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Applicability UNC Medical Center

Central Processing Department (CPD) and Other Surgical Services Support Areas Using Sterilizers or Storing CPD Sterilized Items

I. Description

Describes the process used by the Central Processing Department and Surgical Services for sterilization of medical instruments and supplies.

II. Rationale

Appropriate sterilization of instruments is essential for the safe delivery of surgical care. The Central Processing Department (CPD) provides a centralized service for instrument processing, decontamination, sterilization, and case cart preparation. This policy shall apply to CPD locations in the Ambulatory Surgical Center (ASC), the Medical Center campus, and Hillsborough Hospital. Steam and hydrogen peroxide plasma (e.g., Sterrad) are used. Sterilization will meet parameters outlined by manufacturers, evidence-based guidelines and/or national standards. The Central Processing Departments should have ready access to these recommending and guiding agency's documents. Storage of sterile supplies in Central Distribution is addressed in [Attachment 1 - Central Distribution Storage of Sterile Supplies](#).

III. Policy

A. Personnel

1. Staff responsible for cleaning, disinfecting and/or sterilizing will review and comply with the following Infection Prevention policies:

- a. [Endoscope](#)
 - b. [Exposure Control Plan for Bloodborne Pathogens](#)
 - c. [Hand Hygiene and Use of Antiseptics for Skin Preparation](#)
 - d. [High-level Disinfection \(HLD\) - Manual Reprocessing of Reusable Semi-Critical Medical Devices](#)
 - e. [Infection Prevention Guidelines for Attire in Semi-Restricted and Restricted Zones](#)
 - f. [Sterilization of Reusable Patient-Care Items](#)
 - g. [Tuberculosis Control Plan](#)
2. Access to the department is restricted to departmental personnel unless permission to enter the Central Processing department is granted by a supervisor. Decontamination area may only be accessed by approved badges. Visitors will be instructed regarding dress requirements to enter the area (e.g., disposable coveralls, disposable cap). The decontamination area door is kept locked at all times.
 3. All percutaneous, mucous membrane, and non-intact skin exposure to blood and other potentially infectious materials must be reported by calling the **Needlestick Hotline at 984-974-4480**. This service is available 24 hours a day.
 4. Standard Precautions will be followed when handling equipment contaminated with blood or other potentially infectious materials.
 5. Infection control and prevention education is provided annually, including the OSHA mandatory education for bloodborne pathogens and tuberculosis, through the Learning Made Simple (LMS).

B. Physical Layout

The physical plan of CPD is designed to avoid cross-contamination between soiled and clean supplies and is divided into 5 areas.

1. The decontamination area is for the receiving and cleaning of contaminated instruments and materials that will be subjected to a terminal sterilization process. Ideally, these items are subjected to a washer-disinfector but when that is not feasible, they may be cleaned by hand in a decontamination sink. Some items may be subjected to both cleaning processes.
2. A designated clean/hold area is for the placement of decontaminated instruments and materials.
3. The assembly area is for assembling and packaging decontaminated items bound for sterilization.

4. The sterilizer area contains steam, and/or Sterrad®.
5. The sterile storage area is for the storage of sterile items.

C. Decontamination of Reusable Items

1. Soiled instruments and small equipment that are appropriate for sterilization per the manufacturer's instructions for use (MIFU) are transported from various locations throughout the hospital to CPD in a covered container as follows:
 - a. The covered container is labeled "BIOHAZARD" and delivered to the decontamination area for reprocessing according to accepted national guidelines and MIFU.
 - b. Reusable sharps that are contaminated with blood or other potentially infectious materials must be handled with caution and transported in a puncture-resistant container labeled "BIOHAZARD".
 - c. Tongs or forceps should be used to remove the contaminated sharps from CPD biohazard container. The employee must not reach by hand into the container to remove contaminated sharps.
 - d. The biohazard containers are put through the washer-disinfector between each use.
2. Soiled instruments from the Operating Rooms (ORs) are sent to CPD via a designated elevator in a covered cart.
3. Reuse of single use medical/surgical devices is prohibited at UNC Hospitals, unless the items are reprocessed by approved third party reprocessors. (See Infection Prevention policy: [Reuse of Single Use Devices.](#))
4. Decontamination and sterilization of instruments used for patients known or suspected to have Creutzfeldt-Jakob Disease (CJD) require special procedures. Employees should be familiar with and strictly follow the guidelines provided in the Infection Prevention policy: [Creutzfeldt-Jakob Disease \(CJD\).](#)

NOTE: All chemicals (e.g., detergents, germicides) used in CPD should be examined before opening to ensure the seal has not been broken. If it is unclear if the seal is broken, and the product may have been altered, do not use the chemical and contact the CPD manager.

D. Endoscope Reprocessing

Staff responsible for cleaning and disinfection of endoscopic instruments will be familiar with and comply with the Infection Prevention policy: [Endoscope](#) and the section on endoscope reprocessing in the Infection Prevention policy: [Infection Prevention Guidelines for Perioperative](#)

E. Sterilization by a Third Party

Items sent for third party sterilization are to be kept moist for transport and should be packaged using standard precautions. Sterilized instruments received from a third party will be inspected visually upon arrival for package integrity and external sterility indicators by CPD staff.

F. Handling of Sterile Reusable Materials

1. Contaminated reusable items bound for sterilization are decontaminated with an approved detergent or other method according to the item manufacturer's instructions for use (MIFU).
2. Items are then placed in the appropriate terminal container (wrap, pouch, or tray, e.g., Aesculap® Genesis®) before sterilization. The product used for containment must be able to maintain sterility until the item is used.
3. Validation of Sterilizer Parameters
 - a. Each operator should understand the sterilization parameters for each sterilizer used.
 - b. These parameters will be scanned and uploaded to Censitrac.
 - c. All sterilizer receipts will be maintained in a specified notebook or electronically. Each receipt will be reviewed after each run and then be signed by the person performing the review. The sterilizer operator will also document the results in Censitrac.
 - d. The sterilization parameters will be verified as needed but no less than once a day.
4. Sterilization Control Systems
 - a. Each item sterilized is labeled with the date (month, day, and year), sterilizer number, and load number.
 - b. Chemical integrator strips are placed inside each item. The item is sealed with steam tape or Sterrad® tape. Pouches are either self-sealing or sealed by a heat sealer.
 - c. The Censitrac computer system is used for documenting information for each sterilizer. The sterilizer number, load number, date, contents of the load, daily Bowie-Dick test, biologicals, and chemical indicators are documented. Temperature of the load and total time are documented on the 3M Attest® Rapid Readout Steam or log sheet.
 - d. The Bowie-Dick test is placed in an empty sterilizer the first cycle for each

day in the steam sterilizers to evaluate the efficacy of air removal.

- e. The physical receipts or printouts and chemical and physical indicators will be placed in the QA book and maintained with other sterilizer information. Records are retained for five years.
5. Biological monitoring of sterilizers
 - Review Perioperative Services policy: [Biological Monitoring for Sterilizers](#) for information regarding biological monitoring requirements for the various types of sterilization.
 6. When a positive biological indicator is detected in a Surgical Services Department sterilizer (e.g., OR, CPD, ASC), personnel responsible for that sterilizer will follow the protocol outlined in the Perioperative Services policy: [Positive Biological Recall Procedure](#).
 7. Recall of Equipment
 - The red and white load number sticker with date, sterilizer number, and load number are used to recall sterile items. All items are returned to CPD for reprocessing.

G. Procedures Regarding Shelf Life of Sterilized Items

All items sterilized in the Central Processing Department or other Surgical Services reprocessing areas do not require an expiration date. These items are considered sterile and may be used as long as the integrity of the package is not compromised by becoming torn, wet (or evidence of moisture damage), punctured, opened or have an unsealed or broken seal/lock.

1. A load number sticker will be placed on each reprocessed item. No expiration date will be present.
2. A load number sticker will be placed on each package for recall purposes only. The date on this sticker is NOT an expiration date.
3. All items processed for sterilization will be properly wrapped and processed in such a manner to provide an effective barrier to microorganisms during storage and allow aseptic presentation upon opening.
4. All packages must be inspected before use. If the package is torn, wet, punctured or has a broken seal, it is considered contaminated and should not be used.
5. Any package that has fallen or been dropped on the floor must be inspected for damage to the packaging or contents. If the package is heat-sealed in impervious plastic and the seal is still intact, the package should be considered not contaminated. If undamaged, items packaged in plastic need not be reprocessed.

6. Rotation of supplies is important to ensure previously processed items are used before those more recently processed.
7. The loss of sterility is event-related, not time-related. Storage areas will be routinely cleaned, have the proper pressure differential, air exchanges per hour, temperature, and humidity conditions, and should not in any way compromise the integrity of the package. Microbial growth is only a concern under excessive temperature and humidity conditions (e.g., temperature >90°F, relative humidity >80% for longer than 48-hours).
8. Items to be sterilized will be wrapped with a one-time use disposable wrap where appropriate.
9. When commercially prepared sterile items have an expiration date furnished by the manufacturer, packages are considered sterile until damaged or opened. When the manufacturer has an expiration date on the item, it must be used before the expiration date is achieved. Any package that is not used before the expiration date should either be discarded or reprocessed as appropriate by an approved third party reprocessor.

H. Transport of Sterilized Items

1. Sterilized items are moved from CPD to the ORs in a manner to prevent contamination. This includes inside a case cart, hand carried (with a dust cover), or sent via the clean elevator.
2. If either clean or contaminated elevator is out of service, supplies are transported by staff using staff elevators.

I. Cleaning Sterilizers

1. Steam sterilizer drains are to be cleaned daily in CPD, Monday-Friday in the ASC and Hillsborough.
2. Sterrad sterilizers in CPD, ASC, and Hillsborough are cleaned according to the sterilizer manufacturer's instructions.

J. Storage of Sterile Supplies

1. Sterile supplies shall be stored at least 8-inches from the floor, 2-inches from an outside wall, and 24-inches from ceilings. Items stored on perimeter shelving may be stored to the ceiling. They are stored in the Sterile Storage Area on carts. The bottom shelf of storage carts or shelving should be solid in CPD's sterile storage adjacent to the sterilization area. These carts are cleaned one time per month and when visibly soiled with an EPA-registered germicidal solution.
2. Items received throughout the hospital and clinical areas from CPD will be stored at least 8-inches from the floor, 2-inches from an outside wall, and 24-inches from

ceilings but do not require solid bottom shelving.

3. Sterile supplies are rotated with the most recently sterilized items used last. Any opened or damaged packages are removed from the shelves and reprocessed.
4. Corrugated cardboard boxes and fans are not permitted in CPD.
5. Traffic in the Sterile Storage Area is kept at a minimum.

K. Housekeeping

1. Floors and work surfaces are cleaned and disinfected daily.
2. Begin cleaning and disinfecting the clean work areas, such as the packaging area and sterile storage area, before the dirty work areas, such as the decontamination area, to reduce the possibility of contaminating the clean area.

IV. Implementation

The Manager(s) of Central Processing or his/her designee is responsible for the enforcement of the procedures in CPD.

V. Related Policies

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

[Infection Prevention Policy: Endoscope](#)

[Infection Prevention Policy: Exposure Control Plan for Bloodborne Pathogens](#)

[Infection Prevention Policy: Hand Hygiene and Use of Antiseptics for Skin Preparation](#)

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

[Infection Prevention Policy: Infection Prevention Guidelines for Perioperative Services](#)

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

[Infection Prevention Policy: Sterilization of Reusable Patient-Care Items](#)

[Infection Prevention Policy: Tuberculosis Control Plan](#)

[Occupational Health Services Policy: Infection Prevention and Screening Program: Occupational Health Service](#)

[Perioperative Services Policy: Biological Monitoring for Sterilizers](#)

[Perioperative Services Policy: Mechanical Monitoring for Sterilizer](#)

[Perioperative Services Policy: Positive Biological Recall Procedure](#)

Attachments

[01: Central Distribution Storage of Sterile Supplies](#)

[02: Documentation of Emergency Release of Sterilizer Loads](#)

Approval Signatures

Step Description	Approver	Date
Policy Stat Administrator	Kimberly Novak-Jones: Nurse Educator	03/2024
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Applicability

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