HEALTHCARE PURCHASING NEWS

January 2008

The self-study lesson on this central service topic was developed by STERIS and AAMI (Association for the Advancement of Medical Instrumentation). The lessons are administered by KSR.

Earn CEUs

The series can assist readers in maintaining their CS certification. After careful study of the lesson, complete the examination at the end of this section. Mail the complete examination and scoring fee to Healthcare Purchasing News for grading. We will notify you if you have a passing score of 70 percent or higher, and you will receive a certificate of completion within 30 days. Previous lessons are available on the Internet at *www.hpnonline.com.*

Certification

This in-service has been pre-approved by the CBSPD for 1 Contact Hour. Follow the CBSPD CEU Protocols for pre-approved in-services. The protocols can be found on CBSPD website sterileprocessing.org or by calling CBSPD office at 908-454-9555.

For more information

Direct any questions to Healthcare Purchasing News (941) 927-9345, ext 202.

Learning Objectives

1) Explain the various types of sterilization packaging.

2) Discuss the advantages and disadvantages of each type of packaging.

3) Select appropriate packaging for specific instruments and applications.

Sponsored by:

CBSPD • AAMI Association for the Advancement of Medical Instrumentation

STERIS

SELF-STUDY SERIES *Sponsored by* STERIS

Instrument packaging: The basics for sterile processing professionals

by Heide Ames

The shield is a universal symbol of protection. Shields protect their users from harm and defend against invasion by an enemy. In the world of sterile processing, sterile packaging acts as a shield against bacterial invasion, protecting patients from harm. And like any shield, proper selection, care and use ensure that the items being protected remain safe until needed.

Packaging uses

Sterile processing departments sterilize thousands of instruments daily. Each successful sterilization process ensures that bacteria, viruses and other disease-causing agents left on instrumentation have been destroyed. These instruments remain sterile as long as they are not exposed to sources of bacteria or viruses such as counters, hands, and even the air itself. This is where packaging comes into play. Packaging provides a barrier that shields sterile instruments from recontamination after sterilization.

A wrapped load for steam sterilization

Packaging also serves to organize instrumentation. For example, rigid sterilization containers provide compartments, posts and stringers that help segregate and organize instruments, and smaller pouches can be placed in larger pouches or container systems to manage small components. When used properly, packaging ensures that the organized and packaged instrumentation remains sterile until it is needed.

Types and materials

Packaging is defined in three categories: wraps, pouches and rigid sterilization containers. Each type of packaging has advantages and disadvantages. A clear understanding of packaging pros and cons will help SPD professionals optimize their use of packaging and ensure that sterile devices are delivered each and every time.

Wraps

The simplest of packaging materials is the reusable wrap often referred to as *muslin wrap*. Muslin wraps are made of cotton and come in various forms. Muslin is a woven material. This means that cotton fibers are intertwined in a pattern resulting in a crisscross of fibers creating a weave. The strength of the fabric comes from the fibers' thickness and the weave pattern. The typical muslin wrap used by medical professionals today is 140-thread count muslin in a variety of sizes and colors that allow color coding of wrapped items.

Muslin wraps require laundering and over time become worn and unusable. As an alternative, non-woven wrap materials are available for wrapping instrument trays. *Non-woven wraps* serve the same purpose and are used in the same manner with one important difference: these wraps are disposable. Non-woven wraps are typically constructed from a pulp or spun-bound synthetic material that is made of a single continuous fiber. The non-woven wraps come in a variety of strengths that offer better tear or puncture resistance. Synthetic materials are generally preferred for their greater consistency and better performance. All non-woven wraps are designed for one-time use.

Both muslin and synthetic wraps are used today. Both require double-wrapping, which is accomplished either individually or simultaneously. When done individually, the first sheet is wrapped and secured, and then a second sheet is wrapped over the first and secured. When done simulta-

neously, two wraps are wrapped and secured as one process. Double wrapping offers additional protection from tears and holes. If the first layer is torn or punctured during storage and transport, the second layer maintains the package's sterility.

Pouches

Pouches are sealable envelopes that instruments are placed in before sterilization. Pouches are available in a variety of materials, sizes and designs. They are used for lightweight instruments, and some can be placed within other packaging systems such as rigid sterilization containers or trays.

STERIS Corporation's Vis-U-All pouch family

The most common pouches are constructed from a paper bonded to a transparent plastic material. Pouches used within other packaging materials are constructed of a paper bonded to paper. The paper allows for air removal and penetration of sterilant during a cycle. Paper-backed pouches are used in ethylene oxide and steam sterilization processes. They are not used in hydrogen peroxide or plasma processes, however, because paper will react with the hydrogen peroxide and prevent the sterilant from penetrating the pack.

Some pouches are made of Tyvek®* material bonded either to a transparent plastic or to more Tyvek. This material is not reactive to ethylene oxide or hydrogen peroxide and is the material of choice for hydrogen peroxide and plasma sterilization processes.

Pouches may also have a chemical indicator printed on the pouch. Chemical indicators use chemicals that, when they are exposed to a sterilant, will change color. These chemical indicators can also be printed on the interior side of the pouch to act as an internal indicator. External indicators confirm that the pouch has been processed. Internal indicators are designed to prove that the sterilant penetrated the pouch.

Pouches come in two basic styles: heat-sealed and self-sealed. The most common pouch used in sterile processing departments is the *heat-sealed pouch*. After the instruments are placed into a pouch, heat is applied to the open side to fuse the pouch together. Heat seal pouches are an economical solution and are available in a flat pouch, a gusseted pouch and roll tubing. Flat pouches consist of two pieces of material that have been sealed on three sides. Gusseted pouches have expandable sides that allow bulkier instruments to be enclosed and sealed. Roll tubing has two open ends. The desired length is measured and then cut. Both ends of roll tubing must be sealed to enclose the instruments.

The second style of pouch is the *self-sealed pouch*. These are flat pouches that have three factory sealed sides. The fourth seal is made with a wide adhesive strip. Self seal pouches do not have gusseted or tube-style versions.

Rigid sterilization containers

Sterilization containers are made of durable rigid materials such as metal, plastic or composites. These rigid, reusable types of packaging provide a good physical barrier to protect instruments. Each container includes at least one basket to hold the instruments and allow aseptic removal and presentation of the contents.

Rigid sterilization containers house a filter that allows the sterilant to enter the container and contact the instruments. In order to prevent recontamination, the filters provide a microbial barrier. Filter systems use disposable filters typically made of synthetic materials, or a reusable porous filter.

Shelf life

All packaged items have *event-related shelf life*. This means that the items within the packaging are considered sterile until an event occurs that breaks the sterile barrier. Events include tears, punctures, moisture, or opening of the package.

Amsco® rigid container made of composite material

Which packaging should be used?

Each type of packaging has its place in today's sterile processing environments. The pliable nature and flexible sizes of wraps allows for odd-shaped instrumentation and instrument sets of any size to be packaged and sterilized. Wraps made of synthetic materials have proven performance in a multitude of sterilization processes like ethylene oxide, steam, hydrogen peroxide and plasma sterilization processes. The versatility of wraps makes them a good choice for sterilization packaging.

Though wraps are pliable, they are also fragile. Muslin wraps become worn and threadbare over time. This weakens the bacterial barrier. Synthetic wraps can be prone to tears, rips and punctures during handling. These compromise the sterile barrier making the items unusable. Both types can discharge lint when opened, which allows contaminated debris to come into contact with the sterile instrumentation. When using wraps, it is important to select materials that are low-linting and puncture-resistant. Wrapped items should be stored on lined shelves to prevent accidental tears or punctures. Each package must be inspected prior to use for tears or punctures that may have penetrated both layers of the wrap.

Pouches offer a convenient method for packaging small lightweight items. They can also be a convenient means of organizing small items within a larger container or tray. For example, they can be used to contain items like cords for easier handling and presentation in the OR with the instrument set.

Like wraps, pouches are susceptible to puncture and tears. It is important to evaluate the appropriateness of the instruments being placed in a pouch. Devices with sharp tips can easily puncture pouch materials. However, it is possible to double-pouch instruments to protect against tears and punctures.

It's important to remember that pouches are designed for specific sterilization processes. Using the wrong pouch in a particular sterilization cycle can result in non-sterile and/or damaged instrumentation. For example, the Tyvek pouches used for hydrogen peroxide and plasma sterilization will melt onto instrument surfaces if processed in a steam sterilization process by mistake.

Rigid sterilization container systems provide the best physical protection for instruments. In addition, multiple trays, compartments and a variety of accessories make it easier to organize the instruments. Rigid container systems also allow for several instrument pieces and whole instrument sets to be processed within one container, which can simplify

*See **SELF-STUDY** on page 42*

Self-Test Answers: 1. B, 2. C, 3. D, 4. A, 5. E, 6. A, 7. B, 8. D, 9. B, 10. C

SELF-STUDY *from page 41*

aseptic presentation in the OR and reduce the amount of space required for storage.

Rigid container systems do have some constraints. Depending on the container's design, it may have sterilization limitations. For example, some container systems cannot be used in hydrogen peroxide or plasma sterilization systems. Some designs should not be used for gravity steam sterilization but can be used in dynamic air removal steam sterilization processes. When choosing a rigid sterilization system, it is important to ensure that the containers will be appropriate for the types of sterilization processes that are used by the facility.

Typically, a combination of all three packaging methods is the best choice for many facilities because of the variety of items they must process each day. For example, wraps are best for odd shaped items and loaner sets. Pouches are great for those single items typically found missing from sets or for organizing cords and small items. Rigid container systems provide the best physical protection and organization for the most common surgical sets.

Wrapping it up

Packaging offers a variety of choices to protect sterile instrumentation from contamination. Proper care to select and use the appropriate packaging system for the desired application will ensure that sterility is achieved and maintained. As with any medical device, the packaging manu-facturer's instructions for use must be reviewed and followed to assure proper function and results. When used correctly, packaging is an effective shield of protection for instruments, and ultimately, for the patients on whom these devices are used. HPN

**Tyvek® is a registered trademark of DuPont.*

References:

ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities

ICT Infection Control Today Magazine; That's a wrap; Kathy Dix; 11/7/2006

ICT Infection Control Today Magazine; Choosing a Sterilization Wrap for Surgical Packs; William A. Rutala, PhD, MPH, and David J. Weber, MD, MPH; 05/01/2000

Centers for Disease Control and Prevention; Sterilization – Packaging and Storage; 8/7/2007

Healthcare Purchasing News; Routine inspection and repair of rigid sterilization containers; Linda Clement, Michael E. Russell, John Wheeler; March, 2006

Materials Management in Healthcare; Sterilization cues for containers; Arlene Carlo; 12/3/2007

CONTINUING EDUCATION TEST • JANUARY 2008

Instrument packaging: The basics for sterile processing professionals

Circle the one correct answer:

1. **What are the two uses for packaging?**
   a. Microbial barrier and physical protection
   b. Microbial barrier and organization
   c. Sterile storage and moisture protection
2. **Which of the following materials is not used to construct wraps?**
   a. Cotton
   b. Cellulose
   c. Aluminum foil
3. **Why are synthetic wraps preferred over muslin wraps?**
   a. Synthetic wraps provide consistent performance and better puncture resistance
   b. Synthetic wraps are more pliable than muslin wraps
   c. Synthetic wraps are disposable
   d. a. and c.
4. **Pouches are used to package small lightweight items.**
   a. True
   b. False
5. **What are chemical indicators used for when printed on pouches?**
   a. External indicator shows that the pouch has been through a sterilization process
   b. Internal indicator shows that sterilant penetrated the pouch
   c. Color coding identifies where the instruments should be used.
   d. b. and c.
   e. a. and b.
6. **What are the two ways that pouches are sealed before sterilization?**
   a. Adhesive strips and heat
   b. Indicator tape and heat
   c. Safety pins and adhesive strips
   d. Safety pins and heat
7. **Rigid sterilization containers provide the worst physical protection of all packaging choices.**
   a. True
   b. False
8. **All rigid sterilization systems can be used for:**
   a. All types of steam sterilization
   b. Hydrogen peroxide or plasma sterilization
   c. Gravity steam sterilization
   d. None of the above
9. **Pouches and wraps share which disadvantages?**
   a. Only used for small lightweight items
   b. Prone to tear and punctures
   c. Limited sterilization processes
10. **Which advantage do rigid sterilization containers provide over pouches and wraps?**
    a. Can be used in multiple sterilization processes
    b. Can be used as a microbial barrier
    c. Provide the best physical protection of instrumentation

Presented by HEALTHCARE PURCHASING NEWS

Sponsored by STERIS

Request for Scoring

- I have enclosed the scoring fee of $10. (*Payable to **KSR Publishing, Inc.** We regret that no refunds can be given. Multiple submissions may be paid with a single check.)*

Detach page, and return to:
Continuing Education Division
KSR Publishing, Inc.
2477 Stickney Point Road, Suite 315B
Sarasota, FL 34231
PH: 941-927-9345 Fax: 941-927-9588

Please print or type. Return this page only.

Name	
Title	
Hospital Name	
Mailing Address	
Apt/Suite	
City, State, Zip	
Daytime Phone	