FOCUS ON VALUE

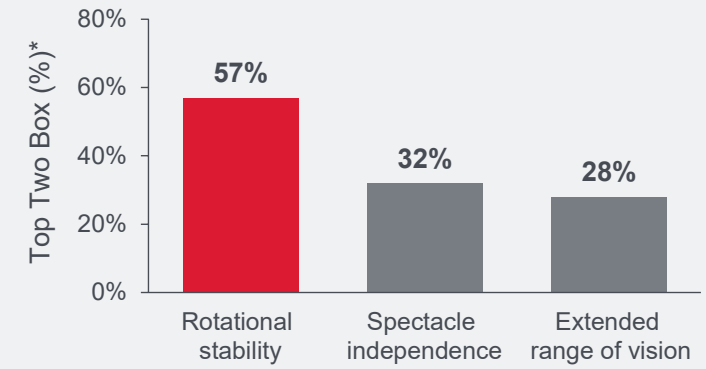
Astigmatism is **highly prevalent** and often **not corrected** during cataract surgery

- Astigmatism **≥1.0 D** affects up to **47% of patients** with cataracts[1]
- Astigmatism **reduces distance and near visual acuity, vision quality, and depth perception**[2,3]
- Astigmatism is **not surgically corrected in 41- 49% of patients** who undergo cataract surgery[4]

Toric IOLs are the **most predictable** method for astigmatism correction in cataract surgery[5]

Rotational stability of toric IOLs is key to **successful visual outcomes** and **broader surgeon adoption** of toric lens implantation[6,7]

Top drivers of initial toric IOL selection[7-9]



* Sum of top two ratings.

For **each degree of IOL rotation**, there is an approximate **3.5% decrease in its effectiveness** at reducing astigmatism[10]

The greatest post-op IOL rotation occurs **within the first hour** of surgery, and IOL orientation is **highly stable after the first post-op day**[6,11,12]

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Toric II 1-Piece IOL
Toric II
Johnson & Johnson VISION

TECNIS
Eyhance™ Toric II IOL
with TECNIS SIMPLICITY® Delivery System
Toric II

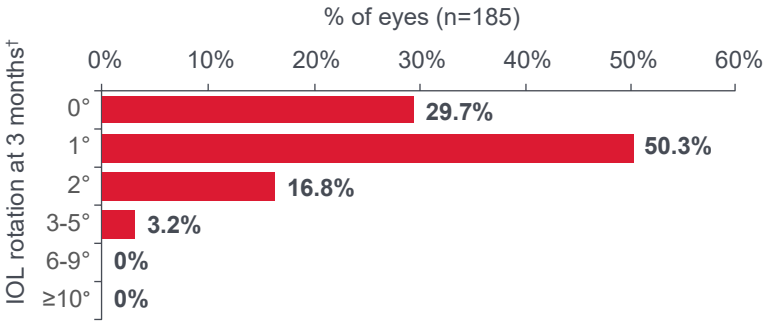
TECNIS
Synergy® Toric II IOL
with TECNIS SIMPLICITY® Delivery System
Toric II

The squared and frosted haptic design of the TECNIS® Toric II platform increases friction between the haptics and the capsular bag[13,14]

The TECNIS® Toric II platform delivers rotational stability[13]

A post-market clinical study of the **TECNIS® Toric II IOL** demonstrated:[15,*]

0.94° mean rotation
(SD 0.712°) at 3 months after surgery



100% of eyes with **≤5° rotation** at 3 months after surgery

* Based on data from 200 eyes after 3 months postoperative follow-up in a postmarket prospective, multicenter, single-arm, open-label study of the TECNIS® Toric II 1-Piece IOL conducted in the US. Outcomes differ from the pivotal investigation data in the product labeling and were collected using different measurement methods, study design and clinical conditions.
† Values were rounded to the nearest degree prior to categorization by degree of rotation.
Abbreviation: SD = standard deviation.

Economic evaluation of toric IOLs based on literature review and survey of 60 US ophthalmologists

Treating astigmatism with **toric IOLs** at the time of cataract removal **can yield benefits**:[16,‡]

Better distance vision outcomes

Reduced spectacle needs

Minimized need for **second surgical procedure**

Long-term healthcare **cost savings**

Toric IOLs may **improve patient health-related quality of life**, and are **cost effective** compared with monofocal IOLs[16,17]

‡ Compared with monofocal IOL implantation.

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References, Indications, and Important Safety Information

REFERENCES: **1**. Anderson DF et al. (2018) Global prevalence and economic and humanistic burden of astigmatism in cataract patients: a systematic literature review. *Clin Ophthalmol* 12: 439-452. **2**. Wolffsohn JS et al. (2011) Effect of uncorrected astigmatism on vision. *J Cataract Refract Surg* 37 (3): 454-460. **3**. Read SA et al. (2014) The visual and functional impacts of astigmatism and its clinical management. *Ophthalmic Physiol Opt* 34 (3): 267-294. **4**. Market Scope (2020) 2020 Annual Sponsored US Cataract Surgeon Survey Report. **5**. Nunez MX et al. (2019) Consensus on the management of astigmatism in cataract surgery. *Clin Ophthalmol* 13 311-324. **6**. Schartmuller D et al. (2020) Comparison of long-term rotational stability of three commonly implanted intraocular lenses. *Am J Ophthalmol* 220 72-81. **7**. Cataract A&U (2016a) Cataract A&U Americas Report. REF2018CT4068. **8**. Cataract A&U (2016b) Cataract A&U APAC Report. REF2018CT4070. **9**. Cataract A&U (2016c) Cataract A&U EMEA Report. REF2018CT4071. **10**. Ma JJ, Tseng SS (2008) Simple method for accurate alignment in toric phakic and aphakic intraocular lens implantation. *J Cataract Refract Surg* 34 (10): 1631-1636. **11**. Inoue Y et al. (2017) Axis Misalignment of Toric Intraocular Lens: Placement Error and Postoperative Rotation. *Ophthalmology* 124(9):1424-1425. **12**. Lee BS, Chang DF (2018) Comparison of the Rotational Stability of Two Toric Intraocular Lenses in 1273 Consecutive Eyes. *Ophthalmology* 125 (9): 1325-1331. **13**. TECNIS® Toric II 1-Piece IOL Directions for Use. DOC No. Z311395 Rev. 02. Revision Date: 10/2019. **14**. Takaku R et al. (2021) Influence of frosted haptics on rotational stability of toric intraocular lenses. *Sci Rep* 11: 15099. **15**. Johnson & Johnson Vision (2021) Data on File: From Study NXGT-202-QROS: Clinical Investigation of Rotational Stability of the TECNIS® TORIC II Intraocular Lens. DOF2021CT4019. **16**. Pineda R et al. (2010) Economic evaluation of toric intraocular lens: a short- and long-term decision analytic model. *Arch Ophthalmol* 128 (7): 834-840. **17**. Laurendeau C et al. (2009) Modelling lifetime cost consequences of toric compared with standard IOLs in cataract surgery of astigmatic patients in four European countries. *J Med Econ* 12 (3): 230-237.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE TECNIS® TORIC AND TECNIS® TORIC II 1-PIECE IOL. Rx Only. **INDICATIONS**: The TECNIS® Toric II 1-Piece and TECNIS® Toric 1-Piece IOL posterior chamber lens is indicated 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 improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance vision. The device is intended to be placed in the capsular bag. **WARNINGS**: Physicians considering lens implantation should weigh the potential risk/benefit ratio for any circumstances described in the TECNIS® Toric II 1-Piece and TECNIS® Toric 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. The clinical study for the TECNIS® Toric 1-Piece IOL did not show evidence of effectiveness for the treatment of preoperative corneal astigmatism of less than one diopter. The TECNIS® Toric II 1-Piece and TECNIS® Toric 1-Piece IOL should not be placed in the ciliary sulcus. Rotation of the TECNIS® Toric II 1-Piece and TECNIS® Toric 1-Piece IOL away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30 may increase postoperative refractive cylinder. **PRECAUTIONS**: Accurate keratometry and biometry in addition to the use of the TECNIS® Toric Calculator (www.TecnisToricCalc.com) are recommended to achieve optimal visual outcomes. The safety and effectiveness of the toric intraocular lens have not been substantiated in patients with certain preexisting ocular conditions and intraoperative complications. Refer to the TECNIS® Toric II 1-Piece and TECNIS® Toric 1-Piece IOL Directions for Use for a complete description of the preexisting conditions and intraoperative complications. All preoperative surgical parameters are important when choosing a toric lens for implantation. Variability in any of the preoperative measurements can influence patient outcomes. All corneal incisions were placed temporally in the clinical study. When the insertion system is used improperly, the haptics of the TECNIS® Toric II 1-Piece and TECNIS® Toric 1-Piece IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. Do not reuse, resterilize, or autoclave. **ADVERSE EVENTS**: The most frequently reported cumulative adverse event that occurred during the TECNIS® Toric 1-Piece IOL clinical trial was surgical re-intervention which occurred at a rate of 3.4% (lens repositioning procedures and retinal repair procedures). **ATTENTION**: Reference the Directions for Use labeling for a complete listing of Indications and Safety Information.

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.

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. **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. **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.

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