IFS® ADVANCED FEMTOSECOND LASER INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE IFS® ADVANCED FEMTOSECOND LASER INDICATIONS

The iFS® femtosecond laser is an ophthalmic surgical laser indicated for use in patients undergoing surgery or treatment requiring initial lamellar resection of the cornea, in treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments, in treatment requiring arcuate cuts/incisions in the cornea, penetrating and/or intrastromal, In lamellar IEK and corneal harvesting; in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the corneal, in the creation of a lamellar cut/resection of the cornea for lamellar IEK and for the creation of a penetrating cut/incision for penetrating IEK, in treatment requiring the creation of corneal channels for placement/insertion of a corneal inlay device.

CONTRAINDICATIONS

Lamellar resection for the creation of a corneal flap is contraindicated in the presence of corneal edema, corneal lesions, hypotony, glaucoma, existing corneal implant, or keratoconus. IEK procedures and arcuate incisions are contraindicated in the presence of any corneal opacity adequately dense to obscure visualization of the iris, descemetocele with impending corneal rupture, previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape, or corneal thickness requirements that are beyond the range of the system. Creation of corneal channels for placement/insertion of a corneal inlay device are contraindicated in the presence of any corneal opacity adequately dense to obscure visualization of the iris, descemetocele with impending corneal rupture, previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape, corneal thickness requirements that are beyond the range of the system, any previous incisional refractive corneal procedure, e.g. radial keratotomy, significant corneal neovascularization in the limbal area for a planned incision, previous history of corneal Herpes Simplex Keratitis, previous corneal transplant, any cataract, corneal edema, corneal lesions, hypotony, existing corneal implant, keratoconus or subjects with severe corneal thinning less than 450 microns.

PRECAUTIONS

A high level of surgical skill is required for these lasers. A surgeon should have successfully completed one or more training courses before attempting to create a corneal resection. The use of the iFS® Laser for IEK procedures or for arcuate incisions is not recommended for patients with severe corneal thinning, preexisting glaucoma, a history of steroid-responsive rise in intraocular pressure, preoperative intraocular pressure greater than 21 mm Hg in the operative eye, more than 1200 mm corneal thickness at the 9 mm peripheral zone, active intraocular inflammation, or active ocular infection or keratoconus. The use of the iFS® laser for creation of corneal channels for placement of a corneal inlay device is not recommended for patients with preexisting glaucoma, a history of steroid-responsive rise in intraocular pressure, preoperative intraocular pressure greater than 21 mm Hg in the operative eye, more than 1200 mm corneal thickness at the 9 mm peripheral zone, active intraocular inflammation, or active ocular infection or keratoconus.

ADVERSE EVENTS

Possible complications resulting from LASIK flap creation include corneal edema/inflammation, corneal pain, epithelial ingrowth, epithelial defect, infection, photophobia, flap decentration, incomplete flap creation, flap tearing or incomplete lift-off, free cap, inflammation (e.g., diffuse lamellar keratitis, corneal infiltrates, or iritis), thin or thick flaps, or flap striae. Transient light sensitivity syndrome (TLSS) and peripheral light spectrum (PLS) have been sporadically reported and may occur following LASIK flap creation. TLSS is characterized by symptoms of mild to severe light sensitivity that manifests between 2 and 6 weeks postoperatively. Patients experience no decrease in uncorrected or best spectacle-corrected visual acuity. The incidence of this sensitivity is observed in approximately 1% of patients who undergo flap creation with either laser. Patients respond to the use of hourly topical steroids and most report improvement within 1 week of treatment. PLS is a temporary phenomenon whereby patients report the perception of a spoke-like spectrum of light in the periphery of their vision. PLS has no clinical examination findings and no effect on visual acuity; however, the potential diffractive effects may be bothersome to some patients. Reported in only 0.03% of cases, the onset of symptoms occurs during the immediate postoperative period, and typically resolves within 3 months

but may be slightly persistent in rare cases. The visual impact of PLS is clinically inconsequential for the vast majority of patients. Arcuate incision complications include corneal edema/inflammation, corneal pain, epithelial ingrowth, epithelial defect, infection, photophobia or corneal endothelium perforation. Creation of corneal channel for placement of a corneal inlay device complications include corneal edema, corneal pain, epithelial ingrowth, epithelial defect, infection, implant de-centration, incomplete inlay channel creation, corneal tearing or incomplete inlay channel dissection, photophobia, corneal inflammation, such as diffuse lamellar keratisis (DLK), corneal infiltrates, and iritis, and inlay channel bleeding.

WARNINGS

Check all treatment parameters for accuracy. The posterior depth should be programmed at least 125 microns above the corneal endothelium. Use of these laser systems allows laser surgical incisions up to 1200 µm deep. Setting the posterior depth too deep could result in injury to other ocular structures. Use caution when setting cut position and cut angle to avoid overlapping arcuate incisions. The applanation lens becomes etched by the laser during the side-cut procedures and must not be reused. Laser light will not effectively permeate an etched lens, and the precision of the laser will be altered. Patient interface disposables should not be reused or resterilized.

CAUTION

U.S. Federal law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner who has been trained in the calibration and operation of this device.