[redacted] [facility name redacted]
San Francisco, CA
Clinical Observations for October 7, 2015

1) All steam cycle parameters were originally set at 4min/270*/20min dry. On our recommendation the dry time was extended to 35 min. Water spotting observed previously on tray liners, filters and count sheets was reduced or eliminated with the 35 min dry time. Please be aware that extending dry time masks underlying issues. It does not preclude the facility from performing periodic device testing and in doing so may result in more efficient (quicker) dry times.

2) We recommend that IFUs for all vendor instruments be obtained and reviewed every time the set/tray arrives at the facility. If needed, sterilization parameters may need to be adjusted to comply with parameters from the OEM of loaned/consigned sets.

3) Set weights are currently not measured. We recommend that all sets be weighed to comply with the validated limits from the sterilizer and container manufacturers.

4) Photographs were taken to demonstrate a properly configured steam sterilization load.

5) We recommend that the facility obtain a copy of AAMI TIR34 regarding water quality.

6) We recommend periodic device testing as outlined in ANSI/AAMI ST79, Section 10. For sets that will be transitioning from blue wrap to rigid containers, we recommend verification testing in the new rigid containers. Until AAMI ST90 is released, please refer to ISO 17665-3 as a contributing systematic approach to placing items processed into device families and testing accordingly.

7) We observed impressions on the inside of blue wrap. These impressions should not be considered a contaminated set. Stains/marks on tray liners are likely a result of water quality issues and/or steam quality issues. Facility reports that a culture was taken on such a set, but there was no microbial growth after three days. To further reduce the possibility of stains/marks, we recommend that autoclave chambers be cleaned as recommended in the Operator Manual of the sterilizer manufacturer.

8) Corner protectors can cause moisture retention for steam sterilization. Consider removing corner protectors for sets sterilized in steam. Once periodic device testing is implemented the facility may determine if the corner protectors can be placed in sets for steam sterilization.

9) We recommend that a lint free surgical towel or approved tray liner be placed under sets with large metal mass, to assist in wicking of moisture. For more information, please refer to ANSI/AAMI ST79, Section 8.4.5.

10) To help reduce excess moisture, instruments should be dry when packing instrument trays for steam sterilization.

11) An in-service will be scheduled and provided for both the Operating Room staff and Sterile Processing staff to cover processing from the perspective of both areas. Root cause analysis should communicate expectations, tolerances and specifications for those processes effecting sterility outcome.

12) Staples attached to previously processed count sheets were observed to be rusted. Staples should not be used on count sheets or in sets. In terms of patient safety, staples may become dislodged and fall into either the tray and/or potentially end up in patient. All count sheets should

be placed inside paper bags if they must be processed inside the sets (per request from SFGH Infection Control Department).

13) We recommend the use of an infrared heat “gun” to measure the temperature of cooling sets. Sets should not be released until they are at room temperature. Be aware that infrared technology has been known to deviate by 10-15 degrees. Please also be aware that this technology measures the external temperature of the set wrap/container. Testing should include unwrapping or removing container lid and recording internal temperature unimpeded to correlate external readings and verify a continuum with internal temperatures.

14) For guidance on the process of opening the sterilizer and removing a load, we recommend that the facility follow the instructions found in the Operator Manual of the sterilizer manufacturer (i.e. removal of the load at the end of cycle and allowing it to return to room temperature). Please document this process and disseminate the information all SPD staff.

15) A sample of steam condensate was taken for testing to be sent for a STERIS TSSR. We recommend that a thorough investigation of all steam traps and delivery systems (i.e., the inspection and cleaning of steam traps) be inspected. We also recommend that the steam filters on the sterilizer be checked.

16) We recommend that the department contact either the hospital’s Facilities Department or a third party water treatment company to discuss deionized water or other water treatment options for the final rinse in the washer/disinfector.

The STERIS Clinical Education Specialist is performing this assessment based on Industry Standards and Guidelines, with the understanding that based on processes observed for the time on site may not include all processes performed by every staff member. The assessment is to be used as identification for areas of process improvement and does not constitute STERIS Recommended Practices.

Arthur Henderson, RN, BA, CNOR, CRCST, GTS
Senior Clinical Education Specialist

Aaron Cloward, BA, ST, CRCST
Clinical Education Specialist

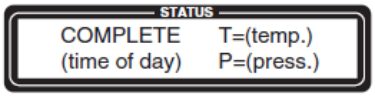
5.4 Unloading the Sterilizer

⚠ WARNING – BURN HAZARD: Sterilizer, rack/shelves and loading car will be HOT after cycle is run. Always wear protective gloves and apron (also face shield if processing liquids) when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.

⚠ WARNING – BURN HAZARD: Steam may be released from the chamber when door is opened. Step back from the sterilizer each time the door is opened to minimize contact with steam vapor.

⚠ WARNING – SLIPPING HAZARD: To avoid slippery floor conditions, immediately wipe up any spilled liquids or condensation in sterilizer loading or unloading area(s).or unloading area.

At the end of a cycle, when end-of-cycle tone sounds and display shows:



... open the chamber door.

NOTE: Before unloading the sterilizer, note the following:

1) Wear clean gloves and use clean towels as "pot holders" when carefully removing load/tray(s) from the sterilizer shelves or loading car.

2) Never place a sterilized tray on an unsterile solid shelf or cold surface. Once cooled, trays may be placed on a wire shelf.

1. Remove the load from chamber shelf (shelves). Avoid unnecessary handling.
2. Visually check outside wrapper for dryness. If there are water droplets or visible moisture on the exterior of the package, or on the tape used to secure it, the pack or instrument tray is considered **unacceptable.**
3. To prevent condensation, transfer the load to a surface which is well-padded with fabric. **Do not place load on a cold surface.** Ensure no air conditioning or cold air vents are in close proximity.
4. Remove packs or instrument trays from the padded surface when they have reached ambient (room) temperature. Depending on the items and environment of the area, this may take a minimum of one hour.

IMPORTANT: After removing load(s) from the chamber, close the chamber door and keep the chamber door closed to minimize utility consumption.