IAHCSMM Sample Policy & Procedure for Loaner Instrumentation

Introduction
This sample Policy & Procedure on Loaner Instrumentation is a draft/template and can be applied to other services and used for other types of loaners. This policy and procedure reflects subject matter associated with loaners, as well as minimal regulatory guidelines.

IAHCSMM is not a standards-making group; therefore, this document is not a standard, but rather a tool to provide guidance and help facilities develop their own loaner instrument-related policies and procedures.

Subject: Processing Loaner Instrumentation

Scope: Central Sterile Supply Department (CSSD), Operating Room, Material Management.

Purpose: To provide effective management of and ensure standardization of processing for all reusable surgical instruments that are not owned or stored in healthcare facility.

Policy: All loaner instruments, instruments not owned by or stored in facility, must be received, inspected, recorded, decontaminated, and sterilized in the CSSD. Loaner instruments will not be accepted by the CSSD without the manufacturers' tray content lists and FDA-cleared manufacturers' written instructions for disassembly, cleaning, packaging, and sterilization methods and cycles (pictures must be provided and on file within the department for each tray/set). Any deviation in this policy may result in immediate termination of relationship with responsible representatives. All items are considered "non-sterile" anytime instrumentation is provided as a loaner from any company and/or its representative. Items loaned from an outside entity that is not part of a system that has a policy in place to transport and share goods will be considered non-sterile.

Procedure: Acquisition of Loaners

- Surgeons or designee requiring loaner instrumentation must first contact the vendor to confirm the availability of the loaner instruments and written Instructions for Use (IFUs).
- Communication from the surgeon's office to the Operating Room (for scheduling of the case) and Materials Management (purchasing) office should be done at the time the procedure is scheduled. The Materials Management office will use this communication to obtain a purchase order for the loaner instrumentation stating that the written IFU must accompany the delivery.
- Arrangements will be made with the vendor for acquisition of the loaner instrumentation. All loaned instruments from a vendor will be considered non-sterile. Supplies and implant pricing should occur before the loaner trays are received.
- All loaner trays should be delivered to the designated area in the CSSD.

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Operating Room Responsibilities:

- Loaner Instruments required by surgeon should be requested when the surgery is scheduled.

- Personnel requesting loaner instruments should specify quantities, estimated time of use and return, and restocking requirements to circumvent the need for Immediate-Use Sterilization (commonly referred to as “flash sterilization”).
- Immediate-Use Sterilization should not be used as a substitute for insufficient instrument inventory resulting from late delivery of loaner instrumentation.
- The above information should be communicated to the CSSD Manager or designee at least one (1) business day prior to expected receipt of loaner trays.
- Upon booking a surgical case that requires loaner instrumentation, the CSSD will be notified of the date of the surgery, doctor, procedure, and type of loaner equipment needed.

Sales Representative Duties before Surgery:

- Supply the OR and CSSD with information about the names and quantity of tray(s) surgeon/case, and method of shipment before the instruments are received and delivered by vendors.
- Provide written inventory of all items on the tray(s) and verify the inventory of any missing stock [to be noted with a CSSD technician upon receipt of tray(s)].
- Discuss responsibility and cost for missing and damaged items before the procedure.
- Ensure all loaner items are delivered in sufficient time for CSSD to:
  - Decontaminate;
  - Inspect;
  - Assemble;
  - Package;
  - Perform routine biological testing if implants are involved and allow adequate time for final results and quarantine;
  - Sterilize;
  - Dry, and cool the tray(s) using the manufacturer’s FDA-cleared written instructions;
  - Perform product testing when required
- Healthcare facility requires receipt of loaner trays at least two (2) business days prior to the scheduled case. All first-time vendor-loaned sets require three (3) business days for inservicing, inspecting and processing.
- In the designated staging area of the healthcare facility’s CSSD, loaner trays received will be logged on an inventory loaner sheet.
- Trays will be weighed upon delivery. The weight of the tray is not to exceed the maximum weight allowance determined by current ANSI/AAMI ST79 (25 pounds) and CSA Z314.3-09 (22 pounds).
- If the vendor and/or CSSD representative need to reconfigure the tray contents for any reason, proper validation and documentation must be supplied to make this change by the device manufacturer.
- All tray(s) will be tagged with date, surgeon name(s) and procedure, and placed and/or stored in the designated area. If a healthcare facility has an instrument tracking system with bar coding capabilities, this can be used in place of a tag system (write on the outside tape the name of surgeon, room number, number of trays, and date and time of surgery). After being logged in and tagged, trays may be placed in a specific area waiting for processing.
- Vendor must provide inservice to CSSD staff for any tray(s) that are brought in as a loaner. This includes, but is not limited to, decontamination, inspection, assembling, packaging, sterilization, handling, and any other information that is needed for proper processing of the instrumentation.

- In advance of the surgical case, the vendor and CSSD Manager must ensure that all information is on file for loaner instrumentation as it pertains to decontamination, inspection, assembly, packaging, sterilization, and storage.

Sales Representatives' Duties Post-Surgery:

- Sign the inventory sheet confirming all contents are present when the sales representative or other company representative picks up the tray(s).
- Remove all loaner instrumentation from the facility (CSSD) within two (2) business days after use.
- Any tray(s) not picked up within this time will be shipped to the company at their own risk and expense. The fee will be deducted from their bill at time of billing for the case.

Central Sterile Supply Department (CSSD):

- When working with loaner trays at any time CSSD staff must be aware and use the proper personal protective equipment (PPE) at all times during this process.
- Loaner inventory sheet information must be reviewed before processing any tray(s) or instrumentation.
- Trays will be weighed upon delivery. The weight of the tray is not to exceed the maximum weight allowance determined by current ANSI/AAMI ST79 (25 pounds) and CSA Z314.3-09 (22 pounds).
- Items/instrumentation/tray(s) must be processed according to FDA-cleared manufacturers' written instructions, in accordance with healthcare facility's policies.
- When a loaner instrument set is received, all moving parts, tips, box locks, ratchets, screws, and cutting edges should be examined for defects and proper working order.
- Items(s)/tray(s) must be decontaminated after use and returned to the loaner shelf as clean.
- Healthcare facility will not reimburse for any item that vendor claims is missing when any lender fails to provide an inventory sheet, and does not verify the inventory with CSSD when the tray(s) are received.
- Inventory loaner sheets in CSSD must be maintained for verification that all components were returned.
- Record-keeping will be maintained according to healthcare facility's policies. All loaned/ borrowed tray(s) and or instrumentation will be placed in a specific place (a designated area).
- Return of loaners after use should be done in accordance with manufacturer guidelines.
- All loaner instrument sets shall be sent to the CSSD Decontamination Room immediately following the procedure for cleaning according to the FDA-cleared manufacturer's written instructions.
- Once cleaned, the loaner sets shall be transported to a holding area for pick-up by the vendor representative. These trays should be picked up within two (2) business days post-procedure. Any tray(s) not picked up within this time will be shipped to the company at their own risk and expense.
- An inspection for cleanliness and content will be done by the vendor representative and the CSSD technician. Discrepancies will be reported to the OR and Materials Management.
- Documentation, including but not limited to: date; signature of individual receiving; name and number of trays, number of instruments, and date removed will be recorded on the initial LOANER form.
- If a loaner system needs to be held in CSSD for another case, [scheduled within two (2) business days], the vendor representative will reassemble and inventory the sets, and then follow the same procedures outlined above.

Surgical Service Billing:

- Will not process any invoice from a surgical case where loaner instrumentation or tray(s) were used without checking with the CSSD to ensure there were no other miscellaneous charges that have to be deducted from the invoice before payment.

Definitions:

Loaner Instrumentation -- Critical and semi-critical medical devices that are used by a healthcare facility under an arrangement based on lending or trial use of new medical devices.

References:

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5. FDA Medical Devices Frequently Asked Questions, at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121093.htm, accessed on March 29, 2011.
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