Minnesota Healthcare Central Services Members Association Vendor Policy
Title: Loaner Instruments and Equipment from outside Vendors
Department Responsible: Central Processing Department
Stakeholders: Operating Room, Central Processing Department, PCLC, MEC, OMD, Vendors, Surgery Physicians, Infection Prevention, Supply Chain Managment
Final Approval Body: MHCSMA Board of Directors
Original Approval Date:
Last Reviewed/ Revised: August 29, 2012

PURPOSE

To identify minimum requirements for implants and loaner instruments that will facilitate appropriate time for reprocessing safe sue of products and ensure healthcare organizations are current on the related new technology.

DEFINITIONS

Chemical indicator: device for monitoring a sterilization process. The device is designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a chemical indicator does not prove the item accompanied by the indicator is necessarily sterile. The Association for the Advancement of Medical Instrumentation has defined five classes of chemical indicators: Class 1 (process indicator); Class 2 (Bowie-Dick test indicator); Class 3 (single-parameter indicator); Class 4 (multi-parameter indicator); and Class 5 (integrating indicator).

CPD: Central Processing Department

Emergency situation: A situation deemed by surgeon as necessitating immediate use of instruments and/or implants prior to obtaining biological result.

Instructions for use :(IFU) Written instructions from manufacture on care/handling, cleaning, sterilization, and storage.

Immediate use sterilization: A process designed for the steam sterilization of unwrapped patient-care items for immediate use (or placed in a specially designed, covered, rigid container to allow for rapid penetration of steam).

Loaner tray: Instruments and/or implants brought into the facility by Vendors for intra-operative use during specific scheduled procedures.

Sterilization: Validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

Vendor: A sales representative offering product and technical support of patient-care items such as equipment, loaner instruments and loaner implants.

POLICY

- Instruments and implants are to be delivered to the designated location within the facility by 12 pm the day before the surgical procedure occurs. This will enable the instruments and implants to undergo thorough cleaning and sterilization by CPD and also prevent the need to use immediate use sterilization. **IFU's must accompany all instruments and implants.**
- For Monday cases, instruments must be brought in by 1:00 pm the Friday before the scheduled case.
- If the surgical procedure is scheduled as an add-on late the day before or is scheduled as an add-on same-day the loaner trays will be brought in 6 hours prior to surgical start time of surgical procedure unless the procedure is scheduled to start less than 6 hours after it is scheduled. There are emergency situations that allow this to happen.
- Under all circumstances, vendor instrumentation is considered contaminated and must be sent for full cycle reprocessing.
- If instrumentation has never been used within the facility an in-service will be required two days prior to use.
- Vendors will not be allowed to bring additional instrumentation at the time of the case (unless it is an emergency).
- No instruments will be rushed through using just in time sterilization. For the safety of the health care worker, vendor instrumentation will be packaged to weigh no more than 25 pounds including sterilization containers. (AAMI ST79 2010, A1:2010 & A2:2011 Section 8.4.2)

Procedure

Pre-Case Handling

Surgery Department Responsibility:

1. Designated Surgery departments/service leaders will arrange for
    a. Delivery of instruments from vendors to CPD
    b. Delivery of implants to the surgery departments/ location of scheduled case
2. Service Leaders will communicate to CPD any changes to the surgery schedule
    a. Name of vendor, surgeon, patient date and time of case will be provided
    b. If hospital is using their own site consignment set(s)
    c. If hospital is borrowing consignment set(s) from another hospital or other facility.
3. Borrowing of consignment set(s) between hospitals will be coordinated between surgery departments. The hospital site that is the lender assumes the responsibility of vendor for pre-case handling.

Vendor Responsibility:

1. Vendors will deliver sterile and non-sterile implants directly to CPD by noon the day before the scheduled procedure (s)
   Vendor includes all required documentation
2. When vendor instrumentation is delivered to CPD the delivery person will request the designated representative to accept receipt of the delivery.
3. Vendors are responsible for completing the CPD Vendor Instrument Form with all the appropriate information pertaining to the case.
4. Vendors will include an instrument pick list with each pan. This list needs to explain what is in every tray and every level.
5. The vendor will provide proper cleaning and sterilization instructions for all instrumentation.

6. If the instrument pick list and the instrument set(s) do not match the vendor representative will be contacted to sort out the discrepancy.
7. The vendor will provide additional implants and instruments required when the amount of instruments and implants required for additional scheduled surgical procedures exceeds the number of consigned instruments and implant trays routinely kept in the Operating Room.

Central Processing Responsibility:

1. Reprocess vendor trays/loaner instruments by:
    a. Be disassembled and cleaned
    b. Have lumens flushed with enzymatic and rinsed thoroughly
    c. Placed in Sonic according to IFU
    d. Washed in the washer disinfector
    e. Wrapped and sterilized according to manufacturer instructions
    f. Be run with a biological indicator
2. Identify all Vendor trays with the hospital tracking system(paper/electronic)
    a. Case, location, Dr, and how many trays, tray name
3. Implants will not be sterilized using just in time sterilization methods.
    a. If an implant has to be flashed for an urgent case, the implant must be held for 3 hours until the biological indicator has been read negative.
    b. If the emergency warrants that the implant must be used immediately, the Early Release form must be filled out and completed. The Class 5 integrating indicator must read negative. Once the biological indicator is read after 3 hours it must be documented on the Flash Log on the sterilizer. The physician must be informed.
4. Enforcement
    a. CPD will only reprocess instruments or equipment that is obtained according to this policy.
    b. Exceptions for emergencies must be cleared with the CPD or OR Manager of the day.
    c. OR Service Leader will communicate with CPD of any changes adds or special instructions
5. Instrumentation that has not left the CPD department may be sterilized without re-wash if they have not been stored over 24 hours and pass vendors assembly inspection.
6. It is CPD responsibility to take pictures of what was in the tray when arrived (only recommended).
7. CPD will keep an electronic record of all vendor trays for a minimum of 30 days

Post Case Responsibility

OR Responsibility:

1. All vendor instruments are separated from hospital owned instruments and placed in original vendor tray.
2. Post-case handling for enzyme application and gross decontamination will be performed following hospital procedures.
3. All vendor instruments are broken down to the lowest level in which they were when sterilized.
4. The surgical technician is responsible for identifying instruments in need of repair before they leave the OR suite.

Central Processing Responsibility:

1. Vendor instruments and implants will be cleaned and sent through the decontamination process according to IFU.
2. All vendor trays will be processed on a priority basis to facilitate the turnaround of instruments for the next case.
3. Vendor trays will be placed in vendor pick up area for sorting
4. Instrumentation will be verified against the original list of contents/ pictures before instrumentation is removed from facility.
5. This facility will not be responsible for loss or damage to instruments brought in outside of the above guidelines.
6. Missing instruments will be logged and reported missing or damaged.
7. The facility site where the instruments were used may authorize purchasing to replace the missing instruments under the following conditions
   a. At the vendors cost
   b. After 14 days from the point of notification, if the missing vendor instruments have not been located.
   c. Vendors have followed instrument pick up and missing instrument notification protocols.
   d. Total joint instruments that are lost are not purchased.

Vendor Responsibility:

1. Vendor will make arrangements for pick of instruments and implants within 24 hours of surgical case completion
2. Vendors will re-assemble and inspect all trays.
3. If trays are needed for another case the vendor must repeat the above process. .

SUPPORTIVE INFORMATION:

Regulatory Statute/ Standard Reference:
Related Policies: •
References: • Rutala, Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. CDC http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf • The Joint Commission Standards 2011. Chapter: Infection Prevention and Control • Recommended Practices for Sterilization in the Perioperative Practice Settings. Association of periOperative Registered Nurses. AORN Standards Recommended Practices and Guidelines. 2009 • The Associatoin for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance ain health care facilities. ANSI/AAMI ST79:2006 and A1:2008 • ASHCSP/IAHCSMM position paper on Loaner Instrumentation (April 2004), located at this website: http://www.iahcsmm.org/pdfs/ASHCSP-IAHCSMMLoanerPaper.pdf
Communication/ Staff Education: • Physician, OR Staff, Vendors, CPD annually informs vendors of instrument policy
Internal References:
Patient Education: none
Effective Date:
Date Reviewed: