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FDA Approves the Next Generation of Customized LASIK Treatment with iDESIGN Refractive Studio

Next generation LASIK platform that measures the eye inside and out to enable highly precise personalized vision correction
Only available LASIK platform indicated for monovision LASIK in presbyopic myopic patients
25 times more precise than the traditional way of measuring refractive errors which rely on subjective input(1)

SANTA ANA, Calif., June 18, 2018 /PRNewswire/ -- Johnson & Johnson Vision announced today the U.S. Food and Drug Administration (FDA) approval of the iDESIGN Refractive Studio, making it the only system to use topography-integrated, wavefront-guided technology.[2] This allows doctors to take a precise measurement of the eye inside and out to deliver a LASIK procedure personalized to the individual patient. It is approved for myopia, hyperopia, and mixed astigmatism. Additionally, it is the only available LASIK platform indicated for monovision LASIK in presbyopic myopic patients. Monovision is a procedure designed for patients over 40 years old who are experiencing blurry near vision due to aging of their eyes. In the U.S., an estimated 130 million people[3] could potentially benefit from a monovision procedure, which includes improved distance and near vision.

Experience the interactive Multichannel News Release here: https://www.multivu.com/players/English/8350051-jnj-vision-idesign-refractive-studio-fda-approval/

"As a practicing ophthalmologist for more than 25 years, I know firsthand the importance of taking precise measurements and tailoring LASIK procedures for each patient," said Jonathan Talamo, MD, Chief Medical Officer and Worldwide Vice President of Medical and Clinical Affairs, Johnson & Johnson Vision. "The new iDESIGN Refractive Studio provides surgeons with the ability to deliver one-of-a-kind custom laser vision correction for each patient to have excellent visual outcomes following their LASIK procedure."

In a single, three-second scan, the iDESIGN Refractive Studio offers a new level of customization for patients. Each treatment plan begins with a wavefront analysis to measure how light travels inside the eye, detailing the imperfections in a patient's vision. The corneal topography scans the outside surface of the eye, measuring and analyzing tiny variations in curvature and elevation. The combination of the two measurements delivers a custom LASIK procedure tailored for each eye.

"The ability to perform monovision LASIK with iDESIGN Refractive Studio will benefit many patients and I'm proud to have been a part of that clinical investigation," said Robert Maloney, MD, Maloney Vision Institute. "More patients are experiencing better quality outcomes with LASIK procedures and wavefront-guided treatments. This technology is truly revolutionizing how we measure and treat refractive errors."

The majority of patients see 20/16 or better six months after laser vision correction based on clinical studies.[4] The iDESIGN Refractive Studio will be marketed by Johnson & Johnson Surgical Vision and be commercially available in Q3 2018.

For more information about LASIK, visit www.backinfocus.com.

About LASIK
Johnson & Johnson Vision has transformed the vision correction industry with the company's LASIK technology (iLASIK) and advancement in wavefront-guided laser treatment. iLASIK is an all-laser procedure that shapes the cornea to help improve a person's vision and the technology has been used in millions of procedures performed on Johnson & Johnson Vision machines around the world.

Johnson & Johnson Vision
Johnson & Johnson Vision, through its operating companies, is committed to improving and restoring sight for patients worldwide. Since debuting the world's first disposable soft contact lens in 1987, Johnson & Johnson Vision Care, Inc. has been helping patients see better through their world-leading ACUVUE® Brand Contact Lenses portfolio. In 2017, with the addition of Abbott Medical Optics Inc., the Johnson & Johnson Surgical Vision business, Johnson & Johnson invested further in eye health by expanding into cataract surgery, laser refractive surgery (LASIK) and consumer eye health. Serving more

than 60 million patients a day across 103 countries, Johnson & Johnson Vision is committed to helping more people in more places improve or restore their sight. Dual headquartered in Jacksonville, Florida, and Santa Ana, California, Johnson & Johnson Vision has more than 10,000 employees worldwide. For more information about Johnson & Johnson Vision, visit us at www.jjvision.com. Follow @JNJVision on Twitter and Johnson & Johnson Vision on LinkedIn.

Indication
The iDESIGN Refractive Studio is indicated for the automatic measurement of wavefront aberrations (including coma, spherical aberrations, trefoil, and other higher order aberrations), corneal topography, pupillometry, keratometry, auto-refraction, and recording the refractive error of the eye; including myopia, hyperopia, astigmatism and keratometry.
The iDESIGN Refractive Studio is also indicated for the calculation of wavefront-guided Laser Assisted in Situ Keratomileusis (LASIK) treatments for myopia, hyperopia, and mixed astigmatism, as well as monovision in myopic patients with presbyopia.
Refer to Chapter 1 in the STAR S4 IR Excimer Laser System Operator's Manual for applicable wavefrontguided LASIK treatment indications.

Contraindications
The licensed eye care practitioner should not rely upon results obtained from patients with refractive errors that exceed the specified range: Spherical equivalent range-16.0 D to + 12.0 ; cylinder range 0.0 D to 8.0 D

Warnings and Precautions
Refractive errors represent only one component of the complex human visual system. Before prescribing any type of optical correction based on this device's output, a licensed eye care practitioner should always do the following:

- Confirm this device's output with measurements obtained from other vision measurement sources.
- Be cautious of measurements from patients who have difficulty remaining still or focusing on the fixation target.

The safety and effectiveness of the iDESIGN Refractive Studio is not established in patients with a known opacity of the lens or cornea, including patients with cataracts, corneal scars, or dry eye syndrome. Refer to Chapter 1 in the STAR S4 IR Excimer Laser System Operator's Manual for applicable wavefront-guided LASIK treatment Contraindications and Warnings and Precautions

ATTENTION: Reference the Directions for Use labeling for a complete listing of Indications and Important Safety Information.

[1] Phoropter measures in 0.25 D increments. Wavefront Aberrometer measures in 0.01 D increments. 25/1 = 25

[2] iDESIGN Refractive Studio treatment calculations are made using wavefront measurements, and use either measured topography or keratometry for propagating the wavefront and compensating for the cosine effect (peripheral loss of laser energy due to corneal curvature)

[3] 2017 Market Scope Global Refractive Report

[4] Based on clinical studies using prior generation Advanced WaveScan Studio

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