


EDUCATION

STERIS UNIVERSITY



**Loaned Instrument Tray Management:
A Shared Responsibility**

The Integrated Approach to Healthcare

STERIS

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Learning Objectives

Upon completion of this program, you will be able to:

- Identify the impact on patient safety when loaned trays are mismanaged and improperly reprocessed
- Discuss the IAHCMM's loaned policy and documents available to support implementing a structured process

The Need for Loaned Instrumentation

- Types of procedures
 - New procedures or instrument systems
 - Implant revisions
 - Patient specific procedures
- Large volume of procedures
- Lack of storage



Loaned Instrumentation Can Be Complex

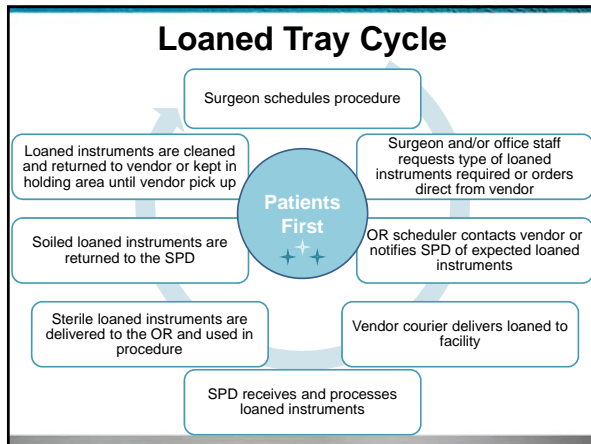
- Must follow manufacturer's IFU for cleaning, packaging and sterilization
- Education and training imperative to help prevent:
 - Healthcare Associated Infections (HAI's)
 - Loss or damage to borrowed systems
 - Inadequate cleaning or sterilization of loaned systems



Challenges with loaned Instruments

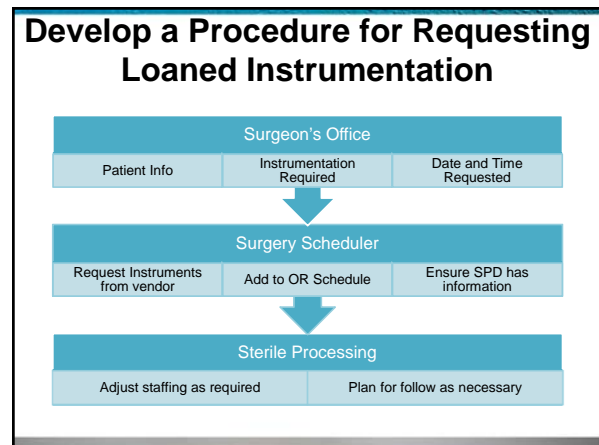
- Unexpected instruments arrive when you are not prepared
- Expected instruments that don't arrive
- Not sure which company rep to call when there is a problem
- Delays in instrument processing
- Unclear or unavailable IFUs
- Loaned instruments that can't be found in the OR when needed






- ### Developing a Successful Loaned Instrument Program
- Form a multi-disciplinary team
 - Develop a procedure for requesting loaned instruments
 - Develop a procedure for processing loaned instruments
 - Develop a communication tool
 - After input from all team members, have all policies and procedures in writing and available to everyone on the team

- ### Form a Multi-Disciplinary Team
- Team should include representatives from the following:
 - Sterile processing
 - Surgery
 - Infection prevention and control
 - Administration
 - Materials management
 - Surgeons
 - Loaned Instrument vendors
- 



- ### Develop a Procedure for Processing Loaned Instrumentation
- Manufacturer's written IFUs for instrument care, cleaning and sterilization
 - Detailed inventory lists (preferably with pictures) delivered with all instruments and set reconciliation pre and post procedure
 - Pre and post procedure cleaning and decontamination of instruments
 - Storage and delivery of instruments to point of use
 - Returning instruments to vendor
 - SPD staff training and competency assessment

- ### Written Policies and Procedures
- 
- Ensure everyone on the team – including instrument company reps – have access to and follow the policy
 - Must be written with realistic expectations for instrument delivery, reprocessing and post procedure pick-up
 - Have a plan for dealing with trays that arrive outside the agreed upon time frame

Emphasis on Evidence-Based Practice

- “The element of performance #3 stipulates that facilities implement policies and practices aimed at reducing the risk of surgical site infections.”
 - National Patient Safety Goal (NPSG) 07.05.01
- Policies and practices must meet regulatory requirements and be aligned with evidence-based guidelines.



Develop a Communication Tool



- Ensure, before it is too late, that the case is scheduled, the vendor is bringing the correct instruments on time, the SPD has adequate staffing and equipment allocation.
- Communication can be in writing (email or communication form) or a scheduled in person “huddle” a day or two before.

In-Service and Annual Competency Assessment

- Review of OEMs IFUs
- Conformity to existing processes
- Necessary consumable accessories
- Education
- Training & competency



Acquisition of Loaned Items...

- Inventory upon receipt
- Inventory intra-operatively & post-operatively
- Inventory upon release/return



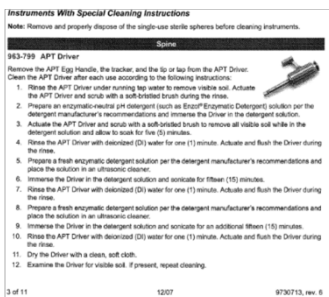
TIME OUT!
All personnel involved in procedure must agree before starting.

<input type="checkbox"/> Correct patient	<input type="checkbox"/> Correct images are displayed if needed
<input type="checkbox"/> Correct side and site marked	<input type="checkbox"/> Correct equipment/supplies/implants
<input type="checkbox"/> Agreement on procedure to be done	<input type="checkbox"/> Antibiotics administered as needed
<input type="checkbox"/> Correct Patient Position	<input type="checkbox"/> Fluids for irrigation
<input type="checkbox"/> Consent Verified	<input type="checkbox"/> Assessed precautions based on medication use or patient history

Signature RN/MD _____ Date/Time _____

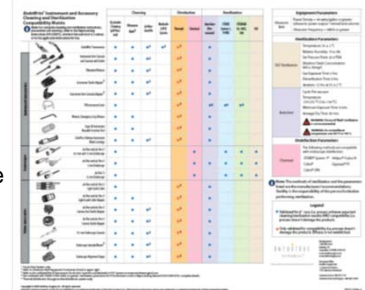
Obtaining FDA Cleared IFU...

Verification of processes required prior to use



Cleaning, Decontaminating, & Sterilizing...

- Establish work instructions
- Performed before each patient use according to device manufacturer's written instructions for use (IFU)



Transporting Processed Loaned Instrumentation to The Point of Use

- Instruments should never be delivered directly to the OR for use!
- All sets must be processed by receiving facility even if delivered "sterile"
- All instruments inspected for cleanliness and functionality and all lumens should be brushed and flushed



Inspection, Packaging and Labeling

- Inspect all instruments for cleanliness, especially lumens
- CIs should be placed on every level of multi-level trays
- Choose appropriate packaging
 - Validated rigid containers
 - Appropriate size and thickness of wrap
- Determine standardized labeling
 - Vendor name
 - Set name
 - Surgeon name
 - Surgery date and time



Sterilization of Loaned Trays

- Follow recommended sterilization parameters from IFU
- Position trays flat
- Follow tray weight limits and total load weight limits
- Conduct product testing
- Load documentation



Quality Management System

- Loaned trays should be part of a facility's Quality Management System
 - Should be included in periodic product quality assurance testing following AAMI/ANSI ST79: 2017, Section 13.9
 - Work with vendors to have sets within recommended weight limits
 - Sets delivered in a timely manner to allow ample time for processing
 - Have manufacturers IFU readily available for staff to follow
 - Identify loaned sets with implants for BI inclusion

Transporting Processed Loaned...

- Following the OEMs IFUs
- Verification of physical, chemical and biological indicators prior to release
- All thrown away when we do not plan for proper transporting to the point of use



Take Steps to Reduce the Need for Rapid Turnaround

- Work with the vendor to ensure enough inventory
- Consider consignment trays
- Identify scheduling conflicts
- Allow SPD enough time to process trays per manufacturer's instruction – NO SHORT CUTS!
- Set up communication between OR/SPD to ensure timely notification of case completion and instrument needs

Post-Procedure Processing

- Follow facility procedure for cleaning and disinfection based on IFU
- Ensure vendor understands outgoing loaned trays will not be given priority processing ahead of facility sets but will be processed in normal turn



Return to Vendor

- Vendor representative- inventory system for completeness
- Vendor representative- signs documentation identifying all items present prior to accepting or shipping the loaned instrument trays
- This should include courier service



Managing Records

- An electronic system is preferred but a manual system can work
- If possible, obtain instruments set count sheets from vendor
- Follow local, state and regulatory requirements as well as facility policy for recordkeeping
- Keep a file of product testing documentation



Loaned Instrument Checklist

- Thorough and easy to use
 - Use for scheduling
 - Compliance with IFU
 - Aid to efficiency

Process Audits and Inspection

- Include loaned trays as part of your Quality Management System
- Perform audits to ensure compliance
- Review cleaning processes to ensure IFU is adhered to
- Review sterilization logs to ensure appropriate sterilization parameters are met
- Retrain as often as necessary
- Celebrate successes!

Other Considerations

- What is unique to your facility's policy on management of loaned instruments?
- When was the last time you read your department's policy?
- When was the last time you read the Manufacturer's IFU?
- Are ALL parties accountable for their respective responsibilities?



Learning Objectives

Upon completion of this program, you will be able to:

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- Discuss the IAHCMM's loaned policy and documents available to support implementing a structured process

IAHCMM Provides Tools to Help

- *Position Paper on the Management of Loaner Instrumentation*
- Loaned Instrument Sample Template and Procedure
- Loaned Instrument Receipt Document
- Follow the link to resources - www.iahcsmm.org

Most Important

- The entire team ensures that appropriate cleaning and sterilization practices are consistently carried out thereby providing the best possible outcome for our patients.
- Patient Safety is Goal #1



Action Items

- Have a thorough policy on the management of loaned instruments developed by a multi-disciplinary team
- Hold all team members accountable for their respective responsibilities
- Complete audits of all aspects of the management of loaned instruments
- Provide continuing staff education and training and competency assessment

References

- American National Standards Institute/Association of the Advancement of Medical Instrumentation. (2017). *ANSI/AAMI ST79:2017 Comprehensive guide of steam sterilization and sterility assurance in healthcare facilities*. Arlington, VA: Author.
- Association of periOperative Registered Nurses. (2017). *Guidelines for Perioperative Practice* (pp. 817, 879). Denver, CO: Author.
- International Association of Healthcare Central Service Material Management. (n.d.). *IAHCMM Position Paper on the Management of Loaner Instrumentation*. Retrieved from: https://www.iahcsmm.org/images/Resources/loaned_Instrument/Position-Paper.pdf

References, continued

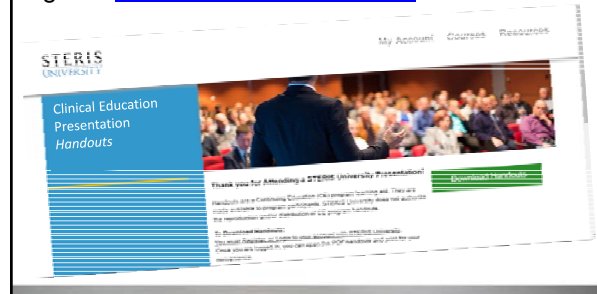
- The Joint Commission. (2016). *Comprehensive Accreditation Manual*. Oak Brook, IL: The Joint Commission Resources, Inc. (JCR).
- Nestman, C., McKinley, M. (2010). Loaner instrument tray management: A shared responsibility. *Healthcare Purchasing News* (January), 32-35.
- Seavey, R. (2007). Loaner instrumentation: Keeping patient safety first! (pp. 78- 92): *Managing Infection Control*.

Questions



Handouts

To access the handouts for this presentation, go to: university.steris.com/loaned



Evaluation and Registration

- Thank you for attending this CE activity
- Please complete and submit the evaluation form



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