Semi-Critical Medical Device Cleaning and Disinfection Protocol

This document has been developed in accordance with current applicable infection control and regulatory guidelines. It is intended for use as a guideline only. At no time should this document replace existing documents established by the facility unless written permission has been obtained from the responsible facility manager.

PREFACE

The overall goal of infection prevention practices for Semi-Critical devices or instruments such as laryngoscope blades, pessary and diaphragm fitting rings, breast pump accessories etc is to eliminate the risk of the transmission of pathogens between patients and between patients and the health care worker. The following recommendations should be implemented when cleaning and disinfecting. These procedures follow the Spaulding Classification of the level of care required for surfaces and instruments.

Laryngoscope blades, pessary and diaphragm fitting rings, breast pump accessories etc are examples of devices or instruments classified as Semi-Critical items. These are devices that come in contact with non-intact skin or mucous membranes but ordinarily do not penetrate them. Reprocessing semi-critical items involves meticulous cleaning followed by high-level disinfection (HLD).

PREPARATION

Appropriate cleaning, disinfection and sterilization of patient care equipment are important in limiting the transmission of organisms related to reusable patient care equipment. Cleaning is an extremely important part of equipment and instrument reprocessing and is necessary to permit maximum efficacy of subsequent disinfection and sterilization treatments.

PROTECTIVE BARRIERS

1. Disposable gloves. Gloves should be changed as required, i.e., when torn, when hands become wet inside the glove or when moving between patient rooms.
2. Household gloves can be worn, but they must be discarded when the cleaning is complete.
3. Protective Eye wear (goggles, face shield or mask with eye protection)
4. Masks (surgical or procedural masks sufficient)
5. Gowns

PRODUCTS

All disinfectant or disinfect-cleaner products to be use for cleaning and disinfection of Patient Care Equipment and Devices must be approved by Health Canada and carry a Drug Identification Number (DIN). Products claiming to be a disinfectant but do not carry a DIN have not been approved for sale in
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Canada and should not be used. For registration as a High Level Disinfectant (HLD), products must provide proven efficacy against Fungi using Trichophyton mentagrophytes, Mycobacteria using *M. terrae* or *M. bovis* and Spores using *Bacillus subtilis* and *Clostridium sporogenes*. Efficacy against vegetative bacteria and viruses is not required as the assumption is that by achieving the requirements for high level disinfection the products will be effective against all classes of organisms.

Disinfectant Chemistries Approved for High Level Disinfection include:
1. Accelerated Hydrogen Peroxide  
2. Paracetic Acid  
3. Gluteraldehyde  
4. Hydrogen Peroxide  
5. Orthophthalaldehyde

The concentration, contact time and reuse claim for each product will differ. For that reason it is important to read the product label prior to commencing any cleaning and disinfection process.

**RECOMMENDED PROCEDURES FOR CLEANING AND DISINFECTION OF PATIENT CARE EQUIPMENT**

Soiled Semi-Critical devices should be clearly identified and kept separate from clean items. Examples of Semi-Critical Devices include: flexible endoscopes, bronchoscopes, laryngoscope blades, pessary and diaphragm fitting rings, breast pump accessories, respiratory therapy equipment, ear syringe nozzles, specula, and anaesthesia equipment. The contaminated devices should be cleaned in the dirty zone. Cleaning removes soil and body materials (e.g. blood, organic soils) and must occur as an integral first step before high level disinfection can occur.

**Summary of Procedure:**
Semi-critical disinfection involves disinfection of items that come in contact with mucous membranes and intact skin, but not with internal, natural sterile areas of the body. Cleaning of semi-critical items/equipment is an important step in the disinfection process to ensure the disinfecting of the items/equipment will be successful. Cleaning must be thoroughly done before “processing” because organic material may protect microorganisms from the disinfection process.

1. Cleaning should take place between each device/equipment usage. Items will be disassembled (as appropriate) and thoroughly cleaned to remove dried or wet sputum and/or blood.
2. To remove debris, thoroughly clean all instrument surfaces and lumens of hollow instruments with a detergent or enzymatic solution.
3. Following the cleaning step, instrument surfaces and lumens should be rinsed with large amounts of fresh water (potable or sterile) to remove residual detergent.
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4. Remove excess moisture from instruments prior to immersing into the HLD solution to avoid diluting the HLD solution below its Minimum Effective Concentration (MEC).

5. The HLD solution should be poured into a Sterilizing/Disinfection Tray or appropriate container with a lid. The tray or container should be clearly identified as to the HLD solution contained inside, the date the solution was placed in the container and the expiry date of the solution found in the container. [Refer to the product label for the reuse claim as well as the shelf life of the HLD Solution once the original container has been opened]

6. To achieve high level disinfection, immerse the device/equipment in the solution ensuring that as surfaces of the device are completely immersed.

7. Soak the devices for the contact time as listed on the product label. Once the contact time has passed, the device/equipment should be removed from the HLD solution using clean, disinfected tongs or forceps.

8. Unless stated on the label, HLD solutions are not intended to be used as storage solutions. Disinfected devices should be removed from the solution once the contact time has been achieved. Excessive soaking time is not recommended as it may result in residues that result in patient allergic reaction, tissue discolouration or degradation to the device itself.

9. The disinfected device/equipment should be thoroughly rinsed with sterile water when practical, otherwise potable water is acceptable for semi-critical devices not intended for use on immunocompromised patients or potentially immunocompromised patients based on institutional procedures (ie. high-risk populations).

10. Following removal from the HLD solution, thoroughly rinse device/equipment by immersing it completely in a large volume of water keeping the device/equipment totally immersed for a minimum of 1-minute repeating this step for 3 consecutive times. [Refer to product labels for specific rinsing instructions.]

11. Manually flush all lumens.

12. Remove device/equipment and discard the rinse water. Always use fresh water for each rinse. Do not reuse the water for rinsing or any other purposes.

13. Following the rinsing step the device/equipment should be dried and stored in a suitable manner to minimize recontamination (eg. a clear polyethylene bag).
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DISPOSAL OF INFECTION MATERIAL

All cleaning cloths gloves and handled tools used for the decontamination of a suspected Avian Flu virus case must be placed in a clearly marked plastic lined waste receptacle. Decontaminate all wastes before disposal; steam sterilization, chemical disinfection and or incineration.

REFERENCES

Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings, Provincial Infectious Diseases Advisory Committee (PIDAC), February 2010

Decontamination of Reusable Medical Devices (Z314.8-08), Canadian Standards Association (CSA), March 2008

Guideline for Disinfection and Sterilization in Healthcare Facilities, CDC, 2008