Johnson & Johnson VISION

LASIK

Fast Facts

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]

83% of nearsighted eyes experience **20/20 vision** or better **6 months** post-treatment [3]

92% of astigmatic eyes experience **20/20 vision** or better **3 months** post-treatment[3]

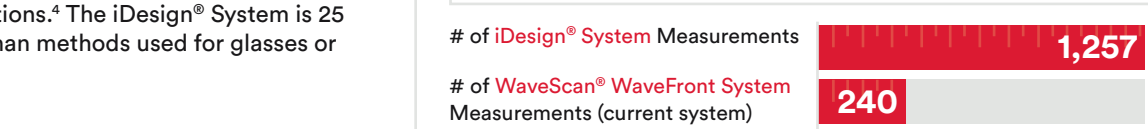
How It Works

Step 1

Prior to the LASIK procedure, the iDesign® Advanced WaveScan Studio System creates a 3-D map of the eye to measure imperfections.[4] The iDesign® System is 25 times more precise than methods used for glasses or contact lenses.[5]*

THE iDESIGN® SYSTEM SENSOR HAS

5x better resolution than current systems (when measuring an average 7 mm pupil).[5]



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

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]

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.[1] 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]

*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

[1]The LASIK Procedure: A Complete Guide. All About Vision. http://www.allaboutvision.com/visionsurgery/lasik.htm. [2]2016 Market Scope - 2016 Refractive Surgery Report: A Global Market Analysis for 2015 to 2021. [3]Clinical studies submitted to FDA via P930016 supplements 044 and 045 [4]Surgical Vision Business Overview. [5]Surgical, iDESIGN® System. Johnson & Johnson Vision. https://surgical.jnjvision.com/us/systems/lasik/idesign-wavescan-studio-system.html. [6]Facts About LASIK. Ophthalmology Associates of the Valley. http://draizuss.com/facts-about-lasik. [7]iFS Femtosecond Laser Specifications for Site Preparation/Installation. Johnson & Johnson Vision. https://surgical.jnjvision.com/content/dam/bss/divisionalsites/jnj_vision/systems/lasik/ifs_femtosecond_laser/pdfs/iFS_Femtosecond_Laser_Specs.pdf. [8]Surgical, iFS® Advanced Femtosecond Laser. Johnson & Johnson Vision. https://surgical.jnjvision.com/us/systems/lasik/ifs-advanced-femtosecond-laser.html.

See product indications and important safety information on page 2.

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Indications and Important Safety Information

Star S4 IR® Laser And iDesign® Advanced Wavescan® Studio System

INDICATIONS: The **STAR S4 IR®** Excimer Laser and the **iDESIGN®** System is indicated for wavefront-guided LASIK in patients with myopia as measured by the **iDESIGN®** System up to -11.00 D SE, with up to -5.00 D cylinder; in patients with hyperopia with or without astigmatism as measured by the **iDESIGN®** System up to +4.00 D SE, with up to +2.00 D cylinder; and in patients with mixed astigmatism as measured by the **iDESIGN®** System where the magnitude of the cylinder (1.0 D to 5.0 D) is greater than the magnitude of the sphere, and the cylinder and sphere have opposite signs; with agreement between manifest refraction (adjusted for optical infinity) and the **iDESIGN®** System refraction of 1) SE: magnitude of the difference is < 0.625 D, and 2) cylinder: magnitude of the difference is ≤ 0.5 D; with patients 18 years of age and older, and with refractive stability (a change of ≤ 1.0 D in sphere or cylinder for a minimum of 12 months prior to surgery).

CONTRAINDICATIONS: Laser refractive surgery is contraindicated for: patients with collagen vascular, autoimmune, or immunodeficiency diseases, pregnant or nursing women, patients with signs of corneal abnormalities including signs of keratoconus, abnormal corneal topography, epithelial basement membrane disease (EBMD) and degenerations of the structure of the cornea, patients with symptoms of significant dry eyes, patients whose corneal thickness would cause the anticipated treatment to violate the posterior 250 microns (µm) of corneal stroma, and in patients with advanced glaucoma, and uncontrolled diabetes. If the patients have severely dry eyes, LASIK may increase the dryness; this may or may not go away. Severe eye dryness may delay healing of the flap or interfere with the surface of the eye after surgery; it may result in poor vision after LASIK.

WARNINGS AND PRECAUTIONS: LASIK is not recommended in patients who: have systemic diseases likely to affect wound healing, such as autoimmune connective tissue disease, diabetes or an immunocompromised status, have a history of Herpes simplex or Herpes zoster keratitis, have severe allergies or tendency rub their eyes often, have glaucoma, elevated IOP, ocular hypertension or being followed for possible glaucoma (glaucoma suspect), are taking the medication Isotretinoin (Accutane®), are taking antimetabolites for any medical conditions. The safety and effectiveness of this laser for LASIK correction have NOT been established in patients: with progressive refractive errors, ocular disease, corneal abnormality, previous corneal or intraocular surgery, or trauma in the ablation zone, who are taking the medication Sumatriptan (Imitrex®), or Amiodarone hydrochloride (Cordarone®), with corneal neovascularization within 1.0 mm of the ablation zone, over the long term (more than 1 year after surgery for myopia and more than 2 years for mixed astigmatism), for patients who engage in activities that could endanger or damage the LASIK flap, for patients who have a family history of degenerative corneal disease, history of inflammation of the eye, for patients who have a history of crossed eyes (strabismus) or who have undergone strabismus surgery, prior LASIK or Refractive Surgery, with history of any eye diseases or abnormalities such as corneal scars or active disease, and whose BSCVA is worse than 20/20. To reduce the risk of corneal ectasia, the posterior 250 microns (µm) of corneal stroma should not be violated. The treatment of highly myopic eyes necessitates the removal of significant amounts of corneal tissue. The **iDESIGN®** System calculates the estimated residual bed depth using the pachymetry and intended flap thickness entered by the user. Actual flap thicknesses may vary. If the estimated residual stromal bed is ≤ 320 microns, an in-the-bed pachymetric measurement should be performed.

ADVERSE EVENTS: Possible adverse events include loss of best spectacle corrected visual acuity (BSCVA), serious Transient Light Sensitivity Syndrome, serious primary open angle glaucoma, miscreated flap, melting of the flap, severe glare, and severe dry eyes. Complications can include corneal edema, epithelial ingrowth, diffuse lamellar keratitis, foreign body sensation, and pain.

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 re-sterilized.