

Timely delivery needed to ensure safety of loaned instruments

Imagine that during a total joint surgical procedure, debris comes out of a surgical instrument and lands directly inside a patient's open wound. Although such a scenario is rare, when it does occur, it creates a major patient infection risk.

Many standards and guidelines recommend best practices that can help prevent this type of situation. Careful management of loaned instrumentation is one such practice.

Loaned devices often consist of multiple trays and many types of instruments and/or implants, and even endoscopes. Some of these are very complex, sophisticated devices that are new to the facility. Loaned instruments are of particular concern for sterile processing staff who are responsible for processing, storing, and issuing reusable medical-surgical devices and equipment to caregivers.

Potential problems

Instrumentation and surgical implants are borrowed from vendors or neighboring healthcare facilities for a variety of reasons, including:

- The cost of the instrumentation needed to perform relatively few procedures is prohibitive.
- More specialty cases are being performed than what the facility's instrument inventory can support.
- A physician or surgical specialty wants to trial the new instrument(s) or technology.
- Changes in technology are rapidly making instruments outdated.

The use of loaned instrumentation is increasing, and it is not unusual for a sterile processing department (SPD) to receive several hundred trays per day. Many of these instruments require special disassembly, cleaning, and assembly.

The process for sterilizing or disinfecting loaned instrumentation in the SPD is essentially the same process used for other instrumentation. All



Loaned instrument sets must be sterilized according to the manufacturer's instructions for use. Photos courtesy of Susan Klacik.

loaned instruments brought into the facility are processed through the decontamination system because they are considered contaminated upon arrival. (This also pertains to any reusable instrumentation still in sterilization packaging.)

Decontamination is necessary because there is no way to verify the quality of the decontamination done previously. In addition, the loaned instrumentation was stored and transported to the receiving facility in uncontrolled conditions.

Loaned instrumentation should be delivered with a packaging slip to ensure all instrumentation was, in fact, received. Then the loaned instrumentation should be carefully inventoried and checked for quality.

Some SPDs take digital photos of each set or individual instruments to serve as visual reminders of the instruments and the condition in which they were received.

Any loaned instrumentation that is lost can cause a dispute between the healthcare facility and the vendor. Lost instrumentation can be costly to replace, so it is important to document the loaned instruments upon arrival. This record will help protect the healthcare facility if some devices were either missing from the delivery or were re-

ceived in poor quality.

The loaned instruments' instructions for use (IFU) should also accompany the instruments unless the IFU were sent to the facility separately. All IFU should be readily available and followed to ensure the instrumentation is reprocessed safely and effectively.

Rigorous sterile processing required

Processing loaned instrumentation requires numerous manual cleaning steps. SPD technicians must be trained, device IFU must be diligently followed, and all required cleaning implements must be readily available.

Without adequate training and access to the IFU, staff may skip processing steps or perform them improperly, especially if they are rushing. Processing time projections should be shared with the surgical services team to help them schedule cases appropriately.

Instrument processing time requirements are based on manual processing steps and equipment processing times. Equipment processing times are dependent upon the cycle time; capacity is based on the chamber size and weight restrictions.

These factors affect how many sets can undergo automatic equipment pro-

Continued on page 24

Continued from page 23

cessing within a certain timeframe. Furthermore, if other instrumentation has been classified as a priority, it may be processed before the loaned instrumentation.

Loaned instrumentation can consist of anywhere from one item to more than 30 instrument sets, such as for a revision. Instrumentation can be simple handheld instruments or complex instruments such as flexible reamers, multi-part instruments, power equipment, or flexible endoscopes.

To allow adequate time for quality processing, the instrumentation should arrive in the decontamination area at least 2 working days (48 hours) be-



Cleaning implant trays manually under the surface of the water to prevent aerosols from forming.

fore the scheduled surgery for existing loaned sets, and 3 working days (72 hours) for new sets, which will require training for both SPD and OR staff.

Because loaned instrumentation increases volume and equipment loads, more staff and supplies will be needed to meet the demand. However, equipment capacity cannot be expanded. Automatic washers and sterilizers are large capital equipment with a fixed capacity.

Devil in the details

SPD staff must review the IFU to ensure all required equipment is available and then record it. Loaned instrument sets that arrive late, especially when they are



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delivered the day of the surgical case, present an unnecessary burden and disrupt schedules. Late deliveries can lead to overtime, improper processing, or failure to process.

Cleaning is the most important part of the sterilization and disinfection process for all instruments, including loaned devices. For thorough cleaning to occur, instrumentation must be disassembled (if designed to do so), and lumened devices must all be brushed (using the correct size and type of brush) and then flushed.

In most cases, loaned instrumentation is processed through automatic instrument washers to the preparation and packaging area. Layered instrument sets all must be removed from their containment device and loaded into the washer separately so that all instrument surfaces are exposed to the cleaning action of the washer. The containment device, including the lid, is also processed separately. Keep in mind that washer capacity can contribute to bottlenecks.

As loaned instrument sets are unloaded into the preparation and packaging area, the different instrument set levels must be matched and placed into the correct containment device with the correct lid, both of which must have labeling information for surgery. The instrumentation is then inspected to ensure it is clean and free of defects.

Inspection can take seconds or minutes, depending on the instrument. Borescopes may be used to inspect internal components, including lumens, for debris and defects. Inspection failures need to be reported to the appropriate surgical services staff and the vendor. Sets that pass inspection are assembled in the instrument tray and packaged unless they undergo high-

level disinfection. During the packaging stage, the SPD technician must know exactly how to label the set so it can be easily located and used in surgery.

Instrumentation must be sterilized or disinfected in accordance with the IFU. Some sterilization loads require the use of a biological indicator (BI), which must be incubated after sterilization. Implants should not be released until the final BI result is known.

The sterilizer may have a weight limit that may cause additional loads to be run. After sterilization, the load must be allowed to cool down before the items are handled; for dense metal sets, this can take up to 4 hours.

To keep surgical cases on schedule, SPD and OR staff must communicate about any problems with loaned instrument sets, particularly late deliveries. Delays will affect the surgical case that requires loaned instruments as well as other surgical cases if staff and equipment are being used to process only the late loaned instrumentation.

It is not unusual for an SPD to receive trauma sets and quickly turned instrument sets at the same time, along with loaned instrument sets that arrived late. The IFU will specify sterilization instructions and may not include immediate use steam sterilization for the loaned instrumentation.

Having a robust communication system in place will allow the surgical team to prioritize instrument processing based on the needs of surgery. SPD staff should know when loaned sets are scheduled to be received so they can have adequate staff and supplies on hand for processing. Equipment capacity may require additional staff to process the additional equipment loads.

The management of loaned instrumentation and implants in healthcare

Sterilization & infection prevention

facilities is addressed in many standards and guidelines:

- The International Association of Healthcare Central Service Materiel Management (IAHCSMM) has a Position Paper on the Management of Loaned Instrumentation, which is available at www.iahcsmm.org (under the Resources tab).
- AORN guidelines address loaned instrumentation in the Guideline for Instrument Cleaning.
- The Association for the Advancement of Medical Instrumentation (AAMI) provides guidance in TIR 63, Management of loaned critical and semi-critical medical devices that require sterilization or high-level disinfection; ANSI/AAMI S79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities; and ANSI/AAMI ST91, Chemical sterilization and high-level disinfection in health care facilities.

These organizations recommend having a formal program for loaned instrument management, with specific policies, procedures, and controls. This program should be based on the recommendations developed by an interdisciplinary team consisting of surgeons and staff from SPD, surgical services, infection prevention and control, administration, materials management, and risk management.

Policies should be based on regulatory requirements and align with evidence-based guidelines such as those from AAMI, AORN, and the Centers for Disease Control and Prevention.

A loaned instrumentation program should address:

- how to request loaned instrumentation or implant(s)
- time requirements for obtaining loaned devices for preprocedure and postprocedure processing
- training, as needed and for new devices
- the acquisition process for loaned items, including a detailed inventory

list (preferably with pictures)

- obtaining US Food and Drug Administration-cleared manufacturers' written instructions for instrument care, cleaning, assembly, and sterilization
- cleaning, decontaminating, and sterilizing borrowed instrumentation by the receiving facility
- transporting processed loaned instrumentation to the point of use
- postprocedure decontamination for processing, inventory, returning to the industry representative, and maintaining records of the transactions.

Expectations for vendors

A partnership based on mutual trust and collaboration should be developed between the vendor and SPD and OR staff. Once a loaned instrumentation policy is set, vendors should be informed about the delivery time requirements for preprocedure and postprocedure processing.

Delivery of loaned instrumentation should include the IFU. (Note: Providing vendor IFU is a requirement under the FDA labeling regulation [21 CFR 801], which states manufacturers must provide current, complete, and comprehensive written instructions for handling, cleaning, disinfection, testing, packaging, and sterilization.)

Vendors should also provide comprehensive inventory lists, preferably with pictures. The SPD should keep a record of each set that is used, including time in and time out, and other processing specifics, along with digital photos. The loaned program should be monitored, assessed, and periodically reviewed for compliance.

In 2020, AORN published a Position Statement on the Role of the Health Care Industry Representative in Perioperative Settings, which applies to loaned instrumentation. This position statement says that the healthcare representative from a surgical instrumentation or implant manufacturer has the

education, knowledge, and expertise to play a valid yet restricted role in the surgical procedure, and must meet all requirements of the healthcare organization.

An interdisciplinary team should develop and periodically review policies and procedures for the healthcare representative. The perioperative administrator must ensure that these policies are followed so that proper inspection and sterilization of loaned equipment take place before the procedure is performed. Equipment and instruments must be received with enough time for these processes, including enough time to meet sterilization and biological monitoring parameters.

To help ensure a positive outcome, the perioperative RN should verify that:

- all members of the perioperative team have received education and completed competency verification on new procedures, techniques, technology, and equipment before they are used in an operative or other invasive procedure
- new or loaned equipment has been approved by the healthcare organization's service provider
- loaned instruments have gone through the healthcare organization's terminal sterilization process before use.

Processing instrumentation, including loaned devices, requires all steps to be performed in strict accordance with the manufacturer's IFU. A loaned instrumentation management program that is communicated to all stakeholders and consistently followed will help eliminate late delivery and other problems, and it will decrease risks to the patient. ❖



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