Department of Veterans Affairs **VHA DIRECTIVE 2009-062**
Veterans Health Administration
Washington, DC 20420 **November 23, 2009**

MANAGEMENT OF NON-BIOLOGICAL IMPLANTABLE DEVICES

1. PURPOSE. This Veterans Health Administration (VHA) Directive establishes policy and procedures for the management of non-biological implantable devices.

2. BACKGROUND

a. As a result of Office of Inspector General (OIG) Report No. 06-03-677-221 dated September 28, 2007, regarding the Audit of the Acquisition and Management of Selected Surgical Device Implants, a policy will be developed to ensure that processes are in place for the proper management of the non-biological implantable devices.

b. A non-biological implantable device is any material of a non-biological nature that is to be placed in the body and is covered with tissue or has the potential to be covered with tissue. See Attachment A for the selected non-biological implantable devices applicable for this policy.

c. Food and Drug Administration (FDA) recalls can be queried through Search for Recalled Items (Prosthetic Package), National Prosthetic Patient Database (NPPD), Implantable Cardiac Defibrillator (ICD) Surveillance Center, and the Surgery Registry.

3. POLICY: It is VHA policy that all non-biological implantable devices must be managed by Supply Processing and Distribution (SPD) who ensures and verifies sterility prior to distribution and before implantation; the devices must be procured utilizing prosthetic specific purpose funds for implants that stay in the body for greater than 30 days. ***NOTE:*** *All non-biological implantable devices that are not received in a sterile condition from the manufacturer, (including third parties) must be properly cleaned, disinfected, and sterilized in accordance with the Department of Veterans Affairs (VA) Handbook 7176 prior to delivery for use or implantation.*

4. ACTION

a. **Service Area Officer.** The Service Area Officer is responsible for the establishment of consignment and contractual agreements when requested by the user and determined advantageous to VA. ***NOTE:*** *The Service Area Officer, under the Office of Procurement and Logistics (10FL), is a regional contracting manager.*

(1) Consignment and contractual agreements authorized by a Contracting Officer (CO) are the preferred method to manage non-biological implantable stock and are negotiated at a local, Veterans Integrated Service Network (VISN), or National level.

(2) Contractual agreements must include VA delivery requirements to observe timely sterilization processes as described in VA Handbook 7176.

THIS VHA DIRECTIVE EXPIRES NOVEMBER 30, 2014

b. **Facility Director.** The facility Director is responsible for:

(1) Creating a facility policy that ensures:

(a) Managing and accountability of non-biological implants,

(b) Identifying assigned responsibilities, and

(c) Addressing the accessibility and limitations of vendor representative contact throughout the facility. ***NOTE:*** *It is required that all vendor representatives must first report to the facility Logistics Offices during regular business hours. Vendor representatives are required to report to Police or Security Service or Administrative Officer on Duty (AOD) during non-business hours.*

(2) Ensuring all non-biological implantable devices are managed by SPD personnel.

(3) Ensuring initial sets are purchased from hospital funds, not with Prosthetic specific purpose funds.

(4) Ensuring all VA owned inventory of non-biological implants is maintained in Generic Inventory Package (GIP).

(a) A complete inventory of all current VA-owned prosthetic non-biological implantable devices will be conducted. This would include non-biological implantables in the Operating Room (OR), as well as specialty areas, e.g., Interventional Radiology, Cardiac Catheterization Laboratory, Dental, Gastro-intestinal (GI) Laboratory, Women's Clinic, etc. This inventory must be entered into the GIP and disposed of according to VA policy (see OIG Report 06-03-677-221).

(b) Subsequent inventories are conducted according to VHA Handbook 1761.02.

(5) Ensuring SPD personnel are notified that loaner instrument trays have been requested, including expected arrival date.

(6) Determining the minimal amount of commonly used trays, instrument sets, and non-biological implants for repurchase to have available for procedures. Initial trays must be purchased from hospital funds, not prosthetic specific purpose funds. As items are implanted into patients, Prosthetics will replenish the items using Prosthetic specific purpose funding based on consults received for specific patients.

c. **Facility Chief, SPD.** The facility Chief, SPD, is responsible for:

(1) Managing an inventory using GIP for all routinely used non-biological implants (e.g., screws, nails, plates, etc.) of assorted sizes that are required in trays or instrument sets which are not on consignment, and ensuring replacements are immediately available.

(2) Ensuring all trays, instrument sets, and non-biological implants are accounted for within SPD GIP by SPD personnel. ***NOTE:*** *This is not applicable for borrowed trays, instrument sets, and implants.*

(3) Ensuring, when trays, instrument sets, and implants are received, contents are inventoried by SPD personnel, and the itemized inventory count sheet is documented using the GIP inventory.

(4) Ensuring no instrumentation or non-biological implantables are received by, or delivered to, the OR, Prosthetics, Cardiac Catheterization Laboratory, Interventional Radiology, Dental, etc., without SPD joint involvement.

(5) Ensuring non-biological implantables used in the procedure are electronically distributed from GIP primary to GIP secondary distribution point by designated inventory manager.

(6) Ensuring GIP inventory quantities are updated to reflect items received.

(7) Managing receipt of all non-biological devices with the understanding that ORs and procedural rooms (i.e., Catheterization and Electrophysiology Laboratories, Interventional Radiology Suites, etc.) must have just-in-time inventory available, and that procedures are in place for immediate delivery to those areas.

(8) Inventorying in-trays, instrument sets, and non-biological implants when the vendor representative brings them, upon arrival for decontamination and sterilization by both SPD personnel and the vendor.

(a) Documentation of itemized inventory count sheet provided by the vendor must be signed by both the vendor and SPD.

(b) Instrument trays without non-biological implants must be received at the facility at least 24 hours before they are to be used to provide adequate time to reprocess them, e.g., decontamination and sterilization. "Flash Sterilization" is not allowed for trays arriving late to the facility. ***NOTE:*** *Failure to bring the non-biological implant into the facility in advance is not a valid reason to release the non-biological implant early from quarantine.*

(9) Ensuring when non-sterile non-biological implants contained in loaner instrument trays that are not part of the facility's inventory are received in the facility at least 72 hours prior to use, in order to provide adequate time for reprocessing (e.g., decontamination, sterilization, and the 48-hour quarantine period required to obtain the biological test results).

(10) Releasing, only in emergency situations, non-biological implants during this quarantine period and a waiver must be obtained from the Chief of Staff or Acting Chief of Staff to do so.

(11) Ensuring designated SPD staff:

(a) Manages non-biological implantable devices to include receipt, inspection, and sterilization.

(b) Manages sterility inspection of non-biological implantable devices to include visual inspection of expiration date.

(c) Conducts a monthly inventory of non-biological implants that do not require SPD sterilization to include visual inspection of expiration dates, and including those located in clinical areas (i.e., OR, Cardiac Catheterization Laboratory, Interventional Radiology Suites, Dental, etc.).

(d) Notifies the surgeon or OR Manager when, for any reason, loaner instrument trays have not been received or cannot be reprocessed in time for the planned procedure.

(e) Accounts for all non-biological implantables within the GIP inventory. ***NOTE****: Not applicable for borrowed non-biological implantables that do not require sterilization by SPD.*

(12) Ensuring, when tray, instrument sets, or non-biological implants are returned to the vendor, the contents are inventoried by both SPD personnel and the vendor.

(a) Documentation of itemized inventory count sheet must be signed by both the vendor and SPD.

(b) The itemized inventory count sheet is retained until items implanted are paid for and replaced. ***NOTE:*** *Vendors conducting business with VA for loaner instrument sets and non-biological implants must comply with the requirement to have an itemized inventory count sheet.*

d. **Facility Clinical Service Chief.** The facility Clinical Chief is responsible for:

(1) Generating an electronic consult to Prosthetics.

(a) This consult specifying non-biological implantables utilized, or wasted, with a copy provided to SPD for inventory distribution, must also specify patient name, social security number, vendor, non-biological implant model, description, size, quantity, and serial or lot number for payment purposes and replenishment of stock. ***NOTE:*** *This ensures appropriate payment will be made and tracking through the NPPD is ensured in case of any recall.*

(b) Prosthetic consults are located in the Graphic User Interface (GUI) package.

(2) Funding of any unaccounted for, or expired, non-biological implantable items.

(3) Ensuring non-biological implantable devices that were wasted or contaminated during surgery, or any other procedure, are included in the consult to Prosthetics for accountability.

e. **Facility Chief, Prosthetics.** The facility Chief, Prosthetics, is responsible for ensuring proper purchasing protocol is followed when receiving consults for payment and replacement of non-biological implants after implantation.

(1) The purchase order must be created in The Prosthetic Purchasing Package for non-biological implantables used in the individual case; this is for:

(a) Paying the vendor for the items used in the individual procedure,

(b) Replacing SPD stock with SPD as the delivery point, and

(c) Providing a copy of the purchase order to SPD for GIP receiving.

(2) Non-biological implants are to be purchased using Prosthetic Specific Purpose funds for implants that stay in the body for longer than 30 days.

f. **OR Manager.** The OR manager is responsible for:

(1) Ensuring OR staff cooperate with SPD staff allowing SPD adequate time to decontaminate and reprocess the tray should it arrive late.

(2) Ensuring that after the procedure is complete, documentation of non-biological implantables used is entered into the Surgical Package and into Veterans Computerized Patient Record System progress notes by OR staff.

(3) Ensuring non-biological implantable devices that were used, wasted, or contaminated during surgery, or any other procedure, must be included in the consult to Prosthetics for accountability.

5. REFERENCES

a. OIG Report 06-03-677-221. Audit of the Acquisition and Management of Selected Surgical Device Implants.

b. VA Handbook 7176.

c. VHA Handbook 1173.2.

d. VHA Directive 1761.02.

e. VA Acquisition Regulations (VAAR) 870.108-3. Consignment Agreements.

6. FOLLOW-UP RESPONSIBILITIES: Office of the Chief Consultant, Prosthetic and Sensory Aids Service (113) is responsible for the contents of this Directive. Questions relating to the technical and programmatic aspects of this Directive should be referred to the Chief Consultant, Prosthetic and Sensory Aids Service at 202-461-1800.

7. RECISSION: None. This VHA Directive expires November 30, 2014.

Gerald M. Cross, MD, FAAFP
Acting Under Secretary for Health

Attachment

DISTRIBUTION: E-mailed to the VHA Distribution List 11/25/09

ATTACHMENT A

EXAMPLES OF NON-BIOLOGICAL IMPLANTABLE DEVICES

Examples of non-biological implantable device include, but are not limited to:

1. Anchors Pins;

2. Any instrument set (including loaners) that may contain any potential non-biological implantable device(s);

3. Bolts;

4. Breast implants;

5. Cranial implants;

6. Heart valves;

7. Internal pacemakers or Implantable Cardiac Defibrillator (ICD);

8. Joints (such as knees, hips, and shoulders);

9. Marlex mesh;

10. Mersilene mesh;

11. Nails;

12. Nuts;

13. Penile implants;

14. Plates;

15. Rods;

16. Screws;

17. Stents;

18. Vascular grafts; and

19. Washers.