Origination:	*02/2016*
Effective:	*01/2020*
Last Approved:	*01/2020*
Last Revised:	*01/2020*
Next Review:	*01/2023*
Owner:	*Roshelle Satterthwait: Dir Perioperative Svcs*
Policy Area:	*Sterile Processing*
References:	
Applicability:	*WA - Kadlec Regional Medical Center*

Sterilization Failure, Malfunction, and Recall 32.16.02

Document Type: Policy

DESCRIPTION:

a. To provide an effective response in the event of a positive biological spore test and or process failure that will promote the safest action for the patient.

b. All devices must be sterilized with a biological indicator and devices will not be used until the result of the biological indicator is known, unless an emergency. Implants must always have a negative BI before use.

PURPOSE:

a. Positive spore tests may occur from a variety of reasons including variations in the BI, improper use of the sterilizer, handling of the biological or the sterilization cycle is faulty. Malfunctions with the sterilizer or quality test may also result in the reprocessing of instruments.

SCOPE:

a. Ideally every sterilized item can be traced to a patient.

b. All sterilization records can be subpoenaed in a court of law.

   i. Ensure the accuracy & legibility of all documentation.

DEFINITIONS:

a. **Biological Indicator (BI**): is the only type of monitor that provides direct evidence that sterilization process conditions are sufficient to kill spores. It uses microbes that are highly resistant to the type of sterilization process you are monitoring.

b. **ICP**: Infection Control Professional

c. **Bowie-Dick test**: is a standard operational test that can demonstrate proper air removal from the pre-vacuum autoclave chamber. It is useful for testing pre-vacuum cycles that are sterilizing wrapped goods or packs.

PROCEDURE:

a. **In the event of an aborted / incomplete cycle**,

   i. The sterilizer load will not be released and the biological spore test will not be incubated because the cycle printout will indicate the cycle is complete and has not met all parameters.

   ii. The load will be considered a failed cycle, re-wrapped, and re-sterilized.

b. **In the event of a Positive BI (Spore Test).**

   i. Immediately quarantine all items from that cycle.

      a. In the case that an item or items were released to the OR already, identify what items were in the load, find the items, and then quarantine them.

      b. If an item was already used on a patient, communicate this with the SPD manager.

      c. The manager will contact Infection Control and provide details of event including which trays if any were not able to be recalled. Infection Control will notify all physicians as necessary.

   ii. The lead technician on duty will be the designated person responsible for the investigation and if necessary, item recall. All other staff will assist in the response process.

   iii. A single positive BI does not indicate a sterilizer malfunction if the mechanical and chemical indicators are acceptable and appear to be functioning properly.

   iv. The sterilizer will be immediately taken out of service until the 2 consecutive biologicals pass in the sterilizer. (no items will be in these loads)

   v. In the event both follow-up BI's turn positive, it must be assumed the sterilizer is faulty, taken out of service and repaired.

   vi. Take the sterilizer out of service until the manufactures technician comes to service it.

   vii. Once the sterilizer has been repaired, 3 consecutive Bowie-Dick test must be run followed by 3 BI's. All must pass before placing the sterilizer back in service.

   viii. Record what was done in for the situation in the notes section of the tracking system.

   ix. All BI's, read outs and other parameters will be re-confirmed by the Lead to prevent misinterpretation of evidence.

      1. Incorrect BI selection for load?
      2. Incorrect placement of BI?
      3. Incorrect incubation process?
      4. Incorrect documentation?
      5. Incorrect verification of results?
      6. Incorrect lot #'s documented?
      7. Incorrect packaging?
      8. Incorrect placement of processed items in sterilizer?

   i. The entire load will still be rewrapped and re-sterilized in different sterilizer. All consumable items must be changed during repackaging.

c. **Infection Control**

i. If patient care items were used before retrieval, the **ICP** should assess the risk of infection in collaboration with **Sterile Processing**, **Perioperative Services**, and **Risk Management** staff.

ii. The patient's **physician / surgeon will be notified** if patient care items are used before retrieval.

iii. Factors to be considered:

1. Chemical indicator result
    a. Non-reactive chemical indicator may indicate temperature was not achieved.
2. The results of other biological indicators that followed the positive biological indicator.
    a. Ex. Positive on Tuesday, negative on Wednesday, etc.
3. The parameters of the sterilizer associated with the positive biological indicator
    a. Ex reduced time at correct temperature
4. The time-temperature chart (or printer
5. There is minimal risk of infection in steam sterilization loads that show a spore growth if the instruments have been properly cleaned and the temperature was achieved.
6.

MALFUNCTION:

Failed Bowie-Test

A. If the Bowie-Dick test fails:
    1. Make sure autoclave settings are correct and run a second test.
    2. If the second test fails, take the machine out of service and call the manufacture's technician to service the machine.
    3. Once the sterilizer has been repaired, 3 consecutive Bowie-Dick test must be run followed by 3 BI's. All must pass before placing the sterilizer back in service.

RESOURCES:

a. AAMI ST79:2013: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities.

Attachments

No Attachments

Approval Signatures

Approver	Date
Kirk Harper: CNO	01/2020
Heather Shipman: Executive Assistant	01/2020
Roshelle Satterthwait: Dir Perioperative Svcs	12/2019

Applicability

WA - Kadlec Regional Medical Center