HEALTHCARE PURCHASING NEWS

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LEARNING OBJECTIVES

1. *Describe the types and material properties of sterilization wraps*
2. *Name five functional factors to consider that impact wrap performance*
3. *Discuss process-related variables that can impact sterilization wrap conversion*

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SELF-STUDY SERIES

Sterilization wrap

Facts to help optimize selection and use

by Jamie Zarembinski

Today is a hectic wrap day in the sterile processing department. Here's the scene; the surgical schedule shows that loaned sets are coming in for several cases, but they have arrived late and require a quick turnaround. The department also received a bunch of batteries that will need to be reprocessed. On top of all this, the operating rooms are calling again about pinholes, rips and tears they have discovered on their wrapped sets, which have caused the entire contents of the packs to be unusable. Needless to say, the plan to find a new sterilization wrap vendor could not have come at a better time!

The wrap selection process

Choosing a new wrap is simple, right? Just get some samples from the vendors, wrap and reprocess some typically challenging items, then send them to the OR for evaluation. But is this everything that needs to be considered before choosing the optimal wrap for a particular healthcare system? The Association for the Advancement of Medical Instrumentation doesn't think so. AAMI recommends a systematic process using a multidisciplinary team of individuals, and includes a review of:

- Product performance
- FDA clearance and legal status
- Expert opinions
- Standards and guidelines
- Contribution to patient safety
- Compatibility, safety, and environmental impact
- Results of documented product trials, if applicable[1]

Furthermore, AAMI recommends that the trials performed at each facility confirm the applicability of the chosen new product to that facility's needs and desired results. For example, if the change in wrap vendor is being driven by moisture events (wet packs) the trial would include appropriate testing demonstrating the impact the new wrap has on moisture events in that facility.

Wrap options

Choosing a new wrap begins by reviewing all available wrap materials. *Reusable woven wrap* consists of many threads interwoven to make a tight weave. One example is muslin sterilization wrap, a lightweight, loose weave, high-thread-count woven cotton fabric. The loose weave gives muslin a lot of flexibility, and the high fiber count enhances its durability. These reusable sheets are both puncture and cut-resistant, benefits that helped them become the sterilization wrap standard of care for many years. Today's woven wraps are typically composed of several types of fiber, such as cotton, polyester, and carbon fiber, to create a water-resistant yet pliable sheet.

If reusable woven wrap is being considered, AAMI recommends that facilities have a means to track the number of launderings and sterilization cycles each piece of wrap has undergone. Facilities should also have procedures in place for inspecting and mending wraps, and these procedures should be consistent with the wrap manufacturer's instructions for use. In addition, it's important to investigate whether the selected woven wraps have a set limit to the number of times they can be laundered and/or sterilized and remain effective.

The variety of materials used in woven wraps requires an assessment of their compatibility with the sterilization processes being used in each facility. Not every woven wrap material can be used for every sterilization process. For example, cellulose wrap materials cannot undergo vaporized hydrogen peroxide sterilization cycles. The wrap's instructions for use will indicate any compatibility limitations and should be followed to assure effective processes.

Single-use nonwoven wraps are the most common sterilization wraps used in the United States. Nonwoven wraps are formed by laying down fibers or filaments over each other and then applying pressure. The fibers create intricate crisscrossed layers, which creates a tortuous pathway that provides a microbial barrier. Fiber-based nonwoven wraps use cellulose fibers obtained from plants. Cellulose fiber-based wraps offer good durability and puncture resistance, and excellent moisture absorption and wicking. Modern fiber wraps combine cellulose

material with synthetic binders and small amounts of polyethylene terephthalate fibers. This increases the material's malleability without compromising the bacterial barrier or moisture absorbent properties.

Synthetic nonwoven wraps using synthetic filaments are the most common sterilization wrap in use. The wraps are created by melting a plastic and spinning the molten liquid to create filaments. When a continuous filament is made and deposited it is referred to as spunbond. When the filament is finer and noncontinuous, the process is called meltblown. Typically, sterilization wrap is composed of three to four spunbond and meltblown layers of polypropylene (a type of polyolefin). These wraps are durable, moisture repellent, and chemically resistant.

Figure 1: Single Use 2-ply synthetic sterilization wrap.

Functional factors impacting performance

There are a number of factors to consider before choosing between a woven reusable wrap and a nonwoven single-use wrap. Moreover, it may actually be necessary to select more than one type, size, and weight of sterilization wrap to address all the needs in a particular facility.

The way in which a sterilization wrap is used in a sterile processing department dictates the performance requirements that are needed. There are five key factors to consider when determining sterilization wrap performance needs for your facility.

Size. Sterilization wrap must be appropriately sized to properly enclose specialty trays, general instrument trays, bowls, and bulky or unusually shaped medical devices for sterilization. The wrap should be large enough to be loosely folded to provide a barrier to environmental contamination but should not be so loose that it could snag or buckle and create an opportunity for contamination. Wrap that is too large creates extra folds or bulky areas that may make sterilant penetration difficult. Wrap that is too small can buckle and reveal open pathways leading directly to the pack's contents.

Strength. Wrap must be strong enough to hold the devices without tearing. Each type of wrap is rated for specific item weights. This is particularly true for nonwoven wraps. Items that weigh more than the wrap's rated weight could cause extra stress on corners that results in tearing. Compare your facility's wrapped item weights against the weight ratings of the wraps under consideration to ensure that a solution is available for all wrapped items.

It's also important to keep this in mind: the higher the weight rating, the thicker the wrap. Thickness combined with the water repellency of a dual-layer wrap can lead to unwanted moisture events when lightweight items are wrapped with thicker wraps. Be sure to follow each wrap product's instructions for use.

Compatibility. The sterilization wrap must be compatible and validated for the sterilization processes used at the facility. Each wrap's instructions for use should include a list of sterilization processes and cycle parameters for which it has been validated. It may be necessary to have more than one wrap type, weight rating, and size to accommodate all sterilization processes.

Malleability. Sterilization wraps must be flexible enough to conform to the shapes of the items being wrapped, but also be rigid enough to prevent snags and abrasions. A wrap's malleability is also especially important for aseptic opening. Aseptically opening a pack requires surgical staff to pull the various folds away from the sterile items without touching them. Malleable wraps can achieve this because they easily drape away from the pack contents when pulled. Wraps with poor malleability can be difficult to unwrap and may retain shape memory after sterilization and storage, both of which complicate aseptic opening of the wrapped item.

Moisture absorption properties. This fifth performance factor is a bit of a double-edged sword. On the one hand, good moisture absorption and wicking help distribute condensate during steam sterilization and promote drying. On the other hand, these same properties can be a negative if a sterile pack is exposed to humidity during storage since they may increase microbial migration into absorbent materials.

Wraps with moisture-repellent natures do not absorb moisture during storage, but they tend to allow pooling of condensate and can be challenging to dry after steam sterilization. This challenge can be easily overcome by following all instructions for use, ensuring good steam quality, and using wicking materials within the wrapped items.

Process factors impacting successful use

There are a few process-related considerations to review when selecting new sterilization wraps. Though they are not directly related to the wrap's performance, failure to address these could lead to a poor conversion experience.

Prep and pack processes. The department's set preparation and wrapping techniques should be reviewed for compliance to manufacturer's written instructions for use. The review should include confirming weight ratings and sterilization parameters and assessing the department's wrap folding techniques. In general, wraps should be folded loosely to prevent stress on corners and edges. However, wraps should not be so loose that they easily catch on other items, which can cause tears, punctures, or premature opening of the pack. There are several recommended methods for wrapping items. Refer to each wrap's instructions for use and to guidelines such as the ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities for specific details. Procedures should be updated, training provided, and competency verified before converting to any new wrap.

Wrap accessories. Items such as tray corner protectors, absorbent/wicking towels, tray liners, instrument organizers, tray pouches and other accessories are used within wrapped items to help protect wrap from damage or to encourage condensate drainage and drying during steam sterilization. It's important to assure that these accessories are validated for use with the new wrap. This is especially important when going to a new wrap material that has different moisture absorbing and wicking properties.

Handling and transport techniques. All wrapped packages should be touched as little as possible. Wrapped items should always be lifted from the bottom and placed onto the sterilizer racks. They should not be pushed or pulled across surfaces, since

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

surface burrs/irregularities can catch and cut the wrap. Items used to carry or protect wrapped packages from damage, such as trays and shelf liners, should also be reviewed for compatibility with the new wrap.

Storage methods. Ensure that wrapped items are not stacked or positioned in a way that could create punctures or tears. Storage shelves should be free of burrs and snag points. Shelf liners may help protect wrapped packages from damage.

Wrap inspection. Sterile processing and operating room staff should be trained on how to properly inspect wraps. Before wrapping and after sterile packs have been moved to the sterile field, each sheet of wrap should be inspected for holes, tears, abrasions, and cuts. Some sterilization wraps now recommend the use of light-boxes for inspection in sterile processing departments. Others recommend holding the wrap up against a light source such as an inspection light or ceiling light.

The ability to see holes in a wrap depends on several factors. One study looked at the ability of OR staff to detect holes within the thickest single-use polypropylene two-ply sterilization wrap available. Holes ranging in sizes from 1.1 to 10 mm were evaluated. The study demonstrated that only the 10 mm hole could be consistently detected by OR staff.[2] A similar study evaluated a medium-weight wrap with hole diameters between 0.86 and 5.0 mm. The results indicated that holes of 2.5mm and higher were readily detectable by the naked eye.[3] However, both studies concluded that the ability to detect holes was not related to experience, the OR light source, or inspection time, and others have suggested that the pattern on these specific wraps may have contributed to the inability to find holes.

In the real world, wrap damage is rarely due to the manufacturing process. Instead, it is more likely to be due to an event that occurred during transport, handling or storage. The tables below summarize some types of damage and their causes for the two primary categories of wrap products.

Assure a positive sterilization wrap conversion

Pin holes, rips, and tears in wrapped surgical sets create havoc in the OR and cause more work and critique for the sterile processing department. Changing wrap products may solve the problem, but only if all functional, process, and human factors are taken into consideration before making the selections. Rather than being reactive, the evaluation and selection process should be systematic and should meet the needs of both the surgical and sterile processing departments. This will lead to a successful conversion experience. HPN

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Jamie Zarembinski is the clinical educator for sterile processing at Key Surgical. She speaks on sterile processing topics at medical facilities and educational seminars around the United States, while also working with sterile processing staff to develop and implement best sterile processing practices. In 2018 Jamie was the recipient of

Table 1: Common damage found on woven sterilization wrap

Damage Description	Cause
Straight-line cut with clean edges	Knife cut from opening shipping packaging with a box knife
Snag cut: Straight line or many smaller cuts or holes in a straight line. Ragged edges	Tray pulled or pushed on rough surfaces
Pressure hole less than 2 mm, typically along tray edges	Dropped packages, or from packages stacked on top of the wrapped tray
Triangular snag hole with loose fibers on the edge	From being pushed or pulled against a bur on a sterilizer cart or rack surface
Puncture hole penetrates package and has ragged edge with fibers	Typically, from instruments within the tray puncturing the wrap
Small pin hole that may or may not go through both sheets	Loosening fibers due to repeated laundering
A fuzzy surface or fuzzy perimeter with a hole in the middle	Caused by repeated pulling and pushing over a hard surface. If frequent enough, it can create a hole.
Staining and discoloration	Minerals within steam or water supply such as copper or iron. Use of bleach or other unapproved cleaning agent

Table 2: Common damage found on nonwoven sterilization wrap

Damage Description	Cause
Straight-line cut with clean edges	Knife cut from opening shipping packaging with a box knife
Straight line cut with compressed edges, typically found at bottom tray edges or top tray edges	Heavy wrapped package is moved along a smooth hard surface Heavy package is stacked on top of the wrapped package
Snag cut: Straight line or many smaller cuts or holes in a straight line. Ragged edges	Tray pulled or pushed on rough surfaces
Pressure hole less than 2 mm, typically along tray edges	Dropped packages, or from packages stacked on top of the wrapped tray
Triangular snag hole with loose fibers on the edge	From being pushed or pulled against a bur on a sterilizer cart or rack surface
Puncture hole penetrates package and has ragged edge with fibers	Typically, from instruments within the tray puncturing the wrap
Small pin hole that may or may not go through both sheets	Manufacturing defect or physical damage from a sharp instrument
Large round or irregular hole with hard melted edges.	Contact with a hot instrument or light bulb
A fuzzy surface or fuzzy perimeter with a hole in the middle	Caused by repeated pulling and pushing over a hard surface, if frequent enough, it can create a hole.

the Robert Hilbolt Award for outstanding healthcare professional in the sterile processing industry from the Michigan Society of Healthcare Central Service Professionals (MSHCSP). She has completed CRCS, CHL and CER certifications through the Healthcare Sterile Processing Association and is currently working towards becoming an HSPA Certified Instrument Specialist.

CONTINUING EDUCATION TEST • JULY 2022

Sterilization wrap: Facts to help optimize selection and use

Circle the one correct answer:

1. **According to AAMI, what should be reviewed when evaluating a new sterilization wrap?**
   A. Product performance
   B. FDA clearance and legal status
   C. Standards and guidelines
   D. All of the above
2. **Which type of sterilization wrap is composed of spunbond and meltblown fibers?**
   A. Egyptian cotton
   B. Reusable woven
   C. Crepe paper
   D. Synthetic nonwoven
3. **Which performance factor is rated using the content's weight?**
   A. Size
   B. Strength
   C. Malleability
   D. Absorption/wicking
4. **A large wrap can be used for any tray because it can be folded over as many times as necessary.**
   A. True
   B. False
5. **What can happen when lightweight instruments are wrapped with a sterilization wrap for heavy items?**
   A. Moisture events
   B. Faster sterilization
   C. Instrumentation overheats
   D. Wrap softens during sterilization
6. **Which practice can lead to wrap tears during storage?**
   A. Placing items on a sterilization rack
   B. Using transfer trays
   C. Touching wrapped packs before they are cooled
   D. Stacking wrapped sets in storage
7. **When should sterilization wrap be inspected?**
   A. Before it is used
   B. After sterile packs have been moved
   C. It does not need to be inspected
   D. Both A and B
8. **All accessories used to protect corners and wick condensate must be replaced when there is a change in the wrap manufacturer.**
   A. True
   B. False
9. **What causes a straight-line cut with compressed edges?**
   A. A heavy package was stacked on top of the wrapped pack
   B. The wrapped item was pulled along a flat surface
   C. The pack was pulled by a burr
   D. An instrument poked through the wrap
10. **What should be developed when using reusable woven wraps?**
    A. A recycling program
    B. A means to track the number of launderings and sterilizations
    C. A way to count threads
    D. A way to measure the wrap's thickness

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