Introducing New Instruments: Proactive Steps for Safety and Success

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LEARNING OBJECTIVES

1. Discuss the planning process when new instruments are evaluated and considered
2. Understand the risks associated with inadequate instrument information
3. Answer critical questions when introducing a new device or instrument system and describe Sterile Processing team members' role when new devices are considered or added

Most surgical instrument inventories contain thousands of devices. Each can aid in treatment and care—but can also malfunction and contribute to patient injury or infection. New instruments are introduced into the system frequently, and every Sterile Processing (SP) technician must know how to process them correctly. Proactive planning is essential for ensuring all technicians who handle instruments understand what is required to handle and process new and existing devices safely, consistently and according to the manufacturers' instructions for use (IFU).

This lesson identifies effective ways to ensure all technicians have the information, training, equipment and supplies to manage new instruments before they are acquired and placed into service.

Objective 1: Discuss the planning process when new instruments are evaluated and considered

Before a new instrument enters the facility's inventory, a plan should be in place to help ensure that adequate information and appropriate training and equipment are available to allow safe, effective processing. A proactive process is essential to ensure that IFU are carefully reviewed and can be followed before a new device is purchased.

Processing areas must have the proper chemistries, decontamination processes, testing supplies and packaging and sterilization methods available. If the facility lacks the equipment, chemistries and supplies required in the device manufacturer's IFU, the facility will either have to obtain them and ensure

technicians are trained to process the device in strict alignment with the IFU, or consider an alternative device.

Once the decision has been made to add a new instrument to the inventory, the SP team should be notified immediately. Staff notification should include an estimated date for the instrument's receipt, training should be scheduled, and the instrument information system should be updated. Without such due diligence, challenges will likely arise when the instrument is introduced, which could contribute to procedural delays and other negative patient outcomes.

Objective 2: Understand the risks associated with inadequate instrument information

There is no single processing method for surgical instruments; each has its own specific IFU, even if devices appear quite similar. In the past, some guesswork was common for instrument processing, and different facilities and processing areas often followed different processes. Fortunately, that came to an end when the U.S. Food and Drug Administration (FDA) began requiring facilities to follow written, manufacturer-provided cleaning, decontamination, inspection, high-level disinfection or sterilization steps that were validated by the manufacturer and cleared by the FDA. All instrument processing procedures and protocols must follow the manufacturer's IFU.

When instruments are not processed according to their IFU, the risk of cleaning, inspection and sterilization failure increases, along with opportunity for patient injury. In addition to patient safety concerns, improperly processed devices can require costly repairs and premature replacement. Diligent adherence to IFU is vital for patients and the healthcare organization.

Objective 3: Answer critical questions when introducing a new device or instrument system and describe Sterile Processing technicians' roles when new devices are considered or added

When a new instrument is introduced, SP professionals should know as much as possible about the device before they are expected to handle and process it. SP leaders and technicians should ask numerous questions such as:

- What is the instrument's name?
- How will the device be used (what is its intended purpose)?
- Which specialty or surgeon will use this instrument?
- Will the instrument be dispensed singly or as part of a set or tray?
- Does the instrument replace another device?
- Does the instrument come in specific sizes, styles, etc.?
- How is the device disassembled?
- Are there any disposable components?
- What manual cleaning or other preparation is required?
- What mechanical cleaning is needed?
- Are there special handling instructions?
- How should the instrument be inspected or tested?
- How should the device be arranged or assembled?
- How should the device be packaged?
- How should the device be sterilized?
- Where will the instrument be stored?
- How many of the new devices are in the system?
- What should be done if the instrument is missing or defective (i.e., is there a back-up device that can be used instead)?

All these questions and any others should be addressed during technician training, and their answers should be included in procedures and readily accessible for all SP staff.

Sterile Processing departments (SPDs) function best when everyone is informed, confident in their roles and responsibilities, and provided proper training, equipment and IFU. SP scheduling and shift rotation takes extra effort to ensure that every team member is informed and able to keep up with device and equipment changes. It is rare when all staff members are present at one time; therefore, lead technicians, supervisors or managers must ensure that technicians across all shifts receive the same information and support.

Even with proper training, tools and written IFU, SP professionals should aim to help one another become more comfortable with new devices, equipment and processes. Answering questions, identifying challenging processes that could benefit from additional training, demonstrating how a new device should be handled, processed and managed, assisting with new tray assembly and providing additional support as needed will reduce the risk for errors, frustration and negative patient outcomes.

Conclusion

As medical technology and procedures advance, new instruments will be developed and enable surgeons to perform more sophisticated and advanced procedures. Before the new instruments can be put into

use, however, it is essential to first ensure that SP professionals have the technology, IFU, chemistries, supplies and training to process them safely and consistently and according to the manufacturers' written instructions. Only when that level of support is provided can technicians ensure that the devices are processed correctly and functioning properly for the procedure. P

RESOURCES

1. *Instrument Resource Manual*, first edition. Chapter 3, p. 18. "Considerations Before Instrument Purchase." HSPA.
2. *Guideline for cleaning and care of surgical instruments*. In: Guidelines for Perioperative Practice. Association of periOperative Registered Nurses.

CIS Self-Study Lesson Plan Quiz: Introducing New Instruments: Proactive Steps for Safety and Success

Lesson No. CIS 306 (Instrument Continuing Education – ICE) · Lesson expires December 2027

1. What is needed for the successful introduction of a new instrument?
   a. A proactive planning process
   b. A cost-effective purchasing program
   c. A specific person responsible for the purchasing decision
   d. All the above

2. An effective instrument system should involve:
   a. Reviewing the instrument and processing information before the purchase is made
   b. Obtaining valid instructions for use (IFU)
   c. Determining that the proper equipment, supplies and processes are available and understood
   d. All the above

3. When the decision is made to purchase a new instrument:
   a. The surgeon should train the processing technicians how to handle, disassemble and process it
   b. The surgeon should be immediately informed by the most senior processing technician of the anticipated receipt date
   c. Sterile Processing professionals should be properly trained to ensure they can process and manage the device safely and effectively
   d. The instrument should be standardized throughout the facility

4. When instruments are not processed according to the manufacturer's IFU:
   a. Instrument processing times may decrease
   b. The risk of sterilization failure increases
   c. More efficient methods may be discovered
   d. None of the above

5. When change is managed as a team:
   a. More technician training occurs
   b. Everyone on the team understands the entire process
   c. Tray assembly always becomes easier
   d. There is a reduced risk for error

6. To help ensure all team members stay informed about new device additions or changes:
   a. A sign-in sheet should be maintained for each shift to document employees' understanding of the new device and processes
   b. Employees should help each other keep abreast of the changes
   c. A mandatory one-day inservice should be scheduled and required for all staff members
   d. The device manufacturers should teach the staff about the change and test their competency

7. If a Sterile Processing department (SPD) does not have the required equipment to process a new instrument:
   a. A plan for manual cleaning should be developed
   b. The manufacturer should train the staff on alternative processing methods for the instrument
   c. The proper equipment should be purchased prior to the new device being placed into service and processed
   d. The instrument should be processed by following a similar device's IFU

8. Which agency requires specific manufacturer's IFU be developed for instruments?
   a. The Joint Commission
   b. U.S. Food and Drug Administration
   c. Association for the Advancement of Medical Instrumentation
   d. Centers for Disease Control and Prevention

9. Technicians should ask and receive an answer for which of the following questions before processing new items?
   a. Does the new instrument replace another instrument?
   b. Which technician and shift will process the instrument?
   c. Will the instrument arrive sterile?
   d. Can the device undergo immediate use steam sterilization?

10. The SPD functions best when:
   a. IFU are computer-based and updated annually
   b. Changes and the introduction of new instruments are infrequent
   c. Everyone on the team is informed
   d. Instrument technicians take the lead on new processes

11. When a new device is introduced, SP staff members can help each other by:
   a. Allowing co-workers to take more breaks
   b. Becoming responsible for a co-worker's most challenging duties
   c. Assisting the SP manager with planning and the development of new policies and procedures
   d. Demonstrating how a process should be performed

12. It is not typically necessary for SP technicians to know the name of the new instrument.
   a. True
   b. False

13. Instruments that look similar:
   a. May have different IFU
   b. Can be processed the same way
   c. Can often be cleaned the same but will have different sterilization instructions
   d. None of the above

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