

**HACKETTSTOWN REGIONAL MEDICAL CENTER
ADMINISTRATIVE POLICY MANUAL**

SAFE MEDICAL DEVICE TRACKING PROGRAM

Effective Date:	02/1996	Policy No:	AD96B
Cross Referenced:		Origin:	Materials Management
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POLICY:

1. Hackettstown Regional Medical Center will collect, maintain and report information on select permanent implantable devices and life support devices used outside of the hospital in order to comply with the Food and Drug Administration Modernization Act (FDAMA).
2. FDAMA requires manufacturers to track implantable devices that fit the following criteria:
 - implanted in the human body for more than one year, or
 - a life sustaining or life supporting device used outside a device user facility.
3. Final distributors, such as hospitals, must report to the manufacturer the name of the patient to whom it distributed the device and other required information:
 - name and address of the final distributor;
 - lot, batch, model, or serial number of the device or other identifier necessary to track the device;
 - name, address, telephone number, and social security number (if available) of the patient receiving the device;
 - date that the device was provided to the patient;
 - name, mailing address, and telephone number of the prescribing physician;
 - name, mailing address, and telephone number of the physician who regularly follows the patient; and
 - (when applicable) the date the device was --
 - explanted, with the name, mailing address, and telephone number of the explanting physician;
 - out of use due to patient death (date of death);
 - returned to the manufacturer;
 - permanently retired from use, or permanently disposed of.

PROCEDURE:

1. The medical device is delivered to the OR and surgically implanted in the patient.
2. The manufacturer, model and serial number is obtained from the medical device.
3. A medical device tracking form is completed by the OR staff and will include the information noted above as required by FDAMA.
4. The medical device tracking form is provided to:
 - The device manufacturer;
 - The OR purchasing staff;
 - Medical records for inclusion in the patient's permanent record.