

## **Johnson & Johnson Vision Introduces TECNIS Toric II 1-Piece IOL as New Monofocal Option for Cataract Patients with Astigmatism; Launching Multi-Center, Post-Market Clinical Trials Across U.S.**

- *First IOL offered on the new TECNIS Toric II platform, features more surface texture and friction on IOL haptics*
- *Two post-market clinical trials initiating across U.S. to demonstrate rotational stability and visual outcomes*
- *Nearly half of all cataract patients have astigmatism, yet often remain untreated due to concerns around rotational stability*

**Santa Ana, Calif. December 3, 2019** – Johnson & Johnson Vision\*, a global leader in eye health, today announced the Food and Drug Administration (FDA) approval and U.S. launch of TECNIS Toric II 1-Piece Intraocular Lens (IOL). This is the first product approved on the new TECNIS Toric II platform, which offers more surface texture and friction on the IOL haptics,<sup>1</sup> which hold an IOL in proper position within the eye. The company is launching two post-market clinical trials to demonstrate the rotational stability and visual outcomes offered by the TECNIS Toric II platform. The trials will be conducted at up to 50 sites across the U.S. to collect qualitative and quantitative measures with up to 1,000 patients.

“Today’s patients with cataracts not only want clear vision, but also less dependence on glasses following surgery—something that has historically been challenging to deliver for those with astigmatism,” said Daniel H. Chang, MD,\*\* Cataract and Refractive Surgeon at Empire Eye & Laser Center. “In my experience, toric IOLs can produce excellent visual outcomes, however, even small misalignments of the lens can lead to blurred vision. I’m looking forward to being part of the post-market clinical trials to further evaluate the rotational stability of TECNIS Toric II IOL in a large population of patients.”

Astigmatism is highly prevalent, affecting nearly half of the 24.4 million cataract patients in the U.S., yet it often goes untreated during cataract surgery.<sup>2</sup> Toric IOLs are the most predictable method for correction, however, surgeon concerns around rotational stability may be acting as a barrier to providing treatment.<sup>3</sup> Properly implanting a toric IOL can be more challenging than a conventional spherical IOL due to the high degree of precision required to align the lens properly in order to correct the astigmatism present in the eye.<sup>4</sup> Movement of the lens after implantation can result in decreased vision and the need for realignment.

“With the launch of TECNIS Toric II IOL, our goal is to provide surgeons with a higher degree of confidence in treating astigmatism so that more cataract patients can enjoy clear, high quality vision,” said Xiao-Yu Song, Global Head of Research & Development, Johnson & Johnson Vision. “This advance represents the latest addition to our TECNIS Family of IOLs, building on our proud history of raising the standard of care for patients with cataracts.”

### **About Cataracts**

More than 90% of people develop cataracts—the clouding and yellowing of the lens in the eye—by the age of 65.<sup>5</sup> While part of the normal aging of the eye, left untreated, cataracts cause vision to deteriorate over time. In fact, cataracts are the #1 cause of preventable blindness worldwide, impacting more than 100 million eyes.<sup>6</sup> Cataract surgery is one of the most common outpatient procedures performed today and has a success rate of approximately 98%.<sup>7</sup> Today, cataract treatments can also offer patients vision correction, reducing or eliminating the need for glasses, in addition to removing the cataract.<sup>8,9</sup>

### **About TECNIS Toric II IOL**

TECNIS Toric II IOL is part of the industry-leading TECNIS Family of IOLs which offers a variety of options for different visual conditions and lifestyles. The TECNIS platform delivers a unique combination of material, manufacturing, and design to deliver exceptional visual outcomes across distances. TECNIS Toric II 1-Piece IOL is the first IOL offered on the new TECNIS Toric II platform, which features more surface texture and friction on the IOL haptics.

Physicians considering use of the TECNIS Toric and TECNIS Toric II IOLs should refer to the Directions for Use labeling for a complete list of indications and safety information.

**INDICATIONS:** The TECNIS Toric II 1-Piece and TECNIS Toric 1-Piece IOL posterior chamber lenses are 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.

**IMPORTANT SAFETY INFORMATION:** 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). Rotation of these IOLs away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. Variability in any of the preoperative measurements can influence patient outcomes. Physicians should weigh the potential risk/benefit ratio for circumstances described in the Directions for Use that could increase complications or impact patient outcomes. Federal law restricts this device to sale, distribution and use by or on the order of a physician.

### **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 around the world. 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 and live better. Visit us at [www.jjvision.com](http://www.jjvision.com). Follow [@JNJVision](https://twitter.com/JNJVision) on Twitter and Johnson & Johnson Vision on [LinkedIn](https://www.linkedin.com/company/johnson-johnson-vision).

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

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

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**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 Toric II 1-Piece Intraocular Lens (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 Vision, other Medical Device Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges inherent in new product development, including the uncertainty of clinical success and obtaining regulatory approvals; 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 Annual Report on Form 10-K for the fiscal year ended December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q and in 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 the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.