Loaner Instrumentation

ADDRESSING CONCERNS; MEETING CHALLENGES

By Arlene Carlo, Marcia Frieze and Mary Olivera

Loaner instrumentation has long been recognized as a concern for central service/SPD and operating room professionals and has more recently become even a greater challenge as 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 recently to the issue of extended sterilization cycle times beyond standard hospital 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 and 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. In addition, 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 or 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 are often flash sterilized in the OR. Sometimes these trays contain implants.

In many cases the CS and OR professional is not aware that some of these trays have specific guidelines for cleaning and prepping and that an extended cycle has been recommended for sterilization. At a recent regional conference, few participants had knowledge of the recommended processing instructions. Their sales representatives either did not know nor did they share the re-processing recommendations. As central service professions push for information, 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.

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, properly check for soil, and to clean.

There is an array of recommendations for exposure times that range from four to 40 minutes depending on the complexity of the instrumentation, the number of layers included in the carrier, and the design and material of the tray. 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 the particular manufacturer’s recommendations for 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 validate the trays themselves for use in the facility’s standard cycles.

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and to clean. And these sets are complex. Some manufacturers offer an organizing tray with a defined layout or roadmap for instrument placement and identification, i.e., the graphic tray. Still it can be puzzling, as these trays may not be easy to put together again. We have observed CS staff struggling to align implants and reamers 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 wrapper or obsolescing the tray. The graphic 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 United States are now containerized in rigid reusable sealed sterilization containers, the loaner trays are primarily wrapped. Orthopedic sets tend to be a particular challenge. The instruments are heavy. Wrapping them is difficult. A dozen 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, broken out sections if worn, tears from pulling these trays off the shelf and other handling mishaps, which contribute to these trays requiring re-processing. 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 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 clearance from FDA. In fact, not all containers have 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 thermo conductivity. As a result, wet packs may occur and extended processing times may be necessary to achieve terminal sterilization. This becomes even a greater challenge when non-woven polypropylene wrap is utilized as a barrier for these plastic instrument sets.

Compiled below is information from three medical device manufacturers. It is clear from the following information provided that these companies recommend extended exposure times over standard hospital cycles for their instruments, implants and graphic cases.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Cycle Set</th>
<th>Temperature</th>
<th>Exposure PSI</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>DePuy</td>
<td>Single &amp; Dual</td>
<td>Prevacuum</td>
<td>121 + 3 C</td>
<td>15 minutes</td>
</tr>
<tr>
<td></td>
<td>Single &amp; Dual</td>
<td>Prevacuum</td>
<td>132 + 3 C</td>
<td>14 minutes</td>
</tr>
<tr>
<td></td>
<td>Multiple 3-4</td>
<td>Prevacuum</td>
<td>132 + 3 C</td>
<td>40 minutes</td>
</tr>
<tr>
<td>Stryker</td>
<td>Individual</td>
<td>Prevacuum</td>
<td>132 &amp; 30 PSI</td>
<td>15 minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prevacuum</td>
<td>132 &amp; 30 PSI</td>
<td>15 min. preheat, 10 min. exposure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gravity</td>
<td>121 &amp; 20 PSI</td>
<td>15 min. preheat, 40 min. exposure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gravity</td>
<td>132 &amp; 30 PSI</td>
<td>15 min. preheat, 20 min. exposure</td>
</tr>
<tr>
<td>Synthes</td>
<td>Individual Trauma, most Maxillofacial</td>
<td>Gravity</td>
<td>132-135</td>
<td>20 min.</td>
</tr>
<tr>
<td></td>
<td>Individual Trauma, most Maxillofacial</td>
<td>Prevacuum</td>
<td>132-135</td>
<td>8 min.</td>
</tr>
<tr>
<td></td>
<td>Individual Spine</td>
<td>Gravity</td>
<td>132-135</td>
<td>28 min.</td>
</tr>
<tr>
<td></td>
<td>Individual Spine</td>
<td>Prevacuum</td>
<td>132-135</td>
<td>10 min.</td>
</tr>
</tbody>
</table>

The above sterilization parameters assume that all instrument sets have been thoroughly cleaned/decontaminated prior to sterilization. Dry times for terminal sterilization and storage are not addressed. Furthermore one manufacturer clearly states that these instruments do not have an indefinite functional life. In fact, all re-usable instruments are subjected to repeated stresses related to bone contact, impaction as well as the stresses from routine cleaning, handling, and decontamination from caustic cleaners.
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 ASHCSPIAHCSMM 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.”

Recently, both professional central service organizations revised the joint position paper on Management of Loaner Instrumentation and Implants 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. Recently, 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 manufacturer’s 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. Most recommend mechanical cleaning including sonification, a full rinse, drying after final rinse, and lubrication. Most recommend a pH-neutral detergent and an enzymatic cleaner. Find out if special cleaning instructions may be 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 flash sterilization for these devices. Flash sterilization may be an appropriate option under certain circumstances. However, AAMI strongly recommends that implants not be flash sterilized. Vendors need to provide the specific re-processing instructions for cleaning and sterilizing these sets as well as specific information relating to flash sterilization if necessary. Staff needs 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 automatic cleaning and terminal sterilization.

Third, healthcare professionals can provide feedback to major medical companies and to the tray suppliers to incorporate into the design of the set elements that meet your needs. This can include a tray where weight can 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. Major medical companies understandably are concerned about patient safety and the need for overkill to be built into the process. However, design changes can address the issue of extended re-processing times.

Healthcare professionals must ask for detailed information and to 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 validating these sets with biological indicators and test packs in the load within their hospital’s sterilizers. Some graphic trays may simply be dropped into the reusable sealed container. Others may need to be re-configured to fit. In some instances, the loaner/graphic trays are eliminated entirely and replaced by a modular system with a layout that is organized and can be re-configured.

Managing these sets requires the cooperation of central service, the operating room and the vendor providing these devices to the healthcare facility. Recently healthcare professionals from Dartmouth Hitchcock, including the OR, CS and materials, approached Case Medical to help them containerize their loaner trays and validate them for use in their standard hospital cycles. According to Lynn Goodrich, the orthopedic team leader, “There is no longer
any tears in the wrappers. There are no wet packs. And no extended reprocessing times. We fully decontaminate our devices beforehand and terminally sterilize. Our instruments are organized and protected and there, when we need them."

Summary

Healthcare professionals are ultimately responsible for positive patient outcome and infection control. 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. 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. 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.

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Marcia Frieze is CEO of Case Medical. She has been instrumental in developing the company’s synergistic line of SteriTite, sealed containers, MediTray, products and Case Solutions for safe and effective decontamination of medical devices. For more information about the company and its line of products, visit www.casemedical.com.

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