Implementing AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization

PAULA J. MORTON, MS, RN, CNOR; RAMONA CONNER, MSN, RN, CNOR

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Purpose/Goal

To provide the learner with knowledge specific to evaluating, selecting, and using packaging systems for sterilization.

Objectives

1. Identify necessary characteristics of packaging systems.
2. Discuss aspects of prepurchase evaluation.
3. Describe different types of packaging materials.
4. Discuss processes related to sterilization.
5. Describe conditions necessary for storage of sterilized items.

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Ms Morton and Ms Conner have no declared affiliations that could be perceived as posing potential conflicts of interest in the publication of this article.

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Implementing AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization

PAULA J. MORTON, MS, RN, CNOR; RAMONA CONNER, MSN, RN, CNOR

ABSTRACT

The delivery of sterile products to the sterile field is essential to perioperative practice. The use of protective packaging for sterilized items is crucial to helping ensure that patients receive sterile items for surgical procedures. AORN’s “Recommended practices for selection and use of packaging systems for sterilization” offers guidance to perioperative team members in evaluating, selecting, and using packaging systems that permit sterilization of the contents, prevent contamination of sterilized items until the package is opened for use, protect the items from damage during transport and storage, and permit aseptic delivery of the items to the sterile field. AORN J 99 (April 2014) 496-502. © AORN, Inc, 2014. http://dx.doi.org/10.1016/j.aorn.2014.02.014

Key words: packaging systems, sterilization methods, biological indicators, chemical indicators, textile processing, peel pouches, container systems.

Sterilization is the process by which all microbial life, including pathogenic and nonpathogenic microorganisms and spores, is destroyed. Sterilizing instrumentation, equipment, and other items used in surgical or other invasive procedures requires packaging that allows sterilization of the contents, protects packaged items from contamination before they are used, and permits aseptic delivery of a package’s contents to the sterile field. Packaging products include woven and nonwoven fabric, plastic and paper pouches, and rigid container systems.

AORN first published the “Recommended practices for selection and use of packaging systems for sterilization” in 1983 and has revised it several times—most recently in 2013. As with all...
new or updated recommended practices (RP) documents, the recommendations in this RP document are based on a review and appraisal of available evidence. The lead author and a doctorally prepared evidence appraiser reviewed relevant literature and used the AORN appraisal tools to assign appraisal scores. The appraisal score depicts the strength and quality of the evidence in an individual article. The collective evidence that supports each intervention statement was then rated using the new AORN Evidence Rating Model. The rating helps perioperative providers understand the best evidence available for the practice recommendations.

The RP document identifies criteria for evaluating and selecting packaging systems and for verifying that the packaging system is appropriate for the sterilization method needed and can meet the required conditions for sterilization, shelf life, transport, storage, and handling. The practical application tactics and rationales provided in the RP document will help perioperative team members avoid risk points that may compromise the integrity of packaged sterilized products in all settings where sterilization processes are performed. More in-depth information and a review of the evidence for each recommendation can be found in the complete RP document.

WHAT’S NEW?

New to this RP document are the recommendations that packaging systems should have US Food and Drug Administration (FDA) clearance for the intended use of the product and that packaging systems should be evaluated for their environmental impact. There are new interventions related to the placement of chemical indicators (CIs) in multilayered trays, the use and placement of peel pouches, and the use of cassettes or organizing trays inside a rigid container. Also new is the recommendation that testing be performed whenever there is a major change in packaging systems or when “there are changes to materials, tray configuration, or content density.”1(p570) Team members should accomplish this using biological indicators (BIs) and CIs placed in the set and running the set in a full load with verification of pass or fail indicator results. After steam sterilization, for example, team members should inspect packages for moisture on the inside or outside of the pack. If present, team members should investigate the cause and resolve the issue. This should include evaluating the weight, density, configuration of the pack, and packaging materials used; the placement of the package in the sterilizer; compliance with manufacturers’ instructions for use (IFU) of the container; the removal process; the conditions in the cool down area; and the water and steam quality. The key to the recommendation is that personnel should seek a resolution of the wet pack issue and not continue similarly processing packs until the issue has been resolved.

RATIONALE

Attaining and maintaining sterility of instruments and equipment used in the OR is a key perioperative practice that helps prevent patient harm. This is not an easy task because instruments and equipment are becoming increasingly complex, as are the processes and products required to sterilize and protect them from environmental contamination until use. Perioperative team members can look to the RP document for guidance and to help educate team members about packaging and the sterilization process. A multidisciplinary team also can use the RP document to guide development of a sterilization quality management program and to create policies and procedures that help ensure safe perioperative patient care.

DISCUSSION

The RP document includes recommendations about packaging system selection, characteristics of packaging materials (eg, woven fabrics, nonwoven materials, paper-plastic pouches, Tyvek®-plastic pouches, plastic-plastic pouches) and containment devices (eg, sterilization containers, instrument cases, cassettes, organizing trays), shelf life, product testing, labeling, use of CIs and BIs, and quality
management. Important interventions include that items should be packaged in a manner that facilitates sterilization and that follows the manufacturers’ IFU of the item, the sterilization method, and the packaging system. Ongoing inspection, verification, and problem investigation and solving should be conducted over the life of the packaging system and after any major changes occur. Perioperative personnel should read the full RP document for more information on these topics and topics not covered in this article.

**Recommendation I**

Perioperative team members should perform pre-purchase evaluation and testing of packaging products and verify that the products can be used with the methods of sterilization used in the facility and the instruments and equipment to be sterilized. An important aspect of this recommendation is that team members should review the manufacturers’ IFU to determine that packaging systems under consideration will perform as intended under the conditions of use in the facility. Team members also should verify the manufacturer’s performance claims for the product and that the products have FDA clearance for performance claims for the intended use.

The products under consideration should meet instrument and equipment manufacturers’ sterilization and packaging requirements to maintain the effectiveness of these items. During the pre-purchase evaluation, the team also should consider the environmental impact of all packaging materials and products used and ensure that packaging systems are not subject to restrictive regulatory requirements for waste disposal.

The team should conduct pre-purchase testing any time a major change will be made in the packaging type (e.g., the acquisition of rigid containers) or sterilization system (e.g., low-temperature hydrogen peroxide gas plasma sterilization). Product testing should include evaluating the system’s efficacy by placing BIs and CIs inside the sets or packages in areas that represent a challenge to the sterilization process (i.e., an area that would be difficult for the sterilant to reach). Team members should evaluate these test sets and instruments for moisture and document the outcome of these tests.

**Recommendation II**

“Not all packaging systems are suitable for all methods of sterilization.” For example, containers for steam sterilization should permit steam penetration and allow adequate drying. Ethylene oxide (EO) packaging should be specified as appropriate for EO sterilization, be permeable to EO, and permit aeration for the recommended time. Items requiring low-temperature hydrogen peroxide gas plasma sterilization or low-temperature hydrogen peroxide vapor sterilization should only be packaged in manufacturer-validated containment devices. If rigid containers require the use of a filter, then the filter should be made of noncellulose material. Team members should obtain written verification from both the packaging system and sterilizer manufacturers that the systems are compatible.

**Recommendation III**

Some packaging system manufacturers may specify environmental storage conditions that are required for their product to perform as designed. This means that certain humidity and temperature parameters in the storage area should be maintained as indicated by the manufacturer’s IFU. Perioperative team members, therefore, should be familiar with the environmental storage conditions required for the products and determine whether the storage requirements can be met. The team should consider the shelf life of the packaged sterile item to be event related (i.e., time does not affect sterility, but an event such as handling or incorrect storage conditions may).

Packaging materials should be processed according to the manufacturer’s IFU. Products labeled for single use should be discarded after one use and not reprocessed. Single-use packaging materials can be recycled if they meet recycling criteria.
**Recommendation IV**

Perioperative personnel should inspect packaging before use and avoid using any packaging that may have defects that could permit pathogens into the packaging. To achieve sterilization, items should be wrapped securely and positioned in the packages so that the sterilant will contact all of the items’ surfaces. The manufacturer’s IFU will guide personnel in how to package the contents. The packaging should be performed in a way that maintains the sterility of the contents until they are delivered to the sterile field.

Health care organizations should weigh the risks and benefits of including nonvalidated material (eg, count sheets) inside instrument trays. There are no known reports of adverse events based on this practice, but there is also limited research on successful sterilization of printer ink or paper. One study suggested that although ink could transfer to surgical instruments, it was not cytotoxic. This is a limited study and cannot be generalized; therefore, health care organizations should use caution with regard to this practice until more research is available.

**Recommendation V**

Team members assembling trays and other packages should be knowledgeable about the use and placement of CIs, which are used to verify that conditions for sterilization have been met. A new activity under this recommendation indicates that “more than one CI may be required in multilayered trays and should be placed according to the tray manufacturer’s IFU” rather than on each level of the container and in areas that represent “a challenge for air removal and sterilant contact” rather than just the center of a tray or container. Perioperative team members should be aware of and understand the various chemical indicators used to verify that the conditions of sterilization have been met.

**Recommendation VI**

Perioperative team members should be knowledgeable about reusable woven materials and the effect that materials and the construction of the textiles used in pack preparation could have on the sterilization process. Perioperative team members should verify a material’s suitability for the packaging of individual items and inspect all woven textiles used for packaging for defects (eg, holes, tears, worn spots) or linting. Small defects can be repaired with vulcanized patches; however, the number of patches should be kept to a minimum because they do not permit the penetration of sterilants. If there is a “question about the suitability of a woven wrap, it should be discarded.”

**Recommendation VII**

The information on peel pouches has been expanded to include the recommendation that double pouching “should not be performed without written instructions from the pouch manufacturer indicating that the practice has been verified and the pouch in question has been cleared by the FDA for this purpose.” If double pouching is permitted by the pouch manufacturer, the inner pouch should fit within the outer pouch without folding and face the same direction as the outer pouch. A new recommendation is that peel pouches should “be placed on edge and spaced to permit contact with the sterilant and to allow adequate drying.” Specially designed racks may be needed to accomplish this.

**Recommendation VIII**

“A rigid sterilization container should be used, cleaned, inspected, repaired, and maintained according to the manufacturer’s written IFU.” Perioperative team members should evaluate and verify that any container system purchased or used is suitable to provide the sterilization and storage needed by the facility. To do this, team members should be familiar with the manufacturer’s IFU for the instruments or equipment to be processed and the use, processing, and maintenance of the rigid container system under evaluation. New to this RP document is the recommendation that users refer to the containment device manufacturer’s IFU before
using any cassettes or organizing trays inside a rigid container. Items used in rigid container systems should be approved by the container manufacturer’s IFU. Nonapproved items (eg, towels, mats) that have not been verified to demonstrate that sterilization will occur represent a threat to the sterilization process if added to the container.³

Rigid containers should be inspected after every use for defects or problems. This inspection should include all mating surfaces (ie, areas where lids and edges meet), the lid to the container, filter retention mechanisms and fasteners, latching mechanisms, handles, filter media, gaskets, and valves for function, integrity, and fit.

**Recommendation IX**

Recommendation IX states that packages to be sterilized should be labeled with information that includes identification of the contents, the sterilizer number or unique identifier, the cycle or load number, the date of sterilization, and the identification of the assembler. This labeling provides personnel with the ability to track items and to identify and retrieve items quickly. Labeling recommendations have not changed since the last version of the RP document.

**The Final Three**

The final recommendations in each AORN RP document discuss education/competency, policies and procedures, and quality assurance/performance improvement as applicable. These topics are integral to the implementation of AORN practice recommendations.

Personnel should receive initial and ongoing education and competency validation as applicable to their roles. Implementing new and updated recommended practices affords an excellent opportunity to create or update competency materials and validation tools. AORN’s perioperative competencies team has developed the AORN Perioperative Competency Verification Tools and Job Descriptions⁹ to assist perioperative personnel in developing competency evaluation tools and position descriptions.

Policies and procedures should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting. New or updated recommended practices may present an opportunity for collaborative efforts among nurses and personnel from other departments in the facility to develop organization-wide policies and procedures that support the recommended practices. The AORN Policy and Procedure Templates,
3rd edition,\textsuperscript{10} provides a collection of 30 sample policies and customizable templates based on AORN’s \textit{Perioperative Standards and Recommended Practices}.\textsuperscript{11} Regular quality improvement projects are necessary to improve patient safety and to help ensure safe, quality care. For details on the final three practice recommendations that are specific to the RP document discussed in this article, please refer to the full text of the RP document.

**AMBULATORY PATIENT SCENARIO**

Ambulatory surgery personnel are scheduled to perform an incisional biopsy on a 68-year-old woman. After opening the instrument tray, the RN circulator notices that the rigid container filter is not intact. She alerts the scrub person and places the tray and the container on the case cart. She contacts the sterile processing department (SPD) personnel, alerts them to the issue of the damaged filter, and arranges for another tray of instruments to be delivered.

The RN circulator then contacts the anesthesia professional and the surgeon and informs them that the room will not be ready for another 15 minutes while replacement instrumentation is obtained. A staff member from the SPD arrives and retrieves the damaged container and delivers a new tray of instruments. The procedure takes place later than planned but runs smoothly, and the patient arrives in the postanesthesia care unit safely. The SPD manager identifies and speaks with the personnel who assembled the tray and reinforces the importance of inspecting rigid containers, including the filters, before sterilization.

**HOSPITAL PATIENT SCENARIO**

At a busy community hospital in the Midwest, processing time for endoscopes poses cleaning and sterilization challenges for SPD personnel, and this frequently causes delays for some procedures. The two peracetic acid systems at the hospital cannot keep up with the workload. Additional endoscopic equipment and a different and more efficient method for terminal sterilization will be required to meet the increased demand. The manager of the SPD recommends purchasing a low-temperature hydrogen peroxide gas plasma sterilization system that requires shorter cycle times for terminal sterilization and produces dry products at the end of the cycle.

The leadership team and perioperative personnel complete a prepurchase evaluation of packaging materials for low-temperature hydrogen peroxide gas plasma sterilization, consult colleagues for information, and research which instruments can be sterilized using the system. They select a non-cellulose-based packaging material that is recommended by the sterilizer manufacturer and that has FDA clearance for its performance claims. The

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**Resources for Implementation**

- AORN Syntegrity\textsuperscript{\textregistered} Framework. AORN, Inc, \url{http://www.aorn.org/syntegrity}.
- ORNurseLink\textsuperscript{\texttrademark}. \url{http://ornurselink.aorn.org}.
- \textit{The Roadmap to ASC Compliance} [CD-ROM]. Denver, CO: AORN, Inc; 2012. \url{http://www.aorn.org/Education/Ambulatory/Ambulatory_Surgery_Center_Resources.aspx}.

\textit{Syntegrity} is a registered trademark and \textit{ORNurseLink} is a trademark of AORN, Inc, Denver, CO.

Web site access verified January 27, 2014.
SPD manager performs product testing to verify that when using this new methodology and packaging materials, sterilization is achievable in this setting. The administrators approve the purchase and acquire the system and suitable packaging materials for the hospital.

The SPD manager assumes the lead role in providing education and training to SPD and OR personnel and verifying their competency. This includes education about the technology, load preparation and loading guidelines, BI and CI use, placement of items for cycle completion, cancelled cycles, data printouts, preventative maintenance required, and technical assistance availability. The manager retains the safety data sheet information and the manufacturer’s IFU in her office. Two months after the purchase, an evaluation of the process confirms that the low-temperature hydrogen peroxide gas plasma sterilization process is a safe and effective means of sterilizing endoscopes.

**CONCLUSION**

Perioperative personnel play an important role in the selection, evaluation, verification, and use of packaging systems. The AORN “Recommended practices for selection and use of packaging systems for sterilization” is a comprehensive document that provides guidance to perioperative personnel in a variety of settings. By understanding risk points in packaging system use, perioperative personnel can apply these principles to their daily practice, thereby ensuring that sterilized items are consistently used for all patients. Perioperative personnel should actively participate in the quality assurance and performance improvement activities related to selection, evaluation, and use of packaging systems to identify that compliance with standards has been met and that any required corrective actions have been taken. AORN

**Editor’s note:** Tyvek is a registered trademark of DuPont, Wilmington, DE.

**References**


**Paula J. Morton,** MS, RN, CNOR, is the director of perioperative services at Sherman Health System, Elgin, IL. Ms Morton has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.

**Ramona Conner,** MSN, RN, CNOR, is the manager, standards and recommended practices, AORN Nursing Department, Denver, CO. Ms Conner has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.
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PURPOSE/GOAL

To provide the learner with knowledge specific to evaluating, selecting, and using packaging systems for sterilization.

OBJECTIVES

1. Identify necessary characteristics of packaging systems.
2. Discuss aspects of prepurchase evaluation.
3. Describe different types of packaging materials.
4. Discuss processes related to sterilization.
5. Describe conditions necessary for storage of sterilized items.

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QUESTIONS

1. Packaging systems should
   a. allow sterilization of the package contents.
   b. be compatible with all types of sterilization.
   c. protect packaged items from contamination before they are used.
   d. permit aseptic delivery of the package contents to the sterile field.
   a. 1 and 3
   b. 2 and 4
   c. 1, 3, and 4
   d. 1, 2, 3, and 4

2. Prepurchase evaluation and testing should include
   a. ensuring the products have US Food and Drug Administration clearance for performance claims for the intended use.
   b. evaluating the system’s efficacy using biological and chemical indicators.
   c. verifying that the packaging products can be used with the methods of sterilization used in the facility.
   d. verifying the manufacturer’s performance claims for the product.
   a. 1 and 4
   b. 2 and 3
   c. 1, 2, and 3
   d. 1, 2, 3, and 4

3. Items requiring low-temperature hydrogen peroxide gas plasma sterilization or low-temperature hydrogen peroxide vapor sterilization should only be packaged in manufacturer-validated containment devices.
   a. true
   b. false
4. The shelf life of the packaged sterile item should be considered
   a. event related.  b. time related.

5. Placing count sheets in instrument trays to be sterilized
   a. is not acceptable because printer ink has been found to be cytotoxic.
   b. is not harmful and therefore should be common practice.
   c. should be considered in terms of risks and benefits because there is limited research on successful sterilization of printer ink and paper.

6. Chemical indicators should be placed in areas that represent a challenge for air removal and sterilant contact rather than just the center of a tray or container.
   a. true  b. false

7. Woven textiles with a minimal number of small defects (eg, holes, tears)
   a. can be repaired with cloth patches.
   b. can be repaired with vulcanized patches.
   c. can be used without requiring repair.
   d. should be discarded, not repaired.

8. Double pouching can be used if
   1. this practice is permitted by the pouch manufacturer.
   2. the inner pouch fits within the outer pouch without folding.
   3. the inner pouch is placed to face the same direction as the outer pouch.
   4. the inner pouch is placed to face opposite the direction of the outer pouch.
      a. 1 and 2  b. 2 and 3
      c. 1, 2, and 3  d. 1, 2, and 4

9. Perioperative personnel should refer to the containment device manufacturer’s instructions for use before using any cassettes or organizing trays inside a rigid container.
   a. true  b. false

10. Packages to be sterilized should be labeled with information that includes
    1. the contents of the package.
    2. the cycle or load number.
    3. the date the contents will no longer be considered sterile.
    4. the sterilizer number or unique identifier.
       a. 1 and 2  b. 2 and 3
      c. 1, 2, and 3  d. 1, 2, and 4
Implementing AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization

This evaluation is used to determine the extent to which this continuing education program met your learning needs. The evaluation is printed here for your convenience. To receive continuing education credit, you must complete the online Examination and Learner Evaluation at http://www.aorn.org/CE. Rate the items as described below.

OBJECTIVES
To what extent were the following objectives of this continuing education program achieved?

1. Identify necessary characteristics of packaging systems. Low 1. 2. 3. 4. 5. High
2. Discuss aspects of prepurchase evaluation. Low 1. 2. 3. 4. 5. High
3. Describe different types of packaging materials. Low 1. 2. 3. 4. 5. High
4. Discuss processes related to sterilization. Low 1. 2. 3. 4. 5. High
5. Describe conditions necessary for storage of sterilized items. Low 1. 2. 3. 4. 5. High

CONTENT
6. To what extent did this article increase your knowledge of the subject matter? Low 1. 2. 3. 4. 5. High
7. To what extent were your individual objectives met? Low 1. 2. 3. 4. 5. High
8. Will you be able to use the information from this article in your work setting? 1. Yes 2. No
9. Will you change your practice as a result of reading this article? (If yes, answer question #9A. If no, answer question #9B.)
9A. How will you change your practice? (Select all that apply)
1. I will provide education to my team regarding why change is needed.
2. I will work with management to change/implement a policy and procedure.
3. I will plan an informational meeting with physicians to seek their input and acceptance of the need for change.
4. I will implement change and evaluate the effect of the change at regular intervals until the change is incorporated as best practice.
5. Other: ________________________________
9B. If you will not change your practice as a result of reading this article, why? (Select all that apply)
1. The content of the article is not relevant to my practice.
2. I do not have enough time to teach others about the purpose of the needed change.
3. I do not have management support to make a change.
4. Other: ________________________________
10. Our accrediting body requires that we verify the time you needed to complete the 1.6 continuing education contact hour (96-minute) program: ________________________________