



**For Immediate Release**

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**JOHNSON & JOHNSON VISION ANNOUNCES THE APPROVAL OF TECNIS SYNERGY™ AND TECNIS SYNERGY™ TORIC II IOLS IN THE U.S. AND TECNIS SYNERGY™ TORIC II IOLS IN CANADA**

*Next-generation presbyopia-correcting intraocular lens (PCIOL) offers continuous vision for cataract patients across every distance regardless of lighting conditions<sup>1,2,3,4†</sup>*

*In a company sponsored study, 9 out of 10 patients who received TECNIS Synergy™ IOL lenses did not need glasses after surgery.<sup>5††</sup>*

**SANTA ANA, CA – May 6, 2021** – Johnson & Johnson Vision\*, a global leader in eye health and part of the Johnson & Johnson Medical Devices Companies\*\*, today announced the U.S. Food and Drug Administration (FDA) approval of TECNIS Synergy™ and TECNIS Synergy™ Toric II IOLs, and the Health Canada approval of TECNIS Synergy™ Toric II IOLs. This next-generation PCIOL is built on the legacy TECNIS® platform and delivers the widest range of continuous vision with the best near vision among leading PCIOLs,<sup>3,4,6,7,8†</sup> superior contrast even in low-light conditions, and reduced spectacle wear.<sup>1,2,3,4,8</sup> In a company sponsored study, 9 out of 10 patients who received TECNIS Synergy™ IOL lenses did not need glasses after surgery.<sup>9††</sup>

Cataracts are the leading cause of preventable blindness worldwide, impacting more than 100 million eyes,<sup>10</sup> with more than 90% of people developing cataracts by the age of 65.<sup>11</sup> Over the last two decades, cataract patients' visual needs have dramatically changed as digital devices have become an

† vs PanOptix® IOL, Symfony, TMF Continuous 20/32 or better based on defocus curve (United States), vs. PanOptix® IOL, AT Lisa Trifocal IOL and FineVision IOL (Canada)

<sup>1</sup> TECNIS Synergy™ IOL with TECNIS Simplicity Delivery System DFU, Z311421E

<sup>2</sup> DOF2019OTH4002 – Weeber H. MTF of the TECNIS Synergy™ OptiBlue® IOL, and other lens models. 27 Mar 2019.

<sup>3</sup> DOF2019OTH4005 – Perez G. Simulated VA of the TECNIS Synergy™ IOL and AT Lisa Tri IOL. 5 May 2019.

<sup>4</sup> DOF2019OTH4006 – Perez G. Simulated VA of the TECNIS Synergy™ IOL and FineVision IOL. 5 May 2019

<sup>5</sup> DOF2020CT4015- ("Forte 1"): A Comparative Clinical Evaluation of a New TECNIS® Presbyopia Correcting Intraocular Lens Against a PanOptix® Intraocular Lens-SPECTACLE WEAR AND SATISFACTION RESULTS

<sup>6</sup> TECNIS® Multifocal 1-Piece IOL ZKB00 and ZLB00 DfU – US – Doc. #Z311328. Rev. A, 04/2018. REF2019CT4049.

<sup>7</sup> DOF2020CT4014 - Forte 1: A Comparative Clinical Evaluation of a New TECNIS® Presbyopia Correcting Intraocular Lens Against a PanOptix® Intraocular Lens-Defocus Curves and Visual Acuity Results

<sup>8</sup> TECNIS Symfony™ Extended Range of Vision IOL DfU – OUS – Doc. #Z311278. Rev. 01, 02/2018. REF2018CT4277.

<sup>9</sup> DOF2020CT4015- ("Forte 1"): A Comparative Clinical Evaluation of a New TECNIS® Presbyopia Correcting Intraocular Lens Against a PanOptix® Intraocular Lens-SPECTACLE WEAR AND SATISFACTION RESULTS

<sup>10</sup> World Health Organization. Blindness and Impairment. <https://www.who.int/en/news-room/fact-sheets/detail/blindness-and-visual-impairment>

<sup>11</sup> University of Michigan Kellogg Eye Center website. <http://www.kellogg.umich.edu/patientcare/conditions/cataract.html>. Accessed October 28, 2017. REF2016OTH0327



integral part of their daily lives.<sup>12</sup> The rapid shift to digital platforms has increased demand from cataract patients for high-quality vision, from distance-to-intermediate-to-near, in all lighting conditions.

“In the past 10 months of implanting the TECNIS Synergy™ IOL lens, I have seen excellent visual performance at all distances, and in a wide variety of lighting conditions, with most patients achieving freedom from glasses,” said Dr. Ike Ahmed,<sup>\*\*\*</sup> Assistant Professor and Director of the Glaucoma and Advanced Anterior Surgical Fellowship, University of Toronto in Canada. “Having used the TECNIS® Toric II platform in other TECNIS® lenses, I’m eager to use the TECNIS Synergy™ Toric II IOL in patients that require astigmatism correction.”

The TECNIS Synergy™ and TECNIS Synergy™ Toric II IOLs are among the latest surgical vision innovations from Johnson & Johnson Vision to receive FDA and Health Canada approval. Over the past year, the company has received clearance or approval across North America for seven innovations designed to be used in the treatment of cataract patients, including the TECNIS Eyhance™ IOLs.

“The TECNIS Synergy™ IOL combines the best of extended depth of focus and multifocal technologies – to deliver the widest range of continuous vision with the best near vision among leading PCIOLs,<sup>3,4,6,7†</sup> without the visual gaps caused by existing trifocal technology,”<sup>†††</sup> said Rajesh Rajpal, Chief Medical Officer and Global Head of Clinical and Medical Affairs at Johnson & Johnson Vision. “Additionally, we’ll offer TECNIS Synergy™ IOL on our new Toric II platform, when it launches later this year, to give surgeons the ability to address astigmatism at the time of surgery.”

The TECNIS Synergy™ IOL was first launched in Europe and Asia Pacific in 2019 and is currently available in Latin America and Canada. The full TECNIS Synergy™ IOL family will be available across North America this summer.

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## About TECNIS® Platform

At Johnson & Johnson Vision, quality begins with the platform. The TECNIS® platform uses a proprietary combination of materials and design to deliver more for patients – more clarity with lower reflectance/lower dispersion vs competitor platform<sup>13,14,15‡</sup>, the lowest level of chromatic aberration available on the market<sup>16‡‡</sup>, and almost complete elimination of spherical aberration<sup>17,18</sup>. The TECNIS® portfolio also delivers more image contrast - day and night - than the leading competitor platform<sup>14,19 ‡‡‡</sup>

<sup>12</sup> Ofcom – Adults’ Media Use and Attitudes Report. 25 April 2018. REF2019CT4116.

† vs PanOptix® IOL, Symfony, TMF Continuous 20/32 or better based on defocus curve (United States), vs. PanOptix® IOL, AT Lisa Trifocal IOL and FineVision IOL (Canada)

‡‡Based on interim data collected at 6-months post-operative

‡‡‡Non head-to-head bench study. Tested with PanOptix® IOL, AT Lisa Trifocal IOL and FineVision IOL.

<sup>13</sup> Zhao H, Mainster MA. *Br J Ophthalmol*. 2007; 91:1225–1229.

<sup>14</sup> Negishi K et al. *Arch Ophthalmol* 2001;119:1154-1158.

<sup>15</sup> Krader CG. *EUROTIMES* 2011/2012;16/17: 18.

<sup>16</sup> Data On File, DOF2018CT4007, Johnson & Johnson Surgical Vision, Inc. 2018

<sup>17</sup> Piers P, Manzanera S, Prieto P, Gorceix N, Artal P. Use of adaptive optics to determine the optimal ocular spherical aberration. *J Cataract Refract Surg*. 2007 Oct;33(10):1721-6 2.

<sup>18</sup> Data On File, Johnson & Johnson Surgical Vision, Inc. 2015.

<sup>19</sup> Data on File, DOF2018OTH 4004 Johnson & Johnson Surgical Vision, Inc. 2018. (Modular transfer function (MTF) is a measure of the amount of contrast transferred by the optics in a visual system. The higher the MTF value, the more contrast transferred to the image, resulting in higher image contrast.)

and more stability to stand the test of time.<sup>20,21,22††††</sup> Finally, TECNIS<sup>®</sup> delivers more choice for surgeons and patients - offering the broadest portfolio of IOLs, with solutions for every vision need, across a variety of different visual conditions and lifestyles.<sup>23</sup>

**INDICATIONS and IMPORTANT SAFETY INFORMATION FOR TECNIS Synergy™ IOL with TECNIS Simplicity™ Delivery System, Model DFR00V and TECNIS Synergy™ Toric II IOL with TECNIS Simplicity™ Delivery System, Models DFW150, DFW225, DFW300, DFW375, in the United States**

**INDICATIONS:**

The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Synergy™ IOL which is indicated for primary implantation for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Synergy™ Toric II IOLs that are indicated for primary implantation for the visual correction of aphakia and for reduction of refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. Compared to an aspheric monofocal lens, the TECNIS Synergy™ IOLs mitigate the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

**WARNINGS**

Intraocular lenses may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the eyesight of patients. Patients should have well-defined visual needs and be informed of possible visual effects (such as a perception of halo, starburst or glare around lights), which may be expected in nighttime or poor visibility conditions. Patients may perceive these visual effects as bothersome, which, on rare occasions, may be significant enough for the patient to request removal of the IOL. The physician should carefully weigh the potential risks and benefits for each patient. Patients with a predicted postoperative residual astigmatism greater than 1.0 diopter, with or without a toric lens, may not fully benefit in terms of reducing spectacle wear. Rotation of the TECNIS Synergy™ Toric II IOL from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible, prior to lens encapsulation. The lens and delivery system should be discarded if the lens has been folded within the cartridge for more than 10 minutes. Not doing so may result in the lens being stuck in the cartridge. 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.

<sup>20</sup> Nagata M, Matsushima H, Mukai K, Terauchi W, Senoo T, Wada H, Yoshida S. Clinical evaluation of the transparency of hydrophobic acrylic intraocular lens optics. J Cataract Refract Surg. 2010 Dec;36(12):2056-60.

<sup>21</sup> Van der Mooren M, Franssen L, Piers P. Effects of glistenings in intraocular lenses. Biomed Opt Express.

<sup>22</sup> Auffarth GU, et al. Analysis of optical purity and optical quality of a new extended range of vision IOL. Poster presented at: The 20th ESCRS Winter Meeting; February 2016, Athens, Greece.

<sup>23</sup> Freeman W. Market Scope - 2017 IOL report: a global market analysis for 2016 to 2022. P. 79, 137, 174. REF2018MLT4002

†Competitor platforms included are Hoya, Alcon & B&L Acrylic

††Against IOLs that use Hoya, Alcon Acrylic, and B&L Silicone

†††Against AcrySof IOL & Clareon IOL

††††Against AcrySof IOL

## **PRECAUTIONS**

Interpret results with caution when using autorefractors or wavefront aberrometers that utilize infrared light, or when performing a duochrome test. Confirmation of refraction with maximum plus manifest refraction technique is strongly recommended. The ability to perform some eye treatments (e.g., retinal photocoagulation) may be affected by the IOL optical design. The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved. The TECNIS Synergy™ IOLs should not be placed in the ciliary sulcus. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or over-inflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS Synergy™ Toric II IOL. All preoperative surgical parameters are important when choosing a TECNIS Synergy™ Toric II IOL for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, the surgeon's estimated surgically induced astigmatism (SIA) and biometry. Variability in any of the preoperative measurements can influence patient outcomes and the effectiveness of treating eyes with lower amounts of preoperative corneal astigmatism. The effectiveness of TECNIS Synergy™ Toric II IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated. Patients with a predicted postoperative astigmatism greater than 1.0 D may not be suitable candidates for implantation with the TECNIS Synergy™ and TECNIS Synergy™ Toric II IOLs, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower predicted postoperative astigmatism.

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

## **INDICATIONS and IMPORTANT SAFETY INFORMATION FOR TECNIS SYNERGY™ OPTIBLUE™ WITH TECNIS SIMPLICITY DELIVERY SYSTEM, MODEL DFR00V, IN CANADA**

**INDICATIONS FOR USE:** The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Synergy™ OptiBlue™ IOL which is indicated for primary implantation for the visual correction of aphakia in adult patients with or without presbyopia, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing vision far through near and reduced spectacle dependence across a range of distances. The lens is intended to be placed in the capsular bag.

**PRECAUTIONS:** Recent contact lens usage may affect the patient's refraction; therefore, in contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power. Prior to implanting, examine the lens package for proper lens model, dioptric power, and expiration date. The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved. Care should be taken to achieve centration of the intraocular lens. When the insertion system is used improperly, the haptics of the IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. Safety and effectiveness in patients 21 years or younger have not been established in clinical studies. The intraocular pressure of implanted patients with glaucoma should be carefully monitored for postoperative changes.

**WARNINGS:** Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio. The lens model ZFR00V should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus. Well-informed patients with well-defined visual needs and preferences should be selected for lens model ZFR00V implantation. The patients should be informed of the possibility of visual effects (such as halo or glare) in nighttime or poor visibility conditions. Patients may perceive these visual effects as an annoyance or hindrance, which, on rare occasions, may be significant enough for the patient to request removal of the IOL. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for lens model ZFR00V implantation since they may not fully benefit in terms of potential spectacle independence. The lens model ZFR00V may affect image quality and lead to some reduction of contrast sensitivity compared to a monofocal lens. Therefore, patients should exercise caution when driving at night or in poor visibility conditions.

**ADVERSE EVENTS:** Potential adverse events during or following cataract surgery with implantation of the IOL may include but are not limited to: Endophthalmitis/intraocular infection, IOL dislocation, Persistent cystoid macular edema, Persistent corneal stromal edema, Persistent raised intraocular pressure (IOP) requiring treatment, Secondary surgical intervention (including implant repositioning, removal, AC tap, or other surgical procedure). Adverse events can lead to permanent visual impairment and may require secondary surgical intervention, including intraocular lens exchange or explantation. **ATTENTION:** Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

## **INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS Eyhance™ and TECNIS™ Eyhance Toric II IOLs with TECNIS Simplicity® Delivery System, In the United States**

### **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.

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

#### **INDICATIONS FOR USE**

The TECNIS Simplicity® Delivery System is used to fold and assist in inserting the TECNIS Eyhance™ IOL which is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens extends the depth of focus, which improves vision for intermediate tasks, and provides similar distance vision as compared to a standard aspheric monofocal IOL. The lens is indicated for placement in the capsular bag only.

The TECNIS Simplicity® Delivery System is used to fold and assist in inserting the TECNIS Eyhance™ Toric II IOL, which is indicated for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with or without presbyopia in whom a cataractous lens has been removed by extracapsular cataract extraction and who desire improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance vision compared to a non-toric IOL. The lens also extends the depth of focus, which improves vision for intermediate tasks, and provides similar distance vision as compared to a standard aspheric monofocal IOL. The lens is indicated for placement in the capsular bag only.

### **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**

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.

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### **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), [@JNJVision on Twitter](https://twitter.com/JNJVision), [Johnson & Johnson Vision on LinkedIn](https://www.linkedin.com/company/jnjvision), and [@JNJVision on Facebook](https://www.facebook.com/jnjvision).

### **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.

### **Cautions Concerning Forward-Looking Statements**

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding TECNIS Synergy™ and TECNIS Synergy™ Toric II IOLs. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson Vision and/or Johnson & Johnson. Risks and uncertainties include, but are not



limited to: uncertainty of regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. Neither Johnson & Johnson Vision nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

\*Johnson & Johnson Vision represents the products and services of Johnson & Johnson Surgical Vision, Inc., Johnson & Johnson Vision Care, Inc., Johnson & Johnson Vision Care division of Johnson & Johnson Inc., AMO Canada Company, and their affiliates.

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

\*\*\*Dr. Ike Ahmed is a paid consultant to Johnson & Johnson Vision.

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