OMIC OPHTHALMIC MUTUAL INSURANCE COMPANY
(A Risk Retention Group)

Endophthalmitis and TASS: Prevention, Diagnosis, Investigation, Response

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Uncomplicated cataract surgery was performed on an elderly woman. At the end of the procedure, the ophthalmologist was informed by the nurse that the sterilization indicator on the instruments had not changed. It was feared that the instruments had been washed but not sterilized. The physician and ASC medical director decided not to inform the patient of the potential problem, opting instead to increase the frequency of topical antibiotics. No signs of infection were noted at the first postoperative visit, but two days later, endophthalmitis developed. Ten days after surgery, the two physicians informed the patient and her family that the same strain of pseudomonas aeruginosa had grown in the eye and the ultrasonic bath water at the ASC, leading them to conclude that problems with sterilization were the likely cause of her endophthalmitis and phthisical eye. The patient's lawsuit was settled on behalf of the ASC for $650,000.

Poor outcomes like this make infectious endophthalmitis one of the most feared complications of ophthalmic surgery. Recently, a type of inflammatory response known as TASS, or Toxic Anterior Segment Syndrome, has garnered attention and prompted calls to OMIC's Risk Management Hotline. While not all adverse events can be prevented, there is much ophthalmologists can do to reduce the incidence of endophthalmitis and TASS. In its review of OMIC's claims experience and the lessons learned from it, this article offers risk management guidance on more effective prevention, recognition, and response to these sight-threatening conditions.

ENDOPHTHALMITIS/TASS CLAIMS EXPERIENCE

Since OMIC's inception in 1987, endophthalmitis has accounted for 0.6% of claims frequency (150 claims out of 2,559 total) and 5% of claims severity ($3,345,964 paid indemnity out of $63,191,199 total). Of these 150 endophthalmitis cases, 25 remain open; of the 125 closed endophthalmitis cases, only 8 were taken to trial, and in all but one, the jury returned a defense verdict. A poll of the jury after the sole plaintiff verdict of $735,000 revealed that the award was in response to the defendant group's practice of locking up medical records on weekends, thus preventing access to key patient information needed to assess the plaintiff's condition. Since the practice's name did not appear on the jury's form, a settlement on its behalf was effected for the amount of the verdict, and the plaintiff award against the ophthalmologist was vacated.

More than three-quarters (78%) of OMIC's endophthalmitis cases have closed without an indemnity payment. The percentage of cases that have settled (22%) and the median settlement amount ($75,000) are comparable to OMIC's overall data. Despite the severity of the outcome for the patient,

endophthalmitis settlements have ranged from $9,000 to $735,000 compared to a low of $500 and a high of $1.8 million for all settlements. Reflecting the relative novelty of TASS, allegations in all but 3 of the 150 claims involve an infectious rather than an inflammatory process.

Table 1. Indemnity Payments by Type of Case

TYPE OF CASE	TOTAL CLOSED CLAIMS	CLOSED WITHOUT INDEMNITY	CLOSED WITH INDEMNITY	SETTLEMENT RANGE	MEDIAN SETTLEMENT
Cataract	77	59	18	$9,000 – 735,000	$75,000
Retina	23	19	4	$58,000 – 101,476	$75,000
Cornea	14	13	1	$300,000	
Trauma	7	3	4	$24,999 – 248,000	$31,000
Glaucoma	2	2	0		
Endogenous	1	0	1	$15,000	
Uveitis	1	1	0		

Given the estimated 2 million cataract procedures performed annually in the United States, it is hardly surprising that cataract surgery would account for 61% of all endophthalmitis cases. Less expected, however, is that only 23% of cataract-related endophthalmitis cases resulted in an indemnity payment. During the informed consent process for cataract surgery, ophthalmologists routinely disclose this rare complication, and most actively try to prevent its occurrence by treating preexisting conditions such as blepharitis, preparing the eye with povidone iodine, and administering antibiotics. Indeed, assuming cataract surgery was indicated in the first place and the endophthalmitis was promptly recognized and treated, expert witnesses view this complication as a tragic maloccurrence rather than malpractice. On the other hand, cases of endophthalmitis resulting from trauma are rare (6%), but they result in settlement 57% of the time. Clearly, ophthalmologists who do not administer antibiotics and/or carefully monitor the eye for signs of endophthalmitis after trauma are not supported by defense or plaintiff experts.

ANALYSIS OF RISK ISSUES

It is helpful to analyze the risk issues associated with substandard care by dividing them into four categories. “Clinical” issues include debates in the ophthalmic community on the standard of care and the natural history of the disease or condition. “Systems” issues involve complicated processes of care, such as medications (research, manufacture, distribution, ordering, etc.), equipment, and follow-up and telephone screening methods. Finally, the acts, omissions, and decisions of individual physicians and patients also impact care outcomes. The following table indicates the type and frequency of risk issues in OMIC’s endophthalmitis and TASS cases.

Table 2. Incidence of Risk Issues in Endophthalmitis/TASS Cases

Clinical **4**

- Antibiotics
  - Route
  - Timing

Systems **32**

- Telephone care (16)

    - After-hours (12)
    - Staff (4)
- Sterilization (6)
    - Not done (2)
    - Ultrasound bath contaminated
    - Cracked irrigation bottle
    - Saline flush contaminated
    - Donor tissue not cultured
- Equipment malfunction (3)
- Product liability (2)
- Access to medical records (1)

Physician **57**

- Diagnostic process (18)
    - Diagnosis did not account for symptoms
    - Exam elements
- Documentation (7)
    - Missing
    - Late
    - Altered
- Surgery not indicated or contraindicated (6)
- Treatment (6)
- Follow-up interval (5)
- Referral delay (5)
- Informed consent and disclosure (4)
- Coordination of Care with PCP (3)
- Supervision of OD (2)
- Discharge instructions (1)

Patient **5**

- Noncompliance

Amid ongoing debate of evidence-based guidelines for prevention of endophthalmitis, it is noteworthy that antibiotic administration was not a key issue in any case; nor was patient noncompliance a significant factor. Instead, systems issues and physician-driven processes predominate. The remainder of this document provides risk management recommendations targeted at these issues.

CAUSES AND PREVENTION OF ENDOPHTHALMITIS/TASS

Systems for ordering, cleaning, sterilizing, and maintaining ophthalmic equipment and products were a factor in 11 OMIC cases. Our claims experience confirms the research findings of Dr. Nick Mamalis and his colleagues at the John Moran Eye Center/Intermountain Ocular Research Center of the University of Utah. Funded by a grant from ASCRS (American Society for Cataract and Refractive Surgery), the ophthalmologists at the Center have been evaluating endophthalmitis and TASS for the past 15 years, searching for what causes these conditions and what steps should be taken to prevent them. In their work on TASS, they found that preparations of BSS, antibiotics, anesthetics, and other medications were not the correct pH and/or osmolality, or that they contained endotoxins or preservatives that triggered anterior segment inflammation. Numerous problems during the cleaning and sterilization of instruments were also noted, such as the use of enzymatic cleaners and inadequate rinsing.

In their capacity as users, surgical directors, board members, and owners, ophthalmologists have a leadership role to play in addressing these systems issues that adversely impact care outcomes. They can review equipment maintenance and infection control measures in hospitals and ASCs, focusing particular attention on flash sterilization, re-use of single-use items, and the ordering, preparation, and use of ophthalmic products, devices, and medications. Table 3 summarizes the causes of endophthalmitis and TASS and the actions needed to prevent them.[1]

Table 3. Steps Ophthalmologists Can Take to Reduce the Incidence of Endophthalmitis/TASS

	TASS	ENDOPHTALMITIS
CAUSE	Noninfectious reaction to toxic agent present in: • BSS solution • Antibiotic injection • IOL • Endotoxin • Residue • Preservative Failure to correct • pH • Osmolality	Bacterial, fungal, or viral infection
PREVENTION	• Whole team approach to ordering, cleaning, sterilizing, and preparation of instruments, viscoelastic, medications, and irrigation solution to **ensure proper pH, osmolality, non-toxicity** • Avoid re-use, especially of cannulas and damaged instruments • Rinse I/A tips and phaco hand pieces at conclusion of each cleaning step with **sterile, deionized water** through both ports • Replace ultrasound water baths daily	• Treat preexisting blepharitis • Eyelid preparation with 5% povidone iodine • Perioperative antibiotics • Careful wound construction • Avoid ophthalmic ointment and patches with clear corneal incisions • Discharge instructions on wound care, signs and symptoms to report, contact information • Careful telephone screening of ophthalmic complaints

[1] Tables 3 and 4 are compiled from information in Mamalis, Nick et al. "Review/Update: Toxic Anterior Segment Syndrome." *J Cataract Refract Surg* Vol 32, February 2006:324-333; Ronge, Laura J. "Toxic Anterior Segment Syndrome: Why Sterile Isn't Clean Enough." *EyeNet*, November/December 2002:17-18; and Davis, Brandon L, and Mamalis, Nick. "Averting TASS: Analyzing the Cause of Sterile Postoperative Endophthalmitis Provides Valuable Clues for its Prevention." *Cataract & Refractive Surgery Today*, February 2003:25-27.

	• Change the steam autoclave sterilizer at least weekly • Careful wound construction • Avoid ophthalmic ointment and patches with clear corneal incisions	

SCREENING OF PATIENT COMPLAINTS KEY TO IMPROVED CARE

The two primary issues in OMIC's endophthalmitis cases—telephone care and the diagnostic process—indicate the need to carefully screen patients who present with ophthalmic complaints, especially postoperatively, and to educate them about which symptoms to report. Each of these identified risks is squarely within physician control and thus can be modified. "Telephone Screening of Ophthalmic Problems" (in the Risk Management Recommendations section of www.omic.com) provides screening protocols and contact forms for both staff and physicians taking after-hours calls.

"A Witty (WIT-D) Approach to Avoiding Mistakes" proposes an easy-to-remember and effective strategy for improving the diagnostic process.[2] Establish a prioritized differential diagnosis in order to rule out the **worst** case scenario; determine the **information** you need to obtain during the history and examination, or through studies, to rule that in or out; **tell** the patient and other health care providers to ensure that you are notified of all signs and symptoms that could help establish the diagnosis and determine the treatment plan; and **document** your decision-making process and follow-up plan. More information is available in "Failure to Diagnose Cases: Focus on Traumatic Eye Injuries," available in the Risk Management Recommendations section of www.omic.com).

ENDOPHTHALMITIS OR TASS?

Failure to rule out endophthalmitis has resulted in harm to patients and significant liability exposure for OMIC policyholders. Emerging research indicates that the ophthalmologist should also include inflammatory reactions such as TASS in the differential diagnosis. Indeed, mistaking one for the other could lead not only to a delay in treatment but may worsen the outcome. The following table summarizes some of the distinguishing features and the recommended treatment. Although this table may be helpful, it can still be difficult or impossible at times to discriminate between endophthalmitis and TASS.

[2] Carolyn Buppert, "A Witty (WIT-D) Approach to Avoiding Mistakes," *Gold Sheet* 4(6), 2002. See "Risk Management Issues in Failure to Diagnose Cases: A Focus on Traumatic Eye Injuries" at www.omic.com for more information.

Table 4. Differential Diagnosis : TASS or Endophthalmitis?

	TASS	ENDOPHTHALMITIS
Onset	12-24 hours	4-7 days
Signs/Symptoms ***distinguishing feature**	• Blurry vision • Pain: none, or mild to moderate • Corneal edema: diffuse, limbus to limbus* • Pupil: dilated, irregular, nonreactive* • Increased IOP* • Anterior chamber: mild to severe reaction with cells, flare, hypopyon, fibrin • Signs and symptoms are limited to anterior chamber* • Gram stain and culture negative	• Decreased VA • Pain (25% have no pain) • Lid swelling with edema • Conjunctival injection • Hyperemia • Anterior chamber: marked inflammatory response with hypopyon • Vitreous involvement • Inflammation in entire ocular cavity*
Treatment	• Rule out infection: culture anterior chamber • Intensive corticosteroids • Monitor IOP closely for signs of damage to trabecular meshwork and side effects of steroids • Watch closely for next few hours for signs of bacterial infection	• Culture anterior chamber and vitreous • Intravitreal and topical antibiotics • Vitrectomy

DISCLOSURE OF A STERILIZATION BREAKDOWN

The malpractice case featured earlier in this document stemmed from a series of breakdowns in the facility's sterilization process. When notified of it, the physician consulted with the ASC's Medical Director and together they decided not to alarm the patient until they knew the facts. By not warning the patient of the symptoms to watch for, they arguably missed an opportunity to diagnose the problem earlier.

As we note in "Responding to Unanticipated Outcomes" (available in the Risk Management Recommendations section of www.omic.com), ophthalmologists are well-advised to tell patients about complications as well as potential problems with sterilization. Patients have a need and a right to know about their own condition, and can help monitor for the development of symptoms. Such disclosure of adverse events is best understood as a continuation of the informed consent process begun before the surgery.

Moreover, communicating with the patient sympathetically and non-defensively within the shortest appropriate time period may help dispel much of the anger, confusion, and distrust that complications may engender, while preventing allegations of fraudulent concealment that could extend the statute of limitations or allow for punitive damages.

When talking to patients, stick to the currently known facts, avoiding speculation or blame. Use language such as this: "I was informed by the nurse at the end of the procedure that one of the sterilization indicators on the instruments had not changed color. This means that the instruments may not have been sterile. If they were not sterile, you are at an increased risk for an infection. The surgery center is evaluating what happened, and I will share information with you as it becomes available. For now, I want to go over with you the medication you are on to prevent an infection, and what symptoms to report to me."

Document all disclosure conversations in the medical record, noting the names of all family or staff members present. Unless the ASC informs you that certain information is confidential, you can document facts disclosed to you about the investigation and note them in the record. As more information becomes available, share it with the patient and document it.

RESPONSE TO A CLUSTER OF ENDOPHTHALMITIS OR TASS CASES

An effective response depends upon careful coordination and cooperation among the facility, surgeon, and patient. **OMIC policyholders are urged to call our risk management department for confidential assistance as soon as possible.** The facility should contact all affected surgeons, and document the notification efforts. Ophthalmologists in turn need to call all patients operated on that day or during that period, and notify them of the events, screen for symptoms, and educate them about when and why to contact the physician.

As in any disclosure discussion, the physician should stick to the facts and avoid speculation or blame: "I don't want to alarm you, but I felt you should know that several patients have contracted a serious infection OR experienced a serious reaction after their cataract surgery two days ago. You may or may not have this infection/reaction. To find out, I'm going to ask you some questions, go over your medications and explain what I want you to watch out for." Document the discussion, instructions, and follow-up plan in the patient's medical record.

Until endophthalmitis or TASS is ruled out and the patient's condition has stabilized, see or speak with the patient on a regular basis. Some ophthalmologists call their patients daily during the at-risk period to both gather accurate information and to reassure the patient. Pay particular attention to follow-up periods for patients whose surgery falls right before a weekend or holiday. Encourage them to call you to report symptoms or ask questions.

The facility needs to sequester all involved materials, interview staff, and evaluate equipment, devices, solutions, medications, and the sterilization process. All aspects of the investigation should be carefully documented. The investigation will help locate the responsible organism or toxic agent, ascertain liability, and determine what steps to take to remedy any identified problems. Dr. Mamalis's group developed an Excel-based protocol that can be used for individual or clustered cases of infectious or sterile endophthalmitis. The protocol is in an Excel format that allows reporting of multiple cases in one document; it is available on the OMIC website, via e-mail nick.mamalis@hsc.utah.edu, or by calling 801.581-6586. Detailed information about each patient's pre- and postoperative course, the facility, equipment, supplies, medication preparation and

sterilization technique are entered into the spreadsheet, compiled, and then sent to the Center for review. Research fellows are available for on-site evaluations, and charge only airfare and nominal expenses.

DECIDING WHEN TO POSTPONE OR RESUME SURGERY AT A SURGICAL FACILITY

Faced with a cluster of either endophthalmitis or TASS cases, both the surgical facility and the individual surgeon will need to decide whether or not it is safe to proceed with other scheduled ophthalmic cases at that location. Ophthalmologists who have an ownership interest in an ambulatory surgical facility may also be involved in these deliberations, and should act as patient advocates promoting quality care. Patient safety should be the driving factor, and all parties must feel confident that the causative factors have been identified and addressed. At times, the surgery center may need the assistance of outside consultants such as Dr. Mamalis or legal counsel in order to conduct the investigation and make the decision to cancel or resume procedures. OMIC's Risk Manager can be a valuable resource.

Most elective cases can be postponed. Patients may be inconvenienced but will appreciate that you are working to ensure the best outcome for their eye condition. For urgent and emergent ones, you will need to find an alternative facility. If you do not have privileges at other facilities, you will need to refer the patient to an ophthalmologist who does. Contact the affected patients: "The _____ surgical facility is evaluating a potential safety issue. For your protection, your surgery will be postponed OR your surgery will need to be done at _____ surgical facility. Since I do not operate at that facility, would you like for me to refer you or do you have another ophthalmologist you would like to see for your surgery?"

When the causes of the endophthalmitis or TASS have been identified and addressed, the surgeon and facility may want to notify patients of the prior problem. A sample letter is included at the end of this document.

AAO AND ASCRS REQUEST PHYSICIANS' HELP TRACKING TASS

In response to over 80 TASS cases nationwide, the AAO (American Academy of Ophthalmology) and ASCRS announced the formation of a task force to help determine the causes and share best practices. Chaired by Dr. Mamalis, it includes Dr. Henry Edelhauser from Emory University, Dr. Arjun Srinivasan from the Centers for Disease Control, Dr. Walter Hellinger (Epidemiologist from Mayo Clinic), Dr. Sam Masket, President of the ASCRS, and members of the ophthalmic product industry.

Ophthalmologists with TASS cases are urged to complete the two short questionnaires that follow about the products involved during cataract surgery and the actual process of cleaning and preparing instruments and patients for surgery and forward them to Dr. Mamalis.

A preliminary report on over 100 cases was communicated to AAO and ASCRS members on June 22, 2006. There is no single cause, but potential sources have been identified. These include pre-operative non-steroidal anti-inflammatory drugs; intracameral anesthetics that remain in the anterior chamber longer due to ophthalmic visco surgical devices (OVD), or those that have been improperly dosed, mixed, or injected; epinephrine stabilized by bisulphites or other preservations added to balanced salt solutions (BSS); and reusable cannulas or viscoelastic that retain residues, enzymatic detergents, or ultrasonic cleaners.

High surgical volume can put pressure on the sterilization process, leading to inadequate rinsing and incomplete cycles. Cases reported on OMIC's Risk Management Hotline point to an inadequate supply of instruments and a reliance on flash sterilization, which was designed to quickly reprocess instruments that had been dropped or contaminated, not those that have been used and need to be cleaned.

OMIC policyholders who have additional questions or concerns about this issue may call our risk management department for assistance at (800) 562-6642, extension 652.

Product Questionnaire Page 1 of 3

Cataract surgical center contact:
Name of center: _____
Contact person: _____
Telephone number: _____
Fax number: _____
Address: _____
_____

On behalf of the American Society of Cataract & Refractive Surgery, please return to:

Nick Mamalis, MD
Intermountain Ocular Research Center
John A. Moran Eye Center
University of Utah
Salt Lake City, Utah 84132
Fax# (801) 581-3357

Please indicate below the products and procedures which were used during surgeries that were followed by cases of TASS in the year 2006.

Preoperative topical mydriatic: _____ (trade name)

Preoperative topical cycloplegic: _____ (trade name)

Preoperative topical NSAID: _____ (trade name)

Preoperative topical cleaning agent (eg Ocusoft, Baby Shampoo):
_____ (trade name)

Preoperative topical anti-septic (circle one): Betadine 5% (ophthalmic) / Betadine 10% / Phisohex / Chlorhexidene 2% / Other:_____

Preoperative topical antibiotic (w/o concentration): _____ (trade name)

Preoperative topical anesthetic (w/o concentration): _____ (trade name)

Intracameral anesthetic: Yes No

Intracameral anesthetic preservative free: Yes No

Retrobulbar or peribulbar anesthetic block: Yes No

Flexible iris retractor: Yes No

Intraocular miotic (circle one): Miostatin / Miochol / Other:_____ (trade name)

Viscoelastic #1 (circle one): Discovisc / Duovisc / Provisc / Viscoat / Cellulgel / Healon / Healon GV / Amvisc+ / Other: _____ (trade name)

Contact tel # (from pg. 1): _____

Viscoelastic #2 (circle one): Discovisc / Duovisc / Provisc / Viscoat / Cellulgel / Healon / Healon GV / Amvisc+ / Other: _____ (trade name)

BSS (500cc) intraocular irrigant (circle one): AMO / Acorn / Cytosol / Alcon / Baxter / Other: _____ (trade name)

Topical (15cc) irrigant (circle one): AMO / Acorn / Cytosol / Alcon / Baxter / Other: _____

Epinephrine added to BSS: _____ (trade name & concentration)
None added

Intraocular antibiotic #1 added to BSS: _____ (trade name)

Intraocular antibiotic #2 added to BSS: _____ (trade name)

Intracameral antibiotic #1: _____ (trade name)

Intracameral antibiotic #2: _____ (trade name)

Incision (circle one): Clear cornea / Scleral tunnel / Other: _____

Suture of incision: Yes No

Type of Blade/Knife (circle one): Reused non-diamond / Reused diamond / Disposed after each case

Blade/Knife Brand (circle one): ASICO / Alcon / Sharpoint / Rhein / Other: _____

Phaco delivery system (circle one): Legacy / Infinity / Sovereign / White Star / Millenium / Other: _____

Phaco tip reused: Yes No

Phaco tubing reused: Yes No

I/A tip reused: Yes No

Insertor tip reused: Yes No

Insertor reused: Yes No

Cartridge for loading IOL to insertor: Alcon / AMO / White Star / Bausch & Lomb Other: _____

Other cannulated equipment reused: Yes No

Custom Pack (circle one): Alcon / Allegiance / Cardinal / Medline / Other: _____

Contact tel # (from page 1): _____

IOL Type (circle one): Silicon / Acrylic hydrophilic / Acrylic hydrophobic / PMMA /
Other: _____

IOL Manufacturer: Alcon / AMO / Bausch & Lomb / Staar / Other: _____

Capsule staining (select one): Trypan blue / ICG / Other: _____

Post-operative topical antibiotic: _____ (trade name)

Post-operative topical steroid: _____ (trade name)

Post-operative topical NSAID: _____ (trade name)

Instrument Re-processing Questionnaire

Cataract surgical center contact:
Name of center: _____
Contact person: _____
Telephone number: _____
Fax number: _____
Address: _____
_____

On behalf of the American Society of Cataract & Refractive Surgery, please return to:

Nick Mamalis, MD
Intermountain Ocular Research Center
John A. Moran Eye Center
University of Utah
Salt Lake City, Utah 84132
Fax# (801) 581-3357

1. How many operating rooms do you use on days of cataract surgery? ____
2. How many cases of cataract surgery do you perform on an average day? ____
3. Have you observed a pattern to your cases of TASS (surgical case of day, surgery day of week, OR number)? Y, N
4. How many trays of cataract surgical equipment do you have? ____
5. Do you have a written protocol which specifies the time, duration, detergents, enzymatics, type of water (tap vs sterile) and rinsing for cleaning the following re-used equipment:

   Phaco handpiece Y N Don't Know Not reused
   Volume of water used to flush handpiece: _____

   Phaco tubing Y N Don't Know Not reused

   I/A tips Y N Don't Know Not reused
   Have you had occluded I/A tips? Y N

   Insertor Y N Don't Know Not reused

   Other cannulated equipment Y N Don't Know Not reused

   Forceps for loading IOL Y N Don't Know Not reused

6. Is any of your re-used equipment cleansed with enzymatic detergents?
   Y N Don't Know
7. Is any of your re-used equipment cleansed or rinsed in an ultrasonic bath? Y, N

Contact tel # (from pg. 1): _____

8. If you use an ultrasonic bath, is it cleaned:
   Between each use ≥Once daily ≥Once weekly <Once weekly
   Don't Know

9. Is re-used cataract surgical equipment separated from non-ophthalmologic surgical equipment through all steps of cleaning before sterilization?
   Y N Don't Know

10. Which method is used for sterilizing your re-used equipment:
    Autoclave
    ETO (ethylene oxide gas)
    Plasma gas
    Glutaraldehyde
    Other: _____

11. If you sterilize your equipment with an autoclave, please indicate all that apply:

Regular inspection & cleaning documented	Y	N	Don't Know
Recent operational problems	Y	N	Don't Know
Steam produced by facility-wide boiler	Y	N	Don't Know
Steam produced only for autoclave	Y	N	Don't Know

NOTE: This is a sample disclosure form intended for use once the causes of the infection or toxic reaction have been identified and addressed, and the responsible parties at the ASC have determined that it is safe to proceed with surgery. Modify it for the particular clinical situation and circumstances. For example, in some cases, the Infection Control Committee may be involved instead of public health officials.

_____ Surgery Center

Consent and Disclosure About Endophthalmitis or TASS Cases

I have been advised that on _____, patients undergoing cataract surgery at _____ Surgery Center contracted a serious bacterial/fungal/viral infection OR experienced an inflammatory reaction in their eye and that some of these patients are still under care for their condition. I understand that public health officials and outside medical experts have reviewed this matter and believe it is safe to proceed with surgery. I have been given the opportunity to ask questions regarding these infections/inflammatory reactions, the investigation into them, my surgery, and any other questions I have had, and my questions have been answered to my satisfaction. Accordingly, I desire to and consent to undergoing surgery at _____ Surgery Center at this time.

Date: _____

Patient's signature_____

Witness _____