# Johnson&Johnson

## Vision

Media contact (EMEA): Sarah Smith ssmith49@its.jnj.com

Media contact (NA): Maggie Lorenz mloren15@its.jnj.com

Investor contact: Sandra Easton investor-relations@its.ini.com

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### FOR IMMEDIATE RELEASE

## Johnson & Johnson Launches New TECNIS Odyssey Next-Generation Intraocular Lens in Europe, the Middle East, and Canada Offering Cataract Patients Precise Vision at Every Distance in Any Lighting<sup>\*</sup>t<sup>1,6</sup>

The new full visual range\*1 IOL enables 93% of patients to become free from glasses at all distances. \*\*2 \*\*\*

With best-in-class image contrast and low-light performance,<sup>#~3,4,5</sup> TECNIS Odyssey IOL expands the Johnson & Johnson portfolio of advanced Presbyopia Correction IOLs.

TECNIS Odyssey IOL enables surgeons to deliver consistent and reliable patient outcomes.<sup>17,15</sup>

**[JACKSONVILLE, FL June 17, 2025]** – Johnson & Johnson,<sup>§</sup> a global leader in eye health, announced today that it is expanding its portfolio of presbyopia-correcting intraocular lenses (PC - IOL) with the roll-out of TECNIS Odyssey IOL in Europe, the Middle East, and Canada. The new full visual range<sup>\*1</sup> IOL offers high-quality and continuous vision with unmatched range.<sup>\$6,16</sup> This will allow patients to see clearly from far to near and in between, minimizing their need for glasses.<sup>‡+2,6,7</sup> Built on the industry-leading TECNIS platform, combining advanced optics and proprietary materials, TECNIS Odyssey IOL offers consistently clear, high-contrast vision.

"TECNIS Odyssey IOL is the fastest growing PC-IOL in the United States,<sup>^</sup> and we are excited to be making it available to more patients around the world. It addresses a significant unmet need for cataract patients seeking greater spectacle independence.<sup>+</sup> Now – together with TECNIS PureSee – TECNIS Odyssey IOL elevates the strength and depth of our global IOL portfolio, meeting the diverse needs of today's aging population," said Peter Menziuso, Company Group Chairman, Vision, Johnson & Johnson.

Currently, an estimated 94 million people aged 50 years and over have moderate-to-severe distance vision impairment or blindness that could be corrected through lens replacement surgery.<sup>8</sup> These figures are projected to increase, since presbyopia and cataract development are part of the aging process. Presbyopia is a progressive eye condition that makes it difficult to focus on close objects and usually becomes noticeable around 40 years of age.<sup>9</sup> Full visual range IOLs provide the opportunity to correct presbyopia at the time of lens replacement surgery.

"From my early experience, what sets the TECNIS Odyssey IOL apart, is its ability to deliver consistent visual outcomes across a wide range of patients, due to its advanced design with higher tolerance to residual refractive error, "<sup>17,11</sup> said Professor Beatrice Cochener-Lamard, Head of the Ophthalmology Department at Brest University Hospital in France.<sup>^^</sup>

TECNIS Odyssey IOL is the latest innovation for those seeking greater visual freedom - offering:

- **Precise vision**: **TECNIS Odyssey IOL** provides crisp and clear vision, allowing patients to see with clarity at every distance<sup>6</sup> whether they are reading, driving or engaging in daily activities.
  - o 94% of patients were satisfied with their overall vision without glasses. &\*\*\*\*12
- At every distance: Its unique, freeform diffractive surface was designed to eliminate the gaps between near, intermediate and far distances, and offer continuous, uninterrupted vision at all distances.<sup>†‡6</sup>
  - 96% of patients were satisfied with reading a smartphone or tablet,<sup>&\*\*\*\*13</sup> and 97% were satisfied with distance vision.<sup>&\*\*\*\*12</sup>
- In any lighting: Engineered to minimize night vision disturbances fewer halos and glare<sup>#14</sup> TECNIS Odyssey
  IOL provides better image quality than PanOptix day and night,<sup>##3,4,5</sup> for a more comfortable night-time experience
  92% of patients were satisfied with their ability to see steps and read street signs at night.<sup>&\*\*\*\*13</sup>

With a variety of options for different visual needs and lifestyles, the TECNIS platform empowers more patients to find the right solution. The Johnson & Johnson portfolio of advanced Presbyopia Correction IOLs available in Europe, the Middle East, Canada, and Japan now includes both TECNIS Odyssey IOL and TECNIS PureSee IOL. TECNIS Odyssey IOL, the full range of vision IOL, is also available in the US, Puerto Rico, and Japan. TECNIS PureSee IOL, the purely refractive, extended depth of focus IOL, is also available across APAC and Latin America. TECNIS PureSee has not received PMA Approval in the US.

For more patient information and tools please visit <u>www.clearvisionforyou.com</u>. Visit us at <u>jnjvisionpro.eu</u> and <u>jnjvisionpro.en-ca</u> and <u>follow Johnson & Johnson | Vision on LinkedIn</u>.

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#### About Vision at Johnson & Johnson

Johnson & Johnson has a deep legacy in developing transformational new products that improve the health of patients' eyes. We have a bold ambition: Vision Made Possible – improving sight for more than 40 million people each year. Through cutting-edge innovation, expertise in material and optical science, and advanced technologies, we are revolutionizing the way people see and experience the world. Visit us at <u>clearvisionforyou.com</u>, <u>follow @JNJVision on</u> <u>Twitter</u>, Johnson & Johnson | Vision on LinkedIn, and @JNJVision on Facebook.

#### About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity. Learn more about our MedTech sector's global scale and deep expertise in cardiovascular, orthopedics, surgery and vision solutions at <a href="https://thenext.jnjmedtech.com">https://thenext.jnjmedtech.com</a>. Follow us at @JNJMedTech and on LinkedIn. Johnson & Johnson Surgical Vision, Inc. is part of Johnson & Johnson.

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

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the launch of TECNIS Odyssey<sup>™</sup> intraocular lens. 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. Risks and uncertainties include, but are not limited to: 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 most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at <u>www.sec.gov</u>, <u>www.jnj.com</u> or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

#### Footnotes

\*According to ISO 11979-7:2024, based on the clinical study of the parent IOL

\*\*(n=82) 1 month results. Q: "Was the patient wearing any spectacles or contact lenses since the surgery?" Six subjects 6/82 (5 subjects for near, 1 subject for both distance and near);

\*\*\*Based on 1-month postoperative data from a multicenter, retrospective, real-world clinical study in the U.S. evaluating visual and patient-reported outcomes from subjects bilaterally implanted with TECNIS Odyssey<sup>™</sup> IOL (n=96). \*\*\*\*Based on 3-month postoperative data from a multicenter, observational clinical study in the U.S. evaluating visual and patient-reported outcomes from subjects bilaterally implanted with TECNIS Odyssey<sup>™</sup> IOL (n=33).

¶based on pre-clinical bench testing. The third-party trademarks used herein are the trademarks of their respective owners.

∫compared to TECNIS Synergy™ and TECNIS™ Multifocal IOLs based on pre-clinical bench testing

#compared to PanOptix® based on pre-clinical bench testing

##compared to leading competitor full visual range IOLs based on pre-clinical bench testing (white light MTF at 50 c/mm measured for 3mm & 5mm pupil in the ACE model)

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

†continuous 20/25 or better

‡based on pre-clinical bench testing

^based on Market Scope's estimated procedure for 2024 vs 2023

^^^Professor Beatrice Cochener-Lamard is a paid consultant of Johnson & Johnson MedTech

~Compared to TECNIS SYNERGY™ based on bench testing

+Individual results will vary. Some TECNIS Odyssey ™ IOL patients may require spectacles post-surgery.

-Results may vary. Consult your doctor to determine the lens options that are right for you.

\$Compared to PanOptix® based on bench testing and head-to-head clinical studies of parent lens

&Values rounded to the nearest 1%

Indication and safety information in regions where these products are available for use is included below. <u>Please</u> <u>note indications may differ based on region</u>. Full safety information is available hyperlinked below.

#### IN THE UNITED KINGDOM

The promoted product is a medical device. For healthcare professionals only.

Please reference the Instructions for Use for a complete list of Indications and Important Safety Information and contact our specialists in case of any question.

#### IN CANADA

#### INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS ODYSSEY<sup>™</sup> IOL WITH TECNIS SIMPLICITY<sup>™</sup> DELIVERY SYSTEM, MODEL DRN00V AND TECNIS ODYSSEY<sup>™</sup> TORIC II IOL WITH TECNIS SIMPLICITY<sup>™</sup> DELIVERY SYSTEM, MODELS DRT100, DRT150, DRT225, DRT300, DRT375, IN CANADA:

#### **Rx Only**

**INDICATIONS FOR USE:** The TECNIS SIMPLICITY<sup>™</sup> Delivery System is used to fold and assist in inserting the TECNIS Odyssey<sup>™</sup> 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 TECNIS SIMPLICITY <sup>™</sup> Delivery System is used to fold and assist in inserting the TECNIS Odyssey <sup>™</sup> Toric II IOLs which are indicated for primary implantation 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. 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.

#### 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 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 residual astigmatism greater than 1.0 diopter, with or without a toric lens, may not fully benefit in terms of potential spectacle independence. Rotation of the TECNIS Odyssey ™ 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.

#### **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 Odyssey ™ 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 Odyssey ™ Toric II IOL. Care should be taken to achieve centration of the toric IOL. Safety and effectiveness in patients 21 years or younger have not been established in clinical studies.

#### ATTENTION:

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

# INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS PURESEE<sup>™</sup> IOL WITH TECNIS SIMPLICITY<sup>™</sup> DELIVERY SYSTEM, AND TECNIS PURESEE<sup>™</sup> TORIC II IOL WITH TECNIS SIMPLICITY<sup>™</sup> DELIVERY SYSTEM IN CANADA

#### INDICATIONS FOR USE

The TECNIS SIMPLICITY<sup>™</sup> Delivery System is used to fold and assist in inserting the TECNIS PureSee<sup>™</sup> IOL which is indicated for primary implantation for the visual correction of aphakia, in adult patients with less than 1 diopter of preexisting corneal astigmatism, in whom a cataractous lens has been removed. The lens is intended to correct presbyopia by providing improved vision over a continuous range of distances including far, intermediate, and near, and decreased spectacle dependence. The lens is intended for capsular bag placement only.

The TECNIS SIMPLICITY<sup>™</sup> Delivery System is used to fold and assist in inserting the TECNIS PureSee<sup>™</sup> Toric II IOL which is indicated for primary implantation for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with and without presbyopia in whom a cataractous lens has been removed. The lens is intended to correct presbyopia by providing improved vision over a continuous range of distances including far, intermediate, and near, a reduction of residual refractive cylinder, and decreased spectacle dependence. The lens is intended for capsular bag placement only.

#### WARNING

Physicians should weigh the potential risk/benefit ratio of IOL implantation in patients with any of the conditions described in the Directions for Use. These conditions are not specific to the design of the IOL and are attributed to cataract surgery and/or IOL implantation in general. The IOL should be placed entirely in the capsular bag. Do not place the IOL in the ciliary sulcus. Patients should be informed of the possibility of visual disturbances. The lens may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL; fully inform the patient of this risk before implanting the lens. Special consideration should be made for patients with macular disease, amblyopia, corneal irregularities, or other ocular disease. Inform patients to exercise special caution when driving at night or in poor visibility conditions.

Rotation of the TECNIS PureSee<sup>™</sup> Toric II IOL away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, IOL repositioning should occur as early as possible prior to lens encapsulation.

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 use if the cartridge tip is cracked or split. Do not implant the IOL if the rod tip does not advance the IOL or if it is jammed in the delivery system. Do not advance the IOL from the Holding Position (located at the half turn rotation position for the initial advancement of the IOL into the cartridge) prior to fully hydrate the system and ready for implantation. A minimum of 1 minute at the Holding Position is required to fully hydrate the system to prevent sticking and a potential scratch or crack to the IOL. Interruptions during delivery may result in the IOL being scratched or cracked or stuck in the cartridge. Discard the device if the IOL has been advanced past the Holding Position but not delivered within 60 seconds. The IOL and delivery system should be discarded if the IOL has been folded within the cartridge for more than 10 minutes. Not doing so may result in the IOL being stuck in the cartridge.

#### PRECAUTIONS

Autorefractors may not provide optimal postoperative refraction of patients with the IOL. Manual refraction with maximum plus technique is strongly recommended. 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. Target emmetropia for optimum visual performance.

For the TECNIS PureSee<sup>™</sup> Toric II IOL, variability in any preoperative surgical parameters (e.g., keratometric cylinder, incision location, estimated surgically induced astigmatism, or biometry) can influence patient outcomes. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case, to avoid lens rotation.

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 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**

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 explanation.

#### ATTENTION

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

#### IN THE UNITED STATES

#### INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS ODYSSEY<sup>™</sup> IOL WITH TECNIS SIMPLICITY<sup>™</sup> DELIVERY SYSTEM, MODEL DRN00V AND TECNIS ODYSSEY<sup>™</sup> TORIC II IOL WITH TECNIS SIMPLICITY<sup>™</sup> DELIVERY SYSTEM, MODELS DRT150, DRT225, DRT300, DRT375 IN THE UNITED STATES

#### **Rx Only**

#### **INDICATIONS:**

The TECNIS SIMPLICITY<sup>™</sup> Delivery System is used to fold and assist in inserting the TECNIS Odyssey<sup>™</sup> 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<sup>™</sup> Delivery System is used to fold and assist in inserting the TECNIS Odyssey<sup>™</sup> 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 Odyssey<sup>™</sup> 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 Odyssey™ 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.

#### **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 Odyssey™ 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 Odyssey <sup>™</sup> Toric II IOL. All preoperative surgical parameters are important when choosing a TECNIS Odyssey <sup>™</sup> 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 Odyssey <sup>™</sup> 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 Odyssey <sup>™</sup> 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 found here: <a href="https://www.injvisionpro.com/en-us/important-safety-information/?tab=2">https://www.injvisionpro.com/en-us/important-safety-information/?tab=2</a>

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<sup>1</sup> Data on File. 2024DOF4002 (prospective, multicenter, randomized, three-way-masked clinical study comparing subjects bilaterally implanted with TECNIS Synergy IOL (n=132) vs TECNIS 1-Piece Monofocal IOL (n=131) at 6-months post-op)

- <sup>2</sup> Data on File. DOF2023CT4051.
- <sup>3</sup> Data on File. 2024DOF4033
- <sup>4</sup> Data on File. DOF2019OTH4002
- <sup>5</sup> Data on File. DOF2023CT4007
- <sup>6</sup> Data on File. DOF2023CT4023
- <sup>7</sup> Data on File. 2024DOF4003

<sup>8</sup> World report on vision. Geneva: World Health Organization, 2019. Available at: https://apps.who. int/iris/bitstream/handle/10665/328717/9789241516570-eng.pdf. Last accessed: May 2025.

<sup>9</sup> What Is Presbyopia – American Academy of Ophthalmology. Access from: https://www.aao.org/eye-health/diseases/what-is-presbyopia. 2024REF5075.

- <sup>11</sup> Data on File. 2024DOF4017
- <sup>12</sup> Data on File. 2024DOF4027.
- <sup>13</sup> Data on File. 2024DOF4029.
- <sup>14</sup> Data on File. 2024DOF4005
- <sup>15</sup> DOF2023CT4052
- <sup>16</sup> DOF2020CT4014

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