Laser refractive surgery (LASIK) is a common procedure to treat nearsightedness, farsightedness and astigmatism. With LASIK, patients can achieve 20/20 vision – or better.¹ LASIK reshapes the cornea, the eye’s outermost layer, to bend light rays to focus on the retina, reducing an individual’s dependence on eye glasses or contact lenses.¹ Johnson & Johnson Vision’s LASIK platform is an industry leader, and through its evolution for the last 25 years, 37 percent of U.S. procedures have been performed on their LASIK devices.²

How It Works

**Step 1**

Prior to the LASIK procedure, the iDesign® Advanced WaveScan Studio System creates a 3-D map of the eye to measure imperfections.³ The iDesign® System is 25 times more precise than methods used for glasses or contact lenses.⁴*

The iDesign® System uses the same technology NASA used to calibrate the lenses of its new space telescope.⁶

**Step 2**

Once the eye’s imperfections have been identified, advanced laser technology is used to improve the shape or curvature of the eye’s cornea.³ Two lasers work together to deliver excellent quality of vision:

- A femtosecond laser is used to create a circular, hinged flap in the cornea, which allows the surgeon access to the tissue affecting the eye’s shape.¹
  - **iFS® Advanced Femtosecond Laser:** Each pulse of a femtosecond laser lasts 600–800 femtoseconds.⁷ The femtosecond laser can take less than 12 seconds per eye.⁸
- A highly specialized excimer laser then uses ultraviolet light to remove corneal abnormalities, effectively reshaping the eye to refocus light on the retina.¹
  - **Star S4 IR® Excimer Laser:** The excimer laser is so precise that each correction is about 0.25 microns of depth.⁶ The excimer laser takes about 1-2 minutes per eye.⁶

| THE iDESIGN® SYSTEM SENSOR HAS
| 5x better resolution than current systems (when measuring an average 7 mm pupil).⁵ |
| # of iDesign® System Measurements |
| # of WaveScan® WaveFront System Measurements (current system) |
| 1,257 | 240 |

- A femtosecond is one trillion times faster than the time it takes a housefly to flap its wings once.⁶
- One micron is 1,000 times smaller than a grain of sand.⁶

* A phoropter is used for vision correction and measures errors in 0.25 diopter increments. Wavefront measurements are in 0.01 diopter increments, making it 25x more accurate. These precise corrections are applied to the right spots on the cornea according to correction needed.

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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, or 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.

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ADVERSE EVENTS: Possible complications resulting from LASIK flap creation include corneal edema/inflammation, corneal pain, epithelial ingrowth, epithelial defect, infection, photophobia, flap decenteration, 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 (TLS) and peripheral light spectrum (PLS) have been sporadically reported and may occur following LASIK flap creation. TLS 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 disruptive 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 keratitis (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 re-sterilized.