Objective 1: Describe requirements for pouches and other packaging materials.

Packaging material must:
- allow effective penetration of the sterilization agent to all surfaces of the package and its contents
- ensure that the sterility of the contents is maintained up to the time the package is intentionally opened
- afford easy removal of the contents without contamination

Objective 2: Explain important factors in selecting a packaging material.

- Suitability of the Sterilization Method. Different methods of sterilization place different challenges on packaging materials. For example, during steam sterilization, a packaging material must withstand high temperatures, allow for adequate air removal, permit steam penetration to the pack’s contents and allow for proper drying. During ethylene oxide (EO) sterilization, the packaging material must allow adequate penetration of the sterilant gas and moisture. After sterilization, it must allow ready release of gas and moisture from the material and from the contents during aeration. During gas plasma sterilization, the packaging must be able to tolerate a deep vacuum draw and allow sterilant penetration.

- Reliable Barrier to Microorganisms and Microbial Vehicles. Effective barrier qualities are essential to protect the sterilized contents from potential sources of microbial contamination from the time the package is removed from the sterilizer until it is intentionally opened.

- Strength and Durability. The material must be sufficiently strong to contain contents during sterilization and handling. It must resist tearing and puncturing and withstand the impacts and pressures that may occur during normal processing and handling. It must not be adversely affected by varying atmospheric and humidity levels. The material must not degrade, develop holes at folds, scuff, or delaminate when stored pack-against-pack. Also, seals must not deteriorate or otherwise compromise the closure. (If accidental tearing or punctures do occur or if seals are ruptured, this compromised condition must be detectable.)

- Efficiency of Use. The material must be efficient to use in as many of the packaging procedures of alternative sterilization methods as possible. It must be easy to handle and to load, adapt, and conform to the size and shape of the items to be packaged. It must cover the contents completely.

- Free of Toxic Ingredients and Nonfast Dyes. The packaging material must not contain any toxic materials or dyes which could cause adverse reactions to personnel handling the package before or after sterilization. Materials should not bleed when exposed to the sterilant. Bleeding can cause discoloration or chemical changes of packaging materials or devices within the pack.

- Proven Seal Integrity. Positive sealing of a packaging material is essential to the protection of the contents for maintaining sterility. Pouches made of plastic, paper, or plastic combinations or paper must be securely sealed either with a heat seal, tape or self-adhesive seal. Self-sealing pouches must be securely sealed according to the written directions of the manufacturer. Upon opening, all sealing methods must destruct and be incapable of resealing.

- Safe and Easy Opening. The packaging material must allow easy opening with minimum risk of contamination by particulate or lint fall-out. It must also allow aseptic removal of the contents to a sterile field or other area of use.

- Sterility Maintenance. The sterilized package must maintain the sterility of the contents until intentionally opened. Industry organizations such as the Joint Commission on Accreditation of Healthcare Or-
Objective 3: Review materials used to manufacture pouches.

- **Kraft-type papers** (medical grade) are generally smooth-surfaced and available in sizes to accommodate many medical devices and porous or soft-good items. Papers of medical grade papers specially formulated for sterilization are available.

- **Glassine-type papers** are synthetically treated papers made in various quality levels with specific coatings or resins applied to increase bacterial barrier properties. Pouches of plain glassine paper coated with plastic polyethylene are commonly used for packaging syringes and other small items.

- **Polyamide** (nylon) films are not appropriate for E0, plasma gas or steam sterilization because of their low gas and moisture permeability. They do, however, tolerate the high temperatures of dry heat sterilization well and are often used to package dental instruments and burrs. Nylon is available in both pouch and roll formats.

- **Paper-plastic and spunbond polyolefin-plastic combinations** (called “peel” or “peel-open pouches”) are the most commonly used package for small and light-weight medical devices and for porous items. They are typically acceptable for use in steam, E0, and gas plasma sterilization processing. They are not, however, compatible with dry heat sterilization. It is always important to receive confirmation of sterilization method compatibility from the manufacturer. Peel-open packaging is generally manufactured by processes that allow one layer of paper and one layer of plastic composite transparent film to be heat-sealed together along the lengthwise edges. This forms pouches of gusseted or ungusseted design and/or tube materials in rolls or reels. Pouches are manufactured with one end open for insertion of the contents and to allow subsequent sealing using heat or adhesive seals. The opposite end is pre-sealed (usually referred to as the “chevron” seal) during manufacture and is designated for the opening and presentation of the sterilized contents. Roll stock or reels allow the user to cut the desired length from a roll and either tape-seal or heat-seal the ends to form a pouch or envelope. The use of peel pouches is recommended for small items or to enable the user to see the pack contents before opening.

Both the paper and plastic film in this packaging must be pinhole free, nontoxic, and resistant to tears and punctures. It should not delaminate to create fiber tear or linting during opening and presentation of the contents. The plastic film of pouches or roll stock, which is designed to be heat-sealed, must be of a quality to assure positive adherence to the paper. Additionally, the manufacturer of heat-sealable pouches and roll stock should inform the user about the acceptable range of temperature, pressure, and time settings to be used on heated jaw sealers, impulse sealers, or rotary action heat sealers to obtain a satisfactory seal. During the sterilization process, the adhesive “cures” and becomes a permanent seal. Manufacturers of self-seal pouches incorporating adhesive seals should provide the user with adequate directions to accomplish a secure seal. The adhesive seals must not permit the pouch to be opened and resealed.

Pouches must be compatible with the sterilization method to which they will be exposed.

Objective 4: Describe basic procedures for using pouch packaging.

Pouches are valuable when it is important to see the contents, such as when a description of the contents is difficult to depict on the label. Foam inserts can help protect delicate instruments from damage and prevent the tips from penetrating the package. If foam inserts or tip protectors are used, make certain the material is appropriate for the form of sterilization to which it will be subjected, and that it is non-toxic and free of non-fast dyes. Items should be placed into the pouch so that the end of the item to be grasped during presentation (for example, the finger rings of an instrument) will be presented first when the package is opened at the point of use (chevron end for pre-made pouches).

Pouches must be compatible with the sterilization method to which they will be exposed. They must be sized and applied properly to allow for adequate air removal, sterilant penetration, and drying. Trapped air acts as a barrier to heat and moisture. Therefore, remove as much air as possible before sealing. It is important not to fill a pouch too full. Stretching film-paper pouches may cause the paper to tear or seals to rupture during sterilization or handling. To allow space for package contraction and proper circulation, leave about one inch of space between the items in the pouch and the sealed edges. Pouches should not, however, be too large, as excessive movement of the contents within could break seals or puncture the paper side of the pouch.

It is important to observe the contents of pouches for moisture after sterilization and again prior to storage. When steam comes in contact with metal instruments, it condenses on the surface as heat is transferred to the metal. This is observed more frequently as metal contents increase in size and weight. The retained moisture forms water droplets on the contents and may compromise the seal integrity or the barrier protection capability of the pouch material, which contaminates the contents. Prevention of this condensation is only possible with the use of sterilizers with heated dry cycle capabilities. Limiting pouch contents to small items, however, can usually reduce the problem.

Paper-plastic pouches have a plastic side to permit visibility of the contents and a paper side that may be penetrated by air, steam, or sterilant. These pouches must be labeled only on the plastic side (for example, with a felt-tip marking pen) or on areas specifically provided by the manufacturer (for example, on fold-over paper-flap seals and paper labels on the plastic). Writing on the paper side may penetrate the package which may not be noticeable but which may compromise barrier protection.

Heat sealing is one method of pouch closure. There are several varieties of heat-sealers available. The manufacturer of the sealers and/or pouch material must verify that the two are compatible; otherwise, the seal may...
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not bond, or there may be burn through, which compromises the seal. Multiple band or wide band heat sealers should be utilized to reduce the possibility of breached seal integrity. It is critical that the manufacturer’s instructions for temperature settings, applied pressure, and contact time be written in procedures and followed. For paper or polyolefin-to-plastic seals, the edges are placed well within the pre-heated jaws of the sealer, pressure is applied for the prescribed time, and the jaws are released. Heat seals must be observed for bubbles, gaps, folds or creases, and burn-throughs.

For plastic-to-plastic seals, the two plastics melt together. The plastic remains inside the jaws through a cooling cycle. Keeping the plastic under the jaw pressure during the cooling cycle prevents shrinkage or stretching of the hot plastic which could weaken the seal. Central Service personnel should use extra caution when operating heat sealers to avoid burns.

Self-adhesive packages are self-sealing without heat. An adhesive portion is covered with a removable strip at one end of the self-adhesive sterilization pouch. To seal, remove the protective strip and carefully fold over the opening; care must be taken to avoid gaps, wrinkles, or creases which compromise the seal integrity.

Sealing tape is used by some facilities to secure the opening of pouches. Ensure that the seal is secure and that there are no compromising gaps. Proper taping technique includes first folding the corners inward so that the side edges of the top corners are parallel to the bottom edge of the pouch. Make certain the plastic is folded onto the plastic and not paper-to-paper, as this will impede access of the sterilant. Next, fold the open bottom edge over the folded corners. Seal with tape overlapping the edge of the pouch by about ¼ inch, and secure. Observe carefully to ensure that there are no gaps, creases, or wrinkles. Check that the tape has completely covered the open edge of the pouch and is securely attached to the plastic.

Objective 5: Review “wrap within a pouch” and “double pouch” techniques.

- **Wrap within a pouch.** Sometimes it is desirable to place a single wrapped package into a pouch. To do this:
  - Select an appropriate-sized single-layer wrapper. Place the item to be packaged, along with a chemical sterilization indicator, in the center of the wrap and enclose
  - Use the commercially available plastic material. It is recommended to use a single-wrap or double-wrap technique.
  - Place the sterilization technique in a separate pouch or wrap. This technique is helpful when the item is too large or bulky to place in the pouch. The sterilization technique must be able to be heat-sealed to the pouch material.
  - Place the package into the pouch, and close using heat-sealer or adhesive tape.

- **Double Pouches.** Double pouches may be required for aseptic presentation of multiple items or those having more than one part. Double pouches are prepared by placing the item(s) into one paper-plastic pouch and sealing. This pouch is placed inside another, slightly larger pouch and end-sealed. Care must be taken to select the appropriate sequential sizing. Never fold the inner pouch because this can interfere with air removal and sterilant penetration. “Paper side to paper side and plastic side to plastic side” is the rule for double pouching. Plastic-paper pouches and similar packages should be positioned in the sterilizer standing on edge in loading racks, or should be placed in baskets specifically designed for these types of packages. They can also be held on edge by an alternate means (for example, a peel pouch rack or tray pins), and they must be properly spaced. Pouches should be loosely spaced in the basket to ensure that the sterilant can reach the breathable paper side of each pouch because the plastic side is not penetrated by air, steam, or sterilant. Arrange the pouches paper-to-plastic, paper-to-plastic in a perforated or mesh bottom tray. Lining the tray or basket with absorbent material, such as a cotton towel or disposable liner made for this purpose, will help remove condensate and speed drying.

Endnote

5. After a package is opened, it must
   a. be easy to reclose
   b. destruct
   c. be reusable
   d. be recyclable

6. Ideally, packaging must be efficient to use in ______ packing procedure(s) and alternative sterilization method(s).
   a. only one
   b. as many as possible

7. Which of the following are synthetically treated papers?
   a. polyamide films
   b. glassine-type papers
   c. kraft-type papers
   d. all of the above

8. Which material is commonly used to package syringes and other small items?
   a. polyamide films
   b. glassine-type papers
   c. kraft-type papers
   d. all of the above

9. The most commonly used packaging material for porous items is
   a. polyamide films
   b. glassine-type papers
   c. kraft-type papers
   d. none of the above

10. Peel (or peel-open) pouches are compatible with which type(s) of sterilization processing?
    a. dry heat
    b. steam
    c. ethylene oxide
    d. all of the above

11. The “chevron” end of a pouch is
    a. tape-sealed at the facility
    b. heat-sealed at the facility
    c. pre-sealed during manufacture
    d. left open until processing begins

12. Adhesive seals of self-seal pouches allow the pouch to be re-
    a. should
    b. should not

13. Paper and plastic film used for packaging ______ delaminate.
    a. can
    b. should not

14. Paper and plastic film must be
    a. easy to laminate
    b. resistant to tears
    c. both of the above
    d. neither of the above

15. Items placed into a pouch should
    a. be placed with the end to be grasped at the point of the pouch’s opening
    b. never be packed with foam inserts
    c. be placed in small pouches which are stretched to eliminate air pockets
    d. none of the above

16. ______ retained moisture is created inside a pouch as its metal contents increase in size and weight.
    a. More
    b. Less

17. Paper-plastic pouches must be labeled on
    a. the paper side
    b. the plastic side
    c. either side
    d. neither side

18. When making a plastic-to-plastic pouch seal
    a. the plastic should not remain in the jaws while cooling
    b. the plastic should remain in the jaws while cooling
    c. a cooling cycle will create wrinkles on the packaging
    d. none of the above

19. When using the “wrap within a pouch” method, a chemical sterilization indicator
    a. may be part of the pouch
    b. may go within the wrap
    c. it depends upon the device being processed
    d. a and b

20. When “double packaging” with a paper-plastic pouch
    a. the first pouch should be sealed
    b. the first pouch should not be sealed
    c. the first pouch should be larger than the second pouch
    d. the first pouch should be folded