

PATIENT INFORMATION LEAFLET

Rayner RayOne EMV Toric

Contents

Terms to remember:	2
Introduction:	3
An overview of cataracts	3
An overview of astigmatism.....	3
Types of available IOLs	3
What to expect from your IOL	4
Warnings	4
Precautions	5
Potential Risks	5
Cataract surgery, explained	5
Important Points to Remember	9

Terms to remember:

Aspheric IOL	A small artificial acrylic lens with a slightly curved surface. This design helps you see more clearly in low levels of light, as well as better differentiate between colors (contrast sensitivity), objects and their background.
Astigmatism	When the front surface of your eye (cornea) is not perfectly round like a basketball. Instead, it's shaped more like a football, causing blurred or distorted vision at all distances.
Cataract	When the natural lens inside your eye becomes cloudy or loses its transparency, from the introduction of natural proteins that build up over time. This can make vision blurry, colors look faded, and night driving harder.
Cornea	The protective clear layer at the front of your eye that helps bend and focus light as it enters the eye.
Crystalline lens	The clear, natural lens behind the colored part of your eye (iris) changes shape to focus light onto the back of the eye.
Diopter	Number that shows the strength of a lens. Also tells how much the lens bends light to help focus your vision. The higher the diopter, the stronger the lens must be to focus vision clearly.
Intraocular Lens (IOL)	A small artificial lens placed in the eye during cataract surgery after the natural cloudy lens is removed.
Iris	A flat colored membrane at the front of the eye that changes size to let light in; the amount of light let into the eye also depends on how bright the environment is.
Monofocal IOL	A small artificial lens that typically only provides distance vision (seeing things far away) after cataract surgery. Glasses are often still needed for reading or close work.
Patient	A person who is receiving or may receive medical care, like you as the reader of this leaflet.
Retina	The thin layer at the back of the eye that senses light, and sends signals to the brain where images are formed.
Subject	A person who takes part in a clinical study.

Introduction:

This patient leaflet provides information about the Rayner RayOne EMV Toric intraocular lens (IOL) – model RAO210T. This IOL is designed to improve your distance vision after cataract surgery and to correct corneal astigmatism.

Please read this leaflet carefully and talk about it with your eye surgeon.

Your eye surgeon will explain the potential risks and benefits of cataract removal and IOL implantation. Be sure to ask any questions you may have, and confirm with your surgeon whether the RayOne EMV Toric is right for you.

An overview of cataracts

A cataract occurs when the natural lens inside your eye becomes cloudy or loses its transparency, from the introduction of natural proteins that build up over time. When you have a cataract, your vision may look blurry, hazy or less colorful. A common sign of when a cataract has developed is when your vision isn't as clear or bright as it used to be.

Cataracts are very common and mostly develop naturally with age. Around the world, cataracts are one of the leading causes of vision problems, with over 65 million people affected¹. Cataract surgery is a common, safe, and effective procedure to restore your vision². There are more than 28 million cataract surgeries performed worldwide each year³.

1. <https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment>
2. Cataract Surgery. National Eye Institute, May 2019
3. Market Scope IOL Report, 2019

An overview of astigmatism

Astigmatism is a common condition where the front surface of your eye (cornea) is not perfectly round like a basketball. Instead, it's shaped more like a football. This uneven shape causes light to bend unevenly, which can make your vision blurry or distorted at all distances.

Wearing glasses or contact lenses can help correct the vision issues caused by astigmatism. However, if the condition has stabilized in adulthood and you want a more permanent solution, your eye surgeon may recommend a special type of IOL called a toric lens. This IOL is designed to reduce astigmatism and improve your vision as part of the surgical treatment.

Types of available IOLs

There are different types of IOLs available, and each provides different visual outcomes after cataract surgery. Your eye surgeon will review the IOL options and help decide which is best for you.

Rayner IOLs available in the United States include:

- **RayOne Aspheric**

The RayOne Aspheric is a monofocal IOL designed to provide high quality distance vision after cataract surgery. The RayOne Aspheric IOL has an aspheric surface, which means it is slightly curved, and is designed to enhance distance vision under low light conditions, such as indoors or at dusk, when wearing full correction glasses. This IOL is designed for people who have a normal corneal shape.

- **RayOne EMV**

The RayOne EMV is similar to the RayOne Aspheric. It is designed to restore clear distance vision and has an aspheric (slightly curved) surface to enhance distance vision under low light conditions such as indoor

or at dusk. The RayOne EMV is designed to provide consistent vision results across a wide range of cornea shapes.

- **RayOne EMV Toric**

The RayOne EMV Toric can provide the same clear distance vision as the RayOne EMV but in addition, it is designed to correct any astigmatism on your cornea, which can reduce blurry or distorted vision caused by an uneven cornea.

What to expect from your IOL

Characteristic	RayOne Aspheric	RayOne EMV	RayOne EMV Toric
Distance vision	This IOL is designed to provide you with high quality distance vision without the need for glasses.	This IOL is designed to provide you with high quality distance vision without the need for glasses.	This IOL is designed to provide you with high quality distance vision without the need for glasses.
Glasses use	You will likely need prescription glasses to clearly see objects up close or to read.	You will likely need prescription glasses to clearly see objects up close or to read.	You will likely need prescription glasses to clearly see objects up close or to read.
Astigmatism	This IOL is not designed to correct any corneal astigmatism.	This IOL is not designed to correct any corneal astigmatism.	This IOL <u>is</u> designed to correct corneal astigmatism.

Please talk with your eye surgeon to decide which intraocular lens (IOL) is right for you.

Cataract surgery is one of the most common surgical procedures performed; however, as with all surgeries there are warnings, precautions, and risks you should be aware of.

Warnings

- Pre-existing diseases or conditions may put 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.
- 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 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.
- 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.
- 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.

- If you are expected to have a large amount of astigmatism after surgery, you may not fully benefit from RayOne EMV Toric. You may need eyeglasses or your intermediate and near vision may not improve as well as patients with lower astigmatism.
- Unexpected results after surgery may result in you needing eyeglasses or another surgery to adjust or replace the IOL.
- Please discuss all risks and benefits with your eye doctor before your surgery.

Precautions

- If your eye is not healthy, as with all IOLs, your vision may not be good even after your cataract is removed.
- In this case, you may not get the full benefit of RayOne EMV Toric. Before surgery, your eye doctor will check if you have any eye diseases that may influence your IOL selection.
- RayOne EMV Toric has not been evaluated for use in patients younger than 21 years of age.
- After surgery, you may need eyeglasses when reading small print or looking at small objects.

Potential Risks

Complications after cataract surgery are uncommon, but as with any surgical procedure, risks are involved. While almost any complication after surgery can be treated successfully, primary risks include inflammation, infection, swelling, and dislocation of the IOL amongst others.

Your risk of complications is greater if you have another eye disease or associated medical condition. On rare occasions, cataract surgery does not improve your vision to the level that was expected due to other eye conditions unrelated to the cataract, such as glaucoma (abnormally high intraocular pressure) or macular degeneration (a wearing down of the macula, the central portion of the eye). Your eye surgeon will evaluate these conditions prior to surgery to ensure the best possible outcome for you.

Discuss any questions about the possible risks and benefits of cataract surgery and the Rayner IOLs with your eye surgeon.

Cataract surgery, explained

Cataract surgery is an outpatient procedure. This means you go home the same day. During surgery, your natural lens is removed and replaced with a new intraocular lens (IOL).

- **Before surgery**

Your eye surgeon will examine your eyes and take several measurements to help you choose the best option for your vision. Your lifestyle and daily activities will also be discussed to make sure the right solution is recommended for you. You should plan to have someone else drive you home after surgery.

Your eye surgeon will also review your personal risk/benefit ratio to determine whether you are a good fit for a Rayner IOL. Factors include whether you have ongoing eye disease, a history of eye surgery, or other factors that may affect your outcome.

The results of cataract surgery and an IOL implantation cannot be guaranteed. It is important to be aware of possible side effects on vision after surgery, and not all patients are good candidates for this type of IOL. Be sure to discuss possible risks and side effects with your eye surgeon, who at the time of

your consultation, will tell you whether this type of IOL is suitable for you. During this discussion, inform your eye surgeon if you have been diagnosed with any eye disease.

Please note that you may still need to wear glasses to benefit from an aspheric IOL when using your distance vision under low light conditions; the RayOne Aspheric, RayOne EMV and RayOne EMV Toric are not designed to provide functional (useful) vision in the near range for activities such as reading a book or sending a text message. Uncorrected (without glasses or contacts) near-sightedness, far-sightedness, and astigmatism (irregularly shaped cornea) may increase the likelihood that you will need glasses for various distances after surgery.

- **Day of surgery**

Before surgery you will be given a patient gown to change into for surgery.

Your eye surgeon will place eye drops in your eye to make your pupils larger (dilate the pupil), followed by sterilizing the skin around your eye and applying a local anesthetic (typically in the form of eye drops) to numb the eye. If needed, a mild sedative may also be provided to help you relax.

Cataract surgery is often a short procedure. If your eye is otherwise healthy, it can take between 10 to 15 minutes to remove the natural lens and replace it with the new IOL. The procedure should not be painful. During surgery, you will simply be asked to look at a bright light.

Immediately after the surgery, your eye will be covered with a protective dressing. You can usually return home after a short rest. Someone must accompany you on the day of surgery to drive you home, as you cannot drive straightaway. Your eye surgeon will also give you a small card that identifies the type of IOL implant placed in your eye.

- **After surgery**

While your eyesight may begin to recover straight after surgery, the total recovery time varies from patient to patient. Full recovery may take a few weeks, but you can normally resume day-to-day activities after a couple of days. Please be patient as your eyes adjust to the new IOL.

Remember to apply any eye drops provided by your eye surgeon to support your recovery after the surgery.

During the recovery process after surgery, be sure to avoid any activity that could harm your eye.

The Results of the US Clinical Study

In this leaflet, we use the word subject when we talk about people who took part in the study.

RayOne EMV Toric

In 2023-2024, Rayner conducted a clinical study in the United States to evaluate the safety and effectiveness of the RayOne EMV Toric for correcting vision after cataract surgery. The study compared the RayOne EMV Toric to a standard monofocal IOL. The main goals were to check how well the IOL stayed centered (centration), how stable it was in position (rotational stability), and to measure how well it performed in improving vision and reducing astigmatism. The study included 234 subjects who were implanted, each randomly assigned to receive one IOL after cataract surgery. One-hundred and seventeen subjects received the RayOne EMV Toric and 116 subjects received the FDA-approved RayOne Aspheric Monofocal IOL. Eye surgeons followed subjects at several study visits over 4 to 6 months. Subjects who received the RayOne EMV Toric showed better astigmatism correction, stable vision, and low risk of complications. Key findings from the study are listed below:

Vision and Astigmatism Correction

- **100%** (117/117) of subjects with the RayOne EMV Toric were able to see 20/40 or better with correction (glasses or contact lenses) at 4 to 6 months after surgery.
- **68.6% $\pm$ 29.2%** was the average percent drop in absolute astigmatism 4 to 6 months after surgery for subjects with a RayOne EMV Toric, compared to 36.1% $\pm$ 45.7% for those with the monofocal IOL.
- **85.5%** (100/117) of RayOne EMV Toric subjects had astigmatism reduced to within 0.50 diopters of their intended target (the level of vision correction your surgeon planned for you) 4 to 6 months after surgery, compared to 48.3% (56/116) of subjects with the monofocal IOL.
- **96.6%** (113/117) of RayOne EMV Toric subjects had astigmatism reduced to within 1.00 diopters of their intended target (the level of vision correction your surgeon planned for you) 4 to 6 months after surgery, compared to 79.3% (92/116) with the monofocal IOL.

Lens Rotational Stability:

- The average rotation of the IOL between 1 and 6 months after surgery was minimal, indicating the IOL stayed in the correct position over time.
- **99%** (100/101 subjects with evaluable data) of RayOne EMV Toric stayed within 5 degrees of their original position between 1 to 6 months after surgery, also indicating that the IOL was able to stay close to the correct position during that time.

Safety and Side Effects:

The rate of serious side effects with the RayOne EMV Toric was similar to or lower than what's typically expected for cataract surgery in most cases, per internationally recognized safety benchmarks for intraocular lenses (ISO 11979-7).

The most common serious side effect was cystoid macular edema (swelling in the back of the eye), which occurred in 1.7% (2/117) of cases.

There were no cases of:

- Endophthalmitis (infection inside the eye)
- Hypopyon (fluid buildup of white blood cells in the front of the eye)
- Retinal detachment (the layer at the back of the eye pulls away)
- IOL dislocation (the IOL shifts out of place)
- Pupillary block (fluid is unable to flow properly through the eye)

One subject (0.9%, 1/117) needed a second surgery for a minor IOL position adjustment due to how the IOL was positioned during the first surgery; however, this was not caused by a problem with the IOL itself. Another subject (0.9%, 1/117) required a cataract lens fragment removal, due to incomplete removal of the cataract at the time of the first surgery, also not caused by the IOL.

Rates of Side Effects Defined by Previous Cataract Research

As part of the study, researchers also monitored side effects defined by previous cataract research known as Masket criteria¹. These included swelling, pressure changes, and IOL repositioning. Among 117 subjects, 5 (4.3%) experienced one or more of these events.

- Increased IOP (elevated eye pressure): 3/117 subjects (2.6%)
 - Clinically significant macular edema (swelling in the back of the eye affecting vision): 1/117 subjects (0.9%)
 - Secondary surgical intervention (IOL repositioning procedure): 1/117 subjects (0.9%)
1. Masket S. Recommended Standard for Reporting Adverse Events for Intraocular Lenses and Cataract Surgery. J Cataract Refract Surg. 2002.

Other Reported Side Effects

The study also tracked other side effects after cataract surgery. Among 117 subjects:

- Posterior capsular opacification (clouding behind the IOL) requiring laser treatment: 14/117 subjects (12.0%)
- Posterior vitreous detachment (gel inside eye separated from retina): 7/117 subjects (6.0%)
- Cornea edema (corneal swelling): 7/117 subjects (6.0%)
- Anterior chamber cells (mild inflammation shortly after surgery): 5/117 subjects (4.3%)
- Corneal abrasions or epithelial defects (abrasions or scratches on the eye): 5/117 subjects (4.3%)
- Eye redness or bleeding (e.g., subconjunctival hemorrhage): 3/117 subjects (2.6%)
- Epiretinal membrane (thin film that can form on retina): 2/117 (1.7%)

Less common events (each in 1/117 subjects, or 0.9%) included:

IOL decentration/malposition (off-center IOLs requiring adjustment), iris pigment epithelium loss (loss of pigment in the colored part of the eye), progression or onset of diabetic retinopathy (diabetes-related retinal changes), retained lens material (small piece of IOL left after surgery), wound burp / paracentesis (fluid release to lower eye pressure), surgical removal of retained lens fragment (minor procedure to remove leftover lens piece), choroidal nevus (benign freckle at the back of the eye), conjunctival injection (eye redness), corneal dellen (dry or sunken area on the eye surface), dermatochalasis (sagging upper eyelid skin), epiretinal membrane (thin scar tissue on the retina), subconjunctival hemorrhage (small bleed on the white of the eye), worsening dry eye disease (increased dryness or irritation), central capsular wrinkle (fold behind the IOL), chemosis (swelling of clear eye tissue), double vision after surgery (temporary double vision due to visual adjustment), dry eye disease (gritty or dry feeling in the eyes), epithelial basement membrane dystrophy (irregular surface of the eye), intraretinal hemorrhage (small bleed within the retina), iritis (inflammation inside the front part of the eye), keratoconjunctivitis sicca (non-autoimmune dry eye), photophobia (light sensitivity), retinal pigment epithelial changes (minor pigment changes in the retina), retinal pigment epithelial mottling, irregular coloring in the retina), superficial punctate keratitis (small spots of irritation on the eye's surface), trace punctate epithelial erosions (tiny surface scratches on the eye), visually significant corneal edema (swelling that temporarily reduced vision), worsening punctate epithelial erosion (progression of small surface damage on the eye).

The US clinical trial proved that the device is effective in improving vision while reducing astigmatism and providing excellent IOL stability, with a safety profile comparable to other toric IOLs used in cataract surgery.

Important Points to Remember

1. The RayOne Aspheric, RayOne EMV and RayOne EMV Toric restore distance vision following cataract surgery.
2. Discussing your wants, needs, and lifestyle with your eye surgeon, that help ensure you receive the right IOL for you.

For further information about this device, please refer to the device's professional labeling.

We appreciate your consideration of Rayner IOLs.