STERILIZATION

Sterilization is the method of reprocessing instruments/equipment in order to destroy or inactivate all forms of microorganisms such as vegetative bacteria, bacterial spores, fungal spores and viruses, that may be found on them. Sterilization is required for critical instruments/equipment.

Critical instruments/equipment are those that penetrate the skin or mucous membranes, enter normally sterile tissue and/or have direct contact with the bloodstream. Some examples of critical instruments/equipment that require sterilization include tattoo and piercing needles and body-piercing jewellery for piercings.

INFECTION RISKS

There is a risk of infection transmission when:

- Critical instruments/equipment become contaminated with microorganisms and are not properly cleaned and sterilized after each use
- Critical Instruments/equipment are not properly packaged. This can compromise the sterility of items, and potentially expose clients and operators to disease-causing microorganisms
- Reusable items that are non-critical are exposed to blood and body fluids during an invasive procedure (e.g., metal grips/tips, receiving tubes, clamps and reusable scalpel handles). These must be treated as critical items and be sterilized after each use

STERILZATION EQUIPMENT

Sterilizers

- The preferred method to decontaminate heat-resistant instruments/equipment is steam sterilization. Sterilizers must meet the standards of Health Canada and Canadian Standards Association (CSA)
- All sterilizers are to be operated and maintained according to the manufacturer's instructions for use
- Regular maintenance and repairs on sterilizers must occur and be recorded
- Sterilizer qualification tests are to be run when installing new sterilizers, after relocating sterilizers, after major repairs or after mechanical malfunctions, power outages or other emergency scenarios. **The sterilizer is not to be used until results of three consecutive spore tests are all negative**

PUBLIC HEALTH
1-877-464-9675
TTY 1-866-512-6228
york.ca/BeSpaSafe

York Region

- All steam sterilizers are to be equipped with either a printout or a digital display that provides details of all three physical parameters (time, temperature and pressure) reached during each cycle. If no printout is generated, then these parameters must be physically monitored and manually recorded
- Sterilizers must have a drying cycle for all sterilization cycles for wrapped or packaged instruments/equipment
- A written backup plan for possible sterilizer failures is to be prepared and reviewed every year

  Important Reminder if sterilization failure has occurred:
  - The instruments/equipment in that load are not to be used
  - The instruments/equipment are to be cleaned, repackaged and re-sterilized
  - The operator is to use another method of sterilization or another procedure that prevents the introduction and/or spread of disease-causing microorganisms
  - If instruments/equipment from a failed load have been used, operators are to conduct appropriate notification and investigate the cause of the sterilization failure

STERILZATION PROCESS

General:

Reusable equipment/instruments **are to be thoroughly cleaned before sterilization** in order to ensure the sterilization process is effective.

- Cleaning of reusable instruments/ equipment is to take place immediately after use, to prevent any organic material (e.g., blood, body fluids, tissue) that is present from drying on them. If immediate cleaning is not possible, the instruments/equipment must be kept wet with detergent and water, an enzymatic cleaner or soaking solution until they can be cleaned. Prolonged soaking is to be avoided
- Before cleaning, instruments/equipment that have multiple components are to be disassembled according to the manufacturer's instructions for use
- Ultrasonic cleaners are to be used for critical instruments/equipment that have lumens, crevices or other areas that are difficult to clean
  - **If ultrasonic cleaners are used before sterilization, they must:**
    - Meet the standards of Health Canada and Canadian Standards Association (CSA)
    - Be provided with a lid, be cleaned, disinfected and refilled with clean solution daily, and tested weekly (at a minimum) to ensure they are working properly
    - Be operated and maintained according to the manufacturer's instructions for use
    - Be regularly maintained and repaired as needed and these activities must be recorded
- All instruments/equipment to be sterilized, are to be cleaned, dried and packaged before sterilization. Instruments placed in packages/pouches must be in the open and unlocked position. Only packages/pouches intended for use with steam sterilizers are to be used
- All instruments/equipment are to be sterilized according to the parameters in the manufacturer's instructions for use
- Operators are to monitor the sterilization process using physical, biological (BI) and chemical indicators (CI) and document results

Sterilization Packaging and Monitoring:

- All instruments/equipment to be sterilized are to be packaged before sterilization, including items sterilized in cartridge-type sterilizers, to ensure sterility of items until the point of use
- Operators are to pick packages/pouches that are intended for use with steam sterilizers and are appropriate for the instruments/equipment to be sterilized
- Operators are to ensure that items to be sterilized are in the open and unlocked position and that packages/pouches are not overloaded to ensure effective steam penetration and sterilization of all items in the package
- Paper-plastic peel pouches are a suggested option because they are easy to use and have a wide range of sizes and features such as self-sealing closures and chemical indicators
- Packages/pouches are to be labelled with the date of sterilization using a permanent, soft-tipped marker, and in a way that does not damage the package/pouch in any way (i.e., the date can be written outside the sealed edge of the plastic side of the paper/plastic pouch, but should not be written on the paper side of the pouch)

1. **Physical (Mechanical) Monitoring:**

   Physical monitoring confirms that the conditions for sterilization were reached in the chamber during each sterilization cycle
   - Sterilizers are to be equipped with either a printout or a display that gives the details of all three physical parameters (e.g., time, temperature and pressure)
   - The sterilizer's manufacturer's instructions for use are to be followed for temperature and cycle length. These should be compliant with current standards
   - Operators are to review the manufacturer's instructions for use for each item to be sterilized, and ensure the sterilizer cycle parameters match the recommended time, temperature and pressure for each item
   - Operators are to review physical monitoring results (i.e., paper printouts or displays) and keep/document the results of physical monitoring for each sterilization cycle/load
   - Operators are to record the date of sterilization and the instruments/equipment processed in each load in case these need to be recalled/held due to a failed (positive) spore test

2. **Chemical Indicator (CI) Monitoring:**

   Chemical monitoring confirms that a packaged instruments/equipment has been processed through a sterilization cycle. Chemical monitoring reveals a change in one or more parameters after sterilization but does not confirm successful sterilization
   - An external chemical indicator is to be used on each package/pouch to be sterilized, unless the design of the package allows the internal chemical indicator to be viewed without opening the package
   - An internal chemical indicator (minimum Type 4) is to be placed inside each package/pouch to be sterilized
   - If a dynamic air removal sterilizer is used, an air removal test with a Type 2 chemical indicator (e.g., a Bowie-Dick test) is to be performed every day the sterilizer is used, before the first load
   - If items within a load are to be released and used before the biological indicator results are available, Type 5 or 6
   - Internal chemical indicators are to be used in each package/pouch

3. **Biological Indicator (BI) Monitoring or Spore Testing:**
    - BI monitoring confirms the ability of the sterilizer to kill microorganisms. It is to be performed at least every two weeks, although testing once each day the sterilizer is used, and for each type of cycle used, is best practice
    - BIs are to be included in every load with implantable devices and devices are to be held until BI results are available
    - BIs are to be contained in a process challenge device (PCD) in a fully loaded sterilizer. The process challenge device should be placed in a packaged set of instruments/equipment that is the most difficult to sterilize. A (PCD) can be commercially manufactured
    - BIs are to be sent to a lab that is capable of performing BI testing and that is certified to recognizable standards (e.g., International Standards Organization)
    - Operators are to maintain records of spore tests. It is best if critical instruments/equipment are held until BI results for the respective load are verified to be negative (i.e., passed)
    - If an operator receives notification of a positive (i.e., failed) BI, operators are to immediately notify the local public health unit and take any action recommend by the public health unit. Operators are to recall and hold any instruments/equipment reprocessed since the last negative (passed) spore test, assess potential risks to clients, and repeat the BI test

REMINDERS

Unacceptable Methods of Sterilization Include:

- Dishwashers, boiling water, ultraviolet light or irradiation, glass bead sterilizers, microwave ovens, pressure cookers, flash sterilization, chemiclaves, and glutaraldehyde

Items Purchased as Pre-packaged, Sterile:

- For instruments/equipment purchased as pre-packaged, sterile, operators must have documentation from the manufacturer that indicates these items are sterile and the method of sterilization
- Pre-packaged, sterile items must be labelled with an expiry date, and must not be used beyond this date

SOURCES

1. Health Protection and Promotion Act, R.S.O. 1990, c.H.7; O. Reg. 136/18: Personal Service Settings
2. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Guide to infection prevention and control in personal service settings. 3rd ed. Toronto, ON: Queen's Printer for Ontario; 2019
3. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices. 3rd ed. Toronto, ON: Queen's Printer for Ontario; May 2013

This fact sheet was adapted with permission from CIPHI Ontario and is based on PSS best practices recommendations, current reprocessing standards and legislation. It is not an inclusive list of all requirements. Operators are responsible to ensure that all services are offered according to local requirements, best practices and legislation.