

## **Central Processing-Surgical Services-Fargo**

**Subject:** Processing Loaner Instrumentation

**Scope:** Fargo Central Supply, Processing, & Distribution (CSPD) and Operating Room (OR), Surgical Services

**Purpose:** To provide effective management of and ensure standardization of processing for all reusable surgical instruments that are not owned or stored at Sanford Health.

### **Policy:**

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

### **Procedure: Acquisition of Loaners**

Loaner instrumentation is categorized as trial and vendor.

- Trial instrumentation is defined as instrumentation a specific vendor is granting for use at Sanford Health and is brought in for an extended period of time as agreed upon by Sanford Health and vendor.
- Vendor instrumentation is defined as instrumentation a specific vendor is granting for use to Sanford Health for a particular surgical procedure.

### **Operating Room Responsibilities:**

1. Loaner instruments required by surgeon should be requested when the surgery is scheduled
2. Personnel requesting instruments should specify:
  - a. Case type
  - b. Physician
  - c. Date & time of Case
  - d. Requesting instrumentation

3. Immediate-Use (flash) sterilization should not be used as a substitute for sufficient instrument inventory resulting from late delivery of loaner instrumentation.
4. A surgical case that requires loaner instrumentation should be communicated to CSPD at least one (1) business day prior to expected receipt of loaner trays. Notification to CSPD should include date/time of surgery, physician, procedure, and type of loaner equipment needed.

### **Sales Representative Requirements:**

1. Vendor representative will sign into vendor login system and obtain appropriate badge. The vendor will wear the badge so it is visible at all times while in the facility.
  - When logging in the system the vendor will list the contact person at the appropriate site, not the physician performing the procedure.
2. RepTrax will retain all vendor immunization and training records.
3. Vendor representatives having appointments or business within the Sanford Surgery areas will adhere to specific guidelines.
  - a. Change into hospital provided scrubs. Vendors frequently in the OR will have Scrub-Ex access.
  - b. Cover all hair with bouffant cap. If a skull cap is worn you must still place a bouffant cap over it when entering the OR.
  - c. Enter only the OR you are here to service. Keeping in mind patient's privacy do not enter the OR until after the patient is draped.
  - d. Wash your hands before entering the OR suite, including cleaning under fingernails. Wash your hands or foam out when exiting OR.
4. Vendors will assume all responsibility of the equipment on loan or evaluation for proper operation or suitability.
5. Vendors bringing in equipment on loan or evaluation will work with Bio-Med for incoming inspection and appropriate testing.
6. Vendor Representatives shall not, under any circumstances:
  - a. Make unauthorized visits into the Sanford OR's
  - b. Take pictures or photographs in Sanford Surgical Services environment (including O.R's) unless previously authorized by patient
  - c. No case specific information entered in any social media format, unless previously authorized by patient
  - d. Discuss any confidential or patient information at any time either within or outside of Sanford
  - e. Operate any equipment or devices while being used on a patient without specific, explicit authorization from a staff member
  - f. Scrub-in to any procedure
  - g. Touch patients at any time
  - h. Transfer sterile items to the surgical field
  - i. Engage in practice of surgery, nursing or medical decision-making

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

All instrumentation must have a valid purchase order assigned before delivery to Sanford Health

1. Instrumentation brought in by a vendor will go through Supply Chain to receive a "No-Charge" purchase order for tracking. Supply Chain may assign generic purchase order according to case volume.
2. Required information for a loaner purchase order:
  - a. Vendor company and representative name
  - b. Date of Case
  - c. Location of case to be done
  - d. Physician
  - e. Type of case (hip, knee, shoulder etc.)
  - f. Name of instrument sets coming in for procedure
3. Sales Rep will assume all liability for trays being brought in. They will ensure that all items are present, clean and functional. Sanford will not assume the cost for any items that are deemed to be "lost" or damaged after use.
4. Ensure all loaner items are delivered in sufficient time for CS to:
  - a. Inspect (first QA)
  - b. Decontaminate
  - c. Inspect (second QA)
  - d. Package
  - e. Sterilize – quarantine implants if necessary
  - f. Allow proper cool down time
5. Receipt of loaner trays would ideally be two (2) business days prior to scheduled case but no later than 1 pm the day prior to the case. All first-time loaner sets should be brought in ideally three (3) days prior to allow for in-servicing of OR and CS staff.
  - a. If instrumentation is delivered directly to CSPD, a packing list or written notification of the delivery must be given to the CSPD Instrument Coordinator.
    - i. Document receipt of number of packages as listed on packing slip
  - b. Delivery of instrumentation to Main OR
    - i. Instrumentation should arrive 24-48 hours of the scheduled case and absolutely no later than 1300 the day before surgery
    - ii. Delivery of instrumentation in emergency cases may be excused
  - c. Delivery of Instrumentation to SU
    - i. Instrumentation should arrive 24-48 hours of the scheduled case and absolutely no later than 1300 the day before surgery
    - ii. Delivery of instrumentation in emergency cases may be excused
  - d. Delivery of Instrumentation to OSC
    - i. Instrumentation should arrive 24-48 hours of the scheduled case and absolutely no later than 1300 the day before surgery
    - ii. Delivery of instrumentation are accepted:
      1. Monday – Thursday 7:00 – 3:00pm
      2. Friday 7:00 – 12:00pm
      3. Friday after 12:00pm – Deliver to SU CSPD for processing

- e. Loaner trays will be logged in the corresponding binder in CS.
- f. Trays will be weighed upon delivery. If weight exceeds 25lbs Sales Rep will be responsible for reconfiguring the trays.
- g. The vendor will be responsible for filling out the vendor tag(s) with the following information:
  - i. Tray/Set Name
  - ii. Date/Time/Room # of surgery
  - iii. Surgeon/Patient Name

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

1. Appropriate information provided by vendor post-op for accurate implant and billing information
2. Loaner instrumentation is removed from facility within 2 business days after use or time frame agreed upon with CSPD/OR.
3. Must document pick-up of loaner instrumentation on the log sheet.
4. If a tray(s) are needed for another case scheduled within two business days, the vendor may reassemble and follow the same steps above.
5. 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 the time of billing for the case.

### **Central Supply, Processing & Distribution (CSPD):**

1. Review loaner inventory sheet, log sheet and trays prior to processing.
2. Perform first QA of tray(s) to ensure cleanliness and functionality.
3. Take pictures of tray(s) in order to prepare visual documentation for CS and OR staff.
4. Take the tray(s) to Decontamination for processing.
5. Once the tray(s) have reached the Assembly area there will be a second QA to ensure cleanliness.
6. The tray(s) will then be prepared for Sterilization. After sterilization, proper cool down and quarantine (if implantable) the tray(s) will be staged until they are required for the case.

### **Definitions:**

- **Owned instrumentation** – critical and semi-critical medical devices purchased, stored, and managed by Sanford Health for its intended use within the facility.
- **Consigned instrumentation** – critical and semi-critical medical devices owned by a vendor and housed at Sanford Health. There is a partnered accountability for product management and financial responsibility between Sanford Health and the vendor.
- **Loaned instrumentation** – critical and semi-critical medical devices used by Sanford Health under an arrangement based on lending for a specific surgical procedure.
- **Trial instrumentation** – critical and semi-critical medical devices used by Sanford Health under an arrangement based on long-term lending for an extended period of time.

### **References:**

1. The Joint Commission: 2011 Hospital Accreditation Standards (HAS)
2. Association for the Advancements of Medical Instrumentation. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. ANSI/AAMI ST70:2010, Arlington, VA, AAMI, 2010.
3. Recommended Practices for Sterilization in the Perioperative Practice Settings. In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc, 2011.
4. FDA Medical Devices Frequently Asked Questions, at [http://www.fda.gov/Medical\\_Devices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121093.htm](http://www.fda.gov/Medical_Devices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121093.htm), accessed on March 29,2011
5. Internal Association of Healthcare Central Service Materials Management: Sample Policy & Procedure for Loaner Instrumentation, at [http://iahcsmm.org/CurrentIssues/Loaner\\_Instrumentation\\_Position\\_Paper\\_Sample\\_Policy.html](http://iahcsmm.org/CurrentIssues/Loaner_Instrumentation_Position_Paper_Sample_Policy.html)