

PROCEDURE FOR: Implantable Devices

POLICY:

1. In accordance with the US Food and Drug Administration (FDA), an implant is defined as a device intended to be implanted into a surgically or naturally formed cavity of the human body to continuously assist, restore, or replace the function of an organ system or structure of the human body for more than one year.
2. As a facility which implants devices that meet the FDA's definition and that must retain certain information in case an investigation, such as a recall, occurs, staff will document the following information:
  - the name and address of the facility where the surgery / procedure took place;
  - the identification numbers used by the manufacturer (eg, lot, batch, model, serial number);
  - the patient's name, address, telephone number, and social security number, unless the patient refuses permission to release that information; and
  - the name, address, and telephone number of the implanting surgeon, as well as the physician who is following the patient, if they are different.
3. All packaged implantable devices will be checked and identified by the implanting surgeon / physician prior to opening. Any "Special order" implants will be clearly identified with the patient's name and date of procedure. Implants will be provided to the surgeon / physician by the circulating nurse, who will verify along with the implanting physician that it is the correct item prior to opening. Prior to presenting the implant to the sterile field, the circulating nurse will inspect all original packaging material for any expiration date or other manufacturer information that affects use of the implant.
4. The sterilization process will include use of a biological indicator for all unsterile implantable devices that are designed to be reprocessed and are not provided sterile. No resterilization of implants that are individually, sterile packaged by the manufacturer and are not intended to be reprocessed will be allowed.
5. All items identified by the FDA and published in the Federal register will be documented in the perioperative information system, in accordance with HAM Policy #11-036 FDA Device Tracking Requirements.
6. Any explanted device that has a visible serial number will be documented in the nursing record. Explanted items must be processed according to Anatomic pathology in compliance with *Appendix A of OR protocol for Specimen Care and Handling*.
7. Release of explants will be done as follows, unless documentation of implant failure is deemed necessary to diagnosis, treatment, or medical litigation:
  - a. explants may never be given directly to a Health Care Industry representative.
  - b. explants may be released to the patient or physician following decontamination, so long as an entry is made in the patient record.

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REFERENCE: Hospital Administrative Manual

[11-036 - Medical Devices to Provide and Effective  
Method for Device Recalls and an Efficient Patient  
Notification Process: Tracking of](#)

APPROVAL: Nursing Standards Committee

EFFECTIVE DATE: 4/94

REVISION DATE: 9/97, 5/00, 2/06, 2/08, 12/08