01.05.04 - High-Level Disinfection of Semi-Critical Medical Devices

Purpose

To provide a process that renders semi-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" 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

All semi-critical medical devices will be cleaned, processed, transported, and stored according to these principles outlined below. Before purchasing a new medical device, the purchasing department will determine MFG IFU for high level disinfection and/or sterilization and will assure the necessary resources for reprocessing are available.

Definitions:

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 FDA-approved liquid chemical sterilants and high-level 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."

High-level disinfection: process that kills all microbial organisms but not necessarily large numbers of bacterial spores.

General principles:

Sterile Processing Departments and areas processing on site will follow the principles outlined below.

1) In hospital sterile processing departments (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 Manufacturer's instruction for use (MFG IFU) prior to use of any FDA-approved liquid chemical sterilants and high-level disinfectants.
3) MFG IFU will be followed for any FDA-approved liquid chemical sterilants and high-level disinfectants.used as well as any equipment or supplies used in any of the reprocessing steps. Conflicts or discrepancies between a device MFG IFU and a chemical/reprocessing equipment MFG IFU will be resolved upon documentation of either of the two manufacturers.
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 high-level disinfectant used.
6) All recommended quality control measures will be followed. Required documentation for device reprocessing cycles, including but not limited 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) Scopes will be sterilized when the use of high-level disinfectants is contraindicated for certain patient populations (e.g., patients with bladder cancer).

9) All staff who perform any part of reprocessing a medical device(s) will be trained and competent to perform their duties. A training checklist will be used to complete initial and annual assessment of staff.

10) Staff who perform reprocessing will follow the prescribed dress code for the area including personal protective equipment (PPE).

11) The following steps will be followed after a semi-critical medical device is used:
    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.

12) Transport after point of use treatment
    a) Transport medical device in an appropriate container tagged/labeled with the appropriate indicator for your area to the room/area where the medical device will be cleaned/decontaminated.
    b) Do not transport medical devices in any material that will allow leakage.

13) Cleaning/decontamination:
    a) MFG IFU will be followed for all cleaning/decontamination steps including leak testing or voltage testing to prevent damage from bioburden or fluid invasion.
    b) Transporting for cleaning/decontamination:
        - A cleaning challenge must be performed on 20% (1 out of every 5) channeled/lumened or non-lumened scopes/TEE probes processed per week prior to HLD or sterilization.
        - A cleaning challenge must be performed on all high-risk scopes. High-risk scopes include elevator channel endoscopes, ureteroscopes, bronchoscopes, EUS and EBUS scopes. Test points must include the suction/biopsy (working) channel and the elevator channel (if present).
        - Inpatient and ambulatory areas sending medical device(s) to SPD for processing: point of use treated medical devices will be transported in the appropriate container to SPD.

14) High-Level Disinfection:
    a) An FDA-approved liquid chemical sterilants and high-level disinfectants will be used for all medical devices and compatible accessories processed by high-level disinfection.
        - Accessories not processed with a FDA-approved liquid chemical sterilant and high-level disinfectant will be sterilized.

- Items processed manually: follow MFG IFU for Cidex OPA© or Revital-Ox RESERT, including quality control measures.
- Scopes processed with an automated endoscope reprocessor (AER): follow MFG IFU for the AER.
- TEE probes will be processed in an Astra Tee
- 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.

b) Transport high-level disinfected medical devices to the storage area in a manner that prevents contamination.
c) Processed medical devices are stored in a manner that prevents contamination.
d) Scopes/TEE probes not used within 14 days after processing will be reprocessed starting with cleaning through disinfection.

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

16) 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.

References

1. Association for the Advancement of Medical Instrumentation. Quality Control 2010:10:97-136.
2. Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ST79:2017.
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.
5. Young M. Quality control of table-top steam sterilizers. Managing Infection Control 2007; 82-97.