

Patient Information Brochure

TECNIS Synergy™ Intraocular Lens (IOL), Models ZFR00V, ZFW150, ZFW225, ZFW300, ZFW375

Note: This brochure applies to all TECNIS Synergy™ lenses, including the toric version and the lenses available with the TECNIS Simplicity Delivery System.

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 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 the information in this brochure, please ask your eye doctor.

What is a Cataract?

Inside your eye is a natural lens that helps focus light. Your natural lens has an outer covering called the lens capsule. The natural lens focuses images onto the back of your eye (called the retina) so you can see clearly. This is similar to how 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.

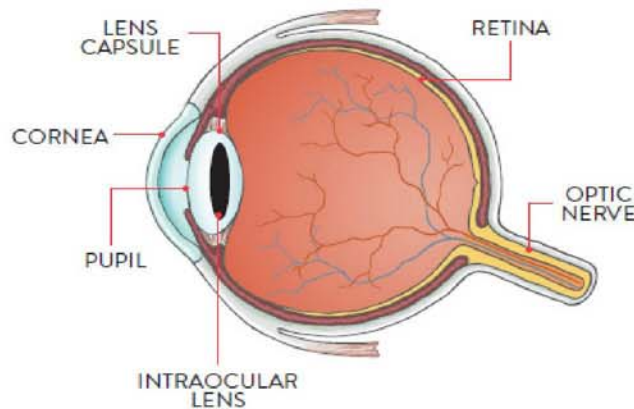


Figure 1: Diagram of eye with intraocular lens

Common signs of cataracts are blurred vision and sensitivity to light. 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 makeup. 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. Having surgery is a personal choice, so here are some questions to help you choose:

- Can you see well enough to do your job and drive?
- Can you read a book or your cell phone, work at the computer, and/or watch television to your satisfaction?

- Can you shop, cook, do housework, climb stairs, shave, apply makeup, and take medications to your satisfaction?
- Does your current ability to see affect your independence?

What is Astigmatism?

Astigmatism is caused by an irregularly shaped cornea. Astigmatism is a variation of normal vision. It is not a disease. Astigmatism results in blurred far and/or near vision. A normal eye has a round cornea, shaped like a baseball. Light 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 does not focus on a single point on the retina. This causes blurred or distorted vision. Ask your eye doctor if you have corneal astigmatism. Many people have some level of astigmatism that was present since childhood.

What is an Intraocular Lens (IOL)?

An IOL is an artificial lens that is implanted into the eye after the cataract (cloudy lens) has been surgically removed by an eye doctor. Figure 2 below compares the size of a TECNIS Synergy™ IOL to a U.S. penny.



Figure 2: Size comparison of the TECNIS Synergy™ IOL and a 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 evaluated. Tell your eye doctor about all of your health conditions. Examples include high blood pressure, diabetes, heart disease, and bleeding disorders. Give your eye doctor a current list of all of your medications including aspirin, NSAIDs like ibuprofen and naproxen, and all other over the counter and herbal medications. For one or two days before surgery, your eye doctor may prescribe antibiotic eye drops for you.

What to Expect During Cataract Surgery

Cataract surgery is usually done as an outpatient procedure. You will be given eye drops to numb your eye. Typically, you will be fully awake or lightly sedated during the surgery. You will be comfortable and should feel little or no discomfort. Your eye doctor will use a microscope to view your eye. A small opening 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. After the pieces of the cataract have been removed, there is room for the IOL to be placed in your eye. Your doctor will insert the IOL through the same tiny opening into the lens capsule (See Figure 1). When the surgery is complete, your eye doctor may place a protective patch or shield over your eye.

What to Expect After Cataract Surgery

Following surgery, you should stay in the recovery area for a short time. Arrange for someone else to drive you home. Your eye doctor should give you an identification card. This card shows the type of IOL implanted in your eye. Present this card to any eye doctor who examines your eyes after your surgery.

Many patients 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 other medicines. This helps speed up healing and prevent infection. Take all prescribed medicines on time 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 after your surgery. It may take 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 IOL That is Best for Your Vision

There are many different IOLs for improving your vision. These include the TECNIS Synergy™ IOLs. Your eye doctor will discuss which type of lens is best for you. Options besides IOLs include glasses with thick lenses and contact lenses. Discuss the potential risks and benefits of your treatment options with your eye doctor. Below are the different types of IOLs currently available.

Monofocal IOLs

Monofocal IOLs restore clear far vision. This means that you should see well when you go to a ball game, read distant signs, or watch TV. 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 tasks such as working on a computer, putting on makeup, or shaving.

Multifocal IOLs

All IOLs are designed to restore far vision. Multifocal IOLs also 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. The multifocal lenses made by Johnson & Johnson Surgical Vision, Inc. (JJSV) 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 with multifocal lenses may decrease compared to your vision with monofocal lenses. This may be noticeable 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 halos and glare are common with multifocal IOLs.

Toric IOLs

Toric IOLs restore clear far 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 far 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 monofocal IOL. Overall, you will likely wear glasses less often for daily tasks. For small print, however, you are likely to need reading glasses.

Extended Depth of Focus IOLs

Extended Depth of Focus (EDF) IOLs are designed to improve near vision compared to a monofocal lens. EDF IOLs provide a continuous range of vision to see clearly at far, intermediate, and near distances.

The TECNIS Synergy™ IOL

The TECNIS Synergy™ IOL is a new IOL that is made using the same materials and has the same overall design as other Johnson & Johnson Vision (JJSV) IOLs. Like a monofocal lens, the purpose of the TECNIS Synergy™ IOL is to focus images clearly onto the back of your eye (retina) to allow clear vision after removal of your cataract. The TECNIS Synergy IOLs provide similar distance, better intermediate and better near vision compared to a monofocal.

Examples of far vision activities are seeing where your drive lands and sinking your putt while playing golf. Examples of intermediate vision activities are reading the shelf labels in the store and your computer screen. Examples of near vision activities are reading package labels and counting your change when shopping. For small print, you are likely to need reading glasses. You may experience halos, glare, starburst, or other visual symptoms.

There are two different kinds of TECNIS Synergy™ IOLs. One is specially designed for eyes that have astigmatism and one is designed for eyes without astigmatism. Compared to a monofocal lens, both kinds give similar far vision and better intermediate and near vision.

It is important to choose the lens that is right for your needs and lifestyle. Talk to your eye doctor about which IOL option is right for you.

Contraindications

There are no known conditions under which the TECNIS Synergy™ IOLs should not be used.

Risks

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.

- Complications are rare. These may include worsening of your vision, bleeding, inflammation, lens removal, lens decentration or infection.
- After surgery and during your recovery period, avoid any activity that could harm your eye. Examples are bending down and playing sports. Your eye doctor will tell you what activities to avoid.

There are risks related to use of lenses like the TECNIS Synergy™ IOL. You may experience some loss in the sharpness of your vision, even with glasses (see warnings below).

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

Warnings

1. You may have more difficulty driving at night or in poor visibility conditions. This can affect your ability to detect road hazards as quickly at night or in fog.
2. You may experience some halos (rings around light), glare (reflected light, making it difficult to see), and starbursts (rays around light).
3. A small number of patients may want to have their TECNIS Synergy™ IOL removed. This can be due to lens-related optical/visual symptoms.
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.

Precautions

1. If your eye is not healthy, 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 Synergy™ IOL. Before surgery, your eye doctor will check if you have any eye diseases that may influence your IOL selection.
2. In rare instances, the TECNIS Synergy™ IOL may make some types of retinal treatment (e.g., retinal tear repair) more difficult.
3. Take all prescribed medicines and apply eye drops as instructed to avoid inflammation and infection.
4. These lenses have not been evaluated for use in patients younger than 22 years of age.

Making the Right Choice

In addition to clinical study of the non-toric TECNIS Synergy™ IOLs, data from other relevant clinical studies of previously approved multifocal, toric, and monofocal IOLs were also used to support the safety and effectiveness of the TECNIS Synergy™ IOLs. Both types of IOLs are used to replace the natural lens of the eye. The monofocal IOLs manufactured by JJSV restore clear far vision. This means that you will most likely need glasses for near vision. The TECNIS Synergy™ IOL gives you a range of vision from far to intermediate to near. Wearing glasses may be less frequent with the TECNIS Synergy™ IOL compared to a monofocal IOL.

Table 1 will help you compare the TECNIS Synergy™ IOL with a monofocal IOL.

Table 1: Comparison of the TECNIS Synergy™ IOL with a monofocal IOL

	TECNIS Synergy™ IOL	Monofocal IOL
Far Vision	A clinical study showed that the TECNIS Synergy™ IOL provided far vision comparable to the monofocal IOL.	A monofocal IOL is designed to provide far vision.
Intermediate Vision (approximately 2-5 feet)	A clinical study showed that the TECNIS Synergy™ IOL provided better intermediate vision than the monofocal IOL.	A monofocal IOL is not designed to provide intermediate vision.
Near Vision	A clinical study showed that the TECNIS Synergy™ IOL provided better near vision than the monofocal IOL.	A monofocal IOL is not designed to provide near vision.
Visual Symptoms (i.e., halos, starburst, glare)	Visual symptoms occur more often with the TECNIS Synergy™ IOL than the monofocal IOL. These could be worse at night and may affect your ability to drive at night or in poor visibility conditions.	These visual symptoms may also occur with monofocal IOLs. However, they occur less often with monofocal IOLs.
Use of glasses	A clinical study showed that the TECNIS Synergy™ IOL patients used glasses less often for overall vision (including far, intermediate and near) compared to the monofocal IOL.	You are more likely to use glasses for intermediate and near vision.
Low-Light Near Vision	A clinical study showed that the TECNIS Synergy™ IOL provided good near vision under low-light conditions, such as reading a menu in a dim restaurant.	You are likely to have more difficulty with near vision under low-light conditions.

Table 2 presents some of the U.S. clinical study results for the TECNIS Synergy™ IOL, Model ZFR00V. At 6 months, there were 131 patients who received the TECNIS Synergy™ IOL in both eyes and 131 patients who received the monofocal IOL in both eyes.

The TECNIS Synergy™ IOL models that correct astigmatism were not evaluated in a clinical study.

These results show that there is a high likelihood of reading small newsprint-sized letters (20/40) without glasses. 97% of the TECNIS Synergy™ patients in the study could read small newsprint-sized (20/40) letters from 16 inches away without reading glasses. By comparison, 44% of patients implanted with monofocal lenses could read newsprint-sized letters (20/40) from 16 inches away without glasses.

Table 2: U.S. Clinical Study Results for the TECNIS Synergy™ IOL and the TECNIS® Monofocal IOL 6 Months after Surgery

	TECNIS Synergy™ IOL, Model ZFR00V (131 Patients)		TECNIS Monofocal IOL (131 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	98% of patients	99% of patients	97% of patients	99% of patients
Far Vision: 20/40 or better with glasses	100% of patients	N/A	100% of patients	N/A
Intermediate Vision: 20/40 or better without glasses	N/A	100% of patients	N/A	88% of patients
Intermediate Vision: 20/40 or better with glasses for far vision only	99% of patients	N/A	52% of patients	N/A
Near Vision: 20/40 or better without glasses	N/A	97% of patients	N/A	44% of patients
Near Vision: 20/40 or better with glasses for far vision only	95% of patients	N/A	19% of patients	N/A
Closest reading distance with 20/32 or better vision	To approx. 11 inches	N/A	To approx. 39 inches	N/A
Wearing glasses overall (according to a patient survey)	88% of patients reported not wearing glasses or contacts for any distance (far, intermediate, near, and overall)		3% of patients reported not wearing glasses or contacts for any distance (far, intermediate, near, and overall)	
Visual Symptoms	<ul style="list-style-type: none"> • More visual symptoms such as halos, starbursts and glare, occurred with the Synergy™ IOL than with the monofocal IOL. • At 6 months, most cases were "mild" to "moderate." Few cases were severe for halos (4%), starbursts (4%), or glare (2%). • Patients reported being extremely bothered with halos (4%), starbursts (5%), or glare (5%) at 6 months. 		<ul style="list-style-type: none"> • At 6 months, a few patients (no more than 2%) reported to their doctors that they experienced moderate halos or glare. • In a survey, no patients reported being extremely bothered with halos, starbursts, or glare. • No patients had the lens removed during the study. 	
Adverse Events	<ul style="list-style-type: none"> • Some serious adverse events were related to the cataract procedure. • One patient had the lens removed from one eye after 1 month due to visual symptoms.* • One patient had a serious adverse event that was possibly related to the device. 		There were no serious adverse events related to the monofocal IOL. Some serious adverse events were related to the cataract procedure.	
	5 out of 135 patients who had cataract surgery had serious adverse events: <ul style="list-style-type: none"> • One had the IOL removed due to visual symptoms • One had eye inflammation in both eyes following surgery • One had detachment/tear of the retina • One had eye inflammation and a small pocket of pus • One had a remnant of the cataract within the eye after surgery All 5 patients were successfully treated.		3 out of 137 patients who had cataract surgery had serious adverse events: <ul style="list-style-type: none"> • One had eye inflammation • One had detachment/tear of the retina • One had a viral eye infection All 3 patients were successfully treated.	

*The lens was removed from the second eye of this patient after study completion due to visual symptoms.

Table 3 presents the patients who reported visual symptoms under two different conditions for the TECNIS Synergy™ IOL and for the monofocal IOL during the U.S. clinical study.

Table 3: Patient Reports of Visual Symptoms While 1) Not Wearing Corrective Glasses, Contacts, or Sunglasses, and 2) At Night, at 6 Months Following Surgery

	Conditions	TECNIS Synergy™	TECNIS Monofocal
Halos	• Not wearing corrective glasses, contacts or sunglasses	79%	37%
	• At night	76%	36%
Starbursts	• Not wearing corrective glasses, contacts or sunglasses	63%	18%
	• At night	60%	21%
Glare	• Not wearing corrective glasses, contacts or sunglasses	44%	15%
	• At night	35%	13%
Multiple or Double Vision	• Not wearing corrective glasses, contacts or sunglasses	13%	10%
	• At night	7%	5%
Occlusions (Shadows)	• Not wearing corrective glasses, contacts or sunglasses	2%	2%
	• At night	3%	1%
Sensitivity to Light	• Not wearing corrective glasses, contacts or sunglasses	51%	42%
	• At night	13%	8%
Poor Low Light Vision	• Not wearing corrective glasses, contacts or sunglasses	39%	29%
	• At night	30%	26%

What This Means to You

You should carefully think about the information provided in the section, “Making the Right Choice”. This will help you choose the IOL that is best for you. We recommend that you ask your eye doctor to help you with this choice.

If it is important that you can see without glasses at intermediate and near distances, then the TECNIS Synergy™ 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.