Distance for What Defines Them.

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.

See back cover for continued Indications and Important Safety Information.

TECNIS®
Monofocal IOLs

See the Passion in Each Patient.

Johnson&Johnson VISION

Life Isn't a Spectator Sport.

Deliver Vision That Keeps Your Patients in the Game.

Outperform expectations with a monofocal IOL that offers high-contrast acuity of

20/16 BCDVA or better.[1,5]

Deliver with preloaded insertion designed for **safety and efficiency.**[4]

TECNIS®
Monofocal IOLs

Beyond 20/20 vision[2,3]

TECNIS
iTec® Preloaded Delivery System

Touchless IOL delivery[4]

TECNIS® Family of IOLs
LEADING INNOVATION | HIGH-QUALITY VISION | EXCEPTIONAL SATISFACTION

Johnson&Johnson VISION

Game-Changing Visual Quality.

Enhance your patients' vision with excellent visual acuity and high image contrast performance.

Consistent Clarity

In multiple large-scale clinical studies, **TECNIS®** Monofocal IOLs consistently demonstrated 20/16 or better best-corrected distance acuity (BCDVA).[1,5]

2/3 of patients see 20/16 or better.[1]

BCDVA: Study A[1]

69.9%
Best Corrected at **20/16** or Better

75.3%
Uncorrected

95.9%
Best Corrected

n=445 Total Subjects
n=146 ZCB00 Group

BCDVA: Study B[5]

66.2%
Best Corrected at **20/16** or Better

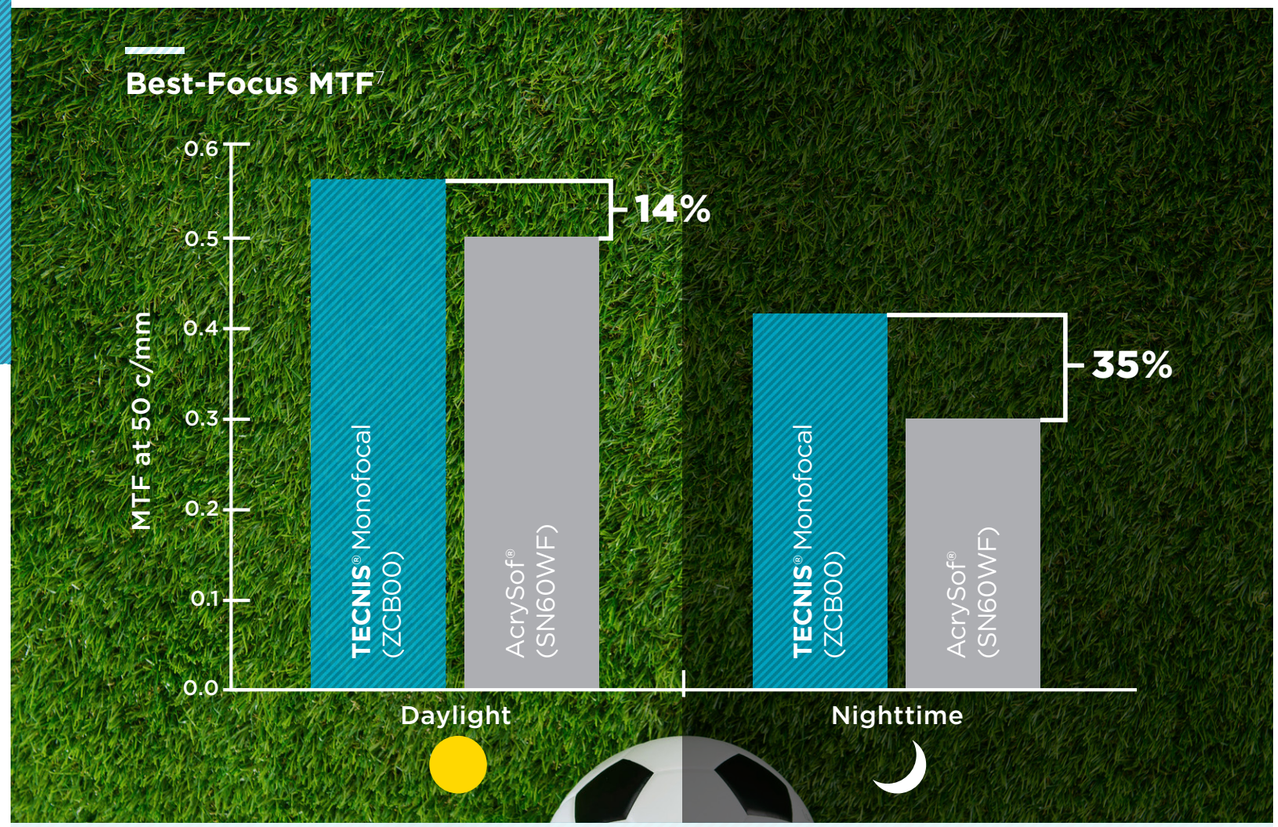
71.6%
Uncorrected

95.3%
Best Corrected

n=295 Total Subjects
n=148 ZCB00 Group

The Difference is Night and Day

Deliver contrast that outperforms the AcrySof® IQ IOL by as much as 35%.[6]



Modular transfer function *(MTF) is a measure of the amount of contrast transferred by the optics in a visual system. The higher the MTF value, the more contrast transferred to the image, which means higher image contrast. The measurements were calculated using the ACE model under white light conditions.*

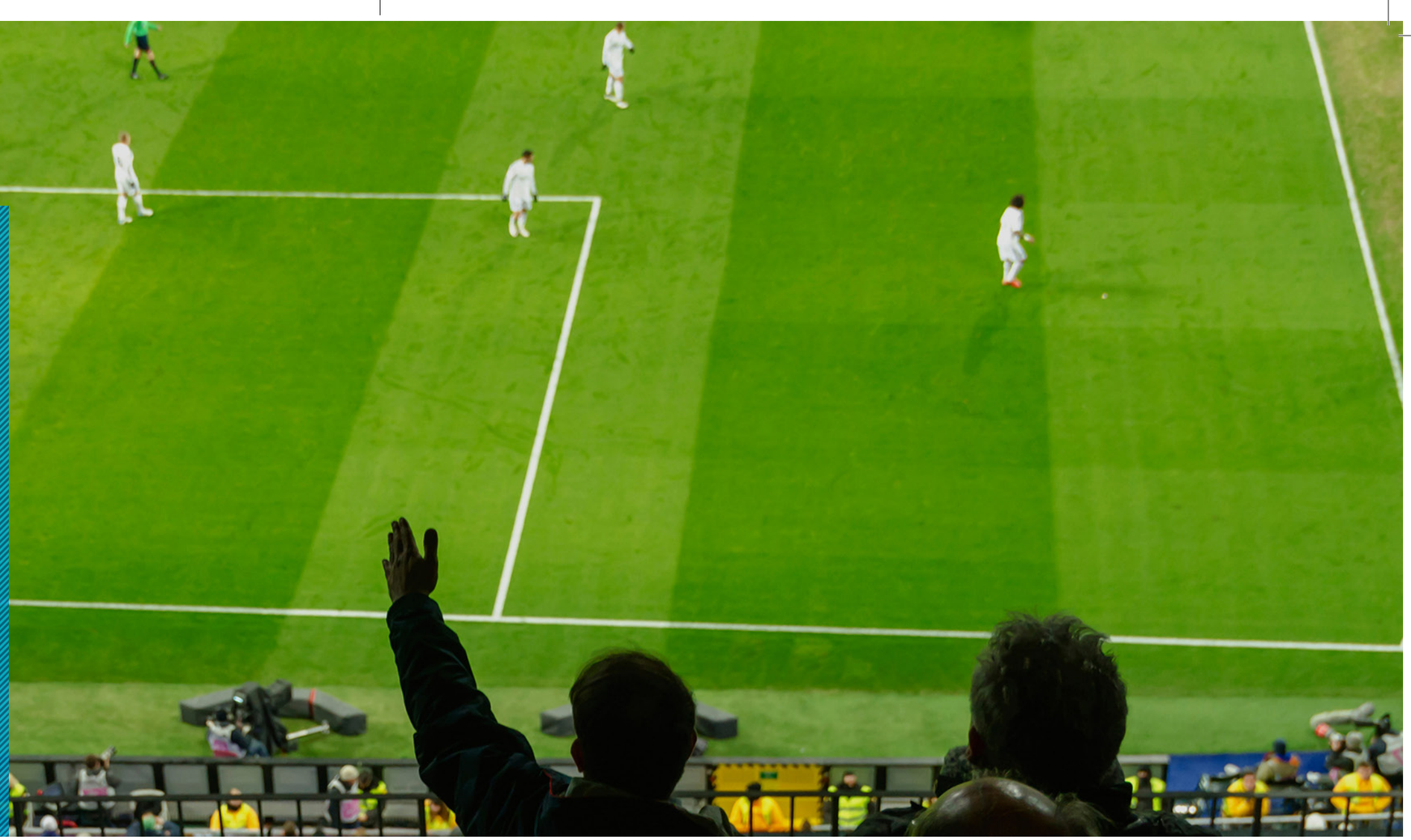
Address aberrations for a better visual experience.

- Essentially zero spherical aberration[7]
- Lower chromatic aberration than AcrySof® IQ IOLs for high contrast performance in different lighting conditions[6,8]

Johnson&Johnson VISION

All-Star Performance at Night.

Give your patients high-contrast vision for clarity that extends from day to night.[7]



Patient Safety

Improve functional vision, which can increase patient safety while driving and in other low-visibility situations.[7]

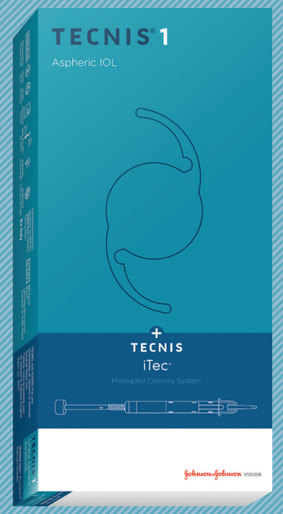
Outperform US federal benchmarks for safe night driving.[7]

Brake lights (center high-mounted stop lamps) **increase reaction time by approximately 0.35 seconds** on average.[9]

VS

Increase distance visibility at 88km/h:[7]

TECNIS® Monofocal IOLs **increase reaction time by 0.50 seconds** on average.[7]



TECNIS
iTec® Preloaded
Delivery System

Touchless Delivery.[10]

Support safety and efficiency in your procedures with the **TECNIS iTec®** Preloaded Delivery System.

Procedural Safety

Minimize the risk of infection and inflammation associated with IOL contamination.[4]

No IOL touches[10]

Reduced loading errors[4]

Preloaded TECNIS® Monofocal IOL Delivery

Full diopter range
from +5.0 D to +34.0 D in 0.5 D steps

2.2–2.4 mm-incision
planar delivery with a bevel tip for all diopters

Consistent, controlled
advance and delivery with screw-style insertion

Not made with
natural rubber latex

Operational Efficiency

Save time and money by trading manual insertion for preloaded IOL delivery.[10,11]

As much as **12% reduced case time**[10]

1 full additional procedure per day[10]

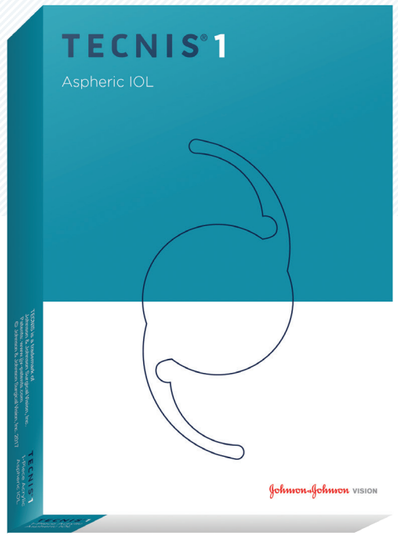
As much as **4.2% cost savings** projected yearly[11]

Individual results may vary.

Johnson&Johnson VISION

TECNIS®
Monofocal IOLs

Drive Total Quality.



Beyond 20/20 vision, with

20/16

or better in ⅔ of patients[1,5]

As much as

35%

improved image contrast over AcrySof® IQ IOLs[6]

Improved patient safety under low-visibility conditions[7]

Touchless delivery with the **TECNIS iTec®** Preloaded Delivery System[10]

Available in:

- Toric
- 1-Piece
- 3-Piece

INDICATIONS: The **TECNIS®** Toric 1-Piece Lens is indicated for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with or without presbyopia in whom a cataractous lens has been removed by extracapsular cataract extraction 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:** Rotation can reduce astigmatic correction. Misalignment greater than 30° may induce refractive error. Accurate keratometry, biometry and www.TecnisToricCalc.com are recommended to optimize visual outcomes. Weigh the potential risk/benefit ratio that could increase pre-existing complications or impact patient outcomes. Variability in any preoperative measurements can influence outcomes.

See back cover for continued Indications and Important Safety Information.

Set your patients up for life with high-quality distance vision.[1,5]

LEADING INNOVATION | HIGH-QUALITY VISION | EXCEPTIONAL SATISFACTION |
TECNIS® Family of IOLs

Johnson&Johnson VISION

Indications & Important Safety Information *Continued*

TECNIS® MONOFOCAL 1-PIECE IOL

PRECAUTIONS: Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects. 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 greater than 45°C. Do not autoclave 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 insertion system is used improperly, the haptics of the **TECNIS®** 1-Piece Lens may become damaged. **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. These conditions include recurrent severe anterior or posterior segment inflammation or uveitis; patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases; surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss); a compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible; circumstances that would result in damage to the endothelium during implantation; suspected microbial infection; or patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL. Children under the age of 2 years are not suitable candidates for intraocular lenses. The **TECNIS®** 1-Piece IOL should not be placed in the ciliary sulcus. **ADVERSE EVENTS:** In 3.3% of patients, reported adverse events of cataract surgery with the 1-Piece IOL included macular edema. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic).

TECNIS ITEC® PRELOADED DELIVERY SYSTEM

WARNINGS: Do not attempt to disassemble, modify or alter this device or any of its components, as this can significantly affect the function and/or structural integrity of the design. Use of methylcellulose viscoelastics is not recommended as they have not been validated for use with the **TECNIS iTec®** Preloaded Delivery System. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the cartridge. Do not push the plunger forward to fully advance the lens until ready for lens implantation. Discard the device if the lens has been fully advanced for more than 1 minute. 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 **TECNIS iTec®** Preloaded Delivery System minimizes the risk of infection and/or inflammation associated with contamination. The reuse/resterilization/reprocessing of single-use devices may result in physical damage to the medical device, failure of the medical device to perform as intended, and patient illness or injury due to infection, inflammation, and/or illness due to product contamination, transmission of infection, and lack of product sterility. The **TECNIS®** 1-Piece IOL should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus. **PRECAUTIONS:** Do not resterilize the lens or the **TECNIS iTec®** Preloaded Delivery System. Most sterilizers are not equipped to sterilize the soft acrylic material and the preloaded inserter material without producing undesirable side effects. Do not store the device in direct sunlight or at a temperature under 5°C or over 35°C. Do not autoclave the device. 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. The combination of low operating room temperatures and high IOL diopter powers may require slower delivery. The use of viscoelastics is required when using the **TECNIS iTec®** Preloaded Delivery System. For optimal performance, use the **HEALON®** Family of Viscoelastics. The use of balanced salt solution alone is not recommended. Do not use if the **TECNIS iTec®** Preloaded Delivery System has been dropped or if any part was inadvertently struck while outside the shipping case. **ADVERSE EVENTS:** The most frequently reported adverse event that occurred during the clinical trial of the 1-Piece IOL was cystoid macular edema, which occurred at a rate of 3.3%. Other reported events occurring in less than 1% of patients were secondary surgical intervention (0.8%, vitrectomy) and lens exchange (0.8%, due to torn lens haptic).

TECNIS® FOLDABLE ACRYLIC IOLS WITH OPTIEDGE DESIGN

INDICATIONS: TECNIS® Foldable Acrylic IOLs with OptiEdge Design are indicated for the visual correction of aphakia in adults in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens is intended to be placed in the capsular bag. **WARNINGS:** Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio described in the Directions for Use. Do not place in ciliary sulcus. **ADVERSE EVENTS:** In the clinical trial of the parent acrylic IOL, no cumulative or persistent reported adverse events were above the FDA grid rate. The most frequently reported adverse event that occurred during the trial was anterior lens tissue ongrowth, which occurred at a cumulative rate of 11.3%. In a separate clinical trial of the parent modified prolate anterior surface IOL, the most frequently reported adverse event was macular edema; these reports were just above FDA grid rate at a cumulative rate of 3.8% a (FDA grid 3.5%) and a persistent rate of 0.9% (FDA grid 0.8%).

ATTENTION: Reference the Directions for Use labeling for a complete listing of Indications and important safety information.

References

1. DOF2015CT0015 – Key clinical outcomes from the IDE clinical study of the **TECNIS®** Multifocal low-add 1-Piece IOL. 7 May 2015. **2. TECNIS Symfony®** IOL DfU – Z311036 – Rev 02 – Sep 2016 – US. REF2017CT0015. **3. TECNIS®** MIOL DfU – ZMB00, ZKB00 and ZLB00 – Z310970 – Rev 02 – 10 Dec 2014 – US. REF2014CT0623. **4. TECNIS iTec®** Preloaded Delivery System DfU - Z310911P – Rev C – Jan 2013. REF2014CT0193. **5.** DOF2017CT0009 – Binocular Distance Visual Acuity Outcomes from the IDE Clinical Study of the **TECNIS Symfony®** Extended Range of Vision IOL vs. **TECNIS®** 1-Piece Monofocal IOL, Model ZCB00. **6.** DOF2015CT0016 – **TECNIS®** Monofocal ZCB00 and AcrySof® IQ SN6AWF MTF data – Piers P. 8 May 2015. **7. TECNIS®** 1-Piece IOL DfU – Z310719P – Rev B. REF2014CT0477. **8.** Zhao H, et al. The additive effect of different optical design elements contributing to contrast loss in pseudophakic eyes implanted with different aspheric IOLs. Paper presented at: XXVII Congress of the ESCRS, Sep. 12-16, 2009. Barcelona., Spain. REF2014MLT0020. **9.** McBride MK, Matson W. Assessing the significance of optically produced reduction in braking response time: possible impacts on automotive safety among the elderly. Potomac Institute for Policy Studies. April 1, 2003; Arlington, Virginia. REF2016CT0459. **10.** Data on File – Evaluating the Operational and Economic Impact of the **TECNIS iTec®** Preloaded Delivery System. REF2015CT0200. **11.** Groves N. Preloaded IOL delivery system results in time savings per case, surgeon. Rocha G, ed. *Ophthalmology Times*. June 2015. REF2016CT0456.

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TECNIS®
Monofocal IOLs

Bring Vision to Life.

Johnson & Johnson VISION

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