Sterilizer On-site

What is Sterilization?

- Sterilization is a process of destroying all microorganisms including viruses, bacteria, fungi, and bacterial spores.
- Thorough cleaning and sterilization reduce the risk of spreading diseases.
- All critical items must be sterilized. Critical items are those that pierce or penetrate the skin, and in some cases, those that hold sterile items. All sterile items must remain sterile until point of use.
- Must be monitored (refer to *Chemical & Physical Monitoring of Sterilizer, Biological Monitoring of Sterilizer* as well as the *Sterilization Log Sheet*).

Approved Sterilizers:

- Must meet standards established by Health Canada and the Canadian Standards Association (CSA).
- Operators must verify sterilizer is licensed for sale by Health Canada by checking the Medical Devices Active License Listing (https://bit.ly/2SL9Mpp).
- Must include:
  - manufacturer's directions on proper use of the sterilizer (e.g., maintenance, proper use of sterilizer, packaging, loading, etc.)
  - a specified drying cycle for packaged goods
  - gauge(s) to measure temperature and pressure
  - a timer
- The sterilizer should be equipped with a print-out (hard copy or digital accepted) that provides details of the mechanical parameters reached during the sterilization phase.
- Dry heat sterilizers are generally not preferred due to the length of cycle, the high temperatures required, and incompatibility with some equipment, instruments, and pouches.

Unapproved Sterilizers:

- Glass bead, ultraviolet (UV) light, ultrasonic, pressure cookers, microwaves, boiling water, dishwashers, ovens, chemiclaves, glutaraldehyde.

Steps for Proper Sterilization:

1. Clean instruments thoroughly (see *Cleaning Instruments Information Sheet*).
   Package item(s) in an open and unlocked position using an appropriate package (e.g., paper-plastic peel pouch).

Continued

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905-668-2020 or 1-800-841-2729
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Source: Guide to Infection Prevention and Control in Personal Service Settings, Public Health Ontario, July 2019.

2. Load sterilizer. Do not overload. Follow manufacturer's instructions for use (MIFU).
3. Monitor each cycle to verify that the sterilizer is in proper working order.
4. Follow MIFU on the drying cycle. Contamination can occur if packages are handled when wet.
5. Store sterilized items (in their packages) in a sanitary manner (e.g., clean containers with lids, storage drawers, etc.).

NOTE: Ensure to label your packages appropriately (e.g., sterilizer used, date, batch/lot number, operator's initials, etc.) on the plastic side beyond the sealed edge/area.

Monitoring Your Sterilizer Properly:

***Operator must notify the Health Department immediately of a spore test failure.**

1. Biological Monitoring: Spore tests must be conducted every other week, unless otherwise directed by the Health Department

- Spore tests use heat resistant bacterial spores to determine if the sterilizer is in proper working order.
- Spore tests must be sent to a laboratory for testing. Test results must be negative indicating spores were destroyed, hence that the sterilization process was satisfactory.

2. Chemical Monitoring: Must be used with each load

- Temperature sensitive tape/packaging must be placed in the sterilizer with each load.
- Chemical monitoring is a thermal indicator that changes colour if an adequate temperature or time has been reached. *This colour change is not indicative that sterilization has occurred*.

3. Physical Monitoring: Keep daily records for at least 1 year on site, and an additional 2 years on file thereafter

- Verify sterilizing parameters are achieved for each cycle.
- Where appropriate, record the sterilization temperature, sterilization time, sterilization pressure and date of each load. Refer to *Sterilization Log Sheet.*

4. Other Monitoring: You must verify that a sterilizer is functioning correctly by running 3 consecutive spore tests and keep records

- Before using a new sterilizer
- After major repairs or mechanical malfunction
- After relocating or power outages (e.g., fire, flood)

Back-up Plans:

- All owners/operators must have a written back-up plan in the event of a spore test failure. The back-up plan must be reviewed annually and located on-site for inspection.

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