Johnson&Johnson

NEWS RELEASE

Johnson & Johnson Announces FDA Approval of TECNIS PureSee Intraocular Lens, a Breakthrough Solution for U.S. Cataract Patients

2026-03-12

- 97% of patients reported no very bothersome visual disturbances, like halos or glare, with TECNIS PureSee IOL[1]
- 97% of patients would recommend this IOL to friends or family[2]
- TECNIS PureSee IOL is the first and only U.S. FDA-approved extended depth of focus (EDOF) IOL maintaining contrast sensitivity comparable to an aspheric monofocal IOL[1]*

JACKSONVILLE, Fla.--(BUSINESS WIRE)-- Johnson & Johnson (NYSE: JNJ) announced U.S. Food and Drug Administration (FDA) approval of TECNIS PureSee IOL, an extended depth of focus (EDOF) intraocular lens (IOL) intended for use in cataract surgery.[1] TECNIS PureSee IOL delivers clarity of vision for patients, with 97% of them reporting no very bothersome visual disturbances.[1] TECNIS PureSee IOL will be available for patients in the U.S. later this year.

“Today marks an exciting milestone for people living with cataracts. The approval of the TECNIS PureSee IOL gives surgeons an important new lens option, reflecting our deep commitment to innovation that delivers high patient satisfaction and supports vision solutions tailored to individual lifestyle needs,” said Peter Menziuso, Company Group Chairman, Vision, Johnson & Johnson. “Cataract surgery is often a once-in-a-lifetime opportunity for patients to restore and enhance their vision. With the addition of TECNIS PureSee IOL to our portfolio, we can help even more patients regain not just sight, but the quality, range, and visual performance they expect from a Johnson & Johnson product.”

Cataracts naturally form as the eye ages, making everyday activities such as reading, driving, and recognizing faces

more difficult. Cataract surgery is one of the safest and most commonly performed procedures worldwide, offering patients the removal of a clouded natural lens and also the opportunity to enhance their vision.[3] In a single procedure, TECNIS PureSee IOL addresses both cataract-related vision loss and the effects of presbyopia,[1] which occurs when your eyes gradually lose the ability to see objects clearly up close.[4] 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.[5]

TECNIS PureSee IOL is the first and only U.S. FDA-approved extended depth of focus (EDOF) IOL with no warning on loss of contrast sensitivity.[1]* Contrast sensitivity refers to a patient's ability to distinguish an object from its background, an important part of visual quality, especially in low-light or foggy conditions. Aspheric monofocal IOLs are widely considered the benchmark for preserving contrast sensitivity, and by maintaining contrast sensitivity comparable to an aspheric monofocal IOL, TECNIS PureSee IOL helps patients experience the visual clarity and confidence they expect, while also benefiting from an extended range of vision.[1]

TECNIS PureSee IOL is built on the industry-leading TECNIS platform, combining advanced optics with proprietary material. It mitigates the effects of presbyopia by providing extended depth of focus, enabling excellent distance and intermediate vision, with some near vision.[1]** TECNIS PureSee IOL reduces patients' reliance on glasses following surgery, with 97% of patients reporting no very bothersome visual disturbances.[1,2]

TECNIS PureSee IOL expands Johnson & Johnson's surgical vision portfolio, which is backed by 25 years of innovation in intraocular lens technology. Each year, millions of patients worldwide receive TECNIS lenses as part of their cataract surgery.[6] The TECNIS portfolio includes TECNIS PureSee IOL, a purely refractive EDOF IOL;[1] TECNIS Odyssey IOL, a Full Visual Range (FVR) IOL;[7] and TECNIS Eyhance IOL, the first monofocal IOL designed to slightly extend depth of focus.[8]

TECNIS PureSee IOL is approved globally, and nearly half a million eyes worldwide have already experienced clearer, uninterrupted vision with TECNIS PureSee IOL after cataract surgery.[1,9]

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

INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS PureSee™ IOL and TECNIS PureSee™ 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 PureSee™ 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 lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the TECNIS PureSee™ IOL provides improved intermediate visual acuity, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

The TECNIS SIMPLICITY™ Delivery System is used to fold and assist in inserting the TECNIS PureSee™ Toric II IOLs, which 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. The lenses mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the TECNIS PureSee™ Toric II IOLs provide improved intermediate visual acuity, while maintaining comparable distance visual acuity. The lenses are intended for capsular bag placement only.

WARNINGS

1. Physicians should weigh the potential benefit/risk ratio of IOL implantation in patients with any of the conditions listed below, as intraocular lenses may exacerbate an existing condition or may pose an unreasonable risk to the eyesight of patients. The following conditions are not specific to the design of the IOL and are attributed to cataract surgery and/or IOL implantation in general:
    a. Recurrent severe anterior or posterior segment inflammation of unknown etiology
    b. Posterior segment diseases of which monitoring or treatment ability may be limited by an intraocular lens
    c. Surgical difficulties at the time of cataract extraction and/or intraocular lens implantation that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss)
    d. Compromised posterior capsule or zonules due to previous trauma or developmental defect in which appropriate support of the IOL is not possible
    e. Risk of damage to the endothelium during implantation
    f. Suspected microbial infection
    g. Congenital bilateral cataracts
    h. Previous history of, or a predisposition to, retinal detachment
    i. Potentially good vision in only one eye
    j. Medically uncontrollable glaucoma
    k. Corneal endothelial dystrophy
    l. Proliferative diabetic retinopathy
2. Rotation of the toric lens away 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.
3. 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.
4. Do not use if the cartridge of the delivery system is cracked or split prior to implantation.
5. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system.
6. Do not stop, reverse or advance the plunger too slowly (for example more than 1 second) during initial lens advancement. Doing so may result in improper folding of the lens.
7. Do not advance the lens from the Holding Position prior to fully hydrating the system. 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 lens.
8. Do not advance the lens from the Holding Position until ready for implantation. Interruptions during delivery may result in the lens being scratched or cracked or stuck in the cartridge. Discard the device if the lens has been advanced past the Holding Position but not delivered within 60 seconds.
9. 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.
10. Johnson & Johnson Surgical Vision, Inc., single-use medical devices are labeled with instructions for use and handling to minimize exposure to conditions which may compromise the product, patient, or the user. When used according to the directions for use, the delivery system minimizes the risk of infection and/or inflammation associated with contamination.
11. The reuse/resterilization/reprocessing of Johnson & Johnson Surgical Vision, Inc. single-use medical devices may result in physical damage to the medical device, failure of the medical device to perform as intended, and patient contamination, transmission of infection, and lack of product sterility.

PRECAUTIONS

1. Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to the patient.
2. Autorefractors may not provide optimal postoperative refraction of patients with the IOL. Manual refraction with maximum plus technique is strongly recommended.
3. This is a single-use device. Do not resterilize the lens or the delivery system. Most sterilizers are not equipped to sterilize the soft acrylic material of the IOL and the preloaded inserter material without producing undesirable side effects.
4. Do not store the device in direct sunlight or at a temperature under 41°F (5°C) or over 95°F (35°C).
5. Do not autoclave the delivery system.
6. The contents are sterile unless the package is opened or damaged.
7. Do not use if the delivery system has been dropped or if any part was inadvertently struck while outside the shipping box. The sterility of the delivery system and/or the lens may have been compromised.
8. The recommended temperature for implanting the lens is at least 63°F (17°C).
9. Do not advance the lens unless ready for lens implantation.
10. Do not leave the lens in a folded position more than 10 minutes.
11. When the delivery system is used improperly, the lens may not be delivered properly (i.e., haptics may be broken). Please refer to the specific Directions For Use section provided.
12. The use of balanced salt solution or ophthalmic viscosurgical devices (OVDs) is required when using the delivery system. For optimal performance when using OVD, use the HEALON™ family of OVDs. The use of balanced salt solution with additives has not been studied for this product.
13. The lens should be placed entirely in the capsular bag. The lens should not be placed in the ciliary sulcus.
14. 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 toric lens with the intended axis of placement.
15. Do not reuse.
16. 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.
17. The IOL is designed for optimum visual performance when emmetropia is targeted.
18. The TECNIS™ Toric IOL Calculator includes a feature that accounts for posterior corneal astigmatism (PCA). The PCA is based on an algorithm that combines published literature (Koch, et al., 2012) and a retrospective analysis of data from a TECNIS™ Toric multi-center clinical study. The PCA algorithm for the selection of appropriate cylinder power and axis of implantation was not assessed in the prospective TECNIS™ Toric IOL U.S. IDE study and may yield results different from those in the TECNIS PureSee™ Toric II IOL labeling. Please refer to the TECNIS™ Toric IOL Calculator user manual for more information.
19. The use of methods other than the TECNIS™ Toric IOL Calculator to select cylinder power and appropriate axis of implantation were not assessed in the TECNIS™ Toric IOL U.S. IDE study and may not yield similar results. Accurate keratometry and biometry, in addition to the use of the TECNIS™ Toric IOL Calculator (**www.TecnisToricCalc.com**) are recommended to achieve optimal visual outcomes for the TECNIS PureSee™ Toric II IOLs.
20. All preoperative surgical parameters are important when choosing a toric lens 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 the toric lens in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism less than 1.0 diopter has not been demonstrated.
21. All corneal incisions were placed temporally in the TECNIS™ Toric IOL U.S. IDE study. If the surgeon chooses to place the incision at a different location, outcomes may be different from those obtained for the TECNIS™ Toric IOL. Note that the TECNIS™ Toric IOL Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.
22. Children under the age of 2 years are not suitable candidates for intraocular lenses.
23. The safety and effectiveness of the TECNIS PureSee™ IOLs have not been substantiated in pregnant women, patients under the age of 22 or those with preexisting ocular conditions and intraoperative complications, including those specified in the Warnings and Precautions. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions.

    Before Surgery
    - Pupil abnormalities
    - Prior corneal refractive or intraocular surgery
    - Choroidal hemorrhage
    - Chronic severe uveitis
    - Concomitant severe eye disease
    - Extremely shallow anterior chamber
    - Medically uncontrolled glaucoma
    - Microphthalmos
    - Non-age-related cataract
    - Proliferative diabetic retinopathy (severe)
    - Severe corneal dystrophy
    - Severe optic nerve atrophy
    - Irregular corneal astigmatism
    - Amblyopia
    - Macular disease

    During Surgery
    - Excessive vitreous loss
    - Non-circular capsulotomy/capsulorhexis
    - The presence of radial tears known or suspected at the time of surgery
    - Situations in which the integrity of the circular capsulotomy/ capsulorhexis cannot be confirmed by direct visualization
    - Cataract extraction by techniques other than phacoemulsification or liquefaction
    - Capsular rupture
    - Significant anterior chamber hyphema
    - Uncontrollable positive intraocular pressure
    - Zonular damage
24. Potential complications generally associated with cataract surgery include, but are not limited to: endophthalmitis/intraocular infection, hypopyon, hyphema, IOL dislocation, persistent cystoid macular edema, pupillary block, retinal detachment/tear, persistent corneal stromal edema, persistent uveitis, persistent raised intraocular pressure (IOP) requiring treatment (e.g., AC tap), retained lens material, or toxic anterior segment syndrome, or any other adverse event that leads to permanent visual impairment or requires surgical or medical intervention to prevent permanent visual impairment.

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

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 **clearvisionforyou.com**, follow **@JNJVision** on X, **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, orthopaedics, surgery and vision solutions at **https://www.jnjmedtech.com/en-US/**. Follow us at **@JNJMedTech** on LinkedIn.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to TECNIS PureSee IOL. 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: competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and global health care reforms 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 **www.sec.gov**, **www.jnj.com**, **www.investor.jnj.com** 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.

*In clinical evaluation, TECNIS PureSee IOL demonstrated contrast sensitivity comparable to an aspheric monofocal intraocular lens, with no clinically meaningful differences (≤0.3 log units) versus aspheric monofocal controls across pupil sizes, while maintaining distance visual acuity and low levels of visual symptoms.

**TECNIS PureSee IOL achieved a 1.5-line difference in mean monocular distance-corrected near VA at 6 months compared to TECNIS 1-Piece.

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1. 2026REF4592 TECNIS PureSee IOL with TECNIS SIMPLICITY Delivery System, Model DEN00V. Directions for Use, current revision. Z312075E, Rev B.
2. DOF2023CT4043 Clinical Investigation. Patient Satisfaction Outcomes. July 18, 2023.
3. Chen X, Xu J, Chen X, Yao K. Cataract: Advances in surgery and whether surgery remains the only treatment in future. 2021.
4. American Academy of Ophthalmology. What Is Presbyopia? **https://www.aao.org/eye-health/diseases/what-is-presbyopia**
5. World Health Organization. Report of the 2030 targets on effective coverage of eye care. 2025.
6. 2024REF6182. 2024 Market Scope IOL Market Report.
7. TECNIS Odyssey IOL with TECNIS SIMPLICITY Delivery System, Model DRN00V. Directions for Use, current revision.
8. TECNIS Eyhance IOL with TECNIS SIMPLICITY Delivery System, US Directions for Use, current revision.
9. Launch to Date Implants. Data on File.

2026PP04412

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Source: Johnson & Johnson