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References:

## Management of Loaner and Consignment Instruments and Implants

Document Type: Administrative Procedure

### PURPOSE

To establish procedures for the acquisition, accountability, processing and disposition of loaner and consignment instrumentation and implants to ensure patient safety at Denver Health.

### RESPONSIBILITY

Vendors  
Reps  
Denver Health Sterile Processing Department (SPD)  
OR staff  
Purchasing

### PROCEDURE

- A. All loaner instrument or implant sets should be received in Sterile Processing by 2:00 p.m. the day prior to surgery. Monday cases need to be received by 2:00 p.m. Friday.
- B. All instrument and implant sets will be completely processed after receipt.
- C. Implant sets will be cleaned after restocking.
- D. All instrument and implant sets will be processed in accordance with the manufacturer's written recommendations. Manufacturer's recommendations will be kept on file in the SPD assembly area.
- E. A biological indicator (BI) will be run in each sterilization cycle containing implantable items.
- F. Implant trays will not be released until the biological has been incubated for the recommended time of three hours for Rapid Read BI or twenty-four hours for standard read BI's.
- G. Implants needed before the incubation is complete, due to an emergency, will be released after completing an Early Implant Release Form and obtaining the required signatures.
- H. Loaner/consignment instrument and implant sets must have an accurate, verified inventory list at time of delivery or vendor will assume responsibility for instrumentation presumed lost or damaged.

- I. Loaner/consignment instruments and implant sets will not be sent to other healthcare facilities without the written permission of the vendor representative.
- J. SPD will not be responsible for loaner instruments or implants not picked up within twenty-four hours after completion of the scheduled surgery.
- K. Procedure Steps / Critical Elements:
  - 1. Ordering/scheduling:
    - a. Need for loaner/consignment instrument and implant sets will be communicated to the appropriate **OR Service Line leader, or designee**, by the requesting surgeon or his designee.
    - b. **OR Service Line Leader** will make the arrangements with the vendor or other health care facility for delivery of needed instruments or implants.
      - 1. **OR Service Line, or designee**, will notify vendor that:
        - a. All sets must have an accurate inventory sheet included with the delivery.
        - b. All sets for the following day's first case must be received in Sterile Processing no later than 2:00 p.m. the day prior to the case. Monday cases need to be received by 2:00 p.m. on Friday.
        - c. Instruments for To-Follow cases must be received by 2:00 p.m. the day prior as well.
        - d. Complete and current manufacturer's processing instructions must be either already on file or delivered with the instrumentation.
    - c. The SPD **shift leads** will be notified by the **OR Service Line Leader, or designee**, of the specifics of the delivery.
  - 2. Delivery:
    - a. Items must be delivered to SPD receiving area.
      - 1. Items will not be accepted in the OR.
    - b. Instrument trays and implant sets must be checked in with a Sterile Processing staff member.
      - 1. A complete inventory list of items delivered must be left at time of delivery.
      - 2. Items not properly checked in are the sole responsibility of the vendor.
      - 3. Missing or damaged instruments must be noted at time of delivery.
      - 4. Ensure manufacturer's written processing instructions are on file.
        - a. If instructions are not already on file, current guidelines must be left at time of delivery.
    - c. Vendor representative will complete the delivery log and affix a completed blue vendor tag to each tray.
    - d. Delivery will be verified by the Sterile Processing shift leader or their designee.
      - 1. delivery date
      - 2. delivery time
      - 3. date of surgery
      - 4. company
      - 5. name of person delivering the instruments

6. deliverer's phone, beeper, and cell numbers
  7. number and name of trays/instruments delivered
    - a. List name of trays on the bottom half of the log sheet and vendor tag
  8. Whether or not implants are in the trays
  9. Surgeon's name
  10. Patient's name
- e. Identify tray by number on the delivery log (i.e., 1 of 7).
- f. Deliver trays/instruments to the decontamination area.
3. Decontamination
- a. Upon receipt all loaner instrument and implant trays will be properly decontaminated.
    1. Remove tray lid(s).
    2. Place tray(s) in washer disinfectant and run on instrument cycle.
    3. Each layer of instruments must be removed from tray and run separately.
    4. Ensure small implants are covered with a mesh covering to avoid losing them in the washer.
    5. If items cannot be placed in washer decontaminators, process as per manufacturers written recommendations.
4. Assembly
- a. Upon removal from washer decontamination
    1. Carefully inspect each tray for cleanliness
    2. Dry instruments
    3. Place appropriate integrator inside tray
      - a. An integrator should be placed on each layer of instrumentation, in opposite corners.
    4. Match the tray number to the appropriate number of the delivery log using vendor tag on tray.
    5. Transfer the vendor tag to the outside of the tray. Ensure the following information is present.
      - a. Name of tray include sequence number (i.e. one of 4)
      - b. Physician name
      - c. Date of surgery
      - d. Time of surgery
    6. Wrap tray using standard facility procedure.
      - a. Ensure proper vendor tag is taped to the tray.
      - b. Create and affix label for tracking, if bar code is available.
5. Sterilization and Release of Trays

- a. Instrument trays and implants will be sterilized according to manufacturer's written recommendations.
    1. Sterilized trays will not be released until completely cool. Should it become necessary to release a tray before tray is cool, the instruments must be unwrapped and flash autoclaved in the OR.
    2. Each sterilization cycle containing an implant will have a biological indicator run with the load.
    3. Implants will be quarantined until the biological indicator has incubated for appropriate time.
      - a. Tray will only be released to OR following a known negative biological result
      - b. If biological indicator is positive all items run in that cycle will be rewrapped and re-sterilized prior to issue. OR team will be notified of the positive result.
  - b. Premature release of implants.
    1. Implants will be released prior to the completed biological incubation only in the event of an emergency.
      - a. Prior to release
        - i. Complete the Early Implant Release Form; Items will not be released until completion of this form.
          - a. Date
          - b. Implant/tray name
          - c. Reason for release
          - d. Physician requesting release
          - e. Signature of surgeon or circulating nurse
        - ii. Results of the incubated biological will be placed on the release form at completion of incubation.
          - a. If results are positive, surgeon will be notified immediately.
6. Post-operative Processing
- a. Upon completion of surgery, loaner instruments and implant trays will be returned, with the case cart, to the decontamination area.
    1. Trays opened but unused will also be returned to the decontamination area.
    2. No opened tray will be returned to the vendor before processing through the decontamination area.
  - b. Process trays per manufacturers written recommendations
    1. Mechanical cleaning.
      - a. Ensure all disposable items have been removed from tray(s) including processed integrators.
      - b. Rinse each tray using cool water to remove gross bioburden.

- c. Soak each tray in dual enzymatic solution (measured per manufacturer's instructions) for minimum five minutes.
  - d. Brush all lumened instruments utilizing an appropriate size brush.
  - e. Flush lumens ensuring water runs clear.
    - i. If water remains bloody re-brush lumen.
    - ii. Rinse thoroughly.
  - f. Inspect instruments and remove gross soil.
    - i. If loss or damage is noticed report to shift leader immediately.
  - g. Process trays in washer decontaminator.
    - i. Ensure all lids are removed from trays to facilitate cleaning process.
    - ii. Each layer of instruments must be removed from tray and processed separately.
    - iii. Place mesh basket over small implants to prevent loss during the decontamination process.
    - iv. Run washer decontaminator on instrument cycle.
- c. Manual cleaning.
- 1. Only for items which cannot be immersed in water or withstand a temperature of 200°F
    - a. Ensure all disposal items have been removed from tray(s) including processed integrators.
    - b. Carefully clean all surfaces utilizing dual enzymatic solution.
      - i. Brush lumens utilizing the appropriate size brush.
      - ii. Carefully flush lumen ensuring water does not come in contact with areas which must be kept protected from solutions.
    - c. Rinse instruments ensuring all enzymatic solution is removed.
    - d. Pass cleaned items through window to the assembly area.

## 7. Vendor Reassembly

### a. Instruments

- 1. Vendor representative will reassemble instruments.
- 2. After assembly vendor representative will:
  - a. Ensure all information is available as in Section 4 above if instruments are to be reused.
  - b. Place labeled and assembled tray on designated cart to be wrapped and sterilized.
  - c. Lost or damaged instruments must be reported immediately to the Sterile Processing shift leader.
    - i. Loss or damage will be verified utilizing inventory sheet.
    - ii. If no inventory sheet on file, vendor assumes all responsibility for presumed loss or damage.

3. Sterile Processing personnel will inspect tray placing appropriate integrator in each layer of instruments.
  4. Wrap tray as per normal procedure.
  5. Sterilize as in step 5 above.
- b. Implants
1. Vendor representative will replace used implants.
    - a. Documentation of implant replacement must be given to OR Manager, or their designee, within one hour of re-stocking for verification and reorder, if necessary.
    - b. Trays will be identified as in step 2 above.
    - c. Stocked tray will be run through the washer decontaminator prior to sterilization.
      - i. After washing follow steps 4 through 7 above.
8. Release of Consigned Instruments
- a. Sets on consignment to facility must have the written permission of the appropriate Team Leader before releasing them to the vendor.
  - b. Upon return Vendor Representative will validate tray completeness.
    1. No discrepancies will be validated after removal from the SPD.
  - c. Document date of removal in the delivery log.
  - d. After verification by Sterile Processing shift leader, trays may be removed from the department.
    1. All trays removed from the department will be unwrapped.

## REFERENCES

- A. ASJCSP position paper "Controlling Loaner Instrument Sets" published 2003.
- B. ANSI/AAMI Recommended Practice ST46; ST 79: 2006 (09)
- C. Basics of Sterile Processing, 3<sup>rd</sup> Edition
- D. Central Service Technical Manual, 7<sup>th</sup> Edition
- E. Perioperative Standards and Recommended Practices, 2010 Edition



## ATTACHMENTS

Attachment A - Missing Instrument Form

Attachment B - Vendor Drop-Off and Pick-Up Guidelines

Attachment C - Vendor Delivery Log

### Attachments:

-  [A: Vendor Instrument Missing Form](#)
-  [B: Vendor Drop-Off and Pick-Up Guidelines](#)
-  [C: Vendor Delivery Log](#)