EVERY TREATMENT IS A TRUE ORIGINAL

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.

Click here for additional indications and safety information.
FDA approved for

**MONOVISION LASIK**

Almost 40% of the myopes in the US are presbyopic, and may benefit from the only approved and available monovision LASIK procedure¹.

In a clinical study of 160 patients, 6 months postop²:

- **88%**
  - Achieved binocular UCVA of 20/20 or better

- **<1%**
  - Reported always having to wear glasses (decrease from 88%)

- **97%**
  - Reported overall satisfaction with their vision

**WHEN YOU MEASURE BETTER, YOU TREAT BETTER.**

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² Monovision Clinical Trial, #P930016 5025 SSED. A clinical performance study of iDESIGN® driven Monovision LASIK Treatment was not conducted. However, results of prior clinical study of monovision LASIK using the WaveScan WaveFront® System aberrometer, supports the safety and effectiveness of iDESIGN® driven Monovision LASIK Treatment, in that it used a prior version of the iDESIGN® aberrometer device to drive the monovision treatment in myopic presbyopes.
**Treat MORE PATIENTS**

Indicated for LASIK patients: 18 years and older

Indicated for monovision LASIK patients: 40 years and older

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myopia, with or without astigmatism</td>
<td>Measured up to -11.00 D SE, with up to -5.00 D cylinder</td>
</tr>
<tr>
<td>Hyperopia, with or without astigmatism</td>
<td>Measured up to +4.00 D SE, with up to +2.00 D cylinder</td>
</tr>
<tr>
<td>Mixed astigmatism</td>
<td>Where the magnitude of the cylinder (1.00 D to 5.00 D) is greater than the magnitude of the sphere, and the cylinder and sphere have opposite signs</td>
</tr>
<tr>
<td>Monovision</td>
<td>Targeted retention of myopia (-1.25 D to -2.00 D) in the non-dominant eye of presbyopic myopes, with myopic astigmatism -6.00 D SE, with up to -3.00 D cylinder</td>
</tr>
</tbody>
</table>

**INDICATIONS (Continued):** 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 preoperative 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®
Deliver personalized treatments WITH EXCELLENT OUTCOMES

In a clinical trial, myopic LASIK patients reported significant improvements in ALL measures of visual functioning and well-being 6 months postoperatively, including\(^3,\tilde{1}\):

- Clarity of Vision
- Satisfaction with Correction
- Near Vision
- Far Vision
- Activity Limitations
- Difficulty Driving at Night

\(^{1}\)Excellent patient reported results seen in the LASIK clinical trial for mixed astigmatism and hyperopia.

3. FDA P930016 supplement 044. Clinical study of myopia patients.
One-of-a-kind planning for

**ONE-OF-A-KIND TREATMENT**

First-and-only topo-integrated, wavefront-guided technology ensures every treatment plan is a true original

**When you measure better, you treat better**

The *iDESIGN*® Refractive Studio, the next level of treatment planning with a proprietary INSIDE+OUT approach that adds corneal topography measurements to the wavefront-guided procedure.

**THE DIFFERENCE IS IN THE DATA.**

**THE NEXT LEVEL OF PERSONALIZATION.**

---

**WAVEFRONT ANALYSIS** Maps the entire optical pathway

- Measures both lower and higher aberrations
- ~1,257 data points capture the most minuscule distortions
- 25X more precise than conventional measurements like manifest refraction*
- 5X the resolution with high-definition Hartmann-Shack Wavefront Sensor†

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*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.

†Based on mathematical calculation: *WaveScan* System = ~240 micro-refractions. *iDESIGN*® Refractive Studio = ~1,257 micro-refractions *iDESIGN*® Refractive Studio 1,257 ÷ 240 = 5.23X the resolution.
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THE DIFFERENCE IS IN THE DATA. THE NEXT LEVEL OF PERSONALIZATION.

CORNEAL TOPOGRAPHY Maps the entire surface of the cornea

• Uses a built-in full-gradient topographer to capture ~1,200 x- and y-slopes to interpret minuscule variations in the corneal surface

INDICATIONS (Continued): 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
One-of-a-kind planning for

ONE-OF-A-KIND TREATMENT

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**THE DIFFERENCE IS IN THE DATA. THE NEXT LEVEL OF PERSONALIZATION.**

INDICATIONS (Continued): 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).
Expanded

**DIAGNOSTIC CAPABILITIES**

### MAPS
- Mean curvature
- Instantaneous curvature
- Internal aberrations
- Ellipsoidal elevation
- CT irregularity
- WF irregularity
- High order CT aberrations

### FEATURES
- Easier scale access
- Data overlays
- User configurable
- Multiple custom review
- Cursor readout
- Summary metrics

**Additional set of topographic maps, views, and summary metrics**

The *iDESIGN®* Refractive Studio adds a comprehensive set of diagnostics capabilities to ensure a more informed view of the patient’s refractive error.
## Improved WORKFLOW

Experience more efficiency in planning for users, technicians and patients

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>One-click acquisition</td>
<td>5-in-1 measurements for efficient workflow and patient qualification</td>
</tr>
<tr>
<td>Selectable fixation targets</td>
<td>New fixation targets and illumination settings to help patient examinations</td>
</tr>
<tr>
<td>Rx at lane length</td>
<td>Wavefront refraction is displayed at the lane length which allows for easy comparison with manifest refraction</td>
</tr>
<tr>
<td>Network printing</td>
<td>Ability to print to a network printer</td>
</tr>
<tr>
<td>Daily verification</td>
<td>Automated and easy to use daily verification</td>
</tr>
</tbody>
</table>

**CONTRAINDICATIONS (Continued):**

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.
iDESIGN® Refractive Studio—

EVERY TREATMENT IS A TRUE ORIGINAL

Next-level treatment planning
- Topo-integrated, wavefront-guided treatment planning enables true personalization

Expanded diagnostic capabilities
- Topographic maps, views, and summary metrics

Improved workflow
- Shorten, automate, and eliminate steps for faster turnaround

Committed to your practice’s success
- Approved for monovision LASIK
- Support and expertise from a proven leader

WHEN YOU MEASURE BETTER, YOU TREAT BETTER.
INDICATIONS AND IMPORTANT SAFETY INFORMATION

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 15º (0.5 D) to 7.5º (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 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: 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, the posterior 250 microns (µm) of corneal stroma should not be violated. Please refer to Operator’s Manual for a list of additional Precautions.

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 antimitabolites for any medical conditions. To reduce the risk of corneal ectasia, the posterior 250 microns (µm) of corneal stroma should be violated. Please refer to Operator’s Manual for a list of additional Precautions.

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 Monovision in Presbyopic Patients with Low to Moderate Myopia and Myopic Astigmatism, Myopia, Mixed Astigmatism and Hyperopia.

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