Don't Be Defective in Dealing with Device Alerts and Recalls

Device manufacturers often contact physicians with issues regarding implantable devices. Contact can range from an alert of issues with the device to a U.S. Food and Drug Administration (FDA) recall.

The FDA classifies recalls into three categories:

- Class I recalls are the most serious. They involve a health hazard with a reasonable probability that the use of the product will cause serious adverse health consequences or death.
- Class II recalls present a remote possibility of adverse health consequences from the use of the product.
- Class III recalls involve a situation where the use of the product is not likely to cause adverse health issues.

The FDA has mandated that manufacturers must include a unique device identifier (UDI) on all devices, starting with implantable devices. Implementation of the UDI system is expected to begin in 2014. UDIs can be captured in the electronic health record and used for device-tracking over time.

Physicians can be at risk for a malpractice suit if they do not handle defective device alerts and recalls properly. Take steps prior to and after surgery to decrease this risk and promote patient safety in case of an eventual device issue. Before a device is implanted, involve the patient in an informed consent discussion that encompasses the possible complications and side effects of device implantation. Once the device has been implanted, dictate in the postoperative report the type of implanted device and its serial number or UDI, and copy the post-op report to the office record. Note the UDI number on the patient's card in the office record on the first post-op visit.

Assign a specific individual in your practice the responsibility of receiving, assessing, and acting on device recall information.

If you receive a recall notification, follow these tips:

- For Class I recalls, work with the surgical facility where the device was implanted to verify which patients have the device. Notify the patients immediately, and determine the appropriate course of action.
- For Class II or III recalls, it is appropriate to inform patients of their options. Contact your patient safety risk manager to see if he or she can provide a sample letter to send to patients.
- Document the date the notice was received, the source of the notice, the device or product name and model number, the names of patients in the practice who were notified, and actions taken. Monitor patient compliance with and response to the notification.
- Follow the established process for properly handling explanted devices.

Contributed by The Doctors Company. For more patient safety articles and practice tips, visit www.thedoctors.com/patientsafety or contact your local representative Sarah Wolfenbarger at (800) 243-3503.