

# IS LASIK FOR ME?

## A Patient's Guide to Refractive Surgery

October 2008

# IS LASIK FOR ME?

## A Patient's Guide to Refractive Surgery

### TABLE OF CONTENTS

<b>LASIK: A COMPREHENSIVE GUIDE</b> .....	2
Introduction.....	2
What Is LASIK? .....	2
How LASIK Works.....	4
Pre-LASIK Correction Prescription Form .....	5
Risk Factors, Side Effects and Complications of LASIK.....	5
FDA:When Is LASIK Not for Me? .....	6
FDA:What Are the Risks? .....	7
Alternatives to LASIK.....	8
Other Forms of Laser Refractive Surgery .....	8
<b>ADVERTISING GUIDELINES</b> .....	9
Informed Consent .....	9
Testimonials .....	9
Advertising Claims .....	9
<b>AN INTRODUCTION TO INFORMED CONSENT</b> .....	11
OMIC:Aid to Informed Consent Document .....	11
Introduction.....	11
Alternatives to LASIK.....	11
Some Potential Vision-Threatening Complications of LASIK .....	11
Non-Vision-Threatening Side Effects .....	12
For Presbyopic Patients .....	13
Remember: LASIK Is Surgery! .....	13
<b>ACKNOWLEDGEMENTS</b> .....	14
<b>ABOUT THE GUIDE'S CONTRIBUTORS</b> .....	15

# LASIK: A COMPREHENSIVE GUIDE

## Introduction

Is LASIK surgery the right choice for you? LASIK has delighted millions of patients worldwide, but it is not suited for everyone. As a patient, it is important that you have a clear understanding of the surgery, the procedure's advantages and risks, and whether or not you would make a good candidate.

That's why the American Academy of Ophthalmology and the International Society of Refractive Surgery have developed this comprehensive guide on LASIK. It provides objective information from the country's leading LASIK experts, the U.S. Food and Drug Administration (FDA) and the Ophthalmic Mutual Insurance Company.

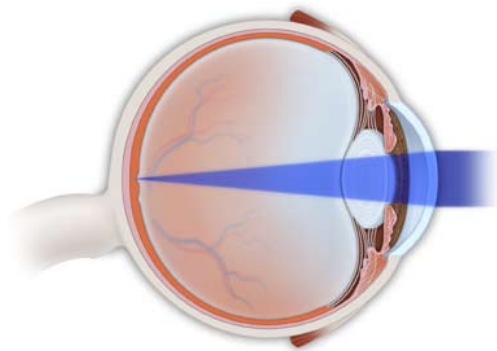
LASIK was first approved for use by the FDA in 1998 and has been gaining steadily in popularity. Each year, approximately 700,000 Americans have the procedure and the vast majority of patients are happy with their results. As with all surgery, however, there are risks associated with the procedure. As a result, some patients have experienced complications or side effects that have negatively affected their eyes and quality of life. The information provided here is intended to help you:

- Understand what LASIK is;
- Be aware of what would make you a good or poor candidate for LASIK;
- Be aware of and understand the possible risks and complications of LASIK;
- Select a surgeon;
- Evaluate LASIK advertising; and
- Become familiar with the Informed Consent process.

## What Is LASIK?

**LASIK (laser in situ keratomileusis)** is an outpatient surgical procedure used to treat nearsightedness, farsightedness, and astigmatism. LASIK cannot reverse presbyopia, the age-related loss of close-up focusing power, which mainly affects near vision.

With LASIK, the ophthalmologist (Eye M.D.) uses a laser to reshape the cornea, which is located at the front of the eye. This improves the way the eye focuses light rays onto the retina, at the back of the eye, allowing for better vision.



With normal vision, light rays focus directly on the retina.

**It is important for anyone considering LASIK to have realistic expectations.**

LASIK allows many people to perform most of their everyday tasks without wearing corrective lenses. However, those hoping to achieve perfect vision and become completely free of the need to wear eyeglasses or contact lenses run the risk of being disappointed. Everyone develops the need to wear reading glasses in their 40s or 50s due to presbyopia. If your vision is fully corrected for distance with LASIK, you will need reading glasses to correct for presbyopia once it has developed. If you are nearsighted and do not yet need reading glasses, having LASIK may mean you will need reading glasses at an earlier age than had you not had laser eye surgery.

If you are having LASIK over the age of 40 and are interested in correcting your presbyopia (i.e., decreasing your dependence upon reading glasses), you may want to consider a strategy called *monovision*. This technique corrects your vision to allow for near or intermediate vision in one eye and distance vision in the other eye. This means that each eye is working independently instead of together. For monovision, your dominant eye — the one you would use to look into the viewfinder of a camera — would become the distance eye and the other would be used for near vision. With this technique, the brain learns to adapt to eyes set to focus at different distances. Not everyone is comfortable with this difference in focus, especially those who spend a lot their time playing sports or do a lot of night driving. However, many people find they adapt well to monovision when they try it out first, using contact lenses, before having LASIK. In fact, many preop LASIK patients over 40 are already using monovision with their contact lenses to decrease their dependence upon reading glasses, and are comfortable with it. Contact lenses are actually the best way to demonstrate monovision before surgery, as they most accurately replicate what the patient will see after surgery. Nevertheless, some patients respond so positively to a “monovision demonstration” with trial frames (spectacles) during the preoperative evaluation that a contact lens trial is not necessary.

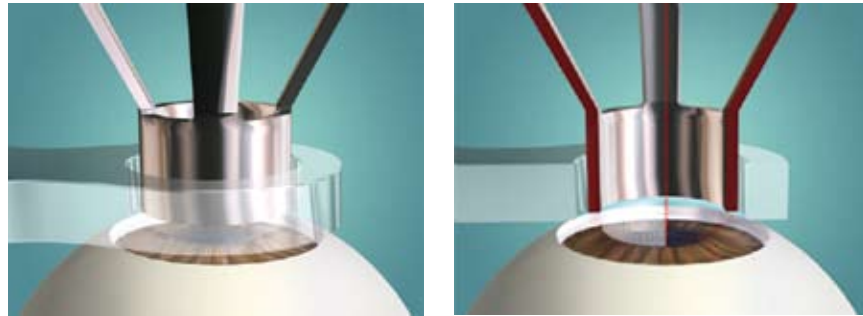
**If 20/20 vision is essential for your job or leisure activities, consider whether 20/40 vision would satisfy you.** More than 90 percent of people who have LASIK achieve somewhere between 20/20 and 20/40 vision without eyeglasses or contact lenses. Also, you would need to be comfortable with the possibility that you might need a second surgery (“retreatment”) in order to attain your desired results, or that you might need to wear glasses for certain activities, such as reading or driving at night. The greater your refractive error (that is, the greater your nearsightedness, farsightedness or astigmatism, or combination of these conditions), the more likely you would require retreatment or glasses.

It is important to discuss your lifestyle, including your work and recreational and leisure activities, with your prospective surgeon before deciding to go ahead with LASIK. Some work, sports and other activities are not compatible with LASIK.

## How LASIK Works

LASIK is performed in an outpatient surgical setting, with the patient reclining under a surgical device called an excimer laser. First, your eye is made numb with a few drops of topical anesthetic. An eyelid holder, called a speculum, is placed between the eyelids to keep them open and prevent you from blinking.

A suction ring placed on your eye lifts and flattens the cornea and prevents your eye from moving. You may feel pressure from the eyelid holder and suction ring, similar to a finger pressed firmly on your eyelid. From the time the suction ring is placed on your eye until it is removed, vision appears dim or goes black.



LASIK with laser making corneal flap

The surgeon then creates a hinged flap of paper-thin corneal tissue using an automated microsurgical device, either a laser or an instrument called a microkeratome blade. The corneal flap is lifted and folded back. The excimer laser, which has been preprogrammed with measurements specifically for your eye, is then centered above your eye. You will look at a special pinpoint of light (called a fixation light or target light) while the laser sculpts the exposed corneal tissue. After the laser has reshaped your cornea, the surgeon replaces the flap in position and smoothes the edges without placing any stitches. Your corneal flap will never adhere to the surface of the eye with quite the same strength it did prior to the surgery, so there is a rare but possible risk of the flap becoming displaced with sufficient force.

After surgery, you should avoid rubbing the eye, which may cause the flap to shift out of place. To help protect the cornea as it heals, the surgeon may place a transparent protective shield over your eye. The shield may only be needed at night to prevent you from rubbing the eye during sleep.



An eye shield worn after LASIK

You should arrange to have someone take you home after the surgery. Taking a nap or simply relaxing for the rest of the day is recommended. Usually your vision will be clear enough to drive to the follow-up visit the next day. The doctor may advise waiting several days before you resume a normal work schedule. The doctor should advise you on how long you should wait before resuming sports, exercise, or strenuous activity.

After LASIK surgery, you will receive eyedrops to help prevent infection and inflammation during the healing process and to alleviate dryness. You must be sure to follow any instructions from your doctor and return for follow-up appointments as directed. Bear in mind that it may take three to six months for vision to stabilize completely.

All LASIK patients should ask their doctors for a record of their pre-LASIK correction prescription. This information is important for you to give to the doctor who may perform a future cataract surgery or other eye disease diagnosis and treatment.

Download a pre-LASIK correction prescription form at [www.aao.org/upload/KCardfinal.pdf](http://www.aao.org/upload/KCardfinal.pdf).

Have your doctor fill out this form, and save it for future reference.

### **Risk Factors, Side Effects and Complications of LASIK**

LASIK, like any surgery, has potential risks, complications, and side effects that should all be carefully considered before you decide to have surgery. Be sure to discuss these, along with any other concerns, with your Eye M.D.

## Risk Factors

The main risk factors that might affect whether LASIK would be appropriate for you are:

- ✦ **DRY EYE SYNDROME.** If dry eye is left untreated prior to surgery, patients may be disappointed with their LASIK results. If dry eye is diagnosed and adequately treated before surgery, you will have the same chance of a successful outcome as a patient without pre-existing dry eye. If you have very severe dry eye, however, it might disqualify you as a candidate for the surgery. You are more likely to have dry eye if you are older, especially if you are a woman after menopause. You are also more likely to have dry eye if you have an immune system disorder, or if you are taking hormone replacement therapy or other medications with dry eye as a side effect, such as anti-depressants or certain blood pressure-lowering medications. **You should be screened for dry eye before you have LASIK or other refractive surgery.**
- ✦ **LARGE PUPIL SIZE,** as evaluated in the pre-LASIK exam, has been thought to be a factor in undesirable side effects such as “glare” and “halos,” but there are conflicting reports about the relationship between pupil size in low light and these disturbing visual symptoms. There is a risk of night vision problems after LASIK, irrespective of pupil size.
- ✦ **KERATOCONUS,** a degenerative corneal condition, or a family history of this disorder. Your Eye M.D. should check you for this condition before surgery.
- ✦ **THIN CORNEAS.** Patients with thin corneas may not be good candidates for LASIK but may be considered for other forms of refractive surgery. Your Eye M.D. should check the thickness of your cornea before surgery.
- ✦ **DEGREE OF REFRACTIVE ERROR.** Very high levels of refractive error (nearsightedness, farsightedness, astigmatism, or certain combinations of these errors) may not be compatible with LASIK. In addition, if your correction prescription has not remained the same for about a year, your vision may not be stable enough to make you a good LASIK candidate.
- ✦ **AGE.** The ideal LASIK patient is over 21 years of age, since the refractive error is more likely to be changing below this age. Some patients over the age of 21 are still experiencing change in refractive error making them unsuitable for LASIK. Your Eye M.D. should confirm stability of your refractive error before considering LASIK.
- ✦ **PREGNANCY.** If you are pregnant or nursing, you are not a good candidate for LASIK, because your refractive error may fluctuate.
- ✦ **OTHER CONDITIONS.** A number of other general health conditions and less-common eye conditions or injuries may affect whether a person is a good candidate for LASIK. Be certain you and your surgeon review your medical and eye health history, current health status and medications during the pre-LASIK exam.

For information from the FDA about risk factors for LASIK, see the “When is LASIK not for me?” section of FDA’s LASIK Web site at [www.fda.gov/cdrh/lasik/when.htm](http://www.fda.gov/cdrh/lasik/when.htm).

## Complications and Side Effects

LASIK has been performed on millions of patients in the United States in the past 10 years, and the overall rate of severe complications is low. Most LASIK complications can be treated without any loss of vision, but vision loss may rarely occur.

- ✦ **INFLAMMATION AND INFECTION** are possibilities with any surgical procedure. These can usually be cleared up with medications, but rarely may lead to the need for another surgical procedure or to the loss of vision.
- ✦ **PROBLEMS WITH THE CORNEAL FLAP** sometimes require further treatment, which might include additional surgery.
- ✦ **ECTASIA, OR BULGING OF THE CORNEA**, may require further treatment.
- ✦ There is a chance, though small, that a LASIK patient's vision will not be as good after the surgery as it was before, even with glasses or contact lenses. The patient may have **significantly reduced vision** (usually correctable by treatment and/or wearing corrective lenses) **or permanent loss of vision** (extremely rare).
- ✦ **OVER-OR UNDER-CORRECTION** of the patient's refractive error, or a **reduction in the refractive correction over time**, could mean that the person might still need to wear corrective lenses for some or all activities, or need a retreatment with LASIK or another, similar refractive surgery to achieve the patient's desired results.

Below is a list of the more common side effects and possible complications of LASIK. In most cases, these side effects disappear within three to six months after the surgery. In a minority of patients, these problems may be permanent:

- ✦ Discomfort or pain
- ✦ Sensations of scratchiness or dryness, which are symptoms of "dry eye"
- ✦ Hazy or blurry vision
- ✦ Poor night vision and/or difficulty driving at night
- ✦ Glare, halos or starbursts around lights
- ✦ Sensitivity to light
- ✦ Reduced sharpness of vision called "contrast sensitivity"
- ✦ Small pink or red patches on the white of the eye

For information from the FDA about complications of LASIK, see the "What are the risks?" section of FDA's LASIK Web site at [www.fda.gov/cdrh/lasik/risks.htm](http://www.fda.gov/cdrh/lasik/risks.htm).



## **Alternatives to LASIK**

There are several alternatives to LASIK for correcting your vision. Eyeglasses and contact lenses are the most common methods of correcting refractive errors. They work by refocusing light rays on the retina, compensating for the shape of the eye and cornea. You should discuss your vision status, goals and lifestyle with your Eye M.D., who will help you weigh the risks and benefits and decide which of these options would be the best choice for you.

## **Other Forms of Laser Refractive Surgery**

Some forms of laser refractive surgery do not require the creation of a corneal flap. These include photorefractive keratectomy (PRK), Epi-LASIK and laser-assisted epithelial keratomileusis (LASEK), in which the surgeon uses the laser to sculpt the cornea without creating a corneal flap. There are advantages and disadvantages to each of these, which you should discuss with the refractive surgeon.

## ADVERTISING GUIDELINES

You've likely seen and heard LASIK advertisements. The American Academy of Ophthalmology encourages its members to follow its ethical guidelines for refractive surgery advertising, which are summarized below. These were developed with the help of the Federal Trade Commission and the American Society of Cataract and Refractive Surgery. For the complete guidelines, see:

[www.aao.org/about/policy/upload/Guidelines-for-Refractive-Surgery-Advertising-3-26-04.pdf](http://www.aao.org/about/policy/upload/Guidelines-for-Refractive-Surgery-Advertising-3-26-04.pdf).

### Informed Consent

Because of space and time limitations, advertising cannot include all of the elements of appropriate informed consent disclosures. Do not depend on advertising as a way to understand all the risks and benefits of any surgical procedure.

### Testimonials

Because of the difficulty in supporting claims made by patients who have had the surgery, some states prohibit the use of patient testimonials by physicians. There is no certainty that your results will be comparable to those of any other patient.

### Advertising Claims

Patients have differing needs and expectations and may experience different surgical outcomes. Accordingly, advertising claims are not a substitute for discussions between you and the surgeon regarding your particular needs and expectations and the range of possible outcomes.

#### **Be wary of the following types of claims:**

**“Throw away your glasses!”** LASIK may correct your farsightedness, nearsightedness or astigmatism, and it may allow you to function without eyeglasses or contact lenses for many activities; however, there is no certainty that you will be permanently free from wearing any eyeglasses or contact lenses following LASIK. LASIK cannot correct presbyopia, the age-related loss of close-up focusing power, and by age 40 or 50, many people, even those who have had LASIK, will need to wear reading glasses.

**“This laser is ranked highest by the FDA.”** The Food and Drug Administration does not rate devices comparatively.

**“We use a scanning laser so that you get the best results.”** Although there may be potential advantages to using a scanning laser, that does not guarantee you a better result.

**“Our (LASIK) surgeons are more experienced than any of their colleagues in (state, city, region).”** Claims of this kind would require reliable, current evidence of the number of LASIK procedures performed by each refractive surgeon in the claimed region, which would be quite difficult to obtain.

**“Find out more about LASIK — the safe and easy alternative to glasses!”**

Generally, it is not appropriate for an advertisement to state that surgery is safe or easy. All surgery has risks. You should discuss the possible risks and side effects of LASIK with your surgeon during your consultation.

**“Unlike other procedures, PRK (LTK, LASEK, “bladeless” LASIK) laser vision correction doesn’t involve knives or cuts to the eye.”** This type of claim downplays the fact that all these procedures are surgeries with risks. Don’t let the use of such words as “treatment,” “therapy,” “vision correction,” or “enhancement” fool you into thinking that laser refractive surgery is anything other than a surgical procedure. Laser procedures are, in fact, surgeries.

**“Achieve permanent vision correction with refractive surgery!”** Not everyone achieves a stable refraction after surgery, and everyone experiences gradual changes in their vision over time due to the normal aging process.

**“Visit the Smith Laser Center and leave with 20/20 vision!”** Results cannot be guaranteed.

**“LASIK surgery is a safe and painless procedure.”** Patients undergoing refractive surgery typically experience some pain and discomfort for a short time following surgery, and, for a rare few patients, these may persist.

## AN INTRODUCTION TO INFORMED CONSENT

The following brief summary of an Informed Consent document developed by the Ophthalmic Mutual Insurance Company (OMIC) indicates many of the possible complications and risks of LASIK and is presented to you here as an example of what you might see on the Informed Consent document you may be asked to sign before having LASIK surgery. Your surgeon will ask you to read and sign a consent form before surgery. This step is required by law to make sure you understand all possible risks and complications of the surgery. It should be read carefully before surgery and if questions arise, talk with your surgeon. For the complete document, see:

[www.omic.com/resources/risk\\_man/forms/consent/  
LASIKconsent071906.rtf](http://www.omic.com/resources/risk_man/forms/consent/LASIKconsent071906.rtf)

### Sample Informed Consent

#### INTRODUCTION

This information is being provided to you so that you can make an informed decision about the use of a device known as a microkeratome, combined with the use of a device known as an excimer laser, to perform LASIK refractive surgery. LASIK is one of a number of options for correcting nearsightedness, farsightedness and astigmatism. For LASIK, the surgeon uses the microkeratome to shave a thin layer of the cornea to create a tiny flap. The flap is opened like the page of a book, exposing tissue just below the cornea's surface. Next, the surgeon uses the excimer laser to remove ultra-thin layers from the cornea to reshape it in order to reduce nearsightedness. Finally, the flap is returned to its original position, without the need for any sutures.

LASIK is an elective procedure. There is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or eyeglasses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur. Should complications arise in your case, they might affect the outcome of your surgery even to the extent of making your vision worse after LASIK than before.

#### ALTERNATIVES TO LASIK

If you decide not to have LASIK, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. These alternatives include, among others, eyeglasses, contact lenses and other refractive surgical procedures.

#### SOME POTENTIAL VISION-THREATENING COMPLICATIONS OF LASIK

I understand that:

1. The microkeratome or the excimer laser could malfunction, requiring the procedure to be stopped or could result in a distorted cornea, and glasses or contact lenses may not correct my vision to the level possible before LASIK; a perforation of the cornea could occur, causing loss of some or all of my vision;
2. An eye infection that could not be controlled with antibiotics or other means could lead to permanent scarring and loss of vision or require corrective additional surgery or, if very severe, corneal transplantation or even loss of the eye;

3. Keratoconus, a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population could develop;
4. Other very rare complications threatening vision could occur. These include, but are not limited to, corneal swelling, corneal thinning (ectasia), appearance of “floaters” and retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

#### **NON-VISION-THREATENING SIDE EFFECTS**

I understand that these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent requiring chronic care or additional surgery:

1. Increased sensitivity to light, glare, and fluctuations in the sharpness of vision; eye irritation related to drying of the corneal surface; overcorrection or under correction causing nearsightedness or increase in astigmatism and that this could be either permanent or treatable;
2. Glare, a “starbursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent.
3. Inadequate correction from LASIK procedure that may require future enhancement procedures, such as more laser treatment or the use of glasses or contact lenses even years after the surgery.
4. There may be a “balance” problem between my two eyes after LASIK has been performed on one eye but not the other, which could cause eyestrain and make judging distance or depth perception more difficult.
5. The corneal incision will not be as strong as the cornea originally was at that site and the treated eye may be more vulnerable to all varieties of injuries, at least for the first year following LASIK. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.
6. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.
7. I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
8. The long-term effects of LASIK are unknown and that unforeseen complications or side effects could possibly occur.

9. Even 90 percent clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. If the enhancement is performed within the first six months following surgery, there generally is no need to make another cut with the microkeratome. The original flap can usually be lifted with specialized techniques. After six months of healing, a new LASIK incision may be required, incurring greater risk. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform an enhancement. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.
10. As with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

**FOR PRESBYOPIC PATIENTS**

For those patients requiring a separate prescription for reading: The option of monovision has been discussed with my ophthalmologist.

**REMEMBER: LASIK IS SURGERY!**

There are millions of satisfied and delighted patients who have undergone LASIK successfully and who are enjoying its many benefits. However, there are some who have experienced side effects or complications that have had a serious, negative impact on their lives. Use the information provided here to help you evaluate your expectations of LASIK, select the right surgeon, and discuss your candidacy along with the risks and benefits with your doctor before making a decision about LASIK. An informed patient is a better, more satisfied patient.

## ACKNOWLEDGEMENTS

The American Academy of Ophthalmology thanks the following individuals and organizations for their help in developing this guide:

**RICHARD ABBOTT, MD**, Secretary of Quality of Care and Knowledge Base Development, American Academy of Ophthalmology

**DANIEL S. DURRIE, MD**

**FLORA LUM, MD**, Policy Director of Quality of Care and Knowledge Base Development, American Academy of Ophthalmology

**MARGUERITE MCDONALD, MD**, President of the International Society of Refractive Surgery of the American Academy of Ophthalmology

**JAMES J. SALZ, MD**

**PAUL WEBER**, Vice President, Ophthalmic Mutual Insurance Company

## ABOUT THE GUIDE'S CONTRIBUTORS

### **AMERICAN ACADEMY OF OPHTHALMOLOGY**

The American Academy of Ophthalmology is the world's largest association of eye physicians and surgeons—Eye M.D.s—with more than 27,000 members worldwide. Eye health care is provided by the three “O’s” – opticians, optometrists and ophthalmologists. It is the ophthalmologist, or Eye M.D., who can treat it all: eye diseases and injuries, and perform eye surgery. To find an Eye M.D. in your area, visit the Academy's Web site at [www.aao.org](http://www.aao.org).

### **INTERNATIONAL SOCIETY OF REFRACTIVE SURGERY (ISRS)**

The International Society of Refractive Surgery of the American Academy of Ophthalmology is the world's largest and strongest eye care organization solely dedicated to refractive surgery. It has a strong international presence, with over 2,300 members from more than 80 different countries.

### **OPHTHALMIC MUTUAL INSURANCE COMPANY (OMIC)**

The Ophthalmic Mutual Insurance Company is the largest provider of professional liability insurance for ophthalmologists in the United States. It is the only insurance carrier endorsed by 25 ophthalmic specialty organizations—including the American Academy of Ophthalmology—for their members.