Taking control of implant processing practices

Are you following recommended practices when processing implants? Both the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of Perioperative Nurses (AORN) state that a load containing an implant should be quarantined until the results of the biological indicator (BI) testing are available. The rationale is to reduce the risk of surgical site infection (SSI).

The Joint Commission’s National Patient Safety Goal NPSG.07.05.01 states that hospitals should “implement evidence-based practices for preventing surgical site infections.” The goal’s EP 3 says:

Implement policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Centers for Disease Control and Prevention and/or professional organization guidelines).

Thus, if you are releasing implants before BI results are available, you are not adhering to guidelines and thus not implementing an evidence-based practice that prevents SSIs.

How should I monitor implant loads?

Routine release of implant loads should be an active decision based on the evaluation of all available data. AAMI recommends in its ST79 steam sterilization standard that an experienced and knowledgeable person should make that decision at the end of the steam sterilization cycle after evaluating the results of each monitoring tool. AAMI recommends using these monitoring tools:

**Physical monitors**

These are the recorders, displays, digital printouts, and gauges on steam sterilizers that read the time, temperature, and pressure of the cycle.

If the sterilizer has a recording chart, it should be checked each morning to ensure chart paper is inserted and the pen is functioning. The date and sterilizer number should be marked on the chart before each cycle is started.

For printouts, verify that the cycle identification number has been recorded and that the paper is functioning. At the end of the cycle, verify by reading and recording your initials that the cycle parameters are correct for the load contents.

**External chemical indicator (CI)**

A Class 1 CI should be used on the outside of each package, unless the internal chemical indicator is visible, to distinguish between processed and unprocessed items. The indicator should be examined at the end of the cycle, before it is dispensed, and before it is used in the operating room.

**Internal CIs**

A Class 3, 4, 5, or 6 CI (use only in the specific cycles for which they are labeled) should be used as an internal chemical indicator inside each package, tray, or containment device (reusable rigid sterilization container system, instrument case, cassette, or organizing tray) to determine that the sterilant penetrated the packaging and
contacted the implant being processed.

Place the CIs in the areas least accessible to the sterilant. The CI should be retrieved and read in the OR before the item is placed in the sterile field. If the CI response indicates an ineffective sterilization process, the package in question should be sent back to the sterile processing department (SPD) for reprocessing.

**Biological indicator**

A BI process challenge pack (BI PCD) containing a Class 5 integrating CI should be used in each load that contains an implant. The implant should be quarantined until the BI testing is available. AAMI states: “Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.”

In documented medical exceptions, the implant could be released based on the results of a Class 5 CI (not a Class 6 CI).

**Documenting exceptions**

AAMI provides an example of an implant log and an exception form to use for documentation in Annex L of the ST79 standard. The form includes the patient’s name, surgeon’s name, time of procedure, reason for premature release of implant, and what could have prevented this premature release.

The Joint Commission uses the AAMI ST79 standard during surveys and expects to see that ST79 Section 10.6.3 and Annex L are being used.

It is important to have a surgeon authorize the early release of implants before the BI results are available. This documentation should be used to determine patterns of events that cause an emergency release of implants so that situation can be corrected.

OR personnel have told me that if the liability is shifted to the surgeon, the practice of releasing implants early or using immediate-use steam sterilization is dramatically reduced.

**If the BI is positive**

If the BI is positive or the Class 5 CI indicates an ineffective sterilization process, the implant should not be used.

If the cycle parameters, the external or internal chemical indicator results are not correct, or the BI is positive, do not use the load. Inform the appropriate supervisor so appropriate follow-up measures can be initiated.

Appropriate follow-up measures for monitoring products that indicate a sterilization process failure are described in the AAMI steam sterilization standard under Section 10.7.5 (Actions to take when biological indicators, chemical indicators, or physical monitors indicate a failure). All monitoring information should be fully traceable to the patient.

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**New guidance on loaner sets**

As a help for managing loaner sets, the International Association of Healthcare Central Service Materiel Management (IAHCSMM) has a new Position Paper on the Management of Loaner Instrumentation.

The paper recommends that loaner instrumentation be received in the facility’s decontamination area at least:

- 2 working days (48 hours) before a scheduled case for existing sets
- 3 working days (74 hours) for new sets.

If loaner sets aren’t received in time, the OR may end up using immediate-use steam sterilization (IUSS) (previously called flash sterilization)–a practice strongly discouraged for implants.

IUSS should not be performed on implants, except in a documented emergency when no other option is available, according to the recent multi-society position paper on IUSS from AAMI, AORN, and other organizations.

AORN states in its recommended practices for sterilization that, in an emergency, when flash sterilization of an implant is unavoidable, a rapid-action BI with a Class 5 chemical integrating indicator should be run with the load.

The implant should be quarantined on the back table and not released until the rapid-action BI provides a negative result.

This statement is intended to discourage use of IUSS. If IUSS is used, the manufacturer’s written IFUs for cleaning, packaging, loading, and sterilization parameters should be followed.
Why are improperly processed implants a risk?
Implants released before the BI result is known may have microorganisms on them that could cause an SSI, which may not be evident for up to a year after surgery.

During implant surgery, removal and manipulation of the tissue immediately adjacent to the implant create an area where microorganisms could multiply. In addition, surgery interrupts the blood supply, which prevents antibiotics from contacting the microorganisms.

Removal of the implant (ie, joint, vascular graft, or intraocular lens) may be necessary to stop the infection, and this could cripple or kill the patient. That’s why it’s critical to take every step possible to ensure implants are properly sterilized and BI results are negative before the implant is used on a patient.

Why aren’t implants quarantined?
There are many reasons why implants may be released prematurely. These are a few:

- Loaner instruments may not arrive in sufficient time to process the devices properly and quarantine implants. That can be the result of a loaner policy that is not successful at meeting the AAMI standard and the facility’s needs.
- Poor scheduling by the hospital or vendor, insufficient vendor inventory, or emergencies are other reasons. Possibly, the manufacturer’s written instructions (IFU) did not arrive with the sets, and obtaining those delayed the processing.
- Lack of inventory, whether loaner, consignment, or owned implants/instruments, may not be sufficient to meet the surgery schedule. Instruments that arrive broken or dirty can also delay processing.
- OR block schedules may require use of one-of-a-kind instruments in specialty trays or loaner/consignment trays for back-to-back cases.
- Resources may be lacking, such as personnel, appropriate equipment, cleaning agents, tools recommended in the IFUs, and space in SPD.

A new position paper on loaner sets can help in developing your own policy (sidebar, p 22).

How do I change practice?
How can you stop the practice of releasing implants for use before the BI results are known or using immediate-use steam sterilization? Be sure you and your superiors are aware of the Joint Commission NPSG.07.05.01, in particular, EP 4, which states: “As part of the effort to reduce surgical site infections, conduct periodic risk assessments for surgical site infections in a time frame determined by the hospital.”

This could be interpreted to apply to the release of implants. If you continue to release implants before the BI results are known or process implants by immediate-use steam sterilization, you need to do a risk assessment to determine how to eliminate these practices.

Management teams from the operating room, SPD, infection prevention, and risk management departments need to work together to develop policies and procedures to ensure all implants are not released until the BI results are available, and implants are never processed by immediate-use steam sterilization.

Meeting the AAMI and AORN recommendations is a step closer to eliminating SSIs and improving patient outcomes.

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References


