Policy and Procedure Template for Steam Sterilization

[Name of clinic, address, logo]

Date of Creation/Last revision:

Instructions for template use: This template is an example of a policy and procedure that can be adapted for use in a clinical office setting. Fill in blanks provided with details specific to your clinic. You are responsible for ensuring that the information is up to date. Please review and delete items that are not relevant to your setting, and add items as needed. For more information about IPAC policies and procedures, refer to the resources below or visit the IPAC Information for Healthcare Professionals page on **halton.ca**.

Purpose:

Sterilization is the elimination of all disease-producing microorganisms, including spores. Sterilization is used on critical medical equipment/devices and semi-critical medical equipment/devices. This procedure is appropriate for reusable critical and semi-critical medical devices, excluding endoscopes. Always refer to the Manufacturer's Instructions for Use (MIFU) for device-specific instructions. This policy shall be reviewed and updated regularly and as needed.

Risk Classification: All medical devices/equipment shall be processed according to Spaulding's risk classification (see table below). Steam-sterilization is the preferred method for sterilization of critical and semi-critical devices.

Table: Spaulding's Classification of medical equipment and required level of processing.

Class	Use	Minimum Level of Reprocessing	Examples
Critical	Enters sterile body site, including the vascular system	Cleaning followed by sterilization	Surgical instruments Biopsy instruments Foot care/podiatry equipment
Semicritical	Comes in contact with non-intact skin or mucous membranes but does not penetrate them	Cleaning followed by high-level disinfection Sterilization is preferred	Vaginal specula Endoscopes Anesthesia equipment Tonometer
Noncritical	Touches only intact skin and not mucous membranes, or does not directly touch the patient	Cleaning followed by low-level disinfection (in some cases cleaning alone is acceptable)	ECG machine Oximeters Stethoscopes

Single-Use Items:

Items labeled “for single use only” shall not be reused or reprocessed. These items must be discarded appropriately after each use.

Table: Medical equipment used in _____ (name of clinic) according to class of instrument and required level of processing.

Non-critical (cleaning followed by low-level disinfection)	Semicritical (cleaning followed by high level disinfection (sterilization preferred)	Critical (cleaning followed by sterilization	Single-use (dispose after each use)

Equipment Requirements:

1. Any instrument/device used in the provision of care to patients must be capable of being cleaned, disinfected and/or sterilized according to the most current standards and guidelines from the Canadian Standards Association (CSA), Health Canada and Ontario’s best practices (unless it is single-use). Ensure that the instrument is compatible with steam-sterilization.
2. Equipment that is used to clean, disinfect or sterilize (e.g., ultrasonic washers, washer/disinfectors or autoclaves) shall meet standards established by CSA, Health Canada and Ontario best practices. The equipment must be approved for use in Canada. For more information, visit Health Canada’s Medical Devices Active Licenses search webpage.
3. The manufacturer’s instructions for use (MIFU) for cleaning, disinfection and sterilization of medical equipment/devices shall be reviewed and followed.
4. The MIFU for all medical equipment/devices and decontamination equipment must be accessible for staff conducting sterilization.
5. The MIFU for installation and preventive maintenance of equipment used in reprocessing of medical equipment/devices (e.g. autoclaves or ultrasonic cleaners) shall be followed and documented. For example, daily/weekly ultrasonic cleaner foil tests shall be performed at the appropriate intervals and recorded in maintenance logs.
6. Following installation of a new sterilizer, sterilizer maintenance or relocation, the sterilizer must pass at least three consecutive cycles with Biological Indicators placed in an empty

sterilizer before the sterilizer is put into routine service. A sterilizer must not be used if the Biological Indicator yields a failed test on any of the three consecutive cycles.

Staff Education, Training and Routine Practices

1. Staff responsible for sterilization of medical equipment/devices shall be knowledgeable and aware of this policy and related procedures.
2. Designated staff must be assigned to equipment reprocessing and shall be trained to a level required for the volume and complexity of the equipment to be reprocessed.
3. Education/training must be completed at orientation and at regular intervals or as needed, and documented:

   Policy/procedure review: _____ (frequency)
   Continuing education _____ (course name, frequency)

4. Routine practices must be followed in the reprocessing area including the following:
   - Appropriate PPE must be worn for all reprocessing activities.
   - No eating/drinking, storage of food, smoking, application of cosmetics or lip balm and handling contact lenses in the reprocessing area.
   - No storage of personal effects, including food and drink, in the reprocessing area.

   Hand hygiene
   - Hands must be cleaned before beginning work, before breaks and upon completion of work, after removing gloves, and whenever hands are contaminated.
   - If there is visible soil on the hands, hand hygiene must be performed with soap and water.
   - If there is no visible soil on the hands, staff may use soap and water or an alcohol based hand rub (ABHR).
   - Hand and arm jewelry or nail enhancements must not be worn.
   - Refer to Policy and Procedure for Routine Practices, Additional Precautions and Personal Protective Equipment (PPE) for further info.

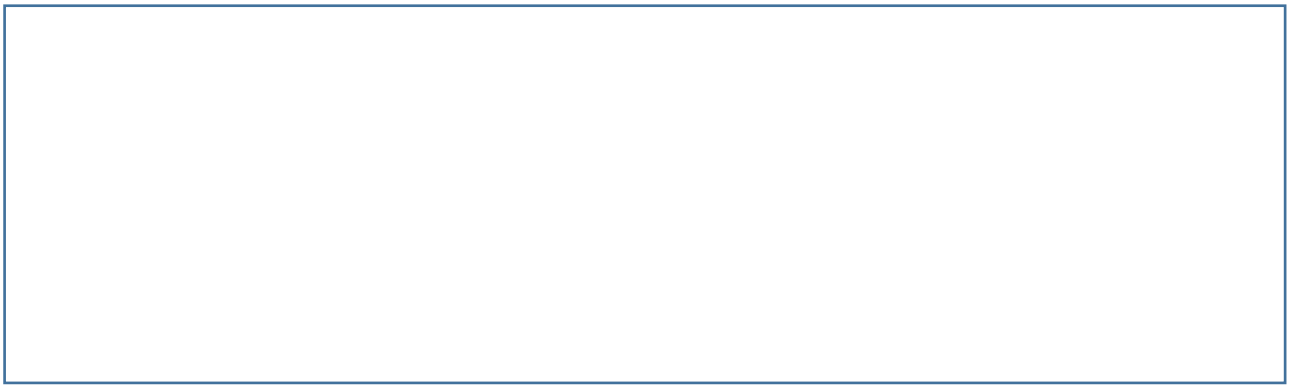
Procedure

Pre Clean

1. Remove gross soil (e.g., feces, sputum and/or blood) immediately at point-of-use.
2. Use _____ (leak-proof container e.g. covered containers or trays) to transport soiled medical equipment/devices from point-of-use to the reprocessing area.

Disassembly, Sorting, Soaking

1. Full PPE must be worn for handling and cleaning contaminated equipment/devices (Gloves, gown, mask and facial protection).
2. Sort equipment/devices into groups of like products requiring the same processes. Segregate sharps to prevent injury to personnel and damage to the equipment/device.
3. All hinged instruments/devices must be cleaned, wrapped and sterilized in the open position.
4. Follow the MIFU for device if disassembly is required prior to sterilization.
5. Equipment requiring disassembly: (e.g. speculum)



6. If not cleaned immediately, immerse instrument into freshly prepared solution of_____ (detergent/enzymatic) solution by adding _____ml to ____ml water. (Follow instructions on label for correct concentration).

Cleaning

1. Completely submerge items during the cleaning process to minimize aerosolization of microorganisms and assist in cleaning.
2. Clean with detergent/enzymatic solution (manual or automated cleaning). Clean with _____(e.g. Brush, Cloth or Ultrasonic) and _____ (detergent or Ultrasonic cleaning solution).
3. Clean equipment/devices that have lumens with a brush, according to the MIFU, then manually or mechanically flush with a detergent solution and rinse.

Rinsing and Drying

1. Implement the following procedure for rinsing and drying, unless otherwise specified in the MIFU of the equipment/device.
2. Rinse with tap water to remove detergent/enzymatic and soil residue. Ensure rinsing is done under the surface of the water using agitation.
3. Allow to air dry or dry with lint free cloth. Inspect device for damage and cleanliness. Remove damaged (rusted, cracked or pitted) equipment from service. Devices that are soiled must be re-cleaned.
4. Check equipment/devices with lumens for obstructions and leakage.
5. Care of cleaning tools: inspect brushes and other cleaning equipment for damage after each use, and discard if necessary. Clean, disinfect, dry and store tools used to assist in cleaning (e.g., brushes or cloths) after each use, or else discard.

Sterilization

1. After cleaning, rinsing and drying, equipment/devices to be steam-sterilized require wrapping. Wrap in _____(wrapping materials to be used such as plastic peel-pouches).
2. Label each package/pouch with date processed, sterilizer, cycle or load number and healthcare provider's initials in a manner that does not puncture or dampen the package.
3. Pack pouches. Ensure that pouches are not over-packed to allow for steam to penetrate all areas of the pouch.

Biological Monitoring:

4. The sterilizer must be tested with a Biological Indicator (BI) in a process challenge device (PCD) each day the sterilizer is used and with each type of cycle used that day.
5. A control BI from the same lot number as the test BI and unexposed to sterilization cycle must be incubated, according to the MIFU, each day that routine BIs are incubated.

Chemical Indicators:

Place chemical indicators (CI) appropriately in (internal minimum Class 4) and on (external – Class 1) each package, if not built into the pouch/package.

*If quarantine (holding instruments from use) pending BI results is not possible, evaluation of a Type 5 or 6 CI in a PCD and the specific cycle physical parameters may be used to justify the release of routine loads.

Chemical Indicators to be used with all sterilization packages:
External Indicator: Class 1 location: _____ (built in/attach)
Internal Indicator/s: Class 4: location: _____ (built in/insert into package)
Other indicators: _____(e.g. Bowie-Dickie test, Class 5)

6. Load the sterilizer with sterilization pouches according to MIFU, ensuring that steam is able to circulate freely around each package and allow steam to enter and exit from each package. Packages should never contact the chamber wall of the sterilizer.
7. Select _____cycle (appropriate cycle for wrapped instruments).
8. Allow processed packages to dry inside the sterilizer chamber before removing and handling.
9. Visually inspect all packages for tears or wetness. Any packages that are still wet or have tears must be reprocessed.
10. Inspect indicators on/in each package: Class 1, Class 4, Class 5/6 (if using) to ensure that the required colour change has happened.
11. Check printout/display to ensure all cycle physical parameters have been met.

Physical parameters required for sterilization (refer to MIFU for sterilizer)

Sterilizer Name: _____
Time: _____
Temperature: _____
Pressure: _____

12. **Sterilization log**: after each sterilization cycle record the following:
    a. Person who processed the load
    b. Load number
    c. Contents
    d. Physical parameters: time, temperature, pressure: pass/fail (write down after

each load or attach printout)

e. Chemical indicator check result: pass/fail
f. Biological Indicator check result: pass/fail

The sterilization process shall be tested and monitored with results recorded and audited. Records must be retained as per the appropriate Regulatory College for _____years.

If there is a failure, instruments have not been sterilized properly. Do not use these instruments. Refer to the Policy and Procedure for Steam Sterilization Failure for required actions.

Storage

1. All sterilized instruments/devices shall be stored in a manner to keep them clean and dry. Storage area(s) for processed, sterile instruments:_____

References

1. Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Infection Prevention and Control for Clinical Office Practice. 1st Revision. Toronto, ON: Queen's Printer for Ontario; April 2015. https://www.publichealthontario.ca/-/media/documents/B/2013/bp-clinical-office-practice.pdf
2. Ontario Agency for Health Protection and Promotion (Public Health Ontario). IPAC Checklist for Clinical Office Practice: Reprocessing of Medical Devices. https://www.publichealthontario.ca/-/media/documents/c/2019/checklist-clinical-office-reprocessing.pdf?sc_lang=en
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. https://www.publichealthontario.ca/-/media/documents/B/2013/bp-cleaning-disinfection-sterilization-hcs.pdf