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Johnson & Johnson VISION

PERSONALIZED VISION

CASE REVIEW SERIES

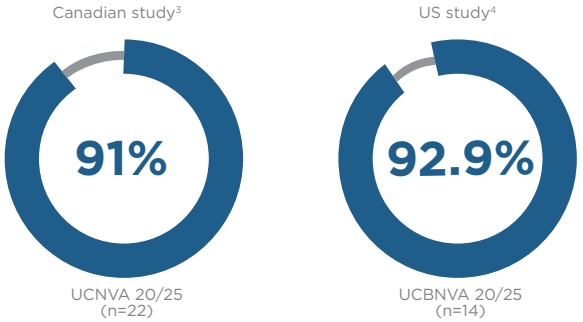
INTRODUCTION

Options for presbyopia correction during cataract surgery continue to evolve, allowing us to develop surgical plans that uniquely fit each patient's individual lifestyle and clinical needs. Where once there were few opportunities for presbyopia correction, there are now many—including monovision, bifocals, trifocals, extended depth of focus and Personalized Vision using two TECNIS Symfony™ IOLs or a TECNIS Symfony™ IOL with a TECNIS® Multifocal IOL. While there is no best choice that applies to all patients, some core guidelines drive the clinical decisions we make in our own practices.

In the pages that follow, we will review several Personalized Vision cases in patients. As you will see, patients have high visual expectations following cataract surgery,[1] making the refractive element of cataract surgery increasingly important.

Personalized Vision is Backed by Research

Personalized Vision with the TECNIS Symfony™ IOL and the TECNIS multifocal +3.25 D provides excellent full range of vision with strong near vision acuity as evidenced in serval recent studies.[2,3,4]



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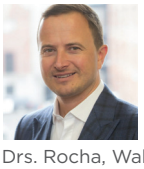


PAUL HARASYMOWYCZ, MSC, MD, FRCSC

Drs. Rocha, Waltz and Harasymowycz are paid consultants of Johnson & Johnson Vision, Inc.

THE PATIENT WHO WANTS TO BE "READY FOR ANYTHING"

BY KAROLINNE MAIA ROCHA, MD, PHD

As cataract surgeons, we know that there's not a one-size-fits-all approach to IOL selection. In that respect, we are fortunate to have a broad selection of lenses to fit patients' diverse clinical needs and lifestyles. But it is up to us to determine the combination that's most appropriate for each individual patient.

PRE-OP

Today, so many of our retired patients are living their best lives and want an IOL that can help them enjoy their active routines with ease. This was the case with Marie*, a 69-year-old Caucasian female, who presented to my office a few months ago expressing interest in being less dependent on glasses at all distances. Marie is a retired nurse who enjoys cooking, golf, yoga, and attending local theatre. She also drives at night on occasion and wants to be ready for anything that life brings.

Her initial exam revealed the following:

- Refraction: OD +1.75 -1.50 @ 105, OS +1.50 -1.00 @ 95
- OD 2+ nuclear sclerosis, 2 + cortical, 1+ PSC
- OS 2+ nuclear sclerosis, 1 + cortical, 1+ PSC
- 1+ punctate staining OD
- See topography below

Based on the initial exam, the topographical evidence of ocular surface disease and the punctate staining, we determined that Marie's ocular surface was not optimized for surgery, so we started her on topical steroids for 2 weeks and lifitegrast BID. We also performed in-office LipiFlow® treatment. At four weeks, we repeated the measurements and found a 0.5D difference in the IOL calculation compared to the previous visit.

SURGICAL PLANNING AND OUTCOMES

We proceeded with surgery on the dominant eye, using the TECNIS Symfony™ IOL and targeting plano. At follow-up, Marie was very happy but expressed a desire for more near vision. Two weeks after the first surgery, we proceeded with the TECNIS® Multifocal +3.25D (ZLB00) in the non-dominant eye.

Also, Marie has narrow angles, which made the use of FLACS a particular benefit in this case, as the SD-OCT shows detailed anterior segment anatomy, including the lens thickness and lens meridian position (LMP). The FLACS lens fragmentation also helped us minimize phaco time and energy once we got to the OR.

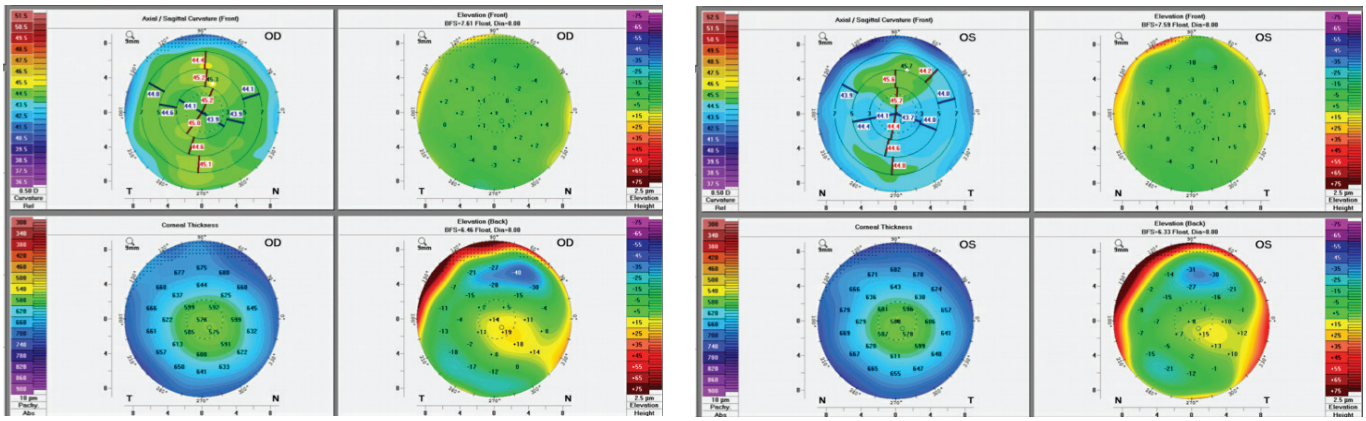
Both surgeries were uneventful, resulting in the following outcomes:

- UCVA OD – 20/20 distance J2 (MRx -0.25+0.50@135)
- UCVA OS – 20/25 distance J1 (MRx -0.25+0.50@95)
- Binocular 20/20 distance J1+

PATIENT SATISFACTION

Today, Marie is thrilled with her outcome and says she no longer uses her glasses. As this case illustrates, cataract surgery is a once-in-a-lifetime procedure, and the IOL we offer impacts quality of life for many years in a lot of our patients.

**Patient's name has been changed to protect privacy.*



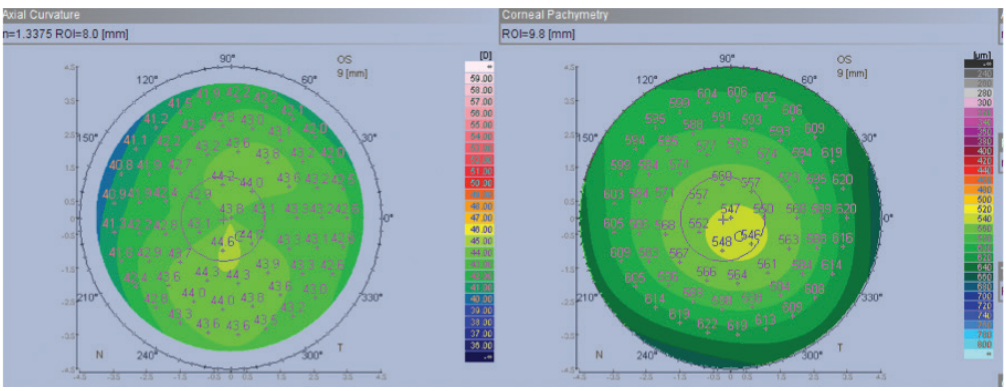
Corneal topography prior to ocular surface optimization showing mild irregular astigmatism secondary to tear film instability.

THE PATIENT WHO WILL HAVE TO WAIT

BY KEVIN WALTZ, OD, MD

A 62-year-old white female presented eager to undergo cataract surgery as soon as possible. Having recently retired from an accounting career, Regina* was looking forward to spending more time doing the things she loves, particularly hiking and golfing with her husband who had successful cataract surgery a few months earlier and couldn't be more pleased. Regina's husband was a former monovision contact lens wearer and opted for the same approach with his cataract surgery. Regina requested the same procedure, but she had no history of monovision.

Whenever patients present with preconceived ideas about what's best, it's important to take the time to explain that there's no one-size fits-all answer to cataract surgery. Although it is helpful when patients have a reference point and a clear understanding of the benefits of presbyopia correction, it can be challenging to explain why their surgery may involve more cost than someone else's. I was certain that monovision was not a good choice for Regina and I wanted to help her achieve her goal of being less dependent on glasses, which meant I had to spend some time explaining the options to her. And that was just the beginning because, as it turned out, Regina also had significant ocular surface disease.



Findings indicate with-the-rule astigmatism.

Pre-op exam indicated the patient was +2.50 in both eyes with approximately 0.75D of cylinder with the rule in both eyes. However, the corneal cylinder didn't match her current prescription. Whenever the topographic astigmatism doesn't match refractive astigmatism, it's important to consider the possibility of lenticular astigmatism, otherwise patients can be very unhappy post-op.

Ocular surface examination, indeed, revealed moderate to significant dry eye and meibomian gland dysfunction (MGD), which meant the patient would have to wait for the surface to stabilize before we could obtain reliable measurements for surgical planning. Following 3 weeks of pharmaceutical therapy, the patient returned for a second evaluation. Her dry eye was greatly improved and we were ready to set a date for surgery.

SURGICAL PLANNING AND OUTCOMES

For the first surgery, in the dominant eye, we selected the TECNIS Symfony™ IOL. I was fairly certain she would want a little more near in the fellow eye for reading the golf card, but I prefer to take it one step at a time.

Regina was very happy after the first procedure, which made me wonder if I should just implant another TECNIS Symfony™ in the non-dominant eye, knowing that she might still need readers at near in certain instances. At day 1, she was 20/25 at distance and intermediate and J3 at near. At one week, she was 20/20 at distance and J2 at near. After talking about it, we decided that we would fine-tune the vision further with a Multifocal IOL in the other eye.

UPS AND DOWNS AT FOLLOW-UP

Two weeks after the first surgery, we implanted the TECNIS® Multifocal +3.25D in Regina's non-dominant eye. At day 1, Regina was 20/25 at distance and J1+ at near, but when she returned a week later, she was J2 at near and was expressing concern. As doctors, we know that this temporary dip was likely due to the 12 preserved drops per day that most of our cataract patients need to use in the post-op period. But the experience can be very alarming for patients as they brace themselves for remorse. For this reason, no matter what IOL you choose, it's essential to mention drop-induced acuity dips ahead of time and offer reassurance if it occurs.

In Regina's case, J1 vision returned within a month's time and she is now plano in both eyes, which she proudly boasts is "better than her husband's vision."

**Patient's name has been changed to protect privacy*

THE PATIENT WHO HAS MEDICALLY-CONTROLLED GLAUCOMA

BY PAUL HARASYMOWYCZ, MSC, MD, FRCSC

A 72-year-old male with a 10-year history of glaucoma was referred to our practice by a local physician who does not perform corneal surgery. Gerry* is a heavy computer user who likes to hike. He doesn't mind wearing glasses sometimes, but he wants to be less dependent on them overall.

At presentation, the patient had 2+ NS cataract OU, and pressures were 14 mmHg OD and 16 mmHg OS with no visual field damage. The initial biometry was considered unusable due to standard deviation in the 20's. We perform meibography on all pre-op cataract patients, which helped to explain the poor biometry in this case.

We switched the patient to preservative-free glaucoma drops and preservative free tears and referred him to our dry eye optometrist who performed thermal pulsation. Six weeks later, biometry differed by 1.5D compared to the first measurement. Standard deviation was now at 5.

SURGICAL PLANNING AND OUTCOMES

In my personal practice as a glaucoma specialist, about 70% of my cataract cases are bilateral TECNIS Symfony™ IOL cases. This decision is based on the need for good light transmission and optimal contrast as well as the heavy intermediate vision demands of modern life. However, in some patients with healthy eyes and medically-controlled glaucoma, we are able to offer a little more near correction using a Personalized Vision approach. In fact, most of the remaining 30% of our patients opt for TECNIS Symfony™ in one eye and a TECNIS® Multifocal in the fellow eye. Depending on the patient's individual needs, we use either a +3.25D or a +4.00D. In this case, Gerry received a TECNIS Symfony™ Toric in the dominant eye and a TECNIS® Multifocal +4.00D in the non-dominant eye. To limit glaucoma drop therapy, MIGS was also performed.

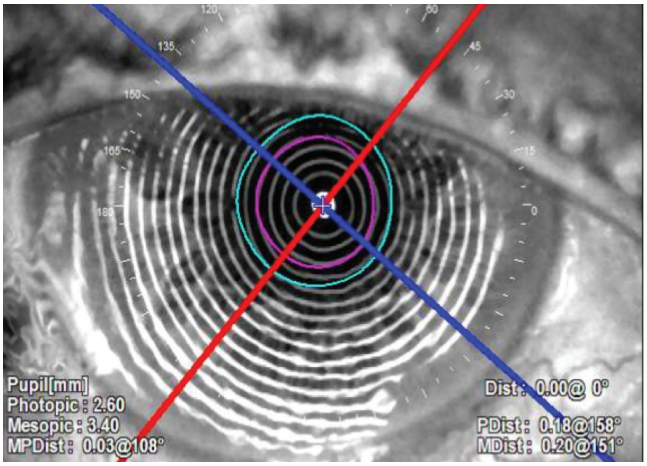
Post-op, the patient was very happy with the result and had outstanding distance vision. In fact, at the one-week follow up exam, Gerry was 20/20 at all distances in both eyes and was J2 at near. However, he did mention that although he enjoys the freedom to see well at near, he prefers the vision in the extended depth of focus eye.

A LIFETIME CHOICE

Although we see a lot of ocular surface disease in cataract patients overall, patients on glaucoma drop therapy are particularly likely to demonstrate dry eye that significantly impacts the reliability of the pre-operative measurements. Since most glaucoma patients will continue therapy for a lifetime, it's essential to manage the ocular surface in the long-term to protect visual quality. MIGS can help minimize the need for drops, but won't eliminate the need altogether in most patients. For that reason, it's important to educate patients about why ongoing dry eye therapy is critical, just as their glaucoma drops are.

**Patient's name has been changed to protect privacy.*

BEFORE



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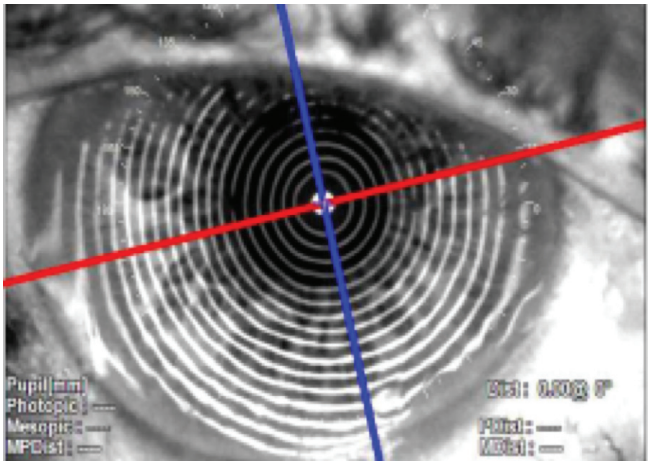


Placido disc images before and after ocular surface treatment.

MATERIAL AND LIGHT

BY KAROLINNE MAIA ROCHA, MD, PHD; KEVIN WALTZ, OD, MD; AND PAUL HARASYMOWYCZ, MSC, MD, FRCSC

The optical and material properties of individual lens platforms may be as important to patient satisfaction as lens category. Indeed, we should never take lens quality for granted or assume that different IOL platforms deliver comparable visual outcomes.

MATERIAL PROPERTIES

The mid-index acrylic material of the TECNIS® platform excels for the following reasons:

Spherical aberration correction essentially to zero.[1,2,3] Spherical aberration occurs when all incoming light rays end up focusing at different points. This affects resolution and clarity, making it hard to obtain sharp images. As we know, the cornea has positive spherical aberration, which needs to be corrected to optimize visual quality. This is why the zero spherical aberration correction with TECNIS® is so important, since it results in sharper vision, especially beneficial in low light conditions.

Lower induction of chromatic aberration. All IOL materials add to the chromatic aberration naturally occurring in the eye. However, TECNIS® material induces less chromatic aberration than many other commonly used IOLs. Specifically, the TECNIS® material induces 3 times less chromatic aberration than AcrySof® material.[4] In short, low chromatic aberration results in better quality of vision, which is a benefit with all TECNIS® lenses, but the TECNIS Symfony™ takes it one step further. Specifically, TECNIS Symfony™ actively corrects the naturally occurring chromatic aberration of the cornea, resulting in enhanced image contrast at far, intermediate, and near.[5]

Low surface reflectance.[6] Johnson and Johnson Surgical Vision utilizes very specific manufacturing techniques. The low surface reflectance inherent in TECNIS® IOLs is due to the quality material used.

PCIOL OPTICS AND LIGHT

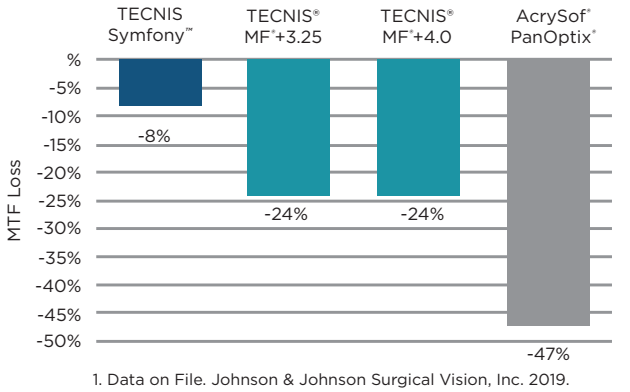
Light is a consideration with any IOL, but particularly with a presbyopia-correcting IOL because these lenses often split light. The TECNIS Symfony™ EDOF IOL is unique in that light is not split between two focal points and does not result in a distinct secondary focal point or peak in defocus as is the case for a multifocal with a fixed add power. Instead, the proprietary echelette design of the TECNIS Symfony™ elongates the focus.[7] Importantly, this allows for 92% of light to be transmitted across the range of vision.[8,9,10,11]*

Consider the impact that reduced light can have on all patients, but particularly on patients who have conditions that could potentially impact contrast. For example, it's very common for cataract patients to have medically controlled glaucoma. We see this all the time and it limits the options for that patient. Many Multifocal IOL designs specify that alternative treatment should be considered for patients with glaucoma, whether or not the glaucoma is controlled with medication. Conversely, the label for the TECNIS Symfony™ EDOF with 92% light transmission* allows for treatment of patients with medically controlled glaucoma, provided physicians weigh the potential risk/benefit ratio.

Even in the healthiest eyes, with outstanding preoperative contrast, the PCIOL we choose can have a huge impact on contrast when the pupil dilates. This is another area where the TECNIS Symfony™ performs exceedingly well. Pupil independence enables patients to maintain their active lifestyles in day and night lighting conditions.[12,13,14,15,16]

Another light-related phenomenon that we want to avoid is the development of glistenings. Glistenings cause light scatter.[17] Conversely, capsular clarity can help sustain high-quality vision.[18] TECNIS® IOL material is not associated with glistenings[19] and has low reflectance due to its low refractive index.[6]

Image contrast when the pupil opens from 3mm to 5mm[1]



1. Data on File. Johnson & Johnson Surgical Vision, Inc. 2019. [DOF2019OTH4002].

As refractive cataract surgeons, we should demand as much from an IOL as our patients demand of us. The TECNIS® platform allows us to do this reliably, in patient after patient.

* The calculation is based on the diffractive theory method.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION
FOR THE TECNIS SYMFONY™ and TECNIS SYMFONY™ TORIC
EXTENDED RANGE OF VISION IOLs
Rx Only
Indications for use:
The TECNIS Symfony™ Extended Range of Vision 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 TECNIS Symfony™ Toric Extended Range of Vision 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. These models of IOLs, ZXR00, ZXT150, ZXT225, ZXT300, and ZXT375, mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, these models of IOLs provide improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. These models of IOLs are intended for capsular bag placement only.
Warnings:
Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
1. 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:
a. Patients with recurrent severe anterior or posterior segment inflammation or uveitis of unknown etiology, or any disease producing an inflammatory reaction in the eye.
b. Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases.
c. 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).
d. A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible.
e. Circumstances that would result in damage to the endothelium during implantation.
f. Suspected microbial infection.
g. Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL.
h. Children under the age of 2 years are not suitable candidates for intraocular lenses.
i. Congenital bilateral cataracts.
j. Previous history of, or a predisposition to, retinal detachment.
k. Patients with only one good eye with potentially good vision.
l. Medically uncontrollable glaucoma.
m. Corneal endothelial dystrophy.
n. Proliferative diabetic retinopathy.
2. The TECNIS Symfony™ IOL should be placed entirely in the capsular bag and should not be placed in the ciliary sulcus.
3. The TECNIS Symfony™ IOL may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL. The physician should carefully weigh the potential risks and benefits for each patient, and should fully inform the patient of the potential for reduced contrast sensitivity before implanting the lens in patients. Special consideration of potential visual problems should be made before implanting the lens in patients with macular disease, amblyopia, corneal irregularities, or other ocular disease which may cause present or future reduction in acuity or contrast sensitivity.
4. Because the TECNIS Symfony™ IOL may cause a reduction in contrast sensitivity compared to a monofocal IOL, patients implanted with the lens should be informed to exercise special caution when driving at night or in poor visibility conditions.
5. Some visual effects associated with the TECNIS Symfony™ IOL may be expected due to the lens design that delivers elongation of focus. These may include a perception of halos, glare, or starbursts around lights under nighttime conditions. The experience of these phenomena will be bothersome or very bothersome in some people, particularly in low-illumination conditions. On rare occasions, these visual effects may be significant enough that the patient may request removal of the IOL.
6. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for implantation with the TECNIS Symfony™ and TECNIS Symfony™ Toric IOLs, Models ZXR00, ZXT150, ZXT225, ZXT300, and ZXT375, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower astigmatism.
7. The effectiveness of TECNIS Symfony™ Toric IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism <1.0 diopter has not been demonstrated.
8. Rotation of TECNIS Symfony™ Toric IOLs away from their intended axis can reduce their 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.
9. TECNIS® IOLs are single-use devices only. Do not reuse this IOL.
Precautions:
1. 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.
2. When performing refraction in patients implanted with the TECNIS Symfony™ IOL, 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 recommended.
3. The ability to perform some eye treatments (e.g. retinal photocoagulation) may be affected by the TECNIS Symfony™ IOL optical design.
4. 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.
5. Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects.
6. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
7. Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C). Do not autoclave the intraocular lens.
8. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved.
9. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.
10. When the insertion system is used improperly, TECNIS Symfony™ IOLs may not be delivered properly (i.e., haptics may be broken). Please refer to the specific instructions for use provided with the insertion instrument or system.
11. The safety and effectiveness of TECNIS Symfony™ IOLs have not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below for examples). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions:
Before Surgery
- Pupil abnormalities
- Prior corneal refractive or intraocular surgery
- Choroidal hemorrhage
- Chronic severe uveitis
- Concomitant severe eye disease
- Extremely shallow anterior chamber
- Medically uncontrolled glaucoma
- Microphthalmos
- Non-age-related cataract
- Proliferative diabetic retinopathy (severe)
- Severe corneal dystrophy
- Severe optic nerve atrophy
- Irregular corneal astigmatism
- Amblyopia
- Macular disease
- Pregnancy

During Surgery
- Excessive vitreous loss
- Non-circular capsulotomy/capsulorhexis
- The presence of radial tears known or suspected at the time of surgery
- Situations in which the integrity of the circular capsulotomy/capsulorhexis
- Cataract extraction by techniques other than phacoemulsification or liquefaction
- Capsular rupture
- Significant anterior chamber hyphema
- Uncontrollable positive intraocular pressure
- Zonular damage

12. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or overinflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS Symfony™ Toric IOL with the intended axis of placement.
13. The PCA is based on an algorithm that combines published literature (Koch et.al, 2012) and a retrospective analysis of data from a TECNIS® Toric multi-center clinical study. The PCA algorithm for the selection of appropriate cylinder power and axis of implantation was not assessed in a prospective clinical study and may yield results different from those in the TECNIS® Toric intraocular lens labeling. Please refer to the Toric Calculator user manual for more information.
14. The use of methods other than the TECNIS® Toric Calculator to select cylinder power and appropriate axis of implantation were not assessed in the parent TECNIS® Toric IOL U.S. IDE study and may not yield similar results. Accurate keratometry and biometry, in addition to the use of the TECNIS® Toric Calculator (www.TecnisToricCalc.com), are recommended to achieve optimal visual outcomes for the TECNIS Symfony™ Toric IOL.
15. All preoperative surgical parameters are important when choosing a TECNIS Symfony™ Toric IOL for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, 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.
16. All corneal incisions were placed temporally in the parent TECNIS® Toric IOL U.S. IDE study. If the surgeon chooses to place the incision at a different location, outcomes may be different from those obtained in the clinical study for the parent TECNIS® Toric IOL. Note that the TECNIS Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.
17. Potential adverse effects (e.g., complications) associated with the use of the device include the following:
- Infection (endophthalmitis)
- Hypopyon
- IOL dislocation
- Cystoid macular edema
- Corneal edema
- Pupillary block
- Iritis
- Retinal detachment/tear
- Raised IOP requiring treatment
- Visual symptoms requiring lens removal
- Tilt and decentration requiring repositioning
- Residual refractive error resulting in secondary intervention.

Secondary surgical interventions include, but are not limited to:
- Lens repositioning (due to decentration, rotation, subluxation, etc.)
- Lens replacement
- Vitreous aspirations or iridectomy for pupillary block
- Wound leak repair
- Retinal detachment repair
- Corneal transplant
- Lens replacement due to refractive error
- Unacceptable optical/visual symptoms
- Severe inflammation

Serious Adverse Events:
The most frequently reported serious adverse events that occurred during the clinical trial of the TECNIS Symfony™ Lens were cystoid macular edema (2 eyes, 0.7%) and surgical reintervention (treatment injections for cystoid macular edema and endophthalmitis, 2 eyes, 0.7%). One eye was reported with pupillary capture and the eye that had endophthalmitis also had a small hypopyon. No other serious adverse events and no lens-related adverse events occurred during the trial.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE TECNIS®
Multifocal Family of 1-Piece IOLs
Rx Only
INDICATIONS: The TECNIS® Multifocal 1-Piece 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: Physicians considering lens implantation under any of the conditions described in the Directions for Use should weigh the potential risk/benefit ratio prior to implanting a lens. 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/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. Contrast sensitivity is reduced with a multifocal lens compared to a monofocal lens. Therefore, patients with multifocal lenses should exercise caution when driving at night or in poor visibility conditions. Patients with a predicted postoperative astigmatism >1.0D 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 centration, as lens decentration may result in patients experiencing visual disturbances, particularly in patients with large pupils under mesopic conditions. Multifocal IOL implants may be inadvisable in patients where central visual field reduction may not be tolerated, such as macular degeneration, retinal pigment epithelium changes, and glaucoma. Patients with certain medical conditions may not be suitable candidates for IOLs. Consult the Directions for Use for more information.
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 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 lens creates a far image focus, therefore patients with abnormally small pupils (~1mm) 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 multifocal patients; manual refraction is strongly recommended. In contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power. Care should be taken when performing wavefront measurements as two different wavefronts are produced (one will be in focus (either far or near) and the other wavefront will be out of focus); therefore incorrect interpretation of the wavefront measurements is possible. The long-term effects of intraocular lens implantation have not been determined; therefore implant patients should be monitored 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 or autoclave. Use only sterile irrigating solutions such as balanced salt solution or sterile normal saline. Do not store in direct sunlight or over 45°C (113°F). Emmetropia should be targeted as this lens is designed for optimum visual performance when emmetropia is achieved. 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 IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system.

ADVERSE EVENTS: The most frequently reported adverse event that occurred during the clinical trials of the TECNIS® Multifocal lenses was surgical re-intervention, most of which were non-lens-related. Lens-related re-interventions occurred at a rate of 0.6% to 1.0%. Other surgical re-interventions included lens exchanges (for incorrect IOL power), retinal repair, ruptured globe repair, macular hole repair, removal of retained lens material, treatment injections for cystoid macular edema and iritis, and blepharoplasty.

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

Johnson & Johnson VISION