Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices

In BC Health Authorities

THIS DOCUMENT IS INTENDED TO DESCRIBE BEST PRACTICES

HEALTH CARE SETTINGS ARE ENCOURAGED TO WORK TOWARDS THESE BEST PRACTICES IN AN EFFORT TO IMPROVE QUALITY OF CARE.

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susceptible to routine sterilization. Sterilization is used on critical medical devices and, whenever possible, semi-critical medical devices. **The preferred method for sterilization of heat-resistant critical devices is steam sterilization (pre-vacuum sterilization is preferred).**

For devices that cannot withstand steam sterilization, some examples of chemical sterilants include:

a) Hydrogen peroxide gas plasma;
b) 0.2% peracetic acid;
c) 7% accelerated hydrogen peroxide;
d) 100% ethylene oxide; and
e) Ozone.

For processes for liquid chemical sterilant manual soaking, follow section 9.D.

- Refer to Appendix B, '*Reprocessing Decision Chart*', and Appendix D, '*Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options*' for chemical products that may be used to achieve sterilization.

A. Sterilization Process

Medical devices that have contact with sterile body tissues or fluids are considered critical items.[181] All critical medical devices shall be cleaned and then sterilized,[182,183,184,185] because microbial contamination could result in disease transmission. Critical items include, but are not limited to, surgical instruments, implants, foot care equipment, endoscopes that enter sterile cavities and spaces, colposcopy equipment, biopsy forceps and brushes, eye and dental instruments.

Whenever possible, semi-critical medical devices should be sterilized. (Semi-critical medical devices have contact with non-intact skin or mucous membranes but do not penetrate them.[186]) When sterilization is not possible, semi-critical devices shall be cleaned, followed by high-level disinfection.[187]

Health care settings shall have written policies and procedures for sterilization processes that:

a) Follow the principles of infection prevention and control as set out in CSA standards,[188, 189, 190] BC Ministry Best Practice Guidelines and PHAC guidelines[191];
b) Follow manufacturer's instructions for installation, operation, cleaning and preventive maintenance of the sterilization equipment;
c) Follow manufacturer's instructions for cleaning and preparation of the medical device. The instructions shall be validated, written and device specific; and
d) Describe the preparation of devices to be sterilized (i.e., disassembly, cleaning, drying, inspection, lubrication, wrapping, sealing and labelling)[192,193,194]

B. Steam Sterilization Methods

Steam sterilization is a process that uses saturated steam under pressure as the sterilant. It is the preferred method for sterilizing critical medical devices. Written policies and procedures for steam shall include:

- Staff qualification, education/training and competency assessment;
- Preparation and packaging of medical devices;
- Sterilization procedures; and
- Monitoring and documenting of cycle parameters.

The manufacturer's instructions for installation, operation and ongoing maintenance of steam sterilization equipment shall be followed.

For each cycle, the sterilization time and temperature shall be monitored and recorded.

Monitoring of the sterilization cycle shall include:

- Physical (displays and printout);
- Chemical (internal and external indicators); and
- Biological.

There are several types of steam sterilizers that utilize different methods to remove air from packages and the chamber. They are dynamic air removal (prevacuum), gravity, and steam-flush pressure-pulse sterilizers.

Prevacuum sterilizers:

- Use a vacuum pump or water ejector to remove air from the chamber and packaged devices during the preconditioning phase and prior to sterilization;
- Operate at 132°C to 135°C.

Gravity sterilizers:

- Use gravity air displacement to remove air from the sterilizer chamber and packaged devices;
- Operate at 121°C or higher.

Steam-flush pressure-pulse:

- Use a repeated sequence of a steam flush and pressure pulse to remove air from the chamber and packaged items;
- Operate at 121°C to 123°C, 132°C to 135°C or 141°C to 144°C.

Steam sterilizers vary in chamber size from small table top models to large floor loading models. The recommended practices described in this guideline shall apply to all types (and sizes) of steam sterilizers, including table top sterilizers.

Users shall obtain written validated device specific instructions from the device manufacturer and sterilizer efficacy testing from the sterilizer manufacturer when utilizing the steam sterilization method.

i. Device Preparation

Devices shall be prepared for sterilization in the following manner:

- Clean, with excess water removed;
- Jointed instruments in the open or unlocked position;
- Multi-piece or sliding pieces disassembled unless otherwise indicated by the device manufacturer;
- Devices with concave surfaces that will retain water are placed in such a manner that condensate does not collect;
- Instruments with lumens moistened with distilled water immediately prior to sterilization;
- Heavy items arranged as to not damage lighter more delicate items; and
- Sharp instruments with tips protected.

ii. Packaging

Packaging materials for steam sterilization shall:

- Be validated for steam sterilization;
- Contain no toxic ingredients or dyes;
- Be capable of withstanding high temperatures;
- Allow air removal from packages and contents;
- Permit sterilant contact with the package contents;
- Permit drying of the package and contents;
- Prevent the entry of microbes, dust and moisture during storage and handling;
- Have a proven and tamper-proof seal;
- Withstand normal handling and resist tearing or puncturing; and
- Allow for aseptic presentation.

Packaging manufacturer's instructions for use shall be followed.

The total weight of instrument sets and their packaging shall not exceed 10 kg.[195]

The total weight of a wrapped basin set shall not exceed 3 kg.[196]

iii. Loading

Steam sterilizers shall be loaded in the following manner to ensure sterilant contact and penetration:

- Package placement to avoid overloading;
- Non-perforated tray and container placed on their edge;
- Packages away from chamber walls;
- Concave devices on an angle to avoid condensate pooling;
- Textile packs perpendicular to the sterilizer cart shelf;
- Steri-peel on its edge with multiple packages being placed paper to plastic; and
- Rigid containers shall not be stacked unless validated by the manufacturer for that configuration.

The operator responsible for loading and initiating the cycle shall be documented.

iv. Unloading

Upon completion of the cycle, the operator responsible for unloading the sterilizer shall:

- Review the sterilizer printout for the following:
    - Correct sterilization parameters;
    - Cycle time and date; and
    - Cycle number matches the lot control label for the load.
- Verify and initial that the correct cycle parameters have been met;
- Examine the load items for :
    - Any visible signs of moisture; and
    - Any signs of compromised packaging integrity.

Printed records of each cycle parameters (i.e., temperature, time) shall be retained in accordance with the health care setting's requirements.[18]

v. Load Cool-Down

Upon removal of the sterilized load the operator shall:

- Visually verify the results of the external chemical indicators;
- Allow the load to cool to room temperature. The amount of time for cooling depends on the Devices that have been sterilized; and
- Ensure cool-down occurs in a traffic free area without strong warm or cool air currents.

vi. Troubleshooting—Wet Pack Problems

Packages are considered wet when moisture in the form of dampness, droplets or puddles are found on or within a package. There are two types of wet packs; those with external wetness and those with internal wetness. Sterility is considered compromised and the package contents considered contaminated when wet packs are found. There are several causes of wet packs. The following is a list of possible causes:

- Packages are improperly prepared or loaded incorrectly;
- Condensation dripping from the sterilizer cart shelf above the item;
- Condensation dripping from rigid sterilization containers placed above absorbent packaging;
- Condensate blowing through the steam lines into the sterilizer chamber;
- Instrument or basin sets that are too dense or lack absorbent material to wick moisture away;
- Linen packs wrapped too tightly; and/or
- Sterilization containers with a low metal-to-plastic ratio.

For a more information on troubleshooting wet packs, refer to:
www.health.qld.gov.au/chrisp/sterilising/section_appendix.pdf

vii. Immediate Use Steam Sterilization (Flash Sterilization)

Immediate Use Steam Sterilization shall be used only for situations where:

(a) There is an urgent or unplanned need

(b) There are documented policies and procedures for this practice that shall include:

- Training of staff performing “Immediate Use Steam Sterilization”;
- Transport of contaminated devices to decontamination area;
- Disassembly and decontamination;
- Preparation and containment;
- Sterilization procedures; and
- Monitoring and documenting of cycle parameters.

The physical layout and documented procedures shall assure direct delivery of the sterilized item to the point of immediate use.

Containers used for “Immediate Use Steam Sterilization” of devices shall be validated for that purpose.

“Immediate Use Steam Sterilization” shall not be used to:

- Sterilize implants;
- Sterilize complete sets or trays of instruments; or
- Compensate for inventory shortages or scheduling difficulties.

Procedures for "Immediate Use Steam Sterilization" shall include daily biological indicator testing of the sterilizer used for the cycles.

"Immediate Use Steam Sterilization" cycles shall be documented so that:

- Devices can be traced to the patient should there be an adverse event.(e.g. failed BI);
- Inventory requirement can be monitored; and
- Ways to reduce the need for "Immediate Use Steam Sterilization" can be identified.

Documentation shall contain the reason for "Immediate Use Steam Sterilization", description of the device, the patient's name, the surgeon's name, and the time and date of the procedure. A report shall be prepared, reviewed, and maintained in accordance with the facility's risk management policy.

For more information regarding the use and requirements of "Immediate Use Steam Sterilization", refer to CSA Standard Z314.3-09, '*Effective Sterilization in Health Care Facilities by the Steam Process'* [*Section 13]*.[197]

viii. Table Top Sterilizers

For detailed information on table top sterilizers, refer to CSA "Plus 1112" *Infection prevention and control in office based health care and allied service (Section 4.4).*[198] and AAMI ST 55: 2010 *Table top steam sterilizers.*[199]

C. Chemical (Low Temperature) Sterilization Methods

Chemical gases (Low Temperature) sterilization shall be used to sterilize heat and moisture sensitive medical devices. Written policies and procedures for chemical sterilization shall include:

- Staff qualification, education/training and competency assessment;
- Preparation and packaging of medical devices;
- Sterilizer operating procedures;
- Monitoring and documenting of chemical or cycle parameters;
- Workplace health and safety protocols specific to the chemical sterilant e.g. WHMIS; and
- Handling, storage and disposal of the sterilant. Consult sterilant manufacturer's instructions for use and local regulations.

Device compatibility will vary with each low temperature sterilization method. The user shall obtain written functional compatibility information from the device manufacturer and sterilizer efficacy information from the sterilizer manufacturer.

Low temperature (gas) sterilization can be achieved using a number of different chemicals including:

- Hydrogen peroxide gas plasma;
- Ozone;
- Liquid peracetic acid; and
- Ethylene Oxide.

Refer to Appendix D, *'Advantages and Disadvantages of Currently Available Sterilization and High Level Disinfection Options'* for information about these methods.

Packaging material used for chemical sterilization shall be validated for that method.