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

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.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document within 120 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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.



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

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Preface

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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This draft guidance recommends content and formatting for patient labeling information for laser-assisted in situ keratomileusis (LASIK) devices.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](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm).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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-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>.

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33 specific regulatory or statutory requirements are cited. The use of the word *should* in Agency
34 guidance means that something is suggested or recommended, but not required.
35

36 **II. Background**

37 LASIK is an outpatient refractive surgery procedure used to help correct refractive errors to
38 reduce dependency on eyeglasses. Refractive errors arise when the shape of the cornea (the clear,
39 round dome at the front of the eye) and the eye are not perfect and the image on the retina is out-
40 of-focus (blurred) or distorted. These imperfections in the focusing power of the eye are called
41 refractive errors, such as myopia (nearsightedness), hyperopia (farsightedness), and
42 astigmatism. In a LASIK procedure, a laser is used to reshape the cornea to improve the way the
43 eye focuses light rays onto the retina at the back of the eye. LASIK is currently one of the most
44 commonly performed elective procedures in the world, as well as the most popular form of
45 refractive surgery that patients choose to correct common vision problems such as
46 nearsightedness, farsightedness, and astigmatism.³
47

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

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

60 As one example of these efforts, in October 2009, the FDA, the National Eye Institute (NEI), and
61 the Department of Defense (DoD) launched the LASIK Quality of Life Collaboration Project
62 (LQOLCP) to better understand the potential risk of severe problems that can result from
63 LASIK.⁵ At the time the collaboration partners developed the project, there was a limited amount
64 of valid scientific data on certain patient-reported outcomes (PROs) related to LASIK. A PRO is
65 a report of how patients feel and function reported by the patient, not the health care provider.
66 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>.

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

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

76
77 FDA is issuing this draft guidance to reflect the Agency's current thinking on labeling specific to
78 LASIK devices, and to enable the public to comment on these recommendations, including the
79 recommended language for inclusion in patient labeling and a patient decision checklist, as
80 described below. FDA believes this information, in conjunction with physician-patient
81 discussion, will help to ensure that a patient receives relevant information on and understands the
82 benefits and risks associated with LASIK so that the patient can make an informed decision as to
83 whether the procedure is the right choice for him/her prior to undergoing the procedure. In
84 addition, the Agency will continue to monitor information about potential safety risks and take
85 steps to ensure they are being adequately conveyed to and understood by physicians and patients.
86

III. Scope

87
88 This draft guidance recommends content and formatting of patient labeling information for
89 LASIK devices, including a patient decision checklist. This draft guidance applies to all
90 refractive lasers with LASIK indications for use (FDA product code LZS).⁶

91
92 LASIK devices are prescription devices and are exempt from having adequate directions for lay
93 use required under section 502(f)(1) of the FD&C Act (21 U.S.C. § 352(f)(1)) as long as the
94 conditions in 21 CFR 801.109 are met. FDA believes it is important for patients considering
95 LASIK surgery to have the information they need for a balanced discussion of benefits and risks
96 with their physicians. It is also important for physicians to know how to educate their patients
97 about risks that might arise as a result of LASIK surgery. As such, FDA believes it is important
98 for manufacturers to include information for both physicians and also for patients about the risks
99 of the device – including but not limited to information that can inform the patient of the possible
100 risks to health associated with LASIK surgery. This information should appear in a format that a
101 physician can easily convey directly to the patient. To help ensure that both physicians and
102 patients receive and have this information, patient labeling, including a patient decision
103 checklist, should be provided by manufacturers and given to physicians and patients prior to a
104 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.

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

107
108 Accurate product labeling and effective communication of that labeling is important to make
109 device users and patients aware of the risks associated with LASIK devices. Moreover, a device
110 shall be deemed misbranded if, among other things: its labeling is false or misleading; its
111 labeling does not contain adequate warnings; or any information required to be in the labeling is
112 not prominently placed with such conspicuousness and in such terms to render it likely to be read
113 and understood by the ordinary individual under customary conditions of purchase and use (see
114 sections 502(a), 201(n), 502(c), and 502(f)(2) of the Federal Food, Drug, and Cosmetic Act
115 (FD&C Act)).⁷ FDA intends to work with manufacturers of new LASIK devices through the
116 premarket approval application (PMA) process, and manufacturers of currently marketed LASIK
117 devices through the PMA supplement process, to integrate these important labeling
118 recommendations. Since it is anticipated that such a change will enhance the safe use of the
119 device, updated labeling may qualify for a submission as a Special PMA Supplement -- Changes
120 Being Effected.⁸

121
122 This guidance should be used as a complement to FDA’s, “[Guidance on Medical Device Patient](#)
123 [Labeling](#)” (which describes FDA’s current thinking on making medical device patient labeling
124 understandable to and usable by patients), existing regulations, and other relevant guidance
125 documents containing additional labeling recommendations.⁹

126

127 **IV. Patient Labeling Components**

128 **A. General Considerations**

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

- 131
- 132 • What is LASIK surgery?
 - 133 • What is the specific LASIK device used for the patient’s procedure?
 - 134 • What are the approved indications for use specific to the LASIK device?
 - 135 • What makes someone a poor candidate for LASIK?
 - 136 • What factors should a patient consider in deciding whether LASIK is appropriate for
137 him or her?
 - 138 • 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)” (<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)” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling>).

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- 139 • What should a patient expect before, during, and after LASIK?
140

141 Patient labeling should be written in simple, lay language that can be read and understood by
142 prospective patients who may not be familiar with LASIK and its related terminology. Clearly
143 labeled, relevant graphics may be used to improve patient understanding.
144

145 Even with technically accurate lay language, poorly designed text can still be confusing and
146 misleading. Before completing the patient labeling, the text should be tested with representative
147 users in a controlled test situation to determine whether they comprehend the information
148 sufficiently to understand the risks, make appropriate choices, and know what to expect from
149 treatment with the device. During the development of the patient labeling, manufacturers should
150 identify the critical information that the labeling needs to convey, and test it iteratively to
151 determine whether the users comprehend that information correctly, e.g., by having users recite
152 what they have learned. Manufacturers should also work to alter the method(s) of delivering this
153 information, as appropriate, until users demonstrate adequate comprehension. Testing in these
154 iterative phases may not necessitate large numbers of subjects.¹⁰
155

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

163 **B. Suggested Format and Content of Patient Labeling**

164 FDA recommends that patient labeling also contains the information in the sections outlined in
165 the FDA’s “[Guidance on Medical Device Patient Labeling](#).”¹¹ As recommended above, the
166 content should be written in a way that informs patients of the benefits, risks, and alternatives to
167 the specific indication for use of the device in simple, lay language they can understand. The
168 sequence of the sections suggested in the guidance may be adapted as appropriate for a specific
169 device and indication, but should enable the patient to easily find and understand information
170 that answers the questions identified above. This section also includes informational content and
171 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>.

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172 **(1) Description of the Eye and the Surgery**

173 **a. How Your Eye Works**

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

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

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

183
184 FDA also recommends explaining what the device and LASIK cannot do, to help ensure that
185 patients have realistic expectations of LASIK.

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

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

- 190
- 191 • Range of the refractive error
 - 192 • Age range
 - 193 • Definition of pre-operative refractive stability

194 **(3) What are the Benefits?**

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

201 **(4) What are the Alternatives?**

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

205 **(5) Contraindications, Warnings, and Precautions**

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

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210
211 FDA recognizes that proper patient selection is a key element in ensuring good outcomes from
212 LASIK. Accordingly, FDA believes it is important that any included descriptions of
213 contraindications, warnings, and precautions be presented in a way that enables patients
214 considering LASIK to easily recognize, understand, and evaluate the characteristics and
215 conditions that may affect their suitability as candidates for the surgery. For each
216 contraindication, warning, and precaution, the patient labeling should include an explanation of
217 why the condition may result in a particular problem. Because certain conditions appear in more
218 than one of the subsections on contraindications, warnings, and precautions, FDA recommends
219 that this information be summarized in table format, as shown in Table 1 below, as well as
220 explained in the text of each subsection. Examples are provided in each of the subsections below.

221
222 The following is an example summary table and text for introducing it:

223
224 **Table 1** is a quick reference that you can use to start a conversation with your doctor about
225 whether LASIK is right for you. Mark those characteristics or conditions that you know
226 apply to you and discuss them with your doctor, if you are considering LASIK. Ask your
227 doctor whether any of the other characteristics or conditions apply to you, and, if so, how
228 they may affect your risk of LASIK complications. Greater detail is provided below the table
229 about these characteristics and conditions and what complications or side effects may arise if
230 you have one of them and choose to have LASIK.





231
232 Table 1. Characteristics and Conditions Considered to Evaluate Suitability for LASIK (to be
233 discussed with your doctor)

234  When you should not have LASIK (Contraindications)

235  When you should consider not having LASIK (Warnings)













236 * Other things that may increase your risk of LASIK complications (Precautions)

237

| Characteristic/Condition | Check the Box <input checked="" type="checkbox"/> if the Characteristic Applies to You |
|--------------------------------------|--|
| Dry eyes | <input type="checkbox"/>  If you have severe dry eyes <input type="checkbox"/>  If you have moderate or mild dry eyes |
| Cornea not thick enough | <input type="checkbox"/>  If the clear front part of your eye is not thick enough |
| Thinning of the cornea (see Image 1) | <input type="checkbox"/>  If you have any condition that causes thinning or bulging of the cornea, including: <ul style="list-style-type: none">• Cone-shaped cornea (keratoconus)• Thinning of the bottom part of the cornea (pellucid marginal degeneration) <input type="checkbox"/> * If you have a family history of thinning of the cornea |

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| | |
|---|---|
| Eye infection | <input type="checkbox"/>  If you have an active eye infection |
| Eye inflammation | <input type="checkbox"/>  If you currently have an eye inflammation <input type="checkbox"/> * If you have a history of any eye disease (e.g., uveitis), abnormality, injury, or surgery |
| Herpes eye infection | <input type="checkbox"/>  If you have had a recent eye infection or problems resulting from a past infection <input type="checkbox"/>  If you have had a past eye infection |
| Autoimmune or connective tissue disease (rheumatoid arthritis, lupus) | <input type="checkbox"/>  If you have an active autoimmune or connective tissue disease <input type="checkbox"/>  If you have an autoimmune or connective tissue disease that is controlled |
| Glaucoma | <input type="checkbox"/>  If you have uncontrolled glaucoma (your eye pressure is too high even with treatment) <input type="checkbox"/>  If you have controlled glaucoma <input type="checkbox"/> * If you have elevated eye pressure (ocular hypertension) or are being followed for possible glaucoma |
| Diabetes | <input type="checkbox"/>  If you have uncontrolled diabetes (your blood sugar is not well controlled despite treatment) <input type="checkbox"/>  If you have controlled diabetes |
| Activities | <input type="checkbox"/>  If you participate in activities that could damage the LASIK flap, including contact sports (e.g., football) <input type="checkbox"/> * If you participate in activities that require good vision in poor lighting conditions to avoid a hazard (e.g., driving at night) |
| Medications | <input type="checkbox"/>  If you take medications that have dry eyes as a side effect, such as: <ul style="list-style-type: none">• Isotretinoin• Steroids• Medications that weaken the immune system (immunosuppressants) <input type="checkbox"/> * If you take any of the following medications: <ul style="list-style-type: none">• Amiodarone hydrochloride• Sumatriptan |

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| | |
|--|---|
| Repeated attacks of sharp eye pain due to epithelial basement membrane dystrophy | <input type="checkbox"/> ⚠ 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 | <input type="checkbox"/> ⚠ If you have a weakened immune system due to medications (such as steroids) or a medical condition (such as AIDS) |
| “Crossed eyes” (strabismus) | <input type="checkbox"/> ⚠ If you have “crossed eyes” |
| Decreased vision in one eye | <input type="checkbox"/> ⚠ If you have decreased vision in one eye |
| Large pupils or very nearsighted | <input type="checkbox"/> * If you have large pupils or are very nearsighted |
| Allergies or eye rubbing | <input type="checkbox"/> * If you have allergies or rub your eyes |

238

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

242

a. When You Should Not Have LASIK (Contraindications)

243 This section should discuss conditions or situations in which the device should not be used
244 because the known or reasonably foreseeable risk of using the device outweighs any reasonably
245 foreseeable benefit. For example:

246

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

251

252 **Severe dry eye.** LASIK can worsen this problem, even if successfully treated before
253 LASIK, and increase your risk of infection and/or scarring. Symptoms of dry eye may
254 include a scratchy or sandy feeling in the eye, stinging, burning, episodes of excessive
255 tearing, a stringy discharge from the eye, pain, redness, eye fatigue, light sensitivity,
256 and blurred vision. If you are not able to tolerate wearing contact lenses, this may be a
257 sign that you have dry eyes. Make sure your LASIK doctor checks you for dry eyes
258 before having LASIK.

259

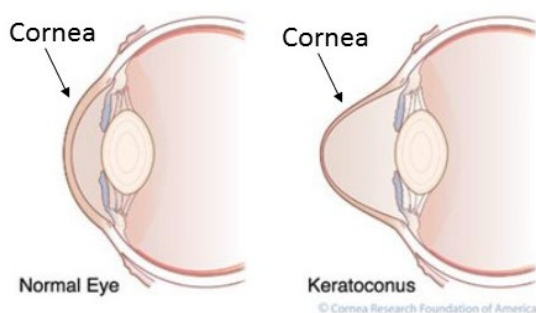
260 **Cornea not thick enough.** Your cornea (the clear front part of the eye) must be thick
261 enough to undergo LASIK without increasing the risk of causing an abnormal bulging
262 forward of the cornea (*ectasia*), which could decrease your vision. Ask your LASIK
263 doctor whether the thickness of your cornea puts you at greater risk for this
264 complication.

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266 **⊘ Thinning of the cornea.** If you have a cone-shaped cornea (*keratoconus*; see Image
267 1), thinning of the bottom part of the cornea along the edges (*pellucid marginal*
268 *degeneration*), or any other condition that may cause a thinning or bulging of your
269 cornea, LASIK can worsen these conditions and cause a permanent reduction in your
270 vision. This may result in the need for additional surgery (such as a corneal
271 transplant) after LASIK. Your LASIK doctor should map the shape of your cornea
272 before LASIK to make sure you do not have any thinning.
273
274



275
276
277 **Image 1** Thinning of the cornea, or keratoconus¹²
278

279 **⊘ Active eye infection or active inflammation.** If you have an active infection or
280 inflammation of the eye (such as keratitis, iritis, or uveitis), LASIK will likely make
281 your condition worse, resulting in permanent eye damage. Let your LASIK doctor
282 know if you are currently being treated, or if you have ever been treated, for such a
283 condition.
284
285 **⊘ Recent herpes eye infection or problems resulting from past infection.** If you
286 have had a herpes (simplex or zoster) eye infection within the past year or you have
287 had corneal damage from prior herpes infections, you are at higher risk for further
288 corneal damage after LASIK. Let your LASIK doctor know if you have ever had a
289 herpes eye infection.
290
291 **⊘ Active autoimmune or connective tissue disease.** If you have an active connective
292 tissue disease or autoimmune disease (such as rheumatoid arthritis and lupus) that can
293 cause corneal melting, LASIK will increase your risk of severe damage to your
294 cornea and vision loss. Let your LASIK doctor know about any medical conditions
295 you have.
296
297 **⊘ Uncontrolled glaucoma.** If you have uncontrolled glaucoma, the increased eye
298 pressure associated with cutting the LASIK flap puts you at greater risk for loss of
299 vision. Let your LASIK doctor know if you have been diagnosed with glaucoma.
300

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

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301 ⊘ **Uncontrolled diabetes.** If your blood sugar is uncontrolled, your eyeglass
302 prescription can fluctuate and your doctor will not be able to accurately determine
303 what degree of LASIK treatment is appropriate. Uncontrolled diabetes can also
304 negatively affect wound healing after LASIK. Let your LASIK doctor know if you
305 have diabetes.

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

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

314
315 Please inform your doctor if you have ANY of the following conditions that may result in a
316 greater risk for poor outcomes or injury related to LASIK. You should discuss your level of
317 risk with your doctor. You and your doctor should determine whether the benefits to you
318 outweigh the risks based on the nature and severity of your condition.

319
320 ⚠ **Moderate or mild dry eyes.** If you have dry eyes, LASIK can worsen dryness,
321 discomfort and blurred vision. This may or may not get better. If you take certain
322 medications, such as nasal decongestants, you are at greater risk of having dry eyes. If
323 you have a condition that can cause dry eye, such as thyroid disease, Sjögren's syndrome,
324 lupus, or rheumatoid arthritis, you are also at greater risk. Make sure your LASIK doctor
325 checks you for dry eyes before having LASIK.

326
327 ⚠ **Past herpes eye infection.** If you have any history of herpes (simplex or zoster) infection
328 in your eyes, LASIK might reactivate the infection. Let your LASIK doctor know if you
329 have ever had an eye infection or eye inflammation.

330
331 ⚠ **Controlled glaucoma.** If you have glaucoma, LASIK may make monitoring your eye
332 pressure more difficult. You may also be at greater risk for damage to your vision
333 associated with cutting the LASIK flap. The steroid drops used after the surgery may
334 raise your eye pressure and cause glaucoma to worsen. Let your LASIK doctor know if
335 you have been diagnosed with glaucoma.

336
337 ⚠ **Activities that could damage the LASIK flap.** The flap is a tongue-shaped section of
338 corneal tissue that is cut and lifted up during LASIK and which can wrinkle, move out of
339 place, or break off even years after surgery. Participation in contact sports, like football
340 or martial arts, increases your risk for dislocation, or even, loss of the flap. You should
341 discuss your work activities and hobbies with your LASIK doctor prior to surgery to help
342 determine whether LASIK is right for you. You should ask your LASIK doctor how long
343 you should refrain from participating in certain activities following surgery. You should

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344 also discuss with your doctor steps you can take to decrease the risk of flap dislocation or
345 loss.

346
347 **⚠ Controlled autoimmune or connective tissue disease.** Connective tissue diseases or
348 autoimmune diseases (such as rheumatoid arthritis and lupus), even if well controlled and
349 stable, may result in delayed healing and less predictable outcomes after LASIK.
350 Depending upon your disease, its severity, and the medication(s) you are taking, there
351 may be additional risks. These may include severe dry eye, infection, inflammation, poor
352 healing, and corneal melting. You should discuss these additional risks with your LASIK
353 doctor, after he or she has consulted with the other doctors who are treating you.

354
355 **⚠ Taking isotretinoin.** This medication, usually used for acne treatment, increases your
356 risk for dry eye and abnormal wound healing after LASIK. If you have taken or plan to
357 take this medication, talk to your LASIK doctor and the doctor prescribing this
358 medication about your risk.

359
360 **⚠ Controlled diabetes.** Even if your diabetes is well controlled, you may have poor healing
361 of your eye following LASIK.

362
363 **⚠ Repeated attacks of sharp eye pain due to epithelial basement membrane dystrophy**
364 **(EBMD).** In this condition, the outer layer of corneal cells does not stick well to the other
365 corneal layers causing the outer cells to rub off easily. These recurring “scratches”
366 (recurrent erosions) on the eye surface often cause blurred vision, pain, light sensitivity,
367 and tearing. LASIK is likely to worsen EBMD. Let your LASIK doctor know if you have
368 had these symptoms in the past, and ask if any signs of this condition have been noted on
369 your eye exam.

370
371 **⚠ Weakened immune system.** If you have a weakened immune system due to medications
372 (such as steroids) or a medical condition (such as AIDS), you may be more prone to
373 infection after surgery. Such conditions and medications may put you at greater risk for
374 other complications as well, such as dry eye or abnormal wound healing. Let your LASIK
375 doctor know about any medical conditions you have and all medications you are taking.

376
377 **⚠ History of “crossed eyes” (strabismus).** If you are having LASIK for farsightedness and
378 have a history of “crossed eyes” (strabismus), you may be at an increased risk of having
379 double vision after surgery. Tell your LASIK doctor if you have ever had “crossed eyes”
380 or double vision.

381
382 **⚠ Decreased vision in one eye.** If you have one eye that does not see clearly, even with
383 glasses, you should discuss this with your LASIK doctor. This condition can be due to
384 amblyopia, a “lazy eye,” or damage from an injury or disease. With this type of
385 decreased vision in one eye, complications that might result from LASIK in your better
386 seeing eye could more severely impact your functioning.

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389 c. Other Things That May Increase Your Risk of LASIK Complications 390 (Precautions)

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

400
401 The list below provides information regarding conditions for which consideration should be
402 given when deciding whether the benefits of LASIK with this device outweigh the risks to
403 you. You should discuss with your LASIK doctor whether the following conditions apply to
404 you and how they may affect your risk of having complications from LASIK:

- 405
- 406 * **Family history of thinning of the cornea.** Eye diseases like a cone-shaped cornea
407 (*keratoconus*), thinning of the inferior part of the cornea (*pellucid marginal*
408 *degeneration*), and other conditions that may cause a thinning or bulging of the cornea
409 can run in families. You may not be aware that you have such a condition if it is in the
410 early stage. If you have one of these conditions and it has not been diagnosed, LASIK
411 may cause more rapid progression of the disease. You should tell your LASIK doctor
412 about any family history of these or any other eye problems.
 - 413
 - 414 * **History of any eye disease (e.g., uveitis), abnormality, injury, or surgery.** If you have
415 a history of any of these conditions, you should discuss them with your LASIK doctor, as
416 they might increase the risks of LASIK. For example, corneal scars may affect LASIK
417 accuracy and vision following the surgery.
 - 418
 - 419 * **Taking amiodarone hydrochloride.** This medication, usually used to treat irregular
420 heartbeats (ventricular arrhythmias), can cause cloudy areas in the cornea and may cause
421 problems with healing after LASIK. Tell your LASIK doctor about all the medications
422 that you are taking.
 - 423
 - 424 * **Taking sumatriptan.** This medication, usually used to treat migraine headaches, may
425 cause problems with healing after LASIK. Tell your LASIK doctor about all medications
426 you are taking.
 - 427
 - 428 * **Large pupils or very nearsighted.** Many factors affect whether someone might
429 experience visual symptoms, making it difficult to predict who will experience them after
430 surgery. However, very nearsighted patients and patients with large pupils may be at
431 greater risk of experiencing visual symptoms, such as halos and glare. In addition,
432 patients who are very nearsighted generally may have less accurate correction than those

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433 requiring less treatment. Ask your doctor whether you have large pupils or are very
434 nearsighted.

435
436 * **Activities under poor lighting conditions.** LASIK may decrease your ability to see well
437 in poor lighting conditions, such as in dim lighting, rain, snow, and fog, when contrast
438 (difference in how bright an object is compared to its background) is low, or when there
439 is glare from bright lights, especially at night. You should discuss these potential
440 problems with your LASIK doctor. After LASIK, you should be careful while driving
441 when you are in poor lighting conditions until you can determine whether you have any
442 difficulties.

443
444 * **Allergies or eye rubbing.** If you rub your eyes after you have had LASIK, you are at a
445 greater risk for dislodging the LASIK flap. This is because the strength of the attachment
446 of the flap to the underlying corneal layers is permanently reduced after surgery.
447 Additionally, some allergy medications cause dry eye symptoms. If you take these
448 medicines, you are at greater risk for severe dry eye after LASIK. Let your LASIK doctor
449 know about all your allergies and medications (even over-the-counter medications) and if
450 you tend to rub your eyes frequently.

451
452 * **Elevated eye pressure (ocular hypertension) or being followed for possible**
453 **glaucoma.** If you have either of these conditions related to eye pressure, there are several
454 ways LASIK can cause problems for you. It is more difficult to accurately monitor your
455 eye pressure after LASIK, which may delay the detection of glaucoma. You may be at
456 greater risk for damage to your vision associated with cutting the LASIK flap.
457 Additionally, steroid drops used after surgery may raise the eye pressure and cause
458 glaucoma to worsen. Let your LASIK doctor know if you have any of these conditions.

459 **(6) What are the Risks?**

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

468
469 Some problems that patients experience after LASIK commonly occur right after surgery and
470 are usually greatly reduced within 3 to 6 months. However, in some patients these problems
471 can be permanent and, in rare cases, may impact their ability to perform daily tasks.

472
473 The risks of LASIK include, but are not limited to, the following:

474
475 • **Loss of vision.** This means that vision becomes unclear (blurry or hazy vision) even with
476 glasses or contact lenses. Your doctor may be able to measure this loss using a vision

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477 chart. The loss may be mild or, in rare cases, severe. In extremely rare cases, people can
478 experience a total loss of vision. Vision loss is usually temporary, but there are
479 complications of LASIK that can cause permanent loss of vision. How clearly you can
480 see may change from day-to-day or even from minute-to-minute (fluctuating vision).
481 Some of the potential causes of vision loss following LASIK are discussed below.
482

- 483 ○ **Corneal complications.** The following corneal complications may lead to permanent
484 vision loss, for example, due to loss of corneal clarity from scarring or swelling, and
485 may require corneal transplant surgery for treatment:
486
 - 487 ■ **Corneal flap complications.** LASIK requires the cutting of a flap of the front-
488 most part of the cornea. The flap is swung out of the way so the laser can treat
489 underlying tissue, and is returned to its original position after the treatment. Flap
490 complications include irregular cutting of the flap, the flap not properly returning
491 to its original position, the flap coming off and even getting lost, and irregular
492 healing. If a flap complication occurs during surgery, the surgery may need to be
493 interrupted and rescheduled. A flap complication can result in the need for
494 additional surgery or, rarely, permanent loss of vision. In almost all LASIK cases,
495 the strength of the flap's re-attachment to the underlying tissue is significantly and
496 permanently weaker than before LASIK. There are reports of the flap being torn
497 off, even many months after surgery. It may be necessary to wear protective
498 eyewear during certain physical activities like contact sports.
499
 - 500 ■ **Infection.** The cornea may get infected right after surgery. This can be treated
501 with topical medication, which may or may not successfully control the infection.
502 On rare occasions, an infection may cause a hole in the clear covering of the eye
503 (perforation of the cornea).
504
 - 505 ■ **Inflammation.** Inflammation after LASIK is the body's reaction to such things as
506 tissue disruption from surgery or infection. Excessive inflammation of the cornea
507 can cause scarring or swelling resulting in cloudiness or haziness (loss of corneal
508 clarity).
509
 - 510 ■ **Irregular corneal shape.** LASIK or the healing process after surgery may result
511 in an irregular shape to the cornea. This can cause blurry vision or other visual
512 symptoms. Such irregularities in shape can be measured by your doctor using
513 special instruments.
514
 - 515 ● **Bulging of the cornea (corneal ectasia)** is the most extreme irregularity. This
516 complication is uncommon, but can cause permanent and significantly blurry
517 vision, sometimes requiring a corneal transplant.
518
- 519 ○ **Retinal detachment.** The retina is the light-sensitive tissue that lines the inside back
520 of the eye and captures images that are transmitted to the brain, much like the film of
521 a camera. If the retina detaches, or comes unglued from its attachments within the

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522 eyeball, it will lose its function and need to be reattached through surgery. This may
523 result in permanent loss of vision, even if the retina is successfully reattached. Retinal
524 detachment after LASIK is rare, and usually only occurs in people who are very
525 nearsighted and are prone to this type of retinal problem.
526

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

531
532 If you have dry eye before surgery, LASIK may increase dry eye symptoms and related
533 problems after surgery. Your doctor should test you for pre-existing dry eye. However,
534 there is no test that can guarantee whether you will, or will not, have dry eye after
535 LASIK. Lubricating drops are usually necessary immediately after surgery to help with
536 dryness. Symptoms of dry eye may include a scratchy or sandy feeling as if something is
537 in your eye, stinging, burning, episodes of excessive tearing, a stringy discharge from the
538 eye, pain, redness, light sensitivity, and blurred vision. The sensation of dryness can vary
539 from mild to severe, but in most cases the feelings are a minor annoyance. Eye drops
540 such as artificial tears, or other treatments, such as plugs in the tear drainage system of
541 the eye, may reduce these symptoms, but may not completely resolve them. A small
542 number of patients experience extreme discomfort that interferes with their ability to do
543 daily tasks.
544

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

- 551 • **Visual Symptoms.** LASIK may cause or worsen visual symptoms, such as glare, halos,
552 starbursts, and ghost images/double images, most commonly experienced in dim lighting
553 conditions as well as blurred and fluctuating vision. These problems usually improve
554 within 3 to 6 months after surgery, but in some cases never go away, even when glasses
555 are worn. Visual symptoms can be mild, but can also be severe enough to cause
556 difficulties in performing daily tasks. **A common complaint is difficulty with driving at
557 night.** Specific visual symptoms are described below with images to help explain the
558 visual symptoms. The images shown may not represent exactly what you might see, and
559 your symptoms may be more or less severe than what is shown:
560

- 561 ○ **Glare.** Glare is *difficulty seeing well when there are bright lights* like headlights or
562 sunlight, as shown in the images below.
563

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No Glare ←————→ Severe Glare



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- **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.

No Halo ←————→ Severe Halo



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

No Starburst ←————→ Severe Starburst

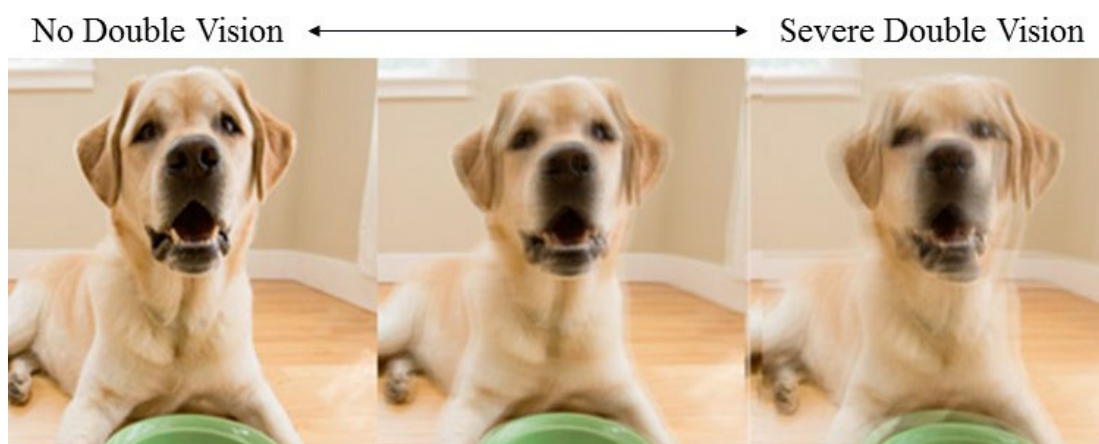


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- **Double vision.** *Double vision*, which some people call “ghost” or “shadow” images, are *distorted or blurry visual images*, such as the ones shown below. If you experience such images, close one eye and then the other to determine if you only 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.



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- **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

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608 but the other eye cannot undergo LASIK. Imbalances between the two eyes may cause
609 headaches, eyestrain, double vision, and reduced depth perception, if both eyes are not
610 able to focus at the same time at the same distance (anisometropia).
611

612 • **Need for glasses for close work.** Almost all people in their 40s or older lose their ability
613 to focus from far to near. LASIK does not treat this condition (called “presbyopia”). After
614 surgery, patients who are already over 40 years old (or once they reach their 40’s) usually
615 need to wear glasses for close work, such as reading, even if they did not need to wear
616 them before surgery.
617

618 • **Drooping eyelid.** The lid of the eye(s) that had surgery may droop. This can be a
619 complication from an instrument used to hold the lid during surgery. Besides the
620 appearance of unevenness in the height of the eyelids, this may result in a feeling of the
621 eyes getting tired during the course of the day or difficulty seeing, and may require eyelid
622 surgery.
623

624 • **Future eye health.** LASIK will likely cause difficulties with:
625

626 ○ **Future assessment of eye pressure.** Thinning of the cornea due to LASIK will affect
627 your eye pressure measurements (used as part of the exam for glaucoma), making
628 them more difficult to interpret. You should inform all eye care providers that you
629 have had LASIK.
630

631 ○ **Future cataract surgery.** Almost everyone needs cataract surgery (removal of your
632 natural lens) later in life. LASIK may make it more difficult for the surgeon to
633 implant the correct artificial lens. You should ask your LASIK doctor for a patient
634 information card (e.g., the “K-Card” found at
635 <http://www.geteyesmart.org/eyesmart/upload/kcard.pdf>) that lists your eye
636 measurements before you have LASIK. You should keep this card to help the cataract
637 surgeon accurately calculate the artificial lens power you will need when you have
638 cataract surgery in the future.
639

640 See the **Clinical Study Section** to find out how often specific problems occurred in those
641 treated with the [XX] laser in clinical studies of the device.

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

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

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651 **(8) Clinical Study Information**

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

663
664 FDA recommends including the purpose and main objectives of the study in this part of the
665 labeling, which should contain a very brief description of the general study design, including the
666 number of months that patients were followed, the number of patients studied, the key evaluation
667 time points, and the primary and secondary safety and effectiveness endpoints.

668
669 Further, the key safety and effectiveness outcomes of the study should be summarized in lay
670 terms, including tabulation and accompanying explanation of the adverse events and
671 complications that occurred during the course of the trial, symptoms, and any patient-reported
672 outcomes. FDA recommends that you do not use percentages to summarize the outcome
673 information, but rather the actual number of subjects in the numerator and denominator to
674 represent rates (e.g., “45 of the 302 patients seen at the 12-month visit”), when applicable.
675 Results of contrast sensitivity testing should be briefly summarized in lay terms with the number
676 of subjects that underwent testing and the outcomes from the perspective of whether losses were
677 experienced under each of the various testing conditions.

678 **(9) Contact Information**

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

682 **(10) Patient Decision Considerations**

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

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

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

703
704 The FDA recommends that a copy of the patient decision checklist be provided to the patient so
705 that the patient can refer back to this important information. The FDA also encourages device
706 manufacturers to develop a plan to ensure that patients are adequately informed of the risks of
707 LASIK.

708
709 Appendix A provides an example of a patient decision checklist. FDA believes that the form and
710 content of the patient decision checklist will help to ensure that patients have adequate and
711 salient information about the risks and warnings of LASIK surgery, with appropriate prominence
712 and conspicuousness such that it is easily read and understood. The rates of certain adverse
713 events identified in the patient decision checklist were based on information from clinical trials,
714 scientific literature, and reports from patients who have undergone LASIK. FDA recommends
715 using these rates unless compelling data regarding the rates of certain events have been collected
716 with post-market experience on a specific device, particularly for the more rare adverse events.
717

718 **Appendix A: Patient Decision Checklist Example**

719

720 To the patient considering LASIK surgery:

721

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

733

734 **Vision Correction Options**

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

743

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

- 746
- 747 • 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.
 - 748 • Even after the corneal flap has fully healed, the cornea will not be as strong as it was
749 before surgery.

750

751 Patient Initials: _____

752

753 **Considerations for a good candidate for LASIK surgery**

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

756

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

758

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

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- 760
- 761
- 762
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- 764
- 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.

765

766 Patient Initials: _____

767

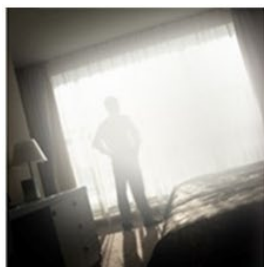
768 What to Expect in the First Six Months.

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

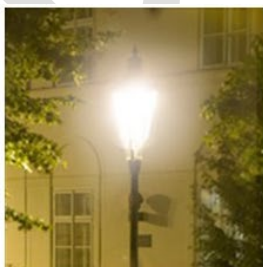
772

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

- 774
- 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.
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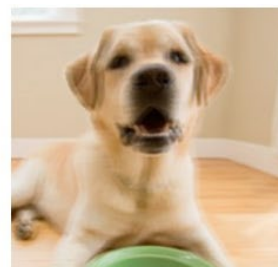
785 Figure 1a: Glare



786 Figure 1b: Halo



787 Figure 1c: Starburst



788 Figure 1d: Double Vision

789

790

791 Patient Initials: _____

792

793 Long-term Risks

- 794
- 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:
- 795
- 796

Contains Nonbinding Recommendations

Draft – Not for Implementation

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- 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: _____

DRAFT

Contains Nonbinding Recommendations

Draft – Not for Implementation

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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