

A close-up, high-angle photograph of a tiger's face, showing its eye and stripes, serving as the background for the slide.

# The Five "PR's" of Product Preservation

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- Issues to consider:
  - How to prevent spoliation allegations
  - How to conduct proper pre-suit investigations
  - Compliance with regulations regarding medical device reporting, investigational devices, and quality systems

# ***Caveat***

- *Spoliation issues are very fact specific.*
- *This presentation is meant to be a general overview and not the final word on whether a particular activity is or should be considered an act of spoliation.*

# What is Spoliation?

- Definition and legal effect varies state to state but generally:
  - “When a party to a products liability action loses or destroys the allegedly defective product, or a critical part thereof, the question often arises what effect this should have on the subsequent trial.” 102 A.L.R.5th 99 (2009)

# Spoliation of Evidence

- “3.2 *Spoliation of evidence*— the loss, destruction, or material alteration of an object or document that is evidence or **potential evidence in a legal proceeding by one who has the responsibility for its preservation.** Spoliation of evidence may occur when the movement, change or destruction of evidence or alteration of the scene significantly impairs the opportunity of other interested parties to obtain the same evidentiary value from the evidence as did any prior investigator.” (ASTM Standard – E860-07: Examining and Preparing Items that Are Or May Become Involved in Criminal or Civil Litigation)

# What is Spoliation?

- Courts generally hold that the appropriate sanction, if any, will turn on the facts;
- Factors that the courts will consider:
  - (1) whether the innocent party was prejudiced by loss or destruction of the evidence;
  - (2) whether the prejudice can be cured;
  - (3) the practical importance of the evidence;
  - (4) the good faith or bad faith of the spoliator; and,
  - (5) the deterrent effectiveness of the court's action compared to a lesser sanction. 102 A.L.R.5th 99.

# The Effect of Spoliation in Litigation

- “A court may ... impose no sanction in a case [with] no prejudice to the innocent party and no fault on the part of the adverse party, and [where] circumstantial evidence of the claim is sufficient to make out a prima facie case;” OR
- “[T]he court may ... sanction the spoliating party, pursuant to [its] authority ..., or ... discovery rules, in ... several ways.” 102 A.L.R.5th 99 (emphasis added.)

# Spoliation Sanctions

- The court may:
  - Instruct the jury on the “spoliation inference,”
  - Preclude the spoliating party from introducing expert testimony concerning testing on the missing product or other evidence concerning the product;
  - Or dismiss ... the defendant's defense or grant summary judgment to the innocent party. 102 A.L.R.5th 99

# Spoliation Cause of Action

- If destruction of the product “prevents an innocent plaintiff from pursuing the underlying products liability claim, ... the plaintiff may attempt to bring a claim for negligent or intentional spoliation” against the alleged spoliator.
- Though these claims have not been widely recognized, they are still a cause for concern in some jurisdictions. 102 A.L.R.5th 99

# Destructive Testing

- “3.2 *destructive testing*– testing, examination, reexamination, disassembly, or other actions likely to alter the original, as-found nature, state or condition of items of evidence so as to preclude or adversely affect additional examination or testing.” (ASTM Standard – E860-07: Examining and Preparing Items that Are Or May Become Involved in Criminal or Civil Litigation)

# Destructive vs. Non-Destructive

- Typically, photographing and visual inspection not thought of as destructive
- Some products may be safely X-ray'd without destroying material evidence
- Any other activities depend on the circumstance of the case and the device in question
- Consult with technical personnel to become educated as to what evidence might be present on a product and how best to preserve it

# The Five "PR's" of Product Preservation

- Public Relations
- Procure
- Preserve and Protect
- Protocol
- Privilege

# Public Relations

- Communicate effectively and strategically with the reporting facility and/or consumer/patient:
  - Keep your legal department in the loop
  - Be straightforward and helpful
  - Ask for as much information as possible
    - **45 CFR 164.512(a)** (HIPAA) allows for disclosure of medical information in the context of mandatory reporting guidelines such as 21 CFR Sec. 803.30 (requires user facilities to report adverse events involving serious injury or death)
  - Assure the consumer/ reporting facility that you are investigating their concerns

# Procure

- Getting the device back from the consumer-
  - *Implanted Devices*
    - These devices by their nature may not be available
    - Obtain as much information from clinicians, patient, and medical records as is possible
    - Request that surgical videos, x-rays and other testing are preserved

# Procure

- Getting the device back from the consumer-
  - *Non-implanted or explanted devices*
    - Who owns the device?
    - Will the facility or patient voluntarily return the device?
      - If the facility is resistant, you may want to offer to compensate the facility or patient fair value for the returned product or offer a replacement product if the device is returned for investigation

# Procure

- Getting the device back from the consumer
  - If a device is explanted, obtain as much information as possible regarding the explantation procedure
    - Medical Records
    - Photographs or videos of procedure
    - If advance notice of the explantation procedure is given -- share concerns with clinician about how the device might safely be explanted while still preserving the device in its present condition and/or document any destructive measures

# Procure

- Getting the device back from the consumer
  - Document the chain of custody and the manner of storage every step of the way
    - Photographs
    - Written reports (keep legal in the loop)

# Procure

- Getting the device back from the consumer
  - You likely already have Standard Operating Procedures (“SOPs”) in place regarding these procurement issues prior to a device ever leaving the facility e.g.:
    - Complaint handling;
    - Failure Analysis; and,
    - Returned Goods.

# Preserve and Protect

- Record/maintain the life history of the product
  - Where manufactured?
  - When sold?
  - How distributed?
  - Medical records regarding implantation and/or use?
  - (all the other records we just discussed re Procurring the product)

# Preserve and Protect

- Preserve/store the product in its post-incident condition
  - Take photographs before you store it
  - Where stored and How stored?
    - i.e. type of container, temperature, what done if anything to clean product prior to storage, etc.
    - Work with technical personnel to verify the best procedure for the device and put it in writing

# Protocol- Should you test?

- Make educated decision as to when and if testing should occur
  - Collaboration between the legal department, regulatory, R & D, and manufacturing
  - Investigator/s must understand design and manufacture of product and circumstances of incident before developing an inspection protocol
  - Investigator/s must have a working hypothesis about what occurred before he/she can test

# Protocol

- ASTM– F561-05a: “Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids”
  - “[I]nvestigation of retrieved ...devices and adjacent tissues can be of value in the assessment of clinical complications associated with the use of a specific ... design;”
  - “Can ... further the development of biocompatible implant materials and devices with improved performance.”

# Protocol

- ASTM Standard – F561-05a: Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids
  - ... “Any destructive analysis of implants must be done so as to not destroy any features that may become the subject of litigation, as per Practice [E860](#). This standard recommendation should be applied in accordance with state or national regulations or legal requirements regarding the handling and analysis of retrieved implants and tissues.”

# Protocol

- If you test, develop an agreed to written protocol in advance
  - Collaborate with legal, R & D, regulatory, manufacturing
  - Get an signed written agreement from the consumer and/or reporting facility (See, ASTM E860-07 [5.2])
  - Document the state of the product prior to testing (ASTM E860-07 [5.1])

# Protocol

- If you test, develop an agreed to written protocol in advance
  - Attempt to determine any change(s), alteration(s) or contamination of the evidence subsequent to the incident and document those findings (ASTM E860-07 [5.1])
  - Use exemplar products instead of involved product when possible. (See, ASTM E860-07 [5.2])
  - Exhaust all non-destructive testing options before pursuing destructive testing. (See, ASTM E860-07 [5.2])

# Additional related CFR

- 21 CFR 803.50 & 803.52 Manufacturer Reporting Requirements
- 21 CFR 820.198 Complaint Files
- 21 CFR 820.200 Servicing
- 21 CFR 820.100 Corrective and preventive action

# Privilege

- Keep in house legal department/outside counsel in the loop
- Preserve any privileged aspects of the investigation

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