

# Getting a Handle on Loaner Instrumentation

## Essentials for a successful loaner program

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

### Objectives

After completion of this self-study activity, the learner will be able to:

1. Explain why loaner instrumentation is a growing concern.
2. Discuss patient safety issues associated with loaner instrumentation.
3. Develop a policy for handling loaner instrumentation.
4. Develop a practical program for enforcing a loaner instrumentation policy.

### Test Questions

1. Loaner instrumentation is a growing concern in most healthcare facilities.  
A. True    B. False
2. When borrowing instruments, it is the using facilities ethical responsibility to ensure the items are safe to use on their patients and that the process is properly documented and fully traceable to the patient.  
A. True    B. False



3. A major responsibility of healthcare providers is to minimize patient risks while increasing patient safety.  
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 American Society for Healthcare Central Service Professionals (ASHCSP) and the International Association of Healthcare Central Service Materiel Management (IAHCSMM) published a joint position paper on effectively managing loaner instruments and implants.  
A. True    B. False
6. The selected staff responsible for the management of loaner instruments and implants must be trained and knowledgeable of all aspects of this process.  
A. True    B. False
7. Loaner instrumentation is transported in a mostly controlled environment.  
A. True    B. False
8. An implant is a device that is placed into a surgically or naturally formed cavity of the human body but removed within 30 days.  
A. True    B. False
9. Implants require additional attention to the sterilization and quality control process because they are foreign bodies left behind; consequently the a threat of surgical site infection is greater.  
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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### Introduction

Loaner instrumentation is a common everyday occurrence in today's surgical environment. Healthcare facilities regularly borrow surgical instruments for a multitude of reasons. However, the quantity and quality of borrowed surgical instruments is an increasing concern for the majority of healthcare facilities. The management of loaner instrumentation creates many challenges, particularly when the trays do not arrive in ample time to permit routine cleaning and terminal sterilization in-house or they are unfamiliar to the staff. Published guidelines recommend each healthcare facility have a well-defined instrument management program and a multi-disciplinary policy on the management of loaner instrumentation, implants, and equipment.

In this article, we will discuss current recommendations and strategies for creating a successful loaner management plan and developing a multi-disciplinary policy on loaner instrumentation. We will also discuss patient safety issues and healthcare provider's ethical responsibilities in regard to handling and sterilization of loaner instrumentation and implants. This inservice replaces "Loaner Instrumentation: Keeping Patient Safety First" published in *Managing Infection Control* (now *healthVIE.com*) in April 2007.

### The Need to Borrow

Surgical technology is always improving and the devices used to perform specific surgical procedures are constantly changing. Equipment used in modern surgeries is often very intricate and usually specific to a certain procedure. Some surgeries are performed so infrequently that a facility cannot afford to purchase or store all of the necessary instruments for these procedures. Particular patient populations such as pediatrics may require specialized instrumentation that the facility does not own.

Scheduling is another reason facilities may need to borrow supplies. Physicians who have scheduled block time may want to do many of the same type cases on a given day. Frequently, hospitals or surgical centers do not have enough instruments available to schedule multiple same-type cases in one day. For these reasons, it is not practical for each healthcare organization to possess every instrument and implant needed for surgical procedures. In addition, some facilities may not have enough storage space for every type of instrument set or piece of equipment required.

### Issues and Concerns

There are many advantages to borrowing instrumentation (i.e., ability to expand services offered, reduced costs, scheduling issues, etc.), nevertheless, all loaner instrumentation should be handled and processed efficiently and effectively and in the same manner as facility owned instrumentation to ensure safe patient care. To ensure sterility of these instruments and trays, they must arrive at the user facility with sufficient time to be appropriately:

- ▶ cleaned,
- ▶ inspected,
- ▶ inventoried,
- ▶ wrapped,
- ▶ sterilized,
- ▶ cooled,
- ▶ implants quarantined until the biological indicators (BI) is negative,
- ▶ documented, and
- ▶ tracked to the patient.

However, all too often, these borrowed devices do not arrive at the institution with sufficient time to be properly reprocessed by the facility. This may be due to many reasons such as poor scheduling on the part of a hospital or vendor, insufficient vendor inventory, and emergencies. The vast majority of items borrowed are very complex instrumentation, and the staff may likely not be familiar with these items or how to reprocess them. The manufactures' written Instructions For Use (IFU) for cleaning, packaging, and sterilizing must be followed and product testing performed. Often these devices are delivered without any instructions or inventory list, which puts the burden on the sterile process department (SPD) staff to track down the documents. The trays must be cleaned, inventoried and inspected before being packaged and they may have to be reconfigured due to weight or size. See section on Weighing in. In addition, if there are implants that need to be sterilized the facility should run a BI and have the BI results before they use the implant on the patient. (AORN Recommendation XVI.h.2.)<sup>1</sup> (ANSI/AAMI ST79 Table 6)<sup>2</sup>

When loaner instrumentation comes into the facility without sufficient time to properly reprocess them, they must be rushed. The SPD technicians have to put everything else on hold and address the situation. This urgent situation causes a disruption, takes the staff away from their other customers or duties, and may result in errors or omission of tasks. When staff is rushed or pressured to reprocess quickly this can result in cutting corners or taking shortcuts to get the instruments to the operating room (OR) quicker. If not properly reprocessed, loaner instrumentation may result in safety issues or a negative impact on patients. Having insufficient time to reprocess loaners can also cause tension between SPD and OR personnel.

### Protecting the Patient

One of the most important responsibilities of healthcare providers is to minimize patient risks while increasing patient safety. In the operating room, this is particularly important in regard to surgical site infections (SSI). A fundamental way to help avoid SSI is to ensure items used in surgery are free of contamination at the time of use.<sup>3</sup> When a healthcare provider borrows instruments from another institution or a vendor, the borrower is responsible to ensure these items are safe and free of contamination when used on their patients.

Loaner instrumentation is a huge concern for SPD professionals. These individuals are responsible for decontaminating, packaging, sterilizing, quarantining implants until the BI results are available, storing, tracking, and issuing medical/surgical devices and equipment for those who provide direct patient care. Many perioperative professionals recognize the management of loaner instrumentation and implants as a growing concern.

Whether borrowing instruments from a vendor or another facility, it is the using facility's ethical responsibility to ensure the items are safe to use on their patients, that the process is properly documented, and all items are traceable to the patient.

### Inspection and Inventory

Personnel should visually inspect each instrument or device in loaner trays and inventory the tray for completeness. However, loaned items are often delivered without instructions, inventory lists, 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. If not inventoried before the procedure begins, missing or damaged items may become a concern during the surgical procedure which can be a safety concern. If there is no inventory list, staff may not return all borrowed items to the vendor or other healthcare facility, and the borrowing organization may be invoiced for the missing items. With an inventory list you will also be able to prove that your facility did not lose instruments. If they were never on the inventory list they were not lost but never arrived. A facility should not be charged in that situation.

### Ensuring Sterilization Effectiveness

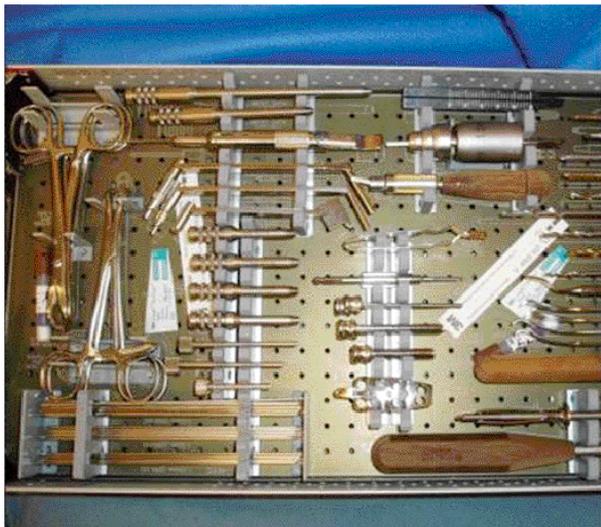
As with any in-house processed devices, controls must be in place for the successful management of loaner instruments and implants. To ensure the effectiveness of the sterilization process product testing should be performed on selected loaner instrumentation as a part of a complete quality assurance program.

In the Association for the Advancement of Medical Instrumentation (AAMI) *Comprehensive guide to steam*

*sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2010 2010), section 10.9 describes the need for product quality assurance testing of processed items and explains procedures for creating product “families.” New or loaner trays should be evaluated to determine if existing product testing is applicable to these sets.

Trays that are similar in construction, materials, size, and packaging can be considered a product family. For example a vendor that has orthopedic and neurological instruments has already established two product families of instruments. Other vendors will have also done the same. A master product should be selected from the most difficult-to-sterilize device/tray in each family from each vendor that should be used as the BI Process Challenge Device

**Figure 1. Examples of placement of biological and chemical indicators in the master product for product testing**



(PCD) for that product family when product testing is performed. Using product families helps to ensure a high level of sterility assurance without the need to test all products. (ANSI/AAMI ST79 section 10.9)<sup>2</sup>

Product testing involves:

- ▶ Placing multiple BIs and chemical indicators (CI) in areas of the loaner instrumentation considered to be greatest challenge for sterilant penetration,
- ▶ Labeling the item as a test product,
- ▶ Placing test package in a typical load,
- ▶ Processing the devices according to the medical device manufacturers’ written instructions, and
- ▶ Documenting the results. (ANSI/AAMI ST79 section 10.9)<sup>2</sup>

Loaner instruments should not be routinely processed until the testing shows negative BIs and acceptable CIs. (ANSI/AAMI ST79 section 10.9)<sup>2</sup>

### Weighing In

Loaner instrumentation, especially orthopedic specialty trays are frequently heavier than the 25 pound weight limit recommended by Association of periOperative Registered Nurses (AORN) and AAMI and may require reconfiguration or repackaging of the instruments into multiple trays. (AORN Recommendation I.4.)<sup>4</sup> (ANSI/AAMI ST79 section 8.4.2)<sup>2</sup> If a tray is overweight it may need to be separated into multiple containers provided by the instrument manufacturer. Do not place the instruments inside generic rigid sterilization containers or other packaging unless you have FDA cleared instructions for use from the instrument manufacturer. Without that information you would not know what sterilization parameters to use. The vendor representative should be consulted in the reconfiguring since he/she will most likely be available during the procedure where the loaner tray will be used.



The complexity of loaner instrumentation, the amount of metal mass, and required containment devices may necessitate sterilization parameters beyond the normal cycle times and thus require an extended sterilization exposure time. As with all instruments, the manufacturer's current written IFU should be available and followed. (AORN Recommendation III.a.)<sup>1</sup> (ANSI/AAMI ST79 section 8.5.1)<sup>2</sup>

### Trays containing implants

ANSI/AAMI ST79 states every load containing implants should be monitored with a process challenge device (PCD) containing a BI and a Class 5 integrating indicator. (ANSI/AAMI ST79 Table 6)<sup>2</sup>

AORN recommendations agree with AAMI's release criteria for implants. AORN states: "Each load containing an implantable device should be monitored with a BI and quarantined until the results of the BI testing are available." (AORN Recommendation XVI.h.2.)<sup>1</sup>

"The sterilization of implantables should be closely monitored and each load containing implants should be quarantined until it is verified that BI testing has yielded negative results." (ANSI/AAMI ST79 section 10.6.3)<sup>2</sup>. The Food and Drug Administration (FDA), defines an implant/implantable item as "a device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also 'implants'." (ANSI/AAMI ST79 section 10.6.3)<sup>2</sup>

AAMI's release criteria for implants recommends, "As with all cycles, the sterilizer operator should review the sterilizer chart or printout and the results of other indicators that have been used to monitor the sterilization process. The load should be quarantined until the results of the BI testing are available (CDC, 2003a)." (ANSI/AAMI ST79 section 10.6.3)<sup>2</sup>

### Why run a BI with implants?

Implants require additional attention to the sterilization and quality control process because they are foreign bodies left behind; as a result, the risk of a SSI is greater. (AORN Recommendation IV)<sup>1</sup>

### Why are there more SSI risks with implants?

- ▶ "First, they are left behind at surgery, so if there are microorganisms on them, these will remain in the body. Infections associated with implants may not be evident for up to a year after surgery.
- ▶ Second, the placement of an implant often means the removal of tissue, with interruption of blood supply and significant manipulation of the tissues immediately adjacent to the implant, creating an area of potential safety for microorganisms to multiply, further increasing the risk of

- ▶ Third, because there is interrupted blood supply, antibiotics cannot easily get to the microorganisms if they do multiply enough to cause a clinical infection.
- ▶ Fourth, the implant itself may be vital to continuing function of a body system, such as would occur with a total joint replacement, vascular graft, or intraocular lens placement. An infection may not be curable with the implant in place, and removing it could cripple or kill the patient."<sup>5</sup>

## Emergency Situations

Immediate-use steam sterilization (IUSS), historically referred to as "flash sterilization," should not be used for implantable devices except in cases of emergency where no other option is available. "Implants are foreign bodies and they increase the risk of surgical site infection." (AORN Recommendation IV.g.)<sup>1</sup> If flash sterilization of an implant cannot be avoided, a rapid-action BI with a Class 5 chemical integrating indicator should be run with the implant. (AORN Recommendation IV.g.)<sup>1</sup>

Releasing implants before the BI results are obtained is not recommended, however in some emergent situations (e.g., the need for trauma-related orthopedic screw-plate sets) it may become necessary to use the implant before the BI has had time to be properly read. In these situations, documentation that the implant was released before the BI was read should be completed for the patient. The BI should continue to be incubated and the result of the BI documented. It is critical that this documentation be completely traceable to the patient the implant was used on. (ANSI/AAMI ST79 section 10.6.3)<sup>2</sup>

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 infection prevention and control (IPC) personnel. (AORN Recommendation IV.h.2.)<sup>1</sup>

## Documentation

The IUSS or flash cycle information and monitoring results should be documented and maintained in an electronic or manual log to provide tracking of the flashed item(s) to the individual patient. Documentation is necessary in order to ensure every load of sterilized items used on patients can be traced. Information that should be documented on the sterilization records of each load include:

- ▶ The item(s) processed,
- ▶ The patient receiving the item(s),
- ▶ The cycle parameters used (e.g., temperature, duration of cycle),
- ▶ the date and time the cycle is run,
- ▶ the operator information, and



Figure L.2—Exception form for premature release of implantable device/tray

**Exception Form for Premature Release of Implantable Device/Tray**

**NOTE**—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

**PLEASE COMPLETE ALL INFORMATION:**

**DATE:** \_\_\_\_\_ **SHIFT:** \_\_\_\_\_ **TIME:**  
\_\_\_\_\_ AM PM

**PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE:**  
\_\_\_\_\_

The following implantable devices/trays were prematurely released to the Operating Room:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:**  
\_\_\_\_\_

**OPERATING ROOM REPORT:**

**PATIENT NAME:**  
\_\_\_\_\_

**SURGEON NAME:**  
\_\_\_\_\_

**TIME OF PROCEDURE:** \_\_\_\_\_ AM PM **DATE:** \_\_\_\_\_

**REASON PREMATURE RELEASE WAS NEEDED:**  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE/TRAY?**  
\_\_\_\_\_  
\_\_\_\_\_

**NAME OF OR PERSON COMPLETING THIS REPORT:**  
\_\_\_\_\_

**DATE REPORT COMPLETED:** \_\_\_\_\_

**FORM RETURNED TO CENTRAL SERVICE ON:** \_\_\_\_\_

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minimize the need to flash sterilize implantable medical devices.” (AORN Recommendation IV.g.)<sup>1</sup>

Ongoing periodic reviews of documentation such as the exception forms and implant logs could disclose consistent patterns causing the need to release implants prematurely. Identifying these patterns would be helpful in quality improvement measures (i.e., purchasing additional instruments or adjusting the surgical schedule) aimed at correcting these issues. (ANSI/AAMI section 10.6.3)<sup>2</sup>

### Arrival Time

One of the biggest concerns with borrowing surgical instrumentation is the delivery time of the items. The user facility should have adequate time to be inserviced if the instrumentation or tray set up is new to ensure that the OR understands the instruments and set up and how to properly disassemble the instruments for pre-cleaning in the OR. The SPD also needs to understand disassemble for cleaning and sterilization. Time is also needed to inventory, weigh the instruments, perform product testing if required, and reprocess the items following the original manufacturers’ written instructions for cleaning, assembling, packaging, and sterilizing.

All too often, the loaner instrumentation does not arrive at the facility in sufficient time to reprocess surgical instruments in the usual wrapped manner before the start of the surgical case. The lack of enough time often leads to the need to hurry the process and facilities may use the IUSS or flash sterilization method and a shorter sterilization time, both of which is not recommended by the medical device manufacturer.

### Managing the Loaner Process

Managing loaner instruments is a very complicated and time-consuming process; therefore, facilities such as hospitals, ambulatory surgery centers and dental offices that borrow surgical instruments should have a well developed loaner program and written policy. These policies and procedures can be used as a guideline to systematically manage loaner instrumentation and surgical implants. SPD and the OR should develop this policy in concert with various departments such as IPC, administration, materials management, RM, and surgeons.

The loaner program should be monitored, assessed, and periodically reviewed to make sure patient safety is not jeopardized anywhere along the loaner process.

### Developing a Policy and Procedure

Loaner instrumentation policies and procedures should address the systematic management of loaner instrumentation and implants from acquisition to disposition. These policies and procedures should include:

- ▶ ordering,
- ▶ transport in,
- ▶ check in,
- ▶ pre-procedure processing,
- ▶ charging (if applicable),
- ▶ post procedure processing,
- ▶ check out and transport out.<sup>6</sup>

Sometimes, the borrowed instrumentation is left at the facility for future use. This is often referred to as being on consignment. Consignment items should be addressed in the loaner management policy.

### Joint position paper

In 1995, ASHCSP and the IAHCSP published a joint position paper on effectively managing loaner instruments and implants. The then two sterile processing professional organizations addressed issues healthcare professionals face daily when managing loaner instrumentation and implants. In April of 2004 this original position paper was updated to help healthcare professionals manage current issues with loaner instrumentation.<sup>6</sup> These up-to-date guidelines can be very helpful in the development of policies and procedures to improve day-to-day handling of loaner instrumentation.

The OR and SPD should develop a partnership built on mutual trust and cooperation with all the various vendors they may borrow instruments from. Healthcare facilities should provide vendors with information regarding expectations and time requirements for the delivery of loaner items. Sufficient time for pre-procedure and post-procedure processing is necessary to ensure patient safety.<sup>6</sup> Having the loaned instruments in the facility before the case will also give the OR staff, who will be scrubbed on the case, time to become familiar with the instrumentation. The vendors should be held accountable for providing proper documentation and adhering to these timelines.

Vendors should supply specific cleaning, packaging and sterilization instructions for us for all loaner items. SPD should follow the manufacturers’ written IFUs including the sterilization exposure cycle time using the packaging provided. Many borrowed instruments are sophisticated devices requiring a longer than the normal cycle exposure time, often referred to as an “extended” cycle time. SPD should maintain a record of each tray that is used on each patient, including time in and out, and other processing specifics.<sup>6</sup>

Staff responsible for the management of loaner instruments and implants should be trained and knowledgeable of all steps of the loaner process. The guidelines should discuss how the loaner instrumentation should be acquired by the facility and should include: initial request, communication, transportation, and designated receiving area.<sup>6</sup>

The policy should address all aspects of accountability and recordkeeping. Records should include:

- ▶ date and time of receiving the instrumentation,
- ▶ date and time of procedure,
- ▶ surgeons name,
- ▶ inventory list,
- ▶ manufacturers' written IFUs including reprocessing instructions,
- ▶ quality checks,
- ▶ cleaning and decontamination,
- ▶ arrangement for replacement of damaged or lost instruments,
- ▶ implants used, and
- ▶ date and time items returned to the vendor or other healthcare facility.<sup>6</sup>

To help facilitate the management of instrumentation and implants brought in from outside organizations and companies, the implementation of tracking and quality controls and procedures are required. (AORN Recommendation X)<sup>1</sup> Depending on the amount and types of loaners coming into the facilities, tracking each item can involve a lot of documentation.

Many facilities now have an instrument tracking software system which can be extremely helpful in management and documentation of loaner instrumentation. A bar-code loaner tracking program can help facilities automatically:

- ▶ document delivery times,
- ▶ identify quality assurance issues,
- ▶ track location of loaner trays,
- ▶ store cleaning and sterilization recommendations,
- ▶ monitor the status of the trays,
- ▶ track quality of service provided by the vendor, and
- ▶ produce management reports.

### Enforcing the policy

Creating a policy is one thing but enforcing it is another. Enforcement of the policy is sometimes harder than creating it. Once a policy is established, the facility should educate all involved parties (including vendors) on what the policy actually entails and what the responsibilities are. Consequences for not following the policy should be spelled out in the policy. One effective way to educate those involved is to hold a meeting with each party to discuss the changes, the intent to enforce the policy, and the consequences for not following the protocol. One example of a consequence may be if a vendor does not supply instrumentation in sufficient time as referenced in the policy; on the third offense the facility will no longer use their products. Another example is if loaner trays are not picked up within a certain time either a rental fee is charged to the company or the items are shipped at the company risk and expense.

For increased buy-in, the invitees to the meeting should include:

- ▶ Sterile Processing;
- ▶ Perioperative Services,
  - Director
  - Specialty Service Leaders for Orthopedics and Neurology
  - OR Education and Quality leaders;
- ▶ Representatives from the surgery staff such as,
  - Surgery in Chief
  - Chief of Orthopedic Surgery
  - Chief of Neuro Surgery;
- ▶ Infection Prevention and Control (Epidemiology);
- ▶ Risk Management;
- ▶ Quality Performance;
- ▶ Nursing Administration;
- ▶ Materials Management; and
- ▶ All manufacturer representatives that provide loaner instrumentation.

### Proper Protocol

Specific steps should be followed when using loaner instrumentation. When a case is scheduled requiring loaner instrumentation, the physician (or designee) should notify the vendor of the date and time of the surgery. The vendor, in turn, should contact the OR and SPD to let them know when to expect the items to arrive.

### Delivery

All loaner instrumentation should 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 and be delivered directly to the SPD decontamination area. In all cases the instruments must be considered contaminated. This includes the items that may have been packaged and sterilized at another facility. Loaner instrumentation is usually transported in an "uncontrolled" environment (i.e., trunks of cars, public transportation, etc.). Therefore, even if the trays have been "sterilized" by another facility, you must reprocess starting with the decontamination process.<sup>6</sup>

Wearing proper personal protective equipment (PPE) the SPD staff should check the accuracy of the order, log the receipt of loaner instruments, verify types and quantities, and visually inspect for damage.<sup>6</sup>

### Why reprocess wrapped items?

Patient safety depends on monitoring and documentation of the sterilization process. The borrowing facility should reprocess all items using the facility's own protocol because they must have the record of the sterilization process and quality assurance measures in order to trace sterile items to the patient. Most items

are transported in an uncontrolled environment and are not always protected during the handling and transportation process.

### Partners and Resources

A few years ago, IAHCSSM crated a dedicated multidisciplinary committee called the Orthopedic Council. This committee was formed to address growing industry concerns related to loaner items. The Ortho Council membership includes representatives from IAHCSSM, AAMI, Association for Professional in Infection Control and Epidemiology (APIC) 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 IAHCSSM's newsletter and Web site.<sup>7,8</sup>

### Summary

Development of a loaner program which includes a well-written policy that spells out the accountability and consequences related to loaner instrumentation, can be extremely helpful in "getting a handle" on the management of loaner instrumentation. Reliable record keeping is necessary to improve patient safety related to loaner instrumentation. Involving various healthcare providers such as IPC, OR, RM and manufacturers' representatives involved in the process is essential for a successful loaner program.

A simple loaner instrumentation checklist (see box) can be extremely helpful in ensuring all the necessary steps are followed.

### Rose's Soap Box

"Healthcare providers sometimes make excuses by saying they cannot follow published best practices, but what they should be saying is they **HAVE** to follow them. Whining and hoping that someone else will make the changes to best practices is not productive. SPD and OR

### Loaner Check List

- SPD notified of loaners prior to receiving them
- Received in facility (decontam) at least two working days (48 hours) for existing loaner sets and three working days (72 hours) for new sets before scheduled case
- Inventory list available
- Written recommendations for cleaning, packaging, and sterilization available
- Inventory and quality check completed
- Multiple trays numbered and labeled (patient name, surgeon)
- Trays do not exceed 25 pounds
- All instruments in good condition, no rusting, pitting
- Container in good condition, no rusting, tape, residue, etc.

professionals need to be the change agents to make this happen. It is time to put away the excuses and do what is morally right in the fight against SSIs. SPD and OR staff can start with sharing their concerns with IPC and RM in their facilities. Share the issues and "excuses" with them and ask for their help. These two departments play an extremely important part in infection prevention and they can make a difference in establishing a successful loaner program and improving patient safety. After all, isn't that what you would want if those instruments were going to be used on you? I know I would!" ✦

### References

1. Recommended Practices for Sterilization in the Perioperative Practice Settings. In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc, 2011.
2. Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2010 & A1:2010.
3. Association of periOperative Registered Nurses (AORN). Position Statement on Patient Safety, accessed October 2, 2010. Available at: [http://www.aorn.org/PracticeResources/AORNPositionStatements/Position\\_PatientSafety/](http://www.aorn.org/PracticeResources/AORNPositionStatements/Position_PatientSafety/)
4. Recommended Practices for Selection and Use of Packaging Systems for Sterilization. In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc, 2011.
5. Schultz, Janet. Monitoring and Load Release for Implants Sterilized by Steam Within Healthcare Facilities. *Managing Infection Control* (now *healthVIE.com*). Jan 2004.
6. ASHCSP/IAHCSSM position paper on Loaner Instrumentation (April 2004), accessed October 2, 2010. Available at: <http://www.ashcsp.org/pdfs/ASHCSP-IAHCSSMLoanerPaper.pdf>
7. Williamson J. New committee aims to ease orthopedic set concerns. *Healthcare Purchasing News*.2009; 33 (10):34-35.
8. International Association of Healthcare Central Service Materiel Management. Complex surgical instruments. In: *Central Service Technician Manual*.7th ed. Chicago, Ill: International Association of Healthcare Central Service Materiel Management; 2007:197-235.



*Rose Seavey, RN, MBA, BS, CNOR, CRCST, 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. Ms. 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. Ms. 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.*

*Ms. Seavey is a member of several AAMI working group committees that are developing recommended practices and is currently a co-chair for the ANSI/AAMI Working Group for Hospital Steam Sterilizers performance standards. In addition she has lectured and authored many articles on various topics relating to perioperative services and sterile processing, locally, nationally and internationally.*

ANSWERS	
1. T	6. T
2. T	7. F
3. T	8. F
4. F	9. T
5. T	10. T

**Sterile Process and Distribution CEU Information**

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Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1.5 contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until recertification is required. **DO NOT SEND LESSON OR TEST TO CBSPD.**

For additional information regarding Certification contact: CBSPD, 148 Main St., Lebanon, NJ, 08833 or call 908-236-0530 or 800-555-9765 or visit the Web site at [www.sterileprocessing.org](http://www.sterileprocessing.org).

IAHCSMM has awarded 1.5 Contact Points for completion of this continuing education lesson toward IAHCSMM recertification.

**Nursing CEU Application Form**

This inservice is approved by the California Board of Registered Nurses, CEP 5770 for 1 contact hour. This form is valid up to five (5) years from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. **KEEP A COPY FOR YOUR RECORDS.**
6. Submit this form and the answer sheet to:  
3M Sterilization Assurance, Attn HC4160  
RR Donnelly Fulfillment Services  
585 Hale Ave N, Oakdale, MN 55128-9935
7. For questions, contact [craig@firstaccessmedia.com](mailto:craig@firstaccessmedia.com).
8. Participants who score at least 70% will receive a certificate of completion within 30 days of [healthVIE.com](http://healthVIE.com)'s receipt of the application.

**Application**

Please print or type.

Name \_\_\_\_\_

Mailing Address \_\_\_\_\_

City, State, Country, Zip \_\_\_\_\_

Daytime phone (            ) \_\_\_\_\_

Position/Title \_\_\_\_\_

Social Security or Nursing License Number \_\_\_\_\_

Date application submitted \_\_\_\_\_

Signature \_\_\_\_\_

*Offer expires March 2016*

On a scale of 1-5, 5 being Excellent and 1 being Poor, please rate this program for the following:

- 1) Overall content \_\_\_\_\_
- 2) Met written objectives \_\_\_\_\_
- 3) Usability of content \_\_\_\_\_