XXXXXXXXX HEALTHCARE SYSTEM
CORPORATE POLICY AND PROCEDURE MANUAL

POLICY TITLE: Loaner Instrumentation

CATEGORY: Sterile Process Department
INDEX NUMBER: SPD
ORIGINAL DATE: 07/25/2013
LAST REVIEW DATE:
SUPERSEDES:

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

POLICY STATEMENT: All loaner instruments, instruments not owned by or stored in facility, must be received, inspected, recorded, decontaminated, and sterilized in the **Sterile Process Department (SPD)**. Loaner instruments will not be accepted by the SPD without the manufacturers' tray content lists and FDA-cleared manufacturers' written instructions for disassembly, cleaning, packaging, and sterilization methods and cycles. Pictures should be provided and on file within the department for each tray/set, whenever feasible. All items are considered "non-sterile" whenever instrumentation is provided as a loaner from any company and/or its representative.

NOTE: If these instruments were already in facility, the vendor must still retrieve them from the loaner instrument storage area, then check and verify they are accounted for. Additionally, the same check in procedure as outlined in this policy, including completion of SPD Loaner Instrument Sign In Sheet must be performed.

PROCEDURE: Acquisition of Loaners for Scheduled/Routine Surgical Cases

RESPONSIBLE PARTY	ACTION
Surgeon	Physician should request use of loaner instrumentation with Posting Office if the vendor has not been previously contacted by his/her office.
Posting Office	Posting Office should notify the OR Representative or Designee when surgery is scheduled.
OR Representative or Designee	OR Representative or Designee should notify vendor of request for use of instrumentation when surgery is scheduled. Provides the vendor the following information: Surgeon's Name Procedure Date and Estimated Procedure Time Procedure Name Specify quantities Inform vendor that Instructions for Use (IFU) must accompany the delivery each time trays are brought into the facility. Inform vendor that instruments should be delivered **at least 24 hours prior to posted start time** of scheduled procedure. Late trays without prior approval should not be accepted. Ensure that new sets are delivered to the facility **72 hours prior to posted start time** of scheduled procedure in order for staff to be adequately trained on use and disinfection/sterilization processes by vendor. Inform SPD manager or designee to expect receipt of loaner trays whenever feasible. Consider all loaner instruments from a vendor non-sterile and process accordingly. Ensure that all loaner trays are delivered to the designated area in the SPD, not directly to the OR. Scan any instrument set that is delivered untimely into Abacus as a "late arrival".

Vendor Check-In responsibilities	"Late arrivals" will be trended and monitored each month and reviewed by the OR Council at least quarterly or as needed. Supply Chain will be notified on a monthly or as needed basis of vendors that are failing to deliver trays according to standard. Vendors that repeatedly fail to comply with this standard will be jeopardizing their relationship with MHHS and could incur consequences up to and including termination of the partnership. Trays that are delivered late may result in a delay or cancellation of the scheduled surgical procedure. Any delayed or cancelled procedure due to late arrival of instruments should be noted by the SPD manager or designee by entering a variance. **Any set delivered in less than 24 hours prior to scheduled case time will need prior approval** from the corporate Supply Chain Department and will be handled on an exception basis. Vendors shall provide IFU's with delivery each time trays are brought into the facility, unless they have been previously provided, scanned, and are readily available to SPD staff. If IFU's are not provided, instruments will not be accepted and processed by SPD staff. Key stakeholders will be notified immediately and may include the vendors, physicians, or OR staff. Vendors will attest on each delivery that the IFU's on file remain current by initialing the vendor log. It is the vendor's responsibility to provide updated IFU's whenever there is a change of any kind to the set. Tray weights should not exceed validated sterilization parameters on IFU. If IFU does not provide a weight parameter, then the 25# recommendation according to AAMI/ANSI ST79

	should be followed. Trays that are received weighing in excess of IFU validated parameter or 25# will be tracked and reported through OR Council to Supply Chain for management of vendor relations. Record the number of pans and complete an adhesive label for each pan. These labels are to accompany a copy of the SPD Loaner Instrument Sign In Sheet to Prep and Pack and be attached to each pan before sterilization. Complete required paperwork to document tray delivery. This may include the following: Surgeon Name Case/Procedure Name Name and quantities of trays delivered Written inventory of all items in the trays Verify any missing inventory with SPD technician upon receipt of trays and document on designated form. Provide inservice to appropriate staff on the care and handling of instrumentation for all new and/or additional pieces in a familiar set. The vendor should provide the campus with a roster of employees that were trained respectively. Validation of tray configuration from the device manufacturer is required if not defined by IFU. Weigh trays upon check in. Document tray weights exceeding 25# or the validated sterilization weight according to the IFU on designated loaner check in form. (“SPD Loaner Instrument Sign In Sheet”) Verify with SPD staff that IFUs are on file or present and written inventory sheets are included. Trays that do not meet the noted criteria will be rejected until vendor can settle discrepancies. Verify that all instruments are disassembled and ready for decontamination and sign the “SPD Loaner Instrument Sign In Sheet”

Sterile Process Department	When trays are delivered by courier, vendor must fax or email required paperwork if it is not accompanying the set on arrival prior to being processed. Scan trays into Abacus instrument tracking system using either a unique barcode provided by the vendor or assign one internally. Follow device manufacturer IFU's and facility processes for decontamination of loaner item. Thoroughly flush and pass appropriately sized brush through all instruments that contain lumens and or are cannulated. Inspect, assemble, and package all loaner items per written inventory sheet or Abacus count sheet. Attach adhesive label to each pan. These labels are to accompany a copy of the "SPD Loaner Instrument Sign In Sheet" to Prep and Pack and be attached to each pan before sterilization Label loaner items with the following information: Surgeon's name Procedure Date and Time Quantity of trays for procedure Identification of cannulated instruments Sterilize loaner items per manufacturer's FDA-cleared written IFU. Immediate Use Sterilization **shall** not be utilized for implants unless necessary for an intraoperative emergency whereby sterility is inadvertently compromised. Sterilization should be achieved utilizing a terminal cycle with drying time preferred. A log book should be maintained with documentation of any item/set that is sterilized utilizing immediate use. Place a Process Challenge Device (PCD) containing a Biologic Indicator (BI) and Class 5 integrating indicator

	in each load containing implants. Perform routine biologic testing if implants are involved. Allow time according to manufacturer's guidelines for quarantine of loaner item(s) prior to use. Document result of biologic. Maintain records for 7 years. Early release of implants should be avoided unless deemed necessary by the surgeon to avoid life or limb threat to patient. Early releases should be escalated to circulating nurse, surgeon, and OR Director/designee. All early releases should be documented in the variance tracking system by OR staff. Maintain loaner records for 5 years.
Staff OR/SPD	Store items in a designated area prior to case cart assembly. Scan all loaner items to case cart. Verify instrument inventory is correct upon opening prior to case start.
OR Staff	Disassemble all loaner items and clean items from all gross bioburden with sterile water. Flush lumens with sterile water. Spray loaners items (if appropriate) with enzymatic agent and return items to decontamination per facility process.
SPD Staff	Scan case cart and all other applicable items into Abacus system. Follow device manufacturer instructions and facility processes for decontamination. Thoroughly flush and pass appropriately sized brush through all instruments that contain lumens and or are cannulated.

	Scan trays to automated washer. Scan trays to designated holding area.
Post procedure Vendor	Verify with SPD technician that loaner items have been decontaminated and are complete. Vendor will be required to sign for tray release. Signature is considered validation that tray is complete and in order as it was on delivery. Loaner items should be picked up by vendor within (2) business days post-procedure. MHHS will not reimburse for any item that vendor claims is missing when any lender fails to provide an inventory sheet, and does not verify the inventory with SPD staff when trays are received or pick up within designated timeframe.
CSPD Staff/Designee	Complete all paperwork. Scan trays out to vendor via Abacus.
Addendum	“SPD Loaner Instrument Sign In Sheet”

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 ST79:2010 & A1:2010 (Consolidated Text), Arlington, VA, AAMI, 2010.
3. Associations for the Advancements of Medical Instrumentation ANSI/AAMI ST77:2006(R) 2010 -- Containment devices for reusable medical device sterilization.
4. Recommended Practices for Sterilization in the Perioperative Practice Settings. In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc, 2011.
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.