The ins and outs of sterile packaging

A regular column on sterilization and infection control issues.

A sterilizer may be functioning properly, but if all the steps leading up to actual sterilization have not been carried out properly, the processed item may not be sterile. One of those steps is packaging. The wrong package or packaging done incorrectly can result in an item not being sterile even though it has gone through the sterilization cycle.

Woven fabrics, nonwoven materials, combination plastic-paper pouches, paper pouches, rigid container systems, and instrument organizing trays are all examples of packaging.

Selection of the appropriate packaging, closure of the package, and placement of packages within trays and within the sterilizer can affect sterilization and maintenance of sterility after processing. (Basic packaging characteristics are in the sidebar.)

Package selection

It is not unusual for a hospital to package identical items in a variety of ways. For example, a device may be packaged in polypropylene wrap one day, in a peel-pouch another day, or in a containment device another time. Best practice is to determine the most appropriate package for a device(s) and stick with it.

The first step in selecting appropriate packaging is to review the package manufacturer’s documentation regarding testing, instructions for use, and instructions for care and handling.

If a container is being considered, determine the appropriate cycle to use. Some packaging systems, eg, rigid containers, may require an extended drying time and/or may only be suitable for one specific sterilization cycle or modality. Any discrepancies in the instructions between the manufacturer of the device to be sterilized and the packaging manufacturer must be reconciled before proceeding.

The size and the weight of the device(s) to be sterilized must be considered. A peel-pouch may not be appropriate for a device that has a sharp edge or is large or heavy. A sharp edge may cause a tear in the package, and a large or heavy item may put extra pressure on the seal and cause it to rupture. A large item in a peel-pouch may make aseptic delivery difficult as well. A very fine or fragile item packaged in a peel-pouch may be damaged during handling and transport and would be better protected in a rigid containment device.

Product testing

If it is necessary to change packaging because of a major change, such as changing from woven to nonwoven materials or adding instruments to a tray, product testing should be performed. Whether the addition of instruments to a tray represents a significant change is a judgment call.

Additional weight can result in increased metal mass or a wet pack, which may in turn require a change in packaging and an extended cycle. The exact amount of weight that makes a difference is not always easy to determine. In the absence of a formula for this determination, product testing should be performed.

Product testing should be part of a quality assurance program. The Association for the Advancement of Medical Instrumentation’s comprehensive steam sterilization standard (ANSI/AAMI ST:79, pp 100-101) states, “Product testing should always be
performed when major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes or changes in the type of material of packaging or wrapper.”

Product testing involves:

- placing biological indicators; Class 3, 4, 5 indicators; or enzyme indicators inside of the package in the most challenging location; ie, the location least accessible to the sterilant
- placing the package within the most challenging location within the sterilizer as determined by the sterilizer manufacturer
- running the sterilization cycle
- incubating the biological indicators.

Product testing should also be done when a change is made from polypropylene wrap to rigid containers or when flash containers replace open trays. Containers should also be tested. Each size of container should be tested using the sterilization method and cycle with which it will be used. For more information on product and container testing, consult AAMI ST:79.

Weight recommendations

The combined weight of the package and its contents should not exceed 25 pounds, according to AAMI’s standard for containment devices (ANSI/AAMI ST:77, 2006, p 7). Packages that weigh more than 25 pounds may require additional drying time. In addition, it is not ergonomically friendly for the staff to have to lift 25-pound packages multiple times in one day.

The users who participated in development of the AAMI ST:77 standard persevered in setting 25 pounds as the maximum weight for 2 reasons: This weight is congruent with the National Institute for Occupational Safety and Health (NIOSH) calculations for manual lifting. Also, lifting heavy packages contributes to back injuries and absenteeism.

At present, the combined weight of the package and contents of many sets exceeds 25 pounds. This is especially true of orthopedic sets and instruments in rigid container systems. To achieve a 25-pound weight limit, sets may need to be split into 2 or more packages. One would hope that any new prepackaged sets released to the market will be designed with a 25-pound weight limit.

Use of pouches

Combination plastic-paper and plastic-Tyvek® pouches are most appropriate for packaging small, lightweight items. The choice to single- or double-pouch is based on institutional preference. When a double-pouch method is used, the inner pouch should fit within the outer pouch without having to fold the inner pouch. Both pouches should face in the same direction. Any writing on the package should be done on the plastic side, which is not permeable to the sterilant, and should be done with a nontoxic marker intended for such use.

Plastic-paper pouches should not be placed within instrument sets, even if they are left open. Although this practice may prove to be safe, at present, there are no studies that validate whether it is effective. Additionally, it is difficult to position pouches within instrument sets to ensure adequate air removal, sterilant contact, or adequate drying.

When instruments need to be segregated within an instrument set, an all-paper pouch may be used if paper is compatible with the intended sterilization modality. Polypropylene wrap should not be used for this purpose unless testing data from the wrap manufacturer supports this practice.

If pouches are to be used in extended cycles, request technical information from the pouch manufacturer that supports this practice.

When placing pouches within the sterilizer, position them on their edge and make sure they all face in the same direction. Baskets are available that will facilitate keeping them in place.

Sealing the package

Woven and nonwoven wrappers are secured with sterilization indicator tape. Pouches may be sealed with tape, a self-seal, or a heat seal. Although a self-seal or a
heat seal is preferable, all 3 methods are acceptable if used properly, and the result is a secure seal with no breach that can permit entry of contaminants. The benefit of a self-seal is that, unlike a heat seal, temperature is not a consideration. However, it is important that the seal portion of the pouch be folded exactly where indicated and that there are no areas along the seal that are not securely sealed. Best practice is to remove as much air as possible, fold where indicated, and seal beginning from the center outward. This method promotes a more even seal.

There are 2 types of heat sealers, a bar sealer and a continuous-feed type. In the bar sealer, the bar is activated and applies heat and pressure to the end of pouch for a specific period of time. The 3 critical parameters of heat sealing are temperature, pressure, and dwell time. If the temperature is too high or too low, or the dwell time and pressure are insufficient, the seal will be compromised. Heat sealers with gauges that monitor the critical parameters and alarm when set limits have been exceeded are preferable. Heat sealers should be put on a preventive maintenance schedule, and calibration should be performed on a regular schedule.

Storage prior to use

Storage prior to use is another important consideration. Packaging materials should be held for a minimum of 2 hours at 20°C to 23°C (68°F to 73°F) and relative humidity of 30% to 60% (AAMI ST:79, p 54).

In summary, appropriate package selection, storage, use, and placement within the sterilizer contribute to increasing the probability that package contents will be sterile after sterilization and will remain sterile until use. ☞

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References


Basic packaging characteristics

All packaging should:

• Permit exit and entry of the sterilant
• Maintain the sterility of the device until opened:
  —Resist tearing or puncture
  —Provide and maintain seal integrity
• Be compatible with the intended sterilization modality:
  —Not all packaging materials are compatible with all sterilization modalities
  —Permit aseptic delivery at the point of use.