

MYOPIA WITH OR WITHOUT ASTIGMATISM**INDICATIONS AND INTENDED USES:**

The LADARVision® Excimer Laser System is approved to perform photo-refractive keratectomy (PRK) for the correction of mild to moderate myopia between -1.00D and -10.00D with up to -4.00D of astigmatism; to perform laser in-situ keratomileusis (LASIK) for the correction of myopia less than -9.00D sphere and -0.50D to less than -3.00D of astigmatism at the spectacle plane; in subjects with documented stability of refraction for the prior 12 months, as demonstrated by a change of less than or equal to 0.50D for corrections up to -7.00D, and less than or equal to -1.00D for corrections greater than -7.00D SE; and in subjects who are 21 years of age or older. Note that the complete name for the device as approved for LASIK is "the LADARVision Excimer Laser System for laser in-situ keratomileusis (LASIK) for the correction of myopia less than -9.00D sphere and -0.50D to less than -3.00D astigmatism at the spectacle plane". An acceptable alternate version of this official name is "LASIK laser correction for nearsightedness with or without astigmatism".

Alternatives to PRK include: eyeglasses, contact lenses, LASIK, radial keratotomy, or automated lamellar keratoplasty. In PRK studies of 604 eyes (417 myopic eyes; 187 eyes with myopic astigmatism) after final treatment with refractive data at 6 months, 95.9% and 93.2%, respectively, were corrected to 20/40 or better and 69.7% and 59.3%, respectively, were corrected to 20/20 or better without spectacles or contact lenses. LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, PRK, radial keratotomy, astigmatic keratotomy or automated lamellar keratoplasty. Approval of the application for LASIK is based on a clinical trial of 347 eyes (186 primary and 161 secondary) of which 177 eyes were treated for spherical myopia and 170 for astigmatic myopia. Of all eyes treated, 330 eyes were available for analysis at 3 months, and 270 eyes were followed for six months. Accountability at 1 month was 97.4%; at 3 months accountability was 95.9%, and 94.4% at 6 months. The analysis of data from 347 total eyes treated and based on refractive data at 6 month follow-up examination, found that 93.7% (224/239) eyes were corrected to 20/40 or better and 56.9% (136/239) were corrected to 20/20 or better visual acuity without spectacles or contact lenses.

CONTRAINDICATIONS:

PRK and LASIK surgery are contraindicated in patients who: are pregnant or nursing; show signs of keratoconus; are taking the medications isotretinoin (Accutane®) or amiodarone hydrochloride (Cordarone®); or have an autoimmune disease, collagen vascular disease, or an immunodeficiency disease.

WARNINGS:

PRK and LASIK are not recommended in patients who have insulin-dependent diabetes, severe allergies, or a history of herpes simplex or herpes zoster keratitis. A minimum pre-operative pupillary dilation of 7mm and a maximum dilation of 11mm must be achieved and maintained in all patients throughout the refractive procedure to optimize tracker performance.

PRECAUTIONS:

The safety and effectiveness of the LADARVision® system have not been established: in patients with progressive myopia, ocular disease, corneal abnormality, previous corneal or intraocular surgery, trauma in the ablation zone, history of glaucoma, or history of keloid formation (PRK only); in patients with a residual corneal thickness less than 250 microns at the completion of the ablation; in patients who are taking the medication Sumatriptan (Imitrex®); in patients under 21 years of age; in patients over the long term (more than 12 months for PRK; 6 months for LASIK); for the treatment of astigmatism less than 0.50 Diopters or PRK refractive treatments greater than -10.00D of myopia combined with greater than -4.00D of astigmatism; for LASIK refractive treatments greater than or equal to -9.00D of myopia combined with greater than or equal to -3.00D of astigmatism.

Eyes with prior intraocular or corneal surgery of any kind were excluded from clinical trials with the LADARVision® system. Safety and effectiveness, as well as tracking performance, have not been established for such eyes. Although the tracker system may acquire track in surgically altered eyes prior to ablation, the optics of the eye may change in the context of the ablation to potentially interfere with further tracking and compromise the completion of the ablation. Medical judgement should be exercised in the use of the LADARVision system in pseudophakic patients and others who have had prior intraocular or corneal surgery.

The effects of LASIK on visual performance under poor lighting conditions have not been effectively determined. Following LASIK treatment, some patients may find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night. In a contrast sensitivity study designed to assess the effects of LADARVision® PRK surgery on how well patients can see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night, the percentage of patients showing clinically significant losses were 10.6% at 6 months and 6.6% at 12 months after surgery, and the percentages of patients showing clinically significant improvements were 5.9% at 6 months and 3.3% at 12 months after PRK surgery.

In addition, U.S. clinical studies of LADARVision® PRK surgery have shown that bandage contact lenses and non-steroidal anti-inflammatory drops used for pain management in the immediate postoperative period following PRK with this device are associated with sterile infiltrates (the rate of sterile infiltrates observed was 1.6%) and that overcorrections greater than +1D may be more likely to occur in older patients, at low room humidity and when attempting higher corrections.

ADVERSE EVENTS AND COMPLICATIONS:**PRK**

The following adverse events and complications were reported during the course of the clinical trial: feeling of something in the eye (3.0% - spherical myopia; 2.4% - myopic astigmatism); double/ghost images (2.6% - spherical myopia; 6.2% - myopic astigmatism); peripheral epithelial defect (1.3% - spherical myopia; 0.5% - myopic astigmatism); pain (1.3% - spherical myopia; 1.9% - myopic astigmatism); halos/starbursts (0.6% - spherical myopia; 0.5% - myopic astigmatism); corneal infiltrates (1.6% combined cohort); increased intraocular pressure above 25mmHg (0.6% combined cohort); corneal ulcer (0.1% combined cohort); and retinal vascular accident (0.1% combined cohort). The loss of > 2 lines best spectacle corrected visual acuity (BSCVA) at 6 months was 0.5% for spherical myopia and 0.0% for myopic astigmatism, and pretreatment BSCVA 20/20 or better with post-treatment BSCVA worse than 20/25 was 0.5% for spherical myopia and 0.0% for myopia astigmatism. Other findings that occurred at a rate of < 0.3% (spherical myopia) included corneal erosion; corneal abrasion (< 0.5% for astigmats); scratchiness; pain; epithelial irregularity; corneal swelling; subconjunctival hemorrhage; light sensitivity; epithelial dots; iritis (< 0.5% for astigmats); and ocular hypertension.

The following complications were reported by subjects: difficulty with night driving (4.3% - spherical myopia; 9.4% - myopic astigmatism); glare (1.7% - spherical myopia; 4.4% - myopic astigmatism); halos (2.3% - spherical myopia; 6.1% - myopic astigmatism); feeling of something in the eye (1.4% - spherical myopia; 0.0% - myopic astigmatism); fluctuation of vision (1.1% - spherical myopia; 3.8% - myopic astigmatism); blurring of vision (0.9% - spherical myopia; 2.2% - myopic astigmatism); light sensitivity (0.9% - spherical myopia; 0.5% - myopic astigmatism); headache (0.3% - spherical myopia; 0.5% - myopic astigmatism); double vision (0.3% - spherical myopia; 0.5% - myopic astigmatism); pain (0.3% - spherical myopia; 0.0% - myopic astigmatism); excessive tearing (0.3% - spherical myopia; 0.0% - myopic astigmatism); burning (0.3% - spherical myopia; 0.0% - myopic astigmatism).

LASIK

The study showed that most adverse events and complications occurred in trace amounts (<1%). At 6 months post treatment, the two events with ≥1% rate are interface debris at 4.2% (11/260) and superficial punctate keratitis at 2.3% (6/260). At 6 months post treatment (n=260), adverse events or complications reported in <1% of eyes include: conjunctival injection (0.8%); corneal folds/striae/wrinkle (0.8%); fibrotic healing at flap edge (0.8%); oil droplets/sheen (0.8%); double/ghost images (0.4%); epithelial defect (0.4%); epithelium in the interface (0.4%); interface haze/opacity (0.4%). The following ocular findings were reported at 6 months at a rate of 0.8%: blepharitis, retinal vessel tortuosity, and lattice degeneration with floaters. Other adverse events and complications that were reported at intervals other than 6 months include: feeling of something in the eye, flap distortion, HSV dendrite, increase in intraocular pressure >10mmHg above baseline, induced astigmatism with flap decentration, misaligned flap, miscreated flap, peau d'orange, serous macular edema, and sterile interface inflammation. Long term (beyond 6 months) risks of LASIK for myopia and astigmatism have not been studied.

Subjects reported the following conditions at 6 months as "significantly worse" compared to before LASIK surgery: difficulty with night driving (5.7% - spherical myopia; 14.9% - myopic astigmatism); glare (2.8% - spherical myopia; 9.9% - myopic astigmatism); halos (3.5% - spherical myopia; 6.9% - myopic astigmatism); light sensitivity (2.8% - spherical myopia; 5.9% - myopic astigmatism); dryness (4.3% - spherical myopia; 3.0% - myopic astigmatism); fluctuation of vision (2.1% - spherical myopia; 2.0% - myopic astigmatism); blurring of vision (2.1% - spherical myopia; 1.0% - myopic astigmatism); redness (0.7% - spherical myopia; 1.0% myopic astigmatism); headache (0.7% - spherical myopia; 0.0% myopic astigmatism); and double vision (0.7% - spherical myopia; 0.0% - myopic astigmatism).

HYPEROPIA WITH OR WITHOUT ASTIGMATISM AND MIXED ASTIGMATISM**INDICATIONS AND INTENDED USES:**

The LADARVision® Excimer Laser System is approved to perform laser in-situ keratomileusis (LASIK) treatments for the reduction or elimination of refractive error of less than or equal to +6.00D of sphere and -6.00D cylinder at the spectacle plane (hyperopia with or without astigmatism and mixed astigmatism); in subjects with documented stability of refraction for the prior 12 months, as demonstrated by a change of less than or equal to 0.50D for corrections up to +6.00D SE; and in subjects who are 21 years of age or older. Note that the complete name of this device as approved is "the LADARVision Excimer Laser System for laser in-situ keratomileusis (LASIK) treatments of hyperopia with or without astigmatism and mixed astigmatism of less than or equal to +6.00D sphere and -6.00D cylinder at the spectacle plane." An acceptable alternate version of this official name is "LASIK laser correction for farsightedness with or without astigmatism."

LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), or laser thermal keratoplasty (LTK). Approval of the application is based on a clinical trial of 360 eyes: 152 eyes were treated for hyperopia, 143 eyes for astigmatic hyperopia, and 65 eyes for mixed astigmatism. Of all eyes treated, 324 eyes were available for analysis at 6 months, and 265 eyes were followed for 9 months. Accountability at 3 months was 95.6%, at 6 months was 95.3%, and at 9 months was 90.4%. The analysis of refractive data at the 6 month stability time point found that 113 (93.4%) hyperopic eyes were 20/40 or better and 59 eyes (48.8%) were 20/20 or better without spectacles or contact lenses. In the astigmatic hyperopic eye group, 100 eyes (90.9%) were 20/40 or better and 41 eyes (37.3%) were 20/20 or better without spectacles or contact lenses. In the mixed astigmatic eye group, 50 eyes (92.6%) were 20/40 or better and 25 (46.3%) were 20/20 or better without spectacles or contact lenses.

CONTRAINDICATIONS:

LASIK surgery is contraindicated in patients who: are pregnant or nursing; show signs of keratoconus; are taking the medications isotretinoin (Accutane®) or amiodarone hydrochloride (Cordarone®); or have an autoimmune disease, collagen vascular disease, or an immunodeficiency disease.

WARNINGS:

LASIK is not recommended in patients who have insulin-dependent diabetes, severe allergies, or a history of herpes simplex or herpes zoster keratitis. A minimum pre-operative pupillary dilation of 7mm and a maximum dilation of 11mm must be achieved and maintained in all patients throughout the refractive procedure to optimize tracker performance. The microkeratome should create a flap large enough to allow for a treatment zone of 9.00 mm needed for this procedure.

PRECAUTIONS:

The safety and effectiveness of the LADARVision® system have not been established: in patients with ocular disease, corneal abnormality, previous corneal or intraocular surgery, trauma in the ablation zone, or history of glaucoma; in patients with a residual corneal thickness less than 250 microns at the completion of the ablation; in patients who are taking the medication Sumatriptan (Imitrex®); in patients under 21 years of age; in patients over the long term (9 months for LASIK); in non-Caucasian patients; for the treatment of astigmatism less than 0.50 Diopters or treatments greater than +6.00D of hyperopia or -6.00D of astigmatism; for retreatments of hyperopia, hyperopic astigmatism or mixed astigmatism.

Eyes with prior intraocular or corneal surgery of any kind were excluded from clinical trials with the LADARVision® system. Safety and effectiveness, as well as tracking performance, have not been established for such eyes. Although the tracker system may acquire track in surgically altered eyes prior to ablation, the optics of the eye may change in the context of the ablation to potentially interfere with further tracking and compromise the completion of the ablation. Medical judgement should be exercised in the use of the LADARVision system in pseudophakic patients and others who have had prior intraocular or corneal surgery.

Eyes with greater than 5.0D of hyperopia may have lower predictability of refractive outcome and improvement in uncorrected visual acuity than eyes with lower levels of hyperopia.

Hyperopic astigmatism eyes with greater than 4.0D MRSE preoperatively may have lower predictability of refractive outcome and improvement in uncorrected visual acuity than eyes with lower levels of MRSE. These eyes may be more likely to experience a reduction of two lines in their best-corrected visual acuity and to require retreatment.

Older patients and women on hormone replacement therapy may be less likely to achieve uncorrected visual acuity of 20/20 or better.

The effects of LASIK on visual performance under poor lighting conditions have not been effectively determined. Following LASIK treatment, some patients may find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night.

ADVERSE EVENTS AND COMPLICATIONS:

The study showed that at the 6 month stability time point, there was a loss of 2 lines of best vision that can be obtained with spectacles in 5 (3.5%) of hyperopic eyes, 7 (5.8%) of hyperopic astigmatic eyes, and 1 (1.9%) mixed astigmatic eye. Most other adverse events and complications occurred with low frequencies (<1%). The four events with ≥1% rate were double/ghost images (1.5%), epithelium on the interface (1.5%), interface debris (1.5%), and superficial punctate keratitis (3.1%). At 6 months post treatment (n=324), adverse events and complications reported in <1% of eyes include: isolated cells in interface (0.6%); corneal abrasion (0.3%); corneal opacities (0.3%); feeling of something in the eye (0.3%); iron line or ring (0.3%); and rolled flap edge with trace corneal melt (0.3%). Each of the following ocular findings was reported at 6 months at a rate of 0.6% or less: allergic conjunctivitis, vitreous floater, cotton wool spot, and drusen. Long term (beyond 9 months) risks of LASIK for hyperopia, hyperopic astigmatism, and mixed astigmatism have not been studied.

Other adverse events or complications that were reported at intervals other than 6 months include: conjunctival injection, corneal infiltrate, corneal folds/striae/wrinkles, corneal swelling, epithelial defect, increase in intraocular pressure, intralaminar haze, irregular epithelium, lagophthalmos, misaligned flap, miscreated flap, pain, sterile interface inflammation, subconjunctival hemorrhage, trichiasis, and vacuoles. In addition, one patient with a history of heart disease experienced a myocardial infarction (heart attack) two weeks after surgery, which was not related to the LASIK procedure or to the LADARVision system. Lens findings were reported postoperatively in 14 eyes of 8 patients. All of these patients experienced lens changes due to age (range 59 to 73 years old). These findings included nuclear sclerosis, cortical spoking, and posterior subcapsular cataract. No eyes had a loss of more than 2 lines of best spectacle corrected visual acuity (BCVA). Only one eye had a related loss of 2 lines of BSCVA. All eyes had a last-reported BSCVA of 20/32 or better.

Subjects reported the following conditions at 6 months as "significantly worse" compared to before LASIK surgery: night driving difficulty (2.3% - spherical hyperopia; 1.8% - hyperopic astigmatism; 7.5% - mixed astigmatism); fluctuation of vision (6.0% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); dryness (3.0% - spherical hyperopia; 5.3% - hyperopic astigmatism; 1.9% - mixed astigmatism); halos (2.3% - spherical hyperopia; 4.5% - hyperopic astigmatism; 0.0% - mixed astigmatism); blurring of vision (1.5% - spherical hyperopia; 1.8% - hyperopic astigmatism; 3.8% - mixed astigmatism); double vision (1.5% - spherical hyperopia; 3.6% - hyperopic astigmatism; 0.0% - mixed astigmatism); feeling of something in the eye (1.5% - spherical hyperopia; 2.7% - hyperopic astigmatism; 0.0% - mixed astigmatism); redness (0.8% - spherical hyperopia; 2.7% - hyperopic astigmatism; 0.0% - mixed astigmatism); light sensitivity (1.5% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); glare (0.8% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); burning (0.8% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); headache (0.0% - spherical hyperopia; 1.8% - hyperopic astigmatism; 0.0% - mixed astigmatism); pain (0.8% - spherical hyperopia; 0.9% - hyperopic astigmatism; 0.0% - mixed astigmatism); and excessive tearing (0.0% - spherical hyperopia; 0.0% - hyperopic astigmatism; 0.0% - mixed astigmatism).