

Reprocessing

(Cleaning, Disinfection & Sterilization)

Critical & Semi-Critical Equipment

- A Physician Toolkit -

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College of
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& Surgeons
of Alberta

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Preface

This document, A Physician Toolkit for Reprocessing Critical and Semi-Critical Medical Equipment, has been developed to assist office physicians and their staff to meet best practice standards on reprocessing medical equipment.

Additional references and standards that physicians and their staff should be aware of and compliant with are:

- Provincial Infectious Diseases Committee (PIDAC) Best Practices for Cleaning, Disinfection and Sterilization, 2010;
- Canadian Committee on Antibiotic Resistance (CCAR) Infection Prevention & Control Best Practices, 2007; and
- A Physician's Guide to Occupational Health and Safety Responsibilities.

Links to all of the above noted references are available on the College's website at <http://www.cpsa.ab.ca/Services/IPAC/overview.aspx>.

Basic Physician Office Supplies for Reprocessing Critical & Semi-Critical Medical Equipment

Personal Protective Equipment (PPE)

- Face Protection: eye protection (safety glasses or goggles) with mask or full face shield. Reusable eye protection should be cleaned and disinfected between uses.
- Gloves: gloves must be of sufficient weight to be highly tear resistant (regular exam gloves are not appropriate protection for reprocessing). 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.
- Gowns: moisture-impervious gown (isolation gowns are not appropriate).

Cleaning

- Brushes (reusable or disposable) or cloths for physical cleaning. Disposable brushes are recommended. Reusable cleaning brushes must be sterilized or high-level disinfected between uses.
- Approved instrument detergent or enzymatic cleaning solutions (e.g. Medzyme).

High Level Disinfection

- High level disinfectant solution (e.g. Glutaraldehyde). Products must have a Drug Identification Number (DIN) from Health Canada.
- High level disinfectant solution chemical test strips.
- Log and documentation record forms.

Sterilization (manufacturers may have starter kits which include all of the products listed here)

- External chemical indicator/autoclave tape (may be built-in with peel pouches) placed on packages with each load.
- Internal chemical indicator: placed inside each package for sterilization.

- Biological indicator (spore-laden strips or vials) (usually *Geobacillus stearothermophilus* for steam sterilizers). Used once each day the sterilizer is in use, or with every load if sterilizing implantable devices.
- Logs books/forms for documentation of sterilization parameters and autoclave maintenance.

Sterilization Monitoring

Sterilization of medical equipment is a two-step process involving:

- (i) Decontamination (aka cleaning) to remove >80% of microbes; and
- (ii) Sterilization to kill the remaining microbes.

Steam autoclaves are the most efficient and non-toxic method of sterilization in a physician office setting.

Because of the difficulty in proving the sterility of a medical instrument, the effectiveness of the *sterilization process* must be monitored. Three complementary types of monitoring are required:

- **Mechanical/Digital indicators** to monitor the autoclave's physical parameters (time, temperature and pressure) for each cycle/load;
- **Chemical indicators** - external indicators on the outside of each wrapped package and internal chemical indicators inside each package, which change color when exposed to the right conditions for sterilization; and
- **Biological Indicators** that confirm the actual annihilation of microbial spores.

All three types of monitors are important to confirming that the conditions necessary to achieve sterility have been met.

Among these, biological indicators may be the most unfamiliar to physicians. Options for biological monitoring include:

- Purchasing a self-contained testing kit with incubator for on-site monitoring; or
- Purchasing only the spore strips, and then transporting them to a microbiology laboratory that offers environmental testing. (Unfortunately, few laboratories in the province offer this service.)

Policies, Procedures & Guidelines

The following policies, procedures, guidelines and templates are not official documents of the College of Physicians & Surgeons of Alberta. They are provided for information only. We hope these documents will assist you in creating your own specific documents for your office setting.

Comments and questions can be forwarded to Shonda.Holt@cpsa.ab.ca.

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.

Policy Template for Reprocessing of Medical Equipment

Name/Address of Office/Clinic: _____

Date Issued: _____

Date Reviewed: (Suggest annually): _____

Signature of Owner/Operator of Clinic/Office: _____

Policy - Reprocessing of Medical Equipment/Instruments:

Purpose:

Reprocessing is the cleaning, disinfection and sterilization of reusable medical equipment between each patient use. The safe use and reprocessing of all reusable medical equipment as well as proper care and maintenance of reprocessing equipment is required to reprocess safely.

The following shall be adhered to when reprocessing medical equipment:

1. Items labeled "for single use only" shall not be reused.
2. The following risk classification shall be used to determine the minimum level of reprocessing to be performed on items that are labeled "reusable":
 - **Critical:** Item that enters sterile body site or vascular system and requires cleaning followed by sterilization.
 - **Semi-Critical:** Item that comes in contact with intact mucous membranes or non-intact skin and requires cleaning followed by a minimum of high level disinfection.
 - **Non-Critical:** Item that comes in contact with intact skin that requires cleaning followed by low level disinfection.
3. The manufacturer's instructions for cleaning, disinfection and sterilization of medical equipment shall be utilized and followed in office procedures.
4. Written office/clinic procedures for reprocessing shall be followed.
5. The manufacturer's instructions for installation and preventive maintenance of equipment used in reprocessing medical devices and instruments shall be followed and documented.
6. All processes related to cleaning, disinfection and sterilization of medical equipment shall be monitored and documented.
7. Staff responsible for reprocessing of medical equipment shall be knowledgeable and aware of current standards of practice (PIDAC, CCAR, AH&W). All education and competencies shall be documented.

Procedure Template for Steam Sterilization

Name of Equipment/Instrument: _____

Performed by: _____

Personal Protective Equipment: Gloves Gown Face Shield/Mask Safety glasses/goggles

Disassembly instructions, if applicable: (Include pictures or diagrams for complex or unusual equipment.)

After each use:

1. Prepare _____ (detergent/enzymatic) solution by adding ____ ml to ____ ml water. (Follow instructions on label for correct concentration.)
2. Immediately immerse instrument into freshly prepared solution of _____ (indicate name of detergent/enzymatic product used) for _____ minutes to prevent drying of soil. (Follow detergent/enzymatic manufacturer's instructions for soak time.)
3. Clean with detergent/enzymatic solution. Requires: Brush Cloth Ultrasonic
4. Rinse with tap water to remove detergent/enzymatic and soil residue. Ensure rinsing is done under the surface of the water using agitation. Rinse water should be changed frequently and before any soap suds appear.
5. Dry with lint free cloth.
6. Inspect device for damage and cleanliness. Remove damaged (rusted, cracked, pitted) equipment from service. Devices that are soiled must be re-cleaned.
7. Reassemble, as necessary, according to manufacturer's instructions.
8. Wrap in _____ (indicate type of wrapping material: peel pouch)
9. If not part of the wrap, apply internal and external chemical indicators.
10. Label with date of sterilization and load number.
11. Place in sterilizer.

12. Load the sterilizer to ensure 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.
13. Select _____ cycle (appropriate cycle e.g., wrapped, porous, nonporous).
14. Check printout/display to ensure all cycle parameters have been met and sign on print out or in log book.
15. Remove when cycle is finished and packs are completely dry.
16. Storage location: _____.

References

- (i) _____ (name of manufacturer) instructions for reprocessing
- (ii) PIDAC or CCAR

Date Issued: _____

Date Reviewed: _____

Procedure Template for High Level Disinfection

Name of Instrument: _____

Performed by: _____

Personal Protective Equipment: Gloves Face Shield/Mask
 Gown Safety glasses/goggles

Disassembly instructions, if applicable: (Include pictures or diagrams for complex or unusual equipment.) _____

Disinfectant used: _____

Check the following: Label Concentration
 Date product activated/opened
 Results of minimum effective concentration (MEC) testing of disinfectant (done daily at a minimum using appropriate test strip)

After each use of equipment:

1. Prepare _____ (detergent/enzymatic) solution by adding ____ml to ____ml water. (Follow instructions on label for correct concentration.)
2. Immediately immerse instrument into freshly prepared solution of _____ (indicate name of detergent/enzymatic product used) for _____ minutes to prevent drying of soil. (Follow detergent/enzymatic manufacturer's instructions for soak time.)
3. Clean with detergent/enzymatic solution. Requires: Brush Cloth Ultrasonic
4. Rinse with clean tap water to remove detergent and soil residue. Ensure rinsing is done under the surface of the water using agitation.
5. Dry with lint free cloth to avoid diluting the disinfectant chemical.
6. Remove cover from container of high level disinfectant.
7. Completely immerse device or instrument in high-level disinfectant.
8. Cover container of high level disinfectant and begin timing (set timer).
9. Soak for _____ minutes at room temperature (according to manufacturer's instructions).

10. Rinse with clean tap water using three separate rinses to ensure removal of residual disinfectant. Ensure rinsing is done under the surface of the water using agitation.
11. If instrument has channels or lumens, purge with alcohol to facilitate drying.
12. Inspect device for damage and cleanliness. Remove damaged (rusted, cracked, pitted) equipment from service. Devices that are soiled must be re-cleaned.
13. Dry with a lint free cloth.
14. Storage location: _____

References

- (i) _____ (name of manufacturer) instructions for reprocessing _____ (name of device/instrument). Date and source of instructions.
- (ii) Instructions for preparation and use of _____ (name of high level disinfectant)
- (iii) PIDAC/ CCAR

Date Issued: _____

Date Reviewed: _____

Control Sheet Template for Cleaning and Disinfection of Flexible Endoscopes Manually*

Date: _____

Instrument code number or identifier: _____

Endoscope processed (time): _____

I.D. Number of soaking container if more than one container is used for disinfection: _____

Comments: _____

Signature of person reprocessing scope: _____

- Ensure water-resistant cap is on
- Perform leak test
- Wash exterior of scope
- Brush valves and piston
- Brush all channels
- Suction biopsy port with cleaning adapter
- Aspirate enzymatic solution through biopsy channel
- Connect appropriate adaptors for instrument
- Inject enzymatic product in all channels
- Soak in enzymatic solution for a minimum of ____ minutes (see enzymatic instructions)
- Rinse scope and flush all channels with fresh tap water
- Dry exterior of scope and flush remaining water from channels
- Completely immerse scope, valves and cleaning brushes in HLD
- Inject HLD into all channels of the scope using appropriate clean channel adaptors
- Ensure all channels are filled with HLD and no air pockets remain
- Ensure temperature of room is not less than _____ degrees (see HLD instructions)
- Set timer for _____ (see HLD instructions)
- When disinfection time is complete, purge all channels with air to remove HLD
- Rinse scope and flush channels with three separate rinses of clean tap water (with sterile or submicron filtered water)
- Dry channels with compressed medical grade air @ ____ psi. (check manufacturer pressure limit)
- Flush all channels with 70% isopropyl alcohol
- Repeat dry channels with air
- Hang/lay scope with all valves and water-resistant cap removed

* Adapted from CSA Z314.8-08. Decontamination of reusable medical devices.

Control Sheet Template for Disinfection of Flexible Endoscopes Using Automated Endoscope Reprocessor (AER)*

Date: _____

Instrument code number or identifier: _____

Endoscope processed (time): _____

AER used: _____

Comments: _____

Signature of person reprocessing scope: _____

- Ensure water-resistant cap is on
- Perform leak test
- Wash exterior of scope
- Brush valves and piston
- Brush all channels
- Suction biopsy port with cleaning adapter
- Aspirate enzymatic solution through biopsy channel
- Connect appropriate adaptors for instrument
- Inject enzymatic product in all channels
- Flush additional ports
- Soak in enzymatic solution for a minimum of ____ minutes (see enzymatic instructions)
- Rinse scope and flush all channels with fresh tap water
- Place in washer using appropriate connectors for final disinfection
- Place valves, separate from scope, into washer
- Place cleaning brush(es) into washer
- Dry with compressed medical grade air at ____ psi (check manufacturer pressure limit)
- Flush all channels with 70% isopropyl alcohol
- Repeat dry with compressed medical grade air
- Hang scope with all valves and water-resistant cap removed
- Clip initial print out from AER to control sheet

* Adapted from CSA Z314.8-08. Decontamination of reusable medical devices.

Common Deficiencies Identified from Recent On-Site Audits

1. Biological Monitoring is not being performed.
2. That all required Personal Protective Equipment is either not available or not worn by staff when reprocessing.
3. The manufacturer's instructions for reprocessing equipment are not available.
4. Sterilization monitoring parameters (digital, mechanical chemical and biological) are not documented.
5. High level disinfectant chemical test strip results are not documented.
6. Quality procedures on new containers of chemical test strips, and lots of biological indicators, are not performed and/or documented.
7. That reprocessing is occurring in patient care areas with patients present.
8. That re-useable cleaning accessories are not cleaned and minimally high level disinfected or sterilized between uses.
9. That documented policies and procedures are not developed for all steps of reprocessing and training procedures for reprocessing staff.
10. Inappropriate wrapping materials and tape used for packaging equipment for sterilization. Use self sealing pouches.
11. Internal, chemical indicators not being placed in each package for sterilization.

Cleaning, Disinfection & Sterilization Products

The following products are examples of appropriate cleaning, disinfection and sterilization products. These products are available and can be ordered by contacting a medical supply vendor.

Instrument Detergents and Enzymatic Cleaners



NPH Klenz Neutral
Detergent



Enzymatic Cleaners - foam or sponge



Medzyme Enzymatic Cleaner

Instrument Lubricants



Instrument Cleaning Accessories

(Must be disposable, or cleaned and minimally high level disinfected or sterilized between uses.)



Glutaraldehyde High Level Disinfectant & Test Strips



Cidex OPA (orthophthalaldehyde) and test strips



Biological Indicators



Self-contained BI



Process Challenge Device PCD or Test Pack containing BI



Incubator



Log for BI monitoring

Chemical Indicators for Sterilization



Steam



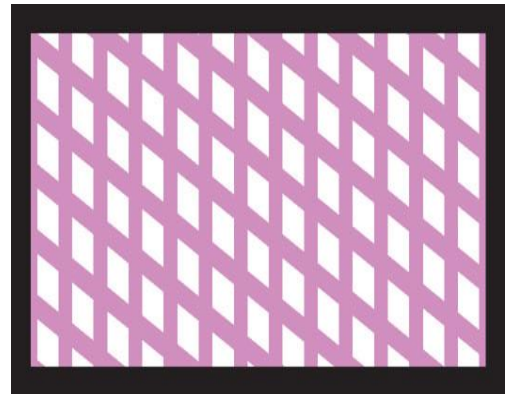
Steam/Ethylene oxide (EO)



Peracetic Acid (Steris System 1)



Bowie-Dick Air Removal Test Packs



Post HLD Rinsing

(Sterile or sub-micron filtered water is **recommended**)

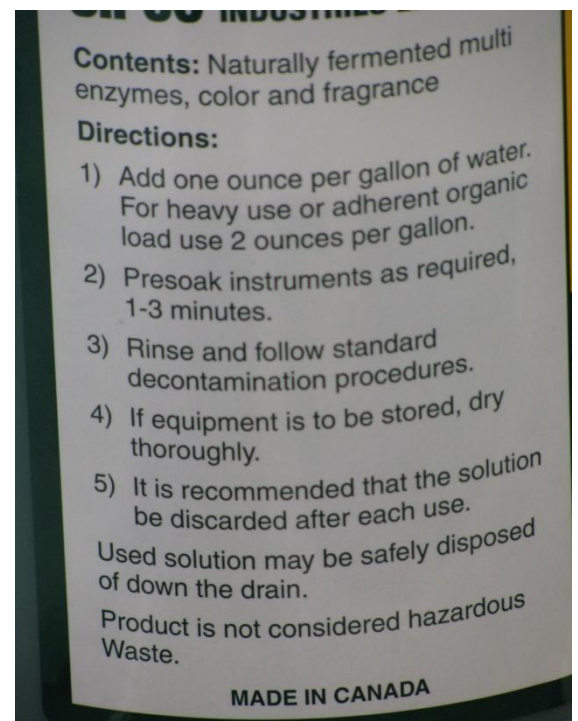


Sterile Water for Irrigation - 500ml
1000ml, 3000ml volumes

Pall-Aquasafe™ Faucet Water
Filter



Read labels on all cleaning/ disinfection products. Ensure directions are followed.

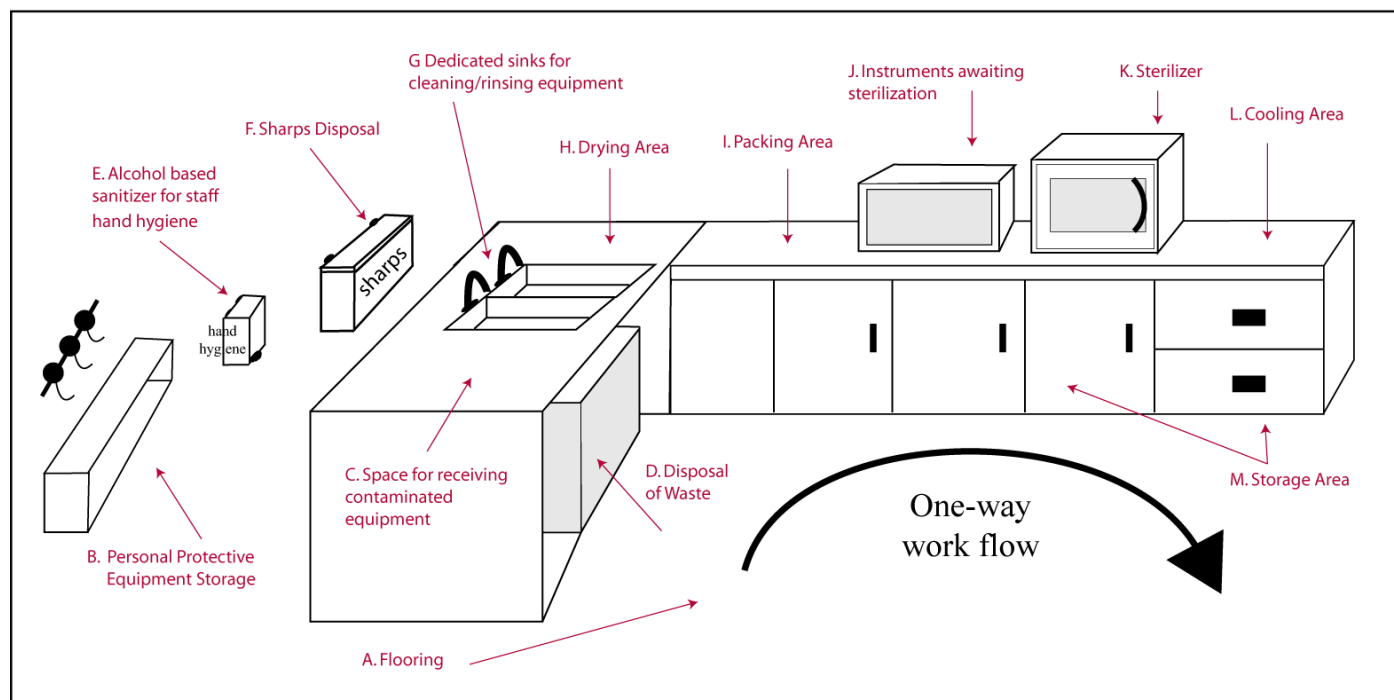


(Sample enzymatic cleaner label)

Additional Resources

Attached are additional resources for reprocessing critical and semi-critical medical equipment.

Suggested Reprocessing Area Design & Layout



- A. **Flooring** – Is easy to clean, and is not slippery when wet.
- B. **Personal Protective Equipment Storage** - A dedicated space for storage of personal protective equipment.
- C. **Space for receiving contaminated equipment**
- D. **Disposal of Waste** - Bins must be available for disposal of waste.
- E. **Alcohol Dispenser** – An alcohol dispenser for hand hygiene.
- F. **Sharps Disposal** - A secure biohazard sharps disposable container is required.
- G. **Dedicated sinks for cleaning/rinsing equipment** – In the absence of two sinks dedicated for equipment cleaning and rinsing, a basin for rinsing equipment post decontamination is an acceptable alternative.
- H. **Drying Area** – An area for drying equipment post rinsing.
- I. **Packing Area** - A clean separate area for packing equipment for sterilization.
- J. **Instruments awaiting sterilization** - A labeled container for instruments awaiting sterilization is recommended.
- K. **Sterilizer** - It is important that a daily sterilizer log book be kept by each autoclave in use.
- L. **Cooling Area** - A clean area for allowing sterilized packs to cool before storage.
- M. **Storage Area** - There needs to be adequate storage areas for cleaned, packaged and sterilized instruments.

Table-Top Steam Sterilizer Checklist

- Sterilizers must be capable of sterilizing the type of instruments that are used in each setting.
- The supplier's claims should be evidenced in the manufacturer's written material.
- Sterilizers must be installed, used and continuously maintained in accordance with manufacturer's instructions.
- Sterilization cycles must be monitored with physical, biological and chemical monitors and the results of monitoring must be documented.

The checklist below may be useful when choosing a new sterilizer. Table-top sterilizers should meet the following criteria:

Criteria Met?		Criteria	Comments
Yes	No		
<u>Prior to Considering Purchase:</u>			
<input type="checkbox"/>	<input type="checkbox"/>	Has an assessment been done to determine that the sterilizer is required? For example it may be more cost effective to use single use (disposable) instruments or equipment instead of reusable.	
<input type="checkbox"/>	<input type="checkbox"/>	Is it possible to send reusable instruments or equipment requiring sterilization to an offsite third party medical device reprocessing provider that complies with recognized reprocessing standards?	
<u>Sterilizer:</u>			
<input type="checkbox"/>	<input type="checkbox"/>	The sterilizer has a printer/data logger to document a permanent record of physical parameters (time/temperature/pressure) plus sterilizer identification, date, time and load number for each cycle.	
<input type="checkbox"/>	<input type="checkbox"/>	The sterilizer uses a dynamic air removal cycle, also known as a 'steam flush pressure pulse' or a 'pre-vacuum' system. This method of air removal is important when if reprocessing complex instruments (e.g. dental hand pieces, textiles, lumened or wrapped items).	
<input type="checkbox"/>	<input type="checkbox"/>	The sterilizer has a Health Canada medical device license.	
<u>The sterilizer manufacturer supplies the following information in writing:</u>			
<input type="checkbox"/>	<input type="checkbox"/>	Statement of the sterilizer's ability to sterilize the proposed medical devices (e.g. lumened instruments, hollow instruments, textiles, power tools, dental hand pieces, wrapped sets of instruments). A summary of documentation is supplied to validate the claim.	
<input type="checkbox"/>	<input type="checkbox"/>	Statement of any unique requirements for installation and maintenance of the sterilizer. These may include operational constraints specific to altitude (e.g. Calgary is at approximately 3500 feet elevation; Ft. McMurray is at approximately 1213 feet elevation) and water supply (e.g. reservoir, potable, treated water).	
<input type="checkbox"/>	<input type="checkbox"/>	Recommended sterility assurance monitoring:	
<input type="checkbox"/>	<input type="checkbox"/>	a. Appropriate biological and chemical monitors.	
<input type="checkbox"/>	<input type="checkbox"/>	b. Appropriate Class II (Bowie-Dick) chemical indicator for dynamic air removal sterilizers.	
<input type="checkbox"/>	<input type="checkbox"/>	Recommended preventive maintenance and care procedures and schedules for sterilizer.	
<input type="checkbox"/>	<input type="checkbox"/>	Qualifications of technical service providers.	

Positive (Failed) Biological Indicator Protocol for the Physician's Office

- I. For each new batch of biological indicators (BIs), determine that the BIs are viable by incubating one BI without running it through the sterilizer. The BI must indicate "growth of organisms" (a positive BI) or the batch must be returned as faulty.
- II. Include a BI in the sterilizer chamber at least once each day that the sterilizer is used to sterilize medical equipment.
- III. Take the following steps after incubating and reading each BI that has been run through the sterilizer.
 - A. If the BI indicates "no growth of organisms" (a negative BI), then document the finding in the sterilization log for that cycle.
 - B. If the BI indicates "growth of organisms" (a positive BI), then proceed as follows:
 1. Notify the person in the office responsible for reprocessing of medical equipment that you have had a positive BI.
 2. Stop using the sterilizer until the reason for the positive BI is identified and the causes are resolved.
 3. Identify and quarantine all equipment and packages that were sterilized between the last successful cycle (which had a negative BI) and this failed cycle (with the positive BI). This may involve notification of other offices or clinics if the sterilizer in question is used to reprocess equipment and packages for any outside facilities.
 4. Check the sterilization log for the monitored sterilizer parameters during the failed cycle. Ideally, this will include the length of the cycle and the temperature and the pressure reached. Check, also, the status of chemical indicators on and, if visible, in packages from that cycle.
 - If the monitored sterilizer parameters were not as required by the manufacturer or the chemical indicators do not indicate a successful cycle, then investigate the cause of the cycle failure, fix any deficiencies and document the cause(s) and the remedies instituted. Recall all equipment that was processed during the failed and subsequent cycles and prepare them for re-sterilization. That preparation must include re-cleaning, rinsing, drying and fresh wrapping or packaging (if the items are to be wrapped or packaged). **Do not re-sterilize devices in a sterilizer that failed a BI test until the sterilizer problem is resolved in accordance with this protocol. Notify the local Medical Officer of Health if medical equipment that was reprocessed in a failed cycle has been used on a patient.*** The MOH, with help from experts in Infection Prevention and Control, will assist in determining the risk of disease transmission and the need for a look-back of potentially affected patients. **Then proceed to step 5.**
 - If the monitored sterilizer parameters met the manufacturer's requirements and the chemical indicators indicate sufficient exposure to heat, **then proceed to 5.**

5. Retest the sterilizer with a new BI and document the result.
 - If the follow-up BI is negative (no growth of organisms), then the sterilizer is ready for use and any quarantined equipment in step 3 above can be returned for use if the relevant sterilization logs and chemical indicators otherwise indicate successful sterilization. (If the monitored sterilizer parameters and the chemical indicators did not suggest a problem with the sterilizer, then an assumption is made that a negative BI following a single positive BI indicates a false positive BI test and that no fault lies with the sterilizer.)
 - If the follow-up BI is positive, then a problem with the sterilizer is likely and it must be assumed that the sterilizer has failed. All equipment quarantined in step 3 above must be prepared for re-sterilization **but must not be sterilized in a sterilizer that failed a BI test until the sterilizer problem is resolved in accordance with this protocol**. That preparation must include re-cleaning, rinsing, drying and fresh wrapping or packaging (if the items are to be wrapped or packaged). The questionable sterilizer must not be used again until it has been serviced by a qualified technician and tested in accordance with section 6 below. Notify the local Medical Officer of Health if medical equipment that was reprocessed in a failed cycle was used on a patient.* The MOH, with help from experts in Infection Prevention and Control, will assist in determining the risk of disease transmission and the need for a look-back of potentially affected patients.
6. Also if the follow-up BI is positive, then the sterilizer must be serviced by a qualified technician and not returned to service until tested with three (3) successive challenges with fresh BIs in an empty sterilizer chamber. Any positive BIs from those challenges require further investigation by a qualified technician. Only three (3) consecutive negative BIs permits the return to service for the sterilizer. Re-sterilization of the quarantined packages which have been prepared in accordance with 5b above can now be performed with this sterilizer.
7. Document all service, testing, and other actions regarding the occurrence of a positive BI.

*The Public Health Act states:

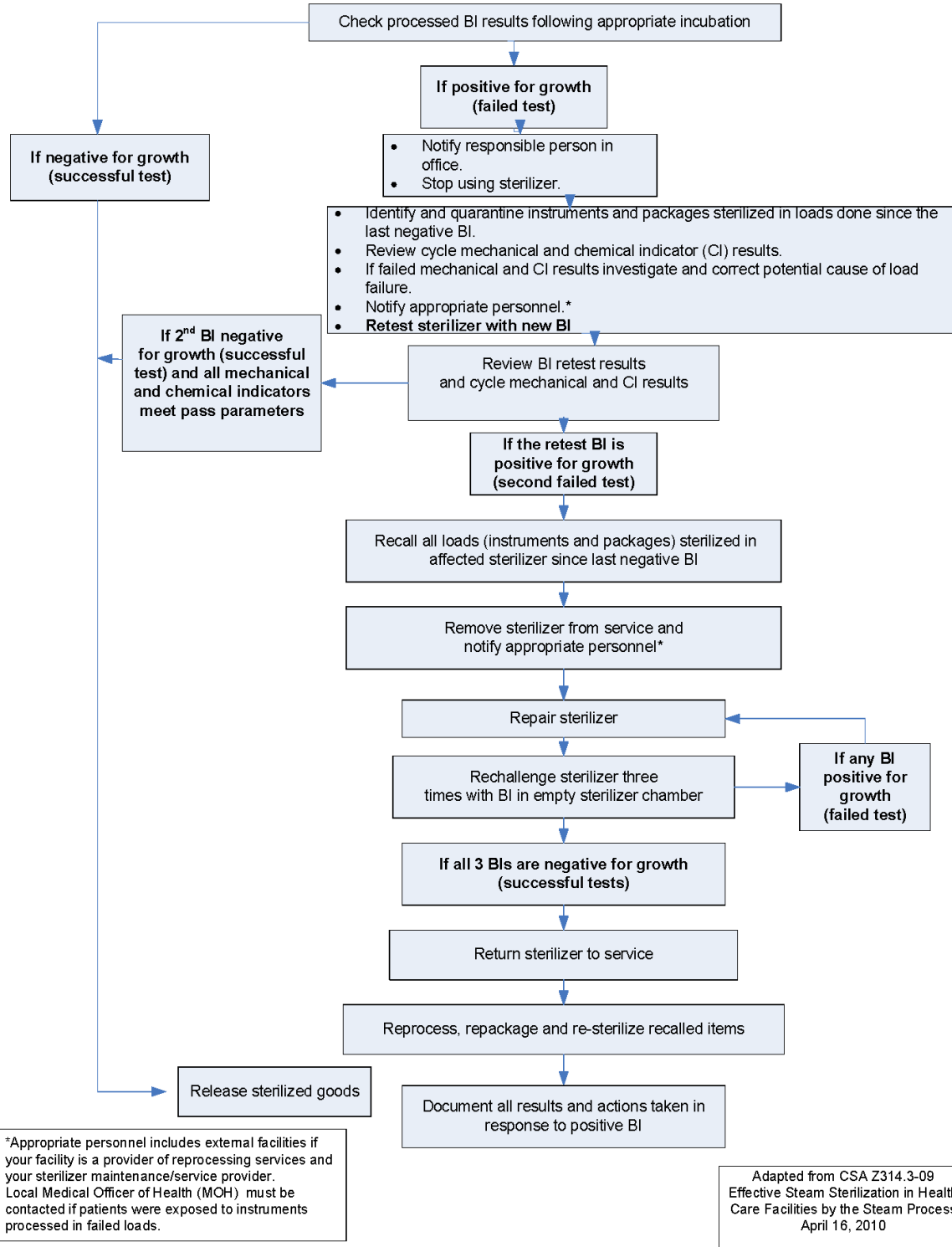
26 A health practitioner, a teacher or a person in charge of an institution who knows of or has reason to suspect the existence of

- (a) a communicable disease in epidemic form,
- (b) another illness or health condition occurring at an unusually high rate,
or
- (c) a communicable disease or another illness or health condition that is caused by a nuisance or other threat to the public health shall immediately notify the medical officer of health of the regional health authority by the fastest means possible.

RSA 2000 cP-37 s26;2002 c32 s12;2007 c23 s4

Comments and questions can be forwarded to Shonda.Holt@cpsa.ab.ca.

Positive (Failed) Biological Indicator (BI) Protocol for the Physician's Office



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