

## STANDARD OPERATING PROCEDURE - 4012

### IMPLANTABLE DEVICE (NON-STERILE) PROCESSING

PURPOSE: To establish a standard operating procedure for processing implantable devices.

POLICY: Implantable devices for use in surgical procedures are received in Supply, Processing, and Distribution (SPD) and must adhere to the requirements of reprocessing of implantable devices.

INFORMATION: All implantable devices (non-sterile) including from third parties must be properly cleaned, disinfected, and/or sterilized prior to delivery to Operating Room (O.R.). It is critical to coordinate the receipt, decontamination, and sterilization of implants with both SPD and O.R. staff.

RESPONSIBILITY: All personnel involved in the receipt and process of surgical instruments.

#### PROCEDURE:

1. Review surgical schedule to check for cases requiring implantable devices.
2. Confirm the need with appropriate surgical staff.
3. Contact the vendor or responsible parties to schedule delivery of devices in sufficient time, which is determined to be greater than 48 hours, to assure that decontamination and sterilization of the items required for scheduled case can be accomplished.
4. Accept and document receipt of the implantable devices.
5. Follow the manufacturer's written instructions for cleaning, packaging, and sterilization. If written instructions have not been provided, contact the manufacturer and have the pertinent information delivered.
6. All steam and ethylene oxide gas sterilization loads containing any implantable devices or intravascular materials will be monitored with the appropriate biological indicator.
7. After sterilization, these devices will be held in quarantine by SPD for 48 hours and will not be used until the biological indicator is found to be negative.
8. Early release for use will be permitted on an emergent basis and requested in writing from the Chief of Staff, or designee.
9. Implantable devices **will not** be sterilized by flash steam sterilization.

Reference: VA Handbook 7176, Supply, Processing and Distribution Operational Requirements Part 7, page 46.