

## **PACKAGING**

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# Packaging



**WRAPPING**

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## **OBJECTIVES**

Following training, employees will be able to:

1. Understand and explain the principles of packaging.
2. Know the ideal packaging materials and how they affect sterility.
3. List the types of packaging materials available for use in the hospital setting.
4. List the importance and guidelines for linen pack construction.
5. Explain how linen packs should be assembled and the proper placement of gowns, drapes, etc., within the pack.
6. Describe the proper assembly of procedure trays, basin sets, and basin packs.
7. Demonstrate the appropriate wrapping techniques as required for various packs, sets, and instrument trays.
8. Explain shelf life and what affects the sterility of items.
9. Explain the length of time various packaging material can be expected to remain on the shelf before reprocessing.
10. Explain the importance of proper handling and storage to assure sterility.

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# PACKAGING

## 1. PRINCIPLES OF PACKAGING

a. Special care should be taken to assure an item is thoroughly cleaned, decontaminated, assembled, and sterilized correctly. All the effort involved to ensure a sterile product can be lost by incorrect packaging and handling. Many conditions must be met in SPD to achieve the desired goal and primary objective of patient safety.

b. Four basic principles must be achieved to maintain the standards of packaging: it must allow adequate penetration of the sterilant, provide a barrier to microorganisms, and allow sterile presentation of the package contents. The fourth and probably most important principle to remember is: sterility is event-related and not time-related. No matter how adequate the packaging, proper handling and storage are vital to provide a sterile product.

c. The ideal packaging material should:

- (1) Allow adequate penetration of the sterilant.
- (2) Not be a barrier to the exhaust of steam from the package or entrap ethylene oxide. (Allow for adequate air removal)
- (3) Maintain a barrier to microorganisms.
- (4) Withstand the extreme pressure during the sterilization cycle.
- (5) Tolerate handling and resist tears and puncture.
- (6) Be easy to use and conform to all wrap procedures. Easy to seal, yet tamper resistant.
- (7) If holes or tearing occur, these holes should be visible to the naked eye.
- (8) Have tamper proof heat seals on pouches and should retain seals during the sterilization process.
- (9) Allow for aseptic delivery.
- (10) Be inexpensive and readily available.

- (11) Be moisture resistant.
- (12) Allow for protection of the package contents.
- (13) Have visible identity of the package contents.

d. Some of these characteristics may be more important than others, depending on the items to be packaged and how they will eventually be used. Packaging materials must be able to withstand the sterilization process. Vacuum and pressures created during sterilization are extreme; packages should not burst or deteriorate during the process. Changes in temperature can cause melting, burning, or otherwise alter the materials.

e. Adequate air removal is required during sterilization to assure that all surfaces of the contents have been exposed to the sterilant, regardless of the type of sterilant -- steam or ethylene oxide. The packaging material must also allow for rapid air and gas removal at the end of the cycle to assure removal of the ethylene oxide and to allow removal of moisture from the steam sterilization cycle. Some packaging is not suitable for use in the steam sterilizer, such as plastic film, since it does not allow penetration of the steam. Ethylene oxide, on the other hand, cannot penetrate packaging that consists of nylon or aluminum foil.

f. After sterilization is achieved, the packaging must maintain a barrier against dust and the microorganisms that use dust as a vehicle to move from place to place. A barrier to dust can be created by providing a "tortuous path." The tortuous path forces dust particles to turn at right angles many times before reaching the package contents, thus creating a barrier to the microorganism.

g. Packaging materials must not allow moisture to "wick" along fibers and move through the spaces between fibers. This is accomplished by retarding wicking action or by being impermeable to water.

h. Materials must allow proper sealing so that the contents will remain within the package and the package will remain closed. Materials should also be tamper proof to prevent opening and resealing; and adapt to the size, shape, and nature of the item being packaged. Too much material may inhibit sterilant penetration, while too little will not provide adequate protection.

i. Packaging materials should be durable and resist tearing, punctures, and withstand normal handling. They should also provide protection to the items contained within. If the items to be sterilized are fragile, rigid plastic and metal containers should be used. Tip guards and foam inserts can provide protection to fragile and sharp items.

j. Aseptic presentation of the sterile contents of any type of packaging is of utmost importance. After taking steps to assure sterility, if the item cannot be presented in a manner to maintain its sterility, all efforts have been in vain. This is one of the most important reasons for selecting the proper packaging material.

## **2. TYPES OF PACKAGING MATERIALS**

### **a. Textiles**

(1) Textiles consist of two layers of fabric sewn together along the edges to create one wrapper. Extensive data has been compiled of all the available packaging, and muslin, even at its best, is the least efficient. This textile product consists of 140 thread count or less. Percale consists of 140 to 180 thread count. (Thread count consists of the number of fabric threads per inch.) Pima cotton has 288 thread count and is treated with quarpel to make it moisture resistant. It is an excellent bacterial barrier, but very expensive.

(2) Woven textiles require laundering, inspection, delinting, and folding between uses. They should only be laundered 50 to 60 times, then replaced. Many facilities do not track the number of washings, resulting in a wrap that has lost most of its barrier capability. Repairs should also be made if holes are found. Holes can be detected with the use of a light table. Light tables are not always utilized as they should be, allowing for use of wraps that do not maintain a barrier. Once tears or holes are discovered, the area will require a patch. A patch must be placed on both sides of the wrap. Patches do not allow penetration of the sterilant. Woven wraps are cheaper, but the laundering costs and man-hours required to maintain them, in the long run, end up costing more than the disposable wraps.

### **b. Nonwoven Materials**

(1) Nonwoven materials are intended for single use and are to be disposed of after use. Many varieties and thickness of disposable wraps are available today. Heavy wraps are designed to wrap heavy objects and large instrument sets. Lighter wraps are available for light weight items. The choices are numerous. Nonwoven packaging materials consist of plastic polymers, cellulose fibers, or washed paper pulp bonded under pressure into sheets. Plastic polymers are impervious to moisture, whereas materials made of untreated, washed paper pulp can become wet, causing strike through.

(2) Recent concerns over excessive disposables in land fills have emerged. To prevent this, several companies, producing nonwovens, have created recycling programs. A carefully planned, safe recycling program for disposable wraps should be thoroughly reviewed to prevent any possibility of cross-contamination. Some programs across the country have been successful with this.

### c. Films

(1) Some plastic polymers can be extruded into sheets of varying thicknesses. The thinner sheets may contain small pinholes, so it is recommended that film for packaging applications be at least 2 mils thick. A mil equals 1/1000th of an inch. Water, in the vapor or liquid phase, cannot penetrate plastic films and should not be used for steam sterilization, unless it is used in conjunction with paper. Films may be used for ethylene oxide sterilization; however, film constructed of polyvinyl chloride (PVC) is not recommended since it is poorly penetrated by ethylene oxide and it is difficult to remove ethylene oxide that remains in the packaging and the film itself.

(2) Plastic films are used after sterilization as a dust cover for woven and nonwoven wrapped sterile items. This dust cover will protect the item from moisture and dust, and will extend the shelf life to 1 year. The sterilized item must be completely cool before placing in the dust cover to prevent condensation inside the cover.

### d. Containerized Packaging Systems

(1) After reusable sterilization containers had been used successfully in European hospitals for several decades, the concept was finally introduced in North America in 1979. This innovation resulted from a need for greater sterility assurance against the common problems of lint, tears, punctures, patches, and moisture strike-through. Greater protection for expensive surgical instrumentation became apparent as instruments became more complex and more expensive.

(2) These systems consist of a metal or plastic outer case, an inner basket constructed of stainless steel, and a gasket along the lid to assure an airtight seal once the lid is locked into place. In the lid, and sometimes the bottom of the case, an area of perforations is covered with a filter paper, then a screen or retainer frame to hold the filter paper in place over the perforations. The filter paper consists of nonwoven material. Inspection of the gasket and retainer frames should be done each time the container is assembled. One type of system utilizes a valve instead of a filter paper and retaining frame. The valve must be checked for proper functioning to assure the sterilization process will not be inhibited.

(3) The tops can be removed aseptically to allow for easy access of the inner basket. After surgery, the soiled items can be placed back into the system to assure safe transportation to the decontamination area.

(4) The containers save time during assembly, versus using the woven or nonwoven wrap. Tamper proof indicators are utilized with all types of containers. This allows a quick visual check to assure the container has not been opened. Labels are located on the end of the containers denoting the name of the set and allows for the placement of

the sterilization date. Sterilization indicators can be part of the tamper proof item or may be included on the tag used for the sterilization date and technician's initials.

#### **e. Packaging Methods**

(1) Methods of packaging depend solely on the type of items to be packaged for sterilization. Instrument sets used by the operating room may be packaged in metal perforated bottom instrument trays that are wrapped with muslin or nonwoven wrap or can be placed into containerized systems. Containerized systems provide more protection than other types of packaging. Containers should be used in prevacuum steam sterilizers, versus gravity displacement sterilizers, since air removal is difficult without the vacuum phase.

(2) Metal containers cannot absorb water like fabric wrappers, so the sterilizer drying times may need to be increased. With so much metal being subjected to heat, moisture will tend to evaporate easier than it does from woven textiles. Containers should be placed on the sterilization rack to allow movement of air and to prevent condensation forming and dripping onto the lower shelf. If a mixed load is necessary, the containers should be placed on the bottom shelf, and all other packages on the top shelf. It is not advisable to mix any load containing fabric packs and metal instruments. Containers should not be stacked on one another during the sterilization process, but may be handled as soon as they cool enough to be handled without burns, and may be stacked for storage without danger of contamination due to puncture or tearing.

#### **f. Linen Pack Construction**

(1) Packs come in a variety of sizes and are mainly used in the operating room. Towels and other small packs may be used in clinic or special procedure areas. The density of fabric packs should not exceed 7.2 pounds per cubic foot. The size should not exceed 12 x 12 x 20 inches. Special care must be taken when folding packs containing woven materials to ensure aseptic presentation and to minimize handling at the point of use. Linen packs are to be arranged in the order in which the items will be used. The layers of linen should be alternated so the folds do not all go in the same direction. This will aid in the air evacuation and steam penetration.

(2) The gowns contained in the linen pack should be folded inside out, allowing the scrub nurse the ability to don the gown without touching the outside, which will maintain the sterility of the gown. Drape sheets are folded so that minimal handling will be necessary to open and place them around the operative site on the patient.

(3) The laundry department of most Veteran Administration Hospitals is required to handle all surgical linen. This includes maintenance and care, and folding and assembly of the surgical linen packs. Folding and delinting should not be carried out in the SPD preparation room. If SPD must fold and delint linen, a separate room, with a light table and linen storage area, must be provided away from the preparation room.

(4) Construction of instrument sets was discussed in the Instrumentation Chapter. In general, instruments should be placed in a tray to allow adequate exposure to the sterilant and provide for safe handling. Instrument sets may be muslin or nonwoven wrapped or a containerized system used.

(5) Procedure trays will be assembled using towels, some instruments, small basins, med cups, and gauze. They will be wrapped in muslin or nonwoven material and usually placed on their side during the sterilization process. Slow moving procedure trays will require the use of dust covers.

(6) Basin sets should be constructed so the smaller basins nest inside the larger basin. Basins should face in the same direction, and a material, such as an absorbent towel, should be placed between them to facilitate steam penetration and allow for moisture to be wicked away from the metal. Basins that face in different directions or fit tightly together can trap air and prevent steam contact to all surfaces. Metalware and linen should not be combined in large packs, since the metal may prevent steam penetration of all the linen and prevent proper drying.



**Procedure Tray**



**Basin Pack**

**g. Wrapping Techniques**

(1) Once an item, pack, or instrument set is prepared, the proper size wrap, whether woven or nonwoven, must be selected. It is very important to choose the size that will be large enough to completely enclose the items being packaged and to allow all edges and corners to be tucked securely. Wrappers too large may impede the penetration of the sterilant and not hold together securely. Wrappers should be just tight enough to hold the contents together and allow easy penetration of the sterilant.

(2) The outside wrappers provide a barrier to contamination during handling and against insects or vermin and serve as a dust barrier. The inside wrap, when opened, may be used as a sterile field, if so desired.

(3) Proper folding of the wrapper is necessary to secure the package contents and to allow the package to be opened correctly without contaminating its contents. There are two most common techniques used for wrapping packs and other medical items. These two techniques are: the square fold (straight method) and the envelope fold (diagonal method).

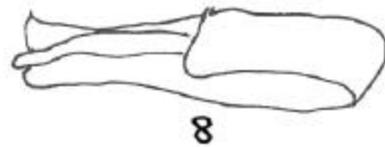
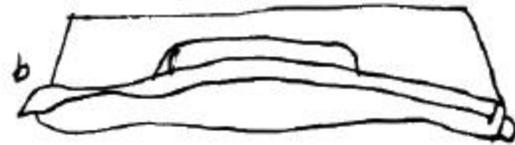
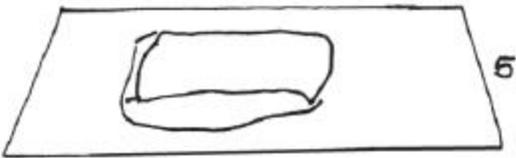
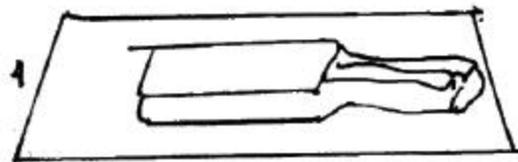
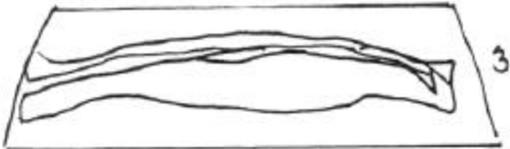
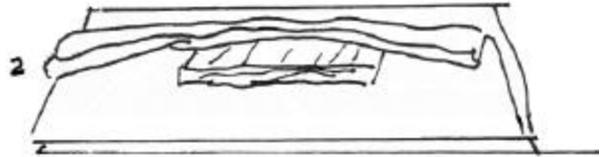
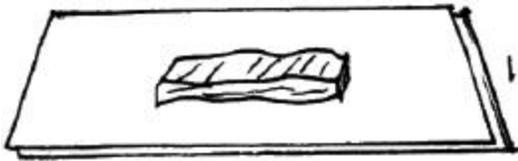
## **Square Fold**

1. Place the wrappers lengthwise across the table. The item to be wrapped should be placed in the center of the wrapper.
2. Fold the edge of the wrapper at the front of the table over the top of the item so as to cover the lower half of the item. Then fold it back to form a cuff.
3. The other (opposite) edge of the wrapper is folded over the upper half, then folded back to form a cuff over the previous cuff.
4. Fold the left edge of the wrapper snugly over the item and fold back slightly to form a cuff.
5. Repeat with the right side, overlapping the previous fold.
- 6-9. Repeat the procedure for the second wrapper, except bring the last fold over the end of the package and secure with sterilization indicator tape.

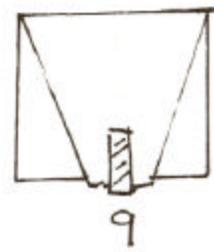
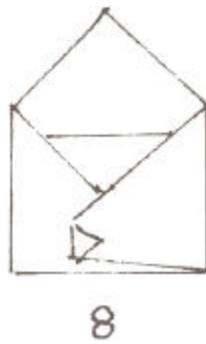
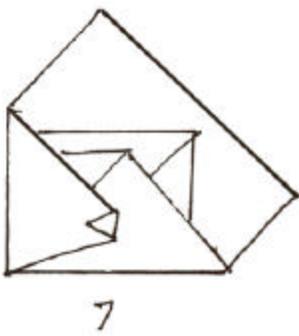
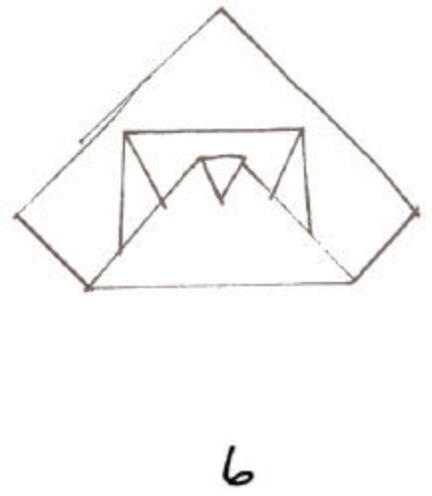
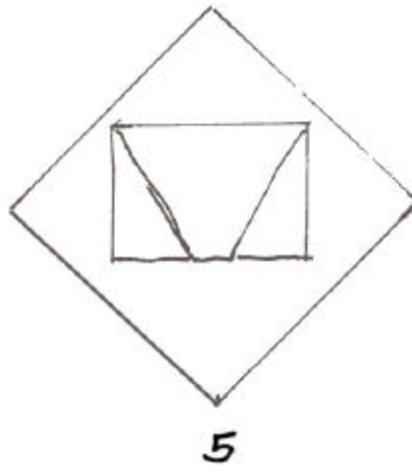
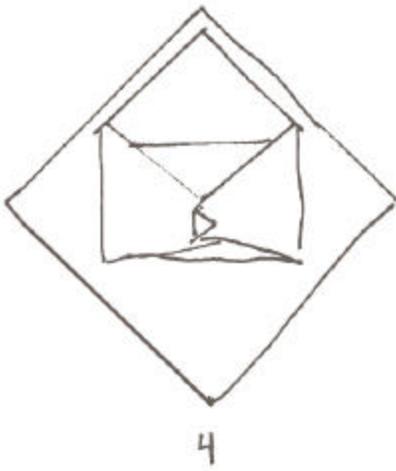
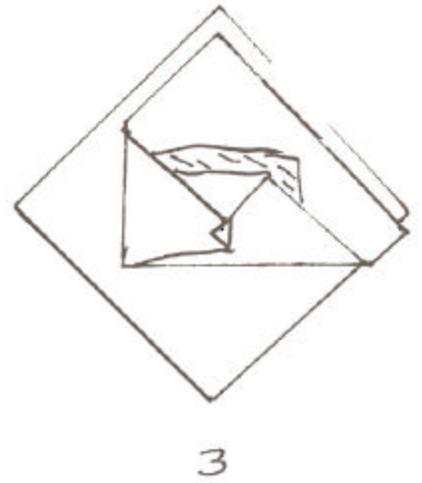
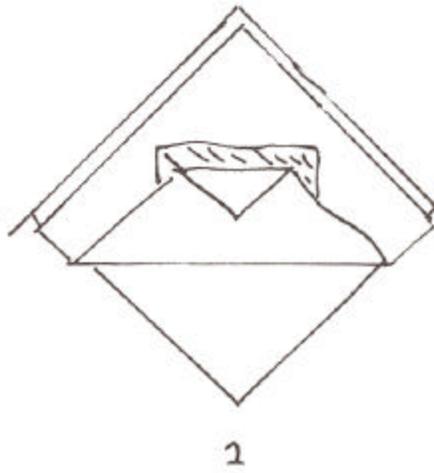
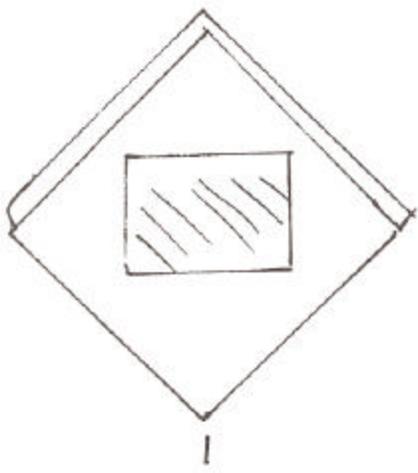
## **Envelope Fold**

1. Place the square wrappers on the table in a diagonal position, with the one corner pointing toward the front of the table. Place the item to be wrapped in the center of the wrapper at right angles to the top and bottom corners.
2. Fold the bottom corner over the item and fold back to form a tab, which will be used to open the package.
3. Fold the left corner over the item and fold back to form a flap.
4. The right corner is then folded over the item, overlapping the previous fold, and then folded back to form a flap.
5. Fold the top corner of the wrapper over the item and previous fold and tuck the flap under the previous left and right folds, leaving a small tab visible for easy opening.
- 6-9. The second wrapper is applied in the same manner, except the last fold is not tucked under the previous folds, but rather is carried around the edge and then secured with sterilization indicator tape.

Remember, the wraps should be sequentially wrapped, meaning one at a time. After the wrapping is complete, the closure must be properly secured. Sterilization indicator tape (autoclave tape) should be used. It secures the wrapper while providing an external visual indication, once processed, that the package has been subjected to



SQUARE FOLD OR STRAIGHT METHOD OF WRAPPING



ENVELOPE FOLD OR DIAGONAL METHOD OF WRAPPING

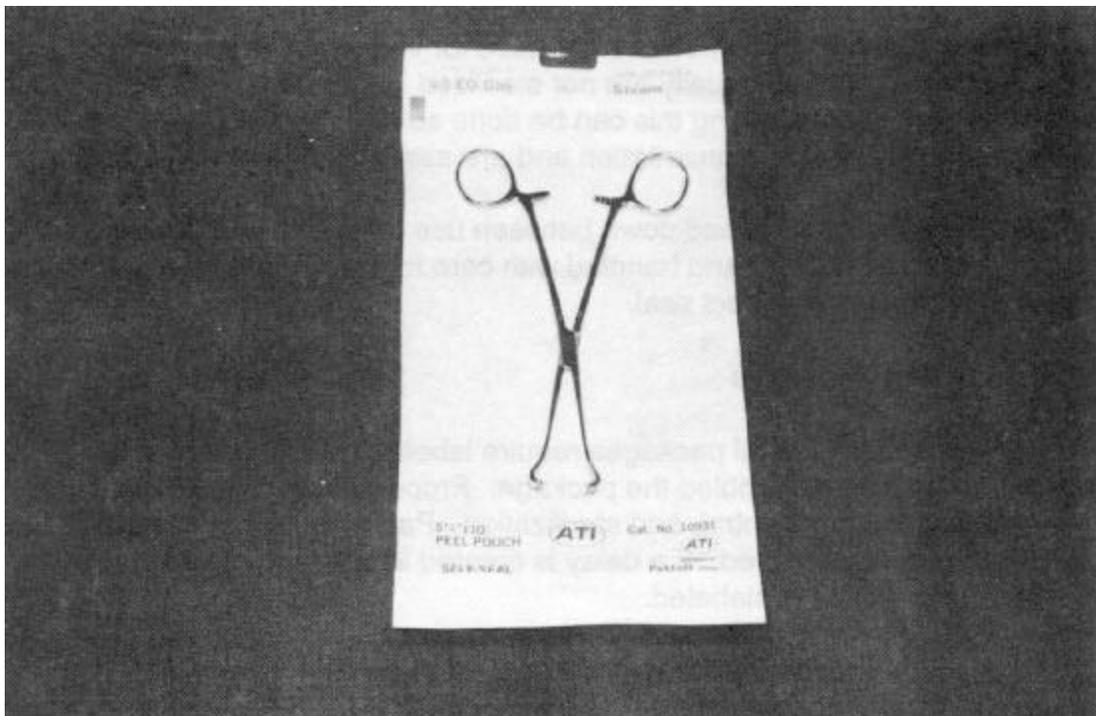
sterilization conditions. The technician will use the tape as a place to label the package and to initial. Packages should never be secured by paper clips, pins, staples, or other sharp objects that could penetrate the surface of the wrapper. Packs should never be secured with string.

#### **g. Pouches**

(1) Pouches are used when the visibility of an item is important, and are used for items too small to wrap. The pouch should fit the size of the object to be placed inside. It should neither be too small, causing the pouch to bulge and burst at the seams, nor too large, allowing the item to move around inside.

(2) Pouches can be preformed, with all sides sealed except one, or may come in rolls, allowing the technician to cut the desired length required. The roll type requires two seals. One at the top, with at least a one-inch section left beyond the seal to allow for proper peel down, and a seal at the very bottom. The seals should be at least 3/8 inches wide to provide for proper closure. Anything smaller than this will require two seals.

(3) Pouches are made from a variety of materials, including paper, polyethylene, cellophane, and spun-bonded olefin, and various paper/plastic combinations. The most commonly used are the paper/plastic preformed pouches.



**Item placed in pouch**

(4) The end or handle of the instrument, that will be grasped first, should be placed in the pouch in such a manner as to allow the user to grasp the item without contaminating it when the pouch is opened. All items packaged in pouches for use in the operating room should be double packaged, as mentioned in the Instrumentation Chapter. This allows for access to the sterile inside pouch by the operating room scrub nurse.

(5) Heat sealing is the most widely used method for sealing pouches. Special heat sealing machines, in several makes and models, are available for this purpose. Always obtain the manufacturer's instructions before operating any type of equipment. The technician using the sealers should be aware of the heat produced, and use care and good judgment to prevent burns. The heat sealing process bonds the plastic to the paper. Once the seal is made, it should be inspected to ensure it is complete and secure.

(6) Some pouches are "self-sealing." A sticky strip at the end of the pouch is removed, and the end is folded over the opening. Care must be taken to seal the pouch correctly to prevent gaps or wrinkles, which will allow microorganisms to enter. Pouches will not be secured by any other means, such as paper clips, pins, staples, or any other method which will damage the package integrity.

#### **h. Containerized Systems**

(1) Containers are mainly used for surgical instrument sets and some powered equipment. Containers sometimes are used for very small sets, and they come in a variety of sizes. Linens usually are not sterilized in these systems, and no studies have been completed stating this can be done safely. Containers provide added protection to surgical instrumentation and are assembled easily and quickly.

(2) They should be wiped down between use (or processed through a washer/decontaminator) and handled with care to prevent damage to the edges, which may prevent a perfect seal.

#### **i. Labeling Packages**

(1) The contents of all packages require labels to identify what is inside the package, and who assembled the package. Proper labeling is necessary for quality assurance, inventory control, and sterilization. Packages should be labeled as soon as the package is wrapped. If a delay is created in labeling, chances increase that the packages will be mislabeled.

(2) For tape-secured packages that are hand-labeled, felt-tip, indelible ink markers will be used to record all the necessary information on the tape. Never write on any wrapper material -- the tape must be used for this purpose. Indelible ink is necessary so the marking will not run or fade, or redeposit onto the surface of the instruments.

Preprinted indicator tape can be purchased for high volume items.

(3) The label information should include:

(a) Description of package contents.

(b) Expiration date and color coded marking to track time on the shelf.

(c) SPD technicians' initials.

(d) Sterilizer label, to include sterilizer number, cycle sequence, expiration date, and date of sterilization.

(e) Service name should the item be marked for return.

(4) Package contents and technician's initials prior to sterilization. The sterilizer expiration date and label will be placed on the package after sterilization.

**j. Shelf Life**

(1) Shelf life literally means the time expected for an item to remain sterile on the shelf. Many things can affect the shelf life, such as storage conditions, climate and humidity controls, traffic, and access to the area.

(2) An SPD processed and packaged item remaining on the shelf unused for 6 months must be evaluated for need and inventory level adjustment. It must be determined at the 6-month evaluation whether to relocate the item to a higher use area or maintain it in its present location. Color codes will be assigned to each package at the time of labeling and packaging. The color codes will designate the month of expiration, and can be used to prompt an inventory evaluation at the end of 6 months. Color codes, designating specific months, will be assigned as follows:

If the month is: apply the appropriate color for a 12-month outdate:

- |             |        |
|-------------|--------|
| 1. January  | White  |
| 2. February | Purple |
| 3. March    | Green  |
| 4. April    | Yellow |
| 5. May      | Blue   |
| 6. June     | Gray   |
| 7. July     | Black  |

8. August	Brown
9. September	Pink
10. October	Orange
11. November	Gold
12. December	Red

(3) Items should not remain on the shelf if not used after a year. Evaluations must be made to determine the necessity of maintaining the item.

Guidelines for shelf life for the following items are:

Woven and nonwoven wrapped items with no dust cover	30 days
Woven and nonwoven wrapped items with a dust cover	1 year
Paper/plastic peel pouch	1 year
Containerized systems	1 year

(4) Commercially sterilized items usually carry an indefinite shelf life. It is indicated on the label that the contents are sterile unless the package integrity has been compromised.

(5) The expiration date does not indicate whether an item is sterile. Contamination doesn't suddenly occur on the last day of the labeled shelf life. Sterility is "event" related, not time-related. Many things can be involved in the life of a sterile item, such as improper handling, not allowing adequate cooling time after sterilization, excessive stacking of items, exposure to extreme climate conditions, the type of bacterial barrier provided by the package material, and how well the package is sealed.

(6) The expiration date does not indicate whether an item is sterile. Package integrity should be checked prior to use.

(7) Many types of materials and systems are available today for use in packaging items for sterilization, including methods of preparing packages and the importance of proper labeling. The newest item on the market is the single nonwoven wrap, which, in itself, will provide a strong barrier without the need of a sequential wrap. Further investigation and documentation are required before hospitals can accept this type of wrapper.

## PACKAGING TERMS

Air Removal  
Barrier  
Container  
Envelope Fold  
Films  
Muslin  
Nonwoven  
Peel Pack  
Plastic Polymer  
Pouch  
PVC  
Shelf Life  
Square Fold  
Textile

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## PACKAGING

### TRUE OR FALSE

1. Any material can be used to wrap a tray or set, as long as it can be taped shut, and opened without contaminating the item.
2. Containerized systems do not need to be entirely cool to move them, since strike through cannot occur with this type of packaging.
3. Proper handling is not a factor in maintaining sterility of an item, since the date determines when it is no longer sterile.
4. Aluminum foil can be used as a packaging material for both EtO and steam sterilization.
5. Textile wrappers, such as muslin, can be laundered as often as necessary without concern to the fabric's integrity.
6. Containerized systems can be used for instrumentation, as well as surgical linen, since guidelines do not state differently.
7. All items to be sterilized must be thoroughly cleaned prior to packaging for sterilization.
8. Materials used for the packaging and wrapping of sterile supplies must be compatible with the sterilization process.
9. Paper, plastic, and a combination of the two are available in various sizes for packaging supplies. These products are not suitable for both steam and EtO gas sterilization.
10. Paper and plastic wrappers may be either heat sealed or sealed with pressure-sensitive tape that indicates by changing color that the package has been subjected to the sterilization process.
11. Achievement of sterilization of supplies is directly related to the preparation and packaging of those supplies.
12. To prevent loss, instruments must remain assembled and in a closed position during sterilization.
13. Paper and plastic wrappers are suitable for steam or gas sterilization.

14. Muslin must be laundered and patched and does not maintain sterility for prolonged periods of time.

15. Reusable container systems are designed to extend shelf life and to eliminate the need for wrapping items in preparation for sterilization.

### **MULTIPLE CHOICE**

16. Packaging materials:

- a. may be any type of paper or plastic that you can find.
- b. must be compatible with just gas sterilization, since anything can be processed through the steam sterilizers.
- c. used for steam sterilization must not permit air removal.
- d. must be compatible with the sterilization process.

17. The minimal accepted thread count for muslin is:

- a. 160 threads per square inch.
- b. 190 threads per square inch.
- c. 240 threads per square inch.
- d. 140 threads per square inch.

18. Container systems have a shelf life of:

- a. 4 months.
- b. 16 months.
- c. 12 months.
- d. 24 months.

19. Nonwoven and woven wrappers can be used for which two classic folds:

- a. The box fold and the accordion folds.
- b. The envelope and the criss-cross fold.
- c. The square and the accordion folds.
- d. The envelope and the square folds.

20. Shelf life is determined by which of the following:

- a. The contents of the package, regardless of the wrapping used.
- b. The expiration date affixed at the time of sterilization, regardless of the condition of the package.
- c. The number of times the package has been handled.
- d. None of the above.