

LOANER INSTRUMENTATION POLICY

PURPOSE:

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

POLICY:

All loaner instruments, instruments not owned or consigned in healthcare facility, must be received, inspected, inventoried with a staff member to identify all contents and recorded to indicate staff receipt, decontaminated, and sterilized in CSS. Loaner instruments will not be accepted by CSS without the manufacturer's tray content lists and FDA-cleared manufacturer's written instructions for disassembly, cleaning, packaging, 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.

Acquisition of Loaners:

- Communication from the surgeon's office to the Operating Room (for scheduling of the case) and Supply Chain (purchasing) office should be done at the time the procedure is scheduled.
- A purchase requisition should be sent to purchasing, supplychainfx@geisinger.edu. The Supply Chain office will use this requisition to issue a purchase order for the loaner instrumentation, stating that the written IFU must accompany the delivery and expectation of product pick-up within 24 hours.
- The vendor is responsible for coordinating the arrival of the loaner instrumentation. All loaned instruments will be considered non-sterile.
- All loaner instruments should be delivered to the designated Loaner Room area in CSS.

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.
- Immediate-Use Sterilization should not be used as a substitute for insufficient instrument inventory resulting from late delivery of loaner instrumentation.

Sales Representative Duties Before Surgery:

- Vendors must inform OR site via email (addresses listed below) with information about the names and quantity of trays, surgeon/case, and method of shipment before the instruments are received and delivered.
- The surgical suite requires receipt of loaner instrumentation at least two (2) business days prior to the scheduled case. Email notification is required 72 hours in advance with the receipt of loaner instrumentation at least 48 hours in advance.
- All first-time vendor-loaned sets require email notification 72 hours in advance and receipt of loaner instrumentation four (4) business days for inservicing, inspecting and processing. Inservicing will include disassembly/reassembly, decontamination, inspection, packaging, sterilization, handling, and any other information that is needed for proper processing of the instrumentation.
- All pertinent information (identified above) will be communicated to the location specific CSR Loaner Email address or via communication with the identified individual listed below:

GMC: csrloaners@geisinger.edu
GWV: GWVloaners2@geisinger.edu
GSWB: GWVloaners2@geisinger.edu

GCMC: GCMCloaners@geisinger.edu

At GLH:

This information will be communicated to the GLH O.R. Charge Nurse and/or CSR Supervisor.

At GHS:

This information will be communicated to the GHS Specialty Clinical Coordinator and/or CSR Supervisor or designee.

- Vendors must provide the Manufacturer's Instructions for Use (IFU).
- Provide written inventory of all items and verify the inventory of any missing stock (to be noted with a CSS staff member upon receipt of the instrumentation).
- Ensure all loaner items are delivered in sufficient time for CSS to decontaminate, inspect, assemble, sterilize, perform biological testing for implants and allow adequate time for final results and quarantine.
- In the designated Loaner Room in CSS, loaner instrumentation will be recorded on a Loaner Check-In Form. Documentation will include, but not be limited to:
 - o Manufacturer Name
 - o Date delivered
 - o Time delivered
 - Vendor Contact information
 - Weight of Provided Tray and Contents
 - o Case date
 - o Physician name
 - o Tray names and quantities, and if any trays include implants
- The weight of a tray is not to exceed the maximum 25-pound weight allowance determined by current ANSI/AAMI ST79.
- If the vendor and/or CSS need to reconfigure the tray contents for any reason, proper validation and documentation must be supplied to make this change by the device manufacturer.
- A Loaner Tag with a label (name and number of tray, date and time of surgery, and surgeon's name) will be attached to every tray.
- When a loaner set is received, all moving parts, tips, box locks, ratchets, screws, and cutting edges should be examined for defects and proper working order.
- When all trays have been logged in and tagged they will be transported to the decontamination area for processing.

Sales Representative Duties Post-Surgery:

- Sign the inventory sheet confirming all contents are present when sales representative or other company representative picks up the tray(s). If exception is noted and contents are suspected to be missing, a CSR Lead / Supervisor must be notified prior to the loaner tray leaving the facility to investigate the situation. Once the tray has left the facility, CSS will be unable to reimburse for any missing instrumentation.
- Remove all loaner instrumentation from the facility (CSS) within 24 hours after use. Exception to this must be arranged prior to the loaner trays original arrival at the facility.
 - o Any instrumentation not removed within this time may be shipped to an offsite storage facility. The responsible vendor will need to make arrangements with the storage facility to retrieve the trays.

Central Sterile Supply Duties:

- When working with loaner trays at any time, CSS 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 instrumentation.
- All loaner instrumentation will be sent to the CSS decontamination area immediately following the procedure to be processed according the Manufacturer's Instructions for

Use (IFU), in accordance with the healthcare facility's policies.

- All clean trays/instruments will be transported to the designated Loaner Room and placed on the "Loaner Out" cart for pick up by the vendor representative.
- An inspection for cleanliness and content will be done by the vendor representative after the instrumentation has been used and processed. Discrepancies will be reported to CSR Lead / Supervisor, the OR and Supply Chain.
- If loaner instrumentation needs to be held in CSS for another case, (scheduled within two (2) business days) the vendor representative will reassemble and inventory the sets, and follow the same procedures outlined above.
- Record-keeping will be maintained according to the healthcare facility's policies.
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REFERENCES:

ANSI/AAMI ST79:2010/A2:2011. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Association for the Advancement of Medical Instrumentation.