

# Packaging for Sterilization

**IT'S NOT JUST A BOX, A BAG OR GIFT WRAPPING!**

by Rose Seavey, RN, BS, MBA, CNOR, ACSP

## Objectives

After completion of this self-study activity, the learner will be able to:

1. Describe available options for sterilization packaging and containment devices.
2. Discuss appropriate use for each type of sterilization packaging.
3. Develop a Quality Control Program for evaluation, selection and use of packaging systems for items to be sterilized.
4. Order the Association for the Advancement of Medical Instrumentation (AAMI) and Association of periOperative Registered Nurses (AORN) documents for your reference library.

## Test Questions

True or False. Circle the correct answer.

1. If major changes are made to packaging such as switching the type of wrappers, peel pouches or containment devices used, or changing the package dimensions or weight of the set, facilities should conduct product testing with biological indicators (BIs) and chemical indicators (CIs) as well as moisture content assessment.  
True      False
2. Both AAMI and AORN recommendations agree on a maximum weight limit of 25 pounds for a containment device, the instruments, and any accessories or wrapper due to ergonomic and drying issues.  
True      False
3. Both solid and perforated bottom rigid containers can be sterilized by gravity or dynamic-air-removal steam sterilization cycles.  
True      False

4. Rigid sterilization container systems should be cleaned after each use following the manufacturers written recommendations.  
True      False
5. Room temperature and relative humidity has no effect on packaging materials and the ability to achieve sterilization.  
True      False
6. Using the proper wrap size and grade is important and wrapping procedures should be standardized.  
True      False
7. If packages are wrapped too loose, it could create low spots that can collect condensate.  
True      False
8. If items are to be put in a double peel pouch, the inner pouch should fit inside the outer pouch without folding and the plastic side of the inner pouch should face the plastic side of the outer pouch.  
True      False
9. Paper-plastic pouches should not be placed inside wrapped sets or containment devices.  
True      False
10. Instrument count sheets should be placed on the inside of sterile packages.  
True      False

Many thanks to the team at 3M Health Care for working with *Managing Infection Control* to provide the following accredited course. IAHCMM has awarded one and one-half (1.5) contact points for completion of this continuing education lesson toward IAHCMM recertification. The CBSPD has preapproved this inservice for one and one-half (1.5) contact hours for a period of five (5) years from the date of publication, and to be used only once in a recertification period. This inservice is 3M Health Care Provider approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five (5) years from the date of publication. Instructions for submitting results are on page 97.

*Managing Infection Control* and 3M Health Care will be working collaboratively to provide continuing education courses in monthly editions of *Managing Infection Control*.

## Introduction

There are several types of sterilization packaging systems on the market today. These devices help to maintain sterility, as well as protect the contents of the package and support aseptic presentation. Most healthcare facilities use a variety of sterilization packaging systems. The available systems include woven and nonwoven wrappers, peel pouches of plastic,

paper and containment devices such as reusable rigid sterilization containers, organizing trays and instrument case/cassettes available in both plastic and metal. There are also a wide variety of devices used to protect instruments or components. These include insert cases or trays, reusable accessories, paper-paper bags, foam and towels.

Sterilization packaging is classified by the Food and Drug Administration (FDA) as a Class II medical device and is defined as:

*“A sterilization wrap (pack, sterilization wrapper, bag or accessories) is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.”<sup>1</sup>*

Sterilization packaging is more complicated than you might think. It is not just a box, bag or wrap! As a Class II medical device, there are specific validated guidelines that must be followed with each type of system used. To ensure patient safety, manufacturers’ written instructions must be followed. Not all packaging systems are compatible with all types of sterilization processes.

This article will cover the various types of sterility packaging and container systems, their intended use, and limitations. This educational offering will also discuss labeling, closures, tamper evidence, product evaluations and testing, weights and density of sets, compability issues, instrument inventory list placement, options for internal containment devices, and maintenance of reusable containers.

### Purpose of packaging

The intention of any sterilization packaging system is to allow sterilization of the package contents, maintain sterility of contents until the package is opened, and permit delivery of contents without contamination.

### PACKAGING OPTIONS

The choice of packaging systems includes:

- ▶ **woven fabrics**, usually 100 percent cotton, cotton-polyester blends and synthetic blends, either treated or untreated;
- ▶ **nonwoven materials**, made of plastic polymers, cellulose fibers or washed paper pulp bonded under pressure into sheets not woven on a loom. These are usually designed for single use;
- ▶ **peel pouches** of plastic and/or paper, made of a variety of materials, including paper, cellophane, polyethylene and various paper-plastic combinations; and
- ▶ **rigid container systems** which are specially designed metal or plastic containers.

### WHICH PACKING TO USE?

Deciding on the appropriate packaging system for sterilizing devices has become a challenging quest. The development of high tech, complicated surgical devices—especially for minimally invasive surgical procedures—and an increasing variety of sterilization processes require greater diligence and critical thinking skills when choosing the type of packaging system to use for each device, or instrument set or sterilization process.

Issues of cost, rapid turnover, ease of use, material compatibility and storage space need to be balanced with patient safety and instrument protection concerns. Healthcare professionals should work closely with the instrument, sterilizer and packaging manufacturers to determine the appropriate devices to wrap, package and contain sterilized items.

### EVALUATING PACKAGING SYSTEMS

Before deciding on which packaging system(s) to purchase and use, an evaluation should take place to investigate suitability for items being sterilized, types and methods of sterilization used. According to the Association of periOperative Registered Nurses (AORN), sterilization packaging systems should:

- ▶ have a sufficient barrier to microbes, particulates and liquid;
- ▶ maintain sterility of contents until used;
- ▶ permit sterilant saturation and removal while allowing direct contact with all surfaces of each item;
- ▶ have no toxic ingredients or nonfast dyes;
- ▶ allow aseptic presentation to the sterile field;
- ▶ close completely and securely;
- ▶ protect items from physical damage;
- ▶ provide a sufficient, reliable tamper-evident seal;
- ▶ be resistant to tears or punctures;
- ▶ have very little lint;
- ▶ allow for content identification;
- ▶ be of sufficient size to uniformly distribute the items;
- ▶ be easy to use when preparing and opening the package or container;
- ▶ be cost effective and;
- ▶ have manufacturer’s written instructions for use.<sup>2</sup>

Important items to consider when evaluating a rigid container system include:

- ▶ Ergonomics of container design for ease of carrying;
- ▶ Empty container weight;
- ▶ Ease of locking and closing the container;
- ▶ Ability to stack containers for storage and transportation;
- ▶ Design of filter retention and ease of use;
- ▶ Types of accessories for organization;
- ▶ Ability to stack baskets internally;
- ▶ Various sizes to accommodate a wide variety of instrument sets;

- ▶ Ability to clearly label sets;
- ▶ Ability to put container through an automatic washer; and Preventative maintenance and service.

### Practical Application

- *Work closely with the instrument, sterilizer and packaging manufacturer to determine the appropriate packaging to use for each device and instrument set.*
- *Evaluate packaging before purchasing.*

### Product testing

Whenever there are major changes made to packaging, e.g., switching the type of packaging material or containers used, and/or changes in the package dimensions or weight, product testing should always be performed. This test should include biological indicators (BIs) and chemical indicators (CIs) as well as moisture content (wet pack) assessment after the cycle is complete.<sup>3</sup>

The BIs and CIs should be placed in the most challenging area of the packages being tested and in multiple locations. More than likely, that will be the center of a wrapped pack or the corners of containers, inside containment devices and on each level of multilevel packs and next to the largest heat sink. The placement of the indicators should be identified for record keeping purposes. The packages should be labeled as product tests and run in a full load using the medical device manufacturer's instructions. The packages are sacrificed and not used so the CIs can be read and the BIs incubated. Test results should be documented and maintained with the sterilization log and the quality assurance records. The products with the changes should not be placed into routine use until the CIs reach their endpoint and the BIs are negative.<sup>2,4</sup>

For specific instructions on facility product testing, healthcare providers should refer to the Association for the Advancement of Medical Instrumentation's (AAMI) *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, ANSI/AAMI ST79:2006 section 10 Quality Control, 10.9 *Periodic product quality assurance testing of routinely processed items*.<sup>3</sup>

### Practical Application

- *Perform product testing whenever there are major changes made to packaging, e.g., switching the type of packaging material or containers used, and/or changes in the package dimensions or weight on loaner instruments.*

### Weight and density of sets

An ongoing issue is the instrument set weights. Instrument sets sometimes seem to take on a life of their own, growing at alarming rates. Some of the complete sets from the original manufactures are almost too heavy to lift. Often additional items get repeatedly added to sets creating a set with a metal mass that is not equally distributed. From time to time, due to lack of storage space or for staff convenience, we merge multiple sets into one. With all of these issues there is a growing concern with the weight of instrument sets.

**Due to ergonomic, sterilization and drying issues, both AAMI and AORN recommendations agree on a maximum weight limit of 25 pounds.** AORN states:

*"The total weight of instrument containment devices should not exceed 25 pounds, including the contents and containment method (eg., wrappers, rigid container systems, cassettes, organizing trays). Excessively heavy instrument sets may compromise sterilization and drying. The focus should be on the set configuration (i.e., how the instruments are distributed in the set) and the overall weight of the set. Lifting and moving heavy instrument sets may cause health care worker injury."*<sup>2</sup>

The AAMI *Containment devices for reusable medical device sterilization*, ANSI/AAMI ST77 and ANSI/AAMI ST79:2006 section 4 Requirements, 4.3.5 recommends a maximum combined weight limit of 25 pound. This weight limit includes the containment device, the instruments, and any accessories or wrappers.<sup>5</sup>

If you are using a containment device, the manufacturer should be consulted on the recommendations for weights and density of instrument sets. However, it is the facility's responsibility to verify that the instrument set can be effectively sterilized and dried in their sterilizers by doing product testing and following the medical device manufacture's instructions for use.<sup>3</sup>

Four years ago, The Children's Hospital of Denver (TCH) chose to institute a maximum weight limit of 20 pounds for any sterilized package. This was instituted to comply with the container manufacturers recommendations of a 16-20 pound limit as well as ergonomic issues for staff. The implementation of this weight limit was established not only for the rigid containers but for any package including wrapped trays and loaner instrumentation trays. This program has proven very successful in many ways. The complaints of back, neck, shoulder and wrist pain from employees have been significantly reduced as well as almost virtually eliminating any wet loads while decreasing some of the dry times. Here are steps for an instrument set weight reduction strategy:

- ▶ Establish the maximum acceptable weight limits for your healthcare facility instrument sets with input from surgical services.
- ▶ Add the established weight limit to your policy and be sure to get the approval of surgical services, infection control and risk management; also inform the facility and loaner instrument vendors.
- ▶ Obtain written reprocessing and sterilization guidelines from all medical device manufacturers including rigid containers.
- ▶ Redesign the instrument sets to even out the metal mass.
- ▶ Perform product testing using biological and chemical indicators inside representative sets in the areas determined to be the most challenging and following the medical device manufacturers' sterilization parameters.
- ▶ Place the sets into use.
- ▶ Routinely monitor sets to ensure the weight is not "inching" up.<sup>4</sup>

**Figure 1. Wrapped pan being weighed**



#### Practical Application

- Establish a maximum weight limit of 25 pounds for a containment device, the instruments, and any accessories or wrapper to protect your employees' health and to decrease drying times.

### Packaging systems compatibility

Not all packaging systems are compatible with all types of sterilization processes. As a Class II medical device, packaging systems must be cleared by the FDA for their intended purposes as well as the method of sterilization used.

### STEAM

Steam sterilization is affected by such things as the amount of available humidity, the altitude, the type of packaging material, its contents, the size and configuration of the load, the size, weight and density of the pack or container, and the parameters of the sterilization cycle. It is important to follow the manufacturers' written instructions for each type of packaging system used in the steam sterilizer.<sup>2</sup>

### ETHYLENE OXIDE (EO)

When using EO sterilization, the packaging systems must be EO, moisture and air permeable, allow aeration of the gas, be constructed of a material recommended by the sterilizer and sterilant manufacturer, and be compatible with the process of EO sterilization. Peel-packs, wrappers, both woven and nonwoven and some rigid container systems are permeable to EO.<sup>2</sup>

### HYDROGEN PEROXIDE GAS PLASMA

Sterilization packaging systems used for packages undergoing hydrogen peroxide gas plasma sterilization must allow vapor phase hydrogen peroxide to penetrate packaging materials, be compatible with the process, and be recommended by the manufacturer. Both the packaging and sterilizer manufacturer's written instructions should be followed. Because cellulose products are not compatible with hydrogen peroxide gas plasma, peel packs used in these sterilizers must be made of plastic. Only compatible container systems which have been validated for this application should be used.<sup>2</sup>

### OZONE

Packages used for sterilization with Ozone must allow Ozone to penetrate the package material, be compatible with the process, and be recommended by the manufacturer. Both the packaging and sterilizer manufacturer's written instructions for use should be followed. Ozone compatible packaging includes uncoated nonwoven materials, plastic pouches and commercially available anodized aluminum containers using noncellulose disposable filters.<sup>2</sup>

#### Practical Application

- ▶ Choose a packaging system that is cleared by the FDA for the purpose and sterilization method you are using.

### Types of packaging systems available

#### RIGID STERILIZATION CONTAINER SYSTEMS

Reusable rigid container systems are used for the packaging, transportation and storage of surgical instruments prior to, during and after sterilization. These self-contained closed sterilization containers use filters or valves as a barrier system to permit air removal and the sterilant to enter and exit the container. The reusable box-like structures act as a microbial barrier and must have a tamper proof seal.

Rigid container systems have internal baskets, come in many sizes, and may have solid or perforated bottoms. The container manufacturer's

written recommendations for sterilization cycle parameters should be followed. In general, the solid bottom containers are to be used in steam sterilizers using dynamic-air-removal cycles only. Perforated bottoms can be sterilized by gravity or dynamic-air-removal steam sterilization. Some containers have been validated for use in Ethylene Oxide, Hydrogen Peroxide Gas Plasma, Ozone and flash sterilization. Solid bottoms can also be used to transport contaminated moist instruments.

**Figure 2. Solid bottom rigid container**



### Pre-assembly

Before placing items in the tray, both the box and the lid of the container system should be inspected to ensure the entire container, top and bottom is free from dents or cracks. The gaskets should be pliable and securely fastened without breaks or cuts. The locking mechanism should function properly.

All of the container's components (top, bottom, valve or filter mechanisms, securing or latching mechanisms) must function effectively as a unit. It is vital to the maintenance of sterility, that these components work together to allow air removal, to facilitate sterilant penetration and removal, and to inhibit contamination.

Filter retention mechanisms, valves and fasteners such as screws and rivets should be secure and not loose. If the filter or valve is found loose, the sterility of the contents should be questioned. If any part of the container is not satisfactory or free of functional defects, the container should be repaired or replaced.

### Assembly

To assure all instruments are exposed to the sterilization agents, the basket(s) placed in the

container should be large enough to allow the metal mass of instruments to be distributed evenly.

Only filter materials that have been tested and documented to be efficacious in the specific container system should be used. If disposable filters are used, a new filter should be used each time the container is sterilized. If mechanical filters are used, their functionality may need to be checked daily or before each use. Follow the manufacturers' instructions.

### Internal stacking

Some container manufacturers have validated internal stacking of two or more layers within a containment device. According to ANSI/AAMI ST77:2006 4.3.4.1, Internal stacking:

*"If organizing trays are to be stacked within a containment device, the following factors shall be addressed for each sterilization method for which stacking is recommended:*

- a) ease of removal of stacked items within a containment device;*
- b) the maximum density of contents within the containment device to allow for proper sterilization and drying;*
- c) adequate perforations to allow for sterilant penetration, sterilant evacuating, drying, and, if applicable, aeration;*
- d) the stability of the stacked items during transport and handling;*
- e) a dry outcome (see 4.4.2.1);*
- f) achievement of sterilization throughout the layers of stacked organizing trays and the recommended accessories (e.g., mats, holders) within the containment device. If any of the accessories are incompatible with a specific sterilization method, the incompatibility should be indicated in the instructions for use."<sup>5</sup>*

If trays are stacked internally, a chemical indicator/integrator (CI) should be placed in each layer in the area of the tray or container system considered to be the least accessible to sterilant penetration.<sup>3</sup> AORN *Recommended Practices for Selection and Use of Packaging Systems* recommends placing two chemical indicators/integrators in opposite corners of each level of trays.<sup>2</sup>

### Tamper-evident closure

Self-contained sterilization containers require a tamper-evident closure (usually a plastic lock) to provide the user with visual confirmation that the container has not been opened after sterilization until the time of use. The tamper-evident closure system shall be effortlessly and safely removed.<sup>5</sup>

**Figure 3. Tamper-evidence closure or lock**



**Immediately before use**

Before it is opened, the container should be inspected for the appropriate appearance of the filters or valves and external chemical indicators and the physical integrity of the outer containers and tamper-evident devices.

The 2007 AORN *Recommended Practices for Maintaining a Sterile Field* states:

*“Rigid container systems should be opened on a separate surface. The external indicator should be verified for appropriate color change. Locks should be inspected for security to verify there has not been a breach of the container seal prior to use. The lid should be lifted toward the person opening the container and away from the container. The filter should be checked and changed according to the manufacturer’s written instructions.”<sup>6</sup>*

Care should be taken to ensure that there is no contact between the lid and the inner rim of the sterile contents, or any part of the inside of the container.

Before removing the instrument basket, the surgically attired scrub person should check the internal chemical indicator(s) for the appropriate change. The scrub person should avoid all contact with the table, external surfaces of the container and the upper rim of the container.

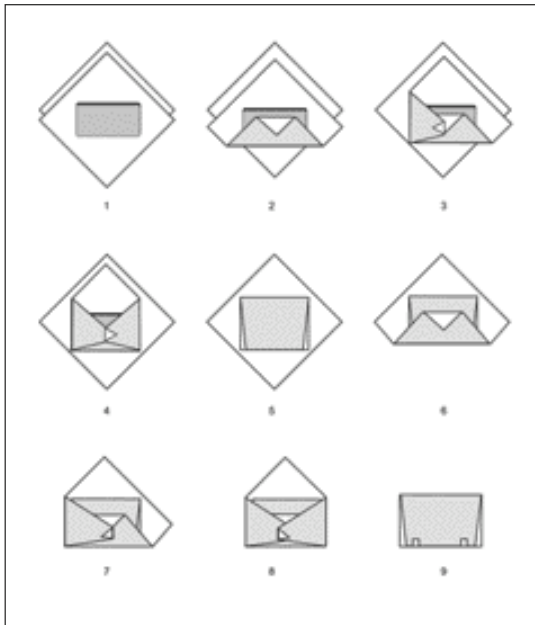
Before the instrument basket is placed on the sterile field, the container bottom should be inspected visually for the proper appearance of the filter or valve assembly; and the instruments, basket and container bottom should be inspected for moisture.

**Cleaning**

Reduction of bioburden is essential for sterilization. Rigid container systems should be cleaned after each use following the manufacturers’ written recommendations. The cleaning and decontamination of rigid sterilization containers systems is as important as the cleaning and decontamination of the soiled/contaminated contents. During routine cleaning, the container should be inspected for mechanical wear and stress.

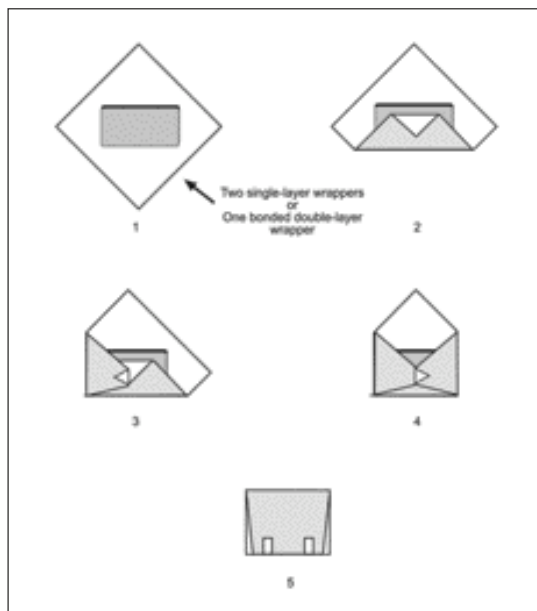
If the container system has removable filters, the filter holders (retention plates) should be removed to disengage the filter. If disposable, the

**Figure 4. Sequential double-wrapping: envelope fold**



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**Figure 6. Simultaneous double-wrapping: envelope fold**



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entire filter should be disposed of. Reusable filters should be disassembled, cleaned and replaced according to the manufacturer’s instructions.

Most container systems can be cleaned and decontaminated in mechanical equipment. The cleaning method selected depends on the container manufacturer’s instructions. If the container has valve-type closures, the manufacturer’s instructions for frequency and method of removal, disassembly and cleaning should be followed.

**Practical Application**

- Follow the rigid container manufacturer’s instructions for pre-assembly, assembly, internal stacking, tamper-evident closures, how to open and cleaning.

**PACKAGING MATERIALS (WRAPPERS)**

Sterilization wrappers used today for sterilization packaging are either disposable nonwoven fabrics made of natural or manmade fibers which are pressure-bonded together to form sheets of fabric; or reusable woven textiles made of natural and/or synthetic materials. Some are treated for water repellence.<sup>1</sup>

Reusable materials must be free of detergents, bleaches or other chemicals that could react with the sterilant and cause discoloration and/or adversely affect the contents of the pack.<sup>1</sup> Wrappers made of reusable woven textile need to be rehydrated by laundering between every use. Superheating, which could limit the ability to achieve sterilization, may result if textiles are not re-laundered.<sup>3</sup>

All reusable textiles need to be de-linted before using. Textile fabrics need to be inspected over a light table for defects before each use. Rips should not be sewn, which would increase the number of holes in the material. Defects should be repaired on both sides with a vulcanized patch applied using heat.<sup>2</sup>

All packaging materials should be at room temperature (68°-73°F/20°-23°C) and at a relative humidity of 30 percent to 60 percent for at least two hours before use. Sustaining room temperature and moisture content of woven material allows sterilant penetration and prevents superheating during the sterilization process.<sup>2</sup>

“Single-use packaging material should be used for one sterilization cycle. Disposable packaging material should be discarded after opening.”<sup>2</sup>

**Pre-assembly**

Packaging materials should be routinely examined for any holes, defects and inappropriate extraneous material. Wrap comes in various sizes and grade (sturdiness). Using the proper wrap size is important. The wrap must be of sufficient size and grade to adequately cover and support the weight and configuration of the medical device being wrapped. If the wrap is too large it will be hard to wrap and open aseptically. If the wrap is not sturdy enough for the weight or design of the items, it may have a tendency to tear during handling.

Using manufacturers’ written recommendations, facilities should develop policies and procedures for all packaging techniques.<sup>3</sup> Wrapping procedures should be standardized. To decrease confusion for the end user, like packages should be wrapped in the same size wrapper every time.

### **Assembly**

When using wrappers, reusable or disposable, the package should be wrapped snug, but not too tightly. If loose it could cause low spots which could collect condensate and if wrapped too tightly it could result in strike-through.<sup>3</sup>

Packages can be wrapped by the envelope fold method or the square fold method that is either sequential (see Figure 4 on page 90) or simultaneous (Figure 6 on page 90).

When sequential wrapping is done the items are wrapped twice, creating a pack within a pack. When a pack is wrapped

simultaneous the package is wrapped once but is done with a special double layered synthetic nonwoven material welded on the sides with a special double layered synthetic nonwoven material welded on the sides.

### **Decreasing the chance for tears**

Some larger devices or items with sharp corners may benefit by placing a towel or foam under the device being wrapped (Figure 5 on page 92). This provides a type of “cushion” to help prevent rips or tears in the wrap. The user



must make sure the “cushion” is compatible with the type of sterilization being used.

**Figure 5. Towel as cushion to decrease chance for tears**



Transfer trays are another device to help protect the integrity of the wrap. These are specifically designed plastic trays that can help alleviate the possibility of tears due to manipulation onto and off of carts. The packages can be placed on the trays before or after sterilization.

**Figure 7. Transfer trays**



### Closures for wrapped packages

Once assembled, the sterilization package needs to be secured. The most common closure for packages is indicator tape. The devices must ensure the package remains together, allow for sterilization penetration, avoid constriction of the pack, and maintain integrity of the package.

*“Tape (other than sterilization indicator tape) should not be used to secure packages, nor should safety pins, paper clips, staples, or other sharp objects. Elastomer bands*

*designed specifically for sterile packaging are acceptable as outside closures only if the wrapper manufacturer explicitly recommends their use and only if care is taken to choose the proper size (relative to the length and width of the package) so that the elastomer band fits snugly yet does not constrict the package (e.g., create an “hour-glass” effect) or cause excessive wrinkles or folds in the package.”<sup>3</sup>*

### Practical Application

- Follow recommended practices and manufacturer’s instructions on pre-assembly, assembly, decreasing the chance for tears, and closures for wrapped packages.

### PEEL PACKS

Paper-plastic or plastic pouches are frequently used to package small lightweight, low-profile items (e.g., one or two needle holders or small retractors). One side of the peel pack is clear plastic which is important when it is necessary to view the items before they are opened. Pouches are not recommended for heavy or bulky items, because the seals may break open.<sup>3</sup>

There are various size peel pouches and peel pack rolls (which can be cut to size) on the market today. Choosing the correct size and application of the pouch is important. If the pouch is too tight, the seal may not hold and if it is too loose, the item will move which could stress the seals to the point of rupturing. Proper sizing also allows for adequate air removal, steam penetration and drying.<sup>3</sup>

Some peel pouches are self sealing, meaning they come with a sticky strip that will fold over to form a seal after the item(s) is placed inside. Some need to be heat sealed with a special machine that applies pressure and heat, bonding the two together to form a seal. The user needs to make sure there are no creases or gaps in the seal which could allow microorganisms to enter the package and contaminate it.

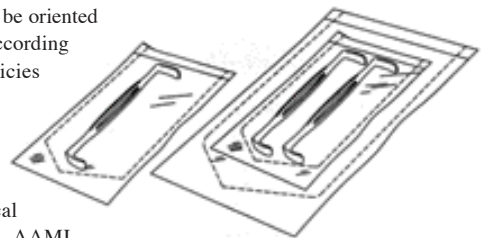
A single peel pouch is adequate unless the package contains more than one item or would be complicated to open aseptically with only one peel package (e.g., very small items).

“If the item is to be double-packaged, two sequentially sized pouches should be used (i.e., the sealed inner pouch should fit inside the other pouch without folding).” When assembled, the pouches should be positioned so that plastic of the inner one faces the plastic of the out one.<sup>3</sup> See Figure 8.

**Figure 8. Example of single- and double-packaging with paper-plastic pouches**

NOTE: Instruments should be oriented within paper-plastic pouches according to the healthcare facility’s policies and procedures.

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**Practical Application**

- Follow recommended practices and manufacturer's instructions on how to use peel pouches.
- When using double peel pouches, the inside peel pouch should fit without folding and be placed so the plastic of the inner pouch faces the plastic of the outer pouch.

**ORGANIZING DEVICES**

Organizing devices are sometimes used inside of containers or trays to help keep items contained together (Figure 9). The devices are also used as protection for sharp and/or small items.

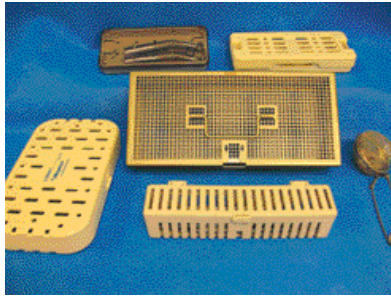
Small basket-type accessory, containers with covers or lids should only be used if they have been designed and tested for this purpose. The user has responsibility to test and evaluate the effectiveness of sterilization and drying of protective organizing devices. Specific recommendations of the device manufacturer should be consulted. See "Product testing" above for more information.

According to both AORN and AAMI:

*"Paper-plastic pouches should not be used within wrapped sets or containment devices because the pouches cannot be positioned to ensure adequate air removal, sterilant contact, and drying. The practice of confining instruments in paper-plastic pouches and then including them in wrapped or containerized sets has not been validated as appropriate and efficacious by packing and container manufacturers."*<sup>2</sup>

Other options for containing devices include all paper bags (Figure 10), foam or woven material that are designed and tested for this purpose.

**Figure 9. Containment devices**



**Figure 10. Paper sterilization pouches**



In order to verify adequate sterilant contact, upon assembly, a CI should be placed inside each organizing device within the instrument set.

**Practical Application**

- Follow recommended practices and manufacturer's instructions on how to use peel pouches.
- Never place paper-plastic peel pouches inside a containment device because you can not ensure adequate air removal, sterilant contact, and drying. This would also be true of plastic peel pouches.

## CHEMICAL INDICATOR/INTEGRATOR

Chemical indicators/integrators, both internal and external, should be specific to the sterilization process being used. The end user should be knowledgeable and demonstrate competency regarding the performance characteristics of the monitoring products.<sup>3</sup>

### Internal CIs

At least one chemical indicator/integrator should be used within each wrapped package. The CI may be a Class 3 (single parameter indicator), a Class 4 (multi-variable indicator), or Class 5 (integrating indicator).<sup>2</sup> AAMI ST79 states the Class 4 and Class 5 CIs provide more information than the Class 3 CIs that only measure temperature.

The CI should be placed in the area of the package considered to be the least accessible to sterilant penetration and air removal. This may or may not be the geometric center of the package. For rigid containers, the corners and the area away from the filters are the likeliest location of air pockets, therefore, resulting in the biggest challenge for the CI. So place two CIs, one in each of two opposite corners of the inside basket. For multi-levels, either in rigid containers or wrapped sets, a CI should be placed on each level of the set in opposite corners.<sup>3</sup> End users should know how to interpret the CI and not use the package if the endpoint is not achieved. Other packages in the load should be quarantined until the BI results are available or other indicators are checked if the BI was not run.<sup>3</sup>

### External CIs

An external chemical indicator, classified as Class 1, should be affixed to each package unless the internal CI is visible. The purpose of the external CI is to distinguish between processed and unprocessed devices. The external chemical indicator maybe located on the package, an identification card, tamper-proof locks, the filter, or elsewhere according to the policy of each healthcare facility. The indicator should be examined after sterilization and before use to make sure that the package and its contents were exposed to a sterilization process.<sup>3</sup>

#### Practical Application

- Place internal CIs inside each package in the areas that create the greatest challenge to air removal and sterilant penetration.
- Place an external CI on the outside of each package unless the internal CI is visible.
- If the external or internal CI have not reached their acceptable endpoint, do not use the package.

## Count sheets

Instrument count sheets should not go inside wrapped or containerized instruments sets. Various types of copy paper (not medical grade paper) and toners are usually used to print count sheets. Currently, there is no available research regarding the effects of the copy paper or toners to the sterilization process. Paper and toner ink may pose a risk of reaction to some sensitized patients due to the chemicals used in the manufacturing of these products.<sup>2</sup>

One option is to attach the instrument inventory count sheets to the outside of the container or wrapped package. Folding and then attaching the count sheet to the container handle or taping it to the wrap is one acceptable method to ensure the count sheet stays with the package (Figure 11 below).

Figure 11. Count sheet placement on outside of package



#### Practical Application

- Do not place count sheets inside of wrapped or containerized instruments sets to avoid the patient contacting paper or toner ink which may cause a reaction in sensitized patients.

## Labeling the packages

Packaging systems should be labeled with the description of the package contents, identification of the person assembling the package and a lot control number. To decrease confusion, packages should be labeled before being put into the sterilizer.<sup>2</sup>

Package labels (i.e., process indicators, product identification, expiration statement labels) should be fixed firmly to the package all the way through processing, storage, and distribution to the point of use. If a marking pen is used to mark surgical packages, the information should be written on the indicator tape or attached label. Marking pens should only be used on the plastic side of peel-pouches.<sup>2</sup>

*“Writing on the paper side of the pouch or on a wrapper (woven or nonwoven) could cause damage to the package (which might not be noticeable) and thereby compromise the barrier protection.”<sup>3</sup>*

To avoid toxins being deposited on packs or instruments, the ink in marking pens should be nontoxic.

When asking sterile processing professionals what they use for package labeling, they tell me they use a black felt tip marker. To my knowledge, the only felt tip marker tested to withstand extreme heat and steam as well as processing chemicals and cleaners is the “Industrial Sharpie.” It comes in fine point (item no. 13601) or extra fine point (item no. 13801). The Industrial Sharpie package states one of the specific uses is for sterilization such as autoclaving.

### Practical Application

- Only write on the indicator tape, attached label or plastic side of a peel pouch so that toxins do not contact the medical devices.

### Extended cycles

Today’s sterile processing professionals are faced with the issue of extended steam sterilization cycles for surgical instruments (a cycle time longer than four minutes at 270°-275°F/132°-135°C in a dynamic-air-removal sterilizer). AORN’s Sterile Processing/Materials Management Specialty Assembly (SP/MM SA) Coordinating Council released a general statement on extended cycles:

*“Each medical facility needs to make sure that all their products used for sterilization (peel pouches, wrap, etc.) can withstand these longer steam sterilization cycles. Each medical facility needs to make sure that the products used in extended cycles are validated for these types of cycles. Many manufactures have tested their products for these longer cycle times. The manufacture of the products should supply information to the user for their records.”<sup>7</sup>*

At the time of writing this article there are two manufacturers of sterilization packaging products that have documentation posted on AORN’s SP/MM SA Web portal at <http://communities.aorn.org/COP/SPMatMngmt/FileSharing/index.fusion> that state their products can withstand sterilization cycles with extended exposure times up to 30 minutes.<sup>7</sup>

### Practical Application

- Check with the manufacturer of the packaging material to make sure it can be used in extended cycles or cycles longer than four minutes at 270°-275°F/132°-135°C in a dynamic-air-removal sterilizer.

### Competency

Employees responsible for selecting and using packaging systems should be knowledgeable about sterilization principles and each manufacturer’s written directions and sterilization compatibility issues of each type of packaging. The competency of each staff member responsible for packaging systems should periodically be evaluated and documented.<sup>2</sup>

### Practical Application

- All the information in this inservice should be part of the competency testing of all employees that select and use packaging systems.

### Summary

Sterilization packaging is not a simple topic. It must adequately allow sterilization of the enclosed medical device and also maintain sterility of the contents until used. Classified by the FDA as a Class II medical device, it is much more than a box, bag or gift wrap! To ensure patient safety, specific manufacturers written validated guidelines for each type of system must be followed and staff must demonstrate competency in each packaging system used. Meanwhile, save the gift wrapping skills for the holidays!

### Glossary of Terms

- ▶ *Aseptic presentation*: Maintaining the sterility of the contents as a sterilized package is opened and the contents are removed.<sup>5</sup>
- ▶ *Containment device*: Reusable rigid sterilization container, instrument case, cassette or organizing tray intended for use in healthcare facilities for the purpose of containing reusable medical devices for sterilization.<sup>5</sup>
- ▶ *Reusable rigid sterilization container*: Sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.<sup>5</sup>
- ▶ *Organizing tray*: Reusable metal or plastic containment device that organizes and protects instruments and components in specified locations within the device, and that is usually wrapped with an approved wrapping material.<sup>5</sup>
- ▶ *Insert case or tray*: Reusable case or tray that is placed inside a reusable rigid sterilization container, that is fixed or not fixed in place, and that serves to group or protect instruments and components.<sup>5</sup>
- ▶ *Reusable accessory*: Optional component not essential in itself but that aids in the organization and protection

of instruments within a sterilization container system. Such items include, but are not limited to, insert cases, organizing trays, cassettes, brackets, posts, partitions, instrument mats, racks and stringers.<sup>5</sup>

- ▶ *Instrument case/cassette*: Sterilization containment device that consists of a lid and a base with means to allow sterilant penetration and removal, and that is enclosed in a sterile barrier system if sterility is to be maintained.<sup>5</sup>
- ▶ *Product testing*: Routinely testing processed items with biological and chemical indicators whenever “major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper.”<sup>3</sup>
- ▶ *Biological indicator(BI)*: “Test system containing viable microorganisms providing a defined resistance to a specified sterilization process.”<sup>3</sup>
- ▶ *Chemical indicator(CI)*: “Device used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment.”<sup>3</sup>
- ▶ *Drying time*: Time required to dry steam sterilized items inside the sterilizer.<sup>5</sup>
- ▶ *Dynamic-air-removal sterilizers*: Type of sterilization cycle in which “air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure-pulse [SFPP] cycle).”<sup>1</sup>
- ▶ *Gravity-displacement steam sterilizers*: Type of sterilization cycle in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber.<sup>3</sup>
- ▶ *Ethylene oxide*: Type of gaseous chemical sterilization cycle in which the four process variables are ethylene oxide (EO) gas concentration, exposure time, temperature and relative humidity.<sup>5</sup>
- ▶ *Hydrogen peroxide gas plasma*: Type of gaseous chemical sterilization cycle in which the four process variables are hydrogen peroxide concentration, time, temperature and gas plasma power level.<sup>5</sup>
- ▶ *Ozone sterilization*: Type of gaseous chemical sterilization cycle in which the four process variables are ozone dose injected, humidity, exposure time and temperature.<sup>5</sup>
- ▶ *Flash sterilization*: Process designed for the steam sterilization of patient care items for immediate use.<sup>5</sup>

### Ordering Information

#### AAMI

ANSI/AAMI ST79:2006, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

Order code: ST79 or ST79-PDF

Available in an attractive binder featuring sturdy metal rings, ledger-weight pages, and a laminated tab for each section for easy navigation. AAMI will issue revised pages that can be substituted into the binder when changes are made.

Also available in PDF format and as part of AAMI’s electronic CD and subscription products.

Price/Member discount price: \$200/\$100.

AAMI documents can be purchased through AAMI by credit card using the following four options:

1. Internet: <http://www.aami.org>
2. Call: 1-877-249-8226 or 240-646-7013
3. Fax: 301-206-9789
4. Mail: AAMI, Customer Service Center, 1100 N. Glebe Road, Suite 220, Arlington, VA 22201-5762

#### AORN

AORN Standards can be purchased through AORN using the following options:

1. Internet: [www.aorn.org/bookstore/ordering.htm](http://www.aorn.org/bookstore/ordering.htm)
2. Call: 1-800-755-2676 ext. 1 or 303-755-6304 ext. 1 (Monday-Friday, 8AM to 4:30PM mountain standard time)
3. Fax: 303-750-3212
4. By mail: AORN, Inc., Customer Service/Book Orders, 2170 South Parker Road, Suite 300, Denver, CO 80231-5711, USA
5. Payment can be made by:  
VISA, MasterCard, American Express, or Discover, either online or by mail/fax/phone.  
By authorized PO, and AORN will bill you (\$100 minimum purchase). Sorry, we cannot accept POs for education conferences or services. (Not available for online orders).
6. A CDRom of the standards is available for the first time this year.

#### References

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Rose Seavey, RN, BS, MBA, CNOR, ACSP, is the director of the sterile processing department at The Children's Hospital of Denver. Ms Seavey is an active member of the Association of periOperative Registered Nurses (AORN) and was elected to the National AORN Nominating Committee for 2005-2007. She was honored with AORN's award for Outstanding Achievement in Clinical Nurse Education in 2001. She served as the President of the American Society of Healthcare Central Service Professionals (ASHCSP) in 2003 and is the 2002 recipient of the ASHCSP National Educator of the Year award. She is currently the chair for the AORN speciality assembly for Sterile Processing Materials Management. Ms. Seavey is a member of several AAMI working group committees that are developing recommended practices and is currently a co-chair for the AAMI ST8, Hospital steam sterilizers. In addition she has lectured and authored many articles on various topics relating to perioperative services and sterile processing, locally, nationally and internationally.

ANSWERS	
1. T	6. T
2. T	7. T
3. F	8. T
4. T	9. T
5. F	10. F

### Sterile Process and Distribution CEU Information

CEU Applicant Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for one and one-half (1.5) contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until recertification is required. **DO NOT SEND LESSON OR TEST TO CBSPD.**

For additional information regarding Certification contact: CBSPD, 121 State Hwy 31N, Suite 500, Flemington, NJ 08822 or call 908-788-3847 or visit the Web site at [www.sterileprocessing.org](http://www.sterileprocessing.org).

IAHCSPM has awarded one and one-half (1.5) Contact Points for completion of this continuing education lesson toward IAHCSPM recertification.

### Nursing CE Application Form

This inservice is approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to one (1) year from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions.
6. Submit this form and the answer sheet to:  
Workhorse Publishing  
Managing Infection Control  
PO Box 25310, Scottsdale, AZ 85255-9998
7. For questions or follow-up, contact [craig@manageinfection.com](mailto:craig@manageinfection.com).
8. Participants who score at least 70% will receive a certificate of completion within 30 days of *Managing Infection Control's* receipt of the application.

### Application

Please print or type.

Name \_\_\_\_\_

Mailing Address \_\_\_\_\_

City, State, Country, Zip \_\_\_\_\_

Daytime phone (                    ) \_\_\_\_\_

Position/Title \_\_\_\_\_

Social Security or Nursing License Number \_\_\_\_\_

Date application submitted \_\_\_\_\_

Signature \_\_\_\_\_

*Offer expires January 2013*

On a scale of 1-5, 5 being Excellent and 1 being Poor, please rate this program for the following:

- 1) Overall content \_\_\_\_\_
- 2) Met written objectives \_\_\_\_\_
- 3) Usability of content \_\_\_\_\_

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