# 01.05.02 – Sterilization of Semi-Critical and Critical Medical Devices

**Purpose**

To provide a process that renders semi-critical and critical medical devices safe for patient use. Spaulding classification system will be used to identify the cleaning and reprocessing of the reusable medical devices referred to as "semi-critical" and "critical" within this policy. Spaulding classification categories are "critical, "semi-critical," and "noncritical." A hierarchy of references and resources is utilized to determine the method for reprocessing.

**Policy**

Where feasible, sterilization procedures will be performed in a sterile processing department (SPD). Sterilization processes outside a SPD will be limited to pre-approved sites for selected equipment. Before purchasing a new medical device, the purchasing department will determine the Manufacturer's instruction for use (MIFU) for high level disinfection and/or sterilization and will ensure the necessary resources for reprocessing are available.

**Definitions**

**Critical Medical Devices**: critical medical devices that enter normally sterile tissue or the vascular system or through which blood flows should be sterilized before each use (refer to methods of sterilization and disinfection in this policy and MIFU for medical devices being sterilized).

**Semi-Critical Medical Device**: Devices that come in contact with mucous membranes or skin that is not intact should be free of all microorganisms except for bacterial spores and are called semi-critical medical devices. Respiratory and anesthesia devices, endoscopes, diaphragm fitting rings, vaginal speculums, and ultrasound probes are included in this category. Semi-critical medical devices require high-level disinfection using chemical disinfectants.

**Manufacturer Instructions for Use (MIFU)** are detailed, step-by-step guides provided by the manufacturer to explain how a product, especially medical devices, should be used and handled. They outline the correct procedures for use, including cleaning, disinfection, and other safety precautions. MIFUs ensure the product is used safely and effectively, while also addressing potential hazards and ensuring compliance with legal and regulatory standards.

**Decontamination (OSHA definition)**: "The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal."

**Gross Soil:** Organic material (e.g., blood, tissue bone) and debris (e.g., bone cement) that accumulates on surgical instruments during operative or other invasive procedures.

**Ultrasonic Cleaner**: A processing unit that transmits ultrasonic waves through the cleaning solution in a mechanical process known as cavitation. Ultrasonic cleaning is particularly effective in removing soil deposits from hard-to-reach areas.

**Washer/decontaminator**: A processing unit that, either by use of single or multiple chambers automatically decontaminates surgical instruments. It employs a cool

water rinse, hot water wash, rinse, and drying. An ultrasonic cleaning feature and lubricant rinse may be added.

**Sterilization**: validated process used to render a product free from viable microorganisms.

**General principles**

SPD and areas processing onsite will follow the principles outlined below.

1. In hospital SPD, the decontamination area/room and the packaging, sterilization, and sterile storage rooms shall be physically separated. In ambulatory surgery and office-based procedure areas where endoscopic and/or minor surgical procedures are performed, separate rooms shall be used where feasible. When separate rooms are not available, the decontamination sink should be separated from the clean work area by either a 4-foot distance from the edge of the sink or by a separating wall or screen.
2. All loaner and consignment surgical instrumentation that is provided by an approved vendor and has followed the proper consignment steps will be processed per MIFU and hospital policy. *See policy 01.48 – Management of Loaner and Consignment Surgical Instrumentation in the Sterile Processing Department (SPD).*
3. All surgical instruments used in clinical procedures must be purchased through the UTMB central purchasing department after value analysis and approval by departmental leadership. Personal surgical instruments are strictly prohibited. All instruments that are not owned by UTMB or by an approved vendor will be removed from circulation. Requests for special instruments must be formally submitted to Value Analysis department.
4. All medical devices will be thoroughly cleaned per MIFU prior to sterilization.
5. MIFU will be followed for the sterilization equipment used as well as any supplies used in any of the reprocessing steps.
6. The area will follow a written procedure which must be approved by infection control. No modifications to this procedure will be made without approval.
7. Maintenance and quality control processes shall be appropriate to the type of sterilizer used (e.g., tabletop sterilizers, sterilizers >2 cubic feet, vaporized hydrogen peroxide system) as per MIFU.
8. All recommended quality control measures will be followed. Required documentation for device reprocessing cycles, including but not limited to sterilizer cycle logs, the frequency of chemical and biological testing, and the results of testing for appropriate concentration for chemicals used in high-level disinfection. All required documentation is outlined within the training checklist for the appropriate chemical or medical device.
9. If the medical device and/or accessories cannot be processed immediately after the point of use treatment process, follow the MIFU for delayed processing as applicable. Workflows must ensure timely reprocessing of medical devices and/or accessories.
10. Devices are quarantined until results of the biological indicator have been recorded.

11. In the event of a sterilization process failure, a risk assessment will be conducted to determine the actions for follow up that may include quarantine of the sterilizer, recall of item(s), stakeholder notification, patient notification, and surveillance. ***See Appendix A.***
12. High risk scopes, such as elevator channel endoscopes, duodenoscopes, cystoscopes, ureteroscopes, bronchoscopes, endoscopic ultrasound scope (EUS) and endobronchial ultrasound scope (EBUS)) or scopes used in patient populations where high-level disinfection is contraindicated (e.g., patients with bladder cancer) will be sterilized by a method approved by the manufacturer.
13. All staff who perform any part of reprocessing medical devices will be trained and competent to perform their duties. A training checklist will be used to complete initial and annual assessment of staff. *(See Quality Section below)*
14. Staff who perform reprocessing will follow the prescribed dress code for the area including personal protective equipment (PPE).
    a. A fluid resistant gown with long sleeves
    b. General purpose utility gloves with a cuff that extends beyond the cuff of the gown
    c. A surgical mask and eye protection or a full-face shield
    d. Shoe covers or boots designed for use as PPE
15. Perform hand hygiene after removing PPE
16. Clean, decontaminate, and confirm the integrity of reusable PPE between uses.

**Medical Device Processing**

The following steps will be followed for all medical devices processed.

1. Point of use treatment
    a. Apply point-of-use treatment promptly in accordance with the MIFU to initiate the cleaning process and/or to prevent soils from drying on the reusable medical device. Blood and body fluids must be removed at point-of-use as it can cause pitting of medical devices and if left to dry can be difficult to remove.
    b. If a delay in treatment occurs, follow the MIFU for remediation due to potential for biofilm formation and drying of soils.
    c. When transport to the decontamination area will be delayed (with the exception of scopes and ultrasound probes), medical devices will remain moistened by applying a product designed for pre-treatment unless the MIFU requires an alternative method to keep the device moist.
2. Transport after point of use treatment
    a. Transporting medical devices from a procedure area to the decontamination area must be done using a puncture resistant, leak-

proof container. The container should be tagged with an appropriate biohazard indicator to ensure proper handling during transport..

b. Do not transport medical devices in any material that will allow leakage.

3. Cleaning/decontamination:
    a. MIFU will be followed for all cleaning/decontamination steps including leak testing to prevent damage from bioburden or fluid invasion.
    b. Manual cleaning
        i. Manual cleaning may be recommended as the preferred method for delicate or complex devices. MIFU must be followed.
        ii. Devices must be removed from the transport container and disassembled to expose all surfaces to the cleaning process.
    c. Mechanical cleaning medical devices (e.g. ultrasound washers, washer disinfector/decontaminator) will be used per MIFU for the medical device being cleaned.
        i. Position surgical instruments and their containment devices in the washer disinfector in a manner that ensures contact of the cleaning solution with all surfaces of the items.
        ii. Disassemble items composed of more than one part according to the MIFU
        iii. Contain small parts.
        iv. Place instruments in open mesh-bottom pans
        v. Open ports, stopcocks, and ratchets.
        vi. Remove any instruments with etching
        vii. Remove stylets from lumened instruments
        viii. Place items with surfaces that will retain water on edge
        ix. Segregate electrical cords and insulated instruments from sharp instruments
    d. For all SPD areas, clean medical devices will be sent through a pass-through window and/or removed from automatic washers on the clean side of SPD.
    e. Following cleaning/decontamination, a sample of cleaned medical devices will undergo a cleaning challenge as a quality control measure, choosing 20% of channeled scopes and at least two of the most difficult medical devices to clean with each batch of processing. High-risk scopes include elevator channel endoscopes, duodenoscopes, cystoscopes, ureteroscopes, bronchoscopes, EUS and EBUS scopes. Test points must include the suction/biopsy (working) channel and the elevator channel (if present).

i. Automatic washers

1. Test the most difficult medical device to wash daily from each rack/layer
2. If there are multiple washers, test items from one washer per day. Rotate through each washer, (ex., Monday check washer one, Tuesday check washer two, until you have rotated through all washers) then repeat process.

ii. Document corrective action for any failed results.

f. If quality control measures indicate a failure in the process, the device is to be quarantined and repeat reprocessing steps. For continued failure, the manufacturer will be contacted for remediation efforts.

4. Transporting after cleaning/decontamination for areas other than an SPD
    a. Transporting medical devices from the cleaning/decontamination area to the clean area is done in an appropriately tagged container for your area and procedure that prevents contamination.
5. Inspection
    a. Inspect surgical instruments to evaluate for cleanliness and correct working order after decontamination, and if soiled or defective (see list below), remove from service until cleaned or repaired.
        i. Lack of cleanliness
        ii. Lack of correct alignment
        iii. Corrosion, pitting, burrs, nicks, cracks
        iv. Tape and adhesive
        v. Inadequate sharpness of cutting edges
        vi. Showing wear and chipping of inserts and plated surfaces
        vii. Missing parts
        viii. Lack of integrity of insulation on insulated devices
        ix. Lack of integrity of cords and cables
        x. Poor clarity of lenses
        xi. Lack of integrity of seals and gaskets
        xii. Presence of moisture
        xiii. Incorrect functioning; and
        xiv. other defects.
    b. Check powered equipment to ensure that
        i. the device is functioning as intended and
        ii. power ceases when the device is turned off.

c. Assemble instruments that work with an accessory instrument to confirm correct fit and that locking mechanisms are working as intended.

i. Disassemble instruments and equipment before packaging for sterilization

d. Use lighted magnification to inspect hard to clean areas of devices for cleanliness

e. Inspect the internal channels of reusable arthroscopic shavers with an endoscopic camera or borescope

f. Visually examine and test insulated devices using equipment designed to detect insulation failure

g. Identify, remove, and initiate repair or discard defective instruments.

h. Verify that instruments are fully dry according to the manufacturer's written IFU before they are assembled in packaging systems in preparation for sterilization.

6. Quality Assurance

a. Quality assurance (QA) checks shall be conducted by a qualified, certified (sterile processing) staff member that did not perform the initial checks after each batch of instruments prior to packaging.

b. Staff assigned to perform quality assurance checks will review a random selection of instruments with minimally 10 instruments per batch reviewed and ensure the quality assurance for the machine met the standards.

c. If a breech in instrument integrity is discovered or the QA for the machine did not meet standards, the department supervisor will be notified, and a risk assessment will be performed and documented by the supervisor.

d. Action items will be outlined in the risk assessment and carried out to avoid future breeches. An additional quality check will be performed randomly after each sterilization process is complete to ensure package integrity, chemical indicator and biological indicator, and instrument integrity are met prior to returning to use.

e. At least one tray must be opened and inspected per shift to ensure integrity. The instruments in inspected trays must undergo the entire process again after inspection.

7. Packaging

a. Following cleaning/decontamination and inspection, medical devices will be packaged and processed by the method prescribed in the MIFU

8. Sterile Transport and storage

a. Sterile medical devices are transported and stored in a manner that prevents contamination.

b. All containers and packaging will be inspected for integrity prior to use. Compromised containers and packaging will not be used and sent for reprocessing.

9. Immediate-Use Steam Sterilization (IUSS): should only be used in carefully selected clinical situations. Requirements include:
    a. IUSS should be performed by trained, competent personnel and in accordance with the MIFU.
    b. The item must be sterilized in a validated container that permits penetration of steam, and which can be used to safely transfer the sterilized item to the operating room.
    c. Each load must be monitored by physical/chemical indicators.
    d. The item must be sterilized at an exposure time and temperature that reliably kills microorganisms
    e. Before patient care, the device or implant that was subjected to IUSS is cooled to body temperature without compromise of sterility.
    f. A record must be kept on every item subjected to immediate use sterilization.
        1. Item sterilized
        2. Patient's name and medical record number
        3. Results of physical/chemical indicator, where applicable.
        4. Sterilizer parameters verified (time, temperature) with verifying operator initials.
        5. Medical devices processed by IUSS are not stored for future use.

**Staff Proficiency**

Perioperative personnel involved in the cleaning and care of surgical instruments and equipment will complete quality assurance and performance improvement activities related to cleaning, decontaminating, and inspecting surgical instruments. All supervisory and QC staff should be certified in sterile processing.

Training checklists are available through the Nursing Service website.

For manufacturer's instruction for use, log on to onesourcedocs.com.

**References**

1. Association for the Advancement of Medical Instrumentation (AAMI). Quality Control 2010:10:97-136.
2. Association for the Advancement of Medical Instrumentation (AAMI). ST79:2017®2022. Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
3. Association for the Advancement of Medical Instrumentation (AAMI). Flexible and semi-rigid endoscope processing in health care facilities. ST91:2021.

4. Association of periOperative Registered Nurses (AORN). Guideline for care and cleaning of surgical instruments. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc; 2021:381-420
5. Centers for Disease Control (CDC). Guidelines for Disinfection and Sterilization in Healthcare Facilities (2008). Updated February 2017.
6. Rutala WA, Weber DJ. Selection and Use of Disinfectants in Healthcare, In Mayhall, CG, Ed. Hospital Epidemiology & Infection Control. Fourth Edition, Lippincott Williams and Wilkins, 2012.
7. The Society for Healthcare Epidemiology of America (SHEA). Multisociety guidance for sterilization and high-level disinfection. Infect Control Hosp Epidemiol. 2025 Apr 28:1-23. doi: 10.1017/ice.2025.41.
8. Association for the Advancement of Medical Instrumentation (AAMI). External transport of reusable medical devices for processing. TIR109:2025.

## Appendix A Sterilization Process Failures

Sterilization failures may occur for a variety of reasons, including malfunction in the sterilization cycle, poor steam quality, operator error, and related factors.

- Recalling or reprocessing medical equipment involves a series of systematic steps to ensure safety and compliance. If a failure occurs, notify the SPD manager or designee. The specific equipment affected by the failures will be identified by identifying the batch or serial numbers and understanding the reason for and impact of the failure on patient safety. SPD managers or designee will notify relevant stakeholders, as applicable, and may include healthcare providers and infection prevention.
- If the malfunction cannot be corrected immediately, the cycle shall be terminated in accordance with the sterilizer MFG IFU. The load is considered nonsterile and will be quarantined to prevent inadvertent release.
- The cause of a sterilizer failure or failure of a process challenge device (PCD) shall be investigated by the manager, department designee, and/or equipment and product manufacturer. The root cause must be identified and corrected.
- Major repair of the steam sterilizer or utilities connected to the sterilizer:
    - A major repair to the sterilizer is a repair outside the scope of normal maintenance, such as a weld repair of the pressure vessel; replacement of the changer door, vacuum pump, or a major piping assembly; or rebuilds or upgrades of controls.
    - After a major repair of any type of steam sterilizer or the utilities connected to the sterilizer, three (3) consecutive test cycles with a PCD shall be run, one right after the other, in an otherwise empty chamber for sterilizers larger than 2 cubic feet and for IUSS cycles and in a fully loaded chamber for small steam sterilizers.
    - Normal preventive maintenance, such as the rebuilding of solenoid valves or the replacement of gaskets, is not considered a major repair.
    - BI PCD tests should be performed before the Bowie-Dick tests
- After a major repair of the VHP sterilizer, follow the manufacturer's written IFU for qualification testing before the processing equipment is returned to service.
- Test results shall be obtained and determined to be satisfactory before the sterilizer is returned to service.