Policy No. IPC-09

Subject:
HIGH-LEVEL DISINFECTION FOR SEMI-CRITICAL INSTRUMENTS

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Departments Consulted:	**Reviewed & Approved By:**	**Approved By:**
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PURPOSE:

Consistent with CMS Conditions of Participation §482.42(c)(2) as well as Joint Commission Standards IC.02.02.01 and EC.02.03.04, the LAC+USC Department of Infection Prevention and Control (IPC) has developed this policy to provide guidelines to frontline staff members involved in the performance and testing of high-level disinfection processes in the medical center.

I. RESPONSIBILITIES

Although the IPC Department will provide consultation and general oversight of and approve all new High-Level Disinfection products and processes (including quality testing procedures), individual medical center units will be responsible for developing, implementing, logging, maintaining, regularly updating, and testing the effectiveness (using approved quality assurance testing methods) of their high-level disinfection procedures and processes. Department performing High-Level Disinfection will do so using only EPA-approved methods, instruments, and solutions and in accordance with updated Manufacturer Instructions for Use -including any and all necessary safety precautions- for all products. All Departments performing reprocessing of Semi-Critical instruments will notify the IPC Department who will provide oversight and guidance on high-level disinfection processes and monitor appropriateness of use.

II. DEFINITIONS

Spaulding Classification: a long-standing, widely accepted framework for approaching cleaning, disinfection, and sterilization of reusable medical equipment & devices which categorizes equipment/devices as either Non-Critical, Semi-Critical, or Critical.

Non-Critical Device: equipment that comes into contact with a patient's intact skin, but not mucous membranes. Intact skin is an effective barrier to most microorganisms; therefore, the complete sterility of items coming in contact with intact skin is not "critical". Such items should be cleaned and an EPA-approved low-level disinfectants used prior to reuse between patients.

Semi-Critical Device: equipment that comes in contact with mucous membranes or non-intact skin. Such instruments should be free from microorganisms; however, small numbers of bacterial spores are permissible as the tissue they contact - such as bowel or oral mucosa - is not considered sterile. Examples include but are not limited to: flexible endoscopes and colonoscopes, cystoscopes, bronchoscopes, nasal & laryngoscopes, as well as vaginal, rectal, and esophageal probes and scopes. These instruments require *high-level disinfection* prior to reuse.

Critical Device: equipment that enters or contacts sterile areas of the body, including the vascular system and blood. Objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease. These instruments are often used during surgery and require *sterilization*.

High-Level Disinfection: defined as elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. High-level disinfection is used for reprocessing of Semi-Critical devices & equipment.

III. BACKGROUND:

Semi-critical medical devices/instruments minimally require high-level disinfection using chemical disinfectants prior to patient use and reuse. Failure to adhere to established instrument reprocessing guidelines may result in healthcare-associated infectious outbreaks related to contaminated semi-critical devices.

IV. APPLICABLE DEPARTMENTS & EQUIPMENT

High-level disinfection may be performed on semi-critical equipment or scopes used in the following departments. Although the departments, devices, & location listed in Table 1 constitute a representative list of instruments requiring high-level disinfection, the list is not exhaustive and high-level disinfection may be performed in additional areas.

TABLE 1: LAC+USC High-Level Disinfection Instruments & Departments

Equipment / Devices	Applicable Departments	Locations
GI Tract: EGD & ERCP scopes, anoscopes, small intestine enteroscopes, colonoscopes, sigmoidoscopes	GI Endoscopy Colorectal Surgery	D&T B4J GI Lab Clinic Tower A4B Surgery Clinic
Respiratory Tract: nose & throat scopes (laryngoscopes & nasopharyngoscopes), non-disposable bronchoscopes, pulmonary function testing (PFT) equipment	ENT/Otolaryngology Pulmonary Anesthesia	Clinic Tower A2E ENT Clinic Clinic Tower A1B Radiation Oncology D&T B4F410 Bronchoscopy Suite D&T B4F417 Pulmonary Physiology Lab Inpatient Tower IPT 7G Clinic
Urinary Tract: cystoscopes	Urology	D&T B4J Urology/GU Lab
Female Reproductive Tract: colposcopes, hysteroscopes	Gynecology	Clinic Tower A3A Women's Clinic Clinic Tower A3B Women's Clinic IPT 3B Room 3P423 Labor & Delivery IPT 3H Room 3M119 OB Triage
Endocavitary Ultrasound Probes: Transvaginal and transrectal ultrasound probes (Reprocessed using a Trophon© machine)	Emergency Department Gynecology Radiology (Ultrasound)	Emergency Department Clinic Tower A3A Women's Clinic Clinic Tower A3B Women's Clinic OPD 5 West MCA Clinic D&T B3A115 Radiology US
Esophageal Probes: TEE probes, esophageal manometry probes	Cardiology GI Endoscopy	D&T Room 4E418 TEE Suite D&T B4J GI Lab
Any other reusable instrument that comes in contact with mucous membranes but cannot tolerate heat associated with sterilization ***or*** whose owning department has arranged for reprocessing to be performed by Central Sterile Services.	All departments	

V. INSTRUMENT TRACKING

All procedural units using High-Level Disinfection for semi-critical device reprocessing must maintain a log which identifies which scope or other semi-critical device was used, including date and time, for all patients undergoing procedures with semi-critical devices. See Appendix A for an example tracking log.

VI. STORAGE OF HIGH-LEVEL DISINFECTANTS AND SEMI-CRITICAL INSTRUMENTS

Procedural units will refer to Manufacturer's Instructions for Use for storage guidelines related to reusable semi-critical devices

The following should generally be followed regarding storage of semi-critical instruments & their high-level disinfection.

- Careful attention will be paid to storage temperature requirements and ensuring updated expiration dates are clearly marked on all high-level disinfectant solution bottles which have been opened.
- Manual cleaning/disinfection equipment should be in a separate area from storage of scopes.
- Best practice, where available, is to store flexible scopes in a drying cabinet which circulates HEPA-filtered air within the cabinet.
- Second and most commonly used option is storage of flexible scopes in a closed cabinet with HEPA-filtered air that provides positive pressure and allows air circulation.
- Ensure that stored scopes are not touching other scopes or the sides/bottom of storage cabinets.
- Industry and literature consensus is scarce regarding optimal Storage Times/Hang Times. Units should always follow Manufacturer's Instructions for Use regarding storage/hang time. Where no Manufacturer's Instructions are available regarding hang/storage time, a 7-day hang time will be utilized.

VII. PERSONAL PROTECTIVE EQUIPMENT (PPE) DURING HIGH-LEVEL DISINFECTION

Appropriate PPE should be worn when personnel are performing high-level disinfection. Many of the chemical disinfectants used in high-level disinfection are caustic and may be irritating to staff mucous membranes and skin if not handled properly and appropriate PPE is not used.

Proper PPE for staff when performing high-level disinfection should include the following:

A. Impermeable gown
B. Gloves fitted at the wrist or above
C. Fluid-resistant surgical mask
D. Face shield/eye protection

VIII. POINT OF USE CLEANING

Hearing "cleaning" refers to the removal of foreign material (e.g., soil and organic material) from objects. Cleaning is required before disinfection can occur since these foreign materials interfere with the effectiveness of disinfection processes and can act as barriers to disinfectant agents.

At the end of all procedures where a semi-critical instrument or scope is used, the instrument should be wiped down and cleaned at the Point-of-Use (e.g., in the endoscopy suite where the procedure was performed) as per Manufacturer's Instructions for Use (MIFU). This typically involves an initial wiping down and/or irrigation of a scope with an approved sponge or wipe and scope irrigation/suctioning as appropriate, and according to MIFU.

Instruments should generally be kept moist prior to transport and decontamination as soiled materials that are dried or baked onto the instrument make the removal process more difficult and the disinfection process less effective. Staff should follow MIFU for instrument transport, but instruments can generally be kept moist by using special containers, a pretreatment product, or towels moistened with water (not saline).

IX. TRANSPORT OF SCOPES & INSTRUMENTS TO BE HIGH-LEVEL DISINFECTED

Contaminated reusable items should be transported to a decontamination area where they must be thoroughly cleaned and decontaminated using water with detergents or enzymatic cleaners. Depending on the procedural area and equipment used, instrument decontamination may occur using mechanical units (e.g., ultrasonic cleaner or washer-disinfector) and by manual brush scrubbing methods. Staff should consult their Unit Standards, instruments' MIFUs, and the Nursing Services Policy entitled "High Level Disinfection Procedure" for specific transport and decontamination procedures for semi-critical equipment in their areas.

Transport of instruments that are to undergo high-level disinfection should occur using an appropriate rigid container or a drawstring bag specifically designed for scope transport (such bags are fully enclosed, puncture-resistant, and leak-proof). Transport vessels, whether a bag or container, should be labeled with a biohazard label.

Reusable scope transport devices should be decontaminated *between each use.*

The between instrument use and decontamination should be minimized to ensure organic bioburden does not dry on the scope or equipment. Though challenging in long cases, a general target time is to complete processing within 1 hour of instrument use during a case. If delayed instrument processing occurs, MIFUs for delayed processing should be followed. Endoscopes and other semi-critical devices should not be left soaking in enzymatic cleaning solutions as this increases biofilm development and/or may otherwise damage instruments.

X. DECONTAMINATION ROOMS

In those areas where instrument decontamination occurs in a separate room, the following should apply:

- Air pressure in decontamination rooms should be negative or neutral to surrounding areas
- Eye wash stations should be present and inspected at least weekly and in accordance with Safety Office procedures. Eye wash station covers should not be dangling off to prevent spray nozzle contamination.
- Appropriate PPE (as in Section VII above) should be available and worn at all times by staff performing high-level disinfection
- Cleaning solutions should be clearly labeled, including with new expiration dates when opened
- Clean and dirty areas should be separated, clearly marked, and should NOT cross over.

XI. AUTOMATED INSTRUMENT REPROCESSING

Several areas performing high-level disinfection of reusable semi-critical instruments and scopes, including but not limited to the GI endoscopy area, utilize automated endoscope reprocessors or washers. In some studies, use of automated washers/reprocessors has been shown to reduce microorganism bioburden more efficiently than manual methods.

In such areas where automated reprocessing methods are used, staff should refer and adhere to the local unit standards and the Nursing High-Level Disinfection Procedures policy for specific procedures related to the reprocessing of semi-critical instruments used in their areas.

Additional general principles that staff performing automated scope reprocessing should adhere to include:

- Staff should follow MIFUs for both the instrument and the automated reprocessing/washing machine
- If for any reason an automated reprocessing machine cycle is interrupted, a full cycle should be repeated
- Quality checks of automated reprocessing solutions should be performed using test strips as per MIFUs
- Automated reprocessors should never be operated with any solution other than that specifically recommended in the MIFU

XII. MANUAL CLEANING

In areas where automated instrument reprocessing is unavailable ***or when*** automated instrument reprocessing machines are in need of repair or unusable, staff will revert to manual high-level disinfection procedures in accordance with their unit standards and instrument MIFUs.

- Special attention should be paid to MIFUs regarding the following during manual cleaning:
  - Solution temperature requirements (requires a thermometer)
  - Chemical disinfectant/solution concentrations (including test strip verification)
  - If solutions do not "Pass" minimum effective concentration verification, solutions should be discarded and not used
  - Manual rinsing (performed automatically as part of most automated reprocessing cycles) should be performed using the water quality required per MIFUs and rinse water discarded after each use
  - Documentation of process and parameters in Processing Log

XIII. STAFF COMPETENCY & TRAINING

Personnel who are engaged in High-Level Disinfection processes

- Must be properly trained by an expert or competent technician in high-level disinfection
- Training checklists of competencies should be thoroughly documented and available for review on request
- Competency review should be done at a minimum at the following intervals:
  a) Upon employment/transfer to the unit performing high-level disinfection
  b) At least annually for all staff performing high-level disinfection
  c) When/if a breach in high-level disinfection practices is identified
  d) When new equipment or reprocessing materials are purchased

REFERENCES:

1. CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities (2008). Available online at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html
2. 2022 APIC Textbook. Chapter 31: *Cleaning, Disinfection, and Sterilization*.
3. LAC+USC Department of Nursing Policy #1207: High-Level Disinfection Procedure.
4. American National Standard Institute /AAMI ST91 (2021) Flexible and semi-rigid endoscope processing in healthcare facilities.

APPENDIX A: Sample Tracking Log

Procedural Unit Name & Location (e.g., D&T B4J Endoscopy)	**SCOPE TRACKING LOG**		
Patient Name / MRN	**Type of Scope Used (Check)**	**TIME**	
	☐ Colon ☐ EGD ☐ Flex ☐ Push ☐ Other: __________	IN	
	Scope Serial No. ________________________________	START	
	Physician Name: ________________________________	END	
	Tech's Name: __________________________________	OUT	
Patient Name / MRN	**Type of Scope Used (Check)**	**TIME**	
	☐ Colon ☐ EGD ☐ Flex ☐ Push ☐ Other: __________	IN	
	Scope Serial No. ________________________________	START	
	Physician Name: ________________________________	END	
	Tech's Name: __________________________________	OUT	
Patient Name / MRN	**Type of Scope Used (Check)**	**TIME**	
	☐ Colon ☐ EGD ☐ Flex ☐ Push ☐ Other: __________	IN	
	Scope Serial No. ________________________________	START	
	Physician Name: ________________________________	END	
	Tech's Name: __________________________________	OUT	
Patient Name / MRN	**Type of Scope Used (Check)**	**TIME**	
	☐ Colon ☐ EGD ☐ Flex ☐ Push ☐ Other: __________	IN	
	Scope Serial No. ________________________________	START	
	Physician Name: ________________________________	END	
	Tech's Name: __________________________________	OUT	