

## FREQUENTLY ASKED QUESTIONS

# IPAC Lapses

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## Reprocessing in Community Health Care Settings

Community health care settings include, but not limited to, clinical office practice, physicians, dentists, chiropodists, podiatrists and midwives.

### Q1. What are the requirements for purchasing a new sterilizer for my clinic?

When purchasing a new sterilizer for your clinic there are a number of criteria that need to be met.

- Verify the sterilizer you are intending to purchase has a Health Canada medical device license and is legal for sale and use in Canada.<sup>2</sup> The cycles available on the sterilizer need to be compatible with the cycles required to sterilize your equipment. You will need to verify this. Check the cycles available against those required by the manufacturer's instructions for use (MIFUs) of your equipment.<sup>2</sup>
- If they are not the same, then this is not the sterilizer for your clinic. Using cycles other than those stated in the MIFUs for the items being sterilized may result in incomplete sterilization or damage to the function and integrity of the items being sterilized.<sup>2,3</sup> As part of the quality assurance for the sterilizer, the physical parameters (time, temperature and pressure) are to be monitored. Purchase a sterilizer with a print-out or the ability to download the information to a USB flash drive and save it to your computer records.

**Note: You need to check, verify and document physical parameters at the end of every load.<sup>2</sup>**

- Pre-vacuum table-top sterilizers are recommended for clinical office settings.

## **Q2. What are other environmental considerations for my sterilizer?**

Ensure you have access to the required water type. This could be potable tap water, distilled, or sterile water depending on the sterilizer's MIFU.<sup>2</sup>

- Ensure the space where reprocessing will occur:
  - is away from patient care areas
  - has sufficient space and is designed to allow for a one-way flow of items from contaminated to clean
  - has a clear separation of clean and contaminated spaces
  - has sufficient space for the reprocessing equipment and all necessary supplies
- Surfaces in the reprocessing area are easily cleaned and disinfected
- There is an eyewash station and a dedicated hand washing sink.<sup>1,2</sup>

## **Q3. Most dental equipment is purchased through a distributor. Every dental office uses similar, if not the same, equipment. Does the manufacturer have to provide the training? Can staff rely on the manufacturer's instructions?**

Staff may rely on the manufacturer's instructions, however, if the manufacturer's instructions are unclear or inadequate, they need to contact the manufacturer for clarification or more information.<sup>2</sup>

The manufacturer's information for all medical equipment/devices and decontamination equipment needs to be received and maintained in a format that allows for easy access by staff carrying out the reprocessing activities. The manufacturer is to supply the following:<sup>3</sup>

- information about the design of the equipment/device
- written and/or electronic manuals/directions for use
- device-specific recommendations for disassembly, cleaning and reprocessing of equipment/device, including evidence that the device has been validated for disinfection/sterilization using the recommended process/processes
- recommended detergents, enzymatic cleaners, disinfectants/sterilants and lubricants for use with the equipment/device
- recommended equipment/device exposure time to chemical agents
- education for staff on use, cleaning and the correct reprocessing of the equipment/device
- limitations related to number of times the equipment/device may be reprocessed without degradation
- recommendations for auditing the recommended process

## **Q4. A sterilizer has been in use in a clinical office practice for a few months; the clinic staff is wondering when they need to use a biological indicator? Is it daily or weekly?**

The sterilizer needs to be tested (challenged) using a biological indicator (BI) each day the sterilizer is used as well as tested for each type of cycle that is used that day. The BI is to be inside a PCD (process challenge device) and placed in the chamber of the sterilizer according to the MIFU.<sup>2</sup>

## **Q5. When reprocessing critical instruments, is disinfection required after cleaning and before sterilizing the instruments?**

Critical instruments are to be cleaned thoroughly before effective sterilization can take place. Disinfection is not necessary following cleaning and prior to sterilization.<sup>3</sup>

**Q6. How often should high level disinfectant be tested for efficacy?**

Chemical test strips are used to determine whether an effective concentration of active ingredients is present, despite repeated use and dilution of a high level disinfectant. The frequency of testing is based on how frequently the solution is used (i.e., test daily if used daily); at a minimum, test according to the manufacturer's instructions.<sup>3</sup>

**Q7. Should instruments ready for sterilization be left in the closed and locked position?**

All instruments need to be sterilized opened, unlocked and disassembled (where necessary) to allow steam contact with all surfaces.<sup>2</sup>

**Q8. A setting is currently cleaning and reprocessing instruments at the end of the day only. The team is working to improve practices. What is recommended regarding the delay in cleaning devices and instruments?**

It is recommended that instruments be cleaned as soon as possible after use so that organic material will not dry on them. If there will be a delay in reprocessing, the instruments should be soaked in an approved instrument soaking solution until reprocessing resumes.<sup>1</sup>

**Q9. Can a single-use medical device be reprocessed and reused if the setting has in place policies and procedures that address the reprocessing of the device?**

Critical and semi-critical medical equipment/devices labelled as single-use are not to be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor (there are currently no licensed reprocessors in Canada). Settings that wish to have their single-use medical equipment/devices reprocessed by a licensed reprocessor must ensure their policies and procedures address the reprocessor's certification by a regulatory authority or an accredited quality system auditor that ensures the cleanliness, sterility, safety and functionality of the reprocessed equipment/devices.<sup>1</sup>

**Q10. Is a spore test the same as a biological indicator (BI)?**

Yes, a spore test is a common term referring to the biological indicator. Sterilization is the destruction of all microorganisms including spores.

**Q11. If my autoclave/sterilizer passes biological indicator testing (spore testing) and chemical testing (external Type 1/internal minimum Type 4 indicators) is it appropriate to use the unit?**

To determine if the autoclave sterilizer is ready to use you need to consider the following:

- whether the unit is licensed for use in Canada<sup>2</sup>
- if the unit has been set up by the vendor as per the manufacturer's instructions for use (MIFU) and verified to be in working order<sup>2</sup>

For the day-to-day running of the autoclave, the following need to be considered:

- If your autoclave has dynamic air removal (i.e., pre-vacuum) a level two indicator (e.g., Bowie Dick) will need to be done to verify that unit is able to pull all the air out of the sterilization chamber. Failure to remove all the air can result in incomplete sterilization.<sup>1,2</sup>
- The Bowie Dick must be done each day the autoclave is used.<sup>2</sup>
- Biological indicators (BIs) confirm that the conditions have been met for sterilization.<sup>2</sup>

- A BI is used to test the sterilizer once each day the sterilizer is used as well as tested for each type of cycle that is used that day. The BI is to be inside a PCD (process challenge device) and placed in the chamber of the sterilizer according to the MIFU.<sup>1,2</sup>
- Physical parameters (time, temperature, pressure) need to be checked, verified, and documented for each load.
- Every wrapped item that is sterilized requires both an external and internal chemical indicator (CI).<sup>3</sup>
- Each package needs an externally visible CI for the purpose of differentiating between processed and unprocessed packages.<sup>2</sup> This indicator is typically a Type 1 (process indicator).
- An internal CI shall be placed inside all packages. This indicator shall be placed in the area of the package that is least accessible to steam.<sup>2</sup>
- At a minimum a Type 4 indicator which responds to two or more of the critical variables (time, temperature, pressure) of the sterilization process can be used as an internal CI.

The type of wrapper/pouch used needs to be verified as suitable for the items being wrapped/pouched for sterilization, and the sterilizer to be used. Check the MIFUs of items to be sterilized and the sterilizer for this information. The cost of wraps needs to be incorporated in the operational costs of the organization.<sup>2</sup>

Ensure that the manufacturer's instructions for installation, operation, cleaning and preventative maintenance of the sterilizing equipment are followed.<sup>3</sup> A preventative maintenance program will help ensure the sterilizer's maximum performance and avoid unnecessary downtime.

Items that have been run through the autoclave can be determined to be sterile and ready to use if the:

- autoclave is licensed for use
- autoclave has been set up as per the autoclave's MIFU
- autoclave has passed the Bowie Dick test (pre-vacuum autoclaves only) and BI on the day of use
- the physical parameters have all been met
- and the external and internal CI have both changed colour to indicate a pass
- items were all properly cleaned prior to packaging

Then, the items run through the autoclave can be determined to be sterile and ready to use provided the items are stored in a manner as to maintain the integrity of the packaging.<sup>1,2,3</sup>

**Q12. The newer autoclaves are USB compatible and automatically record each sterilization cycle's parameters. Some are also designed not to run if the physical parameters are not achieved. An error message will be displayed and the cycle stopped. Should we print out the autoclave data on a regular (daily) basis?**

Whether the autoclave has a printer or uses a USB drive to record and store the physical parameters (time, temperature, pressure) of an autoclave cycle, the physical parameters are to be reviewed after every cycle to verify the conditions sterilization.<sup>2</sup> It is not prudent to rely solely on the error mechanism of the autoclave. After each cycle review the following:

- correct cycle was used for the items in the autoclave (e.g., wrapped or unwrapped)
- correct temperature was attained
- correct pressure was achieved
- correct length of time - the autoclave was at the correct temperature and pressure for the correct length of time (also called the sterilization phase)

After the physical parameters have been verified, the operator of the autoclave is to document, that the parameters have been reviewed and verified, following clinic policy and procedure.<sup>2</sup>

**Q13. What do IPAC guidelines recommend we include in the clinic's reprocessing policies and procedures?**

Each clinic needs to develop written policies and procedures for all aspects of reprocessing based on current recognized standards and these are reviewed annually. Staff responsible for reprocessing are to be provided education on the policies and procedures on hire, when changes are made and on a regularly scheduled basis (e.g., yearly)<sup>1</sup> and ensure that there is a policy, procedure and/or process on the following:

- preventative maintenance of cleaning and sterilization equipment, with written documentation that this has occurred<sup>1</sup>
- quality monitoring and documentation of the reprocessing process (e.g., biological indicators, chemical indicators)<sup>1</sup>
- critical and semi-critical medical instruments labelled as single use are not reprocessed<sup>1</sup>
- removing faulty instruments until repaired or replaced<sup>1</sup>
- the recall of equipment and instruments from a failed load

**Q14. Detergent or enzymatic cleaning solution is discarded after each use. Does this apply to the enzyme cleaner used in the ultrasonic unit? The product monograms typically do not require the solution to be changed after each cycle.**

The manufacturer's instructions are to be followed for use and routine cleaning and maintenance of the ultrasonic washer.<sup>3</sup>

The ultrasonic washing solution is to be changed at least daily or more frequently if it becomes visibly soiled or if the manufacturer's instructions specify more frequent changes.<sup>3</sup>

**Q15. Do we have to hold equipment until the Biological Indicator (BI) passes? What do we have to do to use equipment if we don't hold it until the BI is read?**

Best practices state the equipment/devices needs to be held until the BI results are available. Challenging an autoclave through the use of a BI every day is an important part of the quality assurance program of an autoclave.

- A BI is used to test the sterilizer each day that it is used and with each type of cycle that is used that day. The BI is to be inside a PCD (process challenge device) and placed in the chamber of the sterilizer according to the MIFU.<sup>2</sup>
- Clinics that sterilize implantable devices - a BI is included in every load containing implantable devices.<sup>2</sup>
- Most BIs require up to 48 hours of incubation before the test is complete. However, rapid readout BIs are available that provide results in one hour.<sup>4</sup>

**RELEASING A LOAD**

Items in a processed load are not be released until the results of the daily BI test are available.

If holding back the processed load is not possible, evaluation and documentation of a process challenge device (PCD) containing a Type 5 or 6 chemical indicator and checking, verifying and documenting the specific cycle physical parameters may be used to justify the release of routine loads.<sup>2</sup>

## RELEASING A PACKAGE

If a sterilized package must be released prior to knowing the BI results for the day, the internal CI in each package to be released is to be a Type 5 or 6 CI.

In this situation, evaluate and document the internal CI (Type 5 or 6) results and check, verify and document the specific cycle physical parameters to justify the release of the routine package.<sup>2</sup>

## IMPLANTABLE DEVICES

Implantable devices are to be quarantined until the results of the BI tests are available.<sup>2,3</sup>

In addition, ensure there are robust policies and procedures for documenting the reprocessing quality assurance processes and for recalling items released prior to knowing the BI results in the case of a BI failure.<sup>4</sup> To learn more about Type 5 or 6 chemical indicators see [Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices](#).

**Q16. A practice in dental offices and other healthcare settings is to load sterilization pouches with all the instruments needed for one procedure, often exceeding five instruments per pouch. Is there a limit to the number of instruments per pouch?**

It is impossible to state exactly how many instruments can go into a pouch as both instruments and pouches come in different sizes.

When making your decision apply the following principles:

- Packaging is a critical component of the sterilization process. Improper packaging materials and methods can inhibit steam penetration or lead to failure in maintaining sterility.<sup>2</sup>
- Paper-plastic sterilization pouches may be used for small, lightweight, low-profile items (e.g., one or two clamps), placed in the pouches in accordance with the manufacturers' instructions for use (MIFUs) and allowing for adequate air removal, steam penetration and evacuation to all surfaces.<sup>2,3</sup>
- Unless indicated otherwise by the MIFUs, the pouch can only be filled to a maximum of 75% of the inner surface area of the porous side.<sup>2</sup>
- The pouch size should be adequate to contain the instruments ensuring these do not touch the pouch seams.<sup>2</sup>
- In some circumstances, additional packaging requirements maybe indicated by the MIFUs (e.g., foam corner protectors, tip protectors).<sup>2</sup>

**Q17. I learned that instruments inside a sterilized package remained sterile unless something happened to the packaging (e.g., there was a tear, or the packaging got wet). I was told this was event related sterility (ERS). But now, I have noticed manufacturers' expiration dates for some of the pouches and packaging we use. I am not really sure what to do – should I continue with ERS or use the expiration date on the packaging?**

Pouches and packaging used in reprocessing provide a sterile barrier. The loss of the integrity of the sterile barrier is dependent on both the performance of the sterile barrier (e.g., the seals on a pouch) AND the conditions to which the pouch/package is subjected. These conditions could include storage, handling, transportation, interaction of the device with the sterile barrier (e.g., sharp instrument puncturing the package), or environmental conditions (e.g., temperature, humidity). The contents of a punctured package, caused by any reason, are no longer sterile.

Manufacturers of packaging materials are required to evaluate their products for performance over time. This information is included in the manufacturers' instructions for use (MIFUs). When purchasing packaging be aware there may be an expiration date based on the manufacturer's expected performance of the packaging. Once that time has passed, the manufacturer can no longer guarantee the performance of the packaging.

In summary, **determining if a packaged instrument is still sterile is dependent on events that may have compromised the integrity of the packaging AND any expiration date provided in the packaging MIFUs.**<sup>2</sup>

**Q18. In a medical or dental practice setting, who is responsible for overseeing the reprocessing of medical/dental instruments and devices? Where do I find training on sterilization for staff?**

Depending on the practice setting, the medical director, dental director, nurse practitioner, midwife or dental hygienist leading the practice is the supervisor responsible for overseeing the reprocessing of medical and dental instruments and devices. As such, at a minimum, they are to have completed a formal training program recognized by the health care setting and experience and demonstrated competency in medical device reprocessing.<sup>2,3</sup>

It is the supervisor's responsibility to ensure that any staff involved in the cleaning, disinfection and/or sterilization of medical equipment/devices are properly trained and that their practice be audited on a regular basis to verify that standards are met.<sup>3</sup> To assist staff involved in reprocessing, there are many different resources for education/training on sterilization (reprocessing).

- The first step in choosing the appropriate education, training and certification requirements for staff is to determine what reprocessing activities are being performed in the clinical office setting.
- Conduct an organizational risk assessment to determine what education, training, and certification is recommended for your staff.
- It is important that staff responsible for cleaning and reprocessing be trained to a level required for the volume and complexity of the equipment to be reprocessed.

Information regarding how to perform a risk assessment can be found at [Education, Training and Certification Recommendations for Reprocessing in Clinical Office Settings](#). A list of educational resources can be found in the [Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings](#). Additionally, Public Health Ontario offers an on-line learning course: [The Reprocessing in the Community Health Care Settings](#).

**Q19. How should I document and store the data from my sterilizer?**

Every practice setting needs to have a policy that outlines which records are to be maintained (biological indicator (BI) as a process challenge device (PCD), Type 5 or 6 chemical indicator (CI) PCD (if used) and the physical parameters of the sterilizer). When developing your policy consider:

- how the records will be maintained (printed/electronic)
- how long the records are to be maintained
- the process for the backing up of electronic records, and where the records are kept.<sup>2</sup> Records need to remain legible, readily identifiable, and retrievable.

Documentation of the BI and or CI PCD is to be done in a manner that will link the BI and/or CI PCD test results to the items in the sterilized load.<sup>2</sup> All BIs used in testing the sterilization cycle and as controls shall be accounted for.<sup>2</sup>

## **BI AND CI PCD**

Documentation shall include:

- date and time of sterilization
- sterilizer number (if there is more than one sterilizer used in the practice setting)
- load/cycle number
- location of the PCD within the load
- results of the BI and/or CI PCD<sup>2</sup>

The BI and or CI PCD results are reviewed and verified by the operator of the sterilizer and are recorded in a paper OR electronic form.

## **PHYSICAL PARAMETERS**

The following will be recorded:

- the sterilizer identifier
- date and time of the load/cycle
- load/cycle number in that sterilizer
- exposure time, temperature, and pressure achieved<sup>4</sup>
- the contents and quantity of sterilized packages

The printed or electronic record is to be reviewed the end of each cycle by the operator of the sterilizer. The operator will then confirm that process parameters (exposure time, temperature, and pressure) were met by either initialing the report (if printed) or by means of a password-protected entry (if electronic).<sup>2,3</sup>

In addition, the reason for any PCD or parameter abnormalities (e.g., maintenance test, operator cancellation) and any actions taken are to be documented.<sup>2</sup>

Public Health Ontario has developed a document, [Sterilization Monitoring Log for Table-top Steam Sterilizers](#), to record process parameters for steam sterilization in community health care settings.

**Q20. Multiple-use pre-filled syringe/dispenser with single use disposable tips are used to deliver various dental products including impression materials, adhesives, dental composites, and endodontic (root canal) materials to a treatment site in the mouth. Sometimes the syringe/dispenser comes in contact with a patient's cheek, lips, blood or saliva. How do I ensure the syringe/dispenser is safe to use on the next person?**

There is potential for the multi-patient use dental syringe/dispenser to come into contact with a patient's mucous membranes (e.g., cheeks, lips) or for the oral health care worker to handle the dispenser with contaminated gloves hands; the dispenser is considered a semi-critical device.<sup>6,7</sup> Once contaminated, the remaining material is to be considered not eligible for use on another patient. Semi-critical items require heat-sterilization<sup>3,6</sup> or subjected to immersion in a high-level chemical disinfectant.<sup>6,7</sup> "However, multiple-use dental dispensers cannot be reprocessed using heat sterilization (e.g., steam autoclave) or immersion in high-level disinfectants because this may damage the dispenser



or material contained in the dispensers.”<sup>7</sup> These devices, once contaminated, cannot be adequately disinfected by wiping with a chemical disinfecting solution, therefore, contaminated multiple-use dental dispensers are to be discarded in order to avoid the risk of cross-contamination to patients.<sup>7</sup>

Techniques to reduce the risk of cross-contamination include:

- avoiding contact of the reusable parts (e.g., the body of the multiple-use dental dispenser) with the patient’s mouth by dispensing product in a dappen dish or similar dispensing/mixing well designed for this purpose. Alternatively, the product could be dispensed on a single-use mixing pad.<sup>7</sup>
- using new, uncontaminated gloves when handling multiple-use dental dispensers.<sup>7</sup>
- application disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient.<sup>7</sup>

## Medication Administration

### **Q21. Should the diaphragm of medication vials be wiped with 70% alcohol prior to accessing with a syringe?**

Adherence to aseptic technique when accessing medication vials is of utmost importance. Medication vials should be accessed on a surface that is clean and where no dirty, used or potentially contaminated equipment is placed or stored. The access diaphragm of vials should be scrubbed using friction and 70% alcohol and should be allowed to dry before inserting a new needle and syringe into the vial.<sup>1</sup>

### **Q22. A pharmacist has been using the solutions from multidose vials until the vials are empty. Is this appropriate practice?**

It is important to label multidose vials with the date they were first used. Review the product leaflet for recommended duration of use after entry of the multidose vial and discard opened multidose vials according to the manufacturer’s instructions or within 28 days, whichever is shorter.<sup>1</sup>

### **Q23. During a clinical office practice inspection, we found a needle left protruding from a multidose vial. We were told this facilitated the physician’s access to the solution. Do we need to make recommendations regarding this practice?**

Once the medication is drawn up, the needle should be IMMEDIATELY withdrawn from the multidose vial. A needle is NEVER to be left in a vial to be attached to a new syringe.<sup>1</sup>

## Laboratory

### **Q24. Our public health unit is following up on an IPAC lapse investigation where it was determined that either 1) clients at risk should be advised to have testing performed for blood borne pathogens, or 2) a look back is indicated. What is the role of Public Health Ontario Laboratories (PHOL)?**

PHOL can provide consultation to the health unit regarding selection of appropriate PHOL tests and testing processes when a look-back or clinical testing is indicated. If PHOL is assisting with testing during the testing phase of a lapse, then PHOL can provide support to the health unit including coordination of primary PHOL testing (if any) and further testing to investigate possible linkages (e.g. molecular typing).

## Office design/facilities

### Q25. How do we maintain dental unit water quality when under a boil water advisory?

#### WHAT IS A BOIL WATER ADVISORY

“Drinking water advisories may be issued due to a range of factors that may affect drinking water, such as, water main breaks, low pressure events, presence of microbiological parameters, low disinfectant levels, or drinking water system compliance issues (e.g., equipment failure). The local medical officer of health may issue a boil water or drinking water advisory or require the system owner to take other corrective actions if there is a concern that the drinking water may not be fit for human consumption. The system owner may also recommend its consumers boil their water or use an alternative source as a precautionary measure.”<sup>4</sup>

#### DURING DENTAL PROCEDURES

“During a boil water advisory, water should not be delivered to patients through the dental unit, ultrasonic scaler, or other dental equipment that uses the public water system. This restriction does not apply if the water source is isolated from the municipal water system (e.g., a separate water reservoir or other water treatment device cleared for marketing by FDA). Patients should rinse with bottled or distilled water until the boil-water advisory has been cancelled. During these advisory periods, tap water should not be used to dilute germicides or for hand hygiene unless the water has been brought to a ‘rolling boil for greater than 1 minute and cooled before use).”<sup>5</sup>

#### HAND HYGIENE DURING THE ADVISORY

“For hand hygiene, antimicrobial products that do not require water (e.g., alcohol-based hand rubs) can be used until the boil water notice is cancelled. If hands are visibly contaminated, bottled water and soap should be used for handwashing; if bottled water is not immediately available, an antiseptic towelette should be used.”<sup>5</sup>

#### AFTER THE ADVISORY IS CANCELLED

“When the advisory is cancelled, the local water utility should provide guidance for flushing of waterlines to reduce residual microbial contamination. All incoming waterlines from the public water system inside the dental office (e.g., faucets, waterlines, and dental equipment) should be flushed. No consensus exists regarding the optimal duration for flushing procedures after cancellation of the advisory; recommendations range from 1 to 5 minutes). The length of time needed can vary with the type and length of the plumbing system leading to the office. After the incoming public water system lines are flushed, dental unit waterlines should be disinfected according to the manufacturer’s instructions.”<sup>5</sup>

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