

## Sterilization

**Operators should consult with their local public health unit when considering methods of sterilization.** Pressure cookers, glass-bead sterilizers, microwaves, ultraviolet light, immersion in boiling water and domestic ovens are NOT approved methods of disinfecting or sterilizing equipment.

Instruments that penetrate the skin or mucous membranes (critical items) shall be sterile prior to use. These items may either be supplied sterile as pre-packaged, single-use disposable items or they may be provided as reusable items that must be cleaned, sealed in appropriate packaging and then sterilized on site before each use. Sterilization is a process that kills all forms of microorganisms including viruses, bacteria, fungi and bacterial spores. Sterilization is accomplished by using an autoclave, chemical autoclave, dry heat autoclave or a liquid chemosterilant. Multi-use tools/equipment must be thoroughly cleaned prior to sterilization.

### *On-site sterilization*

- All autoclaves must meet with Canadian Standards Association specifications for use in health care or allied health facilities.
- Follow manufacturer's instructions regarding packaging, loading, temperature, pressure and time requirements. Keep the manufacturer's instruction manual onsite and accessible at all times. It is critical that autoclaves are not overloaded.

Monitoring of an autoclave is critical to ensure adequate sterilization. There are three forms of monitoring required:

- Physical (mechanical)
  - a record/log must be maintained on site for monitoring each load, including recording the temperature, duration, pressure, date, initials of the individual who is responsible for sterilization of the load; and
  - monitoring records must held in a secure location on site for a minimum of one year, and on file for five years.
- Chemical (process)
  - during each cycle, every instrument/package must have a temperature sensitive indicator which changes colour if the packaged item was processed.
- Biological
  - each sterilizer actively used must pass a spore test challenge biweekly at a minimum;
  - spore test strips should be sent to an accredited laboratory for processing; and
  - results must be accessible on site for a minimum of one year and kept on file for 5 years.

**A “negative” test result (no spore growth) indicates the sterilizer is operating properly. A “positive” (spore growth) result means that the sterilizer has failed and is not producing sterile instruments.**

Personal services settings should be prepared in the event the mechanical sterilizer malfunctions or monitoring failures. Single-use disposable items, an alternative means of sterilization is required or no services should be offered. A written back-up plan is required. The written back up plan must be kept on site and ensure staff are well trained on the plan.

**The owner/operator shall contact their local health unit for every sterilizer failure immediately upon notification from the laboratory.**

### *Pre-Packaged Sterile Items*

- Pre-packaged sterilized items must be purchased from a reputable supplier and records of purchase must be kept on site.
- Each package must be clearly marked with the method of sterilization used by the manufacturer and a batch/lot/code number.
- A current copy of the certificate acknowledging the manufacturer's ability to provide sterilization services must be kept on site.

### *Maintaining Sterility*

- **Sterility must be maintained until point of use.**
- Use only packaging materials that are specifically designed and manufactured for use in sterilization.
- Equipment must be handled in a manner that prevents contamination of the item.
- Sterile equipment must be stored in a manner that protects it from contamination:
  - Reprocessed equipment must be stored in a clean, dry location;
  - Containers used for storage of clean equipment should be moisture-resistant and cleanable;
  - Store equipment in a clean, dry, dust-free area (not at floor level);
  - Equipment should be at least one meter away from debris, drains, and moisture; and
  - Processed equipment must be transported in a manner that avoids contamination or damage to the equipment/device.
- When opening sterile equipment, check for integrity of the packaging and the equipment to ensure sterility has been maintained.
- Check chemical indicators (colour change) and internal monitors if present.
- Check for defective equipment/devices and remove from use.
- Sterile packages that lose their integrity must be re-sterilized prior to use. If sterile package has become damp or wet (e.g. due to high humidity), reprocessing is required.

For more information contact York Region Health Connection 1-800-361-5653, TTY 1-866-252-9933