TECNIS Eyhance™ IOL

with TECNIS SIMPLICITY* Delivery System

TECNIS Eyhance[™] Toric II IOL with TECNIS SIMPLICITY* Delivery System

Toric II



PATIENT INFORMATION BROCHURE

TECNIS Eyhance[™] and TECNIS Eyhance[™] Toric II IOLs DIB00 and DIU

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Johnson Johnson vision

TECNIS Eyhance[™] IOL with TECNIS SIMPLICITY® Delivery System

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PATIENT INFORMATION BROCHURE TECNIS Eyhance[™] Intraocular Lenses (IOLs) Models DIB00 and DIU

INTRODUCTION

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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 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. The natural lens focuses images onto the back of your eye (called the retina) so you can see clearly (Figure 1). 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.

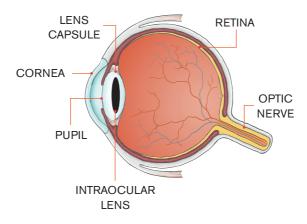


Figure 1: Diagram of eye with intraocular lens

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 cosmetics, 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 far 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. 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 lens capsule of the eye after the cataract (cloudy lens) has been surgically removed by the cataract surgeon. Figure 2 below compares the size of a TECNIS Eyhance[™] IOL to a U.S. penny.



Figure 2: Size comparison of the TECNIS Eyhance™ IOL and a U.S. penny

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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 Eyhance™ 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 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. 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 incision 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. Your eye doctor should give you an identification card to keep in your wallet. 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.

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CHOOSING THE IOL THAT IS BEST FOR YOUR VISION

There are many different IOLs for improving your vision. These include the TECNIS Eyhance™ 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 type of IOLs currently available.

MONOFOCAL IOLs

Monofocal IOLs restore clear 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 crafting. 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 designed to improve unaided near vision compared to a monofocal lens. This means that, without eyeglasses, you should see well whether you go to a ball game or read a book. The multifocal lenses manufactured by Johnson & Johnson Vision (J&J Vision) 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

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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 vision from far to intermediate viewing distances. These lenses provide improved intermediate vision and comparable distance vision compared to a monofocal lens. Eyeglasses may still be needed for near work.

THE TECNIS EYHANCE™ IOLs

The TECNIS Eyhance[™] IOLs are monofocal IOLs made using the same material and overall design as other J&J Vision IOLs and are designed to be positioned in the lens capsule to replace the optical function of the natural lens. Compared to other J&J Vision monofocal IOLs, the lenses have a unique aspheric surface with a small continuous increase in power from the periphery to the center of the lens. Similar to other TECNIS[®] aspheric monofocal IOLs, the TECNIS Eyhance[™] IOLs are designed to provide sharp far vision, even under poor visibility conditions such as low light. Examples of far vision activities are seeing where your drive lands while playing golf and viewing road signs while driving. The toric models of the TECNIS Eyhance[™] IOLs also correct different amounts of 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 Eyhance™ 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, or infection.
- 2 Similar to other monofocal IOLs, patients implanted with the TECNIS Eyhance[™] IOL may require glasses for some tasks.

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

WARNINGS

- 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 include, but are not limited to: ocular inflammation, surgical difficulties at the time of cataract extraction, suspected eye infection, congenital bilateral cataract, history or predisposition to retinal detachment, patients with only one good eye with potentially good vision, medically uncontrollable glaucoma, diabetes, heart disease, and previous trauma to your eye.
- 2 The TECNIS Eyhance[™] Toric II IOL corrects astigmatism when it is placed correctly in the eye. There is a chance that the TECNIS Eyhance[™] 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.
- 3 These lenses have not been evaluated for use in children.

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PRECAUTIONS

- 1 The effects of the TECNIS Eyhance[™] IOL optical design on quality of vision, contrast sensitivity, and subjective visual disturbances (glare, halo, etc.) have not been evaluated clinically.
- 2 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 Eyhance[™] IOL. Before surgery, your eye doctor will check if you have any eye diseases that may influence your IOL selection.
- In rare instances, the TECNIS Eyhance[™] 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 Your eye doctor may tell you if you should avoid certain activities after surgery.

MAKING THE RIGHT CHOICE

The TECNIS Eyhance[™] IOLs and related monofocal IOLs manufactured by J&J Vision have been well-studied. Like other monofocal IOLs, they provide sharp far vision, and patients who receive the TECNIS Eyhance[™] IOL will probably need glasses for tasks at intermediate (reading price tags at the grocery store, seeing a dashboard of a car) and near viewing distance (sewing, reading a newspaper). The toric version of the TECNIS Eyhance[™] IOL is expected to reduce your astigmatism. We recommend that you ask your eye doctor to discuss your IOL options.



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