

Sterile reprocessing

Is event-related dating going away?

Because of recent regulatory activity, some are asking whether event-related sterility dating is going away. The answer is no. The confusion is a result of the Food and Drug Administration (FDA) asking Kimberly-Clark (KC) to submit a new 510k application to confirm that its sterilization wrap meets all current requirements.

The FDA's new Maintenance of Packaging Integrity testing protocol requires additional sterility maintenance testing and product labeling. The FDA requires a minimum of 30 days to test maintenance of sterility, but testing can also be done for longer times. In the future, you will probably see other wrap manufacturers doing the same testing and product labeling.

These developments do not mean health care facilities need to go back to expiration labeling. Years ago, the Joint Commission required expiration dates for hospital-sterilized items, based on a recommendation from the Centers for Disease Control and Prevention (CDC), but this recommendation was dropped 25 years ago.

Follow professional recommendations

The FDA regulates medical devices by requiring manufacturers to demonstrate performance and to provide that information to their users. But the FDA does not regulate health care practices. Health care practices for surgery and sterile processing are based on recommendations from AORN, the Association for the Advancement of Medical Instrumentation (AAMI), and the CDC. The FDA does not expect health care facilities to change their practice of labeling and storing sterile products but to follow the medical device manufacturers' instructions for use.

Ramona Conner, RN, MSN, CNOR, manager, standards and recommended practices at AORN and cochair of the working group that developed *AAMI's Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ST79)*, has these comments about event-related dating as a result of the FDA requiring KC to do new testing on the maintenance of package integrity:

"I think it is premature to revert to the old outdated procedures. The FDA doesn't regulate 'user' practices; they only regulate manufacturers' claims. I don't think that it is the intent of the FDA to require expiration dating and the abandonment of event-related procedures. Event-related sterilization practices remain the widely accepted recommended practice, and there has been no change in the AORN or AAMI recommendations. It is not necessary to change standard practices for evidence-based sterility procedures as long as the organization's policy is consistent with the AORN and AAMI ST79 recommended practices."

The instructions for use

KimGuard Sterilization Wrap and KimGuard One-Step Sterilization Wrap from KC have the following statement:

“Healthcare facilities may use established protocols to monitor sterility maintenance of packages wrapped with the KIMGUARD and KIMGUARD One-Step Sterilization Wraps in accordance with acceptable standards of practice. Real-time testing simulating clinical use supports maintenance of package sterility for at least 30 days; however, this time-point does not prevent facilities from continuing to use established healthcare facility protocols.”

Recommended practices

AORN’s 2010 Recommended Practices for Sterilization in the Perioperative Practice Setting state that “the shelf life of a packaged sterile item should be considered event-related.”

Certain events compromise the sterility of a package. These events include multiple handlings, moisture penetration, and exposure to airborne contaminants, all of which can compromise the integrity of the packaging and seal and allow contaminants to enter the packaging. This is why it is important to limit the exposure of packaging to moisture, dust, excessive light or handling, and temperature and humidity extremes.

AAMI ST79 Section 10.3.3 states that event-related dating can be used unless the product has an identifiable expiration date because of the degradation of the product based on information from the device manufacturer. Each package should have the statement, “Contents sterile unless package is opened or damaged. Please check before using.”

AAMI ST79 Sections 8.9 to 8.11 discuss sterile storage, distribution, and transportation.

To practice event-related dating, a health care facility needs to control handling from the time the item is removed from the sterilizer to patient use, storage, and transportation.

Handling

Packages should be allowed to cool on the sterilizer rack before moving. They should be visually inspected to ensure they are not torn, wet, or compressed. Those that pass this inspection should be moved to sterile storage. AAMI states to not drag, slide, crush, bend, compress, or puncture the packaging when handling. Inspect all packaging for integrity and labeling before use.

Packages should be held away from the body during transportation and should always be inspected again when placed on a transportation cart and at the point of use to ensure they are not damaged. Handling of packages should be limited. All of these steps will prevent packages from becoming contaminated.

Sterile storage

AORN and AAMI state that the following controlled sterile storage conditions reduces the risk of contaminating a medical device:

- Temperature should not exceed 24°C (75°F).
- The storage areas should have at least 4 air exchanges per hour.
- Relative humidity should not exceed 70%.
- Limit traffic to personnel trained to handle sterile supplies.

- Store sterile items at least:
 - 8 to 10 inches above floor
 - 18 inches below sprinkler heads
 - 2 inches from outside walls.
- Do not allow outside shipping containers into sterile storage areas because they are reservoirs for dust and vermin.

AAMI stresses positioning items in storage so they are not crushed, bent, compressed, or punctured. The KC instruction for use for KimGuard Sterilization Wrap and KimGuard One-Step Sterilization Wrap cautions in the Sterility Maintenance section: “Do not stack trays. Stacking trays can result in damage to the wrap caused by undue pressure from the weight.”

Closed or covered shelving should be used for seldom-used supplies. Open shelving may be used if the traffic, ventilation, and housekeeping are controlled.

Transportation

Sterile items should be transported in covered or enclosed carts with solid bottoms that protect the items during transportation. AORN recommends that the transport carts and reusable covers should be cleaned after each use.

AAMI advises that vehicles used for off-site transportation “should provide for complete separation of clean and sterile items from contaminated items.” The vehicles should be checked at least annually to ensure they do not leak, and the carts containing the sterile packages should be secured within the vehicle to prevent damage or contamination. Environmental conditions should be assessed to ensure absorbent items do not become contaminated because of condensation inside the vehicle.

CMS and Joint Commission

In its ambulatory surgery center interpretive guidelines for state surveyors, effective in 2009, the Centers for Medicare and Medicaid Services (CMS) states “that sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility, eg, in a moisture- and dust-controlled environment, and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practices.”

Marilyn Hanchett, infection control lead in the CMS Division of Acute Care Services, Center for Medicaid and State Operations, says “CMS will accept the standards for sterility dating established by nationally recognized professional associations such as CDC, AORN, and APIC.”

Event-related sterility dating is acceptable to CMS, and surveyors will check to ensure that “items are appropriately contained and handled during the sterilization process to ensure that sterility is not compromised prior to use.”

The Joint Commission states in its Standard IC.02.02.01, Elements of Performance 4: “The hospital implements infection prevention and control activities when doing the following: storing medical equipment, devices, and supplies.” The 2010 leadership standards state:

- “The hospital considers clinical practice guidelines when designing or improving processes.” (LD.04.04.07)
- “The hospital provides care, treatment, and services in accordance with licensure requirements, laws, and rules and regulations.”(LD.04.01.01)

Following the AAMI and AORN recommended practices for storing

medical equipment, devices, and supplies along with the instructions from each manufacturer should assist you in meeting the Joint Commission standards.

Event-related sterility dating is here to stay

AORN says that “storage conditions should be evaluated before policies and procedures on event-related sterility are written for perioperative practice settings.” This is recommended because many factors affect the sterility of packages, and you need to correctly handle items, ensure appropriate and adequate storage space, correctly transport packages, and follow the wrapping material manufacturer’s instruction for use for sterility maintenance. For these reasons, you need up-to-date policies and procedures, training, and competency testing to ensure that compromised packages are not used for patient care. By following AORN and AAMI recommended practices, event-related sterility dating can still be used. ❖

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