A growing issue in healthcare facilities that seems to be taking on a life of its own is loaner instrumentation. Operating Rooms (OR) and Sterile Processing Departments (SPD) repeatedly borrow surgical instruments and equipment for a multitude of reasons. Many of these loaner trays are complicated instrument sets or implants that are often unfamiliar to the staff. In addition, the devices do not always arrive in sufficient time to permit routine cleaning, inventory, inspection, wrapping, repackaging (if over weight), process monitoring, and terminal sterilization within the facility.

Some facilities may receive up to 50 loaner sets a day. When loaner instruments arrive just prior to the case, it makes it “beastly” hard for the staff to properly care for these sets which may put patient safety in jeopardy.

Loaner program development
Managing loaner instruments is very complicated. Healthcare facilities that borrow surgical instruments should have a well-developed loaner program and written policy which establishes standardized receipt and use of all loaner instrumentation. These policies and procedures can be used as a guideline to help thoroughly manage loaner instrumentation and any surgical implants contained therein.1

SPD and the OR should develop a written policy in concert with various departments such as Infection Prevention and Control (IPC), Administration, Materials Management, Risk Management (RM), and surgeons. The loaner program should be monitored, assessed, and periodically reviewed for compliance.1

The loaner instrumentation program should include:
• Requesting loaner instrumentation or implant(s),
• Receiving loaner items, including a detailed inventory list (preferably with pictures),
• Obtaining manufacturers’ written instructions for instrument care, cleaning, assembly, and sterilization,
• Cleaning, decontaminating, and sterilizing borrowed instrumentation by the receiving facility,
• Transporting processed loaner instrumentation to the point of use,
• Post procedure decontamination, processing, inventory,
• Return to the industry representative, and
• Maintaining records of the transactions.3

Acquisition of loaners
Requests for loaner instrumentation should be coordinated to allow sufficient time to permit in-house disassembly, cleaning, packaging, weighing, quality assurance testing, and terminal sterilization of the items.1 It is recommended that all loaner instrumentation be delivered at least two working days (48 hours) for existing loaner sets and three working days (72 hours) for new sets before the case is scheduled to start.

All loaner instruments, including newly manufactured loaner items, should be considered contaminated and delivered directly to the decontamination area. New items may be manufactured in an environment in which bioburden is not carefully controlled, also anticrosive agents such as oils or grease might have been left on the device and if not removed may interfere with sterilization.1,2

As with all items, loaner items transported to sterile processing should be removed from external shipping containers. External shipping containers have been exposed to the environment and may harbor a potentially high amount of microbial contamination.1

Inspection and inventory
Instrumentation should be visually inspected for damage. The loaner instruments should be inventoried for completeness and documented. It is important that all loaner devices be delivered with the manufacturers’ instructions for use (IFU), inventory lists, and complete description or pictures of the items. Without a completed inventory list and/or description, it is difficult to determine if the set was complete when delivered.

Rigid sterilization containers which are part of the loaner set should be thoroughly inspected for integrity and function, and decontaminated according to the manufacturer’s IFU.1,2

If the IFU does not come with the borrowed items, the healthcare facility is responsible for obtaining the most current instructions from

Learning Objectives
1. Describe issues associated with the use of loaner instrumentation.

2. Discuss the elements of a comprehensive program for handling loaner instrumentation.

3. Describe quality assurance measures, including product testing and monitoring of implant loads, applicable to reprocessing loaner instrumentation.

by Rose Seavey, RN, MBA, CNOR, CRCST, CSPDT

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Avoid IUSS
Immediate-use steam sterilization (IUSS), previously known as flash sterilization, should not be used as a substitute for insufficient instrument inventory, or as a result of loaner instrumentation not arriving in time. “Flash sterilization may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more steps in the cleaning and sterilization process.”

Implants
Both AORN and AAMI recommendations state every load containing implants should be monitored with a PCO containing a BI and a Class 5 integrator indicator. The implants should be quarantined until the results of the BI testing are available.1, and S Table 6

Emergency situations
IUSS should not be used for implantable devices except in cases of a documented emergency where no other option is available. “Implants are foreign bodies and they increase the risk of surgical site infection.” If flash sterilization of an implant cannot be avoided, a rapid-action BI with a Class 5 chemical integrator indicator should be run with the implant.

Releasing implants before the BI results are obtained is not recommended, however in some emergent situations it may become necessary to use the implant before the BI has been read. In these situations, documentation showing that the implant was released before the BI was read should be completed. The BI should continue to be incubated per the manufacturer’s instructions and the result of the BI documented. It is critical that the implant be completely traceable to the patient on whom it was used.

AORN recommends the implant be quarantined on the back table and not released until the rapid-action BI provides a negative result. If it becomes necessary to use the implant before the BI results are known and the BI is later determined to have a positive result, notification should be sent to the surgeon and IPC.

Written guidelines on what constitutes an emergency should be developed in each institution. More than likely an emergency situation is defined as life or limb threatening. This guidance should be developed in consultation with IPC, Risk Management, and the surgeons. Measures should be taken to reduce the occurrence of emergency release of implantable items. “Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices.”

Position paper on loaners
A white paper on loaner instrumentation is available online at http://www.aashcsm.org/pdfs/AASHCSP-IAHCSMMLoanerPaper.pdf. This position paper was developed to help healthcare professionals manage current issues with loaner instrumentation. These guidelines can be very helpful in the development of policies and procedures to improve day-to-day handling of loaner instrumentation.

Addressing concerns nationally
The International Association of Healthcare Central Service Materiel Management (IAHCSMM) is a multidisciplinary committee called the Orthopedic Council. This committee was created to address the mounting industry concerns related to loaner items. The Orthopedic Council membership includes representatives from IAHCSMM, AAMI, Association for Professionals in Infection Control and Epidemiology (APIC), Orthopedic surgeons, and the Orthopedic Surgical Manufacturer’s Association (OSMA). The Orthopedic Council’s goals include:

- Development of sample policies and procedures,
- Serving as a resource for members,
- Creating interactive learning modules for competency training,
- Serving as a liaison between SPD and OSMA,
- Working with vendors to develop cleaning and sterilization recommendations and standardized steam sterilization cycles for all vendor trays,
- Identifying solutions regarding orthopedic tray concerns,
- Advising and assisting orthopedic and rigid container manufacturers in the validation of their combined products using standardized sterilization parameters,
- Addressing challenges as they arise, and
- Communicating the committee activities through IAHCSMM’s newsletter and website.

Summary
Creation of a multidisciplinary loaner program and development of a well-written policy that includes the accountability and consequences related to loaner instrumentation is necessary in “taming the beast” of managing loaner instrumentation. Reliable documentation is necessary to improve patient safety related to loaner instrumentation. Involving various healthcare stakeholders
Taming the loaner instrumentation “beast”

Circle the one correct answer:

1. Requests for loaner instrumentation should be coordinated to allow sufficient time to permit in-house disassembly, cleaning, packaging, weighing, quality assurance testing, and terminal sterilization of the items.
   a. True
   b. False

2. Loaner instruments should be delivered to the decontam area unless they are newly manufactured.
   a. True
   b. False

3. Loaner items transported to SPD should be removed from external shipping containers.
   a. True
   b. False

4. Implants may be routinely released before the result of the biological indicator has been read.
   a. True
   b. False

5. The maximum weight limit for loaner trays is 30 pounds.
   a. True
   b. False

6. New or loaner trays should be evaluated to determine if existing product testing is applicable.
   a. True
   b. False

7. If flash sterilization of an implant cannot be avoided, a rapid-action BI and a Class 5 chemical integrating indicator should be run with the implant.
   a. True
   b. False

8. Flash sterilization may be associated with increased risk of infection to patients.
   a. True
   b. False

9. Rigid sterilization containers that come with loaner sets do not need to be cleaned or inspected prior to use.
   a. True
   b. False

10. Immediate-Use Steam Sterilization (IUSS) (historically referred to as flash sterilization) should not be used for implantable devices.
    a. True
    b. False

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**Disclosure Statement**
Ms. Seavey is a consultant to 3M.

Rose Seavey RN, MBA, BS, CNOR, CRSTC, CSPDT is the President/CEO of Seavey Healthcare Consulting, Inc, and formerly the Director of the Sterile Processing Department at The Children’s Hospital of Denver. Seavey was elected to the Association of periOperative Registered Nurses (AORN) Board of Directors for 2008-2010. She was honored with AORN’s award for Outstanding Achievement in Clinical Nurse Education in 2001. Seavey served as the President of the American Society of Healthcare Central Service Professionals (ASHCSP) in 2003 and is the 2002 recipient of ASHCSP National Educator of the Year award.

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**References**


