Patient Information Brochure
TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System
TECNIS PureSee™ Toric II IOL with TECNIS SIMPLICITY™ Delivery System

Introduction

If you have a cataract, don't worry. You are not alone. Every year, more than 3.5 million cataract surgeries are performed annually in the U.S. 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 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 is inside of your lens capsule (Figure 1). 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. 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.

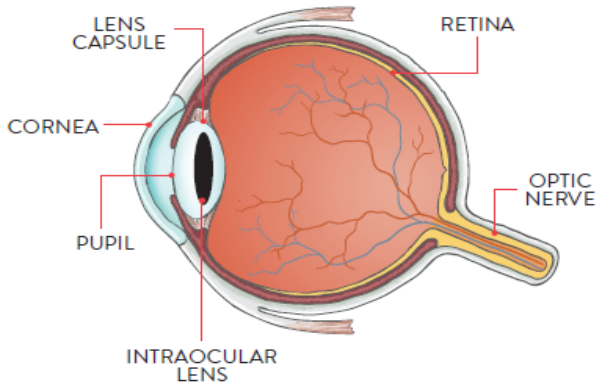

Figure 1: Diagram of eye with intraocular lens

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. Having surgery is a personal choice, so here are some questions to help you choose:

- Can you see sufficiently 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 make-up, 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 and is not a disease. Astigmatism results in blurred 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. 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 the cataract surgeon. Figure 2 below compares the size of a TECNIS PureSee™ IOL to a U.S. penny.

Figure 2: Size comparison of the TECNIS PureSee™ 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 tested for the TECNIS PureSee™ IOL. 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.

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 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 have a magnified view of your eye. Your natural lens sits in a bag-like structure called the lens capsule as shown in Figure 1 above. The lens capsule is located just behind the colored part of your eye (iris). 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 will be 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

Right after surgery, you should stay in the recovery area for a short time. Plan in advance to have someone else drive you home after surgery. For one or two days before surgery, your eye doctor will likely prescribe antibiotic eye drops. 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 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 other medicines to 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 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 IOL That is Best for Your Vision

There are many different IOLs for improving your vision. These include the TECNIS PureSee™ IOLs. Your eye doctor will discuss which type of lens is best for you. Other options beyond 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 make-up, or shaving.

Multifocal IOLs

All IOLs are designed for clear far 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. 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 with multifocal lenses may decrease compared to your vision with monofocal lenses. 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 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 if you choose to have an accommodating IOL implanted. For small print, however, you are likely to need reading glasses.

Extended Depth of Focus IOLs

Extended Depth of Focus (EDF) IOLs provide a continuous range of clear vision from far to intermediate distances, with some benefit at near. You will likely wear glasses less often for daily tasks if you choose to have an EDF IOL implanted. For small print, however, you are likely to need reading glasses.

The TECNIS PureSee™ IOLs

The TECNIS PureSee™ IOLs are Extended Depth of Focus IOLs made using the same material and overall design as other Johnson & Johnson Vision (J&J Vision) IOLs and are designed to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. The lenses have a unique design using the Opticurve™ technology to provide the extended depth of focus with the TECNIS aspheric surface to compensate for corneal shape. The TECNIS PureSee™ IOLs give you a continuous range of clear vision at far and intermediate distances. The IOLs provide far vision similar to a monofocal IOL, including in poor visibility conditions such as dim light or fog.

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 aisle signs in the store or viewing your computer screen.

The toric models of the TECNIS PureSee™ IOLs also correct astigmatism. It is important to choose the lens that is appropriate for your needs and 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 PureSee™ IOLs should not be used.

Risks

There are risks to routine cataract surgery, regardless of 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, or infection.

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

Warnings

1. The TECNIS PureSee™ Toric II IOL corrects astigmatism when it is placed correctly in the eye. There is a chance that the TECNIS PureSee™ Toric II IOL could be placed incorrectly or could move within the eye, resulting in visual distortions. A second surgery may be needed to properly position the lens.
2. 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 PureSee™ IOL. Before surgery, your eye doctor will check if you have any eye diseases that may influence your IOL selection.
2. Your vision with the TECNIS PureSee™ IOL may not be good enough to perform detailed 'up-close' work without glasses.
3. In rare instances, intraocular lenses may make some types of retinal treatment more difficult (e.g., retinal tear repair).
4. Take all prescribed medicines and apply eye drops as instructed to avoid inflammation and infection.
5. You should avoid any activity that could harm your eye during recovery, such as bending down and playing sports. Your eye doctor will tell you what activities to avoid.
6. The TECNIS PureSee™ IOLs have not been evaluated for use in pregnant women and patients younger than 22 years of age.

Making the Right Choice

The TECNIS family of IOLs have been studied for over 20 years. J&J Vision IOLs replace the eye's natural lens when it becomes a cataract. Monofocal IOLs from J&J Vision provide clear vision at far distances. This means you will likely need glasses for intermediate and near vision.

The TECNIS PureSee™ IOL is designed to give clear vision at far and intermediate distances. The toric version of the TECNIS PureSee™ IOL can also reduce astigmatism. Talk with your eye doctor about which IOL is best for you.

A clinical study compared the TECNIS PureSee™ IOL to a monofocal IOL. The PureSee™ IOL was the test IOL. The monofocal IOL was the control IOL. Nine U.S. sites took part. Patients were randomly given either the test or control lens.

A total of 115 patients received the test lens, and 113 received the control lens. Neither patients nor technicians knew which lens was used until the study ended. Patients were followed for six months after surgery. Of these, 113 test patients and 110 control patients completed the study.

Patients had vision and eye health exams. They also answered questions about their vision. The main outcomes (primary endpoints) included:

- Distance vision
- Intermediate vision
- Continuous range of clear vision
- Contrast vision (to see details especially in low light conditions)
- Adverse events

Other data collected included near vision, glasses use, and visual symptoms. These data were not statistically compared between the test and control because the clinical study was not designed for this purpose. The questionnaire asked about glasses use and visual symptoms.

The TECNIS PureSee™ Toric II IOLs for astigmatism were not part of this study but are supported by the clinical data on the TECNIS PureSee™ IOL. Table 1 shows how TECNIS PureSee™ IOL compares to a monofocal IOL.

Table 1: TECNIS PureSee™ IOL Primary Outcomes vs. a Monofocal IOL

	TECNIS PureSee™ IOL	Monofocal IOL
Far Vision	The clinical study demonstrated that the TECNIS PureSee™ 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 demonstrated that the TECNIS PureSee™ IOL provided better intermediate vision than the monofocal IOL.	A monofocal IOL is not designed to provide intermediate vision.
Continuous Range of Clear Vision	The clinical study demonstrated that the TECNIS PureSee™ IOL provided a larger range of clear vision than the monofocal IOL.	A monofocal IOL is designed to provide a limited range of clear vision.
Vision under Low Contrast	The clinical study demonstrated that the TECNIS PureSee™ IOL provided distance vision under low contrast conditions (under dim lighting) at the level of a monofocal IOL.	Does not adversely affect your distance vision under low contrast conditions.

Tables 2 and 3 present some of the U.S. clinical study results for the TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System. Results for the 6-month study were from 113 patients who received the TECNIS PureSee™ IOL and 110 patients who received the monofocal IOL. Table 2 contains results for the main effectiveness outcomes that the study was designed to demonstrate, the primary endpoints of the study. Table 3 contains the results of the other data collected during the study. These data were not statistically compared between the test and control because the study was not designed for this purpose.

Table 2: U.S. Clinical Study Results for Primary Vision Tests the TECNIS PureSee™ IOL and the Monofocal IOL 6 Months after Surgery

	TECNIS PureSee™ IOL (113 Patients)		**Monofocal IOL (110 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 (111 out of 113)	100% of patients (113 out of 113)	99% of patients (109 out of 110)	100% of patients (110 out of 110)
Far Vision: 20/40 or better with glasses	100% of patients (113 out of 113	100% of patients (113 out of 113)	100% of patients (110 of 110)	100% of patients (110 out of 110)
Intermediate Vision: 20/40 or better without glasses	96% of patients (109 out of 113)	99% of patients (112 out of 113)	75% of patients (82 out of 110)	96% of patients (106 out of 110)
Intermediate Vision: 20/40 or better with glasses for far vision only	97% of patients (110 out of 113)	98% of patients (111 out of 113)	61% of patients (67 out of 110)	90% of patients (99 out of 110)
Continuous Range of Clear Vision: Average range of 20/32 or better vision	From far to about 22 inches	From far to about 18 inches	From far to about 35 inches	From far to about 26 inches
Vision under Low Contrast (Dim Lighting)	Within normal ranges	Within normal ranges	Within normal ranges	Within normal ranges

Table 3: Additional U.S. Clinical Study Results for the TECNIS PureSee™ IOL and the Monofocal IOL 6 Months after Surgery (Data for Both Eyes)

	TECNIS PureSee™ IOL (113 Patients)	Monofocal IOL (110 Patients)
Binocular Near Vision	82% of patients (93 out of 113) could see 20/40 or better at near without glasses	57% of patients (63 out of 110) could see 20/40 or better at near without glasses
	81% of patients (91 out of 113) could see 20/40 or better at near with glasses for far vision	42% of patients (46 out of 110) could see 20/40 or better at near with glasses for far vision
Overall Glasses Wear	In a patient questionnaire, 74% of patients (84 out of 113) reported wearing glasses or contacts “none” or “a little” of the time during the last 7 days.	In a patient questionnaire, 50% of patients (55 out of 110) reported wearing glasses or contacts “none” or “a little” of the time during the last 7 days.
Visual Symptoms	Six months after surgery, some patients reported seeing halos, starbursts or glare (rates of approximately 5% or less affecting 6 out of 113 patients) to their doctors.	Six months after surgery, some patients reported seeing halos, starbursts and glare (rates of approximately 5% or less affecting 5 out of 110 patients) to their doctors.
	No patient (0 out of 113) had their lenses removed due to visual symptoms during the study.	No patient (0 out of 113) had their lenses removed due to visual symptoms during the study.
Serious Adverse Events	There were no serious adverse events related to the TECNIS PureSee™ IOL. A few were related to the cataract procedure itself. 7 patients had serious adverse events: • Five patients had increased eye pressure (all recovered). • One patient needed an additional procedure to clear out some cataract remnants. • One patient had a small area of swelling in the back of the eye (retina) that was being monitored at the end of the study.	There were no serious adverse events related to the monofocal IOL. A few were related to the cataract procedure itself. 6 patients had serious adverse events: • Three patients had increased eye pressure (all recovered). • One patient had an additional procedure to remove some ocular tissue (vitreous) that became displaced during surgery. • One patient had a small area of swelling in the back of the eye (retina) during the study (recovered). • One patient had a small area of swelling in the back of the eye

	TECNIS PureSee™ IOL (113 Patients)	Monofocal IOL (110 Patients)
		(retina) that was being monitored at the end of the study.

Table 4 presents responses from the patient questionnaire about bother with visual symptoms with the TECNIS PureSee™ IOL and the monofocal IOL during the U.S. clinical study. As noted above, this is one of the additional outcomes and therefore, these data were not statistically compared between the test and control because the study was not designed for this purpose.

Table 4: Patient Reports of Bother with Visual Symptoms

Symptom	Degree of Bother	TECNIS PureSee™ IOL (113 Patients)	Monofocal IOL (110 Patients)
Halos	• Very Bothered by symptom • Extremely Bothered by symptom	3% of patients; 3 of 113 0% of patients; 0 of 113	3% of patients; 3 of 110 0% of patients; 0 of 110
Starbursts	• Very Bothered by symptom • Extremely Bothered by symptom	2% of patients; 2 of 113 1% of patients; 1 of 113	3% of patients; 3 of 110 0% of patients; 0 of 110
Multiple or Double Vision	• Very Bothered by symptom • Extremely Bothered by symptom	3% of patients; 3 of 113 0% of patients; 0 of 113	1% of patients; 1 of 110 1% of patients; 1 of 110
Sensitivity to Light	• Very Bothered by symptom • Extremely Bothered by symptom	5% of patients; 6 of 113 1% of patients; 1 of 113	4% of patients; 4 of 110 3% of patients; 3 of 110
Glare Related to Scattered Light	• Very Bothered by symptom • Extremely Bothered by symptom	3% of patients; 3 of 113 0% of patients; 0 of 113	5% of patients; 6 of 110 0% of patients; 0 of 110
Occlusions	• Very Bothered by symptom • Extremely Bothered by symptom	0% of patients; 0 of 113 0% of patients; 0 of 113	1% of patients; 1 of 110 0% of patients; 0 of 110
Poor Low Light Vision	• Very Bothered by symptom • Extremely Bothered by symptom	4% of patients; 4 of 113 1% of patients; 1 of 113	3% of patients; 3 of 110 0% of patients; 0 of 110

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. If you desire a continuous range of clear vision at far and intermediate distances, the TECNIS PureSee™ IOLs may be a good choice for you. We recommend that you ask your eye doctor to help you with this choice.