

iDesign
Refractive Studio



CREATING VISION
CORRECTION
as Unique as You

Johnson & Johnson VISION

Our focus. Your vision.

A personalized laser vision correction available.

Vision is more than just seeing better or farther. Vision is about being surrounded in detail. Immersed in each moment. Captivated by every part, of everything.

The **iDESIGN**[®] Refractive Studio gives your doctor the ability to deliver a truly personalized LASIK procedure, one designed specifically for you.

When you choose the **iDESIGN**[®] Procedure, you're choosing a procedure that offers:

- **25 times more precision than conventional measurements***
- **One-of-a-kind custom laser vision correction**
- **20/16 or better vision for the majority of myopic patients¹**

*Based on mathematical calculation:
wavefront aberrometer = 0.01 D.
Manifest refraction = 0.25 D.

Manifest 0.25 ÷ wavefront
aberrometer 0.01 = 25.
25X more precise.





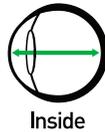
A Difference You Can Truly See

MEASUREMENT

Your vision is complex. It relies on multiple, interconnected parts of your eye to create what you see. That's what makes the **iDESIGN®** Refractive Studio so personalized: **The system measures both inside and out.**



- **Wavefront analysis** measures how light travels inside your eye and creates what you see, detailing the imperfections in your vision
- **Corneal topography** scans the outside surface of your eye, measuring and analyzing every tiny variation in curvature and elevation to help guide the laser during your treatment



These two measurements together create a completely personalized treatment plan.

VISION CORRECTION



Your **Personalized Measurement and Analysis**

The **iDESIGN®** System takes over 1,200 measurements of your eye and maps each data point to create a custom procedure plan designed just for you — all in only three seconds.



Your **One-of-a-Kind Procedure**

Using this custom procedure plan, the laser is able to correct your vision to your exact needs in only a few minutes. No one in the world will receive the same procedure.



Your **New Vision**

Once the procedure is over, you'll immediately notice the difference. After one hour, you'll begin to see more clearly, and within a day, you can return to your normal routine.



VISION IS WHO WE ARE

Johnson & Johnson Vision is the leading provider of laser vision correction technologies, committed to helping people like you reshape your sight and restore your vision so you can live without the hassle of glasses and contacts.

INDICATIONS AND IMPORTANT SAFETY INFORMATION for the **STAR S4 IR®** Excimer Laser System and the **iDESIGN®** Refractive Studio Wavefront-Guided LASIK & Monovision LASIK Treatments **INDICATIONS:** The **STAR S4 IR®** Excimer Laser System and the **iDESIGN®** Refractive Studio is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) to achieve monovision by the targeted retention of myopia (-1.25 to -2.00 D) in the non-dominant eye of presbyopic myopes: 40 years or older who may benefit from increased spectacle independence across a range of distances with useful near vision, with myopic astigmatism, up to -6.00 D spherical equivalent as measured by **iDESIGN®** Refractive Studio, with cylinder up to -3.00 D, and a minimum pre-operative myopia in their non-dominant eye at least as great as their targeted myopia; with an agreement between manifest refraction (adjusted for optical infinity) and **iDESIGN®** Refractive Studio refraction as follows: Spherical equivalent: Magnitude of the difference is less than 0.625 D; Cylinder: Magnitude of the difference is less than or equal to 0.50 D; Cylinder Axis: If either the manifest cylinder entered into the **iDESIGN®** Refractive Studio or the **iDESIGN®** Refractive Studio cylinder selected for treatment is less than 0.50 D, there is no requirement for axis tolerance. When both cylinders have a magnitude of at least 0.50 D, the axis tolerance is linearly reduced from 15° (0.5 D) to 7.5° (7.0 D or greater) based on the average magnitude of both cylinders. With documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination; and with a successful preoperative trial of monovision or history of monovision experience. The **STAR S4 IR®** Excimer Laser System and **iDESIGN®** **Advanced WaveScan Studio** System/**iDESIGN®** Refractive Studio is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) in patients: With hyperopia with and without astigmatism as measured by **iDESIGN®** **Advanced WaveScan Studio** System/**iDESIGN®** Refractive Studio up to +4.00 D spherical equivalent, with up to 2.00 D cylinder; with mixed astigmatism as measured by **iDESIGN®** **Advanced WaveScan Studio** System/**iDESIGN®** Refractive Studio where the magnitude of cylinder (1.0 D to 5.0 D) is greater than the magnitude of sphere, and the cylinder and sphere have opposite signs; with myopia as measured by **iDESIGN®** **Advanced WaveScan Studio** System/**iDESIGN®** Refractive Studio up to -11.00 D spherical equivalent, with up to -5.00 D cylinder; with agreement between manifest refraction (adjusted for optical infinity) and **iDESIGN®** **Advanced WaveScan Studio** System/**iDESIGN®** Refractive Studio refraction as follows: Spherical Equivalent: Magnitude of the difference is less than 0.625 D; Cylinder: Magnitude of the difference is less than or equal to 0.5 D; 18 years of age or 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:** Wavefront-guided LASIK surgery is contraindicated in patients with collagen vascular, autoimmune or immunodeficiency diseases; in pregnant or nursing women; in patients with corneal abnormalities including signs of keratoconus, abnormal corneal topography, epithelial basement membrane disease (EBMD) and degenerations of the structure of the cornea; in patients with symptoms of significant dry eyes. 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. In patients whose corneal thickness would cause anticipated treatment would violate the posterior 250 microns (μm) of corneal stroma; in patients with advanced glaucoma; in patients with uncontrolled diabetes; in patients with documented evidence of a change in manifest refraction of more than +0.5 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination. in patients taking medications with ocular side effects. Examples are Isotretinoin (Accutane®) for acne treatment or Amiodarone hydrochloride (Cordarone®) for normalizing heart rhythm. **WARNINGS AND PRECAUTIONS:** Wavefront-guided 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. To reduce the risk of corneal ectasia, the posterior 250 microns (μm) of corneal stroma should not be violated. Please refer to Operator's Manual for a list of additional Precautions. **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. **ADVERSE EVENTS:** Prior clinical study of monovision LASIK using the WaveScan WaveFront® System aberrometer, supports the safety and effectiveness of **iDESIGN®** driven Monovision LASIK Treatment. Please refer to Operator's Manual for a list of Adverse Events and complications in clinical studies for Wavefront-guided Monovision in Presbyopic Patients with Low to Moderate Myopia and Wavefront-guided Myopic Astigmatism, Myopia, Mixed Astigmatism and Hyperopia.

STAR S4 IR® Excimer Laser System and the **iDESIGN®** Refractive Studio

INDICATIONS AND IMPORTANT SAFETY INFORMATION for the **STAR S4 IR®** Excimer Laser System and the **iDESIGN®** Refractive Studio for Wavefront-Guided Photorefractive Keratectomy (PRK)

INDICATIONS: The **STAR S4 IR®** Excimer Laser System and the **iDESIGN®** Refractive Studio is indicated for wavefront-guided photorefractive keratectomy (PRK) in patients: with myopia, with or without astigmatism, as measured by **iDESIGN®** Refractive Studio System with spherical equivalent up to -8.00 D, and cylinder up to -3.00 D, with agreement between manifest refraction (adjusted for optical infinity) and **iDESIGN®** Refractive Studio System refraction as follows: Spherical Equivalent: Magnitude of the difference is less than 0.625 D, Cylinder: Magnitude of the difference is less than or equal to 0.5 D, in patients 18 years of age or older; with refractive stability (a change of ≤ 1.0 D in manifest refraction spherical equivalent for a minimum of 12 months prior to surgery), and with wavefront capture diameter of at least 4 mm.



Your LASIK can
**BE A TRUE
 ORIGINAL**

CONTRAINDICATIONS: iDESIGN® System driven PRK surgery is contraindicated in patients with any type of active connective tissue disease or autoimmune disease, in patients with signs of keratoconus, abnormal corneal topography, and degenerations of the structure of the cornea, in patients whose corneal thickness would cause anticipated treatment would violate the posterior 250 microns (µm) of corneal stroma, in patients with uncontrolled diabetes, in patients with active eye infection or active inflammation, in patients with recent herpes eye infection or problems resulting from past infection, in patients with significant dry eyes. If the patients have severely dry eyes, PRK may increase the dryness. This may or may not go away. Severe eye dryness may delay healing or interfere with the surface of the eye after surgery. It may result in poor vision after PRK. **WARNINGS AND PRECAUTIONS:** iDESIGN® System driven PRK surgery is not recommended in patients have systemic diseases that may affect wound healing, such as controlled autoimmune, or connective tissue disease, or controlled diabetes, have an immunocompromised status or take medications that may result in a weakened immune system such as antimetabolites for any medical conditions or affect wound healing such as Isotretinoin (Accutane), have a history of Herpes simplex or Herpes zoster keratitis, have glaucoma, In patients with a cardiac pacemaker, implanted defibrillator or other implanted electronic device, have mild to moderate dry eye, have decreased vision in one eye (e.g., amblyopia). Surgeons are reminded that they should instruct the patient to fixate on the Patient Fixation LED during surgery with or without the use of the ActiveTrak System. Please refer to Operator's Manual for a list of additional Precautions. **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. **ADVERSE EVENTS:** Please refer to Operator's Manual for a list of Adverse Events and Complications in clinical studies for wavefront-guided PRK Patients with Myopia and Myopic Astigmatism.

1. FDA Study- P930016/S044.

CAUTION
 CLASS 4 INVISIBLE LASER RADIATION WHEN OPEN
 AND INTERLOCK DEFEATED. AVOID EYE OR SKIN
 EXPOSURE TO DIRECT OR SCATTERED RADIATION.
 MISE EN GARDE
 ÉMISSION DE RAYONNEMENT LASER INVISIBLE DE
 CLASSE 4 EN CAS D'OUVERTURE OU DE
 VERROUILLAGE DÉFECTUEUX. ÉVITEZ
 L'EXPOSITION DES YEUX OU DE LA PEAU À UN
 RAYONNEMENT DIRECT OU DIFFUSÉ.
93001621 Rev. A



Ask your doctor about how you can get
 clear vision with a customized iDESIGN®
 Procedure today.