

Best Practices for Loaner Surgical Instruments

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**This in-service has been Approved by the CBSPD, Inc. for 1.25 CEUs.

Objectives

- To define loaner instruments
- To review the accountability issues with loaner instruments
- To discuss best practices for management of loaner instruments

Loaner Instruments – are instruments the facility did not purchase. They are most often used for specialty type surgery (e.g. spinal, total joint). It is difficult for facilities to inventory these specialty types of instruments due to the routine changes in sets and the variety of devices. Therefore companies loan them to healthcare facilities. Sometimes sets are left at the facility as loaners. These are considered consignment instruments. Consigned inventory is the property of the vendor, not the facility, until it is sold by the vendor. The facility does not own the inventory but agrees to pay for it upon use. The facility is totally responsible for the consignment instruments/implants left at the facility. There needs to be effective management of loaner instrumentation and implants for specialty operative procedures including proper inventory, cleaning and sterilization. Sterile Processing and Operating Room personnel in collaboration with the vendor(s) must work together to see that this inventory is managed correctly to prevent costly delays in the OR and so as to not impact on patient safety.

Loaners can be from another hospital (tray/set borrowed from another facility), doctors instruments (not owned by the hospital), instrument company (Orthopedic, Neuro) and a loaner can be for an instrument that is being repaired, instruments on consignment.

Effective management of loaner instruments/implants can prevent a decline in the quality of service and care of patients and to avoid paying for damage/loss that did not occur. We need to develop policies and procedures between the vendors, physicians, Operating Room and Sterile Processing detailing all procedures related to loaner instruments. Vendors need to know the amount of time the facility will need to process the instruments prior to the start of the case (e.g. 48-72 hours). Furthermore, vendors need to comply with these requirements. There should be a system of accountability for vendor compliance.

Scheduling - For orthopedic and spinal cases – most often 10-30 loaner trays are brought in for a single case. If multiple cases are scheduled for the same day, this impacts on SPD's ability to process all the loaners in addition to the processing for the other scheduled cases and other processing.

It is important for vendors to understand that they must cooperate by delivering the instruments in sufficient time to permit complete processing according to their instructions for use (IFUs). Failure to do so may negatively impact on patient care because items may have to be sterilized by immediate use steam sterilization (IUSS) which is not the best practice unless it is an emergency. In addition, many loaner instruments/sets have not been validated for IUSS.

Vendors must provide specific cleaning, assembly and sterilization instructions including:

- o type of detergents/chemicals recommended
- o sterilization methodology and parameters (steam (pre-vac or gravity)), ETO, etc.
- o immediate use sterilization instructions (if validated)
- o instructions for use (IFUs)

Who is reviewing the IFUs to ensure your department/facility can comply or that the IFUs meet AAMI standards? Are the recommended sterilization temperatures ones that can be used in the US? Many IFUs have temperatures of 272°, 273°, 274°F which are not validated temperatures for US steam sterilizers. Some have incorrect exposure times, (e.g. 3 minutes at 270°F, wrapped, pre-vacuum). Is there time to contact the company to resolve the issue? Many IFUs recommend an extended exposure time (e.g. 8 minutes at 270°F, pre-vacuum.) Have your sterilizers been set-up for extended cycles? Has the staff been inserviced with competencies verified in extended cycles? Is the staff aware that only those sets requiring the extended cycle can be included in the load?

Cleaning - Decontamination personnel must follow manufacturers' cleaning IFU and to do so must have access to them. Also required are the necessary resources to comply with the IFUs:

- o Sufficient ultrasonic cleaners – extended sonic cycles
- o Sufficient washers
- o Sufficient staffing
- o Sufficient sterilization capacity

Problems occur when trays arrive too late before the procedure. This can lead to the staff feeling pressured into getting the sets processed. This can create errors and can cause taking short-cuts of vital processing steps. Another issue is insufficient time to be able to inservice SPD if there are new sets/devices.



Photo Above - Bone Inside Reamer – staff not inserviced prior to cleaning. Did not know how to disassemble the reamer.

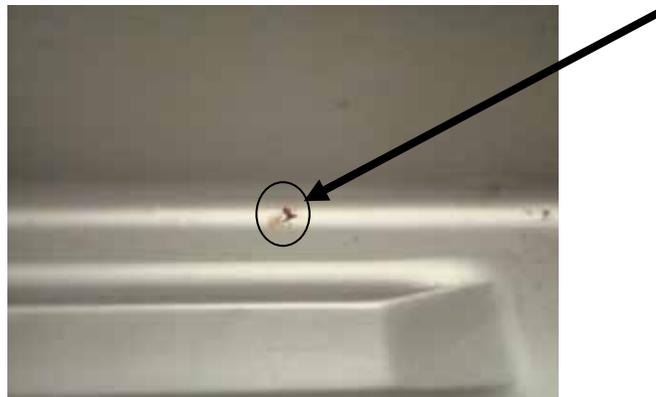


Photo Above - Debris inside loaner set – brought into facility wrapped and “sterile”

Factors:

1. Sufficient time is needed to review the sets with SPD staff. Cleaning protocols are essential. Was an inservice provided by the vendor for new trays? Was the training hands-on? Who monitors staff practices?



Photo above: Loaner Sets washed with lid beneath the container; set inside the container; not removed from container for cleaning.

2. Can you dry the sets under your department's conditions?
3. What is the age of your sterilizers? What packaging materials are used? What are the environmental conditions in the department?
4. Can you assure the OR the sets will be dry?
5. Have your loaner sets been weighed for compliance with AAMI ST-77 recommendations? Excessive weight of sets and overloading the sterilizer are major contributors to wet sets. AAMI ST-77 recommends a maximum weight of 25 pounds for loaner sets (this includes the container).

AAMI recommends Product Testing of sets (includes loaner sets). Have you done this? Product testing is part of the overall Quality Assurance Monitoring program. "Quality assurance testing of routinely processed items, representing a product family should be performed on an ongoing basis" AAMI ST-79 (2013). It is recommended to establish a program to periodically test (before placing into routine use):

- o* routinely sterilized products
- o* newly purchased sets
- o* loaner sets

Why is this necessary? Because the standardized BI test pack (PCD) represents a known challenge to the sterilizer. The test may not reflect the same challenge as the items routinely processed in your facility. Product testing emulates those devices actually processed within your area. Product testing is also recommended to ensure the effectiveness of the sterilization process and to avoid wet packs.

Other Factors:

- o When numerous sets arrive for a case (15, 20, 35, etc.) do you have sufficient sterilization capacity to handle this load in addition to the other processing requirements for your department?
- o What about days when there are multiple cases requiring loaner sets?
- o Is the staff "doing the best they can"?



Photo Above - Overloaded sterilizer cart – not there is no space between the containers.

Other Factors:

AAMI ST-79 does not recommend stacking of wrapped sets. Do you stack sets in your department/area? How do you send your loaner sets to the OR? Are they stacked on a cart? What does the OR do with them when they get there? Have you followed the sets to see what is happening to them?

Understand that each stacked set applies pressure to the tray beneath it. When there are multiple sets (of approximately 25 pounds each) 4 stacked sets are applying 100 pounds of pressure to the packaging on the bottom which can damage the packaging material. Understand that a set with a compromised wrapper is of no use to the OR. Stacking of sets is a major contributor to damaged packaging.



Photo above: Stacking of sets can lead to damage to packaging material and can also damage the instruments inside the container.



Photo Above: Damage to packaging material from stacking of sets.

Sometimes, facilities are placing loaner sets inside rigid container systems. AAMI ST-77 does not recommend this be performed unless the loaner manufacturer has provided documentation they have validated placing their sets inside a rigid container. According to the **FDA clearance considerations**: "It is the responsibility of the medical device manufacturer to provide validation for the sterilization of their devices. If a rigid sterilization container system is used for the validation, it should fall within the cleared indications for the specific manufacturer's rigid sterilization container." Contact your loaner company to see if they have validated for placing their sets inside rigid containers. They should provide you with written documentation for container requirements. Verify with your container manufacturer their containers meet those requirements. Otherwise, keep the loaners out!



Photo Above - Not Acceptable Unless Validated by the Loaner Manufacturer

Partnerships - The vendor performed testing on their instruments and implants therefore is required to provide this information to you. Without this information, the instruments may not be cleaned/sterilized correctly. Your facility may be legally responsible if an infection occurs. Only the loaner manufacturer can advise if their sets can be placed in a rigid container.

Accountability - Sterile Processing should maintain records including:

- when instruments were received (date, time)
- sets used
- processing instructions received
- all items accounted for on the set when it arrives
- all items accounted for on the set when the set is returned to vendor

It is essential that SPD personnel label the sets accurately. Double check your work to avoid delays in the OR.

Policies and Procedures – Policies and Procedures are needed for

- ordering of loaner instruments
- how instruments will be transported to the facility
- verification that all items present on sets upon arrival (need check list from vendor and count should be performed with the vendor)
- pre-procedure processing
- Patient charging (if applicable)

- Processing after the procedure
- Verification that all instruments were accounted for before return to the vendor
- how instruments will be returned

Be sure to state the maximum weight of loaner sets (AAMI ST-77) which is 25 pounds, including the weight of the container. Have you weighed your sets? Do you have a scale to do so? Also include the required condition of the loaner instruments; they must be in good condition; no rusting, pitting, etc. Trays/containers must be in good condition, no damage, holes, etc. There should be a current count sheet for each set. The policy should also specify that there should be sufficient instrumentation provided to permit compliance with the reprocessing IFUs. This is important **because quick turns can lead to cleaning and sterilization failures**.



Photo Above - Organizing Tray with holes in base. Can damage packaging material.

For loaner instruments used in high risk tissue as defined by AAMI ST-79 Annex "C" - Processing CJD-contaminated patient care equipment and environmental surfaces" there should be consideration how these instruments will be handled upon arrival. You will have no information where the neurosurgical sets were last used and if used on a CJD patient. What about loaner neuro-endoscopes? These cannot be processed in low temperature sterilization because these technologies are ineffective against prions. You need to verify if the instruments were validated for extended steam cycles as recommended in Annex C of ST-79.

Your Loaner Policy should also include procedures for sets/devices borrowed from another facility. Upon arrival, these instruments should be completely reprocessed unless you have knowledge of the facility's cleaning and sterilization practices. You may have to visit the facility and look at their

processes. Make sure the instruments arrive with a count sheet. Did anyone inventory the set in the OR before and after the case? Did you get IFUs for cleaning and sterilization?

Include procedures for acquiring loaner Instruments. The initial request should be communicated to designated person(s) (e.g. Purchasing, OR?) who will make arrangements with the vendor or another hospital. Sterile Processing needs to be informed of the arrangements made so they can follow-up. Sterile Processing needs to know:

- number of trays arriving
- surgical procedure they are needed for
- doctor performing the surgery
- date and time of the procedure
- how the instruments will arrive (vendor? FED-X?)
- estimated date and time of arrival

When Sterile Processing does not know that loaner instruments are being requested, they cannot plan. It is important to make sure Sterile Processing is included in all communications regarding loaner instruments.

Check-in Of Instruments – when loaner instruments arrive, document the receipt of loaner instruments and implants including the date and time received; signature of individual receiving loaners, surgeon's name, number of trays, number of implants (if applicable). Then perform an inventory control check. Verify the types of instruments/implants; verify the quantities of instruments/implants, visually inspect instruments and implants for damage. Look at the condition of instruments and container.

A check list should follow the instruments through the entire process. Make sure the staff is following the manufacturer's instructions for processing. If written instructions have not been provided, contact the manufacturer to have the information FAX'd. You may want to develop a tracking form to track sets throughout department. Have each technician sign the form when they have completed their process. Document when the instruments are sent to OR, date, time and by whom.

Document problems (damaged instruments should be documented and reported to the vendor). If the vendor is not available to check-in the instruments you will have to contact them if any defects are identified. Notify the Operating Room immediately for any problems that could delay the case.

After proper processing and cooling, release the instruments to the Operating Room for use. Implants require a biological test pack be included in the load. Hold the implants until the result of the BI is known. If the implants must be released before the result of the BI is known, verify the sterilizer printouts and chemical indicators to make sure all cycle parameters were met; release with an Early Release form (see AAMI ST-79). Document that the implant was released before the BI result was known. The surgeon should be notified of this. Document all implants on an Implant Log.

After Use - Instrument reprocessing starts at point of use with pre-cleaning and timely transport to the Decontamination area. AAMI recommends wiping gross soil off instruments during the procedure and irrigating lumens. Follow with treatment with enzymatic foam or gel which keeps the blood from drying therefore facilitates effective and faster cleaning. All the instruments should be returned to the Decontamination area immediately or in the time frame specified by the instrument manufacturer. Is your OR pre-treating the instruments and placing them back in their respective container? If not, this impacts on processing time in SPD. Disassemble, clean and decontaminate the instruments per manufacturer's instructions. Verify that all loaner instruments are accounted for by type, quantity, condition. Document any discrepancies with the Operating Room for correction. Return loaner instruments to the designated person responsible for returning them to the supplier. Record the date, time, signature of processing technician and authorized purchase order number, if applicable. Return items to the vendor or other hospital. The designated person in the policy should arrange the return via service selected (courier, mail, etc). Include documentation with the instruments to verify items were returned. Arrange for replacements of damaged or lost instruments and used implants.

SUMMARY

Hospitals and SurgiCenters must borrow instruments from vendors and other hospitals due to the sophisticated surgery performed today. Loaner instruments must receive the same level of processing as other instruments. You should not assume "wrapped" instruments are sterile unless you witnessed the process; they should be unwrapped and completely reprocessed. Sterile Processing must be included in all discussions regarding loaner instruments. Your facility must enforce your Loaner Policy or it is a waste of time. Vendors need to be told how many hours in advance of the surgery they must bring in the instruments. We cannot permit vendors to impact on our infection control policies. Operating Room personnel need to account for all instrumentation/implants used. Any discrepancies upon arrival or at the end of the case must be documented and reported. Record keeping and policies will prevent costly delays in the Operating Room and increase patient safety.

References

Association for the Advancement of Medical Instrumentation. "Comprehensive guide to steam sterilization and sterility assurance in health care facilities". Arlington, VA, 2013.

QUIZ ON LOANER INSTRUMENTATION

Please click on the link below to take the quiz.

https://www.spdceus.com/ceus/loaner_instrumentation_quiz.htm

Good Luck!