TECNIS® MULTIFOCAL IOL +4.0 D

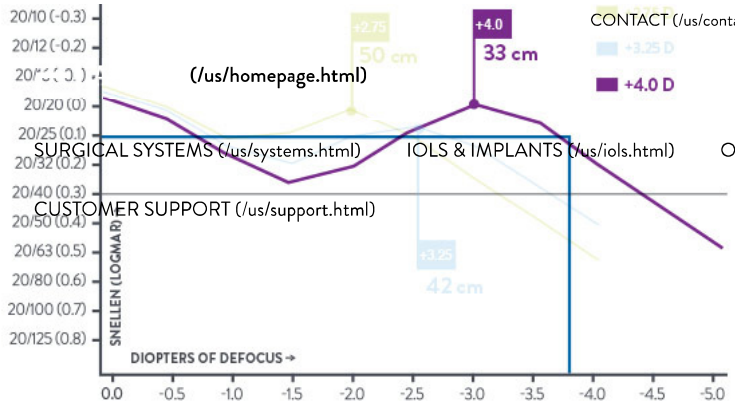
OUTSTANDING, FULL-RANGE VISION TAILORED FOR NEAR DISTANCES

Engineered to help you meet unique visual demands, **TECNIS®** Multifocal IOLs allow you to deliver tailored clarity that suits your patients' daily needs. The **TECNIS®** Multifocal IOL +4.0 D delivers a full range of the sharpest vision tailored for near distances.

DESCRIPTION SPECIFICATIONS

The **TECNIS®** Multifocal IOL +4.0 D is designed with your patients in mind. Optimized for those favoring near-vision activities like reading and knitting, it delivers tailored clarity at a theoretical reading distance of 33 cm.

Binocular Defocus Curve at 6 Months[1,2]



Learn about multifocal lens options optimized for intermediate vision (/us/iols/multifocal/tecnis-multifocal-275d.html) and longer reading distances. (/us/iols/multifocal/tecnis-multifocal-325d.html)

SHARPEST VISION ACROSS ALL DISTANCES

The **TECNIS®** Multifocal Family of 1-Piece IOLs features the only multifocal lenses capable of providing a full range of high-quality vision (20/25 or better),[1,2] tailored for each patient's lifestyle.

- The sharpest vision across near, intermediate and distance vision[1,2]
- Optimized for a theoretical reading distance of 33 cm with the +4.0 D lens

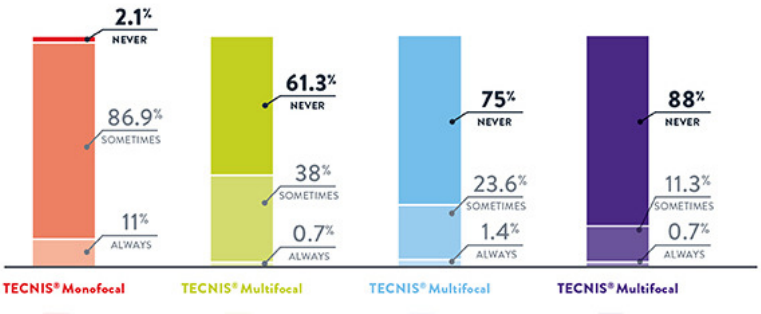
When compared to other leading multifocal IOLs, **TECNIS®** Multifocal IOLs provide:

- Up to 4x higher image contrast at near distance in low light (5 mm pupil)[3]
- 2x higher image contrast at near distance in normal light (3 mm pupil)[3]

ENHANCED FUNCTIONALITY

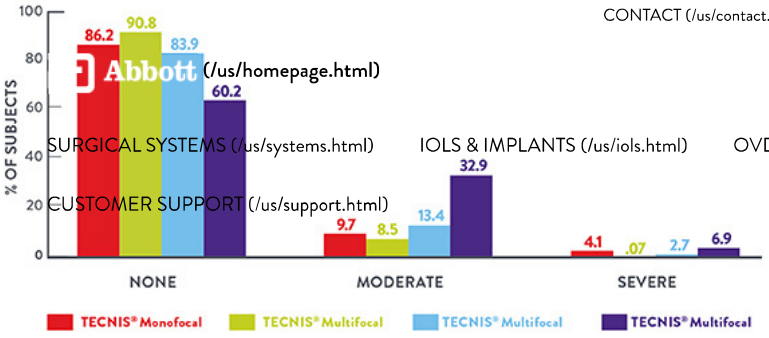
Give your patients a lens designed for real-world performance. The **TECNIS®** Multifocal IOL +4.0 D delivers exceptional spectacle independence.

How Often Do You Wear Glasses?*[1,2]



+4.0 D (purple) data are historical from a separate clinical study using the same test methodology.

Degree of Difficulty** With Night Vision[1,2]

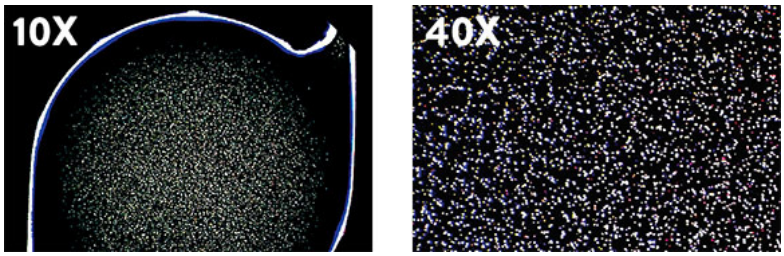


+4.0 D (purple) data are historical from a separate clinical study using the same test methodology.

LONG-TERM SUSTAINABILITY

Unlike another leading IOL, **TECNIS**® IOL material is not associated with glistenings,[4-8] which can inhibit your patients' vision. Glistenings cause light scatter, which can result in a reduction in image contrast.[5-9]

Dark Field Images of Competitor IOL at 10X and 40X Magnification[9]



CONTACT

Start a **TECNIS**® IOL trial (/us/contact.html)

RESOURCES

Directions for Use (/content/dam/bss/divisionalsites/amo/DFUs/multifocal/ZMB00_Z310681_02%20issued.pdf) (PDF, 2.30 MB)

TECNIS® PC-IOLs

Leave a legacy of visual freedom with a lens for each patient's life.

Start Now (/us/tecnis-pciols.html)

RELATED PRODUCTS

(/us/iols/multifocal/tecnis-multifocal-275d.html)

FOOTNOTES

*The questionnaire was not determined to be a psychometrically valid assessment of the concept of spectacle independence.

**On a scale of 1-7, with glasses as needed

†Value theoretically derived for a typical 20.00 D lens. AMO recommends that surgeons personalize their A-constant based on their surgical techniques and equipment, experience with the lens model and postoperative results.

‡Derived from clinical evaluation results of the **TECNIS®** 1-Piece Platform.

REFERENCES

1. TECNIS® Multifocal 1-Piece IOL DFU, Models ZKB00 and ZLB00. Santa Ana, Calif. Abbott Medical Optics Inc.
2. TECNIS® Multifocal 1-Piece IOL DFU, Model ZMB00. Santa Ana, Calif. Abbott Medical Optics Inc.
3. Data on File. Abbott Medical Optics Inc. 2015.
4. Data on File. Abbott Medical Optics Inc. 2013.
5. Nagata M, et al. Clinical evaluation of the transparency of hydrophobic acrylic intraocular lens optics. *J Cataract Refract Surg*. 2010;36(12):2056-2060.
6. Christiansen G, et al. Glistenings in the AcrySof® intraocular lens: Pilot study. *J Cataract Refract Surg*. 2001;27(5):728-733.
7. Colin J, et al. Incidence of glistenings with the latest generation of yellow- tinted hydrophobic acrylic intraocular lenses. *J Cataract Refract Surg*. 2012;38(7):1140-1146.
8. Gunenc U, et al. Effects on visual function of glistenings and folding marks in AcrySof® intraocular lenses. *J Cataract Refract Surg*. 2001;27(10):1611-1614.
9. Van der Mooren M, Franssen L, Piers P. Effects of glistenings in intraocular lenses. *Biomed Opt Express*. 2013;4(8):1294-1304.
10. Calculated based on Holladay I formula: Holladay JT, Prager TC, Chandler TY, Musgrove KH, Lewis JW, Ruis RS. A three-part system for refining intraocular lens power calculations. *J Cataract Refract Surg*. 1988;14(1):17-24.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE TECNIS® MULTIFOCAL FAMILY OF 1-PIECE IOLs

Rx Only

INDICATIONS

TECNIS® Multifocal Intraocular Lenses are indicated for primary implantation for the visual correction of aphakia in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence. The intraocular lenses are intended to be placed in the capsular bag.

WARNINGS

Some visual effects associated with multifocal IOLs may be expected because of the superposition of focused and unfocused images. These may include a perception of halos or glare around lights under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions these visual effects may be significant enough that the patient will request removal of the multifocal IOL. Under low-contrast conditions, contrast sensitivity is reduced with a multifocal lens compared to a monofocal lens. Therefore, subjects with multifocal lenses should exercise caution when driving at night or in poor visibility conditions. Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the patient's eyesight: patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases, 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), a distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible, circumstance that would result in damage to the endothelium during implantation, suspected microbial infection, patients in whom neither the posterior capsule nor zonules are intact enough to provide support, congenital bilateral cataracts, recurrent severe anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye, previous history of, or a predisposition to, retinal detachment, patients with only one eye with potentially good vision, medically uncontrollable glaucoma, corneal endothelial dystrophy, and proliferative diabetic retinopathy. The TECNIS® Multifocal 1-Piece IOL should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus. The splitting of the light into more than one focus may affect image quality and lead to some reduction of contrast sensitivity. Well-informed patients with well-defined visual needs and preferences should be selected for TECNIS® Multifocal 1-Piece lens implantation. The patients should be informed about the possibility that a decrease in contrast sensitivity and an increase of visual disturbances may affect their ability to drive a car under certain environmental conditions, such as driving at night or in poor visibility conditions. Patients with a predicted postoperative astigmatism > 1.0 diopter may not be suitable candidates for multifocal IOL implantation since they may not fully benefit from a multifocal IOL in terms of potential spectacle independence. Care should be taken to achieve IOL centration, as lens decentration may result in patients experiencing visual disturbances, particularly in patients with large pupils under mesopic conditions.

PRECAUTIONS

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. There were no patients 21 years old or younger included in the clinical studies; therefore there are insufficient clinical data to demonstrate safety and effectiveness in this age group. The central one millimeter area of the TECNIS® Multifocal 1-Piece IOL creates a far image focus in accordance with the labeled power of the IOL, so patients with abnormally small pupils (~1 mm) should achieve, at a minimum, the prescribed distance vision under photopic conditions; however because this multifocal design has not been tested in patients with abnormally small pupils it is unclear whether such patients will derive any near vision benefit. Autorefractors may not provide optimal postoperative refraction of patients with multifocal lenses. Manual refraction

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. When performing wavefront measurements on a patient with a multifocal lens, two different wavefronts are produced. One wavefront will be in focus (either far or near) and the other wavefront will be out of focus. In this situation, incorrect interpretation of the wavefront measurement is possible. The long term effects of intraocular lens implantation have not been determined. Therefore the physician should continue to monitor implant patients postoperatively on a regular basis. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively. Do not resterilize this intraocular lens by any method. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline. Do not store the lens in direct sunlight or at a temperature >45°C (113°F). Do not autoclave the intraocular lens. Prior to implanting, examine the lens package for proper lens model, dioptric power, and expiration date. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved. Care should be taken to achieve centration of the intraocular lens. Please refer to the specific instructions for use provided with the insertion instrument or system for the amount of time the IOL can remain folded before the IOL must be discarded. When the inserter/injector is used improperly, the haptics of the TECNIS® Multifocal 1-Piece Intraocular lens may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system.

ADVERSE EVENTS

The most frequently reported cumulative adverse event for first eyes during the clinical trial was secondary surgical re-intervention 3.7% with 0.6% being lens-related. The total number of first eyes with lens-related events during and after the study was 0.9%. Other reported adverse events for first eyes were macular edema (2.6%), hypopyon (0.3%) and endophthalmitis (0.3%).

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE TECNIS® MONOFOCAL 1-PIECE IOL

INDICATIONS

TECNIS® 1-Piece Lenses are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extra capsular cataract extraction. These devices are 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 TECNIS® 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes.

See Full Indications and Important Safety Information (/us/iols/monofocal/tecnis-1-piece.html).

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE UNFOLDER® PLATINUM 1 SERIES IMPLANTATION SYSTEM

INDICATIONS

The Model DK7796 Handpiece is used in combination with the Model 1MTEC30 Cartridge to fold and assist in inserting AMO Acrylic 1-Piece Intraocular Lenses, ONLY into the capsular bag.

CONTRAINDICATIONS

Do not use the handpiece if the rod tip appears nicked or damaged in any way.

WARNINGS

The UNFOLDER® Platinum 1 Series Implantation System should be used ONLY with AMO Acrylic 1-Piece IOLs. Do not use if the cartridge tip is cracked or split prior to implantation. Never release the plunger until the optic body has been completely released from the cartridge tube.

See Full Indications and Important Safety Information (/us/iols/lens-insertion/unfolder-delivery-systems.html).

ATTENTION

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

PP2016MLT0281

MAKING AN EVERLASTING
IMPACT ON HUMAN
HEALTH FOR 125 YEARS.