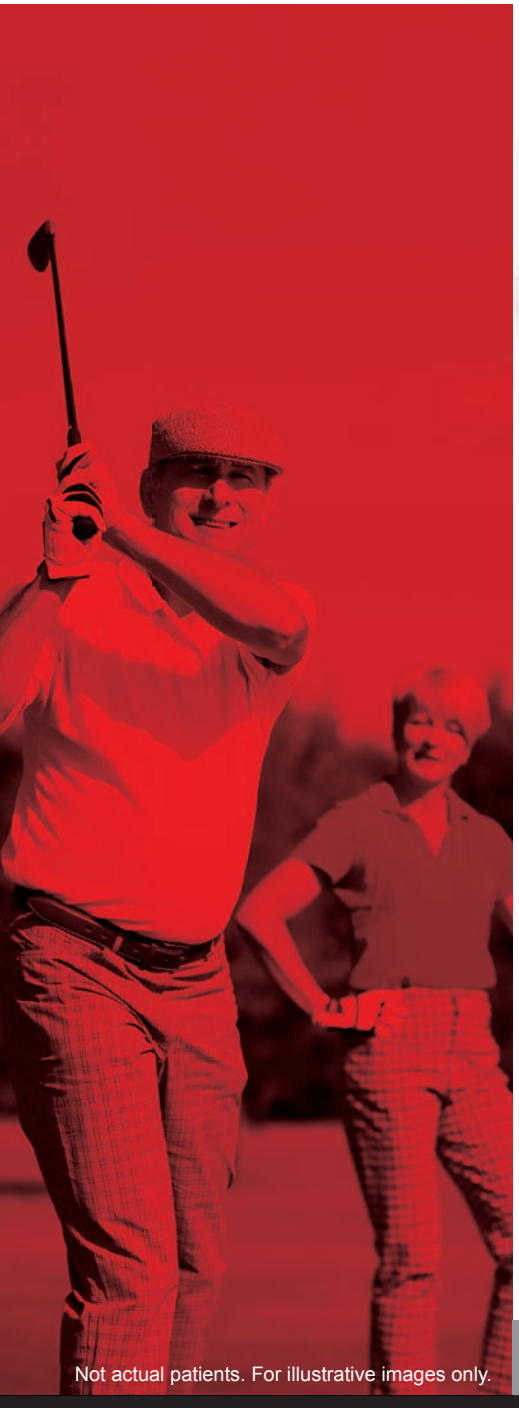
A ROUNDTABLE DISCUSSION

NOVEMBER 2017



Not actual patients. For illustrative images only.

Succeeding with TECNIS Symfony® Extended-Depth of Focus IOLs

Sponsored by Johnson & Johnson VISION

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Dear Reader,

Until recently, there were three primary classes of IOLs—monofocals, accommodating lenses, and multifocals. Each of these was also available in toric designs. However, last year an entirely different class of lens was approved by the FDA. The TECNIS Sym*f*ony® IOL is the first and only Extended Depth of Focus (EDOF) Presbyopia-Correcting IOL for patients with and without astigmatism.

Although the TECNIS Sym*f*ony® IOL mitigates the effects of presbyopia, it is not a multifocal. A multifocal IOL works by splitting light into separate distinct focal points. Conversely, the TECNIS Sym*f*ony® IOL transmits light over a range of distances, creating an elongated focus—hence the term "extended depth of focus." The TECNIS Symfony® IOL has an elongated focus rather than splitting the light and creating a second focal point. This helps provide intermediate and near vision with low incidence of glare and halo and, importantly, it does so without compromising distance vision.[1]

In the pages that follow, a panel of experts will share their knowledge on patient selection, preoperative and postoperative care, and more. Also included are several surgical pearls to help you succeed when implanting this remarkable technology.

PANELISTS

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This report is for and on behalf of Johnson & Johnson Vision. The physicians are paid consultants for Abbott Medical Optics Inc.

Patient Selection

MODERATED BY
GEORGE WARING IV, MD, FACS

DR. WARING: In terms of patient selection, what visual and lifestyle variables should surgeons pay close attention to before deciding to implant a TECNIS Symfony® Extended Depth of Focus IOL?

DR. WALTER: Ask patients about hobbies and what kinds of things they do for fun. If they say they like to read, are they reading paperback novels or an iPad where they can adjust the font size? I also try to get a true sense of how bothered they are by wearing glasses. If they can't bear the thought of ever wearing readers, an extended depth of focus IOL may not meet their expectations.

DR. ROCHA: Active patients who spend a lot of time using iPhones and other electronic devices tend to be a good match in terms of lifestyle. With regard to vision, hyperopes are good candidates. From a personality perspective, beware of Type A patients, especially for your first cases.

DR. CLINCH: The extended depth of focus lens gives patients excellent distance vision and intermediate vision, and an improved level of near vision. I sometimes encounter patients who work a lot at a close range, and for those patients I'll usually suggest a TECNIS Low Add Multifocal 1-Piece lens.

DR. WARING: How has the TECNIS Symfony® Toric IOL changed your approach to astigmatism management?

DR. ROCHA: You have to manage expectations just as you would with a multifocal candidate, but the fact that TECNIS Symfony® Toric IOL allows you to mitigate the effects of astigmatism along with presbyopia opens up the door and allows you to select a whole new group of patients with or without astigmatism that you wouldn't otherwise be able to treat.

DR. WARING: Who's a good candidate for the TECNIS Symfony® IOL? Do you look for patients with any particular hobbies or activities?

DR. BLECHER: Golfers and tennis players are especially good candidates for extended depth of focus, because they really don't want to lose track of the ball as it travels. You'd be surprised at how many people play tennis and golf. A lot of cataract patients are more active and serious about sports than we sometimes give them credit for.

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Patient Education

MODERATED BY MARK H. BLECHER, MD

DR. BLECHER: What's your approach to patient counseling?

DR. WARING: It's multifactorial and it begins before the patient enters our institute. In advance of the appointment, we send out a welcome letter along with some information about surgical options. When the patient arrives, the staff educates him or her at every step and touch point.

DR. CLINCH: Our patients have multiple touch points too, so we have to be careful to ensure that our message is consistent throughout the patient journey. Whether the patient is talking to a technician, a coordinator, or a surgeon, he should hear the same uniform message repeated.

DR. BLECHER: When the patient gets to your chair, do you walk through all the different cataract options?

TELL THE PATIENT TO BE PATIENT

By Thomas E. Clinch, MD

Some surgeons say the neuroadaption process is prolonged with the TECNIS Symfony® IOL[1], but based on what I see in practice, it would be more accurate to say that vision keeps improving between month one and month three. Explain this to the patient in a way that sets appropriate expectations so the patient is not concerned if their immediate, day one outcomes aren't 100%.

This is a very important discussion and each patient reacts a little differently. My advice is that you talk *with* your patient and not at your patient. Start by asking patients what they really want to achieve from surgery.

It's also worth noting that I target both eyes simultaneously and usually operate one week apart because I believe this speeds the neuroadptation process along. I also try not to make adjustments to the second eye, preferring instead to aim as close as possible to emmetropia. In my mind, there's usually no sense tinkering with the original plan since the patient needs both eyes to see well before he can accurately judge visual satisfaction. This has resulted in excellent outcomes for the vast majority of my patients.

OCULAR SURFACE OPTIMIZATION

By Elizabeth Yeu, MD

With refractive cataract surgery in particular, it is essential to look carefully at the ocular surface. This evaluation doesn't begin and end with gross corneal staining. Nuances in the topography can tell you a lot. For example, if you're looking at your topography, and the central corneal power between the two eyes is off, that's an indicator of ocular surface disease that needs to be treated before surgery.

The placido disk image can be another indicator of a problem. If it's blurred, smeared, or not a sharp bull's eye, keep digging for more information. And when you're looking at the axial map, look for hot spots and flat islands that are suggestive of irregular astigmatism. If it appears irregular, it might indicate underlying pathology such as keratoconus or ectasia. Or, it may be due to ocular surface disease.

Often, patients can have mild dry eye disease that doesn't stain the cornea, but it can cause intermittent fluctuations in their vision. If this is not identified and managed preoperatively, patients can become much more dry postoperatively and experience decreased quality of vision as well as intermittent waxing and waning of vision. They may also start to experience symptoms such as foreign body sensation and redness, which can lead to significant overall dissatisfaction.

As surgeons, we want to maximize patient outcomes. Carefully evaluating the ocular surface and pretreating disease is a critical step in this process, both functionally and in terms of diagnostics.

DR. WARING: No. By this point, most patients want to know what you think is best for them, so I don't overwhelm the patient with options and details. I make a recommendation based on what I think is the most suitable solution for that individual. Research shows that patients are seeking a specific recommendation from their doctor.

DR. BLECHER: How do you present the TECNIS Sym*f*ony® IOL to your patients?

DR. YEU: I think it's important to have a scripted message that you can customize or nuance based on individual patients. For example, my core message is something like this: "Mrs. Smith, I understand that you want to wear glasses less, so in my opinion, I think you would do best with the TECNIS Sym*f*ony® IOL. This lens offers a greater range of vision than you currently have. You'll be able to see the computer and the dashboard, and it will give you excellent distance vision as well. You may find that you still need glasses for reading in some conditions, but you'll have excellent vision for activities that you may do on a regular basis."

DR. WARING: I have a relatively scripted approach as well. I try to make the conversation celebratory. For example, I might say something like this: "Congratulations Mrs. Smith, your exam results reveal that you are a great candidate for our advanced technology—and not everyone is. I can't give you your 20-year-old eyes back, but with today's technology I can give you great distance and intermediate vision and improved near vision. On occasion, for example, in low-light conditions or when you're trying to read small print, you may need over-the-counter readers, and that's okay. The other good news is that we're going to address your astigmatism at the same time that we treat your cataracts, and we can use a laser for the procedure. So, congratulations! We're really excited for you."

DR. BLECHER: How do you talk to patients about astigmatism correction?

DR. WALTER: I make sure they know that they have two problems, not just one. Of course, I explain that, no matter what they choose, we're going to take care of their cataract. But if left untreated, the astigmatism will leave them with blur that they can continue to treat with glasses, or we can address it while we're doing their cataract surgery with a Toric IOL.

DR. BLECHER: How do you prepare your patient for what to expect after surgery with Sym*f*ony®?

DR. YEU: My patients are usually pleased with the distance vision right away, following surgery with TECNIS Sym*f*ony® IOL, so most of my education about expectations centers on delivering the message that optimal near vision can take a little longer. I explain that, in my experience, most of my patients achieve the vision that they hoped for at around four to six weeks.

Research shows that patients are seeking a specific recommendation from their doctor. *–Dr. Waring*

Preoperative Evaluation

MODERATED BY
GEORGE WARING IV, MD, FACS

DR. WARING: What do you look for in the preoperative evaluation?

DR. YEU: You have to look at the patient from two perspectives—an objective clinical one and a subjective lifestyle-based one.

DR. ROCHA: Indeed, learning about the patient's personality, work, and hobbies is just as important as topography, optical biometry, and recognizing pathology.

WARNINGS: 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.

DR. BLECHER: With regard to the exam, you always need to pay attention to the overall health of the eye, but when patients are paying out-of-pocket for premium procedures or IOLs, expectations are elevated, requiring you to pay extra attention to every little detail. I want to have confidence that I can achieve the best possible outcome, which requires me to look very carefully at the cornea and the tear film in particular.

DR. CLINCH: For the majority of patients, I separate cataract consults into two visits. In the initial visit, we address cataract surgery in the specific context of the patient's underlying medical conditions. Many have untreated, or insufficiently treated, dry eyes. The presence of mild epiretinal membranes, glaucoma, drusen or ARMD, ptosis and other disease processes should also be explained. It is critical for the patients to have a realistic expectation of what can be achieved with cataract surgery as well as the effect that the surgical process may have on their underlying conditions. We inquire about their specific refractive goals and introduce them to IOL options. In many cases, we need to initiate or increase treatment of underlying medical conditions. Most commonly, this involves more aggressive treatment of dry eyes. Patients are also given print information and have access to educational videos regarding surgery and IOLs. Patients return after one to two weeks for further monitoring of underlying conditions and biometry measurements. As they have had time to digest all of the information, patients are prepared to make a more informed and confident IOL selection. This extra time for patient education and treatment of underlying conditions leads to a more confident, better prepared patient.

DR. WARING: In terms of diagnostic testing, what do you need to look for when considering the TECNIS Symfony® IOL?

DR. ROCHA: You don't need to have all of the latest equipment, but you definitely need optical biometry and topography. Particularly when addressing astigmatism, these measurements need to be reproducible when you're aiming to achieve great outcomes. Corneal topography and tomography helps you differentiate between regular and irregular astigmatism. And there are times when you can tell whether a patient has dry eyes just by looking at topography. If you see irregular rings, the patient may not be ready for surgery. Ocular surface optimization is important before proceeding with cataract surgery.

DR. WARING: Do you follow different preoperative protocols in patients who wear contact lenses?

DR. ROCHA: Yes. When a patient comes in wearing spherical soft contact lenses, we wait three to seven days before taking any preoperative measurements. If a patient wears a soft toric contact lens we wait at least two weeks. We recommend waiting at least three weeks if a patient wears rigid gas permeable (RGP) contact lenses, or one month for every decade of RGP wear if there are signs of contact lens warpage.

The limiting factor here isn't the technology we use; it's the condition of the corneal surface and tear film. *–Dr. Blecher*

Calculating Lens Power

MODERATED BY
KAROLINNE MAIA ROCHA, MD, PHD

DR. ROCHA: What is your process for selecting TECNIS Symfony® IOL power?

DR. BLECHER: As with any IOL, your outcomes hinge on biometry and IOL calculations. You get much better performance when you hit your number. This requires great biometry and accurate keratometry readings. The limiting factor here isn't the technology we use; it's the condition of the corneal surface and tear film. It's tough to measure astigmatism consistently in patients who have dry eye and meibomian gland disease. We need to pay attention to this and treat it when possible to make sure it's not confounding our numbers.

COST VERSUS VALUE

By Keith Walter, MD

When discussing cost, we don't need to be shy. I explain to my patients that many things in medicine are often not covered by insurance. Unfortunately, premium IOLs—like hearing aids and dentures or dental implants—can require out-of-pocket expense. However, with added cost comes value. There is a reason why premium lenses cost more. For example, the patient will have a full range of high-quality vision and be able to wear glasses less often after premium IOL surgery.

It's also helpful to explain the permanence of an IOL. Some patients are concerned that the lens is going to wear out and they're going to need a new one in a few years. You want to make sure that this misunderstanding does not cloud the patient's decision making. Let the patient know that he is making a choice that will impact him every day possibly for the rest of his life. What is that worth from a value perspective?

CLINCH: Intraoperatively, when the TECNIS Symfony® IOL was first approved, the ORA nomogram was not optimized. So initially, I couldn't rely on the intraoperative calculations for the TECNIS Symfony® IOL and TECNIS Symfony® Toric IOL. But, over time, as I developed a larger patient base, I was able to optimize and personalize my own ORA calculations by entering the patient data back into the system. So, for those just starting out with the TECNIS Symfony® IOL, if you choose to use ORA, compare it to a lens to which you have a familiar constant.

When we had only spherical lenses, it reduced the number of patients who could benefit from addressing both presbyopia and astigmatism.
–Dr. Clinch

Astigmatism Pearls

MODERATED BY ELIZABETH YEU, MD

DR. YEU: What surgical pearls are most essential in your OR when using the TECNIS Symfony® Toric IOL platform?

DR. WARING: I account for cyclorotation by marking the patients upright. I also prefer to use the Catalys Laser System for these cases. I make micro arcuate incisions, intrastromal about 10 degrees, which serve as a marker postoperatively to check alignment and determine how well our lens stayed positioned. In addition, to minimize the chance of rotation, I remove OVD from behind the lens implant, and apply gentle posterior pressure to ensure that the lens is seated properly in the capsule. Finally, a micro leak or eye rubbing can increase the chance of rotation. For this reason, I focus on meticulous wound construction and proper hydration.

DR. WALTER: To avoid rotation, I get all the viscoelastic out from behind the lens. I like to do a little bit of polishing but not a lot.

DR. CLINCH: Another useful surgical pearl when implanting any IOL is to make sure you lubricate the cornea frequently and generously to keep the cornea from desiccating. Most patients who have cataract surgery are older, and many older patients have dry eyes. If a patient is in your operating room with a cornea that's slightly compromised despite preoperative treatment, do all you can to keep that cornea hydrated.

DR. YEU: Has the TECNIS Symfony® Toric IOL changed your view on astigmatism correction?

DR. BLECHER: Yes, it's been a total game changer. We didn't have a way to address astigmatism and presbyopia with one IOL before the TECNIS Symfony® Toric IOL was introduced. It made it easy on me because, like many cataract surgeons, I was already used to implanting toric lenses. It made adoption very simple because the principles are so similar.

DR. CLINCH: When we had only spherical lenses, it reduced the number of patients who could benefit from both presbyopia and astigmatism correction. In my practice, with spherical lenses, I was only comfortable correcting small amounts of astigmatism. But the TECNIS Symfony® Toric IOL expanded my choices, so now I can address the needs of more of my patients with an IOL. A multifocal is more sensitive to residual refractive cylinder whereas the extended depth of focus lens is tolerant to small amounts of residual astigmatism. So, whereas I was previously hesitant to use a multifocal on patients with any astigmatism, I'm very comfortable using the TECNIS Symfony® Toric Extended Depth of Focus lens for patients with up to 2.5D of pre-operative corneal astigmatism.

DR. YEU: How much astigmatism should we aim to mitigate when we're implanting a premium lens?

DR. BLECHER: My goal as a surgeon is to try to drive astigmatism as low as possible. If I'm implanting a premium lens, I want to get the best optical performance possible, which means reducing even small amounts of astigmatism.

DR. YEU: How important is it to measure posterior corneal astigmatism?

DR. BLECHER: Though it was tough to measure in the past, you do not want to ignore posterior corneal astigmatism. Fortunately, you don't have to manually calculate this anymore. The Johnson & Johnson toric calculator is very helpful. It offers a posterior corneal astigmatism option to give you a subtle and accurate representation of what the final cylinder will be. ●

1. TECNIS® Symfony DFU

POSTOPERATIVE REFRACTION AND MEASURING OUTCOMES

By Karolinne Maia Rocha, MD, PhD

Postoperative refraction requires a unique approach when using EDOF technology. Mainly, you can't rely on autorefraction. Auto refractors use infrared light that compensates for chromatic aberration. Because the TECNIS Symfony® IOL features achromatic technology with chromatic aberration correction, autorefractor results will generate erroneous myopic results.

When refracting TECNIS Symfony® IOL patients, push plus. You don't want to over minus these eyes.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE TECNIS SYMFONY® 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 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® 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. 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.

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 preopera tive 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. AMO 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 condi tions 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 involving 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, and 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 AMO 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 primaryimplantation 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 should weigh the potential risk/benefit ratio for any conditions described in the Directions for Use that could increase complicationsor impact patient outcomes. 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. The lens should not be placed in the ciliary sulcus. Inform patients about the possibility that a decrease in contrast sensitivity and an increase in visual disturbances may affect their ability to drive a car under certain environmental conditions, such as driving at night or in poor visibility conditions. **PRECAUTIONS**: Prior to surgery, 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. The long-term effects of intraocular lens implantation have not been determined. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. Do not reuse, resterilize or autoclave. **ADVERSE EVENTS**: The rates of surgical re-interventions, most of which were non-lens related, were statistically higher than the FDA grid rate for both the ZMB00 (+4.00 D) and ZLB00 (+3.25 D) lens models. For the ZMB00, the surgical re-intervention rates were 3.2% for first eyes and 3.3% for second eyes. The re-intervention rate was 3.3% for both the first and second eyes in the ZLB00 group. **ATTENTION**: Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

INDICATIONS AND IMPORTANT SAFETY INFORMATION for the CATALYS Precision Laser System
Rx Only
INDICATIONS: The OptiMedica Catalys Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure. **CONTRAINDICATIONS**: Should not be used in patients with corneal ring and/or inlay implants, severe corneal opacities, corneal abnormalities, significant corneal edema or diminished aqueous clarity that obscures OCT imaging of the anterior lens capsule, patients younger than 22 years of age, descemetocele with impending corneal rupture, and any contraindications to cataract surgery. **PRECAUTIONS**: The CATALYS System has not been adequately evaluated in patients with a cataract greater than Grade 4 (via LOCS III); therefore no conclusions regarding either the safety or effectiveness are presently available. **ADVERSE EFFECTS**: Complications include mild Petechiae and subconjunctival hemorrhage due to vacuum pressure of the LIQUID OPTICS Interface suction ring. Potential complications and adverse events include those generally associated with the performance of capsulotomy and lens fragmentation, or creation of a partial-thickness or full-thickness cut or incision of the cornea. **CAUTION**: Should be used only by qualified physicians who have extensive knowledge of the use of this device and have been trained and certified by Abbott Medical Optics/OptiMedica. **ATTENTION**: Reference the labeling for a complete listing of Indications and Important Safety Information.

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