MIDDLESEX-LONDON HEALTH UNIT

Sterilization

Sterilization is a process of destroying all microorganisms, including bacterial spores, which are very resistant to high heat. Instruments that penetrate the skin and instruments that hold sterile items are called critical items and must be sterilized. Some equipment must be supplied sterile and discarded following use.

Methods Approved for Sterilization:

- Autoclaves that use heat and steam under pressure
- Dry heat sterilizers that use dry heat (without steam)
- Chemical autoclaves that use heat and a chemical solution under pressure

Methods *not* Approved for Sterilization:

- Glass-bead "sterilizer"
- Ultraviolet light ("UV Sterilizer")
- Ultrasonic cleaner
- Pressure cookers or cooking ovens
- Microwaves
- Boiling water

Some chemical (cold) sterilants (eg. gluteraldehyde) are not recommended because of issues concerning toxicity and the long contact time required to achieve sterilization. Also, once equipment is removed from the liquid, it is no longer sterile because it is not packaged.

Using your sterilizer

- Manufacturer's instructions regarding packaging, loading, temperature, pressure and time requirements must be followed. The sterilizer unit manufacturer's instruction manual must be accessible for reference within the premise at all times.
- Clean all items thoroughly before sterilization. Instruments that are not clean cannot be sterilized.
- Place all instruments in appropriate sterilization packages and seal.
- Place temperature sensitive chemical test strips or tape in with every load. (The chemical strip may already be part of the packaging).
- Load the sterilizer evenly (avoid overloading the chamber). Follow the manufacturer's instructions for loading.
- Follow the manufacturer's instructions for time, temperature and pressure. For dry heat and autoclave sterilization, time does not start until the appropriate temperature has been reached.
- Allow items to cool and/or dry before removing from sterilizer.
- Store sterilized items in a clean, dry place protected from dust, dirt and moisture.
- The shelf life of a sterilized item depends on storage and handling. Items will remain sterile indefinitely unless the integrity of the package is compromised (opened, wet, dirty). Equipment or devices purchased as sterile must be used before the expiration date if one is given.

There are three forms of monitoring required to ensure sterilization is achieved:

Physical (Mechanical) Monitoring- Record Keeping

- A log must be maintained on site for monitoring of each sterilization load. Records must be maintained on site for one year and on file for five years. Include:
    - **Date and time** of each load
    - **Temperature** of each load
    - **Time** the sterilizer stayed in the recommended temperature range
    - **Maximum pressure** reached in each load
- Temperature, pressure and time must be within the manufacturer's recommended operating range.
- Record when repairs are done, when spore tests are done along with the results of the spore tests, and any other notable occurrences related to the sterilizer.
- Use the **"Sterilization Log Sheet"** or similar to record information.

Chemical Monitoring

- During each sterilization cycle, every instrument/package must have a temperature sensitive indicator (tape or label) which changes colour if the packaged item was processed. The tape or label may already be part of the instrument wrapping or packaging.
- The indicator must be specific to the type of sterilizer used.

Biological Monitoring

- Biological monitoring must also be carried out because chemical indicators (indicator tape) do not provide proof of sterilization.
- Each sterilizer actively used must pass a spore test challenge **bi-weekly** (every other week) at a minimum.
- Different types of sterilizers require different types of spores for testing:
    - *Geobacillus (formerly Bacillus) stearothermophilus* spores are used to test steam autoclaves,
    - Bacillus atrophaeus (formerly .*Bacillus subtilis*) spores are used to test dry heat sterilizers, and
    - Both of the above can be used to test chemical autoclaves.

Test results are interpreted as follows:

- **A *negative* spore test result** (no spore growth) means that the sterilizer is working properly.
- **A *positive* spore test result** (spore growth) means that the sterilizer has failed and must not be used until it has been serviced and demonstrates three consecutive negative tests.
- Prior to using a new sterilizer or after the repair of a used one, three consecutive negative tests (no spore growth) must be demonstrated.
- Spore test results must be available on site for one year and on file for five years.
- Written back-up plans must exist in the case of a failed spore test.

The owner/operator shall contact the health unit immediately upon notification of a positive test from the laboratory.

For more information please contact the Infectious Disease Control Team at 519-663-5317 ext. 2330 or go to www.healthunit.com

Source:
Ontario Ministry of Health and Long-Term Care. (2009). *Infection prevention and control best practices for personal services settings*. Retrieved from http://www.health.gov.on.ca/english/providers/program/pubhealth/oph_standards/ophs/progstds/pdfs/pssp_2008.pdf

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