

ASHCSP/IAHCSMM Position Paper on Loaner Instrumentation

The project to update the Position Paper on the Management of Loaner Instrumentation and Implants has been completed. IAHCSMM and ASHCSP joined together again to provide up-to-date guidelines that may be used to develop policies and procedures to improve your day-to-day handling of these instruments and implants. IAHCSMM is pleased to be able to make this document available on our website (click the link to your right). We hope it will be a resource you will turn to often in handling the many problems inherent in the use of loaner instrumentation and implants.

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Introduction

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.

Healthcare facilities may have a need to borrow instrumentation and surgical implants for a surgical procedure from a neighboring healthcare facility or a specific vendor or consign items from vendors for subsequent use. In such cases, controls must be in place to insure effective management of these instruments and implants so that this practice does not cause a decline in the quality of service and ultimately in the quality of care for patients. In recognition of the need to systematically manage the loaner instrumentation and implants, the American Society for Healthcare Central Service Professionals (ASHCSP) and the International Association of Central Service Materiel Management (IAHCSMM) have collaborated and adopted the following position

- A partnership must be developed between the Vendor, Central Service, and the Operating Room. This partnership must be built on mutual trust and collaboration. Healthcare facilities should provide vendors with information regarding time requirements for pre-procedure and post-procedure processing, and these time requirements should be adhered to by the vendors. Vendors should be able to provide specific instructions for any flash sterilization that may be required. Central Service should keep a record of each set that is used, including time in and out, and other processing specifics.

There should be policies and procedures, created in collaboration with vendors and/or other healthcare facilities, to 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.

- The designated staff responsible for the management of loaner instruments and implants must be trained and knowledgeable of all aspects of this process.

Statement of Purpose

To establish a standardized format that can be used as a guideline to develop policies and procedures to systematically manage loaner instrumentation and surgical implants. This would include items loaned from other healthcare facilities and vendors for specific surgical procedures as well as items consigned by a vendor to a healthcare facility and stored in-house for their use. Emphasis should be placed on developing a standardized system that will allow all involved parties to access information easily.

The recommended guidelines include:

- Acquisition
- Accountability
- Disposition

Scope/Impact

This Position Paper will provide guidelines for the acquisition, accountability, and disposition of loaner instrumentation and implants. The information will help to insure efficient and effective management of such items that can be utilized by any Central Service department or sterile processing area.

Proposed Plan of Action

Central Service departments that borrow or consign surgical instrumentation and implants from other healthcare facilities or vendors need to have policies and procedures in place for their control. These policies should include information regarding time requirements for pre-procedure and post-procedure processing so there can be understanding and agreement on item pick up and delivery times.

The following guidelines will provide a standard format of essential information to all Central Service departments to promote the safe, efficient, and effective management of these high cost items.

Guidelines

1. Acquisition of Loaner Instrumentation

A. Request for loaner communicated to designated person or persons responsible.

- 1) Arrangements made with vendor or other healthcare facility.
- 2) Central Service notified of specifics involved: number of instrument trays and/or items, surgical case, doctor performing case, date and time of anticipated use, mode of transportation and estimated time of arrival.

B. Loaner instrumentation and implants sent to healthcare facility via:

- 1) Courier
- 2) Public transport (bus, train, plane)
- 3) Mail (USPS, UPS, FedEx)
- 4) Vendor (Manufacturer's representative)

C. Items delivered to designated receiving area:

- 1) Delivered to Central Service Processing-Decontamination area. This is the recommended receiving area.
 - a. Wearing proper attire, carefully check in items
 - b. Begin processing

- 2) Delivered to healthcare facility Receiving department
 - a. Document receipt of number of packages as listed on packaging slip
 - b. Deliver promptly to Central Service Processing-Decontamination area.
- 3) Delivered to Operating Room, or other areas where procedures are performed.
 - a. If checking in items, it is necessary to be aware that under all circumstances, the instrumentation is considered contaminated; proper attire must be worn.
 - b. Deliver items to processing area

2. Accountability and Record Keeping

A. Vendor/Other Healthcare facility

- 1) Deliver instruments to healthcare facility allowing sufficient time to permit in-house disassembly, cleaning, packaging, and sterilization of the instruments before the scheduled surgery in accordance with policy and procedures.
- 2) Provide packaging list or inventory sheet of loaner instruments and implants. Identify quantity, catalog number and description.
- 3) Provide manufacturer's written instructions for disassembly, cleaning, packaging, and sterilization of instruments.

B. Check-in Area

Wearing proper attire, check-in area personnel should check loaner instruments for accuracy and completeness of the original order. Responsibility for lost or damaged instruments should be negotiated between the Vendor and the User prior to use.

- 1) Log receipt of loaner instrumentation and implants:
 - a. Date
 - b. Time
 - c. Signature of individual receiving
 - d. Doctor's name
 - e. Number of trays
 - f. Number of implants
- 2) Perform inventory control check
 - a. Verify types of instruments and implants
 - b. Verify quantities of instruments and implants

- 3) Perform quality assurance check.
 - a. Visually inspect instruments and implants for damage.
- 4) The inventory control sheet should follow the instrument set/sets through all the processes.
- 5) Follow the manufacturer's written instructions for disassembly, cleaning, packaging, and sterilization of the instruments. If written instructions have not been provided, contact the manufacturer and have the pertinent information faxed.
 - a. Check instruments for proper function.
 1. Document problems. Damaged instruments should be logged and reported to the vendor.
 2. Notify Operating Room immediately of problems encountered that may delay or compromise the surgical procedure.
 - b. Perform quality control sterilization monitoring per hospital policy and procedures.
- 6) After sterilization is complete, including cool down or aeration, release sterilized instruments to the Operating Room for use.
 - a. If any implantable items have been sterilized, the items should be quarantined until the results of the biological monitoring are available. If an item must be released from quarantine because of a documented necessity, all other monitors (sterilizer chart, chemical indicator/integrator) should be reviewed, and it should be documented that the item was released without the results of the BI being known. The physician should be notified of the situation.
- 7) After the surgical procedure is completed, return the instrumentation to the decontamination area.
 - a. Disassemble, clean, and decontaminate all of the instruments.
 - b. Verify that all loaner instruments are accounted for by:
 1. Type
 2. Quantity
 3. Condition
 - c. Document findings. Report discrepancies to Operating Room for correction
- 8) Return loaner instruments to the designated person responsible for returning them to the supplier.
 - a. Record:
 1. Date
 2. Time
 3. Signature of processing individual

- 9) Maintain complete records

3. Disposition

- A. Return items to vendor or other healthcare facility.
 - 1) Designated person in policy and procedure should arrange return via appropriate service.
 - a. Courier
 - b. Public transport (bus, train, plane)
 - c. Mail (USPS, UPS, FedEx)
 - d. Vendor (Manufacturer's representative)
- B. Include documentation with items to verify items returned

4. Other Considerations

- A. All items received as single-use devices (SUD's) in original packaging from vendor:
 - 1) Inspect for damage and cleanliness and confirm integrity of package.
 - 2) If opened but not used, return to vendor. Do not reprocess unless written manufacturer's instructions for reprocessing are provided, and all Food and Drug Administration (FDA) requirements regarding reprocessing of SUD's are met. (See <http://fda.gov/cdrh/reuse/reuse-documents.html>) (current at time of writing paper)
 - B. Instrument tracking software is becoming more and more common in modern reprocessing departments and can play a major role in managing loaner instrumentation. Efficiencies may be gained from the ease of documentation of specific medical devices and/or trays, including implants and the need for biological testing; usage history, inventory control of implants, and proper cleaning and sterilization parameters built into the system to prevent non-conformance with quality production.
 - C. Asset management may be one in the same when considering tracking software, but given that many healthcare facilities continue operating with manual methods, it is important to focus on management of assets; in this case, loaner instruments and/or consignment trays. Asset controls will provide our customers with a history of usage and help them gather valuable information for fiscal budget planning and capital forecasts. This is a process that should involve the original equipment manufacturer (OEM) representative. Asset management will also allow us to remain on contract with select vendors. When trays outside the negotiated contracts come in, this should send up a flag to contact the key business or purchasing managers that we are operating outside the scope set forth by the product/cost committees
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Food and Drug Administration – <http://fda.gov/cdrh/reuse-documents.html> (current at time of writing paper)