

January 4, 2007

## ENSURING STERILITY OF NON-BIOLOGICAL IMPLANTABLE DEVICES

**1. PURPOSE:** This Veterans Health Administration (VHA) Directive provides policy for verifying the sterility of non-biological implantable devices.

### 2. BACKGROUND

a. Verification of sterility of non-biological implantable devices used in VHA is a critical priority. While this may be self-evident, the variety of sources of non-biological implantable devices, the many mechanisms for purchase of non-biological implantable devices, and the differences in distribution of non-biological implantable devices after arrival at Department of Veterans Affairs (VA) facilities have presented challenges leading to increased vulnerability to risk of infection in the patient care setting. Because of these inconsistencies and the risk they may present to VHA patients, it is necessary to prescribe a system for verification that non-biological implantable devices are sterile for patient use.

b. **Definition of a Non-Biological Implantable Device.** A non-biological implantable device is any material that is to be placed in the body and is covered with tissue, or has the potential to be covered with tissue (see Att. A for examples of non-biological implantable devices).

c. Notwithstanding the source of the order, the funding, the delivery point, or other inconsistencies in the procurement process, all non-biological implantable devices that arrive at a VHA facility must have their sterility status determined by the facility's own local policy on ensuring sterility of non-biological implantable devices.

**3. POLICY:** It is VHA policy that all non-biological implantable devices must be sterile prior to implantation and that a process be established to verify the sterility. *NOTE: This must be done in accordance with VA Handbook 7176 and subsequent additions as well applicable requirements by other valid oversight entities; go to web site:*  
<http://vaww1.va.gov/vasafety/docs/SPDHandbook7176.pdf>.

### 4. ACTION

a. **Facility Director.** The Facility Director is responsible for a written policy for implementing the components of a program for ensuring sterilization of non-biological implantable devices. *NOTE: For locally processed (sterilized) non-biological implantable devices, the pertinent sections of VA Handbook 7176 must be followed.* This policy must include:

(1) A description of the processes and procedures to be followed if the non-biological implantable device is not sterile upon receipt.

**THIS VHA DIRECTIVE EXPIRES ON JANUARY 31, 2012**

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(2) Who in the operating room is responsible for:

(a) Checking the integrity of the package containing the non-biological implantable device, appropriate color change of the external chemical indicator tape, expiration date, and

(b) Documenting this check prior to use of the implantable device(s).

(3) Who in the facility is responsible for managing an inventory of all routinely-used non-biological implants, such as screws or nails or plates that are needed in sets of assorted sizes and not on consignment, to ensure replacements are immediately available. *NOTE: This inventory is not subject to the 30 days-on-hand limit.*

(4) A statement that non-biological implantable devices are not to be sterilized by flash sterilization.

(5) A statement that all sterilization loads containing these non-biological implantable devices are monitored with the appropriate biological monitor.

(6) A statement that after sterilization, non-biological implantable devices are quarantined in Supply, Processing, and Distribution (SPD) and not released until the spore test is found to be negative (48 hours). *NOTE: Early release requires the written permission by the Chief of Staff or the Acting Chief of Staff.*

b. **Chief of SPD.** The Chief of SPD (or person with that function) is responsible for:

(1) Ensuring the sterility of non-biological implantable devices.

(2) Establishing local facility policies and procedures and monitoring activities pertaining to the sterilization of non-biological implantable devices.

(3) Ensuring that manufacturers' instructions are obtained and followed to assure the appropriate mode of sterilization is used on non-biological implantable items sterilized within VHA.

**5. REFERENCES:** VA Handbook 7176 Supply, Processing, and Distribution (SPD) Operational Requirements.

**6. FOLLOW-UP RESPONSIBILITY:** The Office of Patient Care Services, (11) is responsible for the contents of this Directive. Questions relating to the technical and programmatic aspects of the Directive should be referred to the Infectious Diseases Program Office, SPD Section at (513) 487-6030.

**7. RECISSIONS:** None. This VHA Directive expires on January 31, 2012.

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Attachment

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**ATTACHMENT A**

**EXAMPLES OF NON-BIOLOGICAL IMPLANTABLE DEVICES**

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

1. K-wires and/or Steinmann Pin,
2. Stents,
3. Screws,
4. Plates,
5. Vascular grafts,
6. Heart valves,
7. Marlex mesh,
8. Mersilene mesh,
9. Internal pacemakers,
10. Penile implants,
11. Breast implants,
12. Cranial implants,
13. Joints (such as knees, hips, and shoulders), and
14. Any instrument set (including loaners) that may contain any potential non-biological implantable device(s).