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Laser-Assisted In Situ Keratomileusis (LASIK) Lasers - Patient Labeling Recommendations

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

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You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices/DHT1A: Division of Ophthalmic Devices at (301) 796-5620.

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U.S. Department of Health and Human Services
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Preface

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Laser-Assisted In Situ Keratomileusis (LASIK) Lasers - Patient Labeling Recommendations

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance recommends content and formatting for patient labeling information for laser-assisted in situ keratomileusis (LASIK) devices. FDA is issuing this guidance to help ensure that both physicians can share and patients can understand information on the benefits and risks of these devices. The recommendations are being made based on concerns that some patients are not receiving and/or understanding information regarding the benefits and risks of LASIK devices. These labeling recommendations are intended to enhance, but not replace, the physician-patient discussion of the benefits and risks of LASIK devices that uniquely pertain to individual patients.

For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[1] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[2]

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless

[1] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

[2] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

LASIK is an outpatient refractive surgery procedure used to help correct refractive errors to reduce dependency on eyeglasses. Refractive errors arise when the shape of the cornea (the clear, round dome at the front of the eye) and the eye are not perfect and the image on the retina is out-of-focus (blurred) or distorted. These imperfections in the focusing power of the eye are called refractive errors, such as myopia (nearsightedness), hyperopia (farsightedness), and astigmatism. In a LASIK procedure, a laser is used to reshape the cornea to improve the way the eye focuses light rays onto the retina at the back of the eye. LASIK is currently one of the most commonly performed elective procedures in the world, as well as the most popular form of refractive surgery that patients choose to correct common vision problems such as nearsightedness, farsightedness, and astigmatism.[3]

On April 25, 2008, FDA convened its Ophthalmic Devices Panel of the Medical Devices Advisory Committee to discuss recommendations for modifications to patient labeling of excimer lasers for LASIK as well as other LASIK-related activities. During this meeting, patient advocacy groups also highlighted the importance of clearly communicating the risks of LASIK.[4]

Since the time of the LASIK Advisory Committee meeting, FDA has continued to gather new information pertaining to risks associated with LASIK, including dry eye, pain and discomfort, and visual symptoms. Clinical and scientific knowledge about these events and symptoms has increased since the time of the last advisory committee meeting. FDA has diligently collaborated with external experts on research efforts, including focus groups, to better characterize risks to ensure that the recommended labeling discussed in this guidance addresses the concerns uncovered in this collaboration and that risk information is communicated in an understandable format.

As one example of these efforts, in October 2009, the FDA, the National Eye Institute (NEI), and the Department of Defense (DoD) launched the LASIK Quality of Life Collaboration Project (LQOLCP) to better understand the potential risk of severe problems that can result from LASIK.[5] At the time the collaboration partners developed the project, there was a limited amount of valid scientific data on certain patient-reported outcomes (PROs) related to LASIK. A PRO is a report of how patients feel and function reported by the patient, not the health care provider. The Patient-Reported Outcomes with LASIK (PROWL) studies in the LQOLCP assessed visual

[3] 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.

[4] One Hundred and Tenth Meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, Laser-assisted in situ keratomileusis (LASIK) Post Market Experience, April 25, 2008, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=695.

[5] For additional information on the LASIK Quality of Life Collaboration Project, see https://www.fda.gov/medical-devices/lasik/lasik-quality-life-collaboration-project.

symptoms before and after LASIK surgery to identify changes over time. There were multiple phases to the PROWL studies, the final of which was completed in 2014. Although not the focus of the studies, the information gathered regarding risks and patient experiences were informative to these guidance recommendations.

In addition, FDA is aware that patients may not be receiving information in a format that allows them to make a well-informed decision about whether to have LASIK. The recommendations in this guidance are being made to help ensure that patients are informed of the significant risks associated with LASIK prior to choosing this type of surgery and are informed by the latest information about these devices.

FDA is issuing this draft guidance to reflect the Agency's current thinking on labeling specific to LASIK devices, and to enable the public to comment on these recommendations, including the recommended language for inclusion in patient labeling and a patient decision checklist, as described below. FDA believes this information, in conjunction with physician-patient discussion, will help to ensure that a patient receives relevant information on and understands the benefits and risks associated with LASIK so that the patient can make an informed decision as to whether the procedure is the right choice for him/her prior to undergoing the procedure. In addition, the Agency will continue to monitor information about potential safety risks and take steps to ensure they are being adequately conveyed to and understood by physicians and patients.

III. Scope

This draft guidance recommends content and formatting of patient labeling information for LASIK devices, including a patient decision checklist. This draft guidance applies to all refractive lasers with LASIK indications for use (FDA product code LZS).[6]

LASIK devices are prescription devices and are exempt from having adequate directions for lay use required under section 502(f)(1) of the FD&C Act (21 U.S.C. § 352(f)(1)) as long as the conditions in 21 CFR 801.109 are met. FDA believes it is important for patients considering LASIK surgery to have the information they need for a balanced discussion of benefits and risks with their physicians. It is also important for physicians to know how to educate their patients about risks that might arise as a result of LASIK surgery. As such, FDA believes it is important for manufacturers to include information for both physicians and also for patients about the risks of the device – including but not limited to information that can inform the patient of the possible risks to health associated with LASIK surgery. This information should appear in a format that a physician can easily convey directly to the patient. To help ensure that both physicians and patients receive and have this information, patient labeling, including a patient decision checklist, should be provided by manufacturers and given to physicians and patients prior to a LASIK procedure, and should include considerations related to procedural information,

[6] Other ophthalmic laser devices, such as those indicated for photorefractive keratectomy under FDA product code LZS and those covered by FDA product code OTL, are not contemplated by and therefore outside the scope of this draft guidance.

candidate considerations, benefits/alternatives, contraindications, warnings and precautions, and specific health risk information.

Accurate product labeling and effective communication of that labeling is important to make device users and patients aware of the risks associated with LASIK devices. Moreover, a device shall be deemed misbranded if, among other things: its labeling is false or misleading; its labeling does not contain adequate warnings; or any information required to be in the labeling is not prominently placed with such conspicuousness and in such terms to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use (see sections 502(a), 201(n), 502(c), and 502(f)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)).[7] FDA intends to work with manufacturers of new LASIK devices through the premarket approval application (PMA) process, and manufacturers of currently marketed LASIK devices through the PMA supplement process, to integrate these important labeling recommendations. Since it is anticipated that such a change will enhance the safe use of the device, updated labeling may qualify for a submission as a Special PMA Supplement -- Changes Being Effected.[8]

This guidance should be used as a complement to FDA's, "Guidance on Medical Device Patient Labeling" (which describes FDA's current thinking on making medical device patient labeling understandable to and usable by patients), existing regulations, and other relevant guidance documents containing additional labeling recommendations.[9]

IV. Patient Labeling Components

A. General Considerations

The patient labeling should be directed to potential candidates for LASIK and should address the following questions:

- What is LASIK surgery?
- What is the specific LASIK device used for the patient's procedure?
- What are the approved indications for use specific to the LASIK device?
- What makes someone a poor candidate for LASIK?
- What factors should a patient consider in deciding whether LASIK is appropriate for him or her?
- What are the benefits, risks, and alternatives to LASIK?

[7] Under section 301(a) of the FD&C Act, it is a prohibited act to introduce or deliver for introduction into interstate commerce any device that is misbranded.

[8] 21 CFR 814.39(d). For additional information, please also see "Modifications to Devices Subject to Premarket Approval (PMA) – The PMA Supplement Decision Making Process" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process).

[9] See "Guidance on Medical Device Patient Labeling" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling).

- What should a patient expect before, during, and after LASIK?

Patient labeling should be written in simple, lay language that can be read and understood by prospective patients who may not be familiar with LASIK and its related terminology. Clearly labeled, relevant graphics may be used to improve patient understanding.

Even with technically accurate lay language, poorly designed text can still be confusing and misleading. Before completing the patient labeling, the text should be tested with representative users in a controlled test situation to determine whether they comprehend the information sufficiently to understand the risks, make appropriate choices, and know what to expect from treatment with the device. During the development of the patient labeling, manufacturers should identify the critical information that the labeling needs to convey, and test it iteratively to determine whether the users comprehend that information correctly, e.g., by having users recite what they have learned. Manufacturers should also work to alter the method(s) of delivering this information, as appropriate, until users demonstrate adequate comprehension. Testing in these iterative phases may not necessitate large numbers of subjects.[10]

When translating the health care provider labeling into lay language, manufacturers should ensure that there are no changes to the intent of the indications, contraindications, warnings and precautions, or other parts of the health care provider labeling. The lay translation should provide a balanced presentation of the benefits and risks of the device for the indications for use. It should not introduce new information or statements about product performance that are not in the health care provider labeling, but should instead be a reflection of the information provided in the health care provider labeling geared towards a lay audience.

B. Suggested Format and Content of Patient Labeling

FDA recommends that patient labeling also contains the information in the sections outlined in the FDA's "Guidance on Medical Device Patient Labeling."[11] As recommended above, the content should be written in a way that informs patients of the benefits, risks, and alternatives to the specific indication for use of the device in simple, lay language they can understand. The sequence of the sections suggested in the guidance may be adapted as appropriate for a specific device and indication, but should enable the patient to easily find and understand information that answers the questions identified above. This section also includes informational content and format suggestions for inclusion in LASIK patient labeling.

[10] An iterative approach to usability testing is further described as part of the usability engineering process in the currently FDA-recognized version of IEC 62366-1: *Medical devices – Part 1: Application of usability engineering to medical devices.*

[11] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling.

(1) Description of the Eye and the Surgery

a. How Your Eye Works

For this part of the labeling, FDA recommends including a brief description of the optics of the eye and the causes of refractive errors with an emphasis upon the refractive role of the cornea. FDA recommends that manufacturers include appropriate, clearly labeled diagrams to illustrate the described concepts.

b. What Is LASIK and What Does the [XX] LASIK Laser Do?

This part of the labeling should include a brief description of the steps of LASIK (with clearly labeled diagrams) and how the device is used to correct refractive errors consistent with the indications for use. If the device has special features, such as wavefront guidance, these could also be explained in this section.

FDA also recommends explaining what the device and LASIK cannot do, to help ensure that patients have realistic expectations of LASIK.

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

For this part of the labeling, FDA recommends including a brief description of the FDA-approved Indications for Use in lay terms, including the key characteristics that define the intended patient population, such as the following:

- Range of the refractive error
- Age range
- Definition of pre-operative refractive stability

(3) What are the Benefits?

This part of the labeling should include a description of the specific benefits patients should expect from the device in a balanced, factual, and non-promotional manner. FDA also recommends that the description include discussion of the limitations of surgery to try to prevent potential unrealistic expectations about the results of surgery. FDA recommends that you not present the specific results of PMA studies in this section because the results are provided in a separate clinical study section (see section III.B.(8)).

(4) What are the Alternatives?

This part of the labeling should include an explanation that LASIK is an elective surgery, and discuss available alternatives for the correction of refractive error, both non-surgical and surgical, including their key risks and benefits.

(5) Contraindications, Warnings, and Precautions

This part of the labeling should include a description of the contraindications, warnings, and precautions in the patient labeling. These should be the same as those listed in the health care provider labeling (except for those related to the operation of the device) and should be written in lay terms.

FDA recognizes that proper patient selection is a key element in ensuring good outcomes from LASIK. Accordingly, FDA believes it is important that any included descriptions of contraindications, warnings, and precautions be presented in a way that enables patients considering LASIK to easily recognize, understand, and evaluate the characteristics and conditions that may affect their suitability as candidates for the surgery. For each contraindication, warning, and precaution, the patient labeling should include an explanation of why the condition may result in a particular problem. Because certain conditions appear in more than one of the subsections on contraindications, warnings, and precautions, FDA recommends that this information be summarized in table format, as shown in Table 1 below, as well as explained in the text of each subsection. Examples are provided in each of the subsections below.

The following is an example summary table and text for introducing it:

> **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 eyes	❑ ⊘ 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 1)	❑ ⊘ 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 an 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 ❑ ⚠ 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)
Medications	❑ ⚠ 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"
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
Allergies or eye rubbing	❑ * If you have allergies or rub your eyes

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.

a. When You Should Not Have LASIK (Contraindications)

This section should discuss 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. For example:

> 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. 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;* see Image 1), 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.

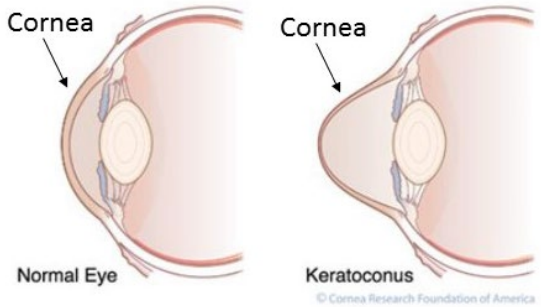


Image 1 Thinning of the cornea, or keratoconus[12]

- **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 you have had 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.

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

⊘ **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.

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

This part of the labeling should discuss conditions under which there is reasonable evidence of an association of a serious harm with the use of the device and a person's suitability for the surgery should be carefully evaluated. This section should also provide information about the patient groups or conditions for which device safety and effectiveness has not been adequately studied, and for which use of the device would be expected to lead to adverse health outcomes or limited effectiveness, e.g., outside the approved refractive range. The following is one example of a set of warnings that follow the above recommendations:

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 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 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.

⚠ **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.

⚠ **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.

⚠ **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.

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

⚠ **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.

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

This part of the labeling should include precautionary statements, which can provide information regarding any special care to be taken by the doctor and/or patient to avoid mild or moderate harms. This section should include precautionary statements concerning conditions that could affect the outcomes of LASIK and are less likely to occur or are less serious than those discussed under **Warnings**. The precautions should include information about other considerations that could affect eye health, as well as patient characteristics not studied in the pivotal study, but for which adverse outcomes would not be expected with use (e.g., based on the inclusion and exclusion criteria and not already reflected in the Contraindications and Warnings). The following is one example of a set of precautions that follow the above recommendations:

> 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 stage. 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.
>
> * **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.

* **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.

* **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.

* **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.

(6) What are the Risks?

This part of the labeling should include a description of patient risks. FDA recommends that the most severe and most frequent potential risks and complications, both associated with LASIK in general and with the device to be used, are discussed first, followed by all others (e.g., headaches, reading difficulty). Manufacturers should define all medical terms used in this section in a glossary and include every medical term in parentheses in the text following a plain language description of the term. FDA recommends including clearly labeled images to help explain visual symptoms when possible. The following is one example of a set of risk descriptions that follow the above recommendations:

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 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 can 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.

- **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 swung out of the way so the laser can treat underlying tissue, and is returned to its original position after the treatment. Flap complications include irregular cutting of the flap, the flap not properly returning to its original position, the flap coming off and even getting lost, and irregular healing. 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, even many months after surgery. It may be necessary to wear protective eyewear during certain physical activities like contact sports.

  - **Infection.** The cornea may get infected right after surgery. 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.

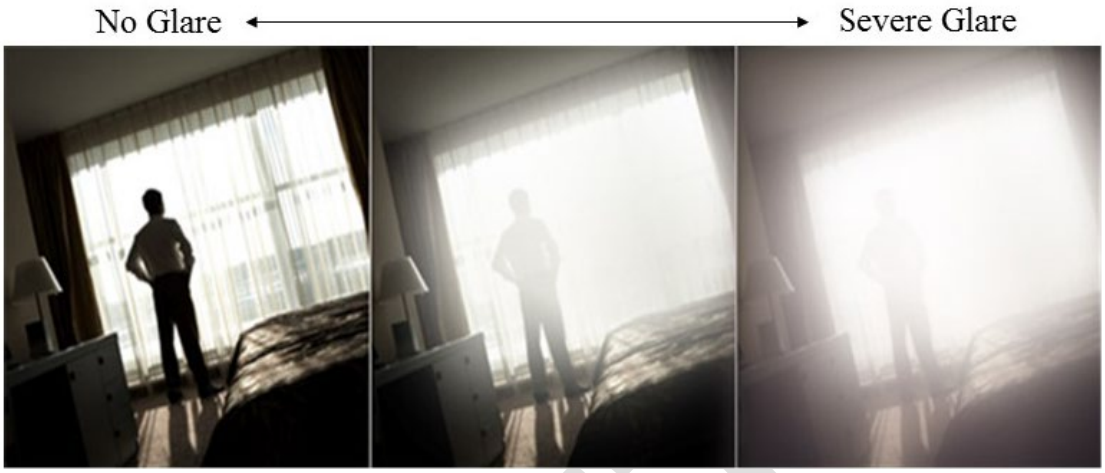
- **Dry eyes.** LASIK may cause or increase eye dryness, which may also cause discomfort and visual problems. The doctor may see dry spots on the normally-moist portions of the cornea, or surface damage caused by dryness. These problems usually improve within 3 to 6 months, but in rare cases never go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

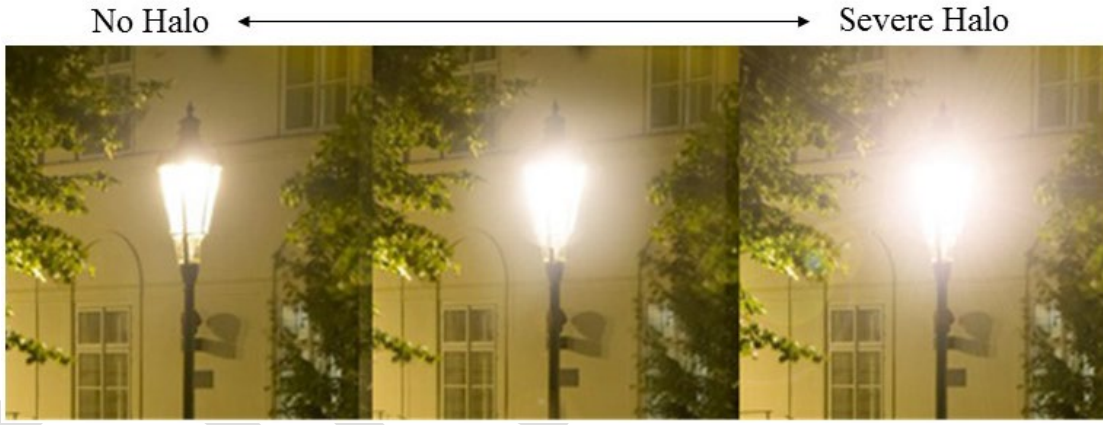
- **Discomfort or pain.** It is not unusual for patients to have some mild discomfort right after LASIK, but it usually goes away within a few weeks or months. Complications like dry eye, inflammation, or infection may cause severe, constant pain in some patients, preventing them from doing their normal activities. **In some patients, the pain may never go away (i.e., chronic pain) and may be resistant to therapy.**

- **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:

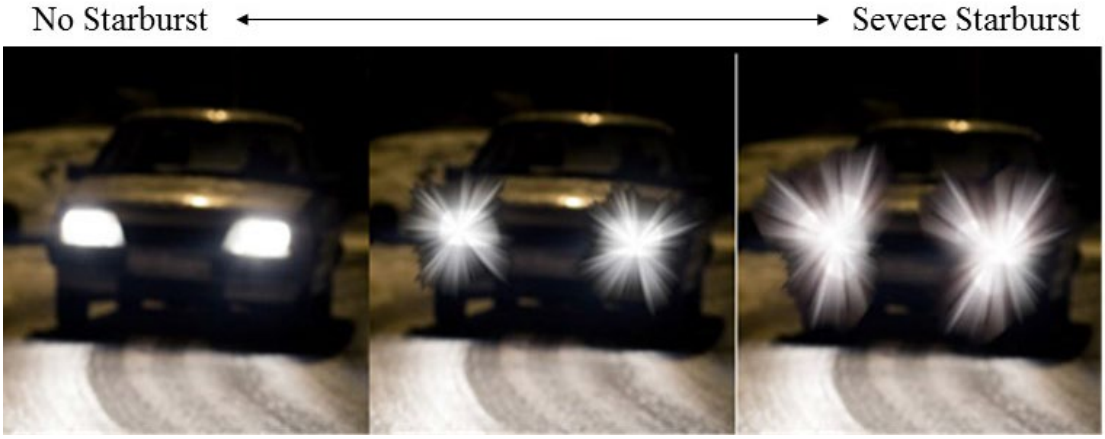
  - **Glare.** Glare is *difficulty seeing well when there are bright lights* like headlights or sunlight, as shown in the images below.



564
565
566 ○ **Halos.** You may see halos. By halos, we mean *seeing a fuzzy cloud of light around*
567 *lighted objects*, such as the ones shown in the images below.
568

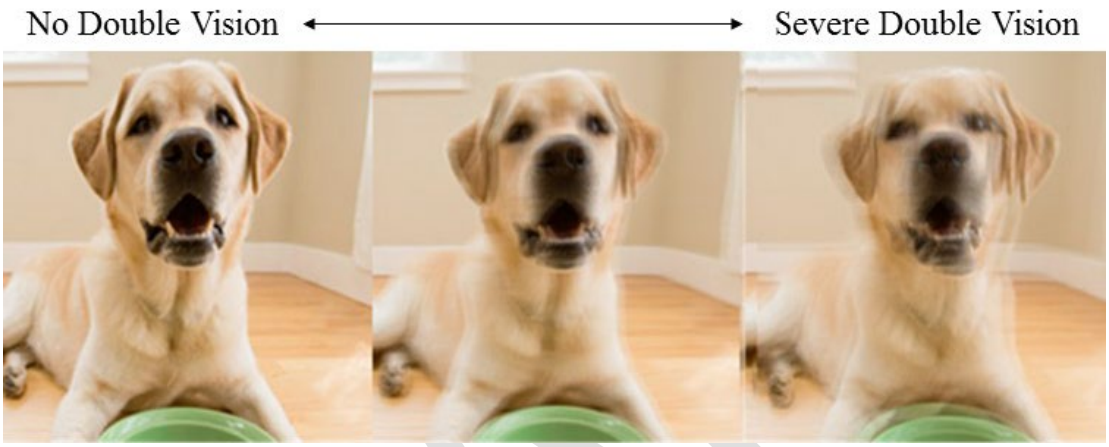


569
570
571 ○ **Starbursts.** You may see *rays of light coming from lighted objects*, such as in the car
572 headlights in the images below.
573



574

- **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 down stairs 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 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 at 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.

- **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 [XX] laser in clinical studies of the device.

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

This part of the labeling should include a description of what a patient should expect before (e.g., informing the LASIK doctor about all medications and all eye and medical conditions, discontinuation of contact lens wear, typical preoperative instructions), during, and after a surgical procedure, including typical postoperative care instructions (e.g., medications, limitations on activities). It is also recommended that approximate postoperative times that various symptoms may be experienced are included in this part of the labeling, along with explanations of what symptoms may be indicative of adverse events and under what circumstances patients should contact their doctors.

(8) Clinical Study Information

This part of the labeling should include descriptions of clinical study information relevant and specific to the LASIK device to be used in the procedure. The clinical study information provides specific context about the LASIK device to be used in the procedure, such as rates and types of adverse events and visual symptoms, and patient reported outcomes. Given the complexities of clinical studies, this information should be described in a way that is meaningful to patients and easy to understand. Tables, graphs, and other technical information should be made as "readable" and "understandable at a glance" to the patient as possible, and should complement any textual descriptions. FDA recommends using lay terms rather than technical words and acronyms, that all symbols and abbreviations included in the tables and graphs be clearly defined, and that any tables or graphs contain brief explanations of what information is shown.

FDA recommends including the purpose and main objectives of the study in this part of the labeling, which should contain a very brief description of the general study design, including the number of months that patients were followed, the number of patients studied, the key evaluation time points, and the primary and secondary safety and effectiveness endpoints.

Further, the key safety and effectiveness outcomes of the study should be summarized in lay terms, including tabulation and accompanying explanation of the adverse events and complications that occurred during the course of the trial, symptoms, and any patient-reported outcomes. FDA recommends that you do not use percentages to summarize the outcome information, but rather the actual number of subjects in the numerator and denominator to represent rates (e.g., "45 of the 302 patients seen at the 12-month visit"), when applicable. Results of contrast sensitivity testing should be briefly summarized in lay terms with the number of subjects that underwent testing and the outcomes from the perspective of whether losses were experienced under each of the various testing conditions.

(9) Contact Information

This part of the labeling should contain the manufacturer's contact information, including the address and phone number, as well as blank lines that can contain the provider's and surgical center's names, addresses, and phone numbers.

(10) Patient Decision Considerations

FDA believes that a patient decision checklist highlighting key risk information should be included at the end of the patient labeling. To help ensure the material is reviewed, FDA recommends the checklist allow for patients and physicians to affirmatively acknowledge (e.g., via initials and/or signatures) that specific information was read and discussed. Additionally, FDA recommends that it should be printed in a fashion where it can be easily separated and marked.

To help ensure the checklist is read and understood by patients, FDA is providing recommendations regarding content and organization below. First, in the introduction for the checklist, FDA recommends including a description of the purpose and importance of the

checklist, as well as instructions to the patient on how to review and complete the document prior to deciding whether to undergo the procedure. Next, to achieve the goals described above, FDA recommends that each topic grouping in the body of the checklist be accompanied by a line for the patient to initial indicating acknowledgment and understanding of that information. At the end, FDA recommends including a section that confirms that the patient has read the patient labeling material and has had the opportunity to satisfactorily discuss the patient's risks with his or her eye surgeon. This should be followed by a signature line for the patient. At the end of the checklist, FDA recommends having a section that confirms that the physician discussed the benefits, risks, and alternatives of the device, as set forth in the patient labeling, including the patient decision checklist, with the patient. FDA recommends that this be followed by a signature line for the physician.

The FDA recommends that a copy of the patient decision checklist be provided to the patient so that the patient can refer back to this important information. The FDA also encourages device manufacturers to develop a plan to ensure that patients are adequately informed of the risks of LASIK.

Appendix A provides an example of a patient decision checklist. FDA believes that the form and content of the patient decision checklist will help to ensure that patients have adequate and salient information about the risks and warnings of LASIK surgery, with appropriate prominence and conspicuousness such that it is easily read and understood. The rates of certain adverse events identified in the patient decision checklist were based on information from clinical trials, scientific literature, and reports from patients who have undergone LASIK. FDA recommends using these rates unless compelling data regarding the rates of certain events have been collected with post-market experience on a specific device, particularly for the more rare adverse events.

Appendix A: Patient Decision Checklist Example

To the patient considering LASIK surgery:

The review and understanding of this document is a critical step in making the decision whether you should choose LASIK surgery. You should carefully consider the benefits and risks associated with the surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of the LASIK laser devices based on information from clinical trials, scientific literature, and reports from patients who have undergone LASIK. After reviewing the information in the patient labeling for the specific LASIK laser that will be used, please read and discuss the items in this checklist with your doctor. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document means that you have read and understood the materials and that your physician has answered all questions to your satisfaction.

Vision Correction Options

I understand that eyeglasses or contact lenses are proven methods for vision correction, and that photorefractive keratectomy (PRK) is an alternative surgical method for vision correction. I also understand that small incision lenticule extraction (SMILE) may be another surgical alternative for me if I am nearsighted, and conductive keratoplasty may be an alternative procedure for me if I am farsighted. I was also informed of the associated benefits and risks of other alternatives. I understand that LASIK may not result in the desired amount of vision correction. Even if my vision results are generally good, I may still need glasses or contact lenses to perform certain tasks, and the results achieved may decline over time.

I understand that during LASIK surgery, a flap is cut in the cornea and corneal tissue is vaporized.

- Corneal tissues and nerves cut during this process must heal following surgery. Corneal nerves may not fully recover resulting in dry eyes and/or chronic pain.
- Even after the corneal flap has fully healed, the cornea will not be as strong as it was before surgery.

Patient Initials: _____

Considerations for a good candidate for LASIK surgery

I understand that I should not have LASIK surgery while I have an active eye inflammation or infection.

I understand that I am not a good candidate for LASIK if:

- I have severe dry eyes.
- My cornea(s) is not thick enough.

- My doctor has told me that I have a condition that causes thinning or bulging of the cornea, such as keratoconus or pellucid marginal degeneration.
- I have problems resulting from a past herpes eye infection.
- I have an autoimmune disease or connective tissue disease (like lupus or rheumatoid arthritis), glaucoma, or diabetes.

Patient Initials: _____

What to Expect in the First Six Months.

I understand that dry eye following surgery is common, and the symptoms of dry eye, including blurred vision, can vary from mild to severe. Based on the estimates below, I am prepared to regularly use lubricating eyedrops to manage dry eye symptoms.

I understand that, following LASIK surgery, estimates of certain common risks are as follows:

- One (1) week following surgery, up to 85% of patients experience dry eye symptoms.
- At six (6) months following surgery:
  - Up to 27% of patients experience dry eye symptoms.
  - About 41% of patients may experience visual symptoms such as glare, halos, starbursts, and double images, as illustrated in Figure 1 (with or without glasses or contact lenses).
  - Around 4% of patients may have "very" or "extremely" bothersome symptoms.
  - Around 2% may have "a lot of difficulty" or "so much difficulty that I can no longer do some of my usual activities" when not wearing glasses or contact lenses.

Figure 1a: Glare

Figure 1b: Halo

Figure 1c: Starburst

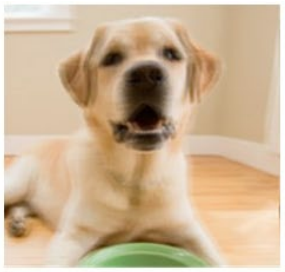


Figure 1d: Double Vision

Patient Initials: _____

Long-term Risks

- I understand that, although rare, 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.
- I understand that dry eye may persist beyond six (6) months.
- I acknowledge the following estimates of the percentage of patients experiencing the persistence of certain symptoms five (5) years after surgery:

- Around 17% of patients may still need to use eye drops daily for dry eye.
- Less than 2% of patients notice some visual disturbance, such as glare, halos, starbursts, and double vision.
- A decreased ability to see under low light conditions; around 8% of patients may have moderate difficulty or a lot of difficulty driving at night.
- Very rare reports (estimated rate of less than 0.8%) of severe, constant pain that may prevent normal activities.

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient labeling for the specific LASIK laser that will be used during my LASIK surgery and that I have had time to discuss the items in it and on this document with my doctor. I have had the opportunity to ask questions and understand the benefits and risks of LASIK surgery for me, given my specific health conditions. I have considered alternatives to LASIK, such as contact lenses, eyeglasses, and PRK, and their risks and benefits.

_____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of LASIK as described in the patient labeling, including this patient decision checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

_____

Physician Signature and Date