

PATIENT INFORMATION BROCHURE

**Facts You Need to Know About the
RxSight Light Adjustable Lens and Light Delivery Device for the Correction of Residual
Astigmatism**

Please read this entire brochure. If you have any questions about it, discuss them with your doctor before you agree to the surgery.

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CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed practitioner

**RXSIGHT
LIGHT ADJUSTABLE LENS AND LIGHT DELIVERY DEVICE**

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GLOSSARY

This section explains important terms in this booklet. Please discuss any related questions with your doctor.

Astigmatism	A type of refractive error in which light rays do not focus on the retina at the same point because the eye is irregularly shaped like a football.
Cataract	Cloudiness of the natural lens of the eye.
Cornea	Transparent front portion of the eye. It covers the iris and the pupil. It provides most of the eye's focusing power.
Diopter (D)	Unit of measure for refractive power of lenses.
Erythropsia	A temporary or long-lasting pink or red tinge to your vision
Farsightedness	Inability to see near objects as clearly as far objects. A common term for Hyperopia.
Glaucoma	Group of diseases marked by increased pressure in the eye. It results in damage to the optic nerve and retinal nerve fibers.
Intraocular Lens (IOL)	An artificial lens that replaces the natural crystalline lens of the eye after cataract surgery.
Iris	The colored membrane in front of the natural crystalline lens that gives color to the eye.
LASIK	Laser-Assisted In-Situ Keratomileusis. Laser eye surgery to reshape the cornea. A flap is made in the outer layer of the cornea prior to using the laser.
LRI	Limbal relaxing incisions. Procedure where small incisions are placed on the front part of the eye to treat corneal astigmatism.
Macula	An area near the center of the retina
Manifest Refraction Spherical Equivalent (MRSE)	A number that doctors use to describe the amount of nearsightedness or farsightedness that has to be corrected for you to see far away things clearly.
Monofocal IOL	A monofocal IOL has a single focusing distance that is chosen to correct vision up close, vision at intermediate range or distance vision.
Natural Crystalline Lens	A clear structure located behind the iris of the eye. It adds optical power to the eye to sharpen the image.
Nearsightedness	Inability to see far objects as clearly as near objects. A common term for Myopia.
Optic Nerve	Carries the visual information captured on the retina to the brain for recognition and interpretation.

PRK	Photorefractive keratectomy. Laser eye surgery to reshape the cornea. The outer layer of the cornea is removed prior to using the laser.
Pupil	The black portion in the center of the eye that allows light into the eye. It shrinks during bright light conditions and enlarges in dim light conditions.
Refractive Error	A problem with focusing light on the retina due to the shape of the eye. This causes blurry vision. The most common types of refractive errors are nearsightedness, farsightedness, and astigmatism.
Retina	The thin layer of nerve cells, or “film,” at the back of the eye. It converts light images into nerve signals sent to the brain.
Toric IOL	An IOL that is designed to correct astigmatism.
Ultraviolet (UV) Light	Light with a wavelength shorter than visible light. UV light is found in sunlight.

INTRODUCTION

This brochure is designed to help you evaluate the RxSight Light Adjustable Lens (LAL) and Light Delivery Device (LDD), which can be used by your doctor during and after cataract surgery. Your doctor will discuss the potential risks and benefits of cataract surgery, as well as the different devices and procedures that are available to you. You should ask your doctor if you have questions about any information in this brochure.

FOCUSING WITH YOUR EYE

Your eye (the cornea and the lens) focuses light from objects in the world onto the retina to form images that you can see, similar to how a camera creates pictures on film. The retina is a thin layer of nerve cells, or “film,” at the back of the eye. It converts light images into nerve signals sent to the brain. Light enters the eye through the cornea (clear front covering of the eye) and the pupil (black portion in the center of the eye) and then passes through the lens. The cornea accounts for two-thirds of the focusing power of the eye. The natural crystalline lens (a clear structure located behind the iris of the eye that adds optical power to the eye to sharpen the image) accounts for the other one-third of the focusing power of the eye.

WHAT IS A CATARACT?

At birth, the natural lens in your eye is clear. Due to the natural aging process, your natural lens may gradually become “cloudy” which is a condition called a cataract. One possible symptom of a cataract is that your quality of vision may not be as good as it once was.

If your doctor has diagnosed you with cataracts after a comprehensive eye examination, cataract surgery may be recommended as an option. Cataract surgery involves removing your eye’s cloudy natural lens and replacing it with an artificial lens implant called an intraocular lens (IOL). It is often performed as an outpatient procedure and does not require an overnight hospital stay.

WHAT ARE REFRACTIVE ERRORS?

Refractive errors are different kinds of focusing problems that cause blurred vision and are most commonly corrected with glasses or contact lenses. The most common refractive errors are nearsightedness, farsightedness and astigmatism. With nearsightedness, light rays focus in front of the retina, causing far vision to be blurred without glasses. In farsightedness, light rays focus behind the retina, causing far and near vision to be blurred without glasses. In astigmatism, light rays do not focus to a single point, again leading to blurred vision without glasses. These refractive errors can be present before or after cataracts develop and often change after cataract surgery.

FOR WHAT PATIENTS AND USES HAS FDA APPROVED THE LAL AND LDD SYSTEM?

FDA has approved the LAL and LDD system for use in patients:

- Who have a cataract and need surgery for it;
- Who have moderate to larger amounts of astigmatism (at least 0.75 diopters) in their cornea before surgery, and thus are likely to have astigmatism after cataract surgery.
- Who do not have pre-existing macular disease.

FDA has approved the LAL and LDD system to:

- Replace the eyes natural lens after it has been removed in cataract surgery; and
- Reduce the amount of residual astigmatism to improve vision without glasses

- Reduce the chances of patients having a large amounts of nearsightedness or farsightedness after surgery.

WHAT ARE THE OPTIONS FOR PATIENTS WHO HAVE A CATARACT AND HAVE DECIDED TO HAVE CATARACT SURGERY AND AN IOL IMPLANTED?

Patients can choose a standard monofocal IOL. This type of lens is generally the least expensive and works well for most people. Doctors try to choose the lens power to minimize the nearsightedness or farsightedness after surgery, but sometimes you will end up with significant amounts. If you have larger amounts of astigmatism you will probably have to wear glasses or contact lenses to see clearly after surgery. (Patients generally also need to wear reading glasses after surgery.)

Patients can choose a toric IOL if they have moderate to larger amounts of astigmatism (in the cornea) before surgery. If you have astigmatism before surgery, you will likely have less astigmatism after surgery with this type of lens. (Patients generally need to wear reading glasses after surgery.)

Patients can choose a multifocal or accommodating IOL. Patients who choose these want to reduce the need for reading glasses after surgery.

Patients can choose the LAL IOL. The LAL IOL, which is shown in Figure 1, is another artificial lens that replaces your natural lens during cataract surgery. Like a toric IOL, it is used for patients with moderate to larger amounts of astigmatism before surgery. (Patients generally need to wear reading glasses after surgery.)

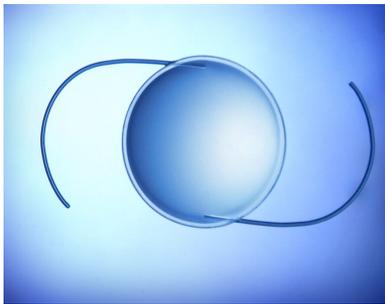


Figure 1. RxSight Light Adjustable Lens (LAL)

WHAT ARE THE OPTIONS CONCERNING REFRACTIVE ERRORS AFTER CATARACT SURGERY?

Before cataract surgery, while at your pre-surgical appointment, your doctor will make measurements of your eye to help select an artificial lens that can minimize the amount of refractive error remaining after cataract surgery. For most patients, a monofocal IOL is selected that can minimize farsightedness or nearsightedness after surgery. For patients with astigmatism, a Toric IOL (an IOL that can also reduce astigmatism) may also be considered. In addition, during your cataract surgery, your doctor may decide to place the incision used to perform your cataract surgery in a specific location to reduce smaller amounts of astigmatism. However, even with careful surgical planning and IOL selection, it is not uncommon for patients to require glasses after cataract surgery to achieve clear distance vision.

The LAL IOL, is another artificial lens that replaces your natural lens during cataract surgery. Like standard monofocal IOLs, your doctor will make measurements of your eye to help them select the LAL IOL to be implanted. However, unlike a standard IOL, the shape of the LAL IOL can be

changed after surgery to reduce astigmatism after surgery to improve vision without glasses and reduce the chances that you will have large amounts of nearsightedness or farsightedness.

OPTIONS FOR CORRECTING REFRACTIVE ERRORS THAT REMAIN AFTER CATARACT SURGERY AND IOL TREATMENT

Non-surgical options for correcting refractive errors that remain after cataract surgery include glasses or contact lenses that can be prescribed by your doctor. Surgical options include Laser-Assisted In-Situ Keratomileusis (LASIK) or Photorefractive Keratectomy (PRK) to treat your refractive error after cataract surgery. In both LASIK and PRK, a laser is used to reshape your cornea so that light rays focus properly on your retina. Another option is a procedure called Limbal Relaxing Incisions (LRIs) in which incisions are made on the front part of your eye which can be used in conjunction with or shortly after cataract surgery to correct for smaller amounts of astigmatism. (With all of these methods, you will still need to wear glasses to help you to read or see anything at near or intermediate distances clearly.)

HOW DOES THE LAL IOL WORK USING THE LDD?

The unique feature of the LAL IOL is that its shape and focusing characteristics can be changed after implantation in the eye using an office-based UV light source called the LDD which is shown in Figure 2. The change in lens shape can reduce your astigmatism after surgery to improve vision without glasses and reduce the chances that you will have large amounts of nearsightedness or farsightedness. The LAL IOL does not adjust its shape to reduce your need to wear glasses for close work (e.g. reading and computer work.)

The LDD light treatment procedures will begin 17-21 days after your doctor has implanted the LAL IOL. The LDD delivers UV light to the LAL IOL in your eye. You will undergo three or four light treatments over a period of 1-2 weeks, each lasting from 40 seconds to 2 ½ minutes, depending upon the amount of correction you still need after surgery. You will need to wear special UV eyeglasses that protect your eye from UV light in the environment that could affect the performance of the LAL IOL from the time of your cataract surgery to the end of the light treatments.



FIGURE 2: RXSIGHT LIGHT DELIVERY DEVICE (LDD)

WHAT ARE THE POTENTIAL BENEFITS?

Most patients undergoing cataract surgery to remove a cloudy lens with implantation of any IOL will experience better far vision without glasses after the procedure. For patients with astigmatism before surgery, the potential additional benefit of the LAL IOL is that the shape and focusing characteristics can be changed using the LDD to further improve your vision without glasses after surgery. However, the clinical study did not prove that patients with the LAL IOL wore glasses less frequently than those who received other IOLs. And after treatment, although the average LAL patient did not have significantly less nearsightedness or farsightedness than the average standard IOL patient, the average LAL patient did have significantly less astigmatism.

After the insertion of the LAL IOL and the application of the light treatments with the LDD, your vision without glasses may improve. As for most patients undergoing cataract surgery and receiving any IOL, your vision without glasses after this procedure may be comparable or even better than your vision with glasses before the procedure.

Please refer to the Clinical Study Information section, for additional information about the benefits of this procedure.

WHAT ARE THE POTENTIAL RISKS?

What potential risks are associated with LDD light treatments?

Possible adverse events and complications that you may experience due to the use of UV light from the LDD include the following related to effects on your retina:

- loss of vision,
- tritan anomaly (a temporary or long-lasting change to your color vision in which colors may be faded and you may have trouble telling the difference between violet, blue and green colors),

- erythropsia (a temporary or long-lasting pink or red tinge to your vision especially noticeable on things that normally look white). More than half of patients are expected to experience at least some level of this problem. (See the clinical study section for details.) The long-term effect on vision due to exposure to ultraviolet light that causes erythropsia (after LDD treatment), has not been determined.

The UV light can also cause activation of a previously undiagnosed herpes eye infection.

In addition, use of a special lens that must contact your eye during LDD treatment may cause temporary scratchiness, irritation, or dryness to the front part of your eye.

Although the LAL IOL is designed to be modified by the LDD light treatments after surgery to reduce remaining refractive error, not all patients may respond identically to treatment and complications can occur. As a result, vision may not improve or can even get worse.

Refer to the clinical study results section of this brochure for additional information.

What potential risks associated with LAL IOL implant surgery?

As with any surgical procedure, there are risks associated with cataract surgery and IOL implantation. Please discuss the risks of cataract surgery and the implantation of the LAL IOL with your doctor.

Cataract surgery complications can include:

- reactions to medicines or anesthesia,
- redness, scratchiness of the eye,
- sensitivity to light,
- bleeding,
- inflammation,
- infection,
- tissue damage,
- tissue swelling of the front or back of the eye,
- an increase in eye pressure, or
- damage to the parts of the eye where the IOL is placed.

There is a small chance that your vision could be made worse or that you may require additional surgery as result of a complication.

Implantation of the LAL IOL must be performed following specific surgical procedures. If these procedures are not followed, the lens may become scratched or improperly placed in your eye and you may require additional surgery to correct the placement of the LAL IOL or have the LAL IOL removed from your eye and replaced with another IOL. These risks are possible with implantation of any IOL.

Other potential risks

Until the completion of your LDD light treatment, your special UV glasses should be worn as specified by your doctor which includes all waking hours for about 4-5 weeks after surgery. If you do not follow these instructions from your doctor, you may experience an unpredicted vision change or loss of quality in your vision after exposure to UV light such as from sunlight or black light. This may require your doctor to surgically remove the LAL IOL from your eye and replace it with another IOL.

CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

Contraindications (Who should not receive this treatment)

If you have any of the following situations or conditions, you should NOT choose the LAL IOL and post-operative LDD light treatments because the risk is greater than the benefit:

- You are taking medications¹ that may increase your sensitivity to UV light. Examples of these types of medications are:
 - tetracycline and doxycycline – antibiotics for bacterial infections
 - Psoralens- treatment for skin conditions
 - Amiodarone- treatment for serious heart rhythm disorders
 - Phenothiazines- treatment for serious mental and emotional disorders
 - Chloroquine- used to prevent or treat malaria
 - Hydrochlorothiazide- treatment for high blood pressure
 - Hypericin- a natural herb (St. John’s Wort)
 - Ketoprofen- treatment for pain
 - Piroxicam- treatment to reduce pain, swelling, and joint stiffness from arthritis
 - Lomefloxacin- antibiotic for bacterial infections
 - Methoxsalen- treatment for skin conditions

This is only a partial list of medications, and you should make your doctor aware of all medications you are taking.

- You are taking a medication that is considered harmful to your retina. An example of this type of medication would be tamoxifen (e.g., Nolvadex®).
- You have a history of herpes eye infection.
- You have a history of uncontrollable eye movements (nystagmus).
- You are unable to comply with your doctor’s post-operative schedule of visits and LDD light treatments and are unable to wear the special UV light glasses during the period specified by your doctor; (these must be worn during all waking hours for about 4 – 5 weeks following cataract surgery)

Warnings

There is reason to believe that the following circumstances can cause increased risks from the LAL or LDD treatments. You should discuss these with your doctor, and carefully consider whether the potential benefits outweigh the risks for your situation.

- Patients with pre-existing macular disease are not suitable candidates for the LAL. Effects from the UV light from the LDD have not been determined in patients with pre-existing macular disease. You may be at an increased risk for macular disease progression. Tell your

¹ Trade names: Tetracycline (Ala-Tet®, Brodspec®, Panmycin®, Sumycin®, Tetracap®, Tetracon®, Robitet 500®, Emtet-500®); Doxycycline (Acticlate®, Adoxa®, Alodox®, Avidoxy®, Doryx®, Mondoxyne NL®, Monodox®, Morgidox®, Oracea®, Oraxyl®, Targadox®, Vibramycin®); Psoralens (8-MOP®, Oxsoralen-Ultra®, Uvadex®); Amiodarone (Cordarone®, Pacerone®); Phenothiazines (Compro®, Thorazine®, Prolixin®), Chloroquine (Aralen®); Hydrochlorothiazide (Aquazide®, HydroDIURIL®, Microzide®); Hypericin (St. Johns Wart); Ketoprofen (Orudis®), Piroxicam (Feldene®); Lomefloxacin (Maxaquin®); and Methoxsalen (Oxsoralen-Ultra®, 8-MOP®, Uvadex®)

doctor if you have ever been diagnosed with macular disease. Ask your doctor whether you have a dense cataract that prevents the diagnosis of macular disease.

Patients with any of the following conditions may not be suitable candidates for this intraocular lens. Discuss with your doctor if you have any of the following conditions:

- You have certain pre-existing conditions, such as:
 - uveitis (intraocular inflammation),
 - zonular laxity or dehiscence (conditions that make cataract surgery and IOL implantation more problematic),
 - You currently have retinal disease or are at high risk for future retinal disease that may require therapy (silicone oil) that is not compatible with the LAL IOL,
 - If you had previous eye trauma or defects that you were born with that make support of the LAL IOL difficult.
- Your doctor must be able to see the edge of the LAL IOL implanted in your eye when performing LDD light treatments. To obtain this view, your pupil needs to be able to dilate to a diameter of at least 7mm. If not, your doctor may need to utilize additional medications to get your eye to dilate further.
- If you have any complications during your cataract surgery (i.e. persistent bleeding, significant damage to the colored part of your eye, or the gel-like material from the back part of your eye is shifted) before LAL IOL implantation, you may need to have another IOL implanted instead of the LAL IOL. If you are unable to maintain steady eye fixation during LDD light treatments.

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

Precautions

The following contain circumstances under which special care must be taken to avoid hazards, or limitations concerning the use of the LAL and LDD system that should be considered. Reasons may include conditions for which there might be increased risks, but there is insufficient evidence on the issue. Discuss these with your doctor.

- The long-term effect on vision due to exposure to UV light that causes erythroptosis (after Light Delivery Device treatment), has not been determined.
- LAL implantation in both eyes was not performed in the clinical study. The effect of UV exposure on the primary eye can only be fully assessed after all LDD treatments are completed and should assist with timing of the fellow eye implantation.
- You must wear the special UV-blocking glasses during all waking hours until 24 hours after the final lock-in treatment. If you fail to wear these glasses, the LAL can become distorted, causing it to give you blurred vision that cannot be corrected with glasses. It might then be necessary for the doctor to perform another surgery to remove the LAL IOL from your eye.
- The LAL IOL must undergo at least 3 light treatments beginning 17-21 days after your cataract surgery.

- Results from the clinical study show that patients receiving the LAL IOL and LDD treatment achieve about the same average magnitude for the final nearsightedness or farsightedness, as do patients receiving the conventional IOL treatment.
- The safety and effectiveness of the LAL IOL and LDD is not known in patients with the following pre-existing conditions or with the following complications experienced during eye surgery, because they were not studied in the clinical trial. You should discuss these issues with your doctor.
 - Patients who do not have a projected best-corrected acuity of 20/20 or better (based upon past ocular history and retinal exam). These patients may not achieve an improvement in distance vision without glasses.
 - Patients with pseudoexfoliation syndrome (condition in which pieces of your natural lens flake off and lead to an increase in intraocular pressure potentially leading to optic nerve damage).
 - Patients with any problems in the back part of the eye that are expected to cause future vision loss.
 - Patients with damage to the back part of the eye from diabetes.
 - Patients with damage to the optic nerve from glaucoma (a condition marked by increased fluid pressure in the eye. This can result in damage to the optic nerve).
 - Patients with any significant problems with the structures in the front of the eye, such as rubeosis iridis (a condition where new, abnormal blood vessels grow into the iris, aniridia (absence of the iris), or iris coloboma (a hole in the iris).
 - Patients with problems on the front of the eye (cornea) that either have the potential to or already reduce best vision to worse than 20/20.
 - Patients with keratoconus (a condition in which the cornea thins out and bulges like a cone) or suspected of having keratoconus.
 - Patients with any corneal dystrophy (eye disorders you are born with affecting the cornea).
 - Patients with prior eye surgery. Exceptions may occur for patients with prior eye surgery to remove tissue of a certain length that may have grown from the white part of the eye to the cornea. You should discuss this with your doctor.
 - Patients with astigmatism that is irregular.
 - Patients that experience complications during cataract surgery before the intraocular lens is implanted including posterior capsule rupture (an occurrence in which the bag the intraocular lens is intended to be placed is damaged), zonular rupture (condition that would make IOL placement more problematic), radial capsulorhexis tear (condition that would make IOL placement more problematic), vitreous loss (condition in which the fluid/gel from the back of the eye moves to the front of the eye from eye trauma), iris trauma, corneal complications or any intraoperative abnormality that may affect pupil dilation or the placement of the LAL IOL in the eye.

- The safety and performance of using the LAL and LDD system in targeting an eye to achieve good near vision instead of good distance vision is unknown. In the clinical trial all eyes were treated to achieve good distance vision.
- There may be a greater risk of loss of cells from the back surface of the cornea associated with the LAL IOL implantation than typically seen.

ARE YOU A GOOD CANDIDATE FOR THE LAL IOL AND LDD LIGHT TREATMENTS?

After a comprehensive eye examination to determine if you have a cataract, your doctor will advise you of the most appropriate option for correcting your vision based on your expectations, lifestyle, vision requirements, and pre-existing medical or eye conditions.

You and your doctor will decide together if the LAL IOL and post-operative LDD light treatments are right for you.

You may be a good candidate for the LAL IOL and LDD light treatments if you:

- Have a cataract
- Have astigmatism (in your cornea) of at least 0.75 diopters
- Do not have pre-existing macular disease
- Are between the ages of 40-80
- Are especially concerned about your level of far vision without glasses after cataract surgery
- Have healthy eyes (except for cataract), including your eye surface
- Have not had any other eye surgeries except for surgery to remove a growth of a certain size on your cornea
- Are not taking medications that may increase your sensitivity to UV light
- Have no history of herpes eye infection
- Are not taking any medication that may be harmful to your retina.

WHAT CAN YOU EXPECT FROM THE LAL IOL AND LDD LIGHT TREATMENTS?

Before the Surgery

A comprehensive eye examination will be conducted in which you and your doctor will decide that cataract surgery and use of the LAL IOL is right for you. If your cataract is dense, your doctor may not be able to fully evaluate the appropriateness of the LAL IOL and LDD light treatment due to the inability to see certain conditions of the back of your eye.

Your doctor will take further measurements to determine the suitable LAL IOL to be placed in your eye during surgery. Your doctor and staff will review your schedule of visits for surgery and follow-ups. Plan in advance to have someone else drive you home after surgery. The doctor will also explain the use of your special UV protective light glasses that should be worn inside and outside during all waking hours after surgery until instructed to discontinue by your doctor. These glasses will prevent the LAL IOL implanted in your eye from changing due to exposure to UV light from other sources such as the sun. Ask questions and inform your doctor of all medications you are on or any problems with your overall health.

The Day of Surgery

Cataract surgery techniques vary widely, but you will be awake for the procedure and the eye is always numbed to make the operation painless. Though painless, you may feel sensations of pressure. After arrival, prepping will occur where your eye is given numbing drops, cleansed, and draped. If needed, you may be given medication to help you relax.

To perform surgery, your doctor will use a microscope to obtain 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, and through this opening, your doctor can insert tiny instruments necessary to break-up and remove your cataract. The LAL IOL is then placed into the capsule to replace your natural lens that has just been removed. The LAL IOL acts in a similar fashion to your natural lens to restore your distance vision. The surgeon will usually place a shield over your eye after surgery for protection.

After a short stay in the outpatient recovery area, you will be ready to go home. Contact your doctor immediately if you have any of the following symptoms after surgery: a significant decrease in vision, a significant increase in eye pain, significant eye itching, significant eye redness, significant eye discharge and sensitivity to light. These symptoms could indicate serious postoperative complications including, but not limited to eye infection, increased eye pressure, retinal detachment, wound leak, or allergic reaction. Activities that could harm your eye such as heavy lifting (over 20 pounds), bending, straining, swimming, or rubbing your eye while you are recovering from surgery should be avoided.

After the Surgery

After surgery, your doctor should give you a wallet card that identifies the type of implant in your eye and the manufacturer's address, phone number and email address. Should you transfer care to a different doctor, this card provides information potentially needed for the care of your eye. Typically, your doctor will examine you the day after surgery. The shield over your eye will be removed and you will be given eye drops to speed up the healing process and to prevent infection. You will be asked to wear special UV light glasses, **during all waking hours** for about 4-5 weeks after surgery, until light treatments are completed. Your vision may change during the time between LAL IOL implantation and the LDD light treatments as your eye continues to heal. LDD treatments may start 2-3 weeks after your LAL IOL implantation as agreed upon with your doctor.

WHAT CAN YOU EXPECT FROM THE LDD LIGHT TREATMENTS?

On the days of your LDD light treatments, your doctor will take measurements of your eye. Based on the vision goals you and your doctor have decided upon, these measurements will be entered into the LDD to program the light treatment your eye will receive.

Once the measurements have been completed, you will be given drops to dilate your pupil. You will be asked to wait until your pupil has opened wide enough for treatment. Once complete, you will be prepped for the LDD light treatment by having a patch placed over the eye not receiving treatment, asked to sit in front of the LDD, and asked to hold onto two black handles on the LDD table. You will place your head into the forehead and chin rest of the LDD and your doctor will adjust it properly for treatment.

Your doctor will instill a drop into your eye to temporarily numb it so that a special contact lens, which is required to complete the LDD light treatment and keep your eye open, can be placed onto the front part of your eye. You should feel no pain once the lens has been placed on your eye, but you

may experience mild discomfort. Your doctor will then ready the LDD for treatment, and you will be asked to look straight ahead at a green blinking light and do your best to keep your eye from moving. Once the LDD light treatment has started, you may notice a light shining into your eye which is painless. The light treatment may last between 40 seconds and 2^{1/2} minutes.

Once completed, your doctor will remove the special contact lens from the front part of your eye and give you instructions on the use of your special UV protective light glasses and further LDD light treatments. Continue to take all prescribed medicines and apply eye drops as instructed by your doctor.

At the completion of your last LDD light treatment, your doctor will inform you when you can discontinue wearing the special UV protective light glasses and of any subsequent eye appointments you may need to attend. Always consult your doctor if you have any questions or concerns as a result of your cataract surgery or LDD light treatments.

QUESTIONS TO ASK YOUR DOCTOR

- Do I have macular disease?
- Does the density of my cataract prevent my doctor from determining if I have macular disease?
- Do I have astigmatism?
- How much astigmatism do I have?
- Is it likely that my astigmatism will require treatment after cataract surgery?
- Do I have any eye condition that leads you to believe that I probably won't get 20/20 vision (with glasses) after surgery?
- Is this the appropriate time to have my cataract removed?
- Which type of IOL is best for my needs?
- Can the LDD treatment correct all of my astigmatism?
- What is my likely benefit from the LDD astigmatic treatment, compared to getting some other type of IOL?
- How much will cataract surgery, the LAL IOL and LDD light treatments cost me?
- Will any of my pre-existing medical or eye conditions affect the surgery with the LAL IOL or the LDD light treatments?
- What happens if I do not wear my special UV sunglasses as required?
- After my LDD light treatments have been completed, can I come back to your office a couple years later to have my lens adjusted again?

SELF-TEST*

You should be able to answer the following true/false statements after reading this brochure.

1. A cataract is when my cornea becomes cloudy (True/False)
2. Corneal astigmatism is where my cornea is irregularly shaped (similar to a football) (True/False)
3. The Light Adjustable Lens (LAL) and Light Delivery Device (LDD) are used together to minimize refractive error after cataract surgery (True/False)

4. If I am taking a UV sensitizing medication, my doctor can use the RxSight Light Adjustable Lens and Light Delivery Device on me (True/False)
5. Cataract surgery is painful (True/False)
6. A lens placed on the front of the eye is used during LDD light treatments (True/False)
7. Special UV glasses need to be worn as required by my doctor (True/False)

* Answers to these questions are provided on the Page 15.

CLINICAL STUDY INFORMATION

A clinical study was conducted to evaluate the safety and effectiveness of the RxSight Light Adjustable Lens and Light Delivery Device for the replacement of the cataractous natural lens. The study consisted of 600 eyes at 17 clinical sites that included 403 patients implanted with the LAL IOL and 197 patients implanted with a common IOL, called a monofocal IOL. The monofocal IOL has a single focusing distance that is chosen to correct vision up close, vision at medium range or distance vision.

The average age for patients studied was 65.6 years of age with a range from 41-80 years. 242 of the patients were female and 161 were male. After the cataract surgery, patients implanted with the LAL IOL underwent light treatment to reduce their postoperative refractive error. Both nearsightedness/farsightedness and astigmatism could be treated. Although all eyes implanted had astigmatism before their cataract surgery, more than 1 in 4 eyes did not require treatment of their astigmatism after cataract surgery.

A. EFFECTIVENESS RESULTS FOR THE LAL IOL AND LDD

Table 1 below presents some of the effectiveness results from the U.S. clinical study for the RxSight Light Adjustable Lens and Light Delivery Device, 6 months after surgery.

Table 1
Effectiveness Results from U.S. Clinical Study

	LAL IOL with LDD System (403 Eyes)	Monofocal IOL (197 Eyes)	Difference in results between LAL IOL and Monofocal IOL
Far Vision: 20/20 or better without glasses	70.1% (274/391) of eyes	36.3% (70/193) of eyes	33.8% more of the LAL IOL eyes had vision without glasses at 20/20 or better than monofocal IOL eyes. (This is due to LDD light treatment.)
Far Vision: 20/40 or better without glasses	99.7% (390/391) of eyes	90.2% (174/193) of eyes	9.5% more of the LAL IOL eyes had vision without glasses at 20/40 or better than monofocal IOL eyes. (This is due to LDD light treatment.)
Percent reduction in astigmatism (between 3 weeks and 6 months after surgery) in eyes that had astigmatism treatment (About 1 in 4 LAL patients had astigmatism after surgery that was too low for treatment)	74.6%	19.9%	54.7% more astigmatism was reduced in the LAL IOL eyes compared to the monofocal IOL eyes. (This is due to LDD light treatment.)

	LAL IOL with LDD System (403 Eyes)	Monofocal IOL (197 Eyes)	Difference in results between LAL IOL and Monofocal IOL
Percent reduction in manifest refraction spherical equivalent (MRSE)* (reduction between 3 weeks and 6 months after surgery)	51.5%	10.4%	41.1% more MRSE was reduced in the LAL IOL eyes compared to the monofocal IOL eyes. (This is due to LDD light treatment.)
* Percent reduction in MRSE is a measure of how much nearsightedness or farsightedness can be reduced by light treatment after implantation. The amount of nearsightedness or farsightedness before surgery is not a predictor of the amount present after surgery.			However at 6 months, the average level of near or farsightedness was about the same in the two groups. (This is because the LDD treatment requires that the LAL lens power must be chosen so that eyes have higher farsightedness just after cataract surgery.)

Improvement in vision without glasses based on postoperative level of astigmatism

On average across all patients, the LAL eyes had vision without glasses that is about one line better than the standard monofocal IOL eyes.

- For low levels of astigmatism (less than 0.75 diopters after surgery), the LAL IOL eyes had vision without glasses that was about the same as the monofocal IOL eyes. (About 1 in 4 patients were in this group.)
- For medium levels of astigmatism (0.75 to 1.25 diopters after surgery), the LAL IOL eyes had vision without glasses that was about one line better than the monofocal IOL eyes. (About 1 in 2 patients were in this group.)
- For higher levels of astigmatism (more than 1.25 diopters after surgery), the LAL IOL eyes had vision without glasses that was about 2½ lines better than the monofocal IOL eyes. (About 1 in 5 patients were in this group.)

Average remaining MRSE

The average remaining amount of MRSE (measure of how much nearsightedness or farsightedness can be reduced) at 6 months after surgery was about the same for both groups.

SAFETY RESULTS FOR THE LAL IOL AND LDD

In the clinical study, the following adverse events were related to exposure to the UV light:

Retinal injury due to device failure

One patient at the beginning of the study had an injury due to UV light overexposure caused by a faulty component within the LDD. This patient had an immediate, large decrease in far vision with glasses and also had a change in color vision. The far vision with glasses returned to normal after 3 months but the color vision has not returned to normal. The LAL IOL was later explanted. No patients treated later in the study had a similar event. (Manufacturing control has been modified to minimize the chances of a device having a defective UV filter.)

Reactivation of herpes eye infection

One patient had a reactivation of a herpes eye infection. This patient was treated successfully with medication and all light treatments were completed. The vision returned to normal.

Color Vision Problems

A total of 7 of 399 LAL IOL eyes (1.8%) had a problem with their color vision after light treatment. Color vision in five of the eyes returned to normal over time while a color vision problem was still present at 12 months after the cataract surgery in 2 of 391 eyes (0.5%). (One of the eyes still was shown to still have the problem 4 years after surgery, but the other eye was not tested after 12 months.) These two cases were treated with an earlier version of the LDD prior to safety improvements, but these types of events still might occur. In the five cases of temporary color vision change, the color vision problem resolved 10 to 30 days after light treatment for 4 of these patients who were seen regularly by the study doctor. One patient was not available for routine study visits until approximately 18 months after the light treatment at which time the problem had resolved.

After light treatment, 233 of 399 LAL IOL eyes (more than half of patients) reported erythropsia, which is a pink or red tinge to vision. The highest rate of erythropsia was reported prior to the last light treatment when 195 of 398 LAL IOL patients (49.0%) reported mild erythropsia which is pink tinge in vision. This proportion decreased significantly 1 week later and was only reported by 2 of 391 patients (0.5%) at 6 months. Only 1 (0.3%) LAL IOL patient continued to report mild erythropsia at the 12-month exam with resolution at 14 months postoperatively. The average duration for mild erythropsia was difficult to establish because subjects were not required to return for regular visits to monitor this mild symptom. An additional 14 patients reported moderate erythropsia which is a red tinge to vision at some point in the trial. The typical duration was approximately 12 days. No LAL IOL patients reported moderate erythropsia after the last light treatment.

Table 2 presents additional adverse events and their rates observed in the clinical study.

TABLE 2
ADDITIONAL ADVERSE EVENTS

Adverse Events (any time during the study)	LAL IOL with LDD System (403 Eyes)	Monofocal IOL (197 Eyes)
Cystoid Macular Edema (temporary swelling in the back part of your eye that can occur after cataract surgery)	3 (0.7%)	3 (1.5%)
Hypopyon (inflammation present in the front chamber of the eye)	1 (0.2%)	0 (0.0%)
Pupillary Block (a restriction in the flow of fluid from the back chamber of the eye to the front chamber of the eye through the black portion in the center of the iris)	0 (0.0%)	0 (0.0%)
Retinal Detachment (a condition in which the tissue connected to the back part of the eye detaches)	0 (0.0%)	0 (0.0%)
Endophthalmitis (a serious infection inside the eye)	1 (0.2%)	0 (0.0%)
Lens Dislocated From Posterior Chamber (a condition in which the natural or artificial lens in your eye becomes dislodged from the bag it normally sits in)	0 (0.0%)	0 (0.0%)
Secondary Surgical Intervention (Additional surgical procedures required after LAL IOL implantation) ¹	7 (1.7%)	1 (0.5%)

Adverse Events (that were present at 12 months postoperatively)	LAL IOL with LDD System (391 Eyes)	Monofocal IOL (188 Eyes)
Corneal Edema (swelling caused by fluid in the transparent front portion of the eye)	0 (0.0%)	0 (0.0%)
Cystoid Macular Edema (temporary swelling in the back part of your eye that can occur after cataract surgery)	0 (0.0%)	0 (0.0%)
Iritis (inflammation that affects the eye)	0 (0.0%)	0 (0.0%)
Elevated IOP Requiring Treatment (an increase in the pressure of the eye requiring treatment)	0 (0.0%)	0 (0.0%)
Other Adverse Events	LAL IOL with LDD System (391 Eyes)	Monofocal IOL (188 Eyes)
Persistent Unanticipated Significant Increase in Refractive Error	5 (1.3%)	N/A
Premature Polymerization of the LAL Causing Visible Distortion of LAL Optic (unintended exposure to UV light causing irregular changes in the implanted LAL IOL)	0 (0.0%)	0 (0.0%)
Intraoperative Iris Prolapse (unexpected movement of the colored part of your eye during surgery) ²	1 (0.3%)	0 (0.0%)
Intraoperative Capsular tear during primary IOL implantation after unremarkable phacoemulsification (during surgery, a tear in the bag in which the natural or artificial lens in your eye sits in)	1 (0.3%)	0 (0.0%)
Horseshoe Retinal Tear (a tear in the thin tissue connected to the back part of the eye) ³	1 (0.3%)	1 (0.5%)

¹ 3 cases where the LAL IOL was replaced with another IOL. One of these cases also required removal of the gel-like material that sits in the back chamber of the eye because the natural bag that holds the lens in place was torn during surgery, 1 procedure to treat damage to the transparent front part of the eye, 2 cases where the colored part of the eye was treated to allow the pupil (the black portion in the center of the eye that allows light into the eye) to open for light treatment, and 1 case in which a laser treatment was used to treat a tear in the thin membrane in the back part of the eye. All additional surgical procedures resulted in good vision.

² One patient experienced trauma to the colored part of the eye when the patient began to cough uncontrollably during the cataract surgery. Appropriate treatment was performed by the surgeon at the time of surgery, and the patient completed the study with good vision.

³ One patient was reported at their 9 months visit with a tear in the thin membrane on the back part of their eye. The patient was treated successfully and completed the study with no effect on their vision.

ANSWERS TO SELF-TEST QUESTIONS

1. False
2. True
3. True
4. False
5. False
6. True
7. True

PATIENT ASSISTANCE INFORMATION

PRIMARY DOCTOR

Name:
Address:
Telephone Number:

SURGEON

Name:
Address:
Telephone Number:

LOCATION WHERE TREATMENT WAS DONE

Name:
Address:
Telephone Number:

MANUFACTURER

Sales and Service

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