OLIVE VIEW-UCLA MEDICAL CENTER
OPERATING ROOM
POLICY & PROCEDURE

NUMBER: 2697
VERSION: 1

SUBJECT/TITLE: IMPLANTATION OF MEDICAL DEVICES

POLICY:

CARE AND HANDLING OF IMPLANTS

A. In-Hospital Sterilization Guidelines
   1. Flash sterilization of implant items are only process in Central Service.
   2. In-hospital sterilization implants are processed in sterilizers that are concurrently biologically monitored/tested..
   3. Whenever feasible, in-hospital sterilized items are not implanted until such time as results of biological monitoring are known.
B. Resterilization of Implants
   1. Only those implant items for which the manufacturer has provided specific instructions may be sterilized.

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 following manufacturer's Instructions for use (IFU)s 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 completed in the eHR (Online Real-Time Centralized Health Information Database - ORCHID)
D. Items to be documented as implanted devices include, but are not limited to:
   1. Vascular grafts
   2. Vascular access devices
   3. Pacemaker leads and generators

4. Orthopedic devices
5. Cosmetic implants
   a. Breast
   b. Chin
6. Dental appliances
7. Ear prosthesis
8. Intraocular lens
9. Penile prosthesis
10. Dialysis catheters
11. Cerebral aneurysm clips
12. Ventriculoperitoneal

E. When applicable, the following entries are documented in ORCHID:
1. Patient's name and medical number
2. Circulating and scrub nurse name
3. Attending physician's name
4. Anesthesiologist's name
5.
6. Name of device
7. Manufacturer
8. Lot number
9. Model number
10. Serial number
11. Size
12. 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 Safety Intelligence and forward the report to Risk Management.

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.

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: **OR, Risk Management**

DEFINITIONS:

PROCEDURE:

References: Hospital Administration, Safety Policy and Procedures	
Approved by: Paula Siler (Clinical Nurse Director III)	Date: 09/22/2017
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