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## JOHNSON & JOHNSON VISION RECEIVES FDA APPROVAL FOR NEXT GENERATION MONOFOCAL INTRAOCULAR LENS - TECNIS EYHANCE™ AND TECNIS EYHANCE™ TORIC II IOLS - FOR THE TREATMENT OF CATARACT PATIENTS

*First innovation in monofocal technology in 20 years is designed to slightly extend the depth of focus<sup>1</sup>*

*Latest IOL in the proven TECNIS® family of IOLs, which celebrates its 20<sup>th</sup> anniversary this year*

**SANTA ANA, CA – February 2, 2021** – Johnson & Johnson Vision\*, a global leader in eye health and part of the Johnson & Johnson Medical Devices Companies\*\*, today announced that the U.S. Food and Drug Administration (FDA) approved the TECNIS Eyhance™ and TECNIS Eyhance™ Toric II intraocular lens (IOL) for the treatment of cataract patients in the United States. With this approval and subsequent commercial launch, ophthalmologists in the U.S. now have the ability to choose this next generation monofocal as the lens of choice for their patients with or without astigmatism. The first implantation of TECNIS Eyhance IOL in the U.S. will happen in Texas next week.

More than 90% of people develop cataracts—the clouding and yellowing of the lens in the eye—by the age of 65.<sup>2</sup> While part of the normal aging of the eye, left untreated, cataracts cause vision to deteriorate over time. In fact, cataracts are the leading cause of preventable blindness worldwide, impacting more than 100 million eyes.<sup>3</sup> Cataract surgery is one of the most common outpatient procedures performed today and has a success rate of approximately 98%.<sup>4</sup> Today, cataract treatments can also offer patients vision correction, reducing or eliminating the need for glasses, in addition to removing the cataract.<sup>5,6</sup>

"84% of surgeons<sup>7</sup> choose monofocal IOLs for their cataract patients, so it's thrilling to see the first breakthrough in monofocal technology in decades enter the market to add to our treatment portfolio," said Douglas Koch, M.D., Houston, TX\*\*\*. "It's the first monofocal designed to provide a slight increase in the depth of focus,<sup>1,8</sup> which is something I need for the patients in my practice looking for more from a monofocal."

The latest innovation in the TECNIS® Family of IOLs - TECNIS Eyhance and TECNIS Eyhance Toric II IOLs – is defining the future of monofocals, with a breakthrough refractive surface designed to:

- **Slightly extend the depth of focus<sup>1</sup>** through the unique shape of the lens
- **Deliver better image contrast in low light<sup>9</sup>** TECNIS Eyhance IOLs deliver 30% improvement in image contrast compared to AcrySof IQ SN60WF at 5mm

<sup>1</sup> Data on file. Eyhance DFU. The TECNIS Eyhance™ IOLs are designed to slightly extend the depth of focus compared to the TECNIS 1-Piece IOL, Model ZCB00 as measured in bench testing.

<sup>2</sup> Kellogg Eye Center. Cataract. <https://www.umkelloggeye.org/conditions-treatments/cataract>.

<sup>3</sup> World Health Organization. Blindness and Impairment. <https://www.who.int/en/news-room/fact-sheets/detail/blindness-and-visual-impairment>

<sup>4</sup> Vision Health Initiative, Common Eye Disorders. Centers for Disease Control and Prevention. <https://www.cdc.gov/visionhealth/basics/ced/index.html>

<sup>5</sup> All About Vision. Will I Need Glasses After Cataract Surgery? <https://www.allaboutvision.com/conditions/faq-cataract-glasses-after-surgery.htm>

<sup>6</sup> Khandelwal SS, et. al. Effectiveness of multifocal and monofocal intraocular lenses for cataract surgery and lens replacement: a systematic review and meta-analysis. Graefes Arch Clin Exp Ophthalmol. 2019 May;257(5):863-875. doi: 10.1007/s00417-018-04218-6.

<sup>7</sup> Market Scope 2020 Global IOL Report.

<sup>8</sup> Data on file. Eyhance DFU.

<sup>9</sup> Data on file. Johnson & Johnson Surgical Vision, Inc. 2021.

- **Provide safe and easy delivery** using the new TECNIS Simplicity® system that streamlines lens delivery and protects against contamination<sup>10</sup>

“Built on the proven TECNIS® platform,<sup>11</sup> TECNIS Eyhance combines low-light performance with breakthrough refractive surface design, providing a new kind of monofocal experience for cataract patients,<sup>12</sup>” said Rajesh K. Rajpal\*\*\*\*, MD, Chief Medical Officer and Global Head of Clinical and Medical Affairs at Johnson & Johnson Vision. “Additionally, the TECNIS Eyhance Toric II lens is engineered with a new squared and frosted haptic design for added friction inside the capsular bag to treat cataract patients with astigmatism.”

The TECNIS Eyhance IOL is the latest lens in the TECNIS Family, which celebrates its 20th anniversary this year. The TECNIS Family portfolio is the broadest mix of IOLs for cataract patients in need of monofocals, multifocals, extended depth of focus (EDOF), and those with or without astigmatism.

“We consistently engage with our surgeons and their patients to better understand their unmet needs, and their feedback drove us to innovate and push the boundaries of the monofocal category – a category that’s largely been stagnant for the last 20 years,” said Sandor Palfi\*\*\*\*\*, Commercial Vice President of the Americas at Johnson & Johnson Vision. “TECNIS Eyhance IOL is built on the foundation of our proven TECNIS platform, designed to deliver more.”

TECNIS Eyhance first launched in Europe in February 2019 and became commercially available in Latin America and Canada in the summer of 2020. TECNIS Eyhance and TECNIS Eyhance Toric II are now commercially available in the U.S., with TECNIS Eyhance Toric II launching in Europe and Canada later this year.

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## **About TECNIS**

The TECNIS® platform offers the broadest portfolio of IOLs to serve patients with a variety of vision conditions and lifestyles; and equip them with the solutions they need to see efficiently, clearly and comfortably. The TECNIS® Family of IOLs includes monofocals, multifocals, extended depth of focus (EDOF), and IOLs for those with or without astigmatism. The industry leading platform, which offers a variety of options for different visual conditions and lifestyles, delivers a unique combination of material, manufacturing, and design to deliver exceptional visual outcomes across all distances.

## **About Johnson & Johnson Vision\***

At Johnson & Johnson Vision, part of Johnson & Johnson Medical Devices Companies\*\*, we have a bold ambition: to change the trajectory of eye health worldwide. Through our operating companies, we deliver innovation that enables eye care professionals to create better outcomes for patients throughout their lives, with products and technologies that address unmet needs including refractive error, cataracts, and dry eye. In communities with greatest need, we work in collaboration to expand access to quality eye care, and we are committed to helping people see better, connect better, live better. Visit us at [jvision.com](http://jvision.com), [follow @JNJVision on Twitter](#), [Johnson & Johnson Vision on LinkedIn](#), and [@JNJVision on Facebook](#).

## **About Johnson & Johnson Medical Devices Companies\*\***

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people’s healthcare experiences. In surgery, orthopaedics, vision, and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere.

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<sup>10</sup> TECNIS Monofocal IOL with TECNIS Simplicity® Delivery System (package insert, DFU DCB00 (Z311063P Rev. D)).

<sup>11</sup> The safety and effectiveness of the TECNIS Eyhance™ IOL has not been substantiated in clinical trials. The effects of the TECNIS Eyhance™ IOL optical design on quality of vision, contrast sensitivity, and subjective visual disturbances have not been evaluated clinically.

<sup>12</sup> Data on file, Johnson & Johnson Surgical Vision, Inc. 2021.

## **INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS Eyhance™ and TECNIS™ Eyhance Toric II IOLs with TECNIS Simplicity® Delivery System**

### **Rx Only**

#### **INDICATIONS FOR USE**

The TECNIS Simplicity® Delivery System is used to fold and assist in inserting the TECNIS Eyhance™ IOL for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens is intended to be placed in the capsular bag.

The TECNIS Simplicity® Delivery System is used to fold and assist in inserting the TECNIS Eyhance™ Toric II IOLs for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire reduction in residual refractive cylinder. The lens is intended to be placed in the capsular bag.

#### **WARNINGS**

Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the Directions for Use that could increase complications or impact patient outcomes. The lens should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus. Do not attempt to disassemble, modify or alter the delivery system or any of its components, as this can significantly affect the function and/or structural integrity of the design. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system. The lens and delivery system should be discarded if the lens has been folded within the cartridge for more than 10 minutes.

#### **PRECAUTIONS**

The safety and effectiveness of the TECNIS Eyhance™ IOL has not been substantiated in clinical trials and the effects of the optical design on quality of vision, contrast sensitivity, and subjective visual disturbances (glare, halo, etc.) have not been evaluated clinically. This is a single use device, do not resterilize the lens or the delivery system. Do not store the device in direct sunlight or at a temperature under 5°C (41°F) or over 35°C (95°F). Do not autoclave the delivery system. Do not advance the lens unless ready for lens implantation. The contents are sterile unless the package is opened or damaged. The recommended temperature for implanting the lens is at least 17°C (63°F). The use of balanced salt solution (BSS) or viscoelastics is required when using the delivery system. Do not use if the delivery system has been dropped or if any part was inadvertently struck while outside the shipping box.

#### **ADVERSE EVENTS**

The most frequently reported cumulative adverse event that occurred during the SENSAR 1-Piece IOL clinical trial was cystoid macular edema which occurred at a rate of 3.3%.

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

\*Johnson & Johnson Vision represents the products and services of Johnson & Johnson Surgical Vision, Inc., Johnson & Johnson Vision Care, Inc., and the affiliates of both.

\*\*The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopedics, vision, and interventional solutions businesses within Johnson & Johnson's Medical Devices segment.

\*\*\*Dr. Koch is a paid consultant of Johnson & Johnson Vision, Inc.

\*\*\*\*Dr. Rajesh K. Rajpal is an employee of Johnson & Johnson Surgical Vision, Inc., serving as Head of Clinical and Medical Affairs across both the Surgical Vision and Vision Care organizations.

\*\*\*\*\*Sandor Palfi is an employee of Johnson & Johnson Vision, Inc., serving as Commercial Vice President of the Americas, with oversight of the U.S., Latin America and Canada regions.

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