REPROCESSING IN PERSONAL SERVICE SETTINGS: STERILIZATION

WHAT IS STERILIZATION?

Sterilization is the complete destruction of all microorganisms, including blood-borne viruses such as hepatitis B, hepatitis C, and HIV as well as bacteria, and spores. When done properly, this process ensures reusable instruments are safe for use on clients.

Critical instruments that pierce the skin or mucous membranes (e.g., needles, piercing jewellery, forceps) must be sterile before use. Reusable, non-critical instruments exposed to blood or body fluids (e.g., tattoo cartridge grips, clamps, scalpel handles), must be sterilized after each use to prevent infections.

STERILIZERS

- Sterilizers are medical devices licensed by Health Canada and approved by the Canadian Standards Association (CSA). Check Medical Device Active License Listing (MDALL) to ensure the sterilizer being used in a personal service setting (PSS) is approved for use in Canada
- Sterilizers must be suitable for all instruments used in the PSS that require sterilization
- Know the type of sterilizer used at the PSS, and keep a record of its model and serial number
- Have a copy of the Manufacturer's Instructions for Use (MIFU) at the PSS. Refer to it to ensure the sterilizer is used and maintained properly
- Document all maintenance and repairs performed on the sterilizer
- Sterilizers used with wrapped or packaged instruments must include a drying cycle to ensure sterilization is complete
- Steam sterilizers are preferred. Dry heat sterilizers are not recommended.

PUBLIC HEALTH

1-877-464-9675
Dial 711 with a TTY device
york.ca/InfectionPrevention

York Region

REPROCESSING STEPS

Step One: Precleaning

- Preclean used instruments at point of service using wet gauze, disposable wipes, or paper towels
- **Reminder:** Use a covered container to transport instruments to the reprocessing area and clean and low-level disinfectant the transport container after each use

Step Two: Cleaning

- Reprocessing must occur away from the area where services are being offered
- Establish a one-way workflow that moves from contaminated (dirty) areas to sterilized (clean) areas
- Dedicated reprocessing sinks must:
  - Not be located in a room with a toilet
  - Have potable hot and cold running water under pressure
  - Be large enough to fit the largest reusable instrument
- Have adequate counter space close to the reprocessing sink for drying and packaging
- Clean reusable instruments immediately after use. If not possible, keep them wet with detergent and water, enzymatic cleaner or a soaking solution
- Disassemble multi-component instruments before cleaning
- Clean instruments manually using friction (brush, water, and detergent) or mechanically using an ultrasonic cleaning device
- Ultrasonic cleaning devices must be operated and maintained according to the Manufacturer's Instruction for Use (MIFU), meet Health Canada and Canadian Standards Association (CSA) standards, and:
  - Be used with the lid on
  - Replace solution daily or more frequently if visibly soiled
  - Clean and disinfect the ultrasonic cleaning device daily
  - Test efficacy weekly using a commercial test or foil test
  - Document all test results and maintenance
- Cleaning brushes must be cleaned, disinfected, rinsed, dried, and stored after each use

Step Three: Physical (Mechanical) Monitoring

- Dry instruments by air or with a lint free cloth before packaging
- Package instruments in the open and unlocked position
- Use the appropriate sterilization pouches intended for the sterilizer. Follow the MIFU
- Avoid overloading the sterilizer to ensure proper steam penetration
- Label each pouch with:
  - Date of sterilization
  - Name of sterilizer
  - Load number
  - Initials of responsible person
  - **Note:** To label pouch, use a permanent, soft-tipped marker, on the plastic side, ideally along the outside edge
- Physical monitoring confirms that the conditions (time, temperature, pressure) were met during each cycle. Acceptable limits for steam sterilizers are 121^0C (250^0F), for 30 to 60 minutes at 15 psi
- Sterilizers must record cycle data (time, temperature, and pressure) on a printout, digital display, or USB port. All results must be documented

- If the sterilizer does not have a printout or USB port available to record time, temperature, and pressure, the operator must manually monitor the sterilizer at regular intervals during each cycle to ensure it reaches the required temperature and pressure for the appropriate time
    - Follow the sterilizer's Manufacturer's Instruction for Use (MIFU) to ensure the correct temperature, cycle length, and pressure for each cycle is achieved

Step Four: Chemical Indicator (CI) Monitoring

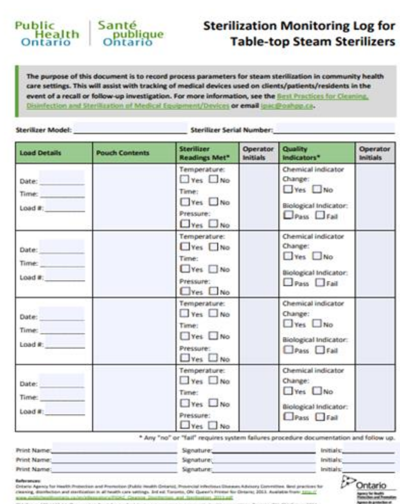
- Use an external Type I chemical indicator tape on each sterilization pouch, unless the indicator is already imbedded on the inside and outside of the pouch
- Place a Type 4 internal chemical indicator inside each pouch if the sterilizer has a printout, digital monitor, or USB
- Place a Type 5 or 6 internal chemical indicator/integrator inside each pouch if the sterilizer does not have a printout, digital monitor, or USB port
- If using a dynamic air removal sterilizer; perform a daily air removal test (e.g., Bowie-Dick test) before the first load

Step Five: Biological Spore Testing

- Biological spore testing is to be performed at least once every two weeks. **Daily testing** is best practice when the sterilizer is in use and when sterilizing implantable devices
- Place the biological spore test inside a Process Challenge Device (PCD) to accurately monitor the sterilizer
- After sterilization, best practice is to withhold instruments and jewelry from use on clients until biological spore test results have been confirmed
- Biological spore testing can be performed in-house using a biological spore test incubator, or by sending the biological spore test to a third-party service provider to ensure the sterilizer is functioning properly
- Follow the Manufacturer's Instruction for Use (MIFU) when using an in-house biological spore test incubator
- Use a biological spore test and the control spore test from the same lot number/box
- For biological spore tests that are sent to a third-party provider, the service must be ISO - certified and capable of performing biological spore testing. The provider must:
    - Deliver results electronically within 48 hours
    - Communicate any positive test results immediately
    - Maintain records of all spore test results
- Record all biological spore test results accurately in a sterilization log

Step Six: Sterilization Log

- Required documentation for sterilization log:
    - The name and type of sterilizer used
    - The load number
    - Instruments reprocessed
    - The date
    - Initials of the person performing the reprocessing
    - Results of chemical indicators (Class 4, 5 or 6) in each pouch or load
    - Results of biological spore test for each load
    - Preventative maintenance or repairs conducted
    - [Public Health Ontario Sterilization Log]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Sterilization Monitoring Log for Table-top Steam Sterilizers

The purpose of this document is to record process parameters for steam sterilization in community health care settings. This will assist with tracking of medical devices used on clients/patients/residents in the event of a recall or follow-up investigation. For more information, see the Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices or email ipac@oahpp.ca.

Sterilizer Model: ____________ Sterilizer Serial Number: ____________

Load Details	Pouch Contents	Sterilizer Readings Met*	Operator Initials	Quality Indicators*	Operator Initials
Date: ____ Time: ____ Load #: ____		Temperature: ☐ Yes ☐ No Time: ☐ Yes ☐ No Pressure: ☐ Yes ☐ No		Chemical indicator Change: ☐ Yes ☐ No Biological Indicator: ☐ Pass ☐ Fail	
Date: ____ Time: ____ Load #: ____		Temperature: ☐ Yes ☐ No Time: ☐ Yes ☐ No Pressure: ☐ Yes ☐ No		Chemical indicator Change: ☐ Yes ☐ No Biological Indicator: ☐ Pass ☐ Fail	
Date: ____ Time: ____ Load #: ____		Temperature: ☐ Yes ☐ No Time: ☐ Yes ☐ No Pressure: ☐ Yes ☐ No		Chemical indicator Change: ☐ Yes ☐ No Biological Indicator: ☐ Pass ☐ Fail	
Date: ____ Time: ____ Load #: ____		Temperature: ☐ Yes ☐ No Time: ☐ Yes ☐ No Pressure: ☐ Yes ☐ No		Chemical indicator Change: ☐ Yes ☐ No Biological Indicator: ☐ Pass ☐ Fail	

* Any "no" or "fail" requires system failures procedure documentation and follow up.

Print Name: ____ Signature: ____ Initials: ____
Print Name: ____ Signature: ____ Initials: ____
Print Name: ____ Signature: ____ Initials: ____

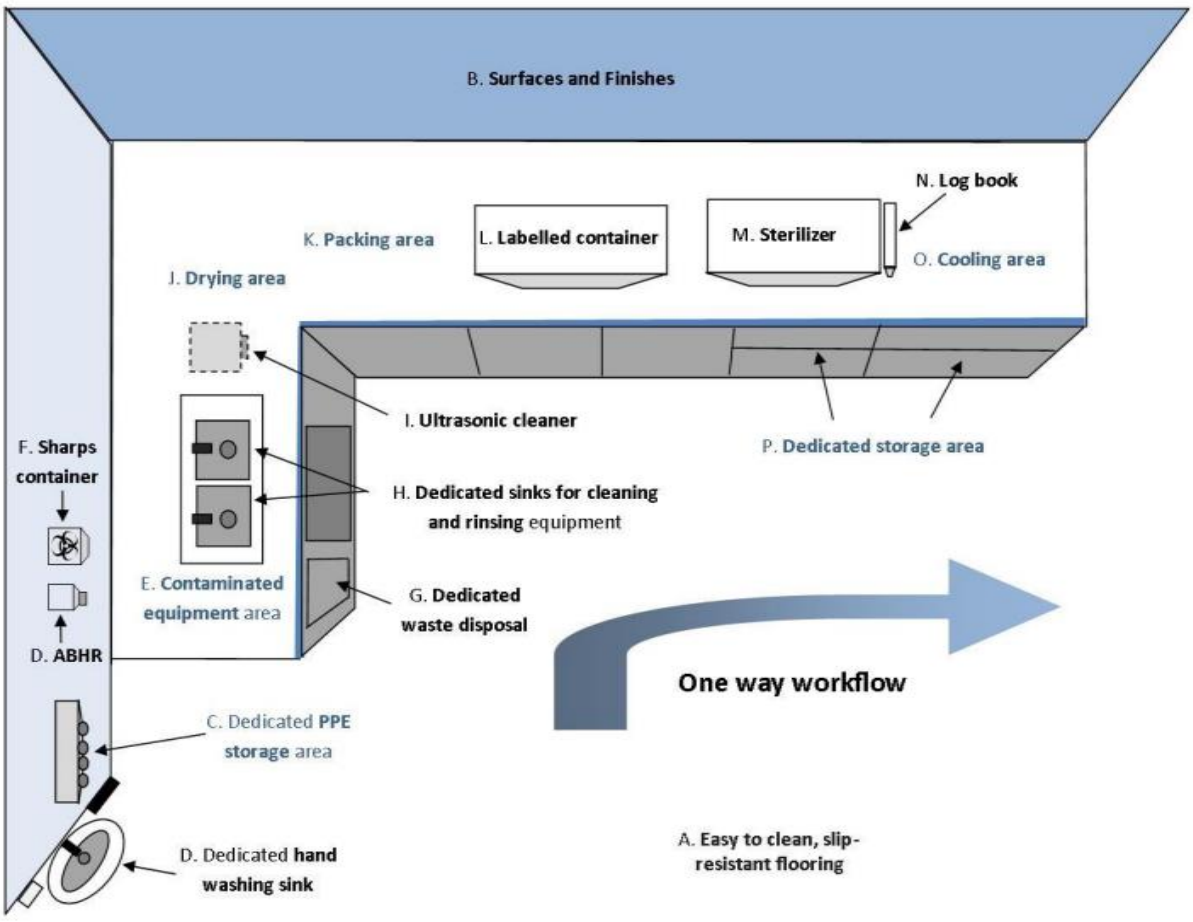
References:

Ontario

RESPONSE TO FAILED BIOLOGICAL INDICATOR (SPORE) TEST

1. Notify York Region Public Health, Health Connection at 1-800-361-5653 or AccessYork@york.ca immediately
2. Inform all users of the sterilizer in writing
3. Recall and stop the use of all instruments reprocessed since the last passed biological spore test
4. Identify instruments used on clients during the affected period
5. Repeat biological spore test
    a. If negative (passed) – resume normal operations
    b. If positive (failed) – investigate and arrange for repair
6. Clean and re-sterilize all affected instruments.

REPROCESSING AREA LAYOUT



The sterilization area includes cleanable flooring and surfaces (A, B), dedicated PPE storage (C), a hand hygiene station with a sink and 70% alcohol-based hand rub (D), and a designated intake area for used instruments (E). It features a sharps container (F), waste disposal (G), reprocessing sinks (H), an ultrasonic cleaner (I), drying (J), packing (K), and cooling areas (O). Used instruments are stored in a labeled container (L), processed in a sterilizer (M), and tracked using a logbook (N).

Figure 1: Adapted from Public Health Ontario Guide to Infection Prevention and Control in Personal Services Settings, 3rd edition 2019

STERILIZER MAINTENANCE PLAN

- Maintain and annually update a written plan for sterilizer failures. It must include:
    - Stop using all the instruments processed since the last passed biological spore test
    - Identify instruments used on clients
    - Repeat the biological spore test
        - Negative (Passed): Resume normal operations
        - Positive (Failed): Repair sterilizer before use
    - Clean and re-sterilize all reusable instruments
    - Notify in writing all personal service providers about the failure and the corrective actions

    - **Note**: Do **three** consecutive spore tests after installing a new sterilizer, relocating a sterilizer, major repairs or mechanical malfunctions, or power outages and emergencies

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

- Operators must have documentation from the manufacturer that purchased pre-package sterile items (i.e., piercing jewelry) 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; Ontario Regulation 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