

Star S4 IR

Excimer Laser

DELIVERING TRUE PRECISION



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.

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.

Make every treatment **A TRUE ORIGINAL**

Unlike most laser vision correction procedures that rely on conventional measurements, our wavefront-guided LASIK uses a more advanced, precise, and modern approach to measuring and treating a wide range of refractive errors. Driven by the market-leading **iDESIGN**[®] Technology, the **STAR S4 IR**[®] Excimer Laser delivers personalized topo-integrated, wavefront-guided treatments for excellent outcomes.

- Many patients achieve 20/16 or better visual acuity^{1-3,5}
- Improvements in contrast sensitivity^{1*}
- Low induction of higher-order aberrations^{1,2}
- Excellent quality of vision^{1-3,5}
- High satisfaction with their vision^{1,3,5}

Results are from a prior clinical study (P930016 S025 SSED) performed with the **iDESIGN**[®] **Advanced WaveScan Studio** System, which supports the safety and effectiveness of the **iDESIGN**[®] Refractive Studio System.

*As compared to preop

“Wavefront-guided technologies have made a significant difference in the quality and consistency of my refractive surgery outcomes.”

—ROBERT MALONEY, MD[†]



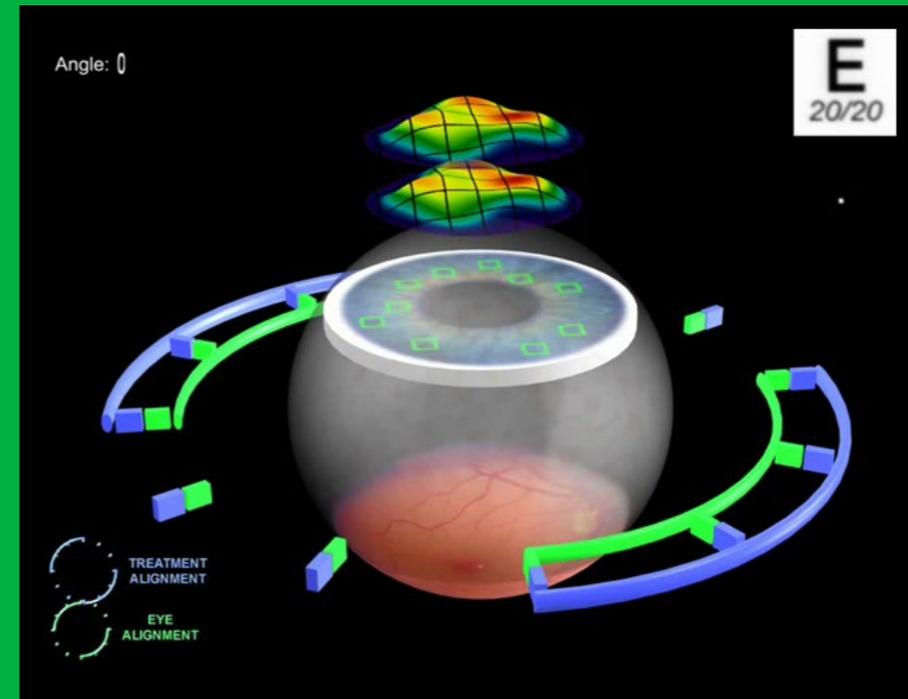
INDICATIONS (Continued): With documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination; and with a successful preoperative trial of monovision or history of monovision experience. 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

More precise delivery for **PREDICTABLE PATIENT OUTCOMES**

The **STAR S4 IR**[®] Excimer Laser delivers precise levels of ablation accuracy driven by the **iDESIGN**[®] Refractive Studio's topo-integrated-wavefront-guided technology.

Built-in technology allows the **STAR S4 IR**[®] Laser to deliver the highly accurate reconstruction of the patient's wavefront, derived from 100% utilization of available Hartmann-Shack data points.

- Iris Registration technology provides alignment accuracy and ablation placement
 - 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

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).

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; 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.

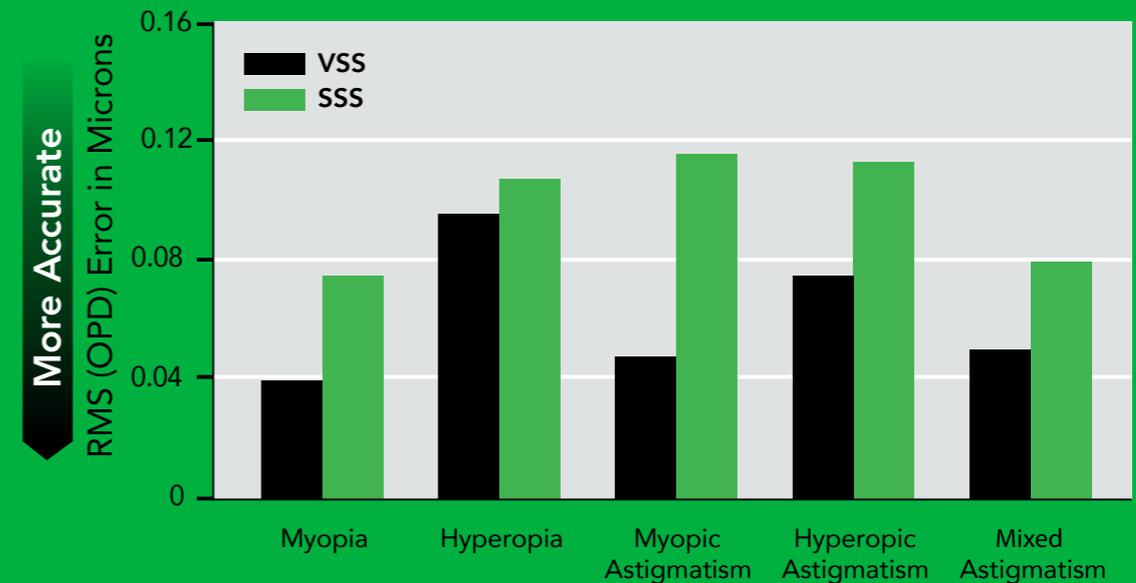
More precise delivery for **PREDICTABLE PATIENT OUTCOMES**

Industry-leading technologies enable the **STAR S4 IR**[®] Laser to rapidly deliver the ablation pattern where intended, minimizing ablation time and thermal effects.*

- **Variable Spot Scanning (VSS)**
produces sophisticated array of laser beam sizes from 0.65 mm up to 6.5 mm
- **Variable Repetition Rate (VRR)**
pulse-packing algorithm varies the laser's delivery rate
- **ActiveTrak 3-D Active Eye Tracking**
with automatic centering
 - Actively follow the tiniest eye movements along all three dimensions (X, Y, and Z axes)
 - Capturing more than 99.4% of eye movements
 - Enables automated Iris Registration for aligning treatment center to the center of the pupil

*Compared to **STAR** Laser conventional treatments

VSS SIMULATION RESULTS⁴



This theoretical simulation of VSS Technology, when compared to the alternative Single Spot Scanning (SSS) ablation (0.68 mm spot size), shows improved accuracy, or decreased fitting error, across the above ablation profiles.

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 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.

Proven results YOU CAN DEPEND ON

Studies evaluating wavefront-guided outcomes, demonstrate excellent visual acuity with many eyes achieving 20/16 UCVA¹, improved contrast sensitivity, and patient reported quality of vision.

Myopic patients reported improvements in visual functioning and well-being, including:^{1*}



Clarity of Vision



Satisfaction with Correction



Near Vision



Far Vision



Difficulty Driving at Night



Activity Limitations

Studies with myopia patients show:

- **>91% of myopia patients** were satisfied with their vision^{3,5**}
- **>96% of myopia patients** were willing to recommend the procedure to friends and family^{3,5**}

Results are from a prior clinical study (P930016 S025 SSED) performed with the **iDESIGN® Advanced WaveScan Studio** System, which supports the safety and effectiveness of the **iDESIGN® Refractive Studio** System

*FDA PMA P930016 Myopia patients. Excellent patient reported results seen in the clinical trial for mixed astigmatism and hyperopia.

**Retrospective study of myopia patients (N = 67 & N = 371). Questionnaire derived from the Joint LASIK Study Task Force. FDA has not evaluated the questionnaire to determine its validity.

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

—MARK KONTOS, MD†



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.

Proven VERSATILITY

The *STAR S4 IR*[®] Excimer Laser enables you to treat a broad range of patients.

Treatment	Refractive Error	Approved Treatment Range
<i>iDESIGN</i> [®] Refractive Studio and <i>iDESIGN</i> [®] Advanced WaveScan Studio System	Myopia	Up to -11.0 D with or without astigmatism up to 5.0 DC (patients 18 years and older)
	Hyperopia	Up to +4.0 D SE with up to 2.0 DC (patients 18 years and older)
	Mixed Astigmatism	From 1.0 to 5.0 DC, cylinder > sphere, and of opposite signs (patients 18 years and older)
<i>iDESIGN</i> [®] Refractive Studio	Monovision	With myopic astigmatism, up to -6.00 D SE, 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 retention. (40 years and older)
WaveScan System Wavefront-Guided LASIK	Myopia	Up to -11.0 D MRSE with or without astigmatism up to 3.0 DC (patients 21 years and older)
	Hyperopia	Up to +3.0 D MRSE with or without astigmatism up to 2.0 DC (patients 21 years and older)
	Mixed Astigmatism	From 1.0 to 5.0 DC, cylinder > sphere, and of opposite signs (patients 21 years and older)
Conventional LASIK	Myopia	Up to -14.0 D with or without astigmatism from 0.5 to 5.0 DC (patients 18 years and older)
	Hyperopia	From +0.5 to +5.0 DS with or without astigmatism up to 3.0 DC, with a maximum MRSE of +6.0 D (patients 21 years and older)
	Mixed Astigmatism	≤ 6.0 DC, cylinder > sphere, and of opposite signs (patients 21 years and older)
Conventional PRK	Myopia	No more than -6.0 D, with no more than 1.0 D of refractive astigmatism (patients 18 years and older)
		No more than -12.0 D, with no more than 4.0 D of refractive astigmatism (patients 21 years and older)
	Hyperopia	Between +1.0 and +6.0 D, with no more than 1.0 D of refractive astigmatism (patients 21 years and older)
		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)

Committed to your **PRACTICE'S SUCCESS**

Sharing expertise and support from the proven leader



Business Development

- Introducing practice-building and patient marketing initiatives.
- Elevating practice performance through diagnostics and innovative solutions.



Application Support

- Maximizing team skills with on-site surgeon and technician training and guidance.
- Ongoing clinical consultation and analysis to enhance patient outcomes.



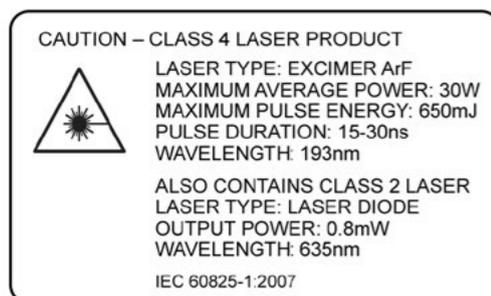
Equipment Service

- Maximizing your system's performance to deliver the highest standard of patient care with our industry-leading service team.
- Tailoring plans to protect your surgical platforms.

†Paid consultant by Johnson & Johnson Vision

REFERENCES:

1. FDA P930016 supplements 044, 045, and 048.
2. Khalifa MA, Alsahn MF, Shafik SM, Pinero DP. Comparative analysis of the efficacy of astigmatic correction after wavefront-guided and wavefront-optimized LASIK in low and moderate myopic eyes. *Int J of Ophthalmol* 2017; 10(2): 285-292.
3. Schallhorn SC, Venter JA, Hannan SJ, Hettinger KA. Outcomes of Wavefront-guided Laser in situ Keratomileusis Using a New- Generation Hartmann-Shack Aberrometer in Patients with High Myopia. *J Cataract Refract Surg* 2015; 41: 1810–1819.
4. Dai GM, Gross E, Liang J. System performance evaluation of refractive surgical lasers: a mathematical approach. *Appl Opt.* 2006;45(9):2124-2134.
5. Schallhorn SC, Brown M, Venter JA, et al. Early Clinical Outcomes of Wavefront-Guided Myopic LASIK Treatments Using a NewGeneration Hartmann-Shack Aberrometer. *J Refractive Surg* 2014;30(1):14-21.



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