PREPARATION OF INSTRUMENTS FOR PACKAGING

INSPECTION OF INSTRUMENTS

Preparing surgical instruments for packaging includes inspection for cleanliness, functionality, and completeness (instruments should not be missing screws, attachments, or other parts). It is unacceptable to find soiled instruments or tissue fragments (e.g., bone) in sets sent to the OR because inspection of instruments during assembly is required. Furthermore, such an event represents a departmental systems failure because the device passed through the decontamination area as well as the preparation and packaging area without the defect being detected. If a soiled instrument or tissue fragment is found in a set, OR personnel must break down the entire table, which is costly and time-consuming and affects the care of the patient. As stated previously, all instrumentation should be inspected using a lighted magnifying lamp to visualize defects and limit eye fatigue. Instruments with defects (Figure 8-40) also cause delays in the OR, which can have an impact on patient care. Later in this chapter, specific information will be provided on the types of inspection and testing that should be performed for various types of instruments and devices.

Figure 8-40 — Part of jaw missing from hemostat (found in sterile wrapped set)

ORGANIZATION OF INSTRUMENTS

Instruments can be packaged singly (usually in paper–plastic pouches) or organized into small procedure trays or larger instrument sets. Procedure trays and instrument sets are either wrapped or containerized.

COUNT SHEETS

When placing instruments into a set, personnel should use a count sheet (also called a tray list), which is used to ensure the accuracy of the set (i.e., that there are the correct number and types of instruments). The count sheet should include the correct names and sizes of the instruments (e.g., 4-inch curved mosquito clamp), the quantity, the manufacturer, and a catalog number. These details are critical to the correct construction of an instrument set and will assist in identifying instruments for replacement, when necessary. Another reason why the accuracy of
the SPD count is important is that the OR and Labor and Delivery use the sheet to verify the instrument count at the beginning of a surgical procedure. If the SPD count is incorrect, the OR or end user must recount the instruments, delaying the case.

Count sheets, which are formulated by the customer who uses the sets, must be updated each time a change of instrumentation occurs. All such changes must be communicated promptly to SPD. There should be a written policy and procedure identifying who in the using department has the authority to change count sheets and who is responsible for making those changes. Set contents should be reviewed routinely to ensure that all instruments are still needed and in the specified quantity (e.g., the number of hemostats might be reduced from eight to four). Including only those instruments needed for the case reduces the amount of time needed to prepare the set in SPD and to count the instruments in the using department.

Using count sheets promotes accountability, prevents delays in surgery because of missing instruments, and, when missing instruments are noted, helps enhance quality improvement. Markers with permanent, non-toxic ink should be used to write on count sheets or tray lists. Table 8-2 is an example of an instrument count sheet.

<table>
<thead>
<tr>
<th>ID:</th>
<th>Gen</th>
<th>Tray:</th>
<th>Gen/Gyn Bookwalter retractor Part II Table Post</th>
<th>Circ:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>12/31/07</td>
<td>Assembled by:</td>
<td>Scrub:</td>
<td></td>
</tr>
<tr>
<td>Qty</td>
<td>Catalog number</td>
<td>Vendor</td>
<td>Instrument description</td>
<td>SPD</td>
</tr>
<tr>
<td>1</td>
<td>50-4552</td>
<td>Codman</td>
<td>Horizontal bar</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>50-4581</td>
<td>Codman</td>
<td>Table post</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>50-4582</td>
<td>Codman</td>
<td>Horizontal flex (movable) bar</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>Codman</td>
<td>Oval ring</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>50-4554</td>
<td>Codman</td>
<td>Post coupling</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>110-165</td>
<td>Jarit</td>
<td>Knife handle #3</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td>TOTAL PIECES</td>
<td></td>
</tr>
</tbody>
</table>

A very small FDA-sponsored study revealed little evidence of toxicity from count sheets placed inside sets (Lucas, et al., 2009), but limited types of toners and only one type of paper were used. In addition, the study did not evaluate whether debris from the paper remains on the instruments or builds up inside the sterilizer chamber. AORN’s latest guideline on packaging states as follows: “The healthcare organization should weigh the risks and benefits of placing a non-validated product (i.e. count sheet) in instrument trays against the need for inventory control and instrument count procedures. Although there are no known reports of adverse events, related to sterilized count sheets, there is limited research regarding the safety of toners and various papers subjected to any sterilization method. Chemicals used in the manufacturing of paper and toner ink pose a theoretical risk of reaction in some sensitized patients. A limited study . . . found that label and toner inks transferred to instruments during sterilization were not cytotoxic.” (AORN, 2016b)

Count sheets can be placed internally (Figure 8-41) or externally (Figures 8-42 and 8-43) in/on trays and wrappers. They can be wrapped in a non-linting towel, an autoclaveable bag (Figure 8-44), or a disposable tray liner for internal use or in a count sheet holder for external use.
Some count sheet holders are reusable; check the manufacturer’s IFU. Only reusable towels that have sterilization instructions should be used.

![Figure 8-41 — Count sheet inside non-linting towel inside tray](image1)

![Figure 8-42 — Count sheet placed in count sheet holder attached to the outside of a rigid container](image2)

![Figure 8-43 — Count sheet placed in count sheet holder outside wrapped tray](image3)
It is important for processing personnel to verify the accuracy of the number and type of instruments placed in the set. Inaccurate counts can delay cases in the OR because of the need to obtain another set (which will increase the workload of processing personnel) or to locate a sterile replacement instrument. The OR staff depends on processing personnel to provide them with a clean, sterile, and accurate set of instruments; otherwise, the delivery of patient care can be delayed or compromised.

INSTRUMENT LOSS

Instrument loss is a major financial burden for a healthcare facility. As part of good instrument inventory management, surgical instruments and devices should be accounted for by every department. Each department is responsible for accounting for instruments at the end of each procedure. There should be a process to ensure that each using department is accountable and can document that all instruments were returned to SPD.

For the following reasons, it is not recommended that SPD personnel count instruments in the decontamination area:

- It increases the likelihood of an exposure to bloodborne pathogens as a result of a puncture injury (and is thus inconsistent with OSHA requirements).
- It increases the workload in the decontamination area, delaying processing and increasing instrument turnaround time.

It is the responsibility of each using department to ensure that instruments are not damaged or lost. Instrument sets should be kept together at the end of the case/procedure and placed back into their respective containers or baskets. This simple task reduces the time that personnel must spend looking for instruments and making up sets. There should be a system for documenting missing instruments (Table 8-3) and for following up with using departments.

In SPD, it is important to ensure that instruments are placed into the correct sets after the cleaning, decontamination, and assembly processes. Because instruments might be separated for the cleaning process, there should be a system for identifying which instruments belong to which sets. Individual baskets can be numbered, waterproof tags can be applied, or a colored chip can be placed in the baskets to indicate which instruments belong together (e.g., all baskets containing chips of the same color belong together when removed from the washer—
decontaminator). This procedure will save time for preparation and packaging personnel when they are assembling instruments into specific sets. For any products used to keep sets together, the manufacturer should be consulted to ensure that they are water-resistant and validated for use in ultrasonic cleaners and mechanical washers.

For instrument sets processed for ancillary departments (e.g., the catheterization lab), it is helpful to have an inventory list to document the sets dropped off and their contents when received and when returned. A three-part form is recommended. When trays are dropped off, a list of trays, identified with the date and department, is recorded. This form remains in the decontamination area. The quantity of trays or single instruments should be verified. The remaining two copies of the form are kept in the preparation and packaging area and are used to track the sets through preparation and sterilization. The final copy is placed with the items; when the items are picked up by or delivered to the using department, the copy is signed to acknowledge receipt. This simple system (similar to that used by dry cleaners) is helpful in keeping track of the multitude of instruments and devices processed daily by SPD.

Many SPDs are purchasing surgical instrument tracking systems to make instrument accountability and patient traceability easier. If a tracking system is not available, a form or spreadsheet for manual tracking of missing instruments can be easily created; this form can include costs associated with instrument loss and can be reviewed with the heads of departments where losses are occurring. Table 8-3 is an example of an instrument loss form.

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Name of set or tray</th>
<th>Set or tray number</th>
<th>Missing item (listed separately)</th>
<th>Catalog number</th>
<th>Vendor</th>
<th>Name of person called</th>
<th>Action taken</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
</tr>
</tbody>
</table>

Four major factors are associated with missing instrument problems:

- Poor or lacking communication between the OR and SPD
- Personnel considerations (are SPD personnel trained in the identification, care, handling, inspection, and testing of surgical instruments?)
- Operations (e.g., the use of correct and accurate count sheets; traceability to the preparer of the set)
- Administrative issues (policies and procedures for the process and support for SPD for needed processing equipment and staffing)
There must be accountability for instrumentation throughout the use cycle. The OR, SPD, and all personnel must be responsible for instrumentation. There is no black hole . . . the instruments are going someplace.

![Figure 8-45 — Instruments in syringe container](image)

![Figure 8-46 — Instruments returned from laundry](image)

All like sets that will be wrapped should also be numbered sequentially for quality assurance and for accurate recording of sets in a sterilization load. The basket or tray should be labeled with a bar code label from a tracking system, or the label should written on the basket with an approved marker (see section on labeling sets). If there is a problem with the set, the specific set can be retrieved to correct the problem.
All assembled sets should be complete and all instruments functional. If an item is missing from a set and a replacement is not available, the service leader or OR manager should be consulted to see if the tray can be assembled without the needed item(s). Some facilities indicate essential items for sets by placing an asterisk (*) next to the item on the count sheet or predetermine that certain trays should be processed even with instruments missing. Whenever items are missing from a set, the outside of the set should be labeled to alert OR personnel, who might wish to use another set or to see if a single wrapped replacement is available (Figure 8-47). This notification can be in the form of a preprinted label, or it can be provided on the sterilization tape. A list of missing instruments should be maintained so that when an instrument is found or a replacement is obtained, it can be added to the tray or set to which it belongs. There should be a policy stating the action SPD is to take when an instrument is missing and cannot be found. Should the tray be processed anyway? Should the tray be held? Who will order the replacement instrument? Whose budget will be charged for the replacement?

Incomplete sets have a direct impact on the operating room and patient safety. Not having the items necessary to complete a procedure puts the patient at risk, delays the procedure because of the time needed to get a replacement to the OR, and causes physician dissatisfaction. Correctly entering the quantities of each individual instrument on the count sheet, manually or by computer, is important. The proper procedure is to place the item on the set and then record it on the count sheet or in the computer — one at a time, not all at once at the end of assembly. In a computerized system, the computer will print out a label sticker identifying the missing items. The SPD management should communicate daily with the OR to identify any missing items so that the items can be replaced in a timely manner.

![Figure 8-47 — Label for an incomplete set](image)

**ASSEMBLY OF SETS**

**General Procedures:** Instruments and sets should be assembled according to AAMI standards; for example, all instruments, including towel clips, should be in the open position when placed in the set or tray (Figure 8-48). Stringers or pins can be used for this purpose; however, the stringer must be wide enough to keep the jaws of the strung instruments sufficiently open to permit sterilant contact with all surfaces of the jaws or blades. When a stringer is used, all instruments should curve in the same direction (e.g., to the left). In small procedure trays, instruments can be kept open by stringers or by folding a towel and making a pocket or cuff (Figure 8-49). Several manufacturers have developed devices that can be used to keep an instrument in an open position when packed in a paper–plastic pouch. To prevent damage to delicate instruments, heavier instruments should be placed on the bottom of the set, and lighter, more delicate instruments should be placed on top. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled unless the device manufacturer provides specific written IFU, supported by test data, to the contrary.
Basins or bowls should not be placed in surgical instrument sets, as shown in the figure below. For sterilization to occur, the sterilant must contact all surfaces of the instruments being sterilized; in Figure 8-50, the basins block direct contact. It is acceptable to place small bowls or cups in floor (procedure) trays because the utensils can be held in place with surgical towels, which are usually a component of the tray.
It is important to ensure that all devices in the set can be sterilized at the same exposure time and in the same type of sterilization cycle (e.g., gravity-displacement or prevacuum steam sterilization). The device manufacturers’ instructions for assembly and for sterilization exposure times should be followed. Exposure times can vary greatly depending on the design or configuration of the set, so SPD must comply with manufacturers’ recommendations.

Instruments are usually relatively dry when they are removed from mechanical washers. However, it is important to ensure that there is no excess moisture in sets to be steam sterilized (because wet packs can occur). All excess moisture must also be removed from sets that are to be sterilized by low-temperature sterilization processes (e.g., EO, hydrogen peroxide gas plasma). (This is especially important when lumened instruments are part of the set.) AAMI recommends the use of “medical air” for the drying of instruments. A medical air compressor is a “compressor that is designed to exclude oil from the air stream and compression chamber and that does not, under normal operating conditions or any single fault, add toxic or flammable contaminants to the compressed air” (Baer, 2016). The use of multi-purpose “duster type air” (used to clean computer keyboards) or nitrogen is not recommended.

**Instrument Air (formerly called instrument or medical air):** After publication the Association for the Advancement of Medical Instrumentation (AAMI) clarified which type of air should be used to dry items prior to sterilization or to “blow” out debris from lumens. The term medical air is now being replaced with the term “instrument air”. Instrument air is defined as a medical gas that falls under the general requirements for medical gases as defined by the NFPA 99: Health Care Facilities Code, is not respired, is compliant with the ANSI/ISA S-7.0.01, Quality Standard for Instrument Air, and is filtered to 0.01 micron, free of liquids and hydrocarbon vapors, and dry to a dew point of -40º F (-40º C).

**Wrapped Sets with Large Numbers of Instruments:** Instruments sets containing large numbers of instruments should be placed in a perforated metal mesh basket. The perforated basket should be placed flat in the sterilizer, which prevents damage to instruments. Non-perforated trays (or Mayo trays with small holes) should be used only for sets containing a small number of instruments. Such trays are ideal for procedure or floor trays such as cut-down trays, which have a limited number of instruments and contain towels that can be used to hold the contents in place. These trays must be tilted on edge (tilted forward) when placed in the sterilizer. The use of other devices for instruments sets, such as rectangular metal pans, should be avoided because of drying difficulties.

For trays that will be wrapped, a non-linting surgical towel or a commercially available tray liner placed in the bottom of the metal tray or basket will create a space between the metal tray or basket and the instruments, help absorb moisture (act as a wick), and prevent the instruments from poking through the basket. A non-linting towel or a medical-grade paper liner placed between layers of instruments will facilitate drying and protect instruments from damage (Figure 8-51). A towel can also be placed between the tray or basket and the wrapper to prevent tears in the wrapper because of sharp edges or corners. (Be sure to inspect the towel for any foreign material that could be present; see Figure 8-52 for an example.) Silicone mats with “fingers” are sometimes used to line trays as a means of protecting instruments; these mats might retain moisture. No other type of packaging material should be used to line trays or baskets or placed between layers of instruments. Other types of packaging materials will not absorb excess liquid; instead, they could cause liquid to pool and create a wet pack that will not be evident until it is opened.
NOTE: Whatever products are used in trays to reduce moisture or prevent instrument damage, it is important to ensure that the product is suitable for the intended purpose. The manufacturer should supply documentation regarding the sterilization methodologies for which the product has been validated. It should also be noted that surgical towels that have not been laundered properly have been shown to cause issues with instrument staining.

Figure 8-51 — Medical-grade paper liner

Figure 8-52 — Gum found in laundered towel

The size of the instrument set, the placement of instruments within the set, and the density of the wrap selected will affect sterilization and drying. Instruments should be evenly distributed within the tray. Too many heavy or large instruments in one area can create extra condensation and make drying more difficult. AAMI recommends that surgical instrument sets not exceed a maximum weight of 25 pounds (11.4 kg) (ANSI/AAMI ST79, ANSI/AAMI ST77). This recommendation is based on ergonomic considerations (the ability of personnel to lift the set without injury) and SPD’s ability to effectively dry the set. Most rigid sterilization container manufacturers have validated their containers only for 16 to 25 pounds (7.3 to 11.4 kg) of instruments (not including the weight of the container). AORN (2016d) recommends that the weight of instrument sets be limited to a maximum weight of 25 pounds (11.4 kg). For loaner sets, AAMI recommends a maximum weight of 25 pounds, including the weight of the container (ANSI/AAMI ST79, ANSI/AAMI ST77).
As noted earlier in this chapter, the predominant use of single-use wrappers has increased the potential for packaging integrity to be compromised. Commercially available single-use or reusable “corner protectors” can be used in place of a towel or tray liner between the tray and the wrapper (Figures 8-53 and 8-54). Corner protectors help prevent holes, rips, and tears in sterilization wraps caused by the weight of the set or by sharp corners or protruding “feet” on the bottom of the set. Some of these devices can resist flattening when placed under heavy trays. Using corner protectors does not negate the need to comply with the AAMI- and AORN-recommended 25-pound weight limit for sets. Such devices just provide added protection for specialty trays. Reusable corner protectors are multi-use and provide a greater level of protection. There are cost-saving opportunities over time in terms of generating less waste material and reducing labor and time for waste management and transport.

For any type of corner protector, it is important to obtain and follow the manufacturer’s instructions for use, including the recommended sterilization cycle parameters for which the device has been validated. The policy and procedure manual should address whether corner protectors are used, whether they are single-use or reusable, and, for reusable corner protectors, the procedure for returning them to SPD for reprocessing. For reusable corner protectors, the policy and procedure manual should also address whether there is a restriction on the number of reuses and, if so, how the number of reuses will be tracked.

Figure 8-53 — Reusable corner protectors on tray

Figure 8-54 — Reusable corner protector
Heavy individual items having a large metal mass (e.g., weighted vaginal specula) should be wrapped in an absorbent material, such as a non-linting surgical towel or medical-grade paper liner, to absorb moisture and enhance drying. The instrument configuration in the set should promote drying. Instruments should be equally divided in the set and arranged throughout the tray.

Figure 8-55 — Weighted vaginal specula

**Floor Trays:** A floor tray permits the physician to perform a procedure (e.g., a cut-down) on a nursing unit. The tray contains instruments and supplies for an entire procedure. The contents of the trays are developed and updated routinely with nursing personnel. Floor trays should be prepared using a “recipe card” that identifies the contents, which usually consist of items for skin preparation (paint cup, cotton balls, sponge stick) and local anesthesia (needles, syringes), as well as surgical instruments (e.g., knife handle, blade, clamps, scissors, needle holder, probe). In addition, the tray should contain a surgical drape and surgical towels; if the drape and towels are reusable, they should be freshly laundered and non-linting. The tray might also contain gauze and cotton balls. It is important that any nonsterile items being placed in the tray be sterilizable (check with the product manufacturer). After sterilization of the tray, sterile items such as suture, chest tubes, and gloves can be placed in a plastic bag labeled with the tray name, then attached to the outside of the sterilized tray. Then the tray and plastic bag can be placed inside a dust cover.

The procedure for assembling floor trays is basically the same as for instrument sets in general: All instruments should be placed on a stringer to ensure that they stay open during the sterilization process. However, many floor trays contain only a few instruments. In those cases, it is acceptable to create a pocket or cuff from a surgical towel, placing one finger ring inside the pocket and the other outside the pocket to keep the instrument open. See Figure 8-49.

When floor trays are opened but not used and then returned for reprocessing, all disposable items (e.g., gauze sponges, cotton balls) must be discarded and replaced with new ones. The gauze and similar products should be nonsterile when placed in the tray. Sterile gauze and similar components should never be opened and then resterilized in the set. The instruments should be completely reprocessed. If the set requires single-use needles and syringes, the manufacturer should be consulted about whether they can be opened and resterilized. If not, they should not be placed in the set.
**NOTE: The Quiz for this topic is given AFTER you complete Module 20.

Please click on the link below to go to Module 20.

https://www.spdceus.com/modules/sixth/tech/module20_pay.htm