Standard Operating Procedure

Reprocessing of Semi-critical Reusable Medical Devices

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OBJECTIVES

AHS is committed to providing safe patient care by ensuring applicable standards are adhered to for Medical Device Reprocessing (MDR).

PRINCIPLES

- Staff will be familiar with the Government of Alberta – Reusable & Single-Use Medical Device Standards.
- All reprocessing shall be done in accordance with Manufacturer Instructions for cleaning, disinfection and sterilization of medical devices.
- Newly purchased medical devices shall be reprocessed before initial use, unless packaged and sterilized by manufacturer.
- Devices that come from an opened or compromised package shall be reprocessed prior to use.
- All reusable medical devices should be pre-cleaned at the point of use.
- All reusable semi-critical devices shall be cleaned before high level disinfection or sterilization.

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
   1.1 Immediately after use, the user shall pre-clean the device.
2. Sorting
   2.1 Contaminated devices shall be sorted before reprocessing so devices requiring similar decontamination procedures or the same cleaning agents are separated from the devices that require a different decontamination procedure or different cleaning agents. Sorting is also important, so where possible, keep medical devices that belong to a set together.

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3. Disassembly
    3.1 All devices consisting of multiple components shall be disassembled in accordance with the manufacturer's instructions prior to cleaning.
4. Soaking
    4.1 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
    5.1 Medical devices should be mechanically cleaned whenever possible in accordance with the manufacturer's instructions.
    5.2 Manual cleaning is required for some delicate or complex devices. The device manufacturer's cleaning instructions shall be followed, including specifications for detergent type, water temperature, and cleaning.
    5.3 Devices with lumens shall be:
        a) cleaned with a brush in accordance with the manufacturer's instructions;
        b) manually or mechanically flushed with a detergent solution and rinsed;
        c) checked during cleaning to ensure they are unobstructed;
        d) properly cleaned according to manufacturer's instructions.
6. Rinsing
    6.1 Following cleaning, devices shall be rinsed thoroughly to remove residue by immersing in clean water. 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, e.g., reverse osmosis to ensure that neither inorganic residue nor bio burden will remain on the device after it has been rinsed.

7. Lubrication
    7.1 Decontaminated devices requiring lubrication shall be lubricated according to the device manufacturer's instructions.
    7.2 Devices shall be clean with all visible soil and rust removed before they are lubricated.
    7.3 The lubricant shall be compatible with the device and with the cleaning, disinfection, and (if applicable) sterilization proves that will be used.
8. Drying
    8.1 The manufacturer's instructions shall be followed for the drying of a device.
    8.2 All medical devices that require no further treatment shall be dried prior to storage.
    8.3 Unless mechanically dried, devices shall be manually dried with a clean, lint-free, soft absorbent towel.
9. Reassembly
    9.1 Reassembly shall take place in a clean area, and it shall be performed in accordance with the manufacturer's instructions and facility procedures.

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9.2 Reassembled devices shall be complete and functional.

10. Inspection

10.1 All devices shall be inspected for proper function, damage and cleanliness in accordance with manufacturer's instructions.

10.2 Inspection of devices shall include examination of:

a) hinge and joint action;
b) jaw and teeth alignment;
c) ratchet alignment and function;
d) cutting edge sharpness; and
e) all surfaces for wear, corrosion, chips, burrs, dents, loss of finish, or other damage.

10.3 Devices that are damaged, or are in poor working condition shall be removed from service, labelled, and segregated from usable devices.

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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