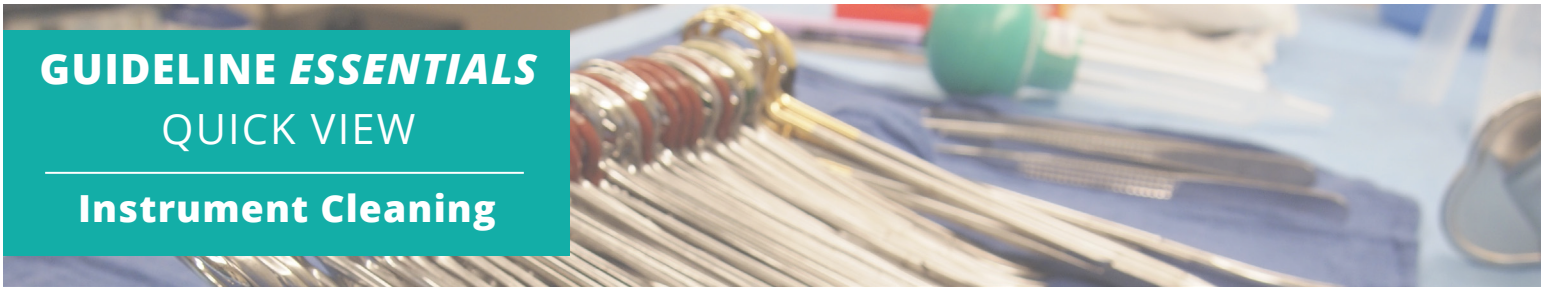
GUIDELINE *ESSENTIALS*
QUICK VIEW
Instrument Cleaning



PRE-PURCHASE EVALUATION

- Convene an interdisciplinary team to develop a standardized process for evaluating and selecting
  - reusable medical devices (eg, surgical instruments and devices) and
  - equipment and supplies that will be used for processing.
- Determine whether the resources are available to perform the processing methods provided in the manufacturer's validated instructions for use (IFU), including:
  - medical device processing personnel who can understand and use the IFU (ie, education and competency needs are met)
  - the time needed to complete all processing steps
  - a water supply of the specified quality
  - other utilities (eg, electricity, ventilation, steam supply, drains, instrument air)
  - facility infrastructure (eg, space; sinks; lighting; heating, ventilation, and air conditioning [HVAC] controls)
  - decontamination equipment
  - inspection equipment (eg, endoscopic camera, borescope, lighted magnification)
  - space for device disassembly
  - accessories (eg, adaptors to connect the device and decontamination equipment)
  - accessories for cleaning lumens, ports, and internal parts
  - cleaning chemicals with the recommended characteristics and compatibility
  - procedures for processing steps (eg, pretreatment, cleaning, decontamination, inspection)
  - any required lubricants or treatments

★ *Cleaning, decontamination, and handling instructions recommended by device manufacturers can vary widely. Some instruments may require special cleaning, packaging, sterilization, or maintenance procedures that cannot be provided by the facility without modifications to existing space, processes, and equipment.*

STERILE PROCESSING AREA

- Perform cleaning and decontamination in an area separate from locations where clean items are handled.
- Do not clean or decontaminate instruments in sinks where eyewash stations are located or hand hygiene is performed.
- The decontamination area must contain
  - an eyewash station and
  - a dedicated hand hygiene sink.

- The decontamination area should be equipped with
  - multiple sinks that are:
    - designated for soaking and cleaning, intermediate rinse, and final rinse
    - large enough to accommodate instrument trays
    - at an ergonomically correct height
    - marked at the water level needed for cleaning solution measurement
  - storage space for personal protective equipment (PPE) and cleaning supplies
  - automated equipment (eg, washer-disinfector, ultrasonic cleaner) consistent with the types of instruments to be cleaned and decontaminated
  - adaptors and accessories to connect instruments with cleaning equipment and utilities
  - utilities that support decontamination, drying, inspection, and documentation, including:
    - access to critical water for rinsing instruments
    - a pressure-regulated, instrument air supply
    - electrical capacity to power all equipment at the same time
    - data lines to support electronic equipment for documentation of processing steps
- Stock the decontamination area with the accessories and supplies needed to clean and decontaminate instruments, including:
  - brushes or other devices designed to remove organic material and debris from lumens, with a diameter and length described in the manufacturers' IFU
  - chemicals for cleaning and disinfecting in accordance with the manufacturers' IFU for the instruments and devices to be processed and equipment used for processing
  - clean, soft, nonlinting cloths
  - equipment and supplies for functionality testing
  - a source of critical water (eg, deionized, reverse osmosis, filtered)
  - a thermometer
  - a device to measure or an automated method to dispense cleaning solutions
- Maintain the decontamination area HVAC system 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.
- Establish a process and frequency for monitoring the quality of water (eg, utility water, critical water) used in decontamination processes as part of the organization's water management program.
- Wear PPE when working in the decontamination area and handling contaminated instruments, including:
  - a fluid-resistant gown with sleeves
  - general purpose utility gloves with a cuff that extends beyond the cuff of the gown
  - a mask with fluid barrier protection
  - eye protection or a full-face shield
  - shoe covers or boots designed for use as PPE
- Make protective equipment immediately available to personnel entering an area in which there is a risk of exposure to transmissible pathogens.
- Remove PPE in a manner that minimizes exposure to the outside, contaminated area of the PPE.
- Perform hand hygiene after doffing PPE.
- Clean and decontaminate reusable PPE and confirm its integrity between uses.

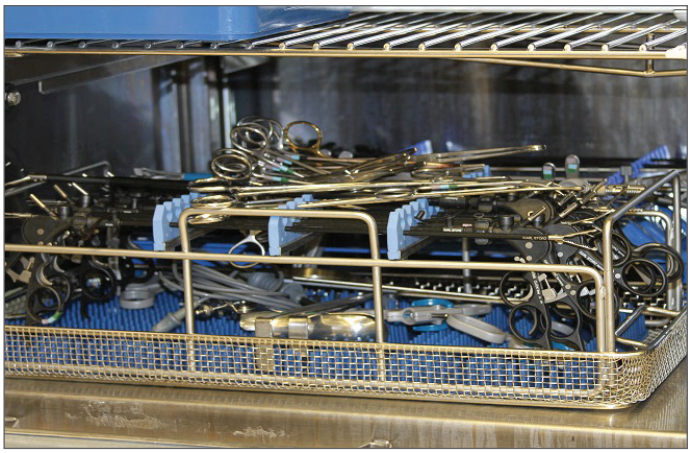
★ *The sterile processing area should be designed for unidirectional functional workflow patterns. The requirements for processing reusable surgical instruments do not vary by location. Equivalent procedures, supplies, and equipment are needed in all locations where sterile processing is performed.*

CLEANING PRODUCTS AND EQUIPMENT

- Use only US Food and Drug Administration–cleared mechanical washer-disinfectors.
- Select compatible products by reviewing the validated manufacturers' IFU for the:
  - surgical instrument or other medical device to be cleaned and decontaminated
  - cleaning chemical (ie, detergent, enzymatic, disinfectant)
  - cleaning equipment

- Select cleaning products that:
  - are compatible with and do not cause damage to the instruments and devices they will be used to clean
  - are nonabrasive
  - are neutral and low foaming
  - are easy to remove during rinsing
  - are biodegradable
  - are environmentally preferable
  - are nontoxic in the specific-use dilution
  - are effective for removing soils under specified conditions
  - have a long shelf life
  - are cost-effective
  - can be tested for effective concentration
- Handle the cleaning solution according to its corresponding safety data sheet (SDS) and the product manufacturer's IFU, and have the SDS readily accessible to employees.
- Follow the cleaning product manufacturer's written IFU for:
  - water quality
  - solution concentration and dilution
  - water temperature
  - contact time
  - conditions of storage (eg, temperature, distance to equipment for automated dispensers)
  - shelf life and use life
- Do not use abrasive devices and products to clean instruments unless their use is specified in the device manufacturer's written IFU.
- Use brushes or other items that meet the specifications (eg, diameter, length, materials) in the instrument or medical device manufacturer's IFU to clean crevices and lumens.
- Use brushes that are either designed for single use and discarded after each use or are reusable and cleaned and decontaminated after each use.

★ *The intended use of cleaning solutions and cleaning equipment varies. Following the manufacturers' validated IFU facilitates correct selection and use of cleaning solutions and equipment, thereby preventing potential damage to instruments. Water supply maintenance can influence water quality. Routine quality evaluation can detect water quality issues that can impede decontamination and sterilization processes.*

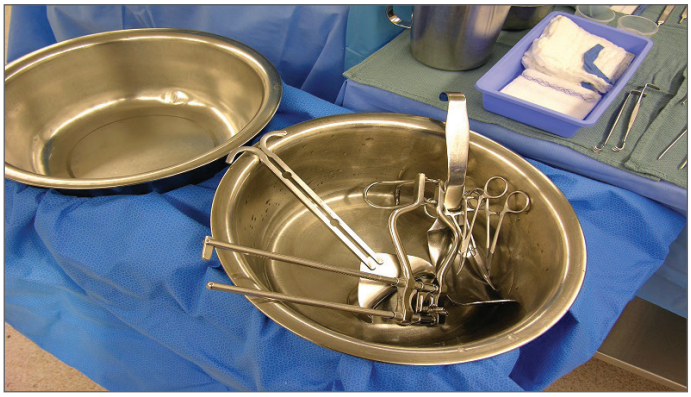


PROCESSING BEFORE USE

- Before use, process all new, repaired, refurbished, and loaned instruments and reusable surgical instruments according to the device manufacturers' IFU.
- Provide the manufacturers' IFU to personnel responsible for processing instruments and reusable medical devices in a format that they can read and understand.
- Establish a process for regular review of instrument and medical device manufacturers' IFU to verify that processing practices comply with the most current manufacturers' IFU.
- Verify that accessories specified by the reusable surgical instrument manufacturer for all processing steps are accessible before use, and use them in accordance with the manufacturer's IFU.
- Remove reusable surgical instruments from external shipping containers and web-edged or corrugated cardboard boxes before transfer into the sterile processing area.
- Inspect instruments for defects and correct function upon receipt.
- Establish standard operating procedures for managing loaned reusable surgical instruments.
- Consider all loaned reusable surgical instruments to be contaminated and deliver them directly to the decontamination area for decontamination, inspection, and packaging before sterilization for patient use.
- Loaned reusable surgical instruments should be delivered to the health care facility to allow time for inventorying and processing in accordance with the organization's standard operating procedures and manufacturers' IFU.

- Obtain and review the manufacturers' written IFU for cleaning before processing and preferably before receipt of loaned instruments.
- Obtain the accessories needed to process loaned instruments according to the manufacturers' written IFU before processing.
- Inventory and record the type and quantity of loaned instruments and confirm receipt with the lender upon delivery.
- After use, process loaned instruments before returning them to the vendor or lending facility.

★ *Failure to clean, inspect, disinfect, or sterilize an item may lead to transmission of pathogenic organisms from a contaminated device and create a risk for patient injury. A successful loaned instrument management program begins with clear and detailed policies and procedures developed in collaboration with all stakeholders.*



POINT-OF-USE TREATMENT

- During the procedure, remove gross soil from instrument surfaces with sterile water. Do not use saline to wipe instrument surfaces.
- Use sterile water to irrigate instruments with lumens at frequent intervals during the procedure.
- Separate sharp instruments from other instruments and confine them in a puncture-resistant container before transport to the decontamination area.
- Remove disposable sharps (eg, scalpel blades, suture needles) and discard them into a closeable, puncture-resistant container that is leak proof on its sides and bottom and is labeled or color coded as biohazardous.
- Protect delicate instruments from damage during transport to a decontamination area by segregating them into different containers or by placing them on top of heavier instruments.
- Keep instruments moist until they are cleaned, by either saturating them with an enzymatic pretreatment product or placing a towel moistened with water over the instruments.
- Transport contaminated instruments to the decontamination area as soon as possible after completion of the procedure.
- Transport instruments in a closed container or enclosed cart that is labeled with a biohazard legend.
- Separate contaminated items from clean and sterile supplies before transport.
- Before transporting instruments, discard liquids used for point-of-use treatment in accordance with local, state, and federal regulations.
- When disposal of the solution before transport is not feasible, transport instruments in a leak-proof, puncture-resistant container to the disposal area.

★ *Moistening and removing gross soil at the point of use can help prevent organic material and debris from drying on instruments and can improve the efficacy and effectiveness of cleaning and decontamination.*

CLEANING AND DECONTAMINATION

- Clean and decontaminate all instruments that were open in the OR or procedure room.
- Before processing, disassemble instruments and devices composed of more than one piece.
- Open ports, valves, stopcocks, ratchets, and joints.
- After disassembly, arrange the instrument or medical device components in a manner that will permit contact of cleaning solutions with all surfaces of the item.

- Rinse instruments in cool water before manual cleaning.
- Submerge the device in a cleaning solution that is compatible with the device.
- Flush lumens with cleaning solution.
- Perform brushing under the surface of the water during manual cleaning.
- Perform manual cleaning for instruments that cannot tolerate mechanical cleaning.
- Change the cleaning solution between each use.
- Change the cleaning solution when the temperature of the solution does not meet the temperature specified in the manufacturers' IFU.
- Establish a process and frequency for cleaning sinks and sink drains in the decontamination area.
- For instruments that require lubrication, use a lubricant that is compatible with the instrument and subsequent sterilization method.
- After manual cleaning, use mechanical methods (eg, ultrasonic cleaner, washer-disinfector/decontaminator) for cleaning instruments and medical devices unless otherwise specified in the manufacturers' IFU.
- Use indicated accessories (eg, flushing ports and tubing for minimally invasive surgery instruments) according to the equipment and device manufacturers' IFU.
- When required in the ultrasonic cleaning device manufacturer's IFU, perform degassing of the cleaning solution before instrument processing.
- Remove gross soil and cleaning solutions used during manual cleaning from instruments before they are placed in the ultrasonic cleaner.
- Do not mix instruments composed of brass, copper, aluminum, or chrome with instruments made of stainless steel in an ultrasonic cleaner.
- Submerge and fill instrument lumens with the cleaning solution or, if the ultrasonic cleaner includes adaptors or connections for internal lumen flushing, attach these to lumens to be cleaned.
- Close the lid when the ultrasonic cleaner is in use.
- Rinse instruments thoroughly with critical water after ultrasonic cleaning.
- Change the cleaning solution in the ultrasonic cleaner after each use.
- Empty, clean, disinfect, rinse, and dry ultrasonic cleaners at least each day the ultrasonic cleaner is used or, preferably, after each use.
- Perform cavitation testing for ultrasonic cleaning devices each day they are used.
- Position surgical instruments and their containment devices and accessories in the washer-disinfector in a manner that facilitates contact of the cleaning solution with all surfaces of the items.

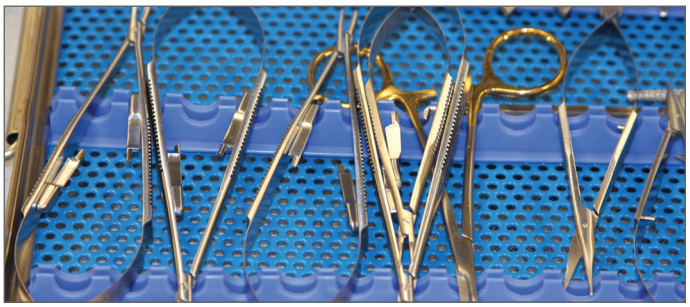
★ *Cleaning instruments as soon as possible after use can help prevent formation of biofilm and dried blood and other body fluids. The presence of bioburden, biofilm, and buildup biofilm interferes with the effectiveness of disinfection or sterilization.*

CLEANING VERIFICATION AND INSPECTION

- Establish and implement a cleaning verification testing protocol.
- Use lighted magnification to inspect surgical instruments and other reusable surgical instruments after decontamination.
- Repeat the decontamination process if retained soil is seen or detected with cleaning verification tests.
- Inspect and evaluate items for:
  - cleanliness
  - completeness (ie, no missing parts)
  - correct alignment
  - surface integrity
  - sharpness of cutting edges
  - integrity of insulation on insulated devices
  - integrity of cords and cables
  - clarity of lenses
  - integrity of seals and gaskets
  - integrity of instrument labels (eg, instrument tape) and similar products, if present
  - correct functioning

- absence of
  - corrosion, pitting, burrs, nicks, and cracks
  - wear and chipping of inserts and plated surfaces
  - moisture
  - any other defects
- Verify that powered equipment can be switched on and off and is functioning as intended. Attach powered equipment to the power source for testing as specified in the manufacturer's IFU.
- Before inspection, assemble instruments that require assembly. After inspection, disassemble instruments before packaging them for sterilization unless the instrument manufacturer's IFU indicates that the item can be sterilized when assembled.
- Inspect the internal channels of reusable arthroscopic shavers using an endoscopic camera or borescope.
- Visually examine insulated devices and test them using equipment designed to detect insulation failure.
- Test insulated equipment for current leakage before use and after decontamination.
- Identify defective reusable surgical instruments and remove them from service for repair or disposal.
- Determine a standardized communication strategy and actions to perform when a reusable surgical instrument is removed from service.
- Thoroughly dry instruments before they are assembled and packaged for sterilization.

★ *Reusable surgical instruments with complex designs (eg, powered devices, robotic instruments, instruments with narrow lumens) can present challenges to decontamination processes, and inspection and cleaning verification may be useful to evaluate cleaning effectiveness in these devices.*



OPHTHALMIC INSTRUMENTS

- Immediately after use during the procedure, wipe ophthalmic instruments with sterile water and a sterile lint-free sponge or cloth and flush or immerse them in sterile water according to the manufacturers' written IFU.
- Clean intraocular instruments in a designated cleaning area, separately from general surgical instruments.
- Use single-use disposable cannulas whenever possible.
- At the close of the procedure, use sterile water to flush the phacoemulsification
  - irrigation and aspiration ports,
  - irrigation/aspiration hand pieces, and
  - accessory reusable tips and tubing

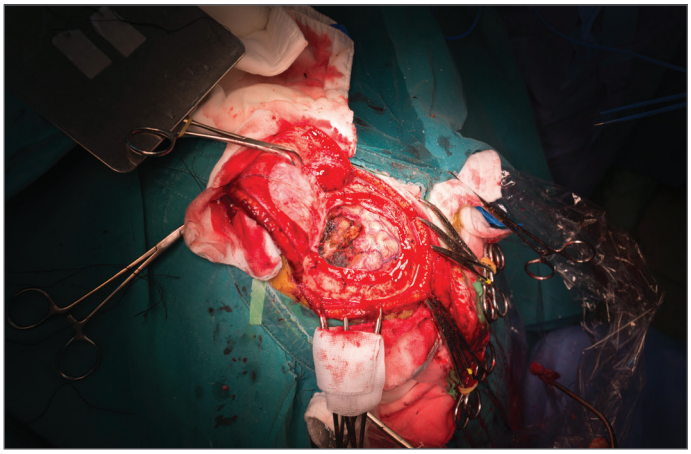
  according to the manufacturer's IFU before disconnecting the hand piece from the unit.
- Select and use cleaning products for intraocular instruments in accordance with the instrument manufacturer's written IFU.
- After cleaning, rinse intraocular instruments with a copious amount of utility or critical water.
- Perform a final rinse, including lumens, with critical or sterile water.
- Dry lumens with pressure-regulated instrument air.
- If an ultrasonic cleaner is used for intraocular ophthalmic instruments, empty, clean, disinfect, rinse, and dry the ultrasonic cleaner after use for non-intraocular ophthalmic instruments and at least daily or, preferably, after each use.
- If not contraindicated by the ultrasonic cleaner manufacturer's written IFU, wipe the chamber with 70% to 90% alcohol and dry it with a lint-free cloth.
- After decontamination, inspect instruments that have been in contact with ophthalmic viscoelastic material for residue under magnification, preferably lighted magnification.
- Maintain records of all processing procedures, decontamination equipment, and cleaning solutions used with ophthalmic instruments.

★ *Procedures for processing ophthalmic instruments differ from those for general surgical instruments. Cleaning intraocular instruments separately from general surgical instruments can help prevent cross contamination with bioburden from heavily soiled nonophthalmic surgical instruments. Most instances of toxic anterior segment syndrome appear to be related to instrument processing.*

LARYNGOSCOPE

- After each use, clean reusable laryngoscope blades and high-level disinfect or sterilize them according to the manufacturer's IFU.
- Clean and low-level disinfect reusable laryngoscope handles after each use. Reusable laryngoscope handles may be high-level disinfected or sterilized if specified in the manufacturer's IFU.
- Package and store reusable laryngoscope blades and handles that have been high-level disinfected or sterilized in a manner that prevents contamination and identifies them as ready for use.

★ *Laryngoscope blades are semicritical items according to the Spaulding Classification system and at a minimum should be high-level disinfected or sterilized if possible. The handle is considered noncritical and should be low-level disinfected according to the Spaulding Classification.*



PRION DISEASE PRECAUTIONS

- Establish, document, and implement evidence-based policies and procedures to minimize the risk of prion disease transmission between patients.
- Promptly identify and isolate instruments used for treating patients with suspected or diagnosed Creutzfeldt-Jakob disease or those whose diagnosis is unclear, and process them by following the most current guidelines for prion inactivation.
- Use an instrument-tracking process or system that provides for tracking of surgical instruments used on high-risk tissue (eg, spinal and brain tissue).
- If the need for a surgical implant is anticipated, only deliver the implant essential for the specific patient to the sterile field. Discard all implants opened to the field during the procedure and do not process them for subsequent use.
- Use instruments designed for single use on high-risk tissue of patients who are known or suspected to be infected with prion disease, and discard them after use.
- If it is necessary to use reusable instruments on high-risk tissue of patients suspected of having prion disease, use instruments that are easy to clean and will tolerate exposure to an extended steam sterilization cycle.
- Use only single-use brain biopsy sets for all patients undergoing brain biopsy.
- Use rigid neuroendoscopes when reusable neuroendoscopes are needed for patients with known or suspected prion disease.
- Do not use power drills and saws for patients with known or suspected prion disease.
- Alert personnel who handle and process instruments that the instruments are contaminated or potentially contaminated with prions.
- Do not use instruments that cannot be cleaned or that require sterilization using low-temperature technologies or discard them after use.
- Keep instruments moist by immersing them in water, draping a wet cloth over the instruments, or applying a pretreatment product until they can be cleaned and decontaminated.
- Decontaminate instruments in a mechanical washer-disinfector as soon as possible after use.
- Decontaminate the mechanical washer-disinfector after processing instruments that may be contaminated with prions.
- Use cleaning chemicals that have evidence of inactivating prion infectivity and that are compatible with the instruments to be cleaned.
- After decontamination, use one of the following three methods recommended by the Society for Healthcare Epidemiology of America to steam sterilize instruments exposed to high-risk tissue:
  - prevacuum sterilization at 273° F (134° C) for 18 minutes
  - gravity displacement sterilization at 270° F (132° C) for 60 minutes
  - 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)

- Do not use immediate use steam sterilization for instruments used for procedures on patients with known or suspected prion disease.
- Process semicritical and critical devices contaminated with low-risk tissue from high-risk patients using processing procedures recommended in the device manufacturers' IFU.

A protocol based on available evidence provides guidance to protect patients and health care workers from prion transmission. For reusable surgical instruments that contact high-risk tissues in procedures for patients with known or suspected prion disease, steam sterilization for an extended cycle time is the only sterilization method recommended in national guidelines at this time.

RECORDS MAINTENANCE

- Include the following information in cleaning and decontamination records:
  - date
  - time
  - identification of instruments
  - method and verification of cleaning and results of cleaning audits
  - number or identifier of the mechanical instrument washer and results of washer efficacy testing
  - name of the person performing the cleaning and decontamination
  - lot numbers of cleaning agents
  - testing results for insulated instruments
  - applicable cleaning verification test used
  - disposition of defective equipment
  - maintenance of cleaning equipment
- Maintain records for a time period specified by the health care organization and in compliance with local, state, and federal regulations.

Record maintenance enables traceability in the event of a failure. The use of automated instrument tracking systems can facilitate the capture of these data elements. Records of washer testing provide a source of evidence for review during investigation of clinical issues, including surgical site infections. Records of equipment maintenance provide evidence that equipment has been maintained.