Censis™

Navigating Your Way to Successful Loaner Set Management

Effective loaner management starts with communication

Censis Technologies, Inc.
www.censis.com

Table of Contents

Introduction 03

The Loaner Set Journey 05

Obstacles in the Process 06

A Strategy for Success 09

Loaner Policy Checklist 10

Managing Communication Traffic 11

How Automation Supports Loaner Management 12

Road to Success 13

About Us 14

Introduction

With the use of loaner sets in hospitals and surgery centers not only becoming standard practice, but also part of an increasing trend, managing and tracking loaner sets effectively is a major focus of many operating rooms and sterile processing departments.

Proper reprocessing of loaner instruments is critical for infection control, especially in the context of multidrug-resistant organisms, Creutzfeldt-Jakob disease, and bioterrorism threats. Having a clear policy and enforcing it is the first step toward ensuring effective reprocessing. Some of the key steps for effective loaner management are:

- Policy Development and Enforcement
- Education and Training

The following sections will provide information and strategies for managing loaner sets effectively. Use this information to promote policy compliance and ensure the safe and efficient use of loaner instruments in your facility. By focusing on these key areas, healthcare facilities can better manage loaner sets, ensuring safety and compliance in the operating room.

What is a Loaner Set?

Loaner sets are compiled of instrument trays and their components that are not purchased by a facility. Typically, they are used in specialty surgeries like joint surgeries, spinal surgeries, and more. Many of these loaner sets are made up of complex, multiple-level trays, some with nested trays within a level. With a variety of implant devices and frequent changes to sets, hospitals often don't purchase the assets due to cost constraints and lack of storage space. Vendors of specialty implants instead loan facilities the needed instrumentation for specific cases. It is important to understand that the healthcare facility is 100% responsible for the loaner instrumentation and the implants, including the cleaning and sterilization of the sets to fill open head count.

The goals associated with managing loaner trays are fairly universal:

- The tray needs to be delivered to the OR in time for a scheduled case after being properly reprocessed.
- The SPD needs to receive the tray in ample time to properly reprocess the assets.
- Validated manufacturers' instructions for use (IFUs) for reprocessing need to be followed to reduce the chance of surgical site infections.
- All steps in the reprocessing loop need to be well documented.

While these requirements seem straightforward, achieving them is not easy. The challenges that come into play are related to several issues: one department is not in the driver's seat regarding schedules and timelines, every loaner set is unique, and there are strict regulatory guidelines that must be followed. Before exploring potential roadblocks, let's first look at what has to happen for a loaner tray to get to the OR.

The Loaner Set Journey

How does a case involving a loaner set get scheduled?

- The surgeon communicates the need for a specific set to the vendor.
- The vendor representative coordinates with the surgeon's office about the availability of the needed set.
- The surgeon's office schedules the case with the hospital or surgery center and confirms the date with the vendor.
- The loaner set(s) are delivered to the facility by the vendor prior to the case, as well as picked up after the case is completed and the instrumentation has been reprocessed.

What happens when a loaner set is delivered?

- The vendor sets are delivered to hospital's SPD where they are checked in and a full inventory is documented.
- Validated manufacturers' IFUs must accompany the trays and sets.
- If the IFUs involve a new sterilization procedure for the SPD, staff education must be completed.
- The set is inspected for bioburden, debris, and abnormalities. It is then cleaned, washed, sterilized, and assembled.
- The tray is processed according to the manufacturers' IFUs including proper dry time and cooling time.
- The tray is delivered to the OR.
- After surgery, the tray returns to the decontamination area of SPD, where it is washed. A full inventory of the set is completed.
- The vendor picks up the tray from the facility.

Obstacles in the Journey

With and understanding of the loaner set journey, let's take a look at some of the industry related issues that can cause problems or delays in getting a loaner set to the OR on time.

Technology is continuously changing

Technology is always advancing, causing constant evolution of surgical procedures. This creates challenges for hospitals and surgery centers such as:

- The need for continuous education for OR and SPD staff.
- Dependency on the vendor to deliver manufacturers' IFUs for new loaner sets in a timely fashion.
- Longer sterilization times related to set size and density.
- Different processing requirements for components of the same instrument set.

Every loaner set is unique

Continued evolution of instrument sets, combined with changing surgeon needs has led to the creation of trays and sets that have different sterilization requirements. When loaner sets are delivered to facilities, regulatory standards require the facility to sterilize that product according to the manufacturer's IFUs. The IFUs need to be provided to the SPD in advance of the loaner set delivery to ensure the staff is trained and prepared to comply with sterilization requirements. Nothing should be routinely processed without written IFUs that specify acceptable BI and CI results.

Special considerations for sets with implants

An implant is a device that is placed into a surgically or naturally formed cavity of the human body, and is intended to remain there for a period of 30 days or more. The FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also "implants" (FDA 21 CFR 812.3). The concerns with implants are:

- By definition, implants stay in the patient.
- The interrupted blood supply and manipulated tissue around an implant provide microorganisms an easier opportunity of creating a surgical site infection (SSI).

Because of these factors, AAMI and AORN recommend against the use of IUSS for implants (AAMI ST 79, 8.6.2.1). It is also important to always include a biological indicator (BI) test in every sterilization load that includes a tray with an implant. The BI then needs time to incubate, so the results can be verified before the surgical set is released to the OR.

Reprocessing wrapped items

It is a facility's ethical responsibility to ensure surgical instrumentation is:

- Safe to use on patients
- Processed properly with corresponding documentation
- Traceable to the patient

When loaner sets are delivered to a facility, there is no way of knowing how the item was reprocessed after its last use at another facility, or whether or not the set was transported in a controlled environment. Therefore, wrapped instrumentation needs to go through a facility's own reprocessing loop.

Adequate dry time and cooling time

Sterilization cycles include a phase for drying the sterilized product at the end of the cycle. The amount of time needed to dry a particular load depends on the product that has been sterilized. Rushing the dry time for trays after they have been sterilized can result in condensation forming, leading to wet packs. According to AAMI Basic Concepts in Sterilization Process: Verification, Validation and Qualification, the length of dry time is based on:

- The type of product sterilized
- The number of packs or trays in the load The load configuration used
- The device and sterilizer manufacturers' recommendations

Additionally, handling items before they have properly cooled can also lead to contamination issues. A 30-minute minimum cooling time is recommended after drying, but longer time may be needed based on load configuration, ambient temperature and humidity, device design, and packaging used.

Other Potential Reprocessing Detours

- The set not being delivered to the sterile processing department by the vendor in ample time for proper reprocessing to occur with on-time delivery to the OR.
- A loaner set or tray being delivered that is over the 25-pound weight restriction. This requires the SPD to break down the overweight tray into multiple trays, which can affect the sterilization parameters.
- Longer sterilization cycle requirements. Sterilization cycle times are not all the same; they can vary from 4-40 minutes and are specified by the manufacturers' IFUs.
- Procedure-specific loaner sets with multiple trays ranging from 3-25 trays per case. If there is a lack of space in SPD, often the trays have to be stacked. Stacking can lead to damaged container wrapping, which in turn, means that container requires re-sterilization before use.
- Instruments and/or trays found in unacceptable condition upon delivery. All loaner instrumentation and trays must be thoroughly inspected when they are checked into the facility. Rusting or pitting of instruments can impact the efficacy of the sterilization process. If a tray was dropped in transport and cracked or dented, this can also affect the ability to maintain sterility.

A Strategy for Success

When it comes to effective loaner set management, regulatory agencies, including AAMI and the Healthcare Sterile Processing Association (HSPA), recommend having a written policy and then enforcing it.

Some suggestions when developing a policy include:

- Include OR, SPD, Risk Management, Infection Prevention, and your surgeons in the creation of the policy.
- Incorporate SPD notification of scheduled cases prior to delivery of loaner sets.
- Require FDA-cleared manufacturers' IFUs to be provided with every set, preferable ahead of loaner set delivery to allow time to ensure staff competency.
- Include delivery timeline that ensures enough time for proper reprocessing.
- Include method of tracking compliance.
- Consider including consequences for non-adherence; i.e. if vendors do not comply with delivery timelines.

Loaner Policy Checklist

When developing a loaner policy, be sure to collaborate with vendors, surgeons, OR & SPD staff, Infection Prevention, and Risk Management. The policy should address the following:

- ☐ Ordering.
- ☐ Transporting instruments.
- ☐ Checking instruments in SPD.
- ☐ Pre-procedure processing.
- ☐ Charging (if applicable).
- ☐ Post procedure processing.
- ☐ Checking instruments out.
- ☐ Transporting instruments out.
- ☐ Accountability.
- ☐ Record keeping.
- ☐ Instrument delivery with sufficient time to permit facility disassembly, cleaning, packaging, and sterilization.
- ☐ Inventory list.
- ☐ Manufacturing reprocessing instructions.
- ☐ Date and time received in facility.
- ☐ Quality checks.
- ☐ Cleaning and decontamination after use.
- ☐ Maintenance of complete records.
- ☐ Items received as single use devices (SUD) from the vendor.
- ☐ Arrangement for replacement of any damaged or lost instruments.

Managing Communication Traffic

The one thing that a loaner policy typically can't fix completely is helping with the communication challenges that result from having multiple departments involved in a process. The good news is that, as the SPD moves from a manual to an automated environment, there are solutions available that bring visibility of the loaner tray journey to the OR.

When considering loaner management automation, there are a few points to keep in mind: Choose a system that can help reinforce your facility's policy.

Make sure a system includes reporting to provide feedback to all parties invested in the process:

- Vendor
- Surgeon
- SPD
- OR

Don't focus on just one side of the loaner tray journey. There are hybrid solutions that help with pieces or parts of the loaner management process, but don't necessarily give all the parties involved visibility to each step. A better solution is one that gives everyone involved visibility to exactly where things are throughout the process.

How Automation Supports Loaner Management

- Provides date and time stamps for loaner set delivery check in and check out with reporting.
- Captures photographs of sets when they are checked in and checked out, so there are no discrepancies between the vendor and facility related to what was delivered and returned.
- Provides appropriate visibility to all parties invested in getting the loaner set to the OR for each step in the loaner set management process. (Eliminates time- consuming phone calls between departments.)
- Provides reliable, paperless record keeping associated with reprocessing steps and testing, that is easily retrievable and traceable to the patient.
- Significantly reduces the amount of time SPD staff spend on the loaner management process.

Road to Success

For all the reasons highlighted in this eBook and more, loaner set management is a challenge for many hospitals and surgery centers. Processes that work for one facility may not necessarily work at another, so it is important for each facility to develop a customized policy, collaborating with all parties invested in the process. Having good communication and visibility to where a loaner set is in the process can save time and avoid frustrations and delays.

If your management process ensures that proper reprocessing is done at your facility in compliance with regulatory guidelines, that the sterilization process is accurately documented, and you have very few case delays related to late delivery, then you have successfully arrived at your destination!

References:

ANSI/AAMI ST79:2010. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Association for the Advancement of Medical Instrumentation. Arlington, VA; 2010.

Recommended Practices for Sterilization in the Perioperative Practice Settings. In" Perioperative Standards and Recommended Practices. Denver, CO; AORN, Inc., 2011.

U.S. Food and Drug Administration, cite: 21 CFR 812.3, April 1, 2015. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.3.

Censis™

About Us

As the first company to engineer a surgical asset management system that tracks down to the instrument and patient levels, Censis Technologies has continually set the standards for perioperative operation.

More than 1,300 hospitals benefit from our one-of-a-kind solutions and clinical services. From tracking individual surgical instruments and sets to overseeing endoscopy workflows and managing vendor loaner inventory, Censis keeps facilities connected with precise, critical data that drives actionable intelligence, positive outcomes, and results.

Learn more about the Censis product portfolio at **www.censis.com.**