THE UNIVERSITY OF TOLEDO MEDICAL CENTER
STERILE PROCESSING DEPARTMENT PROCEDURE

SUBJECT: BI AND INTEGRATOR PROCESS FOR STEAM STERILIZATION

PROCEDURE NO: SP3-4

PROCEDURE STATEMENT

A Biological indicator TEST PACK must be run every 24 hours and in every sterilizer load containing an implantable device and an INTEGRATOR test pack must be run with every load.

PURPOSE OF PROCEDURE

To ensure the effectiveness of the sterilization process.

PROCEDURE

I. BI AND INTEGRATOR PROCESS

Make sure that a CONTROL BI bearing a matching lot number to the BI being used has been activated and placed in an incubator. A new Control BI is activated every 24 hours.

1. Obtain a BI Test Pack and an Integrator Test Pack.

2. Check the Lot # of BI test pack to assure that it matches the Control lot #.

3. Place the BI test pack on bottom shelf, front of cart (Nearest to drain). Place the Integrator Test Pack next to it.

4. Run the sterilizer load.

5. When load is complete:
   a. Remove BI and Integrator Test packs from sterilizer.
   b. Open Integrator Test Pack and, remove Integrator.
   c. Tape integrator to SPM Load Printout.
   d. If Integrator Failed: Load must be torn down, rewrapped and resterilized.
   e. Tape failed integrator to SPM Load Printout and detail the teardown procedure.
   f. Open BI pack, pick up BI and close cap by squeezing BI holding top and bottom.
   g. Allow BI to cool for 2-3 minutes.
   h. Crush BI in incubator (1 time-back and forth).
   i. Tap the BI on the counter vigorously to insure that the liquid mixes in the cotton.
   j. Visually check the BI to assure that the cotton has turned purple.
   k. Place the BI in an open incubator well.

6. Fill out the BI Reminder sheet IMMEDIATELY. Make sure reminder sheet is kept on the front table.
7. After 3 hours, incubator should automatically indicate a “negative” reading on the BI. If at any time the incubator alarms and indicates a “positive” reading, immediately implement policy # SP6-10 Positive BI.

8. *If the incubator and BI read “negative”, enter the data in the BI reminder sheet and enter the following info into the SPM system*
   a. Enter date (dd/mm/yy) time (AM/PM) OUT of incubator.
   b. Initials of person reading and removing BI.
   c. Under “Test Result” If auto reader alarms, enter + under “Test BI Results” and begin load recall process according to procedure #

9. If auto reader indicates negative, enter - under “Test BI Results”. Implants may be released at this time.
   *If implants are requested prior to auto reader indicating negative, make sure that the yellow light is on, release instruments to OR and log in “Implant Log Book”.*

10. At this time, read control and enter + or – under.

11. “Control BI Results.” Results should be positive. If CONTROL is negative, contact the supervisor on duty or On-Call.

12. Remove BI from incubator and place in disposal bin.

Reviewed/Revised
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