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Sterilization of Reusable Patient-Care Items

I. Description

This policy address standards and accepted practices for semi-critical and critical items that require or are amenable to sterilization.

Standard sterilization procedures for reusable patient-care equipment are adequate to sterilize or disinfect items contaminate with blood or other body fluids from persons infected with bloodborne pathogens, emerging pathogens, and bio-terrorism agents, with the exception of prions.

Special precautions are necessary when disinfecting instruments used on patient known or suspected to have disease caused by a prion, i.e., Creutzfeldt-Jakob Disease (CJD). Central Processing Department (CPD) staff shall be familiar with and strictly follow the guidelines provided in the Infection Prevention policy: [Creutzfeldt-Jakob Disease \(CJD\)](#).

High-Level Disinfection (HLD) process are addressed in the Infection Prevention policy: [High-Level Disinfection - Manual Reprocessing of Reusable Semi-Critical Devices](#) and in the Infection Prevention policy: [Endoscope](#).

II. Rationale

Sterilization is the required reprocessing procedure to render all critical items and many semi-critical items safe for patients and to reduce the risk of cross-transmission. This policy guides the practices of UNC Medical Center (UNCMC) healthcare personnel (HCP) with sterilization responsibilities and conveys strategies to reduce or eliminate the risk of transmission of infectious disease associated with reprocessing of critical and semi-critical items.

III. Policy

A. Definitions

<u>Term</u>	<u>Definition</u>
Asepsis	The absence of disease-producing microorganisms.
Aseptic Technique	Practices designed to render and maintain objects and areas maximally free from microorganisms.
Cleaning	<i>Cleaning</i> is the removal of visible soil (e.g., organic and inorganic material) from

	objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.
Competent	Qualified or having adequate ability.
Competency	Documentation of qualified or adequate ability to perform a task.
Critical Device	Per Spaulding classification scheme, devices that enter normally sterile tissue.
Decontamination	<i>Decontamination</i> removes pathogenic microorganisms from objects so they are safe to handle, use, or discard. CDC 2008.
Disinfectant	An agent that destroys microorganisms on inanimate objects, not living tissue.
Disinfection	A process that eliminates many or all pathogens microorganisms, except bacterial spores, on inanimate objects. CDC 2008.
Manufacturer's Instructions for Use (IFU)	Written recommendations and/or guidelines provided by the manufacturer of a device that provides instructions for operation and safe and effective reprocessing.
Medical Device	Instrument, apparatus, material, or other article intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment, or alleviation of disease, injury, anatomical modification, etc.
Procedure	A document or set of activities that describes tasks HCP must perform to achieve requirements set forth in a policy or desired outcome.
Semi-Critical Device	Per Spaulding classification scheme, devices that contact mucous membranes or non-intact skin.
Sterile	The complete absence of all forms of microbial life.
Sterilization	The complete elimination of all forms of microbial life.

B. Spaulding Classification Scheme

The Spaulding classification scheme is a rational approach to disinfection and sterilization of reusable patient care items, equipment, and devices. Based on the degree of risk of infection involved in the use of items, the scheme divides reusable patient care items into three distinct categories: critical, semi-critical, and non-critical.

Critical Items: require sterilization	Enter/contact normally sterile tissue or the vascular system. Examples include but not limited to surgical instruments, certain catheters, implants, laparoscopes, arthroscopes.
Semi-Critical Items: require at least high-level disinfection	Contact intact mucous membranes or non-intact skin. Examples include but not limited to some endoscopes, endocavitary probes, diaphragm fitting rings, laryngeal blades.
Non-Critical Items: require low-level disinfection	Contact intact skin but not mucous membranes. Examples include but not limited to bed pans, blood pressure cuffs, stethoscopes.

C. Departmental Responsibilities

1. Reprocessing Departments

- a. Actual or near-miss safety events related to device reprocessing as well as suspected or actual reprocessing failures are reported immediately via a SAFE report, to Infection Prevention (984-974-7500) and other appropriate leadership.
- b. Infection Prevention shall be involved in the development or revision of department-specific reprocessing procedures.
- c. Disposable, single use patient care items are never reprocessed after use.
- d. When discrepancies between the medical device manufacturer's reprocessing instructions for use (IFUs) and the reprocessing equipment manufacturer's instructions are identified, notify the reprocessing department leadership and the Infection Prevention department. A review of the IFUs and evidence-based practices validated and supported by professional associations and/or governing groups will be used to determine appropriate processing methods.

2. Reprocessing Departments Directors, Managers, and/or Designees

- a. Shall compile a list of all healthcare personnel (HCP) that perform instrument reprocessing and keep the list updated.
- b. Shall compile a list of all instruments/devices that are reprocessed in their units/clinics and keep that list updated.
- c. Shall ensure that reprocessing activities, including cleaning, decontamination, inspection and sterilization are performed by competent, qualified personnel.
- d. Shall be able to readily access manufacturer's instructions for use (IFUs) and/or user's manuals for devices, equipment, and supplies.
- e. Shall oversee compliance with policy, procedures, and IFUs related to cleaning, decontamination, inspection, sterilization, and documentation activities.
- f. Shall ensure that all reprocessing equipment receives routine care, cleaning, and quality assurance testing in accordance with manufacturer's IFUs.
- g. Shall ensure that education, training, and competency verification is provided to personnel upon hire and at least every 365 days. Competencies may require more frequent documentation than yearly, such as when new processing equipment or products are introduced. For additional details see the "Sterilization Competency and Training" section D below.
- h. Shall ensure that breaches in reprocessing activities are reported via a SAFE report, to Infection Prevention (984-974-7500), and other appropriate leadership and investigated.
- i. Shall ensure reprocessing departments are clean and accommodate reprocessing activities in accordance with the Occupational Safety and Health Administration (OSHA).
- j. Shall ensure reprocessing department procedures are reviewed on a regular basis and as needed. Collaborate with appropriate stakeholders, including Infection Prevention, prior to implementing new or revised procedures.
- k. Trial and/or purchase of reusable items or equipment used for sterilization are done in collaboration with Infection Prevention.

- l. Documentation records (paper logs, electronic logs, etc.) are retained for 5 years.
- m. Review the written reprocessing instructions regularly to ensure department is consistent with policy, scientific literature, and manufacturers' IFUs.
- n. Documentation of orientation and annual competency training will be maintained by the department.

3. Environmental Services Department

- a. Cleaning and disinfection of reprocessing environments is performed daily with an EPA-registered disinfectant cleaning solutions.
- b. Decontamination areas are cleaned and disinfected each shift.

4. UNC Medical Center (UNCMC) Infection Prevention Department

- a. Investigates reports of inadequate instrument reprocessing and addresses findings with appropriate stakeholders promptly.
- b. Provides consultation to clinical units and reprocessing departments with decisions regarding cleaning, decontamination, sterilization, documentation, and relevant tracking of reusable critical items.
- c. Conducts routine rounds using a designated instrument reprocessing survey tool to evaluate reprocessing environments and activities. Reports findings to appropriate leadership and collaboratively addresses areas of concern to ensure safe and effective reprocessing principles.

D. Sterilization Competency and Training

All health care personnel (HCP) who perform sterilization activities are required to attend the initial sterilization class in person as soon as possible after assignment of sterilization responsibilities. Thereafter, and at least every 365 days, HCP is required to attend the sterilization refresher (in person and WebEx) class. Registration for the workshop and the refresher is via LMS. Contact Infection Prevention or LMS for class details.

Initially, there are four elements that must be completed in order to meet UNCMC's requirements for sterilization competency:

1. Training
 - a. Sterilization class and on-the-job practice with a competent person
2. Demonstration
 - a. Able to perform sterilization with no assistance
3. Observation
 - a. Competent person observes HCP's entire process
4. Documentation
 - a. Competent person completes HCP's competency form

Yearly (at least every 365 days), three elements must be completed

1. Demonstration
2. Observation
3. Documentation

E. Semi-critical and Critical Items: Transport, Decontamination, and Personal Protective Equipment (PPE) for Sterilization Processes

1. Transport of used, contaminated patient care instruments:
 - a. At point of use, instruments should be wiped to remove gross soil and/or blood. Gauze moistened with water or an approved disinfectant wipe may be used. Manufacturer's IFUs for precleaning/pretreating must be incorporated into the point of use cleaning.
 - b. Lumens should be flushed/suctioned according to manufacturer's IFUs.
 - c. Transport used instruments in a leak-resistant container marked "biohazard."
 - d. Type of transport container depends upon the type of instrument transported:
 - i. Bins should have lids.
 - ii. Carts should be enclosed or covered.
 - iii. Impermeable bags marked "biohazard". A specimen bag marked biohazard or plastic bag with a biohazard label is appropriate if no sharps are present.
 - e. Used instruments must be kept moist until they are transported to the appropriate decontamination area (i.e., central processing department, clinic instrument reprocessing room). Moisture may be maintained by applying an approved moistening product or placing a water-moistened towel or gauze over the instrument(s). Do not use saline for this purpose.
2. Decontamination and PPE
 - a. Wear appropriate PPE in the decontamination area. Remove PPE and perform hand hygiene before leaving the decontamination area.
 - b. Required PPE includes but may not be limited to:
 - i. Fluid-resistant gown tied in the back
 - ii. 12" (or longer) extended cuff nitrile gloves
 - iii. UNCMC Environmental Health and Safety (EHS) department approved face shield
 - iv. EHS approved safety glasses or goggles (ANSI-approved) if indicated
 - c. Manufacturer's IFUs for decontamination must be followed for all instruments reprocessed.
 - d. Visually inspect all parts of all instruments for damage prior to or immediately following decontamination.
 - i. Remove damaged instruments from service, tag "damaged, do not use", and place in a container marked biohazard.

- ii. Notify appropriate leadership of damage and removal from service.
 - e. Measure, mix, label, dispense, and discard detergent solutions appropriately and according to manufacturer's IFUs
 - f. Observe soak times as prescribed by detergent labels.
 - g. Do not reuse detergents.
 - h. Single use brushes are preferred and must be discarded after one use.
 - i. Reusable brushes must be reprocessed after each use. Discard when worn.
 - j. All brushing is performed under water to decrease the risk of exposure to HCP.
 - k. Disassemble all instruments that lend themselves to disassembly before cleaning.
 - l. Rinse decontamination instruments thoroughly to remove organic material, paying special attention to lumens and/or hard-to-reach areas.
 - m. Dry thoroughly according to the terminal process's (i.e., sterilization) instructions.
 - n. When appropriate, use a lighted magnifying glass to inspect instruments after decontamination to ensure that all organic soil and/or material has been removed. Repeat the decontamination process if any soil or debris remains.
 - o. Clean and disinfect work stations and cleaning equipment daily and as needed with an EPA-registered disinfectant following disinfectant manufacturer's IFUs.
3. Washer-disinfectors: Used mainly in central processing departments in place of or in addition to manual decontamination, must be used according to the manufacturer's IFUs and user's manuals.
4. Ultrasonic Cleaning:
- a. Performed when instrument/device manufacturers require as part of a decontamination process.
 - b. Detergents specified by the ultrasonic manufacturer shall be used in ultrasonic cleaners.

F. Methods of Sterilization

Sterilization methods must be selected and utilized based upon the instrument and sterilizers' IFUs and user manuals. Follow the sterilization times, temperatures, and other operating parameters (e.g., gas concentration, humidity) that are prescribed by the manufacturers of the instruments, the sterilizer, and the container or wrap used.

G. Packaging

All wraps, cases, trays, and other materials intended to maintain sterilization shall be used according to the manufacturer's IFUs.

H. Quality Control and Monitoring of Sterilizers

1. Use mechanical, chemical, and biological monitors to ensure the effectiveness of sterilization process according to accepted guidelines.

2. Monitor each load with mechanical (e.g., time, temperature, pressure) and chemical (internal and external) indicators.
3. Keep all monitoring documentation for 5 years.
4. Do not use reprocessed items if the mechanical (e.g., time, temperature, pressure) or chemical (internal or external) or biological indicators (BIs) suggest inadequate processing.
5. Use BIs to monitor the effectiveness of sterilizers at least weekly with an FDA-cleared BI intended specifically for the type and cycle parameters of the sterilizer.
6. Run Bowie Dick tests daily as directed by sterilizer manufacturer and test manufacturer.
7. If a sterilizer is used frequently (e.g., several loads per day), daily use of a BI.
8. Each load with implants shall be monitored with a BI. If feasible, implantable items should not be used until the results of the BIs (test and control) are final and as expected, i.e., test BI is negative and control BI is positive.
 - a. In a documented emergency, (e.g., there is not a replacement instrument/device readily available) implantable devices may be released from quarantine in sterile processing without the BI result. In the event that an implant is released without the BI result, the Emergency Release of Sterilizer Load form (see Attachment 1) must be completed and returned to the CPD manager. The CPD manager will keep these records for 5 years.
9. Lot numbers for test BIs and control BIs must be documented separately on manual and/or electronic logs.
10. For designated clinical areas using counter-top sterilizers, BIs shall be processed and delivered to Infection Prevention immediately after processing on Mondays. Holidays will be addressed as needed.
11. When a positive BI is detected, the clinic/department will discontinue the use of the malfunctioning sterilizer, affix an "out of service" sign to the sterilizer and notify Infection Prevention (984-974-7500) immediately. The following steps will be followed:
 - a. Recall all items since the last negative test BI if possible.
 - b. Contact Biomedical Engineering to assess and repair the sterilizer.
 - c. After repairs are made, run 3 consecutive test runs with biological and chemical indicators for each cycle that is used and deliver to Infection Prevention where applicable.
 - d. If the test BIs are negative and the controls are positive 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.
12. Do not handle items that are warm/hot: cool steam or heat-sterilized items to room temperature before they are handled or used in the operative setting.

I. Load Configuration

1. Load all sterilizers according to sterilizer user manual instructions and IFUs.

J. Sterilization Process Failure

If physical monitoring, test BIs, and/or chemical indicators during the cycle indicates any malfunction of suspicious operation, the following steps should be taken:

1. The department head or designee should be notified.
2. If overloading is suspected, the sterilizer should be reloaded and the cycle rerun.
3. After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated in accordance with the sterilizer manufacturer's written IFU.
4. The load should be removed from the sterilizer and quarantined so that it is not inadvertently released for use.
5. Medical engineering or maintenance contract service should then be notified, the root cause should be identified, and the sterilization process failure should be corrected.
6. The same investigative procedure should be followed at the completion of the cycle if the physical monitors, external chemical indicators (CIs), or the monitor in a Process Challenge Device (PCD) (BI challenge test pack or CI challenge test pack) indicates a questionable cycle.
7. Methods of labeling loads, pouches, trays with date, sterilizer number, and load number shall facilitate the process to recall items.

K. Visible Bioburden After Sterilization

Visible bioburden after sterilization shall be reported to Infection Prevention immediately. Infection Prevention, the sterilizing unit, with other appropriate personnel shall cooperate in the investigation and correction if necessary.

L. Immediate Use Steam Sterilization (IUSS)

1. Limit IUSS to emergency situations only.
2. IUSS must include the following parameters:
 - a. Items must be decontaminated in CPD via normal means (washer/disinfectant or other appropriate method dictated by item manufacturer) and placed into a sterilizing container and sterilized according to the item's IFUs.
 - b. Items must be transported from the sterilizer to the patient maintaining sterility.
 - c. Sterilizer function must be monitored using sterility monitors, i.e., BIs and chemical indicators/integrators when appropriate.
3. Do not use IUSS as a substitution for insufficient inventory and routine turnover of surgical cases.
4. Do not routinely sterilize implantable items via IUSS. In an emergency when IUSS must be utilized for an implant, ensure sterility monitors are utilized and demonstrate successful sterilization.

5. Do not store or redistribute unused items sterilized via IUSS.
6. Audit IUSS documentation and activities on a regular basis.

M. Sterilizer Preventative Maintenance

Sterilizers will be maintained and periodic maintenance performed according to sterilizer manufacturer IFUs and user's manuals. Sterilizer maintenance will be documented and documentation kept for 5 years.

N. Storage of Sterile Items in Central Processing Departments and OR Areas

1. Store sterilized items in a temperature and humidity controlled area with parameters that are not excessive (temperature >90°F, relative humidity >80% for longer than 48 hours).
2. Sterile items 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. Bottom shelving must have a solid bottom surface.
3. Store sterile items so that the packaging is not compromised (e.g., punctured, bent, soiled).
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. CPD departments follow event-related expiration dates and therefore packaged items may be used indefinitely unless the packaging is compromised (i.e., torn, wet, punctured, dirty or the wrap/pouch and/or items' manufacturer IFUs state differently).
6. Packaged items with compromised conditions must be reprocessed before use, including decontamination processes.
7. Storage areas must be clean, uncluttered, and well-organized.

O. Reuse of Single-Use Medical Devices

Reuse of devices/items marked single-use only or single patient use may not be reprocessed for use on another patient. For additional information, refer to the Infection Prevention policy: [Reuse of Single Use Devices \(SUDs\)](#).

IV. Implementation

Implementation of this policy is the responsibility of Infection Prevention, Central Processing Department, Inpatient and Outpatient Services, and the Medical Staff.

V. References

Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST79: 2017.

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VI. Related Policies

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

[Infection Prevention Policy: Endoscope](#)

[Infection Prevention Policy: High Level Disinfection - Manual Reprocessing of Reusable Semi-Critical Devices](#)

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

Attachments

1: [Emergency Release of Sterilizer Load](#)

Approval Signatures

Step Description	Approver	Date
Policy Stat Administrator	Patricia Ness: Clin Nurse Education Spec	04/2020
	Thomas Ivester: CMO/VP Medical Affairs	04/2020
	Emily Vavalle: Director, Epidemiology	04/2020
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Applicability

UNC Medical Center