American National Standard

ANSI/AAMI ST37:1993

Flash sterilization—Steam sterilization of patient care items for immediate use

AAMI Association for the Advancement of Medical Instrumentation

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST37:1993 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.
Single user license only. Copying, networking, and distribution prohibited.

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Rd., Suite 220
Arlington, VA 22201-4795

© 2000 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Copyright and Permissions

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of these documents without the prior written permission of the Association for the Advancement of Medical Instrumentation or the copyright holder (if not AAMI) is prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq*.) to make copies of all or any part of these documents (whether internally or externally) without the prior written permission of the copyright holder. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of these documents, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Violators of this copyright policy should be reported to AAMI's legal counsel:

McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, DC 20006
Attn: Jacqueline A. Henson, Esq.
Phone: (202) 496-7500

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST37:1996 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.
Single user license only. Copying, networking, and distribution prohibited.

ST37 Flash sterilization: Steam sterilization of patient care items for immediate use

American National Standard

ANSI/AAMI ST37—1996 (Revision of ANSI/AAMI ST37—1992)

Flash sterilization: Steam sterilization of patient care items for immediate use

Developed by
Association for the Advancement of Medical Instrumentation
Approved 12 January 1996 by
American National Standards Institute, Inc.

Abstract:

This recommended practice covers flash sterilization in health care facilities. Guidelines are provided for: the functional and physical design of areas in health care facilities where flash sterilization is carried out; staff qualifications, education, and other personnel considerations; sterilization processing procedures; the use and maintenance of *sterilizer*s designed for flash sterilization; and quality control. The recommended practice also includes definitions of terms and a bibliography.

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.

The **AAMI Sterilization Standards Committee** has the following members:

Cochairpersons:
Carl W. Bruch, PhD
Virginia C. Chamberlain, PhD

Members:
Carl W. Bruch, PhD, Consultant, Hudson, WI
Virginia C. Chamberlain, PhD, Consultant, Bethesda, MD*
Neal E. Danielson, D's Enterprise, Wichita, KS**
Judith Dowler, Medical Devices Bureau, Health Canada, Ottawa, ON
Frank B. Engley, Jr., PhD, University of Missouri, Columbia, MO
Collette P. Keyser, RN, Colonel, U.S. Army (Retired), Alexandria, VA
Robert Morrissey, PhD, Johnson & Johnson
Barry F. J. Page, Consultant, Garner, NC
Marimargaret Reichert, RN, Reichert Consulting, Olmsted Falls, OH
Janet K. Schultz, RN, AMSCO International
James Whitbourne, Sterilization Technical Services

© *2000 Association for the Advancement of Medical Instrumentation*

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST37:1996 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.

James L. Whitby, MA, MB, FRCP, University of Western Ontario, London, ON

The **Steam sterilization Hospital Practices Working Group** has the following members:

Cochairpersons:
Barbara J. Goodman, RN
Charles O. Hancock

Members:
Zoe Z. Aler, RN, American Society for Healthcare Central Service Personnel
Thomas A. Augurt, PhD, Propper Manufacturing Company
Diane Brown, Baylor University Medical Center, Dallas, TX
Ross A. Caputo, PhD, Abtox
Anne Cofiell, International Association of Healthcare Central Service Materiel Management
Neal E. Danielson, D's Enterprise, Wichita, KS**
Gerald B. Goethals, RN, Colonel, U.S. Army (Retired), VA Medical Center, Houston, TX
Barbara J. Goodman, RN, James Lawrence Kernan Hospital, Baltimore, MD
Charles O. Hancock, MDT Corporation
Paul A. Honan, Getinge International
Collette P. Keyser, RN, Colonel, U.S.Army (Retired), Alexandria, VA
Carol Kiep, RN, Consultant, Fort Wayne, IN
Charles D. Paige, U.S. Department of Veterans Affairs
Marimargaret Reichert, RN, Reichert Consulting, Olmsted Falls, OH
Richard J. Rosen, Sisters of Providence Health System, Seattle, WA
Peggy Ryan, RN, Ryan Associates, Boulder, CO
Janet K. Schultz, RN, AMSCO International
Retta C. Sengstock, RN, Medical Sterilization
Mark Seybold, Baxter Healthcare Corporation
Linda A. Slone, RN, Sibley Memorial Hospital, Gaithersburg, MD
Frank W. Stout, DDS, University of Florida College of Dentistry, Gainesville, FL
Betty Strickland, Memorial Hospital System, Stafford, TX
Susan Thomaschefsky, Kimberly-Clark Corporation
Timothy Ulatowski, Center for Devices and Radiological Health, Food and Drug Administration
Julie Thompson, RN, Association of Operating Room Nurses
James Whitbourne, Sterilization Technical Services
Kathleen E. Wolf, RN, Cottrell, Ltd.

Alternates:
Ruth Anne Brooks, International Association of Healthcare Central Service Material Management
Sandra A. Lee, RN, AMSCO International
Jack Scoville, Cottrell, Ltd.
James Weber, Kimberly-Clark Corporation

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.

© *2000 Association for the Advancement of Medical Instrumentation*

Documents
Document Sharing Hub
Full document details: ANSI/AAMI ST37:1996 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.
Single user licence only. Copying, networking and distribution prohibited.

Acknowledgment

The Steam sterilization Hospital Practices Working Group gratefully acknowledges the contributions of Ann E. J. Kobs, MS, RN, Joint Commission on Accreditation of Healthcare Organizations, and of former Working Group member, Lillian H. Nicolette, RN, Association of Operating Room Nurses.

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: assuring the *sterility* of devices and materials processed by "flash" steam sterilization; maintaining the *sterility* of processed items until the point of use; and promoting good infection control and safe handling practices.

This is the third edition of *Flash sterilization: Steam sterilization of patient care items for immediate use,* which was first published in June 1986 as *Good Hospital Practice: Steam sterilization using the unwrapped method (flash sterilization)* (AAMI SSUM–9/85). The second edition (ANSI/ AAMI ST37–1992) was published in March 1992 as *Good Hospital Practice: Flash sterilization¾steam sterilization of patient care items for immediate use.* Under AAMI standards-development procedures, the second edition would not have been due for reaffirmation or revision until 1997. In recent years, however, the practice of steam sterilization of unwrapped items ("flash" sterilization) has come under increased scrutiny, and in late 1993, numerous reports and inquiries indicated that many in the health care community desired clarification of AAMI's recommendations regarding flash sterilization. Therefore, the preparation of a revised edition was undertaken in June 1994.

Unlike previous editions, this edition does not attempt to define the circumstances under which flash sterilization is appropriate. Instead, the recommended practice focuses on what is needed to ensure that flash sterilization is safe and effective: work practices for the complete process of sterilization, the physical layout of the facility, and procedures to ensure aseptic transfer of sterilized items to the sterile field. The document also incorporates additional text, taking into account a new technology, steam-flush pressure- pulse steam sterilization, and it addresses continuous quality improvement in a new section entitled "Process performance." Finally, the recommendations concerning temperature and humidity in processing areas have been updated to reflect current guidelines.

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 optimum performance in the processing of medical devices to be steam sterilized by the flash method. It is not intended that these recommendations be construed as universally applicable to all circumstances. It is also recognized that, in many cases, these recommendations might not be immediately achievable. Therefore, the document should be utilized to guide health care personnel towards 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 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.

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

© *2000 Association for the Advancement of Medical Instrumentation*

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST37:1996 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.
Single user license only. Copying, networking and distribution prohibited.

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 are reviewed periodically to assimilate new data and advancements in technology. 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, *Flash sterilization: Steam sterilization of patient care items for immediate use* (ANSI/AAMI ST37—1996), but it does provide important information about the development and intended use of the document.

Introduction: Need for the recommended practice

The delivery of sterile products for use in patient care depends not only on the efficacy of the sterilization process itself, but also on efficient facility design, infection prevention practices, effective quality control, and other aspects of device processing prior to, during, and after sterilization.

A flash sterilization cycle is one that has been designed to meet the following criteria:

a) The cycle is preprogrammed to a specific time/temperature setting established by the manufacturer based on the type of sterilizer control (i.e., gravity-displacement, prevacuum, or steam- flush pressure-pulse) and selected by the user based on the configuration of the load (i.e., the presence or absence of porous materials). For other types of hospital steam sterilization cycles, it is assumed that porous materials (e.g., packaging) will be present in the load.

b) The items to be processed are usually unwrapped, although a single wrapper may be used in certain circumstances if the sterilizer manufacturer's instructions permit. Some rigid, reusable sterilization container systems have been designed and validated by the container manufacturer for use with flash cycles.

c) Since drying time is not usually part of a preprogrammed flash cycle, the items processed are assumed to be wet at the conclusion of the cycle.

d) The processed item(s) must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use, usually the sterile field in an ongoing surgical procedure. Regardless of whether or not the items are wrapped, there is NO storage or shelf life of flash-sterilized items because of the probability of contamination after the sterilizer door is opened and the items are removed.

It is essential for health care personnel to properly carry out the complete multistep process (including *decontamination* and preparation) when flash sterilization is used, just as is the case for items to be processed using wrapped-goods sterilization cycles. In any method of sterilization, it is important to adhere to good processing practices. This is particularly important in flash sterilization because of the difficulties associated with the aseptic delivery of devices sterilized by this method to the point of use. When performed correctly, flash sterilization is safe and effective for the sterilization of medical devices intended for use in contact with compromised tissue or the vascular system, as might occur during surgery or obstetrical delivery. The exposure times used in flash sterilization cycles are capable of producing appropriate lethality, as compared to the exposure times used to sterilize wrapped items.

Several concerns stimulated the development of this recommended practice. First, the committee was aware of inadequate cleaning and *decontamination* practices in flash sterilization. Reduction of bioburden and removal of gross soil are essential steps in preparing an item for sterilization by any method. Decontamination procedures are also designed to protect the worker.

Second, documentation of the flash sterilization process is necessary and should be consistent with the

© *2000 Association for the Advancement of Medical Instrumentation*

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST37:1996 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.

requirements applicable to and the practices used in documenting the routine processing of wrapped loads.

Third, flash-sterilized items should be transported to the point of use in such a way that the potential for contamination is minimized. In deciding on techniques for a particular situation, consideration should be given to the possible ways in which the items could become contaminated and to the safety of workers handling the hot and possibly heavy trays. Contamination is an event-related process, with the probability of an event that could result in contamination increasing over time. When opened to the air, all sterile items will eventually become contaminated unless opened and kept within a true HEPA-filtered, laminar- air-flow unit. Thus, any item that is opened and left on the back table of a surgical setup can become contaminated by particles settling on it. The longer an item is open, the greater the number of particles, with their accompanying microbiological flora.

The risk of contamination of flash-sterilized items increases if they are transported through areas where personnel are scrubbing or washing their hands, creating splashing or aerosolization. Transport through areas where air flow is not filtered to the degree present in the operating room can also increase the rate of contamination. Practitioners should examine their own situations and develop practices to minimize contamination. Some methods are: placing flash sterilizers as close to the intended point of use as can be reasonably accomplished; using rigid, reusable sterilization container systems that have been specifically validated and labeled for use in flash sterilization; using the single-wrapper technique in appropriate cycles; aseptically placing a sterile covering over the sterilized item as it is removed from the sterilizer.

Finally, flash sterilization of instrumentation should be considered only if all of the following conditions are met:

a) Work practices ensure proper cleaning and decontamination, inspection, and arrangement of instruments into the recommended sterilizing trays or containers prior to sterilization.

b) The physical layout of the department or work area ensures direct delivery of sterilized items to the point of use (e.g., the sterilizer opens into the procedure area).

c) Procedures are developed, followed, and audited to assure aseptic handling and personnel safety during transfer of the sterilized items from the sterilizer to the using area.

Implantables should not be flash-sterilized (CDC, 1985). The possible consequences to the patient from even a minimally contaminated device placed in an essentially avascular environment and left there at the conclusion of the procedure are potentially severe. Although the risk of an unrecognized sterilization failure can be minimized if the physical parameters of time, temperature, and pressure are monitored, recorded, and examined for each cycle, it is recommended that health care personnel quarantine implantable devices and await the outcome of biological monitoring of the cycle before releasing these items for use. However, because flash-sterilized items are intended for immediate use, they cannot be held or stored pending the results of biological monitoring. Careful planning, appropriate packaging (e.g., packaging that allows the user to see the device for sizing and verification of features), and inventory management in cooperation with suppliers can eliminate the need to flash sterilize implantable items. This is a goal that all institutions should strive to achieve.

Health care facilities differ in their physical design, the type and quantity of equipment, and the training level of personnel involved in sterilization processing. This recommended practice sets forth guidelines for facility design and work practices to assist health care personnel in the development of procedures to achieve and maintain the *sterility* of devices that are flash-sterilized. Many of the recommendations provided here apply to all steam sterilization processes, not just flash sterilization. For the convenience of the reader, these recommendations cover the entire process in a logical sequence, from considerations of facility design to quality control.

The provisions of this recommended practice should be reviewed by departmental managers and adapted to the

© *2000 Association for the Advancement of Medical Instrumentation*

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST37:1996 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.

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). These policies and procedures should be followed consistently wherever flash sterilization is performed in the health care facility.

Flash sterilization: Steam sterilization of patient care items for immediate use

1 Scope

1.1 General

This recommended practice provides guidelines for flash sterilization in hospitals and other health care facilities. These recommendations are intended to increase assurance of sterility and to assist health care personnel in the proper use of processing equipment.

NOTES—

1) 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" is sometimes used; in all instances, the term encompasses all other health care facilities.

2) Flash sterilization can be performed in various areas of the health care facility, including the operating room, labor/delivery room, emergency/trauma room, and other areas where steam sterilizers are located. The term "department," as used here, refers to the administrative unit responsible for the area in which the sterilizer is located.

1.2 Inclusions

This recommended practice specifically addresses

a) functional and physical design criteria for areas of health care facilities where flash sterilization is carried out;

b) staff qualifications, education, and other personnel considerations;

c) sterilization processing procedures;

d) the use and maintenance of sterilizers used for flash sterilization;

e) quality control;

f) process performance.

Definitions of terms and a bibliography are also provided in this recommended practice.

1.3 Exclusions

Specific construction and performance criteria for steam sterilizers are *not* covered by this recommended practice, nor are guidelines for steam sterilization of wrapped items.

NOTE—For safety and performance criteria for steam sterilizers, see AAMI (1994b). For guidelines on steam sterilization of wrapped items, see AAMI (1994a).

2 Definitions

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

2.1 asepsis: prevention of contact with microorganisms.

© *2000 Association for the Advancement of Medical Instrumentation*

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST37:1996 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.

2.2 bacterial count: method of estimating the number of bacteria per unit sample.

NOTE—The term also refers to the estimated number of bacteria per unit sample, usually expressed as number of colony-forming units (CFUs).

2.3 bioburden: number and types of viable microorganisms with which an item is contaminated; also known as *bioload* or *microbial load*.

2.4 biological indicator: 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 or not 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.

2.5 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 could 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.

2.6 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 could be capable of producing disease or infection.

2.7 control, positive: biological indicator, from the same lot as a test biological indicator, which is left unexposed to the sterilization cycle and then incubated to verify the viability of the test biological indicator.

2.8 culture: growth of microorganisms in or on a nutrient medium; to grow microorganisms in or on such a medium.

2.9 culture medium: substance or preparation used to grow and cultivate microorganisms.

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

2.11 exposure time: period of time during a sterilization process in which items are exposed to the sterilant at the specified sterilization parameters.

NOTE—In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

2.12 flash sterilization: process designed for the steam sterilization of patient care items for immediate use.

NOTE—See also "Introduction: Need for the recommended practice."

2.13 implantable device: according to the Food and Drug Administration (FDA), "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more" [21 CFR 812.3(d)].

© *2000 Association for the Advancement of Medical Instrumentation*

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST37:1996 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.

2.14 incubator: apparatus for maintaining a constant and suitable temperature for the growth and cultivation of microorganisms.

2.15 infectious microorganisms: microorganisms capable of producing disease in appropriate hosts.

2.16 microorganisms: animals or plants of microscopic size.

NOTE—As used in health care, the term generally refers to bacteria, fungi, viruses, and bacterial spores.

2.17 steam sterilization: sterilization process that utilizes saturated steam under pressure, for a specified exposure time and at a specified temperature, as the sterilizing agent.

2.18 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**).

2.19 sterility assurance level (SAL): probability of a viable microorganism being present on a product unit after sterilization.

NOTES—

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

2) A 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 a sterility assurance level of 10^{-6} is appropriate for items intended to come into contact with compromises tissue (that is, tissue has lost the integrity of the natural body barriers). The sterilizer manufacturer is responsible for ensuring that the sterilizer is capable of achieving the desired SAL. The user is responsible for monitoring the performance of the sterilizer to ensure that it is operating in conformance to the manufacturer's recommendations.

2.20 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 reduced to a very low number, it can never be reduced to zero.

2.21 sterilization area: area of a health care facility designed to house sterilization equipment, usually steam or ethylene oxide sterilizers, or both.

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

2.23 sterilizer, 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.

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).

2.24 sterilizer, prevacuum type: type of steam sterilizer that depends upon one or more pressure and vacuum excursions at the beginning of the cycle to remove air.

NOTE—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 to 135° C [270° F to 275° F]; 141° C to 144° C [285° F to 291° F]). This type of sterilizer generally provides for shorter exposure time and accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle.

© *2000 Association for the Advancement of Medical Instrumentation*

Documents
Document Sharing Hub

Full document details: ANSI/AAMI ST37:1996 Flash sterilization-Steam sterilization of patient care items for immediate use, 3ed.