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Policy Area Infection Prevention
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Groups

Sterilization of Reusable Patient-Care Items

I. Description

This policy addresses 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 contaminated 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 a 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) processes 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. Policy

A. 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.

<u>Critical Items</u>	Reusable medical devices that enter sterile tissue or body cavities, or have contact with the vascular system, should be sterilized between patients.
<u>Semi-Critical Items</u>	Reusable medical devices that encounter mucous membranes or non-intact skin; items should be sterilized or high-level disinfected.
<u>Non-Critical Items</u>	Reusable medical devices that encounter intact skin; items should be low-level disinfected.

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

The Manufacturer Instructions for Use (MIFU) for each reusable instrument and device must be followed. Unless otherwise specified by MIFU, follow the guidance below on general reprocessing of instruments.

1. Point-of-use handling, pre-cleaning, and transport of used contaminated patient care instruments:
 - a. Immediately after use, wipe soiled instruments with damp gauze moistened with water (not saline, as it can cause pitting of instruments) or other approved wipe to remove gross soil and/or blood. Be careful with sharp instruments; wipe instrument on gauze or disposable towel.
 - b. Keep hinged instruments open throughout the process to ensure all surfaces are pre-cleaned.
 - c. Lumens should be flushed/suctioned according to MIFU.
 - d. Transport used instruments in a leak-resistant container, red in color or marked "biohazard."
 - e. Use a closed, rigid container or closeable, fluid-resistant bag to transport contaminated devices.
 - f. Used instruments must be kept moist, unless prohibited by the MIFU, 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, as this can degrade the surface of instruments (e.g., cause pitting).
2. Decontamination in Reprocessing or Soiled Utility Room
 - a. Wear appropriate PPE in the decontamination area (e.g., soiled utility room,

instrument reprocessing room). 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
 - ii. 12" (or longer) extended cuff nitrile gloves
 - iii. UNC Hospitals' Environmental Health and Safety (EHS) department approved face shield
 - iv. EHS-approved safety glasses or goggles (ANSI-approved) if indicated
- c. MIFU 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 MIFU.
- 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 should be cleaned after each use and disinfected or sterilized at least once a day.
 - j. All brushing is performed under water to decrease the risk of exposure to staff.
- k. Disassemble all instruments that lend themselves to disassembly before cleaning.
- l. Rinse decontaminated 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 workstations and cleaning equipment daily and as needed with an EPA-registered disinfectant following disinfectant MIFU.

3. Washer-disinfectors: Used mainly in central processing departments in place of or in addition

to manual decontamination, must be used and maintained according to the MIFU 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.

C. Methods of Sterilization

Sterilization methods must be selected and utilized based upon the instrument and sterilizers' MIFU 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.

D. Packaging

1. Visually inspect reusable medical devices prior to packaging to ensure cleanliness prior to sterilization.
2. All wraps, cases, trays, and other materials intended to maintain sterilization shall be used according to the MIFU.
3. Include physical and chemical indicators for all sterilization.

E. Quality Control and Monitoring of Sterilizers

1. Use mechanical, chemical, and biological monitors according to MIFU or per recommendations below if not specified by the manufacturer to ensure the effectiveness of sterilization process according to accepted guidelines.
2. Monitor each load with mechanical parameters (e.g., time, temperature, pressure) noted on printouts or electronic records at least daily.
3. Monitor each package with chemical indicators (internal for all package types; also add external chemical tape for packs when the internal indicator is not visible).
4. Keep all monitoring documentation for 5 years.
5. Do not use reprocessed items if the mechanical (e.g., time, temperature, pressure) or chemical (internal or external) or biological indicators (BI) suggest inadequate processing.
6. Packaging should be assessed for integrity prior to use, as damaged packaging may compromise instrument sterility. Do not use items if packaging is damaged (i.e., torn, stained).

7. Use BI 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.
 - a. Tabletop autoclaves will be monitored at least weekly with BI.
 - b. If a sterilizer is used frequently (e.g., several loads per day), daily use of a BI allows earlier discovery of equipment malfunctions or procedural errors, minimizing any patient surveillance and/or product recall needed in the event of a processing failure.
 - c. For designated clinical areas using counter-top sterilizers, BI shall be processed and delivered to Infection Prevention immediately after processing on the first day of each week.
 - d. Lot numbers for test BI and control BI must be documented separately on manual and/or electronic logs.
8. Run Bowie Dick tests daily as directed by sterilizer manufacturer and test manufacturer.
9. Each load with implants shall be monitored with a BI. If feasible, implantable items should not be used until the results of the BI (test and control) are final and as expected (i.e., test BI is negative and control BI is positive).
 - 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 - Emergency Release of Sterilizer Load](#)) must be completed and returned to the CPD manager. The CPD manager will keep these records for 5 years.
10. 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 BI is 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.
11. 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.

12. In the event it is necessary for clinics using table-top sterilizers to leave their offices or not use their sterilizer for more than 2 weeks, clinics should proceed with the Extended Shutdown and Restart Procedures as instructed by the manufacturer. Refer to the Infection Prevention Instrument Processing page for manufacturer shutdown and startup procedures or the MIFU.

F. Load Configuration

Load all sterilizers according to sterilizer user manual instructions and MIFU.

G. Sterilization Process Failure

If physical monitoring, test BI, and/or chemical indicators indicate any malfunction or 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 MIFU.
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. Methods of labeling loads, pouches, trays with date, sterilizer number, and load number shall facilitate the process to recall items.

H. Visible Bioburden after Sterilization

Visible bioburden after sterilization shall be reported immediately via a SAFE report, appropriate department leadership, and Infection Prevention. Infection Prevention, the clinic/department performing sterilization, and any other appropriate personnel shall cooperate in the investigation and correction if necessary.

I. Rapid Instrument Sterilization

1. As a measure to standardize patient safety during sterilization processes across UNC Hospitals locations, the sterilization 'Quick-cycle' will be utilized in lieu of immediate use sterilization.
2. The CPD/SPD departments at UNC Hospitals (main campus), Ambulatory Surgical Center (ASC), Hillsborough Hospital (HBH), and North Chapel Hill (NCH) campuses will utilize the

appropriate gravity sterilizer settings to process instruments using the 4-minute sterilization with 8-minute drying time 'Quick-cycle'.

3. This cycle of 4 minutes of sterilization with 8-minutes drying time will allow for the standard minimum sterilization and drying time requirements to be met for all instruments that need to be processed for an immediate return to the surgical field.
4. The process for instrument cleaning and disinfection utilizing the MIFU of all instrumentation remains the same.
 - a. Items must be decontaminated in CPD/SPD via normal means (washer/disinfector or other appropriate method indicated by item manufacturer) and placed into a sterilizing container and sterilized according to the item's MIFU.
 - 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).
5. Do not use 'Quick-cycle' as a substitution for insufficient inventory and routine turnover of surgical cases.
6. Implants and loaner trays may not be processed using the 4-minute sterilization with 8-minute drying time 'Quick-cycle'.
7. Do not store or redistribute unused items sterilized via 'Quick-cycle'.
8. Audit 'Quick-cycle' documentation and activities on a regular basis.

J. Sterilizer Preventative Maintenance

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

K. Storage of Sterile Items

1. Central Processing Departments and OR Areas:
 - a. 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).
 - b. Sterile items stored on open shelves in clean storage areas must be 8" from the floor, 2" from the outside wall, and 18" from a sprinkler head. Bottom shelving must have a solid bottom surface.
 - c. Store sterile items so that the packaging is not compromised (e.g., punctured, bent, or soiled).
 - d. 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.

- e. 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' MIFU state differently).
- f. Packaged items with compromised conditions must be reprocessed before use, including decontamination processes.
- g. Storage areas must be clean, uncluttered, and well-organized.

2. All areas storing sterile items:

- a. Store sterile items so that the packaging is not compromised (e.g., punctured, bent, or soiled).
- b. 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.
- c. 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' MIFU state differently).
- d. Packaged items with compromised conditions must be reprocessed before use, including decontamination processes.
- e. Storage areas must be clean, uncluttered, and well-organized.

L. 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 \(SUDs\)](#).

M. Responsibilities

1. Reprocessing Staff

- a. In the event of a reprocessing error or failure identified either prior to the release of the reprocessed item(s), after the reprocessed item(s) reaches the point of use, or item(s) are stored for later use, report the incident immediately via a SAFE report and to appropriate leadership. In the event a processing error or failure is identified after use of the item, report the incident immediately to Infection Prevention and other appropriate leadership, as well as via the SAFE system.
- b. Infection Prevention shall be involved in the development or revision of department-specific reprocessing procedures.
- c. Single-use patient care items are never reprocessed after use.

- d. When discrepancies are identified between the medical device MIFU and the reprocessing equipment manufacturer's instructions, or when an MIFU is unavailable (e.g., devices that are 3D-printed or no longer manufactured), the reprocessing department leadership and the Infection Prevention department must be notified immediately for remediation.

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

- a. Ensures reprocessing activities, including cleaning, decontamination, inspection, and sterilization, are performed by competent, qualified staff.
- b. Ensures access to MIFU and/or user's manuals for devices, equipment, and supplies.
- c. Oversees compliance with policy, procedures, and MIFU related to cleaning, decontamination, inspection, sterilization, and documentation activities.
- d. Ensures reprocessing department procedures are reviewed on a regular basis and, as needed, ensure department is consistent with policy, scientific literature, and MIFU. Collaborate with appropriate stakeholders, including Infection Prevention, prior to any changes and before implementing new procedures.
- e. Ensures all reprocessing equipment receives routine care, cleaning, and quality assurance testing in accordance with MIFU.
- f. Verifies education, training, and competency activities are completed upon hire and annually. Documentation of orientation and annual competency training will be maintained by the department.
- g. Ensures education and training are updated when new processing equipment or products are introduced. For additional details, see the "Sterilization Competency and Training" section N below.
- h. Ensures reprocessing errors or failures identified either prior to the release of the reprocessed item(s), after the reprocessed item(s) reaches the point of use, or item(s) are stored for later use are reported immediately via a SAFE report and to appropriate leadership. In the event a processing error or failure is identified after use of the item, ensure reporting of the incident immediately to Infection Prevention and other appropriate leadership, as well as via the SAFE system.
- i. Ensures staff working in reprocessing areas have appropriate personal protective equipment.
- j. Trials and/or purchases of reusable items or equipment used for sterilization are done in collaboration with Infection Prevention.
- k. Documentation records (paper logs, electronic logs, etc.) are retained for 5 years.
- l. Ensures cleaning and disinfection of reprocessing environments is performed daily

with an EPA-registered disinfectant cleaning solution.

3. UNC Hospitals 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.

N. Sterilization Competency and Training

Staff who perform sterilization activities must be educated, trained, and assessed for competency in sterilization.

NOTE: The initial sterilization class and sterilization refresher LMS module are not required for Central Processing Department (CPD) staff who receive training through CPD.

Initially and on an annual basis, four elements must be completed in order to meet UNC Hospitals' requirements for sterilization competency:

1. Training
 - a. Sterilization classes - Staff are required to attend the initial sterilization class as soon as possible after assignment of sterilization responsibilities. Thereafter and annually, staff are required to complete the sterilization refresher via LMS. Registration for the initial training workshop and the refresher is via LMS, and
 - b. On-the-job practice with a competent person.
2. Demonstration
 - Able to perform sterilization with no assistance
3. Observation
 - Competent person observes staff competency.
4. Documentation
 - Competent person completes staff competency form

O. Definitions - See [Instrument Reprocessing Website](#)

P. Implementation

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

III. References

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IV. 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](#)

V. Responsible for Content

Infection Prevention

Attachments

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

Approval Signatures

Step Description	Approver	Date
Policy Stat Administrator	Judith Strubin: Mgr Program-IP	02/2026
AVP Quality UNCMC	Erin Burgess: HCS Exec Dir Quality Improvement Complex AMC	02/2026
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Applicability

UNC Medical Center

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