This policy has been adopted by UNC Health Care for its use in infection control. It is provided to you as information only.

Infection Control Manual		
UNC HEALTH CARE	Policy Name	**Cleaning, Disinfection, and Sterilization of Patient-Care Items**
	Policy Number	**IC 0008**
	Date this Version Effective	**February 2018**
	Responsible for Content	**Hospital Epidemiology**

I. Description

Describes the appropriate methods for cleaning, disinfecting, and sterilizing items used for patient care.

Table of Contents

II. Rationale

The need for appropriate disinfection and sterilization of patient-care items has been emphasized by published reports documenting infection after improper decontamination practices. Because it is neither necessary nor possible to sterilize all patient-care items, hospital policies must identify whether cleaning, disinfection, or sterilization is indicated, based primarily on an item's use. This policy provides a practical approach to the prudent selection and proper use of disinfection and sterilization processes.

III. Policy

A. Basic Principles Asepsis

1. Microorganisms are capable of causing illness in humans.
2. Microorganisms harmful to humans can be transmitted by direct or indirect contact.
3. Illness caused by microorganisms can be prevented by interrupting the transmission of microorganisms from reservoir to susceptible host.

B. Definitions

1. **Asepsis** - the absence of pathogenic (disease-producing) microorganisms.
2. **Clean technique** - practices that reduce the numbers of microorganisms or prevent or reduce transmission from one person (or place) to another.
3. **Sterile technique** - practices designed to render and maintain objects and areas maximally free from microorganisms.
4. **Sterilization** - the complete elimination or destruction of all forms of microbial life and is accomplished in the hospital by steam under pressure, dry heat, ethylene oxide gas, low temperature sterilization technologies (e.g., hydrogen peroxide gas plasma, Sterrad) or liquid chemicals.
5. **High-Level Disinfection** - a process that eliminates all pathogenic microorganisms on inanimate objects but not ordinarily bacterial spores; generally, disinfection is achieved by chemicals or pasteurization.
6. **Cleaning** - the physical removal of soil and organic material from objects, usually done with water and detergents. Adequate cleaning must precede disinfection and sterilization procedures.
7. **Decontamination** - a procedure that removes or inactivates pathogenic microorganisms on objects so that they are safe to handle.
8. **Germicide** - an agent that destroys microorganisms, particularly pathogenic organisms ("germs"). The term *germicide* is similar to the term *disinfectant* except that germicide applies to chemicals used on both living tissue and inanimate objects, whereas disinfectant applies only to substances used on inanimate objects. Other agents designated by words with the suffix "cide" (e.g., virucide, fungicide, bactericide, sporicide, tuberculocide) destroy the microorganisms identified by that prefix. For example, a bactericide is an agent that kills bacteria.

C. Cleaning/Decontamination

1. Before transport to the preparation and packaging area, all items should be cleaned or decontaminated so that all visible organic soil (blood, proteinaceous matter,

debris, etc.) is removed. This prepares the item for safe handling and for subsequent disinfection or sterilization. There are several procedures for cleaning (decontaminating) instruments.

a. **Presoaking** involves placing soiled instruments in water or in water with a detergent, a disinfectant-detergent, or an enzyme formulation without using mechanical agitation. The objective is to prevent blood and organic soil from drying on the instruments. Follow the manufacturer's recommendations for mixing the effective concentration of enzymatic cleaner.

b. **Manual cleaning** involves washing submerged, disassembled instruments with a brush and/ or soft cloth in a designated sink (non-handwashing sink) containing water and detergent. The instruments should receive a final rinse with tap water. Personnel performing manual cleaning are at risk for exposure to blood and body fluids and must wear personal protective equipment (PPE) to avoid such exposures.

c. **Ultrasonic cleaning** uses a process known as cavitation. A high-frequency device produces ultrasonic waves which travel through the cleaning solution producing tiny air bubbles, which in turn implode on the surface of the device, resulting in a scouring action. Detergents specifically designed for ultrasonic cleaning should be used in this process.

d. **Washer-disinfectors** use rotating spray arms to create water jets which clean by impingement. They are similar to washer-sterilizers except that the water is heated to 85°C.

e. **Washer-sterilizers** use rotating spray arms to create water jets which clean by impingement. Most units begin with a cool water rinse cycle to remove gross debris without coagulating it followed by a wash cycle using a detergent and then by a rinse cycle. The machine then goes into a steam sterilization cycle at 140°C (285°F).

D. A Rational Approach to Disinfecting and Sterilizing Patient-Care Items

1. About 40 years ago, a classic approach to cleaning, disinfecting and sterilizing patient-care equipment was devised by Spaulding. He believed that the nature of disinfection would be understood more readily if items for patient care were divided into three categories based on the potential risk of infection involved in the use of the items. The three categories of risk of patient-care items suggested by Spaulding were critical, semicritical, and noncritical.

   a. **Critical Items** are so named because of the high risk of infection if such an item is contaminated with any microorganism, including bacterial spores. Thus, it is critical that objects that enter sterile tissue or the vascular system be sterile. Examples of critical items include surgical instruments, cardiac and urinary catheters, implantable devices, intravascular devices, and needles. Most of the items in this category are purchased as sterile items or are sterilized by autoclaving if possible. If the item is damaged by heat, it should be treated with a low-temperature sterilization technology (e.g., ETO gas, plasma) or chemical sterilants. Tables 2 and 3 shows several germicides categorized as chemical sterilants. Liquid chemical sterilants can be relied upon to produce sterility only if cleaning, to eliminate organic and inorganic material, precedes treatment and if proper guidelines as to concentration, contact time, temperature, and pH are met.

b. **Semicritical Items** objects are those that come in contact with mucous membranes or non-intact skin that is. These instruments or objects require a disinfection process that kills all microorganisms except high numbers of bacterial spores. Intact mucous membranes are generally resistant to infection by common bacterial spores but are susceptible to other microorganisms. Respiratory therapy and anesthesia equipment (e.g., breathing circuits, laryngeal blades), gastrointestinal endoscopes, tonometers, bronchoscopes are some examples of items in this category. Semicritical items require at least high-level disinfection using wet pasteurization or chemical disinfectants. Glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, and peracetic acid with hydrogen peroxide are cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met (Table 2). When a disinfectant is selected for use with certain patient-care items, the chemical compatibility after extended use with the items to be disinfected also must be considered. Glutaraldehyde is most commonly used at UNC Health Care System for high-level disinfection. Peracetic Acid is used in many automated endoscope reprocessors (AERs).

   i. **HLD chemicals currently used at UNC Hospitals are**:

      - Glutaraldehyde (Cidex® brand
      - Revital-Ox Resert®
      - Rapicide PA® for selected AERs only
      - Rapicide® glutaraldehyde for selected AERs only
      - Steris PA® for the Steris System 1e® only
      - TD-5® for the TD 100® AER only

   ii. **There are 5 essential steps for high-level disinfection**:

      - **Clean** – Mechanically clean the item with water and detergent or enzymatic cleaner. Disassemble the item if indicated prior to cleaning. Lumens should be cleaned and brushed according to manufacturer's instructions for cleaning, flushed then rinsed with tap water prior to disinfecting.
      - **Disinfect** – Immerse the item in high-level disinfectant for at least 20 minutes (or FDA-cleared exposure time specific to product). Lumens and channels should be completely filled with high-level disinfectant.
      - **Rinse** – Rinse the item with sterile water, filtered water, or tap water followed by an alcohol rinse. There is no recommendation to use sterile or filtered water rather than tap water for rinsing equipment that will have contact with the mucous membranes of the rectum or vagina.
      - **Dry** – The item should be dry prior to storage. Flushing air through lumens will facilitate the drying process.
      - **Store** – Items should be stored in a way that prevents recontamination (e.g., hung vertically in a clean location or stored in a clean location).

   iii. If reprocessing endoscopes, refer to the Endoscope Infection Control Policy.

iv. To avoid use of an unprocessed item, it is imperative to have a system in place that identifies that items have been high-level disinfected. Please contact Hospital Epidemiology (984-974-7500) for guidance on separation strategies that should be used.

v. Hydrotherapy tanks used for patient's skin that is not intact (e.g., burn patients) have been effectively disinfected with intermediate-level disinfectants (i.e., chlorine, phenolic, iodophor).

c. **Noncritical Items** are items that only touch intact skin. Intact skin is an effective barrier to most microorganisms and sterility is noncritical. Examples are bedside commodes, bedpans, bathtubs, examination tables, IV poles, blood-pressure cuffs, crutches, bedrails, food utensils, floors, bedside table, and patient furniture. In contrast to critical and semicritical items, most noncritical reusable items can be cleaned where they are used and do not need to be transported to the Central Processing Department (CPD) or an instrument processing area. The low-level disinfectants listed for noncritical items in Table 5 may be used. Environmental surfaces at UNC Health Care System are generally cleaned with a quaternary ammonium compound. Surfaces exposed to blood and body fluids should be cleaned with an EPA registered disinfectant-detergent with an HIV/HBV and/or mycobactericidal claim or a 1:10 dilution of household bleach. The contact time for disinfectants used for low-level disinfection of noncritical items is at least 1 minute.

2. Emerging Pathogens, Multi-Drug Resistant Organisms (MDROs), and Bioterrorism Agents

   a. Standard sterilization and high-level disinfection procedures for patient-care equipment (as recommended in this policy) are adequate to sterilize or disinfect instruments or devices contaminated with blood or other body fluids from persons infected with bloodborne pathogens, emerging pathogens, and bioterrorism agents, with the exception of prions (refer to the Creutzfeldt-Jakob Disease (CJD) Policy). No changes in procedures for cleaning, disinfecting, or sterilizing need to be made. In addition, there are data to show MDROs (MRSA, VRE, multidrug resistant *M. tuberculosis*) are susceptible to the liquid chemicals germicides.

3. Ultrasound Probes

   a. When an ultrasound probe is used on intact skin (includes central line puncture site), low-level disinfection with an EPA approved disinfectant/detergent is adequate. Refer to the product manufacturer for the recommended cleaning product. When a probe is used on non-intact skin or mucous membranes, minimally high-level disinfection is required. When a probe cover is available, it should be used to reduce the level of microbial contamination. Do not use a lower category of disinfection or cease to follow the appropriate disinfection recommendations when using probe covers, because these sheaths (or condoms) may fail. Ultrasound probes that are used in sterile body sites should ideally be sterilized (minimally high-level disinfected) even if a sterile probe cover is used. The Trophon technology consists of stand-alone device that high-level disinfects selected vaginal endocavitary probes. The competency form for using the Trophon is appendix 4. The Trophon EPR system and process are compatible with most ultrasound probe sizes, shapes, and materials. Please verify compatibility with Hospital Epidemiology and Trophon.

E. Properties of Common Germicides

1. Table 1 provides a summary of some common germicides with their use dilutions, properties and approximate cost.

F. Chemical Agents used as a Sterilant

1. Table 3 summarizes advantages and disadvantages of chemical agents used as a sterilant or high-level disinfectants.

G. Quality Control Checks for High-Level Disinfectants

1. **All** labels on **all** HLD products must be read by **all** staff performing HLD. It is imperative that staff understand how to use these products and how to properly protect themselves from potentially hazardous chemicals.
2. Label all solutions with the expiration date as instructed by the manufacturer. These dates must be on the active container of the chemical, e.g., bins, basins, etc. Tanks in automated endoscope reprocessor machines must be dated as well. Permanent markers such as Sharpies ® should be used for durability.
3. Do not use the liquid sterilant/high-level disinfectant beyond the reuse life (i.e., expiration date) recommended by the manufacturer (e.g., 14 days, 21 days, etc.).
4. Chemical test strips must be used to determine if a minimum effective concentration (MEC) of the high level disinfectant (i.e., glutaraldehyde, Revital-Ox Resert®, Rapicide® glutaraldehyde, Rapicide® PA, etc.) is present despite repeated use and possible dilution.
5. Personnel must be careful to ensure that they are using the correct chemical test strip. For example, Cidex® (glutaraldehyde) requires a chemical test strip for use with glutaraldehyde, Revital-Ox Resert® requires a chemical test strip for Revital-Ox Resert, Rapicide PA® requires yet a different test strip. Please be meticulous with this process and choices of test strips. Hospital Epidemiology can assist with this process.
6. Depending on the manufacturer of the test strip, a quality assurance (QA) test for effectiveness of the test strip may be required. Test strip manufacturer's instructions for use must be consulted. There is no industry standard for HLD chemicals and test strips.
    a. Some manufacturers require accessing an online validation form for quality assurance of their specific brand and type of test strips. Rapicide® PA test strips require this process. The online validation form must be printed and kept available.
    b. Some manufacturers require a quality assurance test only with a new lot number of test strips, e.g., Revital-Ox Resert® test strips.
7. HLD chemical solutions must be checked before each use using the appropriate chemical test strip and the results documented on the specific log for the chemical and test strip in use. All approved logs are found in appendices to this policy. The solution should be discarded if the chemical test strip indicator indicates that the concentration is less than the MEC.
8. In the event the product is activated on an as-needed basis, appropriate monitoring with test strips must be performed prior to use.
9. All bottles of test strips must be dated when opened and labeled with the correct "after opening" expiration date using a permanent marker such as a Sharpie®. All

types and brands of test strips have different expiration dates. Again, there is no industry standard. Manufacturer's instructions must be carefully followed for the brand and type of test strip for use in an area.

10. For all manual HLD processes, the attached, specific HLD logs must be used. All HLD logs are in appendices to this policy. For automated HLD processes in an automated endoscope reprocessor (AER), print-outs must be kept for 5 years. These print-outs serve as logs for AERs.
11. All print-outs must be signed by the person removing the scope from the AER. This signature indicates personnel has checked the print-out and verified there were no aborted cycles or other anomalies that may indicate an incomplete cycle and could result in an item that remains contaminated and not fit for use on patients.
12. The temperatures of all high-level disinfectant chemicals require temperature readings at least as often as each day the chemical is used. Automated print-outs document temperatures with each cycle; however, in the event temperatures are not measured and recorded on print-outs, this information must be manually documented on the log specific to the chemical in use. Temperatures must be in accordance with manufacturer's instructions for use.

H. Methods of Sterilization

1. Steam is the preferred method for sterilizing critical medical and surgical instruments that are not damaged by heat, steam, pressure, or moisture.
2. Cool steam or heat-sterilized items before they are handled or used in the operative setting.
3. Follow the sterilization times, temperatures, and other operating parameters (e.g., gas concentration, humidity) that are recommended by the manufacturers of the instruments, the sterilizer, and the container or wrap used, and that are consistent with guidelines published by government agencies and professional organizations.
4. Use low-temperature sterilization technologies (e.g., ethylene oxide, hydrogen peroxide gas plasma) for reprocessing critical patient-care equipment that is heat or moisture sensitive.
5. Completely aerate surgical and medical items that have been sterilized in the ETO sterilizer (e.g., polyvinylchloride tubing requires 12 hours at 50^{o}C, 8 hours at 60^{o}C) before using these items in patient care.
6. Dry-heat (e.g., 340^{o}F for 60 minutes) can be used to sterilize items (e.g., powders, oils) that can sustain high temperatures.
7. Comply with the sterilizer manufacturer's instructions regarding the sterilizer cycle parameters (e.g., time, temperature, concentration).
8. Since narrow-lumen devices provide a challenge to all low-temperature sterilization technologies and direct contact is necessary for the sterilant to be effective, ensure that the sterilant has direct contact with contaminated surfaces (e.g., scopes processed in peracetic acid must be connected to channel irrigators).

I. Packaging

1. Ensure that packaging materials are compatible with the sterilization process and have received FDA 510[k] clearance.
2. Ensure that packaging is sufficiently strong to resist punctures and tears in order to provide a barrier to microorganisms and moisture.

J. Monitoring of Sterilizers

1. Use mechanical, chemical, and biological monitors to ensure the effectiveness of the sterilization process.
2. Monitor each load with mechanical (e.g., time, temperature, pressure) and chemical (internal and external) indicators.
3. Do not use processed items if the mechanical (e.g., time, temperature, pressure) or chemical (internal or external) indicators suggest inadequate processing.
4. Use biological indicators to monitor the effectiveness of sterilizers at least weekly with an FDA-cleared commercial preparation of spores (e.g., *Geobacillus stearothermophilus* for steam) intended specifically for the type and cycle parameters of the sterilizer.
5. Biological indicators are the only process indicators that directly monitor the lethality of a given sterilization process. Spores used to monitor a sterilization process have demonstrated resistance to the sterilizing agent and are more resistant than the bioburden found on medical devices. *B. atrophaeus* spores (106) are used to monitor ETO and dry heat, and *G. stearothermophilus* spores (105) are used to monitor steam sterilization and hydrogen peroxide gas plasma. *G. stearothermophilus* is incubated at 55-60oC, and *B. atrophaeus* is incubated at 35-37°C. Steam and low temperature sterilizers (e.g., hydrogen peroxide gas plasma, peracetic acid) should be monitored at least weekly with the appropriate commercial preparation of spores. If a sterilizer is used frequently (e.g., several loads per day), daily use of biological indicators allows earlier discovery of equipment malfunctions or procedural errors and thus minimizes the extent of patient surveillance and product recall needed in the event of a positive biological indicator. Each load should be monitored if it contains implantable objects. If feasible, implantable items should not be used until the results of spore tests are known to be negative. Do not allow the biological indicator to remain in the sterilizer overnight.
6. For designated clinical areas, biological indicators should be transported to Hospital Epidemiology immediately after processing. Mailing biological indicators is not optimal; however, it is acceptable if the ampules are placed in a hard plastic container (e.g., specimen cup) to prevent crushing of the ampule and must be received within 48 hours of processing.
7. When a positive biological indicator is detected, the clinic/department will discontinue the use of the malfunctioning sterilizer and notify Hospital Epidemiology (974-7500) as soon as the malfunction is discovered. The following steps will be followed:
    a. Recall all items since the last negative biological indicator.
    b. Contact Biomedical Engineering to correct the problem.
    c. After the problem is corrected, run 3 consecutive test runs with biological and chemical indicators.
    d. If the biological indicators are negative after the recommended incubation time, the sterilizer may be released for normal use.
    e. The attending physician and Risk Management Department will be notified immediately by Hospital Epidemiology staff about any infection risk associated with the use of non-sterile supplies.

8. Following a single positive biological indicator, treat as non-sterile all items that have processed in that sterilizer, dating from the sterilization cycle having the last negative biological indicator to the next cycle showing satisfactory biological indicator results. These non-sterile items should be retrieved, if possible, and reprocessed.
9. Use biological indicators for every load containing implantable items and quarantine items, whenever possible, until the biological indicator is negative.

K. Load Configuration

1. Place items correctly and loosely into the basket, shelf, or cart of the sterilizer so as not to impede the penetration of the sterilant.

L. Recall of Equipment

1. A method of labeling loads such as the load indicator labels with date, sterilizer number, and load number should be used to recall sterile items. This will be the mechanism used for the recall of non-sterile items when warranted by the hospital's quality control processes (e.g., positive biological indicator).

M. Immediate Use Steam Sterilization

1. Immediate use steam sterilization may be performed if the patient care item will be used immediately (e.g., to reprocess the inadvertently dropped instrument). Use immediate use steam sterilization for processing patient care items that cannot be packaged, sterilized, and stored prior to use. When immediate use sterilization is used, the following parameters must be met: the items must be decontaminated before placement in sterilizing container; the items must be transported from the sterilizer to the patient maintaining sterility; and sterilizer function must be monitored by mechanical, chemical and biological monitors. Whenever possible, implantable surgical devices should not be reprocessed using immediate use sterilization.

N. Preventative Maintenance and Performance Verification Records

1. Sterilizers will be cleaned routinely according to the sterilizer manufacturer’s instructions for use), by clinic/departmental personnel and this will be documented (e.g., on the sterilizer log).

O. Storage of Sterile Items

1. Ensure that the sterile storage area is a well-ventilated area that provides protection against dust, moisture, insects, and temperature and humidity extremes (e.g., temperature and relative humidity are not excessive (temperature >90F, relative humidity >80% for longer than 48 hours).
2. Sterile supplies stored on open shelves in clean storage areas must be 8” from the floor, 5” from the ceiling, and 2” from the outside wall and 18” from a sprinkler head.
3. Store sterile items so that the packaging is not compromised (e.g., punctured, bent).
4. Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date.
5. All items sterilized in the Central Processing Department (CPD) have no expiration date. An indefinite shelf life label is placed on each hospital-processed item. The shelf life of a packaged sterile item depends on the quality of the wrapper, the storage conditions, the conditions during transport, the amount of handling, and other events (moisture) that compromise the integrity of the package. Packaged sterile items may be used indefinitely unless the packaging is compromised, (see 6 and 7 below).

6. Evaluate packages before use for loss of integrity (e.g., torn, wet, punctured). The pack may be used unless the integrity of the packaging is compromised.
7. If the integrity of the packaging is compromised (e.g., torn, wet, or punctured), the item should be reprocessed and repacked before use.
8. Cabinets/shelving with stored sterile supplies should be cleaned on a routine basis (e.g. monthly).

P. Training, Competency, and Sterilizers

1. Provide comprehensive and intensive training for all staff assigned to reprocess semicritical and critical medical/surgical instruments to ensure they understand the importance of reprocessing these instruments.
    a. In order to achieve and maintain competency, each member of the staff that reprocesses semicritical and/or critical instruments should be trained as follows.
        i. Staff with HLD responsibilities must attend the UNCH High Level Disinfection (HLD) workshop provided by Infection Prevention. The class is offered approximately every month at various locations. Contact Infection Prevention for details.
        ii. Provide hands-on training based on the institutional policy for reprocessing critical and semicritical devices.
        iii. Supervise all work until competency is documented (e.g., checklists completed) for each reprocessing task. The required UNCH HLD competency form is appendix 7. Note that competency consists of three parts:
            - Demonstration
            - Observation
            - Documentation
        iv. Conduct competency testing at commencement of employment and regularly thereafter. HLD competency is annual.
        v. Review the written reprocessing instructions regularly to ensure they are compliant with policy, scientific literature, and the manufacturers' instructions. Documentation of orientation and annual competency training will be maintained by the department.
2. Compare the reprocessing instructions (e.g., for the appropriate use of endoscope connectors, the capping/noncapping of specific lumens) provided by the instrument manufacturer and the sterilizer manufacturer and resolve any conflicting recommendations by communicating with both manufacturers.
3. Hospital Epidemiology will conduct infection control rounds periodically (e.g., annually) in high-risk reprocessing areas (e.g., the Gastroenterology Clinic, Central Processing Department) to ensure that the reprocessing instructions/policies are current and accurate and that the instructions are correctly implemented. Document all deviations from policy. All stakeholders should identify what corrective actions will be implemented.
4. Include the following in a quality control program for sterilized items: a sterilizer maintenance contract with records of service; a system of process monitoring; air-removal testing for pre-vacuum steam sterilizers, e.g., Bowie-Dick testing; visual inspection of packaging materials; and traceability of load contents.

5. For each sterilization cycle, record the type of sterilizer and cycle used; the load identification number; the load contents; the exposure parameters (e.g., time and temperature); the operator's name or initials; and the results of mechanical, chemical, and biological monitoring.
6. Retain sterilization records (mechanical, chemical, and biological) for a time period in compliance with standards (e.g., 5 years), statute of limitations, and state and federal regulations.
7. Prepare and package items to be sterilized so that sterility can be achieved and maintained to the point of use. Consult the Association for the Advancement of Medical Instrumentation or the manufacturers of surgical instruments, sterilizers, and container systems for guidelines for the density of wrapped packages.
8. Periodically review policies and procedures for sterilization.
9. Perform preventive maintenance on sterilizers by qualified personnel who are guided by the manufacturer's instruction.

Q. Reuse of Single-Use Medical Devices

1. Adhere to the FDA enforcement document for single-use devices reprocessed by hospitals. The FDA considers the hospital that reprocesses a single-use device as the manufacturer of the device and regulates the hospital by the same standards that is uses to regulate the original equipment manufacturer. UNC Health Care System may use a Third-Party Reprocessor but will not seek FDA clearance to reprocess single-use items internally. For additional information, refer to the "Reuse of Single Use Devices" Infection Control policy.

R. Creutzfeldt-Jakob Disease

1. Special precautions are necessary when disinfecting instruments used on patients known or suspected to have Creutzfeldt-Jakob Disease (CJD). Employees should be familiar with and strictly follow the guidelines provided in the Creutzfeldt-Jakob Disease Infection Control Policy.

Note: Note: If reusable medical or surgical instruments are used in an animal procedure, restrict future use of these instruments to animals only. The rationale is from a concern for animal prion diseases requiring special reprocessing as well as the moral/ethical/aesthetic of using an instrument on an animal and then human without telling the human.

S. Implementation

1. Implementation of this policy is the responsibility of Hospital Epidemiology, Central Processing Department, Inpatient and Outpatient Services and the Medical Staff.

IV. References

Garner JS, Favero MS. Guideline for handwashing and hospital environmental control, 1985. Am J Infect Control 1986;14:110-126.

Rutala WA, DJ Weber. 2010. Disinfection and sterilization in healthcare facilities. In: Lautenbach E, Woeltje K and Malani PN, editors. Practical Handbook for Healthcare epidemiologists. 61-80.

Rutala WA, DJ Weber. 2010. Disinfection, sterilization and control of hospital waste. In: GL Mandell, JE Bennett, R. Dolan, editors. Principles and Practice of Infectious Diseases, Churchhill Linvingstone, Elsevier, Philadelphia. 3677-3695.

Rutala WA, Weber DJ, and Healthcare Infection Control Advisory Committee. CDC guideline for disinfection and sterilization in health-care facilities 2008.

Rutala, WA, DJ Weber. 2010. Guideline for disinfection and sterilization of prion-contaminated medical instruments. Infection Control Hospital Epidemiology. 31:107-117.

Rutala, WA, DJ Weber. 2013. Disinfection and sterilization: An overview. American Journal of Infection Control. 41: S2-S5

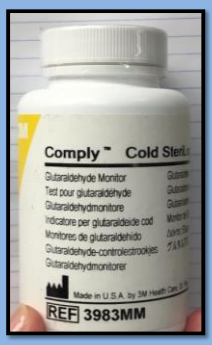
V. Reviewed/Approved by

Hospital Infection Control Committee

VI. Original Policy Date and Revisions

Revised on Aug 2004, Jan 2007, Mar 209, Sept 2011, Sept 2014, Sept 2015, Jan 2017, Feb 2017_{rev}, Feb 2018_{rev}

Appendix 1: Cidex® Activated dialdehyde (glutaraldehyde) High-Level Disinfectant and Comply® Sterilog® Test Strips



UNC Healthcare High Level Disinfection Log

Cidex® Activated dialdehyde (glutaraldehyde) High-Level Disinfectant and Comply® Sterilog® Test Strips

Cidex® brand glutaraldehyde is used ONLY for manual high-level disinfection of semi-critical devices.

Clinic Name:____

1	2	3	4	5	6	7
Staff Initials	**Test Date**	**Daily Chemical Temp Check: 20°C - 25°C (68° F - 77°F)**	**Test Strip Lot #**	**Date Test Strips Expire: 120 days after opening or stamped expiration date whichever comes first.**	**Date Solution Expires: Cidex® glutaraldehyde expires 14 days after mixing or when MEC* test fails.**	**Solution MEC* Test: Pass or Fail? Must be tested before each and every use throughout the day.**
						Pass Fail
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***MEC = Minimum Effective Concentration**

Initials	Signature	Initials	Signature

Appendix 2: Rapicide® Glutaraldehyde High-Level Disinfectant and Rapicide glutaraldehyde test strips

UNC Healthcare High Level Disinfection Log

Rapicide® Glutaraldehyde High-level Disinfectant and Rapicide glutaraldehyde test

Rapicide® glutaraldehyde is used ONLY in automated endoscope reprocessors. Manual high-level disinfection cannot be done with this brand of glutaraldehyde.

Clinic Name:____

1	2	3	5	6	7	8	9
Staff Initials	Test Date	Chemical Temp: 35°C (95°F)	Test Strip Lot #	Rapicide® glutaraldehyde test strips expire 90 days after opening or stamped expiration date <u>whichever comes first.</u>	This brand of test strips requires test strip QC (3 strips in full strength and 3 strips in half strength solution) when opening a new bottle of test strips. Instructions are in instruction leaflet that comes with strips.	Date Solution Expires: 28 days after dispensing or when Minimum Effective Concentration (MEC) test fails.	Solution MEC* Test: Pass or Fail? Must be tested before each and every use throughout the day.
					Pass Fail		Pass Fail
					Pass Fail		Pass Fail
					Pass Fail		Pass Fail
					Pass Fail		Pass Fail
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					Pass Fail		Pass Fail
					Pass Fail		Pass Fail
					Pass Fail		Pass Fail

***MEC = Minimum Effective Concentration**

Initials	Signature	Initials	Signature

Appendix 3: Revital-Ox Resert® High-level Disinfectant and Test Strips

Gallons: Lawson #052156

Test Strips: Lawson #052771

UNC Healthcare High Level Disinfection Log

Revital-Ox Resert® High-level Disinfectant and Test Strips

Revital-Ox Resert® hydrogen peroxide solution is used ONLY for manual processing of semi-critical devices that DO NOT enter the lower gastrointestinal system (i.e., colonoscopes, rectal probes). Automated high-level disinfection cannot be done with this high-level disinfectant.

Clinic Name:____

1	2	3	4	5	6	7	8
Staff Initials	Test Date	Daily Chemical Temp Check: Between 20° C and 24° C (or 68° F and 75° F)	Test Strip Lot #	Date Test Strips Expire: 180 days (6 months) after opening or stamped expiration date whichever comes first.	Resert requires test strip QC (3 strips in full strength and 3 strips in half strength solution) ONLY when opening a new lot # of test strips. Instructions are in instruction leaflet that comes with strips.	Date Solution Expires: 21 days after dispensing into container or when Minimum Effective Concentration (MEC) test fails.	Solution MEC* Test: Pass or Fail? Must be tested before each and every use throughout the day.
					Pass Fail		Pass Fail
					Pass Fail		Pass Fail
					Pass Fail		Pass Fail
					Pass Fail		Pass Fail
					Pass Fail		Pass Fail
					Pass Fail		Pass Fail
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					Pass Fail		Pass Fail

***MEC = Minimum Effective Concentration**

Initials	Signature	Initials	Signature

Appendix 4: Sterilization Log for Table Top Gravity Displacement Sterilizers

UNCH Hospital Epidemiology Department

Sterilization Log for Table Top Gravity Displacement Sterilizers

Clinic Name:_____

Sterilizer Make and Model: _____

Every Monday process and send biological indicators via lab courier to Maria Gergen in Hospital Epidemiology department.

Date MM/DD/YY	Operator Initials	Indicate which cycle run: unwrapped, pouches, packs, handpieces, special	Load Contents ATTACH STERILIZER PRINT-OUT HERE	Class V chemical indicator ("CI") checked in every pack		Biological Indicator ("BI") Run with this Cycle		Sterilizer print-out reviewed, dated and initialed	Date BI sent to hospital epidemiology	BI Type: 1261, 1262, other	BI lot number	BI expiration date	Date reconciled BI report received from Hospital Epidemiology
				Yes	No	Yes	No						
				Yes	No	Yes	No						
				Yes	No	Yes	No						

Staff

Initials	Signature	Initials	Signature	Initials	Signature

Appendix 5: TROPHON® Log

High-Level Disinfection Log
For Trophon EPR Serial # _____

START A NEW PAGE WHEN LOADING A NEW SONEX CARTRIDGE OR NEW BOX OF CHEMICAL INDICATORS
CARTRIDGE REPLACEMENT: WHEN LOADING A NEW SONEX CARTRIDGE, START A NEW PAGE. DOCUMENT DATE LOADED, LOT # & EXP. DATE.
CHEMICAL INDICATOR BOX: WHEN OPENING A NEW BOX OF CHEMICAL INDICATORS, START A NEW PAGE. DOCUMENT LOT # AND EXP. DATE.
CYCLE RESULTS: PLACE LABEL IN SQUARES BELOW.
LABELING YOUR READY-TO-USE PROBE: INITIAL IN THE SMALL BOX BELOW ("INIT") A 2ND LABEL IS PLACED ON THE CLEAN US PROBE COVER.

CARTRIDGE REPLACEMENT		CHEMICAL INDICATOR REPLACEMENT	
Date Loaded & Lot #	Expiration Date	Lot Batch #	Expiration Date

1		2		3	
INIT	2nd Label Placed on Clean Ultrasound Probe Cover	INIT	2nd Label Placed on Clean Ultrasound Probe Cover	INIT	2nd Label Placed on Clean Ultrasound Probe Cover
4		5		6	
INIT	2nd Label Placed on Clean Ultrasound Probe Cover	INIT	2nd Label Placed on Clean Ultrasound Probe Cover	INIT	2nd Label Placed on Clean Ultrasound Probe Cover
7		8		9	
INIT	2nd Label Placed on Clean Ultrasound Probe Cover	INIT	2nd Label Placed on Clean Ultrasound Probe Cover	INIT	2nd Label Placed on Clean Ultrasound Probe Cover
10		11		12	
INIT	2nd Label Placed on Clean Ultrasound Probe Cover	INIT	2nd Label Placed on Clean Ultrasound Probe Cover	INIT	2nd Label Placed on Clean Ultrasound Probe Cover

Appendix 6: TROPHON® COMPETENCY SHEET

NAME_____DATE_____

1. Put gloves on. Note: wear gloves at all times when required as described in the Trophon EPR user manual.

MET_____NOT MET_____

2. Pre-clean the probe before the high-level disinfection (HLD) cycle, following the probe manufacturer's instructions for use (IFUs).

MET_____NOT MET_____

3. Ensure the probe is clean and free of all visible debris, bioburden, gel, or other soil.
    a. Use Sani Cloths to clean
    b. Wipe the transducer cord and all surfaces of the transducer until it is visually clean. Use friction and work from cleanest to dirtiest areas.
    c. Dry the transducer with a soft, dry cloth.
    d. Visually inspect the transducer to ensure it is both clean and dry prior to HLD.

MET_____NOT MET_____

4. Load the clean, dry probe into the Trophon disinfection chamber ensuring:
    a. The probe is secured high in the chamber with tip of probe above embossed line.
    b. Probe does not contact the chamber wall at any point.

MET_____NOT MET_____

5. Place a new red Trophon chemical indicator (CI) into the indicator holder with the red side facing up.
    a. Note: a new CI is to be used for every cycle.

MET_____NOT MET_____

6. Close the chamber door and confirm whether the probe is both clean and dry.
    a. If yes, press Start.
    b. If no, follow the LCD screen prompts.

MET_____NOT MET_____

7. At the end of the 7 minute HLD cycle, Trophon's LCD screen states: "CYCLE COMPLETE REMOVE AND WIPE PROBE."

MET_____NOT MET_____

8. Open the chamber door.

MET_____NOT MET_____

9. Remove CI, check CI color against the color chart on the CI carton and discard.
    a. Note: BOTH the CI and LCD screen must indicate a successful cycle for the probe to be ready for use. If either the CI or Trophon LCD screen indicates a fail, repeat the cycle.

MET_____NOT MET_____

10. Remove and wipe the probe using a clean, dry single use cloth.

MET_____NOT MET_____

11. Close the chamber door. The probe is now ready for use.

MET_____NOT MET_____

12. Record the HLD cycle on the log or printed sticker.

MET_____NOT MET_____

Notes:

- At the completion of a cycle, remove probe immediately to ensure faster warm up times. If probe remains in chamber, the Trophon will shut down heaters to ensure probe is protected. Therefore, warm up times may be longer.
- Sleep mode: to save power, Trophon will enter sleep mode after 2 hours of inactivity.
- Purging the Trophon of disinfectant is required if the device is to be moved or if Sonex-HL® has expired. Manufacturer's instructions for purging the Trophon must be meticulously followed.

NANOSONICS, INC

Trainer: _____

Trainee: _____

Date: _____

Appendix 7: Cleaning Spills for Trophon

To clean up Hydrogen Peroxide spill:

1. Wear PPE – don full personal protective equipment (PPE) to clean it up. This includes a face shield, gloves, and a gown.
2. Once you are wearing PPE, contain the H2O2.
3. Absorb spill in pads &/or paper towels.
4. Transfer absorbent materials to water-filled container (sink or bucket) with more than 11 times the amount of spilled liquid.
5. Allow liquid to neutralize then render liquid down a waste drain.
6. Place absorbent materials in bag.
7. All neutralized materials may then be thrown into the regular trash. It is not necessary to place in the hazardous trash.
8. Coordinate for waste pick-up per hospital policy.
9. Thoroughly clean spill area with wet paper towels to remove any residual spillage that may have remained & repeat.

If you are unsure what to do, call UNCH Environmental Health and Safety office at 984-974-0749.

1. Leave area
2. Post a warning sign
3. Notify supervisor, call UNCH Environmental Health and Safety (EHS)
4. Wait for instructions from EHS.

Appendix 8: Sterilization Competency for UNCH Table Top Sterilizers
(from Ambulatory Care Clinic Services Infection Control Policy: IC0002)

Signature: _____Date:_____

Print name: _____Title:_____

COMPETENCY CRITERIA: Circle appropriate outcome measure.

Date: Initials:	Met	Not Met	Has read the Cleaning, Disinfection, and Sterilization Infection Control Policy.
	Met	Not Met	Knows biological monitoring of steam sterilizers is done at least weekly.
	Met	Not Met	States the "recall procedure" if a positive biological indicator is detected (from Cleaning, Disinfection and Sterilization Policy).
	Met	Not Met	Assures item is appropriately clean and dried prior to packaging for sterilization.
	Met	Not Met	Places a chemical indicator inside each package to verify sterilant (steam, hydrogen peroxide plasma) penetration.
	Met	Not Met	Places a chemical indicator on the outside of each package to verify processing.
	Met	Not Met	Knows how to interpret the chemical and biological indicators for steam, ETO and Hydrogen Peroxide Plasma sterilization (those that apply to your clinic).
	Met	Not Met	Knows the location of the chemical and biological monitoring record. Assures all results are recorded and stored in an organized manner. (Must be retrievable for 5 years).
	Met	Not Met	Documents the following: date or load number and content, exposure time and temperature, results, and operator by name or initials.
	Met	Not Met	Saves all sterilizer print outs in an organized fashion for 5 years.
	Met	Not Met	Cleans the sterilizer on a basis (e.g., weekly, monthly) in accordance with manufacturer recommendations and documents results.
	Met	Not Met	Checks all sterilized packages for tears, moisture, and/or unbroken seals prior to use.
	Met	Not Met	Checks the internal and external package indicators for change in color to determine steam sterilization prior to use.

I certify that this individual has met all competencies for sterilizer use.

Signature: _____ Date: _____

Print Name: _____ Title: _____

Appendix 9: UNCHC High Level Disinfection General Competency

UNCHC High Level Disinfection General Competency

I have read the UNCHC Safety Policy on Glutaraldehyde Control before presenting for competency review.

Circle appropriate outcome measure:			Competencies
Met	Not Met	N.A.	Verbalizes knowledge of cleaning and disinfecting solutions used, labeling, length of effective use life and soak times.
Met	Not Met	N.A.	Documents concentration of high-level disinfectant appropriately, following manufacturer's instructions for use (IFUs).
Met	Not Met	N.A.	Wears personal protective equipment, including gown, gloves, and appropriate face protection.
Met	Not Met	N.A.	Demonstrates initial gross decontamination of exterior of device and accessories. Wipes exterior of device with clean cloth soaked in detergent or enzymatic cleaner.
Met	Not Met	N.A.	If flexible endoscope, leak tests scope according to manufacturer's IFUs.
Met	Not Met	N.A.	Demonstrates the process of manual washing and brushing all channels, ports and valve covers with appropriately prepared detergent or enzymatic cleaner.
Met	Not Met	N.A.	If device has lumen(s), uses suction to fill channels with detergent or enzymatic cleaner.
Met	Not Met	N.A.	Brushes lip of biopsy port if processing scope. Uses appropriate cleaning tools for the device being cleaned, i.e., soft brushes, cloths, and processes cleaning tools appropriately.
Met	Not Met	N.A.	Uses suction to rinse lumens until fluid is clear, ends by suctioning air to clear fluid from lumens (or Scope Buddy) and rinses exterior of scope.
Met	Not Met	N.A.	Fills interior channels of any lumened instrument with high-level disinfectant and immerses completely to prevent air bubbles. Utilizes manufacturer's recommended immersion time for chemical used.
Met	Not Met	N.A.	Demonstrates the proper use of the automated endoscope reprocessor (AER) by completing manufacturer's competency form and training.
Met	Not Met	N.A.	Avoids contaminating clean and/or disinfected items with dirty hands or gloves.
Met	Not Met	N.A.	Rinses device with either sterile water, filtered water, or tap water. Uses three separate volumes of water for three one-minute rinses.
Met	Not Met	N.A.	If appropriate, uses forced air to dry the scope followed by alcohol to assist in drying.
Met	Not Met	N.A.	Demonstrates proper cleaning, high-level disinfection, rinsing and drying of all accessories.
Met	Not Met	N.A.	Demonstrates proper cleaning and sterilization of biopsy forceps and any instrument that enters normally sterile tissues.
Met	Not Met	N.A.	Labels or packages high level disinfected instruments to indicate disinfection has been done.
Met	Not Met	N.A.	Is able to state conditions indicating a device has not been disinfected (e.g., if not labeled or packaged, device is considered contaminated and requires high level disinfection prior to use).
Met	Not Met	N.A.	Properly stores devices, instruments, and/or scopes and their accessories in a clean location.
Met	Not Met	N.A.	Empties and disinfects water bottles on AERs according to manufacturer's IFUs and most current accepted guidelines and UNCH policy.
Met	Not Met	N.A.	Disinfects brushes if reusable; discards disposable brushes after use.
Met	Not Met	N.A.	Empties and cleans pans or sink as indicated.
Met	Not Met	N.A.	Removes personal protective gear and discards appropriately.
Met	Not Met	N.A.	Washes hands before leaving reprocessing room.

I certify that _____ has met the competencies necessary to perform the general duties of high level disinfection.

Name:_____ Date: _____

Signature: _____

This is a document adopted by UNC Hospitals for its use in Infection Control. It is provided to you as information only.

UNCH Hosp Epi, 042814 jb

Table 1: Some common disinfectants with their use-dilutions, properties, and cost[1,3]

Germicide	Use-Dilution	Level of Disinfection	Inactivates[2]					
			Bacteria	Lipophilic Viruses	Hydrophilic Viruses	*M. tuberculosis*	Mycotic Agents	Bacterial Spores
Isopropyl alcohol	60-95%	Int	+	+	-	+	+	-
Hydrogen peroxide	3-25%	CS/High	+	+	+	+	+	±
Formaldehyde	3-8%	High/Int	+	+	+	+	+	±
Quaternary ammonium compounds	0.4-1.6% aqueous	Low	+	+	-	-	±	-
Phenolic	0.4-5% aqueous	Int/Low	+	+	±	+	±	-
Chlorine	100-1000 ppm free chlorine	High/Low	+	+	+	+	+	±
Iodophors	30-50 ppm free iodine	Int	+	+	+	±	±	-
Glutaraldehyde	2%	CS/High	+	+	+	+	+	+

Table 1 (continued)

Important Characteristics									Approximate Cost (in dollars)	
Shelf Life >1 Week	Corrosive/ Deleterious Effects	Residue	Inactivated by Organic Matter	Skin Irritant	Eye Irritant	Respiratory Irritant	Toxic	Easily Obtainable	Purchase ($)/gal	Cost ($)/gal at use-dilution
+	±	-	+	±	+	-	+	+	3.70 (70%)	3.70 (70%)
+	-	-	±	+	+	-	+	+	24.50 (6%)	24.50 (6%)
+	-	+	-	+	+	+	+	+	38.42 (37% wt)	3.84 (3.7% wt)
+	-	-	+	+	+	-	+	+	10.77	.04 (0.4%)
+	-	+	±	+	+	-	+	+	9.70-15.70	0.6(0.4%)-0.8(0.8%)
+	+	+	+	+	+	+	+	+	1.00 (5.25%)	.10 (0.5%)
+	±	+	+	±	+	-	+	+	10.10 10%	.05 (0.05%)
+	-	+	-	+	+	+	+	+	6.50-14.00	6.50-14.00

[1] Modified from Laboratory Biosafety Manual. World Health Organization, 1983 and Rutala, 1995.

[2] Inactivates all indicated microorganisms with a contact time of 30 min or less, except bacterial spores, which require 6-10 hr contact time.

Table 2: Methods for disinfection and sterilization of patient care items and environmental surfaces

Process	Level of microbial inactivation	Method	Examples (with processing times)	Health care application (examples)
Sterilization	Destroys all microorganisms, including bacterial spores	High temperature Low temperature Liquid immersion	Steam (~40 min), dry heat (1-6 hr depending on temperature) Ethylene oxide gas (~15 hr), hydrogen peroxide gas plasma (28-52 min), ozone (~4 hr), hydrogen peroxide vapor (55 min) Chemical sterilants†: >2% glut (~10 hr); 1.12% glut with 1.93% phenol (12 hr); 7.35% HP with 0.23% PA (3 hr); 8.3% HP with 7.0% PA (5 hr); 7.5% HP (6 hr); 1.0% HP with 0.08% PA (8 hr); ≥0.2% PA (12 min at 50°C-56°C)	Heat-tolerant critical (surgical instruments) and semicritical patient care items Heat-sensitive critical and semicritical patient care items Heat-sensitive critical and semicritical patient care items that can be immersed
High-level disinfection (HLD)	Destroys all micro-organisms except high numbers of bacterial spores	Heat automated Liquid immersion	Pasteurization (65°C-77°C, 30 min) Chemical sterilants/HLDs†: >2% glut (20-45 min); 0.55% OPA (12 min); 1.12% glut with 1.93% phenol (20 min); 7.35% HP with 0.23% PA (15 min); 7.5% HP (30 min); 1.0% HP with 0.08% PA (25 min); 400-450 ppm chlorine (10 min); 2.0% HP (8 min); 3.4% glut with 26% isopropanol (10 min)	Heat-sensitive semicritical items (eg, respiratory therapy equipment) Heat-sensitive semicritical items (eg, GI endoscopes, bronchoscopes, endocavitary probes)
Intermediate-level disinfection	Destroys vegetative bacteria, mycobacteria, most viruses, most fungi but not bacterial spores	Liquid contact	EPA-registered hospital disinfectant with label claim regarding tuberculocidal activity (eg, chlorine-based products, phenolics, improved hydrogen peroxide exposure times at least 1 min)	Noncritical patient care item (blood pressure cuff) or surface with visible blood
Low-level disinfection	Destroys vegetative bacteria, some fungi and viruses but not mycobacteria or spores	Liquid contact	EPA-registered hospital disinfectant with no tuberculocidal claim (eg, chlorine-based products, phenolics, improved hydrogen peroxide, quaternary ammonium compounds-exposure times at least 1 min) or 70%-90% alcohol	Noncritical patient care item (blood pressure cuff) or surface (bedside table) with no visible blood

EPA, Environmental Protection Agency; *FDA*, Food and Drug Administration; *GI*, gastrointestinal; *glut*, glutaraldehyde; *HP*, hydrogen peroxide; *OPA*, ortho-phthalaldehyde; *PA*, peracetic acid; *ppm*, parts per million.

*Modified from Rutala and Weber,[4] Rutala and Weber,[7] and Kohn et al.[15]

†Consult the FDA cleared package insert for information about the cleared contact time and temperature, and see reference Rutala and Weber[1] for discussion of why one product is used at a reduced exposure time (2% glutaraldehyde at 20 min, 20°C). Increasing the temperature using an automated endoscope reprocess (AER) will reduce the contact time (eg, OPA 12 min at 20°C but 5 min at 25°C in AER). Exposure temperatures for some high-level disinfectants above varies from 20°C to 25°C; check FDA-cleared temperature conditions.[10] Tubing must be completely filled for high-level disinfection and liquid chemical sterilization. Material compatibility should be investigated when appropriate (eg, HP and HP with PA will cause functional damage to endoscopes).

Table 3: Advantages and disadvantages of chemical agents used as chemical sterilants* or as high-level disinfectants

Sterilization method	Advantages	Disadvantages
Peracetic acid/hydrogen peroxide	• No activation required • Odor or irritation not significant	• Material compatibility concerns (lead, brass, copper, zinc) both cosmetic and functional • Limited clinical experience • Potential for eye and skin damage
Glutaraldehyde	• Numerous use studies published • Relatively inexpensive • Excellent material compatibility	• Respiratory irritation from glutaraldehyde vapor • Pungent and irritating odor • Relatively slow mycobactericidal activity (unless other disinfectants added such as phenolic, alcohol) • Coagulates blood and fixes tissue to surfaces • Allergic contact dermatitis
Hydrogen peroxide	• No activation required • May enhance removal of organic matter and organisms • No disposal issues • No odor or irritation issues • Does not coagulate blood or fix tissues to surfaces • Inactivates *Cryptosporidium* • Use studies published	• Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional • Serious eye damage with contact
Ortho-phthalaldehyde	• Fast acting high-level disinfectant • No activation required • Odor not significant • Excellent materials compatibility claimed • Does not coagulate blood or fix tissues to surfaces claimed	• Stains protein gray (eg, skin, mucous membranes, clothing, and environmental surfaces) • Limited clinical experience • More expensive than glutaraldehyde • Eye irritation with contact • Slow sporicidal activity • Anaphylactic reactions to OPA in bladder cancer patients with repeated exposure to OPA through cytsoscopy
Peracetic acid	• Rapid sterilization cycle time (30–45 min) • Low temperature (50°C-55°C) liquid immersion sterilization • Environmental friendly by-products (acetic acid, O_2, H_20) • Fully automated • Single-use system eliminates need for concentration testing • Standardized cycle • May enhance removal of organic material and endotoxin • No adverse health effects to operators under normal operating conditions • Compatible with many materials and instruments • Does not coagulate blood or fix tissues to surfaces • Sterilant flows through scope facilitating salt, protein, and microbe removal • Rapidly sporicidal • Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)	• Potential material incompatibility (eg, aluminum anodized coating becomes dull) • Used for immersible instruments only • One scope or a small number of instruments can be processed in a cycle • More expensive (endoscope repairs, operating costs, purchase costs) than high-level disinfection • Serious eye and skin damage (concentrated solution) with contact • Point-of-use system, no sterile storage • An AER using 0.2% peracetic acid not FDA-cleared as sterilization process but HLD
Improved hydrogen peroxide (2.0%); high-level disinfectant	• No activation required • No odor • Nonstaining • No special venting requirements • Manual or automated applications • 12-month shelf life, 14-day reuse • 8 min at 20°C high-level disinfectant claim	• Material compatibility concerns because of limited clinical experience • Antimicrobial claims not independently verified • Organic material resistance concerns because of limited data

AER, Automated endoscope reprocessor; *FDA*, Food and Drug Administration; *HLD*, high-level disinfectants; *OPA*, ortho-phthalaldehyde.
NOTE. Modified from Rutala and Weber,[1] Rutala and Weber,[3] Rutala and Weber,[4] Rutala and Weber,[16] and Rutala and Weber.[17]
*All products effective in presence of organic soil, relatively easy to use, and have a broad spectrum of antimicrobial activity (bacteria, fungi, viruses, bacterial spores, and mycobacteria). The above characteristics are documented in the literature; contact the manufacturer of the instrument and sterilant for additional information. All products listed above are FDA-cleared as chemical sterilants except OPA, which is an FDA-cleared, high-level disinfectant.

Table 4: Advantages and disadvantages of commonly used sterilzation technologies

Sterilization method	Advantages	Disadvantages
Steam	• Nontoxic to patient, staff, environment • Cycle easy to control and monitor • Rapidly microbicidal • Least affected by organic/inorganic soils among sterilization processes listed • Rapid cycle time • Penetrates medical packing, device lumens	• Deleterious for heat-sensitive instruments • Microsurgical instruments damaged by repeated exposure • May leave instruments wet, causing them to rust • Potential for burns
Hydrogen peroxide gas plasma	• Safe for the environment • Leaves no toxic residuals • Cycle time is ≥28 minutes and no aeration necessary • Used for heat- and moisture-sensitive items since process temperature <50°C • Simple to operate, install (208 V outlet), and monitor • Compatible with most medical devices • Only requires electrical outlet	• Cellulose (paper), linens, and liquids cannot be processed • Endoscope or medical device restrictions based on lumen internal diameter and length (see manufacturer's recommendations) • Requires synthetic packaging (polypropylene wraps, polyolefin pouches) and special container tray • Hydrogen peroxide may be toxic at levels greater than 1 ppm TWA
100% Ethylene oxide	• Penetrates packaging materials, device lumens • Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure • Simple to operate and monitor • Compatible with most medical materials	• Requires aeration time to remove ETO residue • ETO is toxic, carcinogenic, and flammable • ETO emission regulated by states but catalytic cell removes 99.9% of ETO and converts it to CO_2 and H_2O • ETO cartridges should be stored in flammable liquid storage cabinet • Lengthy cycle/aeration time
ETO mixtures 8.6% ETO/91.4% HCFC 10% ETO/90% HCFC 8.5% ETO/91.5% CO_2	• Penetrates medical packaging and many plastics • Compatible with most medical materials • Cycle easy to control and monitor	• Some states (eg, CA, NY, MI) require ETO emission reduction of 90%-99.9% • CFC (inert gas that eliminates explosion hazard) banned in 1995 • Potential hazards to staff and patients • Lengthy cycle/aeration time • ETO is toxic, carcinogenic, and flammable
Vaporized hydrogen peroxide	• Safe for the environment and health care worker • It leaves no toxic residue; no aeration necessary • Fast cycle time, 55 min • Used for heat and moisture sensitive items (metal and nonmetal devices)	• Medical devices restrictions based on lumen internal diameter and length; see manufacturer's recommendations, eg, stainless steel lumen 1-mm diameter, 125-mm length • Not used for liquid, linens, powders, or any cellulose materials • Requires synthetic packaging (polypropylene) • Limited materials compatibility data • Limited clinical use and comparative microbicidal efficacy data
Ozone	• Used for moisture and heat-sensitive items • Ozone generated from oxygen and water (nontoxic) • No aeration needed because of no toxic by-products • FDA cleared for metal and plastic instruments including some instruments with lumens	• Limited clinical use (no published data on material compatibility/penetrability/organic material resistance) and limited microbicidal efficacy data

CFC, Chlorofluorocarbon; *ETO*, ethylene oxide; *FDA*, Food and Drug Administration; *HCFC*, hydrochlorofluorocarbon; *TWA*, time-weighted average.
NOTE. Modified from Rutala and Weber,[3] Rutala and Weber,[4] Rutala and Weber,[17] and Rutala and Weber.[18]

Table 5: Advantages and disadvantages of disinfectants used as low-level disinfectants

Disinfectant active	Advantages	Disadvantages
Alcohol	Bactericidal, tuberculocidal, fungicidal, virucidal Fast acting Noncorrosive Nonstaining Used to disinfect small surfaces, such as rubber stoppers on medication vials No toxic residue	Not sporicidal Affected by organic matter Slow acting against nonenveloped viruses (eg, norovirus) No detergent or cleaning properties Not EPA registered Damages some instruments (eg, harden rubber, deteriorate glue) Flammable (large amounts require special storage) Evaporates rapidly, making contact time compliance difficult Not recommended for use on large surfaces Outbreaks ascribed to contaminated alcohol[41]
Sodium hypochlorite	Bactericidal, tuberculocidal, fungicidal, virucidal Sporicidal Fast acting Inexpensive (in dilutable form) Not flammable Unaffected by water hardness Reduces biofilms on surfaces Relatively stable (eg, 50% reduction in chlorine concentration in 30 days)[42] Used as the disinfectant in water treatment EPA registered	Reaction hazard with acids and ammonias Leaves salt residue Corrosive to metals (some ready-to-use products may be formulated with corrosion inhibitors) Unstable active (some ready-to-use products may be formulated with stabilizers to achieve longer shelf life) Affected by organic matter Discolors/stains fabrics Potential hazard is production of trihalomethane Unpleasant odor (some ready-to-use products may be formulated with odor inhibitors); irritating at high concentrations
Improved hydrogen peroxide	Bactericidal, tuberculocidal, fungicidal, virucidal Fast efficacy Easy compliance with wet-contact times Safe for workers (lowest EPA toxicity category, IV) Benign for the environment Surface compatible Nonstaining EPA registered Not flammable	More expensive than most other disinfecting actives Not sporicidal at low concentrations

Table 5 continued: Advantages and disadvantages of disinfectants used as low-level disinfectants

Disinfectant active	Advantages	Disadvantages
Iodophors	Bactericidal, mycobactericidal, virucidal Not flammable Used for disinfecting blood culture bottles	Not sporicidal Shown to degrade silicone catheters Requires prolonged contact to kill fungi Stains surfaces Used mainly as an antiseptic rather than disinfectant
Phenolics	Bactericidal, tuberculocidal, fungicidal, virucidal Inexpensive (in dilutable form) Nonstaining Not flammable EPA registered	Not sporicidal Absorbed by porous materials and irritate tissue Depigmentation of skin caused by certain phenolics Hyperbilirubinemia in infants when phenolic not prepared as recommended
Quaternary ammonium compounds (eg, didecyl dimethyl ammonium bromide, dioctyl dimethyl ammonium bromide)	Bactericidal, fungicidal, virucidal against enveloped viruses (eg, HIV) Good cleaning agents EPA registered Surface compatible Persistent antimicrobial activity when undisturbed Inexpensive (in dilutable form)	Not sporicidal In general, not tuberculocidal and virucidal against nonenveloped viruses High water hardness and cotton/gauze can make less microbicidal A few reports documented asthma as result of exposure to benzalkonium chloride Affected by organic matter Multiple outbreaks ascribed to contaminated benzalkonium chloride[41]

NOTE. Modified from Rutala and Weber.[43] EPA, Environmental Protection Agency; HIV, human immunodeficiency virus.