County of Los Angeles **Department of Health Services**

VALLEYCARE
OLIVE VIEW-UCLA MEDICAL CENTER/HEALTH CENTERS
ANGIOGRAPHY SUITE/CARDIOLOGY DIVISION
POLICY & PROCEDURE
PACEMAKER/AICD IMPLANTATION

NUMBER: 1917
VERSION: 1

SUBJECT/TITLE: **IDENTIFICATION OF IMPLANTATED MEDICAL DEVICES**

PURPOSE: To ensure that the identification of an implant is checked prior to implantation and that implant information remains available following surgery and to report medical device related incidents at the hospital.

DEPARTMENTS: All

POLICY:

RESPONSIBILITY OF CIRCULATING NURSE

A. Prior to delivery of implant to sterile field, the identity (i.e., type, size, etc…) of the implant is verified with the surgeon.

B. Only implants verified as having been subject to the sterilization process are implanted.
   1. Factory-packaged sterile implants must be checked for package integrity and expiration date.
   2. In-hospital sterilized implants must be checked for package integrity, expiration date and process indicator results.

DOCUMENTATION

A. All implants must be documented.

B. The Registered Nurse in the circulating role is responsible for the documentation of implant devices.

C. Documentation is made on all appropriate records (i.e., operative record, implant log).
   1. Pacemaker leads and generators are documented as implanted devices.

D. When applicable, the following entries are documented:
   1. Patient's name and medical number
   2. Circulating and scrub nurse name
   3. Attending physician's name

4. Anesthesiologist's name
5. OR log #
6. Name of device
7. Manufacturer
8. Model number
9. Serial number
10. Location of implant

EMPLOYEE RESPONSIBILITY

1. Any individuals who discover, witness, or are notified of a medical device incident that they suspect may have caused a death, illness, or injury to a patient under treatment shall immediately notify their supervisor, who in turn will immediately notify a physician, the Safety Officer and Risk Management. After hours, notify the Nursing Administrator and communicate the following information:
   a. Patient's name
   b. Room and bed number
   c. Name of Attending physician notified
   d. Product name
   e. Location of the product
   f. Serial number of the product
   g. Model number
   h. Name of the manufacturer, if known
   i. Brief description of the incident

2. Within twenty-four (24) hours of the suspected adverse medical device incident, the personnel who reported the incident shall complete an on line Patient Safety Network (PSN).

RISK MANAGEMENT RESPONSIBILITY

1. Risk management, in conjunction with the Safety Officer shall be responsible for establishing and maintaining a hospital wide system for documenting medical device incidents. They shall also be responsible for providing education and training of the medical device program.

2. The Risk Management team shall ensure that all data collected from the hospital's medical device reporting program shall be incorporated into the hospital wide event notification program, the results of which are communicated to Administration, the Quality Improvement Committee, and others when deemed necessary.

References: Hospital Administration, Safety Policy and Procedures	
Approved by: Robin Wachsner (Chief of Cardiology)	Date: 08/04/2011
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