When the Device Fails - Product Liability Meets Hospital Negligence

Most physicians assume that when a medical device fails, it's the manufacturer's problem. But in court, it rarely stays that simple.

Increasingly, product liability claims intersect with corporate negligence, transforming what looks like a manufacturing defect into a question of hospital oversight, documentation, and chain of custody.

A 2024 *New England Journal of Medicine* commentary highlighted that medical device-related events account for nearly 16% of all hospital sentinel events, yet only a fraction ever reach the FDA's MAUDE database. The underreporting isn't just a regulatory issue - it's a litigation trap. Plaintiffs now argue that hospitals have a non-delegable duty to ensure safe device use, maintenance, and reporting.

Consider *Kuykendall v. Banner–University Medical Center (Ariz., 2024)*, where an interbody cage fractured intraoperatively and was reportedly "discarded." The missing device became the linchpin of the case. The plaintiff's team argued that failure to preserve the product for analysis constituted spoliation of evidence and violated both internal hospital policy and FDA reporting obligations under 21 C.F.R. §803. The jury never saw the device—but they saw the chain of negligence: from OR nurse to materials management to risk management.

In product liability cases involving hospitals, key questions include:

- Was the device properly stored, tracked, and documented before use?
- Were maintenance logs and preventive checks performed according to manufacturer and Joint Commission standards?
- Did the hospital have a policy for device failure, retrieval, and reporting?
- Was the event reported to the manufacturer and FDA as required?
- Did procurement or cost-saving decisions affect device selection or reuse protocols?

Hospitals often discover too late that the manufacturer's indemnification clauses don't extend to **improper handling or reporting**. In the courtroom, the line between "product defect" and "institutional neglect" blurs quickly. When a device fails, plaintiffs frame the question not as *what failed*, but *who failed to respond*.

The medicolegal lesson is simple but costly: A defective product doesn't absolve the hospital—it tests its systems.
Hospitals that lack structured device incident protocols, chain-of-custody logs, or cross-

department reporting workflows are increasingly vulnerable to **hybrid liability**—where clinical negligence, corporate negligence, and product liability converge.

References

1. *Kuykendall v. Banner–University Medical Center*, No. CV-2023-1274 (Pima Cty. Sup. Ct., Ariz. 2024).

2. U.S. Food & Drug Administration. *21 C.F.R. §803 – Medical Device Reporting (MDR).* 2023.

3. The Joint Commission. *Environment of Care Standards EC.02.04.03–EC.02.04.05.*, 2023.

4. Halpern SD, “Device Failure, Disclosure, and Accountability in Hospitals.” *N Engl J Med.* 2024;390(7):611–614.