iDesign

Refractive Studio

EVERY TREATMENT IS A TRUE ORIGINAL

INDICATIONS: The **STAR S4 IR®** Excimer Laser System and the **iDESIGN®** Refractive Studio are indicated for wavefront-guided photorefractive keratectomy (PRK) in patients: with myopia, with or without astigmatism, as measured by **iDESIGN®** Refractive Studio System with spherical equivalent up to -8.00 D, and cylinder up to -3.00 D, with agreement between manifest refraction (adjusted for optical infinity) and **iDESIGN®** Refractive Studio 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, in patients 18 years of age or older; with refractive stability (a change of ≤1.0 D in manifest refraction spherical equivalent for a minimum of 12 months prior to surgery), and with wavefront capture diameter of at least 4 mm.

Click here for additional indications and safety information.

Most Expansive Wavefront-Guided Indications

MORE OPTIONS TO TREAT MORE PATIENTS

18 years and older

LASIK

- **Myopia** with or without astigmatism*
- **Hyperopia** with or without astigmatism†
- **Mixed astigmatism**‡

PRK

- **Myopia** with or without astigmatism§

40 years and older

MONOVISION

- **Presbyopic** myopia‖

*Measured up to -11.0 D SE, with up to -5.00 DC. For adults 18 years and older.

† Measured up to +4.00 D SE, with up to +2.00 DC. For adults 18 years and older.

‡ Where the magnitude of cylinder (1.00 D to 5.00 D) is greater than the magnitude of the sphere, and the cylinder and sphere have opposite signs.

§ Measured up to -8.00 D SE, with up to -3.00 DC. For adults 18 years and older.

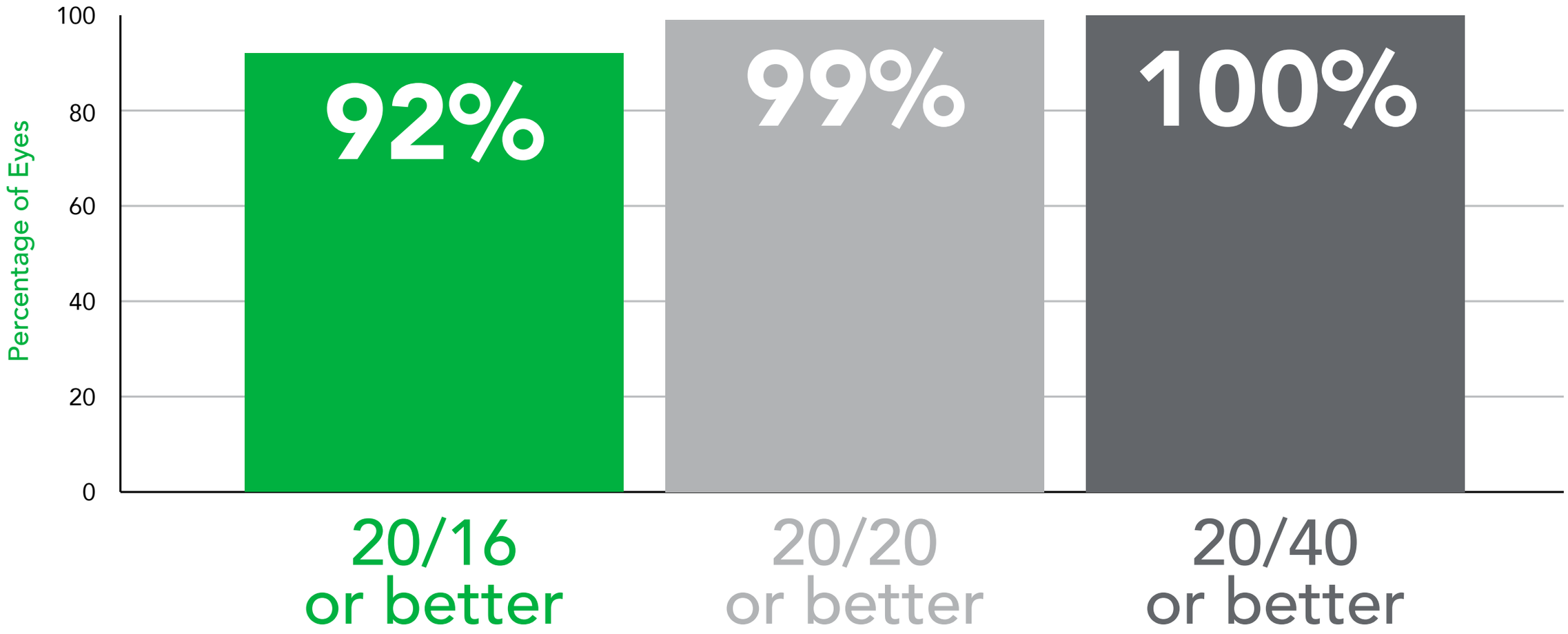
‖ Targeted retention of myopia (-1.25 D to -2.00 D) in the nondominant eye of presbyopic myopes, with myopic astigmatism 6.00 D SE, with up to -3.00 D cylinder. For adults 40 years and older.

CONTRAINDICATIONS: iDESIGN® System-driven PRK surgery is contraindicated in patients with any type of active connective tissue disease or autoimmune disease, in patients with signs of keratoconus, abnormal corneal topography, and degenerations of the structure of the cornea, in patients whose corneal thickness would cause anticipated treatment that would violate the posterior 250 microns (μm) of corneal stroma, in patients with uncontrolled diabetes, in patients with active eye infection or active inflammation, in patients with recent herpes eye infection or problems resulting from past infection, in patients with significant dry eyes. If the patients have severely dry eyes, PRK may increase the dryness. This may or may not go away. Severe eye dryness may delay healing or interfere with the surface of the eye after surgery. It may result in poor vision after PRK.

In a WFG PRK clinical trial of myopia subjects, results show:

92% OF EYES HAD 20/16 OR BETTER UCVA

Monocular UCVA at 6 Months (N=322)[1]



1. PMA P930016/S057 Summary of Safety and Effectiveness Data.

In a WFG PRK clinical trial of myopia subjects at 6 months postoperatively (N=161):

99% OF SUBJECTS REPORTED BEING VERY TO COMPLETELY SATISFIED WITH THEIR VISION[1]

In addition, many measures of visual functioning and well-being had higher postoperative scores compared to preoperative scores, including[1]:

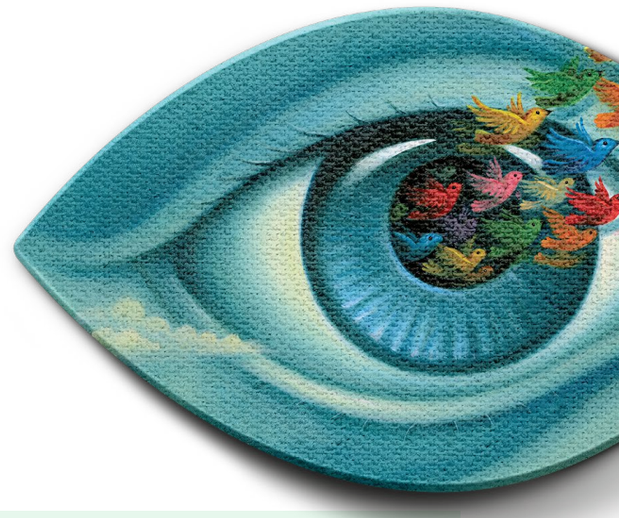
Improvement in difficulty driving at night

82% of subjects reported having no difficulty driving at night at 6 months postoperatively compared to 50% preoperatively[2]

1. PMA P930016/S057 Summary of Safety and Effectiveness Data.
2. Data on file.

In a WFG PRK clinical trial of myopia subjects:

REFRACTIVE PREDICTABILITY AND STABILITY



Accuracy of MRSE[1]:

Intended vs Achieved Outcome at 6 Months Postop (N=322)

85%
of eyes

Within
+/-0.5 D
of **emmetropia**

96%
of eyes

Within
+/-1.0 D
of **emmetropia**

Refractive Stability[1]

>96%

of eyes were found to have a change in MRSE and MRC of ≤ 1.0 D between 3 and 6 months (N=318) and 6 and 9 months (N=226)

1. PMA P930016/S057 Summary of Safety and Effectiveness Data.

Committed to personalized patient and practice success

EVERY TREATMENT IS A TRUE ORIGINAL

Improved treatment planning

- First and only topo-integrated, wavefront-guided technology
- Enables data-driven personalization

Improved diagnostic capabilities

- Topographic maps, views, and summary metrics

Improved workflow

- Shorten, automate, and eliminate steps for faster turnaround

Exceptional patient outcomes

- Raises the bar in visual acuity outcomes and sets a new standard for laser vision correction**

More expansive wavefront-guided indications

- More options to treat more patients

WHEN YOU MEASURE BETTER, YOU TREAT BETTER, AND YOUR PATIENTS SEE BETTER.

** Based on FDA manufacturer excimer platform results, head to head studies, non-comparative studies, and podium abstracts and posters, **iDESIGN**® has been shown to deliver 20/16 or better visual outcomes in majority of myopia patients. Data available upon request.

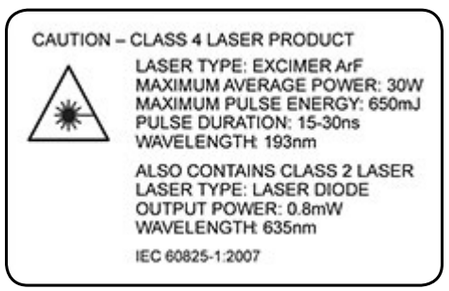
INDICATIONS AND IMPORTANT SAFETY INFORMATION

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 15° (0.5 D) to 7.5° (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 mono-vision 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 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.

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.

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.



Johnson & Johnson VISION