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Guidance for Operators: STERILIZATION

Sterilization is a process of destroying all microorganisms including bacterial spores, which are very difficult to kill. Instruments that break through the skin, or entire sterile tissue, as well as instruments that hold sterile items, are called critical items. These items present a high risk of transmission of microorganisms if contaminated and must be sterilized. Some equipment must be supplied sterile and discarded following use.

EXAMPLES OF REUSABLE ITEMS THAT REQUIRE STERILIZATION:

Piercing equipment:

- Forceps and clamps
- Insertion tapers
- Connectors
- Open ended receiving tubes
- Pliers

Tattooing equipment:

- Metal tubes, grips and tips

APPROVED STERILIZERS:

Operators must ensure that sterilizers used at the setting are suitable for sterilizing the equipment used at the setting and meet the standards established by Health Canada and the Canadian Standards Association. Operators can verify sterilizers that are licensed for sale by Health Canada by checking the **Medical Devices Active License Listing.**

The preferred method for decontamination of heat-resistant equipment and instruments is steam sterilization. Steam sterilizers can be gravity-displacement or dynamic air removal (e.g., pre-vacuum) sterilizers. Dynamic air removal sterilizers are recommended. For critical equipment or instruments that cannot withstand heat sterilization, chemical sterilization is required.

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What is NOT acceptable:

- Chemiclaves
- Flash Sterilization
- Glutaraldehyde
- Pressure Cooker
- Glass bead "sterilizers"
- UV "sterilizers"
- Ovens
- Boiling water
- Dishwasher (including those with sanitizing cycles)

MAINTAINING STERILITY:

- Must have manufacturer's manual on-site at all times.
- Must follow the manufacturer's instructions regarding packaging, loading, temperature, pressure and time requirements:
  - Packaging material must be specifically designed and manufactured for use in sterilizer;
  - Packages must not be damaged (wet, dirty, ripped, etc.). Tools that are in damaged packages must be reprocessed; and
  - Packages must be stored in a clean, dry location.
- Spore strips used for testing are to be packaged in the same manner as the equipment.

MONITORING STERILIZATION:

- Sterilization processes have to be monitored to ensure they are effective. Monitoring for sterilization includes mechanical, biological (spore tests), and chemical indicators.
- **All three processes are essential and must be used.**

Physical monitoring – verifies that the conditions for sterilization were achieved in the chamber during the cycle. The following information must be recorded aftereach sterilization cycle:

- Date and initials of the operator;
- The actual time of the sterilization phase;
- The actual temperature during the sterilization phase; and
- The actual pressure reached and maintained during the sterilization process.

Chemical monitoring – verifies that the package or area within the sterilizer where the device has been placed has been processed through a sterilization cycle.

- An external chemical indicator is to be used for each package or pouch that is undergoing sterilization, unless the design of the package allows the user to view the internal chemical indicator without opening the package. An internal chemical indicator is also to be placed inside each package, container, or bundle that is undergoing sterilization.

Biological monitoring – spore testing of the sterilizer must occur on a bi-weekly basis. Testing once each day that the sterilizer is used and for each type of cycle that is used is best practice. The following information must be recorded:

- Date of incubation;
- Date of reporting the results;
- Worker who conducted the test; and
- Unique identifier for the spore strip and growth medium (e.g., lot number).

*Negative test results (i.e., no spore growth) indicate that the sterilizer is operating properly

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FAILED SPORE TESTS:

- SWPH must be notified immediately in the event of a positive (failed) spore test.
- Work with your Public Health Inspector to assess any potential risk to clients and follow any instructions provided.
- Any equipment used after the last negative spore test result must be reprocessed with a working sterilizer before use.
- Recall and not use any equipment and instruments that were sterilized since the last negative (passed) spore test, including any equipment and instruments in the failed load.
- Repeat the biological monitoring (spore) test.
  - If that test is negative and there is no indication of a system malfunction, re-sterilize any equipment and instruments that were sterilized since the last negative spore test, prior to use, and then continue as normal.
  - If the repeat biological monitoring test is positive, stop using the sterilizer and determine if repair and/or maintenance is necessary.

BACKUP PLANS IN CASE OF FAILED SPORE TEST:

- The operator must have a written back-up plan available on site in case there are issues with the sterilizer and the plan should be reviewed annually. Back-up plans may include:
  - Having a back-up sterilizer;
  - Provide alternate means of sterilization;
  - Having an adequate supply of single-use, disposable and sterilized equipment;
  - Having a pre-arranged agreement with the manufacturer to loan the premises a sterilizer while the original is being repaired; and
  - Stop providing invasive services.

QUALIFYING STERILIZERS:

- Three consecutive negative spore test results must be demonstrated:
- When installing a new sterilizer;
  - After relocating a sterilizer;
  - After repairs;
  - After mechanical malfunctions (e.g., incorrect time, temperature); and
  - After power outages or other emergency scenarios (e.g., fire, flood).
- Operators are to refer to the sterilizer manufacturer's instructions for the types and placement of biological and chemical indicators for qualification testing.
- If backup sterilizers are used, they are to also pass the qualification tests.

RECORDS:

- Operators are required to keep the following sterilization records:
- Name and type of sterilizer used;
  - Date and time when the sterilizer was used;
  - The equipment on which the sterilizer was used;
  - Any preventative maintenance or repairs done on or to a sterilizer and whether the sterilizer functioned properly after the maintenance or repairs; and
  - The results of any checks or tests done on sterilizers
  - See template Sterilizer Record Form

These records must be kept onsite for at least one year. After the first year, records must be retained and kept readily available in a secure location for at least two years.

QUESTIONS?

If you have any questions please contact your area Public Health Inspector **1-800-922-0096**.