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

The **STAR S4 IR** Laser delivers precise levels of ablation accuracy driven by the market-leading **iDESIGN** System’s wavefront-guided technology.

Patient benefits include an advanced, high-definition method of measurement for a 100% personalized vision treatment plan.

- Clearer and sharper vision\(^1\)*
- Little to no difficulty driving at night\(^1\)
- Easily participate in active sports or outdoor activities\(^1\)
- High satisfaction with their vision\(^1\)

*Clearer vision than may be possible with glasses or contacts.

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

—MARK KONTOS, MD
Errors are not limited to spherical and astigmatic errors; they also include the eye’s higher-order aberrations as well as tilt. Therefore, a wavefront-guided treatment represents a higher level of customization than a wavefront-optimized LASIK treatment, which is based on the eye’s refractive error and K-values.

<table>
<thead>
<tr>
<th>OS</th>
<th>DS</th>
<th>DC</th>
<th>@ 12.5 mm (6.00 Rx Calc)</th>
<th>W.F. Diam</th>
<th>Hi Order</th>
</tr>
</thead>
<tbody>
<tr>
<td>OS: -2.36</td>
<td>DS: -0.49</td>
<td>DC x 176°</td>
<td>12.5 mm (6.00 Rx Calc)</td>
<td>6.25 mm</td>
<td>7.6%</td>
</tr>
<tr>
<td>OS: -2.35</td>
<td>DS: -0.32</td>
<td>DC x 91°</td>
<td>12.5 mm (6.00 Rx Calc)</td>
<td>6.00 mm</td>
<td>11.4%</td>
</tr>
<tr>
<td>OS: -2.39</td>
<td>DS: -0.44</td>
<td>DC x 1°</td>
<td>12.5 mm (6.00 Rx Calc)</td>
<td>7.00 mm</td>
<td>3.7%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE = -2.51 D</td>
</tr>
<tr>
<td>SE = -2.61 D</td>
</tr>
<tr>
<td>SE = -2.61 D</td>
</tr>
</tbody>
</table>
The **STAR S4 IR** Excimer Laser uses a **Top-Hat beam** that minimizes thermal effects and optimizes results.

- The flat-top energy distribution of the Top-Hat beam shape ablates more efficiently
- Less heating than Gaussian shape as the energy density is above the ablation threshold across the whole beam
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

Exclusive Iris Registration technology provides alignment accuracy and precise ablation placement.

- First fully automated, noncontact 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.

VSS SIMULATION RESULTS

This theoretical simulation of VSS Technology, when compared to the alternative Single Spot Scanning (SSS) ablation, shows improved 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 visual functioning and well-being.1*

100% Personalized Vision

*Similar results seen in clinical trials for mixed astigmatism.1*

**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** up to -1.00 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).
The **STAR S4 IR** Excimer Laser 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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>iDESIGN System</strong> Wavefront-Guided LASIK</td>
<td>Myopia</td>
<td>Up to -11.0 D with or without astigmatism up to -5 DC (patients 18 years and older)</td>
</tr>
<tr>
<td></td>
<td>Mixed Astigmatism</td>
<td>From 1.0 to 5.0 DC, cylinder &gt; sphere, and of opposite signs (patients 18 years and older)</td>
</tr>
<tr>
<td><strong>WaveScan System</strong> Wavefront-Guided LASIK</td>
<td>Myopia</td>
<td>Up to -11.0 D MRSE with or without astigmatism up to -3 DC (patients 21 years and older)</td>
</tr>
<tr>
<td></td>
<td>Hyperopia</td>
<td>Up to +3.0 D MRSE with or without astigmatism up to +2 DC (patients 21 years and older)</td>
</tr>
<tr>
<td></td>
<td>Mixed Astigmatism</td>
<td>From 1.0 to 5.0 DC, cylinder &gt; sphere, and of opposite signs (patients 21 years and older)</td>
</tr>
<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>
</tr>
<tr>
<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>
</tr>
<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>
</tr>
<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>
</tr>
<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>
</tr>
<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’S SUCCESS

Sharing expertise and support from the proven leader

BUSINESS DEVELOPMENT

• In-person and online educational 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
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).

ATTENTION
Reference the STAR S4 IR 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 (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.
IMPORTANT SAFETY INFORMATION (CONTINUED):

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 antimetabolite 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.
IMPORTANT SAFETY INFORMATION (CONTINUED):

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.

REFERENCES:
Johnson & Johnson VISION