# Recommended Practices for Selection and Use of Packaging Systems for Sterilization

[Clinical]

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The following recommended practices were developed by the AORN Recommended Practices Committee and have been approved by the AORN Board of Directors. They were presented as proposed recommended practices for comments by members and others. They are effective January 1, 2007.

These recommended practices are intended as achievable recommendations representing what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented.

AORN recognizes the numerous settings in which perioperative nurses practice. These recommended practices are intended as guidelines adaptable to various practice settings. These practice settings include traditional operating rooms, ambulatory surgery centers, physicians' offices, cardiac catheterization suites, endoscopy suites, radiology departments, and all other areas where operative and other invasive procedures may be performed.

## PURPOSE

These recommended practices provide guidelines for the evaluation, selection, and use of packaging systems for items to be sterilized. Packaging systems should ensure the integrity of the sterilized contents until opened for use and should permit aseptic delivery of the contents to the sterile field. These packaging systems include woven

fabrics, nonwoven materials, paperplastic pouches, plastic-plastic pouches, and containment devices (eg, rigid sterilization containers, instrument cases and cassettes, and organizing trays). These recommended practices do not include recommendations for loading the sterilizer or sterilization processes.

## RECOMMENDED PRACTICE I

**Packaging systems should be evaluated before purchase and use to ensure that items to be packaged can be sterilized by the specific sterilizers and/or sterilization methods to be used.**[1]

1. Packaging systems should be appropriate for items being sterilized. The package system should

* provide an adequate barrier to microorganisms, particulates, and fluids;
* maintain sterility of package contents until opened;
* allow sterilant penetration and direct contact with the item and surfaces, and removal of the sterilant;
* be free of toxic ingredients and nonfast dyes;
* permit aseptic delivery of contents to the sterile field (eg, minimal wrap memory, removal of lids from containers);
* permit complete and secure enclosure of item(s);
* protect package contents from physical damage (eg, compression, stacking);
* provide adequate seal integrity;
* resist tears, punctures, abrasions, and prevent the transfer of microorganisms;
* be tamper-proof and able to seal only once;
* permit adequate air removal;
* be low-linting;
* permit identification of contents;
* be large enough to evenly distribute the mass;[2]
* allow ease of use by personnel preparing and/or opening the package or container;

* have a favorable cost/benefit ratio; and
* include manufacturer's instructions for use.

2. Packaging systems should be appropriate to the method of sterilization. The packaging system should be compatible with, and designed and approved for use with, the specific technology employed, and able to withstand physical conditions of the sterilization process. Purchasers should request, review, and be familiar with the manufacturer's written sterilization validation studies.[2]

3. Purchasers should evaluate and test the performance of each packaging system before selection and use this information to determine that conditions for sterilization, shelf life, transport, storage, and handling can be met. The packaging system compatibility with the intended sterilization process(es) and equipment should be verified before purchase. If the packaging represents a major change in product type (eg, change from woven textiles to nonwoven materials, increased weight of trays) product testing should be performed. Product testing should include

* placing biological indicators (BIs) inside a variety of items to be processed (eg, basin sets, instrument sets). The BI should be located in the most challenging location inside the package (eg, geometric center of the pack, in between folds of gowns in linen packs, between nested basins in basin sets);
* packages containing the test BIs should be placed in the most challenging locations inside the sterilizer (eg, over the drain) in a full chamber;
* sterilization of the test packages and removal and incubation of the BIs. Test package contents should be reprocessed before use; and
* documentation of the test results should be maintained with the sterilization records.[2]

4. The total weight of instrument containment devices should not exceed 25 pounds including the contents and containment method (eg, wrappers, rigid container systems, cassettes, organizing trays).[2] Excessively heavy instrument sets may compromise sterilization and drying. The focus should be on the set configuration (ie, how the instruments are distributed in the set) and the overall weight of the

set. Lifting and moving heavy instrument sets may cause health care worker injury.[2]

## RECOMMENDED PRACTICE II

**Packaging systems should be compatible with the specific sterilization process for which it is designed**.

1. Packaging systems for steam sterilization should permit adequate drying.[2]The efficacy of steam sterilization can be affected by humidity; altitude; packaging material; package contents; load; position of items within the sterilizer; size, weight, and density of the pack or container; and the parameters of the sterilization cycle. Practice settings should follow manufacturers' written instructions for each packaging system for steam sterilization.[2]
2. Packaging systems for ethylene oxide (EO) should
* be permeable to EO, moisture, and air;
* permit aeration;
* be constructed of a material recommended by the sterilizer and sterilant manufacturer; and
* maintain material compatibility (ie, non-degradable) with the sterilization process.[3]Woven, nonwoven, peel-pouch packages, and some rigid container materials are permeable to EO and do not impede rapid aeration of contents. Woven materials, however, may absorb a large amount of the relative humidity that is needed for EO sterilization. This may prevent adequate hydration of microorganisms for penetration of EO gas to all surfaces of the package contents.[3]
3. Packaging systems for low-temperature gas plasma sterilization should
* allow sterilizing plasmas to penetrate packaging materials;
* be compatible (ie, nondegradable, nonabsorbable) with the sterilization process;
* be constructed of a material recommended by the sterilizer manufacturer; and

* be used according to the packaging manufacturer's written instructions.Low-temperature gas plasma sterilization is affected by absorbable packaging materials (eg, cellulose-based packaging material, textile wrappers, paper-plastic pouches, or porous wrap); both the packaging and sterilizer manufacturer's written instructions should be followed.[4] The absorption of the plasma sterilant (ie, hydrogen peroxide) by paper-plastic pouches or porous wrap could have an adverse effect on the effectiveness of the sterilization process. Pouches used in low-temperature gas plasma sterilizers should be made of all plastic (eg, polypropylene).[4,5] Not all containment systems are compatible with low-temperature gas plasma; the user should obtain the manufacturer's technical data verifying the containment device has been validated for use in low-temperature gas plasma. If the containment device requires a filter, the filter should be made of noncellulose material.

4. Packaging systems for ozone sterilization should comply with the sterilizer manufacturer's written recommendations. Packaging not intended for use in ozone sterilizers may compromise the sterilization process. Packaging materials suitable for ozone sterilization include uncoated non-woven material, polyethylene pouches and commercially available anodized aluminum containers using noncellulose disposable filters.[5]

## RECOMMENDED PRACTICE III

**Packaging materials should be stored and processed to maintain the qualities required for sterilization**.

1. Reusable woven textile materials should be laundered between every use for rehydration. Re-sterilization without relaundering may lead to superheating and could be a deterrent to achieving sterilization.[2] Over-drying, heat-pressing, and storage in areas of low humidity also may lead to superheating and sterilization failure. When woven textiles are not rehydrated after sterilization, and/or if repeated

sterilization is attempted, the textiles may absorb the available moisture present in the steam, thereby creating a dry or superheated steam effect.[2]

2. Packaging materials should be stored at 20° C to 23° C (68° F to 73° F) and at a relative humidity of 30% to 60% for least two hours before use. Maintaining room temperature and moisture content of packaging materials facilitates steam penetration and prevents superheating during the sterilization process. Room temperature and humidity levels in the packaging area should be monitored.[2]

3. Single-use packaging material should be used for one sterilization cycle. Disposable packaging material should be discarded after opening.

## RECOMMENDED PRACTICE IV

**Package contents should be assembled, handled, and wrapped in a manner that provides for an aseptic presentation of package contents**.

1. The appropriate size wrapping material should be selected to achieve adequate coverage of the item being packaged. The item should be wrapped securely to prevent gapping, billowing, or air pockets from forming, which may lead to compromised sterilization.

2. The method of packaging should be performed in a manner that facilitates the aseptic presentation of the contents. Sequential wrapping using two barrier-type wrappers provides a tortuous pathway to impede microbial migration and permits ease of presentation to the sterile field without compromising sterility. A fused or bonded, double-layer, disposable, nonwoven wrapper used according to manufacturers' written recommendations may provide a bacterial barrier comparable to the sequential double wrap, allowing safe and easy presentation to the sterile field. Correct use of a single disposable, nonwoven, double-bonded wrapper may eliminate the need to double-wrap sequentially.[6]

3. Count sheets should not be placed inside wrapped sets or rigid containers. Although there are no known reports of adverse events related to sterilized count sheets, there is no available research regarding the safety of toners and/or various papers subjected to any sterilization method. Chemicals used in the manufacture of paper and toner ink pose a theoretical risk of reaction in some sensitized individuals.[7]

## RECOMMENDED PRACTICE V

**Paper-plastic pouch packages should be used according to manufacturers' written instructions**.

1. Paper-plastic pouch packages should be used only for small, lightweight, low-profile items (eg, one or two clamps, scissors). Heavy metal instruments (eg, drills, retractors, weighted vaginal speculums) should not be sterilized in peel pouches because problems (eg, wet packages following sterilization) and sterility maintenance problems (eg, package seal break) may occur.[2]
2. Paper-plastic pouch packages should have as much air removed as possible before sealing. Air acts as a barrier to heat and moisture. Expansion of air may cause rupturing of packages during the sterilization process.[8]
3. Paper-plastic pouch packages should provide a seal of proven integrity and not allow resealing. A break in the seal may allow microorganisms to enter and contaminate package contents.[8]
4. Paper-plastic pouch packages should be sealed airtight. Air-tight sealing can be accomplished by applying heat to the open end of the peel pouch or pressure to the mating surfaces of self-sealing pouches to cure and make permanent the seal.[5]
5. Paper-plastic pouch packages should be inspected for intact seals and barrier integrity before and after sterilization and before use.
6. Double paper-plastic pouch packaging is not routinely required for sterilization; however, double packaging may be used to facilitate

containment of multiple small items to be sterilized and facilitate aseptic presentation to the sterile field.[5]

* Double paper-plastic pouch packages should be used in such a manner as to avoid folding the inner package to fit into the outer package. Folding edges of inner peel packages may entrap air and inhibit the sterilization process.[2,5]

* During sterilization of double paper-plastic pouch packages, the paper portions should be placed together to ensure penetration and removal of the sterilant, air, and moisture. Sterilizing agents penetrate paper portions of peel-pouch packages; plastic portions allow items to be viewed.[2]

7. Paper-plastic pouches should not be used within wrapped sets or containment devices because the pouches cannot be positioned to ensure adequate air removal, sterilant contact, and drying. The practice of confining instruments in paper-plastic pouches and then including them in wrapped or containerized sets has not been validated as appropriate and efficacious by packaging and container manufacturers.[2]

8. Paper-plastic pouch packages should open without tearing, linting, shredding, or delaminating. Contamination of sterile contents can occur due to functional failure of plastic-paper pouch packages.[9]

## RECOMMENDED PRACTICE VI

**Design, material, and construction of the containment device (eg, rigid containers, instrument cases/cassettes, organizing trays) should be considered before selection, purchase, and use**.

1. Purchasers should verify that the containment device has been tested and validated for the sterilization method and cycles to be used. Purchasers should request, review, and be familiar with the manufacturer's sterilization validation studies.[2]

2. Pre-purchase evaluation and biological testing of the containment device should be performed.[2]

* Pre-purchase evaluation should determine
whether the facility can verify the manufacturer's test results;
if the container device has been cleared by the US Food and Drug Administration (FDA) for use in a sterilization process;
if the container device is compatible with the design of the sterilizer(s) in which it will be used;
if the container device will allow complete air removal, adequate sterilant penetration, and drying; and
requirements for disassembly and cleaning.[2]
* Pre-purchase biological testing should be performed according to Association for the Advancement of Medical Instrumentation standards. Each size container should be tested under the sterilization methods and cycles to be used.[2]
* Sealed flash sterilization containers should be biologically tested during the pre-purchase evaluation and routinely thereafter. The container manufacturer should provide technical data regarding the best method for biologically testing the container.[2]
3. The recommended sterilization method and cycle exposure times for each rigid container system should be provided in the manufacturers' data and instructions. Construction materials and container design may affect compatibility with the sterilization process (eg, penetration of sterilant [gas plasma], release of moisture or sterilant [EO]). Recommendations related to the type of sterilization method vary by the container manufacturer. Prevacuum sterilizers may be preferred because air removal is difficult in gravity displacement sterilizers.[2]
4. Rigid containers with single use or reusable filters and valve systems should be secured and in proper working order before sterilization.
* Filter plates should be examined for integrity both before installation and after the sterilization process. If the filter is damp; dislodged; or has holes, tears, or punctures, the contents should be considered unsterile.[2]
* Only components of the rigid container system specified by the manufacturer and compatible with the system should be used.

* The integrity of the rigid container should be inspected and damaged items repaired or replaced after each use. Inspection should ensure that
sealing and mating surfaces and edges of the container and lid are free of dents or chips;
filter retention mechanisms and fasteners (eg, screws, rivets) are secure and not distorted or burred;
securing mechanisms are functioning;
integrity of the filter media is not compromised;
gaskets are pliable, securely fastened, and without breaks or cuts; and valves work freely.[2]Loosened rivets, improperly maintained valves, worn gaskets, dents, or other damage compromises the integrity of the container and will compromise the sterilization process.[2]

5. Rigid container systems should be cleaned after each use. All components (eg, filter retention plates) should be disassembled for proper cleaning.[2]

6. The manufacturer's written instructions for cleaning, inspection, repair, and preventive maintenance should be followed.[2]

7. The manufacturer's written instructions for loading rigid containers should be followed. Instructions should include instrument set configuration requirements.[2]

8. The manufacturer's instructions for recommended filter material, security locks, and external chemical indicators should be followed.[2]

9. Additional materials placed inside rigid containers (eg, silicone mats, surgical towels) should not be used unless the container manufacturer has provided validation for their use.

10. The manufacturer's technical data for types of devices validated for use inside the container (eg, power equipment, items with lumens) should be obtained and special instructions for sterilization followed.

## RECOMMENDED PRACTICE VII

**Packages to be sterilized should be labeled**.

1. Packaging systems should be labeled before sterilization. The label information should include, but not be limited to,
* a description of the package contents,
* a method to identify the package assembler, and
* lot control number.
2. Package labels should be visible and remain securely fixed to the package throughout processing, storage, and distribution to the point of use. If tape or a computer-generated label is used, it may be placed on either side of the peel-pouch package.
3. Label information should be written on indicator tape and not on the packing material. Markers used to label packages should be indelible, nonbleeding, and nontoxic. If a marking pen is used to label peel-pouch packages, the information should be written only on the plastic side of the pouch. If a marking pen is used to label wrapped packages, the information should be written on the indicator tape or affixed labels.[2]

## RECOMMENDED PRACTICE VIII

**Sterilized packages should be considered sterile until an event occurs to compromise the package barrier integrity**.[2]

1. Health care organizations should determine the best methods and materials for packaging sterile items, based upon the anticipated storage, handling, and environmental events that may be encountered. Loss of sterility of a packaged sterile item is event related. An event must occur to compromise package content sterility. Events that may affect the sterility of a package include, but are not limited to,
* multiple handling that leads to seal breakage or loss of package integrity;
* compression during storage;
* moisture penetration;
* exposure to airborne and other environmental contaminants;

* storage conditions (eg, type of shelving, cleanliness, temperature, humidity, traffic control);
* type and configuration of packaging materials used; and
* use of sterility maintenance covers and method of sealing.

2. Sterile packages should be stored under environmentally controlled conditions. Sterile storage area temperature should be controlled and should not exceed 75° F (24° C). The humidity should not exceed 70%. There should be a minimum of four air exchanges per hour, and the air flow should be under positive pressure in relation to adjacent areas.[2]
3. The end user should visually inspect the package or container before opening for package integrity (eg, free of holes in fabric/paper, effective seal in containers).

## RECOMMENDED PRACTICE IX

**A chemical indicator/integrator should be placed inside each package and an external chemical indicator affixed outside each package to be processed.**[2]

1. External chemical indicators, classified as Class I chemical indicators, should be specific to the sterilization process selected.
2. Internal chemical indicators should be specific to the sterilization process. Class III (single parameter indicators), Class IV (multi-parameter indicators), or Class V (chemical integrators) may be used.
3. End users should obtain and follow the chemical indicator manufacturer's instructions for storage, use, and expiration.
4. The internal chemical indicator/integrator should be placed in the geometric center of the package, not on top, to verify that air has been removed and that the sterilant has penetrated into the center of the pack or set. The indicator should be visible to the user when the package is opened so the user can see that the indicator has changed before touching the contents.

5. Two chemical indicators/integrators should be placed inside rigid containers, one in each of two opposite corners of the inside basket.[2]Multi-level containers should have a chemical indicator/integrator placed in two opposite corners (eg, one in each of two corners) of each level.
6. A chemical indicator/integrator should be placed on each level of multi-level wrapped sets.[2]

## RECOMMENDED PRACTICE X

**The health care organization's quality management program should include sterile packaging selection and use**.

1. Product testing should be performed whenever there is a major change in packaging systems, materials, tray configuration, or content density.[2] Two types of testing should be performed.
* **Biological testing**. The biological indicator should be placed inside the tray, set, or pack being tested, usually in each corner and in the center of the set.
* **Verification of the ability to dry the set under user conditions**. The set should be observed for any condensate on the instruments or package contents, wet or moist towels or silicone mats, or visible water inside the container. Evidence of retained moisture will require additional steps to determine the necessary cycle parameters and sterilizer load configuration required to ensure adequate drying.
2. Wet packs should be investigated and resolved.[10] Internal or external moisture has the potential to provide a pathway for microorganisms to enter and contaminate a sterilized item.[2]
* Measures to resolve wet packs should include, but are not limited to,
determine the set/tray configuration and weight,
evaluate the packaging materials and methods used,
evaluate the pan/tray used to contain the set,
determine the placement (ie, location) of the tray/set on the sterilizer cart,

determine the entire contents of the sterilizer load in question (eg, the number and various types of items) including placement on the sterilizer cart,
determine if the chamber drain line basket is clogged,
investigate the steam quality with the engineering department, and determine if the steam sterilizer is functioning properly (eg, insufficient vacuum during the drying cycle).[2]

* One method that may be used to minimize wet pack issues is to “precondition” the load. Instruments should be placed inside the steam sterilizer before starting the cycle for 10 to 15 minutes with the door closed. The heat in the chamber, from steam stored in the jacket, will heat the instruments. The heating of the instruments before injection of steam may resolve wet pack issues that are not associated with steam quality or packaging/loading errors.[2]

3. A quality control program should be developed and implemented when woven textile packaging is used.

* All woven textiles should be de-linted after washing and before packaging. Textiles should be inspected on a light table for defects (eg, holes, tears) each time they are processed. Any defects should be repaired using a vulcanized patch applied with a heat patch machine. Vulcanized patches do not permit penetration of most sterilants; therefore, the quantity as well as the location of the patches should be evaluated. The defect should be patched on both sides. If there are multiple patches in the same general area, the item should be removed from service even if the overall quality of the material is acceptable.
* Tears should not be sewn. Sewing increases the number of holes in the textile where microbes can enter. Cross stitching of textiles is not recommended due to the number of holes created in the woven material.
* A system of inspection for the overall integrity of the material should be developed, implemented, and monitored for quality. If the material appears very thin, even though there are no patches on the item, the item should be removed from use.
* Reusable textiles should maintain a protective barrier throughout the life of the product. Multiple processing will eventually diminish the

protective barrier of the material. Manufacturers' instructions should be followed for the suggested number of re-processings.[11] A method should be established to monitor, control, and determine useful life when reprocessing woven materials. This should include, but not be limited to, the number of sterilization processes and washing cycles that may occur while maintaining the acceptable barrier quality of the material.[11] If a printed area (eg, grid system) for marking the number of uses is available on the woven textile, the printed area should be marked each time the item is processed. When the grid is full, the item should be removed from service.[11]

4. Evaluation and biological testing of rigid containers should be performed periodically in each specific sterilizer and with each cycle type used.[2] Various sterilizers having the same sterilization cycles may have different air-removal efficiencies.

## RECOMMENDED PRACTICE XI

**Personnel should demonstrate competence in the use of sterilization packaging systems and accessories**.

1. Personnel selecting and using packaging systems should be knowledgeable about the principles of sterilization, manufacturers' instructions, risks, measures to minimize these risks, and corrective actions to employ in the event of a failure of the packaging system.
2. Personnel should be competent in the proper selection and use of packaging systems before use. Education should be provided during the orientation period. Additional periodic educational programs should be provided to reinforce safe use; new information on changes in technology, its application, and compatibility of sterilization equipment and processes; and potential hazards.
3. Administrative personnel should periodically assess and document the competency of personnel in the use of packaging systems, according to hospital and department policy. Incorrect use can result in serious injury to patients. Competency assurance verifies that

personnel have a basic understanding of packaging systems, risks, and appropriate corrective action to take in the event of a product or process failure. This knowledge is essential to minimizing the risks of misuse and providing a safe environment of care.
4. An introduction to related policies and procedures should be included in the orientation and ongoing education of personnel to assist in the development of knowledge, skills, and behaviors that affect patient outcomes.

## RECOMMENDED PRACTICE XII

**Policies and procedures for the selection and use of packaging systems should be written, reviewed periodically, and readily available within the practice setting**.

1. These recommended practices should be used as guidelines for the development of policies and procedures for packaging. The AORN recommended practices that deal with sterilization and protective barrier materials also should be consulted when developing policies and procedures. Policies and procedures establish authority, responsibility, and accountability for the selection and use of packaging systems within the practice setting.
2. Maximum weight and tray configurations should be identified in the policy.
3. Policies and procedures establish guidelines for performance improvement activities to be used in monitoring packaging system efficacy.
4. The Perioperative Nursing Data Set, the uniform perioperative nursing vocabulary, should be used to develop policies and procedures related to sterilization and sterile packaging. The expected outcome of primary import to this recommended practice is, “The patient is free from signs and symptoms of infection” (O10). This outcome falls within the domain of Physiologic Responses (D2). The associated nursing diagnosis is “Risk for infection” (X28). The associated interventions

that may lead to the desired outcome may include “Protects from cross-contamination” (I98).[12]

## GLOSSARY

**Chemical indicators:** Devices used to monitor exposure to one or more sterilization parameters.

**Class I:** Process indicator that demonstrates that the package has been exposed to the sterilization process to distinguish between processed and unprocessed packages.

**Class II:** Process indicators that are used for a specific purpose such as the dynamic air removal test (formerly called the Bowie-Dick test).

**Class III:** A single-parameter indicator that reacts to one of the critical parameters of sterilization.

**Class IV:** A multi-parameter indicator that reacts to two or more of the critical parameters of sterilization.

**Class V** (integrating indicator): An indicator that reacts to all critical parameters of sterilization.

**CONTAINMENT DEVICE:** Reusable rigid sterilization container, instrument case, cassette, or organizing tray intended for the purpose of containing reusable medical devices for sterilization.

**FLASH STERILIZATION CONTAINER:** A container specifically designed for steam flash sterilization. The container is used to contain a device before, during, and after the sterilization process. It is sealed and may require special extended sterilization exposure times.

**INSTRUMENT CASE/CASSETTE:** A device with a lid and a base to sterilize devices that permits air removal and sterilant penetration/removal. These devices require wrapping in packaging material if sterility of the contents is to be maintained.

**LOW-TEMPERATURE GAS PLASMA STERILIZATION:** This type of sterilization process involves an ionizing hydrogen peroxide gas or cloud or low-temperature plasma produced by exciting a strong

electrical field over a contained precursor vapor that serves as a sterilizing agent.

**NONWOVEN MATERIALS:** A fabric made by bonding fibers together as opposed to weaving threads.

**ORGANIZING TRAY:** A reusable metal or plastic tray that permits organization of the contents and provides protection for the contents. Some organizing trays have diagrams of the respective instruments etched onto the surface of the tray to facilitate their location inside. These trays must be wrapped with an approved packaging material.

**PACKAGE INTEGRITY:** Unimpaired physical condition of a final package.

**PACKAGING MATERIAL:** Any material used in the fabrication or sealing of a packaging system or primary package.

**PACKAGING SYSTEMS:** One or more packaging materials assembled into a single unit intended as part or all of a primary package.

**PAPER-PLASTIC POUCH:** A type of packaging suitable for steam and EO sterilization usually made of Mylar® (a polyester film manufactured by DuPont) and paper. The plastic (Mylar®) side is clear, permitting viewing of the contents. Paper-plastic pouches are available in various size pouches or on rolls and can be self-sealed or heat-sealed. They should not be confused with all-plastic (eg, Tyvek®, a polyethylene material manufactured by DuPont) pouches, which are not compatible with steam sterilization.

**Rigid sterilization container system:** Specifically designed heat-resistant, metal, plastic, or anodized aluminum receptacles used to package items, usually surgical instruments, for sterilization. The lids and/or bottom surfaces contain steam- or gas-permeable, high-efficiency microbial filters.

**SEQUENTIAL WRAPPING:** A double-wrapping procedure that creates a package within a package.

**SHELF LIFE:** When this term is used in conjunction with a sterile device, shelf life is considered the length of time a device is considered safe to use.

**STERILITY MAINTENANCE COVER (SYNONYM: DUST COVER):** A plastic bag, usually 2 to 3 thousandths of an inch (ie, mils) in thickness, applied to a cooled, sterilized item to provide extra protection from dust, moisture, and other environmental contaminates. These covers can be heat-sealed or self-sealed closed.

**STERILIZATION VALIDATION STUDIES:** Tests performed by the device manufacturer that demonstrate that a sterilization process will consistently yield sterile container contents under defined parameters.

**SUPERHEATING:** A condition in which dehydrated textiles are subjected to steam sterilization. The superheated package or product becomes too dry, which causes destructive effects on the strength of the cloth fibers. When woven textiles are not re-hydrated after sterilization, and/or if repeated sterilization is attempted, the textiles could absorb the available moisture present in the steam, thereby creating a dry or superheated steam effect and adversely affecting the steam sterilization process.[2]

**USEFUL LIFE:** Length of time, as determined by the manufacturer, for which a product maintains acceptable safety and performance characteristics. The manufacturer should provide data to support useful life of the material.

**WET PACKS:** Packs are considered wet when there is moisture in the form of dampness, droplets, or puddles of water found on or within a textile pack, instrument, basin set, rigid container or containment device after a completed sterilization cycle and at least one hour after cooling. Wet packs generally are associated with steam sterilization; however, they also can occur with EO sterilization.

**WOVEN TEXTILE:** A reusable fabric constructed from yarns made of natural and/or synthetic fibers or filaments that are woven or knitted together to form a web in a repeated interlocking pattern.

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