

Information Statement

Implant Device Recalls

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The recall of orthopaedic implant devices and any subsequent revision surgery is a serious matter that requires the collaborative efforts of manufacturers, insurers, regulatory bodies, hospitals, and orthopaedic surgeons in order to ensure patient safety. The orthopaedic surgeon's role is critical in the identification of implant failure, the appropriate use of resources to address medical concerns related to its failure, and in educating patients on the risks and benefits of the implanted device and of revision surgery.

It is important to note that in most cases of orthopaedic implant recalls, not all devices recalled may be defective. Therefore, many patients may not incur health problems as a result of the implanted device. FDA describes recalls as action taken to remove a product from the market, which may be undertaken at the initiative of the manufacturer, by FDA request, or by FDA order under statutory authority. Recalls are classified as follows:

- Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- Market withdrawal: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.
- Medical device safety alert: issued in situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these situations also are considered recalls¹

Patients with and without immediate symptoms and physical findings of device failure will seek advice from their orthopaedic surgeon regarding replacement of their implant. The American Academy of Orthopaedic Surgeons (AAOS) encourages physicians to talk with their patients about the risks of pain, disability, morbidity, and mortality associated with the implant and with revision surgery.

Re-operation may prove to be the best option for patients whose implants have failed, who are in chronic pain as a result of their faulty implant, and/or whose function has been negatively affected by the failure. Revision surgery, in the absence of evidence of clinical failure, as a preventative measure against possible implant device malfunction is rarely, if ever, recommended.

Adverse events should be reported once the individual patient's safety is ensured. While it is mandatory that hospitals and manufacturers reporting these events, surgeons have no such requirement. Surgeon reporting of any and all device failures and adverse events will provide clinical context to the report and improve the quality of the information available to the FDA as these events are evaluated.

Finally, patients without immediate symptoms and physical findings of device failure should be monitored for any changes in status. Surgeons should reference existing guidelines for the frequency and types of evaluation appropriate for the patient, device, and diagnosis.

The AAOS believes that patient safety must be the highest priority in cases of recalled implant devices, and care should be taken to confirm the device's failure when considering revision surgery as a treatment option. The risks of re-operation are significant and must be carefully assessed and discussed with the patient before treatment is administered.

The AAOS strongly encourages orthopaedic surgeons to:

1. be aware of device recalls and potential health problems associated with them;
2. report incidents of adverse events related to medical products via MedWatch (online at www.fda.gov/medwatch/index.html or by calling 1-800-FDA-1088);
3. cooperate with hospitals and implant manufacturers in notifying patients of the recall and its related concerns in cases where patient safety may be at risk;
4. pursue a course of shared decision making with the patient;
5. maintain the appropriate level of surveillance to inform future activity (revision, monitoring)

The AAOS believes clear communication between patients and physicians is essential when discussing the consequences of an implant recall. The orthopaedic surgeon should provide the patient with relevant information and pursue a course of shared decision making regarding a treatment plan.

The manufacturer of an orthopaedic device implant maintains the primary responsibility for orchestrating the recall of its product. Manufacturers cooperate with private insurance companies as well as with Medicare to reduce the administrative and financial burdens on the patient.

The U.S. Food and Drug Administration (FDA), the federal agency charged with overseeing the safety of medical devices, may order a recall under its statutory authority if it believes a serious risk exists to which the public must be alerted. More commonly, recalls are conducted under a manufacturer's own initiative. The FDA does, however, expect companies to assume responsibility for even voluntary product recalls including follow-up checks to ensure the recall was successful. The FDA's role is to monitor recalls and assess the adequacy of the firm's action.

References:

1. U.S. Food and Drug Administration, Recall Background and Definitions:
<http://www.fda.gov/Safety/Recalls/ucm165546.htm>

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