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Guidelines for the selection and use of reusable rigid container systems for ethylene oxide sterilization and steam sterilization in health care facilities

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Association for the
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ST33 Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities

(Revision of ANSI/AAMI ST33—1990)

American National Standard

**Guidelines for the selection and use of reusable
rigid sterilization container systems for
ethylene oxide sterilization and steam sterilization
in health care facilities**

Developed by
Association for the Advancement of Medical Instrumentation
Approved 15 July 1996 by
American National Standards Institute, Inc.

Abstract:

This recommended practice covers the selection and use of reusable rigid sterilization container systems as packaging for items to be ethylene oxide sterilized or steam sterilized. Guidelines are provided for cleaning and decontamination, preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic presentation. The recommended practice also includes definitions of terms, a bibliography, and annexes providing supplementary information.

Keywords

Containerized, packaging, sterile storage, sterility assurance

Committee representation

**Association for the Advancement of Medical Instrumentation
Sterilization Standards Committee**

This recommended practice was developed by the Steam Sterilization Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. Committee approval of the recommended practice does not necessarily imply that all committee and working group members voted for its approval.

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies

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Foreword

This recommended practice was developed by the AAMI Steam Sterilization Hospital Practices Working Group under the auspices of the AAMI Sterilization Standards Committee. The guidelines contained in this document are intended to assist health care personnel in the selection and effective use of reusable rigid sterilization container systems.

This is the second edition of *Good Hospital Practice: Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems* (ANSI/AAMI ST33), which is now entitled *Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities*. The first edition was published in 1990. Under AAMI standards- development procedures, all standards and recommended practices must be reviewed and either revised or reaffirmed within 5 years of issue. Consequently, the review and revision of this recommended practice was undertaken in 1994.

The new edition reflects the following changes and additions:

- revisions to address the use of reusable rigid sterilization container systems in steam-flush pressure-pulse steam sterilizers;
- revisions of the recommendations concerning temperature and air exchange rate in storage areas to take into account the current *Guidelines for Design and Construction of Hospital and Health Care Facilities* ([American Institute of Architects, 1996](#));
- a new section entitled *Process Performance* to address quality assessment;
- expanded recommendations concerning prepurchase evaluation to take into account the variety of container systems now in use.

This recommended practice reflects the conscientious efforts of health care professionals, in cooperation with representatives of medical device manufacturers, regulatory agencies, accrediting agencies, and professional organizations, to develop recommendations for the optimum use of container systems. It is not intended for these recommendations to be construed as universally applicable to all circumstances. It is also recognized that, in many cases, these recommendations may not be immediately achievable. Therefore, the document should guide health care personnel toward desirable performance objectives, and all of the document's provisions should be considered and applied using professional judgment and experience.

As used within the context of this document, "shall" indicates requirements strictly to be followed in order to conform to the recommended practice; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; "may" is used to indicate that a course of action is permissible within the limits of

the recommended practice; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

The provisions of this recommended practice should be reviewed by departmental managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate hospital committees (e.g., safety, infection control, hazardous materials).

The concepts incorporated herein should not be considered inflexible or static. The recommendations must be reviewed periodically to assimilate new data and advancements in technology. As noted previously, AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities* (ANSI/AAMI ST33—1996), but it does provide important information about the development and intended use of the document.

Introduction: Need for the recommended practice

Reusable rigid sterilization container systems serve as packaging for items prior to, during, and after sterilization. These systems also can be used to contain and transport contaminated items after use. Container systems are made from a variety of metal, plastic, and composite materials.

Such systems have been used in Europe and other parts of the world for many years. Since the early 1980s, rigid sterilization container systems have been purchased and used by many U.S. health care facilities as an alternative to the traditional woven or nonwoven wrapping materials used as packaging systems for the sterilization of instruments, metal devices, and other supplies. Through the years of use, a great deal of scientific evidence, as well as user clinical evidence, has been developed and published as validation that container systems are an effective sterilization packaging method.

Whenever a new packaging configuration or technology for sterilization is introduced in a health care facility, all procedures associated with its use should be carefully evaluated and adapted to maintain the effectiveness of the total sterilization and sterility maintenance system.

This document discusses the factors that should be considered in the selection and use of reusable rigid sterilization container systems in health care facilities. The provisions should be reviewed by departmental managers and adapted to the needs of their particular institutions. Written policies and procedures should be developed and implemented in consultation with appropriate hospital committees (e.g., safety, infection control, hazardous materials).

Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities

1 Scope

1.1 General

This recommended practice provides guidelines for the selection and use of reusable rigid sterilization container systems in hospitals and other health care facilities. These guidelines are intended to increase assurance of sterility by identifying the special considerations that apply to this packaging method and by providing recommendations on the proper use of the container system.

NOTE—For the purpose of this recommended practice, "health care facilities" means hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices. For convenience, the term "hospital" sometimes is used; in all instances, the term encompasses all other health care facilities.

1.2 Inclusions

This recommended practice specifically addresses

- a) cleaning and decontamination of container systems;
- b) preparation and assembly of container systems with instruments;
- c) loading container systems into the sterilizer and unloading them from the sterilizer;
- d) matching the container system to the appropriate sterilization method and cycle (gravity-displacement steam sterilization, dynamic-air-removal steam sterilization, ethylene oxide [EO] sterilization);
- e) quality assurance;
- f) sterile storage;
- g) transport of container systems within and between health care facilities;
- h) aseptic presentation of container systems;
- i) process performance.

Definitions of terms, a bibliography, and annexes containing supplementary information also are provided in this recommended practice.

1.3 Exclusions

This recommended practice does not cover a) labeling or design criteria for container systems or the quality and performance capabilities of the filters; b) the use of container systems for packaging items other than instrument sets or procedural trays; c) ongoing sterility assurance programs; d) rigid, protective organizing cases that require wrapping prior to sterilization; e) flash sterilization; f) any other method of sterilization not noted in 1.2.

NOTE—For guidelines on steam sterilization, see [AAMI \(1994b\)](#) ANSI/AAMI ST8-1993 and [AAMI \(1996a\)](#) ANSI/AAMI ST37-1996. For guidelines on EO sterilization, see [AAMI \(1992\)](#) ANSI/AAMI ST41-1992. For safety and performance criteria for steam sterilizers and ethylene oxide sterilizers, see [AAMI \(1994b\)](#) ANSI/AAMI ST8-1993 and [AAMI \(1993\)](#) ANSI/AAMI ST24-1992, respectively. For information on the use of a container system with sterilization technologies other than ethylene oxide and saturated steam, consult the container manufacturer.

2 Definitions

For the purposes of this recommended practice, the following definitions apply:

2.1 absorbent towel: All-cotton towel having a plain weave with only the warp yarns tightly twisted.

2.2 aerator, ethylene oxide: Machine designed to speed up the removal of ethylene oxide residuals from sterilized items by subjecting them to warm, circulating air.

2.3 biological indicator (BI): Sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored.

NOTE—Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization. A negative biological indicator does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

2.4 chemical indicator: Sterilization process monitoring device designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber.

NOTE—Chemical indicators are intended to detect potential sterilization failures that can result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a chemical indicator does not prove that the item accompanied by the indicator is sterile.

2.5 container, rigid sterilization: Packaging system designed to contain items for sterilization, storage, transportation, aseptic presentation of contents, and return of contaminated items to the decontamination area.

NOTE—The system generally consists of a bottom or base with carrying handles and a lid that is secured to the base by means of a latching mechanism. A basket or tray to hold instruments or other items to be sterilized is placed inside. A filter or valve system is incorporated into the lid and/or base to provide for air evacuation and sterilant penetration during the sterilization cycle and to act as a barrier to microorganisms during storage.

2.6 contaminated: State of having been actually or potentially in contact with microorganisms.

NOTE—As used in health care, the term generally refers to microorganisms that are capable of producing disease or infection.

2.7 cycle time: Total elapsed time of a sterilization cycle from the time the sterilizer door is closed and the cycle is activated until the time the cycle is completed and the door is opened.

NOTE—Cycle time can include come-up or heat-up time, exposure time, come-down time, and cooling or drying time. For appropriate equipment, cycle time also can include prehumidification time, pre- and post-vacuum time, and aeration time.

2.8 decontamination: According to the Occupational Safety and Health Administration (OSHA), "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal" [29 CFR 1910.1030].

NOTE—The term generally is used in health care facilities with reference to all pathogenic organisms, not just those transmitted by blood.

2.9 density: Mass per unit of volume.

2.10 filter: Device secured to the rigid container lid and/or bottom that serves to allow passage of air and sterilants yet provides a microbial barrier.

NOTE—The filter media may be reusable, disposable, or permanently affixed to the container.

2.11 filter retention system: Mechanism that secures disposable filters in place.

NOTE—The filter retention system may be a retention plate or a retaining ring. It is disengaged to release used filters for disposal and reengaged to secure new filters.

2.12 gasket: Pliable strip that serves as a seal between the lid and the container to prevent entry of microorganisms.

2.13 heat sink: Heat-absorbent material; a mass that readily absorbs heat.

2.14 heat-up time: Time required for the entire load to reach the selected sterilizing temperature after the chamber has reached that temperature.

NOTE—Heat-up time is the same as temperature penetration time.

2.15 huck towel: All-cotton surgical towel with a honeycomb-effect weave.

NOTE—Both warp and fill yarns are tightly twisted.

2.16 labeling: Any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device.

2.17 latching mechanism: Mechanical device that secures the container lid to the container bottom.

2.18 performance qualification: Element of the sterilization validation program consisting of selected engineering and microbiological demonstrations that are performed according to a predefined protocol to show process reproducibility and product acceptability.

2.19 steam quality: Ratio of the weight of dry steam to the weight of dry saturated steam and entrained water.

NOTE—For example, if the quality of steam has been determined to be 95%, the wet-steam mixture delivered from the boiler is composed of 5 parts by weight of water, usually in the form of a fine mist, and 95 parts by weight of dry saturated steam. Likewise, if the quality of the steam has been determined to be 100%, the boiler has delivered no wet steam; 100% of the steam delivered is dry saturated steam.

2.20 sterile storage area: Area of a health care facility designed to store clean and sterile supplies and to protect them from contamination.

2.21 sterile/sterility: State of being free from viable microorganisms.

NOTE—In practice, no such absolute statement regarding the absence of microorganisms can be proven (see **sterilization**).

2.22 sterilization: Validated process used to render a product free of all forms of viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

2.23 sterilizer, ethylene oxide: Sterilizer that utilizes ethylene oxide under defined conditions of gas concentration, temperature, and percent relative humidity.

2.24 sterilizer, steam, dynamic-air-removal type: Type of steam sterilizer in which air is removed from the chamber and the load by means of pressure and vacuum excursions or by means of steam flushes and pressure pulses.

NOTES—

1) *Prevacuum steam sterilizers* depend upon one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperature (132° C–135° C [270° F–275° F]; 141° C–144° C [285° F–291° F]). This type of sterilizer generally provides for shorter exposure times and accelerated drying of fabric loads by pulling an additional vacuum at the end of the sterilizing cycle.

2) *Steam-flush pressure-pulse steam sterilizers* depend upon a repeated sequence consisting of a steam flush and a pressure pulse to remove air from the sterilizing chamber and processed materials using steam at above atmospheric pressure (no vacuum is required). Like a prevacuum sterilizer, a steam-flush pressure-pulse sterilizer rapidly removes air from the sterilizing chamber and wrapped items; however, the system is not susceptible to air leaks, because air removal is achieved with the sterilizing chamber pressure at above atmospheric pressure. Typical operating temperatures are 121° C–123° C (250° F–254° F), 132° C–135° C (270° F–275° F), and 141° C–144° C (285° F–291° F).

2.25 sterilizer, steam, gravity-displacement type: Type of steam sterilizer in which incoming steam displaces

residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber. Typical operating temperatures are 121° C–123° C (250° F–254° F) and 132° C–135° C (270° F–275° F).

2.26 tamper-evident device: Seal or disposable "lock" generally secured on the container-latching mechanism.

NOTE—The device is designed so that it cannot be resealed after opening. It is intended to indicate that the container has not been opened intentionally or accidentally and therefore exposed to potential contamination prior to use.

2.27 terminal sterilization: Process whereby a product is sterilized in its final container and permits the measurement and evaluation of quantifiable microbial lethality.

2.28 treated water: Water that has been processed to reduce impurities.

NOTE—Typical water treatment can employ filtration, deionization, distillation, or reverse osmosis, singly or in combination.

2.29 validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process consistently will yield product complying with predetermined specifications.

NOTE—Validation covers three activities: commissioning, verification of process specification, and performance qualification.

2.30 valve, container: mechanical device that opens during sterilization to allow air evacuation and sterilant penetration and closes after sterilization to prevent contamination.

3 Cleaning and decontamination

3.1 General rationale

Reduction of bioburden is essential for sterilization. The cleaning and decontamination of rigid sterilization container systems is as important as the cleaning and decontamination of the soiled/ contaminated contents.

3.2 Transfer of contaminated items to the decontamination area

If the manufacturer's written instructions permit, closed sterilization container systems (with solid bottoms or with filters in place, if applicable) can be used for containment and transport of contaminated instruments and medical devices to a decontamination area, where cleaning procedures can best be performed. Contaminated items should be handled as little as possible. Gloves should be worn when placing the contaminated items into the container. Care should be taken to avoid touching the outer surfaces of the container with gloved, soiled hands.

Rationale: Some manufacturers instruct users not to use the same container system for transport of contaminated items as for sterilization, so it is important to consult the labeling. Contaminated items harbor microorganisms that can cause infection in susceptible individuals; gloves provide a barrier to direct contact with contaminated items. If the outer surfaces of the container are touched with gloved, soiled hands, then the entire container is considered contaminated.

3.3 Disassembly

3.3.1 Removable filters

When using container systems with removable filters, the filter protectors or holders (retention plates) should be removed or released to disengage the filter media. If disposable, the entire filter should be disposed of according to the policies and procedures of the health care institution. Removable, reusable filters should be disassembled, cleaned, and replaced according to the manufacturer's instructions.

Rationale: Filters, by their nature, can be reservoirs of contamination, especially when the container is used to collect or transport used instruments. A disposable filter might not maintain its barrier effectiveness for more

than one cycle, and reuse could result in improper sterilization or contamination of the container contents.

3.3.2 Valves

If the container system is provided with valve-type closures, the manufacturer's instructions for frequency and method of removal, disassembly, and cleaning should be followed.

Rationale: Improperly maintained valves can interfere with sterilant penetration or allow microbial contamination of container contents.

3.3.3 Interior baskets

The interior basket always should be removed from the container for decontamination. Depending on the type of basket and instrument set, the user might need to remove the instruments from the basket before proceeding with the cleaning and decontamination process. In most cases, the interior basket can be processed with the instruments in the basket according to the institution's usual routine.

Rationale: Separation of the basket from the container allows for effective decontamination. The interior basket functions as a tray, much like the mesh-bottomed pan used in a conventionally wrapped set.

3.3.4 Labeling

Reusable identification labels may be affixed to container systems. Depending on the institution's procedure, the user might need to remove the labeling prior to further processing. If a particular container always is used for the same set of instruments, it could be important to keep the label with the container.

Rationale: Labeling enables the identification of container contents.

3.3.5 Process indicators, disposable labels, and disposable locks

Process indicators, disposable labels, and disposable locks should be removed prior to any cleaning of the container system.

Rationale: The presence of process indicators or fragments of disposable labels or locking mechanisms on the surface of the container system impedes cleaning, decontamination, and the proper functioning of mechanical processing equipment.

3.3.6 Dividers and sorting pins

It might be necessary to dismantle dividers and sorting pins that are part of instrument baskets if the dividers and pins will interfere with the proper cleaning of the basket.

Rationale: If the position of the dividers and pins interferes with adequate cleaning, there might not be adequate penetration of the sterilant to these areas.

3.4 Cleaning methods

Reusable sterilization containers should be cleaned carefully prior to sterilization even if they are to be returned immediately to use. The cleaning method generally used should comply with the institution's procedures prior to acquiring container systems. Container systems can be cleaned by either manual or mechanical means.

3.4.1 Manual cleaning

The container manufacturer's instructions for cleaning and rinsing procedures should be followed, as should accepted practices for decontamination and employee safety. Personnel who clean and decontaminate containers and contaminated contents of containers must wear appropriate personal protective attire for the tasks they are performing.

Rationale: Adequate cleaning is the first step in the decontamination and reuse process. Protective attire is necessary for avoiding infection and for complying with OSHA regulations (29 CFR 1910.1030). See also the

rationale statement for [3.5](#).

3.4.2 Mechanical cleaning

Most container systems can be cleaned and decontaminated in mechanical equipment. The selection of method depends on the container manufacturer's instructions. When positioning the outer container in a mechanical washer, care should be taken to avoid the accumulation and subsequent retention of very hot water.

Rationale: It is important to consult the manufacturer's instructions, because some container systems are not compatible with all mechanical cleaning methods. Very hot water can cause burns; spilled water can cause personnel to slip and fall. See also [3.4.1](#).

3.5 Cleaning agents

The container manufacturer's instructions for choice of detergent should be followed, and the container should be rinsed thoroughly after cleaning.

Rationale: Certain cleaning agents can cause corrosion or deterioration of container surfaces, such as discoloration or stress cracking; for example, detergents that do not have a neutral or near-neutral pH can corrode metal, and specific additives can affect adversely some plastics. Therefore, the manufacturer's instructions should be consulted. Thorough rinsing is essential for removal of the cleaning agents.

3.6 Inspection

Nuts, bolts, screws, rivets, filter retention mechanisms, and permanent filters should be inspected for cleanliness and damage.

Rationale: Hidden surfaces and crevices can make thorough cleaning difficult. Residual organic matter can reduce significantly the efficacy of the decontamination process. Damaged components of containers could interfere with the sterilization process or allow contamination of the contents.

4 Preparation and assembly

4.1 General rationale

This section provides recommendations for the preparation and assembly of instrument sets when sterilization container systems are used as the packaging method. In general, these recommendations are not unique to containerized packaging, because the same basic considerations apply to all packaging methods or systems.

4.2 Inspection of container system

Before each use, the container system should be inspected. The sealing or mating surfaces or edges of the container and lid should be checked to ensure that they are not dented or chipped. Filter retention mechanisms and fasteners such as screws and rivets should be secure and should not be distorted or burred; the securing mechanism should function properly, and the filter media should be examined for integrity. The gaskets should be pliable, securely fastened, and without breaks or cuts. The valves should work freely and should be without breaks, cuts, chips, or dents.

Rationale: To assure the container system's operating efficiency, a thorough and clearly delineated inspection procedure is necessary. All of the container's components (top, bottom, valve or filter mechanisms, securing or latching mechanisms) must function effectively as a unit. It is vital to the maintenance of sterility that these components work together to allow air removal, to facilitate sterilant penetration and removal, and to inhibit microbial migration and contamination.

4.3 Configuration of instrument sets

4.3.1 Weight and density of sets

Regardless of the packaging method used, the weight of any instrument set should be based on whether

personnel can use proper body mechanics in carrying the set, on the design and density of individual instruments comprising the set, and on the distribution of mass (density) in the set and sterilizer load. The mass of instruments should be distributed as uniformly as possible throughout the tray. The user should consult the container manufacturer concerning weight and density of instrument sets; however, it is the user's responsibility to determine that the set can be sterilized and dried effectively. In addition, consideration should be given to load size as it affects drying. In hospitals in which steam quality is less than optimal, load size can adversely affect drying time.

Rationale: There is no magic number for instrument set weight. Preparation and assembly procedures should take into account the number of instruments, the size of the instrument tray, and total set weight and density. By considering the density of the individual instruments, the instrument set, and the sterilizer load, as well as the available steam quality, the user will be able to develop a total program that will yield sterile, dry instrument sets. (See also [annex B](#).)

4.3.2 Instrument placement

As with any other packaging method, the principles of instrument preparation should be followed. Items to be sterilized should be arranged in containers according to the following guidelines:

- a) The basket(s) placed in the container should be large enough to allow the metal mass of instruments and devices to be distributed equally in the basket(s). Woven mesh-bottomed trays or baskets generally are acceptable for use.

NOTE—The use of some nonabsorbent tray liners (e.g., plastic/silicone-fingered organizing mats) can cause condensate to pool. See also [4.3.3](#).

- b) Instruments should be positioned to allow the sterilant to come into contact with all surfaces.
- c) All jointed instruments should be in the open or unlocked position with ratchets not engaged. Racks, pins, stringers, or other specifically designed devices can be used to hold the instruments in the open position.
- d) Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled unless the device manufacturer provides specific instructions, supported by test data, to the contrary.
- e) Instruments should not be held together with rubber bands.
- f) Care should be taken in evaluating the placement of items made of glass, rubber, or, in the case of surgical instruments, dissimilar metals.
- g) For steam sterilization, items with lumens should first be moistened with treated water. For EO sterilization, items with lumens should be dried thoroughly.
- h) Items with concave surfaces and/or broad, flat surfaces that will retain water should be placed on edge so that these surfaces will drain water or condensate.
- i) Heavy instruments should be placed in such a way that they will not damage more delicate items. Lighter instruments should be positioned to protect tips and to prevent damage from changes in position.
- j) Complex instruments (e.g., air-powered instruments, endoscopes, and instruments with lumens or channels) should be prepared and sterilized according to the device manufacturer's written instructions. When combining complex instruments in a set, the user might have to test and evaluate the effectiveness of sterilization and drying.
- k) Small, basket-type accessory containers with covers or lids (e.g., nail or bone screw holders), protective organizing baskets, trays, or cases (e.g., microsurgery instrument cases, air-powered equipment sets, orthopedic instrument organizing sets) should be placed into sterilization containers only if the