

FDA APPROVES THE TECNIS SYMFONY® INTRAOCULAR LENSES, THE FIRST AND ONLY EXTENDED DEPTH OF FOCUS LENSES FOR PEOPLE WITH CATARACTS

- Approval includes toric version of Symphony IOL for people with astigmatism

- Lenses provide high-quality continuous vision so patients can see clearly at near, intermediate and far-away distances, and points in between, while wearing glasses less

ABBOTT PARK, Ill., July 15, 2016 /PRNewswire/ -- Abbott announced today that the U.S. Food and Drug Administration (FDA) has approved the Tecnis Symphony® Intraocular Lenses for the treatment of cataracts. The first in a new category of intraocular lenses (IOLs), the Tecnis Symphony lenses are the only lenses in the United States that provide a full range of continuous high-quality vision following cataract surgery, while also mitigating the effects of presbyopia by helping people focus on near objects. The FDA approval includes a version of the lens for people with astigmatism, the Tecnis Symphony Toric IOL.

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Cataracts are a common condition, with almost 4 million cataract surgeries performed each year, and that number is expected to increase.¹ By age 80, more than half of all Americans either have a cataract or have had cataract surgery.² However, cataracts do not just impact seniors. In 2016 it is estimated that nearly one in four cataract surgeries will be performed on people younger than 65.¹ Many people who have cataracts experience other problems with their vision, such as presbyopia and astigmatism, which the Symphony lenses also address. Presbyopia, which affects most people over age 40, means people have lost the ability to focus on objects up close and often require glasses to perform near visual tasks. Astigmatism is when the cornea is misshapen, which causes blurry or distorted vision.

"The Symphony intraocular lens is a new option I can offer my patients to improve their vision following cataract surgery, especially those who have difficulty focusing on objects at near distances because of presbyopia," said Eric D. Donnenfeld, M.D., of Ophthalmic Consultants of Long Island, New York. "Many of my patients live very active lifestyles and want to see clearly at all distances, and without glasses if possible. With the Symphony lens, I can give patients the freedom to enjoy the activities that matter to them, while wearing glasses less."

During cataract surgery, the natural lens of the eye is removed, and an artificial lens, called an intraocular lens, or IOL, is inserted into the eye. The IOL most commonly used in cataract surgery is a monofocal lens, which only allows the person to see at a distance, with closer objects being out of focus. In contrast, the Symphony lens was specifically developed with features to improve both the range and quality of vision.

"Abbott is focused on improving people's vision and their lives by helping them stay healthy and active. Symphony offers patients, including those with astigmatism, an option for crisp, clear vision at all distances," said Thomas Frinzi, senior vice president of Abbott's vision business. "This is an important addition to our portfolio of lenses, as we expect many patients to choose a Symphony lens over a standard monofocal lens, given its benefits. We are happy that we can offer more people around the world this new category of lenses."

The approval was based on results of a U.S. pivotal study that compared the Tecnis Symphony lens to a Tecnis aspheric monofocal lens in 298 patients. Compared with patients in the monofocal group, those who received a Tecnis Symphony IOL achieved greater improvements in intermediate and near vision while maintaining similar distance vision. Patients in the Symphony group were also more likely to achieve reduced overall spectacle wear and high overall visual performance in any lighting condition. Rates of adverse events did not differ between the Symphony and monofocal groups.

The Symphony lens is approved in more than 50 countries around the world, and has been widely studied, with data from numerous clinical studies involving over 2,000 eyes. In clinical studies, the Symphony lens:

- **Provided seamless, day-to-night vision.** Patients could see objects sharply and clearly at near, intermediate and far away distances, and points in between.
- **Provided high-quality vision.** Some IOLs may leave patients with an inability to focus clearly due to competing wavelengths of light passing through the lens at different angles (known as chromatic aberration), or with vision that is not completely focused because of the shape of the lens (known as spherical aberration). The Symphony lens has been engineered to correct these issues.
- **Demonstrated a low incidence of halo and glare**, which may be perceived as rings or blurring around bright lights. Glare and halo can sometimes affect an individual's ability to drive at night or to perform other visual tasks.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS SYMFONY AND TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOLs

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE: The TECNIS Symphony IOL, Model ZXR00, 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 lens provides improved intermediate and near visual acuity while maintaining comparable distance visual acuity. The Model ZXR00 IOL is intended for capsular bag placement only.

The TECNIS Symphony Toric IOLs, Models ZXT150, ZXT225, ZXT300 and ZXT375, are indicated for primary implantation for the visual correction of aphakia and for reduction of residual 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 lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity while maintaining comparable distance visual acuity. The Model Series ZXT IOLs are intended for capsular bag placement only.

CONTRAINDICATIONS: None.

RISKS: Routine cataract surgery risks, irrelevant to lens selection, could be minor, temporary, or affect patients' vision permanently. Rare complications are worsening of vision, bleeding, or infection. Risks related to use of this lens include a slight loss in vision sharpness with decreased use of glasses. Even with glasses, loss of sharpness may worsen under poor visibility conditions such as dim light or fog. This may lead to driving difficulties, and not detecting road hazards as quickly at night or in fog. Patients may also notice halos, starbursts, glare, and other visual symptoms with extended range of vision IOLs. This may impact patients when there are bright lights at night. Patients should discuss all risks and benefits with their eye doctor before surgery.

WARNINGS: A small number of patients may want their TECNIS Symphony IOL removed because of lens-related optical/visual symptoms. Patients with pre-existing diseases or conditions (i.e., diabetes and heart disease) may have higher risk of experiencing complications (e.g., more difficult recovery) after routine cataract surgery. Patients should not receive this lens if they have had previous trauma to their eye. Not evaluated for use in children.

PRECAUTIONS: If the patient's eye is unhealthy (including glaucoma), vision may not be good even after cataract removal; patients may not get full benefit of the TECNIS IOL. Before surgery, the eye doctor will check for any eye diseases. Patients' vision with the TECNIS Symphony IOL may not be good enough to perform detailed 'up-close' work without glasses, and rarely, may make some types of retinal treatment (e.g., retinal tear repair) more difficult. Patients should take all prescribed medicines and apply eye drops as instructed to avoid inflammation and infection. Patients should avoid bending down and playing sports, which can harm the eye during recovery. The eye doctor will tell patients what activities to avoid.

SERIOUS ADVERSE EVENTS: Serious adverse events observed during the TECNIS Symphony clinical trial were not related to the lenses. These events included swelling of the retina, inflammation and secondary surgeries.

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¹ 2016 Comprehensive Report on the Global IOL Market, Market Scope[®], LLC.

² National Eye Institute. Facts About Cataracts. Available at: https://nei.nih.gov/health/cataract/cataract_facts. Accessed July 1, 2016.

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