How to Deal With Recalled Prosthetic Devices

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Can you explain how recalls are viewed by the Food and Drug Administration (FDA)?

Recalls fall under Medical Device Reporting (MDR) regulations, and there are mandatory requirements for manufacturers to report adverse events. The MDR regulation attempts to provide a mechanism for the FDA and manufacturers to monitor and identify significant adverse events involving all medical devices. Potential goals of these regulations are to detect and correct problems in a timely manner. Although the requirements of the regulation can be enforced through legal sanctions that are authorized by the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA also relies on the goodwill and cooperation of all affected parties to achieve the objectives of the regulation that emphasize patient safety.¹

How common are implant recalls in the field of orthopedics?

According to various analyses, implant recalls are quite common, and their incidence is increasing. There were more than 300 orthopedic device recalls from 2005 to 2009. There are many different types of recalls, from very minor to quite major ones. Some of them might also involve only small additions to instrumentation.

What are the different types of recalls?

Overall, there are 2 different types of recalls that frequently occur in the United States: voluntary and involuntary recalls. A voluntary recall is the result of postmarket surveillance evalua-

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tion and is initiated by the manufacturer. However, involuntary recalls are mandated by the FDA. Involuntary recalls often occur after manufacturers have conducted voluntary recalls and have notified the FDA.

What exactly does the term “recall” mean?

A recall typically only means that the device has a higher-than-expected revision rate (lower implant survivorship). There may be an unanticipated event, but a recall does not mean that the device is necessarily defective. Recalls may need different or frequent monitoring protocols.

Where can surgeons obtain information about implant recalls?

A frequently updated list of all implant recalls can be found on the FDA’s Web site. Commonly, a tremendous amount of information can also be obtained from manufacturers. It is their duty to notify surgeons about the recall process. Quite often, manufacturers may advise surgeons on what their duties are and how to approach patients. There are also some information statements on the American Academy of Orthopaedic Surgeons Web site. These statements mainly focus on patient safety as the highest priority.

What are surgeons’ duties when dealing with an FDA recall?

A recalled implant can be a challenging situation for orthopedic surgeons. They may feel that their training has not prepared them regarding informing patients who have received recalled devices, making changes to their routine postoperative follow-up, or revising the implants. Nevertheless, orthopedic surgeons should identify the type of recalled implant and the number of patients who have received it. They need to notify all of the predisposed patients regarding the recall reasons and any potential clinical implications, including risks associated with less favorable outcomes, morbidity, and mortality. It is also important for orthopedic surgeons to identify any possible related medical concerns.

Should surgeons be concerned about litigation when they are dealing with recalls?

Not necessarily. Legally, a recall is categorized as a product liability case by the manufacturer and is typically not the surgeon’s fault. However, orthopedic surgeons have to inform all patients who have received a recalled implant.

When should reoperation for a recalled device be considered, and is prophylactic revision surgery recommended?

Reoperation is the best option for failed implants and for patients who have chronic pain and/or poor function. However, we do not recommend a prophylactic revision surgery for asymptomatic patients who have clinically and radiographically stable prostheses.

How can surgeons obtain specific information on how to deal with metal-on-metal hip recalls?

Guidelines can be found on the Hip Society, American Academy of Hip and Knee Surgeons, and American Academy of Orthopaedic Surgeons Web sites. In addition, several review articles have been published on this topic.2,4 One recent article contains position statements and algorithms that attempt to describe an appropriate way to diagnose and treat patients with recalled metal-on-metal hip devices.2

How can orthopedic surgeons more efficiently identify implants that may potentially be recalled?

The performance of various prostheses and their related unfavorable clinical outcomes could be more efficiently evaluated using a comprehensive US joint registry. This could allow for more specific data collection during various follow-up periods for all patients undergoing total hip arthroplasty. Such a registry could highlight potential clinical issues with implants sooner and help reduce morbidity for patients and the economic burden on the health care system.

REFERENCES