



Informed Consent for Cataract Surgery with the RxSight Light Adjustable Lens (RxLAL™)

What is a cataract and how is it treated?

The lens in the eye can become cloudy and hard, a condition known as a cataract. Cataracts can develop from normal aging, from an eye injury, or if you have taken medications known as steroids. Cataracts may cause blurred vision, dulled vision, sensitivity to light and glare, and/or ghost images. If the cataract changes vision so much that it interferes with your daily life, the cataract may need to be removed. Surgery is the only way to remove a cataract. You can decide not to have the cataract removed. If you don't have the surgery, your vision loss from the cataract will continue to get worse.

How will removing the cataract affect my vision?

The goal of cataract surgery is to correct the decreased vision that was caused by the cataract. During the surgery, the ophthalmologist (eye surgeon) removes the cataract and puts in a new artificial lens called an intraocular lens or IOL. Cataract surgery will not correct other causes of decreased vision, such as glaucoma, diabetes, or age-related macular degeneration. Most people still need to wear glasses or contact lens after cataract surgery for either near and/or distance vision and astigmatism.

What is astigmatism and how is it treated?

Astigmatism is caused by an irregularly shaped cornea. Instead of being round like a basketball, the cornea is shaped like a football. This can make your vision blurry. Astigmatism can be reduced by a toric IOL, glasses, contact lenses, and refractive surgery (LASIK or PRK). There is also a procedure called a limbal relaxing incision (LRI) that can be done at the same time as the cataract operation, or as a separate procedure. A limbal relaxing incision (LRI) is a small incision in the cornea to make its shape rounder. Any attempt at astigmatism reduction could result in over- or under-correction, in which case glasses, contact lenses, or another procedure may be needed.

What are the major risks of cataract surgery?

All operations and procedures are risky and can result in unsuccessful results, complications, injury, or even death, from both known and unknown causes. The major risks of cataract surgery include, but are not limited to bleeding; infection; injury to parts of the eye and nearby structures from the anesthesia, the operation itself, or pieces of the lens that cannot be removed; high eye pressure; a detached retina, and a droopy eyelid. The major risks of a limbal relaxing incision are similar to those for cataract surgery, but also include damage to and/or scarring of the cornea, and under- or over-correction.



Depending upon your eye and the type of IOL used, you may have increased night glare or halos, double vision, ghost images, impaired depth perception, blurry vision, and trouble driving at night. The ophthalmologist might not be able to put in the IOL you choose. In addition, the IOL may later need to be repositioned or replaced.

Depending upon the type of anesthesia, other risks are possible, including cardiac and respiratory problems, and, in rare cases, death.

There is no guarantee that cataract surgery or astigmatism reduction will improve your vision. As a result of the surgery and/or anesthesia, it is possible that your vision could be made worse. In some cases, complications may occur weeks, months, or even years later. These and other complications may result in poor vision, total loss of vision, or even loss of the eye in rare situations. You may need additional treatment or surgery to treat these complications. This additional treatment is not included in the fee for this procedure.

What types of IOLs are available?

Your ophthalmologist will help you decide on the type of IOL that will replace your cloudy lens. There are IOLs available to treat nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. IOLs usually provide either near or distance vision: these single focus lenses are called monofocal IOLs. Some newer IOLs can provide for near, intermediate, and distance vision: these multiple focus lenses are called multifocal IOLs. IOLs that treat astigmatism are called toric IOLs. You can also have one eye corrected for near vision, and the other for distance vision, a choice called monovision.

What is the Rxsight Light Adjustable Lens (RxLAL™) and how will it affect my vision?

The Rxsight Light Adjustable Lens (RxLAL™) is similar to other intraocular lenses (IOLs) that can be implanted in your eye to replace the natural lens that is removed during cataract surgery. The goal of implanting any IOL is to correct the decreased vision that was caused by the cataract. The ophthalmologist measures your eye before surgery to try to calculate the best focus power for the IOL, but it is often not exactly on target. Because of this, most patients will require glasses or contact lenses to improve their vision to the level needed for either driving or reading, or both. The difference with the RxLAL™ is that the focus power can be adjusted after your cataract surgery to meet your particular needs, which may reduce the need for glasses or contact lenses. These adjustments are made beginning 2-4 weeks after your cataract surgery by applying specific patterns of ultraviolet (UV) light to the IOL to change its shape, which results in changes to the refractive correction of your vision. The UV light is delivered with the Rxsight Light Delivery Device (LDD), either by your surgeon or by an optometrist.



The number of light adjustment treatments varies from patient to patient. The adjustments will be completed when your refraction is stable. When you and your doctor agree that the final criteria have been met, a final LDD treatment will lock in the RxLAL™ and make the refraction permanent.

- ***From immediately after surgery until 24 hours after the completion of the lock-in treatment 2-4 weeks after surgery, you will need to protect the RxLAL™ from UV light by wearing protective eyewear during ALL the time you are awake, or as directed by your ophthalmologist.***

Careful follow-up is required after surgery. After your eye heals, you will still need regular eye exams to monitor the health of your eyes.

What are the main risks of the RxLAL™?

It is impossible to list all risks and complications that may occur. The main risks and complications of implanting the RxLAL™ include:

- There is no guarantee that the IOL will improve your vision. Sometimes it doesn't work.
- As with all surgery, there are risks. Sometimes it can make the problem worse, cause an injury, or create a new problem; if it does, this is called a complication.
- Complications can happen right away or not until days, weeks, months, or years later.
- You may need more treatment or surgery to treat the complication.
- Before the RxLAL™ is locked in, you can experience a decrease in vision if you are exposed to daylight or any other UV light source when you are not wearing protective eyewear. If this happens, the RxLAL™ may need to be removed and replaced with a new intraocular lens to improve vision. This can lead to other complications from the additional surgery.
- Therefore, immediately after surgery, when your patch is removed, ***you must wear the provided UV protective eyewear as instructed by your ophthalmologist, until 24 hours after the final treatment, which may be up to 4 weeks.*** The protective eyewear will protect the RxLAL™ from UV light from the sun and other UV sources that are common both indoors and outside. Three pairs of UV protective glasses will be provided to you: a *clear pair*, a *clear pair with readers*, and a *dark tinted pair*, to be worn as follows:
 - When indoors, the clear pair must be worn at all times as it is not always possible to know which light sources may affect the lens.
 - Before moving outside, the clear glasses ***must*** be changed to the dark-tinted glasses as sunlight carries a greater risk of changing the shape of the lens in an uncontrolled manner.
 - You do not have to wear the dark tinted glasses outside at night, as there is no sunlight.
 - The clear glasses may be worn at night to protect the RxLAL™ from other UV light sources, or as recommended by your surgeon.
- ***Patients unwilling to comply with the postoperative regimen for adjustment and lock-in treatment, and wearing the UV-protective eyewear, should not choose the RxLAL™ for their cataract surgery.***



Risks associated with postoperative RxSight Light Delivery Device (LDD) Treatments:

It is impossible to list all risks and complications that may occur. The main risks and complications of the LDD treatments include:

- Your pupil may not dilate sufficiently to perform the light adjustments. If it is not possible to enlarge the pupil enough so that the entire lens can be seen to perform the adjustments, additional eye drops or surgery may be needed to further enlarge the pupil. If the pupil cannot be sufficiently enlarged after these types of treatments, the lens may need to be removed.
- The desired results of the surgery and/or light treatment may not be obtained or may not last.
- UV light can cause a reactivation of previous herpes virus infection in the eye, which is why it is important to tell your doctor about any previous eye infections or problems. Notify your doctor if you suspect previous herpes eye disease.
 - A reactivation of herpes virus may lead to scarring of the cornea, blurred vision, eye pain, extreme light sensitivity, permanent loss of vision, and possible need for corneal transplant. It should be noted that the risk of herpes virus reactivation is not unique to UV light. Herpes can reactivate with any ocular surgery due to the stress of surgery and the use of topical steroids.
- LDD light treatment can lead to a temporary or longer-term pink to red tinge to the vision or color vision deficiency.
- Some medications and supplements can potentially increase your eye's sensitivity to UV light: tetracycline, doxycycline, psoralens, amiodarone, phenothiazines, chloroquine, hydroxychloroquine, hydrochlorothiazide, hypercin, ketoprofen, piroxicam, lomefloxacin, and methoxyarene.
- It is important that you discuss your medications with your doctor and notify your doctor if you are on any of the listed medications prior to pursuing a LAL.
- **A patient taking a systemic medication that is considered toxic to the retina such as tamoxifen (e.g., Nolvadex®) may be at increased risk of retinal damage during LDD treatment.**

How will complications during surgery be handled?

If a complication happens during surgery, the ophthalmologist may need to perform another surgery right away to treat it. The ophthalmologist may discover a new condition or problem for the first time during the surgery. The ophthalmologist may need to change the plan for surgery to treat this condition or problem right away.

Who will perform my surgery?

Your surgery will be performed by your ophthalmologist. Another ophthalmologist may be present at your surgery and may participate in the surgery under the direct supervision of your ophthalmologist for all critical portions of the surgery.



Consent to treatment

By signing below, you agree and consent to the following:

- Your ophthalmologist has discussed the information in this form, including the risks, benefits, and alternatives of the procedure, as well as the consequences of refusing treatment.
- Your doctor has answered your questions to your satisfaction.
- You understand that, during the procedure, unforeseen complications or conditions may occur or be found that require additional or alternative procedures, and you authorize such procedures to be performed.
- You acknowledge that no guarantees or promises have been made to you concerning the results of any procedure or treatment.
- You agree to wear the postoperative protective eyewear and to keep your postoperative appointments for the light adjustments as instructed. You also understand that failure to do so may result in the need for the RxLAL™ to be removed and replaced with a new intraocular lens, which can lead to other complications from the additional surgery.
- You have been offered a copy of this document.

You consent to implanting the RXSight Light Adjustable Lens (RxLAL™) in your:

___ **Left** eye

___ **Right** eye

___ **Both** eyes

Patient Name

Date of Birth

Patient Signature

Date

If patient is unable to consent:

Signature of person authorized to consent for patient

Date

Relationship to patient

