IMPLANT DEVICE TRACKING SYSTEM

Purpose: The purpose of this policy is to establish guidelines to follow FDA device tracking requirements (effective May 92)

Devices subject to tracking per 21CRF 821.20 include any class II or class III devices that falls into one of the three criteria:
1. The device would reasonably be likely to have serious adverse health consequences.
2. The device is intended to be implanted in the human body for more than one year.
3. The device is life sustaining or life-supporting device.

Policy: The hospital is required to track certain implants and life-sustaining devices. The requirements are part of the device tracking provisions of the Safe Medical Devices Act of 1990. The provisions were adopted by congress to ensure that patients with certain devices can be quickly notified of health risks associated with a defective device. Devices defined by the FDA for tracking as of 8/29/93 are identified in the current hospital policy.

The items are also recorded in Optime under the implants section in EPIC of each procedure.
   a. Device model number
   b. Device lot number
   c. Device serial number (if there is no serial number available, you must note the lot number in this space)
   d. Any identification card that is acquired with the implant will be scanned into EPIC and attached to that procedure.

For further tracking purposes, the Interventional Radiology/Neuro-Interventional Radiology Suite has included all implantable items. All records must contain a second reviewer's initials for QC purposes. The top set of initials will be the person who does the documenting and the bottom set will be the person who reviews. This documentation must occur at the end of the case. These logbooks are kept in a secure location in the designated lab behind a locked door and are readily available in the event of a recall.