

PATIENT INFORMATION BROCHURE

**TECNIS[®] Symphony Extended Range of Vision
Intraocular Lenses (IOLs),
Models ZXR00, ZXT150, ZXT225,
ZXT300 and ZXT375**

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CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner.

Table of Contents

| | |
|--|---|
| Introduction | 1 |
| What is a Cataract? | 1 |
| What is Astigmatism? | 1 |
| What is an Intraocular Lens (IOL)? | 2 |
| What to Expect before Cataract Surgery..... | 2 |
| What to Expect during Cataract Surgery..... | 2 |
| What to Expect after Cataract Surgery..... | 2 |
| Postoperative Care Instructions..... | 3 |
| Choosing the Lens Best for Your Vision..... | 3 |
| Monofocal IOLs | 3 |
| Multifocal IOLs..... | 3 |
| Toric IOLs..... | 3 |
| Accommodating IOLs | 4 |
| The TECNIS® Symphony Extended Range of Vision IOLs | 4 |
| Contraindications | 4 |
| Risks | 4 |
| Warnings | 5 |
| Precautions | 5 |
| Making the Right Choice..... | 5 |
| What This Means to You..... | 9 |

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TECNIS[®] Symphony Extended Range of Vision Intraocular Lens (IOL)

Models ZXR00, ZXT150, ZXT225, ZXT300, and ZXT375

Introduction

If you have a cataract, don't worry. You are not alone. Every year, nearly 2,500,000 Americans have cataract surgery. This brochure is designed to help you and your eye doctor decide on the best treatment choice for you. Your eye doctor will advise you about the potential risks and benefits of the procedure. If you have questions about any of the information on this brochure, please ask your eye doctor.

What is a Cataract?

Inside your eye is a natural lens that helps focus light. The natural lens focuses images onto the back of your eye (called the retina) so you can see clearly. This is just like a camera lens focuses images onto film for a clear picture (**Figure 1**). As people age, the natural lens can become less clear, even cloudy. This cloudiness is called a cataract. Just as a dirty camera lens can spoil a picture, a cataract can prevent light from focusing clearly inside the eye.

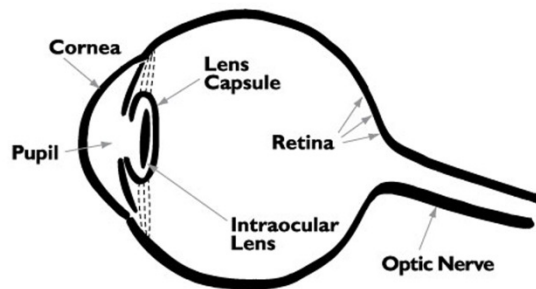


Figure 1: Diagram of eye with intraocular lens

Typical signs of cataracts are blurred vision and sensitivity to light. For example, you may have trouble reading, or driving at night or at dusk. Colors may seem less vivid. It may be difficult to thread a needle, shave, or put on make-up. A cataract can be removed only by surgery. You should consider surgery when cataracts cause enough loss of vision to interfere with your daily activities.

What is Astigmatism?

Astigmatism is caused by an irregularly shaped cornea. This results in blurred distance and/or near vision. A normal eye has a round cornea, shaped like a baseball. Light rays entering the eye focus at a single point on the retina, forming a clear image. An eye with astigmatism has an oblong-shaped cornea, shaped like an American football. As a result, the light rays do not focus on a single point on the retina. This causes blurred or distorted vision. Ask your eye doctor if you have corneal astigmatism.

What is an Intraocular Lens (IOL)?

The most common treatment for cataract today is to remove the clouded natural lens. It is then replaced with an artificial lens. This artificial lens is called an intraocular lens (IOL). **Figure 2** below compares the size of a TECNIS® Symphony Extended Range of Vision IOL to a U.S. penny.



Figure 2: *Size comparison of two TECNIS® Symphony Extended Range of Vision IOL model types and U.S. penny*

What to Expect before Cataract Surgery

You will be evaluated before surgery. This includes checking for any eye diseases. It also includes measuring your eye to choose the correct lens power. If you wear contact lenses, your eye doctor may ask you to stop wearing them before being tested for the **TECNIS® Symphony Extended Range of Vision IOL**. Tell your eye doctor if you have any health conditions that may affect your surgery or vision. Examples include high blood pressure, diabetes, and heart disease. Give your eye doctor a current list of your medications. Plan to have someone else drive you home after surgery.

What to Expect during Cataract Surgery

Cataract surgery is usually done as an outpatient procedure. You will be given anesthesia in the form of eye drops to numb your eye. Typically, you will be fully awake during the surgery. You will be comfortable and should feel little or no discomfort. Your eye doctor will use a microscope to have a magnified view of your eye. Your natural lens sits in a bag-like structure called the lens capsule. The lens capsule is located just behind the colored part of your eye (iris). A small incision is made in the outer surface of the eye. The eye doctor inserts a tiny probe through this opening to break up the cataract. Your eye doctor then uses a device like a small vacuum to remove the cataract pieces from your eye. Now there will be room for the IOL to be placed in your eye, to replace your natural lens that your eye doctor has just removed. Your doctor will insert the IOL through the same tiny incision. When the surgery is complete, your eye doctor may place a protective patch or shield over your eye.

What to Expect after Cataract Surgery

Right after surgery, you should stay in the recovery area for a short time. Your eye doctor should give you an identification card to keep in your wallet. This card shows the type of implant in your eye. Present this card to any eye doctor who examines your eyes after your surgery.

Many patients may begin to see better within 1 to 2 days. Some are stable at 10 to 14 days. Some may take 4 to 6 weeks to recover from surgery. Improvements in vision are different for each person.

Call your eye doctor right away if you experience any itching, pain, flashing lights, “floaters,” redness, severe headache, nausea/vomiting, light sensitivity, or watery eyes after surgery.

Postoperative Care Instructions

You will return home after surgery. Your eye doctor will give you antibiotic eye drops and medicines to speed up healing and to prevent infection. Take all prescribed medicines and apply eye drops as instructed by your eye doctor.

You will be given a date and time for a follow-up visit. It is typically the next day. Your doctor will examine you several more times following your surgery. It may take you some time to get used to your new IOL. Talk to your eye doctor if you have any questions or concerns after your surgery.

Choosing the Lens Best for Your Vision

There are many different lenses for improving your vision. These include the **TECNIS[®] Symfony Extended Range of Vision IOLs**. Your eye doctor will discuss which type of lens is best for you. Other options include glasses with thick lenses and contact lenses. Discuss the potential risks and benefits of your treatment options with your eye doctor.

Monofocal IOLs

Monofocal IOLs restore clear distance vision. This means that you should see well when you go to a ball game or read distant signs. You will probably need glasses for near vision tasks, such as reading a book, writing, or doing crafts. You may also need glasses for intermediate vision activities such as working on a computer, putting on make-up, or shaving.

Multifocal IOLs

All IOLs are designed for distance vision. Multifocal IOLs are also designed to improve near vision compared to a monofocal lens. This means that you should see well whether you go to a ball game or read a book. AMO's multifocal lenses have different powers for near vision, based on your lifestyle needs. Overall, you may wear glasses less often for daily tasks. However, the sharpness of your vision may also decrease compared to a monofocal lens. This is especially the case under poor visibility conditions such as dim light or fog. You may also notice more halos (rings around light) or glare (reflected light, making it difficult to see). Both are common with multifocal IOLs.

Toric IOLs

Toric IOLs restore clear distance vision for patients with astigmatism. As mentioned above, astigmatism is blurred or distorted vision caused by an irregularly shaped cornea. If you have astigmatism, a toric IOL may be the right choice for you.

Accommodating IOLs

Like monofocal and multifocal IOLs, accommodating IOLs provide distance vision. These IOLs may change focus from far to near when you look at near objects. This may result in better near vision than a regular monofocal IOL. Overall, you will likely wear glasses less often for daily tasks. For small print, you are likely to need reading glasses.

The TECNIS[®] Symphony Extended Range of Vision IOLs

The TECNIS[®] Symphony Extended Range of Vision IOLs have the same materials and overall design as the TECNIS[®] Multifocal 1-piece IOLs. The TECNIS[®] Symphony Extended Range of Vision IOLs give you a **continuous range** of clear vision at far and intermediate. The IOLs also provide improved near vision compared to a monofocal lens. For small print, you are likely to need reading glasses. Multifocal IOLs give you good vision at distinct far and near points. Examples of intermediate vision activities are seeing where your drive lands and sinking your putt while playing golf. Examples of near vision activities are reading the aisle signs and the package labels, and counting your change when shopping. You may notice halos, starbursts, glare and other visual symptoms.

There are five different TECNIS[®] Symphony Extended Range of Vision IOLs. All models give similar distance and better intermediate and near vision, compared to a monofocal lens. The toric models also correct different amounts of astigmatism. It is important to choose the lens that is appropriate for your needs and your lifestyle. Talk to your eye doctor to determine which IOL option is right for you.

Contraindications

There are no known conditions under which the TECNIS[®] Symphony Extended Range of Vision IOLs should not be used.

Risks

1. There are risks to routine cataract surgery. This is irrelevant to the lens you choose. The problems could be minor, temporary, or affect your vision permanently.
 - a. Complications are rare. These may include worsening of your vision, bleeding, or infection.
2. There are risks related to use of the TECNIS Symphony lens.
 - a. Your decreased use of glasses may come with a slight loss in the sharpness of your vision.
 - i. Even with glasses, this loss of sharpness may become worse under poor visibility conditions such as dim light or fog.
 - ii. This may lead to difficulties in driving, and may cause problems such as not being able to detect hazards in the road as quickly at night or in fog.
 - iii. You may also notice halos, starbursts, glare, and other visual symptoms with extended range of vision IOLs. This may impact your vision when there are bright lights at night.

Discuss all risks and benefits with your eye doctor prior to surgery.

Warnings

1. A small number of patients may want to have their **TECNIS® Symfony Extended Range of Vision IOL** removed. This is due to lens-related optical/visual symptoms.
2. You may have more difficulty seeing while driving at night or completing tasks in low light conditions such as in fog.
3. You may experience some halos (rings around light), glare (reflected light, making it difficult to see), and starbursts (rays around light).
4. Pre-existing diseases or conditions may place you at higher risk of experiencing complications (e.g., more difficult recovery) after routine cataract surgery. Examples of pre-existing diseases or conditions are diabetes, heart disease, and previous trauma to your eye.
5. These lenses have not been evaluated for use in children.

Precautions

1. If your eye is not healthy (including glaucoma), your vision may not be good even after your cataract is removed. In this case, you may not get the full benefit of the **TECNIS® Symfony Extended Range of Vision IOL**. Before surgery, your eye doctor will check if you have any eye diseases.
2. Your vision with the **TECNIS® Symfony Extended Range of Vision IOL** may not be good enough to perform detailed 'up-close' work without glasses.
3. In rare instances, the **TECNIS® Symfony Extended Range of Vision IOL** may make some types of retinal treatment (e.g., retinal tear repair) more difficult.
4. Take all prescribed medicines and apply eye drops as instructed to avoid inflammation and infection.
5. Avoid any activity such as bending down and playing sports. These could harm your eye during recovery. Your eye doctor will tell you what activities to avoid.

Making the Right Choice

AMO's monofocal IOLs and **TECNIS® Symfony Extended Range of Vision IOLs** have been well studied. Both are used to replace the natural lens of the eye. AMO's monofocal IOLs provide far vision. You will most likely need glasses for near vision. The **TECNIS® Symfony Extended Range of Vision IOL** is designed to provide a continuous range of good vision at far, intermediate, and near. Wearing glasses is reduced compared to a monofocal IOL. The toric version of the **TECNIS® Symfony Extended Range of Vision IOL** will correct your astigmatism.

Table 1 will help you compare the monofocal IOL and the **TECNIS® Symfony Extended Range of Vision IOL**.

Table 1: Expected IOL Performance for Patients based on the U.S. clinical study of the TECNIS Symphony Extended Range of Vision IOL, Model ZXR00.

| | TECNIS® Symphony Extended Range of Vision IOL | Monofocal IOL |
|---|---|--|
| Far Vision | The clinical study showed that the TECNIS Symphony IOL provided far vision comparable to the monofocal IOL. | A monofocal IOL is designed to provide far vision. |
| Intermediate Vision (approximately 2-5 feet) | The clinical study showed that the TECNIS Symphony IOL provided better intermediate vision compared to the monofocal IOL. | A monofocal IOL is not designed to provide intermediate vision. |
| Near Vision | The clinical study showed that the TECNIS Symphony IOL provided better near vision compared to the monofocal IOL. | A monofocal IOL is not designed to provide near vision. |
| Visual Effects (i.e. halos, starburst, glare) | Visual effects occur more often with the Symphony lens than with the monofocal lens. These could be worse at night or in low-light conditions. These visual effects may affect your ability to drive a car at night or in poor visibility conditions. | These visual effects may also occur with monofocal lenses. However, these visual effects occur less often with monofocal IOLs. |
| Use of Glasses | The clinical study showed that the TECNIS Symphony IOL patients wore glasses less often for overall vision compared to patients with the monofocal IOL. | You are more likely to wear prescription glasses overall. |
| Low Contrast Vision | You may have more difficulty distinguishing road signs and hazards as quickly under low-light conditions. | Does not adversely affect your vision in low-light conditions. |

Table 2 presents some of the U.S. clinical study results for the **TECNIS® Symphony Extended Range of Vision IOL, Model ZXR00**, 6 months after surgery. At 6 months, there were 147 patients who had received the **TECNIS Symphony lens**. There were 148 patients who had received the monofocal IOL at 6 months.

Table 2: U.S. Clinical Study Results for the TECNIS® Symphony Extended Range of Vision IOL, Model ZXR00, and the Monofocal IOL 6 Months after Surgery (Binocular Results)

| | TECNIS® Symphony Extended Range of Vision IOL, Model ZXR00 (147 Patients) | | Monofocal IOL (148 Patients) | |
|--|--|---------------------------------------|---|---------------------------------------|
| | Monocular (one eye tested alone) | Binocular (both eyes tested together) | Monocular (one eye tested alone) | Binocular (both eyes tested together) |
| Far Vision: 20/40 or better without glasses | 97% of patients | 99% of patients | 94% of patients | 100% of patients |
| Far Vision: 20/40 or better with glasses | 100% of patients | 100% of patients | 100% of patients | 100% of patients |
| Intermediate Vision: 20/25 or better without glasses | 77% of patients | 97% of patients | 34% of patients | 60% of patients |
| Intermediate Vision: 20/25 or better with glasses for far vision only | 70% of patients | 93% of patients | 14% of patients | 35% of patients |
| Near Vision: 20/40 or better without glasses | 81% of patients | 96% of patients | 31% of patients | 63% of patients |
| Near Vision: 20/40 or better with glasses for far vision only | 62% of patients | 91% of patients | 16% of patients | 35% of patients |
| Average range with vision of 20/32 or better | Far to intermediate to near | | Far to intermediate | |
| | Monocular: to approximately 26 inches | Binocular: to approximately 20 inches | Monocular: to approximately 5 feet | Binocular: to approximately 3 feet |
| Wearing glasses overall (according to a patient survey) | Percentage of patients who reported wearing glasses overall: None/A little of the time: 85% Some of the time: 12% Most/All of the time: 3% | | Percentage of patients who reported wearing glasses overall: None/A little of the time: 60% Some of the time: 25% Most/All of the time: 15% | |
| Wearing glasses for far vision (according to a patient survey) | Percentage of patients who reported wearing glasses for far vision: None/A little of the time: 93% Some of the time: <1% Most/All of the time: 6% | | Percentage of patients who reported wearing glasses for far vision: None/A little of the time: 87% Some of the time: 5% Most/All of the time: 8% | |
| Wearing glasses for intermediate vision (according to a patient survey) | Percentage of patients who reported wearing glasses for intermediate vision: None/A little of the time: 93% Some of the time: 3% Most/All of the time: 5% | | Percentage of patients who reported wearing glasses for intermediate vision: None/A little of the time: 73% Some of the time: 12% Most/All of the time: 16% | |
| Wearing glasses for near vision (according to a patient survey) | Percentage of patients who reported wearing glasses for near vision: None/A little of the time: 68% Some of the time: 15% Most/All of the time: 17% | | Percentage of patients who reported wearing glasses for near vision: None/A little of the time: 28% Some of the time: 14% Most/All of the time: 58% | |
| Visual effects | <ul style="list-style-type: none"> More visual effects such as halos, starbursts and glare, occurred with the Symphony IOL than with the monofocal IOL. | | <ul style="list-style-type: none"> At 6 months, a few patients reported to their doctors that they experienced halos and starbursts. Less than 1% were reported as severe. | |

| | TECNIS® Symphony Extended Range of Vision IOL, Model ZXR00 (147 Patients) | Monofocal IOL (148 Patients) |
|-------------------------------|---|---|
| | <ul style="list-style-type: none"> • At 6 months, most cases were “mild” to “moderate.” A few cases were severe for halos (3%) and starbursts (1%). • In a survey, patients were asked specifically about visual symptoms. Patients reported being very bothered with halos (7%), starbursts (8%), and glare (6%) at 6 months. • No subjects had the lens removed during the study. • Some patients also reported that they had blurred vision, mostly at near (9%). | <ul style="list-style-type: none"> • In a survey, some patients reported being very bothered with halos (3%), starbursts (4%), and glare (3%). • No subjects had the lens removed during the study. • Some patients also reported that they had blurred vision, mostly at near (18%). |
| Serious Adverse Events | <p>There were no serious adverse events related to the TECNIS Symphony IOL. Some were related to the cataract procedure.</p> <p>4 out of 147 patients had serious adverse events:</p> <ul style="list-style-type: none"> ○ Two patients had swelling in the retina. ○ One patient had part of the IOL caught on the pupil. ○ One patient had eye inflammation and a small pocket of pus. <p>These four patients were treated with medication and recovered. One patient with swelling of the retina and the patients with eye inflammation required antibiotic injections.</p> | <p>There were no serious adverse events related to the monofocal IOL. Some were related to the cataract procedure.</p> <p>9 out of 148 patients reported serious adverse events:</p> <ul style="list-style-type: none"> ○ Three patients (five eyes) had swelling in the retina. ○ One patient (two eyes) had inflammation. <p>These four patients were treated with medication and recovered. The patient with inflammation required antibiotic injections in both eyes.</p> <ul style="list-style-type: none"> ○ One patient developed a thin layer of tissue on the retina. ○ Two patients needed removal of small pieces of the cataract that remained after the cataract surgery. ○ One patient had a disease of the cornea. <p>These four patients recovered but needed surgery.</p> <ul style="list-style-type: none"> ○ One patient had optic nerve disease. It resulted in decreased vision. |

| | | |
|--|--|---|
| | TECNIS® Symphony Extended Range of Vision IOL, Model ZXR00 (147 Patients) | Monofocal IOL (148 Patients) |
| | | This patient was treated with medication. The condition was stable. Vision was not expected to improve. |

Table 3 presents the number of patients who reported being “very bothered” by visual symptoms for the **TECNIS Symphony Extended Range of Vision IOL** and for the monofocal IOL during the U.S. clinical study.

Table 3: Patient Reports of Being “Very Bothered” by Visual Symptoms at 6 Months

| | Very Bothered When | Symfony 6 Months | Monofocal 6 months |
|------------------------------|--------------------------------------|-------------------------|---------------------------|
| Halos | Not wearing glasses | 11 out of 147 patients | 5 out of 148 patients |
| | Driving at night not wearing glasses | 15 out of 147 patients | 3 out of 148 patients |
| | Overall | 10 out of 147 patients | 4 out of 148 patients |
| Starbursts | Not wearing glasses | 13 out of 147 patients | 3 out of 148 patients |
| | Driving at night not wearing glasses | 14 out of 147 patients | 3 out of 148 patients |
| | Overall | 12 out of 147 patients | 6 out of 148 patients |
| Glare | Not wearing glasses | 9 out of 147 patients | 12 out of 148 patients |
| | Driving at night not wearing glasses | 11 out of 147 patients | 2 out of 148 patients |
| | Overall | 8 out of 145 patients | 5 out of 148 patients |
| Streaks of Light | Not wearing glasses | 5 out of 147 patients | 2 out of 148 patients |
| | Driving at night not wearing glasses | 6 out of 147 patients | 2 out of 148 patients |
| | Overall | 4 out of 144 patients | 4 out of 148 patients |
| Occlusions (Shadows) | Not wearing glasses | 2 out of 147 patients | 1 out of 148 patients |
| | Driving at night not wearing glasses | 1 out of 147 patients | 1 out of 148 patients |
| | Overall | 2 out of 146 patients | 2 out of 148 patients |
| Sensitivity to Light | Not wearing glasses | 9 out of 147 patients | 20 out of 148 patients |
| | Driving at night not wearing glasses | 9 out of 147 patients | 4 out of 148 patients |
| | Overall | 4 out of 146 patients | 11 out of 148 patients |
| Poor Low Light Vision | Not wearing glasses | 1 out of 147 patients | 16 out of 148 patients |
| | Driving at night not wearing glasses | 2 out of 147 patients | 2 out of 148 patients |
| | Overall | 2 out of 146 patients | 3 out of 148 patients |

What This Means to You

You should evaluate the comparison factors in Tables 1 and 2 as they relate to your quality of life. This will help you choose the IOL that is best for you. We recommend that you ask your eye doctor to assist in this evaluation.

If being able to see well at near, intermediate, and far and being able to use glasses or contact lenses less frequently would make your life better, then one of the **TECNIS® Symphony Extended Range of**

Vision IOLs may be the right choice for you. However, if you do a lot of night-driving or wish to minimize halos, you may prefer a monofocal lens. Weigh the possible advantages and disadvantages before deciding. Whichever IOL you choose, we hope that you are satisfied and have great pleasure in your improved vision.