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Advancing Safety in Health Technology

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Containment devices for
reusable medical device
sterilization

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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(Revision of ANSI/AAMI ST77:2006)



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Abstract: This standard covers minimum labeling and performance requirements for rigid sterilization container systems and for instrument organizers.

Keywords: containment devices, reusable rigid sterilization containers, instrument organizers.

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf



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Committee representation

Association for the Advancement of Medical Instrumentation Reusable Sterilization Container Working Group

This standard was developed by the AAMI Reusable Sterilization Container Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval. At the time this standard was published, the **AAMI Reusable Sterilization Container Working Group** had the following members:

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Foreword

This standard was developed by the AAMI Reusable Sterilization Container Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to provide minimum labeling, safety, performance, and testing requirements to help ensure a reasonable level of safety and efficacy in rigid sterilization containers and instrument organizers, which are referred to in this standard as containment devices for reusable medical device sterilization.

This standard is the second edition of *Containment devices for reusable medical device sterilization*, which was first published as an American National Standard in 2006 as ANSI/AAMI ST77:2006. In comparison to the first edition, this new edition includes an informative annex on integrating medical devices with rigid sterilization container systems.

Compliance with this standard is voluntary. The existence of the standard does not preclude anyone from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed in order to conform to the standard; “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 standard; 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.

This standard should be considered flexible and dynamic. As technology advances and as new data are brought forward, the standard will be reviewed and, if necessary, revised. Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the American National Standard *Containment devices for reusable medical device sterilization* (ANSI/AAMI ST77:2013), but it does provide important information about the development and intended use of the document.

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Containment devices for reusable medical device sterilization

Introduction

Containment devices for reusable medical device sterilization comprise a number of different types of systems, including reusable rigid sterilization containers and instrument organizers. Containment devices are intended to serve as packaging for instruments and other medical devices before, during, and after sterilization of the instruments and devices. Furthermore, such systems can be designed as an aid to the efficiency of the surgical procedure. Instrument organizers with lid and base serve to secure and organize instrument sets and other medical devices within a sealed reusable rigid sterilization container or within a legally marketed sterilization wrap. Reusable rigid sterilization containers require a barrier system (e.g., filters or valves) to maintain the integrity of the package. Reusable rigid sterilization containers and instrument organizers vary in their design, the mechanics of operation, and the materials of construction.

Although AAMI has published recommended practices (ANSI/AAMI ST79 and ANSI/AAMI ST41¹) that contain guidance for users of reusable rigid sterilization container systems, ANSI/AAMI ST79 and ANSI/AAMI ST41 are not device standards. These recommended practices do outline in a broad format the information that the manufacturer should supply the user to demonstrate that a reusable rigid sterilization container system has been qualified in commonly available hospital cycles. However, they do not establish performance requirements for reusable rigid sterilization container systems or other containment devices such as instrument organizers. Therefore, a design and performance standard for containment devices, ANSI/AAMI ST77, was developed to provide manufacturer requirements. These requirements entail labeling, sterilization effectiveness (e.g., sterilant penetration, air removal), sterilant compatibility, sterility maintenance (barrier properties), compatibility with the intended use (e.g., containment for sterilization of endoscopes, implants, and other devices), maximum size, maximum load, and validation of performance (including accessories) in specific sterilization cycles.

There are two primary categories of containment devices: (a) self-contained reusable rigid sterilization containers that require a barrier system (e.g., filters or valves), and (b) containment devices that require a sterilization wrap or pouch to maintain sterile integrity once the containment device and its contents are sterilized. Containment device and packaging manufacturers bear the ultimate responsibility for validating that their products are compatible with a specified sterilization method. Health care personnel bear the ultimate responsibility for using the containment device or packaging material in the recommended sterilization method and for performing tests to ensure that items to be packaged can be sterilized by the specific sterilizers and sterilization methods used within the health care facility.

1 Scope

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1.1 General

This standard applies to containment devices intended for use in sterilizing reusable medical devices in health care facilities.

NOTE—For purposes of this standard, “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” is sometimes used in this recommended practice; in all instances, this term should be taken to encompass all other health care facilities.

¹ Guidance for the use of reusable rigid sterilization container systems was originally provided in ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities*. The provisions of this document pertaining to sterilization container systems intended for use in steam sterilization were updated and incorporated into ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. The provisions of ANSI/AAMI ST33 pertaining to sterilization container systems intended for use in ethylene oxide sterilization were updated and incorporated into the latest edition of ANSI/AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*.

1.2 Inclusions

This standard covers the design, performance, and labeling criteria for reusable rigid sterilization containers and instrument organizers intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization. Definitions of terms, normative references, and informative annexes are also included, as well as the rationale and relevant test methods for the provisions of the standard.

1.3 Exclusions

This standard does not cover the selection and use of containment devices by health care personnel.

NOTE—Guidelines for the selection and use of reusable rigid sterilization container systems in health care facilities are provided in ANSI/AAMI ST79 and ANSI/AAMI ST41.

This standard does not describe the use (including re-use) of packaging materials and systems to contain a contaminated medical device during transportation of the item to the site of reprocessing or disposal.



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2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. AAMI maintains a register of currently valid AAMI technical documents.

2.1 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Part 1: General requirements*. ANSI/AAMI/ISO 11138-1:2006/(R)2010. Arlington (VA): AAMI, 2010. American National Standard.

2.2 Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Part 1: General requirements*. ANSI/AAMI/ISO 11140-1:2005/(R)2010. Arlington (VA): AAMI, 2010. American National Standard.

2.3 Association for the Advancement of Medical Instrumentation. *Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices*. ANSI/AAMI ST81:2004/(R) 2010. Arlington (VA): AAMI, 2010. American National Standard.

2.4 Association for the Advancement of Medical Instrumentation. *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*. ANSI/AAMI/ISO 10993-1:2009. Arlington (VA): AAMI, 2009. American National Standard.

2.5 Association for the Advancement of Medical Instrumentation. *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals*. ANSI/AAMI/ISO 10993-7:2008/(R)2012. Arlington (VA): AAMI, 2008. American National Standard.

2.6 United States Pharmacopeial Convention. *The United States Pharmacopeia and National Formulary*. (Current edition.) Rockville (MD): United States Pharmacopeial Convention Inc. Sterility tests.

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3 Definitions and abbreviations

For the purpose of this standard, the following definitions apply.

3.1 aseptic presentation: Maintaining the sterility of the contents as a sterilized package is opened and the contents are removed.

3.2 biological indicator (BI): Test system containing viable microorganisms providing a defined resistance to the specified sterilization process. (See ANSI/AAMI/ISO 11138-1.)

NOTE 1—According to FDA, "a biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization." [21 CFR 880.2800(a)(1)]

NOTE 2—Biological indicators are intended to demonstrate whether or not the conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that they were not all exposed to adequate sterilization conditions.

NOTE 3—See ANSI/AAMI/ISO 14161 for information on the selection, use, and interpretation of biological indicators.

3.3 chemical indicator (CI): Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment. (See ANSI/AAMI/ISO 11140-1)

3.4 container, reusable rigid sterilization: Sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

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, handling, and transport.

3.5 containment device: Reusable rigid sterilization container, instrument organizer, and any reusable accessories intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization.

NOTE—Although containment devices are primarily intended to contain reusable medical devices for sterilization, they may also contain nonsterile devices intended for one-time use after sterilization.

3.6 cool-down: Period of time after steam sterilization during which containment devices are allowed to cool on the sterilizer rack outside the sterilizer before handling.

NOTE—The time allowed for cool-down should take into account the sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of containment device and/or wrap used, or the user should be instructed that the load may be released following direct non-contact measurement of its temperature showing that the temperature has reached ambient (room) temperature.

3.7 cycle: Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber.

3.8 cycle, ethylene oxide: Type of gaseous chemical sterilization cycle in which the four process variables are ethylene oxide (EO) gas concentration, exposure time, temperature, and relative humidity.

3.9 cycle, hydrogen peroxide gas with plasma: Type of gaseous chemical sterilization cycle in which the four process variables are hydrogen peroxide concentration, time, temperature, and gas plasma power level.

3.10 cycle, hydrogen peroxide gas without plasma: Type of gaseous chemical sterilization cycle in which the three process variables are hydrogen peroxide concentration, time, and temperature.

3.11 cycle, ozone sterilization: Type of gaseous chemical sterilization cycle in which the four process variables are ozone dose injected, humidity, exposure time, and temperature.

3.12 cycle, steam sterilization, dynamic-air-removal type: One of two types of sterilization cycles in which air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure-pulse [SFPP] cycle).

NOTE 1—In prevacuum steam sterilizers, the dynamic-air-removal cycle depends 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 packaged 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 temperatures (132 °C to 135 °C [270 °F to 275 °F]). This type of cycle generally provides for shorter exposure times and accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle.

Note 2—In steam-flush pressure-pulse steam sterilizers, the dynamic-air-removal cycle depends upon a repeated sequence consisting of a steam flush and a pressure pulse to remove air from the sterilizing chamber and processed materials. As is the case with prevacuum sterilizers, the dynamic-air-removal cycle of a steam-flush pressure-pulse sterilizer rapidly removes air from the sterilizing chamber and wrapped items. Air removal is achieved with the sterilizing chamber pressure at above atmospheric pressure (no vacuum is required to remove air for sterilization). Typical operating temperatures are 132 °C to 135 °C (270 °F to 275 °F).

3.13 cycle, steam sterilization, gravity-displacement type: Type of sterilization cycle in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber.

NOTE—Typical operating temperatures are 121 °C to 123 °C (250 °F to 254 °F) and 132 °C to 135 °C (270 °F to 275 °F).

3.14 D value: Time or dose required to achieve inactivation of 90% of a population of a test microorganism under stated conditions.

3.15 drying time: Time required to dry steam-sterilized items inside the sterilizer.

3.16 exposure time: Period for which the process parameters are maintained within their specified tolerances.

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

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

3.18 filter retention system, container: Mechanism that secures filters in place.

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

3.19 gasket, container: Pliable strip that serves as a seal between the lid and the base of a reusable rigid sterilization container to prevent entry of contaminants.

3.20 immediate-use steam sterilization: Process designed for the cleaning, steam sterilization, and delivery of patient care items for immediate use. Previously known as flash sterilization. See also ANSI/AAMI ST79.

3.21 instructions for use (IFU): Written instructions provided by the device manufacturer to direct users on the care, maintenance, reprocessing, and use of a device.

3.22 insert case or tray: Reusable case or tray that is placed inside a reusable rigid sterilization container, that is fixed or not fixed in place, and that serves to group or protect instruments and components.

3.23 instrument organizer: Reusable metal or plastic containment device, sometimes including a rack or cassette, that organizes and protects instruments and components in specified locations within the device, and that is usually packaged with an approved material.

3.24 latching mechanism, container: Mechanical device that secures the lid of a reusable rigid sterilization container system to the bottom of the container.

3.25 load: Similar items requiring the same sterilization parameters that are sterilized together.

NOTE—The load configuration should ensure adequate air removal, penetration of the sterilant into each containment device, and sterilant evacuation.

3.26 polyolefin: Family of polymers made from olefin monomers and including polypropylene, polyethylene, and polyisoprene.

3.27 reusable accessory: Optional component not essential in itself but that aids in the organization and protection of instruments within a sterilization container system. Such items include, but are not limited to, insert cases, instrument organizers, cassettes, brackets, posts, partitions, instrument mats, racks, and stringers.

3.28 stacked: Sterilization containers placed directly on top of one another, without separation between them.

3.29 steam quality: Steam characteristic reflecting the dryness fraction (weight of dry steam present in a mixture of dry saturated steam and entrained water), the level of noncondensable gas (air or other gas that will not condense

under the conditions of temperature and pressure used during the sterilization process), and the degree of superheat. See also ANSI/AAMI ST79.

3.30 sterile barrier system: Minimum packaging configuration that maintains sterility of the package contents until aseptic presentation at the point of use.

3.31 sterility assurance level (SAL): Probability of a single viable microorganism occurring on an item after sterilization.

NOTE 1—SAL is normally expressed as 10^{-n} .

NOTE 2—An SAL of 10^{-6} means that there is less than or equal to one chance in a million that a single viable microorganism is present on a sterilized item. It is generally accepted that an SAL of 10^{-6} is appropriate for items intended to come into contact with compromised tissue (that is, tissue that has lost the integrity of the natural body barriers).

3.32 sterilizer: Apparatus used to sterilize medical devices, equipment, and supplies by direct exposure to the sterilizing agent.

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

3.34 sterilizer, hydrogen peroxide gas with plasma: Sterilizer that uses a multiphase sterilization process combining exposure to hydrogen peroxide and to gas plasma to effect sterilization.

3.35 sterilizer, hydrogen peroxide gas without plasma: Sterilizer that uses vaporized hydrogen peroxide as the sterilizing agent.

3.36 sterilizer, ozone: Sterilizer that uses ozone as the sterilizing agent.

3.37 sterilizer, steam: Sterilizer that uses saturated steam under pressure as the sterilizing agent.

3.38 tamper-evident closure system: Seal or disposable "lock" that is generally secured on the container latching mechanism and that indicates whether the container has been opened.

NOTE—A tamper-evident 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 before use.

3.39 tray: Basket, with or without a lid, that has perforated sides or bottom, that holds instruments, and that is either enclosed in sterilization wrap or a pouch or placed inside a container for sterilization.

3.40 user verification: Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met.

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

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

3.43 volume-to-vent (V-to-V) ratio: Ratio (V-to-V) of the interior container volume to the surface perforation area.

4 Requirements

4.1 General

The containment device shall permit safe and effective execution of the specific sterilization methods and cycles for which it is designed and recommended. These cycles shall include the sterilization cycles commonly available in health care facilities. Its use shall not cause damage to items contained within or limit the efficacy of the sterilization process in sterilizing those items. The performance of the containment device as it relates to sterilization, drying, sterilant residual removal, and sterility maintenance shall be tested and documented. The containment device shall be appropriately labeled and be accompanied by manufacturer's written instructions for use (IFU).

The manufacturer shall provide summary documentation, upon request of the user, of the methodology and results of the performance testing of the containment system.

4.2 Materials of construction

4.2.1 Durability

The materials used to construct containment devices and, if applicable, reusable accessories recommended for the cleaning and sterilization method shall not deteriorate (crack, flake, peel, fracture, become brittle, or deform) within the manufacturer's recommended useful life at the maximum sterilization conditions recommended by the manufacturer. The manufacturer shall determine if processing in accordance with the provided written IFU can lead to a degree of degradation that will limit the useful life of the containment device; in this case, the manufacturer shall provide a recommended inspection protocol that will enable the user to identify the end of the containment device's ability to fulfill its intended use.

Rationale: Containment devices can be manufactured from a variety of materials, including metal, plastic, and composite materials; those constructed from a mixture of these materials (e.g., metals, plastics, and/or composites) are referred to as "hybrid." These materials should be durable and appropriate for the cleaning and sterilization method recommended because containment devices are intended for multiple uses and multiple reprocessing.

4.2.2 Compatibility with the sterilization process

The materials of construction shall not inhibit or interfere with the sterilization and drying process for which the containment device is recommended.

Rationale: Some materials are not compatible with certain sterilization processes.

4.2.3 Corrosion resistance

Metal materials used to construct containment devices shall either be corrosion resistant or be treated to improve their corrosion resistance.

Rationale: Many metals rust, pit, discolor, or corrode when repeatedly exposed to detergents, sterilizing agents, and condensation, especially at elevated temperatures and in the presence of chemical agents.

4.2.4 Biocompatibility

Following exposure to the recommended sterilization process, materials used to construct containment devices shall not adversely affect the biocompatibility of devices processed within the containment device, as defined by the appropriate standards of the ISO 10993 series and using the worst-case sterilization load configuration within the containment device and the worst-case processing parameters.

Rationale: The materials of construction of containment devices do not contact a patient's body directly. However, these materials could potentially, through migration, flaking, or leaching, indirectly transfer toxic chemicals or particles to devices being sterilized.

4.3 Design

4.3.1 General

The configuration of the containment device shall accommodate the proper arrangement of the medical devices to be processed for inspection, sterilization, sterilant removal, and storage. Containment devices intended to be used with sterile barrier systems shall be designed to be compatible with those systems.

Rationale: The main purposes of a containment device are to organize, permit sterilization of and sterilant removal from, protect, and safely store the instrumentation within. Appropriate arrangement of medical devices provides assurance that they will be exposed to the sterilant.

Another purpose of some containment devices is to maintain the sterility of the contents after sterilization until delivery to and aseptic presentation at the point of use. With respect to containment devices using sterilization wrap, for example, sharp edges or points of puncture, such as feet or corners, can potentially cause a breach of this sterile barrier system.

4.3.2 Decontamination

Containment devices shall allow for decontamination of the containment device itself and its reusable accessories by means of either a manual or automated method. If reusable accessories are intended by the manufacturer to allow for decontamination of specific instrumentation within the accessory, then the accessory shall be validated for this purpose, and appropriate written IFU shall be provided to the user.

Manufacturers of containment devices that are not treated or minimally treated for corrosion resistance should state in their labeling and IFU in detail how to properly clean and decontaminate such devices using a manual or automated method after each use.

Rationale: Decontamination of the containment device and its reusable accessories is essential for sterilization. Most containment devices and reusable accessories are not designed to allow decontamination of their contents *in situ*. However, if the containment device or reusable accessory is intended and labeled for this purpose, validation is essential to ensuring that instrumentation can be adequately decontaminated in this manner.

4.3.3 Perforations

The perforations in the containment device shall permit the sterilant to enter into and be removed from the containment device. The size and number of perforations shall be sufficient to support the sterilization and drying processes for which the containment device is labeled.

Rationale: The size and number of perforations can affect the efficiency of air removal, sterilant penetration and evacuation, and drying in the containment device.

4.3.4 Stacking

4.3.4.1 Internal stacking

Internal stacking refers to two or more layers within a containment device.

If instrument organizers are to be stacked within a containment device, the following factors shall be addressed for each sterilization method for which stacking is recommended:

- a) ease of removal of stacked items within a containment device;
- b) the maximum density of contents within the containment device to allow for proper sterilization and drying;
- c) adequate perforations to allow for sterilant penetration, sterilant evacuation, drying, and, if applicable, aeration;
- d) the stability of the stacked items during transport and handling;
- e) a dry outcome (see 4.4.2.1);
- f) achievement of sterilization throughout the layers of stacked instrument organizers and the recommended accessories (e.g., mats, holders) within the containment device. If any of the accessories are not compatible with a specific sterilization method, the incompatibility should be indicated in the written IFU.

4.3.4.2 External stacking

External stacking refers to rigid sterilization container systems stacked one on top of another during the sterilization process, transportation, or storage.

If rigid sterilization container systems are to be stacked during the sterilization process, the following factors shall be addressed for each sterilization method for which stacking is recommended:

- a) The sterilant can adequately penetrate each of the stacked rigid sterilization container systems and any reusable accessories of the rigid sterilization container systems and achieve sterilization of the enclosed medical devices.
- b) Air should not be trapped within the rigid sterilization container systems during the sterilization process, and condensation should not be present inside or outside of the rigid sterilization container systems after the sterilization process.

NOTE—If air becomes trapped within a rigid sterilization container system, the sterilant cannot reach all areas. This issue might not apply to medical devices sterilized by dry heat, provided that it can be validated that sterilization occurs in areas where air could be trapped.

- c) The stacked devices are stable and will not shift during the sterilization process.
- d) The stacked rigid sterilization container systems can be removed from the sterilizer without compromising the sterile barrier of either the rigid sterilization container systems being removed or the rigid sterilization container system(s) adjacent to the device being removed.

If rigid container systems are intended to be stacked during storage or transport, the stability of the stacked configuration shall be ensured.

4.3.5 Maximum weight

The combined weight of the containment device, the instruments, and any accessories or wrappers shall not exceed 25 pounds when the containment device load is configured according to the manufacturer's written IFU.

Rationale: When containment devices, including their contents and any accessories or wrappers, are too heavy, sterilization and/or drying may be compromised in commonly available hospital sterilization cycles (according to ANSI/AAMI ST79, drying time is typically 20 to 30 minutes; see also AAMI TIR12 and ANSI/AAMI ST58). Additionally, there may be ergonomic issues associated with heavy containment devices. A maximum weight limit of 25 pounds was chosen for several reasons. From an ergonomic standpoint, calculations from the NIOSH equation on manual lifting (Waters et al., 1994) yield recommended weight limits intended to protect workers from injuries due to lifting. This weight limit is similar to other weight standards in other countries.

The limit of 25 pounds was chosen as the recommended maximum weight for containment devices because of the aforementioned sterilization and drying considerations and because containment devices and their contents must be handled extensively and repeatedly by personnel when cleaning and preparing them for sterilization, loading them into the sterilizer, unloading them from the sterilizer, and storing and distributing them. It should be noted that the 25 pound weight limit assumes that the user follows the manufacturer's written IFU with respect to contents and accessories.

4.3.6 Additional requirements for reusable rigid sterilization containers

4.3.6.1 Gaskets

The interface between the lid and base of a reusable rigid sterilization container shall be sealed using a closure gasket. The closure interface formed by the gasket shall provide a microbial barrier. The gasket shall be accessible and cleanable. Signs of wear or damage to the gasket shall be readily detectable. The manufacturer shall specify the useful life of the gasket.

In accordance with 4.5.2(h), the manufacturer shall provide a routine maintenance and inspection schedule to ensure that barrier properties remain intact.

Rationale: The gasket interface should provide a microbial barrier in order to prevent recontamination of the containment device contents once they are sterilized. A routine maintenance and inspection schedule is necessary to ensure that the microbial barrier remains intact. Signs of wear or damage to the gasket should be readily detectable so that the user can ensure that it remains functional as a microbial barrier.

4.3.6.2 Filters

The filters of reusable rigid sterilization containers shall completely cover the sterilization port(s). The means by which the filter is held in place shall provide a tight uniform seal.

Filters shall be protected to prevent tears and potential damage. The filters and filter retention mechanisms shall provide a microbial barrier. Compatibility of the filter with the specified sterilization modality shall be demonstrated.

For reusable filters, the manufacturer shall specify the filter's useful life, which has been documented in reuse testing. In accordance with 4.5.2(h), the manufacturer shall provide a routine maintenance schedule and inspection criteria to ensure that barrier properties remain intact, along with decontamination and handling instructions (e.g., whether it is necessary to remove the reusable filter material from the sealed containment device for cleaning). The manufacturer shall specify in the written IFU the frequency with which the reusable filter should be cleaned (e.g., after each use), the cleaning process, the type of detergent, the compatibility of cleaning agents, and a method of tracking the number of uses.

Rationale: The filters and filter retention mechanisms should provide a microbial barrier in order to prevent recontamination of the containment device contents once they are sterilized.

4.3.6.3 Valves (if applicable)

Valves shall open to allow for sterilization and close properly to provide a microbial barrier to their defined limits of reuse.

Mechanical valves shall be readily cleanable. Signs of wear or damage to valves shall be readily detectable. The manufacturer shall specify the valve's useful life, which has been validated in reuse testing. The manufacturer shall specify the instructions for access for cleaning.

Rationale: Valves should provide a microbial barrier throughout their useful life in order to prevent recontamination of the containment device contents once they are sterilized. Damage to valves should be detectable so that the user can ensure that the valves remain functional as a microbial barrier.

4.3.6.4 Handles

Each reusable rigid sterilization container shall be provided with adequate carrying handles. These handles shall

- a) be positioned to provide and maintain the stability of the containment device under the worst-case center-of-gravity loading conditions recommended by the manufacturer;
- b) be designed to carry a minimum of four times the maximum recommended weight of the fully loaded container system (as specified in 4.3.5) without deforming, cracking, or exhibiting other evidence of damage;
- c) have no sharp edges; and
- d) permit opening of the container and removal of the sterile contents without compromising aseptic presentation of the contents.

Rationale: It is important for the handles of reusable rigid sterilization containers to be designed to allow effective transportation and storage and safe handling by users. The ergonomic design of reusable rigid sterilization container systems helps ensure that users can handle them without injury. The safety factor specified in subparagraph b) is consistent with the requirements of UL 61010A-1 and CSA C22.2 No. 601.1-M90.

4.3.6.5 Lid-base compatibility

Lids and bases of reusable rigid sterilization containers shall be designed so that lids of the same model and size are interchangeable throughout the useful life.

Rationale: It is important for the lids and bases of the same model and size of reusable rigid sterilization containers to be compatible so that mixing of components will not affect the integrity of the containment device and thus compromise sterility maintenance.

4.3.6.6 Latching mechanisms

Latching mechanisms shall secure the lid so that it cannot be displaced when locked and shall draw down the gasket for a secure seal. In addition, latching mechanisms shall

- a) be cleanable and accessible;
- b) be capable of being checked for signs of proper function and for signs of wear or damage;
- c) have no sharp edges;
- d) be capable of holding the seal; and
- e) permit opening of the reusable rigid sterilization container without compromising aseptic presentation of the sterile contents.

Rationale: Latching mechanisms ensure a secure gasket seal as part of the microbial barrier.

4.3.6.7 Tamper-evident system

The tamper-evident closure system shall provide a clear indication that the reusable rigid sterilization container has been opened and the microbial barrier compromised.

If a chemical indicator (CI) is provided, it shall comply with ANSI/AAMI/ISO 11140-1.

NOTE—Tamper-evident closures and sterilization indicators might not be the same device.

Rationale: Tamper-evident closures provide the user with visual verification that the container has not been opened after sterilization until the time of use.

4.4 Performance

4.4.1 Sterilization

4.4.1.1 General Requirements

The containment device shall be specified for use with one or more of the sterilization processes and cycles commonly available in health care facilities, including immediate-use steam sterilization (see AAMI TIR12, ANSI/AAMI ST79, ANSI/AAMI ST41, and ANSI/AAMI ST58). Exposure time and/or drying time may be extended if shown to be necessary in validation studies (see also 4.5.2) and there are compatible FDA-cleared BI(s), CI(s), and packaging material(s).

Specific recommendations shall be made, in the manufacturer's written IFU (see 4.5.2), regarding the type, placement, internal stacking (if applicable), loading of items in the containment device (including instruments to be sterilized and reusable accessories), and, if required, the appropriate cool down period after load removal and when the containment device can be "touched" for each different sterilization process. If weight, size, or other limitations of items affect sterilization efficacy within the containment device, the limitations shall be clearly stated. If the number or orientation of containment devices within the sterilization chamber affect sterilization efficacy, the limitations shall be clearly stated.

NOTE—The burn threshold for 10 minutes of contact time has been quantified at 48 °C (118 °F) (CENELEC 2007).

The manufacturer shall demonstrate that the contents of the containment device can be processed to a sterility assurance level (SAL) of 10^{-6} under the conditions of intended use.

NOTE—The manufacturer may claim equivalence if the item is equally or less challenging than a previously validated item.

Rationale: Containment devices should be validated for sterilization efficacy (sterilant penetration and, if applicable, air removal). All efforts should be made to use sterilization cycles commonly available in health care facilities because

- a) health care facilities generally do not have the ability to independently validate sterilization parameters;
- b) sterilizers in some health care facilities do not allow the operator to change the sterilization parameters;
- c) BIs commercially available to health care facilities are FDA-cleared and designed to monitor commonly available hospital sterilization cycles; and
- d) manufacturers of sterile barrier system material typically test their products in commonly available sterilization cycles; if the manufacturer's written IFU calls for increasing the exposure time or drying time of the cycle, this material could deteriorate and lose its barrier properties.

If not properly designed for their intended use, containment devices could inhibit sterilant penetration and/or air removal and thus prevent adequate sterilization of their contents, especially in the case of instruments with lumens or other complexities of design. +1-877-249-8226 or visit www.aami.org.

4.4.1.2 Reconfiguration and combining of cases and sets

Any reconfiguration or combining of cases needs to be assessed based on existing claims, product family, weight, materials of construction, and load distribution. Where the reconfiguration is equal to or less challenging than the existing claims, verification is recommended before the product can be placed into service. Where the reconfiguration exceeds the existing claims, validation testing is recommended before the reconfigured or combined product is put into service.

4.4.1.3 Documentation

Summary documentation of the test methodology and results shall include information verifying that the sterilization efficacy of the containment device has been validated for each method of sterilization for which the containment device is labeled. At least the following information shall be collected by the manufacturer and made available to the user upon request:

- a) the manufacturers, model numbers, and parameters (e.g., pressures, temperatures, number of pulses, time intervals) of the sterilizers used in testing. In prevacuum steam sterilizers, the dynamic-air-removal cycle depends 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 packaged 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

temperatures (132 °C to 135 °C [270 °F to 275 °F]). This type of cycle generally provides for shorter exposure times and accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle. Since air removal is dependent upon the number and evacuation depth of the pulses, container manufacturers should specify, in detail, the prevacuum cycle conditions under which their products were validated;

- b) if applicable, the types, sizes, and placement of filters or valve assemblies in the containment device;
- c) the weight, density, and distribution of the contents of the containment device (e.g., the separation of the contents into layered baskets or other accessories);
- d) the type, placement, and rationale for the use of any inner wrapping, reusable accessories (e.g., mats, holders), or absorbent materials included in the contents that could affect sterilization and, if applicable, drying or EO aeration;
- e) the types, number, placement sites, and performance characteristics (e.g., D value) of the BIs and, if applicable, CIs used for validation of cycle processing;
- f) the methodology used for retrieving and culturing BIs and the results;
- g) if applicable, the method(s) used to inoculate devices with liquid spore suspensions, the types of devices used for inoculation, and the recovery methods and controls used;
- h) if a sterile barrier system is necessary, the type and size used in the validation;
- i) if applicable, the results of chemical monitoring;
- j) the sterilizer load configuration;
- k) if applicable, load preheating time prior to cycle start (if the load was preheated during testing and if preheating is recommended to diminish the formation of condensate during the sterilization cycle);
- l) if applicable, the methodology used to obtain sterilization process variable profiles of the containment device and its contents during the sterilization cycle (e.g., use and placement of thermocouples inside the containment device);
- m) any other factors that influence the sterilization time required for each type of sterilization cycle for which the containment device is recommended.

4.4.2 Drying (if applicable)

4.4.2.1 ; YbYU Requirements

The design of containment devices intended for use in steam sterilization shall provide for adequate drying of contents in commonly available hospital sterilization cycles. After load removal, a cool down time period, if required, should be determined for the containment device.

Rationale: For a terminal sterilization process, there should be no visible condensed moisture present in or on a containment device following any sterilization process because of the potential for recontamination. Condensed moisture may create a pathway for microorganisms to enter the containment device and recontaminate the instruments inside.

4.4.2.2 Documentation

Summary documentation of the test methodology and results shall include at least the following information:

- a) if applicable, the vacuum rate and depth achieved during the drying phase of the cycle;
- b) the minimum time for the drying phase;
- c) the factors that can influence the drying time of the containment device and its contents, such as the following:
 - the materials of construction of the containment device;
 - the total mass and distribution of the contents of the containment device;
 - the type of wrapping material (material, thickness, and porosity), if applicable;

- the number of containment devices in the load;
 - the temperature of the containment device and the contents at the beginning of each test;
 - the steam quality;
 - the environmental conditions (temperature, relative humidity, air exchange rate) of the cool-down area;
 - the duration of cool-down between the time the containment device was removed from the sterilizer and the time it was opened to determine the dryness of the contents and inner container surfaces;
 - the use of any inner wrapping, absorbent materials, or protective devices (e.g., silicone mats) within the contents;
 - the number and configuration of internally stacked instrument organizers;
 - reliable, repeatable sterilizer performance;
- d) the methodology used to test and validate the conditions necessary to ensure consistent and effective drying of the containment device and its contents.

4.4.3 Sterilant residual removal (if applicable)

4.4.3.1 ; YbYfU' Requirements

Containment devices shall provide for adequate removal of sterilant residuals from sterilized contents after sterilization according to the recommended conditions. Process conditions (time, temperature, and number of air exchanges/hour) for effective aeration of the containment device and its contents shall be determined, documented, and provided in the labeling. The analytical results of all sterilant residual tests conducted on the containment device and its components shall be documented, including post-sterilization residual levels (which are tested along with an unsterilized control sample). Residual levels of EO in medical devices sterilized in the containment device shall comply with ANSI/AAMI/ISO 10993-7.

Rationale: The materials used to construct containment devices can retain or accumulate residuals of the sterilant and/or byproducts or decomposition products of the sterilant. If not adequately removed by aeration, such residuals could be harmful to health care personnel and/or patients. Health care facilities rely on the manufacturer to demonstrate that EO residuals are reduced to a safe level following EO sterilization. It is important that the manufacturer establish during the design qualification stage that the materials of construction do not retain excessive levels of sterilant residuals.

The materials used to construct containment devices can strongly influence the efficiency of, and the time necessary for, the aeration of an EO-sterilized load. It is important to assess such materials after repeated sterilizations because of the possibility of accumulation of sterilant residuals over time and the potential adverse impact on aeration of sterilized medical devices.

4.4.3.2 Documentation

Summary documentation of the test methodology and results shall include at least the following information:

- a) residue levels, after repeated cycles, for components and materials of construction;
- b) aeration time requirements.

4.4.4 Sterility maintenance

4.4.4.1 ; YbYfU' Requirements

The sterile barrier system of the containment device shall maintain sterility until the containment device is opened and the sterile contents are aseptically presented. For that reason, there cannot be any sharp areas on the containment device that can puncture the sterile barrier(s).

Rationale: Sterility maintenance is generally regarded as event-related rather than time-related. Once sterilized and removed from the sterilizer, the contents of a containment device must remain sterile until they are used. Handling, transport, and storage could cause a breach of sterility and render the contents unusable. For reusable rigid sterilization containers, the filters or valves and gaskets provide this assurance. For other containment devices, the sterilization wrap, pack, or pouch provide this assurance.

4.4.4.2 Documentation

Summary documentation of the test methodology and results shall include at least the following information:

- a) the design characteristics of the containment device that limit microbial migration and penetration of contaminants to the contents (e.g., filters or valves, gaskets, sterilization wrap);
- b) the test method employed and the results; and
- c) the sterile barrier system(s) used to demonstrate sterility maintenance.

4.5 Labeling requirements

4.5.1 Device markings

Each containment device shall be labeled with

- a) the name of the manufacturer or distributor; and
- b) the manufacturer's model designation.

NOTE—A means of traceability (the serial number, lot number, or date of manufacture) should be considered.

If they can be separated, all major independent components (e.g., base and lid) shall be so labeled.

4.5.2 Instructions for use (IFU)

The manufacturer's written IFU shall comply with ANSI/AAMI ST81 and shall contain at least the following information:

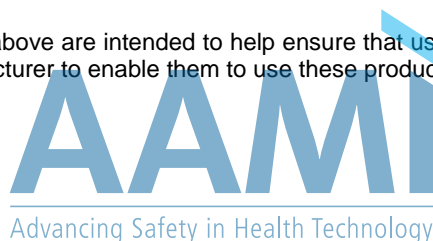
- a) the name and address of the manufacturer;
- b) the manufacturer's model or product family designation;
- c) instructions for the safe and effective use of the containment device, including
 - safety precautions to be taken during routine use;
 - the methods of sterilization (e.g., steam, hydrogen peroxide, ethylene oxide, ozone) and types of cycles, including cycle parameters (e.g., steam; dynamic-air-removal; sterilization time, temperature, and dry time) for which the containment device is designed and recommended; any necessary changes to exposure times or drying times in sterilization cycles commonly used in health care facilities (see AAMI TIR12, ANSI/AAMI ST79, and ANSI/AAMI ST58) shall be clearly and prominently identified;
 - the recommended type (including lumens) and placement of instruments and other medical devices;
 - the recommended cool down time after load removal from the steam sterilizer, if required;
 - the recommended maximum weight and load distribution of the containment device and its contents;
 - the type of filters or wraps that should be used with the containment device;
 - the accessories intended for use in the designated sterilization method or cycle and a list of any accessories found during validation to be incompatible with the associated sterilization method or cycle;
 - if applicable (EO sterilization), the recommended aeration parameters (time, temperature, and number of air exchanges per hour) necessary to reduce sterilant residuals to a safe level;

NOTE—The containment device manufacturer should instruct the user that if the aeration requirements for a device being sterilized inside the containment device exceed the aeration requirements for the containment device, the device manufacturer's aeration recommendations should be followed.

- instructions on whether the rigid sterilization containers can be stacked and, if so, any constraints (e.g., a limitation on the height to which the containment devices may be stacked);
- the most challenging area of the rigid sterilization containers for the placement of internal CIs and BIs for routine monitoring and product testing;
- the reuse limit of reusable rigid sterilization container valves and filters;

- d) instructions for disassembly, cleaning, and reassembly of the containment device, including recommended cleaning agents and cleaning methods;
- e) decontamination methods or chemicals that could be harmful to the containment device;
- f) if applicable, instructions for a method of labeling the containment device;
- g) information on the general categories of medical devices that the manufacturer has tested in the validation of the containment device;
- h) instructions for inspection and routine maintenance, including
 - a schedule for implementing inspection and routine maintenance procedures;
 - a caution that these procedures should be carried out by trained personnel;
 - specific directions concerning the maintenance of critical components; and
 - a recommended inspection protocol that will enable the user to identify the end of the containment device's useful life;
- i) information regarding authorized service companies in the event that the containment device requires service or repair.

Rationale: The requirements listed above are intended to help ensure that users of containment devices will be given sufficient information by the manufacturer to enable them to use these products safely and effectively.



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5 Tests

5.1 General

This section provides test methods and procedures for the critical requirements defined below. The requirements for compatibility with the sterilization process (4.2.2), perforations (4.3.3), and stacking (4.3.4) shall be determined by the test methods specified in 5.6 (Sterilization). Unless otherwise specified below, compliance with all other requirements of Section 4 may be verified by inspection.

NOTE—Other tests may be used if equivalence to the referenced test methods can be demonstrated.

Test apparatus and instruments. Test apparatus and instruments should be calibrated in accordance with the federal Quality System Regulation (21 CFR 820.72). The quality assurance program establishing the frequency and method of calibration should be documented.

5.2 Biocompatibility

The choice of test shall take into account the general principles described in ANSI/AAMI/ISO 10993-1 (e.g., the chemical and physical nature of the material, the toxicological activity of the chemicals forming the final product).

NOTE—Annex B of ANSI/AAMI/ISO 10993-1 provides a bibliography of international standards and guidelines for biological response testing and USP biological reactivity *in vitro* test methods.

5.3 Gaskets and filters

Compliance shall be demonstrated by sterilization validation and sterility maintenance testing. For reusable filters, compliance shall be demonstrated by sterilization validation and sterility maintenance testing at the end of the defined useful life of the filter.

5.4 Valves

Compliance with the requirement that mechanical valves have a defined limit of reuse shall be verified by sterilization efficacy testing and sterility maintenance testing at the end of the defined useful life of the valve.

5.5 Handles

Compliance with the requirements of 4.3.6.4 shall be verified by inspection and by the following test.

A single handle or grip shall be subjected to a force corresponding to four times the maximum design load weight of the containment device. The force shall be applied uniformly over a 70 millimeter (2.75 inch) width at the center of the handle or grip, without clamping. The force shall be increased steadily so that the test value is attained after 10 seconds and maintained for 1 minute.

If more than one handle or grip is fitted, the force shall be distributed between the handles or grips in the same proportion as in normal use. If the containment device is fitted with more than one handle or grip but is designed so that it can be readily carried by only one handle or grip, each handle or grip shall be capable of sustaining the total force.

The handles or grips shall not break loose from the containment device, and there shall be no permanent distortion, cracking, or other evidence of failure.

5.6 Sterilization

Sterilization efficacy tests shall be conducted with all methods and cycle parameters for which the containment device is recommended. These methods and cycle parameters shall be equivalent to those commonly available in health care facilities (see AAMI TIR12, ANSI/AAMI ST79, ANSI/AAMI ST41, and ANSI/AAMI ST58). Exposure time and/or drying time may be extended if shown to be necessary in validation studies (see also 4.5.2), but FDA-cleared BIs, CIs, and accessories may not be available.

Biological testing of containment devices shall demonstrate a sterility assurance level (SAL) of 10^{-6} . Depending on the method of sterilization, testing shall be performed with either half cycles, fractional cycles, or predetermined increments of critical process parameters of the specified sterilization method (e.g., concentration, volume, time). Biological indicators that have been determined to be highly resistant to the sterilization method shall be used (see Table 1).

Table 1—Biological indicators for various sterilization processes

Sterilization process	Biological indicator organism/spore
Steam sterilization	<i>Geobacillus stearothermophilus</i> (formerly called <i>Bacillus stearothermophilus</i>)
Dry heat sterilization	<i>Bacillus atrophaeus</i> (formerly called <i>Bacillus subtilis</i> var. <i>niger</i>)
Ethylene oxide sterilization	<i>Bacillus atrophaeus</i> (formerly called <i>Bacillus subtilis</i> var. <i>niger</i>)
Hydrogen peroxide gas plasma sterilization	<i>Geobacillus stearothermophilus</i> (formerly called <i>Bacillus stearothermophilus</i>)
Hydrogen peroxide vapor phase	<i>Geobacillus stearothermophilus</i> (formerly called <i>Bacillus stearothermophilus</i>)
Ozone sterilization	<i>Geobacillus stearothermophilus</i> (formerly called <i>Bacillus stearothermophilus</i>)

Testing shall be conducted using the types of devices for which the containment device is recommended. Microbiological challenges should be placed in the most difficult-to-sterilize, accessible areas (e.g., lumens, mated surfaces) of the test devices and, if applicable, at the interface of the test devices with packaging accessories. If it is not possible to reach these areas with a BI spore strip or other inoculated carrier (e.g., inoculated thread), then the area may be inoculated with the specified microbiological challenge using a liquid spore suspension.

NOTE—Direct inoculation of a product with a liquid spore suspension can result in variable resistance of the inoculum because of the occlusion of the spores on or in the product, surface phenomena, and/or other environmental factors. Therefore, it is important to validate this practice. See Sections A.7 and C.3 of ANSI/AAMI/ISO 11737-1.

Testing shall include containment devices that represent the worst-case challenge to the sterilization process (in terms of air removal, maximum containment device load, and highest ratio of container volume to surface perforation area).

The maximum weight, density, and distribution of the contents of the containment device (e.g., the use of baskets, mats, layers) shall be determined. If stacking is recommended by the manufacturer, internal and external stacking capability of the containment device shall be determined.

Internal mapping profiles of identified critical parameters inside the containment device, with probes placed in strategic areas, shall be conducted on full cycles unless it can be demonstrated that adequate sterilant penetration is achieved within the containment device for a half-cycle. Areas that may be considered for monitoring are the containment device corners (lid and bottom), on the sides, at the center, and on the inner side of any filter. At a minimum, a probe shall be placed in a lower corner, the diagonally opposite corner, and the center of the containment device. If filters are used in the containment device, a fourth probe shall be placed on the inner side of the filter. For thermal sterilization methods, calibrated temperature sensors shall be used to map the temperature profiles. For sterilization processes that do not have specific mechanical probes, BIs that have been determined to be highly resistant to the process and chemical indicators that have been designed specifically for the process shall be used to map the sterilant penetration inside the containment device. The CIs shall meet the requirements of ANSI/AAMI/ISO 11140-1.

For containment devices that require a filter, testing shall be performed with commercially available filter material that is compatible with the sterilization method and recommended by the containment device manufacturer. Compatible filter material/commercial grades shall be clearly indicated in the product labeling.

For containment devices that require sterilization wrap, testing shall be performed with commercially available sterilization wrap (e.g., high-basis-weight polyolefin). The type of sterilization wrap used shall be identified in the sterility maintenance documentation (4.4.4.2).

For containment devices with valves or filters, the ability of the valve or filter to allow adequate penetration of the sterilant throughout its useful life shall be determined by demonstrating a 12-log reduction and an SAL of 10^{-6} .

5.7 Drying (if applicable)

Compliance with the requirements of 4.4.2 can be verified by visually inspecting the containment device following the drying phase of the recommended sterilization cycle and a cool down time determined, if required. The test methodology shall be documented as required in 4.4.2.2. There shall be no visible condensation or pooling on the external surface of the containment device, and the contents of the containment device shall be free of visible condensation. If wicking material is needed to facilitate drying of containment device contents, the manufacturer shall provide appropriate directions in the IFU. For containment devices that require sterilization wrap, testing shall be performed with commercially available sterilization wrap (e.g., high-basis-weight polyolefin). The type of sterilization wrap used shall be identified in the sterility maintenance documentation (4.4.4.2).

NOTE 1—If condensation is observed within the containment device, gradually increase the drying time in increments until the contents are dry; i.e., no condensation is observed. If it is determined that extended drying time is needed in the sterilization cycle, this information should be included in the written IFU (see 4.5.2).

NOTE 2—Because immediate-use steam sterilization (formerly known as flash sterilization) cycles do not include drying time, some degree of condensation may be present in containment devices FDA-cleared for immediate-use steam sterilization. A validation for maintenance of the sterility of the contents from the sterilizer to the point of use should be performed, as well as any storage time.

5.8 Sterilant residual removal (if applicable)

Testing shall be performed in accordance with ANSI/AAMI/ISO 10993-7 for EO residuals.

The testing shall be performed using maximum load configurations in both the containment device and the sterilizer. The recommended sterile barrier system shall be applied to the containment device prior to exposure to the sterilant. To determine if there is any cumulative effect, the testing shall be conducted after each of 3 sterilization cycles and aeration cycles under the conditions recommended by the manufacturer of the containment device. If a cumulative effect that exceeds the allowable maximums established by ANSI/AAMI/ISO 10993-7 is observed, then changes to the materials or changes to the aeration cycle shall be made and the testing shall be repeated.

5.9 Sterility

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5.9.1 Sterility maintenance

5.9.1.1 General

Compliance with the requirements of 4.4.4 can be verified by performing the sterilization testing of 5.6, exposing the sterile barrier system to the expected stresses of storage, transport, and handling conditions, and then performing either a whole-package microbial challenge test (5.9.1.2) or physical integrity tests (5.9.1.3).

Examples of expected stresses that would be encountered within a health care facility include movement of containment devices into and out of the sterilizer and onto and off shelving or carts. Additional handling stresses and vehicle vibration should be considered if transport outside the health care facility is anticipated.

NOTE—Sterility maintenance testing of wrapped containment devices is intended to ensure that no punctures or tears occur during sterilization and handling as a result of the device design. For containment devices that require wraps to maintain the sterile barrier, the containment device manufacturer should test the containment device for sterility maintenance using wraps that have been FDA-cleared as sterilization wraps.

5.9.1.2 Whole-package microbial challenge test

The containment device in its sterile barrier system shall be placed inside a chamber and then exposed to a defined aerosol of microorganisms. Sterility testing of the contents of the containment device for the recovery of the challenge organism shall be performed in accordance with USP.

5.9.1.3 Physical integrity tests

Physical integrity testing shall consist of the most appropriate test method for the intended sterile barrier system and shall be scientifically sound.

Reusable rigid sterilization containers may be tested in accordance with EN 868-1, Annex G. Filters should be tested separately for any degradation or damage by an appropriate microbial barrier test for porous materials, such as ASTM 1608 or a bacterial filtration efficiency (BFE) test.

For wrapped containment devices, the sterilization wrap(s) shall be visually inspected for any holes or tears. If no holes or tears can be identified, then physical testing of the worst-case areas, such as samples from the edges and corners, shall be conducted. Hydrostatic pressure testing (e.g., AATCC 127) may be an appropriate method for this evaluation.

Annex A (Informative)

Medical device integration with rigid sterilization container systems

This Annex was developed for medical device manufacturers to respond to the increasing requests from users to address the issues related to processing, handling, and validating sterilization for medical devices placed in rigid sterilization containers. Medical device manufacturers need to ensure that their devices are compatible with the recommended packaging methods and provide written instructions for reprocessing.

Questions arise when health care facilities wish to move equipment from a sterilization wrap process to a rigid sterilization container or vice versa. Often manufacturers' written and validated instructions for use (IFU) only detail a singular packaging method, and manufacturers do not know the extent of testing needed to establish validation in a different packaging system. It is often assumed, correctly or not, that all wrapping materials are the same. This is understood to not apply to rigid sterilization containers because they vary in sizes and methodologies for establishing sterilization. Rigid sterilization containers are often produced for specific sterilization modalities. Alternately, rigid sterilization containers may cover a wide variety of sterilization modalities. Rigid sterilization container systems vary in their use. For example, some are for immediate-use steam sterilization (formerly known as flash sterilization) and others are for sterile storage; some have perforations in the lid only and others have perforations in the lid and base; filters used may vary in material type and use, etc. Information in this Annex refers to reusable rigid sterilization containers.

A.1 Introduction

This Annex describes the critical path required to determine if a medical device(s) can be safely integrated into a rigid sterilization container packaging system as an alternative packaging method over previously qualified, medical grade sterilization wrap and processed in various sterilization modalities.

This information has been developed to help qualify the desired medical device(s) for appropriate integration within a rigid sterilization container packaging system. Reviewing the indications for use section, the device manufacturer's claims and labeling for each device should determine whether the new package combination, or device integration, is within the indications for use of each device. These indications include but may not be limited to:

- Sterilization modality and cycle parameters
- Total combined weight (devices, internal trays, and rigid sterilization container system)
- Lumen dimensions (i.e., internal diameter and length) and lumen material
- Complexity of device(s) (e.g., powered instruments, endoscopes, channels, etc.)
- Material compatibility
- Stacking of inner trays, including limitations
- Size of package and proper fit of contents
- Aseptic removal of contents
- Corrosion resistance to the specified sterilization method
- Verification of worst-case scenario for testing

A.2 Critical assessments

Rigid sterilization containers are intended to be used as the primary packaging material. Rigid sterilization container packaging systems were first introduced to North America in the early 1980s. Since that time, new technologies have entered the marketplace in the form of sterilization modalities and complexity of medical devices. Some of these technological evolutions present lethality and sterility maintenance challenges that were not considered earlier. Determining device, material, and modality compatibility has now become a necessary assessment. For these reasons, caution is required when attempting to integrate new devices and materials within any particular rigid sterilization container packaging system, considering these have their own unique device performance characteristics. The rigid container manufacturer's written IFU describes how the container can be used.

The following critical assessment tool was developed to assess whether the device intended or considered for integration in a rigid sterilization container packaging system falls within the rigid sterilization container indications for use and the requirements identified in this standard.

Table A.1 – Critical Assessment Comparison Tool

Medical Device(s)	Rigid Container Packaging System
Material(s) of the device	Material(s) of the container Material compatibility
Lumens: Diameter, length, and material	Validation for lumens: Diameter, length, and material
Complexity of the device*	Testing for complex devices and multiple layers
Total weight	Total weight including devices
Sterilization method(s)	Sterilization method(s)
Cleaning guidelines	Cleaning guidelines
Can device be disassembled	Can container be disassembled
Corrosion resistance to avoid galvanic reactions	Corrosion resistance to avoid galvanic reactions
Passive layer	Passive layer
	Dimensional fit
	Aseptic removal
	Stability of contents
	Stacking
	Worst-case Volume to Vent (V-to-V) ratio validated

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*This must state the configuration of the device including the use of the exterior instrument organizer and lid used, and any orientation requirements in the validation plan. For a complete copy of this AAMI document, contact AAMI at 1-877-249-8226 or visit www.aami.org.

NOTE—The V-to-V ratio may be one of the metrics used in defining a worst-case challenge for a family of containment devices. This ratio is defined as the interior volume of the sterilization container divided by the total cross-section area of the perforated vent holes. V-to-V ratio influence to the container system is influenced by the sterilization methodology. For example, a dynamic air removal system will have lesser V-to-V ratio concerns compared to a gravity displacement system. When the V-to-V ratio is critical to the container system under consideration, a higher V-to-V ratio presents a more difficult challenge to achieve the desired lethality performance and should be assessed.

For example, for a particular container volume, an increase in the cross-section area of the perforations allows easier ingress and egress of the sterilant during the processing cycle. Conversely, for a given perforation ratio—as interior volume is increased, it is more difficult to fill and empty this volume through the same vent area. The worst-case V-to-V ratio does not necessarily coincide with the largest container by volume or footprint. A full-size container with two arrays of perforations may have a lower V-to-V ratio (i.e., easier to empty and fill the internal volume) than a mid- or three-quarter size container with only one array of perforated holes. Similarly, a full-size container with a solid bottom will have a higher V-to-V ratio than the same full-size container with a perforated bottom, resulting in a more difficult challenge to achieve the desired lethality performance.

Examples of groups for critical assessments:

Surface sterilization only:

- Stainless steel instruments
- Mixed loads

Sterilization of lumened devices:

- Rigid
- Flexible
- Lumen claims

Sterilization of power equipment

Sterilization of devices in trays:

- One layer
- Multiple layers

Material types:

- Aluminum
- Stainless steel
- Titanium
- Polymeric
- Hybrid (metal and plastic)
- Other



A.3 Validation plan

When initiating a validation for integrating medical devices into an existing rigid sterilization container packaging system, conditions of the critical assessment are used to determine a test plan. The test plan should incorporate the worst-case conditions of the devices planned for integration using the critical assessment criteria. Appropriate biological organism challenge is used in the defined plan worst-case location(s). The plan should include:

- Medical devices used
- Biological organism challenge used
- Location and type of the biological challenge (liquid suspension, spore strips, etc.)
- Assessment of why these locations were selected
- Appropriate additional challenges in areas throughout the integrated combination to demonstrate homogeneity of interior exposure
- Cycles and sterilization modality used
- Sterility assessment method used (half cycle, fraction negative, etc.)
- Monitoring BI and CI used

A.4 FDA clearance considerations

It is the responsibility of the medical device manufacturer to provide validation for the sterilization of their devices. If a rigid sterilization container system is used for the validation, it should fall within the cleared indications for the specific manufacturer's rigid sterilization container.

Any parameter that extends beyond the acceptable criteria for sterilization, such as extended reprocessing time or a new medical device not previously cleared, should be identified and may require additional 510(k) submissions. If a formal validation project is required (e.g., when the device and package modality—in this instance rigid sterilization container—do not fall within the rigid sterilization container indications for use), the medical device manufacturer should conduct the appropriate validation testing.

NOTE—Validation testing should be done in accordance with applicable standards (i.e., AAMI, AORN, ASTM, etc.).

If the medical device, insert tray, and rigid sterilization container meet the labeling and current claims, a verification of the device utilizing BIs may be conducted at health care facilities per the current standard.

A.5 Change control

Manufacturers' device master records are required to maintain integrity of the device throughout the life of that device, and are used to record any changes to the device that are significant enough in nature to affect the cleared indications for use.

Examples of significant device design changes might include, but are not limited to:

- Additional devices to the original validated integrated set contents
- Increased complexity of a device that has not been tested in the original validated integrated set contents
- Devices with lumens that have a smaller inner diameter or are longer than the cleared lumen dimensions
- Increase in weight from the original validated integrated set
- Inclusion of new materials
- Addition of new intended modality that has not previously been validated
- Design changes to the device(s)
- Changes in the V-to-V
- Changes in the validated filter media
- Number and dimensions/material of lumens



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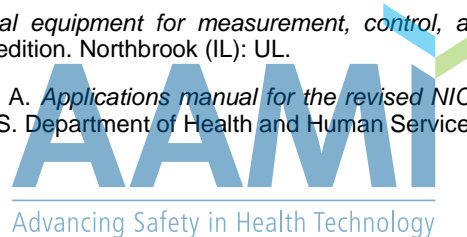
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