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Management of Loaner and Consignment Instruments and Implants

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 and Hospital Authority (DHHA).

SCOPE

- Vendor Representative
- Sterile Processing Department
- Operating Room
- Material Management

DEFINITIONS

Vendor - is a person or company offering products for sale or loan.

Loaner - a products that is borrowed

GUIDELINE/PROCEDURES

A. Delivery Time Line & Receipt Process:

1. External Vendors are managed by a Program called IntelliCentrics and are mandated to wear a Paper Badge every single time they work in the Denver Health hospital areas. This is done so that the Denver Health employees have a method of visual tracking all vendors within the hospital structures. This is also done to track vendor compliance with the Denver Health hospital rules and regulations. All vendors are mandated to provide Vaccination credentials to ensure they have all the current Vaccinations against infectious diseases. Vendors are not allowed skip the Rep Tracks Badge system because their access will be denied. Any Vendor that is not wearing the proper Identification badge is to be reported to your supervisor immediately.
2. 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.
3. All instrument and implant sets will be completely processed after receipt. Implant sets will be cleaned after restocking. 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 Sterile Processing department.
4. A biological indicator (BI) will be run in each sterilization cycle containing implantable items. Implant trays will not be released until the biological has been incubated for the recommended time of three hours for Rapid Read BI. Implants needed before the incubation is complete, due to an emergency, will be released after completing the Early Implant Release tracking form and obtaining the required signatures.
5. Loaner/consignment instrument and implant sets must have an accurate, verified inventory list that is provided by the vendor at the time of delivery or vendor will assume responsibility for instrumentation presumed lost or damaged. Loaner/consignment instruments and implant sets will not be sent to other health care facilities without the written permission of the vendor representative. The Sterile Processing department will not be responsible for loaner instruments or implants not picked up within twenty-four hours after completion of the scheduled surgery.

B. Ordering Procedure Steps / Critical Elements:

1. Ordering/scheduling: Need for loaner/consignment instrument and implant sets will be communicated to the appropriate OR Service Line leader, or assignees, by the requesting surgeon or his assignees.
2. OR Service Line Leader will make the arrangements with the vendor or other health care facility for delivery of needed instruments or implants.

C. OR Service Line Leader, or assignees, will notify vendor that:

1. Complete and current manufacturer's processing instructions must be either already on file or delivered with the instrumentation.

2. Instruments for To-Follow cases must be received by 2:00 p.m. the day prior as well.
3. 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.
4. All sets must have an accurate inventory sheet included with the delivery.
5. The Sterile Processing Department shift leads will be notified by the OR Service Line Leader, or assignees, of the specifics of the delivery.

D. Delivery:

1. Items must be delivered to the Sterile Processing Department receiving area. Delivery will be verified by the Sterile Processing shift leader or another Sterile Processing Technician. Items will not be accepted in the OR.
2. Instrument trays and implant sets must be checked in with a Sterile Processing staff member. The Vendor Representative must Fill out the Denver Health Vendor Instrument set drop off tracking sheet completely and include their name and phone numbers. A complete inventory list of items delivered must be left at time of delivery. Items not properly checked in are the sole responsibility of the vendor.
3. Missing or damaged instruments must be noted at time of delivery. Ensure manufacturer's written processing instructions are on file. If instructions are not already on file, current guidelines must be left at time of delivery.
4. Vendor representative will affix a completed vendor tag to each tray, with all case information included on each tag. Each set tag should have a individual number sequence and be identified as one of how ever many sets are total.

E. Upon receipt all loaner instrument and implant trays will be properly decontaminated:

1. Remove tray lid(s). Inspect all cannulated instruments. If they are blocked or not clean, soak the instruments for 3 minutes in the enzymatic cleaner, flush, and place pipe cleaner through until clear.
2. Place tray(s) in the Decontamination washer 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 Decontamination washer, process as per manufacturers written recommendations.

F. Assembly:

1. Upon removal from washer decontamination, carefully inspect each tray for cleanliness and dry instruments. Place appropriate integrator inside tray. An integrator should be placed on each layer of instrumentation, in opposite corners.
2. Match the tray number to the appropriate number of the delivery log using vendor tag on tray. 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

G. Wrap tray using standard facility procedure:

- 1. Ensure proper vendor tag is taped to the tray. Create and affix label for tracking, if bar code is available.

H. Sterilization and Release of Trays:

- 1. Instrument trays and implants will be sterilized according to manufacturer's written recommendations. 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. Implants will be quarantined until the biological indicator has incubated for appropriate time. Tray will only be released to OR following a known negative biological result.
- 3. If biological indicator is positive all items run in that cycle will be re-wrapped and re-sterilized prior to issue. OR team will be notified of the positive result.

I. Premature release of implants:

- 1. Implants will be released prior to the completed biological incubation only in the event of an emergency. Prior to release Complete the Early Implant Release Form; Items will not be released until completion of this form.
- 2. Signature of Sterile Processing Manager or assignees.
- 3. Reason for release.
- 4. Implant/tray name
- 5. Date/time
- 6. Physician must be notified of the early release.
- 7. Results of the incubated biological will be placed on the release form at completion of incubation. The form will be scanned into the Sterile Processing Micro system program tracking system under 'Quality Event'.
- 8. If results are positive, surgeon will be notified immediately.

J. Post-operative Processing:

- 1. Upon completion of surgery, loaner instruments and implant trays will be returned, with the case cart, to the decontamination area. Trays opened but unused will also be returned to the decontamination area. No opened tray will be returned to the vendor before processing through the decontamination area.
- 2. Process trays per manufacturers written recommendations to include Mechanical cleaning. Process trays in Decontamination washer. Run the Decontamination washer on instrument cycle. Place mesh basket over small implants to prevent loss during the decontamination process. Each layer of instruments must be removed

from tray and processed separately.

3. Ensure all lids are removed from trays to facilitate cleaning process. Inspect instruments and remove gross soil. If loss or damage is noticed report to shift leader immediately. Flush Cannulated ensuring water runs clear & rinse thoroughly. If water remains bloody re-brush lumen. Brush all Cannulated instruments utilizing an appropriate size brush. Soak each tray in dual enzymatic solution (measured per manufacturer's instructions) for minimum five minutes. Rinse each tray using cool water to remove gross bioburden.
4. Ensure all disposable items have been removed from tray(s) including processed integrators. Manual cleaning, only for items which cannot be immersed in water or withstand a temperature of 200°F, pass cleaned items through window to the assembly area. Rinse instruments ensuring all enzymatic solution is removed. Carefully clean all surfaces utilizing dual enzymatic solution. Carefully flush lumen ensuring water does not come in contact with areas which must be kept protected from solutions. .

K. Vendor Reassembly Instruments:

1. Vendor representative will reassemble instruments. After assembly vendor representative will ensure all information is available as in Section 4 above if instruments are to be reused. Place labeled and assembled tray on designated cart to be wrapped and sterilized.
2. Lost or damaged instruments must be reported immediately to the Sterile Processing shift leader. If no inventory sheet on file, vendor assumes all responsibility for presumed loss or damage. Loss or damage will be verified utilizing inventory sheet.
3. Sterile Processing personnel will inspect tray placing appropriate integrator in each layer of instruments. Wrap tray as per normal procedure. Sterilize as in step 5 above.

L. Vendor Reassembly Implants:

1. Vendor representative will replace used implants.
2. Documentation of implant replacement must be given to OR Manager, or their assignees, within one hour of re-stocking for verification and reorder, if necessary.
3. Trays will be identified. Stocked tray will be run through the Decontamination washer prior to sterilization.
 - a. After washing follow steps 4 through 7 above.

M. Release of Consigned Instruments:

1. Sets on consignment to facility must have the written permission of the appropriate Team Leader before releasing them to the vendor.
2. Upon return Vendor Representative will validate tray completeness.
3. No discrepancies will be validated after removal from the Sterile Processing Department.
4. Document date of removal in the delivery log. After verification by Sterile Processing

shift leader, trays may be removed from the department.

5. All trays removed from the department will be unwrapped.

EXTERNAL REFERENCE

ANSI/AAMI Recommended Practice ST46; ST 79: 2017

Basics of Sterile Processing, 3rd Edition

Perioperative Standards and Recommended Practices, 2017 Edition

ATTACHMENTS

Attachments

[2020 Vendor Missing instrument form 07-08-20.doc](#)

[2020 Vendor Pickup Guidelines Forms 07-08-20.docx](#)

[2020 Vendor Drop Off Guidelines Forms 07-08-20.docx](#)

Approval Signatures

Step Description	Approver	Date
	Mitchell Cohen: Physician - Director of Surgery	11/2020
Infection Prevention Committee	Caroline Croyle: Infection Prevention Specialist	08/2020
	Mitchell Cohen: Physician - Director of Surgery	08/2020
	Vincent Fransua: Buyer Supervisor	07/2020
Formatting Review	Colette Morris: Program Manager of Document Management	07/2020
	Joseph Juarez: Sterile Processing Manager	07/2020