Applicable to: Perioperative Services
Team Members Performing: Instrument Processing Staff

I. Purpose:

Provide guidance for sterilization of implantable devices. Implants and other special items should be made available to the hospital with a 24-48 hour lead time to allow for terminal sterilization.

II. Procedure:

A. Sterilization of Implants

1. All implantable items must be properly cleaned, rinsed and dry prior to sterilization.

2. Every terminal sterilization load containing an implant must be monitored with a Process Challenge Device (PCD), containing a biological indicator (BI) and a class (5) five integrator.

3. The implant tray must be processed according to the manufacturer’s recommendations.

4. Daily sterilization and implant logs must be complete and accurate.

5. The class 5 (five) integrator and biological indicator results are interpreted for acceptability according to manufacturer recommendations and the results must be recorded following hospital procedures.

6. If the BI results are positive, the load should be quarantined until the result of the BI testing is available. See Policy # AS 201170-400.25, Load Retrieval Systems for Positive Biological Indicators.

7. In the event it is necessary to release the implantable device before the BI results are known, should be well documented.

8. Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.
B. Immediate Use Sterilization of Implants

1. Immediate-use sterilization of implants is not recommended and is limited to urgent situations.

2. Run the appropriate biological indicator (BI) with each load containing an implantable item.

3. Implants should not be released unless the BI has been read as negative. If the physician chooses to proceed with using the implant before the results of the BI are known, OR staff will then complete a risk management report.

4. All sterilization and biological information must be documented accurately and traceable back to the patient in which the implant was used.

5. A patient sticker must be placed in the biological log book along with the results.