



Recommended Standards of Practice for Monitoring Sterility

Introduction

The following Recommended Standards of Practice were researched and authored by the AST Education and Professional Standards Committee and have been approved by the AST Board of Directors. They are effective October 20, 2008.

AST developed the Recommended Standards of Practice to support health care facilities in the reinforcement of best practices as related to monitoring sterility in the perioperative setting. The purpose of the Recommended Standards is to provide an outline that Certified Surgical Technologists (CSTs) and Certified First Assistants (CFAs) can use to develop and implement policies and procedures for monitoring sterility. The Recommended Standards is presented with the understanding that it is the responsibility of the health care facility to develop, approve, and establish policies and procedures for monitoring sterility according to established health care facility protocols.

Rationale

The following are Recommended Standards of Practice related to monitoring sterility in the perioperative setting. One of several safe patient outcomes related to surgery is all items that are handled and used by the sterile team members, as well as those items that come into contact with the patient's tissues, are sterile. In other words, to prevent surgical site infections (SSIs) only sterile items may be placed within, and come into contact with, a sterile field, and only sterile members of the surgical team should touch and handle the sterile items (Frey, Price, Ross, 2008). Guaranteeing the use of sterile items requires a quality control system that involves chemical and biological indicators that the CST and CFA rely upon to ensure that proper sterilization parameters have been met. Additionally, the use of indicators serves as an aid in pinpointing and resolving processing failures. The delivery of safe, quality patient care demands a team effort in establishing a sterile field to prevent SSIs. All surgical team members should be involved in the process of developing and implementing health care facility policies and procedures for monitoring sterility.

Standard of Practice I

All packaged sterile items should have some type of external indicator that can be visualized by the surgical team members to ensure the parameters for sterilization have been met.

1. As recommended by the Association for the Advancement of Medical Instrumentation (AAMI), a class I process indicator, also referred to as an external chemical indicator (CI), should be used on the outside of every sterile package or container (2006). (See Table A: Five Classes of CIs)

- A. An external CI should be attached to every health care facility package or rigid sterilization container that is intended to be processed through some type of sterilization system.
 - (1) Except for those packages such as paper-plastic peel packs that allow visualization of the internal CI, AAMI recommends an external CI be used on all packages (2006).
 - (2) Commercial packages typically include a printed, color-changing external CI that the surgical team members can visualize.
- B. Types of class I external CIs include sterilizer indicator tape, indicating label and indicator strips that are chemically impregnated. Upon exposure to the sterilization process, the chemical should change color, and the color should be even.
- C. External CIs are used to demonstrate that the pack or container has been exposed to a sterilization process in order to distinguish between processed and unprocessed packs and containers. They do not prove that the enclosed items are sterile. In other words, CIs demonstrate that a package or container has been subjected to specific sterilization processing conditions.
- D. CIs assist in detecting potential sterilization failures. The use of CIs should be part of an overall quality assurance program that includes the use of biological indicators (BI) and sterilization machine monitors.
- E. The surgical team members should visualize and examine the external CI prior to opening a package or container in the O.R. to confirm that the item has been exposed to the sterilization process, and the color change is even.
- F. All types of CIs should be used according to the manufacturer's instructions.

Standard of Practice II

All individual units (peel packs, package, tray, rigid container system) processed by a health care facility should contain an internal CI.

1. It is recommended that the type of internal CI to be utilized by the health care facility be class 3, 4, or 5.
 - A. Internal CIs are used to demonstrate that the pack or container has been exposed to a sterilization process in order to distinguish between processed and unprocessed packs and containers. They do not prove that the enclosed items are sterile. In other words, CIs demonstrate that a package or container has been subjected to specific sterilization processing conditions.
 - B. Internal CIs assist in detecting potential sterilization failures. Specific types of internal CIs may aid in the detection of specific sterilization machine malfunctions, eg, air leaks, improper temperature, poor quality steam. The use of internal CIs should be part of an overall quality assurance program that includes the use of external CIs, biological indicators (BI) and sterilization machine monitors.

- C. Internal CIs must be retrieved, visualized and examined by the CST during the time of preoperative case management to confirm that it has been exposed to the sterilization process and the color change is even. If the CST's interpretation determines that the sterilization process has been inadequate, the contents of the individual unit should be considered non-sterile and the unit immediately removed from the sterile field. The CST will need to make a determination of how much of the sterile field was possibly contaminated by the unit. For example, if the unit was a rigid container system in which the enclosed contents had not yet been placed on the sterile back table, the table will not need to be "broken" down. Second example, a pack of sterile linen towels are tossed onto the back table that may have touched other sterile items and therefore, the towels and other items are considered non-sterile. In this instance, the CST will have to use his/her judgment as well as knowledge of the principles of asepsis in determining the course of action. In all instances, the CST will need to change gloves since they are considered contaminated from handling non-sterile items.
- D. The CST should hand the non-sterile unit to the circulator, who should return it with the internal CI and load identification information to the sterile processing department.
- E. All types of internal CIs should be used according to the manufacturer's instructions.

Table A: Five Classes of CIs (AAMI, 2006)

Indicator	Class	Description
Process Indicator (also referred to as external CI)	1	Intended for use with individual packs, containers, peel packs, etc.
Specific Test Indicators	2	Example is the Bowie-Dick type of indicator
Single-parameter Indicators	3	Reacts to one of the critical parameters of sterilization
Multi-parameter Indicators	4	Reacts to two or more of the critical parameters of sterilization
Integrating Indicators	5	ReactS to all critical parameters over a specified range of sterilization cycles

Standards of Practice III

The health care facility should have written policies and procedures for the training of surgical team members who interpret CIs.

1. Surgical team members who place, retrieve and interpret CIs should complete training in the various sterilization processes and the selection, use and interpretation of CIs (AAMI, 2005).
 - A. Surgical team members handle sterile packages and rigid sterilization containers on a daily basis as well as run the flash sterilizer. The correct use and interpretation of the CI is critical to safe patient care.
 - B. Training should be documented. Periodically, the team members should review the information, and the training should be periodically assessed to determine competence. The health care facility should assume the responsibility of providing updated information concerning CIs to all health care facility personnel, who are involved in sterilization processes.

Standards of Practice IV

Biological indicators (BIs) should be used according to the standards established by AAMI and CDC.

1. BIs are the only sterilization-process monitoring device that provides a direct measure of the lethality of the sterilization process (AAMI, 2006).
 - A. BIs are used to confirm that conditions for sterilization were achieved.
2. BIs should be used within process challenge devices (PCDs) for routine monitoring of the sterilization process at least weekly; however, it is recommended that monitoring should occur every day the sterilizer is used.
3. Every sterilization load that contains implants should be monitored with a PCD containing a BI. A class 5 CI should be included with the PCD (AAMI, 2006).
 - A. The implants should be quarantined until the results of the BI testing are interpreted and documented (CDC, 2003).
 - B. When an implant or implants must be released for use prior to the availability of BI test results (eg, the need for orthopedic screw and plate set on an emergency basis), the release must be documented, as well as the BI result that is later recorded. The documentation should include patient information in the case that the BI result is positive in order to trace the use of the implants to the exact patient.
 - C. Class 5 CI should be used so that if an implant or implants are released on emergency basis information about the critical parameters of the sterilization process is interpreted and documented (AAMI, 2006).
 - D. The health care facility should establish written policies and guidelines for defining emergency situations, when implants are released prior to the availability of BI test results. The development of the policies and guidelines should include the infection control officer, surgeon(s), and risk management.
4. Positive BI results will initiate a recall of the items that were processed in the specific sterilizer. All items since the last negative BI test should be considered non-sterile, and the surgery personnel should assist in retrieving those items from the surgery department sterile storage to send back to the sterile processing department.

References

1. Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST79: 2006. Arlington (VA): AAMI, 2006. .
2. Association for the Advancement of Medical Instrumentation *Sterilization of health care products – Chemical indicators – Guidance for the selection, use, and interpretation of results*. ANSI/AAMI/ISO 15882:2003. Arlington (VA): AAMI, 2006. American National Standard.
3. Centers for Disease Control and Prevention. Guidelines for infection control in dental health-care settings – 2003. *Morbidity and Mortality Weekly Report (MMWR)*, 52(RR-17), 19 December 2003a.
4. Frey KB, Price BD, Ross T. Asepsis and sterile technique. In: K Frey, T. Ross (eds.). *Surgical Technology for the Surgical Technologist: A Positive Care Approach*. 3rd ed. Clifton Park, NY: Delmar Cengage Learning; 2008: 139-184. .