Packaging Systems for Central Service Operations

LEARNING OBJECTIVES
1. Review the three basic types of packaging systems and explain the objectives of all packaging materials
2. Describe basic processing protocols for peel pouches, woven or non-woven material wrappers, and rigid containers

PREVENTING WOUND INFECTION BEGINS BEFORE THE PATIENT reaches the Operating Room (OR). Delivery of sterile surgical instruments to the OR is one of many processes performed by Central Service (CS) personnel each day. After their delivery, OR nurses depend on the consistency of the packaging systems to facilitate the ease of opening and transfer of their contents to the sterile field. The sterility and the integrity of the packages are verified at the point of use before the surgeons receive them.

OBJECTIVE 1: REVIEW THE THREE BASIC TYPES OF PACKAGING SYSTEMS AND EXPLAIN THE OBJECTIVES OF ALL PACKAGING MATERIALS
There are three basic methods of packaging systems used to maintain, store and transport sterile surgical instruments: peel pouching, woven or non-woven material wrappers, and rigid containers. The selection of the packaging system primarily depends on the sterilization method, size and weight of contents, and user preference. Note: the latter may include ease of storage and removal at the point of use, and cost-effectiveness.

There are four primary objectives for all packaging materials:
- They must allow penetration of the chosen sterilant and be compatible with any other requirements of the sterilization process.
- They must be able to maintain the sterility of package contents until opened.
- They must create a package that can be opened without contaminating the contents by the user.
- They must permit the contents to be sterile at the point of use.

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Regardless of the packaging system used, proper storage and handling is necessary to maintain content sterility. The packaging system should be “tamper evident” so a package opened in error cannot be resealed without complete reprocessing. Storage room temperature should be 75°F (24°C) or less with humidity less than 70%.

**OBJECTIVE 2: DESCRIBE BASIC PROCESSING PROTOCOLS FOR PEEL POUCHES, WOVEN OR NON-WOVEN MATERIAL WRAPPERS, AND RIGID CONTAINERS.**

**PEEL POUCHES**

Peel packs are pouches used to hold items during sterilization. Different pouch construction materials may be required to accommodate available sterilization processes. Not all pouches can be utilized in all types of sterilization processes. Plastic/paper peel pouches are used with steam sterilization. The plastic side of the pouch allows for direct visualization of the contents and chemical indicator. The paper side allows for air removal and the sterilant to enter the pouch. Figure 1 shows a photo of an instrument in a self-seal pouch.

Tyvek is a brand name for a peel pouch used with hydrogen peroxide gas plasma sterilization; however, these pouches cannot be used in steam sterilization because they will melt.

Pouches are used only for small, lightweight, low profile items. If the instrument appears to be too heavy or large for peel packaging, another packaging method should be used.

The peel pouch should be large enough to allow the instrument to move from side-to-side and not compromise the seams by over-stretching the material. Important note: the proper size for a single or double peel package should have ¼-inch clearance on all sides of the package. Curved instruments should be placed with the curved end toward the plastic side of the pouch to avoid punctures though the paper side. Placing instruments with handles toward the pre-sealed end allows the scrub person at the sterile field to easily remove the instruments when opening the pouch. If instruments have sharp tips, clear-vented tip protectors should be used to prevent punctures through the pouch.

Before sealing, excess air should be removed from the pouch. The peel pouch is either self-sealed or manually heat-sealed when the instrument is packaged. When using self-sealed pouches, the fold lines provided by the manufacturer should be strictly followed to prevent overlapping and small openings between the package and the sealant. Also, the seal's fold should be free of wrinkles or creases.

If the peel pouch is heat-sealed, the instructions including proper temperature ranges provided by the heat sealer's manufacturer should always be followed. Note: sealing temperatures are affected by the type of pouch being sealed (e.g., Tyvek pouches require a lower temperature range). When manually sealing a pouch, ensure that there is ample space at the end of pouch for users to use their thumb to open the package and present its contents aseptically to the sterile field. This will prevent the pouch from ripping in a way that contaminates the contents during delivery. Some peel pouch manufacturers provide a printed picture on the pouch to indicate which direction the pouch should be opened.

OR personnel typically prefer double-pouching of multiple instruments because the inner pouch keeps the instruments together when opened onto a sterile field. Double pouches also allow
Peel pouches should be labeled with a permanent marker or another labeling technique that is approved for the sterilization process that is used. Petroleum-based inks used in most ball point pens or wax markers are not recommended for labeling of packages before or after sterilization. Information about the item, storage location, date wrapped, and package assembler’s name (or initials, according to facility’s policy) should be included on the plastic side of the pouch package.

Peel pouches should be labeled with a permanent marker or another labeling technique that is approved for the sterilization process that is used. The reason: sterility is compromised if instruments slide to the side when the pouch is opened because the seal edges of the pouch exposed when opening the pouch are not considered to be sterile. If double-pouching is used, each peel pack should be sealed separately, and the paper side of the inner pouch should be placed toward the paper side of outer pouch. Doing so enables the sterilant to enter through the paper side of the pouch. Writing on the paper side of the pouch can compromise package sterility. Plastic paper pouches should not be used within wrapped sets or rigid containers because the pouches may be positioned in a way that interferes with air removal, sterilant contact and drying.

NONWOVEN OR WOVEN MATERIAL WRAPPERS
Woven wrapping materials are usually 100% cotton, cotton-polyester or synthetic blends. Woven materials are reusable and require laundering, de-linting, and inspection for holes and fabric degradation before each use. Inspection and mending of holes and defects are time-consuming tasks, and many facilities select disposable wrappers because they are easier to wrap, and there may be greater confidence in sterility protection; however, all disposable wrappers can incur rips and tears during manufacturing, transportation or storage.

As with peel pouch packaging, the instruments must be wrapped in a manner that facilitates aseptic presentation of the contents. The instrument tray should be wrapped with two layers of wrap. Wrapped packages to be sterilized by steam may require that an absorbent towel be placed under the item for two reasons: to prevent package rips and tears during storage and to absorb moisture that occurs during the steam cycle. A towel is not placed under items when disposable wraps are used for instruments to be processed with hydrogen peroxide gas plasma vapor sterilization. Instead, specialized non-absorbable materials should be used to protect packages from rips and tears. These products also ensure the hydrogen peroxide gas plasma is not absorbed. This is important because absorption depletes the sterilant mixture in the chamber, which would cause the system’s self-monitoring of the sterilization process to cancel the cycle. The ability of sterilization wrappers to maintain the content’s sterility has historically been based on two layers of wrap material. Polypropylene wrappers are available that are sealed together on two sides and allow use of a simultaneous envelope fold wrapping technique. If this product is not available, two layers of wrap should be used with a sequential wrapping technique. Note: this involves wrapping the item completely using one layer of wrap and then wrapping the item a second time with another single layer of wrap; however, no tape is placed to secure the last fold of the inside wrap. It will be held securely in place with the application of the second layer of wrap.

Always utilize wrap materials as
directed by the manufacturer because the company has performed the required testing that demonstrates correct application that provides the required sterility maintenance.

Do not write directly on the wrapping material because doing so will compromise sterility. Instead, use an approved printed label or write on the wrapper's sterilization tape.

The weight of the tray or other item should not exceed 25 pounds total, including container and instruments. Excess weight can compromise the sterilization and drying processes, and increase worker injury from lifting.

After sterilization, the wrapped package must cool and dry before it is handled. If the wrapped package is handled while it is still warm and moist, it can wicked the bacteria from the hands of the person handling it. After the package has cooled and dried, bacteria cannot travel through the wrapper unless they are facilitated by external moisture and/or a wrapper's rips and tears.

**RIGID CONTAINERS**

The locking and filtering mechanisms of rigid containers vary based upon their manufacturer but, despite these variations, they must allow for the removal of moisture, drying, and the aseptic presentation of contents to the sterile field. Selection factors for rigid containers include the size needed for the instrument set, ease of assembly and cleaning, purchase price, and the materials and supplies needed to maintain them including locks, filters, labels, and replacement parts.

Not all rigid containers require a paper filter, but some require a paper filter on the bottom and top of the container. Some containers have a solid bottom and do not require a bottom filter. Other rigid containers feature a reusable filter that, unless damaged, can be used for a specified number of cycles. Other rigid containers have a pressure valve system that allows air removal and entry of the steam sterilant in the container. The valve closes at the completion of the cycle allowing the contents to remain sterile.

Most rigid containers require an integrity lock on both sides of the container to indicate that the container has not been tampered with; however, one rigid container system does not require integrity locks. Instead, locks pop down on both ends when the contents have been processed at the proper pressure and temperature. One potential concern is that there is no chemical indicator color change on the outside of the container. To address this, personnel in many facilities add a strip of wrapping tape on the label to show color change. Money is saved on integrity locks, but personnel must remember to place the tape on the container's exterior during assembly.

Rigid container systems can save resources, including time and money. A concern is that not all rigid containers can be used for all sterilization devices. Some require specific placement in the sterilizer, and some can be stacked for sterilization while others cannot. When rigid containers are utilized, every person involved with their processing and use must be aware of the limitations and recommendations to assure product sterilization.

**IN CONCLUSION**

Proper selection and use of a packaging system is critical to patient care. As explained in this lesson, there are several types of packaging systems available that should be carefully evaluated for each of the facility's processing needs. CRCST personnel should always ensure that the manufacturer's instructions for use are consistently and carefully followed for each type of packaging system used.