

# IAHCSMM Sample Policy and Procedure for Loaner Instrumentation

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## 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. **This document is not a standard but a tool created to provide guidance.**

**Subject:** Processing Loaner Instrumentation

**Scope:** Central Sterile Supply Department, (CSSD), Surgical Services, 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 health care 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 CSSD without the manufacturers' tray content lists and 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 unsterile.

## 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 IFUs, (Instructions for Use).
- Communication from the surgeon's office to the OR (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 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 CSSD by the department Manager.

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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).
- “Immediate-Use sterilization” should not be used as a substitute for sufficient instrument inventory resulting from late delivery of loaner instrumentation.
- The above information should be communicated to the CSSD Manager or designee at least 1 business day prior to expected receipt of loaner trays.
- Upon booking of a surgical case that requires loaner instrumentation, CSSD will be notified of the date of the booked surgery, doctor, procedure, and the type of loaner equipment needed.

## **Sales Representatives Duties Before Surgery:**

- Supplies 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.
- Provides written inventory of all items on the tray(s) and verifies the inventory of any missing stock to be noted with a CSSD technician upon receipt / of trays(s).
- Responsibility and cost for missing and damaged items should be discussed before the procedure.
- Ensures 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 trays(s) using the manufacturer’s written instructions.
  - Perform product testing when required.
- Health care facility requires receipt of loaner trays at minimum no less than 2 business days prior to the scheduled case. All first time vendor loaned sets requires 3 business days for in-servicing, inspecting, and processing.
- In the designated staging area of the health care facility’s CSSD, loaner trays received will be logged in 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 AAMI/ANSI ST79 (25 pounds) CSA Z314.3-09 (22 pounds).

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- 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 health care facility has an instrument tracking system with bar coded capabilities, this can be used in place of a tag system and write on the outside tape, name of surgeon, room number, number of trays and date and time of surgery. Trays after being logged in and tagged may be placed in a specific area waiting for processing.
- Vendor must provide in-service to CSSD staff for any tray(s) that are brought in as a loaner. This includes but not limited to decontamination, inspection, assembling, packaging, sterilization, handling, and any other information that is needed in the proper processing of the instrumentation.
- Vendor and CSSD Manager must make sure that all information is on file for loaner instrumentation in advance of the surgical case concerning: decontamination, inspection, assembly, packaging, sterilization and storage.

## **Sales Representatives Duties Post Surgery:**

- Signs 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 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 needs to be aware and use the proper PPE at all times during this process.
- Reviews the loaner inventory sheet information 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 AAMI/ ANSI ST79 (25 pounds) and CSA Z314.3-09 (22 pounds).
- Process item / instrumentation/tray(s) according to the manufacturer written instructions in accordance with health care 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.
- Decontaminates the item(s)/tray(s) after use and returns to the loaner shelf as clean.
- Health care facility will not give reimbursement 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 trays(s) are received.
- Retains inventory loaner sheets in CSSD for verification that all components were returned.
- Record keeping will be kept according to health care 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 following the manufacturers guidelines.

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- All loaner instrument sets shall be sent to the CSSD Decontamination Room immediately following the procedure where they will be cleaned according to the manufacturer's written guidelines.
- 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 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, 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 2 business days), the vendor representative will reassemble and inventory the sets, and then follow the same procedures as above.

## **Surgical Service Billing:**

1. Will not process any invoice from a surgical case where loaner instrumentation or tray(s) were used without checking with CSSD to make sure there were not any other miscellaneous charges acquired that have to be deducted from the invoice before payment.

## **Definitions:**

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

## **References:**

1. The Joint Commission: 2011 Hospital Accreditation Standards (HAS).
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3. Associations for the Advancements of Medical Instrumentation ANSI/AAMI ST77:2006(R) 2010 -- Containment devices for reusable medical device sterilization.
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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.
6. Canadian Standard Association Z314.3-09 - Effective sterilization in health care facilities by the steam process.