THE UNIVERSITY OF TOLEDO MEDICAL CENTER
STERILE PROCESSING DEPARTMENT PROCEDURE

SUBJECT: Sterilization Monitoring in the OR **Procedure No: SP7-2**

PROCEDURE STATEMENT

Routine sterilizer efficacy monitoring of pre-vacuum Immediate-Use Steam Sterilization Cycles of 5 minutes at 270°F/132°C will be run daily plus in every load containing Implants.

PURPOSE OF PROCEDURE

Per AAMI ST79, all steam sterilizers should be routinely tested using a ***Biological Indicator (BI) Process Challenge Device (PCD)****. Biological indicators are test systems containing viable microorganisms providing a defined resistance to a specified sterilization process.*

PROCEDURE

1. A PCD containing a BI and a Steam **Chemical Integrator (CI)** is used to conduct daily routine efficacy monitoring of a 5 minute 270°F/132°C pre-vacuum immediate-use steam sterilization cycle.

2. A PCD is made by placing a BI and a CI in an empty representative test tray, (empty rigid container cleared for IUSS).

3. The PCD is placed on the bottom shelf of the sterilizer, over the drain, in an otherwise empty chamber.

4. The sterilization cycle is run.

5. When the cycle is complete, the PCD is retrieved and opened and the monitoring products are removed. The BI is allowed to cool for 10 minutes. The BI is then identified with the appropriate sterilizer and cycle information, activated, and incubated in the designated incubator (3M Auto-reader 490) according to instructions provided in the IFU.

6. A positive control BI having the same lot # as the test BI is incubated each day.

7. The result of the control BI is recorded. The Control BI must show a fluorescent positive result (+ symbol on the Auto-reader 490 LCD display) within 1 hour to ensure the test BI result is valid.

8. The final negative reading (- symbol on the Auto-reader LCD display) of the test BI is made at 1 hour and indicates a successful sterilization process. The test BI result and chemical integrator result are documented.

9. Any positive result for a test BI and/or failing chemical integrator result must be reported to the SPD Manager immediately for further investigation and/or action.

10. A Class 5 Integrating Indicator is also used in all loads containing implants. All implants are quarantined until the negative BI result is obtained after 1 hour of incubation.

References

1. ANSI/AAMI ST79:2010 &A1:2010 & A2:2011 & A3:2012 *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.* Section 10.7.4
2. Association of perioperative Registered Nurses. *Perioperative Standards and Recommended Practices, 2013 Edition.* Recommended Practices for Sterilization, Recommendations VII and XX.
3. 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V – manufacturer's written IFU.

Reviewed/Revised
2006, 2007, 2009,
2010, 2014, 10/2017