Standard Operating Procedure

Cleaning of Medical Devices According to Manufacturer's Written Instructions

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OBJECTIVES

Identify the required steps for decontamination of medical devices according to CSA compliant validated Manufacturer's Instructions for Use (MIFU).

PRINCIPLES

- Decontamination procedures shall be based on device manufacturer's instructions, the intended use of the device and the decontamination capabilities of the facility.
- Devices to be disinfected or sterilized shall first be cleaned. Cleaning may be done either manually or mechanically. Cleaning methods shall be consistent with the device manufacturer's instructions, and they shall be appropriate for the type of device, and amount of soil to be removed.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staff, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary) working within Medical Device Reprocessing.

ELEMENTS

1. Pre-cleaning
   - Immediately after use, the user shall pre-clean the device.
2. Sorting
   - Contaminated devices shall be sorted before reprocessing so devices requiring similar decontamination procedures or different cleaning agents. Sorting is also important to keep medical devices that belong to a set together.
3. Disassembly
   - All devices consisting of multiple components shall be disassembled in accordance with the manufacturer's instructions prior to cleaning.

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4. Soaking
    - Immersible devices with heavy or difficult to remove soil should be soaked in water or a cleaning solution to facilitate the cleaning process. Saline must **not** be used as a soaking solution. Prolonged soaking should be avoided to prevent damage to devices.
5. Cleaning
    - The device manufacturer's cleaning instructions shall be followed, including specifications for detergent type, water temperature, and cleaning methods. Medical devices shall be cleaned using an automated process whenever possible. The cleaning process helps to physically remove contamination from an item for further processing.
6. Rinsing
    - Following cleaning, devices shall be rinsed thoroughly to remove residues. The type of rinse water used shall be appropriate to the intended use of the device.

Note: The quality of water used for reprocessing medical devices is important, as poor water quality can contribute to damage (e.g., corrosion and pitting), as well as microbial contamination of devices being reprocessed. Although potable tap water is adequate for initial cleaning of medical devices, the final rinse shall be with water of appropriate quality, to ensure that neither inorganic residues nor bio burden will remain on the device after it has been rinsed.

7. Lubrication
    - Decontaminated devices requiring lubrication shall be lubricated according to the device **manufacturer's instructions.**
    - Devices shall be clean with all visible soil and rust removed before they are lubricated.
    - The lubricant shall be compatible with the device and with the cleaning, disinfection, and (if applicable) sterilization process that will be used.
8. Drying
    - The manufacturer's instruction shall be followed for the drying of a device.
    - All medical devices that require no further treatment shall be dried prior to storage.
    - Unless mechanically dried, devices shall be manually dried with a clean, lint-free, soft absorbent towel.
9. Reassembly
    - Reassembly shall take place in a clean area, and it shall be performed in accordance with the manufacturer's instruction and facility procedures.
    - Reassembled devices shall be complete and functional.
10. Inspections
    - Devices shall be inspected for functionality and damage, as well as cleanliness.
    - Inspection of devices shall include examination of:
        a) hinge and joint action;
        b) jaw and teeth alignment;
        c) ratchet alignment and function;

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d) cutting edge sharpness; and
e) all surfaces for wear, corrosion, chips, burrs, dents, loss of finish, or other damage.

11. Damaged devices

- Devices that are damaged or in poor working condition shall be removed from service, labelled, and segregated from usable devices. They shall be sent out for repair or discarded in an appropriate waste container. Upon return from repair, following re-inspection, the device shall undergo all reprocessing steps.

DEFINITIONS

None

REFERENCES

- Non-Alberta Health Services documents
  - *Reusable & Single-Use Medical Devices Standards.* (Government of Alberta-Alberta Health) (September 2019).
  - *Canadian Medical Device Reprocessing. (Canadian Standards Association*) (CAN/CSA Z314-18).

VERSION HISTORY

Date	Action taken
October 2017	Initial approval
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