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.

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 processing 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 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."

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-registered liquid cold sterilant/disinfectant.
3) MFG IFU will be followed for any FDA-registered liquid cold sterilant/disinfectant used as well as any equipment or 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 high-level disinfectant used.
6) All recommended quality control measures will be followed.
7) If the medical device and/or accessories cannot be processed immediately after the pre-cleaning process, follow the MFG IFU for delayed processing.
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 PPE.

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

a) Pre-clean/pre-treat
   1. Pre-Cleaning will begin as soon as possible after use. Blood and body fluids can cause pitting of medical devices and if left to dry can be difficult to remove.

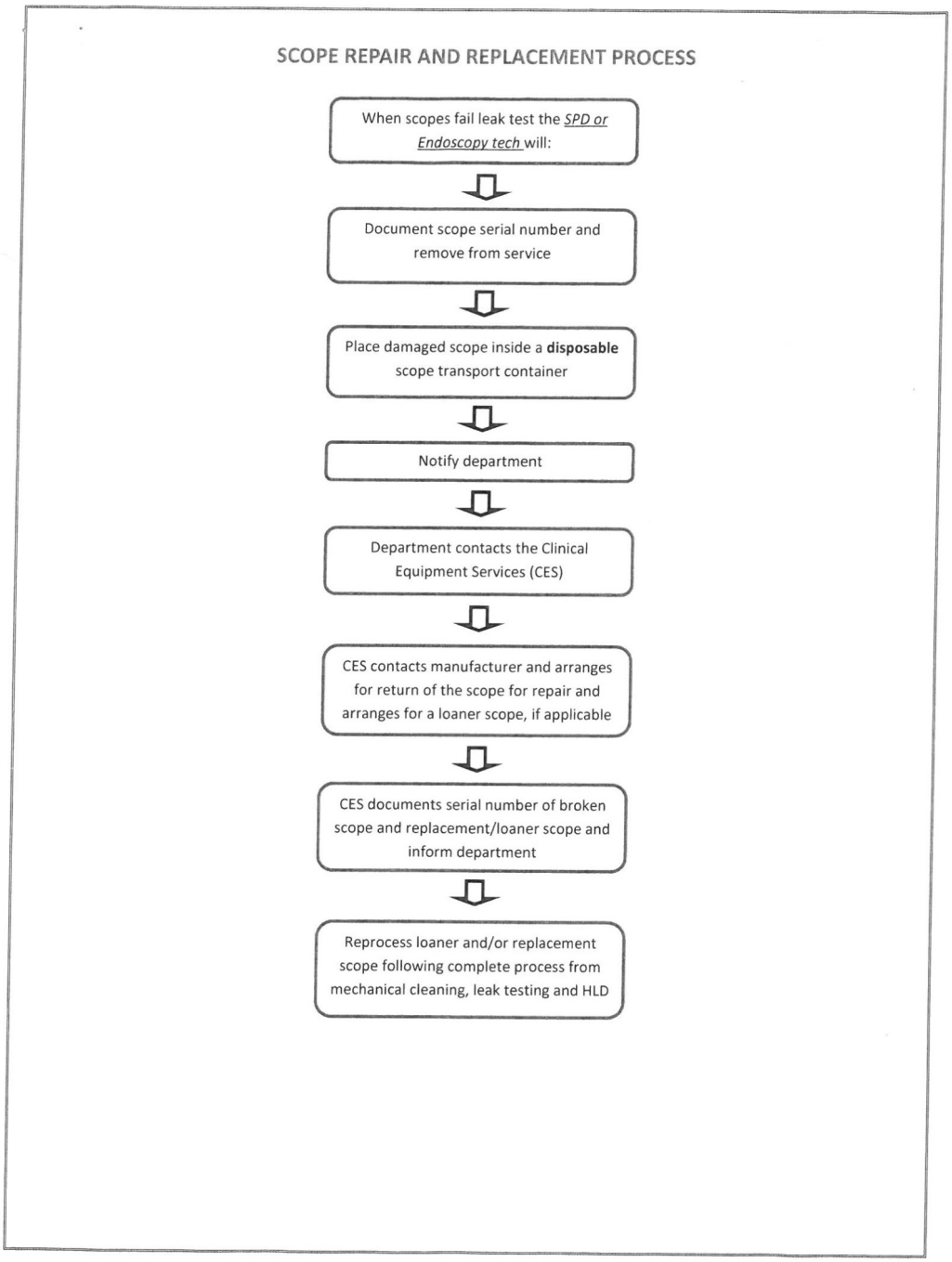
12) Transport after pre-clean
   a) Transport medical device in an appropriate container tagged/labeled with the appropriate indicator for your area to the room/area where the medical device will be cleaned/decontaminated.

13) Cleaning/decontamination:
   a) MFG IFU will be followed for all cleaning/decontamination steps including leak testing of flexible scopes to prevent damage from bioburden or fluid invasion.
   b) Transporting for cleaning/decontamination:
      - Ambulatory and inpatient areas processing on site: Before transporting clean (decontaminated item) to clean area, perform Resi Test.
      - Resi Test or cleaning challenge must be performed on 20% (1 out of every 5) channeled/lumened or non-lumened scopes processed per week prior to HLD or sterilization.
      - Endoscopy areas should perform a Resi Swab Test as well as a Resi Test Slide Thru on all ERCP scopes.
      - Inpatient and ambulatory areas sending medical device(s) to SPD for processing: the pre-cleaned/pre-treated medical device will be transported in the appropriate container to SPD.

14) High-Level Disinfection:
   a) An FDA-registered liquid cold sterilant/disinfectant will be used for all medical devices and compatible accessories processed by high-level disinfection.
      - Accessories not processed with a cold sterilant/disinfectant will be sterilized.
      - Items processed manually: follow MFG IFU for Cidex OPA©, including quality control measures.
      - Scopes processed with an automated endoscope reprocessor (AER): follow MFG IFU for the AER.
      - Ultrasound probes will be processed in a Trophon
      - The TEE will be processed in an Astra Tee
   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 not used within 14 days after processing will be reprocessed starting with cleaning through disinfection.

15) For Training Checklists click link below. For manufacturer's instruction for use, log on to onesourcedocs.com.
https://liveutmb.sharepoint.com/sites/collaboration/webfiles/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2Fcollaboration%2Fwebfiles%2FShared%20Documents%2FAmbulatory%20Training%2FWeb%20Documents%2FCompetencies%2FHealth%20Care%20Epidemiology%20%28HCE%29%2FCompetencies%20Training%20Checklist&p=true&originalPath=aHR0cHM6Ly9saXZldXRtYi5zaGFyZXBvaW50LmNvbS86Zjovcy9jb2xsYWJvcmF0aW9uL3dlYmZpbGVzL0V1NW1vTXdMWE81RnJtRjJvYThobTF3QnpHZ19YUUozUXRGV2RnN243SnZweHc_cnRpbWU9aE1RVFg4UHkxMGc

Appendices **Repair and Replacement of Scope**



References

1. 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.

2. Association for the Advancement of Medical Instrumentation. Quality Control 2010:10:97-136.
3. Young M. Quality control of table-top steam sterilizers. Managing Infection Control 2007; 82-97.