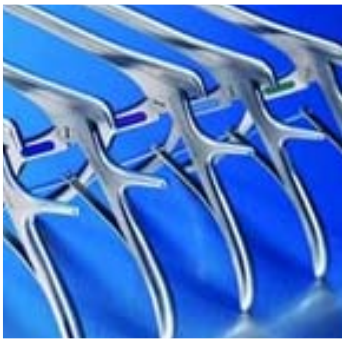
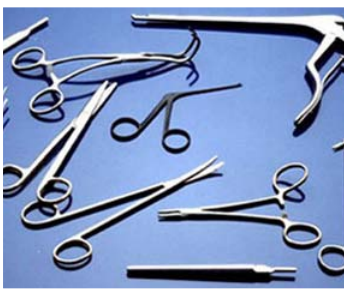
The Care and Handling of Surgical Instruments

(An Online Continuing Education Activity)





A Continuing Education Activity

Sponsored By

Pfiedler ENTERPRISES

Welcome to

THE CARE AND HANDLING OF SURGICAL INSTRUMENTS

(An Online Continuing Education Activity)

CONTINUING EDUCATION INSTRUCTIONS

This educational activity is being offered online and may be completed at any time. We suggest you take the following steps for successful completion:

1. Read the overview and objectives to ensure consistency with your own learning needs and objectives.
2. Review the content of the activity, paying particular attention to those areas that reflect the objectives.
3. Complete the Test Questions and compare your responses with the answers provided.
4. For additional information on an issue or topic, consult the references.
5. To receive credit for this activity complete the evaluation and registration form.
6. A certificate of completion will be available for you to print at the conclusion. Pfiedler Enterprises will maintain a record of your continuing education credits and provide verification, if necessary, for 7 years.

If you have any questions, please call: 720-748-6144.

CONTACT INFORMATION:

Pfiedler ENTERPRISES

2101 S. Blackhawk Street, Suite 220
Aurora, CO 80014-1475
Phone: 720-748-6144
Fax: 720-748-6196
Website: www.pfiedlerenterprises.com

THE CARE AND HANDLING OF SURGICAL INSTRUMENTS

(An Online Continuing Education Activity)

OVERVIEW

The purpose of this educational activity is to provide information on care and handling of surgical instruments in an effort to enhance patient care and safety. The focus of this self-study activity is to review the process beginning with point of use care and ending with quality control methods. The application of recommended instrument handling and maintenance procedures are critical to ensure the long life of surgical instruments. Guidelines for the care and maintenance of surgical instruments are provided, along with recommendations for the proper handling of these items. Methods for the decontamination, sterilization, and high-level disinfection of surgical instruments are discussed in detail. A post-test will provide an opportunity for immediate feedback regarding you grasp of the information presented.

OBJECTIVES

Upon completion of this self-study activity, the learner should be able to:

1. Describe the steps in the precleaning and transport of surgical instruments.
2. Outline procedures for decontamination of surgical instruments.
3. Discuss all of the methods of sterilization for surgical instruments.
4. Differentiate high-level disinfection and sterilization.
5. Explain the rationale for a quality control program in your practice setting.

INTENDED AUDIENCE

This continuing education activity is intended to be used by healthcare professionals involved in the handling, cleaning, decontamination, sterilization, and high-level disinfection of surgical instruments.

CREDIT/CREDIT INFORMATION

State Board Approval for Nurses

Pfiedler Enterprises is a provider approved by the California Board of Registered Nursing, Provider Number CEP14944, for **2.0 contact hour(s)**.

Obtaining full credit for this offering depends upon completion, regardless of circumstances, from beginning to end. Licensees must provide their license numbers for record keeping purposes.

The certificate of course completion issued at the conclusion of this course must be retained in the participant's records for at least four (4) years as proof of attendance.

AST Credit for Surgical Technologists

This continuing education activity is approved for **4.25** CE credits by the Association of Surgical Technologists, Inc., for continuing education for the Certified Surgical Technologists and Certified Surgical First Assistant. This recognition does not imply that AST approves or endorses any product or products that are discussed or mentioned in enduring material.

CBSPD

The Certification Board for Sterile Processing and Distribution (CBSPD) has approved this program for **2.0 contact hours**.

IAHCSMM

The International Association of Healthcare Central Service Materiel Management has approved this educational offering for **2.0 contact hours** to participants who successfully complete this program.

IACET Credit for Allied Health Professionals

Pfiedler Enterprises has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102.

CEU STATEMENT

As an IACET Authorized Provider, Pfiedler Enterprises offers CEUs for its programs that qualify under ANSI/ IACET Standard. Pfiedler Enterprises is authorized by IACET to offer **0.2 CEU (2.0 contact hours)** for this program.

RELEASE AND EXPIRATION DATE

This continuing education activity was planned and provided in accordance with accreditation criteria. This material was originally produced in September 2011 and updated May 2012 and can no longer be used after May 2014 without being updated; therefore, this continuing education activity expires in May 2014.

DISCLAIMER

Accredited status as a provider refers only to continuing nursing education activities and does not imply endorsement of any products.

SUPPORT

Grant funds for the development of this activity were provided by **CareFusion.**

PLANNING COMMITTEE/REVIEWERS

Judith I. Pfister, RN, BSN, MBA — **Aurora, Colorado**
Program Manager
Pfiedler Enterprises

Julia A. Kneedler, RN, MS, EdD — **Aurora, Colorado**
Director of Education
Pfiedler Enterprises

Rose Moss, RN, MN, CNOR — **Larkspur, Colorado**
Nurse Consultant
Moss Enterprises

Penny Austin, CST — **Aurora, Colorado**
Surgical Technologist
Aurora Medical Center

DISCLOSURE OF RELATIONSHIPS WITH COMMERCIAL ENTITIES FOR THOSE IN A POSITION TO CONTROL CONTENT FOR THIS ACTIVITY

Pfiedler Enterprises has a policy in place for identifying and resolving conflicts of interest for individuals who control content for an educational activity. Information listed below is provided to the learner, so that a determination can be made if identified external interests or influences pose a potential bias of content, recommendations or conclusions. The intent is full disclosure of those in a position to control content, with a goal of objectivity, balance and scientific rigor in the activity.

Disclosure includes relevant financial relationships with commercial interests related to the subject matter that may be presented in this educational activity. **"Relevant financial relationships"** are those in any amount, occurring within the past 12 months that create a conflict of interest. A **"commercial interest"** is any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients.

Activity Planning Committee/Authors/Reviewers:

Rose Moss, RN, MN, CNOR
No conflicts of interest

Judith I. Pfister, RN, BSN, MBA
Co-owner of company that receives grant funds from commercial entities

Penny Austin, CST
No conflicts of interest

Julia A. Kneedler, RN, MS, EdD
Co-owner of company that receives grant funds from commercial entities

PRIVACY AND CONFIDENTIALITY POLICY

Pfiedler Enterprises is committed to protecting your privacy and following industry best practices and regulations regarding continuing education. The information we collect is never shared for commercial purposes with any other organization. Our privacy and confidentiality policy is covered at our website, www.pfiedlerenterprises.com, and is effective on March 27, 2008.

To directly access more information on our Privacy and Confidentiality Policy, type the following URL address into your browser: http://www.pfiedlerenterprises.com/privacy-policy

In addition to this privacy statement, this Website is compliant with the guidelines for internet-based continuing education programs.

The privacy policy of this website is strictly enforced.

CONTACT INFORMATION

If site users have any questions or suggestions regarding our privacy policy, please contact us at:

Phone:	720-748-6144
Email:	tonia@pfiedlerenterprises.com
Postal Address:	2101 S. Blackhawk Street, Suite 220 Aurora, Colorado 80014
Website URL:	http://www.pfiedlerenterprises.com

INTRODUCTION

Every year, patients in healthcare institutions across the country contract healthcare-associated infections (HAIs) that require extended hospital stays and increased use of antibiotics. Such infections can cause patients great discomfort and adversely impact the overall quality and cost of healthcare. Healthcare facilities strive to lower the incidence of HAI by implementing surveillance programs and policies and procedures that aid in breaking the chain of infection.

The number of surgical procedures performed continues to grow, and surgical instruments become more and more complex. Consequently, the risk that a surgical patient may come in contact with an unsterile or improperly cared for instrument continues to increase. Such contact may result in an unfavorable outcome for the patient and a financial burden for the institution.

Many HAIs can be prevented by hospital personnel who are diligent and conscientious when carrying out their duties and responsibilities with regard to the care of surgical instrumentation. Instrument care is an ongoing process that is repeated every time an instrument is used in surgery and returned for reprocessing. It begins with proper handling of instruments at the point of use and proceeds through precleaning, transport to the decontamination area, cleaning, decontamination, inspection and repair, packaging (if appropriate), sterilization (or high-level disinfection), and sterile storage.

In addition to patient safety, which is the primary rationale for proper care of instruments, advantages to properly caring for surgical instrumentation include the following:

- Decreased instrument repair and replacement costs
- Increased instrument longevity
- Potential reductions in instrument inventory

CARE AND HANDLING

Throughout all phases of handling and processing surgical instruments, it is important to carefully observe the following guidelines:

- Know the proper name and intended use for each instrument. Hand the surgeon the correct item for each task. Most instrument damage is caused by inappropriate usage.
- Pass and place delicate-tipped instruments carefully, making sure not to drag across draping material. Rinse off blood and debris after each use, using a nonfibrous sponge to prevent snagging and breaking of delicate instrument tips.
- Remove any loose instruments from the sterile field and place them on the Mayo stand or instrument table. This prevents extraneous instruments from injuring the patient or falling to the floor.
- After the procedure, place used instruments, except sharps and delicate items, in a tray or basin. Avoid carelessly throwing or dropping any instrument.

- Place reusable sharps and delicate instruments in separate containers, such as emesis basins or mesh bottom trays.
- Place heavier items on the bottom on the tray, with smaller, lighter instruments on top.
- Remove defective instruments from the sterile field or processing area, decontaminate them, and label them for repair. (Note: All instruments from the sterile field need to be decontaminated before being repaired.)
- Protect sharp edges of instruments during handling, cleaning, sterilization, and storage.
- Separate sharp instruments (e.g., scissors or osteotomes) from dull instruments (e.g., hemostats, forceps, or retractors) during processing.

POINT-OF-USE CARE

Effective instrument processing begins at the point of use—during the surgical procedure. To prevent blood, soil, or any protein-containing material from drying on instruments, and/or to soften and remove dried blood and soils, remove gross blood and debris from instruments immediately after use by wiping with a damp gauze sponge that has been moistened with sterile water.[1]

After wiping, separate delicate and sharp instruments, especially those used in eye and microsurgical procedures, from heavier items. Open all hinges and box locks and place instruments in mesh trays or baskets. Submerge the instruments in a soaking solution (tap water, enzymatic solution, mild neutral detergent solution, or disinfectant solution) or spray with an instrument presoak. Be sure to select a product that is safe and indicated for use on surgical instruments. Do not immerse or soak instruments in saline, which tends to corrode or pit instrument surfaces. When disposal at the point of use is not feasible, containing the solution will prevent spills. If items are soaked in water or an instrument cleaning solution at the point of use, the liquid should be contained or discarded before transport. Instruments may be covered with a moist towel for transportation.[2]

TRANSPORT

Following any surgical procedure, all of the instruments opened for the case are considered contaminated. Therefore, they must be properly contained and properly labeled in leak-proof containers (i.e., plastic bags or closed containers/carts) for transfer from the operating suite to the decontamination area of the central services department, where they will be rendered safe for further handling.

Do not allow instruments to dry during the transport process. Dried soils will adhere to surgical instruments, making them very difficult to clean. Soak instruments in an enzyme solution or spray with a presoak product before and/or during transport.

If a cart system is used for transporting soiled instruments, cover or close the cart before transporting it to a central decontamination area. Clean the closed cart with a suitable

disinfectant before taking it out of the OR suite. If possible, transport loaded carts through the outer corridor of the operating room suite.

CLEANING/DECONTAMINATION

All soiled medical devices and equipment must enter the central services department through a decontamination area. “Decontamination” is defined as a physical or chemical process that reduces the number of microorganisms on inanimate objects to a level that makes those objects safe for handling by personnel who are not wearing protective apparel.

To prevent transfer of microorganisms from personnel to items being processed, personnel working on the clean side of the reprocessing department should wear clean scrub attire, durable shoes with nonskid soles, and a surgical-type hair covering or hood; they should not wear jewelry. To protect themselves from pathogenic microorganisms that may be on the items they are processing, personnel who clean and decontaminate surgical instruments must wear protective attire appropriate for the tasks they are performing. General-purpose utility gloves, a liquid-resistant covering with sleeves, a high-filtration efficiency face mask, eye protection, and disposable shoe covers should be worn at all times.[3]

Decontamination can be done manually or mechanically or with a combination of both methods. It typically involves the use of a chemical cleaning solution.

Cleaning Solutions

- The most common chemical cleaning products used in the decontamination area include:[4]
- Enzymatic products, which are organic substances (usually buffered to about pH 7.6) that assist in the breakdown of organic soils. Enzymes are typically used for soaking solutions in the precleaning process but can also be used in automated washers. Always follow the manufactures recommendations for the correct amount and temperature of water.
- Detergents for manual cleaning, which are concentrated surfactant solutions with a neutral pH of 7 to 9. They should also be soluble in cool water and be free rinsing. Avoid detergents that foam excessively as they make it difficult to see through the water where sharp instruments have been submerged. Ultrasonic cleaners, which are generally liquid products, should be low foaming to prevent interference with the cavitation process.
- Detergents and other chemicals designed for automatic washing equipment, which should be liquid for easy dispensing and should be compatible with the specific washer system. Some washers use neutral or alkaline detergents and enzymes, while others work best with high-alkaline detergents and mild acidic rinses. Consult detergent and equipment manufacturers to identify the best product for your equipment.[5]

Manual Cleaning

Although mechanical cleaning with an automated washer/decontaminator or washer/sterilizer is the preferred method of decontamination, some instruments cannot tolerate mechanical cleaning and will need to be manually cleaned. Instruments that must be manually cleaned include some delicate microsurgical instruments, powered instruments (e.g., orthopaedic saws and drills), rigid and flexible endoscopes, and electronic cables and probes.

Take the following steps for the manual cleaning of medical instruments:

1. Fill a sink or basin with cool to tepid water containing an enzyme or detergent designed for manual cleaning.
2. Carefully remove instrument trays from transport carts, containers or plastic bags. Watch for sharp edges or instrument parts that can penetrate gloves. Make sure that all hinged instruments are wide open and that instruments with removable parts are disassembled.
3. Rinse instruments under cold water to remove gross debris.
4. Submerge instruments in the detergent solution.
5. Clean the items while submerged to avoid splashing and spraying. Use soft-bristle brushes, pipe cleaners, and other cleaning tools to remove soil from hard-to-reach places like joints, hinges, and serrations. Do not use abrasive powders or soaps, steel wool, or other abrasive scouring pads, which will damage the protective coating on the surface of the instrument. Flush cannulated parts or items while submerged, using tube brushes if necessary. If reusable brushes are used for cleaning, they should be decontaminated at least daily to prevent cross contamination.[6]
6. If debris has been allowed to dry on the surface, soak instruments to remove adherent soil.
7. Rinse thoroughly. Again, flush all lumens and be sure the water rinses clean all joints, serrations, and hinges. Rinse all detergent residue.
8. Rinse again in deionized water and dry thoroughly to prevent spotting. (Tap water may contain mineral salts and other contaminants that remain on items after drying and can result in instrument staining.)

Mechanical Cleaning

For most types of instruments, mechanical cleaning is preferred over manual cleaning because it minimizes handling by healthcare workers, thus reducing the risk of exposure to infectious materials. Mechanical cleaning equipment for instruments includes utensil washers, washer/sanitizers, washer/disinfectors, washer/decontaminators, and washer/sterilizers. Mechanical cart washers are available for case cart reprocessing.[7]

Mechanical washing equipment cleans by a process called impingement. The water forced through nozzles on rotating spray arms onto the surface of the instrument aids in removing soils. Washers can be single-chambered or multichambered. They have several cycles to ensure that the instruments are properly cleaned, rinsed, and lubricated. Modern tunnel washers typically have a cold prerinse, an enzymatic rinse, an ultrasonic wash, a spray

wash and rinse, a deionized water rinse with instrument lubricant, and a drying cycle. Some automatic washers (washer/disinfectors) also incorporate a chemical disinfectant cycle.

NOTE: Heat-, moisture-, and pressure-sensitive instruments, such as powered surgical instruments, lensed instruments and microsurgical instruments, should not be placed in automated washing equipment. Follow the manufacturer's instructions when processing these devices.

Ultrasonic Cleaning

Some automated multichamber tunnel washer/decontaminators include an ultrasonic chamber. The sonic is usually the first "wash" cycle on the system. Ultrasonic cleaners should be used only after gross soil has been removed.[8]

Ultrasonic cleaners clean by a process called cavitation. The ultrasonic waves generate tiny bubbles, which eventually implode (collapse inward), causing minute vacuums that lift soil from the surface of the instrument. They are used to remove soil from joints, crevices, lumens, and other difficult-to-clean areas.

NOTE: Do not process delicate microsurgical instruments, plated instruments, rigid endoscopes, or powered surgical instruments in an ultrasonic cleaner, as they may be damaged by mechanical vibrations. Metal lumened instruments may be ultrasonically cleaned if the lumens are free of air. Some ultrasonics have adapters that attach to devices to ensure air removal and total filling of the lumens.

When processing instruments in an ultrasonic cleaner, take the following steps:

1. Separate instruments into separate batches by metals: copper and bronze or stainless steel and silver. Ultrasonic cleaning of dissimilar metals causes ion transfer, resulting in etching and pitting.
2. Follow manufacturers' instructions regarding water temperatures. Temperatures between 27° C (80° F) and 43° C (109° F) usually are indicated for water-based cleaning solutions.[9] Temperatures above 60°C (104°F) will cause protein to coagulate and make cleaning more difficult.
3. Submerge the instruments completely for the recommended length of time. (The time required for ultrasonic cleaning depends on the type and number of instruments, the degree of contamination, the frequency and power of the ultrasonic cleaner, the type and temperature of the detergent, and the hardness of the water.[10] However, a cleaning cycle of 5 minutes is usually adequate.)
4. Thoroughly rinse items in running tap water or the automatic rinse cycle of the ultrasonic cleaner to remove finely suspended soil particles that can cling to instruments.
5. Complete a final rinse with deionized water.
6. Drain and allow instruments to dry completely, unless an ultrasonic drying cycle is available.

Change the cleaning solution in an ultrasonic unit whenever the detergent solution is visibly soiled or at least once or twice per shift. Each time the chamber is filled, the water must be "degassed" (run one cycle without instruments) to remove any air bubbles caused by the turbulence of tank filling. To degas a unit, fill the sonic cleaner, close the lid, and run it for 5-10 minutes. The lid of the sonic cleaner should be closed when the unit is operating.[11]

Lubrication

Lubrication is essential every time instruments are processed to prevent binding and excessive wear. Proper lubrication also helps instruments remain clean by preventing build-up of "baked-on" protein and mineral deposits, and by permitting a more effective detergent cleaning. Instruments can be sprayed with a lubricant in the rinse cycle of the washer/decontaminator or they can be manually dipped in an instrument lubricant. To manually lubricate clean medical instruments, take the following steps:

1. Mix a non-silicone, water-soluble instrument lubricant in distilled or demineralized water (to avoid dissolved salts). Do not use mineral oil, petrolatum, machine oils, silicone sprays, or other oils on instruments, since they can inhibit sterilization and build up in box locks and crevices.
2. Immerse open instruments for 30 to 40 seconds in a properly mixed instrument lubricant. (If removal of lubrication causes frozen box locks, immerse the instruments in the lubricant solution overnight.)
3. Let instruments drain for a few seconds to remove excess lubricant. Do not rinse with water or towel dry, for this will remove the protective lubricating film.
4. Change the instrument lubricant according to manufacturers' recommendations.

INSPECTION, REPAIR, AND ONGOING MAINTENANCE

Upon completion of cleaning and decontamination, instruments are delivered to the "clean" side of the central processing department. There, inspection and set assembly take place.

Inspection

Although inspection is an ongoing process, the time for up-close inspection is when clean instruments are being organized into sets. Routine inspection of instrumentation is important to identify minor problems before they become major ones. When inspecting surgical instruments, it is important to look for:

- Retained soil
- Misalignment
- Defects, such as bent tips, breakage, burrs, nicks, cracks, worn spots, pitting or missing pieces
- Roughness or dullness of edges
- Worn or loose box screws

- Staining
- Corrosion
- Malfunction

Inspect instruments under magnification so that damage and other problems are not missed. If you discover a defective instrument, tag it, remove it from the set and send it for repair.

Instrument Maintenance and Repair

Scheduled preventive maintenance is the best way to prolong the life of your instruments and enhance the quality of care you provide. Periodic refurbishment of surgical instruments:

- Prolongs instrument life
- Helps ensure sterility
- Maintains proper functioning
- Lowers costs for major repairs
- Minimizes downtime
- Reduces the risk of patient liability problems
- Ensures that all instruments will perform their designated tasks, reducing complaints regarding nonfunctioning instruments

On-Site Repair and Maintenance Services

Damaged instruments can be quickly repaired by an on-site repair service. Such a service allows the instruments to be repaired right at the healthcare facility—without ever leaving the premises. The availability of a qualified, factory-trained, onsite repair specialist can:

- Reduce the need for additional instrument inventory
- Prevent premature purchases of replacement instruments
- Reduce downtime
- Help prioritize, monitor and manage repair efforts
- Identify minor repair problems, thus eliminating the need for more costly major repairs
- Eliminate paperwork and shipping costs associated with factory repair centers
- Eliminate hidden or unexpected costs
- Prevent misdirected shipments or billing problems
- Allow the hospital to retain control over their instruments

When choosing an on-site repair service, look for a service that:

- Provides fast turnaround
- Has a proven track record in instrument repair
- Offers the latest in repair techniques and equipment, in addition to ongoing training
- Employs qualified experts that are fully trained and knowledgeable
- Stands behind its work with written warranties
- Provides free parts, if necessary, to complete the repair process
- Provides guaranteed pricing with no hidden charges
- Provides full-service capabilities for all types and brands of instruments
- Offers the option of prioritized inspection and refurbishing of all instrument sets
- Will advise you when repairs are not cost-effective
- Is affiliated with a major instrument manufacturer's qualified repair center
- Is available when the need arises
- Will provide in-service training on instrument care and maintenance
- Is ISO 9000 certified, ensuring consistently high-quality products and services
- Has adequate liability insurance coverage

ASSEMBLY

After careful inspection, assemble instruments into sets according to institutional procedures and the following guidelines.

- Load heavier instruments first, cover with a towel, and then place lighter instruments on top.
- If practical, wrap like metals (e.g., copper and brass or stainless steel and silver) together, using towels to separate items.
- Place ring-handled instruments on stringers, pins, or racks to keep them open.
- Point clamps with curved jaws in the same direction to protect their tips.
- Position cupped or concave instruments to avoid water collection.
- Wrap smaller instruments and sharp cutting instruments in woven or nonwoven towels.
- Use towels to segregate instruments in the tray or container.
- Place sharps so that their points do not touch, and protect their delicate tips with perforated tip protectors.

- Use dividers, pin mats, and clamps when needed to secure instruments in place to avoid damage during sterilization and transport.

The AORN Recommended Practices specify that the total weight of an instrument set should not exceed 25 pounds. Weight and tray-loading techniques are both important in the effective sterilization and drying of surgical instruments. Avoid overloading or crowding the containers or trays, for this will prevent the sterilizing agent from reaching all surfaces of the instruments. Factors to consider in determining appropriate weight is the size and design of the instruments, the distribution of mass (density) in the set, and risk of injury to personnel.[12]

PACKAGING

Most items to be sterilized will be packaged or wrapped to prevent subsequent contamination by dust, dirt, and microorganisms. Choice of sterilization packaging material is based on the following general standards of performance:

- Ability to conform to the medical device
- Freedom from toxic ingredients and non-fast dyes
- Strength, durability, and seal integrity during transport and sterilization
- Effectiveness of sterilant penetration and removal
- Ability to maintain sterility of contents until the package is intentionally opened
- Ease of aseptic delivery of the contents without contamination
- Cost-effectiveness

Most hospitals provide a variety of packaging materials, which should be chosen based on the type of instrument or instrument sets being packaged. All have benefits and limitations that should be considered when selecting a packaging material.

Sterilization Wrap

Sterilization wraps come in many sizes, grades, and materials. They are used for trays, mesh containers, cassettes, and racks, as well as single items (Figure 1). Before use and after use, inspect wrappers for holes and other signs of wear. (Wrapping materials may break down when challenged by the concentrated weight of instrument sets or poorly designed instrument trays, as well as excessive handling or stacking.) Inspect trays for loose, bent, or frayed edges, feet, or wires that may puncture packaging materials or catch loose instruments.

Figure 1: CSR Wrap

Woven Fabrics

Woven textiles are made of natural cotton or linen fibers and/or fiber blends of cotton muslin and synthetic materials, such as polyester and chemically treated fibers, in various thread counts and thread weights. They are created using a weaving process of overlapping fiber threads. Woven fabric wraps provide the least effective sterile barrier. Although they are reusable, they require laundering to rehydrate as well as time-consuming attention for maintenance and inspection. They must be repaired with double-vulcanized, heat-sealed patches according to the manufacturer's written instructions. The amount of surface area covered by heat-sealed patches should be carefully examined before the fabric is reused. Woven fabrics are losing popularity to nonwoven disposable wraps.

Nonwoven Fabrics

Nonwoven wrappers are single-use fabric wrappers made from engineered fiber laydowns of natural (e.g., cellulose) or synthetic (e.g., polypropylene) materials bonded by methods other than weaving. For example, wet-laid fabrics are manufactured by suspending fibers in a liquid slurry formed on a wire frame, then dried into a sheet using additives to bond the fibers. SMS (spunbond-meltblown-spunbond) fabrics are made up of a meltblown layer of short, thin polyolefin (plastic) fibers sandwiched between spunbond layers of longer outer fibers. Nonwoven wrappers are disposable, resistant to tears and punctures, and virtually lint-free, which reduces labor-intensive care and handling. They are available in a wide range of weights and sizes.

Wrapping Method

Double-sheet sequential wrapping is the traditional method of wrapping instruments for sterilization. Institutes today, however, have a choice between double-sheet sequential wrapping and a single sheet nonsequential wrapping, which utilizes a multi-layered, double-thickness sheet. Nonsequential wrapping has become the method of choice for many central service departments. The advantages of nonsequential wrapping include labor, time, and storage space savings as well as reduced waste. Choose the system that best serves the needs of your practice setting.

Generally, instrument sets should be wrapped using an envelope fold, except where the oblong (or square) fold may be more appropriate (e.g., with long, narrow sets). These wrapping methods make opening sets easier at the time of use.

Rigid Containers

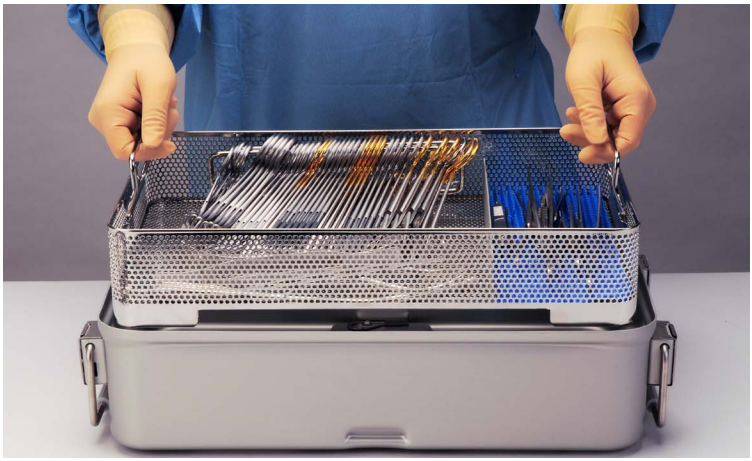
Rigid container systems are specially designed heat-resistant metal, plastic or anodized aluminum receptacles used to package items, usually surgical instruments, for sterilization. The lids and/or bottom surfaces contain steam- or gas permeable high-efficiency microbial filters. They generally consist of a bottom or base with carrying handles and a lid secured to the base by means of a latching mechanism. A basket or tray inside the container holds devices to be sterilized (See Figure 2 and 3).

To help secure the instrument in rigid containers or instrument cassettes, various types of dividers and tools are available, including pins, holding clamps, cradles and silicone mats. These tools hold the instruments in place during sterilization, storage, and transport, preventing instrument breakage and damage. Make sure that filter and/or valve systems are secure and in proper working order before sterilization.

The advantages of rigid container systems over sterilization wraps include ease of handling, avoidance of wrapping material problems, and maximum protection for instruments. When integrated properly into the packaging mix, rigid containers also offer the greatest financial return to the hospital.

Figure 2: Rigid Containers

Figure 3: Basket



Cassettes

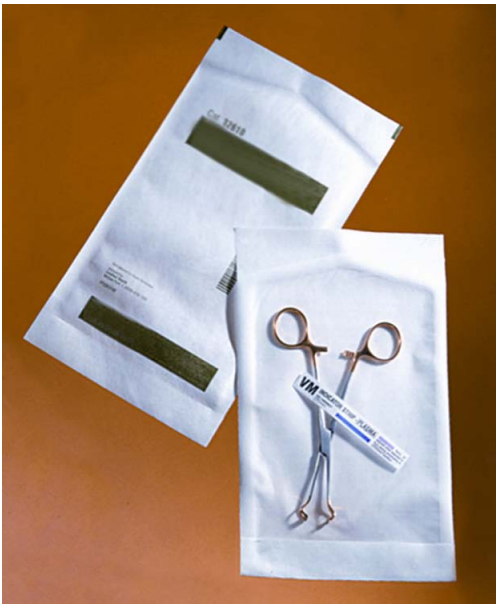
Cassettes are designed for convenient storage and sterilization of surgical instruments inside rigid containers. Alternatively, the cassettes themselves may be wrapped in sterilization wrap. Instruments are loaded into the appropriate brackets inside the cassettes to ensure they stay in place during reprocessing, sterilization, and transport. Look for cassette systems that do not exceed recommended weight limits, are manufactured of stainless steel or anodized aluminum rather than resins, have durable latches, and have rounded corners that enhance overall drainage and will not tear surgical wraps.

Peel Pouches

Peel pouches are flexible packaging materials that combine a paper or synthetic barrier material and a transparent plastic film. They are available in three designs:

- Standard pouches, which are preformed bags composed of a plastic film bonded to a barrier material, sealed on three of four sides (see Figure 4)
- Tubing, which is preformed pouch roll stock sealed on two sides along its length
- Vent bags, which are plastic bags with a barrier material patch

Figure 4: Peel Pouches



Peel pouches are used primarily when visibility of the instrument is critical for its effective use. They were designed for individual, lightweight devices and as a means to separate dissimilar metals and delicate or surgeon-specific instruments from the rest of a standardized set. When using peel packages, remove as much air as possible before sealing. (Air acts as a barrier to heat and moisture, and expansion of air may cause rupturing of packages.) When double peel pouches are required for aseptic presentation of multiple items or those having more than one part, assemble the two pouches without folding or bending and align with like surfaces (e.g., paper to paper and plastic to plastic). During sterilization, pouches should be loosely packed, standing on edge in loading racks or baskets. The paper portion of one pouch should be facing the plastic portion of the next pouch to ensure penetration and removal of sterilant, air, and moisture.

STERILIZATION

After decontaminated instruments are assembled, packaged and labeled, they are ready to be sterilized for the next case. “Sterilization” is defined as the process of killing the microorganisms that remain on a clean instrument. The absolute definition of sterility is the “state of being free of viable microorganisms.” In practice, sterility is expressed as the probability of a single viable microorganism being present on a product unit after sterilization. For example, if there is less than one chance in 1,000,000 that a single viable microorganism is present on a sterilized item, that item is said to have a sterility assurance level (SAL) of 10^{-6}.[13]

The most common sterilizing agents for surgical instruments are:

- Steam, including flash sterilization of unwrapped items
- Ethylene oxide gas
- Dry heat
- Hydrogen peroxide plasma
- Ozone
- Liquid peracetic acid

In general, steam sterilization is the most effective and common practice for instruments that are not sensitive to heat or moisture. Research and development continue in search of alternative low-temperature methods of sterilization for heat and moisture-sensitive devices.

Steam

Steam sterilization is relatively simple, inexpensive, safe, and reliable. The two types of steam sterilizers used for surgical instruments are gravity displacement and dynamic air removal.

- In a gravity-displacement sterilizer, steam under pressure is injected into the top of the chamber, forcing the air to settle to the bottom. This air is then forced out through the chamber drain. The major drawback of gravity displacement sterilizers is the long cycle time required to ensure complete steam displacement of air and steam penetration into the load.
- In a dynamic air removal sterilizer, air is actively removed from the chamber and load by means of either creation of a vacuum in the conditioning phase of the cycle (prevacuum sterilizers), or a series of positive pressure pulses to move the air out (steam flush pressure pulse sterilizers). Both of these types of dynamic air removal sterilizers provide a more effective method of eliminating the air in the chamber and the load. Effective and uniform steam contact with instruments is achieved, thus ensuring rapid sterilization. Dynamic air removal sterilizers usually operate at a higher temperature then gravity air displacement sterilizers. [14]

Steam sterilization requires that four conditions be met: adequate contact between the steam and the microorganisms, sufficient moisture, exposure to temperatures lethal to heat-resistant microorganisms, and adequate time. The most common temperature and time parameters for gravity-displacement steam sterilizers are a 10- to 25-minute exposure time at 132° C to 135° C (270° to 275° F) or a 15- to 30-minute exposure time at 121° C to 123° C (250° F to 254° F). For dynamic air removal sterilizers, the most common temperature and time parameters are 3 to 4 minutes exposure at 132° C to 135° C (270° to 275° F).[15]

The proper care and maintenance of the steam sterilization apparatus is an important factor in providing appropriate instrument care. Instruments exposed to poor water and

steam conditions are candidates for staining and pitting. To minimize damage due to these conditions, take the following steps:

- Final rinse water in wash cycles should be treated to remove minerals from the water and prevent spotting.
- A well-managed boiler treatment program will prevent fluctuations in steam quality and prevent carryover of harsh chemicals.
- Special filters added to steam lines can filter out impurities in the steam, preventing them from depositing onto instruments, racks, and the interior of the sterilizer.
- When stains appear, instruments should be properly refurbished to prolong instrument life and help ensure sterility and proper functioning.

Immediate Use Steam Sterilization

Previously known as "flash sterilization," immediate use steam sterilization is generally defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. The term implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that reduces its exposure to air and other contaminants in the environment. Furthermore, any item sterilized for immediate use is not stored for future use, nor is it held from one case to another. This process should be used only when there is insufficient time to sterilize an item by the preferred prepackaged method or when the surgical suite has been specifically designed to incorporate flash sterilization of instrumentation. It should not be a common practice, since it is difficult to ensure achievement of sterility using this method and flash sterilization may shorten the life of surgical instruments, particularly delicate ones.[16]

For flash sterilization in gravity-displacement steam sterilizers, the minimum exposure time and temperature for nonporous items (e.g., routine metal instruments) is 3 minutes at 132° C (270° F). When porous and nonporous items are sterilized together, the minimum exposure time and temperature is 10 minutes at 132° C. For prevacuum sterilizers, the minimum exposure time and temperature for nonporous items is 3 minutes at 132° C. When nonporous and porous items are sterilized together, the minimum exposure time and temperature is generally 4 minutes at 132° C. For steam flush pressure pulse sterilizers, consult the manufacturer's written instructions for cycle parameters.[17]

Dry Heat

For certain items (e.g., powders and oils, glassware) that cannot be sterilized by either steam heat or gas, dry heat sterilization is an option. Sterilization by dry heat is accomplished in hot-air convection ovens. In this process, the death of microorganisms occurs by denaturation, which is the slow process of coagulating the protein of the cells.

Ethylene Oxide Gas

Ethylene oxide (EO) gas is a very effective alkylating agent which reacts with DNA and destroys the ability of microorganisms to metabolize or reproduce. It has been the method of choice for many heat- and moisture-sensitive devices, including microsurgical instruments, for many years, but new types of low heat processes are now often used as substitutes.

EO sterilizers use either a mixture of 10% EO and 90% hydrochlorofluorocarbon (HCFC); 10% EO and 90% carbon dioxide; or 100% EO. Regardless of mixture, it is the concentration of EO (mg/l) present during sterilization that determines efficacy. Effective EO sterilization depends on four parameters:

- Concentration of sterilant
- Relative humidity
- Temperature
- Exposure time

Because EO is toxic, potentially flammable, and explosive, it must be used with caution. EO sterilizer safety features should include, but are not limited to, a purge system at the end of the processing cycle, door locking and sealing mechanisms, audible alarms at the end of the cycle, and automatic door controls.

EO is compatible with all commonly available hospital packaging materials. Certain types of polyvinylchloride materials absorb EO gas during the sterilization cycle, including products made from rubber, polyethylene or silicone. These items require an aeration period to reduce residual EO. Length of aeration depends on the item(s) sterilized, type of sterilizer, temperature of the aeration chamber, air exchange, and intended use of the items. Manufacturers of aerators and sterilizers can provide information about materials and/or medical devices that may be aerated in their equipment.

Plasma Systems

Plasma systems use a combination of peroxygen compounds (e.g., hydrogen peroxide) and low-temperature gas plasma to kill microorganisms. A “plasma” is defined as a highly ionized gas composed of ions, electrons, and neutral particles. Plasmas are generated by introducing a precursor gas or vapor (e.g., hydrogen peroxide or peracetic acid) into a chamber under low-vacuum conditions and then exciting the gas or vapor with microwave or radiofrequency energy.[18] Lightning is an example of a plasma that occurs in nature; fluorescent and neon lights are man-made plasmas.

Low-temperature plasma sterilization systems are good for heat-sensitive devices, but they have specific packaging needs. Cellulose-containing disposable wrappers and muslin wraps are incompatible with hydrogen peroxide processes because they absorb the peroxide and do not allow effective penetration. Commercially available nonwoven polypropylene wraps and polyolefin pouches and plastic trays are a better choice.[19]

Ozone

Ozone is an unstable oxygen molecule that has three oxygen atoms instead of the usual two. It is a powerful oxidizing agent, making the gas an effective low-temperature sterilant under controlled conditions within the specially designed sterilization equipment that uses this process. The ozone is generated within the sterilizer from oxygen and water, and at the end of the cycle, the remaining ozone is exhausted through a catalytic converter, returning to oxygen and water. Thus, no aeration is needed.

An ozone sterilizer has been cleared by the FDA for sterilization of metal and plastic surgical instruments. The sterilizer and device manufacturers' written instructions should be consulted for limitations on lumen size and strength, as well as overall compatibility with the process. As with gas plasma systems, cellulosic packaging materials and products are not compatible with this process and should not be used. Non-woven pouches and rigid sterilization container systems that have been tested with the system are recommended.[20]

Liquid High-Level Disinfectants/Sterilants

For delicate, but immersible, medical devices, 30 liquid chemical high level disinfectants and/or sterilants are currently cleared by the FDA with general claims for reprocessing reusable medical devices.[21]

Each of these products has advantages and disadvantages. They are essentially equivalent in spectrum of microbiocidal activity, effectiveness in the presence of organic matter, and relative ease of use. Major disadvantages include issues with material incompatibility and human health toxicity.

The difference between high-level disinfection and sterilization is that high-level disinfection results in the destruction of all vegetative bacteria, viruses, fungi, and mycobacteria, but not necessarily all bacterial spores. Several of these chemical agents are high-level disinfectants under normal conditions of use, but can be considered sterilants with prolonged exposure times. Professional associations and regulatory agencies recognize high-level disinfection as the standard of care in reprocessing items that come in contact with intact skin or mucous membranes (e.g., respiratory therapy and anesthesia equipment, gastrointestinal endoscopes, cystoscopes), but do not enter sterile tissue or the vascular system.[22]

Steps in high-level disinfection typically include the following:

1. Perform meticulous manual cleaning. For endoscopes, this includes purging the air/water channel, using enzymatic detergent solution for cleaning the exterior of the instrument and brushing all valves and accessible channels, followed by immersion in fresh enzymatic detergent solution, which must be flushed through all channels.
2. Disassemble instruments with removable parts to ensure that all parts contact the chemical agent.
3. Rinse thoroughly.

4. Make sure the instrument is dry to avoid dilution of the chemical agent.
5. Test the soak solution for minimum effective concentration (MEC). At least once each day, or more often if necessary, use product-specific test strips to test that reusable disinfectant solutions are at or above their minimum effective concentration.
6. Immerse instruments in solution, taking care to avoid entrapment of air bubbles. Be sure that all lumens and channels fill with solution.
7. Cover the container to prevent evaporation of solution.
8. Soak for the appropriate amount of time in accordance with the manufacturer's instructions.
9. Remove items from soaking solution using sterile technique.
10. Rinse the device twice, using sterile distilled or demineralized water to avoid reintroducing microorganisms such as those found in tap water. Use clean or sterile water for the final rinse and follow with air-drying, a rinse with 70% isopropyl alcohol obtained from a tightly closed container, and a second air-drying.
11. Reassemble and use immediately. Because no wraps or pouches are employed with this liquid process, items processed with liquid high-level disinfectants must be used immediately.

Peracetic Acid

Liquid peracetic acid is a clear, colorless sterilizing solution with a pungent odor. It is a highly effective antimicrobial agent, even in the presence of high levels of organic soil. A concentration of 0.2% peracetic acid is rapidly active against all microorganisms, including bacterial spores, and is effective in the presence of organic matter. It will kill gram-positive and gram-negative bacteria, fungi, and yeasts present at less than 100 ppm in 5 minutes or less.

Liquid peracetic acid is used only in an automated system that is designed for use with immersible medical devices, particularly flexible and rigid endoscopes. The complete processing cycle, including a series of four sterile rinses, is approximately 30 minutes and reaches temperatures of 50° to 55.5° C (122° to 131.9° F) during exposure time.

Hydrogen Peroxide

Hydrogen peroxide at or above 7.5% concentration is a reusable high-level disinfectant/ sterilant cleared by the FDA for high-level disinfection with a contact time of 30 minutes at 20° C (room temperature). No mixing or activation is required. This chemical may be used in manual or automated reprocessing protocols.

Peracetic Acid/Hydrogen Peroxide

A peracetic acid/ hydrogen peroxide formula may also be used. Data show that this formula has wide biocidal activity at a 25-minute exposure time. It is currently marketed and available as a high-level disinfectant at 20° C/68° F with an immersion time of 25 minutes. It may be used in manual or automated reprocessing protocols.

Glutaraldehyde

Glutaraldehyde is the most widely used product for the high-level disinfection of endoscopes. It is marketed under various product names. These products are available in a variety of concentrations, with and without surfactants. Glutaraldehyde may be used in manual or automated reprocessing protocols. Glutaraldehyde must be mixed with the activator vial.

Orthophthaldehyde (OPA)

Orthophthalaldehyde is cleared by the FDA as a high level disinfectant. It is not a sterilant and extending the exposure time will not produce sterility. Effective high level disinfection contact time is 12 minutes at 20° C/68° F for manual use. In specifically designed automatic endoscope processors, the contact time is reduced to 5 minutes at 50 ° C/ 122° F. OPA should not be used for high level disinfection of urology endoscopes or devices that will be used in treatment of patients with bladder cancer. Anaphylactic reactions have been reported with OPA in this patient population.[23]

Processing of Instruments Exposed to CJD Prion[24]

Creutzfeldt-Jakob disease (CJD) is a degenerative and invariably fatal disease of the central nervous system. The CJD pathogen is not a typical bacterium, virus, fungus, or parasite. The pathogen is made up of protein only, without detectable DNA or RNA. This type of pathogenic protein is known as a prion.

The CJD prion is highly resistant to standard sterilization and disinfection methods. Special protocols must be used to ensure that the pathogen does not survive on contaminated instruments.

The protocol used depends on infectivity of the tissue. High-infectivity tissues for CJD are the brain, dura mater, spinal cord, and corneas. Other tissues have medium, low, or no infectivity.

For critical or semicritical instruments exposed to high-infectivity tissues, AORN recommends the following:

- If the instrument is not heat and moisture stable, or is impossible to clean, discard.
- If the instrument is heat and moisture stable and easily cleanable:
    1. Clean thoroughly with a germicidal detergent.
    2. Sterilize using one of the following:
        - Prevacuum sterilization at 272° F (134° C) for 18 minutes
        - Gravity sterilization at 272° F (132° C) for 60 minutes
        - Immersion in 1 normal (N) sodium hydroxide at room temperature for 60 minutes, followed by removal and a water rinse, followed by a steam sterilization cycle as noted above.

3. Clean thoroughly, wrap, and sterilize according to standard facility protocol.

- If the instrument is heat and moisture stable and difficult to clean:

    1. Discard, or decontaminate initially using one of the following:
        - Prevacuum sterilization at 272° F (134° C) for 18 minutes
        - Gravity sterilization at 272° F (132° C) for 60 minutes
        - Immersion in 1 N sodium hydroxide at room temperature for 60 minutes, followed by removal and a water rinse, followed by a steam sterilization cycle as noted above.
    2. Clean thoroughly, wrap, and sterilize according to standard facility protocol.

For noncritical instruments exposed to high-infectivity tissues, AORN recommends the following:

- If the instrument is not cleanable, discard.
- If the instrument is cleanable:

    1. Clean according to standard protocol.
    2. Disinfect with 10% sodium hypochlorite (bleach) or 1 N sodium hydroxide, whichever is least damaging to the item.
    3. Continue processing according to standard facility protocol.

For environmental surfaces exposed to high-infectivity tissues, AORN recommends the following:

1. Cover surface with disposable, impermeable material. Incinerate material after use.
2. Disinfect surface with sodium hydroxide or bleach (sodium hypochlorite).
3. Wipe entire surface according to standard facility protocol for surface decontamination.

For instruments exposed to tissues with medium, low, or no infectivity, AORN

recommends the following:

- If the instrument is not cleanable, discard.
- If the instrument is cleanable, clean, disinfect, and sterilize according to standard facility protocol.

For environmental surfaces exposed to tissues with medium, low, or no infectivity, AORN recommends the following:

1. Cover surface with disposable, impermeable material. Dispose of material after use according to facility protocol.
2. Disinfect surface with OSHA-recommended agent for decontamination of surfaces contaminated with blood.

STERILE STORAGE

Transport sterilized packages from the point of sterilization to the storage location and/or the point of use in a manner that protects them from inadvertent contamination by moisture or gross amounts of dust.

Store sterile surgical instruments on carts or shelving that is at least 8 to 10 inches from the floor, 18 inches from the ceiling, and 2 inches from outside walls. Do not allow packaging to be crushed, bent, compressed, punctured, or compromised in any way. Take care to avoid storage near exposed water pipes, sinks, or other areas where water damage could occur. Keep the storage area free of dust, insects, vermin, and temperature and humidity extremes. Ambient humidity should not exceed 70% and the temperature should not exceed 24°C (75°F). Minimize unnecessary traffic in the sterile storage area.

The shelf life of packaged sterile surgical instruments is event related and depends on the frequency and method of handling as well as the conditions of the storage location. That is, microbial contamination of a sterile package is caused by an event—such as careless handling or transport—not by time alone. By closely controlling the events to which a sterile package might be exposed, the probability of contamination can be minimized.[25]

QUALITY CONTROL

A quality control program should be established within the practice setting that applies to all aspects of the sterilization process and sterilizer performance, including:[26]

- Sterilizer equipment documentation
- Preventive maintenance
- Mechanical, biological, and chemical monitoring
- Product identification, traceability and recall procedure
- Visual inspection of packaging when applicable
- Residual-air (Bowie-Dick type) testing of prevacuum steam sterilizers

Documentation

Information recorded from each sterilization cycle should include, but not be limited to:[27]

- Identification of the sterilizer used (e.g. sterilizer #1)
- Type of sterilizer and cycle used
- Load or lot control number

- Contents of the load
- Exposure time and temperature if not provided by recording chart
- Name of operator
- Results of biological and chemical monitoring

Preventive Maintenance

Preventive maintenance of sterilizers, including inspection and cleaning, should be performed on a scheduled basis by qualified personnel using manufacturers' written service instructions. Preventive maintenance should also include periodic inspections, maintenance, and replacement of components subject to wear (e.g., recording devices, steam traps, filters, valves, drain pipes, and gaskets).

Mechanical, Biological, and Chemical Monitoring

Mechanical, chemical, biological, and enzyme-based indicators are used to confirm that parameters associated with the sterilization process have been achieved. Together, they form a complete system of checks and balances for a sterility assurance program. (See Figure 5).

Figure 5: Variety of Indicators.

No indicator, chemical or biological, can tell with certainty that a product is sterile; indicators provide information to demonstrate that the conditions for sterilization have been met. [28] The determination that an item is sterile comes from careful control of the entire process from cleaning through sterilization, storage, and handling until the point of use.

Mechanical Indicators

Mechanical types of monitors include time-, temperature-, and pressure-recording device and gauges that either graph the relevant parameters on recording charts or provide a printout of values from a digital recorder. These charts must be marked at the beginning

and end of every cycle to indicate whether sterilization parameters were met. Recording charts also indicate if a malfunction occurred during a particular load.

Chemical Indicators

There are three major types of chemical indicators:[29]

- Process indicators (class 1) (e.g., process-specific tape and some chemical indicators) react upon exposure to a specific condition, such as heat or a change in pH. They are not intended to measure accurately the quality or quantity of exposure but only to indicate that exposure has occurred. Process indicators need to be visible on or through the package as a means of distinguishing packages that have been exposed to a sterilization cycle from those that have not.
- Multiparameter indicators (class 4) may integrate the effect of temperature and exposure to the actual sterilant over time. They should be placed in the area of the package that is most difficult to sterilize, which is usually in the middle of the set. They are used to detect failures in packaging, loading, or sterilizer function.
- Integrating indicators (class 5) chemical indicators have been shown to closely mimic the response of biological indicators to controlled test conditions. These indicators can be used for routine process monitoring, just as any other chemical indicator. In addition, they can be used in place of biological indicators as a criterion for release of processed loads, providing that mechanical monitoring parameters are in order. Loads containing implants should still be monitored with a biological indicator or a biological indicator that includes an early read-out enzyme based indicator, and the implant quarantined until satisfactory results are obtained.

A large number of external and internal chemical indicators are available, each capable of detecting different parameters, such as temperature, time, or moisture. It is important to obtain data from manufactures on the reliability, safety, and performance characteristics of each type.

Biological and Enzyme-based Indicators

A biological indicator is a concentration of microorganisms (of a sufficient number and degree of resistance) for the purpose of indicating whether or not sterilization conditions have been achieved. Such indicators are available on spore strips or in glass vials. Biological indicators require incubation for 1 to 7 days to assess whether the bacterial spores have survived the sterilization process.

An enzyme-based indicator contains an enzyme normally found in the spore coat of resistant bacteria, which has been shown to be highly reliable in matching the response of the actual spore itself when exposed to conditions within a sterilizer. Enzyme-based indicators may be a part of a biological indicator or packaged alone. These indicators can be read with special equipment after a short interval following the sterilization process, facilitating early release of processed goods, including implants. Enzyme-based indicators are not available for use with all sterilization methods.

Biological and enzyme-based indicators are placed inside challenge test packs based on standards established by the Association for the Advancement of Medical Instrumentation (AAMI). These indicators tell the central sterile department whether the sterilization cycle is delivering a lethal dose so that products can be confidently released to surgery.

All loads containing implants should be monitored with a biological indicator or biological indicator that includes an early read-out enzyme response within a challenge test pack. In an emergency, an implant load can be released based on the response of a Class 5 or enzyme-only indicator alone, providing that other mechanical monitoring results are satisfactory. Routine release criteria for implants should be based upon the results of incubation of a biological indicator or the early read out response of a biological indicator-enzyme combination product.[30]

According to AORN, biological indicators should be used:[31]

- To monitor nonimplant loads.
- In every load containing implants; load should also contain a Class 5 integrating indicator or an enzyme-only indicator.
- At least weekly, but preferably daily (ie, each day the sterilizer is used) for routine steam sterilizer efficacy testing. The indicator should be run in a full load for wrapped items; for table-top sterilization, it should be run in a fully loaded chamber; for immediate use sterilization, it should be run in an empty chamber.
- For sterilizer qualification testing (after sterilizer installation, relocation, malfunction, major repairs, sterilization process failures).
- Three times consecutively in an empty chamber except for table-top sterilizers, where the test should be run three times consecutively in a full load.
- For periodic product quality assurance testing.
- With every load in EO sterilizers.
- For routine load release, routine sterilizer efficacy monitoring (should be done daily, preferably with each load), sterilizer qualification testing and periodic product quality assurance testing in low temperature hydrogen gas plasma sterilizers.
- For routine load release, routine sterilizer efficacy monitoring (should be done daily, preferably with each load), sterilizer qualification testing and periodic product quality assurance testing in ozone sterilizers.
- Daily for routine sterilizer efficacy monitoring in liquid peracetic acid sterilizers.
- For routine load release, routine sterilizer efficacy monitoring (should be done weekly, but preferably daily), sterilizer qualification testing and periodic product quality assurance testing in dry-heat sterilizers.

Product Identification and Recall

Each package to be sterilized should be labeled with the lot or load control number and the sterilization date. If a sterilization failure occurs, materials processed in that sterilizer, dating from the sterilization cycle with the last negative biological indicator to the next cycle with

satisfactory biological indicator challenge results, must be considered nonsterile. They must be recalled, if possible, and reprocessed after the cause for the sterilization failure is corrected.[32]

Visual Inspection

Inspection is an ongoing, dynamic process that should take place every time a healthcare professional encounters a sterile instrument or package. Particularly before presentation to the sterile field, sterile items should be inspected for proper packaging; seal integrity; package integrity; inclusion of a process indicator; and expiration date, if any.

Bowie-Dick Type Testing

The Bowie-Dick test is a type of chemical indicator. It is used in the first run of the day in prevacuum sterilizers to check for air removal from the sterilizer and the efficiency of the vacuum system.

SUMMARY

Implementing proper protocols in your hospital can go a long way toward protecting your instruments from unnecessary damage. With everyone on the team working together to ensure that all instruments are adequately cleaned, decontaminated, inspected, repaired, packaged, and sterilized, your patients will receive the quality of surgical care they expect and deserve. By paying attention to detail during each step, you can help make sure that your instruments function properly for a long time.

GLOSSARY

Aeration	Method by which absorbed EO is removed or reduced in EO-sterilized items that uses warm air circulating in an enclosed cabinet specifically designed for this purpose.
Biological indicator	A standardized, commercially prepared, calibrated amount of microorganisms of high resistance to the method of sterilization being monitored; used to demonstrate that sterilization conditions were met during the cycle being monitored.
Chemical indicator	A commercially prepared device to monitor one or more process parameters of the sterilization cycle for operator error or failures in packaging, loading, or sterilizer function; also known as a sterilization process monitoring device.
Container system	Specifically designed rigid metal or plastic receptacle used to package items for sterilization.
Decontamination	Any physical or chemical process that reduces the number of microorganisms on any inanimate object to render that object safe for subsequent handling.
Deionized or demineralized water	Water prepared by passing main water through synthetic anion- or cation-exchange resin beds to remove positive or negative ions.
Detergent	A cleaning agent composed of a “surface wetting agent,” which reduces surface tension; a “builder,” which is the principle cleaning agent; and a “sequestering or chelating agent” to suspend the soil.
Disinfection	A process that destroys some forms of microorganisms, with the exception of bacterial spores.

Distilled water	Water prepared by evaporating raw water by boiling, followed by immediate condensation of the liberated steam or water vapor.
Dynamic Air Removal	A method of monitoring the adequacy of air removal from Test (Bowie-Dick Test) the chamber and porous load during the prevacuum stage in a high-vacuum steam sterilizer. The air removal test is not a test for sterilization.
Gravity displacement	A type of sterilizer in which incoming air displaces the sterilizer residual air through a port or drain, usually in or near the bottom of the sterilizer chamber.
High-level disinfection	A process that results in the destruction of all vegetative bacteria, viruses, fungi, and mycobacteria, but not necessarily high numbers of bacterial spores.
Mechanical indicator	A recording device or gauge that monitors sterilization parameters (e.g., time, temperature, and pressure) and generates charts and/or digital readouts, which provide permanent records that equipment did not malfunction during a particular load, but do not indicate sterility.
Packaging	The application or use of closures, wrappings, cushioning, and containers.
Physical monitor	Automated devices (e.g., graphs, gauges, printouts) that monitor sterilization parameters for the sterilization method in use.
Prevacuum steam	A type of sterilizer that relies on one or more pressure and sterilizer vacuum excursions at the beginning and/or end of the cycle; usually results in shorter cycle times because of the rapid removal of air from the chamber and the load by the vacuum system.
Preventive maintenance	Repair performed to prevent malfunction or breakdown of equipment.

Shelf life	The length of time an item is considered sterile and safe to use.
Spore	A resistant form of a bacterium, capable of forming a thick wall around itself, enabling it to survive in adverse conditions.
Steam-flush pressure-pulse	A steam sterilization cycle in which air is removed from the (SPPP) chamber and load via a series of steam flushes and pressure pulses.
Sterilant	A material capable of destroying all microorganisms, including all bacterial spores.
Sterile	In theory, the state of being free from all living microorganisms; in practice, having a probability of a surviving microorganism of one in 1,000,000.
Sterilization	A process that results in the complete elimination or destruction of all forms of microbial life.
Tap water	Water that comes from the local water supply and varies in quality with the source and the local authority responsible.
Ultrasonic cleaner	A processing unit that transmits through a cleaning solution a vibrating wave of a frequency above that of the upper frequency limit of the human ear.
Washer-decontaminator	A single- or multichambered unit which includes a prerinse, wash, and sustained rinse at 180° to 190° F (82.2° to 87.8° C) to clean, decontaminate, and remove excessive amounts of dried debris from instruments.
Washer-disinfector	An automated processing unit that prerinses, washes, lubricates, chemically disinfects, and dries a wide variety of surgical products.
Washer-sterilizer	A mechanical device designed to wash, disinfect, and sterilize instruments and metalware, most commonly used for the decontamination process.

REFERENCES

1. AORN. “Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment” in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 515.
2. AORN. “Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment” in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 516.
3. AAMI. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2010 & A1:2010. Arlington, VA: AAMI; 2010; p. 40.
4. Lind, N., Ninemeier JD, eds. Central Service Technical Manual. 7th ed. Chicago, IL: International Association of Healthcare Central Service Material Management; 2007; p. 138.
5. Lind, N., Ninemeier JD, eds. Central Service Technical Manual. 7th ed. Chicago, IL: International Association of Healthcare Central Service Material Management; 2007; p.137.
6. AAMI. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2010 & A1:2010. Arlington, VA: AAMI; 2010; p. 59.
7. AAMI. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2010 & A1:2010. Arlington, VA: AAMI; 2010; p. 57.
8. AORN. “Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment” in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 520.
9. Lind, N., Ninemeier JD, eds. Central Service Technical Manual. 7th ed. Chicago, IL: International Association of Healthcare Central Service Materiel Management; 2007; p.143.
10. Lind, N., Ninemeier JD, eds. Central Service Technical Manual. 7th ed. Chicago, IL: International Association of Healthcare Central Service Materiel Management; 2007; p.144.
11. Lind, N., Ninemeier JD, eds. Central Service Technical Manual. 7th ed. Chicago, IL: International Association of Healthcare Central Service Materiel Management; 2007; p.143.
12. AORN. “Recommended Practices for Sterilization in the Perioperative Practice Setting”, in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 548.

13. AAMI. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2010 & A1:2010. Arlington, VA: AAMI; 2010; p. 15.

14. Lind, N., Ninemeier JD, eds. Central Service Technical Manual. 7th ed. Chicago, IL: International Association of Healthcare Central Service Materiel Management; 2007; p.293

15. AORN. "Recommended Practices for Sterilization in the Perioperative Practice Setting", in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 550-551.

16. AAMI. "Immediate-Use Steam Sterilization" accessed at: http://www.aami.org/publications/standards/ST79_Immediate_Use_Statement.pdf, April 19, 2012. AORN. "Recommended Practices for Sterilization in the Perioperative Practice Setting", in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 550-551.

17. AORN. "Recommended Practices for Sterilization in the Perioperative Practice Setting", 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 552.

18. Lind, N., Ninemeier JD, eds. Central Service Technical Manual. 7th ed. Chicago, IL: International Association of Healthcare Central Service Materiel Management; 2007; p.337

19. Lind, N., Ninemeier JD, eds. Central Service Technical Manual. 7th ed. Chicago, IL: International Association of Healthcare Central Service Materiel Management; 2007; p.337

20. AORN. "Recommended Practices for Sterilization in the Perioperative Practice Setting", in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 557.

21. US FDA. "FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices - March 2009," accessed at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm, April 19, 2012.

22. SGNA. "Guideline for the Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes", Society of Gastroenterology Nurses and Associates, Inc., 2007; p. 4

23. Sokol WN . "Nine episodes of anaphylaxis following cystoscopy caused by Cidex OPA (ortho-phthalaldehyde) highlevel disinfectant in 4 patients after cystoscopy." J Allergy Clin Immunol. 2004 Aug;114(2):392-7.

24. AORN. “Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment” in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; pp. 528-531. “Recommended Practices for Environmental Cleaning in the Perioperative Practice Setting” in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; pp. 244-246.

25. AORN. “Recommended Practices for Sterilization in the Perioperative Practice Setting”, in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 559-560.

26. AORN. “Recommended Practices for Sterilization in the Perioperative Practice Setting”, in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 561-566.

27. AORN. “Recommended Practices for Sterilization in the Perioperative Practice Setting”, in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 560-561.

28. Nicolette LH. Infection prevention and control in the perioperative setting. *Alexander’s Care of the Patient in Surgery,* 14th ed.; JC Rothrock, Ed. St. Louis, MO: Mosby; 2011: 74.

29. AAMI. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2010 & A1:2010. Arlington, VA: AAMI; 2010; p. 101.

30. AAMI. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2010 & A1:2010. Arlington, VA: AAMI; 2010; p. 104-105.

31. AORN. “Recommended Practices for Sterilization in the Perioperative Practice Setting”, in 2012 Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc; 2012; p. 561-566.

32. AAMI. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2010 & A1:2010. Arlington, VA: AAMI; 2010; p. 114.

Please click here for the Post-Test and Evaluation