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 Perioperative Svcs*
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 Center*

Delivery and Processing of Loaner Instrumentation and Implants for Perioperative Services, 32.05.05

Document Type: Policy, Procedure

POLICY:

All loaner instruments, instruments not owned by or stored in facility, must be received into tracking system if available, inspected, recorded, decontaminated, and sterilized in Sterile Processing Department (SPD). Loaner instruments should not be accepted by the SPD without the manufacturers' tray contents lists, and FDA-cleared manufacturers' written instructions for disassembly, decontamination, cleaning, packaging and sterilization methods and cycles. All instrumentation is considered "non-sterile" when provided as a loaner from any company and/or its representative. Any deviation in this policy may result in immediate termination of relationship with responsible representatives. All instrumentation used for surgical procedures must be processed following Kadlec Regional Medical Center (KRMC) guidelines and standards. Immediate-Use Sterilization is not advocated nor will it be used as a substitute for insufficient instrument inventory resulting from late delivery of loaner instrumentation. Loaner instrumentation should arrive at KMRC at least 24 hours prior to the date of surgery to allow sufficient processing time.

KRMC will not reimburse for any item claimed missing when the Lender/vendor fails to provide an inventory sheet and does not verify the inventory with a SPD employee when the tray(s) are received.

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 the Operating Room Inventory Specialist should be done at the time the procedure is scheduled. The Operating Room Inventory Specialist will use this communication to obtain a purchase order for the loaner instrumentation requiring a written IFU with the delivery.
- Arrangements will be made with the vendor for acquisition and return of the loaner instrumentation. Identification of supplies and implant pricing should occur before the loaner trays are received

- All loaner trays should be delivered to the designated area in the Sterile Processing Department at least 24 hours prior to surgery date.
 - In case of emergent last minute cases where trays will arrive less than 24 hours before the scheduled case, SPD will reprocess them as a priority as fast as reasonably possible while following all manufactures and facilities guidelines.

Operating Room Inventory Specialist

- Loaner instruments required by surgeon should be requested when the surgery is scheduled.
- Personnel requesting loaner instruments should specify quantities, estimated time of use, date of arrival, and return.
- The above information should be communicated to the SPD supervisor or designee and information written on the communication board. The information written or communicated should consist of the date of the surgery, doctor, procedure, and type of loaner equipment needed.

Sales Representative Duties before Surgery:

- Ensure receipt of loaner trays at least 24 hours prior to the scheduled case. All first-time vendor-loaned sets should arrive three (3) business days for in servicing, inspecting and processing.
- Provide inventory of all items in the tray(s) and verify the inventory of any missing stock (to be noted with a SPD technician upon receipt of tray(s)).
- 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) standards.
- All tray(s) will be tagged with date, surgeon name(s) and procedure, and placed and/or stored in the designated area. After being logged in and tagged, tray may be placed in a specific waiting area for processing.
- In advance of the surgical case, the vendor and SPD Manager must ensure that all information is on file for loaner instrumentation as it pertains to decontamination, inspection, assembly, packaging, sterilization, and storage.
- An inspection for cleanliness and content will be done by the vendor representative and SPD staff.

Lender/Sales Representatives' Duties Post-Surgery:

- If a loaner system needs to be held in SPD for another case, scheduled within two (2) business days, the vendor representative will reassemble and inventory the sets, and then follow the same procedures outline above.
- Remove all loaner instrumentation from the facility (SPD) 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.

Sterile Processing Department (SPD)

- Items/instrumentation tray(s) must be processed according to manufacturer's IFU, and in accordance with facility's policies.
- Loaner inventory sheet information must be reviewed before processing any tray(s) or instrumentation.
- 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.
- Record-keeping will be maintained according to health care facility's policies. All loaned/borrowed tray(s) and or instrumentation will be placed in the designated area.
- All loaner instrument sets shall be sent to the SPD Decontamination room immediately following the procedure for cleaning according to the manufacturer's IFU's and facility policies.
- Once cleaned, the loaner sets shall be transported to a holding area for pick-up by the vendor

representative.

- An inspection for cleanliness and content will be done by the vendor representative. Discrepancies will be reported.

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.

IFU: Instruction for Use

SPD: Sterile Processing Department

KRMC: Kadlec Regional Medical Center

Sales Representative: Vendor, Lender, or Loaner

REFERENCES:

IAHCSMM Sample Policy & Procedure for Loaner Instrumentation. Retrieved from <http://iahcsmm.org/pdfs/IAHCSMMLoanerInstrumentationSamplePolicyandProcedureJWEditions.1.30.2012%20FINAL.pdf>

Attachments

No Attachments

Approval Signatures

Approver	Date
Kirk Harper: CNO	01/2020
Heather Shipman: Executive Assistant	01/2020
Roshelle Satterthwait: Dir Perioperative Svcs	01/2020

Applicability

WA - Kadlec Regional Medical Center