GUIDELINE FOR CLEANING AND CARE OF SURGICAL INSTRUMENTS

The Guideline for Cleaning and Care of Surgical Instruments has been approved by the AORN Guidelines Advisory Board. It was presented as a proposed guideline for comments by members and others. The guideline is effective November 15, 2014. The recommendations in the guidelines are intended to be achievable and represent 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 guideline can be implemented. AORN recognizes the many diverse settings in which perioperative nurses practice; therefore, this guideline is adaptable to all areas where operative and other invasive procedures may be performed.

Purpose
This document provides guidance for cleaning surgical instruments, including point-of-use cleaning, selecting cleaning chemicals, and determining water quality. Guidance is also provided for decontaminating, transporting, inspecting, and care of surgical instruments. Processing of laryngoscope blades and handles and ophthalmic instruments, special precautions necessary to minimize the risk for transmitting prion diseases from contaminated instruments, and the use of personal protective equipment (PPE) that must be worn during cleaning and care of instruments are also addressed. The recommendations are general recommendations, as it is not possible to make a separate recommendation for every instrument used.

Sterilization, packaging for terminal sterilization, high-level disinfection, and processing of flexible endoscopes are outside the scope of this document. Guidance for these topics is provided in the AORN Guideline for Sterilization,² Guideline for High-Level Disinfection,® Guideline for Selection and Use of Packaging Systems for Sterilization,³ and Guideline for Cleaning and Processing Flexible Endoscopes and Endoscope Accessories.²

Evidence Review
On August 2, 2013, a medical librarian conducted a systematic search of the databases MEDLINE®, CINAHL®, and the Cochrane Database of Systematic Reviews for meta-analyses, systematic reviews, randomized controlled and non-randomized trials and studies, case reports, letters, reviews, and guidelines. The search was limited to literature published in English from January 2008 through June 2013.

Search terms included surgical instruments, equipment reuse, surgical procedures, instrument reprocessing, cross infection, infection control, surgical wound infection, surgical site infection, equipment contamination, washing system, washer-disinfector, medical device washer, presoak, soak, disinfection, decontamination, sterilization, detergents, sterile water, water purification, water microbiology enzymatic detergents, non-enzymatic detergents, toxic endothelial cell deconstruction, prion diseases, Creutzfeldt-Jakob syndrome, fatal familial insomnia, and Gerstmann-Straussler-Scheinker. Surgical instruments as a broad search term was augmented by the inclusion of terms related to specific instruments, such as laryngoscopes, blades, forceps, scalpels, dilators, lumens, drills, and retractors.

At the time of the initial search, the librarian established weekly alerts on the search topics and until June 2014, presented relevant results to the lead author. During the development of this guideline, the author requested supplementary literature searches and additional literature that either did not fit the original search criteria or was discovered during the evidence-appraisal process; this additional literature included book chapters and manufacturers’ materials. The librarian and author also identified relevant guidelines from government agencies and standards-setting bodies.

Articles were excluded if they addressed the use of a device or the care of patients rather than the practices associated with instrument processing. Articles related to processing single-use devices were excluded as outside the scope of this document. Articles that were clearly biased or written as product promotion for marketing purposes also were excluded.

Articles identified in the search were provided to the lead author and assigned evidence reviewer for review and critical appraisal using the AORN Research or Non-Research Evidence Appraisal Tools as appropriate. The literature was independently evaluated and appraised by the lead author and evidence reviewer according to the strength and quality of the evidence. Each article was then assigned an appraisal score determined by consensus. The appraisal score is noted in brackets after each reference as applicable.

The evidence supporting each activity and intervention statement within a specific recommendation was summarized, and the AORN Evidence-Rating Model was used to rate the strength of the collective evidence. Factors considered in the review of the collective body of evidence were the quality of similar evidence on a given topic, the consistency of the evidence supporting a recommendation, and the...
potential benefits and harms. The assigned evidence rating is noted in brackets after each intervention and activity statement.

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Recommendation I

All instruments and devices used in surgery should be cleared by the US Food and Drug Administration (FDA) for use in surgery and have written, manufacturer-validated cleaning and decontamination instructions for use (IFU).

Manufacturers of reusable instruments and devices cleared by the FDA provide validated cleaning and decontamination instructions and instructions on how to process devices between uses. Items cannot be assumed to be clean, decontaminated, or sterile unless the manufacturer’s IFU are derived from validation testing and the user has followed those instructions. Instructions for use provide users with validated techniques for processing instruments.

I.a. A multidisciplinary team consisting of sterile processing personnel, perioperative registered nurses (RNs), physicians, infection preventionists, and other stakeholders should develop a mechanism for evaluating and selecting the products that require cleaning and decontamination and the associated cleaning products that will be used at the health care facility. [2: Moderate Evidence]

Involvement of a multidisciplinary team in the product selection process allows input from personnel with expertise beyond that of the clinical end users. Facility areas in which personnel are responsible for cleaning, decontamination, and care of instruments may include operating rooms (ORs), sterile processing areas, procedure areas, physician offices, and clinics where processing is performed. Personnel working in these areas have information concerning equipment and resource capabilities that will help determine the facility’s ability to follow the manufacturer’s written IFU.

A standardized product evaluation and selection process that includes input from key personnel may assist in the selection of functional and reliable products that are safe, cost-effective, and environmentally friendly; promote quality care; and prevent duplication or rapid obsolescence. [2]

I.b. Before the purchase of surgical instruments and other devices used for surgical or other procedures performed in the facility, a designated person responsible for processing surgical instruments should obtain and evaluate the applicable manufacturer’s written IFU, including:

- instructions for precleaning at the point of use,
- transport of the soiled device,
- cleaning,
- decontamination,
- inspection,
- functionality testing,
- packaging,
- high-level disinfection, and
- sterilization,

to determine whether the facility has the capability to comply with the manufacturer’s instructions. [2: Moderate Evidence]

Cleaning, decontamination, and handling instructions recommended by device manufacturers vary widely. Some instruments may require special cleaning, packaging, sterilization, or maintenance procedures that cannot be provided by the facility. [5-8]

I.b.1. A designated person responsible for processing surgical instruments should review the instrument manufacturer’s written IFU to determine the requirements for replicating the validated cleaning and processing methods. [4: Benefits Balanced with Harms]

I.b.2. The manufacturer’s written IFU should be reviewed for requirements related to:

- utilities (eg, water, compressed air);
- cleaning equipment;
- device disassembly required for cleaning;
- accessories (eg, adaptors for creating a correct connection between the device and equipment, utilities, and cleaning equipment);
- accessories for cleaning lumens, ports, and internal parts;
- cleaning agents;
- lubricants; and
- procedures for handling, cleaning, disinfecting, testing, packaging, and sterilizing. [10-13]

I.b.3. Prepurchase evaluation of the health care facility’s capability to comply with the instrument manufacturer’s instructions for care and cleaning should include determining requirements for cleaning and decontaminating equipment (eg, washer/decontaminators, ultrasonic cleaners, forced-air dryers, sinks, detergents, brushes, adaptors, lubricants) and whether:

- the instructions are clear and understandable to personnel who will be handling the instrument or device,
- a water supply of the specified quality is available, and
- utilities (eg, electrical, ventilation, steam supply) are in place. [3: Limited Evidence]
The instrument manufacturers’ IFU provide instructions for cleaning and processing that are required to achieve the validated results.6

**Recommendation II**

**Before use, all new, repaired, refurbished, and loaned instruments and devices should be cleaned and decontaminated, inspected, and sterilized or high-level disinfected according to the instrument or device manufacturer’s written IFU.**

It is not possible to verify how all new, repaired, refurbished, and loaned instruments and devices have been handled, cleaned, inspected, or processed before receipt in the facility. Failure to clean, inspect, disinfect, or sterilize an item may lead to transmission of pathogenic microorganisms from a contaminated device and create a risk for patient injury, including surgical site infection (SSI).14

Inspecting instruments and devices upon receipt and before processing in accordance with the manufacturer’s written IFU can help verify that there are no obvious defects and may prevent damaged or incorrectly functioning devices from being used in patient care.44

Cleaning and decontamination remove soil that may interfere with subsequent processing and reduce or eliminate viable microorganisms, thereby rendering devices safe to handle.2,10

II.a. The manufacturer’s written IFU should be readily available to the personnel responsible for processing instruments and devices used for surgical or other procedures performed in the facility.14 [1: Strong Evidence]

Instructions for use identify the processes necessary to achieve effective decontamination and sterility.11

II.a.1. Manufacturer’s IFU should be reviewed periodically, and processing practices should comply with the most current IFU. [2: Moderate Evidence]

Manufacturers may make modifications to their IFU when new technology becomes available, when regulatory requirements change, or when modifications are made to a device.24

II.b. Accessories specified by the device manufacturer for cleaning and processing should be obtained at the time of the device purchase and used in accordance with the IFU. [3: Limited Evidence]

Using accessories that are designed and manufactured to the device manufacturer’s specifications facilitates performance of the required cleaning and processing procedures.6

II.c. Instruments and related accessories should be removed from external shipping containers and web-edged or corrugated cardboard boxes before transfer into the decontamination area. [2: Moderate Evidence]

External shipping containers and web-edged cardboard boxes may collect dust, debris, and insects during transport and may carry contaminants into the facility.1,19

II.d. Instruments should be inspected for defects and correct function upon receipt.14,21 Instrument inspection should include verifying

- tip integrity and alignment,
- security of screws,
- ability of ratchets to hold,
- sharpness of cutting edges,
- integrity of box locks,
- freedom of moveable parts, and
- insulation integrity (for instruments used for electrosurgery). [2: Moderate Evidence]

Inspection of instruments before processing may minimize the risk of damaged, nonfunctioning, or incorrectly functioning instruments being used in patient care.

II.e. A multidisciplinary team appointed by the health care facility should establish policies and procedures for managing loaned items (eg, instruments). The policies and procedures should include

- a process for requesting and communicating the need for loaned instrument sets;
- time requirements for preprocedure delivery, product testing, and processing (ie, cleaning, decontaminating, inspecting, packaging, sterilizing) and for postprocedure processing and pick-up;
- requirements for education and competency verification of personnel before new or loaned instrumentation is used;
- a process for obtaining and reviewing manufacturers’ written IFU;
- delivery requirements (eg, location, documentation);
- a process for returning the item(s) to the lender;
- time requirements for vendor retrieval;
- inventory requirements and a process for taking inventory;
- processes for care, cleaning, decontaminating, inspecting, packaging, and sterilizing before use;
- responsibility for ensuring each instrument set weighs no more than 25 lb (11.3 kg);
- method of transport;
- processes for point-of-use and postprocedure cleaning and decontamination; and
- documentation of processes and transactions related to loaned instruments.21,22

[3: Limited Evidence]

A successful loaned instrument management program begins with clear and detailed policies and procedures developed in collaboration with all stakeholders.22

II.e.1. Loaned instruments should be cleaned, decontaminated, inspected, and sterilized
by the receiving health care organization before use. [3: Limited Evidence]

Conditions of transport vary, and an event could occur during transport that could compromise sterility or cause damage to the instruments before they are received at the facility. Inspection verifies that the instruments have no visible defects or damage. Parameters of inhouse sterilization can be verified immediately after a cycle is complete. Even if the instruments have been sterilized in another health care facility, the user will have no record of the sterilization process in the event of a recall.29-30

II.e.2. Before processing and preferably before receipt of loaned instruments, a designated person responsible for processing surgical instruments should obtain and review the manufacturers’ written IFU for cleaning. [3: Limited Evidence]

When instructions are received in advance, preparations can be made for cleaning and sterilization before the arrival of the instruments. Advance preparation can prevent potential delays in patient care and help ensure correct cleaning and sterilization procedures are followed. Review of processing instructions before receipt of the instruments may improve the efficiency of processing.29

II.e.3. The accessories needed to process loaned instruments according to the manufacturer’s written IFU should be received before processing.5 [3: Limited Evidence]

Accessories specified in the manufacturer’s written IFU are those the manufacturer has determined are needed to perform required cleaning procedures.5

II.e.4. Loaned instruments should be requested when the surgery is scheduled and delivered to the health care facility in sufficient time to allow inhouse inventorying, inspection, disassembly, cleaning, packaging, and terminal sterilization in accordance with the manufacturer’s written IFU.23,25 [3: Limited Evidence]

When there is insufficient time to process instruments according to the manufacturers’ written IFU, patient safety may be at risk.23,25,26 Management of loaned instruments requires planning. Requesting the instruments well in advance of the surgical procedure allows adequate time for the vendor to deliver the instruments and for facility personnel to perform the required cleaning; decontamination; inspection; sterilization; and if needed, product quality assurance testing procedures.

II.e.5. Loaned instruments and accessories should be removed from external shipping contain-
The evidence review for this guideline found only one published article related to the condition of loaned instruments. This limited, single-facility, quality assurance project evaluated the cleanliness of loaned instruments upon receipt. A total of 139 sets were visually inspected and tested for blood residue during a two-month period. Six sets (4.3%) were visibly contaminated. Twenty-three sets (16.5%) tested positive for blood residue. The authors recommended that that all loaned instruments be enclosed in biohazard containers, that some method of documentation of the decontamination and quality assurance processes used by the lending institution be included with each shipment, that designated receiving areas be established, that institutions establish standard procedures for loaned instrumentation, and that the procedure be communicated not only to sterile processing personnel and the hospital infection prevention committee, but also to perioperative personnel.

II.e.9. Loaned instruments should be disassembled, cleaned, decontaminated, and inspected before they are returned to the vendor or lending facility.[2: Moderate Evidence]

Instruments used in surgery may be contaminated with blood, body fluids, or other potentially infectious materials and may pose a safety risk to health care and other personnel if they are not handled or decontaminated correctly.

II.e.10. Loaned instruments should be inventoried and documentation should be provided to the lender and receiver regarding the processing and disposition of items after decontamination.[3: Limited Evidence]

Documentation makes it possible to determine where an instrument may have been lost or damaged and provides a description of the steps taken to help ensure the return of items that are safe to handle.

Recommendation III

**Instruments should be cleaned and decontaminated as soon as possible after use.**

Cleaning instruments as soon as possible after use can help prevent formation of biofilm and dried blood. When blood or other bioburden is allowed to dry on instruments, it can become more difficult to remove. The effectiveness of disinfection or sterilization can be compromised when thorough cleaning is not accomplished.

III.a. Preparation for decontamination of instruments should begin at the point of use.[2: Moderate Evidence]

Moistening and removing gross soil at the point of use can help prevent organic material and debris from drying on instruments. Organic material and debris are more difficult to remove from surgical instruments when they are allowed to dry. Removal of organic material and debris at the point of use can improve the efficacy and effectiveness of cleaning and decontamination.

III.b. Instruments should be kept free of gross soil during the procedure.[2: Moderate Evidence]

Gross soil left to dry on instruments can affect the efficacy of subsequent disinfection and sterilization processes.

III.b.1. During the procedure, the scrub person should remove gross soil from instruments by wiping the surfaces with a sterile surgical sponge moistened with sterile water. Saline should not be used to wipe instrument surfaces.[3: Limited Evidence]

Blood, organic material, debris, and saline are highly corrosive to instrument surfaces and can cause corrosion, rusting, and pitting when allowed to dry on surgical instruments. These materials can be difficult to remove from all surfaces during the cleaning and decontamination process, reducing the efficacy of the subsequent sterilization process.

III.b.2. Periodically during the procedure, the scrub person should use sterile water to irrigate instruments with lumens.[1: Strong Evidence]

Irrigating instrument lumens periodically throughout a procedure removes gross soil and may reduce the risk of biofilm formation. Biofilm can form on many surfaces but is particularly problematic when it forms in lumens because it is difficult to see and remove. After a biofilm forms, mechanical action is required to remove it.

In an experimental longitudinal study, Vickery et al. grew a mature biofilm of *Pseudomonas aeruginosa* on 20 Teflon® endoscope tubings and subjected them to 20 decontamination and recontamination cycles. Decontamination consisted of a manual wash followed by a 2% glutaraldehyde disinfection in an automated endoscope reprocessor. This process was repeated 20 times. At the 20th cycle, 90% of the tubing was biofilm free. The researchers concluded that washing endoscopes under high flow rates with some detergents removed established biofilms. Although the researchers examined endoscopes, the results of this study may be applicable to decontamination of other lumened instruments.

If not removed, a biofilm can reduce the efficacy of subsequent disinfection or sterilization processes.
STERILIZATION AND DISINFECTION

III.c. All instruments opened onto the sterile field in the operating or procedure room should be cleaned and decontaminated whether or not they have been used.10,12 [2: Moderate Evidence]

Scrubbed persons may touch and contaminate instruments without being aware of it. Instruments that were used may come in contact with unused items. Airborne microorganisms may come in contact with instruments that have not been used. Contamination of unused instruments on the sterile field can occur without the occurrence being noticed.10,12

III.d. In preparation for transport to a decontamination area, sharp instruments must be segregated from other instruments and confined in a puncture-resistant container. [1: Regulatory Requirement]

Segregation of sharps from other instruments minimizes the risk of injury to personnel handling instruments during cleaning and decontamination. The Occupational Safety and Health Administration (OSHA) prohibits processes that require employees to place their hands into basins of sharp instruments because of the risk for percutaneous exposure to bloodborne pathogens.10 The reader should refer to the Guideline for Sharps Safety10 for guidance related to preventing sharps injuries.

III.d.1. Disposable sharps (e.g., scalpel blades, suture needles) must be removed and discarded into a closeable, puncture-resistant container that is leak-proof on its sides and bottom and is labeled or color-coded as biohazardous.10,40 [1: Regulatory Requirement]

III.e. When an instrument is composed of more than one piece, it should be opened and disassembled according to the manufacturer’s written IFU and arranged in a manner that will permit contact of cleaning solutions with all surfaces of the instruments. [1: Strong Evidence]

When surfaces cannot be contacted by cleaning solutions, thorough cleaning cannot be achieved; thus, these surfaces can retain organic material and debris. These retained materials can prevent contact of cleaning solutions and disinfecting or sterilizing agents with instrument surfaces, reduce the effectiveness of subsequent disinfection or sterilization processes,4,10,12 and cause patient injury if they are not removed before sterilization.10,12,41,42 Further research is warranted to determine the clinical significance of retained organic material and debris on instruments during disinfection and sterilization processes.

In a case series investigation, Parada et al12 characterized the relationship between sterilization failure and SSIs. During a 14-week period, the investigators collected laboratory data on five patients who sustained SSIs after anterior cruciate ligament reconstruction and determined the infection rate was 12.2%. Before this period, the infection rate for anterior cruciate ligament reconstruction was 0.3%. The investigators found gross organic material inside an instrument common to all the surgical procedures. The inadequate removal of debris had occurred because there was no brush available with a diameter small enough to clean the cannula on the device.

III.f. Delicate instruments should be protected from damage during transport to a decontamination area. Delicate and other easily damaged instruments, such as fiberoptic cords, rigid endoscopes, and microsurgical instruments, should be placed on top of heavier instruments or segregated into separate containers.10,12 [3: Limited Evidence]

Instruments may shift during transport, causing heavy instruments to damage more-delicate instruments.

III.g. Instruments should be kept moist until they are cleaned. A towel moistened with water placed over the instruments may be used. Saline should not be used. [3: Limited Evidence]

Keeping instruments moist helps prevent blood, organic materials, and debris from drying and adhering to the instruments. Dried organic materials and debris can make instruments more difficult to clean and potentially lead to the formation of biofilm. Prolonged exposure of instruments to saline can cause pitting.10,12

III.g.1. Instruments that cannot be cleaned immediately should be treated with an instrument cleaner according to the device and the instrument cleaner manufacturers’ written IFU.10,12,13 [2: Moderate Evidence]

Treating instruments with an instrument cleaner at the point of use can help prevent rusting and corrosion; prevent blood, organic materials, and debris from drying on the instruments; and inhibit biofilm formation.10,12

III.g.2. Liquids used to soak contaminated items at the point of use should be discarded before transport. When disposal of the solution is not feasible, it must be transported in a leak-proof container to the decontamination area for disposal.10,12 [1: Regulatory Requirement]

Contaminated liquids may be spilled during transport, presenting a risk of contaminating the environment and exposing personnel to blood, body fluids, and other potentially infectious materials.10,12,29

Recommendation IV

Contaminated instruments must be contained during transport to a decontamination area.28,29

Containment of contaminated instruments decreases the potential for injury to personnel or their exposure
to blood, body fluids, or other potentially infectious materials and helps prevent damage to the instruments during transport.

IV.a. Contaminated instruments should be transported to the decontamination area as soon as possible after completion of the procedure. [1: Strong Evidence]

Removal of blood, organic materials, and debris from instruments becomes more difficult after they have dried. [1: Regulatory Requirement]

IV.b. Soiled instruments must be transported to the decontamination area in a closed container or enclosed transport cart. The container or cart must be

- leak proof, [2]
- puncture resistant, [2]
- large enough to contain all contents, and
- labeled with a fluorescent orange or orange-red label containing a biohazard legend. [2]

[1: Regulatory Requirement]

Transporting soiled instruments in a manner that prevents exposing personnel to bloodborne pathogens and other potentially infectious materials is an OSHA requirement. [2]

Labeling the transport containment device communicates to others that the contents are potentially infectious.

IV.b.1. Biohazard labels should be affixed so as to prevent separation from the contents. When appropriate to the configuration of the contents, a red bag or red container may be used instead of a label to indicate contaminated waste. [1: Regulatory Requirement]

IV.b.2. If the instrument containment device has been contaminated, it must be either cleaned at the point of use or placed inside another containment device and labeled as biohazardous. [1: Regulatory Requirement]

Contact with contaminated surfaces can transmit potentially infectious microorganisms. [2] The reader should refer to the AORN Guideline for Prevention of Transmissible Infections for guidance.

IV.b.3. Contaminated instruments and other items should be separated from clean and sterile supplies before transport to the processing area. [3: Limited Evidence]

Separation of soiled instruments from clean supplies minimizes the risk of cross-contamination. [2]

Recommendation V

Instruments should be cleaned and decontaminated in an area separate from locations where clean items are handled. [1: Regulatory Requirement]

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 are placed on surfaces upon which clean items are later placed. Droplets and aerosols created during cleaning of soiled instruments can cause cross-contamination of any nearby clean items or surfaces.

V.a. The sterile processing area should have

- separate clean and decontamination spaces, which may be rooms or areas;
- decontamination and clean spaces that are separated by one of three methods:
  - a wall with a door or pass-through,
  - a partial wall or partition that is at least 4 ft high and at least the width of the counter, or
  - a distance of 4 ft between the instrument washing sink and the area where the instruments are prepared for sterilization;
- separate sinks for washing instruments and for hand hygiene;
- decontaminating equipment (eg, automated washer, ultrasonic cleaner); and
- storage space for PPE and cleaning supplies in the decontamination area.

[3: Limited Evidence]

The requirements for processing reusable medical devices do not vary by location. Equivalent procedures, supplies, and equipment are needed in all locations where sterile processing is performed. [1: Regulatory Requirement]

V.b. Instruments should not be cleaned or decontaminated in scrub or hand sinks. [4: Benefits Balanced with Harms]

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

V.c. The decontamination area must contain

- an eyewash station and
- a hand-washing sink. [1: Regulatory Requirement]

The Occupational Safety and Health Administration requires that an eyewash station be provided where chemicals that are hazardous to the eyes are located. Hand hygiene facilities are required by OSHA for use after removal of PPE. [1: Regulatory Requirement]

V.c.1. Eyewash stations, either plumbed or self contained, must be provided within the immediate area where chemicals such as instrument cleaning solutions or disinfectants that are hazardous to the eyes are located. [1: Regulatory Requirement]

Eyewash stations should be located so that travel time is no greater than 10 seconds from the location of chemical use or storage, or should be immediately available if the chemical is caustic or is a strong acid. Eyewash stations should be located on the same level as the hazard, with the path of travel free of obstructions (eg, doors)
that may inhibit immediate use of the eye-wash station.\textsuperscript{42}

Eyewash stations should

\begin{itemize}
  \item be identified with a highly visible sign\textsuperscript{42};
  \item deliver warm water (ie, 60° F to 100° F [15.6° C to 37.8° C]) at a rate of 1.5 L/minute for 15 minutes\textsuperscript{42};
  \item be designed to flush both eyes simultaneously using a hands-free, stay-open feature\textsuperscript{42};
  \item be flushed weekly to remove stagnant water, which may contain microbial contamination, from the system\textsuperscript{42}; and
  \item be tested regularly and maintained in accordance with the manufacturer’s written IFU.\textsuperscript{42}
\end{itemize}

V.f. The decontamination area should contain

\begin{itemize}
  \item automated equipment consistent with the types of instruments to be cleaned and decontaminated,
  \item adaptors and accessories to connect instruments with cleaning equipment and utilities,
  \item a filtered medical-grade compressed air supply,\textsuperscript{43} and
  \item access to water of appropriate quality for rinsing instruments (eg, deionized or reverse-osmosis water).
\end{itemize}

[2: Moderate Evidence]

Automated cleaning and decontamination provides an effective level of cleaning that is difficult to replicate consistently using manual methods.\textsuperscript{42,44} Compressed air is used to clear lumens of detergent and rinse water after cleaning.

V.d. The decontamination area should contain

\begin{itemize}
  \item adapted to accommodate the individual comfort needs of the occupants.\textsuperscript{45}
\end{itemize}

V.e. The decontamination area should be stocked with the accessories and supplies needed to clean and decontaminate instruments in accordance with the manufacturer’s written IFU.\textsuperscript{42}

Supplies should include

\begin{itemize}
  \item brushes or other devices intended to remove organic material and debris from lumens, with a diameter and length appropriate to the lumen to be cleaned;
  \item enzymatic and nonenzymatic detergent;
  \item soft, low-linting cleaning cloths;
  \item testing equipment;
  \item a source of treated water (eg deionized, reverse-osmosis, filtered);
  \item 70% to 90% alcohol;
  \item a thermometer; and
  \item a measuring device.
\end{itemize}

[3: Limited Evidence]

Brushes or devices of the correct size used in accordance with the brush or device manufacturer’s IFU can facilitate cleaning of lumens. The instrument manufacturer’s IFU may recommend either an enzymatic or a nonenzymatic detergent for cleaning. Soft, low-linting cleaning cloths may prevent scratches to the surface of instruments and prevent lint from adhering to the surfaces of the instruments.

Treated water is used for final rinsing. Impurities in untreated water can leave residues on instruments that may lead to corrosion, pitting, or staining.\textsuperscript{43,45,46} A thermometer is used to measure that the detergent solution is within the recommended temperature range as specified by the detergent manufacturer’s written IFU. Measuring devices are used to mix detergents at the concentration specified by the detergent manufacturer’s written IFU.

The decontamination area heating, ventilation, and air conditioning (HVAC) system should be maintained within the HVAC design parameters at the rate that was applicable according to regulatory and professional guidelines at the time of design or most recent renovation of the HVAC system.\textsuperscript{47} [2: Moderate Evidence]

The HVAC system controls the air quality, temperature, humidity, and pressure of the room in comparison with the surrounding areas. The HVAC system is designed in accordance with the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)\textsuperscript{48} and local regulatory requirements to reduce the amount of environmental contaminants and to provide a comfortable environment for occupants in the area.\textsuperscript{49}

V.f.1. A multidisciplinary team that includes infection preventionists, perioperative RNs, sterile processing personnel, representatives from facility maintenance, and other stakeholders representing the health care organization should develop and implement a systematic process for monitoring HVAC performance parameters in the decontamination area and a mechanism for resolving variances.\textsuperscript{48} [3: Limited Evidence]

The HVAC parameters recommended by ASHRAE and the Facilities Guidelines Institute for decontamination areas are

\begin{itemize}
  \item 2 outdoor air changes per hour.\textsuperscript{45,46}
  \item 6 total air changes per hour.\textsuperscript{45,46}
  \item negative air pressure.\textsuperscript{45,46} and
  \item temperature between 72° F and 78° F (22° C and 26° C).\textsuperscript{45,46}
\end{itemize}

Room temperature may be intentionally adjusted to accommodate the individual comfort needs of the occupants.\textsuperscript{45} Negative pressure helps prevent contaminated air from entering into positive-pressure, clean areas. The evidence on the effect of relative humidity on bacterial, fungal, and viral growth is inconclusive. Further research is warranted to determine optimal relative humidity levels to control environmental contamination.

In a descriptive study, Panagopoulou et al\textsuperscript{52} examined air and surface fungal levels of two buildings in a Greek tertiary care hospital during a 12-month period. Each room in building A had a separate air-conditioning
unit. Building B had a central air-conditioning unit. The researchers determined that, independent of the method of air-conditioning, the fungal levels were higher during the months in which the temperature and humidity levels were higher.

In a literature review on the effects of humidity on bacterial survival, Tang found that various levels of humidity created differing responses in different strains of bacteria. The responses included structural changes and death. The bacterial survival rates were dependent on the species. The author was unable to find a link between humidity and bacterial survival.

In a laboratory setting, Thompson et al found that aerosolized Staphylococcus epidermidis, used as a surrogate for Staphylococcus aureus, survived at relative humidity levels of <20%, 40% to 60%, 70% to 80%, and >90%. The researchers concluded that S epidermidis was not affected by the level of relative humidity.

In a literature review of the effect of temperature and humidity on viruses, Memarzadeh reviewed 120 articles and found no conclusive evidence supporting a maximum or minimum relative humidity level to decrease the survival rate of viruses and the ability of viruses to cause diseases.

The ASHRAE guidelines related to room temperature ranges for the decontamination area are the accepted professional guidelines for HVAC systems in the United States. Personnel working in the decontamination area and wearing PPE may become uncomfortable at room temperatures above 72° F (22° C). Lower room temperatures may contribute to the comfort of personnel wearing PPE.

VI.a. Personal protective equipment consistent with exposure risks in the decontamination area must be worn,[32] including
- a fluid-resistant gown with sleeves,
- gloves (ie, general purpose utility gloves with a cuff that extends beyond the cuff of the gown),
- a mask and eye protection or a full face shield, and
- shoe covers or boots designed for use as PPE.[33]

[V1: Regulatory Requirement]
Splashes, splatters, and skin contact can be reasonably anticipated by personnel handling contaminated instruments. Fluid-resistant gowns can prevent transfer of microorganisms from contaminated items to skin.[34] General purpose utility gloves can minimize the potential for punctures, cuts, and nicks and exposure of the hands to blood, body fluids, and other potentially infectious materials. Utility glove cuffs that extend beyond the cuff of the gown help to provide adequate fluid protection during instrument cleaning in a sink. A mask and eye protection or a full face shield can protect the face and eyes from contact with contaminated aerosols and chemicals used for cleaning purposes.[36] Fluid-resistant shoe covers can protect shoes from contaminants and splashes, splatters, and spills.

VI.a.1. Personal protective equipment should be placed where it is readily available to personnel entering an area in which there is a risk of exposure to transmissible pathogens.[37] [V1: Regulatory Requirement]

There is potential for exposure to transmissible pathogens in the decontamination area, and OSHA requires the employer to provide PPE.[38] Placing PPE in an area readily available to decontamination area personnel can facilitate compliance with OSHA requirements for wearing PPE when there is
danger of exposure to blood, body fluids, or other potentially infectious materials.

VI.b. Hand hygiene must be performed after PPE is removed. [1: Regulatory Requirement]

Perforations can occur in gloves, and hands can become contaminated during removal of PPE; OSHA requires hand hygiene after removal of PPE. [2]

VI.c. Reusable PPE must be cleaned and decontaminated and its integrity confirmed between uses. [1: Regulatory Requirement]

Personal protective equipment is appropriate only if it does not permit potentially infectious materials to pass through and contact the individual. [3] Reusable gloves, gowns, aprons, face shields, and eye wear can become contaminated and their integrity compromised during use. Decontamination and confirmation of integrity helps to protect the wearer from exposure.

Recommendation VII

The type of water used for cleaning should be consistent with the manufacturers’ written IFU and the intended use of the equipment and cleaning product. [4][5][6][7]

Water quality is affected by the presence of dissolved minerals, solids, chlorides, and other impurities and by its acidity and alkalinity (ie, pH). [8][9][10] Minerals can cause deposits, scale, or water spots to form on instruments. [11][12] Excessive chlorides can cause pitting. [13][14][15] The pH level affects the performance of enzymatic and detergent agents. [16][17][18] Untreated water can contain contaminants, including endotoxins, which can be deposited on instruments during the final rinse. Rinsing with treated water can prevent deposits of impurities or contaminants on instruments. [19][20][21]

Endotoxins are heat stable and may not be destroyed by subsequent steam sterilization. Tissue contaminated with endotoxins can cause severe inflammation. [22]

Treated water can prevent spotting, stains, deposits, and corrosion on the surfaces of instruments. [23][24][25]

VII.a. The final rinse should be performed with treated (eg, distilled, reverse osmosis, filtered) water of a quality that will not stain or cause damage to instruments or contribute to recontamination of the instrument. [26] [2: Moderate Evidence]

Untreated water can contain contaminants, including endotoxins, which can be deposited on instruments during the final rinse. Rinsing with treated water can prevent deposits of impurities or contaminants on instruments. [27][28][29][30][31]

Endotoxins are heat stable and may not be destroyed by subsequent steam sterilization. Tissue contaminated with endotoxins can cause severe inflammation. [32]

Treated water can prevent spotting, stains, deposits, and corrosion on the surfaces of instruments. [33][34][35][36][37]

VII.b. Device-processing personnel, in collaboration with clinical engineering personnel, should perform a water-quality assessment periodically [38] and after major maintenance to the water supply system to determine water quality relative to the requirements for cleaning as specified in the detergent and cleaning equipment manufacturers’ written IFU. [3: Limited Evidence]

Water quality varies seasonally and after water-source maintenance. Periodic testing can indicate whether the chemical combination used to condition the cleaning and decontamination water requires adjusting. Water-quality checks determine the hardness (ie, mineral content) of the water and any impurities present.

Water quality that does not meet the requirements specified in the detergent or the cleaning equipment manufacturers’ IFU can adversely affect the efficacy of cleaning chemistries. [28][39][40][41][42]
The need for repairs or modifications to the treatment system can be identified from a water-quality check. [43]

A nonexperimental study by Harnroongroj et al [44] compared 32 first-burst water samples with 29 running tap samples of water supplied to an OR and found the bacterial count in first-burst water was three times higher than in running tap water. This research was performed in Thailand and may not be generalizable to the United States.

In a nonexperimental study to determine the effectiveness of a commercially available test for determining the presence of organic soil on instruments after cleaning in automated washers, Alfa et al [45] found that surgical instruments cleaned in automated washers may have visually undetected high post-cleaning residuals of carbohydrate and endotoxin. An objective of the researchers was to determine the level of protein, hemoglobin, carbohydrate, and endotoxin before and after cleaning in an automated washer. The researchers evaluated five types of surgical instruments from plastic surgery trays for residuals both before and after cleaning. Of a total of 25 instruments tested, 21 (84%) had substantially higher carbohydrate levels and 15 (60%) had higher endotoxin levels after cleaning than before cleaning. The results of the study suggest that endotoxins remaining on surgical instruments after cleaning in automated washers may be related to water quality. The researchers recommended monitoring of water quality.

Recommendation VIII

Surgical instrument, cleaning product, and cleaning equipment manufacturers’ validated, written IFU should be reviewed for compatibility during selection and followed during use of cleaning products and equipment for cleaning and decontaminating surgical instruments. [46]

The intended use of cleaning products and cleaning equipment varies. Following the manufacturers’ written IFU decreases the possibility of selecting and using cleaning products and equipment that may damage instruments. [47]
VIII.a. A multidisciplinary team that includes infection preventionists, perioperative RNs, sterile processing personnel, and other stakeholders representing the health care organization should develop a mechanism for evaluating and selecting products for cleaning surgical instruments. [3: Limited Evidence]

The chemical actions of cleaning products vary, and products are intended for different applications. Some cleaning products target specific types of bioburden (eg, protein, lipids, other organic material); others are intended for general purpose cleaning.

Some cleaning products contain one or more enzymes to break up soil and facilitate its removal. Enzymes are specific in terms of the soils they remove. Some enzymatic detergents contain more than one enzyme and are intended to be used as all-purpose detergents; others are intended for a specific type of soil. Protease enzymes target blood and body salts. Amylases target carbohydrates, starches, and sugars. Lipases break down fats and oils. The pH and the rinsability of cleaning products vary.

Cleaning equipment manufacturers’ requirements for selection and use of cleaning products also vary. Some instrument manufacturers’ written IFU specifically recommend against using some cleaning agent formulations.

VIII.a.1. Neutral detergents with a pH of 7 that are low foaming and easy to remove during rinsing should be used for manual or mechanical cleaning unless contraindicated by the device or cleaning equipment manufacturer’s IFU. [2: Moderate Evidence]

Detergents help to dislodge solids from the surface of instruments. Neutral pH or slightly alkaline detergents are compatible with most instruments and work well with enzymes that may be added to detergents to help break down and facilitate removal of organic materials. Detergents that are low foaming facilitate observation of the cleaning process.

VIII.a.2. Cleaning products should

- be nonabrasive,
- be low foaming,
- be easy to remove during rinsing,
- be biodegradable,
- provide for soil dispersion,
- be nontoxic in the specific-use dilution,
- be effective for clinically relevant soils under specified conditions,
- have a long shelf life,
- be cost-effective, and
- be able to be tested for effective concentration. [3: Limited Evidence]

Cleaning products that are nonabrasive can help protect the surface of instruments from damage. Cleaning products that are low foaming are less likely to interfere with the action of mechanical cleaning equipment. Cleaning products that are easy to remove facilitate removal of detergent during rinsing. Cleaning products that are nontoxic contribute to personnel safety. Use of cleaning products that are effective on clinically relevant soils may increase the efficacy of the cleaning process.

VIII.b. Cleaning products must be handled according to the safety data sheets (SDSs) and the manufacturers’ written IFU. The SDSs must be readily accessible to employees within the workplace. [1: Regulatory Requirement]

Highly acidic or alkaline cleaning agents are corrosive and can cause injury to skin or mucus membranes. Exposure to enzymatic detergents can cause asthma. Access to the cleaning product IFU and SDS provides opportunities for personnel to use the product correctly and obtain information useful for implementing processes that prevent injury.

VIII.c. The cleaning product manufacturer’s written IFU should be followed for:

- water quality, hardness, and pH;
- concentration and dilution;
- water temperature;
- contact time;
- conditions of storage; and
- shelf life and use life. [2: Moderate Evidence]

Water quality, including hardness and pH, can affect the effectiveness of cleaning products. Using the product in the concentration recommended by the manufacturer’s written IFU helps to ensure consistent and accurate cleaning chemistry. The manufacturer has determined the correct temperature and contact time to facilitate cleaning with the specific product. Shelf life and use life indicate the time span or use after which the cleaning product’s effectiveness cannot be assured. Using the product after expiration or at a temperature other than specified in the IFU can render the product ineffective.

VIII.c.1. An automated titration unit may be used to efficiently concentrate chemicals at a consistent ratio. [4: Benefits Balanced with Harms]

The concentration of the solution can vary when it is mixed manually. Use of a titration unit can aid in accurate measurement of the chemical during preparation of the cleaning solution and help personnel to consistently obtain the recommended concentration of the cleaning product.

VIII.d. Abrasive devices and products should not be used to clean instruments unless their use is...
STERILIZATION AND DISINFECTION

STERILIZATION

DISINFECTION

Cleaning of instruments (ie, removal of organic and inorganic soil) is the first step in decontamination and can be accomplished through manual or mechanical processes. The instrument and equipment manufacturers have determined the manual or mechanical steps and processes necessary to effectively clean a device. Decontamination (ie, rendering instruments safe to handle) may require a microbiocidal process after cleaning (eg, wiping with 70% to 90% alcohol). Factors that determine whether a microbiocidal process is required after cleaning include device materials and design (see Recommendation XIII).

IX.a. Manual cleaning as specified in the instrument manufacturer’s written IFU should be used for instruments that cannot tolerate mechanical cleaning. [3: Limited Evidence]

Manual cleaning is often recommended for devices that cannot tolerate the action of mechanical cleaning or cannot be immersed (eg, power drills, delicate microsurgical instruments, flexible endoscopes, cameras). Seals on lensed instruments can be damaged when processed through ultrasonic equipment. Mechanical cleaning of devices when the manufacturer’s written IFU recommend against it can result in damage to instruments and can limit the associated warranty.

IX.a.1. In preparation for manual cleaning, instruments should be disassembled and ports, valves, stop cocks, ratchets, and joints should be opened. [3: Limited Evidence]

Opening and disassembling instruments facilitates contact of the cleaning solution with all surfaces of the instruments.

IX.a.2. Instruments should be rinsed in cool water before washing. [2: Moderate Evidence]

Hot water can denature blood proteins, which makes them more difficult to remove. Cool water can help to prevent coagulation of blood on instruments and can help remove gross soil from lumens, joints, and crevices. Rinsing with cool water can wash away water-soluble blood proteins and prevent denaturing.

IX.a.3. Unless contraindicated in the device manufacturer’s written IFU, the instrument should be submerged for cleaning in a solution of water and detergent intended for cleaning surgical instruments. The detergent should be compatible with the device to be cleaned and used at the concentration and temperature specified in the detergent manufacturer’s IFU. [3: Limited Evidence]

Full submersion of the instrument in the cleaning solution reduces the risk of splashing potentially contaminated cleaning solution onto personnel and into the environment. The concentration and temperature of the cleaning solution specified in the detergent IFU have been validated by the detergent manufacturer as necessary for the detergent to be effective.
INSTRUMENT CLEANING

IX.a.4. Lumens should be flushed with cleaning solution and brushed with a brush of the length, diameter, type, and material specified in the device manufacturer’s IFU.6 [3: Limited Evidence]

Brushing is necessary to ensure detergent contact of the cleaning solution within lumens. Brushes that are too short cannot contact the entire lumen. Brushes with a diameter that is too small will not contact all surfaces within the lumen.6

IX.a.5. Devices with lumens should be immersed in the cleaning solution in a vertical position.10 [3: Limited Evidence]

Air may become trapped within lumens when the device is soaked in a horizontal position. Entrapped air may prevent contact of the cleaning solution with the surfaces within the lumen.

IX.b. Cleaning solutions should be changed before they become heavily soiled, when the temperature of the solution does not meet the temperature specified in the manufacturer's written IFU, and as needed.10 [3: Limited Evidence]

Bioburden is deposited in the cleaning solution during the cleaning process. Frequent changes of the cleaning solution can help to minimize bioburden. Following the manufacturer’s written IFU helps facilitate effective cleaning.

IX.c. Instruments that require lubrication should be lubricated with a type of lubricant that is recommended by the instrument manufacturer and is compatible with the subsequent sterilization method.3 [3: Limited Evidence]

Instruments require different types of lubricant depending on the design of the device or the sterilization method. Oil-based lubricants may be recommended for the internal mechanisms of powered devices. Water-soluble lubricants are compatible with steam sterilization.12 Following the device manufacturer's instructions for lubrication can facilitate selection and use of the correct lubricant.

IX.d. Mechanical methods (eg, ultrasonic cleaner, washer disinfector/decontaminator) should be used for cleaning surgical instruments unless otherwise specified by the instrument manufacturer.1,5,6,10 [1: Strong Evidence]

Mechanical cleaning is preferred over manual cleaning because it is reproducible and provides consistent detergent concentration, temperature control, and washing and rinsing processes, whereas manual cleaning is subject to variation among personnel.1,5,6,10,12 Mechanical cleaning reduces the risk to personnel of exposure to blood, body fluids, other potentially infectious materials, and other hazards.1,5,6,10 Mechanical cleaning is more easily monitored for quality than manual cleaning.6

IX.d.1. When mechanical equipment incorporates cleaning accessories specifically intended for use with specific types of instruments (eg, robotic or laparoscopic instruments), these accessories should be used according to the equipment and device manufacturers’ written IFU.6 [3: Limited Evidence]

IX.e. Ultrasonic cleaners may be used to remove soil from hard-to-access areas of instruments.14 [3: Limited Evidence]

Ultrasonic cleaners can provide an effective means of removing soil from hard-to-reach areas, such as joints and crevices.6 Ultrasonic cleaners vary by design, intended use, operation, and maintenance. Some ultrasonic cleaners are designed and intended for use on specific instruments. Instructions for use will vary accordingly.6

IX.e.1. Cleaning products compatible with the ultrasonic cleaner should be used.5 [3: Limited Evidence]

Ultrasonic cleaners remove debris through a process of cavitation. Cleaning chemistries that are not compatible with the ultrasonic cleaner can interfere with the cavitation process and result in inadequate cleaning.6

IX.e.2. Ultrasonic cleaning device manufacturers’ written IFU should be followed regarding degassing the cleaning solution before instrument processing. [3: Limited Evidence]

Water contains air bubbles that can interfere with the cavitation process if not removed.67

IX.e.3. Gross soil should be removed from instruments before they are placed in the ultrasonic cleaner. [3: Limited Evidence]

Ultrasonic cleaners are not designed to remove gross soil. They are designed to remove debris from joints, crevices, lumens, and hard-to-reach areas.6

IX.e.4. Only instruments made of similar metals should be combined in the ultrasonic cleaner unless otherwise specified in the instrument manufacturer’s written IFU.12 Instruments composed of brass, copper, aluminum, or chrome should not be mixed with instruments made of stainless steel in an ultrasonic cleaner.5 [3: Limited Evidence]

Placing instruments made of dissimilar metals in the ultrasonic cleaner can cause the transfer of ions from one instrument to another (ie, electroplating), which can result in etching and pitting of the instrument. Damage to the finish of the instrument can create surface imperfections that can harbor microorganisms and debris.6

IX.e.5. Only instruments compatible with the ultrasonic cleaning process should be subjected to ultrasonic cleaning. [3: Limited Evidence]
Some instruments, such as lensed instruments, air-powered drills, flexible endoscopes, and chrome-plated instruments, will sustain damage if cleaned in an ultrasonic cleaner. Lenses may loosen, internal components of air-powered drills may sustain damage if immersed, and chrome plating can loosen.

IX.e.6. Instruments with lumens should be thoroughly submerged and filled with cleaning solution. If the ultrasonic cleaner includes adaptors or connections for internal lumen flushing, these should be attached to lumens that are intended to be cleaned. [3: Limited Evidence]

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

IX.e.7. Instruments should be thoroughly rinsed after ultrasonic cleaning. The rinse should be performed with treated (eg, distilled, reverse osmosis, filtered) water of a quality that will not stain or cause damage to the instruments or contribute to recontamination of the instruments. [2: Moderate Evidence]

Rinsing removes the cleaning solution. Solution in the cleaner may contain debris that can be deposited on the instruments as they are removed.

IX.e.8. The lid should be closed when the ultrasonic cleaner is in use. [3: Limited Evidence]

A closed lid prevents aerosolization of contaminants.

IX.e.9. The cleaning solution in the ultrasonic cleaner should be changed before it becomes visibly soiled, when the temperature of the solution does not meet the temperature specified in the manufacturer’s written IFU, and as needed. [3: Limited Evidence]

Organic material and debris that is lifted from instruments during the ultrasonic processing is deposited in the solution and can become a growth medium for bacteria and other microorganisms. The effectiveness of the cleaning can be reduced when the cleaning solution is heavily soiled. Some manufacturer’s written IFU specify using a fresh cleaning solution each time an ultrasonic cycle is run. Following the manufacturer’s written IFU helps facilitate effective cleaning.

IX.e.10. Ultrasonic cleaners should be emptied, cleaned, disinfected, rinsed, and dried at least daily or, preferably, after each use. If not contraindicated by the ultrasonic cleaner manufacturer’s written IFU, the chamber should be wiped with 70% to 90% alcohol and dried with a lint-free cloth. [3: Limited Evidence]

IX.f. Mechanical washer disinfectors/decontaminators should be used according to the manufacturer’s written IFU. [3: Limited Evidence]

Washer disinfector equipment designs vary among manufacturers and models. Following the manufacturer’s written IFU will help ensure that the equipment is used correctly and functions as intended.

IX.f.1. Surgical instruments and their containment devices and accessories should be positioned in the washer disinfector in a manner that ensures contact of the cleaning solution with all surfaces of the items. [3: Limited Evidence]

• Items composed of more than one part should be disassembled according to the manufacturer’s IFU. Small parts should be contained.
• Instruments should be placed in open mesh-bottom pans.
• Ports and stopcocks should be opened.
• Stylets should be removed from lumened instruments.
• Instrument ratchets should be in the open position.
• Items with surfaces that will retain water should be placed on edge.
• Electrical cords and insulated instruments should be segregated from sharp instruments.

Preparing and positioning items as described above helps ensure contact of the cleaning solution with all surfaces of the instrument. Contact with the cleaning solution is critical to effective cleaning and decontamination. Containing small parts helps to prevent loss. Placing on edge the items with surfaces that will retain water helps prevent water retention. Sharp items can damage the softer material of cords and cables and can damage insulation coverings.

The instrument manufacturer’s written IFU should be followed during use of automated washing equipment, including placement of the instrument within mechanical washers, cycle parameters, and any other specific cleaning requirements.
The variety of equipment available and the complexity of devices make it essential to consult and follow the manufacturer’s IFU to achieve optimal cleaning effectiveness.  

IX.f.3. The operator of the mechanical washer should consult with the mechanical washer manufacturer’s written IFU to determine  

- the level of decontamination that is achieved (eg, low-level, intermediate) and  
- how to monitor the cycle to determine that the parameters necessary to render the processed items safe to handle are met (see Recommendation XVII).  

[4: Benefits Balanced with Harms]

Recommendation X

Surgical instruments should be inspected and evaluated for cleanliness and correct working order after decontamination and if soiled or defective, should be removed from service until they are cleaned or repaired.  

Items that are not clean or do not function correctly can put a patient at risk for injury or SSI.  

Inspection and evaluation provide an opportunity to identify soiled or damaged instruments and to remove these items from service until they are cleaned or repaired.

X.a. Items should be inspected and evaluated for  

- cleanliness;  
- correct alignment;  
- corrosion, pitting, burrs, nicks, cracks;  
- sharpness of cutting edges;  
- wear and chipping of inserts and plated surfaces;  
- missing parts;  
- integrity of insulation on insulated devices;  
- integrity of cords and cables;  
- clarity of lenses;  
- integrity of seals and gaskets;  
- presence of moisture;  
- correct functioning; and  
- other defects.  

[2: Moderate Evidence]  
Use of instruments that are not thoroughly cleaned, are damaged, or do not function correctly poses a risk to patient safety.  

X.a.1. Powered equipment should be checked before use to verify that power ceases when the device is turned off and that the device is functioning as intended. Instruments that require power to operate should be attached to the power source for testing as specified in the manufacturer’s written IFU.  

[3: Limited Evidence]  
Power that does not cease when a powered device is turned off can cause harm to personnel or patients.  

Verifying that instruments requiring a power source are functioning as intended may help to prevent injury to patients and personnel.

X.a.2. Instruments that require assembly or that work with an accessory instrument should be assembled to confirm correct fit and that locking mechanisms work as intended. After inspection, these instruments should be disassembled before packaging for sterilization.  

[3: Limited Evidence]  
Attachments and accessory items not designed to the instrument manufacturer’s specifications may not fit or seal correctly and may be ejected with force and pose a risk to patients and personnel. Disassembling items before sterilization helps ensure that the sterilant contacts all surfaces of the item being sterilized.

X.a.3. Lighted magnification should be used to inspect hard-to-clean areas of devices for cleanliness.  

An instrument that appears clean to the naked eye may harbor debris that cannot be seen without magnification.  

Lipscomb et al compared the results of 202 cleaned and decontaminated instruments by first visually examining them and then examining them using microscopic analysis (ie, episcopic differential interference contrast microscopy). Visual inspection by the researchers showed that 37% of the instruments (75 of 202) had a low level of contamination, and 4% (eight of 202) had a high level of contamination. The microscopic assessment showed 66% (133 of 202) were severely contaminated and 27% (55 of 202) were moderately contaminated.

X.a.4. The internal channels of reusable arthroscopic shavers should be inspected using an endoscopic camera or borescope.  

It is not possible to visually inspect lumens without a device that can penetrate the lumen. Retained organic material or debris in lumens can lead to patient injury.  

In a 2007 case-control study, Tosh et al reported on an outbreak of Pseudomonas aeruginosa SSI in seven patients on whom the same arthroscopic shaver was used. Upon investigation, the researchers found debris in a lumen of the shaver although the shaver had undergone repeated decontamination and sterilization procedures. The researchers concluded that the retained surgical debris allowed the bacteria to survive the sterilization process, and the subsequent use of the shaver was likely related to the SSI outbreak.

The FDA recommends that the inside of the device be inspected and that consideration be given to using a 3-mm videoscope
to inspect the channels of the shaver hand piece.\textsuperscript{24}

X.a.5. Insulated devices should be visually examined and tested using equipment designed to detect insulation failure. [2: Moderate Evidence]

Electrode insulation damage caused during use or processing may create an alternate pathway for the electrical current to leave the active electrode and cause patient injury. Some insulation failures are not visible. Damage to insulation may not be seen during visual inspection.\textsuperscript{22}

In a two-part study, Espada et al\textsuperscript{20} tested 78 robotic and 298 insulated laparoscopic instruments for insulation failure using a porosity detector. The researchers found that 25 of 78 robotic instruments (32%) had an insulation defect, but only seven of 25 defects (28%) were visible to the naked eye. Thirty-nine of the 298 laparoscopic instruments (13%) had an insulation defect, but only 27 of the 39 defects (69%) were visible to the naked eye.

In a nonexperimental study that examined insulated instruments from four hospitals, Montero et al\textsuperscript{18} used a porosity detector to detect insulation failure. The researchers found that 33 of 226 insulated instruments (15%) had an insulation failure. There was no significant difference in insulation failure between hospitals that routinely checked for failure and those that did not.

Serious patient injury, such as thermal bowel injury, can occur when instruments with insulation defects are used.\textsuperscript{24}

X.b. Defective instruments should be identified, removed from service, and repaired or discarded.\textsuperscript{12} [3: Limited Evidence]

Identification of defective instruments and removal from service facilitates segregation of these instruments from instruments to be used when assembling sets. Removing defective instruments from service reduces the risk that defective instruments will be used.\textsuperscript{12}

X.c. Instruments should be thoroughly dried before they are assembled in packaging systems in preparation for sterilization.\textsuperscript{12} [3: Limited Evidence]

Moisture can interfere with sterilization processes.\textsuperscript{23} Excess moisture on instrument surfaces can alter the content of steam and can pose a challenge for effective heating of the instrument during steam sterilization.\textsuperscript{23} Hydrogen peroxide vapor and hydrogen peroxide gas plasma sterilization cycles may abort in the presence of excess moisture.\textsuperscript{23} Ethylene oxide combines with water to form ethylene glycol (ie, antifreeze), which is toxic and is not removed during aeration.\textsuperscript{24}

### Recommendation XI

**Special precautions should be taken during processing of intraocular ophthalmic instruments.\textsuperscript{8}**

Prevention of toxic anterior segment syndrome (TASS), an acute inflammation of the anterior segment of the eye, requires thorough cleaning and rinsing of intraocular instruments and strict adherence to the manufacturer’s written IFU and to professional guidelines.\textsuperscript{81-\textsuperscript{83}}

Toxic anterior segment syndrome is a complication of anterior segment eye surgery and is most commonly associated with cataract surgery.\textsuperscript{84} According to the FDA, hundreds of surgical centers in North America reported outbreaks of TASS between 2000 and 2011.\textsuperscript{85}

Most instances of TASS appear to be related to instrument processing.\textsuperscript{69,70,81-\textsuperscript{83},87-\textsuperscript{90}} Factors associated with TASS include:

- contaminated instruments,
- contaminated ultrasonic cleaners,
- detergent residues (eg, soaps, enzymatic cleaners) remaining on instruments,
- insufficient rinsing of instruments,
- endotoxin residues on instruments,
- steam impurities during steam sterilization,\textsuperscript{21}
- use of glutaraldehyde during processing,\textsuperscript{22}
- dried debris and residues of ophthalmic viscoelastic (OV) material remaining on instruments,
- use of reusable cannulated instruments, and
- insufficiently dried lumens.\textsuperscript{81}

Further research is warranted to determine the multifactorial risk factors for TASS.\textsuperscript{81}

In response to a number of TASS outbreaks, the American Society of Cataract and Refractive Surgery (ASCRS) and the American Society of Ophthalmic Registered Nurses issued recommended practices for processing ophthalmic instruments.\textsuperscript{3} The ASCRS formed a task force composed of members of industry and the ASCRS to educate surgeons who perform anterior segment eye surgery on the causes, symptoms, and treatment of TASS, and to help investigate outbreaks of TASS.\textsuperscript{88} The task force posted a questionnaire on the ASCRS web site to allow surgeons to self-report cases of TASS and provide information about instrument cleaning and processing practices; surgical protocols; substances and techniques used for cleaning phacoemulsification and irrigation/aspiration hand pieces; and products used during the perioperative period, including medications, irrigation fluids, cannulas, and instrument tips.\textsuperscript{88-89} The questionnaire has been maintained on the ASCRS web site since June 2007.\textsuperscript{81} In addition, members of the TASS task force made site visits at the request of personnel from the facilities reporting TASS cases.\textsuperscript{84}

Cutler Peck et al\textsuperscript{82} conducted a retrospective analysis of 77 questionnaires submitted to the ASCRS web site from June 1, 2007, through May 31, 2009, and evaluated the findings from 54 TASS task force site visits conducted between October 1, 2005, and May 31, 2009. The researchers found there were common practices associated with TASS that included:

- inadequately flushing phacoemulsification and irrigation/aspiration hand pieces,
using enzymatic cleaners,
using detergents at the wrong concentration,
using contaminated fluids in ultrasonic cleaners,
adding antibiotics to balanced salt solutions,
using epinephrine with preservatives,
using preoperative skin antiseptics incorrectly,
using powdered gloves,
reusing single-use products, and
failing to maintain instruments correctly.

The researchers concluded that changing these practices could help prevent TASS.

Bodnar et al. conducted a retrospective analysis of 130 questionnaires submitted to the ASCRS web site from June 1, 2007, through March 1, 2012, and of information from 71 site visits conducted by the TASS task force between October 1, 2005, and December 31, 2011. The researchers noted several trends when comparing their data with the data previously analyzed by Cutler Peck et al. When analyzing data obtained from the questionnaires, the researchers found a 26% reduction in sites reporting inadequate flushing of hand pieces and a 27% increase in sites reporting the use of deionized or distilled water for the final rinse. When analyzing data from the site visits, the researchers found a 36% reduction in the use of epinephrine with preservatives and a 36% reduction in the use of enzymatic detergents; however, they found a 21% increase in the handling of intraocular lenses and instrument tips with gloved hands, a 47% increase in poor instrument maintenance, and a 34% increase in use of contaminated fluids in ultrasonic cleaners. The researchers concluded that education had improved some practices but had not improved others.

The findings from these studies indicate a need to improve education of personnel who use or process ophthalmic instruments regarding best practices for improving education of personnel who use or process ophthalmic instruments. Procedures for processing ophthalmic instruments differ from those for general surgery instruments. Cleaning intraocular instruments separately from general surgery instruments can help prevent cross-contamination with bioburden from heavily soiled nonophthalmic surgical instruments.

XI.a. Immediately after use during the procedure, ophthalmic instruments should be wiped clean with sterile water and a lint-free sponge and flushed or immersed in sterile water according to the manufacturer’s written IFU. [1: Strong Evidence]

Ophthalmic viscoelastic material can harden and dry within minutes, making subsequent removal difficult. Keeping OV or other organic material moist can prevent drying and hardening of such material on ophthalmic devices.

Biofilm adheres to the surfaces of instruments and is very difficult to remove. Keeping the OV and organic material moist helps facilitate removal and prevent biofilm formation.

XI.b. The instrument manufacturer’s written instructions for cleaning should be reviewed and followed. [2: Moderate Evidence]

The method of cleaning and the compatibility of cleaning products may vary among instrument manufacturers. Instructions for cannulated instruments indicate the type and volume of solution to be used for rinsing and cleaning and the number of times and for how long the cannula should be flushed.

XI.c. Adequate time, an adequate number of personnel, and sufficient instrument inventory should be provided to permit thorough instrument cleaning and sterilization. [2: Moderate Evidence]

Time constraints may create a disincentive for personnel to adhere to recommended cleaning and disinfection procedures.

In a retrospective analysis of 77 questionnaires and 54 site visits to identify risk factors associated with TASS, an ASCRS task force reported that 23 of the sites (43%) were noted to have an insufficient number of instrument sets or of personnel to provide adequate time to process ophthalmic instruments. Personnel at six sites (11%) did not follow the manufacturer’s written IFU, and four individuals were observed to perform inadequate flushing of phacoemulsification and irrigation/aspiration hand pieces.

XI.c.1. An inventory of ophthalmic instruments sufficient to meet the anticipated demand should be maintained. [2: Moderate Evidence]

An adequate instrument inventory provides sufficient time for personnel to follow correct cleaning, decontamination, and terminal sterilization procedures and helps eliminate or reduce the need for immediate-use steam sterilization (IUSS).

XI.d. Intraocular instruments should be cleaned in a designated cleaning area. Intraocular instruments should be cleaned separately from general surgical instruments. [2: Moderate Evidence]

Procedures for processing ophthalmic instruments differ from those for general surgery instruments. Cleaning intraocular instruments separately from general surgery instruments can help prevent cross-contamination with bioburden from heavily soiled nonophthalmic surgical instruments.

XI.e. Single-use disposable cannulae should be used whenever possible. [1: Strong Evidence]

Thorough cleaning of these devices is difficult because the lumens are exceptionally small. Use of reusable cannulae has been associated with TASS.

In a 2006 review of the literature to identify possible causes of TASS, Mamalis et al. identified detergent residues and denatured OV material on reusable intraocular instruments as possible causes.

XI.f. The scrub person should flush the irrigation and aspiration ports of phacoemulsification and irrigation/aspiration hand pieces and accessory reusable tips and tubing with sterile water according to the manufacturer’s written IFU.
before disconnecting the hand piece from the unit.\textsuperscript{8} \textsuperscript{2} [2: Moderate Evidence]

Inadequate flushing of phacoemulsification hand pieces has been associated with TASS.\textsuperscript{69} When OV material is allowed to dry on phacoemulsification hand pieces, it is difficult to remove. Flushing immediately after the procedure can help prevent OV material from drying. Flushing the hand piece prevents buildup of OV material inside the hand piece, which is difficult to remove during cleaning.\textsuperscript{69},\textsuperscript{82} [2: Moderate Evidence]

XI.g. Cleaning products used to clean intraocular instruments should be selected and used in accordance with the instrument manufacturer’s written IFU.\textsuperscript{69} [2: Moderate Evidence]

Some IFU for ophthalmic instruments recommend against the use of enzymatic detergents.\textsuperscript{69} \textsuperscript{83}

In a retrospective analysis of questionnaires and site visits to examine instrument cleaning and processing of extraocular and intraocular products used during cataract surgery, Culter-Peck et al\textsuperscript{69} identified common practices associated with TASS. They analyzed 77 questionnaires and 54 site visits; 909 cases of TASS were reported. Use of enzymatic cleaners was reported in 36 questionnaires (47%) and observed at 48 sites (89%). The researchers concluded that the benefit of using enzymatic cleaners to clean ophthalmic instruments had not been established and, in fact, was prohibited in some manufacturers’ instructions for specific-use products.

In a randomized controlled trial (RCT) to determine whether enzymatic detergents used to clean ophthalmic instruments could cause TASS, Leder et al\textsuperscript{86} randomly assigned rabbits to seven treatment groups to receive intracameral injection of three different doses of enzymatic detergent. Although the enzymatic detergent caused a severe inflammatory response, the response did not include TASS. The researchers concluded that given that patient exposure to an enzymatic detergent would be significantly less than the lowest dose used in the experiment, enzymatic detergent on ophthalmic instruments was not a cause of TASS.

Mamalis and Edelhauser raised concerns about the validity and generalizability of the study conducted by Leder et al\textsuperscript{86} in a letter to the editor and stated “there are significant differences in the inflammatory reaction of the rabbit, as well as their response to toxic insults, that make it difficult to extrapolate findings from the rabbit to the human.”\textsuperscript{86} They noted that the conclusions of the researchers were inconsistent with the results presented in the study and contended that the results of the study actually provided additional support for the role of enzymatic detergents as a potential cause of TASS.

Following the instrument manufacturer’s IFU helps ensure compatibility of the cleaning product with the device. Incorrect selection and incorrect detergent dilution has been associated with TASS.\textsuperscript{86} [2: Moderate Evidence]

XI.g.1. After cleaning, ophthalmic instruments should be rinsed with a copious amount of water.\textsuperscript{8} [2: Moderate Evidence]

Thorough rinsing helps remove residual cleaning product. Detergent residue has been identified as a possible cause of TASS, although studies performed on rabbits have not supported enzymatic detergent residues alone as a cause of TASS.\textsuperscript{69},\textsuperscript{85} [2: Moderate Evidence]

In a review of the literature, Ozcelik et al\textsuperscript{69} identified detergent residues/soaps, enzymatic cleaners, inappropriate rinsing, and dried debris and OV material residues as potential causes or risk factors for TASS. However, in an RCT to investigate whether enzymatic detergents used to clean ophthalmic instruments could cause TASS, Leder et al\textsuperscript{86} concluded that enzymatic detergent residues alone did not cause TASS. The researchers randomly assigned 35 rabbits into seven treatment groups (ie, low, medium, and high detergent concentration of three detergents, plus a control group of untreated rabbits) and injected their eyes with detergent accordingly. The enzymatic detergents caused a severe but unusual response; however, this response has not been reported in humans.

When the instructions for cleaning are strictly followed, it is possible to remove all detergent.\textsuperscript{69} 83 [2: Moderate Evidence]

XI.g.2. A final rinse should be performed with sterile distilled or sterile deionized water.\textsuperscript{69},\textsuperscript{84} [2: Moderate Evidence]

Untreated water may contain endotoxins, which are heat stable and as such will remain biologically active after sterilization and which have been implicated in occurrences of TASS.\textsuperscript{70},\textsuperscript{83} [2: Moderate Evidence]

Residual enzymes and detergents not rinsed from instruments have been associated with TASS.\textsuperscript{69} [2: Moderate Evidence]

XI.g.3. After cleaning, lumens should be rinsed with sterile deionized or distilled water. The rinse fluid should be expelled from the lumen into a drain and not back into the rinse water. Lumens should be dried with medical-grade compressed air.\textsuperscript{86} [2: Moderate Evidence]

Rinsing removes detergent and other residue from the lumens. Expelling the lumen rinse into a drain prevents reuse of the rinse water and prevents recontamination of the lumen with debris that has been rinsed out of the lumen. Compressed air forced through the lumen eliminates moisture that can serve as a medium for microbial growth.
XI.g.4. After manual cleaning, unless contraindi-
cated in the manufacturer’s written IFU, instru-
tments should be disinfected by wiping and by rinsing lumens with 70% to 90% 
alcohol and should be dried before they are 
packaged for sterilization. [2: Moderate 
Evidence]

Wiping with alcohol disinfects the 
instruments and renders them safe to han-
dle. Endotoxins are removable with alco-
hol. Rinsing lumens with alcohol facil-
itates drying.

XI.h. If an ultrasonic cleaner is used, it should be 
emptied, cleaned, disinfected, rinsed, and dried 
at least daily or, preferably, after each use. If 
not contraindicated by the ultrasonic cleaner 
manufacturer’s written IFU, the chamber should 
be wiped with 70% to 90% alcohol and dried 
with a lint-free cloth. [2: Moderate Evidence]

Inadequately cleaned ultrasonic cleaners and 
endotoxins have been associated with TASS. Fluid in the ultrasonic cleaner can harbor gram-
negative bacteria. Growth of these bacteria 
can result in the production of endotoxins, 
which are heat resistant, can survive steam ster-
ilization, and can cause serious consequences 
for patients. Alcohol promotes drying, inhibits microbial growth, and can prevent bio-
film formation.

XI.h.1. Ophthalmic instruments should be thor-
oughly rinsed after ultrasonic cleaning. A 
final rinse should be performed with treated 
water before drying, inspecting, and packag-
ing in preparation for sterilization. [1: 
Strong Evidence]

Adequate rinsing removes the cleaning 
solution. Residual cleaning products have 
been implicated in the occurrence of 
TASS.

In an RCT, Tamashiro et al filed 30 
reusable 25-gauge injection cannulas with OV material and allowed them to dry for 50 
minutes. Cannulas were then presoaked, washed using a high-pressure water jet, 
backwashed with enzymatic detergent in an 
ultrasonic cleaner, rinsed with tap water, 
rinsed with sterile distilled water, dried with compressed filtered air, wrapped in 
surgical-grade paper, and steam sterilized. 
After sterilization, the cannulas were tested 
for cytotoxicity. The results showed that all 
extracts were noncytotoxic. Six of the can-

nulas were then immersed in enzymatic 
detergent and rinsed, and the extracts from 
these were tested for cytotoxicity. The 
researchers found that the extracts were not 
cytotoxic; however, they observed changes 
in cell morphology and a reduction in cell 
growth. The researchers concluded that the 
cleaning protocol had the potential to min-
imize the occurrence of TASS associated 
with residues of OV material and enzymatic 
detergents remaining on ophthalmic instru-
ments.

XI.i. After cleaning and decontamination, instru-
ments that have been in contact with OV 
material should be inspected for residual OV mate-
rial under magnification. [1: Strong Evidence]

Retained OV material has been associated 
with TASS.

Viscoseelastic material is difficult to remove 
during cleaning, especially if it has been 
allowed to dry. Inspection under magnification 
can facilitate detection of residual OV material. 
Although studies conducted on rabbits showed that OV material alone, even if denatured by 
steam sterilization, did not cause ocular inflam-

mation, the presence of endotoxin in OV mate-
rials can cause severe ocular reaction.

Buchen et al conducted an RCT to deter-
mine the ocular reactivity of rabbits to bacterial 
endotoxin contained in an aqueous medium 
and in a cohesive and dispersive OV material. 
The researchers found that inflammation 
ocurred after injection of as little as 0.02 endo-
toxin units in OV material and 0.08 endotoxin 
units in a phosphate buffered saline.

XI.j. Records should be maintained of all cleaning 
methods, cleaning solutions, and lot numbers of 
cleaning solutions used with ophthalmic instru-
ments. [2: Moderate Evidence]

Records of cleaning methods and solutions 
can assist in surveillance efforts and be used to 
facilitate investigation of any suspected or con-

firmed cases of TASS.

**Recommendation XII**

**Laryngoscope blades and their handles should be cleaned, decontaminated, dried, and stored in a manner that reduces the risk of exposing patients and personnel to potentially pathogenic microorganisms.**

Laryngoscope blades and handles may be a potential source of contamination. In a comprehensive integra-

tive review, Negri de Sousa et al identified 77 arti-
cles that addressed the laryngoscope blade or handle as a potential source of contamination. Based on the 
quality of the research, the authors selected 20 articles for further review. In five of the studies, blood was 
found on the laryngoscope blade. None of the studies 
that investigated the handles found blood.

In a descriptive study of laryngoscope blades and 
handles, Phillips and Monaghan found that although 
none of the blades or handles had visible blood, 13 of 
65 blades (20%), and 26 of 65 handles (40%) tested 
positive for occult blood.

**XII.a. After each use, laryngoscope blades should be 
cleaned and high-level disinfected or sterilized according to the manufacturer’s written IFU.** [1: 
Strong Evidence]
Cleaning and disinfection minimizes the risk of pathogen transmission. Semicritical items are those that contact mucus membranes or nonintact skin. Laryngoscope blades are considered semicritical items that require a minimum of high-level disinfection.

Jones et al conducted an investigation of an outbreak of Serratia marcescens that involved two geographically distinct neonatal intensive care units during a nine-week period. They found that 17 infants were colonized and three developed septicemia, two of whom died. The investigators found that during the outbreak, two infants had been transferred between the two units and two employees worked in both units. Because of a shortage of laryngoscope blades, the blades had been shared without being sterilized between uses. At one of the facilities, S marcescens was isolated from a laryngoscope blade and a sample of breast milk. The outbreak isolates were of the identical serotype and phage type as those identified in the outbreak. The investigators concluded that infection prevention measures, including disinfection of laryngoscope blades, were insufficient at these facilities.

Foweraker reported four cases of Pseudomonas aeruginosa infection in a pediatric cardiac intensive care unit. They infections were believed to have been transmitted by a single laryngoscope blade disinfected between uses by wiping with alcohol. Sampling of the laryngoscope blade in question revealed P aeruginosa of the identical type as a blood culture from one child who died from the infection. The author recommended thorough cleaning and disinfection of blades and handles to reduce the potential for infection.

XII.b. Laryngoscope handles should be cleaned and low-level disinfected after each use and may be high-level disinfected or sterilized according to the manufacturer’s written IFU. [2: Moderate Evidence]

Laryngoscope handles are classified as noncritical items according to the Spaulding Classification. Noncritical items are those that contact intact skin. According to the Centers for Disease Control and Prevention (CDC), low-level disinfectants are used for noncritical items. Although the laryngoscope handle by itself is a noncritical device, the laryngoscope consists of two parts that are handled concurrently. In a comprehensive, integrative review, Negri de Sousa et al recommended that both parts of the laryngoscope be classified as semicritical.

Laryngoscope handles have a knurled surface (ie, a series of small ridges cut into the metal) to facilitate grip; the rough surface can accumulate bioburden. When the laryngoscope blade is folded closed, the tip of the blade is in contact with the handle. Studies have demonstrated the presence of microorganisms on laryngoscope handles. To date, no studies have demonstrated patient infection as a result of contaminated laryngoscope handles; however, studies have demonstrated the potential for pathogen transmission from the laryngoscope handle to the patient.

In a nonexperimental study to identify the extent and nature of contamination of laryngoscope handles considered to be clean and ready for use in the OR, Williams et al cultured 192 laryngoscope handles. The researchers found 99 positive cultures that yielded a total of 128 different microorganisms on the handles.

In a quasi-experimental study, Call et al sampled 60 laryngoscope handles considered to be clean and ready for use in the OR. Samples from 40 handles were sent to the laboratory for aerobic bacterial culture; samples from 20 handles were examined for viral contamination. The researchers found that 30 of the 40 samples sent for bacterial culture (75%) were positive for bacterial contamination, and all 20 of the other handles were negative for viral contamination. The researchers recommended a minimum of low-level disinfection of laryngoscope handles after each use.

Some manufacturer’s IFU recommend low-level surface disinfection while others recommend high-level disinfection or sterilization between uses.

Recommendations for processing vary within the published literature; however, the Association of Anaesthetists of Great Britain and Ireland suggests that laryngoscope handles do become contaminated with bacteria and blood during use and as such they should be cleaned, disinfected, and sterilized after every use.

Further research is warranted regarding processing protocols and the risk of infection associated with laryngoscope handles.

XII.c. Cleaned and disinfected laryngoscope blades and handles should be packaged and stored in a manner that prevents contamination. [1: Strong Evidence]

Packaging assists in preventing recontamination of items that have been high-level disinfected. Packaging of laryngoscope blades to prevent recontamination is a CDC recommendation.

XII.c.1. Laryngoscope blades should be stored in individual packages. [2: Moderate Evidence]

Storing blades individually minimizes the potential for contaminating multiple blades, which could occur if a contaminated blade is placed back into a package of uncontaminated blades. Individual storage eliminates the need to process multiple blades.
Recommendation XIII

Special precautions should be taken to minimize the risk of transmission of prion diseases from contaminated instruments.

Prions are a unique class of infectious proteins that cause fatal neurological diseases known as transmissible spongiform encephalopathies (TSEs). Examples of prion diseases are Gertsmann-Straussler-Scheinker syndrome, fatal familial insomnia syndrome, and Creutzfeldt-Jakob disease (CJD). Variant Creutzfeldt-Jakob Disease (vCJD) is acquired from cattle with bovine spongiform encephalopathy or “mad cow disease.” Transmissible spongiform encephalopathies have been described in a number of animal species. To date, with the exception of cattle, there is no evidence of transmission of TSEs to humans from animals.

Creutzfeldt-Jakob disease has been transmitted iatrogenically through direct inoculation (ie, with contaminated cadaveric human growth hormone), use of contaminated cadaveric dura mater, and use of contaminated medical equipment. Human cadaveric growth hormone has been replaced with growth hormone produced using recombinant DNA technology, and cadaveric dura mater is no longer used in neurosurgeries.

Iatrogenic CJD resulting from use of contaminated medical equipment has been reported in two circumstances: two cases from contaminated electroencephalography electrodes and four suspected cases from contaminated neurosurgical devices, all occurred in Europe during the period from 1952 through 1976. No other cases have been reported of transmission from instruments used in other types of surgeries or since that time.

Prions are resistant to conventional physical and chemical sterilization. Special precautions and protocols are required to inactivate prions. Instrumentation used for neurosurgery procedures performed on a patient suspected or known to have a prion disease is of particular concern because of the high concentrations of prions in the brain and spinal cord.

XIII.a. A multidisciplinary team that includes infection preventionists, perioperative RNs, sterile processing personnel, surgeons, representatives from the clinical pathology laboratory, and other stakeholders should establish, document, and implement evidence-based policies and procedures to minimize the risk of prion disease transmission. [2: Moderate Evidence]

These processes should be based on:
- the patient’s risk of having a prion disease;
- the level of infectivity of the tissue involved, as defined by the World Health Organization (WHO) Tables on Infectivity Distribution in Transmissible Spongiform Encephalopathies; and
- the intended use of the medical device.

A defined protocol based on available evidence provides guidance to protect patients and health care workers from prion transmission. Anesthesia professionals, infection preventionists, perioperative team members, risk management personnel, neurosurgeons, and sterile processing personnel are involved when surgery is performed on a patient known or suspected to have a prion disease. A coordinated effort among disciplines is important and may increase the likelihood of developing effective strategies to protect patients and personnel.

Common laboratory methodologies are ineffective in diagnosing prion disease. Diagnosis can be confirmed through neuropathological examinations of brain tissue, usually performed at autopsy. Research to develop additional laboratory techniques for diagnosis is ongoing.

The WHO has published clinical diagnostic criteria for CJD. These criteria are used to identify patients at risk of having or developing CJD. Patients at high risk of having or developing prion disease include those with:
- progressive dementia consistent with CJD in whom a diagnosis has not been confirmed or ruled out,
- a familial history of a prion disease,
- a history of dura mater transplants, or
- a history of receiving cadaveric-derived pituitary hormone.

Although all prion diseases are infectious, the risk of infection is not the same for all tissue. Based on successful experimental transmission, the risk of infection from tissue types is categorized as high, low, or no risk.

- Tissue from the posterior eye retina or optic nerve, brain, pituitary gland, and spinal cord are categorized as high risk.
- Liver, lung, spleen, kidney, and lymph nodes are categorized as low risk, as are body fluids, blood, and urine.

Prions are found in other tissue, and studies to determine whether they can transmit prion disease are ongoing. The definition of high- and low-risk tissue has continued to change. Infectivity in similar tissue can vary according to the type of prion.

Research directed toward understanding tissue infectivity is ongoing. In particular, blood has been studied to determine whether transfusion is a risk factor. Four potential cases of vCJD from blood transfusion have been reported. The risks associated with having received blood or blood components from a donor with CJD have been studied. Although there is no direct evidence of a causal relationship, the long incubation of CJD, as long as 20 years, is a limitation of these studies. The risk associated with receipt of blood or blood products from a donor with vCJD is significantly higher than that associated with receipt of blood or blood components from a donor with CJD.
There are no known cases of prion disease transmission attributable to the reuse of devices contaminated with blood. Because of the long incubation period of CJD and the discovery of prion protein in tonsils, gut, and muscle, the risk of prion contamination may extend to surgeries on tissue not currently listed as high risk, and categories of high-risk tissue may continue to change.

XIII.b. Patients should be screened for the risk of prion disease before surgery, and information about patients identified to be at risk should be communicated to personnel who are directly or indirectly involved in the patient’s care (eg, anesthesia professional, surgeon, nurses, infection preventionist, clinical pathology laboratory representatives, sterile processing personnel, risk manager, surgery scheduler). [1: Strong Evidence]

Preoperative screening provides a mechanism to identify patients at high risk of having a prion disease. Early communication provides an opportunity to plan for the provision of instruments that can be discarded or taken out of service (ie, quarantined) until a definitive diagnosis is made or to identify alternatives to the use of complex instruments.

Early communication is crucial as it provides an opportunity for review of policies and procedures related to sterilization, disinfection, and environmental cleaning. Early communication may allow time to track the instruments used in surgery, and prevent them from being discarded or returned to service without undergoing special disinfection and sterilization procedures.

XIII.c. Single-use surgical drapes, gowns, and supplies should be used whenever possible and discarded after use. [1: Strong Evidence]

The use and disposal of single-use gowns and supplies eliminates the need to institute special protocols for laundering and may reduce the risk of exposing personnel to prion-contaminated materials.

Although there is no known correlation between contact with work surfaces and attire worn in surgery with transmission of prion diseases, use of single-use gowns and drapes eliminates the need to determine protocols for reusable drapes and gowns potentially contaminated with prions.

Use and incineration of single-use gowns and drapes is recommended in the 1999 WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The more current 2010 Society for Healthcare Epidemiology of America (SHEA) “Guideline for disinfection and sterilization of prion-contaminated medical instruments” recommends that masks, gowns, and protective eyewear be worn if mucus membrane or skin exposure to blood, body fluids, or other potentially infectious materials is anticipated and that laundry be managed according to the OSHA bloodborne pathogens standard.

XIII.c.1. Noncritical work surfaces should be covered with fluid-resistant drapes, and if contaminated with high-risk tissue, the drape should be discarded as nonregulated medical waste. Regulated waste, (eg, bulk blood, pathologic waste, sharp devices) should be managed according to state regulations. [1: Strong Evidence]

Minimizing contamination of surfaces reduces the need for special precautions or protocols for environmental cleaning.

There are no known studies that correlate prion disease transmission with the disposal of waste contaminated with high-risk tissue from a patient known or suspected to have a prion disease. Previous WHO guidelines recommended incineration of potentially prion-contaminated medical waste; however, current guidelines recommend disposal as nonregulated waste.

XIII.d. If the need for an implant is anticipated, only the implant essential for the specific patient should be delivered to the sterile field. Implants opened and handled by scrubbed personnel after the surgery has started should be discarded and not processed for subsequent use. [4: Benefits Balanced with Harms]

Discarding potentially contaminated implants eliminates the risk of implanting a prion-contaminated implant into a patient. Implants, such as screws, are often supplied in racks that hold multiple implants. When sets containing multiple implants are open, there is a risk of cross-contamination of implants that are not used. Removing implants that will not be needed for the patient before sterilizing the tray decreases the amount of implant inventory that will need to be discarded.

XIII.e. Reusable instruments used on high-risk tissue of patients suspected of having prion disease should be easy to clean and should tolerate exposure to an extended steam sterilization cycle. [1: Strong Evidence]

Depending on the cleaning management before sterilization (eg, cleaning process, cleaning product), extended steam sterilization cycles may not be necessary. However, at the time of this publication and on the basis of current knowledge, an extended cycle steam sterilization is still recommended as the option for sterilization that provides the greatest margin of safety.

XIII.f. Instruments used on high-risk tissue of patients at high risk for prion disease should be designed for single use. If single-use instruments are not available, reusable instruments...
should be limited to those that are easy to clean. The number of instruments used should be kept to a minimum. [1: Strong Evidence]

Use of single-use instruments eliminates the need to implement special processing protocols and eliminates the risk of instruments contaminated with prions being used on another patient. Use of single-use instruments also eliminates the risk of exposure of personnel who process instruments.

Successful cleaning is a critical step in processing instruments exposed to high-risk tissue. When instruments are difficult to clean thoroughly, the potential for incomplete cleaning is increased. The challenge to cleaning is reduced when easy-to-clean devices are used.

XIII.f.1. Single-use brain biopsy sets should be used on all patients undergoing brain biopsy. [2: Moderate Evidence]

Creutzfeldt-Jakob disease is often definitively diagnosed by brain biopsy, and whether the patient has a prion disease may not be known at the time of surgery. Until the later stages of CJD, most patients developing a prion disease cannot be identified. Patients undergoing surgery for a brain biopsy are considered to be at high risk for prion disease. Commercial single-use brain biopsy sets are available, or sets can be assembled using instruments at the end of their useful life and discarding them after use.

XIII.f.2. Rigid, as opposed to flexible, neuroendoscopes should be used for patients with known or suspected prion disease. [4: Benefits Balanced with Harms]

Flexible neuroendoscopes contain narrow lumens. Narrow lumens are difficult to clean. Neuroendoscopes may not be compatible with the cleaning procedures and extended steam sterilization cycles recommended for items contaminated with prions.

XIII.f.3. Power drills and saws should not be used for patients with known or suspected prion disease. [1: Strong Evidence]

Power drills and saws create aerosols and may splatter potentially infectious material. Although there are no reported cases of occupational transmission of prion disease through exposure to aerosols, much about prions and their infectivity is unknown.

Stitz and Aguzzi reviewed the literature related to prion-containing aerosols and concluded that although not identified as a source of prion transmission in humans, the high rate of prion transmission by way of aerosols in mice suggested that it was advisable to avoid inhaling aerosols from prion-containing materials.

Power drills are difficult to clean, and the cleaning and sterilization methods recommended to eliminate prion infectivity may damage these instruments.

XIII.f.4. Single-use instruments that have come in contact with high-risk tissue from patients known or suspected to have a prion disease should be discarded. [1: Strong Evidence]

Prions are highly resistant to conventional disinfection and sterilization processes. Discarding these devices eliminates the risk of inadequate prion inactivation.

XIII.g. Reusable instruments that have come in contact with high-risk tissue from patients known or suspected to have a prion disease should be treated in accordance with the most current infection prevention guidelines. [1: Strong Evidence]

Reducing infectivity is crucial to providing instruments that are safe to use on patients. When a potentially contaminated device can be cleaned and prion tissue removed, the risk of prion disease transmission is minimized. There is currently no consensus on the best method of managing instruments that are likely to be contaminated with prions. Until recently, the most referenced guidelines for managing prevention of TSEs were the WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. These were published in 1999 and were based on studies that

- did not incorporate conventional cleaning procedures that reduce protein contamination,
- investigated inactivation using tissue homogenates dried onto carriers,
XIII.g.1. Instruments that cannot be cleaned or require sterilization using low-temperature technologies should not be used or should be discarded. [1: Strong Evidence]

Steam sterilization for an extended cycle time is the only sterilization method recommended in national guidelines at this time. Low-temperature sterilization technologies have not been incorporated into recognized guidelines for inactivating prions.

Research into the effectiveness of gaseous hydrogen peroxide for inactivating prions is ongoing. Several studies have demonstrated that hydrogen peroxide vapor and some hydrogen peroxide gas plasma technologies in combination with specific cleaning agents are effective in inactivating prions, and researchers have suggested that sterilization with gaseous hydrogen peroxide protocols will be practical and widely used in the future.

In a quasi-experimental study designed to test the effectiveness of a gaseous hydrogen peroxide sterilization process to inactivate prions, Fichet et al. contaminated stainless steel wires with prion-infected brain homogenates and then exposed them to gaseous hydrogen peroxide sterilization. Sterilization parameters included a vacuum process at 86°F (30°C) for three or six pulses. The researchers concluded that exposure under these conditions demonstrated that gaseous hydrogen peroxide was effective in inactivating prions.

In a quasi-experimental study to test effectiveness of decontamination methods to inactivate prions, Yan et al. contaminated stainless steel wires with prion-infected brain homogenate material and subjected them to a variety of decontamination and sterilization procedures including exposure to gaseous hydrogen peroxide, steam sterilization, sodium hydroxide, enzymatic detergent, enzymatic detergent plus gaseous hydrogen peroxide, peracetic acid, alkaline detergent, alkaline detergent plus orthophthalaldehyde, alkaline detergent plus steam sterilization, and alkaline detergent plus gaseous hydrogen peroxide. The researchers injected the wires into the brains of living hamsters. Successful processing was defined as a total group survival time of 18 months after implantation. After 18 months, only those hamsters incubated with wires reprocessed with an alkaline detergent followed by sterilization with a four injection gaseous hydrogen peroxide cycle showed no clinical signs of prion disease.

In a quasi-experimental study to determine the effectiveness of hydrogen peroxide gas plasma for inactivating animal and human prions, Rogez-Kreuz et al. decontaminated prion-contaminated steel wires with combinations of enzymatic or alkaline detergents and gaseous hydrogen peroxide. The researchers found that gaseous hydrogen peroxide decreased the infectivity of the prions; however, its efficacy was dependent on the concentration of the hydrogen peroxide and the systems used to deliver it. Only one specific model of a hydrogen peroxide gas plasma sterilizer was 100% effective in inactivating prions.

XIII.g.2. Instruments should be kept moist until they are cleaned and decontaminated. Instruments may be kept moist by immersion in water, a wet cloth draped over the instruments, or use of a transport gel or foam. [1: Strong Evidence]

When prions are allowed to dry on instruments, they become highly resistant to removal. Dried films of tissue are more resistant to prion inactivation by steam sterilization than tissue that is kept moist.

Prions are hydrophobic and in the absence of moisture can strongly attach to surfaces, particularly stainless steel. Keeping instruments moist until cleaning and decontamination can help reduce the tenacity of prions to adhere to surfaces.

XIII.g.3. Instruments should be decontaminated in a mechanical washer as soon as possible after use. [1: Strong Evidence]

Mechanical washing is preferred because process consistency is more likely than with manual washing, and the mechanical process is more easily monitored. Automation of cleaning helps ensure reproducibility. Mechanical washers employ a validated cycle that is not possible with manual cleaning.

Stainless steel has a high affinity for prion adsorption. The longer prion-contaminated instruments are permitted to dry, the greater the adsorption and the more difficult the prion removal.
XIII.g.4. Cleaning chemicals that have evidence of prioncidal activity and that are compatible with the instruments to be cleaned should be used.\textsuperscript{[1: Strong Evidence]}

It is important that product selection decisions take into consideration the combined effect of precleaning, cleaning, disinfection, and sterilization and effectiveness against other infectious diseases and not just the ability to inactivate prions.

The WHO recommendation to soak instruments in 1 N sodium hydroxide (NaOH)\textsuperscript{[118]} is effective at eliminating prion infectivity but, because of incompatibility with most instruments, is impractical. A number of alkaline and enzymatic cleaning agents in combination with steam sterilization have been shown to be effective as well and are compatible with instruments.\textsuperscript{[119,120]}

Some cleaning formulas have a demonstrated ability to remove and inactivate prions.\textsuperscript{[111,119]} However, it has also been shown that some cleaning agents may increase the resistance of prions to subsequent steam sterilization.\textsuperscript{[111,120]} In an investigatory study of the effectiveness of innovative physical and chemical methods of prion inactivation, Fichet et al\textsuperscript{[110]} subjected prion-contaminated stainless steel wires to a variety of cleaning chemistries and sterilization technologies. The researchers found that one phenolic formulation increased the resistance of prions to inactivation.

In a quasi-experimental study, McDonnell et al\textsuperscript{[114]} found that cleaning with certain chemical formulations, alkaline formulations in particular, in combination with steam sterilization was an effective prion-decontamination process. The researchers found that low-temperature gaseous hydrogen peroxide sterilization reduced infectivity in both the presence and absence of cleaning.

In an RCT to determine effectiveness of prion inactivation, Schmitt et al\textsuperscript{[111]} subjected prion-contaminated stainless steel wires to either an automated decontamination procedure developed for prion decontamination, or a routine automated alkaline disinfection process used for sterile processing in Germany. The routine procedure included an alkaline wash and thermal disinfection. The specially designed prion decontamination process included an alkaline wash, thermal disinfection, and an oxidizing process using hydrogen peroxide combined with an alkaline detergent. After processing, the researchers implanted the wires into the brains of eight hamsters. The researchers found that the specially designed process was more effective than conventional alkaline cleaning, was as effective as exposure to a steam sterilization process at 273° F (134° C) for two hours, and left no detectable prion infectivity. The researchers also found that although the alkaline cleaning resulted in significant reduction of prion infectivity, it did not eliminate prion infectivity in six of eight animals in which the stainless steel wires were implanted.

XIII.g.5. After decontamination, one of the following three methods recommended by SHEA should be used to steam sterilize instruments exposed to high-risk tissue:

- prevacuum sterilization at 273° F (134° C) for 18 minutes,\textsuperscript{[120,121]} or
- gravity displacement sterilization at 270° F (132° C) for 60 minutes;\textsuperscript{[122,121]} or
- immersion in 1 N NaOH for 60 minutes, then removal, rinsing with water, and sterilization using one of the cycles noted above (1 N NaOH is a solution of 40 g NaOH in 1 L water).\textsuperscript{[119,121]}

\textsuperscript{[1: Strong Evidence]}

These measures have demonstrated safety and efficacy.\textsuperscript{[119,121]}

The SHEA guidelines state “it is unclear from the published literature which of these options is best for complete inactivation of prions because some studies have revealed excellent but not complete inactivation of the test prions with autoclaving only . . . and the same result for use of NaOH and autoclaving. . . .”\textsuperscript{[121]}

A fourth option described in the SHEA guidelines is to immerse the contaminated instruments in 1 N NaOH for 60 minutes and heat them in a gravity displacement sterilizer at 250° F (121° C) for 30 minutes, then clean and subject the instruments to routine sterilization.\textsuperscript{[122]} This option is effective for prion inactivation; however, it can damage many devices, especially anodized aluminum-containing devices (depending on the quality and finish of the materials used) and therefore is not recommended by many device manufacturers.\textsuperscript{[114]}

XIII.h. Instruments exposed to high-risk tissue should not be subjected to IUSS.\textsuperscript{[120,122]}

\textsuperscript{[1: Strong Evidence]}

Steam sterilization cycles for IUSS of surgical instruments are different from those recommended by SHEA for prion inactivation.\textsuperscript{[122]} The steam sterilization cycles recommended by SHEA for instruments exposed to high-risk tissue are supported by prion investigational studies and have been shown to inactivate prions.\textsuperscript{[3]}

XIII.i. Semicritical and critical devices contaminated with low-risk tissue from high-risk patients should be processed using conventional processing procedures.\textsuperscript{[5]}

\textsuperscript{[1: Strong Evidence]}

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Instruments contaminated with low-risk tissue are unlikely to transmit infection after processing using conventional protocols because those instruments would not be used in the central nervous system.\textsuperscript{61}

The SHEA guidelines make no recommendation regarding processing of devices exposed to low-risk tissue.\textsuperscript{62} Studies to determine the risk associated with low-risk tissues are ongoing, and until evidence indicates that special processing protocols are required to prevent transmission of infection, SHEA makes no recommendation. Transmission of infection from low-risk tissue has only been demonstrated in animal studies of direct inoculation into the brain.\textsuperscript{63}

XIII.j. Instruments that require special prion processing procedures should be identified in a manner that alerts personnel who handle and process instruments that the instruments are contaminated or potentially contaminated with prions.\textsuperscript{60} [3: Limited Evidence]

Awareness that instruments are contaminated or potentially contaminated with prions reduces the risk of these instruments being ineffectively processed and subsequently used on other patients.

XIII.j.1. An instrument-tracking process should be used that provides for tracking of surgical instruments used on high-risk tissue (eg, spinal and brain tissue). [4: Benefits Balanced with Harms]

Instrument tracking systems identify items used during the procedure and also identify the patient for whom the items were used.

XIII.k. Noncritical environmental surfaces contaminated with high-risk tissue from a patient known or suspected to have a prion disease should be cleaned and then spot decontaminated with a 1:5 or 1:10 dilution of hypochlorite for a contact time of 15 minutes or with 1 N NaOH.\textsuperscript{62} [1: Strong Evidence]

Because there is no Environmental Protection Agency-registered antimicrobial product specifically for prion-contaminated environmental surfaces, a solution of diluted hypochlorite or 1 N NaOH is recommended.\textsuperscript{64}

No transmission of prion diseases from environmental surfaces, other than devices used in surgery, has been reported. However, current evidence on prion diseases suggests the need for continued research to better explain transmission. It remains prudent to eliminate highly infectious material from OR surfaces that patients and personnel will be in contact with during subsequent surgeries.

XIII.l. Noncritical environmental surfaces contaminated with low-risk tissue should be cleaned using standard disinfection processes.\textsuperscript{62} [1: Strong Evidence]

Transmission of prion disease from surfaces contaminated with low-risk tissue has not been reported.

XIII.m. When 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 high-risk tissue from the patient should be removed from service and decontaminated according to the most current professional guidelines for prion inactivation.\textsuperscript{62} [1: Strong Evidence]

Inadequately decontaminated instruments may pose a risk to subsequent patients who have contact with the instruments. The current SHEA Guidelines\textsuperscript{62} describe six cases of CJD transmitted by neurosurgical instruments in Europe between 1952 through 1976, demonstrating prion survival of several years. Two of these cases occurred in 1967. These patients developed CJD 15 and 18 months after stereotactic electroencephalographic explorations using electrodes that had been implanted earlier in a patient with CJD and sterilized with 70% alcohol and formaldehyde vapor. Two years later, the electrodes were retrieved and implanted into the brain of a chimpanzee who then developed CJD.\textsuperscript{62}\textsuperscript{64} These classic cases are frequently cited in prion-related articles.\textsuperscript{110-111-112-113-114}

XIII.n. Perioperative personnel who may be exposed to prions should review current research on methods of detecting prion infectivity and decontamination methods and incorporate new evidence into practice.\textsuperscript{111} [2: Moderate Evidence]

Research related to prion disease, tissue infectivity, potential risks of transmission, and effectiveness of cleaning chemistries and sterilization technologies and cycles is ongoing. Incorporating current, evidence-based knowledge into practice may help minimize risks associated with prions.

Recommendation XIV

Documentation of instrument cleaning and disinfection processes should be maintained.

Documentation provides data for the identification of trends and demonstration of compliance with regulatory requirements and accreditation agency standards.

Effective management and collection of health care information that accurately reflects the patient’s care, treatment, and services is a regulatory requirement and accreditation agency standard for both hospitals and ambulatory settings.\textsuperscript{123-124}

XIV.a. Cleaning and decontamination documentation should include the date,
Perioperative team members with responsibilities for cleaning and care of instruments used in surgery should receive initial and ongoing education and complete competency verification activities related to cleaning and care of surgical instruments.

It is the responsibility of the health care organization to provide initial and ongoing education and to verify the competency of perioperative team members. Initial and ongoing education of perioperative personnel about cleaning and care of instruments facilitates the development of knowledge, skills, and attitudes that affect safe patient care.

Competency verification activities measure individual performance, provide a mechanism for documentation, and help verify that perioperative personnel have an understanding of the principles and processes related to recommended practices for cleaning and care of surgical instruments.

Perioperative team members should receive education and complete competency verification activities that address specific knowledge and skills related to cleaning and care of surgical instruments. Ongoing development of knowledge and skills and documentation of personnel participation is a regulatory requirement and accreditation agency standard for both hospital and ambulatory settings.

Education regarding cleaning and care of surgical instruments should include:
- adherence to manufacturers’ IFU,
- methods of cleaning and verification of cleaning,
- types of contamination of medical devices,
- methods of decontamination,
- selection of cleaning chemistries,
- safe use of cleaning chemistries,
- safe use of cleaning equipment,
- how to verify washer cleaning efficacy,
- use of PPE during instrument processing,
- risks and hazards associated with contaminated instruments,
- prions and risks associated with prion-contaminated instruments,
- procedures for decontaminating instruments that are potentially contaminated or known to be contaminated with prions,
- measures to minimize risks of exposure to transmissible pathogens,
- TASS and measures to prevent its occurrence,
- corrective actions to employ in the event of a cleaning failure,
- corrective actions to employ in the event of an equipment or instrument failure,
- new instruments and equipment, and
- evidence-based information about changes in cleaning chemistries and technologies.

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

Recommendaion XV

Recommendation XVI

Policies and procedures for cleaning and care of instruments used in surgery should be developed, reviewed periodically, revised as necessary, and readily available in the practice setting in which they are used.

Policies and procedures assist in the development of patient safety, quality assessment, and performance improvement activities. Policies and procedures also serve as operational guidelines used to minimize patients’ risk for injury or complications, standardize practice, direct perioperative personnel, and establish continuous performance improvement programs. Policies and procedures establish authority, responsibility, and accountability within the practice setting.

Policies and procedures regarding cleaning and care of surgical instruments used in surgery should be developed using professional guidelines and validated, written manufacturers’ IFU.

Having policies and procedures that guide and support patient care, treatment, and services is a regulatory requirement and an accreditation agency standard for both hospital and ambulatory settings.

Policies and procedures related to cleaning and care of surgical instruments should include:
- prepurchase evaluation;
- a review of the manufacturer’s IFU before purchase or consignment;
- management of loaned instruments, including advance notification, time frame
for delivery and pickup, requirements for and delineation of responsibilities for inventory, and processes for care and handling, cleaning, decontamination, packaging, and sterilization of instruments;  
- point-of-use cleaning of instruments;  
- transport of contaminated instruments;  
- precautions to be taken when handling contaminated instruments;  
- precautions to be taken when handling cleaning chemistries;  
- processes for cleaning and decontaminating instruments after use in surgery;  
- care and handling of accessories and supplies necessary for cleaning and decontaminating contaminated instruments;  
- processes for manual and automated cleaning;  
- use and care of cleaning equipment and cleaning chemistries;  
- requirements for water quality used for cleaning instruments;  
- methods for processing ophthalmic instruments;  
- design of decontamination areas to accommodate efficient workflow;  
- requirements for ventilation, temperature, and humidity of decontamination areas;  
- use of PPE in relation to cleaning and decontaminating instruments;  
- methods for monitoring cleaning processes and cleaning equipment;  
- inspection and testing of instruments to determine cleanliness, integrity, and function;  
- preparation of instruments for packaging;  
- procedures for managing laryngoscope blades and handles;  
- criteria for identification and precautions taken for instruments used on patients with known or suspected prion disease;  
- documentation of cleaning;  
- education and competency verification;  
- maintenance of SDSs;  
- procedures for reporting exposure to bloodborne pathogens; and  
- procedures for reporting adverse events.  

[4: Benefits Balanced with Harms]

Recommendation XVII

The health care organization’s quality management program should evaluate the cleaning, decontamination, and care of instruments.

Quality assurance and performance improvement programs can facilitate the identification of problem areas and assist personnel in evaluating and improving the quality of patient care and formulating plans for corrective actions. These programs provide data that may be used to determine whether an individual organization is within benchmark goals and, if not, to identify areas that may require corrective actions. A quality management program provides a mechanism to evaluate effectiveness of processes, compliance with manufacturers’ written IFU, sterile processing policies and procedures, and function of equipment.

Collecting data to monitor and improve patient care, treatment, and services is a regulatory requirement and an accreditation agency standard for both hospital and ambulatory settings. 135 136 149 152

XVII.a. A quality management program should include monitoring of manual and mechanical cleaning. [2: Moderate Evidence]

Cleaning is a critical component of instrument processing and can affect the efficacy of a subsequent sterilization processes. Items that have been sterilized after inadequate cleaning processes have caused patient injury. 21 22 153

XVII.a.1. Mechanical cleaners (eg, washer disinfectors/decontaminators) should be tested for correct function on installation, at least weekly (preferably daily) during routine use, after major repairs, and after significant changes in cleaning parameters (eg, changing cleaning solutions). 14 [3: Limited Evidence]

Monitoring washer function provides information about whether the equipment is functioning correctly. Thorough cleaning is dependent on how the equipment is used, how instruments are placed in the machine, and whether the equipment is functioning correctly.

Adequate cleaning is essential to remove or destroy microorganisms and eliminate endotoxins. Testing washer disinfectors/decontaminators on a regular basis verifies that the equipment is functioning correctly or identifies an opportunity for corrective action. Commercial tests to monitor cleaning efficacy of mechanical washer disinfectors/decontaminators are available.

XVII.a.2. Manual cleaning should be evaluated using objective measures (eg, chemical reagent tests for detecting clinically relevant soils (eg, protein)) when new types of instruments requiring manual cleaning are processed and periodically at intervals determined by the health care facility. [4: Benefits Balanced with Harms]

Manual cleaning is a learned skill and is subject to human error.

XVII.a.3. When verifying the effectiveness of manual cleaning, the instruments most difficult to clean should be used. [5: No Evidence]

Using the most difficult instruments to clean provides a robust measure of cleaning effectiveness.

XVII.a.4. Testing should be performed to assess efficacy of cleaning of medical devices. [1: Strong Evidence]
Currently, there is no single standard of clean, nor is there a standard test soil. Agreement as to what level of residual soil is acceptable after cleaning and what level of residual soil is clinically significant is also lacking.\[23\]

Efficacy of cleaning has traditionally been evaluated visually. Several studies comparing visual analysis with microscopic analysis have demonstrated that visual inspection alone is not sufficient to determine levels of cleanliness.\[24\] Visual inspection is subjective. In addition, infectious microorganisms and residues are not visible to the naked eye. It is also not possible to visually inspect most lumens. Even under ideal cleaning conditions, instruments may retain debris.\[24\]

There are, however, a number of tests that can be used to assess cleaning efficiency.\[155-158\] Qualitative tests usually involve swabbing a device, immersing it in a reagent, and observing for a color change that indicates the presence of organic markers, such as protein or blood.\[2,4,9,45,155\] Qualitative tests provide a measure or action limit against which test results are measured. Adenosine tri-phosphate (ATP) bioluminescence is an example of a quantitative test.\[155,157\] The item to be tested is swabbed to collect ATP, the swab is inserted into a reaction tube, and the ATP on the swab is released using chemicals in the reaction tube. The reaction tube is then inserted into a hand-held luminometer that converts the ATP released from microorganisms or human cells into a light signal, which is measured in relative light units (ie, RLUs). Manufacturers may establish “benchmark cutoffs” for manual cleaning of instruments (eg, flexible endoscopes) that users can employ so that any instrument failing this quantitative cutoff after cleaning is re-cleaned before disinfection/stereilization.\[155\]

Quantitative testing can be used in a quality monitoring program to observe for trends and to monitor performance of a washer disinfector/decontaminator or of manual processes.\[37,154-159\] Readings that trend lower indicate improved cleaning, whereas readings that trend higher can indicate a need for improvement.

XVII.b. Instruments and equipment should be maintained and serviced in accordance with the equipment manufacturer’s written IFU. [2: Moderate Evidence]

Preventive maintenance requirements or recommendations are what the device manufacturer has determined are necessary to keep instruments and equipment in optimal working order. Providing instruments and equipment in optimal working order is critical to patient safety.\[23\]

XVII.b.1. Cleaning equipment should be maintained and serviced in accordance with the equipment manufacturer’s written IFU, and maintenance and service should be documented. [4: Benefits Balanced with Harms]

The manufacturer has determined that the maintenance requirements specified in the manufacturer’s written IFU are necessary for optimal performance. Documentation of maintenance provides a record that can be used to determine compliance with the IFU. Documentation of service can provide information useful in determining whether equipment needs to be replaced.

XVII.b.2. Instruments and cleaning equipment should be serviced by personnel who are qualified to repair the instruments and equipment in need of service. Instrument or equipment service should be documented. [4: Benefits Balanced with Harms]

Instruments and cleaning equipment used in surgery are complex. Having qualified personnel service instruments and equipment increases the probability that repair and service will be performed correctly. Documentation of instrument repairs may help to identify trends in instrument and cleaning equipment damage and define practices that may reduce damage.

XVII.c. Insulated equipment should be tested for current leakage before use and after decontamination. [4: Benefits Balanced with Harms]

Testing before use and after decontamination allows a defective device to be replaced before use or sterilization and provides an opportunity for corrective action in advance of the surgical procedure.\[45\]

XVII.d. Adverse events should be reported and documented according to the health care organization’s policy and procedure and should be reviewed for potential opportunities for improvement. [4: Benefits Balanced with Harms]

- During investigation of SSIs, the cleaning process and its documentation should be reviewed by infection preventionists, perioperative RNs, and designated sterile processing personnel.
- Near misses (ie, unplanned events that do not result in injury, such as organic or inorganic material discovered in a processed instrument tray) should be investigated and corrective action taken to prevent serious adverse events. Surgical site infection has been documented as a result of inadequate cleaning of surgical instruments.\[18,22,22\] Reports of near misses can be used to identify actions that should be taken to
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prevent actual adverse events and can reveal opportunities for improvement.

Editor’s note: Teflon is a registered trademark of DuPont, Wilmington, DE.

Glossary

Adsorption: The adhesion of extremely thin layers of molecules to the solid surfaces they contact.

Aerosol: A suspension of fine solid or liquid particles in air.

Borescope: A device used to inspect the inside of an instrument through a small opening or lumen of the instrument.

Cavitation: A process that uses high-frequency sound waves to form microscopic bubbles that become unstable and implode, creating tiny vacuums capable of removing debris from instrument surfaces and crevices.

Cleaning: A process that uses friction, detergent, and water to remove organic debris; the process by which any type of soil, including organic debris, is removed to the extent necessary for further processing or for the intended use. Cleaning removes rather than kills microorganisms.

Creutzfeldt-Jakob disease: A fatal degenerative neurological disease caused by a prion.

Decontamination: Any physical or chemical process that removes or reduces the number of microorganisms or infectious agents and renders reusable medical products 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.

Distilled water: Water that has been boiled, vaporized, cooled, and condensed to remove impurities.

Electroplating: A process whereby electrical current reduces dissolved metal cations that then form a coating on an electrode, causing a change in the surface properties of a device.

Gross soil: Organic material (eg, blood, tissue, bone) and debris (eg, bone cement) that accumulates on surgical instruments during operative or other invasive procedures.

Homogenate: A tissue that is or has been made homogenous, as by grinding cells into a creamy consistency for laboratory studies. A homogenate usually lacks cell structure.

Hydrophobic: Absence of affinity to water.

Loaned items: Medical devices used in health care facilities that are not owned by the facility.

Lumen: A channel or path through a tubular structure.

Medical-grade compressed air: Air supplied from cylinders, bulk containers, or medical air compressors or reconstituted from oxygen USP and oil-free dry nitrogen NF.

Porosity detector: A high-voltage device designed to find pinholes and flaws in nonconductive coatings. Porosity detectors can only be used to find flaws in coatings when the layer beneath the coating is made of a conductive material.

Product quality assurance testing: A quality assurance process used to verify that a device manufacturer’s instructions for sterile processing can be achieved in the health care setting.

Reverse osmosis: A water purifying process whereby water under pressure is passed through a semi-permeable membrane to eliminate impurities.

Toxic anterior segment syndrome (TASS): A complication of ophthalmic surgery involving a severe, non-infectious inflammation of the anterior segment of the eye, caused by various contaminants in solutions, medications, steam, and residue on surgical instruments and supplies.

Transmissible spongiform encephalopathies (TSEs): A fatal prion disease that effects the brain and nervous system. The development of tiny holes in the brain cause it to appear like a sponge, hence the term “spongiform.”

Treated water: Water that has been filtered, deionized, distilled, or subjected to reverse osmosis to reduce impurities.

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.

Validating: A documented procedure performed by manufacturers for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product that complies with predetermined specifications.

Variant Creutzfeldt-Jakob disease (vCJD): A fatal degenerative neurological disease caused by a prion. The human form of bovine spongiform encephalopathy (ie, mad cow disease).

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, either by use of single or multiple chambers, automatically decontaminates surgical instruments. It employs a cool water rinse, hot water wash, rinse, and drying. An ultrasonic cleaning feature and lubricant rinse may be added.

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