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## Cleaning, Disinfection, and Sterilization of Patient-Care Items

### I. Description

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

### 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 of 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/aseptic 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. Pre-Cleaning/Pre-Treatment

**NOTE:** this section does not apply to flexible Endoscopes: See [Infection Prevention Endoscope policy](#) for Endoscope Point of Use Cleaning.

1. Care of Instruments (other than flexible endoscopes) at Point of Use:
  - a. At point of use, used instruments should be wiped per manufacturer's instructions, which may include the use of a gauze moistened with water for Sani-Cloth and lumens should be flushed as applicable.
  - b. Transplant soiled reusable instruments in a leak resistant container marked biohazard to the soiled utility room/instrument processing room.
    - i. A specimen bag marked biohazard or red trash bag is appropriate if no sharps are present.
    - ii. Always carry used sharps in a puncture proof and leak resistant container marked biohazard.
  - c. Used instruments should be kept moist until they are transported for cleaning and sterilization in their appropriate reprocessing area (i.e., CPD).
    - i. Moisture should be maintained by one of two methods and may be done at the bedside or in a soiled utility room:
      - Applying a product (i.e., Prepszyme) designed for pretreatment per manufacturer's recommendations.
      - Placing a cloth towel or gauze moistened with water (not saline) over the instruments.
    - ii. Deliver instruments to CPD by the end of business day, ideally not to exceed 24 hours.
2. 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 that 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 that 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 that 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 [Infection Prevention Endoscope 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 Infection Prevention (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 Infection Prevention and Trophon.

## E. Properties of Common Germicides

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

## F. Chemical Agents used as a Sterilant

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 specific HLD logs available on the Infection Prevention website

must be used. All HLD logs are in appendices to this policy. For automated HLD processes in an automated endoscope reprocessor (AER), printouts must be kept for 5 years. These printouts serve as logs for AERs.

11. All printouts must be signed by the person removing the scope from the AER. This signature indicates personnel has checked the printout 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 printouts document temperatures with each cycle; however, in the event temperatures are not measured and recorded on printouts, 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°C, 8 hours at 60°C) before using these items in patient care.
6. Dry-heat (e.g., 340°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 55-60°C, 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. Lot numbers for the biological indicator test and control need to each be recorded separately on the appropriate log.
6. For designated clinical areas, biological indicators should be transported to Infection Prevention 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 Infection Prevention (984-974-7500) 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 Infection Prevention 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.
  - a. In a documented emergency, (Note: there is not a replacement readily available) implantable devices may be released from quarantine in sterile processing without the biological monitor result. In the event that an implant is released without the biological monitor result, the Emergency Release of Sterilizer Load form (see Attachment 15) must be completed and returned to the CPD manager. The CPD manager will keep these records for 5 years.

## **K. Load Configuration**

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**

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**

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**

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 high-level disinfection (HLD) responsibilities must attend the UNCH High Level Disinfection (HLD) workshop provided by Infection Prevention.
      - Sign up via LMS: UNCHIPHLD.
    - ii. After attending the HLD workshop, staff with HLD responsibilities must attend in person the HLD refresher at least every 365 days.
      - Sign up via LMS: UNCHHLDREFRESH.
    - iii. Staff in outpatient clinics with counter-top sterilizer responsibilities must attend the UNCH Sterilization Workshop.
      - Sign up via LMS: UNCHIPSTERILZER.
    - iv. Provide hands-on training based on the institutional policy for reprocessing critical and semicritical devices.
    - v. 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
- vi. Conduct competency testing at commencement of employment and regularly thereafter. HLD competency is annual.
  - vii. 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. Infection Prevention 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

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 [Infection Prevention's Reuse of Single Use Devices Policy](#).

## R. Creutzfeldt-Jakob Disease

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 [Infection Prevention's Creutzfeldt-Jakob Disease \(CJD\) Policy](#).

**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

Implementation of this policy is the responsibility of Infection Prevention, 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.

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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. Related Policies

[Infection Prevention: Endoscope policy](#)

[Infection Prevention: Creutzfeldt-Jakob Disease \(CJD\) policy](#)

[Infection Prevention: Reuse of Single Use Devices policy](#)

## Attachments:

01: Cidex® Activated dialdehyde (glutaraldehyde) High-Level Disinfectant and Comply® Sterilog® Test Strips  
02: Rapicide® Glutaraldehyde High-Level Disinfectant and Rapicide Glutaraldehyde Test Strips

- 03: Revital-Ox Resert® High-level Disinfectant and Test Strips
- 04: Sterilization Log for Table Top Gravity Displacement Sterilizers
- 05: High-Level Disinfection Log for Trophon® EPR
- 06: Trophon® Competency Sheet
- 07: Cleaning Spills for Trophon
- 08: Sterilization Competency for UNCH Table Top Sterilizers
- 09: UNCHC High Level Disinfection General Competency
- 10: Table 1: Some Common Disinfectants with their use-Dilutions, Properties, and Cost<sup>1,3</sup>
- 11: Table 2: Methods for Disinfection and Sterilization of Patient Care Items and Environmental Surfaces
- 12: Table 3: Advantages and Disadvantages of Chemical Agents used as Chemical Sterilants\* or as High-Level Disinfectants
- 13: Table 4: Advantages and Disadvantages of Commonly used Sterilization Technologies
- 14: Table 5: Advantages and Disadvantages of Disinfectants used as Low-Level Disinfectants
- 15: Emergency Release of Sterilizer Load

## Approval Signatures

Step Description	Approver	Date
Policy Stat Administrator	Patricia Ness: Clin Nurse Education Spec	12/2019
	Thomas Ivester: CMO/VP Medical Affairs	12/2019
	Emily Vavalle: Director, Epidemiology	10/2019
	Sherie Goldbach: Infection Prevention Registrar	10/2019

## Applicability

UNC Medical Center