

Reprocessing

(Cleaning, Disinfection & Sterilization)

Critical & Semi-Critical Equipment

- A Physician Toolkit -



College of
Physicians
& 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, 2006;
- 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 www.cpsa.ab.ca/collegeprograms/ipac.asp.

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

Personal Protective Equipment (PPE)

- Face Protection: mask, protective eye ware (safety glasses or goggles) and/or full face shield).
- Gloves: gloves must be of sufficient weight to be highly tear resistant (regular exam gloves are not appropriate protection for reprocessing).
- Gowns: gowns must be of a quality to provide an adequate barrier to moisture (isolation gowns are not appropriate).

Cleaning

- Brushes (reusable or disposable) or cloths for physical cleaning.
- 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 (maybe 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 tlubkey@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).
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 patients are present.
5. Personnel responsible for reprocessing in the office setting must have documented training.
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.
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.)

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.
2. Detergents or enzymatic solutions are used according to manufacturer's instructions that are written on the label.
3. Detergents or enzymatic cleaning solutions are discarded following each use.
4. 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).
5. Cleaning may be done manually (using detergent or enzymatic solution, water and friction) or mechanically in an automated washer decontaminator/disinfector.
6. 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.
7. 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.
8. Devices must be dried following cleaning. Devices must be dry before storage, immersion in disinfectant or wrapping and sterilization.
9. Devices are visually inspected to ensure that no visible soil remains. Devices that do not pass inspection are returned for re-cleaning.
10. Devices with lumens or channels must be cleaned using an appropriately sized brush or stylet as recommended by the manufacturer.

11. Cleaning accessories (e.g. brushes, sponges) are disposable, or must be thoroughly cleaned and high level disinfected or sterilized between uses.
12. Sinks used for cleaning medical devices are cleaned at least once daily.

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 recoded 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.
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.
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.
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/devices are sterilized in the open position and according to the manufacturer's instructions if disassembly is required for sterilization.
13. 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.
5. Dry with lint free cloth.
6. Reassemble, as necessary, according to manufacturer's instructions.
7. Wrap in _____ (indicate type of wrapping material: peel pouch)
8. If not part of the wrap, apply internal and external chemical indicators.
9. Label with date of sterilization and load number.
10. Place in sterilizer.
11. Select _____ cycle (appropriate cycle e.g., wrapped, porous, nonporous).
12. Check printout/display to ensure all cycle parameters have been met and sign on print out or in log book.
13. Remove when cycle is finished and packs are completely dry.
14. 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.
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.
11. If instrument has channels or lumens, purge with alcohol to facilitate drying.
12. Dry.
13. 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.

Sterilization Log Template

Sterilization Parameter and Cycle Documentation Autoclave # _____

Date and Time	Load Number	Contents of the load	Temperature achieved (°C or °F)	Time length of cycle (minutes)	Internal Chemical Indicator (Pass or Fail)	Daily Biological Indicator (Pass or Fail)	Daily Biological Indicator Control (Pass or Fail)	Reprocessing staff name

Internal Chemical indicator:
 Type in use:
 Lot number:
 Expiry:

Biological indicator:
 Type in use:
 Lot number:
 Expiry:

Common Deficiencies Identified from Recent On-Site Audits

1. Biological Monitoring not being performed.
2. That all required Personal Protective Equipment is either not available or not worn by staff when reprocessing.
3. That the manufacturer's instructions for reprocessing equipment are not available.
4. That sterilization monitoring parameters (digital, mechanical chemical and biological) are not documented.
5. That high level disinfectant chemical test strip results are not documented.
6. That 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)

