

IOWA HEALTH – DES MOINES

Iowa Lutheran Hospital/Iowa Methodist Medical Center/Methodist West Hospital/Eye
Surgery/Laser Eye Center

POLICY & PROCEDURE

DEPARTMENT: OPERATING ROOM **POLICY # OR 29**

POLICY TITLE: HANDLING OF IMPLANTS AND LOANER INSTRUMENTATION

APPROVED BY: SEE SIGNATURE PAGE

PURPOSE: To provide effective management of and standardization of processing for all reusable surgical instruments/implants that are not owned or stored at IHDM.

POLICY: All loaner instruments, instruments not owned by or stored in facility, must be received, inspected, recorded, decontaminated, and sterilized in CSP. Loaner instruments will not be accepted by CSP without the manufacturer's 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 the 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:

- Surgeons or designee requiring loaner instrumentation must first contact the vendor to confirm the availability of the loaner instruments.
- Communication from the surgeon's office to the Operating Room should be done at the time the procedure is scheduled.
- 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. Loaner fees are not paid for routine use of instruments and equipment associated with implantable items. Any loaner fees must be agreed upon prior to receipt or such fees will not be paid.
- All loaner trays should be delivered to the designated area in CSP no less than Than 48 hours before date of case.

OPERATING ROOM RESPONSIBILITIES:

- Loaner instruments required by surgeon may be confirmed by OR designee.
- Personnel requesting loaner instruments should specify quantities, estimated date and time of use.
- 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 CSP 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 CSP will be notified of company name, date of the surgery, doctor, procedure, and type of loaner equipment needed.

SALES REPRESENTATIVE DUTIES BEFORE SURGERY:

- Supply the OR and CSP 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.
- Healthcare facility requires receipt of loaner trays at least to (2) business days prior to the scheduled case. All first-time vendor-loaned sets require (3) business days for inservicing, inspecting and processing. If delivered inside 24 hours of scheduled case or add-on case, must make verbal contact with CSP staff.
- Provide written inventory of all items on the tray(s) and verify the inventory of any missing stock [to be noted with a CSP technician upon receipt / of tray(s)].
- Ensure all loaner items are delivered in sufficient time for CSP 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 manufacture's FDA-cleared written Instructions
 - Perform product testing when required
- In the designated staging area of SCP, loaner trays received will be logged on an inventory loaner sheet.
- Trays may be weighed upon delivery. The weight of the tray should not exceed the maximum weight determined by current AAMI/ANSI ST79 (23 pounds) and CSA Z314.3-09 (22 pounds) according to IHDM policies/procedures/
- When a loaner instrument set is delivered, all moving parts, tips, box locks, ratchets, screws and cutting edges should be examined for defects and proper working order.
- If the vendor and/or CSP representative need to reconfigure the tray contents for any reason, proper validation and documentation should be supplied to make this change by the device manufacturer.
- All tray(s) will be tagged with date on a tongue blade along with the surgeon's name and procedure and place in a designated area waiting for processing.
- Vendors must provide inservice to CSP and OR staff for any tray(s) that are brought 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 CSP designee should 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-SURGRY:

- Confirm all contents are present when the sales representative or other company representative picks up the tray(s)
- Remove all loaner instrumentation from the facility CSP/OR within two (2) business days after use.
- Vendors will be contacted regarding any tray(s) not picked up within this time may be shipped to the company at their own risk and expense.

CENTRAL STERILE PROCESSING DEPARTMENT (CSP)

- When working with loaner trays at any time CSP 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.
- Item(s)/instrumentation/tray(s) must be processed according to FDA – cleared manufactures' written instructions, in accordance with IHDM policies/procedures.
- Item(s)/tray(s) must be decontaminated after use and returned to the loaner shelf as clean.
- Healthcare facility will not reimburse for nay item that vendor claims is missing when any lender fails to provide an inventory sheet, and does not verify the inventory with CSP when the tray(s) are received.
- Inventory loaner sheets in CSP must be maintained for verification that all components were returned.
- An inspection for cleanliness and content will be done by the vendor representative and the CSP technician. Discrepancies will be reported to the OR and CSP.
- Documentation, including but not limited to: date; signature of vendor; name and number of trays will be recorded on the loaner log.
- If a loaner system needs to be held in CSP for another case, the vendor representative will reassemble and inventory the sets, and then follow the same procedure outlined above.

SURGICAL SERVICE BILLING:

- Will not process any invoice from a surgical case where loaner instrumentation or tray(s) used without checking with the CSP or OR.

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:

- Association for the Advancement of Medical Instrumentation. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. ANSI/AAMI ST79:2010 & AL:2010 (Consolidated Test), Arlington, VA, AAMI, 2010.
- Recommended Practices for Sterilization in the Perioperative Practice Setting, In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc, 2012
- [http://iahcsmm.org/Current Issues/Loaner Instrumentation Position Paper Sample Policy.html](http://iahcsmm.org/Current%20Issues/Loaner%20Instrumentation%20Position%20Paper%20Sample%20Policy.html)