Standard Operating Procedure

Reprocessing of 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.

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 critical devices shall be cleaned before 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.
3. Disassembly
   3.1 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
   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.

11. Packaging

11.1 Examples of packaging materials (i.e. sterile barrier systems) include but are not limited to:

a) pouches;
b) wrappers; and
c) rigid container systems.

11.2 Select the type of wrappers/containers/packages according to sterilization methods and device manufacturer's instructions.

11.3 Securing and closing of packaging (e.g., heat sealing) shall be done following manufacturer's instructions of packaging material.

11.4 Internal pouches and wraps shall not be used inside a wrapped set or rigid container, unless specifically validated by the packaging material manufacturer.

11.5 Processed containers or packages that are damaged, visibly soiled, wet or have been dropped on the floor shall be considered contaminated.

12. Sterilization

12.1 Type of sterilization and parameter for each cycle in accordance with manufacturer's written Instructions. Examples of sterilization methods and cycles include but are not limited to:

a) Steam sterilization: heat tolerant devices
   I. Gravity cycles
   II. Dynamic air removal cycles
   III. Steam flush pressure pulse
b) Low temperature sterilization STERRAD® NX: heat and moisture sensitive devices
   I. Standard
   II. Flex
   III. Express
   IV. Duo

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c) Low temperature sterilization V-Pro® maX 2: heat and moisture sensitive devices
    I. Non-lumen
    II. Fast non-lumen
    III. Flexible
    IV. Lumen
d) Ethylene oxide sterilization: heat and moisture sensitive devices
    I. Standard
e) Liquid chemical sterilization: heat resistant and moisture tolerable devices
    I. Standard

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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