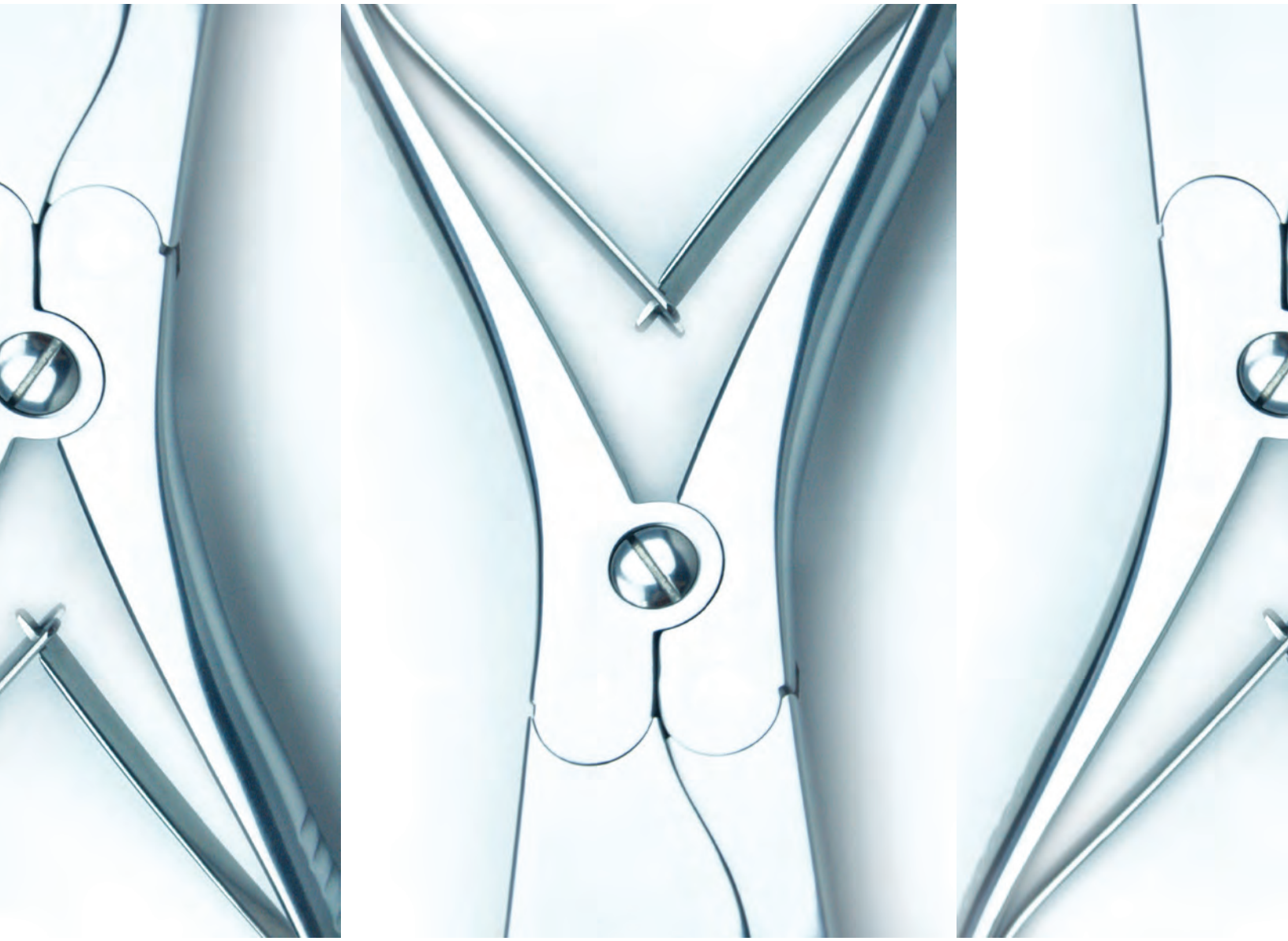

Sterile Processing

Knowledge, Skills, Competencies

Terri Goodman, PhD, RN

AAMI
Advancing Safety in Healthcare Technology

This publication is intended to be a helpful information resource,
and reflects the expert advice and views of the author.
It is not to be construed as an interpretation of AAMI standards,
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Published by
Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 1-57020-595-7

Table of Contents

Preface

Every sterile processing department (SPD) strives to assign responsibilities to well-prepared employees who can demonstrate competence in the entire scope of sterile processing: decontamination, assembly, inspection, packaging, sterilization, monitoring, and storage of sterile items. Only employees with a commitment to a high level of performance can promote patient safety.

Processing instruments and equipment is an integral part of the facility's mission to provide *safe patient care*. In both inpatient and outpatient facilities, SPDs ensure that instruments and equipment used for patients will not cause injury or infection. Each individual, and every process performed in the SPD, has an impact on patient safety. SPD employees, together with clinicians who use the instruments, are partners. Safe patient care requires good communication and coordination. Our patients are everybody's business.

Competent employees make informed decisions because they know why a practice is safe and effective. They go to appropriate sources for answers and don't rely solely on information from colleagues. In addition to mastering competencies, outstanding personnel in the SPD have integrity and demonstrate accountability. Adults pursue learning for professional growth and development. A personal commitment to excellence is also essential for ensuring that we do not place our patients at risk for injury or infection.

Sterile processing competencies are relevant regardless of the venue in which you work (e.g., separate department in an acute care facility, the sterile processing area within the operating room (OR) suite, or ambulatory surgery center). Although equipment may differ from site to site, principles and best practices remain the same. Each facility should use the manufacturer's instructions for use (IFU) to create a competency checklist for each specialized item or piece of equipment for which employees will be responsible.

This manual assumes that you have been oriented to your position in the SPD and have mastered the basic skills required for your position. Contained here are evidence-based concepts that will help you achieve excellence in the SPD. Included are competency documents for each phase of sterile processing. Each facility should augment these basic competencies with competency documents crafted from the IFU for each specialized item and piece of equipment.

Module III

Cleaning and Decontamination

Cleaning refers to the removal of visible soil, and *disinfection* refers to the removal of harmful microorganisms. *Decontamination* includes both activities: *cleaning* + *disinfection* = *decontamination*.

Cleaning is the most important step in sterile processing; thorough cleaning removes most microorganisms and other organic material from contaminated items. Unless an item is clean, it cannot be effectively disinfected or sterilized. Any soil, no matter how little, can prevent disinfectant or sterilant from contacting the surface of an item. A common saying is worth remembering: *"An item can be clean but not sterile; however, no item can be sterile if it is not clean!"*

Key Concepts And Terminology

Aerosolization

Forcing microorganisms into the air on tiny droplets by spraying or splashing water while cleaning contaminated instruments.

Clean

Free of visible contamination.

Contaminated

A contaminant is any substance that can cause infection (pathogen), irritation, or inflammation. Pathogens on contaminated instruments can cause surgical site infections. Toxic anterior segment syndrome (TASS) is a serious inflammation of the eye caused by residual chemicals on improperly rinsed instruments. An item that is sterile is free of contaminants. When a sterile item comes in contact with any item or surface that is not sterile, it then must be considered contaminated.

Decontamination

Cleaning + disinfection = decontamination

The removal of soil and a sufficient number of microorganisms to make an item safe to handle.

Detergent

A cleaning agent.

Enzymatic cleaner

A product containing specific proteins that speed up the cleaning process.

Eye wash station/emergency shower

OSHA requires a special sink with attachment for safely irrigating eyes (see Figure III.1) and the immediate availability of a shower to wash away harmful chemicals from eyes or body wherever employees are potentially exposed to injurious materials.[7]

Figure III.1. OSHA regulations require facilities to provide an eye wash station and an emergency shower wherever employees are exposed to chemicals. The stations must be checked regularly to ensure that they are functioning properly.

Instrument tracking

Some facilities have tracking systems that can serve as a valuable resource for SPD personnel. The system might be programmed with the contents of each instrument set so that count sheets can be printed. Set labels can be printed with all the information required to identify the set, when it was assembled, and by whom (see Figure III.2). The label can be

[7] Occupational Safety and Health Administration. 29 CFR 1910.151(c). Available at: www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9806. Accessed June 4, 2015.

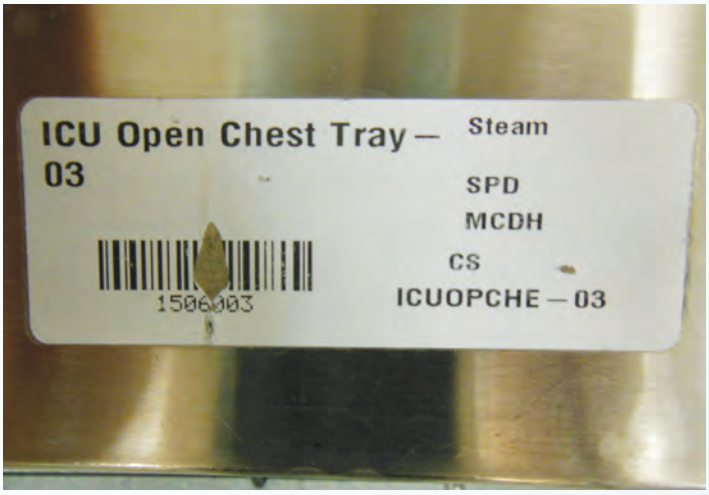

Figure III.2. An instrument tracking system allows every set to be scanned at each step on its journey. If you search for the set, its current location will show up on the computer. Right now, this set is in decontam. The package label was removed at the point of use. This label is on the set itself and includes the set name, type of sterilization required, and location in storage.

scanned at each step in the process (e.g., arrival in decontam, prep and packaging, sterilization, storage, on case cart pulled for a procedure, in OR suite). A search of the system will indicate exactly where the set was last scanned. The printed label for a set might also include its location in storage so it can be retrieved and returned easily. A tracking system can enhance practice in the SPD in a variety of ways.

Lubrication

Lubricating surgical instruments with a water-based lubricant (sometimes called "instrument milk" because of its cloudy white coloration) helps to decrease friction between working surfaces, keeping hinges and box locks working smoothly.

Negative pressure environment

Cleaning is done in a negative pressure environment where employees wear proper PPE. The air outside of decontam has a higher pressure than inside the room. The outside air pushes inward, keeping the air inside the room from escaping into areas where people are not wearing proper PPE. To maintain the negative pressure, the doors to decontam must remain closed. Microorganisms from contaminated instruments, supplies, and equipment that escape into the air are trapped inside the decontamination room and are removed by the air filtering system.

Prion

A rare infectious protein that causes a disease of the brain that is incurable. Prions are resistant to chemical disinfection and routine sterilization procedures. Items used on a patient with known or suspected prion disease must be managed according to a specific protocol.[8]

Reverse osmosis

A popular system for producing treated water by removing harmful chemicals.

Spaulding classification

In the 1970s, a physician named Earle H. Spaulding suggested that the level of preparation of an item should be based on the degree of risk of infection when it is used on the patient. Spaulding organized items into three categories[9]:

1. **Critical** items (e.g., instruments for surgical procedures) must be sterile because they are used in sterile tissue and the vascular system, where the risk for infection is highest.

2. **Semicritical** items (e.g., anesthesia equipment and scopes for endoscopy or cystoscopy) contact mucous membranes or nonintact skin, which are more resistant to infection. These items are prepared with high-level disinfection.

[8] Rutala WA, Weber DJ; Society for Healthcare Epidemiology of America. Guideline for disinfection and sterilization of prion-contaminated medical instruments. *Infect Control Hosp Epidemiol.* 2010;31(2):107–17.

[9] Rutala W, Weber C (HICPAC). *Guideline for Disinfection and Sterilization in Healthcare Facilities.* Centers for Disease Control and Prevention, Atlanta, GA. 2008:10–11. Available at: www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed June 4, 2015.

3. **Noncritical** items contact intact skin, the body's best defense against infection, and therefore pose the lowest risk for infection. Noncritical items like wheelchairs, crutches, blood pressure cuffs, and computers require only low-level disinfection. Environmental surfaces are also considered noncritical and require low-level disinfection.

Strikethrough

When liquid that potentially contains microorganisms passes through a protective barrier. For instance, if clothing under a gown worn for protection becomes wet, strikethough has occurred. Another example is moisture that accumulates at a point of pressure on the wrapping of a sterilized package that has not yet cooled.

Treated/distilled water

Water that contains no chemicals that can damage instruments or cause patient reactions (see TASS under "contaminated" definition).

Ultrasonic cleaner (cavitation)

A machine in which ultrasonic waves pass through the cleaning solution, creating millions of bubbles that burst when they contact metal. Bursting bubbles create a vacuum (negative pressure) that pulls soil from instruments. This process is called *cavitation*. Ultrasonic cleaners are used to remove soil from delicate instruments with joints and crevices that are hard to clean. Ultrasonic cleaning loosens debris but does not kill microorganisms.

Washer/decontaminator/disinfector

Mechanical cleaning machines designed to process instruments and equipment to a level that makes them safe for handling by SPD personnel. Washers take items through a series of phases in the cleaning process, such as cool water rinse, enzymatic rinse, detergent wash, hot water rinse, final rinse with treated water, and drying cycle. Some washers also include an ultrasonic cycle. The washer is loaded in decontam and unloaded from the opposite end, which opens into the prep and packaging area.

Workflow

The SPD is designed for efficiency, to promote safety, to minimize environmental contamination, and to maintain the sterility of processed items. Contaminated items and personnel in the contaminated area (decontam) are kept separate from clean areas. When working in decontam, you must put on appropriate PPE. When leaving, you must remove PPE to prevent carrying contamination into clean areas. Keep doors to the decontamination area and any pass-through windows connecting decontam to the packaging area closed at all times.

Considerations For Excellence

Items arriving in decontam are contaminated with potentially harmful microorganisms. Protecting employees and the environment from exposure to these microorganisms is important. Microorganisms are contained by the negative pressure of the decontamination area and removed by the air handling system. Keep the doors to the decontam closed, and try to keep traffic in and out of decontam to a minimum.

Employees in the decontamination area wear personal protective equipment to protect them from exposure to harmful microorganisms and chemicals. PPE includes anything needed to keep microorganisms and chemicals from touching or entering the body. Wearing a fluid-resistant gown, gloves, head cover, mask, goggles, or face shield, and perhaps shoe covers, will keep you safe from exposure. If your clothing becomes wet under the gown (strikethrough), take the time to change clothes. If exposure occurs, an eye wash station or emergency shower should be used immediately.

We can assess visible contamination by examining items carefully, but microorganisms are invisible so we consider items contaminated even when we cannot see any soil. In healthcare, all items that are opened for a procedure (even those that do not come in contact with the patient) are considered contaminated and potentially infectious. Used and unused items are cleaned and disinfected at the same time. Cleaning is not microbicidal (it does not kill microorganisms); however, thorough cleaning reduces the number of microorganisms (the microbial load) to the point that items can be handled safely.

One important aspect of cleaning and decontamination of soiled items is to contain the microorganisms to protect personnel and the environment from exposure to infectious material. The CDC's *Standard Precautions* remind us that all items used on patients are considered contaminated and potentially infectious. Everything you learn about sterile processing— including how to prepare, contain, and transport contaminated items; how to choose the right personal protective equipment; and how to perform each procedure properly—is designed to keep microorganisms from getting into the air, from contacting skin, and from remaining on equipment and work surfaces. Containing microorganisms will protect you, your colleagues, and ultimately patients from infection.

At the point of use, any sterile item that has been opened (removed from its barrier protection) is considered contaminated, even if it has not been used for direct patient care. When an instrument set is opened, all of the contents are considered contaminated, even the instruments that remain in the tray and do not come in contact with the patient. When the tray is returned to the SPD, all of the instruments (used and unused) must be cleaned, disinfected, and inspected. Obviously, the used ones will have bioburden and will require more rigorous cleaning, but the process remains the same for all items.

Cleaning should begin as soon as possible after the items have been used to prevent soil from hardening and becoming very difficult to remove and to prevent the formation of biofilm. When instruments arrive in the SPD, they are sorted according to how they need to be cleaned. This is also a good time to be wary of surgical blades and other sharps that were not removed at the point of use and to identify instruments that must be handled with special care.

Everything is rinsed or wiped down before continuing through the cleaning process. Utility items like basins with smooth surfaces will not need the complex cleaning procedures that surgical instruments require. Items with sharp points or sharp edges must be handled with extra care. Items such as certain cameras and pneumatic drills cannot be immersed in liquid; others cannot tolerate high temperatures. The best resource for determining how best to manage an item is the manufacturer's IFU.

Maintaining the cleanliness of equipment is essential. After manual cleaning and inspection, sturdy items like carts and basins and trays of basic instruments can go into automated washers, cart washers, and washer-sanitizers. If a cart washer is not available, remove all visible soil from the cart and clean it according to the IFU. Automatic washers have drain screens that collect debris during the wash cycle. These drains must be cleaned frequently or the collected debris will interfere with the cleaning process.

Instruments should first be rinsed with cool running water to remove as much visible debris as possible. Instruments that are intended to be disassembled, but were not taken apart at the point of use, should be disassembled before the cleaning process begins. Be careful to keep all of the parts together.

A three-part sink is very convenient for items washed by hand. The first basin contains an appropriate detergent, the second is for rinsing, and the third basin is for the final reverse osmosis or treated water rinse to remove any chemicals from tap water.

There are mechanical washers designed for specific instruments and equipment. For example, ultrasonic washers are designed to clean delicate instruments and cannula washers are made for cleaning cannulated instruments. Robotic instrumentation, endoscopic instruments, laser instruments, power equipment, and rigid and flexible endoscopes require specialized protocols or specific equipment for cleaning. The design of a device and the degree of bioburden determines whether cleaning is done manually with a cleaning agent, brushes, and sponges, or mechanically in an automatic washer or ultrasonic cleaner.

Not all SPDs have all of this specialized equipment, but the responsibilities associated with effective sterile processing are the same everywhere. Your facility will have a procedure for managing each specialty item properly, and an IFU should be available for each piece of equipment in your area.

Manual Cleaning

The first step in the cleaning process is a cool water rinse to remove as much bioburden as possible. Bioburden can be rinsed from some items under running water; other items like power cords and electrical equipment must be wiped clean by hand. Handle items in a manner that keeps contamination under control. Avoid splashing and spraying. Place items gently in the sink to soak. When flushing lumens, hold the instrument and syringe or brush under the surface of the water to prevent splashing and spattering that will carry microorganisms into the air (aerosolization). Similarly, when using a brush to clean instruments, hold the brush and instrument under the surface of the water or under running water.

After rinsing, immerse instruments in warm water with an appropriate detergent to loosen debris in hard-to-clean nooks and crannies like serrations, box locks, and joints. Many powered instruments cannot be submerged in liquid. These instruments and their attachments can be sprayed in an empty sink as long as water does not collect in the bottom of the sink. Using a colander or strainer for batteries and attachments is an innovative way to ensure that the instruments will be held above the water level during rinsing. Disinfectant wipes can be used to clean cameras and batteries. Avoid hot water for cleaning anything soiled with blood. Meticulous manual cleaning is essential. The effectiveness of disinfection and sterilization is dependent on how well you clean each item. Remember: *an item can be clean, but not sterile; an item can never be sterile if it isn't clean!*

Cleaning solutions should be replaced often. It makes little sense to wash items in dirty water. Solutions for instruments are gentle and low sudsing. Nonabrasive cleaning supplies (no harsh cleaners or steel wool pads) are best for safe and effective sterile processing. One exception is the wire brush for cleaning gross soil from sturdy instruments like bone rasps. The IFU will describe the correct brush (the right size, length, and stiffness) for each instrument. Dirty supplies can transfer microorganisms from one item to another. The IFU for brushes will describe whether they are disposable or require decontamination.

Flush items with lumens with a syringe or powered cannula sprayer. Use a soft brush large enough to fill the lumen to brush debris from the lumen walls. When the lumen is free of debris, flush with treated water and dry with forced air.

Rinse cleaned items again to remove loosened debris. You can use tap water until the item is visibly free of debris, then use treated water for the final rinse. Rinsing takes lots of water, so using treated water for the entire process would be very expensive. The final rinse with treated water is important. Incomplete rinsing of eye instruments can cause TASS—toxic anterior segment syndrome—a severe inflammation of the patient's eye that can interfere with vision. Chemicals in tap water can contribute to staining, and biofilm can attach to impurities in the water. Before moving to the next phase of processing, inspect each item carefully to verify that no visible debris remains.

Delicate and complex instrumentation such as microsurgical instruments or instruments with lenses usually are cleaned by hand. Items that cannot be immersed in liquid must be carefully wiped with a cleansing agent and dried thoroughly. Remember, when you are not sure how an item should be handled, consult the manufacturer's IFU.

Ultrasonic Cleaner

Delicate metal instruments can be cleaned in an ultrasonic cleaner. Ensure that the water is clean and that you are using the correct detergent for the machine. Lumens must be filled with cleaning solution, as the presence of air interferes with cavitation.

To prevent aerosolization of contaminants, the lid must be in place during the cleaning process. AAMI recommends emptying, cleaning, rinsing, drying, and refilling the ultrasonic cleaner at least once per day or, preferably, after each use. When filling the ultrasonic cleaner, *degassing* the water to remove air and improve cavitation is sometimes necessary. Consult the manufacturer's IFU to determine if, when, and how this process should be done.

Instruments should be positioned in a single layer, not stacked. When more metal is present during the cleaning process, cavitation is decreased and the cleaning is less effective. Rinse items thoroughly with treated water when they come out of the ultrasonic cleaner to remove the debris that has been dislodged by cavitation.

Only instruments of the same type of metal should be placed in the ultrasonic cleaner at one time; ions from one type of metal can damage other metals during the cleaning process. Items that should never be placed in an ultrasonic cleaner include chrome-plated instruments; powered instruments; rubber, silicone, or plastic; and endoscope lenses.

Lubrication

After instruments are thoroughly clean and dry, those that have moving parts should be immersed in a water-soluble lubricant bath. Placing wet instruments into a lubricant bath dilutes the product and decreases its effectiveness. Applying lubricant to soiled instruments can compound the problem of stiff joints and inhibit smooth movement.[10]

The lubricant solution is sometimes called "instrument milk" because of its cloudy white coloration. The IFU for the lubricant will tell you how long to soak the instruments. Inspect instruments as you remove them from the bath. If a hinged instrument is stiff, open and close it several times to lubricate the joint. If this does not improve the function, set the instrument aside for repair.

Oil-based lubricants can interfere with the sterilization process. The sterilant cannot penetrate the oil and therefore does not come in contact with all surfaces of the instrument. Lubricants containing oil are used only to lubricate the internal mechanism of powered instruments when specified by the manufacturer.

Drying

All instruments must be thoroughly dry at the end of the cleaning process. If instruments coming out of the washer-decontaminator/disinfector are wet, they must be dried prior to inspection and assembly. Moisture can impede the processes of disinfection and sterilization. In some cases, like with ethylene oxide (EtO) sterilization, moisture combines with the sterilant to create a toxic byproduct that can remain on the instruments and cause harm to patients. Moist items in a hydrogen peroxide plasma sterilizer will cause the sterilization cycle to fail.

Specialty Items

Pay close attention to IFUs for all specialty items, such as powered equipment, cameras and lensed instruments, light cords, laser instruments, and robotic instruments. The instructions might be quite extensive and include steps that are different from routine sterile processing. For instance, an item might require a specific water pressure for rinsing, or the item might not be able to withstand high-temperature sterilization. This type of equipment is cleaned and sent directly to prep and packaging, bypassing the washer (see Figures III.3A and III.3B).

[10] Occupational Safety and Health Administration. 29 CFR 1910.151(c). Available at: www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9806. Accessed June 4, 2015.

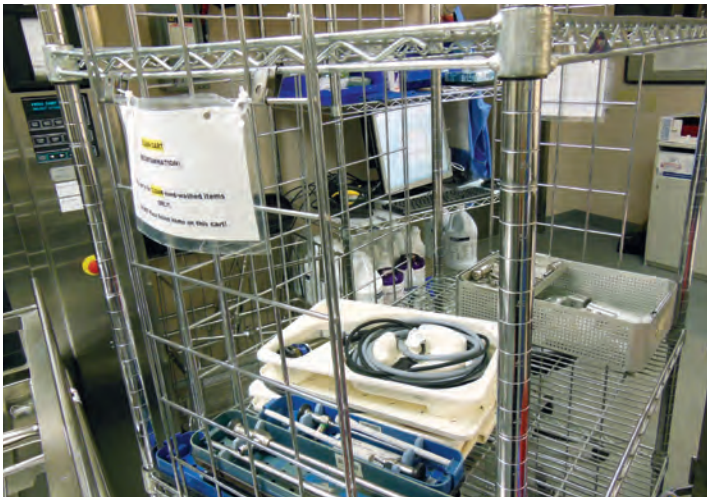

Figure III.3A. Specialty instruments that have been manually cleaned are kept separate from dirty items.

Figure III.3B. Labels with clear instructions can prevent costly, time-consuming mistakes.

Powered equipment (i.e., devices powered by batteries, electricity, or pneumatic air) must be decontaminated, lubricated, assembled, and tested by hand prior to packaging for sterilization. Most powered equipment cannot be placed in an automatic washer, immersed, or cleaned with running water. IFUs will provide instructions for each step in the process. Powered equipment can be very expensive, and improper handling can be costly. Debris not removed during cleaning can interfere with function.

Drills and saws may have a retractable collet that holds the bit or blade in place. As blood and debris can get under the collet during surgery, pull it back and clean the area underneath. Place trigger handles in the "safe" position when you change attachments. Use the correct pressure settings for testing, as the equipment may not function properly at settings that are higher or lower than recommended. Be sure to package the correct battery with battery-operated equipment. Improperly assembled equipment can malfunction and cause significant injury to the patient.

Prions and Creutzfeldt-Jakob Disease

Prions are highly contagious and resistant to routine protocols for decontamination and sterilization. When a surgical patient is known or suspected to have a prion disease such as Creutzfeldt-Jakob disease (CJD), disposable equipment or equipment that is relatively easy to clean should be used. Special precautions must be taken with prion-contaminated items.[11] Procedures involving prions are rare, and technologies for managing CJD-contaminated items are changing rapidly. The policy at your facility should reflect the most recent evidence and recommended protocol for cleaning, disinfecting, and sterilizing instruments used in these procedures.

[11] Occupational Safety and Health Administration. 29 CFR 1910.151(c). Available at: www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9806. Accessed June 4, 2015.

Competency Checklist

AAMI
Nov 2015

CLEANING AND DECONTAMINATION

Date		Reviewer	
Employee Name			

3 = Outstanding **2 = Acceptable** **1 = Improvement Required**

When improvement is required, document the action plan for performance improvement with target dates for reassessment.

General considerations for working in the decontamination area		3	2	1
1	Dons appropriate PPE			
2	Removes and discards PPE without contaminating self or environment			
3	Keeps doors and pass-through windows closed (negative pressure environment)			
4	Locates IFUs for each piece of equipment and cleaning agents			
5	Demonstrates proper use of eye wash station and shower			
6	Follows IFU for preparing solutions (e.g., enzymatic, sonic, washer/disinfector)			
7	Changes solutions when they are soiled			
8	Uses and maintains cleaning equipment (e.g., brushes, power rinse) according to IFU			
9	Loads and operates equipment (e.g., ultrasonic machine, automated washers, cart washer) according to IFU			

Receives and processes contaminated items		3	2	1
1	Inspects trays for disposable sharps			
2	Removes and discards trash and linen from instrument trays			
3	Removes baskets from rigid containers			
4	Opens hinged instruments and arranges instruments in baskets or trays for exposure of all surfaces to cleaning solutions			
5	Segregates cannulated instruments			
6	Disassembles any instruments not disassembled at the point of use			
7	Places carts in cart washer			

Processes immersible items		3	2	1
1	Places immersible instruments in enzymatic or detergent bath			
2	Uses nylon or wire brush to remove debris from serrations			
3	Rinses cannulated instruments with pressure sprayer or syringe (prevents aerosolization)			
4	Rinses items thoroughly; final rinse with treated water			
5	Places items in automatic washer			
6	Uses ultrasonic washer for delicate instruments and instruments with challenging bioburden (e.g., laparoscopic instruments without lenses)			

Processes instruments that cannot be immersed		3	2	1
1	Wipes down items that cannot be immersed according to each item's IFU (e.g., cords, cameras, lensed instruments, rigid and flexible telescopes, robotic instrumentation, endoscopic instrumentation, batteries)			
2	Flushes cannulated items (e.g., rigid scopes)			
3	Cleans debris from jaws of laparoscopic scissors, graspers, needle holders			

Special needs cleaning		3	2	1
	Each facility should create a competency checklist for each special needs item or category of items based on its IFU			

Comments/Action Plan

Employee Signature	
Reviewer Signature	

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Nov 2015

Sterile Processing

Knowledge, Skills, Competencies

Terri Goodman, PhD, RN

Processing instruments and equipment plays an integral part in achieving every healthcare facility's mission to provide safe patient care. Each individual, and every process performed in the sterile processing department (SPD), has an impact on patient safety. Demonstrating and assessing competencies permit everyone in the SPD to insure that the instruments and equipment used for patients will not cause infection.

Achieving competence means that we understand why we do what we do. That's not the same thing as just doing what we're told. Competent employees are prepared to make informed decisions because they know where to find the answers to "How do I do this?" or "Why should I do it this way?"

Designed for both technicians and managers, *Sterile Processing—Knowledge, Skills, Competencies* is organized into modules that describe the key terms and principles critical to sterile processing. This resource provides new (and maybe not-so-new) employees with the evidence needed to make the right decision every time they face a question about instrument processing in each of the essential areas:

- Point of use/transporting soiled instruments
- Cleaning and decontamination
- Assembly and packaging
- Sterilization
- Sterilization monitoring
- Storage

A series of eight competency checklists, included at the end of each module, provides valuable tools for managers who wish to assess their staff members' performance in safe sterile processing at every step of the way.

About the Author

Terri Goodman, PhD, RN, CNOR, is a perioperative nurse and active member of the Association of periOperative Registered Nurses (AORN). As director of education at Johnson & Johnson Medical, Dr. Goodman participated in the development of a postgraduate course designed to establish sterilization and disinfection as a professional specialty in Latin America. She believes strongly that SPD and OR employees must become true partners in the delivery of safe patient care. Dr. Goodman is the editor of Essentials of Perioperative Nursing, *and the recipient of AORN's 2014 Jerry G. Peers Distinguished Service Award.*

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