

Independent Serious Incident Investigations

When medical technology or care harms rather than helps, you need answers

When a serious incident occurs in your facility, you want to know how it occurred, the root causes, whether the incident must be reported, and how to prevent recurrence. For many types of accidents, retaining a third-party investigator is critical to restoring operations, minimising interdepartmental conflict, and maintaining staff confidence in the affected technology.

You need a third-party investigator if the incident involves:

- ▶ A serious event involving injury or death
- ▶ Probability of litigation
- ▶ A need to eliminate bias

Unique experience to address serious events

ECRI Institute is uniquely qualified to determine how a medical device, technology, or the delivery of care may or may not have contributed to an injury, death, or close call to help you prevent a repeat occurrence. For nearly 50 years, we have investigated thousands of injuries and deaths related to hundreds of classes of medical devices—both capital equipment and medical-surgical supplies. We provide specialised services to investigate, analyse, and prevent incidents, injuries, and deaths related to medical devices, the environment of care, and organisation systems and processes. We also investigate accidents associated with healthcare facility physical infrastructure, sterilisation processing, and many other themes.

Our healthcare accident investigation, risk management assessment and related patient safety support services—available to healthcare facilities worldwide—include:

- ▶ On-site and in-laboratory accident investigations
- ▶ Risk-reduction strategies
- ▶ Critical and sentinel event investigations and analyses
- ▶ Expert-witness testimony
- ▶ Root-cause analyses
- ▶ Forensic engineering investigations
- ▶ Database searches



Your trusted partner for unbiased answers when a medical device or medical care harms rather than helps.



An investigative approach coupled with objective advice

When a serious incident occurs, you need a thorough, unbiased, and objective investigation, an accurate conclusion, and timely recommendations. We help organisations react quickly and knowledgeably to restore operations and maintain confidence.

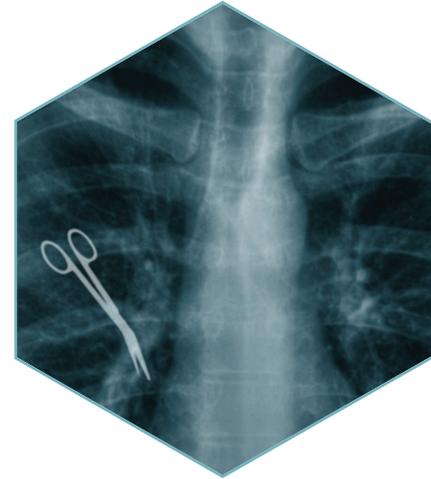
During investigations, many causes of the incident are considered, including:

- ▶ Human factors and user errors
- ▶ Failures in communication
- ▶ Staffing
- ▶ Systems errors
- ▶ Information flow
- ▶ Culture
- ▶ Manufacturing or design defects
- ▶ Process flaws
- ▶ Sabotage or malicious intent
- ▶ Device interactions
- ▶ Training and education

Our laboratories are fully equipped with the instrumentation needed to investigate and document medical device problems. Our capabilities also include instrumentation for electronic, mechanical, and environmental testing and visual microscopy.

Trust ECRI Institute's experienced investigation team

We are there when you need us most. For critical emergencies, we can begin our investigation immediately. Healthcare facilities worldwide rely on our Accident and Forensic Investigation services for an objective understanding of serious events.



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