



State of California—Health and Human Services Agency
Department of Health Services



SANDRA SHEWRY
Director

Governor

April 30, 2007

AFL 07-09

TO: Facility Administrators and Infection Prevention and Control Professionals
Of:
General Acute Care Hospitals (GACH)
Correctional Treatment Centers (CTC)
Surgical Clinics (SC)

SUBJECT: Inadequate Reprocessing of Semicritical Instruments:
Recommendations for Reprocessing of Rigid Laryngoscopes

Over the past 18 months, the California Department of Health Services was notified of events in healthcare facilities where reusable semicritical medical instruments were routinely not subjected to adequate high level disinfection or sterilization. These included the following:

1. An outbreak of *Pseudomonas aeruginosa* in an acute care hospital was related to rigid laryngoscopes used to intubate neonates which were subjected to cleaning but no further reprocessing. According to the hospital, the laryngoscope blade manufacturer recommends cleaning (including soaking in enzymatic solution) and then either disinfection using glutaraldehyde or autoclave sterilization.
2. An acute care hospital reported that facility staff had not been disinfecting bougies (solid non-lumened silicon instruments used to dilate the esophagus) according to the manufacturer's recommendations. This practice had been ongoing since 2003; 64 patients were identified for possible exposure to bloodborne pathogens. The identified patients were notified by their physicians.
3. An acute care hospital reported that a per diem medical assistant, previously trained and found to be competent to clean and sterilize gastrointestinal endoscopes, had been reassembling the parts of endoscopes incorrectly and may not have correctly sterilized the internal parts as recommended by the manufacturer. Patients on whom the endoscopes had been used were notified by their physicians.

4. An acute care hospital reported that during infection control rounds it was discovered that flexible laryngoscopes used for difficult intubations were being reprocessed in the surgery department, using a single automated reprocessor. When the reprocessor was unavailable due to maintenance procedures, the laryngoscopes were cleaned but not disinfected. Patients who had been intubated at those times were notified and tested for tuberculosis.
5. An outbreak of *E. coli* respiratory tract infections in an acute care hospital was related to the use of a transesophageal echocardiography probe that was frayed and should have been returned to the manufacturer for repair or replacement.

In addition to failures to perform disinfection or sterilization as recommended, the Department continues to be notified of deficiencies in reprocessing of endoscopes as described in the All Facilities Letter AFL 04-21, October 12, 2004, [Immediate Assessment of Endoscope Reprocessing Procedures and Event Notification](#). These deficiencies, although less common than prior to the AFL, continue to be primarily the result of human error.

Attached are general recommendations for reprocessing rigid laryngoscopes. These are provided as a guide in the development of specific policies and procedures for the reprocessing these items, in conjunction with the reprocessing instructions provided by the laryngoscope's manufacturer. Recommendations for the reprocessing of other semicritical devices have not been provided here; it is presumed that the facility will reference manufacturer's recommendations for that equipment and write their reprocessing policies accordingly.

It is recommended that each facility review their existing policies and procedures, and modify them as indicated for the facility and the type and model of each instrument. It is also strongly recommended that infection control staff conduct a thorough inspection of all areas in their facilities where such instruments are used. Areas include crash carts on nursing units, surgery, emergency department, intensive care, invasive radiology, gastroenterology, pulmonology, etc. Actual practices for reprocessing should be observed. When reprocessing changes are indicated, stake-holding staff should be involved in the improvement process. Occurrences of inadequate reprocessing identified should be reported as unusual occurrences to the Licensing and Certification district office with jurisdiction over the facility as well as to the local health department. Please contact Jon Rosenberg or Sue Chen at (510) 620-3434 or Marian McDonald at (707) 576-2380 if you have any questions or comments.

Sincerely,

Original Signed by Pamela Dickfoss for Kathleen Billingsley, R.N.

Kathleen Billingsley, R.N.

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Deputy Director

Attachments

cc: District Office Managers and Administrators
District Office Preceptors
Central Training Unit

Disinfection of Medical Instruments

Classes of Instruments

Reusable medical instruments are divided into three classes for the purpose of determining the level of disinfection required (Spaulding Classification): critical, semicritical, and noncritical.

Critical instruments are those that penetrate normally sterile tissue, including blood vessels. Examples, in addition to surgical instruments and implants, include arthroscopes, laparoscopes, and endoscopic biopsy forceps.

Semicritical instruments contact mucous membranes or non-intact skin, but are not intended to penetrate sterile tissue. Examples include gastrointestinal endoscopes, cystoscopes, bronchoscopes, anesthesia and respiratory therapy equipment, vaginal probes used in diagnostic radiology, fitting diaphragms, flexible laryngoscopes, and the blades of rigid laryngoscopes. Items directly attached to instruments that contact mucous membranes, such as the handles of rigid laryngoscopes, should be considered semicritical instruments. Tonometers (used to measure ocular pressure) are also often not appropriately disinfected, resulting in outbreaks of epidemic keratoconjunctivitis.

Noncritical items are those that come in contact with only intact skin, and include blood pressure cuffs, linens, tourniquets, and general use equipment, furnishings, and environmental surfaces.

Critical instruments should be sterilized before reuse and semicritical instruments should be subjected to at least high level disinfection or sterilization, while non-critical items require only low or intermediate level disinfection prior to use.

Levels of Disinfectants

Sterilants destroy all microorganisms, including bacterial endospores. Examples of sterilants include pressurized steam, ethylene oxide gas, and hydrogen peroxide plasma.

High level disinfectants destroy all pathogenic microorganisms, including some bacterial endospores during short exposure times, and can destroy high numbers of bacterial endospores during long exposures times. Examples include 2% glutaraldehyde, 7.5% hydrogen peroxide, and 0.2% peracetic acid.

Intermediate-level disinfectants, labeled as tuberculocidal, destroy many types of microorganisms including *Mycobacteria*, but not endospores. Examples include bleach, phenolic compounds, alcohols, and concentrated quaternary ammonium compounds. These are also commonly used for disinfection of environmental surfaces, including blood spills.

Low-level disinfectants destroy some types of microorganisms, but not endospores or *Mycobacteria*. Examples include alcohols and diluted quaternary ammonium compounds.

Intermediate and low level disinfectants are not licensed for use in reprocessing critical or semicritical patient care equipment. The classification and disinfection requirements are shown below.

Body Contact	FDA Device Class	Disinfection Requirements
Sterile site, vascular	Critical	Sterilization
Mucous membranes	Semicritical	High level
Intact skin	Non-critical	Low level

California Department of Health Services

Recommendations for Reprocessing Rigid Laryngoscopes

Flexible and rigid laryngoscopes, both blades and handles, are classified as semicritical devices, and therefore require **(1) cleaning** and **(2) high-level disinfection or sterilization**. We recommend high-level disinfection or sterilization regardless of whether a protective barrier or sheath is used during the procedure, since the laryngoscope may be contaminated during use or removal of the sheath. Quaternary ammonium products and other cleaner/disinfectants, labeled to achieve intermediate-level (or low-level) disinfection, including alcohol or other disinfectant wipes, should never be used for reprocessing flexible and rigid laryngoscopes or other semicritical devices. Finally, the laryngoscope should always be **(3) dried** to prevent contamination after reprocessing. The laryngoscope should be **(4) examined** for visible evidence of damage and removed from use if damage is observed or suspected.

The following recommendations have been adapted from Muscarella LF. "Guidelines for reprocessing rigid laryngoscopes." The Q-Net Monthly 2004 Sept-Oct; 10(9, 10):17-20 (www.myendosite.com/htmlsite/2004/septoct04.pdf). To our knowledge these are the only published guidelines specific to reprocessing rigid laryngoscopes. They may be used to develop a facility specific policy and procedure for reprocessing laryngoscopes, in conjunction with the reprocessing instructions provided by the laryngoscope's manufacturer, which may require additional reprocessing steps.

STEP 1. Transportation (from point of use)

After use, the laryngoscope blade and handle should be promptly transported in an enclosed bag, package, or container to a dedicated decontamination area for reprocessing. Prolonged delay between use of the laryngoscope and reprocessing can result in the drying and hardening of debris on the laryngoscope's surfaces. Dried debris can be difficult to clean, can interfere with the effectiveness of disinfection or sterilization, and can damage the laryngoscope

STEP 2. Disassembly (in the decontamination area)

The blade should be disconnected from the handle and disassembled as described in the laryngoscope manufacturer's reprocessing instructions. For some models the light bulb or fiber optic light pipe or bundle may need to be removed from the blade, and/or the batteries or lamp cartridge assembly from the handle.

STEP 3. Cleaning

The blade and handle should be cleaned using fresh, clean potable water, enzymatic detergent, a soft brush, and a cloth. Soak the entire blade and handle in the detergent solution (unless complete immersion of either is contraindicated according to the laryngoscope's manufacturer's reprocessing instructions) for the recommended time. Rinse the blade and handle with a large volume of fresh, clean potable water (or, clean, demineralized water), dry with a clean, dry, soft lint-free cloth or towel and examine the blade and the handle for cleanliness and for damage. Unless recommended by the manufacturer, the handle and blade should not be ultrasonically cleaned.

STEP 4. Sterilization or High-Level Disinfection

The blade and handle should be packaged and steam sterilized unless it is contraindicated in the laryngoscope's reprocessing instructions. If steam sterilization of the blade and/or handle is contraindicated, consider using a low-temperature sterilization process. Refer to the laryngoscope's reprocessing instructions for a list of recommended low-temperature sterilization processes. Pasteurization may also be a recommended method for reprocessing the laryngoscope's blade and/or handle.

If sterilization of the blade and/or handle is not feasible, high-level disinfection should be used according to the laryngoscope manufacturer's reprocessing instructions. The concentration of the liquid chemical sterilant should be monitored to ensure it is equal to or above its *minimum effective concentration*, or "MEC."

After high-level disinfection, rinse the blade and/or handle with a large volume of sterile, demineralized water (or, fresh, clean potable water). Inadequate rinsing may result in instrument damage or injury to the patient's respiratory mucosa. Do not reuse the rinse water. The blade and/or handle should then be dried with a clean, dry, soft lint-free cloth or towel. A cloth dampened with 70% alcohol may be used to facilitate drying.

STEP 5. Transportation, Storage, Handling, and Care

If the laryngoscope is to be used immediately following reprocessing, transport the blade and handle from the reprocessing area to the point of use. Reassemble the blade and handle.

If the laryngoscope is to be stored prior to use, transport it to where it is to be stored, using care to prevent re-contamination and damage prior to and during storage. Refer to the laryngoscope's instructions for proper storage. The area should be clean and dry. To avoid bacterial colonization, it is recommended that the blade and handle not be stored in a closed carrying case, container, or kit. The availability of laryngoscopes assured to be in proper working order can reduce the risk that inadequately disinfected laryngoscopes will be used.

References

Muscarella LF. "Guidelines for reprocessing rigid laryngoscopes." *The Q-Net Monthly* 2004 Sept-Oct; 10(9, 10):17-20 (www.myendosite.com/htmlsite/2004/septoct04.pdf).

Muscarella LF. Recommendations to resolve inconsistent guidelines for reprocessing of sheathed and unsheathed rigid laryngoscopes. *Infect Control Hosp Epidemiol* 2007; 28:504-507.