

Selection of Packaging Materials and Methods

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Today there are many choices for packaging materials. While there is no perfect packaging system the ideal packaging should:

- Withstand the conditions of the sterilization process selected
- Allow for adequate air removal from the package
- Be easily penetrated by the sterilant
- Allow for adequate removal of the sterilant after sterilization
- Be a reliable barrier to microbes
- Repel water and other liquids
- Be tamper evident
- Adapt to the size/shape of the item to be packaged
- Resist tearing/puncturing
- Protect the package contents from physical damage
- Allow for aseptic removal

The competent sterile processor identifies the correct packaging material based upon the number of factors which include:

- What are the items to be packaged (weight)?
- How will the item be used?
- How and where the item will be stored (OR? ER?)

Packaging Materials

Woven textiles were at one time, the only packaging material available. These are textile (cloth) based and reusable. They can be bleached or unbleached muslin (100%), muslin/polyester blend (50/50), all synthetic blends and the new high density textiles for maximum moisture and bacterial barrier.

Generally, woven textiles (e.g. muslin) are poor moisture and bacterial barriers. Take a cloth wrapper and place water on it to see how quickly the water penetrates. The barrier quality of textiles is usually represented in "thread counts" per square inch. The more threads per square inch, the less space between the fibers, the better the barrier. Therefore, the higher thread count textiles provide better barriers to bacterial. The **minimum** acceptable thread count for surgical textiles is 140 threads/inch. To improve the bacterial barrier, two layers of material are sewn together around the edges. The newer textiles have improved moisture and bacterial barriers due to the higher thread counts.

So why use reusable textiles as wrappers and drapes? First, this system is lower in cost, especially if the facility has its own laundry. Since they are reusable, there is no waste generation (it costs money to haul trash away).

The disadvantages include high lint generation; they must be washed, de-linted and inspected before each use. The inspection must be on light table (table with light underneath to see holes/defects). If defects are identified, they must be patched with heat patch machine placing a patch on both sides of the textile. The defects should not be sewn and no cross stitching of textiles is permitted because the needle makes additional holes in the wrapper. The overall quality of the wrapper should be assessed each time. Placing multiple heat patches in the same area is not recommended, as steam cannot penetrate through the patches.

The inspection, de-linting, etc. should be performed in a separate room with sufficient air exchanges to keep dust/lint at a minimum and prevent lung illnesses in staff.

Non-woven Materials (man-made)

Non-woven materials (man made) are single use. There are many types including: crepe paper, plastic polymers (e.g. polyolefin), cellulose fibers and washed paper pulp.

The advantages are that they may be cost effective, no laundering is needed and they have small spaces between the fibers (as compared to muslin) so they provide better bacterial/moisture barrier. Many of these products are water repellent (not all).

The disadvantages are that they create waste, can cost more and can tear easily. For quality assurance purposes, a random sampling of wrappers should be inspected when a new box is opened.

The products are available in single ply or double ply.

Wrapping techniques

There are two basic techniques; the square fold and the envelope fold. Usually, the square fold is used for large sets while the envelope fold is used for most other items.

The single ply material and reusable textiles requires two separate wrappers be applied sequentially (one wrapper applied at a time). This is called "sequential wrapping".

The double ply material only requires one piece of packaging material because it has two wrappers bonded at least one end. This is called "simultaneous wrapping".

Packaging Principles

You need to select the correct size wrapper- not too big or too small. When wrapping the first fold should completely cover the item inside the pack. Apply the wrapper secure

enough to keep contents secure but loose enough to allow air removal and sterilant penetration. A wrapper that is too loose can cause microorganisms and dust to enter the pack. When a package is wrapped, it is important to understand how the end user will open the package; the opening should be on the top; not the bottom.

Items which cannot be used to secure packs includes staples, pins, rubber bands, paper clips or anything sharp that can damage the packaging material. Always use sterilization tape specific to the sterilization process being used.

Pouches

Pouches (also peel pouch, visi peel) have a material composition of paper and mylar (clear side) or all plastic (Tyvek - polyethylene). Tyvek pouches are all plastic and therefore cannot be used in steam or they melt. They are only intended for low temperature sterilization processes.

The placement of items inside pouch is critical. It is recommended to leave at least a one inch space around the device. The end of device (finger rings) should be facing the end where the pouch will be opened.

It is important to select the correct size pouch; if the pouch is too large, the item can get damaged from moving around; if the pouch is too small, the seals on the pouch can rupture during sterilization. **NOTE; pouches are intended for single, light weight items!**

Pouches can be closed by heat sealing - (use the heat sealer (temperature and pressure) according to the sealer manufacturer) or self sealing (make sure there are no creases, crevices in folds). All air should be expelled from the pouch before sealing to prevent pressure on the seals during and after sterilization.

Double pouching is not required. If it is necessary to contain small items, the inside pouch must lay flat inside outer pouch with **NO FOLDING OVER THE ENDS!**

Plastic Films (Dust or Sterility Maintenance Covers)

Plastic films (sterility maintenance covers) are effective to keep out moisture and contaminants from sterile packages. They are applied to traditional packaging (textiles of non-wovens) after sterilization. They must be applied correctly and selection of the correct size bag is important. Before applying, the item must be completely cool (about 1 hour after sterilization). Never apply a dust cover to a warm/hot tray because condensate can form inside.) When applying the dust cover, expel all the air from the bag before sealing. Make sure your hands have been washed before starting the sealing process or wear gloves to prevent adding more microbes inside the bag.

Dust covers must be a specific thickness (2-3 millimeters). Thicknesses less than 2 mils can have defects which can cause contamination. Only products labeled as dust covers should be used for this purpose.) Dust covers can be closed by heat sealing - (use the heat sealer

(temperature and pressure) according to the sealer manufacturer's instructions for heat sealing plastic bags) or self sealing (make sure there are no creases, crevices in folds). Verify the seal has no defects.

Rigid Containers

Rigid containers are commonly used today to protect instruments in transport/storage. The components of the system include a top, base, inner basket, filter retention rings/plates, etc. Containers must be cleaned, inspected and sterilized according to the manufacturer's instructions. Containers can have single use filters or a valve system. Some offer a location for a load card to place the lot control number sticker. Always use the filters recommended by the container manufacturer. Generally, remove/discard the filters after each use and remove the load card. Containers must be disassembled and washed (not wiped) after each use.

For quality control, rigid containers should be inspected each time they are used. Check that the gasket is free of defects, that there are no dents in the container, that the lid fits correctly and the filter retention plate fits snugly (filter cannot remove around). Some containers have valves (no filters); you need information on the frequency of valve Replacement.

To keep the container closed and to assure no open opened the container after sterilization; containers require a locking mechanism at each end. It is important to make sure the locks are present. Some locks have a chemical indicator printed on them.

Chemical Indicators

All items being sterilized must have an internal and external chemical indicator. The external chemical indicator (CI) simply identifies an item that has been through a process from one that has not. Internal chemical indicators play an important role in sterility assurance. In order for the CI to turn color, the sterilant must make contact with the CI. If air is present or if there is insufficient sterilant, the color change will be incomplete or not take place at all. It is important to know and understand the correct color change for the CI being used and to always verify that the correct color change took place.

The CI should always be placed in the geometric center of the pack or tray since this is the most difficult location for the sterilant to reach. The **only** exception is with rigid containers where the CI should be placed in two opposite corners since corners are usually where air gets trapped in containers. Multi-level trays should have a CI placed on each level.

Packaging uses

The recommended sterilization processes for the various types of packaging materials are:

- a. Muslin/textiles – steam, ETO, dry heat (if not in excess of 425°F)
- b. Peel packs – steam, ETO
- c. Paper wrap (crepe paper) – steam, ETO
- d. Tyvek – ETO, low temperature gas plasma, **NO STEAM**
- e. Polyolefin (plastic) wrap (e.g. Kinguard) – steam, ETO, LTGP

Package Labels:

Whenever an item is packaged, it should be identified with the department, name of the device and the initials of the preparer. This helps to track quality issues. Writing should always be done on autoclave tape, **not on the packaging material**. It is recommended that non-toxic markers that will not bleed or smear be used. Use of lead pencils or ball point pens is not recommended as they may contain toxins which can be distributed in the sterilizer. It is not recommended to write on the packaging material because the pen can possibly damage the fibers of the packaging. On peel pouch material, writing can be made on the clear side, not the plastic side.

Packaging Closures: Autoclave tape is the recommended closure for wrapped sets. Masking tape should never be used because it was not intended to be sterilize and will not differentiate a set that has been in a sterilizer from one that has not. Use as little tape as possible so the end user can easily get into the package; excessive tape can hamper correct opening of the tray.

SUMMARY:

Packaging materials are needed to maintain the sterility of devices and to provide protection to the package contents from damage. Selection of the correct packaging material, correct application of the packaging and correct closure for the device and sterilization process is critical to assuring the safety and sterility of the device when used.

QUIZ ON SELECTION OF PACKAGING MATERIALS:

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1. The recommended packaging material for an item to be steam sterilized is:
 - A) nylon
 - B) Tyvek
 - C) Polyester
 - D) Paper/plastic

2. Woven textiles are infrequently used today because they
 - A) Are more expensive to use
 - B) Generate excessive trash
 - C) Require inspection and patching
 - D) Provide superior barrier to microbes

3. The minimum thread count per square inch for surgical muslin is:
 - A) 100 threads
 - B) 120 threads
 - C) 140 threads
 - D) 160 threads

4. To improve bacterial barrier of woven textiles:
 - A) Two layers are sewn together
 - B) Paper wrap is placed under the textile
 - C) Four wrappers are needed
 - D) Four layers are sewn together

5. Which of the following statements about non-wovens materials is **NOT true?**
 - A) They are more expensive to use than woven materials.
 - B) They generate excessive lint.
 - C) They do not require inspection of each piece.
 - D) They have improved bacterial and moisture barriers.

6. Simultaneous wrapping refers to a package that
 - A) Has been wrapped immediately after cleaning.
 - B) Has two wrappers applied; one after the other.
 - C) Has two wrappers applied at the same time.
 - D) Has a layer of non-woven and a layer of woven material.

7. One of the most important factors in wrapping is:
 - A) Keep the packaging material as tight as possible.
 - B) Keep the packaging material as loose as possible.
 - C) Use at least 6 pieces of tape to secure the pack.
 - D) The first fold should completely cover the item inside.

8. When placing items inside a pouch, it is recommended that what amount of space be left around the device inside?
 - A) ½ inch
 - B) 1 inch
 - C) 2 inches
 - D) 3 inches

9. If an item must be double pouched
- A) The two pouches can be applied simultaneously.
 - B) The inner pouch should be folded over to fit inside the outer pouch.
 - C) The inner pouch should lay flat inside the outer pouch.
 - D) The ends should be sealed with tape.
10. The best way to label a package is with
- A) Ball point pen
 - B) Non-toxic markers
 - C) Lead pencils
 - D) Magic markers
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Directions for Payment and Results

This in-service = \$10

Re-do's = \$10 each

No refunds (all sales are FINAL), prices subject to change.

Payment is accepted in the form of a Credit Card, Facility Check, or Money Order only.
Sorry, no personal checks.

Please see the form on the following page.

Upon passing this in-service, your certificate will be mailed to you within 7-10 business days.

Please fill out the form below and submit it with your payment and the quiz to:

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If you have any questions, please email heidi@spdceus.com

Thank you!