

# PATIENT INFORMATION BROCHURE

## enVista Envy™ / enVista Envy™ Toric IOL Trifocal Intraocular Lens

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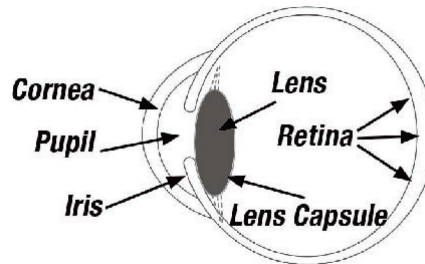
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## Introduction

This brochure is to help you and your eye doctor decide on the best intraocular lens (IOL) for your cataract surgery. Your doctor will tell you about the potential risks and benefits of surgery to remove the cataract and put in a new lens. This brochure can help you decide if the **enVista Envy** or **enVista Envy Toric** IOL from Bausch + Lomb is right for you. See the section “What types of IOLs are available for this procedure” to learn about other options you may have.

## What is a Cataract?

To understand what a cataract is, it helps to understand how the human eye works<sup>1</sup>. The front of the eye has the cornea, iris, pupil and a natural lens inside the lens capsule (**Figure 1**). The back of the eye is the retina, where images are focused. When you look at an object, light reflected from the object enters through the cornea. The cornea focuses the light before it passes through the pupil. The amount of light that can reach the retina is controlled by the iris. The iris adjusts the size of the pupil to allow light through. The natural lens further focuses light onto the retina, the light-sensitive inner lining of the back of the eye. When light reaches the retina, the retina converts optical images into signals. Then the optic nerve sends these signals to the part of brain that controls our sense of sight.



**Figure 1** – Drawing of the Human Eye

When the natural lens is clear, it helps focus images so you can see objects and text clearly. Over time, the natural lens of your eye can become “cloudy.” When this happens, it is called a cataract. Most cataracts are related to the natural aging process. Cataracts can also be caused by medical conditions, medications or eye injuries. Cataracts may start out small and have little effect on vision. As they grow larger, they may cloud more of the lens and

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<sup>1</sup> <https://www.allaboutvision.com/resources/anatomy.htm>

distort the light passing through. If left untreated, cataracts can result in complete loss of vision. Early noticeable symptoms include:

- Cloudy, blurry, foggy, or filmy vision
- Glare from lamps, the sun, or headlights
- Frequent changes in eyeglass prescription
- Double vision

Cataracts can only be removed with cataract surgery. You should consider cataract surgery when vision loss affects your daily activities. The surgery is usually done as an outpatient procedure with anesthesia. The cloudy lens is removed and replaced with a permanent IOL implant.

See “*What to Expect During Cataract Surgery*” for more information about this surgery. See “*Types of IOLs*” for more details about the IOL options available today. There are other options for restoring your functional vision following cataract removal besides implanting an IOL, such as glasses and contact lenses. You should discuss these options with your doctor to select the option best for you.

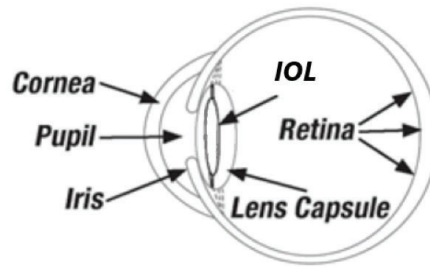
## What is Corneal Astigmatism?

Astigmatism is a common eye condition that causes blurry vision. In a normal eye, the cornea is round. It focuses light at a single point on the back of the eye (retina) to form a clear image. In an eye with corneal astigmatism, the cornea is oval. As a result, the light focuses at different points, making vision blurry. This may also lead to eye discomfort and headaches. Your eye doctor can tell you if you have astigmatism during an eye exam.

## What is an Intraocular Lens (IOL)?

During cataract surgery, the cloudy natural lens of the eye is removed and replaced with a clear artificial lens called an intraocular lens (IOL).

**Figure 2** shows the basic parts of the human eye with an implanted IOL.



**Figure 2** – Drawing of the Human Eye with an Implanted IOL

## What to Expect Before Cataract Surgery

After an eye exam, you and your eye doctor will discuss cataract surgery. Your doctor will measure your eye to help determine which IOL is best for you.

## What to Expect During Cataract Surgery

Cataract surgery is usually done as an outpatient procedure. Local anesthesia is applied in the form of eyedrops. Sometimes patients also receive medicine intravenously (through an IV). You will typically be awake during the surgery and lying down. You should feel little or no discomfort. Your eye doctor will use a microscope to look at your eye. A small incision is made in the outer surface of the eye to access your eye's natural lens. Through this opening, the eye doctor will insert a tiny instrument to break up and remove the cataract. Your doctor will then place an IOL into the empty capsule to replace your natural lens. The IOL will help focus light inside the eye to allow you to see more clearly. See "What types of IOLs are available for this procedure" for information about IOL options.

## What to Expect After Cataract Surgery

Your surgeon may place a shield over your eye after surgery. You can go home after a short stay in the recovery area. After the medicine wears off you might feel some itching or minor eye discomfort. Most people manage this with short-term use of over-the-counter pain medication. Plan to have someone else drive you home.

Your eye doctor should give you a patient implant identification card to keep. This card shows the type of implant in your eye and some other general information. Show this card to any eye doctor who examines your eyes after surgery.

## Potential Risks Associated with Cataract Surgery

As with any surgery, there are risks associated with cataract surgery and IOL implantation. This is unrelated to the lens you choose. Cataract surgery complications are rare, but may include inflammation, infection, bleeding, swelling, drooping eyelid, dislocation of the artificial lens, retinal detachment, increased eye pressure (glaucoma), secondary cataract, and injury to the eye. The problems could be minor, temporary, or they could last permanently. There is a small chance that your vision could be made worse by the operation. You should discuss these risks with your eye doctor.

## Types of IOLs

There are many types of IOLs. Your eye doctor will discuss your options with you based on your needs. IOL types include monofocal, multifocal, extended depth of focus, accommodating, and toric. Each option has its own advantages and disadvantages. Discuss all options with your doctor to choose the best one for your expectations and lifestyle.

### Monofocal IOLs

Monofocal IOLs are single-focus lenses. They are designed to provide far vision. This means you will see objects far away, but you will likely need glasses for near and intermediate vision activities. These include reading, sewing, writing, working on a computer, putting on make-up, or shaving.

### Multifocal IOLs

Multifocal IOLs provide vision at two or more specific distances. There are two types of multifocal IOLs: bifocal IOLs and trifocal IOLs. Bifocal IOLs offer far and intermediate or near vision. Trifocal IOLs offer vision at three distances: near, intermediate and far. They can reduce the need for glasses or contact lenses. However, they may cause problems with night vision, like glare and/or halos around lights. They may also decrease the sharpness of your vision compared to a monofocal lens. The **enVista Envy** IOL is a trifocal type of multifocal IOL-see "*The enVista Envy IOL*" section for more details.

## Extended Depth of Focus IOLs

Extended depth of focus (EDF) IOLs are the newest type of IOL for the treatment of presbyopia. Unlike multifocal IOLs, EDF IOLs provide a continuous range of vision from far to intermediate, with some lens designs also providing functional near vision.

Reading glasses may still be needed to see fine details and small print.

## Accommodating IOLs

Accommodating IOLs are designed to mimic the natural focusing process of the eye. These lenses provide far vision and may change focus, enabling you to see up close (near). You may still need reading glasses to see fine details and small print.

## Toric IOLs

Toric IOLs are designed for people with astigmatism. There are three types of toric IOLs – monofocal toric IOLs, multifocal toric IOLs, and EDF toric IOLs. Toric IOLs can correct the refractive error caused by astigmatism due to a cornea with an oval shape. Like the other types of IOLs, there is a chance you may still need glasses for far, intermediate, and/or near vision. The **enVista Envy Toric** IOL is a multifocal toric IOL –see “*The enVista Envy toric IOL*” section for more details.

## The enVista Envy IOL

The **enVista Envy** IOL is a multifocal, or more specifically, a trifocal IOL designed for patients with cataracts. The **enVista Envy** IOL is intended to replace the natural lens in adult patients after the cataracts has been removed. The **enVista Envy** IOL provides improved intermediate and near vision, while providing similar distance vision compared to a monofocal IOL.

The **enVista Envy** IOL provides many key benefits, including:

- Delivering reliable range of vision from near (such as reading) to intermediate (such as computer work) to far (such as looking at a street sign).
- Providing high-quality optics.

Please discuss with your eye doctor whether this IOL is the right option for you.

## The enVista Envy Toric IOL

The **enVista Envy Toric** IOL is a trifocal toric IOL designed for patients with cataracts. The **enVista Envy Toric** IOL replaces the natural lens in adult patients after the cataracts has been removed. The **enVista Envy Toric** IOL also corrects astigmatism. The enVista Envy IOL provides improved intermediate and near vision, while providing similar distance vision compared to a monofocal IOL. The **enVista Envy Toric** IOL also corrects astigmatism.

Benefits of the **enVista Envy Toric** IOL include:

- Delivering reliable, continuous range of vision from near (such as reading) to intermediate (such as computer work) to far (such as looking at a street sign).
- Helping patients with astigmatism up to 5.75 D
- Providing high-quality optics

Discuss whether this option is right for you with your eye doctor.

## Potential Risks and Side Effects Associated with **enVista Envy / enVista Envy Toric** IOLs

Cataracts affect your vision. They may cause glare, rings around lights, starburst, faded colors, blurry or double vision or trouble seeing at night. After cataract surgery, you should see less of these visual effects. Patients treated with a monofocal lens usually have few side effects after cataract surgery. For lenses that provide clear vision at many distances, patients may notice some visual effects that make it hard to see in some situations.

## The US Clinical Study

Bausch + Lomb performed a US clinical study for the **enVista Envy IOL** from 2018 to 2023. The study compared this device to the enVista Model MX60E monofocal lens. This section provides a summary of the results. The study was done using the **enVista Envy IOL**. This IOL does not correct corneal astigmatism.

The clinical study tested one and/or both eyes at different distances. Some of the results at 4-6 months after surgery are shared in **Table 1**.

**Table 1: Study Results - A comparison of enVista Envy IOL and enVista Monofocal IOL at 4-6 months After Surgery**

	<b>enVista Envy IOL (this device)</b>		<b>enVista Monofocal IOL</b>	
	Percentage of patients who achieved approximately 20/40 or better vision		Percentage of patients who achieved approximately 20/40 or better vision	
	One eye tested alone	Both eyes tested together	One eye tested alone	Both eyes tested together
Distance Vision with correction	99%	100%	99%	100%
Distance Vision without correction (glasses)	97%	100%	99%	100%
Intermediate Vision without glasses (tested at approximately 66 cm)	95%	99%	56%	85%
Intermediate Vision with glasses for distance (computer work, smartphone use) tested at approximately 66 cm	95%	99%	50%	74%
Near Vision without glasses (reading) tested at approximately 40 cm	89%	99%	17%	32%
Near Vision with glasses for distance (reading) tested at approximately 40 cm	92%	99%	13%	25%

## Adverse Events

**Table 2** provides a list of serious adverse events from the clinical study. No secondary surgeries were reported due to the optical properties of the **enVista Envy IOL**. No serious adverse events were caused by the **enVista Envy IOL**.

**Table 2: Serious Adverse Events**

<b>Adverse Event Term</b>	<b>enVista Envy IOL (this device)</b>	<b>enVista Monofocal IOL</b>
All serious adverse events after surgery	5 of 332	2 of 169
Macular hole ( <i>A hole formation in the center of retina in an area called the Macula, leading to blurred vision</i> )	1	0
Retinal tear ( <i>A tear in the retina which is the tissue layer in the back of the eye that is sensitive to light</i> )	1	0
Retinal vein occlusion ( <i>A block in the vein that carries blood away from the retina</i> )	1	0
Ophthalmic herpes zoster ( <i>Herpes Zoster infection of the eye</i> )	0	1
Endophthalmitis ( <i>An infection of the tissues or fluids inside the eye</i> )	1	0
Seidel test positive ( <i>A test that identifies defects in the cornea or sclera that may cause a leak of aqueous humor which is the fluid in the front of the eye that provides nourishment and inflation of the eye</i> )	1	0
Cataract operation complication ( <i>Any complication due to the cataract surgery procedure</i> )	0	1

IOL = intraocular lens

## Contrast Sensitivity

Contrast sensitivity is the ability to identify clear outlines of objects and differences in shadings and backgrounds. It is an important function of vision, especially in low lighting. Contrast sensitivity was tested with and without glare under different lighting conditions. Contrast sensitivity was reduced with the **enVista Envy IOL** after surgery compared to the Monofocal IOL. This reduction may lead to visual difficulty with completion of tasks under certain low lighting conditions like driving at night.

## Visual Disturbances

Participants filled out a survey for visual disturbances before and after surgery. The survey asked if issues like glare, halos, and starbursts were better or worse after surgery. Participants rated how often, how severe, and how much they were bothered by these issues. The results showed improvement after surgery for most visual disturbances in both this device (**enVista Envy IOL**) and the Monofocal IOL groups.

The rate of participants who reported the effects are shown in **Table 3**. Halos were reported more for this device than the monofocal lens, although about 80% reported the halos as “not at all” to “a little” bothersome. About 10% more participants experienced glare and starbursts at least occasionally for this lens compared to the monofocal group.

**Table 3: Quality of Vision Survey Responses, 4-6 Months after surgery** - Rates of patients reporting visual disturbances, per 100 participants

Visual Disturbance	Device	Frequency (%)				Severity (%)				Bothersome (%)			
		Never	Occasionally	Quite often	Very often	Not at all	Mild	Moderate	Severe	Not at all	A little	Quite	Very
Glare	Monofocal	47.4	43.5	5.8	3.2	50.3	32.5	15.2	2.0	56.3	31.8	10.6	1.3
	This device	37.6	48.4	8.9	5.1	40.0	41.6	15.2	3.2	47.7	40.3	7.4	4.5
Halos	Monofocal	59.1	33.8	5.2	1.9	62.9	27.2	8.6	1.3	68.9	23.8	6.0	1.3
	This device	26.8	36.3	19.7	17.2	29.1	36.9	27.8	6.1	40.8	38.8	13.3	7.1
Starbursts	Monofocal	65.6	26.6	3.9	3.9	72.2	19.2	4.6	4.0	78.1	15.2	2.6	4.0
	This device	53.5	33.8	8.9	3.8	56.3	29.3	11.9	2.6	65.6	25.1	6.1	3.2

Visual Disturbance	Device	Frequency (%)				Severity (%)				Bothersome (%)			
		Never	Occasionally	Quite often	Very often	Not at all	Mild	Moderate	Severe	Not at all	A little	Quite	Very
Hazy Vision	Monofocal	66.2	28.6	3.9	1.3	66.4	23.7	9.2	0.7	68.4	24.3	7.2	0.0
	This device	67.2	25.8	5.4	1.6	68.8	23.5	7.1	0.6	71.4	20.6	6.8	1.3
Blurred Vision	Monofocal	53.6	35.9	8.5	2.0	56.2	31.4	11.1	1.3	60.4	29.9	8.4	1.3
	This device	62.1	32.8	3.8	1.3	64.3	29.6	4.8	1.3	68.8	24.4	4.8	1.9
Distortion	Monofocal	84.4	14.9	0.6	0.0	84.8	13.2	2.0	0.0	85.4	12.6	1.3	0.7
	This device	89.5	9.3	1.3	0.0	90.6	8.1	1.3	0.0	91.3	7.1	1.6	0.0
Double or Multiple Images	Monofocal	82.5	13.0	3.9	0.6	83.6	9.9	5.9	0.7	84.2	12.5	2.6	0.7
	This device	87.9	10.2	1.6	0.3	89.0	7.8	2.9	0.3	89.0	8.1	2.3	0.6
Fluctuation in Vision	Monofocal	50.6	46.8	2.6	0.0	54.9	40.5	4.6	0.0	62.1	34.0	3.3	0.7
	This device	57.0	37.9	4.5	0.6	60.1	32.8	5.8	1.3	66.6	28.3	3.5	1.6
Focusing Difficulties	Monofocal	45.5	43.5	10.4	0.6	47.7	39.1	13.2	0.0	49.7	41.1	8.6	0.7
	This device	42.7	50.6	5.4	1.3	47.2	44.0	7.8	1.0	55.7	37.5	5.5	1.3
Judging Distance or Depth Perception	Monofocal	70.1	22.7	5.8	1.3	70.9	21.2	5.3	2.6	72.8	20.5	4.0	2.6
	This device	71.3	25.2	3.2	0.3	73.5	21.0	5.2	0.3	74.5	20.6	4.5	0.3

## Binocular Defocus Curve Testing

Binocular defocus curve testing measures vision at different distances. The **enVista Envy IOL** group showed better intermediate and near vision compared to the monofocal IOL group. The largest benefit was observed in participants with large pupils.

## Effect of Astigmatism after cataract surgery

Patients with astigmatism before surgery may still have astigmatism after receiving an IOL. The effect was studied by simulating astigmatism for participants in the clinical study. A total of 50 participants were tested from 9 different sites across a span of 6 months. The average age of the participants were 55 and 77 years in the two groups. More than half were female and the majority were white and non-Hispanic or Latino. The results suggest the **enVista Envy Toric IOL** may provide improved intermediate and near vision and similar distance vision compared to monofocal IOLs.

## Warnings

1. Some visual effects may be expected, such as halos or glare, issues in dim light conditions, and other visual symptoms regardless of lighting conditions. As with all IOLs, there is a possibility that visual symptoms may be significant enough that a patient may request removal of the IOL.
2. Contact your eye doctor immediately if you have any of the following symptoms after surgery: a significant decrease in vision; double vision persisting more than a few days; a significant increase in pain in the implanted eye; significant itching, redness, and/or watering of your eye; significant eye discharge; or increased sensitivity to light. These symptoms could indicate postoperative complications including a potentially serious eye infection.
3. Vision with the **enVista Envy / enVista Envy Toric** IOL eye may be poorer in dim or low-contrast conditions. As a precaution, extra care should be taken when engaging in activities that require good vision in dimly lit environments (such as driving at night or in poor visibility conditions).
4. As part of routine eye health monitoring, the eye doctor may perform certain diagnostic tests that may take longer to perform and require some additional effort to complete in the **enVista Envy / enVista Envy Toric** IOL treated eye. If glaucoma or retinal conditions develop, some difficulty with conducting examinations and/or administering treatments is possible. In rare cases, the eye doctor may decide to remove the lens.
5. Although cataracts do not grow back, some patients may experience blurry vision after cataract surgery due to the membrane behind the lens becoming cloudy. In those instances, a secondary procedure may be necessary to improve vision. Damage to the lens is possible during the procedure which may result in increased visual effects, and in rare cases, the IOL may need to be exchanged.
6. If you are expected to have a large amount of astigmatism after surgery, you may not fully benefit from an **enVista Envy / enVista Envy Toric** IOL. You may need eyeglasses or your intermediate and near vision may not improve as well as patients with lower astigmatism.
7. Unexpected results after surgery may result in you needing eyeglasses or another surgery to adjust or replace the IOL.
8. Please discuss all risks and benefits with your eye doctor before your surgery.
9. Any activity while recovering from surgery that may harm your eye (For example: sports, heavy lifting) should be avoided. Please follow your doctor's instructions on postoperative care and prescribed medications including eye

## Precautions

1. Prior to surgery, your eye doctor will check if you have any eye diseases. You should tell your eye doctor about any eye problems or if you have been diagnosed with any eye conditions. (For Example, Glaucoma: increased pressure in the eye, or Diabetic retinopathy: a complication of the eye due to uncontrolled diabetes). If your eye is not healthy, you may not get the full benefit of the **enVista Envy / enVista Envy Toric** IOL.
2. If you wear contact lenses, your eye doctor may ask you to stop wearing contact lenses for a certain period of time before the surgery so the doctor can choose the right lens power for you.
3. After surgery, you may need eyeglasses when reading small print or looking at small objects.
4. The **enVista Envy / enVista Envy Toric** IOL has not been studied for use in children.
5. Pre-existing diseases or conditions may place you at higher risk of experiencing complications during and after routine cataract surgery. Examples of pre-existing diseases or conditions are diabetes, heart disease, and previous trauma to your eye. Examples of complications include not being able to implant the **enVista Envy / enVista Envy Toric** IOL into your eye, poorer visual outcome, and more difficult recovery.
6. The **enVista Envy Toric** IOL has not been evaluated in a clinical study. The effects of astigmatism remaining after surgery was simulated in a clinical study for patients implanted with the non-toric **enVista Envy** IOLs. Results are summarized in the clinical study results section. If you have a greater amount of astigmatism after surgery with the enVista Envy Toric IOL, you may need eyeglasses to see clearly (for far, intermediate, and near distances).

## MRI Safety Information

It is safe for you to get an MRI with an **enVista Envy / enVista Envy Toric** IOL. The implant is made from acrylic, which is a type of plastic. It does not contain metal or electronics and it is not magnetic. Therefore, the MR environment will not affect the device.

## Postoperative Care Instructions

- You will return home after surgery. Your vision should improve within four (4) to six (6) weeks after cataract surgery. Many patients may see better within one (1) to two (2) weeks. Recovery time varies, but full healing can take up to three (3) months. During the healing process, your vision may fluctuate. You will need to take eye drops as prescribed by your doctor to help control inflammation and prevent the risk of infection. Do not rub or press on your eye. Your ophthalmologist may ask you to wear eyeglasses or a shield to protect your eye.
- Avoid activities that could harm your eye while you are recovering from surgery, such as playing sports, bending down, lifting heavy objects, or any activities where objects can put pressure on the eye or come in contact with the eye. Typically, your eye doctor will examine you the following day.

Be sure to talk with your eye doctor so you can fully understand the recovery process after your cataract surgery. It may take you some time to get used to your new IOL(s). Always talk with your eye doctor if you have any questions or concerns.

After your cataract surgery, maintaining regular eye exams is important.

## Key Points to Remember About Your Choice

- It is important to discuss your lifestyle and/or visual needs with your eye doctor to help select the best IOL for you.
- If being able to see a continuous range of vision (far, intermediate, and near) is important for your lifestyle, the **enVista Envy / enVista Envy toric** IOL may be a good option for you.
- Review the advantages and disadvantages with your doctor before deciding which IOL is right for you.

Thank you for considering the **enVista Envy / enVista Envy toric** IOL.

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**BAUSCH+HEALTH**

**DESCRIPTION:** Bausch + Lomb IOL Patient ID Card / GBL / CLW  
**SPEC No. or SPEC DIMENSIONS:** 141190  
**SPECIAL INSTRUCTIONS:** N/A

PRINT SUPPLIERS: Please refer to Bausch Health's *Print Supplier Guidelines*

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