



## **AST Standards of Practice for Packaging Material and Preparing Items for Sterilization**

### **Introduction**

The following Standards of Practice were researched and authored by the AST Education and Professional Standards Committee and have been approved by the AST Board of Directors. They are effective October 19, 2009.

AST developed the following Standards of Practice to support healthcare facilities in the reinforcement of best practices related to the selection and use of packaging material for the sterilization of items, including evaluation of the characteristics that are important to the selection of the packaging material. Additionally, general recommendations are provided regarding the preparation of items for sterilization. The purpose of the Standards is to provide an outline that Certified Surgical Technologists (CSTs) and Certified Surgical First Assistants (CSFAs) can use to develop and implement policies and procedures for packaging material and preparing items for sterilization. The Standards are presented with the understanding that it is the responsibility of the healthcare facility to develop, approve, and establish policies and procedures for evaluating packaging material according to established healthy care facility protocols.

### **Rationale**

The following are Standards of Practice related to the evaluation, selection and use of packaging material in the perioperative setting, including general recommendations for the preparation of items for sterilization. The four overall purposes of any type of packaging system is to ensure the packaging material allows the penetration of the sterilant, maintains the sterility of the contents until opened for use, and allows ease of use in order to open in an aseptic manner, and are cost effective. There are a variety of packaging systems, including woven fabrics, nonwoven materials, plastic-plastic pouches, paper-plastic pouches (commonly called peel packs), and rigid instrument containers.

### **Standard of Practice I**

**Packaging materials should be evaluated prior to adoption and purchase. This includes receiving samples of the packaging material as test products to ensure it will meet the performance standards of the healthcare facility.**

1. Packaging materials and seals should have the following general characteristics:
  - A. Allow the sterilizing agent to penetrate and reach all surface areas of the item(s) to be sterilized.
  - B. Maintain the sterility of the item up until its use; perform as a reliable barrier to microorganisms.

- C. Permit the package to be opened in an aseptic manner that allows for sterile items to be easily removed or transferred to the sterile field without contamination.
  - D. Conform to the size and shape of the item(s).
  - E. Cover the contents in their entirety.
  - F. Provide for maximum amount of use.
  - G. Allow air to be completely removed during the sterilization process.
  - H. Withstand the physical conditions produced by the autoclave, including moisture, pressure and high temperatures.
  - I. Be permeable to the sterilizing agent and moisture.
  - J. Allow the escape and removal of the sterilizing agent at the end of the sterilization process.
  - K. Allow the contents to be dried after sterilization with no presence of moisture. The packaging material must also have the characteristic of being able to be dried to avoid wet packages upon removal from the sterilizer. This is particularly important when using ethylene oxide sterilization, since water combined with EtO can produce toxic byproducts.
  - L. Allow ethylene oxide gas and moisture to escape during the aeration cycle, when using ethylene oxide sterilization.
  - M. Resist tears and punctures, during sterilization and normal handling.
  - N. Should not easily degrade when the sterile packages are stored.
  - O. Provide a barrier to the penetration of dust and particles, and resist moisture penetration.
  - P. Woven fabrics should be lint free and also free of loose fibers.
  - Q. Must not contain any toxic material or dyes that could produce a chemical reaction during the sterilization process. The toxic residue could be harmful to the patient and the members of the surgical team, who are handling the packaging material, and sterile team members, who are handling the contents.
  - R. Reusable packaging materials should be free of bleaches and detergents that could produce a chemical reaction during the sterilization process. The toxic residue could be harmful to the patient and the members of the surgical team, who are handling the packaging material, and sterile team members, who are handling the contents, as well as cause instrument discoloration.
  - S. Promote integrity of the seal that is used to secure items, so that content sterility is maintained. The seal should not spontaneously open, when the package is in sterile storage.
  - T. Incapable of being re-sealed, once the seal is broken or package is opened.
2. Specific characteristics related to rigid container systems are:
- A. Easily open and provide for excellent sterile presentation of contents.
  - B. Contain a removable lid that is sealable with some type of locking device.
  - C. Broken locking device should be readily apparent.
  - D. Manufactured of a sturdy anodized aluminum, stainless steel, plastic or plastic-metal combination.

- E. Allow removal of all moisture and prevent collection of water in bottom of container.
  - F. Be permeable to the sterilizing agent and moisture
  - G. Allow complete removal of the sterilizing agent and drying of the contents and container itself.
  - H. Allow for easy, aseptic removal of the sterile contents for use on the sterile field.
3. Specific characteristic related to paper-plastic peel packs are:
- A. Thickness of the plastic layer must be a minimum of 2 mm.
  - B. Plastic side should allow visualization of the content(s).
  - C. Pouch should be commercially heat sealed along the edges lengthwise. One end may be commercially heat sealed with the other end open for placement of the item(s) to be sterilized, and the open end is either heat-sealed, adhesive self-sealed or sealed with chemical indicator tape. Or the pouch may have two open ends that must be heat-sealed.
  - D. The peel pack must allow the open end to be easily sealed to prevent tunneling (incomplete contact) of the seal.
  - E. Peel pack material must allow for total air removal.
  - F. Be permeable to the sterilizing agent and moisture.
  - G. Peel pack material must allow for complete removal of the sterilizing agent.
  - H. Peel pack material must allow for complete drying of the contents and drying of the packaging material itself.
  - I. Peel pack must permit the package to be opened in an aseptic manner that allows for easy removal of the sterile items without contamination.
4. When evaluating packaging material or a packaging system, the healthcare facility should request and review the manufacturer's information to ensure it is appropriate for the method of sterilization to be used, and to review and maintain a written copy of the sterilization validation studies.
5. Healthcare facilities should request a sample of the packaging product to evaluate and test the efficacy prior to making a selection and purchasing. The product should be tested in a manner to determine that it meets all the general and specific performance characteristics unique to the packaging material, including sterilization parameters with the use of a biological indicator and recording of the results.

## **Standard of Practice II**

### **Rigid containers, including instrument cases and plastic-metal combination instrument organizing trays, should be evaluated for design and construction prior to final selection and purchase.**

1. When evaluating the rigid container system, the healthcare facility should request and review the manufacturer's information to ensure it is appropriate for the method of sterilization to be used, and to review and maintain a written copy of the sterilization validation studies.
2. Biological and chemical indicator testing of the container system should be performed according to the Association for the Advancement of Medical

- Instrumentation (AAMI) standards. The container should be tested according to the type of sterilizing agent(s) that will be used and the cycles to be used.
3. Evaluation of the container system should include:
    - A. Verifying manufacturer's test and validation study results.
    - B. Verifying that the container system meets all the prerequisite characteristics, including allowing complete air removal, penetration of the sterilizing agent, drying, ease of opening in an aseptic manner, user friendly sealing, ease of changing filters, ease of disassembly and decontamination.
    - C. Verify container system has been approved by the US Food and Drug Administration for sterilization purposes.
    - D. Verify efficacy of single use filters and valve systems.
  4. As recommended by AAMI, the manufacturer should provide instructions and documentation related to the tested performance qualifications and written instructions for the use of the container system including:
    - A. Manufacturer's recommendations related to the type of sterilization method can vary. Example, a manufacturer may indicate that a container system should only be used with pre-vacuum cycle because of the difficulty of air removal associated with gravity cycle.
    - B. Methods for verifying sterilization conditions including penetration of the sterilant, time, placement of the biological and chemical indicators, drying times and aeration times. Example, a manufacturer may recommend extended sterilization and drying times for a container system.
    - C. Recommendations related to the placement and uniform distribution of the instruments/contents, including weight and density.
    - D. Methods recommended by the manufacturer for verifying testing the barrier effectiveness and sterility maintenance of filters and valves.
    - E. Manufacturer's recommendations for disassembly of container system for decontamination, including recommended type of cleaning agents; inspection, maintenance and re-assembly of gaskets, filter covers, and valves; use of sealing devices; placement of the container on the sterilizing cart; handling, transportation and storage after sterilization process.
  5. Selection factors to consider when evaluating a container system include:
    - A. Content visibility. If container lid is not semi-transparent, visibility of the contents and inner basket upon removal of the lid.
    - B. Removal of contents can be done in an easy manner employing aseptic technique.
    - C. Manufacturer can provide varying sizes of container system, if needed.
    - D. Estimated life expectancy of the container system.
    - E. Cost analysis, including consideration of the following:
      - (1) Comparison of rigid container system to CSR wrappers, including costs related to labor, capital and materials for both.
      - (2) Labor costs associated with container systems, related to the time required to clean, inspect and assemble

- (3) Analysis of cost of ancillary supplies for the container system, including seals/locks, filters, labels and specific cleaning agent, and cost of replacement parts such as worn out gaskets.
- F. Availability of manufacturer's refurbishing services.
- G. Ease of assembling container.
- H. Ease of identifying worn out parts that need replacing, such as worn out gaskets and filter-retention-plates.
- I. Manufacturer recommended maximum weight of container with instruments.
- J. Manufacturer recommended guidelines, related to how the containers should be handled when loading and removing from autoclave.
- K. Manufacturer's recommendations are available for cool-down of the container, after removal from the autoclave.
- L. Any special recommendations from the manufacturer, concerning necessity to preheat load prior to initiation of the sterilization cycle in order to ensure a dry set at the end of the cycle.
- M. Manufacturer recommendation for length of time load with containers should be left in the autoclave chamber to dry before removal.

### **Standard of Practice III**

#### **Packaging and container systems should only be used with the sterilization process for which it was manufactured.**

1. Packaging and container systems for steam sterilization should be able to withstand the physical conditions without breaking down and also allow adequate drying.
  - A. Healthcare workers (HCWs) should follow the manufacturer's instructions for the use of the steam sterilization packaging and container systems.<sup>4</sup>
  - B. Several factors should be considered by the healthcare facility that can affect the efficacy of the packaging and container systems. Appropriate adjustments should be made when preparing items for steam sterilization. Factors include:
    - (1) Altitude
    - (2) Humidity of environment
    - (3) Size of package or container
    - (4) Contents of package or container
    - (5) Weight and density of the package or container
  - C. Paper-plastic combination peel packs should be used for steam sterilization.
  - D. Tyvek® combination peel packs **should not** be used for steam sterilization.
    - (1) Tyvek is a flammable material in steam sterilization; steam melts and/or burns the material.
2. Packaging and container systems for EtO sterilization should be able to withstand the physical conditions without breaking down as well as allow penetration of EtO and moisture, and allow for proper aeration.<sup>2</sup>

- A. HCWs should follow the manufacturer's instructions for the use of the EtO sterilization packaging and container systems.<sup>2</sup>
  - B. Paper-plastic combination peel packs can be used for EtO sterilization.
  - C. Tyvek combination peel packs can be used for EtO sterilization.
3. Packaging and container systems for gas plasma sterilization should be able to withstand the physical conditions, without breaking down as well as allow penetration of the hydrogen peroxide plasma sterilizing agent.
- A. The manufacturer's written instructions should be followed for the use of packaging materials and container systems that are compatible for gas plasma sterilization. Not all packaging materials and container systems can be used with gas plasma sterilization. HCWs should refer to the manufacturer's written information and results of studies verifying the packaging material or container system's use in gas plasma sterilization.
    - (1) The use of absorbable packaging material should be avoided; paper material and textiles can absorb the gas plasma sterilization, thus decreasing the effectiveness of the sterilization process.<sup>3</sup>
    - (2) Only peel pack pouches that are entirely plastic (no paper is present) should be used in gas plasma sterilization.<sup>6</sup>
    - (3) For container systems that require a filter, the filter should be made of non-cellulose material.<sup>6</sup>
4. Packaging and container systems for ozone sterilization should be able to withstand the physical conditions without breaking down and also permit penetration of the ozone sterilizing agent.
- A. The manufacturer's written instructions should be followed for the use of packaging materials and container systems that are compatible for ozone sterilization. Not all packaging materials and container systems can be used with ozone sterilization. HCWs should refer to the manufacturer's written information and results of studies verifying the packaging material or container system's use in ozone sterilization.
  - B. Tyvek is the recommended packaging material for ozone sterilization.<sup>6</sup>

#### **Standard of Practice IV**

**Reusable packaging materials should be laundered, inspected and properly stored between every use to preserve the packaging properties of the material. Single-use packaging materials should be properly stored to preserve the packaging properties of the material.**

1. Reusable woven packaging materials must be laundered and inspected between each use. Laundering aids in rehydration of the packaging material. Experience has shown that if the packaging product is too dry, superheating during steam sterilization and positive biological indicators can result.<sup>5</sup>
  - A. All woven packaging material should be de-linted prior to use.
  - B. All woven packaging material should be inspected for holes, tears, and thinning of the material each time after laundering. It is recommended the inspection take place with the use of a lighted table. Defects should be

- repaired with the use of a vulcanized patch that is heat sealed onto the woven material. A patch should be placed on each side of the defect.
- C. Defects **should not** be sewn. The needle from sewing creates multiple holes in the woven material, producing multiple routes of microbial entry to the sterile field.
  - D. Multiple laundering and defect repairs eventually cause the woven material products failure to meet the criteria for performance and must be retired.<sup>3</sup>
    - (1) The healthcare facility should have a tracking system in place, such as a marking grid or bar code system to track the number of times a woven product is laundered and sterilized.
    - (2) The manufacturer of the woven products should provide written recommendations for the number of times the product can be processed and used.<sup>3</sup>
2. To further aid in the prevention of superheating, all types of packaging materials should be stored at the proper temperature and humidity for at least two hours before use. Storage at room temperature and humidity permits adequate steam penetration and prevention of superheating.<sup>4</sup> Room temperature and humidity should be monitored and recorded on a daily basis. The recommended temperature and humidity are 20° C to 23° C (68° F to 73° F); 30% to 60% humidity.<sup>5</sup>

### **Standard of Practice V**

#### **Wrapped packages should be prepared to facilitate ease of opening the package and transferring to the sterile field, while maintaining the sterility of the contents.**

1. The correct size wrapper should be chosen in order to ensure complete coverage of the contents and sterilization.
  - A. The wrapper should not be too large in order to prevent air pockets from forming, which can inhibit the penetration and release of the sterilant. However, it should not be too small as to not allow adequate coverage of the contents and possibly tear at the corners.
  - B. Wrappers that will be used to establish a sterile field should be large enough to extend a minimum of six inches below the four sides of the table or basin ring.<sup>8</sup>
  - C. Wrappers must be large enough to cover the hand of the individual opening it, if the package is to be handed to the CST in the scrub role, using sterile technique or transferred (tossing) to a sterile field.
  - D. Before wrapping an instrument tray, an absorbent lint-free linen towel should be placed between the bottom of the tray and wrapper to cushion the corners of the tray and prevent tearing, as well as serve to absorb the condensation during steam sterilization.
  - E. Density is a key factor related to the sterilization of items. The more densely items are packed, the greater the percentage that the sterilant will not contact the surface areas of all items, and drying will be inadequate.
    - (1) AAMI has recommended that instrument sets should not exceed 25 pounds.<sup>5</sup>

## **Standard of Practice VI**

**The preparation of items for sterilization begins after decontamination and the three steps should be completed for all items to be sterilized: inspection, reassembly, and preparation.**

1. Items should first be inspected for blood and soil that could be left after decontamination.
2. Instrument function should be tested to determine if the instrument needs repair, sharpening or replacement.
  - A. Cutting edges of scissors and other sharp instruments such as trocars should have no burs, cracks, scratches or bends and have not become dulled. The blades of scissors should close smoothly and be sharp enough to easily cut two 4 x 4 gauze sponges.<sup>8</sup>
  - B. Instrument ratchets must lock properly and not spring open. The instrument should be tested by lightly tapping the ring handle in the palm of the hand; if the instrument remains closed, the ratchet is assumed to be working properly.
  - C. Ratchets on self-retaining retractors should be tested to ensure they remain locked in the open position and smoothly and easily release when closing.
  - D. The jaws of clamps should close evenly with no gaps and the tips aligned.
  - E. Forceps should close evenly and the tips aligned. The teeth of tissue forceps should be aligned and fit smoothly and evenly into the groove of the opposite side when closed.
  - F. Manufacturer's instructions must be followed for the proper inspection and testing of powered instruments.
    - (1) The powered instrument may require lubrication and operation for a specific amount of time as indicated in the manufacturer's instructions.
    - (2) The power hose should be inspected in detail for cracks or cuts.
  - G. Manufacturer's instructions must be followed for the proper inspection and testing of endoscopic equipment.
    - (1) The endoscope may require testing according to the manufacturer's instructions.
    - (2) The light cord should be inspected for breaks in the integrity of the cord and function should be tested.
3. Instruments with multiple parts usually should not be reassembled in order to make sure the sterilant contacts all surface areas. Manufacturer's instructions should be followed related to the disassembly and assembly of instruments with multiple parts, including if the instrument should remain disassembled for sterilization purposes.
4. The three principles that should be followed in the preparation of items to facilitate effective sterilization are: the sterilant comes into contact with all surface areas, instruments are positioned in a protective manner, and instruments are evenly distributed.<sup>8</sup>
  - A. Instruments should be placed in a mesh-bottom or wire mesh basket.



- (1) An absorbent linen towel should be used to line the bottom. A nonwoven disposable wrapper **should not** be used to line the tray due to its water-repellent characteristic, causing the moisture to collect at the tray bottom.
  - (2) It is recommended that instruments with ring handles be placed on a “stringer” to maintain the instruments in an open (ratchets fully unlocked) manner and prevent scattering of the instruments in the tray. Instruments of like size, length, shape and function should be grouped together on the stringer as an aid to the CST in the first scrub role to quickly identify instruments during counts and when setting up for the surgical procedure.
  - (3) When using steam sterilization, a residual amount of water should be left inside instruments with a lumen to facilitate the displacement of air, when the water boils during sterilization. When using EtO sterilization, no water should be left inside the lumen; EtO combines with water to produce the toxic by-products ethylene glycol and ethylene chlorohydrin.<sup>8</sup>
  - (4) Instruments with concave surfaces should be positioned on their side to allow the sterilant to contact the entire surface and allow for moisture that collects in the concave portion to drain.
  - (5) Loose instruments, such as retractors, should not be tightly grouped together or wrapped. Instrument grouping and disproportionate metal contact inhibits the contact of the sterilant with all surface areas and may allow condensate to collect.
  - (6) Heavier instruments should be placed on the bottom or end of the tray to avoid damaging small, more delicate instruments. An absorbent towel can be used to separate layers of instruments and facilitate the absorption of moisture.
  - (7) Instruments **should not** be held together with rubber bands. The rubber bands can deflect the sterilant and prevent it from contacting the surface areas of the instruments.
  - (8) Instrument trays and rigid containers should be placed flat on the shelves of the sterilizing cart.
- B. Microsurgical instruments should be placed in special trays designed specifically for the sterilization of these delicate instruments.
- C. Basins that are nested within each other and/or contain other metal items should be assembled to allow the sterilant to contact all surface areas and allow the complete removal of air and condensate.
- (1) Nested basins should differ in diameter by a minimum of one inch.<sup>5</sup>
  - (2) An absorbent linen towel should be placed between two nested basins to facilitate the sterilant contacting all surface areas, aid in air removal and absorb condensate.
  - (3) Hollow OR lights should be placed in the basin handle down to allow the condensate to drain out.<sup>8</sup>

- (4) Sponges and woven fabrics **should not** be placed inside a basin; the material can deflect the sterilant, thus inhibiting the ability to contact all surface areas.
  - (5) The maximum recommended weight of wrapped basin sets is seven pounds.<sup>5</sup> (AAMI, 2006).
  - (6) Basins should be placed on the sterilizing cart on their side with the fold down to aid in the removal of air and prevent the accumulation of condensate.<sup>5</sup> The basin sets should be placed all facing the same direction.
5. The healthcare facility should establish policies and procedures for wrapping techniques and should reflect the manufacturer's recommendations.
  - A. The two recommended wrapping methods are the envelope (diagonal) fold and square fold. Sequential double-wrapping and simultaneous double-wrapping are acceptable methods of packaging.
    - (1) The diagonal fold is recommended for use when wrapping individual items and small to medium-sized instrument trays.
    - (2) The square fold is recommended for use when wrapping large instrument trays, basin sets and large packs.
6. Rigid containers should be disassembled and decontaminated after each use and assembled according to the manufacturer's written instructions.
  - A. All components of the rigid container, eg lid, container, filter retention plates, should be disassembled and decontaminated prior to clean instruments being placed in the container for sterilization.
    - (1) The manufacturer's instructions for decontaminating, inspecting, performing preventative maintenance and repair should be followed.
  - B. The manufacturer's instructions for type of filter, internal and external chemical indicators, and security locks should be followed.<sup>4</sup> (AAMI, 2006).
  - C. The manufacturer's instructions for assembling the instrument trays should be followed.<sup>4</sup>
  - D. The manufacturer's instructions related to whether or not other objects can be placed in the rigid container, such as linen towels, should be followed.
  - E. Protective organizing baskets or trays **should not** be placed inside a rigid container system, unless the manufacturer provides written verification that these devices can be safely used with the rigid container system.
    - (1) Protective organizing baskets or trays can inhibit air removal, sterilant penetration, sterilant evacuation and drying.
7. Surgical supplies, such as cotton balls, dressings and needles should be individually packaged, according to healthcare facility policies.<sup>5</sup>
  - A. Canisters with lids should not be used for the sterilization of surgical supplies.<sup>5</sup> It is necessary to remove the canister lid for sterilization of the contents and therefore, the sterility of the items is compromised once the sterilizer door is opened. Additionally, the canisters usually have solid bottoms, which do not allow for the removal of air and are conducive to condensate collecting at the bottom.

8. Packages should be labeled prior to being sterilized.
  - A. Labeling must be performed in order to allow the user to identify the contents of the package, in particular when woven and non-woven wrappers are used. It should also be performed as an aid for purposes of quality assurance, inventory control, and rotation of stock.
  - B. If a marking pen is used to label wrapped packs, it should be non-toxic.<sup>5</sup>
    - (1) The use of a non-toxic marking pen avoids toxins adhering to the packs or instruments.
  - C. Information should be written on the chemical indicator (CI) tape or on the front, plastic portion of peel packs. The following information should be included:
    - (1) Package contents
    - (2) Date sterilized (for purposes of rotating packages)
    - (3) Identification of the sterilizer
    - (4) Sterilization cycle number
    - (5) Initials of the employee who prepared the package
  - D. The use of a label gun that discharges printed labels can be used as a substitute for providing some of the information. The label should be placed on the chemical indicator tape or plastic of a peel pack. Printed labels may contain the following information:
    - (1) Julian date to indicate date of sterilization
    - (2) Identification of the sterilizer
    - (3) Cycle number
9. Devices used to close a package should allow the sterilant to penetrate, maintain the integrity of the package and prevent constriction of the package.<sup>5</sup>
  - A. Only CI tape should be used to secure packages; no other type of tape should be used.
    - (1) Tapes, other than CI tape, are not designed to withstand the sterilization cycle and may lose their ability to keep the package closed.
  - B. Staples or other sharp items should not be used for package closure.
    - (1) Sharp items, such as staples do not fully secure the closure of the package, thus compromising the sterility of the enclosed items.
    - (2) Sharp items can puncture the packaging material, causing the enclosed items to be contaminated.
10. Only instrument tip protectors that the manufacturer indicates are sterilant permeable should be used and should fit loosely.
  - A. Tip protectors made of the wrong material or fit too tightly can inhibit the sterilant from making contact with the instrument surface.
  - B. Latex tubing **should not** be used as a tip protector due to the sterilant-inhibiting property of the material.

## **Standard of Practice VII**

### **Paper-plastic peel pouches or peel packs should be used for small items or lightweight items that require sterilization.**

1. The open end of the pouch should be sealed by heat seal, CI tape, or self-seal.

- A. Staples **should not** be used to close a peel pack. The staples cause small holes, creating entry for microbes and contamination of the contents.
2. Rubber bands, tape or paper clips **should not** be used to bind package contents together.
  - A. The binding material can prevent the contact of the sterilant with the surface of the contents.
3. An item or items should be placed inside the peel pack that allows the circulator to present the contents to the CST in the first scrub role using sterile technique.
  - A. The item should be placed in the peel pack so the portion of the item that has the most surface area for the CST to grasp should be first presented when the pack is opened, eg clamp or scissors placed with ring handles at the end of the pack that will be opened.
4. The correct size pouch must be selected.
  - A. Pouches that are too small may prevent adequate air removal, penetration of the sterilant, and drying. Additionally, the contents may tear a pouch that is too small.
  - B. Pouches that are too large allow excessive movement of the content(s), which may cause tears.
5. As much air as possible should be forced from the pouch prior to sealing to prevent the pouch from bulging during sterilization and breaking the heat seals.
6. Sharp edges and tips of items should be protected with a tip protector or foam sleeves to prevent the pouch from tearing.
  - A. Latex tubing **should not** be used as a tip protector due to the sterilant-inhibiting property of the material.
7. Multiple items or items with multiple pieces should be kept together by double peel packs.
  - A. The items should be placed in a pouch that can be inserted inside a larger pouch. The inner pouch should fit inside the outer pouch without having to be folded; folding can cause entrapment of air which can prevent penetration of the sterilant.
  - B. The inner pack should not be sealed; sealing can cause entrapment of air which can prevent penetration of the sterilant.
8. Paper-plastic pouches **should not** be placed within wrapped sets or rigid container systems.<sup>5</sup>
  - A. The pouches cannot be properly positioned within the wrapped set or rigid container system to ensure adequate air removal, sterilant contact and drying.
  - B. The practice of placing pouches in wrapped instrument sets or rigid container systems has **not** been validated as appropriate and effective by any paper-plastic pouch, rigid container system or wrap manufacturer.<sup>5</sup>
9. Pouches should be placed on their edge, paper side to plastic side when positioned on the sterilizer cart to ensure air removal, sterilant penetration, and drying.

## Standard of Practice VIII

**Chemical indicators (CI) should be used in combination with mechanical monitors and biological indicators as part of the healthcare facility quality assurance sterilization program.**

1. The manufacturer’s written instructions for the use of CIs should be followed.
2. An external CI should be used on all healthcare facility prepared packages with the exception of those packages, such as paper-plastic pouches that allow visualization of the internal CI.
  - A. External CIs that are acceptable for use include, CI tape, CI label or CI printed legend that are affixed to or printed on all healthcare facility prepared packages and rigid container systems.
  - B. Only Class 1 CIs should be used.<sup>5</sup>
3. An internal CI should be used within all healthcare facility prepared packages and rigid container systems.
  - A. Class 3, 4 or 5 CI may be used.<sup>5</sup> See Table 1.
  - B. The internal CI should be placed in the area of a wrapped package, instrument tray or rigid container system where there can be the greatest chance of entrapped air.

**Table 1: Five Classes of Chemical Indicators<sup>1</sup>**

<b>CI Name</b>	<b>CI Class</b>	<b>Definition</b>
Process indicators	1	External CIs. Used with individual wrapped packages, trays and rigid container systems to demonstrate package has been exposed to the sterilization process.
Specific-test indicators	2	Bowie-Dick type indicators
Single-parameter indicators	3	Indicator that reacts to only one of the parameters of sterilization.
Multi-parameter indicators	4	Indicator that reacts to two or more of the critical parameters of sterilization.
Integrating indicators	5	Indicator that reacts to all critical parameters of sterilization.

**Standard of Practice IX**

**Sterilized wrapped packages, instrument trays, peel pouches and rigid container systems are considered sterile until an event occurs causing a break in the integrity of the wrap, pouch or rigid container system.**

1. Healthcare facilities should follow the concept of event-related sterility for economic purposes.

- A. The concept of event-related sterility is related to how sterile packages are handled and that contamination is event related rather than time related. Items are considered to be indefinitely sterile until an event occurs that compromises the sterility.

### **Standard of Practice X**

#### **Healthcare facilities should have written policies and procedures for evaluating the competencies of surgical personnel responsible for preparing items for sterilization as well as completion of continuing education.**

1. Healthcare facilities should have written policies and procedures for the preparation and packaging of items to be sterilized.
  - A. Written policies and procedures should address the following:
    - (1) Inspection, assembly and preparation of rigid container systems
    - (2) Inspection, assembly and preparation of items for sterilization
    - (3) Use of various types of pouches
    - (4) Use of various types of wraps
    - (5) Handling and use of CIs
    - (6) Labeling packages
2. The competencies of CSTs and other surgical personnel, who are responsible for preparing items for sterilization and using CIs, should be evaluated and documented.
  - A. Training and/or continuing education should be documented and periodically reviewed.
    - (1) Continuing education should be completed by surgical personnel in order to remain current in their knowledge of packaging systems and use of CIs.
    - (2) Continuing education should be completed by surgical personnel any time the healthcare facility implements new policies and procedures, when new sterilization equipment or surgical instrumentation is purchased.
    - (3) Documentation of completion of continuing education and verification of competencies aid in ensuring the personnel have the basic knowledge and understanding of the packaging systems and use of CIs; potential hazards to the patient, self and other healthcare workers in the event of a product or process malfunction; and actions that should be taken to correct the malfunction.
    - (4) The completion of continuing education contributes to meeting the competency standards that are a part of The Joint Commission's National Patient Safety Goals and providing safe quality patient care.
  - B. Competency verification should be performed during the following time periods.<sup>7</sup>
    - (1) New hire
    - (2) End of orientation period
    - (3) Annually

- (4) Healthcare facility revises policies and procedures
- (5) New sterilization equipment or supplies is purchased
- (6) New surgical instrumentation is purchased

**Competency Statements**

<b>Competency Statements</b>	<b>Measurable Criteria</b>
<p>1. The CST and CSFA have the knowledge and skills for participating in the evaluation of packaging systems, including rigid container systems, wraps, and pouches.</p> <p>2. The CST and CSFA have the knowledge and skills for participating in the evaluation of CIs, as well as the skills in the use of CIs.</p> <p>3. The CST and CSFA have the skills in the use of various packaging systems, including rigid container systems, wraps, and pouches.</p> <p>4. The CST and CSFA have the skills for properly preparing items for the various methods of sterilization.</p>	<p>1. Educational standards as established by the <i>Core Curriculum for Surgical Assisting</i> and <i>Core Curriculum for Surgical Technology</i>.</p> <p>2. The subjects of the evaluation and use of packaging systems and CIs is included in the didactic studies as a student.</p> <p>3. The subject of properly preparing items in preparation for sterilization is included in the didactic studies as a student.</p> <p>4. Students demonstrate knowledge of the above listed didactic subjects in the lab/mock OR setting and during clinical rotation.</p> <p>5. As practitioners, CSTs and CSFAs participate in the evaluation and use of packaging systems and CIs.</p> <p>6. CSTs and CSFAs complete continuing education to remain current in their knowledge of packaging systems, CIs, and preparation of items for sterilization.</p>

**References**

- 1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST60:1996 Sterilization of healthcare products – chemical indicators – part 1: General requirements. 1996. Arlington, VA.
- 2. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST41:1999/(R)2005 Ethylene oxide sterilization in healthcare facilities: Safety and effectiveness. 2000. Arlington, VA.

3. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST65: 2000 Processing of reusable surgical textiles for use in healthcare facilities. 2000. Arlington, VA..
4. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST58: 2005 Chemical sterilization and high-level disinfection in healthcare facilities. 2006. Arlington, VA.
5. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79: 2006 Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. 2006. Arlington, VA: AAMI.
6. *Central Service Technical Manual*. 7<sup>th</sup> ed. International Association of Healthcare Central Service Material Management. Chicago, IL; IACSMM; 2007.
7. Chobin N. (2008). Verifying competencies in sterile processing. *Biomedical Instrumentation & Technology*. 2008; 42(6): 474-476.
8. Frey KB, Price BD, Ross T. (2008). Asepsis and sterile technique. In: KB Frey, T Ross (eds.). *Surgical Technology for the Surgical Technologist: A Positive Care Approach*. 3<sup>rd</sup> ed. Clifton Park, NY: Delmar Cengage Learning; 2008: 139 – 184.

Tyvek is a registered trademark of the Dupont Corporation.