Steam Sterilization Cycles in Healthcare Facilities: What to Use and When to Use It

Biological Indicators for Monitoring

By Sandra Lee, BSM, RN

What is a biological indicator?

According to the Association for the Advancement of Medical Instrumentation (AAMI) document "Steam Sterilization & Sterility Assurance in Health Care Facilities, ST46," "a biological indicator is an inoculated carrier contained within its primary pack, ready for use, and providing a defined resistance to the specified sterilization process."

Food and Drug Administration (FDA) regulations state, "a biological sterilization process indicator is a device intended for use by a healthcare provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization." [21 CFR 880 2800 (a) (1)]

Does a negative biological test result prove that everything in the load is sterile?

It is important to understand that a biological indicator is used to determine if the set sterilization cycle parameters were sufficient to kill the test microorganisms. Remember that a negative biological result does *not* prove that everything in the load is sterile nor does it prove that all items were adequately exposed to sterilization conditions. The probability of sterilization of an item(s) is not only dependent on a properly functioning sterilization cycle, but also on properly decontaminated, assembled, wrapped, and loaded items that can all be adequately exposed to sterilization conditions.

Which test microorganism is used to monitor steam sterilization cycles?

Spores of *Geobacillus stearothermophilus* are used to comply with the AAMI/American National Standards Institute (ANSI) standard titled "Sterilization of Health Care Products-Biological Indicators-Part 3: Biological Indicators for Moist Heat Sterilization, ST19." *Geobacillus stearothermophilus* is not harmful to humans. This spore/microorganism is incorporated into a process monitoring device to test steam sterilization cycles.

What are process monitoring devices and how are they configured?

There are currently two types of process monitoring devices available for use in healthcare facilities. They are also known as biological indicators or process challenge devices (PCDs). According to the AAMI, "A PCD is an item used to assess the effective performance of a sterilization process, which is designed to simulate product to be sterilized and which constitutes a defined challenge to the sterilization process." The conventional biological indicator is a carrier (usually a spore strip/disc) that is inoculated with *Geobacillus stearothermophilus*, placed into its primary pack, which is a self-contained unit that also houses a unit of growth medium, and is ready for use. This self-contained unit is used by itself to test flash sterilization cycles, and is contained in a prescribed AAMI test pack or equivalent commercially prepared test pack to monitor steam sterilization cycles for wrapped goods. Death of the *Geobacillus stearothermophilus* indicates that appropriate parameters for sterilization were achieved. A biological indicator with enzyme-based early-readout capability is also available. Its construction is essentially the same as the conventional biological indicator, but a non-fluorescent substrate is incorporated into the medium. After sterilization and a rapid incubation time, a special reader is used to detect fluorescence that results from an enzymatic breakdown of the non-fluorescent substrate. This fluorescence indicates an ineffective steam sterilization process. If no fluorescence occurs, the enzyme has been inactivated, which predicts that the biological spores will not grow upon further incubation.

Is a rapid enzymatic indicator a biological indicator?

A rapid enzymatic indicator contains enzymes that have been isolated from spore-forming bacteria. It is not a biological indicator because it does not contain bacterial spores.

The enzymes have a temperature and pH sensitivity that is similar to the microorganism they came from. When the enzyme is exposed to steam sterilization conditions, its activity is lost over time and is said to correlate to the destruction of *Geobacillus stearothermophilus*. Incubation is not required because there is no microorganism included in this test material, but an activation solution is applied to the sterilized indicator vial and the color change indicates a positive or negative result.

When is it necessary to biologically monitor steam sterilization cycles?

According to AAMI (ST46), conventional biological indicators should be used to monitor steam sterilization cycles under the following conditions:

- Upon installation of a new sterilizer
- After relocation of an existing sterilizer
- After a sterilizer malfunction
- After a sterilizer process failure that is indicated by a positive biological test
- After major repairs to a sterilizer that are outside the scope of routine or preventive maintenance (Examples of major repairs would be: weld repairs to the sterilizer chamber/pressure vessel; repair of the chamber door; repair of a major plumbing assembly; or rebuilds or upgrades to the sterilizer controls)
- After repairs to the steam generator/delivery system
- When performing periodic quality assurance testing of items that you routinely sterilize

The use of biological enzyme-based early-readout or rapid enzyme indicators is not acceptable under the circumstances listed above because the best way to verify the lethality of a sterilization cycle is to kill large populations of microorganisms that are resistant to steam sterilization.

Routine biological monitoring of steam sterilizer cycles (gravity, pre-vacuum, and flash cycles) is also the standard, as well as additional biological monitoring when implantable medical devices are in a load. In this case, either conventional biological indicators or enzyme-based early-readout indicators can be used.

Which process monitoring device should I use to perform routine biological monitoring of steam sterilization cycles and loads with implantable medical devices? How often do I need to do it?

Conventional biological indicators and enzyme-based early-readout indicators can each be used to routinely monitor steam sterilization cycles and serve as the basis for release of sterilized items for use, including implantable medical devices. Routine monitoring is performed in a sterilization load at least weekly, but preferably every day the sterilizer is in use (testing every sterilizer and type of sterilization cycle used). Every sterilization load that contains implantable medical devices must be biologically monitored. For maximum sterility assurance, implantable medical devices should be quarantined until negative biological test results are confirmed.

If I use an enzyme-based early readout indicator, do I need to do anything else to verify the performance of a steam sterilization cycle?

Yes. According to AAMI (ST46), the use of this method of monitoring requires that the performance of the sterilization cycle be periodically verified by one of two methods. Use one of the following test methods at least weekly, but preferably every day that the sterilizer is used:

- Continue incubation of the enzyme-based early-readout following the manufacturer's instructions. The amount of time necessary to ensure that any surviving microorganisms will grow out will be specified by that manufacturer.
- Use a conventional biological test pack to verify sterilizer performance.

Details regarding monitoring steam sterilization cycles can be found in AAMI ST46, and ST47, "Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use." **ICT**

Sandra A. Lee, BSM, RN, is the senior manager of professional education for STERIS Corporation. Her professional experience includes medical-surgical and perioperative nursing, central service management, materials management, and project management/system planning. Since 1982 Lee has actively participated in the writing and continuous updating of decontamination and sterilization standards and recommended practices with the AAMI, and she is a member of the AAMI Sterilization Standards Committee. She is also a member of the Technical Committee on Sterilization at CSA International in Canada. In addition, she serves as a U.S. representative to the European Committee for Standardization (CEN) as an ISO Technical Advisory Group 198 liaison.

Reprinted with permission from Infection Control Today, *Dec. 2004*