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Learning Objectives

1. *Define chemical disinfection and sterilization*
2. *Describe various standards and guidelines for chemical disinfection/sterilization of devices*
3. *Explain the key factors in the safe handling and use of chemical disinfectants and sterilants*

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Chemical disinfection and sterilization

by Dr. Gerald McDonnell, BSc PhD

Reusable devices and processing

Reusable medical devices are widely used in healthcare facilities for a variety of surgical, therapeutic and diagnostic purposes. It is important that these devices are safely handled to reduce the risk of adverse events such as device malfunction or damage, the transmission of pathogenic (harmful) microorganisms, or a toxic event in a patient. Reusable devices can become soiled with a variety of patient materials (including blood and tissues) during their use, and these soils may harbor pathogenic microorganisms, posing an infection risk to staff who handle used devices or to patients on which such devices are subsequently reused. Effective device processing (or reprocessing) is required to render these devices safe for subsequent staff handling or patient use. This generally includes cleaning, to physically remove soil from the device, followed by an antimicrobial process appropriate to the intended use of the device. The antimicrobial processes include disinfection and sterilization. Disinfection may be defined as a reduction in the number of viable microorganisms on a surface to a level previously specified as appropriate for its intended handling or use. There are various levels of disinfection: low-, intermediate- and high-level,[1,2] defined by their ability to kill particular types of microorganisms. The purpose of disinfection is to reduce the level and types of microorganisms. The result achieved will depend on the label claims of the disinfectant (to include activity against different types of microorganisms under stated conditions) as well as its correct and effective use as part of a standardized process. Sterilization is also an antimicrobial process, but is expected to render the device free from, and inactivates, all types of microorganisms.

Disinfection and sterilization can be achieved using a variety of methods. The most common methodologies currently used in healthcare facilities are heat (such as hot water or steam), other physical methods (such as UV light) and a variety of chemicals and related processes, or a combination of these methods. This self-study guide considers the use of chemical disinfectants and sterilization processes.

Guidelines and standards

An important consideration for device processing is the risk that each device could pose to patients when it is used. For this reason, reusable devices can be categorized under the Spaulding Classification system[1,3,4]. This classification system is based on three different levels of risk and defines devices as being *non-critical*, *semi-critical* and *critical* (Figure 1).

Non-critical surfaces only contact intact skin and are considered to have the lowest infection transmission risk. Labeled low- or intermediate-level chemical disinfectants are typically used in these situations. Specific product claims can vary, but in general low-level disinfectants are expected to be effective against many types of bacteria, some fungi and some viruses in accordance with their stated claims. Intermediate-level disinfectants are also effective against other more resistant forms of viruses (non-enveloped, such as polio and noroviruses) and bacteria (mycobacteria, such as *Mycobacterium tuberculosis*).

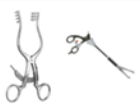
Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Low Level or Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	High Level Disinfection
Sterile areas of the body, including blood contact		Critical	Sterilization

Figure 1. *A summary of the Spaulding Classification system.*

Semi-critical devices pose a greater risk as they may also contact mucous membranes or non-intact skin during use. The most well-known examples are flexible gastrointestinal endoscopes. Sterilization of semi-critical devices is preferred, but if this is not practical then high-level disinfection is considered acceptable. High-level disinfectants are expected to inactivate most forms of microbial life, including mycobacteria and some bacterial spores (although this may require extended time). *Critical devices* present the highest risk as they are intended to enter a normally 'sterile' area of the body, such as the bloodstream. Sterilization of these devices is required.

While heat-based disinfection and sterilization are widely used for device processing, there are many instances when this is not possible. Examples include a variety of environmental surfaces and particularly devices that can be damaged by heat. In these cases chemical disinfection or sterilization is recommended. Some of the important guidelines and standards in the U.S. include:

- CDC-HICPAC *Guideline for Disinfection and Sterilization in Healthcare Facilities* (2008)[1]. This guideline provides a review of the methods for cleaning, disinfection and sterilization of patient-care medical devices and the healthcare environment.
- AORN *Perioperative standards and recommended practices* (2013)[2].
- ANSI/AAMI ST58 *Chemical sterilization and high-level disinfection in healthcare facilities* (2013)[3]. This recommended practice, a parallel document to the widely used reference ANSI/AAMI ST79 for steam sterilization, provides detailed guidelines on high-level disinfectants, liquid chemical sterilants and gaseous chemical sterilization processes that have been cleared by the U.S. FDA for use in healthcare facilities.

It is also important to consider that chemical disinfectants and sterilization processes are registered in the U.S. by two agencies:

- Environmental Protection Agency (EPA), registers chemicals that are used on environmental surfaces.
- United States Food and Drug Administration (FDA) has jurisdiction over chemicals and processes intended for medical device processing.

Similar, yet often distinct, registration or licensure processes are used in other countries or regions. An example for chemical sterilization are the requirements in the ANSI/AAMI/ISO 14937 standard for the characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices. It is therefore important to understand what specific use each type of product is intended for and to closely inspect the written instructions for use provided. They can vary significantly.

Device reprocessing

The recently published recommended practice ANSI/AAMI ST58 (2013) provides up-to-date guidance on device processing with chemicals. It focuses on legally marketed products including high-level disinfectants, liquid chemical sterilants, and liquid chemical and gaseous sterilization processes. The terms "high-level disinfection" and "sterilization" have already been described. When used appropriately, high-level disinfectants (which in the U.S. are often also labeled as liquid chemical sterilants) should be capable of rendering a device free of most pathogens, but often require significantly longer exposure times to ensure effectiveness against bacterial spores. A high-level disinfectant is essentially a liquid chemical sterilant, generally used for a shorter exposure time than that required to be considered a sterilant (i.e., to pass a specified spore test method). Chemical sterilization is defined as using a chemical agent to render a product free of viable microorganisms. Overall, these chemical products and processes utilize either the liquid (liquid chemical sterilization) or gas (gas sterilization) form of the active chemistry. Notably ANSI/AAMI ST58 excludes consideration of gaseous chemical sterilization process based on ethylene oxide, as it is the topic of a different recommended practice, ANSI/AAMI ST41.

Chemical disinfection and sterilization technologies

Only a limited number of chemicals have been successfully developed for use in high-level disinfectants, sterilants and sterilization processes.

These include liquid solutions (typically the active ingredient in combination with other chemicals, known as 'formulations') and gaseous processes (under controlled exposure conditions). The most widely used chemicals include:

- glutaraldehyde solutions: 1.1-3.4% formulations with high-level disinfection claims ranging from 5 min (at 35C/95F) to 90 min (20C/68F). Any claims for sterilant (sporicidal) activity typically require longer exposure times. It is important to review the specific label of each product prior to use, as they vary in preparation (activation) method, exposure time/temperature, rinsing, safety requirements, etc.
- ortho-phthaldehyde (OPA) solutions: high-level disinfectants including single use (0.05% OPA, 50-55C/122-131F for 10 min) and multiple use (0.55% OPA, 20C/68F for 12 min) formulations.
- hydrogen peroxide formulations: 2% (20C/68F for 8 min) and 7.5% (20C/68F for 30 min) for multi-use high-level disinfection.
- a sodium hypochlorite solution created within a closed system: generates 650-675 ppm of a chlorine-based disinfectant for use at 10 min and 25C (77F).
- peracetic acid high-level disinfectant formulations: 0.08% (25 min) to 7% (5 min) at 25C (77C).
- a peracetic acid-based liquid chemical sterilization process, using formulated 0.2% PAA in buffered aqueous solution for 6 min at 46-60°C (115-140°F) followed by extensively treated water rinsing.
- a specific mixture of water, alcohol and formaldehyde in a high-temperature sterilization process.
- Hydrogen peroxide gas, used for sterilization processes. These may be categorized into two types: processes that contain plasma or no plasma during the process.
- Humidified ozone gas, used in a low-temperature sterilization process.

It is important to remember that these products and processes can vary significantly in product claims as well as use requirements such as exposure times, rinse times (for liquid products to remove toxic substances following disinfection), stability (e.g., single or multiple use), device restrictions, etc. Therefore, care should be taken to review in detail the manufacturer's written instructions regarding the safe and effective use of these technologies. In addition, it is important to check that the product or process is applicable for your particular intended use; for example, a list of U.S.-FDA cleared sterilants and high-level disinfectants for processing reusable medical/dental devices is maintained by the FDA at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm.

In preparation

ANSI/AAMI ST58 provides guidance on the full processing cycle, which starts with the safe handling of devices through transportation to a defined area where processing can occur. Although this can be in a defined, centralized sterilization depart-

*See **SELF-STUDY SERIES** on page 52*

Self-Study Test Answers: 1. D, 2. A, 3. D, 4. A, 5. D, 6. E, 7. C, 8. G, 9. E, 10. G

ment, often it will include small localized areas in a facility close to where the device is being clinically used on the patient. Regardless where processing occurs, the same requirements apply. These include established procedures for safe transport, receiving and handling, designated and appropriate areas for reprocessing, separation of areas for cleaning, disinfection/sterilization and storage, unidirectional flow of devices from dirty (receiving) to clean areas to avoid cross-contamination, and restricted access to the area. Specific consideration for the use of chemicals will include adequate ventilation, chemical storage and disposal facilities/procedures. All chemicals used for disinfection/sterilization can pose safety risks to staff, but some require strict use of very specific safety controls to reduce staff risks. A review of safety information provided by the manufacturer should be done in parallel with the use of guidelines and standards. In all cases, personal protective equipment (PPE) should be used (to include safety glasses and chemical-resistant gloves when appropriate). Defined procedures, competencies and staff training should be in place and periodically inspected to ensure the effective and safe use of chemicals.

An essential stage in processing will include thorough cleaning prior to any disinfection or sterilization step. Cleaning is a multi-step process that includes the physical removal of visual soil (residual patient or procedural materials), and also adequate rinsing to ensure that no harmful or interfering chemicals remain on the device. The choice and correct use (preparation, temperature and exposure time) of cleaning chemistries are important considerations. Initial steps typically include disassembly, pre-washing, washing and then rinsing. Packaging may be appropriate before processing for gaseous sterilization methods. Post-processing steps can include removal of excess water, drying and packaging depending on the disinfection or sterilization process to be applied. It has become increasingly important to visually inspect the device for cleanliness following a cleaning process. Cleaning processes may be monitored on a regular basis using a variety of commercially available cleaning indication methods.

Selecting the appropriate method

Effectiveness and safety are essential requirements for every aspect of any disinfection/sterilization process. The first step in selecting an effective method is based on the previously discussed Spaulding Classification system in compliance with best practices. This includes determination of the criticality of the device and the recommended level of disinfection/sterilization. Convenience should not dictate the method chosen. Each facility should have a policy developed in collaboration with those familiar with infection prevention/control, and staff trained on its correct implementation. The policy should include which products/processes are appropriate for what use, with close attention to their cleared claims. Finally, the policy should include how each product should be correctly used, with consideration of the manufacturer's instructions for use for both the medical device being reprocessed and the reprocessing method. In some cases, many different instructions may need to be considered; for example, for a high-level disinfectant used within a washer-disinfector or automated endoscope reprocessor (AER), it is important to first verify the compatibility of the reusable device, and to follow the labeled use instructions of the chemistry as well as the machine, including cycle parameter controls, routine checks (such as the use of process or chemical indicators, temperature verification, etc.) and equipment maintenance.

There are at least four safety considerations: staff, patient, environment and devices. Staff should be trained on all chemical safety data sheets and understand any risks to themselves in the preparation, use and handling of any associated chemicals. Management must ensure that the correct facilities and environmental conditions are made available to ensure their safe use (e.g., adequate ventilation, disposal policies, etc.).

Patient safety can be ensured by the correct disinfection/sterilization and thorough rinsing of the device without damage during processing. For example, aldehyde-based disinfectants can require up to six fresh-water rinses in a defined way to ensure that no toxic residuals remain following exposure.

The chemistry manufacturer should provide in its labeling evidence of compatibility with devices being proposed for exposure. Examples of physical compatibility include correct device positioning/loading and the number, length and diameters of device lumens that can be successfully processed. Chemical compatibility will include the identification of what materials used in medical device design are compatible with the chemistry or process, and which are not compatible. The chemistry or associated process used should not damage the device; such an event could lead to a patient safety risk or significantly reduce the expected usable life of the device. Many factors can affect the device over time, such as repeated medical use, accidental damage, water quality and any of the variety of chemicals that can be used during patient procedures, maintenance or processing of the device. Environmental safety considerations can include restrictions and methods for disposal into the environment, and the overall 'green' footprint of the facility.

Recommended practices such as ANSI/AAMI ST58 also discuss other requirements, such as product registrations, peer-reviewed publications that highlight safety/efficacy concerns and cost effectiveness in the decision process.

Safe handling and use

ANSI/AAMI ST58 provides informational annexes on the various chemicals used for high-level disinfection and sterilization, encompassing their properties/applications, effective use, safety, related emergency procedures, disposal and any safety monitoring recommendations. These should be considered in the development of facility policy, procedures and training to ensure the effective and safe use of selected chemistries and methods by staff. High-level disinfectants and sterilants can range significantly in their label claims, such as the requirements for correct preparation, effects of water quality (used for preparation or rinsing), routine testing, exposure methods, contact times and temperatures, rinsing (times, temperatures and methods), reuse requirements, adverse health risks, storage, and emergency procedures. Automated reprocessors may be useful to standardize processing steps, but these systems also require routine inspection, correct use and maintenance. Chemicals for reusable device processing must meet similar requirements to ensure their safe and effective use. Care should be taken to follow label and operating instructions carefully, including recommended routine quality control testing. Quality control methods can include the use of solution test strips, spore test strips, biological and chemical indicators, and other chemical monitoring devices.

These should be used in combination with any associated physical monitors or gauges used with automated equipment to record key parameters such as temperatures, pressures and contact times. It is important to remember that quality control includes not only the use of appropriate indicators/monitors, but also record-keeping and

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ongoing training and verification that established policy and procedures are being closely followed.

As a final note, it is important to ensure that the transport and/or storage of processed devices does not allow for re-contamination before patient use. For liquid based processes this can include correct drying prior to storage and storing devices in locked cabinets. Although devices are typically packaged for chemical sterilization, procedures should ensure the correct packaging, storage and inspection to prevent cross-contamination.

Staff training and competency

Chemical disinfection and sterilization continue to play an essential role in device processing. As the variety and complexity of temperature-sensitive devices increase in availability and usage, it is expected that the demand for low temperature disinfection/sterilization will keep pace. There are many types of products and processes available, and their consistent, correct use by trained and competent staff is essential. When used appropriately chemical processing methods can yield significant benefits in the productive provision of safe reusable devices for repeated surgical and medical use. HPN

Dr. Gerald McDonnell is vice president of research and clinical affairs for STERIS Corporation. He holds a BSc in Medical Laboratory Sciences and a PhD in Microbial Genetics. He has more than 18 years of experience in the infection prevention and contamination control arenas, both in the U.S. and internationally. He has more than 170 publications and patents, including a new book published in 2012 entitled A Practical Guide to Decontamination. Dr. McDonnell is actively involved in the development of national and international standards and guidelines.

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4. AORN, 2012. *Recommended Practices for High-Level Disinfection.*

5. ANSI/AAMI/ISO 14937:2009/(R) 2013. *Sterilization of healthcare products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.*

CONTINUING EDUCATION TEST • MARCH 2014

Chemical disinfection and sterilization

Circle the one correct answer:

1. **Disinfection and sterilization can be achieved by using**
   A. Heat
   B. Chemicals
   C. Heat and Chemicals
   D. All of the above

2. **The purpose of device disinfection is to reduce the level and types of microorganisms.**
   A. True
   B. False

3. **Sterilization is**
   A. an antimicrobial process
   B. expected to render a device free from microorganisms
   C. expected to be effective against all microorganisms
   D. all of the above

4. **In the United States, only high level disinfectants and chemical sterilization processes cleared by the FDA should be used during semi-critical and critical device processing following cleaning.**
   A. True
   B. False

5. **Following cleaning, a device that contacts patient mucous membranes or non-intact skin should be**
   A. Disinfected with alcohol
   B. Disinfected with a high-level disinfectant
   C. Sterilized
   D. B or C
   E. A, B or C

6. **Which are examples of antimicrobial chemicals used in formulation as high-level disinfectants or sterilants?**
   A. Peracetic acid, Hydrogen peroxide
   B. Iodine, Chlorhexidine
   C. Glutaraldehyde, OPA
   D. Enzymatic cleaners, Bleach
   E. A & C
   F. All of the above

7. **The _____Classification can be used to determine the most appropriate antimicrobial process.**
   A. Pasteur
   B. CDC
   C. Spaulding
   D. WHO

8. **Which are examples of antimicrobial chemicals used in device sterilization processes?**
   A. Peracetic acid liquid
   B. Glutaraldehyde
   C. Hydrogen peroxide gas
   D. Ozone gas
   E. Ethylene oxide
   F. All of the above
   G. A, C, D, and E.

9. **When performing processing of medical devices with chemicals, which of the following statements are accurate?**
   A. The designated areas for cleaning, disinfection/sterilization and storage should be from dirty to clean in a uni-directional flow
   B. Chemical manufacturers' instructions for use should be closely followed
   C. Recommended PPE should be used
   D. Cleaning is always recommended before disinfection/sterilization
   E. All of the above

10. **High-level disinfection should kill/inactivate:**
    A. Vegetative bacteria
    B. Enveloped and non-enveloped viruses
    C. Mycobacteria
    D. Bacterial and fungal spores (over time)
    E. Fungi
    F. A, B and E
    G. All of the above

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