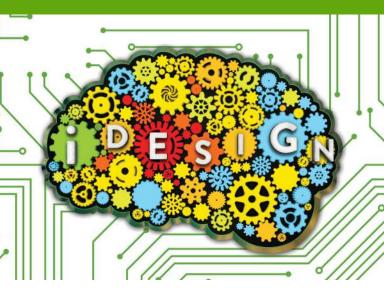
# YOUR LASIK PROCEDURE JUST GOT SMARTER

With the iDESIGN® Advanced WaveScan Studio System



### MORE BRAIN POWER TO HELP YOU SEE CLEARLY WITHOUT THE HASSLE OF CONTACTS OR GLASSES\*.

\*You may need reading glasses after laser surgery even if you did not wear them before. Your vision may not be perfect, and you may need to wear glasses or contact lenses for some activities even after laser vision correction.

### 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.

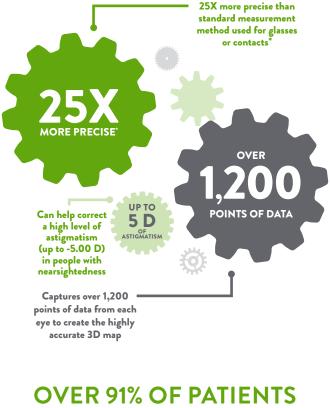
INDICATIONS: Advanced CustomVue LASIK (laser assisted in situ keratomileusis) is a customized wavefront-guided laser surgery procedure that uses the *iDESIGN*<sup>®</sup> Advanced WaveScan Studio System to measure visual imperfections of your eye and the STAR S4 IR<sup>®</sup> Excimer Laser to permanently reshape the cornea. Advanced CustomVue LASIK treatment is used to correct or reduce myopia (nearsightedness) with and/or without astigmatism, correct or reduce hyperopia (farsightedness) with and/or without astigmatism, as well as mixed astigmatism for patients 18 years of age and older and whose vision has been stable for at least one year. Only eye care professionals trained in laser vision correction can determine whether you are a suitable candidate.

**CONTRAINDICATIONS:** You should not have LASIK if you have collagen vascular (e.g., rheumatoid arthritis), autoimmune (e.g., lupus), or immunodeficiency diseases (e.g., AIDS) because they affect the body's ability to heal. You should not have this procedure if you are pregnant or nursing; show signs of corneal abnormalities or corneal thinning; have symptoms of significant dry eyes; advanced glaucoma; and uncontrolled diabetes. If you have severely dry eyes, LASIK may increase the dryness, may delay healing after surgery, may or may not go away and it may result in poor vision after LASIK.

## THE BRAIN POWERING YOUR PERSONALIZED TREATMENT PLAN

Working like a "brain," the **iDESIGN**<sup>®</sup> **Advanced WaveScan Studio** (**iDESIGN**) System captures more data than ever before to create a detailed picture of your eye's unique imperfections and accurately plan a treatment for you alone.

Your 100% personalized LASIK procedure begins with a custom treatment plan, created by proprietary wavefront eye-mapping technology from the **iDESIGN** System.



WERE SATISFIED TO VERY SATISFIED WITH THEIR VISION.<sup>1-3</sup>

\* The wavefront system can measure more precisely down to 0.01 D vs. phoropter in 0.25 D increments. These precise corrections are applied to the right spots on the cornea according to correction needed.

# CLEARER, SHARPER VISION YOU'LL ENJOY DAY AND NIGHT

At 6 months after surgery, nearsighted patients in a clinical study reported significant improvements in ALL measures of quality of vision, including:<sup>4</sup>



Clinical trials from mixed astigmatism and hyperopia also yielded good results.<sup>4</sup>

WARNINGS AND PRECAUTIONS: LASIK is not recommended if you have cataracts, corneal scars, or dry eye syndrome; glaucoma; diabetes; severe allergies; history of Herpes simplex or Herpes zoster keratitis; are taking Isotretinoin (Accutane®), Sumatriptan (Imitrex®), Amiodarone hydrochloride (Cordarone®) or antimetabolites for any medical conditions; history of crossed eyes; previous corneal, intraocular surgery, LASIK or refractive surgery; family history of degenerative corneal disease; and history of inflammation of the eye. Your doctor will examine your eyes to determine if you are a candidate for this procedure. Talk to your doctor about any eye-related conditions, injuries, or surgeries you have had, any medications you are taking, and any changes to your vision in the past year. After surgery, you may find it more difficult to see in conditions such as dim light, rain, snow, fog, or glare from bright lights at night. Future measurements of your eye pressure or future cataract surgery can be affected by this procedure. Tell your future doctor you've had **Advanced CustomVue** LASIK surgery.

### ASK US ABOUT THE *iDESIGN*<sup>®</sup> SYSTEM-DRIVEN LASIK PROCEDURE TODAY.

#### **REFERENCES:**

- 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 (N=371)
- Schallhorn SC, Venter JA, Hannan SJ, Hettinger KA. Wavefront-guided Photorefractive Keratectomy with the Use of a New Hartmann-Shack Aberrometer in Patients with Myopia and Compound Myopic Astigmatism. *J. of Ophth*, volume 2015. (N=296)
- Schallhorn SC, Brown M, Venter JA, Teenan D, Hettinger KA, Yamamoto H. Early Clinical Outcomes of Wavefront-Guided Myopic LASIK Treatments Using a New-Generation Hartmann-Shack Aberrometer. J Refract Surg. 2014;30(1):14-21. (N=67)
- 4. FDA PMA Approval P931006 S044, S045, S048

#### IMPORTANT SAFETY INFORMATION (CONTINUED)

**RISKS:** As with any surgical procedure there are risks associated with **Advanced CustomVue** LASIK treatments. It is important to discuss these risks with your doctor before you make any decision to have the surgery. If the results of the surgery are not satisfactory, your doctor may want to perform additional laser treatment in either one or both eyes. Talk to your doctor about what is best for you. Some risks are related to the creation of the corneal flap. Corneal flap complications include but are not limited to: cutting an incomplete, irregular flap or free flap; misalignment of the flap; and perforation of the cornea. Corneal flap complications range in severity from those that simply require the treatment to be postponed for several months, to those which create corneal irregularities resulting in permanently blurred vision. You may need reading glasses even if you did not wear them before. Your vision may not be perfect, and you may need to wear glasses or contact lenses for some activities even after laser vision correction.

**SIDE EFFECTS:** Possible side effects include loss of vision and visual disturbances such as double vision, sensitivity to bright lights, increased difficulty with night vision, fluctuations in vision, and other visual irregularities that may be debilitating.

Please consult with your eye care professional and carefully review the *Patient Information Booklet* regarding the potential risks and benefits of this procedure. Results may vary for each individual patient.

Johnson+Johnson vision

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