Guideline Quick View: Packaging Systems

The AORN Guideline Quick View is a key component of Guideline Essentials, a suite of online implementation tools designed to help the perioperative team translate AORN’s evidence-based guidelines into practice. Each Guideline Quick View highlights important elements of the full guideline and includes images, implementation steps, and the rationale for why these steps are important to promote safety and optimal outcomes for patients undergoing operative and other invasive procedures. Access to the full set of Guideline Essentials is included with AORN membership. To access them online, visit https://www.aorn.org/Member_Apps/MyAorn.

PREPURCHASE EVALUATION

- Evaluate packaging systems before purchase using the following criteria:
  - has US Food and Drug Administration (FDA) clearance for performance claims for intended use
  - is suitable for the items being sterilized
  - is free of toxic ingredients
  - is odor free
  - is low linting
  - is large enough to permit equal distribution of the contents
  - is easy to use for personnel who prepare, transport, and/or open the package
  - permits secure and complete closure of items

- Evaluate packaging materials before purchase based on the following considerations:
  - FDA clearance for performance claims for intended use
  - verifiability of the manufacturer’s instructions for use (IFU) through facility product testing
  - barrier effectiveness
  - compatibility with the intended sterilization method(s) and cycles used within the facility
  - biocompatibility
  - availability of an external chemical indicator (CI)
  - durability

http://doi.org/10.1002/aorn.12644
© AORN, Inc, 2019
PREPURCHASE TESTING

- Verify the performance of the packaging system and materials in the environment in which they will be used, to determine whether conditions for sterilization, shelf life, transport, storage, and handling can be met.

- Perform prepurchase product testing if the packaging represents a major change in packaging type (eg, a change from using woven to using nonwoven materials, a change from using nonwoven materials to using rigid sterilization containers).

- Test the product by:
  - placing biological indicators (BIs) and CIs inside a variety of sets and packages to be processed (eg, basin sets, instrument sets)
  - placing BIs and CIs within the package in the areas that present the greatest challenge to sterilant contact
  - assessing moisture
  - reprocessing the product before use

- Document product testing activities, including:
  - the date of the test
  - a description of the package and contents
  - the location of BIs and CIs within the test package
  - test results

★ Product testing is used to verify that adherence to the device manufacturer’s instructions for sterilization is achievable in the health care setting.

PACKAGING

- Package items to be sterilized in a manner that facilitates sterilization and provides for an aseptic presentation of the package contents.

- Use packaging materials according to the packaging manufacturer’s and sterilizer manufacturer’s written IFU.

- Inspect packaging materials, including filters for rigid sterilization container systems, for defects and extraneous matter before use.

- Choose wrapping material in a size adequate to achieve coverage of the item(s) being packaged.

- Wrap items securely to prevent gapping, billowing, or formation of air pockets.
• Position items within packages in a manner that will allow sterilant contact with all surfaces.
• Place items in the package or tray in an open or unlocked position.
• Disassemble instruments composed of more than one part unless the manufacturer’s IFU specifies that disassembly is not required.
• Position items that have concave or convex surfaces in a manner that will prevent those surfaces from retaining water.
• Ensure towels placed within instrument sets are lint free and freshly laundered by a health care-accredited laundry facility.
• Package items in a manner that facilitates maintenance of sterility and aseptic presentation of the contents (ie, sequential wrapping with two single wraps or single wrapping with a doubled-bonded wrap).
• Do not exceed 25 lb for the total weight of the instrument containment device, including the contents.

Incorrect packaging may prevent sterilization from occurring or make aseptic delivery of the contents to the sterile field difficult or impossible. Inappropriate handling can lead to loss of package integrity.

• Follow the manufacturer’s IFU for storage of CIs.

Chemical indicators verify that one or more of the conditions necessary for sterilization have been achieved. External CIs verify that the package has been exposed to the sterilization process and differentiates processed packages from unprocessed packages. Internal CIs verify that the sterilant has reached the contents of the package and that critical variables of the sterilization process have been met. External and internal CIs do not verify sterility of the contents.

CHEMICAL INDICATORS

• Place a CI on the outside and inside of every package to be processed unless the internal indicator is readable through the package material.
• Use a CI specific to the sterilization method selected.
• Use a class I CI (ie, process indicator) on the outside.
• Use a class III CI (ie, single-parameter indicator), class IV CI (ie, multiparameter indicator), class V CI (ie, integrating indicator), or class VI CI (ie, emulating indicator) on the inside.
• For multilayered trays, use more than one CI placed according to the tray manufacturer’s IFU.
• Place CIs in an area within the package that presents a challenge for air removal and sterilant contact.

PACKAGING MATERIALS

• Use all packaging materials according to the manufacturer’s IFU.
• Store packaging materials at room temperature and at a relative humidity that is in accordance with the manufacturer’s IFU.
• Discard or recycle wrapping materials labeled for single use after one sterilization cycle.
• Send reusable woven textiles to be laundered after every use to maintain hydration.
• Inspect and monitor reusable woven packaging materials throughout the life of the product.
• Use peel pouches only for small, lightweight, low-profile items (eg, one or two clamps, scissors).
• Do not use peel pouches within wrapped sets or containment devices unless the pouch manufacturer can supply documented validation for this practice.
• Do not use double pouching (ie, placing the item in one pouch and then placing this pouch inside another) without written instructions from the pouch manufacturer indicating that this practice has been validated and the pouch in question has been cleared by the FDA for this purpose.
• When loading the sterilizer, place peel pouches on their edges and space them to permit sterilant contact and drying.
• Inspect the integrity of a rigid sterilization container after each use to determine that:
  - the mating surfaces and edges of the container and lid are free of dents and chips
  - the lid and container fit together properly and securely
  - the filter retention mechanisms and fasteners are secure and not distorted or burred
  - the latching mechanisms are functioning as they should
  - the handles are in working order
  - the integrity of the filter media is not compromised
  - the gaskets are pliable, securely fastened, and without breaks or cuts
  - the valves are in working order
• Clean rigid sterilization containers after each use.

Accurate labeling provides identification of the package contents as well as information that enables tracking of the sterilizer, sterilization cycle, personnel involved in the sterilization process, and the patient for whom the items were used.

QUALITY ASSURANCE
• Monitor activities related to the use of packaging systems, including compliance with policies and procedures for:
  - using packaging systems according to the manufacturers’ IFU
  - verifying the compatibility of packaging systems with sterilization processes
  - storing packaging materials
  - assembling, handling, and packaging wrapped, pouched, and containerized items
  - labeling packages for sterilization
  - determining event-related sterility
  - product testing
  - investigating wet packs
• Perform quality assurance testing of packaging systems and related equipment (eg, heat sealers) before initial use as well as periodically, according to the manufacturers’ written IFU.
• Investigate and resolve the occurrence of wet packs, including evaluation of:
  - package weight, density, and configuration
  - packaging materials and methods used
  - load contents and configuration
  - placement of the package on the sterilizer cart
  - compliance with the manufacturer’s recommendations for containers, instruments, and wrappers
  - process of removal of the load from the sterilizer after sterilization
  - conditions (eg, temperature, humidity) in the cooldown area
  - location of air-conditioning vents in the cooldown area
  - water and steam quality

Reviewing and evaluating quality assurance and performance improvement activities helps to identify failure points that contribute to errors in the use of packaging systems and helps define actions for improvement and increased competency.

LABELING
• Before sterilization, label packages with:
  - the sterilizer number or unique identifier if more than one sterilizer is in use
  - the cycle or load number
  - the date of sterilization
  - a description of the package contents (eg, major abdominal set, Kerrison rongeur, Kleppinger bipolar forceps)
  - the identity of the package assembler
• Ensure package labels are visible and remain securely fixed to the package throughout processing, storage, and distribution to the point of use.
• When using a marker to enter label information, use ink that is nontoxic, nonbleeding, and indelible.

Packaging systems include woven fabrics, nonwoven materials, paper-plastic pouches, Tyvek®-plastic pouches, plastic-plastic pouches, and containment devices (eg, sterilization containers, instrument cases, cassettes, organizing trays) composed of a variety of materials. Packaging manufacturers’ IFU provide information that identifies correct use with the intended sterilization method(s) and equipment.