

Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment

The following proposed recommended practices for Cleaning and Care of Surgical Instruments and Powered Equipment were developed by the AORN Recommended Practices Committee. It is being presented for public comment at this time.

These recommended practices are intended as achievable recommendations representing what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented.

AORN recognizes the various settings in which perioperative nurses practice. These recommended practices are intended as guidelines adaptable to various practice settings. These practice settings include traditional operating rooms, ambulatory surgery centers, physician's offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, and all other areas where surgery may be performed.

References to nursing interventions (I) used in the *Perioperative Nursing Data Set, second edition*, (PNDS) are noted in parentheses when a recommended practice corresponds to a PNDS intervention.¹ The reader is referred to the PNDS for further explanation of nursing diagnoses, interventions, and outcomes.

Purpose

These recommended practices provide guidelines to assist perioperative nurses in decontaminating and preparing surgical instruments and powered equipment for terminal sterilization and disinfection. These recommended practices are general recommendations, as it is impossible to make a separate recommendation for every instrument used. These recommended practices complement AORN's "Recommended practices for sterilization in perioperative practice settings,"² and "Recommended practices for high-level disinfection in perioperative practice settings."³

Perioperative nurses should consult these documents to assist them in providing a safe environment for the patient. Perioperative nurses are advised to review the Association for the Advancement of Medical Instrumentation (AAMI) standards for additional practice details. Information about flexible endoscope cleaning can be found in the AORN "Recommended practices for endoscopes-cleaning and processing."⁴

Recommendation I

The manufacturer's written, validated instructions for handling and reprocessing should be obtained and evaluated to determine the ability to adequately clean and reprocess the equipment within the health care facility before purchasing surgical instruments and powered

equipment.(PNDS:I122)

Cleaning and handling instructions recommended by the device manufacturer vary widely. Specific types of equipment, pneumatically powered instruments, and specialty instruments can require special cleaning and maintenance procedures.⁵

I.a. The manufacturer's written instructions should be used to determine how to replicate the validated cleaning and processing methods.⁶(PNDS:I122)

I.a.1 The manufacturer's written instructions should identify requirements related to

- utilities (eg, type of water, compressed air);
- cleaning equipment;
- accessories (eg, adaptors) for creating a proper connection between the instruments and equipment, utilities, and cleaning equipment;
- accessories for cleaning lumens, ports, and internal parts;
- cleaning agents;⁶
- lubricants; and
- processing methods.

1.b. The accessories necessary to reprocess the instrument according to the manufacturer's validated instructions should be obtained at the time of purchase. (PNDS:I122)

Using the proper accessories, which fit the instruments and equipment and were used during testing, provides the best opportunity to replicate validated cleaning methods.

Recommendation II

New, repaired, and refurbished instruments should be examined, cleaned, and sterilized according to manufacturers' written instructions before use in a health care organization.

II.a. When new, repaired, or refurbished instruments are received into a facility all moving parts, tips, box locks, ratchets, screws, and cutting edges should be examined for defects and to ensure proper working order. (PNDS:I98)

Inspecting the instrument verifies that the instrument has no obvious defects and has not sustained damage during shipping.

II.b. When indicated, new instruments should be pretreated according to the instrument manufacturer's written instructions. (PNDS:I98;I122;)

Some manufacturers recommend a series of treatments in a steam sterilizer to harden the coating on the instruments before initial cleaning. When this is indicated, details are provided in the manufacturer's written instructions.

II.c. New, repaired, or refurbished instruments should be decontaminated according to the manufacturer's written instruction before use.

Decontamination of newly acquired or repaired instruments removes any soil related to manufacturing, repair, refurbishing, or shipping.

Recommendation III

Borrowed or consigned (ie, loaner) instruments should be examined, cleaned, and sterilized by the receiving health care organization before use, according to manufacturers' written instructions.
(PNDS:I70;I77;I85;I98;I122)

Parameters of in-house sterilization can be verified. If an instrument has been sterilized by another health care organization, the user will have no record of the sterilization process in the event of a recall. There is a high probability of an event occurring during transport that could compromise sterility.

III.a. Before receiving loaner instruments, the instrument manufacturer's instructions for handling and reprocessing should be obtained and evaluated to determine the ability to adequately clean and reprocess the equipment.

When instructions are received in advance, proper conditions can be created for cleaning and sterilization before the arrival of the instruments. This can prevent a potential delay in the scheduled case and help ensure adequate sterilization. Requests that cleaning instructions arrive before receiving the instrument tray, improves the efficiency of reprocessing.⁷

III.b. The accessories necessary to reprocess loaner instruments according to the manufacturer's validated instructions should be received at the same time as the instruments.

The best opportunity to replicate valid cleaning methods is to use the proper accessories which fit the instruments and equipment and have been used during testing.

III.c. When a loaner instrument is received all moving parts, tips, box locks, ratchets, screws, and cutting edges should be examined for defects and to ensure proper working order. (PNDS:I77;I85;I128)

Inspecting the instrument verifies the absence of obvious defects and damage during shipping.

III.d. Loaner instruments should be decontaminated and sterilized according to the manufacturer's written instructions before use. (PNDS:I70:I98;I122)

Instruments consigned or borrowed from other facilities may not have been adequately decontaminated. Conditions during storage and transport are not known. The quality of any previous processing has not been verified, and sterile storage conditions have not been maintained during transport.⁷

III.e. Loaner instruments should be requested when the surgery is scheduled and delivered to the health care organization with sufficient time available before the surgical procedure to allow inspection and inventory of the instruments and to perform reprocessing in the same manner as a facility-owned instrument. (PNDS:I85)

Managing loaner instruments requires planning. Requesting the instruments when the surgery is scheduled allows the vendor to deliver the instruments far enough in advance for proper cleaning, decontamination, inspection, and sterilization to occur. Vendor collaboration is more likely when delivery and other expectations are communicated in advance.

III.f. Loaner instruments should be logged in and inventoried within the receiving facility before use.

Keeping logs and inventory lists of instruments verifies that the instrument set is complete and available for the intended surgical procedure upon their arrival. Requesting that an inventory list accompany the instrument tray improves the efficiency of reprocessing.⁷ Digital images may be used for documentation.

III.g. Loaner instruments should be disassembled and decontaminated after use. (PNDS:I98)

III.g.1 Loaner instruments should be inventoried and documentation created regarding the disposition of the items after completion of decontamination.

Recommendation IV

Instruments should be kept free of gross soil during surgical

procedures. (PNDS:I70:I98)

Blood and body fluids can cause pitting of instruments and, if left to dry, can be difficult to remove. If blood and body fluids are not removed, they can prevent adequate sterilization, which could be an avenue for transmission of other potentially infectious materials.

IV.a. Instruments should be wiped as needed with sterile surgical sponges moistened with sterile water during the procedure, to remove gross soil. (PNDS:I70:I98)

Blood and body fluids, as well as saline, are highly corrosive. Corrosion, rusting, and pitting occur when saline, blood, and debris are allowed to dry in or on surgical instruments. Dried blood and debris can be difficult, if not impossible, to remove from all surfaces during the decontamination process; therefore, subsequent disinfection or sterilization may not be achieved.

IV.b. Instruments with lumens should be irrigated with sterile water, as needed, throughout the surgical procedure. (PNDS:I70:I98)

Cannulated instruments or instruments with lumens can become obstructed with organic material. Irrigating these instruments with sterile water helps remove residue. Instruments should be rinsed with water because of the corrosive nature of saline.

IV.c. Electrosurgical unit (ESU) active electrode tips should be cleaned frequently, away from the surgical site, to remove eschar. (PNDS:I72:I76:I98)

Eschar on the ESU electrode tip impedes the current flow, causing the equipment to work less efficiently. Eschar also serves as a fuel source which can lead to surgical fires.⁸ Debris on the tip can cause tissues to tear and lead to bleeding.⁹

Recommendation V

Cleaning and decontamination should occur as soon as possible after instruments and equipment are used. (PNDS:I70)

Cleaning and decontamination should occur as soon as possible after instruments and equipment are used to prevent the formation of biofilm. Cleaning and decontamination must be thoroughly accomplished or disinfection and sterilization may not be effective.

V.a. Preparation for decontamination of instruments should begin at the point of use. (PNDS:I70;I98)

Removing gross soil and moistening soil at the point of use improves the efficiency and effectiveness of decontamination.

V.b. All instruments opened in the operating or procedure room should be decontaminated whether or not they have been used. (PNDS:I70;I98)

All instruments opened during a surgical procedure are considered contaminated. Scrubbed persons may touch instruments without being aware of it. Used instruments also may come in contact with other instruments.

V.c. Sharp instruments should be segregated from other instruments.

Segregation of sharp instruments minimizes the risk of injury to personnel handling the instruments during decontamination. The Occupational Safety and Health Administration (OSHA) prohibits processes that require employees to place their hands into basins of sharp instruments submerged in water, because of the risk of a percutaneous exposure to bloodborne pathogens.¹⁰

V.c.1. Disposable sharps (eg, scalpel blades, suture needles) should be removed and discarded into the proper receptacles.

V.c.2. Reusable sharp instruments, including scissors, should be placed in a separate receptacle.

V.c.3. Reusable scalpel handles should be considered sharp and placed in a receptacle designated for sharp instruments.

Considering a reusable scalpel handle to be sharp minimizes the risk of injury, if a blade has been left on the handle.

V.c.4. Reusable sharps must be placed in a puncture-proof container for transport.¹⁰

V.d. Instruments should be opened and disassembled when possible and arranged in an orderly fashion within the original set configuration. (PNDS:I70; I98)

Disassembling and opening of instruments followed by their placement into original set configuration minimizes the risk of instrument displacement and improves the efficiency of reprocessing.

V.d.1. Instruments should be placed in a perforated or mesh-bottom instrument tray before mechanical decontamination.

Using perforated trays allows all surfaces to be exposed when processed in an automated cleaner.

V.d.2. Instrument box locks should be fully open and the instrument secured to prevent closing by using stringers, racks, or instrument pegs designed to contain instruments.

V.e. Delicate instruments should be protected from damage. (PNDS:I70)

Instruments shift during transport. The weight of heavy instruments can easily damage delicate instruments, unless preventive measures are taken.

V.e.1. Light-weight instruments and microsurgical instruments should be placed on top of heavier instruments or segregated into separate containers.

V.e.2. Heavy instruments should be placed on the bottom of storage containers or in a separate tray.

V.f. Instruments should be treated with an enzymatic cleaner before transport, following the instrument or device manufacturer's recommendation. (PNDS:I70)

When decontamination will not occur immediately, or the decontamination area is remote from the surgical suite, treating instruments with an enzymatic cleaner at the point of use can facilitate the efficiency and effectiveness of cleaning. Corrosion, rusting, and pitting occur when blood and debris are allowed to dry in or on surgical instruments. Cannulas or lumens can become obstructed with organic material.

V.f.1. If items are soaked in water or an enzymatic solution at the point of use, the liquid should be contained or discarded before transport.

Disposal of liquid enzymatic solution before transport of instruments minimizes the risk of a spill and limits the weight of the container, which makes transportation easier and less likely to result in injury to personnel. When disposal at the point of use is not feasible, containing the solution will prevent spills and subsequent exposures.

V.f.2. A towel soaked with water, not saline, may be used to cover instruments to keep them moist.

Recommendation VI

Contaminated instruments must be contained during transport and should be transported in a timely manner to a location designed for

decontamination.¹⁰

Proper containment of instruments decreases the potential for injury to personnel or their exposure to infectious organisms and prevents damage to the instruments during transport.

VI.a. During transport to a decontamination area, soiled instruments must be contained in a manner to prevent exposure of patients or personnel to bloodborne pathogens and other potentially infectious organisms.¹⁰(PNDS:198)

The OSHA requires contaminated instruments be contained in a leak-proof container to minimize the risk of exposing personnel to contaminants during transport.¹⁰

VI.a.1. Hand-carried items must be contained (eg, enclosed by a plastic bag, container with a lid).¹⁰

VI.a.2. Large quantities of items may be contained within a larger transport container (eg, transport cart with doors or plastic cover).

VI.a.3. Items placed on top of a transport cart must be contained (eg, plastic bag).¹⁰

VI.a.4. Items with sharp or pointed edges must be contained in a puncture-resistant container.¹⁰

VI.a.5. Liquids must be contained in a spill-proof container.¹⁰

VI.a.6. Transport carts should be designed to prevent items from falling over or off the cart during transport to the decontamination area.

VI.b. The transport container must be labeled indicating biohazardous contents.¹⁰ The type of label may include, but is not limited to, magnetic signs, stickers, or plastic placards.

Labeling the transport container communicates to others that the items are potentially infectious. This labeling is required by OSHA.¹⁰

VI.c. Care should be taken to avoid contaminating the outside of the transport containment method. If the outside container has been contaminated, it must be either cleaned at the point of use or enclosed during transport.¹⁰

Contact with contaminated surfaces can transmit infectious agents during transport.

VI.d. Transport of soiled instruments should be separated from the delivery of clean and sterile supplies to the operating or procedure room.¹¹ (PNDS:I98)

Separation of soiled instruments from clean supplies minimizes the risk of cross-contamination.¹¹

VI.e. Contaminated surgical instruments should be transported to the decontamination area as soon as possible after completion of the surgical procedure.

Removal of organic material from instruments becomes more difficult after the debris has dried. Blood and body fluids that have dried on the instruments are hard to remove, can cause continuing surface corrosion damage (ie, pitting) over time, and can inhibit sterilization.

Recommendation VII

Instruments should be decontaminated in an area separated from locations where clean activities are performed.¹²(PNDS:I70)

Physical separation of decontamination areas from areas where clean items are handled minimizes the risk of cross-contamination. Cross-contamination can result when soiled items are placed in close proximity to clean items or placed on surfaces upon which clean items are later placed. Aerosols created during cleaning can also cause cross-contamination.

VII.a. Instruments should not be decontaminated in scrub sinks.

Cleaning soiled instruments in a scrub sink can contaminate the sink and faucet, which also may be used for clean activities (eg, hand washing, surgical hand antisepsis).

VII.b. The decontamination area should be physically separate from clean areas and include a door.¹² This area should contain, but not be limited to, the following equipment:

- sinks to manually clean instruments,
- hand washing facilities;¹⁰
- eye wash station,¹³
- automated equipment consistent with the types of instruments to be decontaminated,
- adaptors and accessories to connect instruments with cleaning equipment and utilities, and
- compressed air supply.

The design of the decontamination area facilitates the appropriate decontamination of instruments. Having equipment and utilities in place facilitates desired infection control practices. Keeping the door closed

exhausts aerosols out of the building, minimizing contamination of adjacent rooms.

Sinks are required to provide a place to manually clean or remove gross bioburden from instruments before using a washer decontaminator and are required for single instruments.

Hand washing facilities are required by OSHA for use after removal of personal protective equipment (PPE).¹⁰

An eyewash station is required by OSHA when chemicals, such as those used to clean instruments, are used.¹³

Automated cleaning and decontamination of equipment is recommended because it provides a high level of cleaning that is difficult to consistently replicate using manual methods. Compressed air is needed to clear lumens after cleaning.

VII.c. The decontamination area heating, ventilation, and air conditioning (HVAC) system should be controlled and monitored according to local requirements. (PNDS:I98)

Proper HVAC controls facilitate desired infection control practices. Local requirements vary depending upon the location.

VII.c.1. At a minimum, the following HVAC settings should be maintained in the decontamination area:

- negative air pressure;¹²
- at least six air exchanges per hour;¹²
- temperature of 68 °F to 73 °F (20° to 23 °C);¹² and
- 30% to 60% humidity.⁵

VII.c.2. Doors to the decontamination area should be kept closed, except when moving personnel and equipment.

Keeping the door closed exhausts aerosols out of the building, minimizing contamination of adjacent areas. Negative pressure within the decontamination room cannot be maintained, if the door is held open.

VII.d. The decontamination area should be stocked, at a minimum, with the following supplies:

- enzymatic cleaner,
- soft-bristle brushes,
- cleaning cloths,
- alcohol, and
- appropriate PPE.

Enzymatic cleaner is used for manual and automated cleaning of instruments. Soft-bristle brushes, designed for surgical instrument cleaning

can effectively clean instruments without damaging surfaces. Cleaning cloths are used for external surfaces. Alcohol is used to render instruments safe to handle after cleaning, if not rendered safe by another means. When cleaning instruments with water, it can be reasonably anticipated that there will be some splatter or splash of potentially infectious material. In these situations OSHA requires that personnel wear skin and mucous membrane protection (ie, fluid-resistant or impervious gown, gloves, face protection).¹⁰

Recommendation VIII

The type of water available for cleaning should be consistent with the manufacturer's written instructions and intended use of the equipment and cleaning agent. (PNDS:I70;I75;I122)

Water quality is affected by conductivity; the presence of dissolved mineral solids, chlorides, and other impurities; and its acidity or alkalinity. Water quality also fluctuates over time. The optimum combination of chemicals used in a washer decontaminator is based on the hardness of the available water.

VIII.a. Potable water should be used for manual or mechanical (ie, automated) decontamination methods unless contraindicated by instrument manufacturers' instructions.⁵(PNDS:I75)

VIII.b. Softened or de-ionized water should be used for the final rinse. (PNDS:I75)

Softened or de-ionized water removes soil and detergent residues more efficiently. Water with a high chloride or chlorine content can damage surgical instruments and equipment. Water softeners remove the calcium and magnesium ions that cause spots on instruments. De-ionizing water removes ionized salts and particles that could harm instruments.⁵

VIII.c. A water quality assessment should be performed periodically and after major maintenance to the water source.

Water quality varies seasonally and after water source maintenance. Periodic testing can indicate if the chemical combination used to condition the cleaning and decontamination water should be adjusted. Water quality checks determine the hardness of the water and if any impurities are present.

Impurities present in the water also can be a reflection of insufficient filtration. Repairs or modifications in the filtration system should be made based upon this testing.

Recommendation IX

Surgical instrument, medical device, and equipment manufacturers' validated instructions should be followed regarding the types of cleaning agents (eg, enzyme preparations, detergents) to be used for decontamination. (PNDS:I122)

Following manufacturers' instructions decreases the possibility of selecting cleaning agents that can be harmful to instruments (eg, abrasives can damage the protective surfaces of instruments, contribute to corrosion, impede sterilization). Use of inappropriate cleaning agents can result in damage to surgical instruments and equipment, and possibly limit their warranties.

IX.a. Manufacturers' written instructions and AORN's "Recommended practices for product selection in perioperative practice settings," should be followed for cleaning agent selection and proper use.¹⁴(PNDS:I70;I75;I122)

IX.a.1. Neutral detergents with a pH of seven, that are low-foaming, and free-rinsing, should be used for manual or mechanical cleaning of surgical instruments and equipment unless contraindicated by instrument or equipment manufacturers' instructions. (PNDS:I70;I75;I122)

Neutral pH detergents work well when enzymatic solutions are used as a part of the cleaning regimen. Low-foaming detergents are more easily removed during rinsing and are generally recommended for use by mechanical washer manufacturers.

IX.b. Highly acidic or highly alkaline pH detergents should be handled carefully and used only if recommended by instrument or equipment manufacturers.

Highly acidic or highly alkaline detergents can cause injuries to the skin or mucous membranes. Careful handling minimizes the risk of exposure.

IX.c. Cleaning agent manufacturers' written instructions should be followed

- during dilution,
- when selecting water temperature, and
- during use. (PNDS:I70;I75;I122)

IX.c.1. A titration unit may be used to efficiently dilute chemicals at a consistent ratio.

IX.d. Abrasive cleaning devices and agents (eg, metal scouring pads, metal brushes, cleaning agents containing chlorides, abrasive cleaners, scouring powders) should not be used.

Abrasive cleaning devices and agents can cause permanent damage to the instruments and equipment.

Recommendation X

All surgical instrument and medical device or equipment manufacturers' validated instructions should be followed regarding the types of cleaning methods (eg, manual, automated) to be used for decontamination. (PNDS:I70;I75;I122)

Use of inappropriate cleaning methods could result in damage and can limit the warranty of the surgical instruments or equipment.

X.a. Before beginning the cleaning process, instruments received into the decontamination area should be rinsed with cold running water. A rinse with cold running water will remove gross debris and help prevent coagulation of the blood present on the instrument.⁵

X.b. When manually cleaning, instruments should be washed in a manner that provides proper decontamination.⁵(PNDS:I70;I98)

Although automated methods are preferred, some delicate instruments (eg, microsurgery, eye), power equipment, and other instruments that cannot be submerged can require manual cleaning.

X.b.1. Manual cleaning should be accomplished by submerging the instrument in warm water with an appropriate detergent followed by complete submersion of the instrument in rinse solution to minimize aerosolization of contaminants.⁵

Aerosolization of contaminants, splashing of infectious material, and injury from sharp objects are possible when manual cleaning is performed under a stream of running tap water.

X.c. Mechanical cleaning of surgical instruments should be accomplished by ultrasonic cleaners, washer decontaminators/disinfectors, or washer sterilizers.⁵

Mechanical cleaning is preferred because it removes soil efficiently and provides consistent washing and rinsing parameters during the process. Mechanical equipment specifically designed to decontaminate (ie, clean, disinfect) special types of medical devices is also available.

X.c.1. Ultrasonic cleaners should be used according to the manufacturer's operating instructions.

Ultrasonic cleaners use a process called cavitation that facilitates removal of small particles and debris from instrument joints, crevices, and hard to reach places (eg, lumens).⁵ Ultrasonic energy is passed through a water bath, creating bubbles that implode. This process of implosion creates a suction action that pulls debris away from instrument surfaces.¹⁵

X.c.2. Ultrasonic cleaners should be used only after gross soil has been removed.

X.c.3. Manufacturers' instructions should be followed regarding detergent selection for use in ultrasonic cleaning devices.

Low-foaming detergents are commonly used in ultrasonic cleaning devices.

X.c.4. Ultrasonic cleaning device manufacturers' written instructions should be followed regarding "degassing" the cleaning solution before processing instruments.

Degassing conditions the solution by removing some air to improve cavitation and soil removal.

X.c.5. Only instruments made of similar metals should be combined in the ultrasonic cleaner unless specified otherwise in the instrument manufacturer's written instructions.¹⁵

Placing only instruments made of similar metals in the ultrasonic cleaner will prevent instrument etching and pitting from occurring because of the transfer of ions from one instrument surface to another.

X.c.6. Some instruments should not be placed in an ultrasonic cleaner, these include

- chrome-plated instruments;
- power instruments;
- rubber, silicone, or plastic instruments; and
- endoscopic lenses.

The mechanical vibrations can cause chrome plating to flake.¹⁵

Power instruments can be damaged by fluid contacting internal parts.

Rubber materials, plastics, and endoscopic lenses can be damaged by the vibration.⁶

X.c.7. Instruments with lumens should be fully submerged and filled with cleaning solution to remove air from within the channel.

The presence of air prevents the solution from contacting the inner lumen of instruments and affects the cavitation process.⁵

X.c.8. Instruments should be thoroughly rinsed after ultrasonic cleaning.⁵

X.c.9. A lid should be in place when the ultrasonic cleaner is in use.

The presence of the lid prevents aerosolization of contaminants.⁵

X.c.10. Cleaning solution should be checked between cycles and changed, if visibly soiled.

The presence of gross soil in the water impedes the effectiveness of cavitation on the instruments surface.⁵

X.c.11. Ultrasonic cleaners should be emptied, cleaned, rinsed with sterile water, and the chamber wiped with alcohol when visibly soiled and at least daily.

The fluid in the ultrasonic cleaner can harbor gram negative bacteria. Growth of these bacteria results in the production of endotoxins, which are heat-resistant, can survive steam sterilization, and can have serious patient consequences. Endotoxins from contaminated eye instruments have been shown to cause toxic anterior segment syndrome (TASS), an acute inflammation of the anterior segment of the eye.¹⁶ Alcohol disinfects the ultrasonic cleaner and prevents microbial growth.

X.c.12. Automated washer decontaminators or disinfectors and washer sterilizers should be used according to the manufacturer's written instructions.

Washer decontaminator cycles are intended to process instruments and equipment to a level that renders them safe to handle by persons who will inspect and prepare them for terminal sterilization. This type of decontamination equipment can use a single chamber for rinsing, cleaning, and drying or can use multiple chambers and is usually referred to as a "tunnel washer" (ie, one chamber for each phase of the cycle). These phases can include

- an initial cool-water rinse to remove protein debris,
- an enzymatic rinse,
- a detergent wash,
- an ultrasonic cleaning,
- a sustained hot-water rinse,
- a de-ionized water final rinse,
- a lubrication rinse,
- a liquid chemical germicide rinse, and
- a drying cycle.¹⁵

The sequencing and number of stages can vary among manufacturers.

Washer decontaminators or disinfectors can accomplish the microbicidal

part of the process by thermal or chemical means, once the items have been thoroughly cleaned and rinsed.

The washer sterilizer first cleans instruments through several phases of the cycle that can include a cold water pre-rinse, a high-temperature wash with final rinse, and then sterilization. This process can be accomplished in a small or large chamber.

X.c.13. The instrument manufacturer's instructions should be used to determine the amount of time necessary to efficiently clean and rinse the instruments.

X.c.14. The operator should ensure the proper cycle is being used.

Many mechanical washers have pre-programmed cycles, and the wash and rinse phases of the cycles are often adjustable. The manufacturer of the mechanical washer should be consulted to determine

- what level of decontamination is achieved with the washer decontaminator (ie, low-level, intermediate-, high level-disinfection); and
- how the user can verify that a cycle was sufficient to render the processed items safe to handle.

Recommendation XI

Surgical instruments should be inspected for cleanliness and proper working order after decontamination. (PNDS:I70)

Inspecting instruments for sterilization before assembly of trays provides an opportunity to identify those instruments that require additional cleaning or repair before use.

XI.a. Instruments should be inspected for:

- cleanliness;
- alignment;
- corrosion, pitting, burrs, nicks, and cracks;
- sharpness of cutting edges;
- loose set pins;
- wear and chipping of inserts and plated surfaces;
- missing parts;
- any other defects;
- removal of moisture; and
- proper functioning. (PNDS:I70)

Instruments can become damaged during use or decontamination. Sterilization may not occur in the presence of soil or water.

XI.b. Instruments should be thoroughly dried.(PNDS:I70;I98)

Elimination of moisture helps prevent rust formation during instrument storage. The presence of moisture can impede the sterilization process.

- Moisture on instrument surfaces alters the moisture content of steam and can pose a challenge for effective heating of the instrument.
- Ethylene oxide (EO) combines with water and creates ethylene glycol (ie, antifreeze) which is toxic and not removed during aeration.
- Excess moisture inhibits the hydrogen peroxide plasma sterilization process and can result in an aborted cycle.²

XI.c. The instrument manufacturer's written instructions should be followed for selection and appropriate use of lubricants. (PNDS:I122)

Lubricants decrease friction between working surfaces. Some instruments do not require lubrication. Cleaning, particularly ultrasonic cleaning, removes lubricants from instruments.

XI.c.1. Instruments should be clean before lubricant is applied.

Applying lubricants to soiled instruments can compound the problem of stiff joints and inhibit smooth movement.

XI.c.2. Lubricants should be compatible with the method of sterilization to be used.

Water soluble lubricants allow steam penetration during sterilization; oil-based products, however, cannot be penetrated and prevent the sterilant from contacting the instrument's surface.

XI.d. Instruments in disrepair should be tagged or labeled and removed from service until repaired. (PNDS:I70)

Identification of defective instruments facilitates segregation of these instruments from those to be used when assembling sets and prevents defective instruments from being used on patients.

XI.e. Instruments to be sterilized should be packaged according to AORN's "Recommended practices for selection and use of packaging systems for sterilization."¹⁷(PNDS:I70)

XI.f. The AORN “Recommended practices for sterilization in the perioperative practice setting”² should be referred to for recommendations regarding instrument sterilization.(PNDS:I70)

Recommendation XII

Cleaned surgical instruments should be organized for packaging in a manner to allow the sterilant to contact all exposed surfaces. (PNDS:I70)

Proper organization will facilitate sterilant contact on all surfaces and adequate drying.

XII.a. Instruments should be placed in a container tray or basket that is large enough to evenly distribute the metal mass in a single layer. (PNDS:I70)

Instruments should be contained within the tray or basket in a manner which protects the instruments from damage and prevents puncturing of the sterilization wraps. Overloading trays can cause wet packs as an increase in metal mass in the tray results in more condensate, which requires additional drying at the end of the cycle.

XII.b. Broad-surfaced instruments and those with concave surfaces (eg, malleable retractors, hip skids) should be placed on edge. (PNDS:I70)

Instruments placed on edge facilitate drying because in this position, steam condensate will drain off the instrument rather than pool on it.

XII.c. Instruments with hinges should be opened and those with removable parts should be disassembled when placed in trays designed for sterilization, unless the manufacturer has provided validated instructions to the contrary. (PNDS:I70)

Sterilization only occurs on surfaces which have direct contact with the sterilant. Disassembly of multiple-part instruments and those with sliding parts (eg, retractors) enables the sterilant to contact all surfaces.

XII.c.1. Instruments should be kept in the open and unlocked position using instrument stringers, racks, or instrument pegs designed to contain instruments. (PNDS:I70)

XII.d. Delicate and sharp instruments should be protected using a device such as a tip protector. The tip protector should be used according to the manufacturer's instructions. (PNDS:I70)

Damage to delicate and sharp instruments can render them ineffective.

XII.d.1. Tip protectors should be

- used for sharp or delicate instruments,
- validated for use with the chosen method of sterilization,
- used according to manufacturers' instructions, and
- loose-fitting so that the sterilant can contact the surface to be sterilized. (PNDS:I70;I122)

XII.d.2. Heavy instruments should be positioned on the bottom of trays. (PNDS:I70)

Positioning heavy instruments on the bottom of trays helps prevent damage to delicate items that may be present.

XII.e. Only validated containment devices should be used to organize or segregate instruments within sets. (PNDS:I70;I122)

Many devices used to organize or segregate instruments within sets have not been validated as safe and effective by container or wrap/pouch manufacturers. The presence of these devices inside of a packaged instrument set can prohibit

- air removal,
- sterilant contact with instruments in close proximity to the containment device,
- sterilant evacuation, and
- condensate drainage and drying.

XII.e.1. Rubber bands should not be used to keep several instruments together.

Sterilant cannot contact surfaces beneath rubber bands and instruments may not be sterilized.

XII.e.2. Paper-plastic peel pouches should not be used to organize or segregate instruments within sets unless their use is validated by the containment device manufacturer.

XII.e.3. Small accessory baskets or boxes with lids or covers to contain instruments, parts, or accessories should not be incorporated into sets unless

their use is validated by the containment device manufacturer.

XII.e.4. Non-absorbent, non-woven disposable wrap material (eg, polyolefin spun-bound) should not be used as a tray liner or to organize or segregate a small group of instruments to be placed into the instrument set.

This type of material is not intended for use within an instrument set that is to be steam sterilized because it does not absorb moisture. Moisture can pool on this material causing a wet pack.

XII.f. Suction lumens and other devices with similar channels should be flushed with distilled, de-mineralized, or sterile water immediately before steam sterilization.⁵(PNDS:I70;I75)

When the moisture within the lumen is heated it will produce steam, which moves air out of the lumen resulting in lumen sterilization. The steam in the compartment does not move into the lumen because the lumen acts as a diffusion restrictor. Tap water might contain pyrogens.

XII.g. Stylets should be removed from lumens.

Removal of stylets enables sterilant contact with the inside of lumens.

XII.h. The instrument tray or basket should be lined with an absorbent, lint-free, surgical towel if indicated.

The towel will absorb and disperse moisture to assist in drying the set.⁵

XII.i. Non-absorbent plastic or silicone fingered mats should be used according to the mat manufacturer's validated instructions for the various sterilization cycles in which they will be used. (PNDS:I122)

Improper use of non-absorbent plastic or silicone mats may cause condensate to pool and inhibit drying.

XII.j. Information provided by the container manufacturer describing how instruments should be placed within the container or tray should be followed for each sterilization method used. (PNDS:I70;I122)

Recommendation XIII

Powered surgical instruments and all attachments should be decontaminated, lubricated, assembled, sterilized, and tested before use

**according to the manufacturer's written instructions.
(PNDS:I77;I75;I122)**

Proper care and handling of powered surgical instruments minimizes the risk of injury to patients and personnel. Manufacturers' instructions are validated for specific instruments only and are not transferable to other devices because the design of powered surgical instruments and equipment varies.

XIII.a. Powered equipment and attachments should be cleaned and maintained according to manufacturers' written instructions.
(PNDS:I77;I75;I122)

Improper care and cleaning of powered equipment lead to exposure to pathogens and injury to patients and personnel.

XIII.b. Attachments should be properly affixed to the units and tested before use. (PNDS:I77)

Improperly seated attachments can be ejected from the equipment with great force and cause injury to patients and personnel. Testing the equipment or device before use can decrease the risk of injury.

XIII.b.1. Trigger handles should be placed in the safety position when changing attachments. (PNDS:I77)

Accidental activation of powered equipment can cause injury.

XIII.c. Medical-grade compressed air or compressed dry nitrogen (ie, 99% pure) should be used to operate air-powered equipment according to the manufacturer's written instructions.

Use of contaminated gases to run powered equipment can result in equipment damage and patient injury.

XIII.d. Manufacturers' written instructions should be used to determine the correct pressure settings required to operate equipment. The setting should be measured with the equipment operating. (PNDS:I77;I122)

Using excessive pressure can damage equipment and exert great stress on air hoses. Unless pressure is set with the equipment operating, incorrect pressures can result. Pneumatic equipment may not perform in the designated manner, if the pressure is set above or below recommended limits.

XIII.d.1. When an extension hose is used, the manufacturer should be consulted for appropriate pressure setting.

Pressure at the hand piece decreases when an extension hose is used.

XIII.e. Only grounded outlets should be used for electrical powered equipment.

XIII.f. Powered equipment should be cleaned and decontaminated thoroughly after use, following manufacturers' written, validated, cleaning instructions. (PNDS:I70;I75;I98)

Organic debris left on powered equipment hinders the sterilization process and can interfere with proper functioning. Powered instruments contain complex lumens and movable parts, intricate internal components, and may not be immersible in cleaning solutions. Permanent damage can result if fluid enters the internal mechanisms of powered equipment. Special attention is required to assure that blood and contaminated tissue are adequately removed from the instrument before sterilization. Following manufacturers' instructions reduces the possibility of damaging or inadequately cleaning the instrument.

XIII.f.1. Blades and drill bits should be removed from powered equipment in the OR by the scrub person after the procedure has ended.

XIII.f.2. Instrument manufacturers' written recommendations for detergent or germicide should be followed.

Abrasive detergents can damage protective surfaces, contribute to corrosion, and impede sterilization.

XIII.f.3. Powered equipment should not be immersed or placed under running water, in ultrasonic cleaners, washer disinfectors, or washer sterilizers, unless indicated in the equipment manufacturers' instructions.

XIII.f.4. When pneumatic hand pieces are cleaned, air hoses should be attached.

Attaching the air hose to the pneumatic hand piece during cleaning facilitates keeping the internal parts of the hand piece dry.

XIII.f.5. All traces of detergent or germicide and excess fluids should be wiped from the equipment and attachments. (PNDS:I75)

XIII.f.6. The outer surfaces of the powered equipment and attachments should be dried with lint-free towels. (PNDS:I75)

XIII.f.7. Powered equipment, batteries, attachments, and power cords should be inspected for damage or wear after decontamination and before use.

XIII.g. Air hoses should not be immersed or placed in ultrasonic cleaners, washer disinfectors, or washer sterilizers, unless indicated in the air hose manufacturer's instructions. (PNDS:I122)

Ultrasonic cleaners, washer sterilizers, and washer decontaminators force fluids into internal parts. Fluid in air hoses is not evacuated during these cycles, possibly leading to evacuation of this contaminated fluid during the surgical procedure

XIII.g.1. Air hoses should be inspected for damage or wear before and after decontamination and before use. (PNDS:I70;I85;I98)

XIII.g.2. Air hoses should be wiped with a clean, damp cloth using detergent or germicidal solution.

XIII.g.3. All traces of detergent or germicide and excess fluids should be wiped from the surface of the air hose. (PNDS:I77)

XIII.h. Powered equipment and attachments should be lubricated with a product specifically recommended by the manufacturer and applied according to manufacturers' instructions. (PNDS:I122)

Lubricants decrease friction between working surfaces, which is essential for optimal functioning of the instrument and helps to prolong equipment life. Some instruments are sealed and do not require lubrication. Manufacturers may recommend oil-based or non-oil based lubricant for powered equipment.

XIII.i. Manufacturers' written instructions for packaging powered equipment and attachments should be followed. Packaging instructions should include methods to

- disassemble powered equipment before sterilization,
 - protect delicate parts of the equipment, and
 - loosely coil air hoses when packaged for sterilization.
- (PNDS:I70;I122)

Manufacturers' sterilization validated parameters should be followed for powered equipment, batteries, and attachments.

Recommendation XIV

Special precautions should be taken for reprocessing ophthalmic surgical instruments.¹⁸ (PNDS:I70)

Toxic anterior segment syndrome (TASS) can result from contaminants introduced into the eye during ophthalmic surgery.^{16,19,20,21} An incidence of TASS can cause serious damage to a patient's intraocular tissue and result in vision loss.¹⁶ More than 300 cases of TASS associated with balanced salt solution contaminated with endotoxins were reported to the US Food and Drug Administration (FDA) leading to the contaminated product being recalled by the FDA.²² Other potential etiologies of TASS include

- antiseptics,^{23,24}
- antibiotic ointment,¹⁹
- medications,²⁵ and
- powder from surgical gloves.^{26,27}

Most cases of TASS appear to result from inadequate instrument cleaning and sterilization.¹⁶ Other reported TASS cases were associated with glutaraldehyde and detergent residue on instruments,^{28,29} endotoxins from gram-negative bacteria in ultrasonic cleaners,^{30,31} impurities in steam from improperly maintained sterilizers,²⁰ and degradation of brass surgical instruments sterilized by hydrogen peroxide gas plasma.³² Prevention of TASS requires thorough cleaning and rinsing of surgical instruments.¹⁸

XIV.a. Instruments should be wiped clean with sterile water and a lint-free sponge during the surgical procedure. (PNDS:I70;I75)

Viscoelastic solution can harden on instruments within minutes.

XIV.b. Instruments should be immersed in sterile water immediately at the end of the procedure. (PNDS:I70)

Biofilm adheres to the surfaces of instruments and is very difficult to remove. Keeping the organic material moist prevents the formation of biofilm.

XIV.c. Single-use cannulae should be used whenever possible. If reusable cannulae are used, the lumens should be flushed with sterile water immediately at the end of the procedure. (PNDS:I70;I75)

Lumens are difficult to clean and can harbor contaminants.

XIV.d. Manufacturers' written instructions for cleaning each instrument should be reviewed and followed. (PNDS:I70;I75;I122)

The method of cleaning and the compatibilities of cleaning agents are unique to each instrument. Instructions for cannulated instruments indicate the type and volume of solution to be used for rinsing and cleaning, the

frequency of flushing, and the number of times the cannula should be flushed.

XIV.e. The irrigation and aspiration ports of phacoemulsification hand pieces, tips, and tubing should be flushed before disconnecting the handpiece from the unit. (PNDS:I70;I75)

Several centers have reported occluded tips as a potential cause of TASS.¹⁶ Flushing the handpiece prevents build-up of material inside the handpiece, which is difficult to remove during cleaning.

XIV.f. Intraocular lens injectors/inserters should be carefully cleaned. (PNDS:I70)

Residue in the injector can be inserted into the eye chamber and cause TASS.¹⁶

XIV.g. Single-use items must be used only once and discarded or reprocessed using validated methods in accordance with FDA regulations.³³

XIV.h. Detergents and enzymatic detergents should be used and diluted according to cleaning agent manufacturers' written instructions. (PNDS:I70;I75;I122)

Some cleaning agent manufacturers' instructions require the use of de-ionized or distilled water for diluting the detergent.

XIV.i. Enzymatic detergents should be used only if recommended by the surgical instrument manufacturer. (PNDS:I122;I75)

Following instrument manufacturers' instructions assures compatibility of the detergent with the instrument.

XIV.j. After cleaning or decontamination, instruments should be thoroughly rinsed with distilled or de-ionized sterile water and dried. (PNDS:I70;I75)

Residual enzymes and detergents not rinsed from the instruments can cause TASS.^{16,18}

XIV.k. After cleaning, lumens should be thoroughly flushed with sterile

water (expelling the liquid into a drain not the rinse water) and dried with filtered, oil-free, compressed air. (PNDS:I70; I75)

Sterile water removes detergent residue. Expelling the lumen rinse into a drain prevents recontamination of the instrument with lumen contents. Compressed air forced through the lumen eliminates moisture which can serve as a medium for microbial growth

XIV.l. Syringes and brushes used to clean ophthalmic instruments and cleaning solutions should be discarded after each use (if designed for single use) or sterilized following all recommended precautions.

Cleaning tools can harbor contaminants that can be reintroduced during cleaning of the next instrument.

XIV.m. After manual or ultrasonic cleaning, instruments should be wiped with alcohol before preparation for sterilization.

Wiping with alcohol disinfects the instruments and renders them safe to handle.

XIV.n. After cleaning and disinfection, instruments contacting viscoelastic material should be inspected for residue with a magnifying lens.

Viscoelastic material is difficult to remove during cleaning, and inspection with magnification can enhance detection of residual material.

XIV.o. Records should be maintained of all cleaning methods; detergent solutions used, and lot numbers of cleaning solutions.

These records can be used to facilitate investigation of any suspected or confirmed cases of TASS

XIV.p. An adequate inventory of instruments should be provided to allow for thorough instrument cleaning and sterilization.

An adequate inventory of instruments facilitates compliance with proper decontamination and sterilization processes.

XIV.q. Adequate time should be provided for thorough instrument cleaning and sterilization.

Time constraints may create a disincentive for personnel to adhere to decontamination procedures, and may result in noncompliance.

Recommendation XV

Insulated electrosurgery instruments should be decontaminated after use according to manufacturers' validated, written instructions and inspected for damage. (PNDS:I70; I72)

Breaks in the insulation of electrosurgery instruments can occur during use and handling. These insulation failures can result in current leakage and subsequent burns. Inspection of the instruments provides a screening mechanism to identify visible insulation breaks.³⁴ Additional information about electrosurgery can be found in AORN's "Recommended practices for electrosurgery."⁹

XV.a. Insulated electrosurgical instruments should be inspected for small breaks in the insulation before initial use. (PNDS:I72)

Breaks in insulation can occur during manufacturing and transportation.

XV.b. Insulated instruments should be handled in a manner to prevent sharp instruments from contacting the insulation, and they should be segregated from sharp objects during use, transport, and decontamination.

Sharp objects and rough handling can damage the insulation during use, transport, and decontamination.

XV.c. Electrosurgical instruments should be decontaminated according to manufacturers' written instructions using care to avoid damaging the insulation on the device. (PNDS:I72;I122)

Abrasive cleaning may damage insulation.

XV.d. The insulation on electrosurgical instruments should be inspected for impairment using a magnifying lens after decontamination. (PNDS:I72)

Visual inspection identifies obvious breaks in insulation, but will not identify all insulation failures. Using a magnifying lens can assist with identifying small imperfections.³⁴

XV.e. Technology should be used to conduct stray current leakage tests at the end of each decontamination cycle.

Current can leak through insulation, even when breaks are not clearly visible. Performing a visual inspection and performing any recommended technological evaluation before preparation for sterilization minimizes the risk of using defective instruments that could lead to patient injury. Detecting insulation failures well in advance of a surgical procedure provides time for equipment replacement.

XV.f. Equipment found to have insulation damage should be immediately removed from service and repaired or replaced.

Instruments with impaired insulation are unsafe for use.

XV.g. Manufacturers' written recommendations limiting the use of insulated instruments to a specific time frame or number of reprocessings should be followed. (PNDS:I122)

Manufacturers validate the life span of the equipment insulation, and use after that period of time can result in injury to the patient. If injury occurs in this situation, the health care organization may have to assume the liability.

Recommendation XVI

Special precautions should be taken when cleaning robotic instruments.

Robotic instruments and equipment have lumens with complex, difficult to clean internal and external components that require special attention to adequately decontaminate the instruments.

XVI.a. Gross soil should be removed from the external surfaces using a soft-bristled brush. (PNDS:I70)

Robotic "wrists" and electrosurgical tips can become soiled during use.

XVI.b. The ports of robotic instruments and equipment should be flushed

- with a water line,
- in the sequence and for the duration identified by the manufacturer's written instructions,
- while moving the robotic wrist through a full range of motion, and
- until the fluid exiting the ports is clear.

Moving the robotic wrist through a full range of motion exposes all of its surfaces to the cleaning solution.

XVI.b.1. The fluid expelled from the ports during flushing should be directed into a drain and not allowed to run into the receptacle of clean solution.

XVI.c. Ports should be primed with clean enzymatic cleaner and the device cleaned in an ultrasonic cleaner according the manufacturer's written instructions. (PNDS:I70; I122)

Ultrasonic cleaning facilitates removal of debris that has adhered to components.

XVI.c.1. After ultrasonic cleaning, ports should be flushed:

- with de-ionized water, under pressure; and
- in the sequence and for the duration identified by the manufacturer's written instructions. (PNDS:I70;I75)

Flushing of ports removes residual cleaning solution.

XVI.d. Ports should be cleared with compressed air in the sequence and duration identified by the manufacturer's written instructions. (PNDS:I122)

Clearing lumens and internal components with compressed air removes residual water that can serve as a medium for microbial growth.

XVI.e. Movable parts of the robotic instruments and equipment should be lubricated according to the manufacturer's written instructions. (PNDS:I122)

Lubrication facilitates the functioning of the hinges and joints of robotic instruments and equipment which coordinate fine dissection and manipulation of tissue.

XVI.f. The outside of the instruments should be wiped with alcohol or an instrument disinfectant, before preparation for steam sterilization. (PNDS:I70;I98)

Wiping with alcohol or another disinfectant renders the instrument safe to handle.

Recommendation XVII

Special precautions should be taken to minimize the risk of transmission of prion diseases. (PNDS:I145)

Prions are a unique classification of infectious agents with a genetic component that are thought to be transmitted through direct inoculation, rather than the traditional routes (ie, bloodborne, skin contact, droplet, airborne). The resulting human prion diseases (ie, Creutzfeldt-Jakob disease[CJD], variant CJD, fatal familial insomnia, Gertsman-Straussler syndrome) are fatal, degenerative, neurological disorders.³⁵

Prions have been transmitted experimentally through direct inoculation (eg, oral ingestion, inoculation of scratched skin, injection, implantation) and

have been transmitted iatrogenically through transplanted, contaminated tissue (eg, cornea, dura mater) and injections of human pituitary hormones (eg, growth hormone, gonadotropin).³⁶ Six cases of transmission via neurosurgical instruments occurred before 1980 in Europe.³⁶ No other cases have been reported resulting from transmission via instruments in other types of surgery or since that time.

Prions are resistant to chemical disinfection (eg, alcohol, glutaraldehyde) and routine sterilization (ie, steam, ethylene oxide, gas plasma, peracetic acid).³⁷ These agents remain infective for years and special precautions are required to eliminate their infectivity.³⁸

XVII.a. An interdisciplinary team should develop processes to minimize the risk of prion disease transmission. These processes should be based upon the probability or possibility of

- a patient having a prion disease,
 - the level of infectivity of the tissue involved, and
 - the characteristics of the surgical instruments involved.
- (PNDS:I145)

Use of a defined protocol helps protect patients and health care workers from pathogen transmission. Including personnel with different types of expertise (eg, anesthesia providers, central sterilizing employees, housekeeping personnel, infection control team members, neurosurgeons, perioperative services personnel) in the protocol development maximizes the likelihood of developing effective strategies and enhances compliance with the procedures that are developed.

Diagnostic criteria for CJD have been developed by the World Health Organization (WHO). Diagnosis can be confirmed, but cannot be ruled out, by brain biopsy.³⁵ Prion diseases can be genetically acquired or acquired through contact with infectious material; however, all prion diseases are infectious regardless of mode of acquisition.

Patients at high risk of having or developing prion diseases include:

- patients with rapidly progressive dementia consistent with CJD in whom a diagnosis has not been confirmed or ruled out;
- members of families in which prion disease has occurred (eg, two or more family members with a confirmed diagnosis); and
- recipients of cadaveric dura mater grafts or human pituitary gland hormones (eg, growth hormone, gonadotropin).

Cadaveric dura mater has been replaced with fascia grafts, and synthetic pituitary hormones have replaced those derived from human pituitary glands to reduce the risk of prion transmission.³⁶

While all prion diseases are infectious, infectivity is based primarily on laboratory studies of different prion diseases in humans and animals.^{36,39}

Central nervous system tissue (eg, brain, spinal cord, dura mater, pituitary) has been shown to be highly infectious as has tissue from the posterior eye (eg, optic nerve, retina). Other tissues and fluids that have shown to have a lower level of infectivity include

- corneal tissue;
- lymphoid tissue, the spleen, thymus, appendix, tonsils, and lymph nodes;
- the kidneys, liver, lungs, and placenta;
- skeletal muscle;
- olfactory cilia and pathways;
- cerebral spinal fluid; and
- blood.

Other areas of the body demonstrate no infectivity, such as

- the heart muscle, intestine, peripheral nerves, prostate, testis, thyroid;
- adipose tissue, bone marrow, skin; and
- feces, milk, nasal mucus, saliva, semen, serous fluid, sweat, tears, urine, and vaginal secretions.

XVII.a.1. Considerations regarding instruments used on patients suspected of having prion disease should include, but not be limited to, the

- use of single-use versus reusable instruments, if possible;
- ability of the instrument to tolerate heat;
- complexity of cleaning required (eg, lumens); and
- intended use of the instrument (eg, in internal tissues).

XVII.b. Patients should be screened for the risk of prion disease and any information discovered should be conveyed to the OR during scheduling of the surgical procedure. (PNDS:I145)

Screening patients provides a mechanism to identify which patients are at high risk of having a prion disease. Conveying this information during scheduling provides adequate time to plan instrument use and decontamination and to discuss alternatives to the use of complex instruments and implant sets requiring reprocessing.

XVII.c. When treating patients at high risk for a prion diseases, instruments used on highly infective tissue should be minimized, limited to those that are

easily cleaned, and replaced with single-use devices, when possible(PNDS:I70;I145)

Minimizing the number of instruments limits the number of items that need to be decontaminated and reduces the risk of an error that can result in exposure of subsequent patients or personnel.

XVII.c.1. Single-use brain biopsy sets should be used.

Creutzfeld-Jacob disease is often definitively diagnosed by brain biopsy. Single-use brain biopsy sets are commercially available or can be assembled using older instruments.

XVII.c.2. Instruments with lumens (eg, suction tips, needles) should be single use when possible.

Lumens are difficult to effectively decontaminate.

XVII.c.3. Flexible neuroendoscopes should be replaced with rigid alternatives.

Flexible endoscopes are difficult to clean and will be damaged during the cleaning and sterilization methods known to deactivate prion infectivity.

XVII.c.4. Power drills should not be used.

Power drills may splatter potentially infective material, are difficult to clean, and cleaning and sterilization methods known to eliminate prion infectivity damage these instruments.

XVII.c.5. Surgical drapes, gowns, and single-use supplies should be used, whenever possible, and incinerated after use. (PNDS:I70;I145)

Drapes and gowns are in contact with highly infectious tissue during these procedures. Routine hospital laundry does not de-activate prions.

XVII.c.6. Work surfaces should be covered with disposable, impervious material that can be removed and incinerated after the procedure.

Minimizing contamination of the room minimizes the need for special precautions during environmental cleaning.

XVII.c.7. Trays of implants (eg, burr hole covers, screws) should be limited to those implants essential for the specific patient. Implants opened and handled by scrubbed personnel after the surgery has started should be

discarded and not reprocessed for subsequent patient use.

The determination of the need for and size of implant rests with the surgeon. Collaboration between the perioperative nurse and surgeon can result in elimination of implants that the surgeon determines are nonessential. If implants normally delivered to the sterile field in sets (eg, plates and screws) are required, removing implants that are not needed for the patient before sterilizing the tray decreases the amount of implant inventory needing to be discarded.

XVII.d. Single-use instruments that have come in contact with tissue considered to be highly infective from patients at high risk for a prion disease should be incinerated.

XVII.e. Work surfaces contaminated with prions should be cleaned per manufacturers' written instructions with sodium hydroxide (NaOH), sodium hypochlorite (ie, bleach), or a phenolic or alkaline solution proven to be effective at inactivating prions.^{40,41}

An alkaline cleaner is commercially available that has been found to be effective against prions.⁴¹ A specific phenolic which is commercially available has been found to be more effective in inactivating prions than other phenolic products.⁴⁰ No transmissions of prion diseases from environmental surfaces have been reported; however, it remains prudent to eliminate highly infectious material from operating room surfaces that patients and personnel will be in contact with during subsequent surgeries.

For more information on cleaning of work surfaces contaminated consult AORN's "Recommended practice for environmental cleaning in the surgical practice setting."⁴²

XVII.f. Reusable instruments that have come in contact with highly infective tissue of patients at high risk for a prion disease should be treated to reduce infectivity using the following steps listed below. (PNDS:I70)

When a potentially contaminated device can be cleaned and prion or tissue load decreased or physically removed, the probability of infection transmission is reduced significantly. There is currently no consensus on the best method of managing instruments that are likely contaminated with prions. Peracetic acid is ineffective and hydrogen peroxide gas plasma alone is only partially effective against prions.⁴³

XVII.f.1. Instruments that cannot be adequately cleaned or require low-temperature sterilization (ie, EO, hydrogen peroxide gas plasma) should be discarded.

XVII.f.2. Instruments should be kept moist until they are cleaned and decontaminated

Drying renders prions more resistant to steam sterilization. Keeping instruments moist and cleaning them immediately after use minimizes drying.

XVII.f.3. Personnel should wear impervious gowns, heavy duty gloves, and face shields while decontaminating instruments. (PNDS:I70)

XVII.f.4. Instruments should be cleaned with a cleaner or detergent that has demonstrated effectiveness against prions as soon as possible after use. (PNDS:I70)

Enzymatic cleaners are ineffective or only partially effective when used alone and use of some of these cleaners make subsequent exposure to steam less effective.⁴⁴ Commercial cleaners are available which have demonstrated effectiveness against prions.^{40,43} Using one of these cleaners for initial instrument cleaning minimizes the risk of a less effective steam sterilization cycle.

XVII.f.5. After thorough cleaning, one of the following methods should be used to steam sterilize the instruments.

- Eighteen minutes in a pre-vacuum sterilizer with a cycle temperature of 134° C (272° F).
- Sixty minutes in a gravity displacement sterilizer with a cycle temperature of 132° C (272° F).
- Immersion of instruments in 1N sodium hydroxide (NaOH) (1 Normal or 1 Molar concentration of NaOH) for one hour, followed by removal and a water rinse, followed by a steam sterilization cycle as noted above.

The WHO has recommended instruments exposed to prions be immersed in 1N sodium hydroxide for one hour followed by steam sterilization of the immersed instruments in the container at 121° C (250° F) for 30 minutes. Sterilizing instruments in a bath of sodium hydroxide creates dangerous vapors that can injure the airway and eyes of health care workers and can cause burns.⁴⁵ This practice also damages sterilizers, invalidates the sterilizer warranty, and corrodes some surgical instruments.^{46,47} Using a polypropylene containment pan with a lid when sterilizing the instruments in the 1N sodium hydroxide bath has been found to contain the vapors within the pan.⁴⁵

A combination of the enzymatic cleaner found to be effective against prions and hydrogen peroxide gas plasma sterilization for three hours was found to be as effective as pre-vacuum sterilization for 18 minutes.⁴³ The extended exposure time would require consultation with the sterilizer manufacturer. The effect of this combination on instrument surfaces is unknown.

XVII.f.6. After initial deactivation of the prion, instruments should be processed in a washer decontaminator and sterilized in the usual fashion. (PNDS:I75)

XVII.f.7. Solidify and incinerate any liquids used for cleaning.

XVII.g. Devices that have been contaminated with medium-, low-, or no-infectivity tissue can be cleaned and disinfected or sterilized using conventional protocols of heat, chemical sterilization, or high-level disinfection.

When a device is contaminated with tissue or body fluids that are not deemed to be of high-infectivity and the device can be cleaned effectively, the probability of infection transmission appears to be so low that it would not be measurable. During surgery on patients at high risk for prion disease, most surfaces in the operating room are not contaminated with highly infectious material and routine cleaning will limit contamination to what is considered a safe level.⁴⁸

XVII.h. If a patient is identified postoperatively as having had a prion disease at the time of surgery, special precautions should be taken. Devices determined to be potentially contaminated with highly infectious tissue of this patient should be pulled from service and decontaminated as described above after the device has been reprocessed.

Prions can survive for years.³⁸ Inadequately decontaminated instruments pose a risk to subsequent patients who have had contact with the instruments.

XVII.i. Perioperative nurses should review current research on methods of detecting prion infectivity and decontamination methods.

Knowledge about detection of prion contamination on instruments and the effectiveness of various methods of deactivation is evolving as new research is published.

Recommendation XVIII

Personnel handling contaminated instruments and equipment must wear appropriate personal protective equipment (PPE)¹⁰ and should be vaccinated against the hepatitis B virus. (PNDS:I70)

Personal protective equipment helps to protect the employee from exposure to bloodborne pathogens and other potentially infectious materials.

XVIII.a. Personal protective equipment consistent with the anticipated exposure must be worn.^{10,49}(PNDS:I70)

Splashes, splatters, and skin contact can be reasonably anticipated when handling contaminated instruments.

XVIII.a.1. The appropriate PPE for these types of exposures include, but are not limited to,

- A fluid-resistant gown,
- heavy-duty gloves,
- a mask, and
- face protection.

XVIII.b. Hands must be washed after removing PPE.¹⁰(PNDS:I70)

Perforations can occur in gloves, and hands can become contaminated when removing PPE. The OSHA requires hand washing after removal of PPE.¹⁰

XVIII.c. Reusable protective attire must be decontaminated and the integrity of the attire confirmed between uses.¹⁰

Reusable gloves, gowns, aprons, and face shields become contaminated and their integrity can be compromised during use. Decontamination and confirmation of integrity helps to protect the wearer from exposure.⁴⁹

XVIII.d. Two pair of gloves should be worn when cleaning instruments and equipment, if there is a risk for perforation of the outer glove.

XVIII.e. Personnel working with contaminated instruments should be vaccinated against hepatitis B virus.

Hepatitis B vaccination provides protection against one of the most common bloodborne pathogens. The OSHA requires the vaccination be offered to employees at risk of exposure at no charge.¹⁰

XVIII.f. Exposures to bloodborne pathogens should be reported immediately through the approved health care organization channels.

Antiviral medication is most effective if given as soon as possible after an exposure.

Recommended Practice XIX - Competency

Personnel should receive initial education and competency validation on procedures, chemicals used, and personal protection, and should receive additional training when new equipment, instruments, supplies, or procedures are introduced.

Ongoing education and competency validation of perioperative personnel

facilitates the development of knowledge, skills, and attitudes that affect patient and worker safety.

XIX.a. Personnel should receive initial education on

- decontamination methods;
- preparation of instruments and equipment for sterilization;
- selection of cleaning agents and methods;
- proper use of cleaning agents including an understanding of specific applications, appropriate dilution, and special precautions;
- decontamination of specific instruments and equipment used within the practice setting;
- procedures for decontamination of instruments contaminated with prions and the effectiveness of various methods of deactivation;
- personal protection required during instrument processing; and
- exposure risk associated with chemical cleaning agents.⁴⁹

Workers have the right to know the hazards in the workplace and OSHA requires that employers provide this information.⁴⁹ An understanding of procedures involved in cleaning each type of instrument is necessary to provide the foundation for compliance with procedures.

XIX.b. Personnel should receive education on

- new instruments and equipment,
- new cleaning agents and methods, and
- new procedures.

XIX.c. Administrative personnel should validate the competencies of personnel participating in decontamination of surgical instruments. The validation of competencies should include all types of instruments that the individual is authorized to reprocess.

Validation of competencies provides an indication that personnel are able to appropriately perform decontamination procedures.

Recommendation XX - Documentation

Documentation should be completed to enable the identification of trends and demonstrate compliance with regulatory and accrediting agency requirements.

Documentation provides a source of data to review processes and evaluate corrective actions.

XX.a. Documentation should include maintaining records of the cleaning of instruments including, but not limited to,

- date,
- time,
- instruments,
- method of cleaning,
- number or identifier of mechanical decontaminator,
- name of person performing the cleaning,
- lot numbers of chemicals used,
- testing results on mechanical instrument washers,
- testing results on insulated electrical instruments, and
- disposition of defective equipment.

Most sterilization failures result from inadequate cleaning of the instruments before sterilization. Toxic anterior segment syndrome has been associated with inadequate cleaning processes. Some washer decontaminators have digital readouts or printers that facilitate recordkeeping. Bar code scanning technology also is available making this process more efficient. Records of washer testing provide a source of evidence for review when investigating clinical issues including surgical site infections.

XX.b. Records should be maintained for a time period specified by the health care organization and in compliance with local, state, and federal regulations.

Recommended Practice XXI - Policies and Procedures

Policies and procedures regarding the care and cleaning of surgical instruments and powered equipment should be developed using the validated instructions provided by the medical device manufacturers, reviewed at regular intervals, revised as necessary, and be readily available in the practice setting.

Policies and procedures serve as operational guidelines and establish authority, responsibility, and accountability within the organization. Policies and procedures also assist in the development of patient safety guidelines; and quality assessment and improvement activities

XXI.a. Policies regarding instrument cleaning should be developed by a multidisciplinary team to include perioperative nurses, sterile processing personnel, surgeons, and an infection control professional.

Using a multidisciplinary team provides varied input and improved ownership of policies and procedures. Involving surgeons in review of policies educates them on the expectations for instrument cleaning and facilitates planning for instrument use. The expertise of infection control professionals facilitates establishment of minimum standards of infection

control.

XXI.b. Policies should include, but not limited to,

- review of validated manufacturers' written instructions before purchase or consignment;
- cleaning of instruments before initial use;
- management of loaner instruments, to include advanced notification of vendors, required time frame for advance delivery, a process for cleaning and sterilization before use, and a process for cleaning and return after use;
- precautions to be taken when handling contaminated items;
- precautions to be taken when handling chemical agents;
- reprocessing powered surgical equipment;
- reprocessing ophthalmic surgical instruments;
- reprocessing robotic instruments and equipment;
- frequency of mechanical washer checks;
- frequency and method of evaluation of manual cleaning;
- frequency of checking insulated electrosurgery instruments for leakage current;
- criteria for identification and precautions taken for instruments used on patients with known or suspected prion disease;
- documentation of cleaning;
- initial education and annual competency;
- maintenance of MSDS sheets;
- reporting exposures to bloodborne pathogens; and
- reporting adverse events.

Recommendation XXII - Quality

The health care organization's quality management program should evaluate the care of instruments to improve patient safety.

XXII.a. A quality management program should be in place to test mechanical cleaning equipment.

- Mechanical instrument washers should be tested for proper functioning before initial use, weekly during service, and after major maintenance.
- Manual cleaning should be evaluated when new types of instruments are reprocessed, and periodically, at intervals determined by the health care organization.
- Insulated electrical instruments should be tested for leakage current before initial use and after decontamination. Testing after decontamination allows a defective device to be replaced before sterilization.
- Personnel should identify and respond to opportunities for

improvement.

- Reporting mechanisms for adverse events and near misses related to instrument cleaning should be in place.

Adequate cleaning of surgical instruments is essential to remove or destroy microorganisms and eliminate endotoxins. Testing washer decontaminators on a regular basis verifies that the equipment is functioning properly or identifies an opportunity for corrective action. Washer testing products are commercially available.

Periodic testing provides an opportunity to evaluate the performance of personnel. Manual cleaning is a learned skill and subject to human error. New instruments can pose unique challenges when cleaning. Protein indicators are commercially available to assist with this evaluation.

Visual inspection of insulation on electrosurgery instruments provides a screening mechanism to identify obvious breaks. Electrical testing can identify very small insulation failures that may not be apparent visually. Doing this testing after decontamination provides an opportunity to take corrective action well in advance of the surgical procedure.

Adverse events should be reported in the adverse event reporting system and reviewed for potential opportunities for improvement. When investigating surgical infections, documentation of the cleaning process of instruments should be reviewed. Near misses should be investigated and corrective action taken to prevent serious adverse events.

Glossary

Term	Definition
Biofilm:	A thin coating containing biologically active organisms, that have the ability to grow in water, water solutions, or in vivo, which coat the surface of structures (eg, teeth, inner surfaces of catheters, tubes, implanted or indwelling devices, instruments and other medical devices). Biofilms contain viable and nonviable microorganisms that adhere to the surface and are trapped within a matrix of organic matter (eg, proteins, glycoprotein's, carbohydrates), which prevents antimicrobial agents from reaching the cells.
Decontamination:	Any physical or chemical process that removes or reduces the number of microorganisms or infectious agents and renders reusable medical products or equipment safe for handling or disposal; The process by which contaminants are removed, either by hand cleaning or mechanical means, using specific solutions capable of rendering blood and debris harmless and removing them from the surface of an object or instrument.

Endotoxin	A toxin produced by certain bacteria and released upon destruction of the bacterial cell.
Enzymatic cleaner:	A cleaner that uses enzymes to remove protein from surgical instruments.
Eschar:	Charred tissue residue.
Ethylene oxide:	An alkylating agent that, under the right conditions of time, temperature, concentration, and humidity, can result in microbial death.
Free-rinsing	Ability to be removed without leaving residue.
Iatrogenic	A response to medical or surgical treatment, usually denoting an unfavorable response.
Normal:	Denotes a solution containing 1equivalent of replaceable hydrogen ion per liter or a solution containing 1gram of a substance or its equivalent in hydrogen ions.
Personal protective equipment (PPE):	Specialized equipment or clothing for eyes, face, head, body, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the worker from injury or exposure to a patient's blood, tissue, or body fluids. Used by health care workers and others whenever necessary to protect themselves from the hazards of processes or environments, chemical hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation, or physical contact.
Potable water:	Water that is of sufficient quality to be considered appropriate for drinking.
Prion:	A proteinaceous and infectious agent containing no DNA or RNA.
Robotic surgical instruments:	A remote-controlled surgical instrument system, including scalpels, scissors, forceps, and needle holders, used to perform minimally invasive surgery.
Toxic anterior segment syndrome (TASS):	A complication of ophthalmic surgery involving a severe, noninfectious inflammation of the anterior segment of the eye, caused by various contaminants in solutions, medications, steam,

	and residue on surgical instruments and supplies.
Ultrasonic cleaner:	A processing unit that transmits ultrasonic waves through the cleaning solution in a mechanical process known as cavitation. Ultrasonic cleaning is particularly effective in removing soil deposits from hard-to-reach areas.
Viscoelastic	A gel injected into the anterior chamber during ophthalmic surgery to maintain the depth of the chamber, protect the corneal endothelium, and stabilize the vitreous.
Washer/decontaminator:	A processing unit that cleans by a spray-force action known as impingement. This machine combines a vigorous agitation bath with jet-stream air to create underwater turbulence. A sterilization cycle follows the washing cycle.

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