CLINICAL POLICY

STEAM STERILIZATION AND MONITORING

Sterile Processing

A. EFFECTIVE DATE :

April 6, 2020

B. PURPOSE :

To address the process for use and monitoring of steam sterilization.

C. POLICY :

1. Saturated steam under pressure should be used to sterilize heat-stable and moisture-stable items unless otherwise indicated by the MIFUs.
2. Devices labeled as single-use will not be reprocessed on site; single-use devices may be collected for reprocessing by an approved vendor.
3. The sterilizer manufacturer's written IFU may be referenced for proper use of the sterilizer accessories (e.g., carts and carriages) and sterilizer control operation.
4. Staff who operate steam sterilizers will have validated competency to operate the sterilization equipment.
5. A vacuum challenge process challenge device (Bowie-Dick) will be run in the first load of the day (no other items) in each pre-vacuum dynamic air removal steam sterilizer.
6. A biological indicator (BI) will be run to provide evidence of sterilization efficacy in:
   a. the first load of the day in all steam sterilizers
   b. every load done in Pre-vacuum Dynamic Air Removal sterilizers
   c. any gravity displacement steam sterilizer load that contains an implant
7. Chemical indicators / integrators (CI) will be used to assist in detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunction of the sterilizer. A single non-responsive or inconclusive CI will not be considered definitive evidence of a contaminated load or malfunctioning sterilizer.
8. Items requiring the same cycle parameters should be processed in the same load.
9. Load configuration should ensure adequate removal of air and penetration of steam into each package, and steam evacuation.
10. Heavier items should be placed on the bottom of the sterilizer racks and the weight distributed evenly.
11. Stacking of items should be avoided unless the packaging manufacturer's written IFU supports such practice.

Immediate Use Steam Sterilization and Early Release

12. Immediate use steam sterilization (IUSS) should be kept to a minimum and used only in selected clinical situations and in a controlled manner. IUSS will not be used for purposes of convenience or as a substitute for insufficient instrumentation.
13. If IUSS is used, the identity of the patient will be traceable and all prompts in the IUSS log will be completed.
14. Late receipt of loaned instruments should not be used to justify IUSS.

15. One Tray enclosed container system should be used instead of IUSS when the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field items is needed and drying time can be bypassed per MIFUs.
16. Release of implants for patient use before BI results are known is unacceptable and should be the exception, not the rule.
17. In the event that an implant is requested before BI results are known, the surgeon must sign an Exception Form for Premature Release of Implantable Device/Tray form (appendix A) to acknowledge s/he has been made aware of the potential risk to the patient.

D. SCOPE :

Sterile Processing, Inpatient Units, Ambulatory Units, Emergency Dept., Procedural Areas, Dental Clinics And the Ambulatory Medical Office Practices in Storrs and Willimantic.

E. DEFINITIONS :

1. Chemical indicator (CI): sterilization process monitoring device designed to respond with a chemical or physical change to one or more physical conditions within the sterilizing chamber.

2. Biological indicator (BI): sterilization process challenge device that directly measures of the lethality of the sterilization cycle to resistant spores. The BI provides a challenge to the process that is equal to or greater than the challenge posed by the most difficult-to-sterilize item routinely processed.

3. Pre-vacuum Dynamic Air Removal Sterilizer: steam sterilizer with vacuum pump / ejector that removes air from the autoclave chamber before entry of steam into the chamber, which results in nearly instantaneous steam penetration. Packaged instrument set standard sterilization times are 4 minutes at 270 degrees F.

4. Gravity Sterilizer: steam sterilizer in which steam enters from the top or sides of the sterilizer chamber, forcing cooler air out of the bottom of the chamber through the drain vent. Packaged instrument set standard sterilization times are 30 minutes at 270 degrees F.

F. MATERIAL(S) NEEDED :

1. Steam sterilizers, accessories, and printouts / graphs – pre-vacuum and gravity displacement
2. Autoclave cart shelf liners
3. Autoclave logs and load control records
4. Biological indicator / tape, integrater, and incubator
5. Chemical indicator / tape and integrater
6. Early Release log and form
7. IUSS log
8. Process challenge device: Bowie-Dick
9. Rigid containers, wrappers, peel pouches

G. PROCEDURE :

When performing daily process challenge testing of dynamic air removal system steam sterilizers, the CSS/Instrument Aide will:

1. Run a process challenge device (PCD) as the first load of the day according to MIFUs:
   a. Pre-vacuum Dynamic Air Removal sterilizer: Bowie-Dick test with BI
   b. Gravity-displacement sterilizer (UHSC OR): BI only
2. Run a BI in every load processed in Pre-vacuum Dynamic Air Removal sterilizer and any load with implants processed in gravity-displacement sterilizer. Place BI directly on lowest shelf above drain for maximum challenge.

3. Remove PCD and examine for end-point response;
4. Wait 5 minutes after end of cycle and then place BI vial in incubator incubate per MIFUs
5. Document all parameters in incubator logs, as appropriate.
6. Record all results of PCDs in sterilizer logs.

When performing biological indicator (BI) testing of steam sterilizers, the CSS/Instrument Aide will:

1. Select two BIs with the same lot number.
2. Place the test BI in the first run of the day.
3. Place BI that does not go into sterilizer and is not exposed to the sterilant in steam BI incubator as a control vial.
4. Record test and control lot numbers in log.
5. Run standard cycle.
6. Allow 5 minutes to pass before removing test BI from autoclave.
7. Place test BI in same steam BI incubator as control vial.
8. Read results of both BIs in incubator and record results in log, ensuring all documentation is complete for each incubation.
9. If the control BI fails to grow, consider results from the test BI invalid.
10. Remove all BIs with failed lot number and notify supervisor.

When loading the dynamic air removal system steam sterilizer, the CSS/Instrument Aide will:

1. Stand paper–plastic peel pouched items on edge in relation to the cart or shelf, with the paper side of one pouch next to the plastic side of the next pouch. Use baskets or racks designed for this purpose whenever possible.
2. Place instrument sets in wrapped, perforated trays or rigid sterilization container systems horizontally on the sterilizer shelf or cart so that the set is level.
3. Position items capable of holding water, such as solid-bottom pans, bowls, and trays, tilted on edge and oriented in the same direction so that condensate can drain.
4. Place rigid sterilization container systems on shelves below peel pouched or woven-wrapped items and parallel to the shelf.
5. Ensure every item has been labeled with corresponding load and sterilizer.
6. Complete load inventory record that includes all items contained in the load.
7. Roll sterilizer cart into autoclave chamber.
8. Close and secure autoclave door.
9. Operate sterilizer according to the MIFUs.
10. Place completed load contents record in approved location.

When determining acceptability of releasing items from steam sterilizer, the CSS/Instrument Aide will:

1. Evaluate all data available from the load prior to unloading the sterilizer, including appearance of sterilized items and external CIs, results of the BI, and process critical physical parameters (exposure, dry time, temperature) on print-outs.
2. Sign the recording printer / tape to signify acceptability of data.
3. Release loads deemed acceptable, pending any BI results.
4. Withhold and reprocess items from loads that do not meet the criteria for release so that they are not mistakenly distributed.

To detect and/or respond to a failed load, the CSS/Instrument Aide will:

1. Observe for any wet packs by looking for visible moisture left in or on a package after sterilization and cooling.

2. Consider any load to be a wet load if two or more wet packs are present, and reprocess the load.
3. Observe for any evidence of inadequate steam processing such as incomplete coloration of CIs.
4. Notify the supervisor or designee', as appropriate, and withhold autoclave use until PCD verification is obtained with an empty load.
5. Reprocess items by repackaging items with:
    a. Exchanging old CIs with new CIs
    b. Re-wrapping items with fresh wrap
    c. Replacing any non-woven tray liners
    d. Using clean / dry containers, with fresh filters if disposable ones used.

To ensure product identification and traceability, the CSS/Instrument Aide will:

1. Ensure that each item being loaded into the sterilizer has a label that contains:
    a. Sterilizer identification number
    b. Item description
    c. Identity of person who packaged the item
    d. Date of sterilization
    e. Cycle number
    f. For IUSS: patient name
    g. Expiration date for any item with time-related specific MIFUs.
2. Prior to starting the cycle, document on individual load contents log form:
    a. load number
    b. specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towel packs, type/name of instrument sets)
    c. start and end time of sterilizer cycle
    d. exposure time and temperature
    e. operator identification
3. After completion of cycle, document any BI testing results in BI log book.
4. Tape CI integrator from PCD to information card of PCD, enter correct information from sterilizer printout, staple card to corresponding sterilization log form.

When unloading the steam sterilizer, the CSS/Instrument Aide will:

1. Allow terminally sterilizer items to cool to ambient temperature before handling and BI has been read.
2. Leave sterilized items on sterilizer cart throughout cooling process.
3. Do not touch items during cooling process, including moving warm items to cool metal shelves for completion of process.
4. Minimize risk of burns by exerting extreme care when moving sterilizer racks into and out of the autoclave chamber.
5. Inspect cooled items when removing from cart for:
    a. Damage: holes, tears, staining, non-intact seals, missing security locks
    b. Package identification
    c. Visual change of external chemical indicator
    d. Moisture
6. Return to clean assembly area any items with damaged or wet packaging area for reprocessing.
7. Return to Decontamination any item that has dropped to the floor and/or whose integrity is compromised.
8. Complete sterilization log form and place in approved location.

H. <u>ATTACHMENTS :</u>

None

I. REFERENCES :

1. ANSI/AAMI ST79: 2017. A comprehensive guide to steam sterilization and sterility assurance in health care facilities.
2. AORN Guidelines for Perioperative Practice 2018. Guideline for Sterilization.
3. Steam Sterilization. Communique' (International Association of Healthcare Central Service Material Management (IAHCSMM)). (March / April 2016).
4. Exception Form for Premature Release of Implantable Device/Tray form (appendix) https://multimedia.3m.com/mws/media/409982O/st79-quality-control-key-changes-tutorial.pdf

J. SEARCH WORDS :

autoclave, biological indicator, channel, chemical indicator, CSS, cycle, device, IUSS, instruments, load, packaging, processing, release, results, sterilizer, sterilization

K. ENFORCEMENT:

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

L. STAKEHOLDER APPROVALS :

On File

M. COMMITTEE APPROVALS :

None

N. FINAL APPROVAL :

1. Andrew Agwunobi, MD (Signed) 06/01/2020
Andrew Agwunobi, MD, MBA Date
UConn Health Chief Executive Officer

2. Anne D. Horbtauck, RN, BSN, MBA (Signed) 06/01/2020
Anne D. Horbatuck, RN, BSN, MBA Date
Clinical Policy Committee Co-Chair

3. Scott Allen, MD (Signed) 06/17/2020
Scott Allen, MD Date
Clinical Policy Committee Co-Chair

4. Caryl Ryan, MS, RN (Signed) 06/17/2020
Caryl Ryan, MS, RN Date
VP Quality and Patient Service & Chief Nursing Officer

O. REVISION HISTORY :

Replaces Sterile Processing UPM Protocol: Packaging, Sterilization, and Storage of Surgical Instrumentation.