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 sterile processing department (SPD) will be limited to pre-approved sites for selected equipment. Before purchasing a new medical device, the purchasing department will determine Manufacturer's instruction for use (MFG IFU) for high level disinfection and/or sterilization and will assure 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 manufacturer's instructions for use [MFG's IFU] 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.

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."

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

General principles SPD and areas processing on site 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 medical devices will be thoroughly cleaned per MFG IFU prior to sterilization.
3. MFG IFU will be followed for the sterilization equipment used as well as any supplies used in any of the reprocessing steps.
4. The area will follow a written procedure which must be approved by infection control. No modifications to this procedure will be made without approval.
5. Maintenance and quality control processes shall be appropriate to the type of sterilizer used (e.g., tabletop sterilizers, sterilizers > 2 cubic feet, Vpro). Follow MFG IFU.
6. 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.

7. If the medical device and/or accessories cannot be processed immediately after the point of use treatment process, follow the MFG IFU for delayed processing as applicable. Workflows must ensure timely reprocessing of medical devices and/or accessories.
8. Devices are quarantined until results of the biological indicator have been recorded.
9. Sterilization process failures: In the event of a 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.
10. Scopes used for sterile procedures or used in any patient populations for which use of high-level disinfectants is contraindicated for certain patient populations (e.g., patients with bladder cancer) will be sterilized by a method approved by the manufacturer.
11. 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.
12. Staff who perform reprocessing will follow the prescribed dress code for the area including personal protective equipment (PPE).
13. The following steps will be followed for all medical devices processed.

    a. Point of use treatment
        1) Point of use treatment will begin as soon as possible after use. 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.
        2) 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 MFG IFUs requires an alternative method to keep the device moist.
    b. Transport after point of use treatment
        1) Transporting medical devices from a procedure area to the Decontamination area is done in an appropriate container for your area and procedure and is tagged with an appropriate biohazard indication.
        2) Do not transport medical devices in any material that will allow leakage.
    c. Cleaning/decontamination:
        1) MFG IFU will be followed for all cleaning/decontamination steps including leak testing to prevent damage from bioburden or fluid invasion.
        2) Mechanical cleaning medical devices (e.g. ultrasound washers) will be used per MFG IFU for the medical device being cleaned.
        3) 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.
        4) 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 endoscopes (e.g., duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes, and as determined by the facility) shall be evaluated with cleaning verification test after each use. Test points must include the suction/biopsy (working) channel and the elevator channel (if present).
        5)

a) Automatic washers:
   i) Test most difficult medical device to wash daily from each rack/layer
   ii) If there are multiple washers, test items from one washer per day. Rotate through each washer, for example Monday check washer one, Tuesday check washer two, until you have rotated through all washers, then repeat process.
b) Document corrective action for any failed results.

6) If quality control measurers 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.

d. Transporting after cleaning/decontamination for areas other than an SPD: 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.
e. Packaging: Following cleaning/decontamination, medical devices will be packaged and processed by the method prescribed in the MFG IFU.
f. Sterile Transport and storage: Sterile medical devices are transported and stored in a manner that prevents contamination.

14. Immediate-Use Steam Sterilization (IUSS): should only be used in carefully selected clinical situations. Requirements include:
   a. 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.
   b. Each load must be monitored by physical/chemical indicators.
   c. The item must be sterilized at an exposure time and temperature that reliably kills microorganisms
   d. A record must be kept on every item subjected to immediate use sterilization.
      - Item sterilized
      - Patient's name and UH#
      - Results of physical, chemical indicator where applicable.
      - Sterilizer parameters verified (time, temperature) with verifying operator initials.
      - Medical devices processed by IUSS is not stored for future use.

15. Training checklists are available through the Nursing Service website. For manufacturer's instruction for use, log on to onesourcedocs.com.

Appendix A:

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. First 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 and/or vendor. The root cause must be identified and corrected.
- Major repair of the 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. Normal preventive maintenance, such as the rebuilding of solenoid valves or the replacement of gaskets, is not considered a major repair.
    - 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. The test results shall be obtained and be determined to be satisfactory before the sterilizer is returned to service.

References:

1. Association for the Advancement of Medical Instrumentation. Quality Control 2010:10:97-136.
2. Association for the Advancement of Medical Instrumentation. ST79:2017. Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
3. Association for the Advancement of Medical Instrumentation. Flexible and semi-rigid endoscope processing in health care facilities. ST91:2021.
4. 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.

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