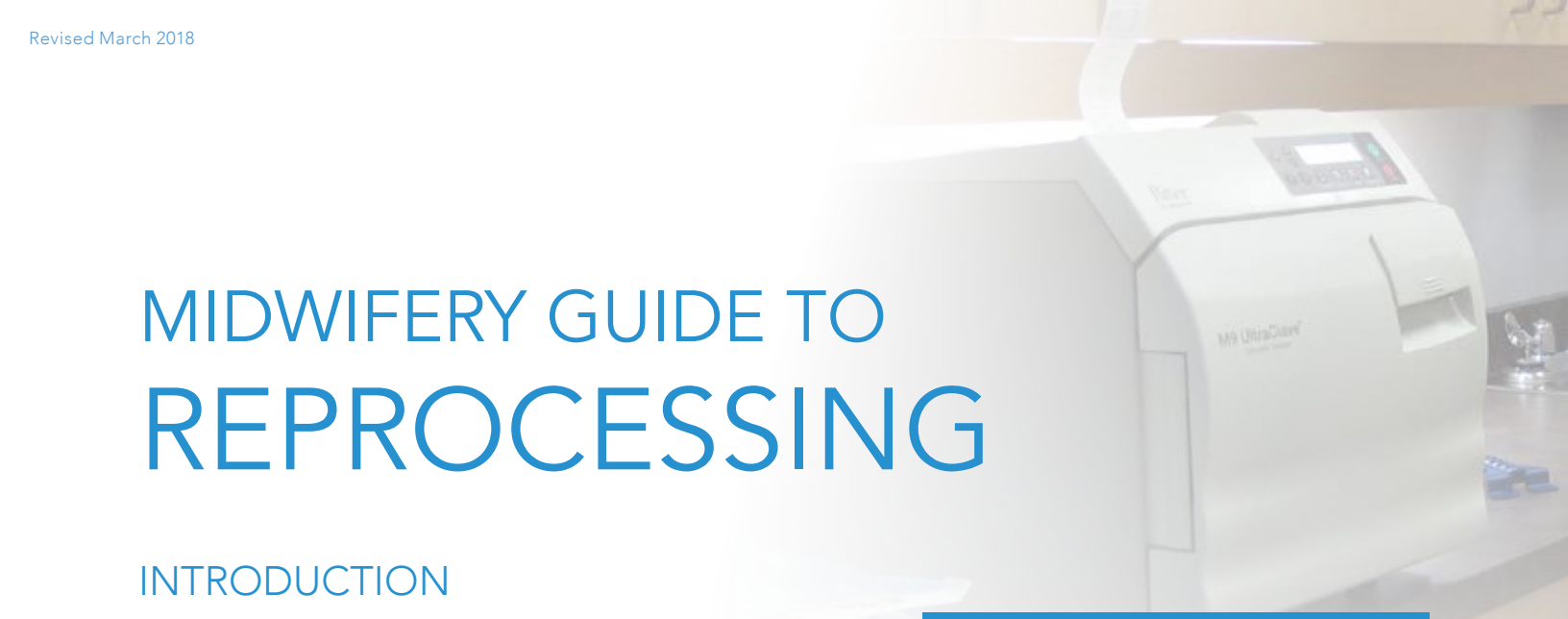


MIDWIFERY GUIDE TO REPROCESSING

INTRODUCTION

There isn't one surefire way to know if an instrument has been effectively sterilized. However, there are a number of steps that can be taken to ensure the greatest chance of effective sterilization, and to confirm that the ideal sterilization conditions have been met.

REPROCESSING refers to the steps needed to prepare a potentially contaminated reusable medical device for use - that is to achieve sterility (pre-cleaning, cleaning, packaging, autoclaving and verification).

This document provides guidance about each of these elements in relation to gravity displacement autoclaves (what most midwives use, e.g., Ritter M9 or M11) – not dynamic air removal autoclaves. Gravity displacement autoclaves let steam fall through the contents of the autoclave and out; dynamic air removal autoclaves (and others) are more complex and use connections to pull air or steam out of the autoclave. While most of the information is relevant to both, some aspects are different and specific guidance is needed if a midwifery practice group (MPG) is using a dynamic air removal autoclave.

The Association of Ontario Midwives (AOM) and College of Midwives of Ontario are working with Public Health Ontario (PHO) to help midwives incorporate reprocessing best practices. Local public health units have expertise in assessing existing practice, but are less knowledgeable about the details of midwifery and finding solutions to challenges. As a result, we encourage midwives to call the AOM as a first step to get more advice on reprocessing. The AOM, with the assistance of experts and outside resources, has developed a series of reprocessing resources specific to the midwifery profession. Some clinics have also consulted with their hospital's infection control department for guidance and advice.

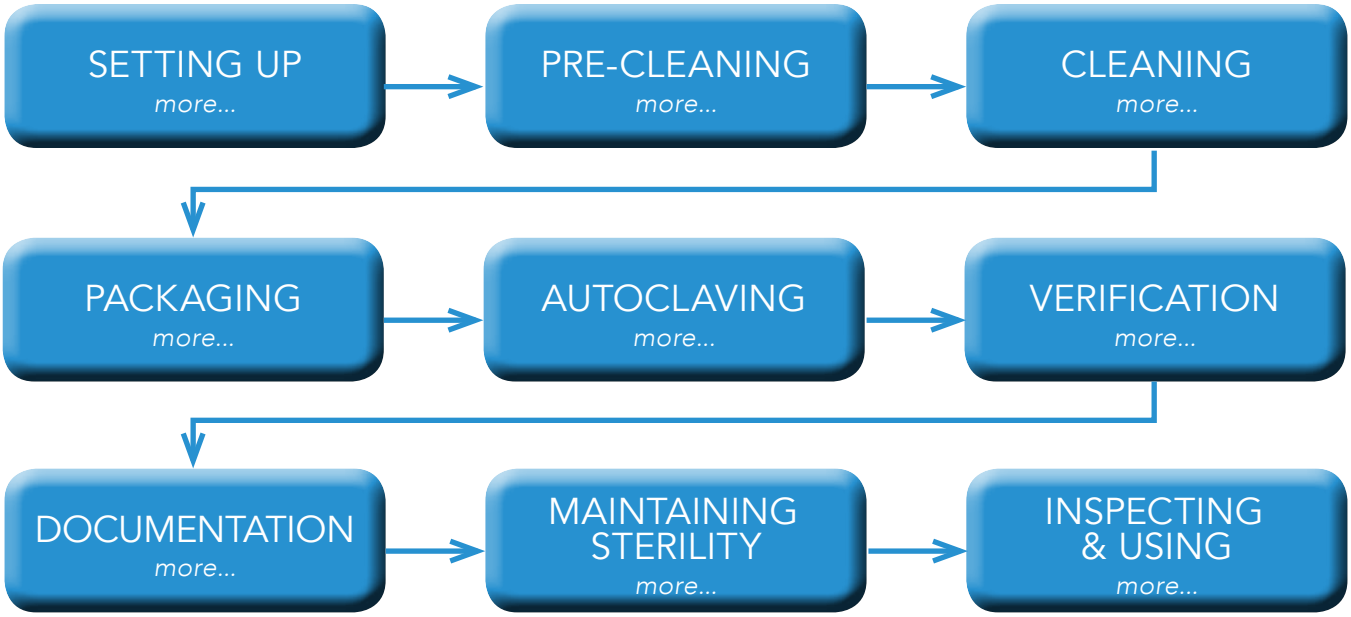
This document is organized according to the reprocessing cycle: setting up, pre-cleaning, cleaning (including soaking and packaging), autoclaving, verification, and maintaining sterility. A self-assessment checklist and additional resources are found in the appendices.

TO ENSURE INSTRUMENTS ARE STERILIZED:

- the autoclave needs to be functioning well (so as to be able to sterilize the instruments;
- instruments need to be cleaned and disinfected (without contaminants);
- they need to be appropriately packaged (to allow steam to penetrate); and
- they need to be stored in a way that maintains sterility.

More resources, including those mentioned in this guide, can be found on the AOM website.

REPROCESSING CYCLE



QUICK HITS

Although all of these practices are important, implementation takes time. There are some simple, straightforward changes that your MPG can implement immediately – many of which your MPG may already be doing – while you consider how to make more fulsome changes.

- Package your instruments in pouches, without overloading the pouches. Consider episiotomy scissors in one pouch, a hemostat and a pair of cord scissors in another pouch, and a pair of hemostats in a third pouch. Suture instruments can be packaged in two pouches - e.g., needle driver and scissors in one pouch and forceps and a snap in a second pouch. You could also use disposable cord clamps instead of one or both of the reusable hemostats.
- Buy single packs or five-packs of sterile gauze instead of sterilizing your own. Unless the gauze is specifically intended to be sterilized in a steam autoclave and is autoclaved in a dedicated cycle, it is not going to be effectively sterilized in your autoclave.
- Use biological indicators (with a control) each day that your autoclave is used and putting Class 5 chemical indicators in each pouch.
- Take care of your autoclave. Go look at it right now - is it flashing weekly, daily or monthly maintenance? Pull out your instruction manual and do the recommended maintenance.
- Determine a schedule for autoclave maintenance and assign one or two people to this task so that it happens regularly.
- Pre-clean your instruments as soon as possible after use and clean and package your instruments at the clinic. Take a minute to use a new brush to scrub instruments (even a gentle, disposable toothbrush will do) with an appropriate cleaning product, such as enzymatic detergent, according to manufacturers' instructions.

- Be mindful of cross-contamination: keep clean and dirty separate from each other, wear gloves, and wash your hands frequently. Ensure that the instruments are totally dry before you package them.
- When you unload your instruments, make sure the packs are not wet and the chemical indicators have changed.
- Look at instruments when you unpack them for use. Make sure the indicator within demonstrates a "pass" and that the pack has no signs of water damage or tiny tears or rips.
- Pack your pouches in a way that keeps them safe, dry and not too squished, such as a rectangular Tupperware.

Once you have done these first few steps, you are well on your way to improving your reprocessing practices. These steps will require some decision-making about your clinic's reprocessing procedure and your priorities (e.g., workload versus cost).

If, after reading this guide, you are feeling overwhelmed, you might want to investigate outsourcing or disposable options before investing in new reprocessing equipment or while waiting for your MPG to decide what to do.

Alternatives

Because of the complexity of reprocessing standards, some MPGs have chosen alternatives to reprocessing within the clinic setting. Some have contracted with a private reprocessing service provider or hospital Medical Device Reprocessing Department (MDRD); others have switched to disposable instruments.

Some MPGs have switched to disposable instruments or have out-sourced reprocessing to their hospital.

Midwives who have outsourced reprocessing to their hospital suggest starting with the manager of the hospital's MDRD. They found that MDRD managers were supportive because they understood that safe sterilization practices in the community are challenging for those without dedicated space and specialization.

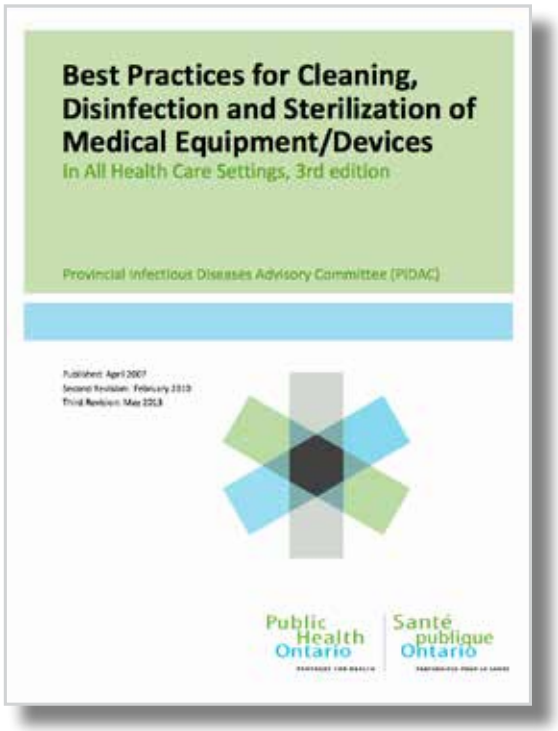
For tips on approaching your hospital or advice before your MPG signs a contract, call the AOM's risk management team who can share comparative pricing, connect you with others who have done this, and provide some contractual recommendations (1-866-418-3773). For example, although the third party will take responsibility for reprocessing, this does not completely relieve the MPG of their obligations to ensure the third party is doing it properly. As a result, you want to be sure that the company or hospital accepts legal responsibility for their procedures in the contract.

Other MPGs have switched to disposable instruments. There are a few different options for this, some of which come in kits and others can be purchased individually. At this time, there are no specific disposable cord scissors or episiotomy scissors, however, there are various scissor options that may be appropriate. For more information on this, consult your supplier.

Training and Other Resources

The AOM has developed a series of resources to help midwives understand the very complicated volumes of material on reprocessing. In developing these recommendations, the AOM has referenced numerous documents from PHO and the Canadian Standards Association (CSA). If you are just starting to think about reprocessing, start with the AOM webinars on reprocessing; check-out the archived webinars on the AOM website.

Everyone involved in reprocessing needs training from a recognized reprocessing course as well as on the MPG procedures.



PHO recommends that each person who engages in reprocessing take a course in the topic (which the webinars are not). The AOM's Infection Prevention and Control (IPAC) Work Group has considered this recommendation and decided that, in the midwifery context, it makes the most sense for one person from each MPG to attend such a course and that other people involved in reprocessing complete an e-learning from PHO on Reprocessing in Community Health Care Settings.

There are a number of courses available, but the one that the IPAC Work Group recommends (as the shortest course recognized by public health) is with the Medical Device Reprocessing Association of Ontario. This course takes approximately one week.

Through the AOM's Professional Development Fund, each practice group that autoclaves its own instruments qualifies for an additional $750 (over and above the maximum funding for individual midwives) to send an administrator or midwife to instrument sterilization training. See the AOM website for more information.

SETTING-UP

What should I reprocess?

According to the Spaulding Classification of medical devices, all items that come into contact with blood or sterile areas of the body are considered "critical" items that require sterilization. However, only those critical items that are also intended to be autoclaved should be autoclaved.

Before purchasing new instruments, confirm whether it can be safely reprocessed according to manufacturer's instructions. When reprocessing new equipment, check the manufacturer's instructions about how it needs to be reprocessed.

Before purchasing new instruments, confirm whether they can be safely reprocessed according to manufacturer's instructions. When reprocessing new equipment, check the manufacturer's instructions about how it needs to be reprocessed.

As a result, you may want to check the instructions before purchasing an item to confirm that the item can be safely reprocessed according to current recommendations and with the autoclave that you are using. Some devices have reprocessing instructions that do not reflect best practice, that require specific considerations or are not possible with the autoclaves that midwives use.

For example, laryngoscope handle sleeves, handle inserts and blades come with specific disassembly and sterilization instructions depending on the model that you are using. These help ensure appropriate reprocessing without damaging the device.

Other items are intended for single-use or single-patient use and cannot be reprocessed (e.g., needles, vacutainer, or nipple shields).

What equipment do I need in order to reprocess?

To pre-clean, clean, package, autoclave, verify and store instruments, your practice will need the following:

- ☑ Enzymatic detergent
- ☑ Cleaning brush
- ☑ Disposable lint-free towels
- ☑ Packaging for instruments (e.g., pouches, wraps)
- ☑ Autoclave
- ☑ Class 4 or 5 chemical indicators
- ☑ Autoclave printer
- ☑ Biological indicators
- ☑ Incubator
- ☑ Felt-tip marker
- ☑ Log book
- ☑ Practice protocol
- ☑ Autoclave cleaning products
- ☑ Distilled water

Where should I reprocess?

MPGs planning renovations may wish to consider infection prevention and control and reprocessing layout.

PHO recommends that reprocessing occur in a dedicated area that is physically separate from direct care areas and from where clean, disinfected and sterile items are handled or stored. Many clinics do not have an extra room available for this purpose, however, it is possible to create a space that is as ideal as possible for reprocessing within most existing clinic spaces.

To the extent possible, set-up dedicated cleaning and reprocessing space to prevent cross-contamination.

Key things to consider:

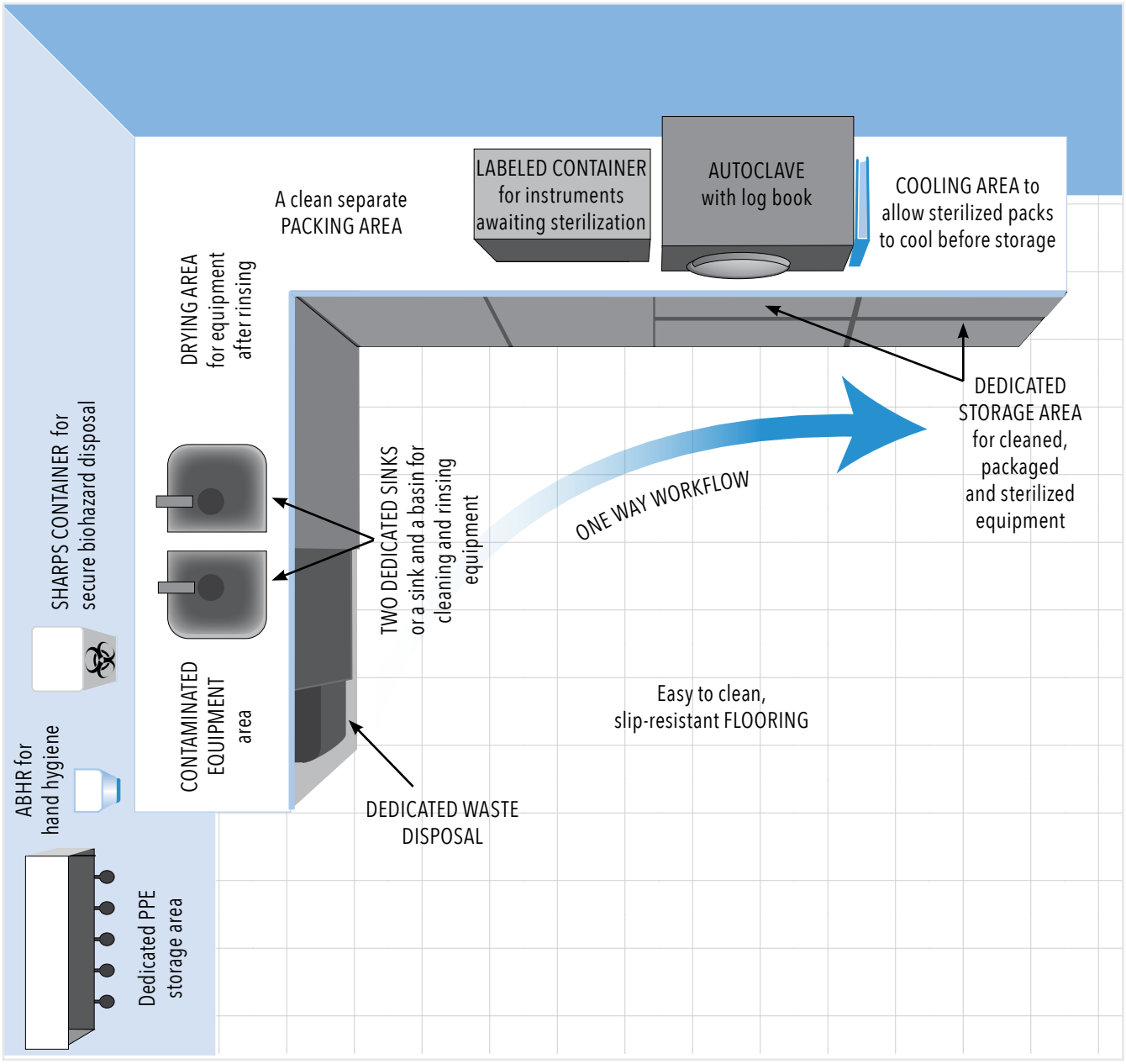
- Ensure your work flow goes from dirty to clean, so that dirty items aren't contaminating clean items during storage (by direct or indirect contact), washing (by splash) or packaging (by contact with dirty surfaces).
- Find an area that clients do not access, or at least do not access during the reprocessing time.
- Find an area that does not have laundry facilities, as humidity affects package integrity and lint can interfere with sterilization.

- Dedicate an area that is uncluttered and easy to clean that allows for adequate space between areas used for dirty storage, cleaning, packaging, autoclaving, storage pending verification results, and storage after results.

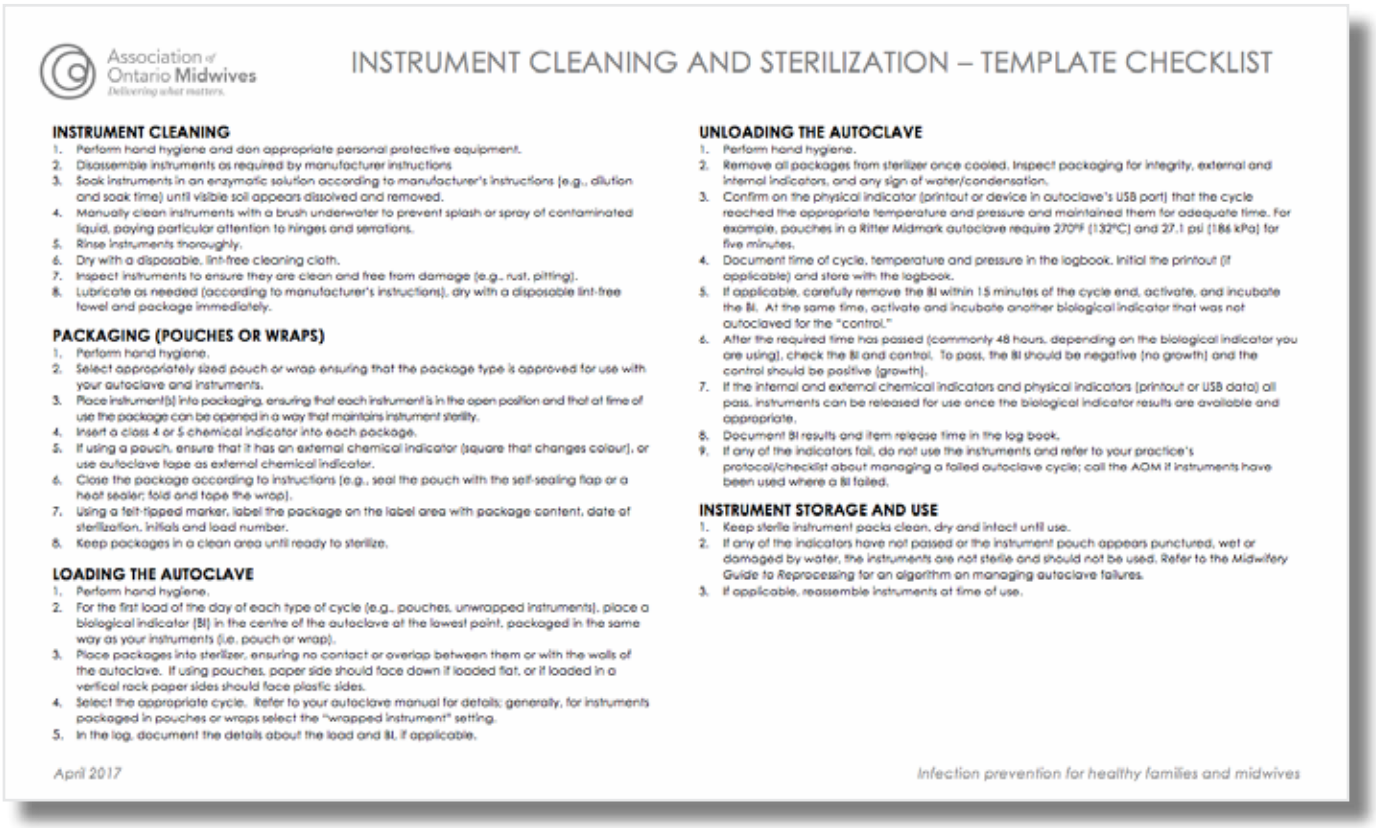
It may be helpful to review pages 75-78 of the Provincial Infectious Diseases Advisory Committee list of recommendations for the set-up of reprocessing areas in any health-care settings. As this information is not specifically designed for midwifery, it may seem overwhelming. Please feel free to contact the AOM's Quality and Risk Management team with any questions.

LAY-OUT OF REPROCESSING AREA

Adapted from the College of Physicians and Surgeons of Alberta



You may also want to include prompts and informational aids in the reprocessing area so that those who are carrying out the reprocessing are reminded of the steps involved. The AOM has autoclave logs, sample practice protocols and a reprocessing checklist.



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INSTRUMENT CLEANING AND STERILIZATION – TEMPLATE CHECKLIST

INSTRUMENT CLEANING

1. Perform hand hygiene and don appropriate personal protective equipment.
2. Disassemble instruments as required by manufacturer instructions.
3. Soak instruments in an enzymatic solution according to manufacturer's instructions (e.g., dilution and soak time) until visible soil appears dissolved and removed.
4. Manually clean instruments with a brush underwater to prevent splash or spray of contaminated liquid, paying particular attention to hinges and serrations.
5. Rinse instruments thoroughly.
6. Dry with a disposable, lint-free cleaning cloth.
7. Inspect instruments to ensure they are clean and free from damage (e.g., rust, pitting).
8. Lubricate as needed (according to manufacturer's instructions), dry with a disposable lint-free towel and package immediately.

PACKAGING (POUCHES OR WRAPS)

1. Perform hand hygiene.
2. Select appropriately sized pouch or wrap ensuring that the package type is approved for use with your autoclave and instruments.
3. Place instrument(s) into packaging, ensuring that each instrument is in the open position and that at time of use the package can be opened in a way that maintains instrument sterility.
4. Insert a class 4 or 5 chemical indicator into each package.
5. If using a pouch, ensure that it has an external chemical indicator (square that changes colour), or use autoclave tape as external chemical indicator.
6. Close the package according to instructions (e.g., seal the pouch with the self-sealing flap or a heat sealer; fold and tape the wrap).
7. Using a felt-tipped marker, label the package on the label area with package content, date of sterilization, initials and load number.
8. Keep packages in a clean area until ready to sterilize.

LOADING THE AUTOCLAVE

1. Perform hand hygiene.
2. For the first load of the day of each type of cycle (e.g., pouches, unwrapped instruments), place a biological indicator (BI) in the centre of the autoclave at the lowest point, packaged in the same way as your instruments (i.e. pouch or wrap).
3. Place packages into sterilizer, ensuring no contact or overlap between them or with the walls of the autoclave. If using pouches, paper side should face down if loaded flat, or if loaded in a vertical rack paper sides should face plastic sides.
4. Select the appropriate cycle. Refer to your autoclave manual for details; generally, for instruments packaged in pouches or wraps select the "wrapped instrument" setting.
5. In the log, document the details about the load and BI, if applicable.

UNLOADING THE AUTOCLAVE

1. Perform hand hygiene.
2. Remove all packages from sterilizer once cooled. Inspect packaging for integrity, external and internal indicators, and any sign of water/condensation.
3. Confirm on the physical indicator (printout or device in autoclave's USB port) that the cycle reached the appropriate temperature and pressure and maintained them for adequate time. For example, pouches in a Ritter Midmark autoclave require 270°F (132°C) and 27.1 psi (186 kPa) for five minutes.
4. Document time of cycle, temperature and pressure in the logbook. Initial the printout (if applicable) and store with the logbook.
5. If applicable, carefully remove the BI within 15 minutes of the cycle end, activate, and incubate the BI. At the same time, activate and incubate another biological indicator that was not autoclaved for the "control."
6. After the required time has passed (commonly 48 hours, depending on the biological indicator you are using), check the BI and control. To pass, the BI should be negative (no growth) and the control should be positive (growth).
7. If the internal and external chemical indicators and physical indicators (printout or USB data) all pass, instruments can be released for use once the biological indicator results are available and appropriate.
8. Document BI results and item release time in the log book.
9. If any of the indicators fail, do not use the instruments and refer to your practice's protocol/checklist about managing a failed autoclave cycle; call the AOM if instruments have been used where a BI failed.

INSTRUMENT STORAGE AND USE

1. Keep sterile instrument packs clean, dry and intact until use.
2. If any of the indicators have not passed or the instrument pouch appears punctured, wet or damaged by water, the instruments are not sterile and should not be used. Refer to the *Midwifery Guide to Reprocessing* for an algorithm on managing autoclave failures.
3. If applicable, reassemble instruments at time of use.

April 2017

Infection prevention for healthy families and midwives

How do I test the autoclave when it is first set-up? What is a challenge pack?

Because autoclaves can be temperamental, you want to confirm that they are consistently killing spores when the autoclave is first set-up, relocated or whenever it stops working. To do that, you use a challenge pack (also called a process challenge).

When an autoclave is set-up, moved or repaired, test it to be sure that it is consistently functioning.

In short, a challenge pack means running the most difficult cycle of your autoclave that you would ever run to confirm that it works. Take the following steps three times:

1. Package instruments as you normally would and put a biological indicator (BI) in the middle of the most difficult pack (i.e., the pack that is the densest and largest) – this is your "challenge pack."

2. Load the autoclave to the fullest that you normally would (noting that the test will fail if you overfill it) and put the challenge pack in the part of the autoclave that is hardest for the steam to reach. For most MPG autoclaves, this will mean in the bottom, near the drain (confirm this in the autoclave manufacturers' instructions).

3. Run the cycle as you normally would, check the physical and chemical indicators immediately (as you normally would). If they were successful, open the package to remove and incubate

the BI with a control BI to confirm if the load was successful. The instruments in the package will need to be set aside and reprocessed again for use. The other packages in the load can be released if the BI passes.

4. If the load was unsuccessful, see the algorithm for failed indicators.

Once your three challenge packs have passed, then you know that your autoclave works when loaded in that particular way. You can then use the autoclave regularly, with the appropriate indicators, as long as you load it in the same way.

What should I wear to reprocess?

PHO recommends that anybody performing reprocessing wear personal protective equipment (PPE). This is to protect the person doing the reprocessing from potentially infectious body fluids that may be on the instruments, as well as from chemicals and heat that could affect their health. Additionally, this protects the clients by keeping the reprocessor's bacteria, body fluids and hairs off of the instruments which could prevent their proper sterilization.

PHO recommends wearing PPE when performing reprocessing.

The PPE recommended by PHO for reprocessing includes an impermeable gown and face protection (such as a face shield or mask and eye shield), appropriate gloves and a hair net.

PRE-CLEANING AND CLEANING

How should I clean my instruments?

Cleaning involves both initial pre-cleaning immediately after use and cleaning immediately prior to autoclaving.

PRE-CLEANING: Home pre-cleaning will be more extensive than it would typically be in hospital because of different reprocessing equipment used and the delay between pre-cleaning at home and the completion of reprocessing at clinic.

Instrument pre-cleaning card
Available by emailing anna.ianovskaia@aom.on.ca


PRE-CLEANING

1. Dilute instrument cleaner* in lukewarm water according to the manufacturer's instructions (usually 30 mL is diluted in 3.8 L of water).
2. Soak instruments in the open position to prevent contaminant from drying on the instruments.
3. Using a designated brush, scrub instruments in the water, keeping them below the surface to prevent splash or spray.
4. Drain sink and rinse instruments with clean tap water.
5. Inspect instruments to ensure there is no organic material residue remaining on the instruments. If residue is noted, repeat steps 2 – 5.
6. Thoroughly dry pre-cleaned instruments using a disposable paper towel.*
7. Place dry, pre-cleaned instruments in closed container labelled ***dirty*** for cleaning, packaging and autoclaving in the clinic or alternate facility.

*Instrument cleaner and disposable paper towels should only be used if pre-cleaning – not for cleaning. Instead, use enzymatic cleaner and lint-free towels when cleaning prior to autoclaving.

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Keeping a clean brush and an instrument cleaner (preferably an enzymatic detergent) in a separate container with your birth equipment will allow you to pre-clean them at the client's home.

- Wash your instruments soon after use to ensure that all visible material is removed easily and prevented from drying before pre-cleaning.
- Used instruments are soaked according to manufacturers' instructions (approximately 10 minutes in lukewarm water and detergent) depending on how long it takes to remove

Remove visible material from the instrument as soon as possible after use to prevent the material drying on the instruments (which will hamper sterilization).

Clean instruments again before packaging and autoclaving.

organic material, then cleaned with a brush underwater to remove visible soil and rinsed with tap water.

- Unless pre-cleaning took place at clinic and will be immediately followed by cleaning and packaging, dry the instruments using a disposable towel. Pay particular attention to locks, hinges and grooves. Put instruments in a container separate from your clean equipment as these are still considered "dirty." The towel used for pre-cleaning does not need to be lint-free as the instruments will be cleaned again.

CLEANING: Once instruments are back in the clinic, they will need to be cleaned again before packaging as follows:

- Disassemble instruments, if manufacturer's instructions suggest doing so (e.g., speculums).

Follow the cleaning products' instructions.

- Soak instruments according to manufacturers' instructions (approximately 10 minutes) in a container or sink full of lukewarm water and enzymatic detergent, to enable the solution to break down any remaining organic material. Enzymatic cleaners are prepared and used according to manufacturer's instructions (e.g., volume to dilute and water temperature). Clearly label cleaning products with expiry dates to prevent use past expiry. Store detergents in a manner that will prevent risk of contamination.
- Manually clean instruments with a brush underwater to prevent splash or spray of contaminated liquid, paying particular attention to hinges and serrations. If the solution becomes visibly solid during cleaning, discard and replace with new solution before proceeding.
- Rinse the instruments with water.
- Discard used enzymatic cleaning solution and disposable brushes.
- Inspect, lubricate (as needed) dry the instrument using a disposable, lint-free towel, and reassemble (if it was disassembled). All reusable equipment should be free of any signs of soil (e.g., blood, tissue), rust and damage prior to sterilization.

Why should I pre-clean, then clean my instruments again?

The primary purpose of pre-cleaning and cleaning is to remove contamination so that the instruments can be sterilized. All reusable equipment should be free of any signs of soil (e.g., blood, tissue) prior to sterilization. Effective pre-cleaning ensures that gross soil (e.g., blood, tissue) is removed at point-of-use before drying onto the instruments. This is particularly important when there will be a delay between home pre-cleaning (or use of instruments during clinic visits) and completion of reprocessing in clinic. This delay will increase the chance of organic material drying on the instruments, acting as a barrier to effective cleaning. If any soil (e.g., blood, tissue) remains on the instruments, sterilization will not be achieved.

Once instruments have been pre-cleaned, dried and boxed, they are ready for transport to where reprocessing will be completed.

What are some space considerations for pre-cleaning at home?

You want to consider the extent to which the space is set-up to avoid cross-contamination. For example, cleaning the surface area with a disinfectant wipe before and after pre-cleaning can reduce the risk of cross-contamination between instruments and other items.

To the extent possible, set-up cleaning space to prevent cross-contamination.

Consider the following:

- Are there items nearby with bodily fluid that could recontaminate the instruments (e.g., blood or placenta on the counter or sink)?
- Are there items that could be contaminated from splash when cleaning instruments (e.g., toothbrushes)?
- Is the cleaning area a shared living space (e.g., with family or roommates)?
- Could you make adjustments to the space, such as removing clutter or cleaning the counter to prevent cross-contamination and facilitate surface cleaning?

What kind of brush should I use?

The brush should be firm enough to remove any material from nooks and crannies of instruments, but not so firm that it damages the instrument.

Specific instrument brushes can be purchased for this purpose – both autoclavable and disposable are available – or a generic brush (e.g., a toothbrush) can be used and disposed of.

If you select the reusable brush, develop a process to ensure the brush is cleaned and sterilized between uses according to manufacturer's instructions.

PHO recommends a new brush for each episode of cleaning. It is not necessary to use a new brush for each client, especially if you are cleaning a collection of many instruments from many different clients at the same time. However, if you clean instruments on Monday, and then clean a different set on Tuesday, a new brush is recommended.

I have heard people talking about soaking their instruments. Is this necessary?

It is important that instruments are washed or soaked after use before there is time for body fluids to dry on them. Soak times to remove debris will depend on manufacturers' instructions but may be 10 to 20 minutes. Dried fluids and/or debris are harder to remove effectively from your instruments than when they are still wet. However, soaking instruments for long periods of time increases the likelihood that they will rust – an instrument with rust marks cannot be sterilized unless the rust can be gently removed without affecting the instrument's surface coating. Any instrument that has deep rust or pitting, or is damaged, must be replaced.

Ideally, instruments will be soaked (in an enzymatic detergent solution) or washed almost immediately after use.

Can I air dry my instruments?

For most MPGs, air drying is not practical and instead, instruments would need to be dried with a lint-free towel.

Use lint-free disposable towels to dry instruments.

Instruments can be air dried if laid out to dry in a clean area, where there is no risk of contamination from things such as a water source, laundry, or an area with people. The best area to air dry instruments is in a room behind closed doors, without any dirty equipment, no sink or people walking around. If people might go near the drying instruments or "dirty" items are stored in the same area (which would allow instruments to get splashed or touched), then it is more appropriate to dry them with a lint-free towel.

Can I use paper towel to dry them? Can I use a reusable towel to dry them?

Regular paper towels, tissue papers or any other paper product can potentially leave small pieces of lint, fuzz or paper on the instruments, which could prevent them from becoming sterilized in the autoclave. If drying instruments following a pre-cleaning at the client's home, a disposable paper towel will be sufficient to dry instruments as instruments will be thoroughly cleaned (soaked in an enzymatic solution, scrubbed with a disposable brush and dried with a lint-free towel) once in the clinic.

Reusable towels can easily become contaminated and so generally should not be used to dry instruments. Theoretically, an MPG could purchase lint-free reusable towels, but would need to launder and store them in a very specific way that most MPGs would find impossible (e.g., monitoring of the temperature and duration in the dryer and washer; testing of the water quality etc.).

For these reasons, the best option for most MPGs is to purchase disposable lint-free towels to be used for drying the clean instruments.

Am I supposed to be lubricating my instruments?

Instruments with a "joint" such as hemostats and scissors become stiff and benefit from lubrication (e.g., instrument milk). Non-jointed instruments can also benefit from regular lubrication as it prevents staining, rusting and preserves the instrument's proper function.

Only use lubricants approved for use on surgical instruments. These should be steam permeable and water soluble to allow steam to penetrate through the lubricant during sterilization. Lubricants should only be used once instruments are clean and dry, as lubricant may seal residual deposit. Following lubrication, instruments should not be rinsed, instead they should be wiped dry using a lint-free towel, then packaged for sterilization.

What if my instruments have scratches, nicks or rust?

When drying and lubricating instruments, it is important to inspect them to make sure that they are in good condition. As instruments age they may develop areas with rust, scratches or nicks. These areas can potentially harbour bacteria, making the instrument impossible to sterilize. Any instruments with

Inspect instruments for nicks, scratches and rust, which inhibit sterilization.

scratches, indentations, etc. need to be discarded and replaced. Engravings may also harbour bacteria (though embossing is not of concern).

Light rust can be gently removed without affecting the instrument's surface coating; instruments with heavier rust need to be replaced.

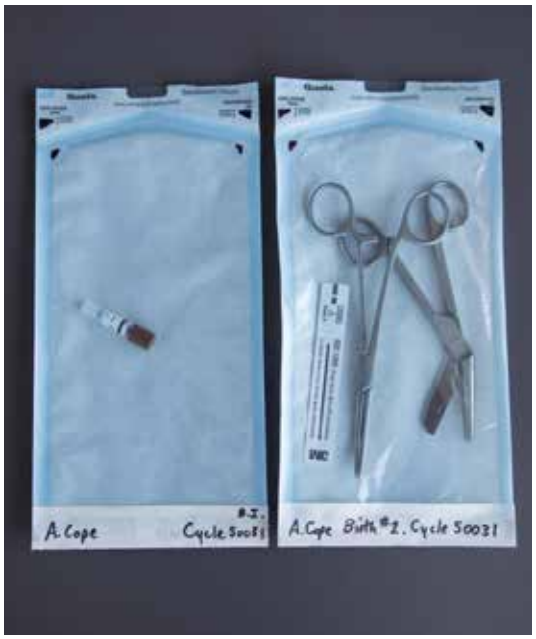
PACKAGING

How should I package my instruments?

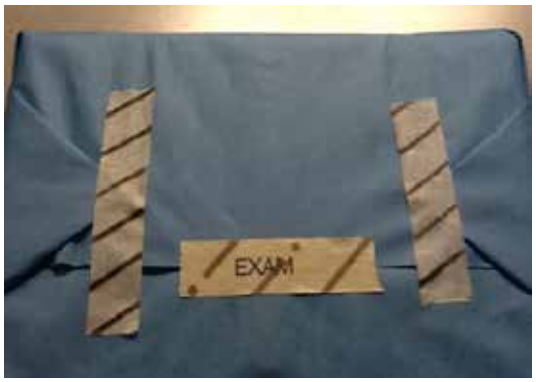
Instruments can be packaged in one of two ways: in a pouch or in a wrap. Regardless of the technique you choose, it is important that you always use packaging according to manufacturer's recommendations.

If a pouch is used, it should not be overfilled. This means different things depending on the size, but generally instruments should fit easily in the pouch without pulling or straining the seams and the weight should not be heavier than the manufacturer's recommendations. The CSA advises that pouches are intended for one or two small instruments.

If a textile wrap is used, there are specific guidelines about how instruments should be wrapped and the type of material used for the wraps. Both disposable and reusable wraps exist, but the laundering and verification processes for reusable wraps are so complicated that disposable wraps are advisable.



Top: instruments in pouches
Bottom: a wrapped package



Proper wrapping materials and technique allow steam to penetrate the entire contents of the package while preventing non-sterile air from entering the package after the cycle is complete. Instruments can either be placed in a wrap or pouch or placed in a specialized hard-sided container in a wrap. They should not be placed into other containers that are not specifically intended for this purpose as proper air circulation is critical to effective sterilization.

Manufacturer's instructions should explain how to load instruments, load the autoclave, and wrap the container. The manufacturer of these products is usually willing to come to your clinic and provide an in-service; your MPG and/or midwifery community may wish to consider this option to ensure that equipment is being used correctly.

Pouches are intended for one or two small instruments.

Regardless of the packaging you choose, make sure instruments are in an open position and not locked in a closed position; and don't put gauze, plastic cord clamps or towels in with your metal instruments. Air needs to circulate evenly around the metal, and different materials (such as fabric or plastic) can affect the air flow and sterility.

Does this mean that I shouldn't put gauze in a package with my instruments?

If gauze is not approved for sterilization in a steam autoclave, it is not necessarily sterile after it goes through a cycle. You may wish to purchase sterile gauze in its own separate pack, rather than purchasing large packs and splitting them up.

Do not put gauze in instrument pouches. Before putting gauze through the autoclave, be sure that it can be sterilized in a steam autoclave.

If you purchase gauze that is intended for sterilization in a steam sterilizer (which the AOM is not aware of), note that different materials need to be sterilized in separate cycles. Steam and heat circulate differently around different materials, and mixing them together could affect the sterilization process. Gauze, plastic and metal are best packaged and autoclaved separately.

Can instruments be sterilized if they are unwrapped?

PHO recommends that all instruments being sterilized are packaged in a pouch, wrap or hard-sided container. This allows them to be kept clean and sterile and reduces the risk of contamination. Even if the item does not need to remain sterile, such as a speculum for a Pap smear, keeping it packaged until use will keep it clean (e.g., dust free) until the time of use.

USING AND MAINTAINING THE AUTOCLAVE

Is there guidance on loading the autoclave?

Autoclave manuals will provide instructions for loading. Generally, is important to make sure that it is not overloaded so that steam can circulate around all packages. This means ensuring that packages don't touch the front, back or sides of the autoclave and aren't stacked on top of each other. Although some manufacturers state that the packages can overlap a little bit, PHO and the CSA recommend ensuring that there is a gap between packages.

Packages can be placed horizontally on the racks that come with the autoclave or vertically in an additional autoclave rack available for purchase. Vertical loading allows more packages to be loaded in the autoclave and promotes better steam circulation and drainage.

If you are using pouches and placing them horizontally, the plastic side should face up and the paper should face down to let steam flow properly. If you choose to purchase the vertical rack (for pouches only), all the pouches in the load face the same way – either the plastic sides all point to the right or they all point to the left. This allows for adequate steam flow.

The AOM's YouTube infection control playlist includes a video tutorial on loading autoclaves.

Autoclave with vertical rack

Follow the manufacturer's instructions when using the autoclave.

Load the autoclave so that steam can properly circulate throughout and penetrate all packages.

What cycle should I use?

It is important to make sure that the autoclave is running on an appropriate cycle for the contents of the load. Autoclaves often have preprogrammed cycles for different packages – your autoclave manual will describe what parameters each cycle uses (e.g., temperature, length of time). For example, the Ritter MidMark autoclaves sterilize pouches on a cycle that provides a temperature of at least 132^{0}C, at 27.1 psi, for five minutes. Check the manufacturer's instructions for your autoclave and your instruments to determine the appropriate cycle. The AOM's YouTube infection control playlist includes a video tutorial on using Ritter M9 or M11 autoclave.

What if my instruments are wet when they come out of the autoclave?

> Wet packages are a sign that the autoclave cycle did not work properly.

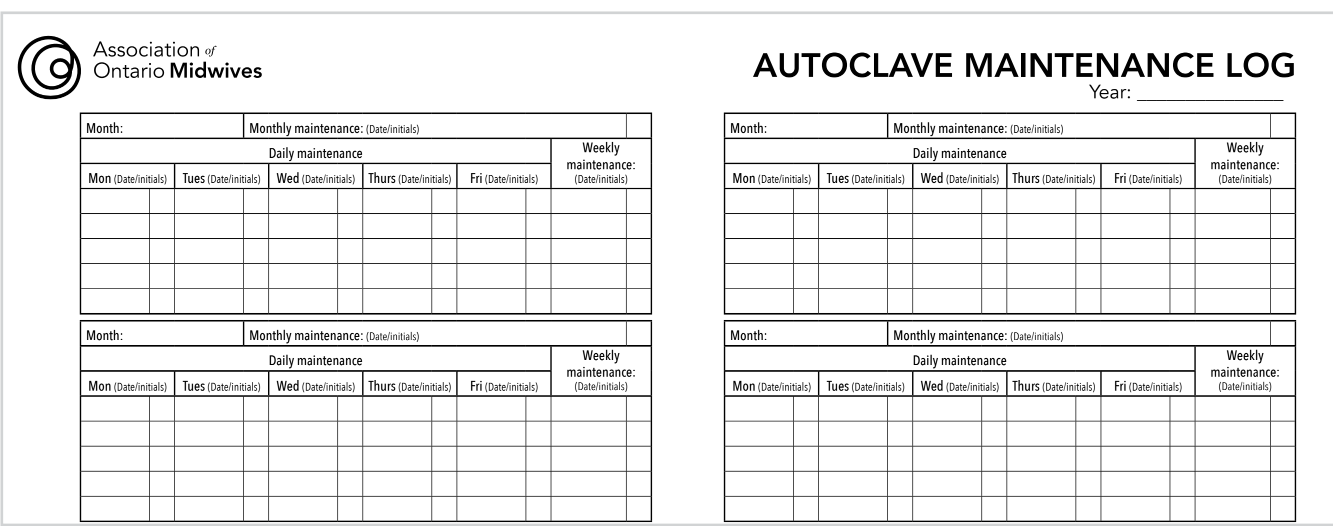
If you interrupt your autoclave before the dry cycle is complete, you might find some condensation within the package. It is important to let the autoclave go through its entire cycle before moving the packages.

If the entire cycle has run through and the pack is noticeably wet when you unload, this is a sign that the autoclave process has not worked correctly. This could be a sign of an autoclave in disrepair, or an overloaded autoclave, or poorly packaged instruments. These instruments should not be used as they are not sterile. To try and remedy the problem, see the section below about What if the autoclave isn't functioning properly or one of the indicators fails?

What does autoclave maintenance involve?

> To extend the life of your autoclave, maintain it according to the manufacturer's instructions.

Each model has different requirements but this generally means cleaning daily or weekly (e.g., with SpeedClean) and flushing the water out weekly or monthly (with distilled water). Additionally, some MPGs choose to have their autoclave serviced annually. See the AOM's YouTube playlist for maintenance videos for some autoclaves and the maintenance log on the AOM website.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AUTOCLAVE MAINTENANCE LOG

Year: ____________

Month:	Monthly maintenance: (Date/initials)				
Daily maintenance					Weekly maintenance: (Date/initials)
Mon (Date/initials)	Tues (Date/initials)	Wed (Date/initials)	Thurs (Date/initials)	Fri (Date/initials)	

Month:	Monthly maintenance: (Date/initials)				
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VERIFYING AUTOCLAVE FUNCTIONING

Does the colour changing box on the pouch tell me that they're sterile? How do I know if the autoclave is working properly?

The colour changing box on the pouch (or autoclave tape) is an indicator called a Class 1 chemical indicator. Its purpose is to allow you to easily tell whether a pouch has been autoclaved or not, not to indicate sterilization. It changes colour when exposed to heat, and can even change colour when left on the dash of your car on a hot day.

Using tools such as chemical indicators, physical indicators and biological indicators are ways to show that the autoclave cycle has reached the specific temperatures and pressures that kill bacteria.

When first setting up your autoclave, you also want to use a challenge pack to confirm that the autoclave is consistently functioning.

Class 1 indicator on pouches

Use external and internal chemical indicators, physical indicators, and biological indicators to confirm the autoclave's functioning.

Why do we need to use three different indicators? Isn't one of them enough?

Since each indicator tells you something different, none of them alone are able to confirm sterility. Instead, the three together are the best confirmation of sterility.

- The PHYSICAL INDICATOR (e.g., autoclave printer) tells you what happened in the chamber during a cycle. Did the chamber reach the temperature and pressure expected for the amount of time expected? It does not tell you anything about the conditions inside a particular package and whether steam was able to reach the contents.
- Different classes of CHEMICAL INDICATORS are designed to react to different things (e.g., amount of time at a specific temperature or pressure). They show what happened at its location (e.g., the outside of a package; the inside of a package). An external chemical indicator (outside of a package) tells you that the package went through an autoclave cycle and nothing else. An internal chemical indicator confirms that certain conditions were met inside the package, however, because the chemical indicator is not perfectly sensitive, it cannot actually confirm sterility. A failed chemical indicator does, however, provide an immediate indication of a failed cycle.
- BIOLOGICAL INDICATORS test the autoclave with live spores but do not provide immediate results, do not tell you what happened in loads where no biological indicator was included, and do not confirm the conditions in individual packages. BIs do confirm that the autoclave actually killed bacterial spores during the cycle.

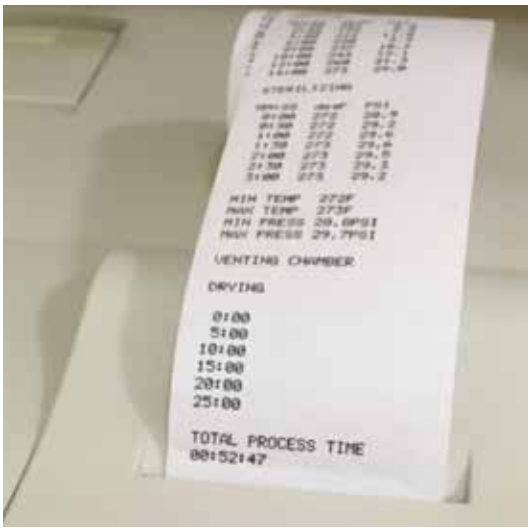
What about the printer – or the "physical indicator"?

Each autoclave cycle reaches certain temperatures and pressures for specific times. PHO and CSA recommend that these levels be monitored for each cycle, to ensure the autoclave actually has reached appropriate conditions. This monitoring can also provide immediate information about whether or not the cycle has failed (though it doesn't confirm that it passed).

You could stand beside the autoclave during the cycle and watch the numbers on the screen while timing how long they are at certain levels. This is, however, time-consuming and creates the potential for misinterpretation.

Instead, practices can purchase an autoclave printer that automatically prints out the conditions for the cycle. Some autoclaves can have a printer added-on, rather than a built-in printer or USB port (for downloading this data). Alternatively, if you are due to purchase a new autoclave, look for one with a built-in printer.

The physical printout can be read and logged, and should also be kept for as long as you keep your charts.



Physical indicator (i.e., autoclave print-out)

After the autoclave cycle is complete, check and log the results of the internal chemical indicator and the physical indicator.

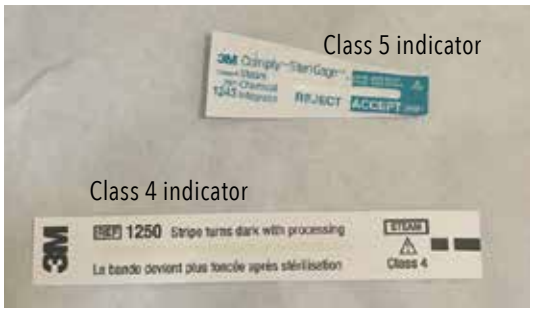
What is a chemical indicator?

A chemical indicator is a device or tool that indicates when specific conditions have been met.

Class 1 chemical indicators (i.e., the autoclave tape or the colour changing square on the outside of a pouch) changes colour when a specific temperature has been reached. A Class 1 indicator only confirms that the package went into the autoclave, but not that conditions were met that would allow sterilization. Its purpose is to allow you to quickly differentiate between packages that went into the autoclave and those that have not.

Chemical indicators

Class 4 or 5 chemical indicators are placed inside of each package. Class 4 indicators change colour when certain temperatures and steam penetration have been reached. Class 4 indicators do not confirm sterilization in the same way that a biological indicator does, but they can provide immediate confirmation of whether the package might have been sterilized (colour change) or whether it could not have been (no colour change) and needs to be repackaged and re-sterilized.



The Class 5 indicator changes colour when certain temperature, steam and pressure has been reached inside of the package and is more sensitive than the Class 4 indicator.

When deciding between Class 4 and 5 indicators, Class 4 indicators are cheaper and less sensitive (though still adequately sensitive when used alongside other indicators) than Class 5 indicators.

What is a biological indicator?

Biological indicators showing no bacterial growth

A biological indicator (BI) is also known as a spore test. It is a small tube that contains a strip of live bacteria, and a glass ampoule of growth medium. The BI is put through an autoclave cycle, activated and then incubated along with a BI that did not go through the autoclave (the control). These two BIs are later compared to see if the autoclave successfully killed the bacteria.

There are outside services available to process your spore test, but many MPGs find it simple and straightforward to purchase an incubator and process the BI themselves.

PHO and CSA recommend that a BI be run on each day that you use your autoclave for each cycle that you use (e.g., pouches, containers). Each manufacturer has slightly different instructions (which should be followed) but, essentially, running a BI involves the following steps:

- Package a BI in the same way your instruments are packed (e.g., in a pouch or in a wrap) and place it in the area of the autoclave where it is hardest for steam to reach along with your instruments. For most MPG autoclaves, this will mean in the bottom near the drain (confirm this in the autoclave manufacturers' instructions).
- Record the BI's lot number and expiry in your autoclave log.
- When the autoclave is finished, remove the BI from the packaging, activate the BI by breaking the glass ampoule of growth medium (see manufacturer's instructions for specifics– most incubators have an area that is intended for this use), which will cover the bacteria with the growth medium to encourage bacterial growth (if any is alive). Identify the BI with the date and load number before placing it in the incubator.
- Activate a second BI from the same lot, identify it with the date and as the control BI before placing it in the incubator.
- Incubate the two BIs according to directions (this usually takes 24 to 48 hours).
- After the incubation period has passed, examine the results. The BI that went through the autoclave should show no growth (no colour change) and the BI that did not go through the autoclave should show growth (colour change). This indicates that there was live bacteria put through the autoclave and that it was killed by the cycle.
- Record the results in your autoclave log.
- Dispose of the BIs in your sharps container.

Run a biological indicator every day that the autoclave is used, incubating it alongside a control BI according to the manufacturer's instructions.

A steam incubator with biological indicator showing growth (left) and four showing no growth (right)

We heard that if we use a Class 5 indicator, we don't have to have a printer or use biological indicators. Is that true?

Confirm and log the BI results before releasing instruments for use.

Some manufacturers are advising suppliers and midwives that Class 5 indicators are sensitive enough that a biological indicator (BI) is not needed. However, PHO and CSA state that **physical, chemical and biological indicators are all needed**; in their opinion a Class 5 indicator is not a substitute for a BI.

As a result, the AOM's Infection Prevention and Control Work Group recommends that midwives use Class 5 indicators, as an interim step while determining how to implement physical and biological indicators. Once physical and biological indicators are being used, either Class 4 or 5 indicators can be used.

What do I do with my instruments while waiting for biological indicator results?

CSA and PHO recommend that instruments not be released for use until you can confirm that a biological indicator (BI) run the same day as they were processed has had no growth, the control BI has had growth, and that the chemical indicator (Class 4 or 5) indicates that appropriate conditions have been met during the cycle. This means that instruments are out of use for 24 to 48 hrs.

Each MPG will need to consider how to deal with this. Some have decided to purchase more instruments for each midwife. Others have decided to treat instruments as MPG instruments shared by all midwives, instead of midwife specific, to increase the number of instruments available to on-call midwives.

Others have decided to use them anyway, and track which instruments were used with which client. If the BI then fails, those instruments would need to be tracked and the clients possibly notified that their instruments may not have been sterile. See the algorithm below. This is a sensitive disclosure; the AOM and HIROC recommend that midwives call the AOM immediately if an MPG finds itself in this situation (1-866-418-3773).

What if the autoclave isn't functioning properly or one of the indicators fails?

The AOM has developed the following flow chart outlining the steps involved if the indicators fail. These steps involve ensuring client safety, remedying the cause of the failed indicator, and confirming that the remedy was successful.

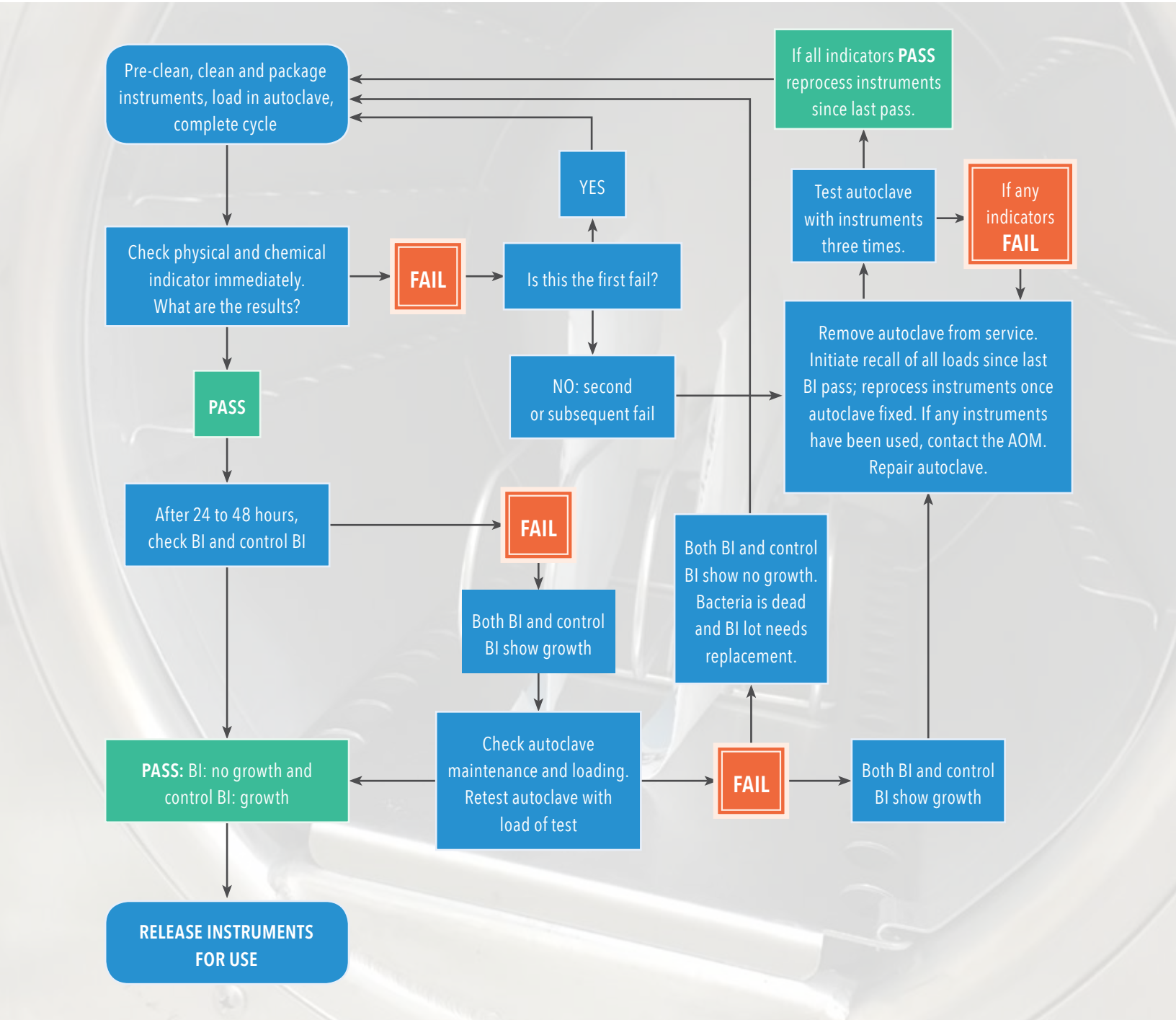
The instruments in the load with the failed indicators should not be used until the issue is addressed and you may need to recall any instruments that were autoclaved since the last successful biological indicator (BI). If you have used instruments that were autoclaved since your last successful BI, clients may need to be notified and instruments recalled. This is a sensitive disclosure; the AOM and HIROC recommend that midwives call the AOM immediately if your MPG finds itself in this situation (1-866-418-3773).

CSA notes that most indicators fail as a result of how the autoclave was used (i.e., overloading, packaging, maintenance). So the first consideration is whether one of these issues is the cause –

check how the MPG is using the autoclave by looking at the rest of this guide and other autoclaving resources from the AOM. You may also want to look at the manufacturer's instructions for possible solutions or contact a repairperson.

Once you believe that you have identified and remedied the source of the problem, you will need to run test loads to confirm that the autoclave is functioning properly. This involves running three separate loads (with instruments and indicators) and waiting until the indicators for all three loads have passed.

CONFIRMING AUTOCLAVE FUNCTIONING AND MANAGING FAILURES



DOCUMENTING AUTOCLAVE USE

Do we need a protocol on reprocessing?

Describe MPG reprocessing practices in a protocol.

PHO and CSA recommend that written policies be developed to describe reprocessing procedures that reflect the various elements described in this guide. As an example, the AOM website has sample reprocessing protocols from MPGs. These documents can all be found online.

What am I supposed to record or track about the autoclave?

PHO and CSA recommend that a log be kept of all autoclave use and maintenance. Record-keeping will allow you to:

1. Recall instruments if a biological indicator (BI) fails.
2. Identify which clients had which instruments used for their care and, therefore, possibly need notification if a BI fails.
3. Demonstrate after the fact that a particular client had instruments that were appropriately reprocessed (e.g., if a client develops a contagious illness).

As a result, autoclaving records include:

- maintenance log;
- labelling of packages of instruments;
- autoclave cycle log; and
- charting the use of instruments.

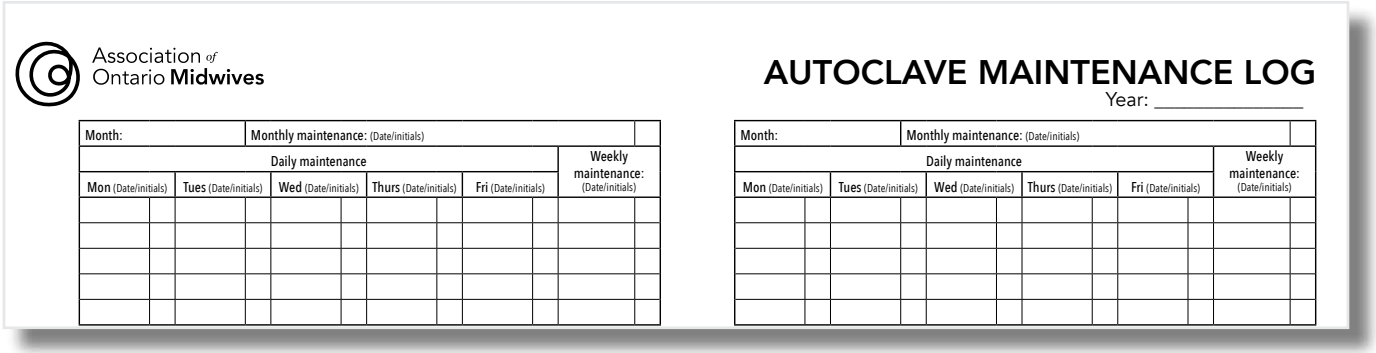
The AOM website has a template autoclave maintenance log and an autoclave log which also provide prompts and reminders.

What is an autoclave maintenance log?

Track completed and due maintenance in an autoclave maintenance log.

An autoclave maintenance log tracks the maintenance of your autoclave, which can help you confirm that it was properly maintained and can serve as a reminder if maintenance is scheduled and not yet completed.

The log should track all required maintenance of the autoclave, whether daily, weekly, monthly or annual. The AOM has developed an autoclave maintenance log to help.



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AUTOCLAVE MAINTENANCE LOG

Year: _____

Month:	Monthly maintenance: (Date/initials)										
Daily maintenance										Weekly maintenance: (Date/initials)	
Mon (Date/initials)		Tues (Date/initials)		Wed (Date/initials)		Thurs (Date/initials)		Fri (Date/initials)			

Month:	Monthly maintenance: (Date/initials)										
Daily maintenance										Weekly maintenance: (Date/initials)	
Mon (Date/initials)		Tues (Date/initials)		Wed (Date/initials)		Thurs (Date/initials)		Fri (Date/initials)			

How are packaged instruments labelled?

The packages need to be labelled in a way that allows you to connect it to the entry in the autoclave log (which records process verification), the packages that the instruments are in, and the client the instruments were used on (if any). This allows you to identify which instruments may need to be recalled or which clients might have been exposed if a biological indicator fails.

Label packages with a felt-tip marker to track the load number, autoclave number (if you have more than one), the date (to allow it to be traced to the autoclave log) and the contents of the package.

2016-1 Jan, 2/2016
Ali's cord scissors A
Ali's kocher A

2016-2 Jan, 4/2016
Clinic speculum A

2016-1 Jan, 2/2016
Ali's needle driver A
Ali's scissors A

Package label example

Embossed instruments may be used to distinguish them from other instruments. However, engravings may harbour microorganisms.

What is tracked in the autoclave log?

To allow individual instruments to be traced back to the autoclave log and confirm that the sterilization process was verified, an autoclave log would contain details of the content of those packages, the process verification that took place, and the results. As a result, the log needs to include the following:

To track instruments from autoclave cycle and process verification to client, develop a system for labelling and documenting instrument packages, autoclave cycles, and instrument use.

- the load number and date;
- autoclave number if you have more than one autoclave;
- contents of the load;
- results of the BI, control BI, and chemical indicator; and
- the printout initialed by the person who reviewed it and attached to the log; or details of the temperature, pressure and timing recorded on the log.

Sample logs are available through autoclave and biological indicator vendors. However, these logs provide few prompts and reminders to users about what to record and what results to look for. The AOM developed an autoclave log with additional prompts and reminders for midwives.

Association of Ontario Midwives

SAMPLE REPROCESSING DOCUMENTATION AND TRACKING

Logging each autoclave load and tracking the instruments used would allow you to confirm that the instruments used on a client were properly sterilized. The intention is not to track a specific instrument through its lifetime, but instead to be able to retrospectively provide documentation that shows the instruments passed their biological indicator, chemical indicator and physical indicator. There is no one specific way that this must be documented, as details will vary according to how you use and package instruments at your practice. Here are some examples.

AUTOCLAVE LOG (SAMPLE)

LOAD #: 2016-1	CONTENTS		STERILIZATION CYCLE	CHEMICAL INDICATOR	WAS BI USED FOR THIS LOAD?	AFTER INCUBATION	SAFE TO RELEASE INSTRUMENTS?
Date: Jan 2, 16 Time load began: 0930 Loaded by: AM ☑ Daily maintenance log checked	Ali's needle driver A	Ali's kocher A	Duration: 5 min Temperature: 132°C Pressure: 27.1 psi	Internal: ☑ ALL PASS ☐ Any Fail External: ☑ ALL PASS ☐ Any Fail	☑ Yes ☐ No (Also incubate a control BI if this is the first BI of the day) Lot# 54321 Expiry 2016/11	BI (if applicable): ☐ Growth ☑ NO GROWTH Control BI (if applicable): ☑ GROWTH ☐ No Growth	☑ YES ☐ No Initials: AM Date: Jan 4, 2016 Time: 1200
	Ali's snap A	Ali's kocher B					
	Ali's scissors A	Ali's cord scissors A					
	Ali's tissue forceps A						

LOAD #: 2016-2	CONTENTS	STERILIZATION CYCLE	CHEMICAL INDICATOR	WAS BI USED FOR THIS LOAD?	AFTER INCUBATION	SAFE TO RELEASE INSTRUMENTS?
Date: Jan 4, 16 Time load began: 1200 Loaded by: JT ☑ Daily maintenance log checked	Jan's kocher A	Duration: 5 min Temperature: 132°C Pressure: 27.1 psi	Internal: ☑ ALL PASS ☐ Any Fail External: ☑ ALL PASS ☐ Any Fail	☑ Yes ☐ No (Also incubate a control BI if this is the first BI of the day) Lot# 54330 Expiry 2016/12	BI (if applicable): ☐ Growth ☑ NO GROWTH Control BI (if applicable): ☑ GROWTH ☐ No Growth	☑ YES ☐ No Initials: JT Date: Jan 6, 2016 Time: 1400
	Jan's kocher B					
	Jan's cord scissors A					
	Clinic sterile speculum A					

What is recorded in the chart?

When instruments are used with a client, note the instrument load number and date (as recorded on the package) in the client's chart so that the specific load details can be linked to the client.

INSTRUMENTS USED (birth and suturing)	
Sterilization load/ tracking #/ tray #	Date sterilized

How long should we keep these autoclaving records?

Autoclaving records demonstrate the safety of care that you provided. As a result, they should be maintained for the same time and in the same way as charts. The AOM's template record retention protocol suggests maintaining these records for 28 years – the same length of time that charts are maintained.

KEEPING INSTRUMENTS STERILE

Once my instruments have been sterilized, what should I do to ensure they stay sterile?

Because wraps and pouches are porous to allow steam to penetrate, sterility may be compromised if packages come into contact with contaminants (e.g. dust) from the environment or high relative humidity (via the wicking of micro-organisms or microbial growth of airborne fungi). Ripping or crushing a package compromises its sterility, as does moisture damage and condensation. Therefore, packages should be treated with the utmost care to ensure that they maintain sterility.

In the clinic, store sterile packs away from dirty instruments, water (i.e., not under or within one metre of a sink), and people walking around). Where separate storage space is limited, use closed containers to create physical separation between sterile instrument packages and potential contaminants.

Sterile packs also need to be protected while being transported (e.g. in midwives' cars). To create physical separation between sterile packs and dirty instruments, use separate closed containers to protect sterile packs from cross-contamination.

Protect clean and sterile instruments from becoming compromised by moisture, dust, or cross-contamination.

Hard-sided, well-sealed containers are recommended to protect sterile packs from damage due to penetration, crushing, tearing and moisture. Packs should fit snugly inside containers; the

contents should not slide around inside the containers, but also not fit so tightly that the pack's contents could be crushed.

Condensation can accumulate in the packs due to temperature and relative humidity fluctuations, compromising their sterility. Hard-sided containers that seal well or lock are most effective at preventing damage due to condensation. Look for containers with a rubber seal around the top and sides that click or lock into place. Please note that there does not appear to be any benefit to bringing the packs (or the closed containers carrying the packs) in and out of your home rather than leaving them in the car. Some MPGs have added desiccant to their containers to protect the sterile packs, but the AOM has found that high quality sealable containers are more effective than desiccant at maintaining stable humidity.

How long do sterile packages remain sterile?

In general, the sterility of a package (e.g., pouched or wrapped instruments) is not affected by the length of time since autoclaving. With climate control and storage away from people, water and dirty instruments, packages will remain sterile indefinitely, or at least until the expiry date listed by the manufacturer on the packaging material. However, sterility can be compromised by the expiry of packaging materials or events that compromise sterility. **Any package that has come unsealed, torn or been punctured, or is or has been wet or dropped, is no longer considered sterile.**

Because instrument packages are generally not stored in a climate-controlled setting and over time are likely to experience a sterility compromising event, consider adopting a schedule to reprocess instrument packs. Some MPGs do this whenever a midwife goes on vacation or every six months, if not used sooner.

Additionally, the longer an item is stored, the greater the opportunity for dust and micro-organisms to accumulate on the outside packaging, jeopardizing its sterility when opened. MPGs should adopt an approach where they use the oldest packages of instruments first.

How should I inspect packages before use?

Inspect instruments before taking them from clinic and before use to ensure that the packages have not been compromised.

Thoroughly inspect packs before using them to ensure that they have not been compromised and their contents are still sterile. If the external chemical indicator has not changed, the pack has not been autoclaved and is not sterile. Before opening the pack, check that the seal is intact and assess the pack for rips, punctures, water marks, and signs of crushing or dampness. Check that the external and internal indicators have changed. Depending on how the instruments are packaged, this may be visible before opening the pack or only after opening. After you have opened the pack, check for signs of moisture (e.g., current wetness or past watermarks) and debris on the inside.

If the pack does not pass this inspection, the instruments are not sterile and should not be used.

APPENDIX - SELF-ASSESSMENT

This self-assessment contains items from the Public Health Ontario checklist for reprocessing medical equipment, simplified and prioritized for midwifery applicability and ease of understanding. For the full list, refer to the PHO Checklist for Reprocessing of Medical Equipment/Devices in Clinical Office Practice

Policies and training

- Reprocessing procedures are documented in a protocol, including maintenance schedules.
- Everyone involved in reprocessing has been trained on reprocessing generally and on the procedures at the MPG.
- One person at the MPG has completed a recognized reprocessing course such as the course offered by the Medical Device Reprocessing Association of Ontario.

Setting-up

- Check manufacturer's instructions before purchasing and before reprocessing equipment.
- Single-use items are not reprocessed.
- Instruments are cleaned away from direct care areas and where sterile or clean instruments are stored (e.g., separate physical space; at different times).
- To the extent possible, the space has a one-way workflow from dirty to sterile to prevent cross-contamination.

Pre-cleaning and Cleaning

- Chemical cleaning products are used according to manufacturer's instructions.
- Gross soil is removed at the point of use (pre-cleaning).
- Enzymatic detergent is used for cleaning.
- Cleaning equipment (e.g., brushes) is disposable or thoroughly cleaned and disinfected with a high-level disinfectant or sterilized between uses.
- Instruments are dried with lint-free towels before autoclaving.

Autoclaving, Verification and Documentation

- Class 4 or 5 chemical indicators are placed in every package.
- The autoclave is loaded according to manufacturer's instructions.
- Sterilizer mechanical printout (i.e., physical indicator) is checked and signed for each cycle by the person sterilizing the instrument.
- Biological indicator (BI) and control BI are used every day that the autoclave is used.
- Indicator results are checked and logged for each autoclave cycle (e.g., autoclave log).
- Reprocessed instruments are not released for use until the BI results are verified.

Storage

- Sterile items are stored in their sterile packaging until time of use.
- Steps are taken to keep sterile packages clean, dry, and away from contamination.
- Reprocessed items are readily distinguishable from those not reprocessed.

RESOURCES

CSA Group. Decontamination of reusable medical devices. 2014 February. Z314.8-14.*

CSA Group. Effective sterilization in health care settings by the steam process. 2014 August. Z314.3-14.*

CSA Group. Medical device reprocessing - General requirements. 2013 March. Z314.0-13.*

CSA Group. Storage, transportation, and distribution of single use and reusable medical devices. 2015 August. Z314.15-15.*

CSA Group User Handbook for Medical Device Reprocessing in Community Health Care Setting SPE 112-14 March 2014

Medical Device Reprocessing Manual 3rd ed. Central Service Association of Ontario

National Standard of Canada. Sterilization of Health Care Products – Chemical Indicators – Guidance for Selection, Use and Interpretation of Results. CAN/CSA-Z15882-09. Reaffirmed 2014.*

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices. 3rd ed. Toronto, ON: Queen's Printer for Ontario; May 2013.

Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Infection Prevention and Control for Clinical Office Practice. 1st Revision. Toronto, ON: Queen's Printer for Ontario; April 2015. Public Health Ontario acknowledges the financial support of the Ontario Government.

Provincial Infectious Diseases Advisory Committee (Public Health Ontario). Routine Practices and Additional Precautions in all Health Care Settings. 3rd edition. 2012 Nov. Available from: https://www.publichealthontario.ca/en/eRepository/RPAP_All_HealthCare_Settings_Eng2012.pdf

Public Health Ontario. Checklist for reprocessing. Excerpt from Infection Prevention and Control for Clinical Office Practice. 2013 June. Available from: http://www.publichealthontario.ca/en/eRepository/IPAC_Clinical_Office_Practice_Checklist_Reprocessing_2013.pdf

Public Health Ontario. Reprocessing in Community Health Care Settings [Online Course]. Available at: https://www.publichealthontario.ca/en/LearningAndDevelopment/OnlineLearning/InfectiousDiseases/Reprocessing/Pages/default.aspx

*Documents from the Canadian Standards Association (CSA Group or National Standards of Canada) are only available by purchase. Midwives wishing information from these documents may ask the AOM, which has purchased these resources through a grant.