Laser assisted in-situ keratomileusis (LASIK) can only be performed by a trained ophthalmologist and for specified reduction or elimination of myopia, hyperopia, and astigmatism as indicated with product labeling. For important safety information, tap here.
PROVEN WAVEFRONT-GUIDED TECHNOLOGY

**STAR S4 IR®** Laser delivers precise levels of ablation accuracy driven by market leading wavefront-guided technology

- **Fourier Algorithm** technology delivers the most accurate reconstruction of the patient’s wavefront
  - Fourier shape is derived from 100% of available Hartmann-Shack data points

“The **STAR S4 IR®** Laser is a device that has been consistent, reliable, and produces excellent outcomes.”

—MARK KONTOS, MD
PROVEN WAVEFRONT-GUIDED TECHNOLOGY

• Exclusive **Iris Registration** technology provides alignment accuracy and precise ablation placement

  • First fully automated, non-contact method of aligning treatment, replacing manual, ink-based methods

  • Centers treatment correctly, independent of changes in pupil center from measurement to treatment

  • Allows for instant re-registration in the event of intraoperative cyclotorsional movement

Aligns treatment on the cornea and provides greater alignment accuracy
PROVEN WAVEFRONT-GUIDED TECHNOLOGY

**Variable Repetition Rate (VRR)** technology varies the laser’s pulse rate
- Delivers Fourier reconstructed shapes with optimized ablation time
- Minimizes thermal impact on the cornea

**Variable Spot Scanning (VSS)** technology incorporates a sophisticated array of laser pulse diameters ranging from 0.65 mm to 6.50 mm
- Ensures an accurate match between target and ablation shapes
- Optimizes treatment times and efficiency

**ActiveTrak 3-D Active Eye Tracking** technology allows the laser’s infrared cameras to actively follow the tiniest motions of the eye in all three dimensions
- Capturing more than 99.4% of eye movements

**ActiveTrak Automatic Centering** technology locates and automatically sets the treatment center to the center of the pupil

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**VSS SIMULATION RESULTS**

This theoretical simulation of VSS Technology, when compared to the alternative Single Spot Scanning (SSS) ablation, shows improved precision and accuracy, or decreased fitting error, across the above ablation profiles.
**PROVEN RESULTS**

In a **STAR S4 IR®** Excimer Laser and **iDESIGN®** System wavefront-guided clinical study, at six months after surgery, myopic patients reported significant improvements in ALL measures of quality of vision and visual function (without retreatment)\(^2\)

- 99% had little to no difficult participating in their active sports or outdoor activities\(^2\)
- 99% experienced little or no difficulty with the clarity of their vision\(^2\)
- 97% were satisfied with their vision\(^2\)
- 93% had little to no difficulty driving at night\(^2\)
- ~90% of patients had improvements or no change in contrast sensitivity in all lighting conditions\(^2\)
- Majority of study participants achieved 20/16 or better visual acuity\(^3\)

**INDICATIONS:** The **STAR S4 IR®** Excimer Laser System and **iDESIGN® Advanced WaveScan Studio** System are indicated for wavefront-guided laser-assisted in situ keratomileusis (LASIK) in patients with myopia as measured by **iDESIGN®** System 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®** System refraction of 1) spherical equivalent: magnitude of the difference is less than 0.625 D, and 2) cylinder: magnitude of the difference is less than or equal to 0.5 D; with patients 18 years of age or older, and with refractive stability (a change of \(\pm 1.0\) D in sphere or cylinder for a minimum of 12 months prior to surgery).
**PROVEN VERSATILITY**

The *STAR S4 IR®* offers you a solution to treat a broad range of patients

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Refractive Error</th>
<th>Approved Treatment Range</th>
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<tr>
<td><strong>iDESIGN® System</strong></td>
<td>Myopia</td>
<td>Up to -11.0 D with or without astigmatism up to -5 DC (patients 18 years and older)</td>
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<tr>
<td>Wavefront-guided LASIK</td>
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<td>Hyperopia up to +3.0 D MRSE with or without astigmatism up to +2 DC (patients 21 years and older)</td>
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<td></td>
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<td>Mixed Astigmatism from 1.0 to 5.0 DC, cylinder &gt; sphere, and of opposite signs (patients 21 years and older)</td>
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<tr>
<td>Conventional LASIK</td>
<td>Myopia</td>
<td>Up to -14.0 D with or without astigmatism from 0.5 to 5.0 DC (patients 18 years and older)</td>
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<td></td>
<td>Hyperopia</td>
<td>From +0.5 to +5.0 DS with or without astigmatism up to +3 DC, with a maximum MRSE of +6.0 D (patients 21 years and older)</td>
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<tr>
<td></td>
<td>Mixed Astigmatism</td>
<td>Up to 6.0 DC, cylinder &gt; sphere, and of opposite signs (patients 21 years and older)</td>
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<tr>
<td>Conventional PRK</td>
<td>Myopia</td>
<td>No more than -6.0 D with no more than 1.0 D of refractive astigmatism (patients 18 years and older)</td>
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<tr>
<td></td>
<td></td>
<td>No more than -12.0 D, with no more than 4.0 D of refractive astigmatism (patients 21 years and older)</td>
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<tr>
<td></td>
<td>Hyperopia</td>
<td>Between +1.0 and +6.0 D, with no more than 1.0 D of refractive astigmatism (patients 21 years and older)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Between +0.5 and +5.0 D with refractive astigmatism from +0.5 to +4.0 D with a maximum MRSE of +6.0 D (patients 21 years and older)</td>
</tr>
</tbody>
</table>
COMMITTED TO YOUR PRACTICE SUCCESS

Sharing expertise and support from the proven leader

BUSINESS DEVELOPMENT

• In person and online education-practice-building tools and patient marketing initiatives
• Diagnosis and solutions to elevate practice performance

APPLICATION SUPPORT

• 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
IMPORTANT SAFETY INFORMATION:

INDICATIONS FOR USE

The **STAR S4 IR®** Excimer Laser and **iDESIGN® Advanced WaveScan Studio** (iDESIGN®) System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) in patients: with myopia as measured by iDESIGN® System 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® 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; 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).

The **STAR S4 IR®** Excimer Laser System with **Variable Spot Scanning (VSS)** and the **WaveScan WaveFront®** System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK): for the reduction or elimination of myopia and myopic astigmatism from -6.00 to -11.00 D MRSE, with cylinder between 0.00 and -3.00 D; in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 1.0 D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination. For the reduction or elimination of myopia and myopic astigmatism up to -6.00 D MRSE, with cylinder between 0.00 and -3.00 D; in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 0.50D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination. For the reduction or elimination of hyperopia and hyperopic astigmatism up to 3.00 D MRSE, with cylinder between 0.00 and 2.00 D; in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 1.0 D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination. For the reduction or elimination of naturally occurring mixed astigmatism when the magnitude of cylinder (from 1 to 5.0 D) is greater than the magnitude of sphere, and the cylinder and sphere have opposite signs; in patients 21 years of age or older; and in patients with documented
IMPORTANT SAFETY INFORMATION (CONTINUED):

evidence of a change in manifest refraction of no more than 0.5 D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination.

Laser assisted in situ keratomileusis (LASIK) procedure using the STAR S4 IR® Excimer Laser System is intended for use: in patients with documented evidence of a change in manifest refraction of no more than 0.5 D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination; and in patients 18 years of age or older in treatments for the reduction or elimination of myopia (nearsightedness) of no more than -14.0 D with or without refractive astigmatism from 0.5 to 5.0D*; or in patients 21 years of age or older in treatments for the reduction or elimination of naturally occurring hyperopia between +0.5 and +5.0 D sphere at the spectacle plane with or without refractive astigmatism up to +3.0 D, with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D. In patients 21 years of age or older in treatments for the reduction or elimination of naturally occurring mixed astigmatism where the magnitude of cylinder ($\leq$6.0 D at the spectacle plane) is greater than the magnitude of sphere and the cylinder and sphere have opposite signs.

Photorefractive Keratectomy (PRK) procedure using the STAR S4 IR® System is intended for use: in patients with documented evidence of a change in manifest refraction of no more than 0.5 D (in both cylinder and sphere components) for at least one year prior to the date of preoperative examination; and in patients 18 years of age or older in treatments for the reduction or elimination of myopia (nearsightedness) of no more than -6.0 D spherical equivalent at the corneal plane, with no more than 1.0 D of refractive astigmatism; or in patients 21 years of age or older in treatments for the reduction or elimination of myopia (nearsightedness) of no more than -12.0 D spherical myopia at the spectacle plane with no more than 4.0 D of refractive astigmatism; or in patients 21 years of age or older in treatments for the reduction or elimination of naturally occurring hyperopia between +1.0 and +6.0 D sphere at the spectacle plane, with no more than 1.0 D of refractive
IMPORTANT SAFETY INFORMATION (CONTINUED):

astigmatism; or in patients 21 years of age or older in treatments for the reduction or elimination of naturally occurring hyperopia between +0.5 and +5.0 D sphere at the spectacle plane with refractive astigmatism from +0.5 to +4.0 D with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D.

CONTRAINDICATIONS
Laser refractive 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.

WARNINGS
LASIK is not recommended in patients who: have systemic diseases likely to affect wound healing, such as autoimmune connective tissue disease, diabetes or an immune compromised status; have a history of Herpes simplex or Herpes zoster keratitis; have severe allergies or tendency to 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; lower uncorrected visual acuity may be anticipated in the PRK treatment of higher degrees of myopia with and without astigmatism (>−5.0 D MRSE).

PRECAUTIONS
Preoperative pachymetry measurement must be performed. To reduce the risk
IMPORTANT SAFETY INFORMATION (CONTINUED):

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.

There is no safety and effectiveness information for LASIK refractive treatments greater than -14 D of myopia or greater than 5.0 D of refractive astigmatism. Long-term risks of wavefront-guided LASIK beyond 12 months have not been studied. It is possible, after wavefront-guided LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes or decentered pupils. Dry eye may develop post-surgery.

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

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.

REFERENCES:
3. Clinical studies submitted to FDA via P930016 supplement 044.