PATIENT INFORMATION BOOKLET

PROSCAN MYOPIA SW1.40

FACTS YOU NEED TO KNOW ABOUT LASER IN SITU KERATOMILEUSIS (LASIK) SURGERY WITH THE TECHNOLAS TENEO 317 MODEL2 US EXCIMER LASER SYSTEM WITH PROSCAN ASPHERIC ABLATION PROFILE

For nearsightedness (Myopia) between -1 and -10 diopters (D) with astigmatism between 0 and -3 D

Please read this entire booklet. Discuss its content 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.

Precaution

Federal (U.S.) law restricts this device to sale by, or on the order of a, a physician.

Publishing details

TECHNOLAS TENEO 317 MODEL2 US

Patient Information Booklet

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(1) Introduction

This booklet contains information to help you decide whether or not to have Laser in situ Keratomileusis (LASIK) laser surgery for the correction of nearsightedness.

Alternative practices and procedures to LASIK for the correction of nearsightedness are glasses, contact lenses, or the refractive surgical procedures known as Photorefractive Keratectomy (PRK) and Radial Keratotomy (RK). You should discuss these alternatives with your doctor to select the method that best meets your expectations and lifestyle.

If you are nearsighted in both eyes, it may be necessary to have both eyes treated with LASIK. Sometimes, it is better to have LASIK done on only one eye. Talk with your doctor about whether it would be better to treat one eye or both eyes.

Please read this booklet completely and discuss your questions with your doctor. Only your eye care professional can determine whether or not you are a suitable candidate. Some jobs, have vision requirements that RK, PRK, and LASIK presently cannot meet, check with your employer to understand if there are any work restrictions to you having LASIK surgery.

(2) Description of the Eye and Surgery

a. How Your Eye Works

When you look at an object, the light that is reflected off of the object enters your eye through the clear front layer of your eye, called the cornea. The clear tissue of the cornea is responsible for two-thirds of the focusing power of the eye. The cornea bends the light before it passes further through the pupil to the crystalline lens behind it. The lens adjusts its shape to bend and focus the light a second time and then passes further to the back of the eye until it reaches the retina, the light-sensitive layer at the back of the eye. Your eye changes the images into electrical signals and sends them to the brain.

In a ‘perfect’ normal eye the refractive power (the bending of the lights) of the cornea and crystalline lens and the axial length of the eye are balanced, which means that rays coming from far away are focused precisely on the retina, resulting in perfectly sharp distance vision.

Focusing with your Eye

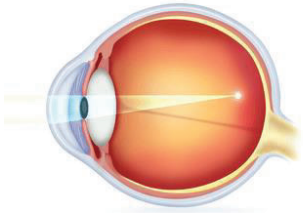
The eye focuses light by bending all light rays to meet at a single point. If it works perfectly, a sharp image of the object you look at will be focused exactly on the retina. You will see a clear image. However, if the light focuses either in front of or behind the retina, the image you see will be blurred. Depending on where the image focuses, you will be nearsighted, farsighted, or astigmatic.

The shape of the cornea determines the focusing power of the eye. The more sharply curved the cornea, the more light rays are bent. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. If the cornea is curved too much, the image focuses in front of the retina and the eye is nearsighted. If the cornea is irregularly shaped (like a football rather than a basketball), it is called astigmatic.

The nearsighted Eye (Myopia)

In the case of nearsightedness (myopia) the axial length of the eyeball is too long, or the refractive power is too high to focus incoming parallel rays onto the retina. Nearsighted people see near objects clearly, but distant objects are blurry. With myopia, incoming light rays from objects are focused in front of the retina, the light sensitive part of the inner eye, resulting in blurred distant vision. Myopia usually starts in childhood and stabilizes in the late teens or early adulthood. It can be diagnosed easily through refraction by an optometrist or physician using trial frames and glasses or a phoropter (subjective refraction - negative sphere).

Figure 1: Schematic refraction of parallel rays in myopic eyes



To bring the focus of a myopic eye onto the retina of the eye, the curvature of the cornea can be changed with the help of the excimer laser.

Checking your Focus

Your doctor checks where your eye focuses light. When your vision is corrected, a lens or a combination of lenses is added to move the point where the light focuses so that the focal point strikes your retina perfectly. Good focus depends on the shape and size of your eyeball, the shape of your cornea, and the power of your natural lens.

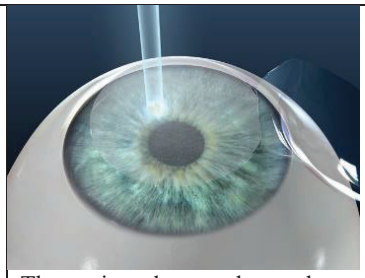
b. What Is LASIK and What Does the TECHNOLAS TENEO 317 MODEL2 US Excimer Laser System Do?

LASIK is an outpatient, elective refractive surgery procedure used to help correct refractive errors to reduce dependency on eyeglasses or contact lenses i.e. it is your choice if you are seeking to be as independent as possible from a visual aid, but the operation is not urgently necessary. You do not need to stay overnight in the hospital.

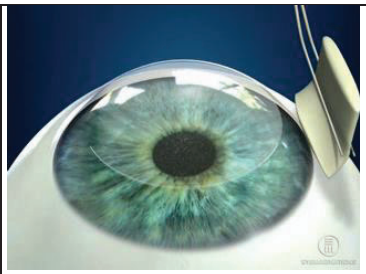
The LASIK procedure is characterized by the creation of a thin lamellar flap of the cornea by a microkeratome or femtosecond laser. This flap is then folded aside to reshape the cornea to improve the way the eye focuses light rays onto the retina at the back of the eye. The laser removes small amounts of tissue with ultraviolet light. After the laser treatment is finished, the corneal flap is placed back into its original position on the cornea (see Figure 2).

Figure 2: Illustration of LASIK procedure

A corneal flap is created and the corneal flap is folded back



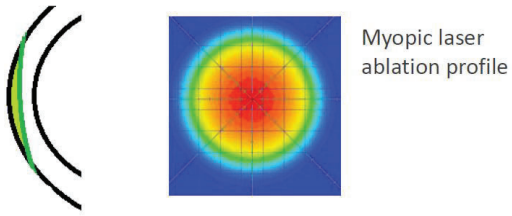
The excimer laser reshapes the cornea



The corneal flap is folded back in place

To bring the focus of a myopic eye onto the retina of the eye, the curvature of the cornea is flattened in order to restore the relationship between the length of the eye and the refractive power. To achieve this, the excimer laser removes more tissue in the centre of the anterior cornea than in the periphery.

Figure 3: Schematic illustration of myopic laser ablation.
The image on the left shows a schematic cross section of the cornea with the intended change effective by LASIK. The centre image shows a schematic top view of the laser ablation pattern. Red colours indicate areas where the laser vaporises a larger amount of tissue and yellow/green areas with fewer laser pulses and therefore less tissue that is vaporised, right down to the blue area where no tissue is vaporised. The image on the right shows a schematic eye in comparison to Figure 1, demonstrating that after LASIK surgery the incoming light rays are focused on the retina.



TECHNOLAS TENEO 317 MODEL2 US

The TECHNOLAS TENEO 317 MODEL2 US excimer laser is a machine that produces and aims a beam of ultraviolet light at a rate of 500 pulses per second. Due to the high 500 Hz repetition rate of the TECHNOLAS TENEO 317 MODEL2 US the system can operate using a small spot size of 1mm while still performing the whole ablation in a sufficiently short timeframe.

The excimer laser produces a brief, intense pulse that lasts only a few billionths of a second. Each pulse removes a microscopic amount of tissue from the surface of the cornea. It produces little heat and leaves the tissue beneath unchanged[1].

[1] Vitale, S., et al., Costs of refractive correction of distance vision impairment in the United States, 1999-2002. Ophthalmology, 2006. 113(12): p. 2163-70.

Standard laser procedures assume that the cornea is shaped like a sphere. However, generally a person's cornea is not round like a sphere but becomes flatter towards the periphery. The so-called aspherical PROSCAN treatment of the TECHNOLAS TENEO 317 MODEL2 US is designed to take this natural shape of the cornea into account.

LASIK surgery is performed on one eye at a time. The second eye can be treated if there are no complications during the treatment of the first eye. Laser surgery on the second eye can usually be done on the same day as the first eye, or may be done later, depending on your doctor’s evaluation of your particular case.

Tracking System

TECHNOLAS TENEO 317 MODEL2 US excimer laser system also includes an eye tracker system that automatically monitors the position of your eye 1740 times per second and adjusts the laser treatment to compensate for any small, involuntary movements your eyes might make during surgery. The eye-tracking system works in multiple dimensions, i.e. one tracker monitors whether the eye moves left and right, or up and down and ensures correct centering. A second tracker compensates for the rotation of the eye around its optical axis. Finally, a third tracker monitors whether the head moves forward or backward (e.g., when you press the back of your head into the headrest or relax). If the eye moves out of the active tracking range, the laser system will stop firing until the eye is back in this area. All three modules together ensure that the treatment is performed exactly at the intended position.

(3) Purpose of the Device (Indications for Use)

The TECHNOLAS TENEO 317 MODEL2 US is indicated for laser-assisted in situ keratomileusis (LASIK) in:

- Patients for the reduction or elimination of nearsightedness (Myopia) between -1 and -10 diopters (D) with astigmatism between 0 and 3 D.
- Patients who are 22 years of age or older.
- Patients must have a stable refraction in the last 12 months as documented by previous clinical recordings (that means your eyeglass/contact lens prescription has not changed more than 0.5 diopters (D) in the last 12 months).

(4) What are the Benefits/What are the Limitations of LASIK?

a. Benefits

- LASIK surgery, performed with the TECHNOLAS TENEO 317 MODEL2 US, is reasonably safe and effective in reducing or eliminating nearsightedness of -1.00 to -10.00 diopters [D] (unit of your prescription) with astigmatism ≤3.00 D.
- LASIK may reduce overall nearsightedness while reducing or eliminating dependency on contact lenses or glasses.

b. Limitations

- You may require additional correction (e.g., glasses, contact lenses, additional surgery) after LASIK to achieve the best possible vision for specific daily activities.

- With increasing age, your prescription might change necessitating additional correction (e.g., glasses) in the future. This can affect your distance and/or near vision.

(5) What are the Alternatives?

The LASIK procedure is an elective surgery, i.e. it is your choice if you are seeking to be as independent as possible from a visual aid, but the operation is not urgently necessary.

There are also several other alternatives for the correction of your nearsightedness:

Non-surgical alternative Therapies such as Eyeglasses and Contact Lenses

Glasses

Glasses are the simplest way which can help to achieve clear vision by refocusing light rays on the retina, compensating for the shape of the eye. Which visual aid individually achieves the best result depends on the respective ametropia, but also on the individual needs and especially on the state of health of the eyes. Patients who are aided with spectacles have a higher risk of injuries due to broken glasses for example in case of an accident and are dependent on their optical aid, which can be a risk due to loss of the glasses in critical situations or simply unpractical for example in athleticism. Also, glasses change the size of the seen image. This is particularly noticeable with lenses that correct severe refractive errors. E.g. with severe myopia, the seen image is smaller. The spectacle frame can also restrict the field of vision. Furthermore, lenses used to correct higher myopia can also affect the weight of the glasses and the personal appearance. Eyeglasses are known to fog up under certain conditions, for example during winter.

For this reason, they are not suitable for certain activities and professions.

Contact Lenses

Another non-surgical option is the utilization of contact lenses, which are aesthetically more pleasing for some patients and may also provide a wider field of vision. However, it is mandatory to exercise a careful cleaning and hygiene regimen. The FDA reports on its website about possible adverse events like conjunctivitis, corneal abrasions, and eye irritations due to contact lens wear and as possible serious hazards of wearing contact lenses corneal ulcers, eye infections, and even blindness are mentioned. Similarly, a risk due to loss of the contact lenses in critical situations is also possible in certain circumstances.

Surgical alternative Therapies

Implantable lens Surgery (phakic Intraocular Lens)

The phakic intraocular lens (pIOLs) is a technology is a reversible procedure that expands the range of refractive surgery to cover higher degrees of myopia (up to -18 diopters), hyperopia (up to +10.0 diopters), and astigmatism (up to +6.0 diopters). The phakic intraocular lens is used in addition to the own natural lens. With the use of phakic IOL, the eye is opened at the edge of the cornea and an additional lens is inserted into the eye. This additional lens is either attached to the iris or in the edge area of the anterior chamber (chamber angle) supported. Other models sit behind the iris, on the natural lens of the eye. After the insertion of the IOL, the incision either seals itself or is closed with a suture. In rare cases complications are

described as an increase in intraocular pressure (glaucoma attack), occurrence of iris damages ,damage to the posterior surface of the cornea (endothelium) with clouding of the cornea, a clouding of the eye lens (cataract), displacement or loosening of the artificial lens, as well as chronic inflammation of eye. Furthermore, the occurrence of retinal detachment is described, especially after myopia correction and bacterial infections. Since the eye is opened during the operation, in extremely rare cases, blindness can occur due to infection.

Custom LASIK/PRK

Custom LASIK/PRK laser treatments are based on unique visual characteristics of each eye. Up until now, glasses, contact lenses, and conventional laser surgery take only lower-order aberrations into account, which are experienced as nearsightedness, farsightedness, and astigmatism. They do not address the Higher-Order Aberrations which make each eye unique. Higher order aberrations can result in visual symptoms such as halos, starbursts and glare and typically cause problems for patients when while driving - especially at night. A Custom LASIK/PRK involves measuring each eye's unique by an advanced technology, known as "wavefront" technology, to create a three-dimensional (3-D) image of the eye. The information contained in the wavefront-map guides the laser in customizing the treatment to the individual visual system. In addition to correcting lower order aberrations, the Custom treatment procedure can help to improve satisfaction with night vision, by reducing the risk of glare, halos, or starbursts around lights at night, and ghost images.

The treatment is not ideally suited for severely aberrated eyes, as wavefront devices cannot achieve consistent or useful measurements at high aberrations. These measurements are especially problematic for patients who require improvements due to small, decentered or pseudo centered optical zones or other irregularities caused by flap problems and scarring.

Topography-guided LASIK

The topography-guided LASIK is an advanced treatment for nearsightedness and astigmatism. The procedure customizes the laser treatment to the unique surface shape of the eye. Topography-guided LASIK attempts to create a more uniform corneal surface to reduce aberrations while correcting the refractive error and avoiding side effects such as glare and halos at night.

Although visual symptoms, like glare and halos, and difficulty driving at night tend to be less frequent and less severe after Topography-guided LASIK, some patients may notice an increase in these symptoms after Topo-guided LASIK.

Refractive Lenticule Extraction (ReLEx)

ReLEx is a surgical treatment for the correction of myopia and myopic astigmatism by using a femtosecond laser to create a disc-shaped piece of tissue within the cornea and a small incision in the surface of the cornea. The surgeon removes the peace of tissue trough the small incision. This removal of tissue causes the shape of the cornea to change which corrects your nearsightedness and astigmatism.

By avoiding the creation of a flap, this procedure induces less dry eye and entails less stromal alteration compared to laser in situ keratomileusis (LASIK).

The procedure is suitable only for patients with myopia and astigmatism. Patients with farsightedness must resort to another procedure, as this requires concave lens removal.

Standard Photorefractive Keratectomy (PRK)
In PRK, the top cell layer of the cornea (the epithelium) is ablated, and the corneal tissue immediately below is removed with the excimer laser. Following the treatment, a therapeutic contact lens is therefore used as a wound patch for a few days to protect the treated area. The recovery process of the eyes with PRK is a bit slower compared to LASIK.

Each alternative has its own advantages and disadvantages. You should fully discuss these alternatives with your physician to select the method that best meets expectations and lifestyle.

(6) Contraindications, Warnings, and Precautions

Table 1 is a quick reference that you can use to start a conversation with your doctor about whether LASIK is right for you. Mark those characteristics or conditions that you know apply to you and discuss them with your doctor if you are considering LASIK. Ask your doctor whether any of the other characteristics or conditions apply to you, and, if so, how they may affect your risk of LASIK complications. Greater detail is provided below the table about these characteristics and conditions and what complications or side effects may arise if you have one of them and choose to have LASIK.

Table 1: Characteristics and Conditions Considered to Evaluate Suitability for LASIK (to be discussed with your doctor)
⃠ When you should not have LASIK (**Contraindications**)
⚠When you should consider not having LASIK (**Warnings**)
* Other things that may increase your risk of LASIK complications (**Precautions**)

Characteristic/Condition	**Check the Box if the Characteristic Applies to YOU**
Dry eye	❑ ⃠ If you have severe dry eyes ❑ ⚠ If you have moderate or mild dry eyes
Cornea not thick enough	❑ ⃠ If the clear front part of your eye is not thick enough
Thinning of the cornea (see Image I)	❑ ⃠ If you have any condition that causes thinning or bulging of the cornea, including: • Cone-shaped cornea (keratoconus) • Thinning of the bottom part of the cornea (pellucid marginal degeneration) ❑ * If you have a family history of thinning of the cornea
Eye Infection	❑ ⃠ If you have active eye infection
Eye Inflammation	❑ ⃠ If you currently have an eye inflammation ❑ * If you have a history of any eye disease (e.g., uveitis), abnormality, injury, or surgery
Herpes eye infection	❑ ⃠ If you have had a recent eye infection or problems resulting from a past infection ❑ ⚠ If you have had a past eye infection
Autoimmune or connective tissue disease (rheumatoid arthritis, lupus)	❑ ⃠ If you have an active autoimmune or connective tissue disease

Characteristic/Condition	Check the Box if the Characteristic Applies to YOU
	❑ ⚠ If you have an autoimmune or connective tissue disease that is controlled
Glaucoma	❑ ⃠ If you have uncontrolled glaucoma (your eye pressure is too high even with treatment) ❑ ⚠ If you have controlled glaucoma ❑ * If you have elevated eye pressure (ocular hypertension) or are being followed for possible glaucoma
Diabetes	❑ ⃠ If you have uncontrolled diabetes (your blood sugar is not well controlled despite treatment) ❑ ⚠ If you have controlled diabetes
Activities	❑ ⚠ If you participate in activities that could damage the LASIK flap, including contact sports (e.g., football) ❑ * If you participate in activities that require good vision in poor lighting conditions to avoid a hazard (e.g., driving at night)
Cataract	❑ ⚠ If you have suspected Cataract
Retinal disease	❑ ⚠ If you have evidence of retinal vascular disease
Cardiologic disease	❑ ⚠ If you have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device you should consult your cardiologist before considering LASIK
Medications	❑ ⃠ If you have a known sensitivity to medications used for standard LASIK surgery ❑ ⚠ If you take medications that have dry eyes as a side effect, such as: • Isotretinoin • Steroids • Medications that weaken the immune system (immunosuppressants) ❑ * If you take any of the following medications: • Amiodarone hydrochloride • Sumatriptan
Repeated attacks of sharp eye pain due to epithelial basement membrane dystrophy	❑ ⚠ If you have a condition in which the outer layer of corneal cells does not stick well to other layers (epithelial basement membrane dystrophy)
Weakened immune system	❑ ⚠ If you have a weakened immune system due to medications (such as steroids) or a medical condition (such as AIDS)
“Crossed eyes” (strabismus)	❑ ⚠ If you have “crossed eyes”

Characteristic/Condition	Check the Box if the Characteristic Applies to YOU
Decreased vision in one eye	❑ ⚠ If you have decreased vision in one eye
Large pupils or very nearsighted	❑ * If you have large pupils or are very nearsighted
Synechiae	❑ * If you show anterior or posterior synechiae.
Anatomical conditions	❑ * If you have anatomical conditions that may have a negative impact on the performance of flap cutting
Allergies or eye rubbing	❑ * If you have allergies or rub your eyes
Pregnancy	❑ * If you are pregnant or nursing

If you are considering LASIK, make sure that you have been checked by your doctor for the characteristics and conditions above and let your doctor know if you have any of these characteristics or have ever experienced any of these conditions.

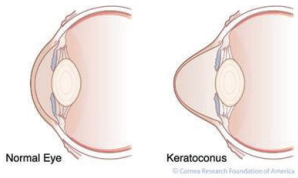
c. When You Should Not Have LASIK (Contraindications)

This section discusses conditions or situations in which the device should not be used because the known or reasonably foreseeable risk of using the device outweighs any reasonably foreseeable benefit.

Please inform your doctor if you have ANY of the following conditions, which greatly increase the risk of harm from LASIK, including possible permanent loss of vision. Your doctor may determine, based on this information and/or your clinical examination, that you should NOT have LASIK:

- ⃠ **Severe dry eye.** LASIK can worsen this problem, even if successfully treated before LASIK, and increase your risk of infection and/or scarring. Symptoms of dry eye may include a scratchy or sandy feeling in the eye, stinging, burning, episodes of excessive tearing, a stringy discharge from the eye, pain, redness, eye fatigue, light sensitivity, and blurred vision. If you are not able to tolerate wearing contact lenses, this may be a sign that you have dry eyes. Make sure your LASIK doctor checks you for dry eyes before having LASIK.
- ⃠ **Cornea not thick enough.** Your cornea (the clear front part of the eye) must be thick enough to undergo LASIK without increasing the risk of causing an abnormal bulging forward of the cornea (ectasia), which could decrease your vision. The residual corneal thickness should not be less than 250 µm. Ask your LASIK doctor whether the thickness of your cornea puts you at greater risk for this complication.
- ⃠ **Thinning of the cornea.** If you have a cone-shaped cornea (keratoconus; Figure 4), thinning of the bottom part of the cornea along the edges (pellucid marginal degeneration), or any other condition that may cause a thinning or bulging of your cornea, LASIK can worsen these conditions and cause a permanent reduction in your vision. This may result in the need for additional surgery (such as a corneal transplant) after LASIK. Your LASIK doctor should map the shape of your cornea before LASIK to make sure you do not have any thinning.

Figure 4: Thinning of the cornea, or keratoconus[2]



- ⃠ **Active eye infection or active inflammation:** If you have an active infection or inflammation of the eye (such as keratitis, iritis, or uveitis), LASIK will likely make your condition worse, resulting in permanent eye damage. Let your LASIK doctor know if you are currently being treated, or if you have ever been treated, for such a condition
- ⃠ **Recent herpes eye infection or problems resulting from past infection:** If you have had a herpes (simplex or zoster) eye infection within the past year or have corneal damage from prior herpes infections, you are at higher risk for further corneal damage after LASIK. Let your LASIK doctor know if you have ever had a herpes eye infection.
- ⃠ **Active autoimmune or connective tissue disease:** If you have an active connective tissue disease or autoimmune disease (such as rheumatoid arthritis and lupus) that can cause corneal melting, LASIK will increase your risk of severe damage to your cornea and vision loss. Let your LASIK doctor know about any medical conditions you have
- ⃠ **Uncontrolled glaucoma:** If you have uncontrolled glaucoma, the increased eye pressure associated with cutting the LASIK flap puts you at greater risk for loss of vision. Let your LASIK doctor know if you have been diagnosed with glaucoma.
- ⃠ **Uncontrolled diabetes:** If your blood sugar is uncontrolled, your eyeglass prescription can fluctuate, and your doctor will not be able to accurately determine what degree of LASIK treatment is appropriate. Uncontrolled diabetes can also negatively affect wound healing after LASIK. Let your LASIK doctor know if you have diabetes.
- ⃠ **Medication:** If you have known sensitivity to medications used for standard LASIK surgery let your LASIK doctor know what sensitivity you have.

d. When You Should Consider Not Having LASIK (Warnings)

Please inform your doctor if you have ANY of the following conditions that may result in a greater risk for poor outcomes or injury related to LASIK. You should discuss your level of risk with your doctor. You and your doctor should determine whether the benefits to you outweigh the risks based on the nature and severity of your condition

- ⚠ **Moderate or mild dry eyes:** If you have dry eyes, LASIK can worsen dryness, discomfort, and blurred vision. This may or may not get better. If you take certain medications, such as nasal decongestants, you are at greater risk of having dry eyes. If you have a condition that can cause dry eye, such as thyroid disease, Sjögren's

[2] Image from http://www.cornea.org/Learning-Center/Conditions-Research-Areas/Keratoconus.aspx.

syndrome, lupus, or rheumatoid arthritis, you are also at greater risk. Make sure your LASIK doctor checks you for dry eyes before having LASIK.

⚠ **Past herpes eye infection:** If you have any history of herpes (simplex or zoster) infection in your eyes, LASIK might reactivate the infection. Let your LASIK doctor know if you have ever had an eye infection or eye inflammation.

⚠ **Controlled autoimmune or connective tissue disease:** Connective tissue diseases or autoimmune diseases (such as rheumatoid arthritis and lupus), even if well controlled and stable, may result in delayed healing 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 melting. You should discuss these additional risks with your LASIK doctor, after he or she has consulted with the other doctors who are treating you.

⚠ **Controlled glaucoma:** If you have glaucoma, LASIK may make monitoring your eye pressure more difficult. You may also be at greater risk for damage to your vision associated with cutting the LASIK flap. The steroid drops used after the surgery may raise your eye pressure and cause glaucoma to worsen. Let your LASIK doctor know if you have been diagnosed with glaucoma.

⚠ **Controlled diabetes**. Even if your diabetes is well controlled, you may have poor healing of your eye following LASIK.

⚠ **Activities that could damage the LASIK flap**. The flap is a tongue-shaped section of corneal tissue that is cut and lifted up during LASIK and which can wrinkle, move out of place, or break off even years after surgery. Participation in contact sports, like football or martial arts, increases your risk for dislocation, or even, loss of the flap. You should discuss your work activities and hobbies with your LASIK doctor prior to surgery to help determine whether LASIK is right for you. You should ask your LASIK doctor how long you should refrain from participating in certain activities following surgery. You should also discuss with your doctor steps you can take to decrease the risk of flap dislocation or loss.

⚠ **Cataract:** LASIK surgery is not advised if cataracts are affecting your vision. Make sure your LASIK doctor checks you for Cataract before having LASIK.

⚠ **Retinal disease:** Retinal vascular diseases generally involve a blockage of blood flow, leakage of fluid, or rupture of a retinal vessel (i.e., artery, capillary, or vein), all of which can result in loss of vision. Let your LASIK doctor know if you have a retinal vascular disease.

⚠ **Cardiologic disease:** If you have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device, you should consult their cardiologist before considering LASIK. Let your LASIK doctor know if you have an implantable electronic device.

⚠ **Taking isotretinoin.** This medication, usually used for acne treatment, increases your risk for dry eye and abnormal wound healing after LASIK. If you have taken or

plan to take this medication, talk to your LASIK doctor and the doctor prescribing this medication about your risk.

⚠ **Repeated attacks of sharp eye pain due to epithelial basement membrane dystrophy** (EBMD). In this condition, the outer layer of corneal cells does not stick well to the other corneal layers causing the outer cells to rub off easily. These recurring "scratches" (recurrent erosions) on the eye surface often cause blurred vision, pain, light sensitivity, and tearing. LASIK is likely to worsen EBMD. Let your LASIK doctor know if you have had these symptoms in the past and ask if any signs of this condition have been noted on your eye exam.

⚠ **Weakened immune system:** If you have a weakened immune system due to medications (such as steroids) or a medical condition (such as AIDS), you may be more prone to infection after surgery. Such conditions and medications may put you at greater risk for other complications as well, such as dry eye or abnormal wound healing. Let your LASIK doctor know about any medical conditions you have and all medications you are taking.

⚠ **History of "crossed eyes" (strabismus).** If you are having LASIK for farsightedness and have a history of "crossed eyes" (strabismus), you may be at an increased risk of having double vision after surgery. Tell your LASIK doctor if you have ever had "crossed eyes" or double vision.

⚠ **Decreased vision in one eye**. If you have one eye that does not see clearly, even with glasses, you should discuss this with your LASIK doctor. This condition can be due to amblyopia, a "lazy eye," or damage from an injury or disease. With this type of decreased vision in one eye, complications that might result from LASIK in your better seeing eye could more severely impact your functioning.

e. Other Things That May Increase Your Risk of LASIK Complications (Precautions)

The list below provides information regarding conditions for which consideration should be given when deciding whether the benefits of LASIK with this device outweigh the risks to you. You should discuss with your LASIK doctor whether the following conditions apply to you and how they may affect your risk of having complications from LASIK:

* **Family history of thinning of the cornea:** Eye diseases like a cone-shaped cornea (keratoconus), thinning of the inferior part of the cornea (pellucid marginal degeneration), and other conditions that may cause a thinning or bulging of the cornea can run in families. You may not be aware that you have such a condition if it is in the early stages. If you have one of these conditions and it has not been diagnosed, LASIK may cause more rapid progression of the disease. You should tell your LASIK doctor about any family history of these or any other eye problems.

* **History of any eye disease (e.g., uveitis), abnormality, injury, or surgery**. If you have a history of any of these conditions, you should discuss them with your LASIK doctor, as they might increase the risks of LASIK. For example, corneal scars may affect LASIK accuracy and vision following the surgery.

* **Elevated eye pressure (ocular hypertension) or being followed for possible glaucoma**. If you have either of these conditions related to eye pressure, there are

several ways LASIK can cause problems for you. It is more difficult to accurately monitor your eye pressure after LASIK, which may delay the detection of glaucoma. You may be at greater risk for damage to your vision associated with cutting the LASIK flap. Additionally, steroid drops used after surgery may raise the eye pressure and cause glaucoma to worsen. Let your LASIK doctor know if you have any of these conditions.

* **Activities under poor lighting conditions**. LASIK may decrease your ability to see well in poor lighting conditions, such as in dim lighting, rain, snow, and fog, when contrast (difference in how bright an object is compared to its background) is low, or when there is glare from bright lights, especially at night. You should discuss these potential problems with your LASIK doctor. After LASIK, you should be careful while driving when you are in poor lighting conditions until you can determine whether you have any difficulties.

* **Synechiae:** Synechiae are adhesions of the iris to the anterior cornea (anterior synechiae) or the posterior lens (posterior synechiae), tell your LASIK doctor if you have anterior or posterior synechiae.

* **Anatomical conditions:** If you have anatomical conditions (e.g. very small eyes) hat may have a negative impact on the performance of flap cutting.

* **Allergies or eye rubbing:** If you rub your eyes after you have had LASIK, you are at a greater risk for dislodging the LASIK flap. This is because the strength of the attachment of the flap to the underlying corneal layers is permanently reduced after surgery. Additionally, some allergy medications cause dry eye symptoms. If you take these medicines, you are at greater risk for severe dry eye after LASIK. Let your LASIK doctor know about all your allergies and medications (even over-the-counter medications) and if you tend to rub your eyes frequently.

* **Pregnancy:** Women who are pregnant or nursing should not have laser eye surgery during this time and until they have weaned. During this phase, hormonal changes occur in the female body, which can often affect vision as well. You should tell your LASIK doctor if you are pregnant or nursing.

* **Taking amiodarone hydrochloride**. This medication, usually used to treat irregular heartbeats (ventricular arrhythmias), can cause cloudy areas in the cornea, and may cause problems with healing after LASIK. Tell your LASIK doctor about all the medications that you are taking.

* **Taking sumatriptan:** This medication, usually used to treat migraine headaches, may cause problems with healing after LASIK. Tell your LASIK doctor about all medications you are taking.

* **Large pupils or very nearsighted**. Many factors affect whether someone might experience visual symptoms, making it difficult to predict who will experience them after surgery. However, very nearsighted patients and patients with large pupils may be at greater risk of experiencing visual symptoms, such as halos and glare. In addition, patients who are very nearsighted generally may have less accurate correction than those requiring less treatment. Ask your doctor whether you have large pupils or are very nearsighted.

Safety and effectiveness of TECHNOLAS TENEO 317 MODEL2 US driven LASIK have **NOT** been established in patients:

- With progressive refractive errors, ocular disease; corneal abnormality.
- With previous corneal or intraocular surgery; or trauma in the ablation zone.
- Who are taking the medication Amiodarone hydrochloride (Cordarone) or isotretinoin (Accutane).
- With mesopic pupil size > 7.0 mm
- Whose vision when wearing glasses is worse than 20/25.
- Who were wearing contact lenses unless they had a stable refraction (within ± 0.5 D), as determined by MRSE, on 2 consecutive examinations at least 1 week apart, in an eye to be treated and the axis of cylinder should not differ by more than 15 degrees.

(7) What are the Risks?

To get the best possible vision, you may need to have additional correction (glasses, additional surgery) if your initial surgery results are not satisfactory. In addition, it is possible that LASIK surgery may result in a decrease in your best corrected vision compared to before you had the surgery.

LASIK surgery may cause visual problems or symptoms that you did not have before the surgery or may make such pre-existing problems or symptoms worse following the surgery.

There is a risk of infection of the cornea or other parts of the eye, as a result of the LASIK surgery, due to removal of tissue from the front surface of the eye as part of the procedure.

There is a risk of perforation (cutting completely through the cornea) of the eye, which could lead to loss of fluid from inside the eye, cataract formation, and infection of the eye.

During the first week following the surgery, ocular pain and discomfort may last for up to seven days after surgery. Blurred vision and tearing may occur as the cornea heals.

Some problems that patients experience after LASIK commonly occur right after surgery and are usually greatly reduced within 3 to 6 months. However, in some patients these problems can be permanent and, in rare cases, may impact their ability to perform daily tasks.

The risks of LASIK[3] include, but are not limited to, the following:

- **Loss of vision**. This means that vision becomes unclear (blurry or hazy vision) even with glasses or contact lenses. Your doctor may be able to measure this loss using a vision chart. The loss may be mild or, in rare cases, severe. In extremely rare cases, people can experience a total loss of vision. Vision loss is usually temporary, but there are complications of LASIK that may cause permanent loss of vision. How clearly you can see may change from day-to-day or even from minute-to-minute (fluctuating vision). Some of the potential causes of vision loss following LASIK are discussed below.

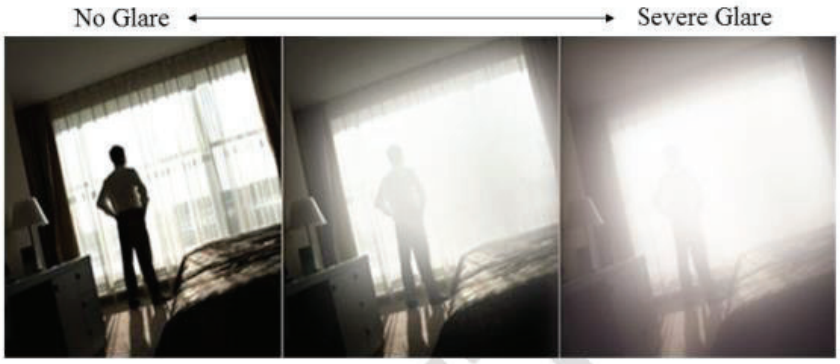
[3] Please note: The potential complication / side effects reported during use of the device are not related exclusively to the laser device itself. For example, subconjunctival hemorrhage are a common complication of LASIK, but is not related to the excimer device, but to the flap creating devices.

- **Corneal complications**. The following corneal complications may lead to permanent vision loss, for example, due to loss of corneal clarity from scarring or swelling, and may require corneal transplant surgery for treatment:
    - **Corneal flap complications**. LASIK requires the cutting of a flap of the front most part of the cornea. The flap is folded away from the area in order for the laser to photoablate the underlying tissue after which the flap is folded back to its original position.
      Flap complications include irregular cutting of the flap, the flap is incorrectly created, is to thin, not aligned or a flap that tears off or is incomplete. If the flap becomes detached or even lost, healing may be irregular and foreign bodies may get under or grow into the flap. If a flap complication occurs during surgery, the surgery may need to be interrupted and rescheduled. A flap complication can result in the need for additional surgery or, rarely, permanent loss of vision. In almost all LASIK cases, the strength of the flap's re-attachment to the underlying tissue is significantly and permanently weaker than before LASIK. There are reports of the flap being torn off, , or folding, even many months after surgery. It may be necessary to wear protective eyewear during certain physical activities like contact sports.
      It is also possible that the outermost layer of the cornea is damaged during the operation. However, these painful injuries heal within a few days in most cases.
    - **Infection.** The cornea may develop an infection during the postoperative period. This can be treated with topical medication, which may or may not successfully control the infection. On rare occasions, an infection may cause a hole in the clear covering of the eye (perforation of the cornea).
    - **Inflammation**. Inflammation after LASIK is the body's reaction to such things as tissue disruption from surgery or infection. Excessive inflammation of the cornea can cause scarring or swelling resulting in cloudiness or haziness (loss of corneal clarity).
    - **Irregular corneal shape.** LASIK or the healing process after surgery may result in an irregular shape to the cornea. This can cause blurry vision or other visual symptoms. Such irregularities in shape can be measured by your doctor using special instruments.
    - **Bulging of the cornea (corneal ectasia)** is the most extreme irregularity. This complication is uncommon, but can cause permanent and significantly blurry vision, sometimes requiring a corneal transplant
- **Retinal detachment.** The retina is the light-sensitive tissue that lines the inside back of the eye and captures images that are transmitted to the brain, much like the film of a camera. If the retina detaches, or comes unglued from its attachments within the eyeball, it will lose its function and need to be reattached through surgery. This may result in permanent loss of vision, even if the retina is successfully reattached. Retinal detachment after LASIK is rare, and usually only occurs in people who are very nearsighted and are prone to this type of retinal problem.

- **Dry eyes. LASIK may cause or increase eye dryness, which may also cause** discomfort and visual problems. The doctor may see dry spots on the normally moist portions of the cornea, or surface damage caused by dryness. These problems usually improve within 3 to 6 months, but in rare cases never go away.

  If you have dry eye before surgery, LASIK may increase dry eye symptoms and related problems after surgery. Your doctor should test you for pre-existing dry eye. However, there is no test that can guarantee whether you will, or will not, have dry eye after LASIK. Lubricating drops are usually necessary immediately after surgery to help with dryness. Symptoms of dry eye may include a scratchy or sandy feeling as if something is in your eye, stinging, burning, episodes of excessive tearing, a stringy discharge from the eye, pain, redness, light sensitivity, and blurred vision. The sensation of dryness can vary from mild to severe, but in most cases the feelings are a minor annoyance. Eye drops such as artificial tears, or other treatments, such as plugs in the tear drainage system of the eye, may reduce these symptoms, but may not completely resolve them. A small number of patients experience extreme discomfort that interferes with their ability to do daily tasks.

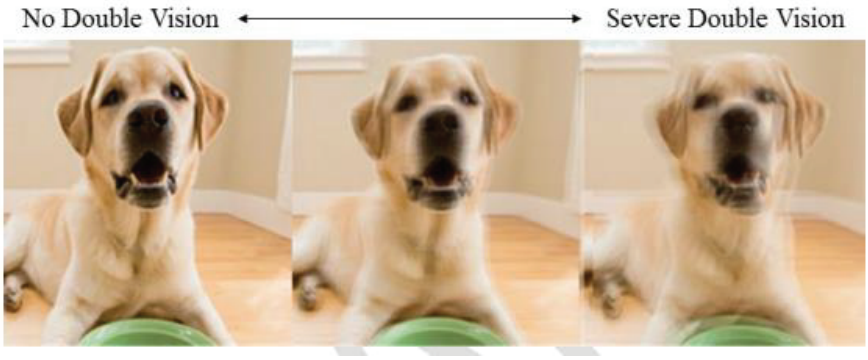
- **Discomfort or pain.** It is not unusual for patients to have some mild discomfort right after LASIK, but it usually goes away within a few weeks or months. Complications like dry eye, inflammation, or infection may cause severe, constant pain in some patients, preventing them from doing their normal activities. In some patients, the pain may never go away (i.e., chronic pain) and may be resistant to therapy.
- **Light Sensitivity:** You may experience sensitivity to light. These symptoms should improve considerably within 3 to 6 months after surgery. It can also create the feeling that light is painful or unpleasant. In rare cases, extreme and sudden sensitivity to light may occur several weeks after the operation, which requires treatment.
- **Visual Symptoms**. LASIK may cause or worsen visual symptoms, such as glare, halos, starbursts, and ghost images/double images, most commonly experienced in dim lighting conditions as well as blurred and fluctuating vision. These problems usually improve within 3 to 6 months after surgery, but in some cases never go away, even when glasses are worn. Visual symptoms can be mild but can also be severe enough to cause difficulties in performing daily tasks. **A common complaint is difficulty with driving at night.** Specific visual symptoms are described below with images to help explain the visual symptoms. The images shown may not represent exactly what you might see, and your symptoms may be more or less severe than what is shown:
    - **Glare.** Glare is difficulty seeing well when there are bright lights like headlights or sunlight, as shown in the images below.



- **Halos.** You may see halos. By halos, we mean seeing a fuzzy cloud of light around lighted objects, such as the ones shown in the images below.

- **Starbursts.** You may see rays of light coming from lighted objects, such as in the car headlights in the images below.

- **Double vision.** Double vision, which some people call “ghost” or “shadow” images, are distorted or blurry visual images, such as the ones shown below. If you experience such images, close one eye and then the other to determine if you only see the double images with both eyes open. If you still have double vision with one eye closed, note in which eye you are experiencing the double images. This information is important to report back to your doctor to help him or her determine the cause of the problem.



  - **Decreased ability to see under low lighting conditions.** You may have more difficulty seeing in low lighting conditions after surgery than before surgery. For example, some patients describe having more trouble reading the menu in a dimly lit restaurant or climbing downstairs in a theater. Driving during certain periods of the day, such as dusk and dawn, may become difficult, because of trouble reading signs, distinguishing the curb from the road, and being able to see people crossing the street. Some people have reported having so much difficulty seeing under these types of conditions that they avoid doing certain activities.
- **Potential risk of psychological harm.** There have been reports that some patients who have had LASIK have experienced severe depression or suicidality that they believe to be a result of complications following the procedure. A definitive causal link between LASIK and these reported psychological harms has not been established.
- **Desired correction not achieved or does not last.** LASIK may not result in the desired amount of vision correction, or the level of vision correction may decrease over time. Additional corrective surgery may not always be possible, and when it is possible may not result in the desired correction. Even if your vision results are generally good, you may still need glasses or contact lenses to perform certain tasks.
- Unintentional imbalance between two eyes. LASIK may cause an imbalance in vision between the two eyes if the desired correction is not achieved, or one eye is treated with LASIK but the other eye cannot undergo LASIK. Imbalances between the two eyes may cause headaches, eyestrain, double vision, and reduced depth perception, if both eyes are not able to focus on the same time at the same distance (anisometropia).
- **Need for glasses for close work.** Almost all people in their 40s or older lose their ability to focus from far to near. LASIK does not treat this condition (called "presbyopia"). After surgery, patients who are already over 40 years old (or once they reach their 40's) usually need to wear glasses for close work, such as reading, even if they did not need to wear them before surgery.
- **Drooping eyelid**. The lid of the eye(s) that had surgery may droop. This can be a complication from an instrument used to hold the lid during surgery. Besides the appearance of unevenness in the height of the eyelids, this may result in a feeling of the eyes getting tired during the course of the day or difficulty seeing and may require eyelid surgery.
- **Red eye:** After the operation, you may notice that the white part of your eye is bright red. This may be a complication from an instrument used to cut the flap. In many

ways, it's just like having a bruise on your skin. Over time, the conjunctiva will absorb the blood and the eye will become white again.

- **Elevated pressure in your eye.** For the first week to one month following the surgery the pressure in your eye may increase due to use of anti-inflammatory medications. When you stop the medication or use other drug therapy, the pressure goes back to normal. Other allergic reactions to the different medications may also occur.
- **Future eye health.** LASIK will likely cause difficulties with:
    - **Future assessment of eye pressure.** Thinning of the cornea due to LASIK will affect your eye pressure measurements (used as part of the exam for glaucoma), making them more difficult to interpret. You should inform all eye care providers that you have had LASIK.
    - **Future cataract surgery**. Almost everyone needs cataract surgery (removal of your natural lens) later in life. LASIK may make it more difficult for the surgeon to implant the correct artificial lens. You should ask your LASIK doctor for a patient information card (e.g., the "K-Card" found at http://www.geteyesmart.org/eyesmart/upload/kcard.pdf) that lists your eye measurements before you have LASIK. You should keep this card to help the cataract surgeon accurately calculate the artificial lens power you will need when you have cataract surgery in the future.

See the **Clinical Study Section** to find out how often specific problems occurred in those treated with the TECHNOLAS TENEO 317 MODEL2 in clinical studies of the device.

Please discuss with your doctor any questions you may have about Adverse Events and Complications.

(8) What to Expect Before, During, and After Surgery

Before Surgery/ Pre-Operative Visit

If you are interested in LASIK, you will need a pre-surgical examination to determine if your eye is healthy and suitable for LASIK. The exam includes an eye examination and ocular history (e.g., evaluation for dry eye syndromes or a contrast sensitivity test). Both eyes will be checked. A complete examination, including but not limited to cycloplegic manifest refraction, must be performed. If it is necessary to dilate the pupil with medication (applied in the form of eye drops), it is not allowed to drive a car three to six hours after. You should arrange to have someone drive you home.

Your cornea will be mapped by computer to determine if it is smooth and properly shaped.

If you wear contact lenses, the doctor will ask you to stop wearing them two weeks (hard or toric lenses) or 3 days (soft contact lenses) before your preparative exam, and through the day of surgery. Failure to do this may produce poor surgical results.

Before surgery, talk to your doctor about any medicine you take.

The Day of Surgery

Before the actual surgery, you will be given the opportunity to hear the sounds the laser makes so that you will be prepared for the noise during surgery. When you go into the room that contains the laser system, you will see a large machine that has a computer screen, a

surgeon's chair, and a patient bed. You will be asked to lie down on the bed. You will lay face up toward the laser microscope and the ceiling.

Extensive clinical experience has shown that laser refractive surgery is well tolerated and rarely causes significant pain. For this reason, systemic sedatives and injected local anesthetics are not required. Nevertheless, you will be given some topical anesthesia in the eye that will be treated to provide adequate control of pain during the surgery. A lid speculum will be placed on your eye. During the treatment , the fellow eye which is not undergoing surgery will be covered with a temporary shield.

The surgery takes about 10-20 minutes overall. The use of the laser, however, lasts only a few seconds. A thin flap with a predefined diameter and thickness will be cut into the cornea. Then the cut tissue is folded back to the cornea. When the surgery begins, you will be asked to look directly at a red fixation light. Try to keep both eyes open without squinting. It is very important that you keep looking directly at the red fixation light, even if the light fades or becomes blurry. Your results depend on how well you look directly at this red fixation light throughout the treatment. As the procedure progresses, the computer-controlled laser beam makes changes to specific areas of the cornea. The laser ablates tissue according to a previously precisely calculated plan and corrects the refractive power in this way. A special eye tracker of the laser corrects for the smallest movements of the eye during surgery.

After treatment is completed, the treated surface is cleaned, and the flap is folded back. Cleaning of the treated area removes any foreign bodies. This concludes the operation and within two days the edge of the created flap should heal on its own.

Immediately after the Surgery

After the surgery, your doctor will put some topical non-steroidal anti-inflammatory solution and one or two drops of an appropriate ophthalmic steroid-antibiotic combination into your eye. For the first 24 hours after surgery your doctor may apply a protective shield to your eye to prevent the corneal flap from being displaced. Numbing drops make the surgery painless. When these drops wear off, your eye may hurt for a day or two. Most patients describe the pain as moderate to severe. Your doctor may prescribe pain medicine to make you more comfortable. Do not remove the patch or shield until instructed to do so. Do not rub or touch your treated eye for the first one to seven days after surgery.

First Days after the Surgery

The patch or shield is usually removed the next day. You may be mildly sensitive to light and glare. Wearing sunglasses may make you more comfortable. You may also have the feeling that something is in your eye. This happens while the outer layer of your cornea is healing. Your vision should stabilize within a few weeks. Some patients report small changes in vision such as improvement or worsening. These changes may occur up to six months or more after surgery. You may see haze or cloudiness in the cornea following surgery. It usually does not affect your vision. This haze tends to decrease over time. It usually disappears completely by 12 to 24 months after the surgery. It is important that you follow your study doctor's post-surgery medication schedule and attend all scheduled follow-up visits. The doctor will schedule typical follow-up visits with you, as is common with any LASIK surgery.

(9) Clinical Study Information

A pivotal study (Investigational Device Exemption # G180286) for safety and effectiveness was conducted with the TECHNOLAS TENEO 317 MODEL2 excimer laser system.

Patients were treated between July 30, 2019, and December 4, 2020. The study included 333 eyes of 168 patients from 10 investigational sites.

- The key effectiveness results among all treated eyes at the 3-month postoperative visit showed that 287 of the 305 eyes had predictable Manifest Refraction Spherical Equivalent [MRSE] (eye prescription) within ± 0.50 Diopters (D unit of your prescription) and 302 of the 305 treated eyes had predictable Manifest Refraction Spherical Equivalent within ± 1.00 D.
- Among the treated eyes targeted for emmetropia ("20/20 correction"), 304 of the 305 eyes could see 20/40 or better without glasses. The study showed that the treatment was effective.
- Additionally, at the 3-month postoperative visit a number of 274 of the 305 eyes could see 20/20 or better without glasses.

Furthermore, no unexpected safety findings were observed. Among all treated eyes at the 3-month postoperative visit, none of the eyes lost 2 or more lines of clear vision when reading an eye chart with glasses three months after the procedure. None of the treated eyes had an increase of astigmatism greater than 2.00 D (Diopters).

The results of the study show that the TECHNOLAS TENEO 317 MODEL2 excimer laser system is safe and effective for LASIK correction of myopia and myopic astigmatism.

For the incidence of adverse events by visit please refer to Table 3. The incidence of complications/possible adverse events by visit presented in Table 3.

- The most frequently reported Adverse Events throughout the study was vision while wearing glasses worse than 20/25, if 20/20 or better preoperatively, occurring in 5 of the 333 eyes. None of these events were serious or led to treatment discontinuation, and all were resolved.
- Two of the 333 eyes experienced loss of more than 2 lines of vision when wearing glasses at 1 week; 1 resolved by 1 month and 1 resolved by 3 months.
- One of the 333 eyes has been reported at 1 week to have vision with glasses worse than 20/25, if 20/20 or better preoperatively associated with corneal edema(visual acuity improved by 1 month, the corneal edema (swelling) resolved by 6 months).
- One of the 333 eyes experienced a miscreated corneal flap prior to LASIK treatment and was treated with another vision correction method called PRK (Table 3).
- At the Month 3 Visit, 2 AEs of the 331 eyes were reported in the same eye: 1 corneal edema (swelling) at 1 month or later and 1 vision with glasses worse than 20/25 (in an eye that had preoperative vision with glasses 20/20 or better). Both AEs were due to trauma not related to the study device or the study procedure. The corneal edema resolved within 4 days and the vision with glasses worse than 20/25 resolved by the Month 6 visit (Table 3).
- Two eyes of the 333 eyes of 1 subject were noted to have corneal pigmentation (i.e., Krukenberg spindles – increased pigmentation) at the 1 day visit, this was considered unrelated to the device or the procedure.

- One eye developed a retinal vein occlusion (blockage) observed at the 1 week visit. This finding was considered unrelated to the device or the procedure (Table 3).

Complications:

- The most frequently reported complication or potential AE throughout the study was Superficial Punctate Keratitis [SPK] (inflammation of the outer layers of the eye), occurring in 128 of the 333 eyes.
- At the Month 3 Visit, complications or potential Adverse Event (AEs) reported were SPK (8 of the 331 eyes), other: conjunctival hyperaemia [increase in blood flow in the conjunctiva] (3 of the 331 eyes), subconjunctival hemorrhage [bleeding from damaged blood vessels in the conjunctiva] (2 of the 331 eyes), trace microstriae [superficial wrinkles in the corneal flap] (2 of the 331 eyes), debris in the interface [small particles under the flap] (2 of the 331 eyes), vitreous floaters [small dark shapes that float across your vision] (2 of the 331 eyes), allergic conjunctivitis [inflammation of the conjunctiva] (2 of the 331 eyes), corneal haze [corneal opacity] (2 of the 331 eyes), double/ghost images in operative eye (1 of the 331 eyes), iritis [inflammation of the iris] (1 of the 331 eyes), other: face injury (1 of the 331 eyes), and peripheral corneal epithelial defect [see glossary] at 1 month or later (1 of the 331 eyes).
- One of the 333 eyes underwent corneal flap lifting between 1 day to 1 month post-surgery for a wrinkled flap considered related to eye rubbing; this eye maintained 20/20 or better vision with glasses throughout the course of the study.
- One of the 333 eyes had corneal haze starting at month 3 that was ongoing at study completion (Table 3). This eye was followed up with resolution of corneal haze at 21 months postoperative.

Patients were followed through 9 months of clinical follow up after the LASIK procedure. The following results show Uncorrected Distance Visual Acuity (UDVA) of 20/20 at month 9 for each dioptric bin (Table 2).

Table 2: Uncorrected Distance Visual Acuity (UDVA) of 20/20 at month 9 for each dioptric bin

MRSE Dioptric Bin (prescription)	**Uncorrected Distance Visual Acuity (UDVA) – percentage n/N (%)**
-1.00 to -2.00 Diopters	28/28 (100%)
-2.00 to -3.00 Diopters	26/29 (89.7%)
-3.00 to -4.00 Diopters	36/39 (92.3%)
-4.00 to -5.00 Diopters	33/35 (94.3%)
-5.00 to -6.00 Diopters	32/34 (94.1%)
-6.00 to -7.00 Diopters	33/36 (91.7%)
-7.00 to -8.00 Diopters	32/39 (82.1%)
-8.00 to -9.00 Diopters	40/46 (87.0%)
-9.00 to -10.00 Diopters	21/23 (91.3%)
-10.00 to -11.00 Diopters	6/7 (85.7%)

N is the number of eyes with non-missing postoperative results at month 9 visit, which is used as a denominator in the percentage calculation; n is the number of eyes with Uncorrected Distance Visual Acuity (UDVA) of 20/20 at month 9 for each dioptric bin.

Treatment of diopter ranges indicated by shaded rows and columns is locked out by TENEO software.

Please discuss with your doctor any questions you may have about adverse events and complications.

Table 3: Adverse Events by Visit

Adverse Events	Operative n/N	Day 1 n/N	Week 1 n/N	Month 1 n/N	Month 3 n/N	Month 6 n/N	Month 9 n/N
Vision with glasses worse than 20/25, if 20/20 or better preoperatively	0/333	0/333	4/333	0/333	1/331	0/321	0/316
Corneal edema at 1 month or later	0/333	0/333	1/333	0/333	1/331	0/321	0/316
Loss of > 2 lines (10 letters) BSCVA	0/333	0/333	2/333	0/333	0/331	0/321	0/316
Other ocular event: Corneal pigmentation	0/333	2/333	0/333	0/333	0/331	0/321	0/316
Miscreated flap (lost, incomplete, too thin)	1/333	0/333	0/333	0/333	0/331	0/321	0/316
Other ocular event: Retinal vein occlusion	0/333	0/333	1/333	0/333	0/331	0/321	0/316

Abbreviations: N= Total number of treated eyes; n= Number of eyes with Adverse Events; Note: Adverse Events (AEs) that started on or after the visit and before the next visit were counted under the first visit.

Table 3: Complications/Possible Adverse Events by Visit (All Treated Eyes)

Complications	Operative n/N	Day 1 n/N	Week 1 n/N	Month 1 n/N	Month 3 n/N	Month 6 n/N	Month 9 n/N
Superficial punctate keratopathy (SPK)	0/333	63/333	36/333	29/333	8/331	9/321	10/316
Subconjunctival hemorrhage	0/333	66/333	0/333	0/333	2/331	1/321	0/316
Trace microstriae	0/333	11/333	5/333	6/333	2/331	0/321	0/316
Diffuse lamellar keratitis (Grade 2 or less)	0/333	16/333	5/333	0/333	0/331	0/321	0/316
Debris in the interface	1/333	9/333	3/333	2/333	2/331	2/321	0/316
Corneal edema between 1 week to less than 1 month after procedure	0/333	5/333	5/333	0/333	0/331	0/321	0/316
Meibomian gland dysfunction	0/333	0/333	4/333	1/333	0/331	0/321	0/316
Other: Conjunctival hyperaemia	0/333	1/333	1/333	0/333	3/331	0/321	0/316

Table 3: Complications/Possible Adverse Events by Visit (All Treated Eyes)

Complications	Operative n/N	Day 1 n/N	Week 1 n/N	Month 1 n/N	Month 3 n/N	Month 6 n/N	Month 9 n/N
Vitreous floaters	0/333	1/333	2/333	0/333	2/331	0/321	0/316
Allergic conjunctivitis	0/333	0/333	0/333	0/333	2/331	0/321	2/316
Corneal abrasion	0/333	4/333	0/333	0/333	0/331	0/321	0/316
Corneal haze	0/333	0/333	2/333	0/333	2/331	0/321	0/316
Loose epithelium	1/333	3/333	0/333	0/333	0/331	0/321	0/316
Epithelium in the interface	0/333	0/333	0/333	1/333	0/331	1/321	1/316
Rough epithelium	0/333	2/333	1/333	0/333	0/331	0/321	0/316
Conjunctivitis	0/333	0/333	0/333	0/333	0/331	2/321	0/316
Corneal flap lifting between 1 day to 1 month post-surgery for wrinkled flap	0/333	1/333	1/333	0/333	0/331	0/321	0/316
Dry eye	0/333	0/333	2/333	0/333	0/331	0/321	0/316
Epithelium at the flap edge	0/333	1/333	0/333	1/333	0/331	0/321	0/316
Other: Conjunctivitis viral	0/333	0/333	2/333	0/333	0/331	0/321	0/316
Other: Corneal oedema	0/333	1/333	1/333	0/333	0/331	0/321	0/316
Other: Hordeolum	0/333	1/333	0/333	1/333	0/331	0/321	0/316
Steroid-induced IOP increase	0/333	0/333	0/333	2/333	0/331	0/321	0/316
Blepharitis	0/333	0/333	1/333	0/333	0/331	0/321	0/316
Double/ghost images in operative eye	0/333	0/333	0/333	0/333	1/331	0/321	0/316
Iritis	0/333	0/333	0/333	0/333	1/331	0/321	0/316
Mucus under edge of flap	0/333	0/333	0/333	1/333	0/331	0/321	0/316
Other: Corneal disorder	0/333	1/333	0/333	0/333	0/331	0/321	0/316
Other: Corneal epithelium defect	0/333	1/333	0/333	0/333	0/331	0/321	0/316
Other: Corneal erosion	0/333	1/333	0/333	0/333	0/331	0/321	0/316
Other: Eye injury	0/333	0/333	0/333	0/333	0/331	1/321	0/316
Other: Face injury	0/333	0/333	0/333	0/333	1 /331	0/321	0/316
Peripheral corneal epithelial defect at 1 month or later	0/333	0/333	0/333	0/333	1 /331	0/321	0/316

Abbreviations: IOP = intraocular pressure, N = Total number of treated eyes; n = Number of eyes with Complications/Possible Adverse Events by Visit; Note: Complications that started on or after a visit and before the next visit were counted under the first visit.

(10) Contact Information

Primary eye care professional	Name:	
	Address:	
	Telephone Number:	
Lasik doctor	Name:	
	Address:	
	Telephone Number:	
Location where treatment was done	Name:	
	Address:	
	Telephone Number:	
Laser manufacturer	Name:	Technolas Perfect Vision GmbH
	Address:	Messerschmittstrasse 1+3 D-80992 München, Germany
	Website	www.technolaspv.com
	Customer Service Hotline:	1-800-553-5340

(11) Glossary of Terms

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

Accutane: A medication: Accutane Reg TM of Hoffmann-LaRoche, Inc.

Adverse Event: Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

Astigmatism: A distortion of the image on the retina caused by irregularities in the cornea or lens.

Anti-Inflammatory Solution: A drug that reduces inflammation or the body's reaction to injury or disease. Any eye surgery can cause inflammation. Your doctor may prescribe this medication after LASIK surgery.

Autoimmune Disease: A condition in which the body attacks itself and results in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. If you have this type of condition, you should not have LASIK surgery.

CDVA (BSCVA): Corrected Distance Visual Acuity (Best Spectacle Corrected Visual Acuity) refers to the measurement of the best vision correction that can be achieved using glasses or contact lenses.

Diopter (D): A diopter is the unit of measurement used for an eye prescription. The focusing strength of your glasses or contacts is measured in diopters. In other words, diopters measure how powerful your prescription is. A higher prescription will have larger numbers, whereas a milder prescription will have smaller numbers.

Blepharitis: Inflammation of the eyelid.

Cataract: An opacity, or clouding, of the lens inside the eye that can blur vision.

Conjunctival Hyperemia: A conjunctival reaction that appears as dilation and redness of the conjunctival vessels.

Conjunctivitis: An inflammation of the conjunctiva, which is the tissue that covers the inside of eyelids, as well as the white part of the eyeball.

Conjunctivitis Viral: A highly contagious acute conjunctival infection usually caused by an adenovirus.

Cornea: The clear, front part of the eye. The cornea is the first part of the eye that bends (or refracts) the light and provides most of the focusing power.

Corneal Decompensation: Opacity of the cornea.

Corneal Ectasia: Thinning of the cornea (e.g. as a result of the LASIK when too much tissue from the cornea is removed.

Corneal Edema/ Corneal Swelling: A buildup of fluid in the cornea.

Corneal Erosion/Abrasion: A corneal erosion or abrasion occurs when there is loss of the

corneal epithelium, due to scraped or injured cornea.

Contraindications: Any special condition that results in the treatment not being recommended.

Contrast Sensitivity: A measure of the ability of the eye to detect small lightness differences between objects and the background in daylight and in dim light. For example, black lines on a gray background are easier to see than gray lines on a gray background. Objects in daylight are also easier to see than in dim light. Contrast sensitivity testing is a way to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog.

Cordarone: A Medication: Cordarone Reg TM of Sanofi Corp.

Corneal Flap: A thin slice of tissue on the surface of the cornea made with a microkeratome of femtosecond laser at the beginning of the LASIK procedure. This flap is folded back before the laser shapes the inner layers of the cornea.

Corneal Flap Re-Lifting: Flap re-lift after primary LASIK procedure (e.g. for a retreatment)

Corneal Haze: Clouding of the middle area of the cornea, usually as a result of scarring due to infection, injury, or inflammation.

Complication: A medical problem that occurs during a disease, or after a procedure or treatment

CTK (Central Toxic Keratopathy): Describes a rare, acute, non-inflammatory corneal disease that usually appears during the first few days after laser refractive surgery.

Debris or Foreign Body under Flap: Small particles (e.g. metal, glass, or organic material) has penetrated into the flap.

Visuals symptoms: Common symptoms are e.g. glare, halo, starburst, ghost, and double images.

Diopter: The measurement of refractive error. A negative diopter value signifies an eye with myopia and positive diopter value signifies an eye with hyperopia.

Diffuse Lamellar Keratitis (DLK): Is a rare, noninfectious complication of refractive surgery that occurs in the early post-operative period. It is characterized by inflammatory infiltrates beneath the corneal flap interface.

Double Vision (Diplopia)/ Ghost Images: A condition that occurs when eyes that normally work together start to see two slightly different images. Ghost images are a type of double vision that is a sign of a binocular vision dysfunction.

Dry Eye Syndrome: A common condition that occurs when the eyes do not produce enough tears to keep the eye moist and comfortable. Common symptoms of dry eye include pain, stinging, burning, scratchiness, and intermittent blurring of vision**.**

Excimer Laser: A medical device that produces a very powerful and pure beam of light of a single specific wavelength (color) that is used to remove tissue from the clear front part of the eye (cornea). This is done in a computer-controlled fashion to re-shape the cornea to correct refractive errors. This re-shaping allows incoming light rays to be more accurately focused on the retina.

Endothelium: The inner layer of cells on the inside surface of the cornea.

Epithelium: The outermost layer of cells of the cornea and the eye's first defence against infection.

Epithelial Ingrowth: Proliferation of epithelial cells in the space between the stromal bed and flap.

Epithelial at the Flap Edge: Proliferation of epithelial cells under the edge of the corneal flap.

Excimer laser: An ultraviolet laser used in refractive surgery to remove corneal tissue.

Eye Injury: Damage or trauma inflicted to the eye by external means.

Face Injury: Face injuries include cuts and wounds to the face, nose bleeds, a broken nose, and injuries to the eyes and airways.

Farsightedness: The common term for hyperopia

Glare - scatter from bright light that decreases vision.

Glaucoma: eye disease usually associated with high eye pressure. Glaucoma damages the optic nerve of the eye and usually causes a progressive loss of vision.

Halos: Hazy ring around bright lights seen by some patients with refractive error or optical defects.

Herpes Simplex: A type of viral infection that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body. You should discuss any history of this condition with your doctor before having LASIK surgery.

Herpes Zoster: A type of viral infection that can recur. This condition is a reactivation of the chicken pox virus as an adult. Vesicles appear on only one side of the body. You should discuss any history of this condition with your doctor before having LASIK surgery.

Hordeolum: A bacterial infection of glands on the edge of the eyelid.

Hyperopia: The inability to see near objects as clearly as distant objects, and the need for accommodation to see distant objects clearly.

Immunocompromised Status: A condition that compromises the body’s ability to heal. An example is acquired immunodeficiency syndrome (AIDS). If you have this type of condition, you should not have LASIK surgery.

Iris: The colored ring of tissue suspended behind the cornea and immediately in front of the lens.

Iritis: Inflammation of the iris of the eye.

Inflammation: The body's reaction to trauma, infection, or a foreign substance, often associated with pain, heat, redness, swelling, and/or loss of function

Inadequate Treatment Result: The visual result after the treatment is not completely corrected even after a reasonable healing time (overcorrection, undercorrection, induced or remaining cylinder, decentered ablation, anisometropia).

In Situ: A Latin term meaning "in place" or not removed.

Keratomileusis: Carving of the cornea to reshape it.

Keratectomy: The surgical removal of corneal tissue.

Keratotomy: A surgical incision (cut) of the cornea.

Keratitis: Inflammation of the cornea

Keratoconus: Hereditary, degenerative corneal disease characterized by generalized thinning and cone-shaped protrusion of the central cornea.

Laser: The acronym for *light amplification by stimulated emission of radiation*. A laser is an instrument that produces a powerful beam of light that can vaporize tissue.

LASIK: The acronym for laser assisted in situ keratomileusis which refers to creating a flap in the cornea with a microkeratome and using a laser to reshape the underlying cornea.

Lens: A part of the eye that provides some focusing power. The lens is able to change shape allowing the eye to focus on different distances.

Loose Epithelium/ Epithelial Defects: Cell loss in focal areas of the epithelium (outermost corneal layer) due to mechanical trauma, corneal dryness, postoperative changes, infections, etc. Epithelial defects result from failure of re-epithelialization and complete healing.

Meibomian Gland Dysfunction (MGD): A condition where the glands are not secreting enough oil or when the oil they secrete is of poor quality.

Medication Intolerance: Inability to tolerate the adverse effects of a medication (Increased intraocular pressure, allergically reaction, etc.).

MRSE: Manifest Refraction Spherical Equivalent is a measurement that describes the total refractive error of the eye. It is comprised of the myopia and one half of the astigmatism (e.g. eyes with a predictable MRSE within ± 0.50 D are unlikely to need glasses or contacts)

Miscreated Flap: Lost, incomplete, too thin, misaligned, buttonhole, etc.

Myopia: The inability to see distant objects as clearly as near objects.

Nearsightedness: The common term for myopia.

Ocular Hypertension/ Elevated IOP: Increased Intraocular Pressure. A rise in IOP can also occur as an adverse effect of corticosteroid therapy.

Ocular Penetration: Deeply perforating or puncturing type intraocular injuries.

Overcorrection A complication of refractive surgery where the achieved amount of correction is more than desired.

Pupil: A hole in the center of the iris that changes size in response to changes in lighting. It gets larger in dim lighting conditions and gets smaller in brighter lighting conditions.

PRK: The acronym for photorefractive keratectomy which is a procedure involving the removal of the surface layer of the cornea (epithelium) by gentle scraping and use of a computer-controlled excimer laser to reshape the stroma.

Ptosis: The drooping of the upper eyelid.

Photophobia: Eye discomfort in bright light.

Posterior Vitreous Detachment: Diagnosed by the presence of a low-reflected mobile echogenic membrane partially or completely detached from the retina.

Psychological Harm: Psychiatric complications such as psychosis, depression etc.

Radial Keratotomy: commonly referred to as **RK**; a surgical procedure designed to correct myopia (nearsightedness) by flattening the cornea using radial cuts.

Refractive Surgery: Several different procedures used for altering the shape of the cornea and thus how it bends light, in order to change or correct the eye's refractive error.

Refraction: A test to determine the refractive power of the eye; also, the bending of light as it passes from one medium into another.

Refractive Errors: Imperfections in the focusing power of the eye, for example, hyperopia, myopia, and astigmatism.

Retina: A layer of fine sensory tissue that lines the inside wall of the eye. The retina acts like the film in a camera to capture images, transforms the images into electrical signals, and sends the signals to the brain.

Retinal Detachment: A disorder of the eye in which the retina peels away from its underlying layer of support tissue.

Retinal Vein Occlusion: Is a blockage of the small veins that carry blood away from the retina.

Steroid Antibiotic Combination: A combination drug that contains a topical steroid and an antibiotic that reduces inflammation or the body's response to an injury or disease. Your doctor may prescribe this medication after LASIK surgery for a short time to modify the healing of your eye. If you are taking this medication for a disease condition, you should not have LASIK surgery.

Stroma: The middle, thickest layer of tissue in the cornea

Subconjunctival Hemorrhage or Bleeding: When a small blood vessel breaks open and bleeds within the conjunctiva.

Superficial punctate keratopathy (SPK): It is a non-specific clinical finding of varied etiology characterized by the punctate loss of epithelial cells.

Transient Light Sensitivity Syndrome (TLSS): A condition that produces moderate-to-severe photophobia in both eyes two to eight weeks after ocular surgery.

Undercorrection: A complication of refractive surgery where the achieved amount of correction is less than desired.

Visual Acuity: The clearness of vision; the ability to distinguish details and shapes (e.g. A vision of 20/40 without glasses is good enough to drive without glasses or contacts in most of the United States).

Vitreous Floaters: Collagen fibers within the vitreous that tend to clump and cast shadows on the retina.

Wrinkles in Flap/ Striae: Defined as small wrinkles or folds in the cornea as a result of LASIK surgery.

Wavefront: a measure of the total refractive errors of the eye, including nearsightedness, farsightedness, astigmatism, and other refractive errors that cannot be corrected with glasses or contacts.