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 myopic 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 (MRESE) 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 -5.0 D had 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 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 postoperative visual acuity (UCVA) analysis of effectiveness at the 3-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 studies found 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 objects (30.1%), night driving glare (4.2%); light sensitivity (4.9%); visual fluctuations (8.1%); and halos (6.4%). Long term risks of LASIK for myopia with and without astigmatism beyond 12 months have not been studied.

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 had been studied in clinical trials in the United States with 901 eyes treated, of which 913 of 966 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 93.9%. The studies found that of the 844 eyes eligible for the UCVA analysis of effectiveness at the 3-month stability time point, 95.3% were corrected to 20/40 or better, and 67.6% were achieved acuity of 20/20 or better without spectacles or contact lenses. The studies found 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 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 had been studied in clinical trials in the United States with 111 eligible 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, 95.3% 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 12 months have not been studied.

Adverse Events: Certain adverse events and complications occurred after the LASIK surgery. No protocol defined adverse events occurred during the postoperative period of the clinical study. 2% (2/84) had a retinal detachment or retinal vascular accident 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 >1 mm; epithelium =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 irregual astigmatism as shown by hard contact lens refraction. The following complications occurred 6 months after LASIK during this clinical trial: 0.3% (2/22) 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.

Adverse Events and Complications for Myopia: Certain adverse events and complications occurred after the LASIK surgery. No protocol defined adverse events occurred during the clinical study. 0.3% (2/687) had a retinal detachment or retinal vascular accident reported at the 1 month examination. The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment, loss, 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 >1 mm; epithelium =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 irregual 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.

Adverse Events and Complications for Hyperopia: Certain adverse events and complications occurred after the LASIK surgery. No protocol defined adverse events occurred during the clinical study. 0.3% (2/687) had a retinal detachment or retinal vascular accident reported at the 1 month examination. The following adverse events did NOT occur: corneal infiltrate or ulcer requiring treatment, loss, 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 >1 mm; epithelium =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 irregual 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.