

PATIENT INFORMATION BROCHURE

AcrySof™ IQ Vivity™ Extended
Vision IOL Models DFT015,
DAT015

AcrySof™ IQ Vivity™ Toric Extended
Vision IOL Models DFT315, DFT415,
DFT515, DAT315, DAT415, DAT515

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134-2099 USA
Toll free (800) 757-9785

Table of Contents

Introduction	3
What is a cataract?	3
What is corneal astigmatism?.....	3
What is an Intraocular Lens (IOL)?.....	3
What is the surgical procedure to restore my vision?.....	4
Potential Risks Associated with Cataract Surgery	4
What types of IOLs are available for this procedure?	5
Monofocal IOLs	5
Monofocal Toric IOLs	5
Multifocal IOLs	5
Multifocal Toric IOLs	5
Alcon AcrySof® IQ Vivity Extended Vision IOLs.....	5
Potential Side Effects Associated with AcrySof® IQ Vivity Extended Vision IOLs	6
Range of Vision Results.....	8
Warnings	10
Precautions	11
Postoperative Care Instructions	12
Key points to remember regarding your choice.....	12

Alcon AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens (IOL)

Introduction

This brochure has been written to assist you and your surgeon in making an informed decision regarding the best intraocular lens (IOL) for your cataract surgery. Your surgeon will advise you about the potential risks and benefits of the surgical procedure for cataract removal and IOL implantation. This brochure will aid you in deciding if an Alcon AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens (IOL) would be an appropriate choice for you. Please see the “What types of IOLs are available for this procedure” section for other options you may have.

What is a cataract?

Your eye functions much like a camera. Your natural lens focuses images onto the back of your eye so you can see clearly, much like the lens of a camera focusing images onto film for a clear picture. At birth, your natural lens is clear. However, as you age, the lens may begin to gradually become “cloudy.” This condition is called a cataract, and is usually a result of the natural aging process. As the lens becomes cloudier, your quality of vision may decrease.

A cataract can progress until eventually there is a complete loss of vision in your eye. Surgery is the only way a cataract can be removed. You should consider surgery when cataracts cause enough loss of vision to interfere with your daily activities.

What is corneal astigmatism?

Astigmatism is a focusing error in the eye that results in blurred distance and/or near vision. In a normal eye, the cornea has a round shape (like a basketball); therefore, the light rays entering the eye focus at a single point on the back of the eye (retina) to form a clear image. In an eye with corneal astigmatism, the cornea has an oblong shape (like an American football). As a result, the light rays do not focus at the same point on the retina and parts of an object may not appear clear. During your eye examination, your eye doctor will be able to tell you if you have corneal astigmatism.

What is an Intraocular Lens (IOL)?

An intraocular lens, commonly referred to as an IOL, is an artificial lens that is implanted into the eye to replace the natural lens when a cataract is removed. Figure 1, below, shows the basic parts of the human eye with an implanted IOL.

In general, IOLs have two basic features. The optic portion is the round part of the IOL that focuses an image onto the back of your eye. Two arm-like structures called haptics are attached to the edge of the optic. The haptics help to maintain the location of the IOL in the eye.

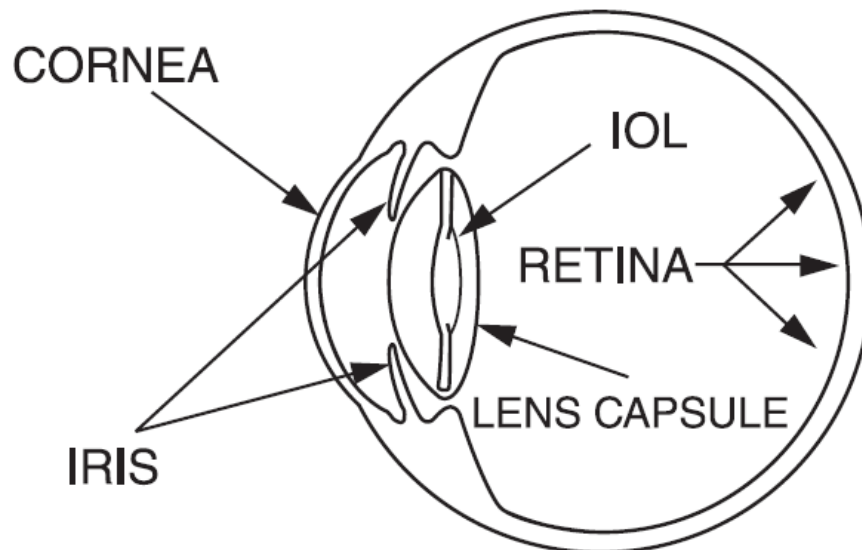


Figure 1 – Drawing of the Human Eye with an Implanted IOL

What is the surgical procedure to restore my vision?

After you and your eye doctor have decided that you will have your cataract removed, your eye will be measured . This will help to determine the suitable IOL for you that will be placed in your eye during surgery.

When you arrive for surgery, you will be given eye drops and perhaps medicines to help you relax. Cataract surgery techniques vary widely. However, the eye is always numbed to make the operation painless. To perform surgery, 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. Through this opening, the eye doctor removes the center part of the front of the lens capsule and then inserts a tiny instrument to break-up and remove the cataract. An IOL is then placed into the capsule to replace your natural lens that your eye doctor has just removed. The IOL will focus light inside the eye to allow you to see. The surgeon will usually place a shield over your eye after surgery. You will be ready to go home after a short stay in the outpatient recovery area. Plan to have someone else drive you home.

Potential Risks Associated with Cataract Surgery

As with any surgery, there are risks and potential complications associated with routine cataract surgery and IOL implantation. General surgery risks include reactions to medicines, bleeding, infection, inflammation, tissue damage, tissue swelling of the front or the back of the eye, redness, scratchiness of the eye, sensitivity to light, and increased eye pressure. If your lens is not in the correct position, your vision may also be affected and the normal flow of fluid within the eye may be blocked. You may require additional surgery to treat these side effects, and there is a small chance that your vision could be made worse by the operation. Please discuss these general risks associated with cataract surgery with your eye doctor.

What types of IOLs are available for this procedure?

There are many different IOLs to choose from. Your eye doctor will discuss your options, including AcrySof™ IQ Vivity™ Extended Vision IOLs and other IOLs. Discuss all of your IOL options with your eye doctor.

Monofocal IOLs

A monofocal IOL is designed to provide clear distance vision. This means you will usually be able to see objects far away, but there is still a small chance that you may need glasses for distance vision especially if you have corneal astigmatism. You will most likely need glasses for near vision activities such as reading, writing, and sewing, as well as intermediate vision activities such as applying makeup or shaving, and working on a computer. These lenses do not correct for corneal astigmatism.

Monofocal Toric IOLs

A monofocal toric IOL is designed to provide clear distance vision and correct corneal astigmatism. There are different models of monofocal toric IOLs for varying levels of corneal astigmatism. With a monofocal toric IOL, you will be able to see objects far away more clearly than with a monofocal IOL, but there is still a chance that you may need glasses for distance vision. Also, you will most likely still need glasses for near distance activities such as reading, writing, sewing as well as intermediate distance activities such as viewing a cell phone, applying makeup or shaving or working on a computer.

Multifocal IOLs

Multifocal IOLs allow for clear distance vision (e.g., for watching children playing in the backyard). The design of the IOL also allows for better near (reading) and intermediate (computer work) vision than a monofocal lens would provide. Different multifocal IOLs have different optical strengths for near vision. There is a chance you may still need glasses for distance, intermediate, and/or near vision. These lenses do not correct for corneal astigmatism.

Multifocal Toric IOLs

In addition to the potential benefits of Multifocal IOLs, the Multifocal Toric IOLs provide corneal astigmatism correction, which may provide clearer vision if you have corneal astigmatism. There is a chance you may still need glasses for distance, intermediate, and/or near vision.

Alcon AcrySof® IQ Vivity Extended Vision IOLs

The AcrySof™ IQ Vivity™ Extended Vision IOLs are another IOL option that has the same basic shape and identical materials as many other Alcon AcrySof® monofocal and monofocal toric IOLs. Like a monofocal lens, the purpose of the AcrySof™ IQ Vivity™ Extended Vision IOL is to focus images clearly onto the back of your eye (retina) to allow clear vision after the cataract removal.

The AcrySof™ IQ Vivity™ Extended Vision IOL provides clear distance vision (e.g., for watching children playing in the backyard). In addition, the AcrySof™ IQ Vivity™ Extended Vision IOL allows for better intermediate (working on a computer, applying makeup or shaving) and some

near (reading, knitting) vision compared to what a monofocal IOL would provide. The AcrySof IQ Vivity IOL is not a multifocal IOL, as it uses a new Wavefront-Shaping technology to provide the broader range of vision.

In addition to the potential benefits of the AcrySof™ IQ Vivity™ Extended Vision IOLs, the AcrySof IQ Vivity Toric IOLs provide corneal astigmatism correction, which may provide clearer vision if you have corneal astigmatism. The AcrySof™ IQ Vivity™ Toric Extended Vision IOL is offered in several models for varying levels of corneal astigmatism. The most appropriate model will be chosen by your surgeon based on the amount of your corneal astigmatism, if any. There is a chance you may still need glasses for distance, intermediate, and/or near vision.

You will get the full benefit of the AcrySof™ IQ Vivity™ Extended Vision IOL when it is implanted in both eyes. Please discuss with your eye doctor whether this is the right IOL for you.

Potential Side Effects Associated with AcrySof™ IQ Vivity™ Extended Vision IOLs

There are some side effects that can be associated with the design of IOLs that provide a broader range of vision, which may be worse than with a monofocal IOL. These side effects include visual disturbances such as glare, rings around lights, starbursts, and a decrease in ability to distinguish objects from their background, especially in dim lighting. These side effects may make it more difficult to see in some situations.

A clinical study of the AcrySof™ IQ Vivity™ Extended Vision IOL Model DFT015 (without the toric feature for correcting corneal astigmatism) was conducted in the United States. Reports of visual disturbances were obtained for this lens compared to a monofocal IOL. Table 1 below shows the number of patients who reported being most bothered (“Bothered very much”) by visual disturbances, during a clinical study conducted in the United States for the AcrySof™ IQ Vivity™ Extended Vision IOL (Model DFT015, without the toric feature for correcting corneal astigmatism) and the monofocal IOL (Model SN60WF). Similarly, Table 2 shows the number of patients who reported “severe” visual disturbances, during the same clinical study. Overall, Vivity IOL patients reported these side effects at low rates.

Table 1. Rates of “Bothered very much” responses regarding Visual Disturbances, per 100 patients, 6 months After Surgery

Visual Disturbance	AcrySof IQ Vivity IOL Rate	Monofocal IOL Rate
	6 Months	6 Months
Starbursts	2 out of 100 patients	1 out of 100 patients
Halos	1 out of 100 patients	No (0) patients
Glare	No (0) patients	No (0) patients
Hazy Vision	No (0) patients	No (0) patients
Blurred Vision	1 out of 100 patients	2 out of 100 patients
Double Vision	No (0) patients	No (0) patients
Dark Area	1 out of 100 patients	1 out of 100 patients

Table 2. Rates of “Very Severe” responses regarding Visual Disturbances, per 100 patients, 6 months After Surgery

Visual Disturbance	AcrySof IQ Vivity IOL Rate	Monofocal IOL Rate
	6 Months	6 Months
Starbursts	4 out of 100 patients	3 out of 100 patients
Halos	1 out of 100 patients	1 out of 100 patients
Glare	No (0) patients	No (0) patients
Hazy Vision	No (0) patients	No (0) patients
Blurred Vision	No (0) patients	No (0) patients
Double Vision	No (0) patients	No (0) patients
Dark Area	1 out of 100 patients	1 out of 100 patients

Serious adverse events observed in one or both eyes for clinical study patients implanted with either the AcrySof IQ Vivity IOL or the Monofocal IOL are presented in Table 3.

Table 3. Summary of Serious Adverse Events in the Clinical Study

AcrySof IQ Vivity IOL	Monofocal IOL
<p>4 out of 107 patients reported having serious adverse events:</p> <p>Adverse events related to cataract surgery but not to the Vivity IOL:</p> <ul style="list-style-type: none"> One patient experienced a hyphema (blood in their eye) after cataract surgery, which decreased their vision temporarily. The event resolved without treatment. Two patients experienced cataract material left in their eye after cataract surgery. These patients required a second surgery to remove the remaining cataract material. <p>Adverse events not related to the Vivity IOL or cataract surgery:</p> <ul style="list-style-type: none"> One patient experienced cystoid macular edema in one eye (swelling of the central part of the retina at the back of the eye), which resolved after treatment with medications One patient experienced a mild stroke approximately 1 month after cataract surgery, symptoms included pain around the eye. The event resolved without treatment. 	<p>3 out of 113 patients reported having serious adverse events:</p> <p>Adverse events related to cataract surgery but not the Monofocal IOL:</p> <ul style="list-style-type: none"> One patient reported a shadow in their vision, which was due to a retinal detachment. A surgical procedure was performed (vitrectomy) to treat the retinal detachment, and the event resolved. One patient experienced cystoid macular edema in both eyes (swelling of the central part of the retina at the back of the eye), which resolved after treatment with medications. <p>Adverse events related to the Monofocal IOL but not cataract surgery:</p> <ul style="list-style-type: none"> One patient experienced photopsia (seeing a dark area in their vision), which was resolved by removing the IOL and replacing it with a different IOL.

Contrast Sensitivity

Contrast sensitivity, an important measure of visual function, is the ability to distinguish objects from their background, especially in dim lighting. In the Vivity clinical study, contrast sensitivity in dim lighting was reduced in patients who received the AcrySof IQ Vivity IOL compared to those who received the Monofocal IOL.

Effect of Astigmatism Remaining After Cataract Surgery

A toric IOL corrects astigmatism only when it is placed in the correct position in the eye. Some patients may have some level of astigmatism remaining after IOL placement, especially if they had a lot of astigmatism before surgery. There is also a possibility that the toric IOL could be placed incorrectly or could move within the eye. As with any toric IOL that provides an extended range of vision, if the lens is not positioned correctly in your eye, or if the amount of astigmatism to be corrected is calculated incorrectly:

- You may experience poor vision.
- You may need to wear glasses to see clearly at all distances.
- You may need additional surgery to reposition or replace the IOL.

Range of Vision Results

The clinical study of the Vivity IOL tested for vision using eye charts, at distance (far away objects, like when driving, playing golf, etc.), intermediate (objects about 26 inches away: computer work, cooking, etc.), and near (objects about 16 inches away: reading, knitting, etc.). The clinical study tested patients when they used only one eye (monocular testing), and when they used both eyes at the same time (binocular testing). Table 4 presents monocular (one eye) range of vision results from this study, and Table 5 presents binocular (both eyes at the same time) range of vision results from this study.

Table 4. Comparison of Monocular (One Eye) Range of Vision Results between AcrySof™ IQ Vivity™ Extended Vision IOL Model DFT015 and AcrySof® Monofocal IOL Model SN60WF at 6 months After Surgery.

	Vivity IOL	Monofocal IOL
Distance Vision 20/25^{-2*} or better with glasses (driving, playing golf, etc.)	95% of patients	97% of patients
Intermediate Vision 20/25^{-2*} or better with glasses for distance (computer work, cooking, etc.) at approximately 26 inches.	51% of patients	10% of patients
Near Vision 20/40^{-2**} or better with glasses for distance (reading, knitting etc.) at approximately 16 inches.	56% of patients	14% of patients

*On an eye chart, reading all the letters on the 20/25 line with no mistakes means you have 20/25 or better vision. Reading the majority of the 20/25 line correctly, written as 20/25⁻², means you have approximately 20/25 or better vision.

**On an eye chart, reading all the letters on the 20/40 line with no mistakes means you have 20/40 or better vision. Reading the majority of the 20/40 line correctly, written as 20/40⁻², means you have approximately 20/40 or better vision.

Table 5. Comparison of Binocular (Both Eyes) Range of Vision Results between AcrySof™ IQ Vivity™ Extended Vision IOL Model DFT015 and AcrySof® Monofocal IOL Model SN60WF at 6 months After Surgery.

	Vivity IOL	Monofocal IOL
Distance Vision 20/25^{-2*} or better in both eyes without glasses (driving, playing golf, etc.)	89% of patients	95% of patients
Distance Vision 20/25^{-2*} or better in both eyes with glasses (driving, playing golf, etc.)	100% of patients	100% of patients
Intermediate Vision 20/25^{-2*} or better in both eyes without glasses (computer work, cooking, etc.) at approximately 26 inches.	86% of patients	63% of patients
Intermediate Vision 20/25^{-2*} or better in both eyes with glasses for distance (computer work, cooking, etc.) at approximately 26 inches.	88% of patients	34% of patients
Near Vision 20/40^{-2**} or better in both eyes without glasses (reading, knitting, etc.) at approximately 16 inches.	91% of patients	56% of patients
Near Vision 20/40^{-2**} or better in both eyes with glasses for distance (reading, knitting, etc.) at approximately 16 inches.	77% of patients	43% of patients

*On an eye chart, reading all the letters on the 20/25 line with no mistakes means you have 20/25 or better vision. Reading the majority of the 20/25 line correctly, written as 20/25⁻², means you have approximately 20/25 or better vision.

**On an eye chart, reading all the letters on the 20/40 line with no mistakes means you have 20/40 or better vision. Reading the majority of the 20/40 line correctly, written as 20/40⁻², means you have approximately 20/40 or better vision.

Patients in the study were also asked about how often they needed glasses to see distance, intermediate, and near objects overall, and in bright and dim light separately. A comparison of the rate of patients reporting “rarely” or “never” needing to wear glasses is presented in Table 6. Overall, Vivity IOL patients reported needing to wear glasses less than monofocal IOL patients,

especially at intermediate distance.

Table 6: Comparison of Patients Reporting “Rarely” or “Never” Needing to Wear Glasses by Condition and Distance between AcrySof® IQ Vivity Extended Vision IOL Model DFT015 and AcrySof® Monofocal IOL Model SN60WF at 6 months After Surgery.

Condition and Distance		Rate of “Rarely” or “Never” Needing to Wear Glasses	
		Vivity IOL	Monofocal IOL
Overall		About half of the patients (45 out of 100)	Some patients (17 out of 100)
Bright Light	Distance	Almost all patients (94 out of 100)	Almost all patients (92 out of 100)
	Intermediate	Almost all patients (87 out of 100)	More than half of the patients (58 out of 100)
	Near	About half of the patients (46 out of 100)	Some patients (16 out of 100)
Dim Light	Distance	Almost all patients (93 out of 100)	Almost all patients (90 out of 100)
	Intermediate	Almost all patients (84 out of 100)	About half of the patients (53 out of 100)
	Near	Some patients (39 out of 100)	Some patients (11 out of 100)

Patients were also asked about the quality of their vision when they were not wearing glasses, in bright light and in dim light. These results are summarized in Table 7. Overall, Vivity IOL patients reported “good” or “very good” vision at intermediate and near distances in both bright and dim light more often than monofocal IOL patients.

Table 7: Comparison of Patients Reporting “Good” or “Very Good” Vision Without Glasses by Condition and Distance between AcrySof™ IQ Vivity™ Extended Vision IOL Model DFT015 and AcrySof® Monofocal IOL Model SN60WF at 6 months After Surgery.

Condition and Distance		Rate of “Good” or “Very Good” Vision Without Glasses	
		Vivity IOL	Monofocal IOL
Bright Light	Distance	Almost all patients (94 out of 100)	Almost all patients (92 out of 100)
	Intermediate	Almost all patients (92 out of 100)	More than half of the patients (63 out of 100)
	Near	About half of the patients (57 out of 100)	Some patients (25 out of 100)
Dim Light	Distance	Almost all patients (88 out of 100)	More than half of the patients (78 out of 100)
	Intermediate	Almost all patients (83 out of 100)	About half of the patients (51 out of 100)
	Near	Some patients (38 out of 100)	A small number of patients (8 out of 100)

Warnings

- Your vision may not be as good with the Vivity IOL if you have irregular astigmatism (if before surgery it is determined that the front surface of your eye is irregular in shape).
- Your vision may not be as good if you choose the non-Toric AcrySof IQ Vivity IOL and have a large amount of astigmatism before surgery and/or are expected to have a large amount of astigmatism after surgery.
- Your vision may not be as good if you choose the AcrySof IQ Vivity Toric IOL and have a

large amount of astigmatism after surgery.

- As with other IOLs, if there are unexpected results, there is a chance you may need to continue wearing eyeglasses or may need a second surgical procedure to reposition your IOL.
- Contact your eye doctor immediately if you have any of the following symptoms after surgery: a significant decrease in vision, a significant increase in pain, significant itching, significant redness, watering of your eye, double vision persisting more than a few days, significant eye discharge, and increased sensitivity to light. These symptoms could indicate potential serious postoperative complications including, but not limited to, eye infection, increased intraocular pressure, retinal detachment, wound leak, allergic reaction to medications, or lens dislocation.
- If you have pre-existing retinal problems that reduce your vision, you may not receive the full visual benefit of the AcrySof IQ Vivity IOL.
- After surgery, it may be more difficult to see well in dim or low-contrast situations, especially with a bright light shining in your eyes, than it would be with a monofocal IOL. Therefore, you should take extra care in situations like driving at night, especially if there is oncoming traffic.

Please discuss all risks and benefits with your eye doctor before your surgery.

Precautions

- Before surgery, your eye doctor will check to see if you have any eye diseases or swelling. Be sure to tell your eye doctor if you have any health conditions (e.g., breathing difficulties, heart trouble, allergies, previous eye surgery) that may affect your surgery or vision.
- The Vivity IOL has not been studied in patients with certain eye conditions, such as glaucoma or diabetic retinopathy (an increase in eye pressure or complications of diabetes in the eye). The outcome of cataract surgery will depend on the health of your eye before surgery. You should tell your eye doctor if you have been diagnosed as having amblyopia (lazy eye) or any other eye disease.
- The AcrySof IQ Vivity Toric IOL has not been evaluated in a clinical study. As with any IOL that provides an expanded range of vision, you may need eyeglasses to see clearly (for far, intermediate, and near distances) if you have a large amount of astigmatism after surgery.
- You should avoid any activity that could harm your eye while you are recovering from surgery. Your eye doctor will tell you what activities you should avoid.
- Take all prescribed medicines and apply eye drops as instructed.
- It is possible you could be bothered very much by visual disturbances, to the extent that you may request explant of the AcrySof IQ Vivity IOL. In the Vivity clinical study, one (1) to two (2) out of 100 Vivity patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported.

You should tell your eye doctor of any eye problems or if you have been diagnosed with any eye condition.

Postoperative Care Instructions

You will return home after surgery. Typically, your eye doctor will examine you the following day. Your eye doctor will give you eye drops to speed up the healing process and to prevent infection.

Your vision should improve within 4 to 6 weeks after cataract surgery. Many patients may see better within 1 to 2 weeks or less. The specifics of surgery may be different for each individual. Be sure to consult your eye doctor so you can fully understand the recovery process after the cataract surgery. It may take you some time to get accustomed to your new IOL(s). Always consult your eye doctor if you have any questions or concerns as a result of cataract surgery.

Key points to remember regarding your choice

- IOLs can restore your vision following cataract surgery. There are several IOL options, including monofocal, multifocal, and Extended Vision IOLs. Toric versions of many of these IOLs are also available for eyes with corneal astigmatism.
- These IOL options each provide different potential benefits and potential side effects, so it is important to discuss your lifestyle and visual needs with your eye doctor to help select the most suitable IOL for you.

Thank you for considering the Alcon AcrySof™ IQ Vivity™ Extended Vision family of IOLs.

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134-2099 USA