INDICATIONS: The STAR S4 IR® Excimer Laser System and iDESIGN® Advanced WaveScan Studio (iDESIGN®) System is indicated for wavefront-guided LASIK in patients with myopia as measured by iDESIGN® System up to -11.00 D SE, with up to -5.00 D cylinder and in patients with mixed astigmatism as measured by 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 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).
MORE BRAIN POWER IN YOUR SURGERY

5 MEASUREMENTS IN 1 CAPTURE SEQUENCE

1. Wavefront aberrometry
2. Wavefront refraction
3. Corneal topography
4. Keratometry
5. Pupillometry

EASY-TO-USE INTERFACE WITH ALIGNMENT AIDS AND ON-SCREEN TOOLS SEAMLESSLY INTEGRATES WITH THE STAR S4 IR® EXCIMER LASER

Screen is a simulated image
5X THE RESOLUTION WITH A HIGH-DEFINITION HARTMANN-SHACK WAVEFRONT SENSOR*

Offering outstanding accuracy and ability to measure complex wavefronts

- Up to 1,257 micro-refractions over a 7 mm pupil
- 3X the dynamic range*
- Captures more ocular aberrations unique to every eye*

*As compared to the Hartmann-Shack sensor in the *WaveScan WaveFront®* System.
“The iDESIGN® System gives us a mechanism to capture the entire wavefront in our LASIK patients. It really hits the target in terms of astigmatism and then allows that to be translated to the patient’s treatment plan and results.”

–JAY S. PEPOSE, MD
U.S.
MORE PATIENT POWER IN YOUR PRACTICE

Approved to treat patients 18 Years and older

Capture wide range of pupil sizes 4.0–9.5 MM
In a clinical trial, myopic patients reported significant improvements in all measures of visual functioning and well-being 6 months postoperatively, including:

- **Clarity of Vision**: 83% of myopia (with and without astigmatism) eyes at 6 months had 20/20 or better vision,
- **Satisfaction with Correction**: Up to -5 D Cylinder,
- **Near Vision**: 20/20 or better for up to 92% of mixed astigmatism eyes at 3 months,
- **Far Vision**: 1.0—5.0 D,
- **Activity Limitations**: Driving at Night,
- **Difficulty**: Where the magnitude of cylinder is greater than the magnitude of sphere, and the cylinder and sphere have opposite signs.

*Similar patient reported results seen in the clinical trial for mixed astigmatism.*

**REFERENCE:**
“Clinical study in mixed astigmatism patients demonstrated refractive stability for patients at 3 months post-operative and no adjustments were needed for the complex correction, proving an accurate algorithm from the iDESIGN® System.”

—ROBERT MALONEY, MD
POWERING A NEW ERA IN LASIK

Dedicated to helping your practice succeed in today’s market with comprehensive support and expertise

- **Business Development**
  - In-person and online education — practice-building tools and patient-marketing initiatives
  - Diagnosis and solutions to elevate practice performance

- **Clinical Training**
  - On-site surgeon and technician training and support to help improve outcomes by maximizing team skills
  - Highly skilled application support team and renowned medical monitors — ongoing clinical consultation and analysis to enhance patient outcomes

- **Field Service Support**
  - Multiple service plans to meet your practice needs — so you can be confident in your system’s performance
  - 10-time recipient of the Omega Management Group’s Annual NorthFace ScoreBoard Award for consistently exceeding customer expectations
MAKE THE iDESIGN® SYSTEM YOUR SMARTEST CHOICE
Contact your Sales Representative today
Product Description

The iDESIGN® Advanced WaveScan Studio (iDESIGN®) System measures the wavefront of the eye within a defined range using the Hartmann-Shack sensor. The sensor evaluates the deflection of rays emanating from a small beam of light projected onto the retina. The measurements determine regular (sphero-cylindrical) refractive errors and irregularities (aberrations) that cause reduced visual function. Laser vision-correction treatments can be calculated using measurements obtained from the iDESIGN® System. Two sets of laser instructions can be generated: one for PreVue (Expert Mode only) plastic lenses and the other for the patient procedure. In addition, the iDESIGN® System can measure and display corneal topography, pupil size, and keratometry.
Recommended Room Requirements

- Do not place the unit near windows or in a room that cannot be sufficiently darkened to allow the patient’s eyes to dilate naturally
- Ambient operational temperature range: 60°F–80°F (15°C–27°C)
- Humidity: Relative humidity no less than 35% and no greater than 65% (noncondensing)
- Barometric pressure range: 11–16 psi (76–110 kPa)

Storing Requirements Before Installation

When storing the iDESIGN® System before installation, adhere to the following site requirements:
- Storage temperature must be between 41 and 104°F (between 5 and 40°C) at a relative humidity of 35 to 65% (noncondensing)

System Specifications

- Optical Head
  - Physical dimensions: (L, W, H): 20”, 18”, 27”, (50.8 cm, 45.7 cm, 68.6 cm), including base
  - Weight: 80 lbs (36 kg)
  - Enclosure construction: Aluminum and plastic
Motorized Table
- Physical dimensions: (L, W, H) 52.5”, 28.3”, 31.9”–46.7” (min.–max.), (133.4 cm, 71.8 cm, 81.0–118.6 cm)
- Weight: 149 lbs (68 kg)
- Electrical ratings are 120 V, 50/60 Hz, 6 A
- Vertical position is controlled by a rocker control switch (vertical height can range from 630 to 1,030 mm)
- Tabletop supports iDESIGN® System and USB v2.0 keyboard
- Shelves hold printer and isolation transformer

High-resolution color printer included

Medical-Grade Isolation Transformer
- Input: 100/120/220/240 VAC at 50/60 Hz
- Power: 750 VA
- Complies with IEC 60601-1 regulations. All power cords connect to the isolation transformer

Measurable Range: Sphere and Cylinder measurements in 0.01 D increments. Spherical equivalent range (6 mm pupil) -16 to +12 D. Cylinder range (6 mm pupil) 8 D.
- Axis in 1° increments
- Pupil measurements 2.0 to 9.5 mm, with 0.1 mm resolution
- Maximum wavefront diameter 8.5 mm
- Zernike terms displayed through the sixth order
**System Specifications Cont.**

- Measurement spatial resolution 0.177 mm (approximately 1250 measurement points for a 7 mm pupil)
- Integrated corneal topographer 37 x 37 spot measurement grid
- Topographer grid extent (X and Y) ±4.1 mm for eye with 8 mm radius of curvature
- Illumination ranging from 535 to 940 nm

**Hardware Components**

The **iDESIGN®** System includes, a built-in power supply, computer, and monitor. The computer central processing unit (CPU) is housed inside the **iDESIGN®** System. The USB port is located on the right-hand side of the computer case. The computer keyboard and built-in glidepad are integrated into the table. A USB mouse can also be connected to the system based on user preference.
IMPORTANT SAFETY INFORMATION

ATTENTION: Reference the Operator’s Manual for a complete listing of Indications and Important Safety Information.

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 (\( \mu m \)) 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\(^\text{a} \)), 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\(^\text{c} \)), or Amiodarone hydrochloride (Cordarone\(^\text{c} \)), 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 (\( \mu m \)) of corneal stroma should not be violated. The treatment of highly myopic eyes necessitates the removal of significant amounts of corneal tissue. The iDESIGN\(^\text{c} \) 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 \( \leq 320 \) 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.

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.

REFERENCE: iDESIGN\(^\text{c} \) System Operator’s Manual 0110-0624 Rev. B

STAR S4 IR\(^\text{c} \) LASER LABEL

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