Loaner Instrumentation

Objectives

• Discuss issues and concerns relative to loaner instrument sets
• Discuss guidance from a professional organization paper and AAMI
• Examine the steps to take in managing the issues with loaner instrumentation

Introduction

Loaner instrumentation has long been recognized as a concern for central service/SPD and operating room professionals. It has become an even greater challenge as surgical instruments are becoming more complex and the cost of specialty instruments has skyrocketed. Some describe “loaners” as a nightmare. Concerns range from delivery of loaner trays without sufficient time to properly process them before the scheduled surgery, to tears in the wrapper, lack of manufacturer’s instructions, weight of the trays, possibility of wet loads and more to the issue of extended sterilization cycle times beyond standard acceptable parameters.

When healthcare facilities have a need to borrow instrumentation for surgery, they must have policies and procedures in place to ensure effective management of these instruments to avoid any negative impact on patient care. Managing these loaner sets requires the cooperation of the healthcare staff and the vendor providing the sets and a knowledgeable, trained, and competent staff is critical to the success of the process.
Issues and Concerns

A loaner instrument set can range from one tray to a system of trays brought into a healthcare facility to be used in a specific surgery on a specified individual. They can be trays brought in by a vendor or borrowed from another facility. This practice can be a risky proposition since there may be little or no information relating to its prior use or re-processing nor the infectivity of the previous patient. Therefore, all loaner sets must be considered contaminated. The loaner trays are frequently brought into the facility without sufficient time for processing in the CS/SPD department. Shortcuts are taken and the trays may go directly to the OR for IUSS without undergoing proper cleaning, prior to sterilization.

In many cases, the CS and OR professional may not be aware that some of these trays have specific guidelines for cleaning and prepping, and that an extended cycle has been recommended for sterilization. Few SPD and OR staff have knowledge of the recommended processing instructions. Sales representatives either do not know or do not provide the reprocessing instructions. As central service professions push for information, many times they find that the manufacturer’s recommendations do not match their standard hospital processing times. Many have been astonished when they receive the actual recommendations relating to exposure time.

There is an array of recommendations for exposure times that range from 4 to 50 minutes, depending on the complexity of the instrumentation, the number of layers included in the set, and the design and material of the instruments and container. At least one major medical manufacturer has
made a recommendation to use a 40-minute exposure time for multi-level wrapped orthopedic trays in pre-vacuum steam. A minimum of 10 minutes in pre-vacuum steam is their recommendation or single-level trays. These recommendations force the end user to extend processing times for all sets or to dedicate a sterilizer for trays with extended cycles. Furthermore, many manufacturers have validated their loaner trays with only one set in the sterilizer. Some manufacturers add to their recommendations that the user can verify the trays themselves for use in the facility’s standard cycles.

Assembling these trays is another challenge for the CS professional. Many of the instruments and implants are unfamiliar to the staff. Sometimes staff must assemble loaner instruments that they have never seen before and may have little or no knowledge of how to disassemble, to properly check for soil, or to clean. These sets are often very complex. Some manufacturers offer an organizing tray with a defined layout or roadmap for instrument placement and identification (i.e. the graphics tray). Still, it can be puzzling, as these trays may not be easy to put together either. CS staff have often struggled to align implants and instruments into their correct slot.

As the custom graphics tray is specifically designed to house specific instrumentation, any change in the length or diameter of an instrument or the addition of an instrument may make it nearly impossible to place the new item in the existing tray without potentially damaging the instrument or obsolescing the tray. Caution must be taken when receiving loaner trays as they may show signs of wear. Set contamination can be evident in the
form of nylon coating deterioration on the custom holders. Additionally, vendors sometimes combine two or three sets to help eliminate the amount of sets that need to be wrapped, but this can increase the metal mass of the set, making it more difficult to sterilize and dry. The graphics trays are sterilizable, but not intended to provide a sterile barrier. They must be wrapped or placed within a sealed container for sterilization. While approximately 50% of all surgical trays in the U.S. are now containerized in rigid reusable sealed sterilization containers, the loaner trays are still primarily wrapped.

Orthopedic sets tend to be a particular challenge. The instruments are heavy and wrapping them is often difficult. A dozen or more individual wrapped trays may be required for one procedure. This is extremely time-consuming. It may take a minimum of three to four minutes to wrap each tray. Furthermore, the wrapped sterilization trays may have sharp corners that may cause tears, holes cuts and abrasions from pulling these trays off the shelf and other handling mishaps, which contribute to these trays requiring re-processing before use. Tears in the wrapper are a too common occurrence and result in delayed surgical procedures. This translates to increased costs for re-processing, rescheduling, and significantly impacts patient care.

All sterilization trays, including loaner trays and sealed containers, are considered class II medical devices and manufacturers are required to obtain FDA 510k pre-market clearance for the intended use of the device. Original equipment manufacturers (OEM suppliers) under the direction of the major medical companies design and manufacture the graphic
instrument trays and most loaner trays. Few suppliers have had any input or feedback from end-users, nor have they obtained proper clearance from FDA. In fact, some containers have not been cleared for multi-level trays or for a maximum load of orthopedic instruments. Over the last several years, many custom trays have been manufactured out of plastic or metal plastic hybrids. The plastic materials of construction have low thermoconductivity. As a result, wet packs may occur and extended processing times may be necessary to achieve terminal sterilization. This becomes an even greater challenge when non-woven polypropylene wrap is utilized as a barrier for these plastic instrument sets.

Meeting the Challenges

Healthcare professionals are raising their voices and requesting information from vendors as they establish new policies and procedures to address the problems. According to the IAHCSMM position paper on loaner instrumentation, “The management of loaner instrumentation and implants for specialty operative procedures in healthcare institutions is recognized as a problem by many healthcare professionals today. It is a particular concern for Central Service personnel who are responsible for processing, storing, and issuing medical/surgical devices and equipment for those who provide direct patient care.” The position paper, “Management of Loaner Instrumentation and Implants” was updated to provide updated guidelines to assist healthcare professionals in the management of loaner instrument sets from acquisition to disposition. An emphasis was placed on developing a partnership between the Vendor, Central Service, and the Operating Room. In addition, the issue of packaging and containerizing the loaner
trays has been a focus in the container-working group of AAMI. Discussions have led to recommendations to limit the weight of the sets and make allowances for sealed containers cleared for this purpose.

What can be done?

First, it is important to obtain the manufacturers written instructions for cleaning and sterilizing loaner instruments and instrument cases and then compare this information to your facility’s written policies and procedures.

Manufacturers have written instructions for cleaning/decontaminating medical devices prior to sterilization. Ask for them. Your sales reps should have access to them. Some of them are even posted on-line at the manufacturer’s website. Most recommend mechanical cleaning, including sonification, a full rinse, lubrication and drying after the final rinse. Most recommend a pH neutral detergent and an enzymatic cleaner. You must find out if special cleaning instructions are required for certain devices.

Second, each healthcare facility should determine what time frame is necessary for the delivery of loaner instruments and implants in order to allow for adequate reprocessing of the sets prior to the scheduled surgery. A specific time-frame should be established and sales representatives made aware of and held accountable for meeting the agreed upon schedule. Remember, if extended times for sterilizing these sets is required, this information must be added to your facility’s written policies and procedures and implemented.

Be sure to include any information about the suitability of IUSS sterilization for these devices. IUSS sterilization may be an appropriate option under certain circumstances. However, AAMI strongly recommends that IUSS not
be used on sets containing implants. Vendors need to provide the specific re-processing instructions for cleaning and sterilizing these sets as well as specific information relating to IUSS sterilization, if necessary. Staff need to be trained to properly manage these sets following the facility’s policies and procedures and the recommended re-processing instructions from the manufacturer. On a practical level, all parties should establish a minimum time prior to use for delivery of such trays to allow for appropriate cleaning and terminal sterilization.

Third, healthcare professionals can provide feedback to instrument manufacturers and to the tray suppliers to incorporate into the design of the set elements that meet facility needs. This can include a tray where weight may be distributed into layers, where materials utilized facilitate drying and where the layout of the set is simplified and can accommodate the addition of new instruments. Manufacturers are understandably concerned about patient safety and the need for overkill to be built into the process. However, design changes can help address the issue of extended re-processing times.

Healthcare professionals must ask for detailed information and explore options. Some are beginning to place their loaner/graphic trays into sealed containers designed for this purpose. They are addressing the issue of torn wrappers, wet packs, and increased re-processing times by verifying these sets with biological indicators and test packs in the load within their hospital’s sterilizers. Some graphics trays may simply be dropped into the reusable sealed container. Others may need to be re-configured to fit. In some instances, the loaner/graphics trays are eliminated entirely and replaced by a modular system with a layout that is organized and can
be re-configured. Effective management of these sets requires the cooperation of central service, the operating room and the vendor providing these devices to the healthcare facility.

Summary

Healthcare professionals are ultimately responsible for positive patient outcomes and infection prevention. They are faced with an increasing volume of patients, a shortage of specialty instruments and a lack of time to properly process instrument sets, when they come in from the loaner bank or another facility. Yes, loaner trays are a challenge. However, new products and safe processes are available to help meet the challenge. Healthcare professionals need to be informed and trained and must ask for information and guidance. Manufacturers and healthcare providers must come together to address problems and to develop innovative technology that facilitates productivity, standardization and safety. A team approach to problem solving can address the needs of the provider as well as the patient.