Health Care Professional Information Sheet-All WaveLight(R) Allegretto Wave® System Indications

The WaveLight(R) ALLEGRETTO WAVE(R) / ALLEGRETTO WAVE(R) Eye-Q Excimer Laser System

Statements regarding the potential benefits of wavefront-guided and Wavefront Optimized(R) laserassisted in-situ keratomileusis (LASIK) are based upon the results of clinical trials. These results are indicative of not ony the WaveLight(R) ALLEGRETTO WAVE(R) / ALLEGRETTO WAVE(R) Eye-Q Excimer Laser System treatment but also the care of the clinical physicians, the control of the surgical environment by those physicians, the clinical trials' treatment parameters and the clinical trials' patient inclusion and exclusion criteria. Although many clinical trial patients after the wavefront-guided and Wavefront Optimized(R) procedure saw 20/20 or better and/or had or reported having better vision during the day and at night, compared to their vision with glasses or contact lenses before the procedure, individual results may vary.

As with any surgical procedure, there are risks associated with the wavefront-guided and Wavefront Optimized(R) treatment.

Indications: The WaveLight(R) ALLEGRETTO WAVE(R) / ALLEGRETTO WAVE(R) Eye-Q Excimer Laser System is indicated to perform LASIK treatments in patients with documented evidence of a stable manifest refraction for the reduction or elimination of myopic refractive errors up to -12.0 D of sphere with and without astigmatic refractive errors up to -6.0 D; for the reduction or elimination of hyperopic refractive errors up to +6.0 D of sphere with and without astigmatic refractive errors up to 5.0 D at the spectacle plane, with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D; and in patients 21 years of age or older for the reduction or elimination of naturally occurring mixed astigmatism of up to 6.0 D at the spectacle plane.

LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK or ASA), and other refractive surgeries.

Clinical Data Myopia: The WaveLight(R) ALLEGRETTO WAVE(R) / ALLEGRETTO WAVE(R) Eye-Q Excimer Laser System for LASIK treatments of myopic refractive errors up to -12.0 D of sphere with and without astigmatic refractive errors up to -6.0 D at the spectacle plane was studied in clinical trials in the United States with 901 eyes treated, of which 813 of 866 eligible eyes were followed for 12 months. Accountability at 3 months was 93.8%, at 6 months was 91.9%, and at 12 months was 93.9%. The studies found that of the 844 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 3-month stability time point, 98.0% were corrected to 20/40 or better, and 84.4% were corrected to 20/20 or better without spectacles or contact lenses.

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months posttreatment: visual fluctuations (12.8% at baseline versus 28.6% at 3 months). Long term risks of LASIK for myopia with and without astigmatism beyond 12 months have not been studied in the FDA Clinical Trials.

Clinical Data Hyperopia: The WaveLight(R) ALLEGRETTO WAVE(R) / ALLEGRETTO WAVE(R) Eye-Q Excimer Laser System for LASIK treatments of hyperopic refractive errors up to +6.0 D of sphere with and without astigmatic refractive errors up to 5.0 D with a maximum MRSE of +6.0 D has been studied in clinical trials in the United States with 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 69.9%. The studies found that of the 212 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 95.3% were corrected to 20/40 or better, and 67.5% were corrected to 20/20 or better without spectacles or contact lenses.

The study showed that the following subjective patient adverse events were reported as much worse by at least 1% of the subjects (in order of increasing frequency) at 6 months post final treatment: glare from bright lights (3.0%); night driving glare (4.2%); light sensitivity (4.9%); visual fluctuations (6.1%); and halos (6.4%). Long term risks of LASIK for hyperopia with and without astigmatism beyond 12 months have not been studied.

Clinical Data Mixed Astigmatism: The WaveLight(R) ALLEGRETTO WAVE(R)/ ALLEGRETTO WAVE(R) Eye-Q Excimer Laser System for LASIK treatments of naturally occurring mixed astigmatism of up to 6.0 D at the spectacle plane has been studied in clinical trials in the United States with 162 eyes treated, of which 111 were eligible to be followed at 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%. The studies found that of the 142 eyes eligible for the UCVA analysis of effectiveness at the 3-month stability time point, 95.8% achieved acuity of 20/40 or better, and 67.6% achieved acuity of 20/20 or better without spectacles or contact lenses.

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months posttreatment: sensitivity to light (43.3% at baseline versus 52.9% at 3 months); visual fluctuations (32.1% at baseline versus 43.0% at 3 months); and halos (37.0% at baseline versus 42.3% at 3 months). Long term risks of LASIK for mixed astigmatism beyond 6 months have not been studied.

Contraindications: LASIK treatments using the WaveLight(R) ALLEGRETTO WAVE(R) / ALLEGRETTO WAVE(R) Eye-Q Excimer Laser System are contraindicated if any of the following conditions exist. Potential contraindications are not limited to those included in this list: pregnant or nursing women; patients with a diagnosed collagen vascular, autoimmune or immunodeficiency disease; patients with diagnosed keratoconus or any clinical pictures suggestive of keratoconus; and patients who are taking one or both of the following medications: isotretinoin (Accutane(R)1), amiodarone hydrochloride (Cordarone(R)2).

Warnings: Any LASIK treatment with the WaveLight(R) ALLEGRETTO WAVE(R) / ALLEGRETTO WAVE(R) Eye-Q Excimer Laser System is not recommended in patients who have: systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status; a history of Herpes simplex or Herpes zoster keratitis; significant dry eye that is unresponsive to treatment; severe allergies; and unreliable preoperative wavefront examination that precludes wavefront-guided treatment. The wavefront-guided LASIK procedure requires accurate and reliable data from the wavefront examination.

Precautions: Safety and effectiveness of the WaveLight(R) ALLEGRETTO WAVE(R) / ALLEGRETTO WAVE(R) Eye-Q Excimer Laser System have not been established for patients with: progressive myopia, hyperopia, astigmatism and/or mixed astigmatism; ocular disease; previous corneal or intraocular surgery, or trauma in the ablation zone; corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage; residual corneal thickness after ablation of less than 250 microns increasing the risk for corneal ectasia; pupil size below 7.0 mm after mydriatics where applied for wavefront-guided ablation planning; history of glaucoma or ocular hypertension of > 23 mmHg; taking the medication sumatriptan succinate (Imitrex(R)3); under 18 years (21 years for mixed astigmatism) of age; over the long term (more than 12 months after surgery); corneal, lens and/or vitreous opacities including, but not limited to, cataract; iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eyetracking; taking medications likely to affect wound healing including, but not limited to, antimetabolites; treatments with an optical zone below 6.0 mm or above 6.5 mm in diameter; treatment targets different from emmetropia (plano) in which the wavefront-calculated defocus (spherical term) has been adjusted; myopia greater than –12.0 D or astigmatism greater than 6 D; hyperopia greater than + 6.0 D or astigmatism greater than 5.0 D; mixed astigmatism greater than + 6.0 D; and in cylinder amounts > 4.0 to < 6.0 D. Due to the lack of large numbers of patients in the general population, there are few subjects with cylinder amounts in this range to be studied. Not all complications, adverse events, and levels of effectiveness may have been determined. Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see in such conditions as very dim light, rain, fog, snow and glare from bright lights. This has been shown to occur more frequently in the presence of residual refractive error and perhaps in patients with pupil sizes larger than the optical zone size. The refraction is determined in the spectacle plane, but treated in the corneal plane. In order to determine the right treatment program to achieve the right correction, assessment of the vertex distance during refraction testing is recommended. Preoperative evaluation for dry eyes should be performed. Patients should be advised of the potential for dry eyes post LASIK and post wavefront-guided LASIK surgery. This treatment can only be provided by a licensed healthcare professional.

Adverse Events and Complications for Myopia: Certain adverse events and complications occurred after the LASIK surgery. Two adverse events occurred during the postoperative period of the clinical study: 0.2% (2/876) had a lost, misplaced, or misaligned flap reported at the 1 month examination. The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment, corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of >1 mm.; epithelium of >1 mm.in the interface with loss of 2 lines or more of BSCVA; uncontrolled IOP rise with increase of >5 mmHg or any reading above 25 mmHg; retinal detachment or retinal vascular accident; and decrease in BSCVA of >10 letters not due to irregular astigmatism as shown by hard contact lens refraction. The following complications occurred 3 months after LASIK during this clinical trial: 0.8% (7/844) of eyes had a corneal epithelial defect; 0.1% (1/844) had any epithelium in the interface; 0.1% (1/844) had foreign body sensation; 0.2% (2/844) had pain; and 0.7% (6/844) had ghosting or double images in the operative eye. The following complications did NOT occur 3 months following LASIK in this clinical trial: corneal edema and need for lifting and/or reseating the flap/cap.

Adverse Events and Complications for Hyperopia: Certain adverse events and complications occurred after the LASIK surgery. Only one adverse event occurred during the clinical study: one eye (0.4%) had a retinal detachment or retinal vascular accident reported at the 3 month examination. The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment; lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month; corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of > 1 mm.; epithelium of > 1 mm.in the interface with loss of 2 lines or more of BSCVA; uncontrolled IOP rise with increase of > 5 mmHg or any reading above 25 mmHg and decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction. The following complications occurred 6 months after LASIK during this clinical trial: 0.8% (2/262) of eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface. The following complications did NOT occur 6 months following LASIK in this clinical trial: corneal edema; foreign body sensation; pain, ghosting or double images; and need for lifting and/or reseating of the flap/cap.

Adverse Events and Complications for Mixed Astigmatism: Certain adverse events and complications occurred after the LASIK surgery. No protocol defined adverse events occurred during the clinical study. However, two events occurred which were reported to the FDA as Adverse Events. The first event involved a patient who postoperatively was subject to blunt trauma to the treatment eye 6 days after surgery. The patient was found to have an intact globe with no rupture, inflammation or any dislodgement of the flap. The second event involved the treatment of an incorrect axis of astigmatism which required retreatment. The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment; corneal epithelial defect involving the keratectomy at 1 month or later; corneal edema at 1 month or later visible in the slit lamp exam; epithelium of > 1 mm.in the interface with loss of 2 lines or more of BSCVA; lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month; decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction; any complication leading to intraocular surgery; melting of the flap of > 1 mm.; uncontrolled IOP rise and retinal detachment or retinal vascular accident. None of the following complications occurred at 3 months after LASIK during this clinical trial: corneal edema; corneal epithelial defect; any epithelium in the interface; foreign body sensation, pain, ghosting or double images; and need for lifting and/or reseating of the flap/cap.