Ref 18

Sterilization

- Cleaning
- **Monitoring**
- Packaging & Storage

Monitoring

- **How is the sterilization process monitored?**
- **Does the Centers for Disease Control and Prevention (CDC) recommend a specific type of chemical indicator?**
- **Are bead sterilizers an effective means of sterilization?**
- **What is air removal testing (e.g., Bowie-Dick Test)?**
- **How often should biological monitoring (spore testing) be done?**
- **What are the next steps if a spore test result is positive?**

If the mechanical (e.g., time, temperature, pressure) and chemical (internal or external) indicators suggest that the sterilizer is functioning properly, a single positive spore test result probably does not indicate sterilizer malfunction. Items other than implantable items do not necessarily need to be recalled. However, the sterilizer should be removed from service and sterilization operating procedures reviewed to determine whether operator error could be responsible. Sterilizer operators should repeat the spore test immediately using the ...e cycle that produced the positive spore test.

...the result of the repeat spore test is negative and operating procedures were correct, then the sterilizer can be returned to service. If the repeat spore test result is positive, do not use the sterilizer until it has been inspected or repaired and rechallenged with spore tests in three consecutive fully loaded chamber sterilization cycles. When possible, items from suspect loads dating back to the last negative spore test should be recalled, rewrapped, and resterilized. Results of biological monitoring and sterilization monitoring reports should be documented.

See Table 12 (PDF-948K) (https://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf) of the *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008* for the suggested protocol to manage a positive biological indicator in a steam sterilizer.

- **What can cause sterilization failure?**
- **What type of information should be included in my sterilization records?**
- **How long should sterilization monitoring records be maintained?**

References

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Table 12. Suggested protocol for management of positive biological indicator in a steam sterilizer.

1. Take the sterilizer out of service. Notify area supervisor and infection control department.
2. Objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization procedure is defective. As soon as possible, repeat biological indicator test in three consecutive sterilizer cycles. If additional spore tests remain positive, the items should be considered nonsterile, and supplies processed since the last acceptable (negative) biological indicator should be recalled. The items from the suspect load(s) should be recalled and reprocessed.
3. Check to ensure the sterilizer was used correctly (e.g., verify correct time and temperature setting). If not, repeat using appropriate settings and recall and reprocess all inadequately processed items.
4. Check with hospital maintenance for irregularities (e.g., electrical) or changes in the hospital steam supply (i.e., from standard ≥97% steam, <3% moisture). Any abnormalities should be reported to the person who performs sterilizer maintenance (e.g., medical engineering, sterilizer manufacturer).
5. Check to ensure the correct biological indicator was used and appropriately interpreted. If not, repeat using appropriate settings.

If steps 1 through 5 resolve the problem

6. If all three repeat biological indicators from three consecutive sterilizer cycles (step 2 above) are negative, put the sterilizer back in service.

If one or both biological indicators are positive, do one or more of the following until problem is resolved.

7. A. Request an inspection of the equipment by sterilizer maintenance personnel.
   B. Have hospital maintenance inspect the steam supply lines.
   C. Discuss the abnormalities with the sterilizer manufacturer.
   D. Repeat the biological indicator using a different manufacturer's indicator.

If step 7 does not resolve the problem

Close sterilizer down until the manufacturer can assure that it is operating properly. Retest at that time with biological indicators in three consecutive sterilizer cycles.

Modified from Bryce. [839]

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