01.48 – Management of Loaner and Consignment Surgical Instrumentation in the Sterile Processing Department (SPD)

Purpose

To provide effective management of and ensure standardization of processing for all reusable surgical instruments that are not owned by UTMB.

Audience

Operating Room (OR) Staff, Sterile Processing Department (SPD), Supply Chain, Clinical Equipment Services (CES)

Definitions

Critical Medical Devices: critical medical devices that enter normally sterile tissue or the vascular system or through which blood flows should be sterilized before each use (refer to methods of sterilization and disinfection in this policy and MIFU for medical devices being sterilized).

Semi-Critical Medical Device: Devices that come in contact with mucous membranes or skin that is not intact should be free of all microorganisms except for bacterial spores and are called semi-critical medical devices. Respiratory and anesthesia devices, endoscopes, diaphragm fitting rings, vaginal speculums, and ultrasound probes are included in this category. Semi-critical medical devices require high-level disinfection using chemical disinfectants.

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.

Vendor – a person or company offering products for sale or loan.

Manufacturer Instructions for Use (MIFU) are detailed, step-by-step guides provided by the manufacturer to explain how a product, especially medical devices, should be used and handled. They outline the correct procedures for use, including cleaning, disinfection, and other safety precautions. MIFUs ensure the product is used safely and effectively, while also addressing potential hazards and ensuring compliance with legal and regulatory standards.

Decontamination (OSHA definition): “The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.”

Policy

Controls are in place to ensure effective management of loaner tray instrumentation. All loaner instruments, instruments not owned by or stored in the facility, must be received, inspected, recorded, decontaminated, and sterilized in the 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 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. 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

- Prior to scheduling the procedure, the surgeon or designee requiring loaner instrumentation must contact the vendor to confirm the availability of the loaner instruments and written manufacturer instructions for use (MIFUs).
- Communication from the surgeon's office to the OR and Purchasing regarding the need for loaner instrumentation should be done at the time the procedure is scheduled. The Purchasing Department will use this communication to obtain a purchase order for the loaner instrumentation stating that the written MIFU must accompany the delivery.
- Upon booking a surgical case that requires loaner instrumentation, the OR and SPD will be notified of the date of the surgery, doctor, procedure, type and quantity of the loaner equipment needed, method of delivery/return and restocking requirements at least one (1) business day prior to expected delivery by vendors.
- Supplies and implant pricing should occur before the loaner trays are received.
- Responsibility and cost for missing and damaged items must be determined before the procedure.
- All tray(s) will be tagged with date, surgeon name(s) and procedure.
- All loaner trays should be delivered to the designated area in the SPD no less than 48 hours before a scheduled case for SPD to process the instruments. All first-time vendor-loaned sets require three (3) business days for servicing, inspecting and processing.
- Written inventory of all items on the tray(s) must be provided and inventory of any missing stock must be verified by 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).
- All loaned instruments from a vendor will be considered non-sterile and will be processed according to the MIFU and hospital policy. *See 01.05.02 – Sterilization of Semi-Critical and Critical Medical Devices*

- When working with loaner trays at any time SPD staff must be aware and always use the proper personal protective equipment (PPE) during this process.
- The vendor must provide in-service to SPD staff for any tray(s) that are brought in 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.
- If the vendor and/or SPD representative need to reconfigure the tray contents for any reason, proper validation and documentation must be supplied to make this change by the device manufacturer.
- When a loaner instrument set is received, each instrument should be inspected for instrument integrity.
- Immediate-Use Sterilization should not be used as a substitute for insufficient instrument inventory resulting from late delivery of loaner instrumentation.
- All loaner instrument sets should be sent to the SPD Decontamination Room immediately following the procedure for cleaning according to the MIFU.
- Inventory loaner sheets must be signed confirming all contents are present and maintained in SPD for verification that all components were returned.
- The inventory sheet must be when the sales representative or other company representative picks up the tray(s).
- Reimbursement for any item that vendor claims is missing when an inventory sheet is not provided and does not verify the inventory with SPD when the tray(s) is received.
- All loaner instrumentation should be removed from SPD and transported to a holding area for pick-up by the vendor representative 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. The fee will be deducted from their bill at time of billing for the case.
- An inspection for cleanliness and content will be done by the vendor representative and the SPD technician. Discrepancies will be reported to the OR and SPD.
- Documentation, including but not limited to: date; signature of individual receiving; name and number of trays, number of instruments, and date removed will be recorded on the SPD Loaned Instrument Drop Off Log and the Instrumentation Management System (Abacus) where applicable, *See Appendix.*
- If a loaner system needs to be held in SPD for another case that is scheduled within two (2) business days, the vendor representative will reassemble and inventory the sets, and then follow the same procedures outlined above.
- Any invoice from a surgical case where loaner instrumentation or tray(s) were used without checking with the SPD to ensure there were no other miscellaneous charges that have to be deducted from the invoice before payment will not be processed.

References

- The Joint Commission. Hospital Accreditation Standards (HAS). 2025.
- ANSI/AAMI ST79:2017/®2022 & A1:2020. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
- ANSI/AAMI ST77:2006(R): 2010. Containment Devices for Reusable Medical Device Sterilization. Arlington, VA. Association for the Advancements of Medical Instrumentation; 2010.
- Association of periOperative Registered Nurses (AORN). Guideline for care and cleaning of surgical instruments. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc; 2021:381-420
- Centers for Disease Control (CDC). Guidelines for Disinfection and Sterilization in Healthcare Facilities (2008). Updated February 2017.
- FDA Frequently Asked Questions About Medical Devices, January 2006, current as of 7/13/2018.

Appendix

☐ LCC ☐ Galveston ☐ ADC ☐ CLC

SPD LOANED INSTRUMENT DROP OFF LOG

Date: _____ Vendor: _____ Time: _____

Name of Tray	Method of Sterilization	Date of Procedure	Time of Procedure	Surgeon	Tray Weight
	☐ Steam ☐ V-Pro				
	☐ Steam ☐ V-Pro				
	☐ Steam ☐ V-Pro				
	☐ Steam ☐ V-Pro				
	☐ Steam ☐ V-Pro				
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	☐ Steam ☐ V-Pro				

Signature of Person Making the Delivery: _____

SPD Decontam Receiving Employee: _____ Time: _____ Date: _____

SPD Instrumentation Employee: _____ Time: _____ Date: _____

SPD Sterilization Employee: _____ Time: _____ Date: _____

Comments: _____

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