

## Reprocessing Medical Equipment – Policy, Procedures & Guidelines

The following information is provided to assist you in developing policies and procedures relating to reprocessing of medical equipment in the office setting. Templates for developing office/clinic based policy and procedures are included.

### A. General Requirements:

1. Medical equipment that is to be reprocessed **must** be labeled reusable by the manufacturer and must be accompanied by the manufacturer's written instructions for reprocessing (cleaning, disinfection and sterilization) or surrogate instructions for similar equipment from another supplier.  
Note: gauze, cotton balls and q-tips do not have manufacturer instructions for reprocessing. Single-use sterile pre-packaged gauze, cotton balls and q-tips should be used.
2. Critical or semi-critical medical equipment labeled as "single use" or "disposable" shall not be reprocessed.
3. In order to determine the level of reprocessing that is required for a piece of medical equipment, the following risk classification is used:
  - **Critical equipment** - contacts sterile tissue or the vascular system and requires sterilization. (surgical instruments, biopsy forceps, suture scissors, devices entering sterile body cavities, etc.)
  - **Semi-critical equipment** - comes in contact with intact mucous membranes or non-intact skin and requires a minimum of high level disinfection (vaginal specula, nasal specula, vaginal/anal ultrasound probes, gastro-intestinal/nasopharyngeal endoscopes, laryngoscopes, etc.)
4. Medical equipment reprocessing must take place in a designated area that is separate from patient care areas, or is not to occur when:
  - i. patients or other personnel are present
  - ii. cleaned equipment is not secure from potential recontamination.

The use of a dual-purpose area also requires that all surfaces are cleaned and disinfected twice – once immediately before and again immediately following the decontamination of instruments.

5. Personnel responsible for reprocessing in the office setting must have documented training. Training may be in-house from an experienced staff member or a medical equipment supplier or may be delivered by a third party such as a hospital reprocessing department or an educational institution. Documentation may be a simple statement attesting to the completion of the required training.

However, we recommend that your orientation process for new staff includes a checklist of the key steps in reprocessing, such as are listed in the Audit tool used for this inspection.

6. Office-specific procedures are developed for medical equipment reprocessing that are written, current, and incorporate existing recognized standards of practice (PIDAC, CCAR and AH&W).
  - Manufacturer's instructions must be accessible and incorporated into office specific procedures.
7. Personnel responsible for reprocessing must wear the appropriate personal protective equipment (PPE) (e.g. gowns, gloves and facial protection) while reprocessing medical devices.

PPE consisting of:

  - i. eye protection with mask or full-face shield. Reusable eye protection should be cleaned and disinfected between uses.
  - ii. moisture-impervious gown
  - iii. tear- and chemical-resistant gloves covering much of the forearm must be worn during the cleaning steps in reprocessing.

If gloves are reusable, they should be cleaned and disinfected at least daily and each staff member should have their own pair.

Tear- and chemical- resistant gloves are also required when disinfectants, enzymatic cleaners and instrument detergents are handled.

Remove PPE used in cleaning and handling soiled instruments and clean hands prior to handling clean and sterile instruments.
8. At least one dedicated sink or hand hygiene station must be present in the reprocessing area.
9. Medical equipment is to be stored in clean areas that are protected from contamination, vermin, excessive handling and crushing. They are NEVER stored beneath the sink, in the soiled equipment cleaning area or in the immediate area where examinations/procedures are performed (e.g. beneath the end of the table where pelvic exams are done.)
10. Clean the reprocessing area and remove excess and unrelated equipment and supplies. Ensure there is adequate space for all steps of reprocessing. Ensure that clean/sterile items are not stored in the same area as dirty items.

## **B. Cleaning:**

1. All medical equipment must be cleaned first, using water and detergents or enzymatic solutions that are appropriate for use on instruments, prior to any subsequent disinfection or sterilization. All manual cleaning must be done under the surface of the water to minimize splashing and aerosolization of contaminated water.

2. Immersible devices with heavy or difficult-to-remove soil should be soaked before cleaning. Soaking is used to prevent soil drying on the device. Soaking is also used to soften residue and to make devices easier to clean.

Ensure that items are fully submerged in the sink or tub with detergent or enzymatic and soaked according to detergent or enzymatic product manufacturer's instructions.

Soaking shall be for the minimum time possible before further processing.

If the manufacturer does not provide a maximum soak time, a reasonable approach is to remove devices from the soak solution and clean, rinse and dry them on the day they are used. A new batch of soaking solution should be made up at the beginning of each day and should be discarded at the end of each day and the container cleaned and dried following emptying.

Prolonged soaking (e.g., overnight) of devices should be avoided, as this can cause damage or lead to biofilm formation.

3. Adhere to manufacturers' instructions for preparing solutions and use measuring devices (e.g. measuring cups) or methods (e.g. marking a permanent line on cleaning sink or basin) to ensure consistent concentrations.

Do not pre-mix solutions for which there is no available data on subsequent stability.

Only re-use containers for mixed solutions that are designed for cleaning and re-use; ensure they are properly cleaned and dried between each filling and solution is never "topped up" or new solution added to existing solution in the container.

4. Detergents or enzymatic cleaning solutions are discarded following each use.
5. There are written office-specific procedures for cleaning that include protocols for containment of contaminated equipment at the point of use, transport to disassembly, sorting, soaking, physical removal of soil, rinsing, drying, inspection and wrapping (if necessary), and correct loading of the sterilizer according to the sterilizer manufacturer's instructions.
6. Cleaning may be done manually (using detergent or enzymatic solution, water and friction) or mechanically in an automated washer decontaminator/disinfector.

All manual cleaning must be done under the surface of the water to minimize splashing and aerosolization of contaminated water.

7. Automated cleaning equipment, if used, must be installed and operated according to the manufacturer's instructions, and a preventive maintenance program for the equipment must be established and documented.

8. If ultrasonic cleaning equipment is used:
  - Pre-cleaning of devices is necessary to remove gross matter;
  - Rinsing of devices with clean, fresh tap water must follow the ultrasonic cycle;
  - Efficacy of the equipment must be tested using a method recommended by the manufacturer;
  - Solution must be changed at least daily and whenever it appears soiled; and
  - The unit must be covered when in operation.
9. Devices must be dried with a clean, lint-free, soft absorbent towel. Following cleaning devices must be dry before storage, immersion in disinfectant or wrapping and sterilization.
10. All equipment must be inspected for damage and cleanliness. Remove damaged (rusted, cracked, pitted) equipment from service. Devices that are soiled must be returned to be re-cleaned.
11. Devices with lumens or channels must be cleaned using an appropriately sized brush or stylet as recommended by the manufacturer.
12. Cleaning accessories (e.g. brushes, sponges) are disposable, or must be thoroughly cleaned and high level disinfected or sterilized between uses.
13. Sinks used for cleaning medical devices are cleaned at least once daily. Do not use the reprocessing sink for hand hygiene. If it is not possible to dedicate a sink to the purpose of hand hygiene, install a waterless alcohol based hand sanitizer station for the reprocessing area.

The use of a dual-purpose area requires that all surfaces are cleaned and disinfected twice – once immediately before and again immediately following the decontamination of instruments.

### **C. High Level Disinfection**

1. Semi-critical medical devices require a minimum of high level disinfection.
2. The disinfectant has a Drug Identification Number (DIN) from Health Canada.
3. The disinfectant label indicates that the product is a chemo sterilant or a high level disinfectant (HLD).
4. The HLD is prepared and used according to the manufacturer's instructions specified on the label, MSDS or accompanying product literature.
5. An appropriate chemical test strip specified by the disinfectant manufacturer is purchased and used to test disinfectant minimum effective concentration (MEC) at least daily.

6. Results of all disinfectant MEC testing are recorded in a log.
7. When opened, each container of chemical test strips is checked using a quality control procedure recommended by the manufacturer to verify accuracy.
8. Results of all quality control testing of test strips are recorded in a log.
9. Containers of test strips are dated when opened and not used beyond the shelf life indicated by the manufacturer.
10. There is documentation that the correct HLD solution is used when solution is changed.
11. Devices are completely immersed in HLD for the recommended time.

#### **D. Sterilization**

1. Critical equipment is sterilized using an approved process. (Unacceptable sterilization methods include boiling, glass bead sterilizers, microwaves and ultraviolet light.)
2. The sterilizers are installed and have a documented preventive maintenance program according to the manufacturer's recommendations (daily, weekly, monthly and yearly).
3. The type of sterilizer used has cycles capable of sterilizing the instruments that are used in the office setting. Check with sterilizer manufacturer's written claims.
4. There are written procedures for sterilization of all medical equipment.
5. Chemical indicators are placed on the outside of each load and inside each package to be sterilized.
6. Each sterilization cycle is monitored with physical parameters (time, temperature and pressure) that are recorded on a print out or otherwise logged. In the absence of a printout or data logging system, gauges on the outside of the sterilizer must be observed to ensure that the correct sterilization time and temperature have been achieved and observations are documented in a log.
7. Sterilizers are monitored with an appropriate biological indicator each day the sterilizer is used.
8. A log of biological indicator monitoring is maintained.
9. There is a written recall procedure that is followed in the event of a failed biological indicator. **(Positive (Failed) Biological Indicator Protocol for the Physician's Office)**

10. Each package that is sterilized is labeled with a date and load number.
11. A log is kept of each load and items in the load.
12. Instruments must be disassembled for sterilization according to manufacturers' instructions.
13. All hinged instruments/devices must be cleaned, wrapped and sterilized in the open position. Follow the manufacturer's instructions if disassembly is required for sterilization. Sharp tips of instruments in peel pouches should be protected using tip protectors that have been validated for sterilization to prevent perforation of packaging.
14. Instruments/devices must be wrapped in approved material prior to autoclaving. Individual self-sealing peel packs are recommended for individual or small sets of instruments.

Peel packages must not be over-stuffed and must be loaded on edge with paper side to the plastic side of the next pack.

Bulk roll packing is acceptable but requires heat sealing for acceptable closure.

Loading of the sterilizer must ensure that steam is able to circulate freely around each package to allow steam to enter and exit from each package.

Packages should never contact the chamber wall of the sterilizer.

15. All reprocessed instrument sets and devices are stored in a manner to keep them clean and dry.