month 12	Last Available Visit
Number of Patients	335	329	309	336
moderate*	16	21	7	10
severe*	10	6	8	9

Total Scores for Dryness-related Symptoms = (sum of scores) x 25/(# of questions answered). The responses of N/A were excluded.
*Total Scores for Dryness-related Symptoms: "Moderate": ≥ 23 to < 33 and "Severe": ≥ 33.
Scoring based on Miller et al. Minimal Clinically Important Difference for the Ocular Surface Disease Index *Arch Ophthalmol.* 2010;128(1):94-101.

Contrast Sensitivity Testing

Contrast sensitivity testing measures how well a person is able to distinguish between an object and its background, especially in low light conditions. Contrast sensitivity is important in everyday tasks such as driving a car at night or in fog or rain. Even with 20/20 vision, poor contrast sensitivity can make the vision feel compromised. In this study, contrast sensitivity was tested in dim conditions without glare, before surgery and at 3, 6, 9 and 12 months following surgery. 305 out of 310 treated eyes in the study had no marked decrease in contrast sensitivity 12 months after the surgery compared to before surgery, but in 5 eyes, there was a significant decrease after the surgery.

Corneal Topography

Computerized corneal topography provides a way to measure the shape of the corneal surface. By measuring light reflected from the eye, the corneal topography system can map out differences in elevation that appear on the corneal surface. This is especially useful to measure astigmatism, and in some cases, diagnose and manage corneal diseases.

For this study, corneal topography was performed for all patients preoperatively and at the 3, 6, 9, and 12-month visits following surgery. Evaluation of the corneal topographies before and after surgery were done to identify any issues with, as well as to monitor the stability of the corneal shape.

Other than short-term irregularities from surface dryness, the only abnormality reported was a decentered treatment involving one patient.

Wavefront Aberrometry Outcomes

The quality of a person's vision depends on the amount of focusing imperfections present, which can be measured by an instrument called a wavefront aberrometer. Everyone's eyes have some focusing imperfections. These focusing imperfections can be divided into two groups. One group can be corrected with glasses or contact lenses and the other group cannot. In the nearsighted eye, most of the focusing imperfections are due to myopia and astigmatism and belong to the first group. In this study, a wavefront aberrometer was used to measure the second group of focusing imperfections before surgery and then at 3 and 12 months after surgery as another way to monitor for problems caused by the corneal reshaping procedure. Results from this study showed that on average, there was a slight increase in focusing imperfections uncorrectable with glasses or contact lenses after surgery as compared to before surgery.

Results to Evaluate Benefits

Visual Acuity without Glasses Before and After Treatment

In the clinical study, vision without glasses was measured using a standard letter chart before the procedure, and then at each of the follow up visits (1 day, 1 week, 3, 6, 9 and 12 month) after treatment. Before surgery, there were no patients whose vision without glasses was 20/40 or better. At the 6 month follow-up after treatment, 327 out of 328 patients were seeing 20/40 or better (Table 11) without glasses, 287 patients were 20/20 or better, and 197 patients were 20/16 or better.

Table 11
Vision Without Glasses After Treatment

Vision	Month 6 (Number of patients out of 328 total)	Month 12 (Number of patients out of 310 total)
20/16 or better	197	198
20/20 or better	287	273
20/25 or better	313	301
20/32 or better	322	305
20/40 or better	327	309

Vision without Glasses after Treatment Compared to Vision with Glasses before treatment

Table 12 shows a comparison of vision with glasses before the VisuMax SMILE procedure to vision without glasses after the procedure, in terms of lines on an eye chart. At 6 months following surgery, 229 patients saw as well or better *without* glasses than they did before *with* glasses.

Table 12
Vision Without Glasses After Treatment
vs. Vision With Glasses Before Treatment

Change in Lines of Vision	Month 6 Number of patients out of 328 total)	Month 12 Number of patients out of 310 total)
More than 2 Lines Better	1	3
2 Lines Better	12	13
1 Line Better	83	93
No Change	133	119
1 Line Worse	67	57
2 Lines Worse	19	18
More than 2 Lines Worse	13	27

To test for the effects of age, the study analyzed patients in different age groups. Six months after the surgery less patients older than 40 years of age had uncorrected vision of 20/20 or better than patients younger than 40 years of age.

Accuracy and Stability of Correction

To determine how accurate the VisuMax SMILE procedure was, the amount ofcorrection that was measured from patients after treatment was compared to the amount of correction they were supposed to receive. The accuracy was within ±1.00 Diopter of attempted correction in 323 out of 328 patients and within ±0.50 Diopter in 305 out of 328 patients at 6 months, the time point at which the correction was determined to be stable.

Patient Assistance Information

PRIMARY DOCTOR

Name:
Address:

Telephone Number:

REFRACTIVE SURGEON

Name:
Address:

Telephone Number:

LOCATION WHERE TREATMENT WAS DONE

Name:
Address:

Telephone Number:

LASER MANUFACTURER

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