

Equipment and device issues in malpractice claims

ANNE M. MENKE, RN, PHD, OMIC Patient Safety Manager

Ophthalmologists regularly use equipment and medical devices (EMDs) while caring for their patients. Sometimes, things go wrong. Injured patients may allege that an EMD malfunctioned or was used improperly. They may sue the ophthalmologist, the surgery center, and the manufacturer of the EMD. This issue of the Digest will use select closed claims to illustrate the initial steps the ophthalmologist, staff, and surgery center should take to manage these EMD events. The claims have been chosen for their instructive value even if the EMD is no longer in use or has been redesigned or retired.

Step 1. CARE for the patient

When malfunctioning equipment injures a patient, the first step is always to mitigate the harm and preserve

vision, as the following cases illustrate. In one OMIC claim, an eye surgeon had just installed viscoelastic in the patient's eye prior to cataract surgery when the technician informed him that she could not calibrate the phacoemulsification machine. It had worked normally during the prior three cases. The surgeon decided to stop the procedure, and began to wash out the viscoelastic. He rescheduled the surgery for two days later, and asked the patient to return to his office the next day. She did not, and he made no attempt to contact her. (The investigation showed that the patient had not been informed at discharge of the office appointment). He proceeded with the surgery the following day, even though the cornea was swollen. Postoperatively, the patient developed severe corneal edema and needed a

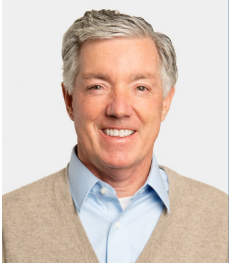
corneal transplant. Both defense and plaintiff experts criticized the ophthalmologist's care right after the first surgery. They felt he needed to ensure that all the viscoelastic had been removed, and measure the IOP. They also faulted his failure to measure the IOP before performing the procedure a second time. The case settled for \$175,000.

In another case, a patient was scheduled for bilateral laser eye surgery. Before beginning the procedure on the first eye, a technician informed the surgeon that the microkeratome was off-track, but the surgeon opted to proceed anyway. When the microkeratome jammed, he manually pushed it (instead of reversing per the instructions in the manual), creating a free, shallow flap that required additional surgery. The ophthalmologist later testified that he did the procedure on the second eye at the patient's request, and achieved the desired outcome. A defense expert and all three members of the medical review panel criticized him for proceeding with the first surgery without evaluating the microkeratome, and for continuing the surgeries after the complication. The case settled for \$95,000.

Step 2. PRESERVE the evidence

Determining the cause of an EMD malfunction is crucial to the safety of subsequent patients, and to the ophthalmologist's defense. Sometimes, the EMD may need to be sequestered until the facility and manufacturer can test it. Other times,

MESSAGE FROM THE CHAIR



DANIEL BRICELAND, MD, OMIC Board of Directors

During a recent busy clinic day my entire EMR system suddenly crashed, leaving our staff scrambling to cope with the loss of access to our records. A brief flash, screens flickered, then an ominous dialogue box warned about potential data loss. The chaos that followed, with patients backing up as we managed through various treatment and documentation issues, was a reminder to me that technology presents an entirely new risk to my practice and my patients.

In the days that followed I would learn of similar disruptive events from colleagues, and even within massive hospital networks, where software glitches brought entire systems down and arguably threatened patient safety. In many instances, back-up procedures proved woefully inadequate.

Because technology is central to our practice of ophthalmology, it is only a matter of time until an unanticipated event happens to each of us. This could be at the most inopportune moment, perhaps in the midst of a busy clinic as happened to me, or even worse during a surgical procedure, potentially causing serious injury to a patient.



OMIC forms partnerships with private equity organizations

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Although the vast majority of OMIC's physician policyholders are not currently employed by practices owned and operated by private equity (PE) groups, we recognize this is an emerging trend in entity ownership within the ophthalmic community.

While it is impossible to fully understand how these organizations will impact the future of ophthalmic practice, we have engaged with PE stakeholders, demonstrating how OMIC is the best choice for their coverage needs as well as risk management advice and consultation.

To date, OMIC has partial or exclusive partnerships with seven PE organizations. We encourage you to contact us early in the process if your practice is considering being acquired by a PE entity. We will then be able to advocate for the continuation of your OMIC coverage.

Streamlined process

OMIC has initiated a series of changes to our processes to improve efficiencies and reduce workload for insureds. Underwriters will ask for renewal applications to be completed less

MESSAGE FROM THE CHAIR

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While we all understand the opportunities medical technology provides to our ever-expanding treatment options for patients, we also must recognize that technology may present frustrations to staff and risks to patients.

When my EMR system went down, it brought back memories of my paper charts and how I was able to adequately evaluate and manage my patients' complex problems without relying on software that could be compromised or unavailable during the course of treatment.

As bad as the system failure seemed at the time, it forced my staff and me to adapt and prioritize what was best for each of my patients until the records returned.

Ultimately, we saw the temporary loss of our EMR system as a learning experience that would make us more efficient in managing unanticipated events going forward. We implemented new protocols so that the next time it happens we will be better prepared to transition to back-up procedures and manual processes. We no longer fear

frequently. Some applications and coverage questionnaires have been eliminated. Others have been significantly shortened and consolidated. We ask that insureds proactively inform OMIC of practice changes in a timely manner to assist us in ensuring your coverage is up-to-date and accurate.

Planned coverage enhancements for higher limit cyber coverage

Since the late 1990s, OMIC has provided a comprehensive collection of benefits within its professional liability policy (on top of the insured's limit of liability) for regulatory and cyber events. Insureds may visit the OMIC web site at www.omic.com/policyholder/benefits to learn more about these coverages. There is a maximum \$100,000 limit for these benefits, per insured, each policy year.

Beginning in late 2020, insureds who purchase or renew higher limits for this regulatory and cyber coverage will see several coverage enhancements. More information about these changes will be disseminated in the coming months.

that a software glitch or power surge might result in a complete shutdown of our patient care.

In this *Digest* we examine equipment and medical device (EMD) malfunctions and misuse. Some of the issues and concerns arising from EMD events are similar to my EMR experience and some present new and unique challenges. The important takeaways for handling almost any unanticipated event is to (1) implement protocols and procedures ahead of time whenever possible so that staff is prepared when they happen, and (2) follow the advice from OMIC's risk management experts in order to mitigate the risks of lawsuits after events occur.

As we adopt new technologies we will rely on our team of technicians, nurses, and managers to ensure equipment is calibrated and maintained properly. We must train our staff to handle systems failures calmly and appropriately so that patients have confidence that their best interest and safety are our first priorities.

Coverage When Machines Malfunction

KIMBERLY K. WYNKOOP, ESQ, OMIC General Counsel

The articles in this issue of the Digest explore equipment malfunction and patient injury - how to prevent it, what to do when it occurs, and professional liability claims that may result. Here we will look at how your OMIC policy covers you in such an event.

OMIC's policy covers insureds for injury to a patient because of an act or error in their provision of direct patient treatment (i.e., direct liability) or direct patient treatment by someone for whom they are legally responsible (i.e., vicarious liability). An example is the case from the lead article where the patient was burned due to the insured physician igniting the drape with the cautery tip. This was user error, and is plainly covered under the OMIC medical professional liability insurance policy.

Sometimes the patient alleges both that the equipment was defective and that it was used improperly. OMIC's policy specifically does not cover the defense of or pay any damages due to claims based on the manufacturing or assembling of a medical device. That is the responsibility of the device manufacturer, which should have its own insurance for just such claims. If medical negligence and products liability are both alleged against an insured, OMIC would defend the claim, but would reserve its right not to pay any damages due to products liability. This might occur where the cause of the injury is less clear, such as in the phaco disconnection claims described in the Lead article.

The OMIC policy covers named ophthalmologists, named business entities like ASCs, named ODs and CRNAs, and the insured ophthalmologists' and entities' non-physician employees. While ophthalmologists are subject to direct liability for their errors in equipment usage, they also may be

held vicariously liable for the actions of others. OMIC's policy covers both. Vicarious liability could be due to employer liability, where the employer is legally responsible for the acts of its employees; captain of the ship theory (the doctor is the "captain" during a medical procedure so any mistakes by other providers in the care group are ultimately the captain's responsibility); or, a similar theory where the physician is legally responsible for the actions of persons under his or her "direction or control." Although the techs in the loose microkeratome case of the Closed Claim Study were not the ophthalmologist's employees, under the captain of the ship theory, the ophthalmologist was considered the person with the greatest responsibility for the various parties' actions.

Likewise, OMIC's policy covers non-physician employees for their direct and vicarious liability in equipment-related claims. As discussed in the Risk Reduction Strategies article, technicians may be found liable for improperly setting up phaco and vitrectomy machines, programming lasers, or preparing gas for retina procedures. Their limits of liability are almost always shared with the employing ophthalmologist or entity (who is generally vicariously liable for the employees' actions).

Entity liability arises from several avenues in equipment claims, all of which OMIC cover. First, the entity (or its directors, officers, or other members) can be held directly liable for the hiring and training of employees and credentialing of utilizers. Entities can also be held vicariously liable for the actions of their employees and others for whom they are legally responsible. In the loose microkeratome claim, the ASC contributed to the settlement, likely due to its direct liability for hiring and training the employed technicians

and possibly the credentialing of the ophthalmologist utilizer, in addition to its vicarious liability as the techs' employer.

Entities may also be directly liable for improperly maintaining and calibrating equipment. In the Lead Article's LASIK calibration claim, the claim was settled on the ASC's behalf because it was determined that the ASC's tech had improperly calibrated the laser, making it off-center for a number of procedures.

When claims against OMIC insureds are clearly products liability cases, OMIC will work to get the ophthalmologist, ancillary staff, and entity dismissed from a suit that should be against the manufacturer alone. For example, both the Lead article's scleral burn from phaco and fiberoptic burnout cases were determined to be manufacturer issues and the OMIC insureds bore no liability. Other times, it takes settlement by various defendants to close a claim, such as the case with the extra piece of plastic on the phaco sleeve, which was settled by the manufacturer and ASC, while the physician was dismissed.

These cases can be complicated and often include both covered and uncovered allegations. While OMIC has a responsibility to its member-owners to reserve its rights in these situations, we work hard to defend the claim, cover our insureds where they are responsible, and appropriately shift liability when it lies elsewhere. If you lease equipment to other providers, see the articles on liability and coverage titled "Equipment Leasing Liability" and "Leasing Equipment, Space, or Employees" at www.omic.com.

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the “evidence” may be the settings on the equipment, which can be captured with a cellphone camera.

In one OMIC claim, during cataract surgery, the syringe separated from the cannula and entered the posterior chamber, rupturing the posterior capsule. The surgeon did not instruct the nurse to save the syringe and cannula, so no testing was done. The plaintiff attorney alleged operator error, which could not be refuted without the inspection. Fortunately for the insured, the medical panel ruled in his favor, and the case was dismissed.

A careful analysis of equipment after an adverse event can help answer questions about it for both the patient and the physician. An ophthalmologist was excising a papilloma from a 9-year-old child’s cheek using a battery-operated cautery unit. The cautery ignited the drape and burned the patient. The ophthalmologist instructed the nurse to preserve the drape. It showed a tiny burn mark in the exact shape of the cautery tip where the flames started. The team tried to recreate the event, and determined that the only way to ignite the drape was for the cautery tip to touch it. Once the cause was clear, the ophthalmologist disclosed it to the parents. The child’s burns healed without scars; the case settled on behalf of the physician for \$10,000.

Step 3. DISCLOSE the unanticipated outcome

Patients often lose trust in their ophthalmologist after an adverse event. Informing the patient about an unanticipated outcome as soon as possible can begin to rebuild an effective physician/patient relationship.

In one OMIC claim, the iris became incarcerated in the phaco tip during cataract surgery. The tip did not release when the ophthalmologist tried to stop the suction using the foot pedal. The iris was pulled from its root, causing an iridodialysis. While the ophthalmologist informed the patient of the iris injury, he did not

disclose the presence of retained cortex. Instead, the patient learned of it when she sought care from another ophthalmologist, and became very angry that she had not been told. The plaintiff attorney alleged fraudulent concealment. The physician had documented both the intraoperative complication and the presence of retained cortex. The records thus refuted the concealment allegation. Experts supported the care, so the case was dismissed.

An honest discussion may not always prevent a lawsuit, but may facilitate the management of a claim, as the following case shows. An ophthalmologist opened the tray for an Avastin injection, and noticed there was no lid speculum. A staff member brought one from the autoclave. It felt cool to the touch but the patient immediately called out in pain when it was inserted. She sustained burns on her eyelid and cornea. When she later developed an ectropion that needed surgical repair, she contacted an attorney. The plaintiff attorney acknowledged that the ophthalmologist had clearly explained the error. OMIC was able to quickly settle the case for \$15,000.

Step 4. DOCUMENT in medical record and incident report

When a patient is injured by an EMD event, the medical record becomes the main evidence plaintiff attorneys and medical experts review in order to determine if any of the care was negligent. As the following case shows, incomplete or untimely documentation can hinder the ophthalmologist’s defense.

When a phaco cannula disconnected and was injected into a patient’s eye during wound irrigation, the posterior capsule ruptured. As was his typical practice, the ophthalmologist waited 13 days to dictate his operative report. The plaintiff attorney challenged its veracity and alleged fraudulent concealment since there was no record of any

disclosure discussion with the patient. The ophthalmologist remembered writing about the discussion in the EHR. Review of the EHR showed that he had never pressed “enter,” so the documentation never became part of the official record. Fortunately, the EHR saved a draft of what he had written, and the allegation was successfully refuted. The plaintiff attorney had not filed the claim properly, and did not address the deficiencies before the expiration of the statute of limitations, so the claim closed without payment.

In another cataract procedure, the phaco became blocked, so the surgeon asked for a new sleeve. The patient appeared to sustain a corneal burn, so the physician inspected the sleeve and found an extra piece of plastic. He disclosed the problem to the patient, and asked that the piece of plastic be sent to the manufacturer. He wrote a very detailed operative note—but not until three weeks later.

The patient sued the surgeon, surgery center, and device manufacturer. The plaintiff attorney alleged that the late operative note was designed to protect the physician. The defense was further complicated when the sworn testimony of the physician, nurse, and scrub tech differed, making it difficult to determine the sequence of events. Defense experts supported the physician’s care, and a biomedical expert determined that the incident was caused by a manufacturing defect. Despite the delayed documentation, the physician was dismissed from the case, while the ASC paid \$15,000 and the manufacturer paid \$35,000.

In other cases, the surgeon did not always confirm with the nurse that an incident report would be completed. It is this form that prompts an investigation process that can help determine liability, and ensure that the equipment is either properly repaired or retired. For more advice on documentation and incident reports, see the “Responding” advice mentioned at the end of this article.

Step 5. REPORT when and if required

EMD manufacturers are required to report adverse events to the Food and Drug Administration. They rely upon physicians and others who use these EMDs to let them know when problems occur. These reports play a vital role in EMD lawsuits, especially in determining whether the cause was the EMD or operator error.

In one OMIC cataract suit, a patient sustained a scleral burn from a phaco machine and experienced CF vision and 5 diopters of astigmatism for one month after. The ASC reported the incident to the manufacturer. It in turn conducted a survey of other clients and learned that this problem had occurred a number of times. The manufacturer settled the claim for an undisclosed amount, and the physician was dismissed without payment.

Completing and saving reports as required can at times lead to quick dismissals of malpractice claims. In another case, an ophthalmologist tried to slowly increase the power of the laser used in a PRP procedure. When it became clear that the machine would not work, he stopped the procedure before any laser energy had been applied. The ASC sent the laser back to the manufacturer, who determined that the fiber optic had burned out. The laser was repaired, and the ASC kept the paperwork. When a disgruntled former employee convinced the patient to sue the physician, this paperwork showed that the problem was not caused by the surgeon, and the claim closed without a payment.

Sometimes a manufacturer's inspection concludes that an event was caused by operator error, not malfunction, as this LASIK claim shows. A surgeon performed three subsequent LASIK procedures. During the third procedure, he noted that the laser was off-center and stopped the procedure. He asked the technician who had calibrated

the machine to report the problem to the manufacturer, who was under contract to do all maintenance. When he examined the first two patients the next day, he noted that their ablations were off-center as well, causing significant visual problems that required additional surgeries. After inspecting and testing the laser, the manufacturer informed the ASC that there were no problems with

fully heal for an entire year. When the manufacturer of the OCT reviewed the intraoperative data, it became clear that the anterior chamber and iris had not been visualized on OCT, and that the ophthalmologist had fired the laser without noting the absence of these crucial anatomical marks. Experts and the device manufacturer criticized him for not stopping and re-docking the laser. The case settled for \$237,500.



centration, although other unrelated repairs were made. Defense and plaintiff experts then focused on the technician, and concluded that she had not properly calibrated the machine. The manufacturer and ophthalmologist were dismissed from the case; the ASC settled on behalf of the technician for \$300,000. Another case involved a femtosecond laser and intraoperative OCT to guide the placement of the incisions during a premium IOL cataract case. The patient had an unexpected circular incision in the cornea, which did not

These lawsuits illustrate that when EMD events occur, swift care, preservation of evidence, and effective communication and documentation may result in the best outcome for the patient and prevent or minimize claims. For more details, see "Responding to Unanticipated Outcomes" at www.omic.com.



CLOSED CLAIM STUDY

Equipment Malfunction or Improper Set Up of a Surgical Device?

RYAN M. BUCSI, OMIC Vice President, Claims

Allegation

Failure to inspect microkeratome prior to LASIK resulting in corneal laceration and the need for a corneal transplant OD.

Disposition

OMIC paid \$450K to settle this case while the manufacturer paid \$250K and the surgery center contributed \$50K for a total settlement of \$750K.

A 51-year-old male patient presented to the OMIC insured's practice for consideration of LASIK and was subsequently scheduled for the procedure. Our insured physician's first encounter with the patient was on the day of the surgery. The procedure was complicated when the blade of the microkeratome entered the anterior chamber of the right eye, causing a corneal laceration. The insured recognized the complication and placed four sutures in an attempt to repair the injury.

Following this unanticipated event, the microkeratome was inspected and the blade was found to be loose. The insured contacted the manufacturer and was informed that two other similar occurrences had been previously reported. The insured examined the patient post-operatively on numerous occasions. On the last examination, the visual acuity was 20/50 OD with the development of folds underneath the healing cornea.

The patient eventually sought care with another corneal specialist who performed a corneal transplant, which was marginally successful. In the lawsuit, the plaintiff claimed that the procedure caused disfigurement, as well as pain and suffering. The plaintiff also alleged that he had to retire early since his vision did not allow him to see clearly enough to perform his tasks. As a result of this early retirement, there was a substantial wage loss claim of \$700,000.

Analysis

Our insured and two technicians employed by the surgery center testified that they used appropriate measures to assemble the microkeratome, including securing the blade in the holder and checking the security of the blade. They did not know how the blade came loose during the procedure and entered the anterior chamber of the eye. Despite this testimony about carefully checking the blade prior to the procedure, the defense was not able to provide an explanation as to how an initially tight blade became loose.

There was no dispute that the blade caused the patient's injury and led to the need for a corneal transplant. We found an expert who had the exact same complication and was willing to testify that there was a design flaw that could have been corrected easily by the

manufacturer. Specifically, he testified that the blade was probably overtightened and that the manufacturer should have provided wedges to prevent any possibility of the blade loosening or being overtightened. While trying to be supportive, this expert's explanation did put some blame on the insured for overtightening the screw.

A second expert for the defense pointed out that the insured continued to use the same microkeratome, without complication, after the problem with this patient. This gave the appearance that the insured was simply not paying as close attention as he should have on the date of the surgery with this patient. This expert felt all the other care provided by the insured met the standard.

The plaintiff attorney's position was that the OMIC insured was the "captain of the ship" and that it was his duty to ensure that the equipment was properly assembled before the procedure. He also sued the manufacturer, alleging that the device was defectively designed. Our evaluation determined that we would likely lose this case if it was tried in front of a jury, so a settlement was negotiated.

Takeaway

This was a "perfect storm" for the plaintiff: the equipment had inherent design flaws that complicated the insured's and the technician's set up of the microkeratome, making both the manufacturer and the ophthalmologist liable for the harm.

The responsibility to make sure that surgical equipment is functioning properly prior to surgery is the responsibility of the surgery center and the ophthalmologist. However, the ophthalmologist is the individual who actually performs the procedure so the lion's share of the liability will often fall on the surgeon's shoulders if the equipment causes a serious complication.

Ensure safe use of equipment

ANNE M. MENKE, RN, PHD, OMIC Patient Safety Manager

The lead article provided detailed advice on what to do if equipment or a medical device (EMD) malfunctions and harms a patient. This article will focus on identifying opportunities for ensuring safe use of EMDs, drawing upon opinions voiced by defense and plaintiff experts in EMD lawsuits.

The experts agreed that the owner of ophthalmic EMDs is responsible for maintaining them, and physicians may rely upon facility staff to verify that instruments have been properly sterilized. But there were differing opinions on the following questions:

Who is responsible for correctly assembling devices and testing equipment prior to each surgical procedure?

How much of that assembling and testing must be directly verified by the ophthalmologist?

To prevent operator error, what are the best strategies for training and verifying competency when new equipment arrives, or when new surgeons or staff members are added?

There are so many types of EMDs, and the physicians and staff who use them vary greatly in their skill and expertise. There is thus no “one size fits all” set of recommendations. Instead, here are some additional claims that highlight the problems and suggest ways to approach oversight of EMD use.

New EMDs, inexperienced users

In one OMIC claim, a young ophthalmologist was using a new viscoelastic for the first time. When it caused a flow problem in the phaco cannula, the patient sustained a corneal burn. The risks

of this viscoelastic were known, and measures had been put in place to prevent such a problem. Ophthalmologists knew they had to be certified on its use before it could be shipped and used, and this certification had to be verified, per written policy, by both the shipper and the hospital. All three failed to implement these safeguards.

In another case, a hospital acquired a laser that could perform both YAG capsulotomies and SLT treatment for glaucoma. The facility did not alert all users that the surgeon had to choose one mode or the other when operating the laser. The user in this case failed to select a mode and a patient’s retina was permanently damaged.

To prevent such events, ask medical staff leaders to identify equipment that must not be used until training and competency are verified and ensure that all physicians and staff know which EMDs are on the list and who has completed the required training.

Setting up and testing equipment

Technicians or nurses are responsible for setting up equipment such as phaco and vitrectomy machines, and for conducting tests to ensure that they work. Experts agreed that staff members should be held liable if they do not inform the surgeon of calibration problems, alarms that sound, or other issues encountered during set up, and a patient is injured as a result.

A significant number of OMIC’s EMD claims involved irrigation systems that stopped working, or cannulas that came apart. Experts disagreed on whether ophthalmologists themselves needed to verify that this equipment was set up properly and in working order and how extensive that verification

process needed to be. They all testified that they personally confirm that connections are secure and do at least some kind of testing prior to beginning their cases, such as checking foot pedal operation. The level of oversight needs to be higher with new or unfamiliar staff members.

Equipment whose settings change for each procedure

Some equipment such as phaco or vitrectomy units are set up the same way for each patient. For refractive surgery procedures, however, the patient’s data and the laser settings must be input for each patient. Indeed, determining the precise settings is a key component of the ophthalmologist’s surgical planning. Technicians are often asked to program the laser for refractive surgery. Plaintiff and defense experts in refractive surgery cases all testified that the surgeon must verify the settings by comparing them to the calculations in the medical record before beginning each case.

During retinal surgery, the type of gas and concentration needed varies from one patient to the next. Experts in such cases have opined that the ophthalmologist must either mix the gas or watch the mixing process, since getting oral confirmation of the correct gas and amount does not adequately protect the patient. Build “hard stops” into the time out to get team input before the use of such EMDs. Revise the surgical checklist form to make it clear when this needs to happen (a sample ophthalmic-specific checklist is available at www.omic.com).

The entire ophthalmic care team needs to be aware of the risks EMDs pose to patient safety, and work together to confirm and communicate that equipment is safe to use.





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Upcoming Events

OMIC will be sponsoring special events in 2020. For more information on the events OMIC will be supporting in the coming year please visit omic.com/sponsorships.

Partnerships

OMIC has partnerships with most ophthalmic societies in the United States. Members of state, subspecialty, and special interest societies that partner with OMIC receive special discounts when they participate in our risk management program. In 2020, nine state, subspecialty, and special interest societies will have partnered with OMIC for **20 years or more**. We would like to recognize them here and encourage your support of these organizations. Learn more at omic.com/partners.



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Illinois Society of Eye Physicians and Surgeons
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Louisiana Academy of Eye Physicians and Surgeons
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Missouri Society of Eye Physicians and Surgeons
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