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Rigid Containers for Immediate Use Steam Sterilization

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Rigid Containers for Immediate Use Steam Sterilization

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RIGID CONTAINERS FOR IMMEDIATE USE STEAM STERILIZATION

(A Continuing Education Self-Study Activity)

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RIGID CONTAINERS FOR IMMEDIATE USE STEAM STERILIZATION

OVERVIEW

Infection prevention has become a primary goal for the perioperative nurse and an area of greater scrutiny today, as healthcare professionals are continually challenged by new pathogens and multi-drug resistant organisms, as well as the increased economic pressures to reduce healthcare-associated infections. One key measure in reducing the risk for surgical site infections is to provide surgical instruments and devices that are sterile at the time of use. Under certain clinical conditions, instruments may be subjected to an immediate use sterilization process utilizing rigid containers. While this is common practice in many operating rooms today, the when, where, and how of this process are often misunderstood. This continuing education activity will provide an overview of the clinical considerations related to immediate use sterilization using rigid containers. It will provide a brief overview of both the clinical and economic impact of surgical site infections today. The current guidelines and professional recommendations that outline the indications for immediate use sterilization and the use of rigid containers will be reviewed. Considerations for the proper use and care of rigid container systems for immediate use sterilization will be discussed.

OBJECTIVES

After completing this continuing nursing education activity, the participant should be able to:

1. Discuss the clinical and economic impact of surgical site infections.
2. Define immediate use sterilization.
3. Identify the organizations involved in guidelines for Immediate Use Sterilization.
4. Describe the proper use of rigid container systems for immediate use sterilization cycles.
5. Explain the trends in terminology change from flash to immediate use sterilization.

INTENDED AUDIENCE

This continuing education activity is intended for perioperative registered nurses who are interested in learning more about the clinical considerations regarding the use of rigid containers with immediate use sterilization of surgical instrumentation.

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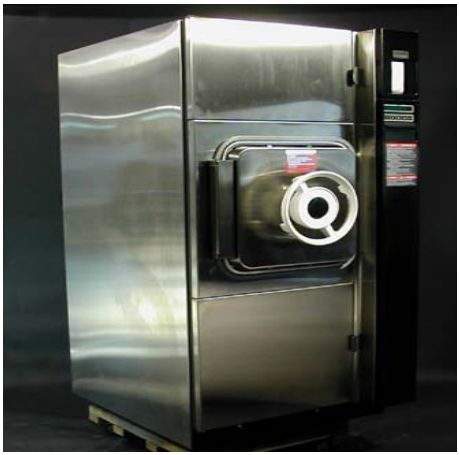
INTRODUCTION

Infection prevention is a primary goal for all patients undergoing surgery: one of the expected outcomes for surgical intervention is that the patient is free from signs and symptoms of infection.[1] Therefore, a major responsibility of the perioperative nurse is to minimize the patient's risk for the development of a surgical site infection (SSI).[2] The creation and maintenance of a sterile environment has a direct influence on patient outcomes; one key component in providing an aseptic environment is the provision of surgical instruments that are free of contamination at the time of use. This is accomplished by subjecting the instruments to cleaning and decontamination, followed by a sterilization process. Sterilization provides the highest level of assurance that surgical instruments are free of viable microbes.

The use of immediate use sterilization is one method used in most operating rooms (ORs) today to sterilize surgical instruments. It is commonly used at many facilities as a means of quickly turning around needed equipment under certain circumstances; however, the term immediate use sterilization is also often misunderstood. In addition, the evolution of rigid containers for use in immediate use sterilization cycles offers perioperative personnel with new options for proper immediate use sterilization techniques. When performed correctly, immediate use sterilization is safe and effective for sterilizing medical devices.[3] Therefore, the effective use of immediate use sterilization requires knowledge of where, when, and how in order to provide safe patient care.



SURGICAL SITE INFECTIONS: THE DANGER IS REAL

In order to appreciate the implications associated with immediate use sterilization in today's challenging surgical practice environment, the perioperative nurse must remain aware of both the clinical and economic impact of healthcare- associated infections (HAIs), specifically surgical site infections, on both patients and healthcare facilities. Healthcare-associated infections are infections that patients acquire during the course of receiving treatment for other conditions within a healthcare setting; they are one of the top ten leading causes of death in the United States.[4] A new report from the Centers for Disease Control and Prevention (CDC)

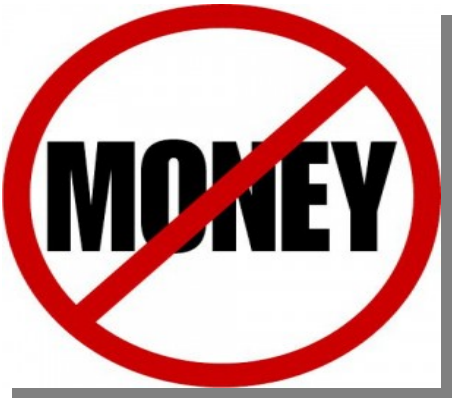
updates previous estimates of healthcare-associated infections. In American hospitals alone, healthcare-associated infections account for an estimated 1.7 million infections and 99,000 subsequent deaths each year; of these HAIs:[5]

- 32 % are urinary tract infections;
- 22 % are surgical site infections;
- 15 % are pneumonia; and
- 14 % are bloodstream infections.

The CDC's National Nosocomial Infections Surveillance (NNIS) system has defined surgical site infections as those associated with surgical procedures that occur at or near the surgical incision within 30 days of an operative procedure, or within one year if an implant is left in place.[6] SSIs are common complications of surgery, occurring in 2% to 5% of patients after clean extra-abdominal operations and in up to 20% of patients undergoing intra-abdominal operations.[7]

In addition to the clinical impact on the patient (e.g., injury, mortality, pain and suffering, and life-style changes), the economic burden of SSIs is also considerable. In a sample of 723,490 surgical hospitalizations reviewed in the 2005 Healthcare Cost and Utilization Project National Inpatient Sample (HCUP NIS),[8] 6,891 cases (1%) of SSIs were identified. The data also demonstrated that, on average, an SSI increased the length of stay by 9.7 days, and also increased costs by $20,842 per admission. These results were projected to the national level; from this perspective, these cases of SSIs would have resulted in an additional 406,730 hospital days and hospital costs exceeding $900 million; furthermore, an additional 91,613 readmissions for treating the SSIs accounted for 521,933 extra days of care at a cost of nearly $700 million.

The economics of surgical site infections received greater attention from the Centers for Medicare and Medicaid Services (CMS) when, in July 2008, CMS announced new Medicare and Medicaid reimbursement and coverage policies.[9] The acute-care Inpatient Prospective Payment System (IPPS) final rule, which updated Medicare payments to hospitals for the fiscal year 2009, included payment provisions to reduce preventable medical errors that occur in health-care facilities in an effort to provide additional incentives for health-care facilities to improve the quality of care provided to Medicare patients. The rule specifically states that, if a condition is not present upon admission, but is subsequently acquired during the course of the patient's hospital stay, Medicare no longer pays the additional costs of the hospitalization; moreover, the patient cannot be held responsible for the additional costs. Initially, hospitals were not reimbursed for infections associated only with vascular catheters and coronary artery bypass graft surgery. However, as of October 1, 2008, hospitals were no longer reimbursed for surgical site infections after selected elective procedures, including certain orthopedic surgeries and bariatric surgery for obesity.



The Joint Commission also recognizes the significance of preventing HAIs and SSIs. Goal 7 of the 2010 Joint Commission National Patient Safety Goals (NPSGs) is to reduce the risk of HAIs, including SSIs; this goal also recommends implementation of policies and practices that meet regulatory requirements and are aligned with evidence-based guidelines (e.g., the CDC and/or professional organization guidelines) aimed at reducing the risk of surgical site infections.[10]

SURGICAL SITE INFECTIONS: PROCEDURE-RELATED RISK FACTORS

Microbial contamination of the surgical site is a prerequisite for an SSI; furthermore, the risk of an SSI increases with the dose of bacterial contamination and the virulence of the bacteria.[11] Microbial contamination of the surgical site may be from either the endogenous microorganisms (i.e., the bacteria from the patient's own skin, mucous membranes, or hollow viscera) or exogenous microorganisms (i.e., the microorganisms from healthcare personnel, the environment, surgical instruments and other materials). Most SSIs are caused by the patient's endogenous bacterial flora; when introduced into body tissues by surgery or through surgical instruments, the pathogenic potential of endogenous microorganisms increases.[12] The top five pathogens that are most often associated with cases of SSIs include (in rank order):[13]

- *Staphylococcus aureus,*
- Coagulase-negative staphylococci (CoNS),
- *Enterococcus* species (*E. faecalis; E. faecium;* not otherwise specified),
- *Escherichia coli, and*
- *Pseudomonas aeruginosa.*

There are both patient-related and procedural-related factors that contribute to the development of SSIs. While perioperative personnel cannot control the patient-related factors (e.g., the patient's status in regard to age, overall health, nutrition, and history

of drug and/or tobacco use), proper instrument processing and sterilization is a significant risk factor that *is* under the control of the hospital; furthermore, it is one which has the potential for a significant impact on the prevention of surgical site infections (see Table 1).[14] Failure to properly sterilize equipment carries not only the risk associated with breach of host barriers, but also the risk for person-to-person transmission as well as transmission of environmental pathogens.[15] Therefore, thorough cleaning of the item is required prior to a sterilization process because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of this process.

TABLE 1 – Procedure-Related Factors That May Influence the Risk of Surgical Site Infection Development

Procedure-Related Factors Related to SSI Risk
• Duration of surgical scrub • Skin antisepsis • Preoperative shaving • Preoperative skin prep • Duration of operation • Antimicrobial prophylaxis • Operating room ventilation • Inadequate sterilization of instruments • Foreign material in the surgical site • Surgical drains • Surgical technique • Poor hemostasis • Failure to obliterate dead space • Tissue trauma

IMMEDIATE USE STEAM STERILIZATION

"Flash Sterilization", a practice used in the operating room suites, is an antiquated term that is slowly being replaced with the newer descriptor "Immediate Use" steam sterilization. The practice of "flashing" was reserved for the practice of quick sterilization of an instrument that was needed for immediate use, and not for storage or packaging. Now, several educational and certification agencies such as the Certification Board for Sterile Processing and Distribution (CBSPD) and the International Association of Healthcare Central Service Materiel Management (IAHCSMM), as well as standards and practices associations such as the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), and the Centers for Disease Control and Prevention-Healthcare Infection Control Practices Advisory Committee (CDC-HICPAC) are promoting the new terminology of Immediate Use steam sterilization.[16]

IMMEDIATE USE STERILIZATION: GUIDELINES AND RECOMMENDATIONS

Today, perioperative professionals face two conflicting challenges on a daily basis: on one hand, regulatory agencies including the federal CMS as just discussed, are now holding health-care facilities more accountable for the costs associated with surgical site infections; on the other hand, surgical services departments are under increasing pressure to increase productivity and efficiency by increasing surgical case volume and reducing turnover time. In many practice settings, immediate use sterilization utilizing rigid containers is used to meet these challenges.

Sterilization is defined as a validated process used to render a product free from viable microorganisms.[17] In any sterilization process, the nature of microbiological inactivation is described by an exponential function, i.e., the sterility assurance level (SAL) or the probability of a single viable microorganism occurring on an item after sterilization; therefore, the presence of a viable microorganism on any individual item can be expressed in terms of probability. This probability can be reduced to a very low number, but it can never be reduced to zero. SAL is normally expressed as 10^{-6} for items intended to come into contact with compromised tissue (i.e., tissue that has lost the integrity of natural barriers). 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.

Saturated steam under pressure is the preferred sterilization method for heat- and moisture-stable instruments and devices, unless otherwise indicated by the device manufacturer.[18] Steam is an effective, inexpensive, and relatively rapid sterilization method for most porous and nonporous materials. Immediate use sterilization is defined as a process designed for the steam sterilization of patient care items for immediate use. And, as noted above, when performed correctly, immediate use sterilization is a safe and effective process for sterilizing surgical instruments and medical devices. However, performing immediate use sterilization requires control of many variables. One of the major concerns with immediate use sterilization is maintaining the sterility of the items from the sterilizer to the OR. Rigid containers address this concern by protecting the sterilized items from contamination during transport to the point-of-use.[19]

Several professional organizations have developed and regularly update guidelines and recommendations that provide guidance for perioperative nurses regarding the use of immediate use sterilization and rigid container systems. In addition, The Joint Commission recently updated its position on immediate use sterilization. The applicable guidelines and recommendations issued by the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN), as well as The Joint Commission's updated position on immediate use sterilization, are summarized below.

AAMI Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities[20]

The AAMI guideline outlines recommendations for guide health-care personnel in the proper use and processing of equipment. Selected recommendations related to cleaning and flash sterilization of surgical instruments and devices are summarized below.

- Cleaning and other decontamination processes. To be rendered safe to handle, surgical instruments must be prepared before subjected to terminal sterilization (e.g., steam sterilization). The type of decontamination required for a specific contaminated device depends on the biohazard that the device presents. The cleaning and/or microbial process appropriate for a particular device is dependent on:
  - The device manufacturer's written instructions.
  - The level of microbial kill needed, i.e., a higher assurance of lethality is required for items that have been in contact with body tissues, blood, or body fluids.
  - The design of the device; i.e., items that have been contaminated with blood or body fluids and that have sharp points or edges capable of puncturing or abrading the skin should be subjected to a decontamination process that includes disinfection or sterilization.
  - Other device characteristics, e.g., whether the materials from which the device is manufactured can tolerate high temperatures or if the device is fully immersible.
  - Whether the device had been exposed to prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD), and therefore would require specialized processing steps.

    It is important to note that health-care personnel should make every effort to select and purchase only those devices that can be decontaminated appropriately by a method available in their facility. In addition, appropriate personal protective equipment (PPE) should be worn to prevent occupational exposure incidents when handling contaminated instruments and devices.

- Disassembly. All surgical instruments composed of more than one piece or part should be disassembled to expose all surfaces to the cleaning process. Hidden surfaces and crevices can prevent thorough cleaning; residual organic matter or large numbers of microorganisms can reduce the effectiveness of the subsequent microbiocidal processes.

- Cleaning and rinsing.
  - For all reusable medical devices and instrumentation, the first and most important step in decontamination is thorough cleaning and rinsing. Effective cleaning is a multistep process that depends on several mutually dependent factors, such as the quality of the water; the quality, concentration, and type of detergent or enzymatic cleaner; an acceptable cleaning method; proper rinsing and drying; and correct preparation of the items to be processed by the cleaning equipment. The device manufacturer's instructions should be consulted to determine the

appropriate type of cleaning agent; the instructions from the cleaning agent manufacturer should then be followed.

- Methods of cleaning. The appropriate cleaning method for a medical device depends on the device's characteristics and should be specified by the device manufacturer. Cleaning may be accomplished by manual or mechanical methods, or a combination of both. Whichever cleaning method is used, the method selected should be effective, should not affect the functionality of the device, and should be safe for the healthcare worker performing the task.
  - Manual cleaning. Any device should be able to be cleaned manually. Manual cleaning is often recommended for delicate or complex medical devices, such as microsurgical instruments, lensed instruments and air-powered drills.
  - Mechanical cleaning. Mechanical cleaning equipment removes soil and microorganisms through an automated cleaning and rinsing process. Some types of mechanical cleaning equipment incorporate thermal disinfection processes and/or chemical disinfectant rinses that are capable of destroying various numbers and types of microorganism. Ultrasonic automated cleaners are designed for fine cleaning of medical devices, not for disinfection or sterilization. They are used to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods. Ultrasonic cleaning should be used only after gross soil has been removed from the item. The medical device manufacturer's instructions should be followed to verify that ultrasonic cleaning will not damage the device; since not all metals can withstand ultrasonic cleaning process, the device manufacturer should specify any restrictions.
- Rinsing. A device cleaned by either a manual or mechanical process should be rinsed thoroughly to ensure that loosened debris and detergents are adequately removed. This is an important step, since any residuals that remain on the item could affect disinfection and sterilization efficacy and/or cause adverse reactions in the patient on which the item is used.
- Rigid sterilization container systems instructions for use should be consulted regarding the use of FLASH sterilization. Before obtaining container systems, the facility should confirm that the manufacturer's validated cleaning method complies with the facility's procedures. Container systems can be cleaned by either manual or mechanical methods. The container system manufacturer's instructions for cleaning and rinsing should be followed. Before it is cleaned, a container system should be disassembled. For container systems with filters, disposable filters should be removed or the filter holder should be released. For container systems with valves, the valves should be cleaned according to the manufacturer's written instructions. Interior baskets should be removed and cleaned. Process chemical indicators (CIs), disposable labels, and locks should be removed. It may also be necessary to remove dividers and pins if they interfere with the cleaning process. Most rigid container systems can be cleaned in mechanical equipment. The selected cleaning method depends on

the container systems manufacturer's instructions in conjunction with the mechanical cleaning equipment manufacturer's instructions. When placing the outer container in a mechanical washer, personnel should do so in a manner to avoid the accumulation and subsequent retention of very hot water to avoid damage to mating surfaces and gaskets. The manufacturer's instructions for the type of detergent should be followed; the container should be rinsed thoroughly after cleaning. Once the cleaning process is complete, all nuts, bolts, screws, rivets, filter retention mechanisms, gaskets, and permanent filters should be inspected for cleanliness and damage.

- Some rigid, reusable, sealed containment devices are designed to be used in flash sterilization cycles, including prevacuum, pulsating gravity-displacement, and gravity-displacement cycles. Such containers are designed to permit flash sterilization of their contents, including single instruments as well as instrument sets. The container manufacturer should supply supporting scientific data that demonstrates sterilization can be achieved when a sealed container is used in a flash sterilization cycle. Containment devices are designed to confine the sterilized items and protect them from environmental contamination that may occur en route from the sterilizer to the point-of-use. It is important to follow the container manufacturer's instructions regarding the types of instruments that are suitable for this type of cycle; in some cases, instruments with lumens, powered equipment, and porous items cannot be processed by this method due to potential difficulties with air removal and steam penetration.

- Placement. Instruments to be sterilized should be positioned to allow the sterilant to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position, with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled, unless the device manufacturer provides specific instructions, supported by test data, to the contrary.
- Flash sterilization parameters.
  - Flash sterilization should be used only if the following criteria are met:
    - Flash sterilization can be performed in two different cycles: gravity displacement and dynamic air-removal cycles (prevacuum). The cycle is preprogrammed to a specific time-temperature setting established by the manufacturer based on the type of sterilizer control and is selected by the user based on the configuration of the load (see Table 2).
    - The items to be processed may be unwrapped, although a single wrapper may be used in certain circumstances if the sterilizer or packaging manufacturer's instructions permit. Some rigid container systems have been designed and validated by the container manufacturer for use with immediate use sterilization.

- The items processed are assumed and should be wet at the end of the cycle, since drying time is not usually part of the preprogrammed flash cycle.
- The processed item(s) must be aseptically transferred immediately from the sterilizer to the actual point-of-use. Regardless of whether the items are wrapped, there is NO storage or shelf life of flash sterilized items.

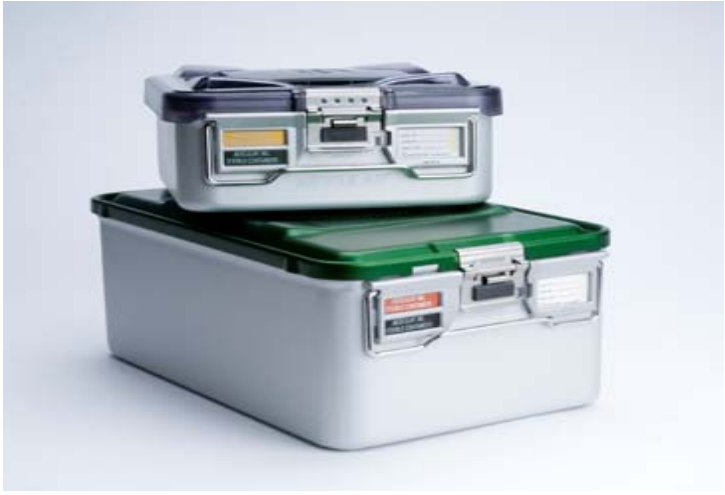
- In addition, flash sterilization of instruments should be considered only if the following conditions are met:
  - Work practices ensure proper cleaning and decontamination, inspection, and arrangement of instruments into the recommended sterilizing trays or other containment devices before sterilization.
  - The physical layout of the department or work area ensures direct delivery of the sterilized items to the point-of-use (e.g., the sterilizer opens into an area either within or directly adjacent to the procedure room).
  - Procedures are developed, followed, and audited to ensure aseptic handling and personnel safety during transfer of sterilized items from the sterilizer to the point-of-use.
  - The item is needed for use immediately following flash sterilization.

- Other considerations when considering flash sterilization include:
  - Flash sterilization of implants is *not* recommended.
  - For certain devices, the exposure time may have to be extended; drying may be necessary for some devices in order to ensure longevity and proper performance.
  - Certain manufacturers do not recommend flash sterilization of specialty devices. The instrument or device manufacturer is best able to determine the required sterilization parameters; therefore, the device manufacturer's written instructions should be consulted and followed.

Table 2 – Examples of Typical Immediate Use Steam Sterilization Parameters

Type of Sterilizer	Item	Time	Exposure Temperature	Drying Times
Gravity Displacement	Metal or nonporous items only (i.e., no lumens).	3 minutes	270°F - 275°F (132°C - 135°C)	0 – 1 minute
	Metal items with lumens and porous items (e.g., rubber, plastic) sterilized together. Complex devices (e.g., powered instruments requiring extended exposure times). Manufacturer instructions should be consulted.	10 minutes	270°F - 275°F (132°C - 135°C)	0 – 1 minute
Dynamic Air-Removal (Prevacuum)	Metal or nonporous items only (i.e., no lumens).	3 minutes	270°F - 275°F (132°C - 135°C)	N/A
	Metal items with lumens and porous items (e.g., rubber, plastic) sterilized together.	4 minutes 3 minutes	270°F (132°C) 275°F (135°C)	N/A N/A

* Note: This table is from AORN's 2010 Sterilization Recommended Practices.



AORN Recommended Practices

As noted, the creation and maintenance of an aseptic environment and the provision of surgical items that are free from contamination at the time of use are key factors in minimizing the patient's risk for SSI and thereby promoting positive patient outcomes. AORN publishes two recommended practices related to the use of rigid container systems and flash sterilization; selected recommendations from these documents are outlined below.

AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization[21]

- Recommendation I–Packaging systems should be evaluated before purchase and use to ensure that items to be packaged can be sterilized by the specific sterilizer and/or sterilization methods to be used.
- Recommendation II–Packaging systems should be compatible with the specific sterilization process for which it is designed.
- Recommendation VI–Design, materials, and construction of the containment device (e.g., rigid containers, instrument cases/cassettes, organizing trays) should be considered before selection and use.
    - Purchasers should verify that the containment devices has been tested and validated for the sterilization method and cycles to be used. Purchasers should request, review, and be familiar with the manufacturer's validation studies.
    - Prepurchase evaluation and biological testing of the containment device should be performed. Sealed flash sterilization containers should be biologically tested during the prepurchase evaluation and routinely thereafter. The container manufacturer should provide technical data regarding the best method for biologically testing the container.
    - The recommended sterilization method and cycle exposure items for each rigid container system should be provided in the manufacturer's data and instructions.
    - Rigid container systems should be cleaned after each use. All components (e.g., filter retention plates) should be disassembled for proper cleaning.
    - The manufacturer's written instruction should be followed for:
        - Cleaning, inspection, repair, and preventive maintenance;
        - Loading; and
        - Recommended filter material and chemical indicators.
    - Additional materials placed inside rigid containers (e.g., surgical towels) should not be used unless the container manufacturer has provided validation for their use.
    - The manufacturer's technical data for the types of devices validated for use inside the container (e.g., powered equipment, items with lumens) should be obtained and special instructions for sterilization followed.

- Recommendation X–The healthcare organization's quality management program should include sterile packaging selection and use.

- Recommendation XI–Personnel should demonstrate competency in the use of sterilization packaging systems and accessories.

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

AORN Recommended Practices for Sterilization in the Perioperative Practice [22]

- Recommendation I–Items to be sterilized should be cleaned, decontaminated, sterilized and stored in a controlled environment in accordance with AORN's *Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment* [23] and the device manufacturer's written instructions.

    - Effective sterilization cannot take place without effective cleaning. The process of sterilization is adversely affected by the amount of bioburden and the number, types, and inherent resistance of microorganisms, including biofilms, on the items to be sterilized. Soil and other materials may shield microorganisms from contact with the sterilant, or combine with and inactivate the sterilant.

- Recommendation II–Items to be sterilized should be packaged according to with AORN's *Recommended Practices for Selection and Use of Packaging Systems for Sterilization.* The weight of an instrument set should not exceed 25 pounds.

- Recommendation III–Saturated steam under pressure should be used to sterilize heat-and moisture-stable items unless otherwise indicated by the device manufacturer. Saturated steam under pressure is the preferred sterilization method because it is an effective, inexpensive, and relatively rapid sterilization method for most porous and nonporous items.

- Recommendation IV–The use of flash sterilization should be kept to a minimum. Flash sterilization should be used only in selected clinical situations and in a controlled manner. Flash sterilization may be associated with an increased risk of infection to patients because personnel may be pressured to eliminate one or more steps in the cleaning and sterilization processes.

    - Flash sterilization should be used only when there is insufficient time to process by the preferred wrapped or container method. It should not be used as a substitute for sufficient instrument inventory. Proper decontamination is essential in removing bioburden and preparing an item for sterilization by any method; failures in instrument cleaning have resulted in transmission of infectious agents. Items to be flash sterilized should be subjected to the same decontamination processes as items for any other sterilization method,

according to the AORN *Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment.*

- Flash sterilization should be considered only if all of the following conditions are met:
  - The device manufacturer's written instructions on cycle type, exposure times, temperature settings, and drying times (if recommended) are available and followed.
  - The items are disassembled and thoroughly cleaned with detergent and water to remove soil, blood, body fats, and other substances.
  - Lumens are brushed and flushed under water with a cleaning solution and rinsed thoroughly.
  - The items are placed in a closed sterilizer container or tray that is validated for flash sterilization, in a manner that allows steam to contact all the instrument surfaces.
  - Measures are taken to prevent contamination during transfer to the sterile field. Flash sterilized items must be used immediately and not stored for later use.
- Process challenge devices (PCDs) should be used with routine process monitoring devices (i.e., chemical indicators, biological indicators, physical monitoring devices). Process challenge and process monitoring devices provide information to demonstrate that the conditions for sterilization have been met.
- Each sterilization cycle should be monitored to verify that parameters required for sterilization have been met.
- Physical monitoring devices should be used to verify cycle parameters for each load.
- Biological indicators (BIs) and chemical indicators (CIs) should be used to monitor sterilizer efficacy and assess compliance of monitoring standards established for gravity-displacement and dynamic air-removal sterilizers. Class 5 chemical integrating indicators should be used within each sterilizer container or tray.
- Users should adhere to aseptic technique for flash-sterilized items during transport to the point-of-use. It is important that sterilization processing be carried out in a clean environment and that flash-sterilized devices are transferred to the point-of-use in a manner that prevents contamination.
- Rigid container systems designed and intended for flash-sterilization cycles should be used. These systems:
  - Reduce the risk of contamination during transport to the point-of-use;
  - Facilitate ease of presentation to the sterile field; and
  - Protect sterile items during transport.

- Flash sterilization containers should be used, cleaned, and maintained according to the manufacturer's written instructions
  - Flash sterilization containers should be opened, used immediately and not stored for later use.
  - Flash sterilization containers should be differentiated from other types of containers.
- Flash sterilization should not be used for implantable devices except in cases of emergency when no other option is available. In an emergency, when flash sterilization of an implant is unavoidable, a rapid-action BI with a Class 5 chemical integrating indicator (or enzyme indicator) should be run with the load. The implant should be quarantined on the back table and should not be released until the rapid-action BI provides a negative result. If the implant is used before the BI results are known, and the BI is later determined to have a positive result, the surgeon and infection control personnel should be notified as soon as the results are known. If the implant is not used, it cannot be saved as sterile for future use; it must be resterilized for later use.
- Documentation of cycle information and monitoring results should be maintained in a log (either manual or electronic) to provide tracking of the flashed item(s) to the individual patient. Sterilization records should include information on each load, including:
  - Item(s) processed;
  - Patient receiving the item(s);
  - Cycle parameters used (e.g., temperature, duration of the cycle);
  - The date and time the cycle is run;
  - Operator information; and
  - The reason for flash sterilization.

- Recommendation XIII–An introduction and review of policies and procedures should be included in personnel orientation to sterile processing of surgical instruments in the perioperative setting. Continuing education should be provided for employees when new equipment, instruments, and processes are introduced.

- Recommendation XIV–Sterilization records should be maintained for a time specified by the healthcare organization's policies and in compliance with local, state, and federal regulations.

- Recommendation XV–Policies and procedures for sterilization processes should be developed, reviewed periodically, and readily available in the practice setting.

- Recommendation XVI–A quality control program should be established and maintained.

RIGID CONTAINERS AND IMMEDIATE USE STERILIZATION CYCLES: CLINICAL CONSIDERATIONS FOR PROPER USE AND CARE

As noted, the use of rigid containers is a key component in providing safe patient care when using immediate use sterilization because rigid containers provide a suitable mechanism for aseptic transfer of the sterilized items to the point-of-use. The manufacturer's written instruction for the specific immediate use sterilization rigid container in use should always be followed. In addition, personnel should always wear PPE appropriate for the task being performed. General clinical considerations for the use and care of rigid containers are described below.

- Inspection prior to use.
  - Container lids and bottoms should be free from:
    - Noticeable cracking.
    - Corrosion or pitting.
    - Misalignment in which the top and bottom do not adequately mate.
    - Rivets penetrating through the surface.
  - Valve-type closures (if applicable) should be inspected, disassembled and cleaned according to the manufacturer's instructions.
  - Retention plates and gaskets should be free from:
    - Signs of cracking or damage.
    - Damage to the filter post preventing proper filter placement (if applicable).
    - Misalignment or improper seating of the gasket to the lid.
    - Pitting of surfaces.
    - Soil.

If any of the above conditions are present, the container should not be used.

- Cleaning.
  - Recommended cleaning agents. Use only mild alkaline or neutral pH (7) detergents to clean effectively without causing damage to the container. If in doubt, contact the detergent manufacturer to determine suitability for use.
  - Pre-cleaning preparation.
    - Remove the lid from the container bottom.
    - Remove the basket and any instruments from the container.
    - Remove the lid retention plate(s).
    - Remove the container bottom retention plate if using perforated container bottoms.

        - Discard the disposable filter (if applicable).
        - Remove all processing indicators and disposable locks.
    - Manual cleaning.
        - Use a soft sponge and a mild detergent to clean the container and all the components under water.
        - Rinse thoroughly to remove all detergent residue.
        - Thoroughly dry the container and all components with a soft, dry cloth.
    - Mechanical cleaning.
        - Place the container in the washer with the inside surface facing down to avoid water collection.
        - Fold the handles toward the inside of the lid; place the lid with the inside surface facing down to avoid water collection.
        - Retention plates should be placed away from the direct force of pressurized washer jets to avoid damage.
        - Thoroughly dry (either with a soft, dry cloth or by air drying) the container and components before final assembly.
- Assembly.
    - Container.
        - Identify the appropriate size basket and container bottom type (i.e., perforated or solid) for the method of sterilization. Note: solid bottom containers cannot be used in gravity steam sterilizers.
        - Assure the container and component pieces are completely dry.
        - Inspect the rim of the lid to ensure the gasket or valves are in good condition. A cracked gasket indicates age and/or deterioration and should not be used. Furthermore, the lid should be removed from service and returned for repair.
    - Filter (if applicable). Place filters according to the manufacturer's instructions.
    - Instruments.
        - Sort and assemble thoroughly cleaned instruments into the basket, according to facility policy. All instruments should be disassembled per the instrument manufacturer's instructions to allow for uniform exposure to steam sterilization.
        - Place the instruments into the prepared container bottom. All items should be contained within the basket or tray. Leave the minimum recommended amount of free space (e.g., at least two inches) between the instruments and the inside of the container lid for effective processing.
        - Place the assembled lid onto the container bottom; simultaneously close both locking latches on the lid.

- Processing assembly.
  - Use internal and external indicators according to facility protocol.
  - Insert tamper-proof seal.
  - Secure and lock the seals.

- Load the sterilizer.
  - Place the container flat in the sterilizer. Position the container according to the sterilizer manufacturer's guidelines for optimum immediate use sterilization conditions.
  - Stacking containers is not recommended for immediate use sterilization.

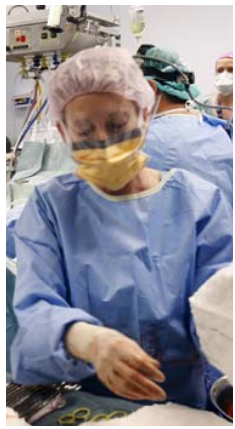
- Immediate use sterilization cycle parameters.
  - Verify that the container and item(s) have been validated for immediate use sterilization.
  - Verify that immediate use sterilization is appropriate for the sterilizer.
  - Sterilize the item(s) according to the manufacturer's validated immediate use sterilization parameters.

- Aseptic presentation to the sterile field.
  - The circulating nurse places the container on a separate dry flat surface at or slightly above the level of the sterile field.
  - The circulating nurse inspects the physical integrity of the closed container system to assure seals are in place; then checks the exterior chemical indicator(s).
  - The circulating nurse breaks and removes the locks; then opens the latch and removes the lid in one single step, taking care to ensure that the container edge/bottom is not contaminated.
  - The circulating nurse and/or scrub assistant checks the internal indicators.
  - If the rigid container has a filter, the circulating nurse checks the integrity of the filter(s) by removing and examining the filter retention plate.
  - The scrub assistant removes the sterile contents inside the container by grasping both handles using appropriate aseptic technique, lifting the basket and contents out and placing them on a sterile surface.
  - The circulating nurse checks the filter(s) on the bottom if a perforated bottom container is used.

Additional clinical considerations regarding the use of flash sterilization include:[24, 25]

- Audit and monitor work practices to ensure that they provide for both personnel safety and aseptic transport of sterilized items from the autoclave to the point-of-use.

- Avoid patient burns, i.e., ensure ample cooling time before use of flashed item.
- Use flash sterilization appropriately. Monitor what is being flashed and why. Flash sterilization should be used only when there is insufficient time to process instruments by the preferred wrapped or container method. It should not be used as a substitute for insufficient instrument inventory or failure to anticipate patient care needs.
- Establish and enforce guidelines. Define the rules for flash sterilization and establish appropriate guidelines for all personnel to follow. Require the use of a flash sterilization log.
- Build more efficient instrument sets. Conduct an instrument inventory and determine those that are most frequently used. Streamlined instrument sets should be built to include only those instruments. Fewer instruments per set allows for faster overall processing. In addition, with streamlined sets, money isn't wasted on instruments that are rarely used.
- Dedicate someone to instrument reprocessing. Ensure that all instruments are sterilized through proper reprocessing by dedicating someone to this responsibility. Patient safety is an important measure for all facilities, and the reprocessing of instruments is a crucial element of a sterile and safe environment.
- Seek outside support. If the current budget or systems can't keep up with patient care needs, seek outside support. Certain companies can serve as outsourced sterilization services or even provide sterile instruments on a just-in-time and charge-by-use basis.
- If you are going to immediate use sterilize, do it right.
    - Thoroughly clean, decontaminate, and inspect the items for immediate use. When surgical instruments are needed immediately or the surgeon is asking for an item, it may be tempting to take shortcuts or entirely skip this step. Proper cleaning and decontamination requires more than a quick rinse. Every facility should have a policy describing the proper method to clean and decontaminate instrumentation, as well as a designated separate decontamination area away from areas that perform sterilization of surgical instrumentation. All surgical instruments should go through the same cleaning and decontamination process regardless of how they're sterilized.

      As discussed, immediate use sterilization can be performed in either a gravity displacement or dynamic air-removal (prevacuum) cycle. The exposure times and temperature settings should be set according to the written instructions of the instrument manufacturer and the manufacturer of the sterilizer. Either sterilization cycle can be used for immediate use as long as the manufacturer's recommendations are followed.

When using rigid containers, be sure the manufacturer of the container provides written documentation confirming that the containers are compatible with immediate use sterilization. Each facility should validate that sterilization can be achieved when using the containers in their specific sterilizer.

- Disassemble and load the items so that the steam can penetrate all surfaces. Use a rigid, closed sterilization container system designed for immediate use sterilization so that instruments are protected from contamination from the autoclave to the point-of-use. Such a system is easy-to-use, sterilization is fully validated, and the instruments can be transported aseptically to the point-of-use.
- Select the correct sterilization settings.
- Verify that the correct parameters have been met.

SUMMARY

Prevention of surgical site infections is the goal for all surgical patients. In today's dynamic health-care environment, the perioperative nurse must remain aware of both the clinical and economic implications of SSIs. One key infection prevention measure is the provision of sterile instruments and devices. In selected clinical situations, immediate use sterilization may be used to effectively sterilize certain patient care items. In addition, the use of rigid container systems with this process assists in overcoming one potential issue with immediate use sterilization: aseptic delivery to the point-of-use. Therefore, perioperative nurses must remain aware of when, where, and how to use the immediate use sterilization and rigid containers. Through this knowledge, the perioperative nurse and all members of the surgical team members involved in immediate use sterilization can effectively reduce the risk for surgical site infections and ultimately promote positive patient outcomes.

Immediate-Use Steam Sterilization

"Flash sterilization" has traditionally been used to describe steam sterilization cycles where unwrapped medical instruments are subjected to an abbreviated steam exposure time and then used promptly after cycle completion without being stored. This is in contrast to traditional "terminal sterilization" cycles, where instruments are sterilized within containers, wrappers, or primary packaging designed to maintain the instruments' sterility and allow the devices to be stored for later use. The term "flash" arose out of the abbreviated time of exposure of the unwrapped device.

Today, however, "flash sterilization" is an antiquated term that does not fully describe the various steam sterilization cycles now used to process items not intended to be stored for later use. Current guidelines may require longer exposure times and/or the use of single wrappers or containers designed to allow for aseptic transfer of an item to the point of use. The term "immediate-use steam sterilization" more accurately reflects the current use of these processes. The same critical reprocessing steps (such as cleaning, decontaminating, and transporting sterilized items) must be followed regardless of the specific sterilization cycle employed; a safe process does not include short-cuts or work-arounds.

"Immediate use" is broadly defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another. Immediacy, rather than being defined according to a specific time frame, is established through the critical analysis and expert collaboration of the health care team.

We agree that:

- Personnel involved in reprocessing should be knowledgeable and capable of exercising critical thinking and judgment, and should implement standardized practices. The supervising organization is responsible for ensuring appropriate training, education, and competency of staff and ensuring that the necessary related resources are provided.
    - Examples of education and certification resources include the Certification Board for Sterile Processing and Distribution (CBSPD) and the International Association of Healthcare Central Service Materiel Management (IAHCSMM).

- Sterilization personnel should be educated regarding the different types of steam sterilizers (i.e., gravity-displacement and dynamic air removal—prevacuum, high vacuum, and steam-flush-pressure-pulse sterilizers) and the different types of steam sterilization cycles (i.e., gravity-displacement and dynamic air removal cycles) used in health care facilities.
- Sterilization cycles with little or no dry time are efficacious when used in compliance with validated written instructions provided by the device manufacturers, sterilization equipment manufacturers, and (if applicable) container manufacturers and when done in accordance with professional guidelines.
- Cleaning, decontamination, and rinsing are critical and users must follow and complete all required processing steps regardless of the sterilization exposure parameters being used.
- Aseptic transfer from the sterilizer to the point of use is critical to protect items from contamination.
- Only items sterilized and packaged in materials cleared by the FDA for maintenance of sterility can be stored.
- The device manufacturer's written instructions for reprocessing any reusable device must be followed. The cycle parameters required to achieve sterilization are determined by the design of an instrument, the characteristics of the load, the sterilizer capabilities, and the packaging (if used).

  NOTE: The device manufacturer's instructions are not always compatible with the sterilizer instructions or the instructions for the container/ wrapper. Device manufacturers' instructions are sometimes unclear, incomplete, or require processes or cycles that are not available in the health care facility. Where instructions conflict or are insufficient, the device manufacturer should be contacted for more information/guidance. If differing instructions cannot be resolved and the instrument is urgently needed, the device manufacturer's instructions must be followed.

- Survey personnel involved in evaluating organizations that sterilize medical items should be knowledgeable and capable of exercising critical thinking and judgment. The regulatory or accrediting agency should evaluate whether the organization's leaders ensure that training, education, and resources are provided and the competency of staff is validated.
- Quality management is important to ensure compliance with processes and relating those processes to outcomes.
- Sterilization process monitoring is essential to ensure that sterilization practices are efficacious.
  - Examples of process monitoring tools are physical indicators, biological indicators, and chemical indicators.

- Instrument inventories should be sufficient to meet anticipated surgical volume and permit the time to complete all critical elements of reprocessing.

Immediate-use sterilization should NOT be performed on the following devices:

- Implants[1], except in a documented emergency situation when no other option is available.
- Post-procedure decontamination of instruments used on patients who may have Creutzfeldt–Jakob disease (CJD) or similar disorders.
- Devices or loads that have not been validated with the specific cycle employed.
- Devices that are sold sterile and intended for single-use only.

Resources

Association for the Advancement of Medical Instrumentation. *ANSI/AAMI ST79: 2010—Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.* Arlington, VA: Association for the Advancement of Medical Instrumentation, 2010.

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Centers for Disease Control, *Guideline for Disinfection and Sterilization in Healthcare Facilities,* 2008.

[1] The FDA defines an implant as a "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. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also 'implants.' " [21 CFR 812.3(d)]

GLOSSARY

Bioburden

The number of microorganisms (i.e., microbial load) with which an object is contaminated.

Biofilm

A thin coating containing biologically active organisms that have the ability to grow in water and water solutions. Biofilms contain viable and nonviable microorganism that adhere to the surface and are trapped within a matrix of organic matter, which prevents antimicrobial agents from reaching the cells.

Biological Indicator

A sterilization process monitoring device commercially prepared with a known population of highly resistant spores that test the effectiveness of the method of sterilization being used. The indicator is used to demonstrate that conditions necessary to achieve sterilization were met during the sterilizer cycle being monitored.

Chemical Indicator

A sterilization monitoring device used to monitor the attainment of one or more critical parameters required for sterilization. A characteristic color or other visual change indicates a defined level of exposure based on the classification of the chemical indicator used.

Class 5 Chemical Integrating Indicator

A chemical indicator designed to react to all critical parameters over a specified range of sterilization cycles and whose performance has been correlated to the performance of the stated test organism under the labeled conditions of use.

Cleaning

The removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

Contamination	The presence of potentially infectious pathogenic microorganisms on animate or inanimate objects or surfaces.
Decontamination	The use of physical or chemical means to remove, inactivate, or destroy pathogenic microorganism on a surface or item to the point where they are rendered safe for handling, use, or disposal.
Endogenous	Growing from or on the inside; caused by factors within the body or arising from internal structural or functional causes of the body.
Exogenous	Growing from or on the outside; caused by factors (as food or a traumatic factor) or an agent (as a disease-producing organism) from outside the organism or system; introduced from or produced outside the body.
Hospital Acquired Infection (HAI)	An infection acquired by patients during hospitalization, with confirmation of diagnosis by clinical or laboratory evidence. The infective agents may originate from endogenous or exogenous sources. HAIs, which are also known as nosocomial infections, may not become apparent until the patient has been discharged from the hospital.
Immediate Use Steam Sterilization Container	A container specifically designed for immediate use steam sterilization. The container is used to contain a device before, during, and after the sterilization process. It is sealed and may require special extended sterilization exposure times.
Infection	The invasion and multiplication of microorganisms in body tissues that cause cellular injury and clinical symptoms.
Infectious Agent	A parasite (e.g., bacterium, fungus, virus) that is capable of producing an infection.
Log Reduction	The logarithmic death progression of microorganisms after exposure to a sterilant or antiseptic agent. The reduction difference between average surviving microbes for control and test carriers used as an efficacy parameter.

Microorganism	An organism that is too small to be seen with the naked eye and requires a microscope. Bacteria, viruses, fungi, and protozoa are generally called microorganisms.
Pathogen	A microorganism that causes disease.
Personal Protective Equipment (PPE)	Protective equipment (e.g., masks, gloves, goggles, face shields, and gowns) for eyes, face, head, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the wearer from injury.
Physical Monitor	An automated device (e.g., graphs, gauges, printouts) that monitors sterilization parameters for the sterilization method in use.
Process Challenge Device	A predetermined item/package (i.e., test pack) designed to simulate the product to be sterilized and that is used to assess the efficacy of the sterilization process.
Rigid Sterilization Container System	Specifically designed heat-resistant, metal, plastic, or anodized aluminum receptacles used to package items, usually surgical instruments, for sterilization. The lids and/or bottom surfaces contain steam- or gas-permeable, high-efficiency microbial filters.
Sterile	The state of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of a microorganism surviving sterilization being 1 in 1,000,000.
Sterility Assurance Level (SAL)	The probability of a viable microorganism being present on a product unit after sterilization. Usually expressed as 10^{-6}; a SAL of 10^{-6} means <1/1 million chance that a single viable microorganism is present on a sterilized item. A SAL of 10^{-6} generally is accepted as appropriate for items intended to contact compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers). The sterilizer manufacturer is responsible for ensuring the sterilizer can achieve the desired SAL.

Sterilization	A validated process that removes or destroys all viable microorganisms, including bacterial spores, to an acceptable sterility assurance level, usually 1 in 1,000,000. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to this very low number, it can never be reduced to zero.
Sterilization Process Monitor	A device used to monitor sterilization processes; e.g., biological, chemical, or physical.

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