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COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Guidance for Medical Clinics

Reusable & Single-Use Medical Device Requirements

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Contents

PURPOSE & SCOPE

This guidance is intended to assist physicians and medical clinic staff in understanding of the requirements for handling single-use medical devices and for reprocessing reusable medical devices. This document is a companion to CPSA's Reusable & Single-Use Medical Device Requirements for Medical Clinics.

HOW TO USE THIS GUIDANCE DOCUMENT

Content displayed within grey boxes provides advice that will assist clinic staff in implementing and maintaining requirements. Insight is offered into how compliance with requirements can be achieved and maintained.

This is a living document that will be updated as CPSA gathers new and helpful information. We encourage clinics to refer to this document online to ensure you are working with the most current information. If you print this document, please check our website regularly for updates.

For additional resources, please see the MDR tools and templates on our website: https://cpsa.ca/mdr

ADDITIONS FOR NOVEMBER 2022

Additional insight around the storage and use of biological indicators was added to Sections 8.10.1 and 8.10.4.

PART A: SINGLE USE MEDICAL DEVICES

1. Single-use medical devices

1.1. Single-use medical devices shall only be used on a single patient for a single procedure and then shall be discarded.

1.2. A single-use medical device shall not be used beyond the expiry date specified by the manufacturer.

1.3. A sterile critical single-use medical device shall be maintained as sterile until point of use.

1.4. Opened but unused single-use medical devices shall be discarded, unless the manufacturer provides validated manufacturer's instructions for use (MIFU) for reprocessing.

1.5. Prior to using a single-use medical device that was purchased in a non-sterile state, that single-use medical device shall be inspected and processed according to the validated MIFU.

Equipment must be discarded after use on one patient if its manufacturer has labelled or associated it with any of the following terms, symbols, or equivalent wording:

- ☐ single-use
- ☐ not for reuse
- ☐ do not re-use
- ☐ disposable
- ☐ discard after single-use
- ☐ do not use twice
- ☐ 

Needles, filaments, lancets, and other equipment with sharp edges used to puncture the skin or mucous membrane must be discarded after use on one patient.

Medical devices that are not accompanied by validated manufacturer's instructions for use (MIFU) must not be used or reprocessed.

PART B: REPROCESSING OF REUSABLE MEDICAL DEVICES

2. Environmental & structural requirements for a medical device reprocessing area

2.1. The medical device reprocessing (MDR) area shall be a designated area, separate from patient care, and activity in the area shall be restricted to the reprocessing of reusable medical devices.

Designate an area in the clinic that is dedicated to reprocessing medical devices and is separate from areas where patient care is provided. Non-MDR staff are restricted from entry during reprocessing. Bathrooms and kitchens are not acceptable locations for medical device reprocessing.

Resources are available for recommended MDR area layout and design to ensure one-way work flow of reprocessing.

See MDR Tools & Templates (www.cpsa.ca/mdr)

2.2. All MDR areas shall:

2.2.1. Have physical separation of clean and dirty areas. In existing clinics and settings where physical separation (i.e., with walls or partitions) of reprocessing areas is not possible, spatial separation and a one-way work flow pattern shall be established to limit cross-contamination.

If it is not possible to physically separate clean and dirty areas in an existing clinic, establish spatial separation (e.g., walls or partitions) and a pattern of one-way workflow from dirty to clean to decrease potential for cross-contamination.

If you need support to determine adequate spatial separation, please contact the CPSA IPAC Program for advice: ipac@cpsa.ab.ca

2.2.2. Have at least two adjacent sinks, large enough to immerse the largest piece of equipment, to clean and rinse soiled items. In existing smaller clinics where two adjacent sinks dedicated for equipment cleaning and rinsing are not possible, a dedicated basin for rinsing equipment after cleaning in a dedicated sink is an acceptable alternative. The dedicated basin shall be large enough to fully submerse the item being rinsed.

Install a minimum of two adjacent sinks that are dedicated to equipment cleaning and rinsing. Sinks must be large enough to immerse, clean and rinse the largest piece of equipment that is reprocessed in your clinic.

If an existing clinic does not have two adjacent sinks dedicated to reprocessing, we strongly suggest you replace or upgrade clinic sink(s). A clinic with a one-compartment sink may obtain and use a dedicated basin for the rinsing process. This basin would function strictly as a rinse basin and be used following the cleaning of devices in the permanent sink. Basins must be clearly identified as for use in rinsing devices only. Clinic policies and procedures must detail that the basins are to be cleaned and disinfected after device decontamination is complete.

Newly constructed or renovated clinics should have two adjacent sinks or a two-compartment sink installed.

2.2.3. Have hand hygiene stations (either hand hygiene sinks or alcohol-based hand rub (ABHR) dispensers with products that have a Health Canada Drug Identification Number (DIN) or Natural Product Number (NPN), and contain 60% to 90% alcohol) at all entrances to, and exits from, the MDR area and readily available within the MDR area.

Ensure hand hygiene stations are readily available to MDR staff. Hand soap and paper towel should not be installed or available for use at sink(s) designated for reprocessing medical devices.

2.2.3.1. Designated hand hygiene sinks shall have properly functioning soap dispensers and paper towel dispensers.

Install soap and paper towel dispensers at hand hygiene sinks. Repair or replace dispensers that do not function properly.

2.2.3.2. Designated hand hygiene sinks shall be used for the purpose of hand hygiene only.

Do not use the reprocessing/decontamination sink for hand hygiene.

If it is not possible to dedicate a sink for hand hygiene in the MDR area, install alcohol-based hand rub stations. In these instances, ensure staff wash visibly soiled hands with soap and water in a dedicated hand hygiene sink that is readily accessible to the MDR area.

Discourage handwashing in a reprocessing/decontamination sink by removing hand washing soap and paper towels dispensers. If wall-mounted fixtures are removed, ensure that any holes and cosmetic damage to the area are repaired.

2.2.4. Have surfaces that can be cleaned. All work surfaces and surrounding area shall be intact, cut-resistant, and seamless, and shall be composed of non-porous, non-shedding material capable of withstanding frequent cleaning.

Repair or replace any damaged, porous, moisture-permeable and non-intact surfaces in the MDR area.

2.2.5. Restrict access to areas where reprocessing occurs. In existing smaller clinics, where MDR areas may also be used for other purposes, access shall be restricted during reprocessing activities and until the area has been appropriately cleaned.

Clearly identify and post signage at the MDR entrance indicating access restrictions and requirements for personal protective equipment (PPE) and hand hygiene.

If it is necessary for reprocessing to occur in a multi-purpose area, do not perform reprocessing when patients or other personnel are present or when clean devices are not secure from potential contamination. Clean and disinfect all surfaces, including counters, sinks and/or basins, before and after performing reprocessing.

In shared spaces, dedicate reprocessing—including operation of the sterilizer—to a time of day when patient care is not occurring and non-MDR staff are not present. Do not use staff bathrooms or kitchens as the designated MDR area.

In situations where shared spaces are problematic, consider alternatives to in-clinic reprocessing, such as:

- switching to single-use/disposable devices,
- outsourcing reprocessing to an external facility that operates in compliance with CPSA requirements, or
- renovating the existing space.

2.2.6. Be designed to facilitate one-way workflow.

Ensure the layout of the reprocessing area allows for the reprocessing workflow to move from dirty to clean. This decreases the potential for cross-contamination of clean devices and equipment.

Resources are available for recommended MDR area layout and design to ensure one-way workflow of reprocessing.

 **See MDR Tools & Templates (www.cpsa.ca/mdr)**

2.2.7. Have adequate lighting for the tasks being performed in all work locations.

Install lighting that assists reprocessing staff to safely handle and accurately inspect medical devices.

2.2.8. Use a water source which meets the equipment manufacturer's specifications for water and steam quality.

Ensure the water used for reprocessing medical devices is in accordance with the equipment manufacturer's instructions for use (MIFU).

Equipment MIFU may specify the use of distilled water or require water that has been filtered/treated using reverse osmosis.

Medical clinics located in rural areas that may be served by wells or cisterns should be aware of the water quality requirements of their equipment.

3. Procurement of reusable medical devices & reprocessing equipment and supplies

3.1. The decision to purchase or trial reusable medical devices, reprocessing equipment and supplies, or reusable surgical textiles shall involve representatives from the personnel in the clinic that will use, reprocess, and maintain the items.

Establish a decision-making/selection process that involves personnel who will use, reprocess and maintain medical devices, reprocessing equipment and supplies, or reusable surgical textiles that will be trialed or purchased.

CPSA recommends that the clinic develop and maintain a log to keep track of purchases of any new or second-hand/previously-used reusable medical devices, equipment and supplies.

3.2. Prior to purchasing or trialing a medical device, including medical device reprocessing equipment, the clinic shall confirm that the device has a valid medical device license issued under the Government of Canada's *Medical Devices Regulations*. The clinic shall not purchase or trial a reusable medical device that does not have a valid medical device license.

Do not purchase, trial or use medical devices/instruments or medical device reprocessing equipment that do not have a valid Health Canada medical device licence. Confirm that devices and equipment are properly licensed in Canada and are purchased from a distributor that has an establishment licence. This requirement applies to all brand new, second-hand, previously-owned and/or loaned devices, instruments and equipment.

Any imported reusable medical device instruments, including reprocessing equipment such as autoclaves or ultrasonic cleaning devices, must also carry a valid Health Canada Medical Device Licence.

Information regarding valid licensing can be obtained from Health Canada Medical Device Active Licence Listing (MDALL):
https://health-products.canada.ca/mdall-limh/index-eng.jsp

CPSA offers a Table-Top Sterilizer Checklist to assist clinics in making decisions about purchasing a new table-top steam sterilizer.

See MDR Tools & Templates (www.cpsa.ca/mdr)

3.3. Prior to purchasing or trialing a reusable critical or semi-critical medical device, personnel accountable for medical device reprocessing (MDR) shall review the written, validated MIFU to determine that the recommended reprocessing procedures can be achieved, given the clinic's reprocessing resources.

Obtain manufacturer's validated medical device reprocessing (MDR) instructions for all reusable critical and semi-critical devices. Request instructions prior to device purchase or trial to ensure MDR requirements can be met onsite. This requirement applies to all brand new, second-hand, previously-owned and/or loaned devices, instruments and equipment.

Clinic staff who are responsible for medical device reprocessing are expected to review the manufacturer's instructions for use (MIFU) prior to purchase or trial of devices to ensure clinic procedures, equipment and devices can adhere to validated processes. Involving all relevant MDR staff will help to identify potential issues while fostering a culture of health and safety in the clinic.

Medical devices that are not accompanied by validated MIFU must not be used or reprocessed.

The following link is an example of what instructions may look like (applicable only to Padgett instruments manufactured by Miltex):
https://www.integralife.com/file/general/padgettcareifu.pdf

4. General reprocessing requirements

4.1. Reusable medical devices that have been used shall be reprocessed. Contaminated reusable medical devices that have not undergone reprocessing shall be clearly identified.

Establish a process that clearly identifies non-reprocessed devices from reprocessed devices to prevent the use of contaminated devices on patients. Consider labelling or colour-coding transport containers and ensure labels can withstand repeated cleaning and disinfection.

4.2. Reusable medical devices that come from an opened or compromised package shall be reprocessed prior to use.

Inspect all packages containing sterile devices and do not use devices if the packaging is compromised (e.g., open, damaged, torn, wet or water marks indicating previous wetting, dropped on the floor). In these instances, always reprocess devices using new packaging material.

Packaged devices that were opened during a patient service must be reprocessed, even if they were not used in the service.

4.3. Newly purchased reusable critical and semi-critical medical devices shall be reprocessed before initial use unless they are packaged and sterilized by the manufacturer.

Reprocess all newly purchased or acquired critical and semi-critical medical devices that are received from the manufacturer in a non-sterile or non-disinfected state. Follow the manufacturer's instructions for use (MIFU) when reprocessing devices.

When using methods to mark or identify instruments, use only products or methods that do not breach integrity of the instruments.

Cleaning accessories

4.4. Cleaning accessories shall be inspected before use to ensure they are not damaged. Damaged cleaning accessories shall not be used.

Visually inspect cleaning accessories (e.g., brushes, cloths, syringes) before each use. Inspect for worn or missing bristles, exposed metal, rust, cracks, etc. Discard and do not use damaged cleaning accessories.

4.5. Reusable cleaning accessories shall be reprocessed after use in accordance with the manufacturer's instructions for use (MIFU), inspected for damage, and stored in a clean, dry place.

Reprocess reusable cleaning accessories following use according to the manufacturer's instructions for use (MIFU). Following reprocessing, inspect accessories and store them in a clean, dry location. Discard damaged cleaning accessories.

4.6. Single-use cleaning accessories shall be discarded following use.

Discard and do not reuse single-use cleaning accessories following use. Cleaning accessories that are not accompanied with cleaning instructions in the manufacturer's instructions for use (MIFU) will be considered single-use by CPSA assessors.

Brushes (reusable or disposable) or clothes are typically used to assist in the removal of soil from devices. Disposable brushes are recommended. If brushes are reusable, they must be cleaned and high-level disinfected, or sterilized, as per device or cleaning accessory MIFU between uses.

5. Pre-cleaning & transportation of contaminated reusable medical devices

5.1. Personnel shall pre-clean used reusable medical devices immediately after use and prior to transportation and further manual or automated cleaning.

Pre-clean reusable medical devices at the point of use, immediately after use and before transporting to the reprocessing area. (e.g., remove gross soil with sponge or cloth moistened with water). Do not use saline or surface disinfectant cleaning products.

5.2. At the point of use, single-use sharps shall be removed from reusable medical devices and disposed of in a puncture-resistant sharps container.

Remove single-use sharps (e.g., blades, needles) from reusable medical devices and dispose into a puncture-resistant sharps container at point-of-use before reusable medical devices are transported to the reprocessing area.

5.3. Organic matter shall not be allowed to dry on reusable medical devices. Reusable medical devices shall be kept moist by using foam, spray, or gel specifically intended for this use, or by using a towel moistened with water, and in accordance with the manufacturer's instructions for use (MIFU).

Cover used and soiled devices with a towel moistened with water (never saline) or apply a foam, spray or gel product specifically intended to prevent drying of soil on medical devices. Apply these products to soiled devices in an enclosable, durable, leak-proof container when soiled devices cannot be immediately cleaned. CPSA recommends you clean devices as soon as possible after use.

5.4. Contaminated items shall be transported in covered, fully-enclosed, leak-proof containers or closed carts that are designed to prevent the spill of liquids, protect reusable medical devices from damage, and allow for effective decontamination after each use.

Obtain and use fully enclosable, leak-proof, protective containers or closed carts to transfer reusable items that have been used on patients. Containers should be designed to be effectively decontaminated after each use.

Characteristics of acceptable instrument transport containers are that they:

- can be covered, fully-enclosed or sealable,
- are leak proof and designed to prevent the spillage of liquids,
- protect reusable devices from damage during transport,
- can be cleaned and disinfected, and
- are durable and can withstand chemical (e.g., foam, gel, spray) application.

5.5. Sterile or clean reusable medical devices and soiled reusable medical devices shall be transported in a manner that prevents cross-contamination (i.e., in separate containers and carts).

Transport sterile, disinfected or cleaned reusable medical devices and soiled reusable medical devices in separate, appropriately-labelled containers or carts to prevent cross-contamination.

5.6. All containers and carts containing contaminated medical devices shall be so identified.

Clearly identify all containers and carts that contain used, contaminated medical devices (e.g., label, colour code) with materials/methods that can withstand repeated decontamination.

5.7. Contaminated reusable medical devices shall be transported to the medical device reprocessing (MDR) area in such a way so as not to contaminate the surrounding environment.

Designate a route for transport of contaminated reusable medical devices to the MDR area that minimizes exposure to high-traffic and patient care areas or other areas of the clinic and avoids clean and sterile device storage areas.

6. Preparation & Cleaning of Reusable Medical Devices

Clinic-specific written policies and procedures are required for the following section.

Sample policy and procedure templates for medical clinics are available on the CPSA website.

See MDR Tools & Templates (www.cpsa.ca/mdr)

Sorting & disassembly

6.1. All contaminated medical devices shall be inspected and sorted before reprocessing to ensure that the appropriate cleaning agents and procedures are applied to the correct devices.

Inspect and sort contaminated, reusable items before reprocessing to ensure that appropriate cleaning agents and procedures are applied to each device. Segregate delicate medical devices to prevent damage.

When using instruments that are marked or identifiable (e.g., physician-specific devices identified using a stamp or tape), use only products or methods that do not breach the integrity of the instruments.

6.2. All medical devices consisting of multiple components (e.g., minimally invasive surgical medical devices) shall be disassembled in accordance with the manufacturer's instructions for use (MIFU).

Disassemble and/or open all medical devices consisting of multiple components before cleaning according to the manufacturer's instructions for use (MIFU).

Cleaning

6.3. Each medical device shall be thoroughly cleaned prior to disinfection or sterilization.

Thoroughly clean devices according to the manufacturer's instructions for use (MIFU), including the use of appropriate detergent or enzymatic cleaner, prior to subsequent disinfection or sterilization.

6.4. Cleaning methods shall be consistent with the medical device's MIFU and appropriate for the type of medical device and the amount of soil to be removed.

Follow the manufacturer's instructions for use (MIFU) for the medical device, and ensure cleaning methods are consistent with the MIFU and appropriate for the type of medical device and the amount of soil to be removed.

Manual cleaning

6.5. If manual cleaning is required, the medical device's MIFU for reprocessing shall be followed, including any specifications for detergent type, water type, or water temperature and cleaning methods.

Obtain the medical device's manufacturer's instructions for use (MIFU) for manual cleaning and follow instructions that specify detergent type, water type, water temperature and cleaning methods.

Best practice is to demarcate a water line in the sink to aid in preparing the required volume of cleaning solution.

Relying on "pumps" to dispense the correct amount of product is not recommended. Verify proper amount of product with a proper measuring tool, such as a measuring cup.

Suitable instrument detergent or enzymatic cleaning solutions must be clearly labelled to identify that their intended use is for surgical instrument/device cleaning. Household detergents and general all-purpose cleaners are considered unacceptable by CPSA assessors.

6.6. Immersible medical devices shall be completely submerged during cleaning to prevent the generation of aerosols, and non-immersible medical devices shall be cleaned according to the MIFU.

Fully submerse immersible devices under the surface of the cleaning solution to minimize splashing and aerosolization of contaminated water. Do not scrub devices under running water.

Follow the medical device's manufacturer's instructions for use (MIFU) for cleaning non-immersible devices.

Automated cleaning

6.7. Automated washers and ultrasonic cleaners used for cleaning shall be used in accordance with the MIFU.

Obtain and follow the manufacturer's instructions for use (MIFU) for automated washer and ultrasonic cleaner. Information to be followed includes but is not limited to loading procedures, inspecting equipment, water temperature, water quality, inspecting medical devices following each cycle, and routine maintenance.

6.7.1. The performance of the automated cleaning system (e.g., automated washers) shall be tested each day that it is in use, using commercially available indicators or test kits.

Obtain and use commercially-available indicators or test kits to test the performance of the automated washer each day that it is used. Document test results in a daily test log.

See MDR Tools & Templates (www.cpsa.ca/mdr)

6.7.2. Ultrasonic cleaners shall be tested for sonication performance (e.g., commercial methods or the foil test) at least weekly.

Test the ultrasonic cleaner for efficiency at least weekly using a commercially available test kit or foil test. Follow the ultrasonic equipment manufacturer's instructions for use (MIFU) for appropriate testing methods. Document test results in a Foil Ablation Weekly Test Log.

If efficiency testing procedures are unavailable, contact the IPAC Program for support: ipac@cpsa.ab.ca

See MDR Tools & Templates (www.cpsa.ca/mdr)

6.7.3. The ultrasonic detergent solution shall be changed at least daily or more frequently when visibly soiled or if the ultrasonic cleaner or solution MIFU specifies more frequent changes (e.g., with every cycle).

Change the ultrasonic detergent solution at least daily or more frequently when visibly soiled or if the ultrasonic cleaning equipment or detergent solution manufacturer's instructions for use (MIFU) require more frequent changes (e.g., with every cycle).

Ensure that this task is included in clinic's policy and procedure documentation.

6.8. The medical device's MIFU shall be followed to ensure medical devices are compatible with the automated washer's process conditions (e.g., moisture, temperature, chemicals, water quality, and pressure).

Obtain and follow the manufacturer's instructions for use (MIFU) for the medical device to ensure the device is compatible with the automated washer's process conditions (e.g., moisture, temperature, chemicals, water quality, and pressure). For example, some medical devices can be damaged by being in the same load with incompatible medical devices (e.g., mixing surgical grade stainless steel with utility grade stainless steel or other types of metals).

Manufacturers of medical devices typically provide instructions for both manual and automated cleaning. If the medical device MIFU do not have instructions for both, it is a good indicator that the MIFU may be outdated.

Rinsing & drying

6.9. Chemical residues and loosened soil shall be completely rinsed from the medical device prior to disinfection or sterilization. Rinsing may be included as a final step in an automated cleaning process. If not, the medical device shall be rinsed manually.

Completely rinse chemical residues and loosened soil from each medical device following cleaning and before further reprocessing. Rinsing may be included as a final step in an automated cleaning process. If the manufacturer's instructions for use (MIFU) does not specifically indicate that a final rinse step occurs, rinse the device manually in a sink or basin, beneath the surface of clean water.

6.10. Reusable medical devices shall be dried prior to disinfection or sterilization, as directed by the MIFU. Unless dried using an automated process, the exterior surfaces of medical devices shall be manually dried with a clean, lint-free or low-lint soft-absorbent towel.

Dry all medical devices following cleaning, before disinfection or sterilization. Drying can be accomplished using an automated process (e.g., automated washer cycle or drying cabinet). If you are not using an automated process, manually dry exterior surfaces of devices using a clean, lint-free or low-lint soft, absorbent towel.

If decontaminated medical devices are not being packaged immediately, dry them before storage to prevent microbial growth and deterioration of materials.

Drying cloths must be described as "lint free" or "low-linting" by the manufacturer. Disposable cloths are strongly recommended. When using reusable drying cloths, they must be mechanically washed and dried between uses as per the manufacturer's instructions for use (MIFU) for the cloths.

Effective drying is an important and critical step in reprocessing. Residual water can dilute the activity of chemical disinfectants and/or damage sterilization packaging. Drying also prevents corrosion of stainless steel devices.

Paper towel is not an acceptable tool for drying devices.

Reassembly

6.11. Decontaminated medical devices shall be reassembled according to the MIFU. Reassembly shall take place in a clean and dry area.

Obtain and follow medical device manufacturer's instructions for use (MIFU) for reassembly of decontaminated medical devices. CPSA recommends that reassembly be performed in a clean, dry area of the reprocessing space between the cleaning sink and the sterilizer/disinfectant.

Instrument Lubricants: some device and product manufacturers require the use of an instrument lubricant to ensure proper ongoing function of the device. Lubricants must be compatible with the sterilization method (i.e., steam) and applied after the reassembly of clean and decontaminated instruments.

Inspection

6.12. Medical devices shall be visually inspected for cleanliness, damage, integrity, and functionality prior to disinfection, sterilization, or subsequent use.

Inspect each decontaminated medical device for cleanliness, damage, integrity, and functionality prior to disinfection, sterilization or subsequent use.

A magnification device is often required to verify the cleanliness and integrity of instruments.

Consult the device manufacturer's instructions for use (MIFU) for inspection and functionality test information. Include the following, as applicable, when inspecting devices:

- hinge and joint action,
- jaw and teeth alignment,
- ratchet alignment and function,
- cutting edge sharpness,
- lens clarity, and
- materials integrity (e.g., surface damage such as wear, corrosion, chips, burrs, dents, loss of finish, insulation integrity and bends or kinks).

6.12.1. Cleaned medical devices that are visibly soiled shall be cleaned again.

Return any devices that have residual/remaining soil back to the decontamination area to be re-cleaned.

6.12.2. Medical devices that are damaged or in poor working condition shall be removed from service, labelled, and segregated from usable medical devices. Such medical devices shall either be repaired or disposed of in accordance with the documented procedures.

Remove from service, label and segregate medical devices that are damaged or in poor working condition. Indicate on the label that the medical device is out of order, specify the problem and action to be taken (e.g., send for repair, dispose of the instruments).

Examine engraved or stamped areas of personalized instruments for the development of new damage and take them out of service if new crevices are forming.

Ruts and crevices (e.g., dents and chips) challenge reprocessing.

7. Disinfection of reusable medical devices

Clinic-specific written policies and procedures are required for the following section.

Resources are available on the CPSA website to assist clinics in developing MDR policies and procedures.

See MDR Tools & Templates (www.cpsa.ca/mdr)

7.1. Disinfection of reusable medical devices shall take place in accordance with the manufacturer's instructions for use (MIFU) of the device and shall also follow the MIFU for the disinfection process, equipment, and products.

Obtain and follow the manufacturer's instructions for use (MIFU) for the disinfection process specific to each medical device, disinfectant products and disinfection equipment (as applicable).

Disinfection instructions can often be found on the container label and include mixing and storage instructions, expiry dates, contact time, etc.

Medical devices that are not accompanied by validated MIFU must not be used or reprocessed.

7.2. Only chemical disinfectants that have a Health Canada drug identification number (DIN) or a medical device license (MDL) issued by Health Canada, shall be used in clinics and settings for the disinfection of reusable medical devices.

Only purchase and use chemical disinfectants that have a Health Canada drug identification number (DIN) or a medical device licence (MDL) issued by Health Canada.

Disinfectants without a valid DIN or MDL are inappropriate for use in the clinic.

To verify if your product or device has a valid Health Canada MDL, please see:
https://health-products.canada.ca/mdall-limh/index-eng.jsp

To verify if your product has a valid DIN, please see:
https://health-products.canada.ca/dpd-bdpp/index-eng.jsp

7.3. A liquid chemical disinfectant shall not be used beyond its expiry date and in-use life.

Discard and do not use liquid chemical disinfectants that are beyond the expiry date and in-use (use and re-use) life.

7.4. Reusable liquid chemical disinfectant solutions shall be:

7.4.1. Clearly identified and include the expiry date.

Clearly label disinfectant solutions that are decanted or stored in containers with name of disinfectant product and date when re-use ends (e.g., 14 days from decanting).

7.4.2. Stored in containers that are cleaned, disinfected, and dried prior to changing the solution.

Clean, disinfect and dry the disinfectant solution container after discarding used solution.

7.4.3. Kept covered with a tight-fitting lid, except when introducing or removing a medical device to or from the solution.

Cover disinfectant solution container with a tight-fitting lid. Only remove the lid for the purpose of introducing or removing a medical device to or from the solution.

Non-critical devices

7.5. Non-critical reusable medical devices shall be disinfected between patient uses using an intermediate-level disinfectant (ILD) or low-level disinfectant (LLD).

Ensure that devices are adequately cleaned prior to intermediate or low-level disinfection. Use an ILD or LLD to disinfect reusable non-critical medical devices between each patient use.

Non-critical devices are those that only come into contact with intact skin (e.g., blood pressure cuff).

7.5.1. ILD or LLD wipes shall be moist enough to thoroughly wet the surface for the indicated contact time and a new wipe shall be used if the area to be disinfected cannot be completely wetted with a single wipe.

Ensure that ILD and LLD wipes are moist enough to thoroughly wet the surface for a contact time indicated on the disinfectant product label. Use a new wipe if the area to be disinfected cannot be completely wetted with a single wipe.

Ensure wipes container lid is closed when not in use to prevent drying of wipes.

Semi-critical medical devices

7.6. If a reusable semi-critical device cannot be sterilized, then it shall, at a minimum, be high level disinfected between patient uses.

High-level disinfectants (HLD) are too strong for environmental or clinical surfaces. High-level disinfectants should only be used to reprocess semi-critical devices. Suitable HLDs will carry either a Health Canada Drug Identification Number (DIN) or a Medical Device Licence (MDL).

Clinics may use HLD to reprocess reusable semi-critical medical devices that are heat-sensitive or otherwise not able to withstand steam sterilization. Heat-tolerant semi-critical devices must be sterilized in a steam sterilizer.

Semi-critical devices are those that come into contact with mucous membrane or non-intact skin, but do not penetrate them.

Liquid chemical high-level disinfection (HLD)

7.7. The minimum effective concentration (MEC) of a reusable HLD shall be tested and recorded, according to the MIFU of the disinfectant.

To ensure the disinfectant strength is adequate, test the minimum effective concentration (MEC) of reusable high-level disinfectant (HLD) as directed by the disinfectant manufacturer. Document the MEC results in a tracking log.

MEC tracking log templates are often available directly from the manufacturer. Resources are also available on the CPSA website to assist clinics in the development of logs.

See MDR Tools & Templates (www.cpsa.ca/mdr)

7.7.1. MEC testing shall be performed at the beginning of each day that the solution is used for manual HLD (or more frequently if specified in the MIFU of the disinfectant) and in each cycle for automated HLD.

Test the minimum effective concentration (MEC) of the high-level disinfection (HLD) at least daily, at the beginning of each day that the HLD solution is used for manual disinfection or more frequently if specified in the HLD manufacturer's instructions for use (MIFU).

Test the MEC of the HLD for each cycle of automated HLD processing.

7.7.2. Quality assurance testing of test strips used to test MEC shall be followed in accordance with test strip MIFU.

The test strip manufacturer will indicate how to perform quality assurance testing for their product. Clinics are expected to perform quality assurance testing of these strips as describe by the test strip manufacturer's instructions for use (MIFU).

Record the results of quality assurance testing in a log.

See MDR Tools & Templates (www.cpsa.ca/mdr)

7.7.3. Test strips used to test MEC shall not be used beyond the test strip's expiry date or the manufacturer's in-use shelf life.

Verify the expiry date of the test strip before use and follow the manufacturer's in-use shelf life.

Record in-use shelf life (beyond use date) of test strips directly on the container upon opening.

7.7.4. An HLD shall not be used beyond a failed MEC test.

Discard and do not use high-level disinfectant (HLD) product when a minimum effective concentration (MEC) test indicates failure. This means that the product is no longer effective.

7.8. When performing manual disinfection of a semi-critical medical device:

7.8.1. All parts of the medical device shall be in complete contact with the HLD, and all air bubbles shall be removed.

Ensure that all parts of the medical device are immersed in the disinfectant and in complete contact with the disinfectant solution. Ensuring that all air bubbles are removed.

Air removal and complete contact can be achieved by the following means:

- completely disassemble the medical device according to the manufacturer's instructions for use (MIFU),
- fill all lumens with disinfectant solution and ensure that fluid flows from the distal end (in the opposite direction),
- position the medical device to allow trapped air to escape, and
- weigh down items that float.

7.8.2. The contact time and temperature shall be measured from the point at which the semi-critical medical device achieves complete contact with the HLD and there are no trapped air bubbles.

Monitor the contact time and temperature of the disinfectant during high-level disinfection (HLD). Measure the contact time and temperature from the point at which the medical device is in complete contact with the disinfectant and there are no trapped air bubbles.

To prevent damage to the instrument, remove it from HLD once contact time has been achieved.

7.9. If an automated disinfection system is used, the contact time and temperature shall be monitored as specified in the MIFU and the disinfectant maintained within the manufacturer's recommended ranges for temperature and concentration throughout the contact time.

Ensure the contact time, concentration and temperature of disinfectant solution, as specified in the manufacturer's instructions for use (MIFU), is monitored and maintained throughout each cycle, when an automated disinfecting system is used.

7.10. Automated disinfection systems shall provide a record that critical cycle parameters (e.g., disinfectant temperature, concentration, contact time) have been met**.**

Ensure that the automated disinfection system in use has the means (e.g., printout or electronic record) to document that critical cycle parameters of disinfectant temperature, concentration and contact time are achieved.

7.11. Following chemical HLD, each semi-critical medical device shall be thoroughly rinsed.

Thoroughly rinse each semi-critical device following chemical high-level disinfection (HLD).

7.11.1. If rinsing is done manually, it shall include at least three separate rinses in water of acceptable quality unless otherwise specified by the disinfectant manufacturer.

Unless otherwise instructed by the manufacturer of the device, manually rinse devices using three separate rinses of water of acceptable quality. Acceptable water quality is described as sterile or bacteria-free. Potable (tap) water does not meet this description.

Rinse water must be changed for each separate rinse, unless otherwise specified by the manufacturer.

Do not rinse devices under running water. Fully immerse devices under the surface of the water during rinsing to minimize aerosolization and to ensure that disinfectant residues are removed from all surfaces of devices.

Flush lumens of devices with a volume of rinse water that is at least three times the volume of the lumen.

7.12. After HLD and rinsing, the semi-critical medical device shall be dried in accordance with the MIFU.

Dry each semi-critical device according to the manufacturer's instructions for use (MIFU) after rinsing. If manually drying, use a clean, soft, lint-free or low-linting cloth.

7.13. At a minimum, the clinic shall document and maintain records on:

7.13.1. HLD solution.

7.13.2. HLD test strips.

7.13.3. Results of MEC testing.

7.13.4. Contact time and temperature during HLD.

Document the following:

- High-level disinfection (HLD) solution including product name, drug identification number (DIN) or medical device licence (MDL), lot number, expiry date of HLD in use, and date of solution change,
- test strip information including name of test strip, lot number, expiry date, and quality control test result,
- routine minimum effective concentration (MEC) testing (test strip results pass/fail),
- contact time of the HLD and temperature of the HLD solution (if applicable), and
- initials of staff doing the routine testing and documentation.

See MDR Tools & Templates (www.cpsa.ca/mdr)

7.13.5. Cycle parameters.

7.13.6. Medical device name or type documentation.

Document medical device name or type in a daily high-level disinfection (HLD)/automated disinfection testing and minimum effective concentration (MEC) log and include:

- medical device name or type,
- unique identifier (serial number),
- date and time of disinfection,
- contact time in HLD solution,
- tested concentration and temperature of the HLD in that cycle,
- results of electrical leak test (if applicable), and
- initials of staff doing the reprocessing.

See MDR Tools & Templates (www.cpsa.ca/mdr)

Thermal disinfection/pasteurization

7.14. If a washer-disinfector or washer-pasteurizer is intended to provide thermal high level disinfection (HLD), the clinic shall obtain documentation from the washer-disinfector or washer-pasteurizer manufacturer or a third party to confirm that it has been validated for thermal HLD.

Obtain documentation from the washer-disinfector or washer-pasteurizer manufacturer, or a third party, and confirm that the equipment has been validated to perform thermal high-level disinfection (HLD).

7.15. If a washer-disinfector or pasteurizer is used for thermal disinfection, it shall be equipped with sensors and a recording device for time and temperature and/or equivalent A_0 value.

Ensure that there is a recording device or printer that:

- is accessible to the user on the preparation and packaging (clean) side of the automated washer,
- identifies the automated washer or pasteurizer,
- identifies the cycle number,
- records the cycle parameters of exposure time and temperature (or equivalent A0 value) for automated washers,
- records the date and time of the cycle, and
- indicates the reason for any parameter abnormalities (e.g., error messages, operator cancellation).

7.15.1. The accuracy of the recording device shall be periodically confirmed with an independent calibration device, and the frequency and method of testing shall be in accordance with the MIFU.

Periodically confirm and document the accuracy of the recording device with an independent calibration device. Follow the manufacturer's instructions for use (MIFU) for the frequency and method of testing.

7.15.2. When a washer-disinfector is used for the thermal HLD of semi-critical medical devices (e.g., respiratory devices), the washer-disinfector shall provide a record of attaining A_0 600 through either printed or electronic means.

Ensure the recording device or the printer of the washer-disinfector provides a record of attaining A_0 600 through printed or electronic means.

7.16. The clinic shall ensure the washer-disinfector or pasteurizer and the selected cycle are appropriate to the medical device being reprocessed and its intended use.

Ensure that the washer-disinfector or washer-pasteurizer and the selected cycle are appropriate for the equipment being processed and its intended use (e.g., washer-disinfector can achieve A_0 value of 600 or washer-pasteurizer using hot water immersion at 71 to 77 °C [160 to170°F] for 30 minutes when reprocessing respiratory devices).

7.17. The washer-disinfector or pasteurizer MIFU for loading configurations and cleaning agents shall be followed.

Follow the washer-disinfector or pasteurizer manufacturer's instructions for use (MIFU) for loading and cleaning agents. Correct positioning of devices allows water and cleaning solutions to reach all internal and external surfaces of the medical device being processed.

7.18. Validated manifolds and attachments shall be used to facilitate optimal circulation of water through the reusable medical devices being reprocessed.

As specified by the manufacturer's instructions for use (MIFU), obtain and use validated manifolds and attachments in the washer-disinfector to connect to the devices being processed and facilitate optimal circulation of water through them.

7.19. Pasteurizers shall reach a minimum temperature of 71° Celsius for a minimum contact time of 30 minutes, unless a higher temperature is specified in the MIFU for the medical device.

Ensure that the pasteurizing equipment can achieve a minimum temperature of 71 °C for a minimum contact time of 30 minutes, or a higher temperature if specified in the manufacturer's instructions for use (MIFU) for the medical device.

7.20. Air pockets shall be displaced from the load before pasteurization via manipulation of the load by the washer-pasteurizer in accordance with the equipment MIFU and all devices shall be completely submerged in a water bath during the pasteurization cycle.

Disassemble, clean, and rinse devices before pasteurization. Observe the load prior to commencing the pasteurization cycle to ensure that all air pockets are displaced in accordance with the equipment MIFU.

Air pockets will inhibit hot water contact with medical device surfaces and potentially jeopardize microbial kill.

7.21. Following thermal disinfection in a washer-disinfector or pasteurizer, reusable medical devices shall be handled in a manner that minimizes contamination.

Handle medical devices in a manner that minimizes contamination during unloading and when transferring devices after thermal disinfection.

To minimize contamination:

- Remove soiled PPE and perform hand hygiene before unloading.
- Disinfect the exterior of the washer pasteurizer with low-level or intermediate-level disinfectant before unloading.
- Transport medical devices directly from the washer-disinfector or pasteurizer to a clean area for drying or subsequent handling.

7.22. Following the disinfection cycle, respiratory devices shall be dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and is used only for the drying of disinfected medical devices.

After pasteurization, reusable respiratory devices must be dried in a HEPA-filtered drying cabinet.

Ensure the drying cabinet:
- has documented preventive maintenance,
- is used exclusively for the drying of disinfected medical devices,
- is decontaminated weekly, and
- has filters changed according to the manufacturer's instructions for use (MIFU).

See MDR Tools & Templates (www.cpsa.ca/mdr)

8. Sterilization of reusable medical devices

8.1. A reusable critical medical device shall be sterilized between patient uses.

Ensure that all reusable critical medical devices are sterilized before use. Critical devices are those that contact sterile body tissues or cavities or enter the blood stream. Do not re-sterilize medical devices that have been previously sterilized by the manufacturer unless instructions are provided in the manufacturer's instructions for use (MIFU).

Steam sterilizers offer an efficient and non-toxic method of sterilization to the clinic settings. They are safe, readily available and can be easily monitored. Sterilizers need to be capable of sterilizing the type of instruments that are used in the clinic setting (e.g., lumened instruments, hollow instruments, textiles, power tools, hand pieces and wrapped sets may all have unique sterilization requirements).

8.2. Sterilization of reusable medical devices shall take place in accordance with:

8.2.1. The manufacturer's instructions for use (MIFU) of the device.

Obtain and ensure that all devices have written confirmation of validated reprocessing instructions from the manufacturer.

8.2.2. The MIFU for the sterilization process, equipment, and products.

Obtain and follow the manufacturer's instructions for use (MIFU) for the medical devices, packaging systems, products and cleaning and sterilization equipment used in your clinic. Device and equipment MIFU must be readily available.

8.3. Installation qualification of sterilization equipment (including large chamber and table-top steam sterilizers and chemical sterilizers) shall be performed and documented according to the manufacturer's specifications.

Ensure that when a new sterilizer is acquired, installation qualification and calibration is completed. This is typically conducted by the sterilizer manufacturer or designated representative (certified service technician) of the manufacturer in conjunction with the clinic's individual responsible for MDR.

Jointly, the manufacturer (or designate) and the clinic representative must:

- verify that all engineering controls and safety devices are installed and operating according to the manufacturer's specifications,
- complete the equipment installation requirements checklists, and
- approve records of installation qualification.

Retain records of installation qualification. Qualification results can be recorded in the clinic's sterilization log (Indicate "Sterilizer Installation Qualification" in the load content column).

Sterilizers moved to new locations will also require certified installation qualification and calibration.

8.4. Operational qualification and requalification shall take place at least annually and following a major sterilizer repair, sterilizer relocation, an unexplained sterility failure, and, for steam sterilizers, following any disruption to steam supply or change to steam pressures.

Perform operational requalification at least annually and when the following events or conditions occur:

- major sterilizer *repairs (that could affect sterilizer performance) including:
  - replacing sterilizer controls,
  - replacing plumbing packages,
  - major rebuilding, including weld repairs of the pressure vessel, or
  - installation of major new components, including a chamber door, a vacuum pump, and major piping assemblies,
- sterilizer relocation,
- unexplained sterility failures,
- any major interruptions in steam supply or delivery, or
- changes to static and dynamic steam pressure feeding the sterilizer

* Normal preventive maintenance, such as the rebuilding of solenoid valves or the replacement of gaskets, are not considered to be major repairs.

8.4.1. Operational qualification and requalification testing shall include a verification of each cycle used by the clinic, according to the MIFU for testing.

Follow the manufacturer's instructions for use (MIFU) from the sterilizer manufacturer and test each cycle used in your clinic when conducting operational qualification and requalification.

Qualification and requalification results can be recorded in the clinic's sterilization log (indicate "Sterilizer Operational Qualification" in the load content column).

 **See MDR Tools & Templates (www.cpsa.ca/mdr)**

8.4.2. Operational qualification and requalification testing shall be conducted by:

8.4.2.1. Running three consecutive cycles in an empty chamber using process challenge devices (PCDs) with biological indicators. For table-top steam sterilizers, testing will take place in a fully loaded chamber.

Nearly all medical clinics use table-top steam sterilizers, which will require three consecutive cycles using process challenge devices (PCDs) with biological indicators (BIs) in a **fully-loaded chamber** when conducting operational qualification and requalification testing.

Process Challenge Packs (PCD) are also referred to as "test packs" or "challenge packs." These packs represent the greatest possible challenge to the indicators used in the sterilization process. Construct an in-house PCD by packaging the indicators alongside devices in a manner that mimics the most difficult pack that the clinic will sterilize.

PCD contents can be re-packaged and re-used in subsequent tests.

Packages, other than the PCD, sterilized in the fully-loaded chamber can be quarantined and released for patient use if all operational qualification, chemical monitoring and biological monitoring is successful.

Note: wrapped packages as a "test pack" are typically more challenging to sterilizer than a peel pouch.

8.4.2.2. Additionally, in dynamic air removal sterilizers that use pre-vacuum cycles, ensuring that the sterilizer meets the requirements of an air removal test and leak-rate test and is tested with three consecutive air removal tests (e.g., Bowie-Dick) in an otherwise empty sterilizer.

Run three consecutive air removal tests (e.g., Bowie-Dick) in an otherwise empty sterilizer when conducting operational qualification and requalification testing of a dynamic air removal sterilizer that uses pre-vacuum cycles. Ensure that the sterilizer is tested with a leak-rate test and has an average leak rate that meets the manufacturer's specifications. Refer to the manufacturer's instructions for use (MIFU) for frequency of leak-rate testing.

See MDR Tools & Templates (www.cpsa.ca/mdr)

Packages & labels

8.5. Packaging of reusable medical devices for sterilization shall take place in accordance with the MIFU of the device, the sterilization equipment, and the sterilization packaging manufacturer, and when packaging is required, it shall be done using a validated sterile barrier system (e.g., pouches, wrappers, or rigid sterilization container systems).

Ensure that packaging practices are based on the manufacturer's instructions for use (MIFU) from the device manufacturer, sterilizer manufacturer, and sterilization packaging manufacturer. Use only validated sterile packaging systems intended to contain devices and maintain sterility. Unless otherwise specified by the manufacturer, only fill pouches to a maximum of 75% of the inner surface area of the porous side to allow the pouch to close without creating wrinkles in the seal.

Do not overstuff packages. Leave room between the medical device(s) and the inside edge of the package to prevent compromising the integrity of the seal. Orient devices in the package so the handles can be accessed from the end of the package that is peeled open.

Instrument guards and tip protectors help prevent sharp devices from puncturing peel pouches.

Additional guidance on wrapping techniques are available:
AHS Envelope Wrapping Method
CSA Envelope Wrapping Method

8.6. Packages shall be labelled with sterilizer load identification information, including the sterilizer number, the load number in that sterilizer, and the sterilization date.

Label each package with information that will identify the sterilizer load.

Include:
- the number/name of the particular sterilizer,
- the load number, and
- the date of sterilization.

8.6.1. Labelling systems shall be validated for the sterilization process.

Only use labels validated for sterilization. If using markers, use a permanent, soft-tipped marker validated for use with the sterilization process.

Ensure labels and marking:
- are clear, intact, and adhere to packaging until packages are used,
- have print or ink that is not transferred through packaging to medical devices, and
- does not react with packaging materials.

8.6.2. For pouches, a label shall be placed on the transparent portion of the packaging.

Place sterilization pouch labels or markings on the transparent side of the package. When using a pen to label the package, use a permanent, soft-tipped marker validated for use in sterilization.

8.6.3. For wrapped packages, writing shall be on the closure tape, not directly on the wrappers.

Write only on the closure tape. Do not write directly on the wrapper when labelling wrapped packages.

Loading & unloading

8.7. Packages shall be placed in the sterilizer chamber in a manner that facilitates air removal, sterilizing agent penetration, sterilant evacuation, and, in the case of steam sterilization, drying.

Load packages into the sterilizer chamber according to the sterilizer's manufacturer's instructions for use (MIFU) to ensure air removal and allow the sterilant (e.g., steam) to circulate freely, enter, and exit each package, and to aid the packages in drying.

Overloading may cause a sterilization failure.

8.7.1. Wrapped items shall not contact the interior walls of the sterilizer chamber, as contact can damage the wrapper.

Do not allow pouches or wrapped packages to contact the interior walls of the sterilizer chamber, as contact can damage the wrapper.

8.7.2. Pouches and wrapped packages shall not be stacked or compressed.

Avoid stacking and compressing pouches and wrapped packages when loading the sterilizer.

Avoid overloading the sterilizer chamber. In the absence of the manufacturer's instructions, peel pouches should be placed paper-side down in gravity displacement or steam flush pressure pulse sterilizers. Place packs paper-side up in vacuum sterilizers.

8.7.3. Between packages there shall be adequate space to ensure effective sterilizing agent penetration, evacuation, and drying.

Allow adequate space between packages to ensure effective sterilizing agent penetration, evacuation, and drying. If pouches are loaded into the sterilizer on edge, obtain a rack manufactured for this purpose. Position pouches so the paper side of one pouch is facing the plastic side of the adjacent pouch.

8.8. Sterile packages shall be cooled to room temperature before handling.

Allow packages to fully dry and cool prior to handling. Place the load in a draft-free location where it will be undisturbed. Do not stack warm packages or place them on cool metal surfaces or near air vents or diffusers to avoid condensation that can wick external micro-organisms into packages.

Do not place packages in dust covers or designated storage bins until they are completely cooled.

8.9. During unloading, packages shall be inspected for package integrity, dryness, presence of a label, the correct change in an external chemical indicator, an intact seal if used, and evidence of potential contamination. If a package does not meet the inspection criteria, the contents shall not be used.

During unloading, inspect packages for:
- integrity,
- dryness,
- presence of a label,
- correct change in external and/or internal chemical indicators if visible,
- intact seals, and
- evidence of contamination (e.g., soiling, wetness).

Do not use packages that fail to meet inspection criteria and return for re-packaging and reprocessing.

Sterility assurance

8.10. Sterilization indicators shall be used only for the sterilizer type and sterilization cycle for which they were designed and validated and shall be used according to the sterilizer and indicator MIFU.

Purchase and use sterilization indicators designed and validated for the sterilizer(s) and cycle(s) used in your clinic and follow both the sterilizer and indicator manufacturer's instructions for use (MIFU). Sterilization monitoring tools include chemical and biological indicators.

Using the incorrect chemical and biological indicators in sterilizers or cycles for which they are not designed can produce misleading pass or fail results.

8.10.1. Sterilization indicators shall not be used beyond their expiry date and shall be stored according to the MIFU.

Establish a process for checking product expiration dates. Do not use sterilization indicators beyond their expiration date. Store sterilization indicators according to their manufacturer's instructions for use (MIFU). Keep indicators in original packaging to allow tracking of expiration date and to protect them from light, etc.

Expired or improperly stored biological chemical indicators can produce misleading pass or fail results. For example, biological indicators have been known to produce inaccurate results when stored in direct sunlight, transported in cold weather or kept adjacent to chemicals (e.g., disinfectants, sterilants).

Chemical indicators

8.10.2. Both internal and external chemical indicators shall be included with each package prepared for sterilization.

Ensure a clearly visible external chemical indicator is included with each sterilized package, unless the internal indicator can be clearly seen (e.g., through the plastic wrapper) without opening the package.

The external chemical indicator does not provide proof of sterility. It is used only to distinguish reprocessed packages from non-reprocessed packages.

Place a Type 5 or 6 internal chemical indicator inside each package that is being prepared for sterilization.

8.10.2.1. The internal chemical indicator shall be placed in the area of the package that is least susceptible to sterilizing agent penetration. If a multi-layer container is being used, chemical indicators shall be placed at each level.

Place the internal chemical indicator in the area of the package deemed to be the most difficult for the sterilant (e.g., steam) to penetrate. Place chemical indicators on each level of a multi-layer container. Internal chemical indicators do not prove sterility, but they can detect potential sterilization failures caused by incorrect assembly or packaging, incorrect loading of the sterilizer, or equipment malfunction.

Air removal testing

8.10.3. For dynamic air removal-type sterilizers (pre-vacuum cycles), an air removal test shall be performed every day the sterilizer is used.

Perform an air removal (e.g., Bowie-Dick) test in dynamic air removal type sterilizers every day the sterilizer is used. Position the air removal test in the chamber, on the bottom shelf above the drain in an empty sterilizer. Use a commercially-manufactured air removal test that is appropriate for the sterilizer in use (e.g., table-top) and meets the sterilizer manufacturer's criteria for testing.

Air removal test packs are Type 2 indicators used strictly for dynamic air removal sterilizers that have pre-vacuum cycles.

Biological indicators

8.10.4. A biological indicator contained within a process challenge device (PCD) shall be used to test the sterilizer for each type of cycle used (e.g., dynamic air removal, gravity) and at the shortest exposure time, within a full load. This test shall be done at least daily when the sterilizer is in use.

Run a biological indicator contained in an appropriate test pack in a fully-loaded chamber at least daily for each day the sterilizer is used. Most clinics will perform this task as the first cycle of that day.

Package the indicator in a manner that is deemed to be the most challenging to sterilization and place the test pack in the cold point of the sterilizer, as specified by the manufacturer.

Run biological indicator "controls" a minimum of once per lot (box) of indicators.

All "test pack" and "control" biological indicator results must be recorded in a log.

The biological indicator chosen must be appropriate for the sterilization cycle it is measuring. The incubator used must be appropriate for use with the biological indicator chosen.

8.10.4.1. If a steam sterilizer will be used for multiple types of cycles, each type of cycle used shall be tested daily.

Test each type of cycle if using multiple types of cycles (e.g., unwrapped, wrapped) at least daily. In most instances, these tests will be the first cycle of each day.

If sterilizing implantable devices, run a biological indicator in **every** load containing these types of devices.

For each new batch of biological indicators, determine that the indicators are viable by incubating one vial/strip without running it through the sterilizer. This unsterilized control must indicate "growth of organisms" (positive) or the entire batch of indicators is to be considered "faulty" and discarded.

8.11. At the conclusion of a sterilization cycle and before the load is removed, the operator shall confirm that the required parameters and all phases of the sterilization cycle including aeration (if required) have been met.

Check the recording or printout at the conclusion of the sterilization cycle and confirm that the required parameters (e.g., time, temperature, pressure for steam sterilization) and all phases (e.g., steam evacuation, drying) of the sterilization cycle were met before the load is removed from the sterilizer. Record the identity of the individual checking the parameters.

See MDR Tools & Templates (www.cpsa.ca/mdr)

8.12. If a package is released based on monitored physical parameters and internal chemical indicator results, the internal chemical indicator shall be Type 5 or Type 6.

Use a Type 5 or Type 6 internal chemical indicator when packages are released for use based on monitored physical parameters (printout) and internal chemical indicator results.

Type 5 or 6 internal indicators measure all critical parameters for steam sterilization and provide additional quality assurance for monitoring medical devices. Other types of internal chemical indicators are not designed to measure all critical parameters.

Type 4 internal chemical indicators may only be used when:
- the sterilizer that has a printer or electronic recorder, and
- sterilized packages are quarantined until daily biological indicator testing is deemed successful.

Sterilized implantable devices cannot be released until confirmation of successful physical monitoring, internal indicators and biological indicators.

8.13. All sterilizers used in Alberta clinics and settings shall come equipped with a printer or electronic record that records cycle parameters effective January 1, 2023.

In the period before the transition required by 8.13 is completed, if a clinic is using a sterilizer that does not come equipped with a printer, personnel shall check the sterilizer's displays and manually record the sterilization time and temperature at intervals during each cycle and use a Type 5 chemical indicator in each package.

Ensure that the steam sterilizer has a printer or an electronic recorder. Sterilizers that do not have this capacity must be retrofitted or replaced by January 1, 2023.

Prior to January 1, 2023, in the absence of a printer or electronic recording capacity:
- check the sterilizer's displays and manually record the sterilization time and temperature at intervals during each cycle, and
- use a Type 5 or 6 chemical indicator in each package.

8.14. Documentation of sterility assurance shall include a printout or electronic cycle parameter record, a load control label, a load contents record, and associated chemical or biological indicator test results for each cycle.

Create and retain a load record for each cycle that includes:
- a load control label (label can be hand written on package),
- a printout or electronic cycle record that:
  - identifies the sterilizer,
  - identifies the load number,
  - describes the critical process parameters (e.g., exposure time, temperature, pressure, date and time of the cycle for steam),
  - indicates the reason for any parameter abnormalities (e.g., maintenance test, operator cancellation), and
  - is inspected and initialed or confirmed via a password protected entry by the operator of the sterilizer at the conclusion of each cycle that process parameters were met.
- a load-contents record of the contents of the sterilizer that includes:
  - the types or package names of items in the load, and
  - the quantity of each type of item.
- Test results associated with the load (e.g., chemical or biological indicator results).
- Any additional information that the clinic might require in the event of a medical device recall.

9. Storage

9.1. Reprocessed critical and semi-critical medical devices shall be protected from contamination by:

9.1.1. Rotating stock via first-in, first-out.

Rotate stock by using items in a first-in, first-out (FIFO) method. For example, place newly-sterilized stock behind older stock when replenishing supplies.

9.1.2. Keeping items clean, dry, and protected**.**

Store items in a clean, dry, and protected area. Avoid cramming or crushing packages into tight or limited storage spaces. Packages or pouches must be stored in unstacked, unbound single layer. Do not store devices directly adjacent to a water source (e.g., under the sink) or in areas that could be contaminated by patients (e.g., the foot of an examination bed).

9.1.3. Keeping items well-separated from soiled items and soiled areas via barriers and/or distance.

Maintain separation of clean and sterile supplies from soiled items and areas using barriers and/or distance.

9.1.4. Ensuring they are not stored on the floor or a window sill, under sinks or near water sources, in open corridors or patient rooms, or in the same area as hazardous materials.

Do not store sterilized devices in areas where they can become contaminated during patient examinations, such as the foot of an examination table. Do not store medical devices near liquids, running water or plumbing. Do not store medical devices on the floor or windowsill, or in open corridors. Store medical devices in a separate area from where hazardous materials are stored.

10. Education & training

10.1. The clinic shall ensure all personnel involved in the reprocessing of critical and semi-critical medical devices are appropriately educated and trained for the reprocessing duties/tasks that they perform.

All personnel involved in reprocessing critical and semi-critical medical devices must be sufficiently skilled and knowledgeable in the reprocessing duties and tasks that they perform. Skills and knowledge can be gained through formal and/or informal education and training. All training should be documented and tracked.

Clinics must have a documented plan in place for instances when designated reprocessing staff are away (e.g., due to illness or vacation). In these situations, clinics may choose to:

- postpone procedures that require the use of reusable devices,
- have a fully-trained and oriented back-up person on staff,
- use only single-use devices, or
- outsource reprocessing to another clinic or facility.

10.1.1. Personnel who reprocess critical and semi-critical medical devices, but are not employed as medical device reprocessing technicians, shall receive training in a formal medical device reprocessing training program recognized by the clinic, or comprehensive in-house training, and shall successfully complete competency testing.

A medical device reprocessing technician is a person with a formal post-secondary (or equivalent) degree in MDR.

All personnel who reprocess critical and semi-critical devices, including temporary/"back-up" reprocessing staff, are expected to have obtained training in either a formal medical device reprocessing program or through comprehensive in-house training. To verify that personnel have appropriate skills and knowledge after training, clinics must ensure competency testing is successfully completed and documented.

Competency is assessed by determining whether the individual has adequate and sufficient knowledge and skills in this area. Skills are often assessed through visual observation. Knowledge is often assessed by the ability to communicate requirements set out in clinic policies, by the manufacturer's instructions for use (MIFU) and in CPSA or other requirements/standards.

MDR staff and employers are encouraged to seek continued development and training in medical device reprocessing throughout their careers.

Training may be provided by a qualified MDR staff, medical supplier or manufacturer. CPSA recommends that the training process includes review of this guidance, followed by competency testing using CPSA's Reusable and Single-Use Medical Device Requirements. Clinics can develop their own competency exams and may wish to use resources from other organizations (e.g., CSA) or clinics to develop these tests.

A list of recommended courses can be found on the CPSA website: http://www.cpsa.ca/mdr

10.2. The clinic shall document and maintain records of education, training, orientation, and competency assessments of personnel who reprocess critical and semi-critical medical devices.

Document in-clinic records that all staff members performing medical device reprocessing, including temporary/"back-up" reprocessing staff, have been appropriately trained and oriented and include the results of competency assessments. Documentation may be a simple statement attesting to the completion of the required training, competency testing and date of training.

See MDR Tools & Templates (www.cpsa.ca/mdr)

PART C: QUALITY MANAGEMENT SYSTEMS

11. Quality management systems

11.1. The clinic shall have clear accountability and lines of responsibility for all aspects of medical device reprocessing (MDR), wherever MDR takes place in the clinic, and the appropriate use of single-use medical devices.

Designate one staff member to be responsible for overseeing all aspects medical device reprocessing, including routine review and updating of clinic MDR policies and procedures and ensuring that MDR staff are appropriately trained.

11.2. The clinic shall have written policies and procedures in place that meet or exceed appropriate provincial and national standards and guide the clinic through all aspects of MDR. The clinic's medical device reprocessing policies and/or procedures shall include (but not be limited to):

11.2.1. All critical steps in the reprocessing of reusable medical devices, based on MIFU.

- □ Pre-cleaning and transportation
- □ Sorting, disassembly, and soaking
- □ Manual and/or automated cleaning
- □ Rinsing
- □ Drying
- □ Inspection
- □ Chemical high level disinfection (HLD) if applicable
- □ Thermal disinfection / pasteurization (if applicable)
- □ Packaging and labelling
- □ Sterilization
- □ Sterility assurance, including physical, chemical, and biological
- □ Storage

Develop clinic-specific policies and procedures for medical device reprocessing that are in writing, dated, available to staff, and based on both the device manufacturer's instructions for use (MIFU)and current CPSA requirements. Each critical step should have both a policy and procedure.

See MDR Tools & Templates (www.cpsa.ca/mdr)

11.2.2. Education and training.

Develop clinic-specific policies and procedures for the education and training of staff who perform reprocessing. Please also refer to requirements set out in sections 10.1 to 10.1.2.

11.2.3. Recall procedures.

Develop clinic-specific policies and procedures for recalling devices after a failed biological and/or chemical indicator result is obtained.

CPSA recommends that clinics support staff by also developing written procedures that outline other possible sterilization failures scenarios such as:

- wet packaging
- failure to meeting parameters of sterilization (time, temperature)
- instruments found at point of use soiled

CPSA offers templates clinics can work from to address recall after a failed (growth) biological indicator and/or chemical indicator.

See MDR Tools & Templates (www.cpsa.ca/mdr)

11.2.4. Specific, detailed procedures for medical devices that present unique and complex challenges for reprocessing, such as flexible endoscopes, based on manufacturer's instructions for use (MIFU).

Develop clinic-specific policies and standard operating procedures for reprocessing devices that present unique and complex challenges for reprocessing. (e.g., flexible endoscopes or other devices with small, closed-ended lumens). Policies and procedures must reflect requirements set out in CPSA's Reusable and Single-Use Medical Device Requirements and the device manufacturer's instructions for use (MIFU).

Refer to of Part D of the CPSA Reusable and Single-Use Medical Device Requirements for measures on reprocessing flexible endoscopes.

11.2.5. The required occupational health and safety activities, including use of appropriate personal protective equipment (PPE) when performing MDR and when using single-use medical devices.

- □ Facial protection (eye protection with mask or full face shield)
- □ Disposable, moisture impervious gown
- □ Tear and chemical resistant gloves
- □ Cleaning and disinfection of reusable PPE

Develop clinic-specific policies and procedures that speak to the use of appropriate PPE while reprocessing.

Policy and procedures should speak to supply purchase and replenishment, and proper donning and doffing of:

- facial protection (eye protection with mask or full face shield)
- disposable, moisture impervious gowns
- tear and chemical resistant gloves
- cleaning and disinfection of reusable PPE (if applicable)

See MDR Tools & Templates (www.cpsa.ca/mdr)

11.3. The clinic shall have a written policy regarding single-use medical devices that is consistent with Part A of these requirements.

Develop a written policy regarding single-use medical devices, even where single-use medical devices are not used.

Refer to Part A of CPSA's Reusable and Single-Use Medical Device Requirements.

See MDR Tools & Templates (www.cpsa.ca/mdr)

11.4. The clinic shall conduct a regularly scheduled review of all written policies and procedures.

Clinics must designate a time for regular review of clinic policies and procedures. This is typically done annually, or more often if new information becomes available.

See MDR Tools & Templates (www.cpsa.ca/mdr)

Documentation

11.5. The clinic shall retain records of reprocessing according to the clinic's policy and applicable legislation. These records shall include, but not be limited to, the following:

11.5.1. Preventative maintenance of reusable medical devices and equipment.

Document and retain records of preventative maintenance performed on reusable medical devices and equipment. Track and document all upgrades and repairs made to equipment.

CPSA recommends that clinics retain records for a minimum of five years.

See MDR Tools & Templates (www.cpsa.ca/mdr)

11.5.2. Results of installation, operational qualification and requalification, and routine testing of reprocessing equipment and products.

Document and retain records of installation, operational qualification and requalification and routine testing of reprocessing equipment and products.

CPSA recommends that clinics retain records for a minimum of five years.

See MDR Tools & Templates (www.cpsa.ca/mdr)

11.6. The MIFU for medical devices, equipment, and supplies shall be received and maintained in printed form (e.g., in binders, manuals, or monographs) or in electronic format and be readily accessible to those needing access and shall be updated as required.

Obtain and maintain current manufacturer's instructions for use (MIFU) for all medical devices, equipment and supplies. MIFU can be in printed form (e.g., in binders, manuals) or in an easily accessible electronic format. MIFU shall be readily available to those needing access.

11.7. If reprocessing of reusable medical devices is being performed by an external or internal subcontractor, the subcontractor shall comply with these Requirements.

Specify, and make it a requirement, that if reprocessing is outsourced to an external or internal subcontractor, that person/company must comply with these Requirements. The medical director of the clinic where the soiled device originate remains responsible for adherence to CPSA's Reusable and Single-Use Medical Device Requirements, even where reprocessing is outsourced.

PART D: FLEXIBLE ENDOSCOPE REPROCESSING

Note: Where appropriate, requirements in Parts A, B, and C are applicable.

12. General requirements

12.1. Endoscopes and reusable accessories that come into contact with mucous membranes shall be cleaned and receive at least high level disinfection (HLD) after each patient use.

Clean and high-level disinfect (at a minimum) all endoscopes and accessories that come into contact with mucous membranes after every patient use.

12.2. Reusable accessories (e.g., biopsy forceps, other cutting instruments) that break the mucosal barrier (enter sterile tissues or sterile body cavities) shall be cleaned and sterilized in accordance with manufacturer's instructions for use (MIFU) and Part B of these Requirements after each patient use.

Clean and sterilize all reusable accessories that enter sterile tissues or sterile body cavities or break the mucosal barrier (e.g., biopsy forceps and other cutting instruments) in accordance with manufacturer's instructions for use (MIFU) and Part B of CPSA's Reusable and Single-Use Medical Device Requirements. after every patient use.

12.3. The water bottle used to provide sterile intra procedural flush solution and its connecting tube, shall be sterilized or receive HLD at least daily.

Clean and sterilize the reusable water bottle, and its connecting tubing, where it is used to provide sterile intraprocedural flush solution. This should be completed at least daily and according to the manufacturer's instructions for use (MIFU).

Change the bottle and tubing frequently, particularly when:
- performing invasive procedures (e.g., ERCP).
- the bottle is contaminated as evidenced by turbid, discoloured fluid.

12.4. Processes for endoscope reprocessing shall be in accordance with endoscope, equipment, and supplies validated MIFU.

Develop detailed written reprocessing procedures for endoscopes that reference CPSA's Reusable and Single-Use Medical Device Requirements and the endoscope manufacturer's instructions.

See MDR Tools & Templates (www.cpsa.ca/mdr)

13. Cleaning, flushing, rinsing, and drying

13.1. Pre-cleaning of the endoscope shall be performed at the point-of-use immediately following the clinical procedure.

Pre-clean the endoscope at the point-of-use (e.g., procedure area, assessment room, bedside) immediately following the clinical procedure by:
- wiping exterior with water or detergent (as recommended by endoscope manufacturer).
- flushing or suctioning all channels with detergent (or tap water if recommended by endoscope manufacturer).

13.2. A leak test shall be performed prior to and/or during immersion of the endoscope in accordance with manufacturer's instructions for use (MIFU).

Perform a leak test on the endoscope after every use, prior to or during immersion, and before cleaning to check the integrity of the internal or external sheath of the endoscope. Consult with the endoscope manufacturer's instructions for use (MIFU) for the recommended procedure.

Perform the leak test before adding detergent to water. Check the MIFU to see if placement of a water-resistant cap is necessary to prevent liquid from damaging the internal components of some models of endoscopes. Remove the endoscope from the water (and from future use) if a leak is detected and contact the manufacturer for further advice on repair or replacement.

13.3. Meticulous cleaning shall be performed prior to high level disinfection (HLD) or sterilization.

Meticulously clean endoscopes prior to high-level disinfection or sterilization. Disinfection or sterilization cannot be adequately achieved on endoscopes that are not clean and completely free of soil.

13.4. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be immersed in detergent or enzymatic cleaning solution unless otherwise specified in MIFU. Non-immersible components shall be cleaned in accordance with MIFU.

Disconnect or disassemble all accessories and completely immerse in cleaning solution during cleaning. Consult with the endoscope manufacturer's instructions (user's manual) to determine which components are detachable. If the manufacturer states the endoscope is not entirely immersible, clean all non-immersible components with cleaning solution and low- or intermediate-level disinfect with a product recommended by the manufacturer. Fully immerse the immersible components in the cleaning solution during cleaning.

13.5. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be soaked in detergent or enzymatic cleaning solution in accordance with MIFU to ensure proper contact time.

Completely immerse and soak the endoscope and accessories in a freshly-made solution of water and detergent or enzymatic cleaning solution that is compatible with the flexible endoscope.

Follow the detergent manufacturer's instructions for use (MIFU) regarding correct in-use dilution, exposure time, and water temperature. Use detergents or enzymatic cleaners according to the manufacturer's instructions (label directions) when preparing solutions. Use devices (e.g., measuring cups) and methods (e.g., marking a permanent line in the decontamination basin) to ensure consistently accurate concentrations. Do not pre-mix solutions for which there is no available data on subsequent stability. Use detergents or enzymatic cleaners that are low-sudsing so that the flexible endoscope can be clearly seen during the cleaning process to prevent injury to personnel and to allow for good fluid contact with surfaces and lumens of the endoscope.

13.6. Accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be disconnected and disassembled as far as possible and completely immersed in detergent or enzymatic cleaning solutions.

Disassemble the endoscope as specified in the manufacturer's cleaning instructions. Remove and clean valves, caps, inlet seals, suction buttons, air/water buttons according to the manufacturer's instructions for use (MIFU). Remove all debris from the exterior of the endoscope by brushing and wiping the instrument while it is completely immersed in the detergent or enzymatic cleaning solution.

13.7. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be completely immersed during the entire cleaning process to prevent splashing or aerosolization unless otherwise specified in MIFU.

Completely immerse the endoscope, and accessory valves, caps, inlet seals, suction buttons, air/water buttons, etc., throughout the cleaning process to prevent splashing or aerosolizing contaminants and to minimize air bubbles, unless otherwise specified in manufacturer's instructions for use (MIFU).

13.8. The bending section shall be kept straight so brushing does not damage the endoscope.

Keeping the bending section of the endoscope straight during manual cleaning (brushing) will help to prevent damage.

13.9. The exterior of the endoscope shall be cleaned with a soft brush or lint-free or low-lint soft absorbent towel.

Clean the exterior of the endoscope with a soft brush or lint-free or low-lint cloth until all visible debris is removed.

13.10. Brushing and flushing channels (e.g., brush biopsy/suction channel in the insertion channel) until returns are clear (all visible debris removed), including brushing and flushing endoscopes with an elevator in both the up and down positions shall be done. The brush shall be cleaned in detergent or enzymatic cleaning solution each time it is passed through the channel.

Brush and flush all channels and lumens of the endoscope. Repeat this process until returns are clear and according to the manufacturer's instructions for use (MIFU)—some MIFU might require suctioning of fluid in addition.

Brush and flush in both the "up" and "down" orientation.

Remove debris from the brush after each pass through the channel.

13.11. The suction valve housing and instrument channel port shall be cleaned with a channel-opening brush until all debris is removed.

Clean the suction valve housing and instrument channel port with a channel opening brush until all visible debris is removed. Consult with the endoscope manufacturer's instructions for use (MIFU) for validated brush sizes.

13.12. Brushing and flushing channels shall be done using only brushes, cloths, syringes, and other cleaning devices of a correct size, and inspected for cleanliness and good repair before use.

Use brushes, cloths, syringes, and other cleaning devices for cleaning lumens that are of a correct size.

Inspect to check that cleaning devices are clean and in good repair before each use. Discard single-use cleaning devices after each use. Clean, high-level disinfect or sterilize, dry and inspect reusable cleaning accessories. Discard any damaged reusable accessories.

13.13. A 30 mL syringe shall be attached to the adapter and detergent or enzymatic cleaning solution injected into all channels at least three times, or an approved automated system provides equivalent cleaning.

Attach a 30 ml syringe to the adapter and inject detergent or enzymatic solution into all channels of the endoscope at least three separate times. Alternatively, use a validated, automated system that provides equivalent cleaning.

13.14. Detergent or enzymatic cleaning solutions shall be discarded after each use.

Discard detergent or enzymatic cleaning solutions following cleaning of each endoscope. Do not reuse cleaning solution for multiple endoscopes.

13.15. The endoscope, channels, and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be thoroughly rinsed by immersing in tap water and brushing/flushing to remove all traces of detergent or enzymatic cleaning solution and debris.

Immerse and thoroughly rinse the endoscope, channels and accessories with clean, fresh tap water. Brush and flush to remove all traces of debris and detergent or enzymatic cleaning solution according to the manufacturer’s instructions for use (MIFU).

13.16. Final rinses prior to disinfection shall be performed in clear tap water followed by air purges using 30 mL syringes, or an approved automated system provides equivalent rinsing and drying.

Immerse the entire endoscope and accessories in clean tap water for final rinsing. Flush lumens with clear tap water and follow by air purges using 30 ml syringes, or an approved automated system that provides equivalent rinsing and drying. Ensure that the flexible endoscope is not subjected to excessive pressure.

13.17. The exterior of the endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be thoroughly dried using a clean, lint-free or low-lint soft absorbent towel.

Dry the exterior of the endoscope including all detachable components, using a clean, lint-free or low lint cloth prior to high-level disinfection or sterilization.

14. High-level disinfection (HLD), final rinsing, and drying

Manual disinfection

14.1. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be immersed in a basin of high level disinfectant unless otherwise specified in manufacturer's instructions for use (MIFU). Non-immersible components shall be intermediate or low-level disinfected in accordance with MIFU.

Immerse the endoscope and its accessories in a basin of high-level disinfectant (HLD), unless otherwise indicated in manufacturer's instructions for use (MIFU). Ensure that the basin is large enough to accommodate the entire endoscope without undue coiling and that it has a tight-fitting lid to contain chemical vapours.

Follow MIFU for disinfection of non-immersible components.

14.2. Immediately following cleaning, rinsing, and drying, the endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be completely immersed in HLD solution for the recommended time and temperature.

Completely immerse the endoscope and its accessories in high-level disinfectant (HLD) solution immediately following cleaning, rinsing and drying. Follow the disinfectant manufacturer's instructions for use (MIFU) for recommended time and temperature. Check the temperature of the HLD. Do not perform manual high-level disinfection if the manufacturer's recommended temperature cannot be maintained.

Use a timing device to monitor exposure time to HLD.

Record the time, concentration, temperature, disinfection strength and other parameters as set out in Section 5.10 of these requirements.

14.3. The HLD solution shall be flushed through all channels using a 30 mL syringe to purge air from the channels and to ensure that all channels are perfused.

Inject the high-level disinfectant (HLD) solution into all channels of the endoscope using a 30 ml syringe or dedicated and clean channel adaptors supplied by the endoscope manufacturer. Ensure all channels are filled with the HLD solution and that no air pockets remain within the channels. Ensure that the HLD remains in the channels for the contact time specified by the disinfectant manufacturer's instructions for use (MIFU).

If using channel adaptors, follow the MIFU for the channel adaptor.

14.4. Air shall be flushed through the endoscope channels using adapters (suction cleaning adapters).

Purge all endoscope channels completely with air using suction cleaning adapters before removing the endoscope from HLD. Purging channels preserves concentration and volume of HLD and prevents exposure from dripping and spilling.

14.5. The endoscope, channels, and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be immersed in fresh water.

Immerse the endoscope, its channels and accessories in fresh water.

14.6. The endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be rinsed/flushed, and all channels flushed (water volume at least 3 times the volume of the channel) using three separate rinses in water of acceptable quality unless otherwise specified by MIFU.

Perform manual rinsing using at least three separate fresh water rinses (unless otherwise specified by the high-level disinfectant (HLD) manufacturer). Flush lumens or channels with a volume of water at least three times the volume of the lumen (e.g., approximately 300 ml for a colonoscope).

Water of acceptable quality refers to sterile or bacteria-free water. Tap water is not bacteria-free.

14.7. A channel air flush, followed by 70% alcohol, and a second forced-air purge shall be performed.

Flush all channels with air followed by 70% isopropyl alcohol and a second forced air purge to facilitate drying. Follow the manufacturer's instructions for use (MIFU) for alcohol flush or flush until alcohol can be seen exiting the opposite end of each channel. Dispense alcohol aseptically from its original container and store in a manner to prevent evaporation and contamination and to ensure that the correct alcohol concentration is maintained. Use instrument-grade or filtered air for air flushes. Instrument air is dry and oilless.

14.8. The exterior of the endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be thoroughly dried using a clean, lint-free or low-lint soft absorbent towel.

Thoroughly dry the exterior of the endoscope and all valves, caps, suction buttons, air-water buttons using a clean, lint-free or low-lint soft absorbent towel.

Automated endoscope reprocessor (AER)

14.9. There shall be documentation from manufacturers confirming the AER and connectors can effectively reprocess the specific brand and model of endoscopes.

Obtain written documentation from the automated endoscope reprocessor (AER) manufacturer that confirms the AER can effectively reprocess the specific brand(s) and model(s) of endoscope used in the clinic.

14.10. High level disinfectant concentration is checked daily, at a minimum, with an appropriate chemical test strip and discarded/changed if the concentration is less than the minimum effective concentration (MEC).

Test the minimum effective concentration (MEC) of the high-level disinfectant (HLD) at least daily, or more frequently if specified in the manufacturer's instructions for use (MIFU). Do not use HLD and discard/change HLD if concentration is less than MEC.

Single-dose disinfectants do not require testing for MEC.

14.11. Immediately following manual cleaning, the dried endoscope and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be placed in the AER and loading shall be in accordance with manufacturer's instructions for use (MIFU).

Load the automated endoscope reprocessor (AER) immediately following manual cleaning so the endoscope and its accessories are positioned and channel connectors are connected in accordance with the manufacturer's instructions for use (MIFU) to ensure optimal exposure to high-level disinfectant (HLD)—e.g., complete immersion, perfusion or spray.

14.12. The AER channel attachments shall be appropriate to the endoscope being reprocessed.

Obtain written documentation that automated endoscope reprocessor (AER) channel attachments/connectors, if required, are validated for compatibility with the specific endoscope model(s) being reprocessed. Ensure attachments for specific models of endoscope are being used.

14.13. The endoscope connectors/adapters shall be attached to the AER.

Ensure connectors/adapters are clearly labelled to indicate the appropriate connection site on the AER and the endoscope.

Labels should indicate:
- endoscope manufacturer,
- model for which they are validated for use, and
- connection ports for the endoscopes and the automated endoscope reprocessor (AER).

14.14. The AER shall be run so that the endoscope is completely immersed in high level disinfectant solution for the recommended time and temperature.

Follow automated endoscope reprocessor (AER) manufacturer's instructions for use (MIFU) for loading the AER to ensure the endoscope is properly exposed to high-level disinfectant (HLD) solution for the recommended time and temperature.

14.15. The AER or an external system shall provide final rinse water of acceptable water quality.

Ensure the final rinse water provided by the AER provides a sufficient volume of sterile or bacteria-free water. Refer to HLD and endoscope MIFU to determine recommended volumes.

14.16. The endoscope shall be removed promptly after the final cycle has been completed.

Remove the endoscope from the automated endoscope reprocessor (AER) as soon as possible following completion of the final cycle.

Do not allow endoscopes to remain in the AER for prolonged periods (e.g., overnight). If not removed from the AER within 1hour of cycle completion, microbial contamination or chemical damage might occur.

14.17. A channel air flush, followed by 70% alcohol, and a second forced-air purge shall be performed.

Flush all channels with air, followed by 70% isopropyl alcohol, and a second forced air purge to facilitate drying. Follow the manufacturer's instructions for use (MIFU) for alcohol flush or flush until alcohol can be seen exiting the opposite end of each channel. Dispense alcohol aseptically from its original container and store in a manner to prevent evaporation and contamination and to ensure that the correct alcohol concentration is maintained. Use instrument-grade or filtered air for air flushes. Instrument air is dry and oilless.

14.18. Endoscopes and accessories (e.g., valves, caps, inlet seals, suction buttons, air/water buttons) shall be thoroughly dried before being stored.

Thoroughly dry reprocessed endoscopes and channel valves prior to storage.

15. Storage

15.1. Endoscopes shall be stored in a well-ventilated, protected, clean area to facilitate drying, with channeled endoscopes hung in a vertical position.

Store channeled endoscopes vertically in a dedicated closed, ventilated space (e.g., cabinet) with a sealable door. Storage should occur outside of the decontamination area, procedure room, hallway, or high-traffic area to minimize environmental contamination. Do not store endoscopes in a wooden cabinet.

15.2. Endoscopes shall be stored in a manner that protects them from contamination (e.g., do not touch the floor of the cabinet).

Ensure endoscopes do not touch the bottom of the storage cabinet. Storage should occur outside of the decontamination area, procedure room, hallway, or high-traffic area to minimize environmental contamination. Do not store endoscopes in a wooden cabinet.

15.3. Caps, valves, and other detachable components shall be removed during storage and reassembled before use.

Remove caps, valves and other detachable components from the endoscope prior to storage.

Do not store endoscopes with channel valves or a water-resistant cap in place. Store caps, valves and other detachable components near the endoscope in a manner that minimizes contamination. Drying of the endoscope is facilitated with the valves removed, and microbial growth is inhibited.

15.4. Endoscopes shall not be coiled or stored in their cases.

Do not store endoscopes coiled in their transport cases as these cases contain materials that cannot be effectively cleaned.

15.5. Endoscope storage cabinets shall be cleaned and disinfected at least weekly.

Clean and disinfect endoscope storage cabinets at least weekly. Clean and low- or intermediate-level disinfect endoscope storage cabinets using a hospital-grade disinfectant with Health Canada issued drug identification number (DIN) and achievable contact time. Remove endoscopes and accessories before cleaning cabinets. Document when endoscope storage cabinets have been cleaned.

15.6. Channeled endoscopes shall be reprocessed if in storage for more than 7 days.

Develop a process to identify the date of reprocessing for each endoscope. Fully reprocess flexible channeled endoscope that have been in storage for more than seven days.

16. Documentation

16.1. There shall be a permanent record of endoscope use and reprocessing.

Establish and retain a permanent record of endoscope use, maintenance and reprocessing.

See MDR Tools & Templates (www.cpsa.ca/mdr)

16.2. There shall be a system to track endoscopes and patients that includes recording the endoscope number in the patient record.

Implement a system to track endoscopes and patients. Record the endoscope identifier (e.g., serial number) in the permanent patient record.

See MDR Tools & Templates (www.cpsa.ca/mdr)

16.3. For each procedure, the patient's name and record number, the date and time of procedure, type of procedure, endoscopist, and serial number or other identifier of both the endoscope and the automated endoscope repressor (if used) shall be documented.

Document for each procedure:

- the patient's name,
- identification number,
- date,
- time,
- type of procedure,
- endoscopist, and
- serial number or other identifier of both the endoscope and the automated endoscope reprocessor (AER), if used.

See MDR Tools & Templates (www.cpsa.ca/mdr)

PART E: REFERENCES

1. Alberta Health, Government of Alberta. 2019. Reusable & Single-Use Medical Devices Standards: Standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings.

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

4. Public Health Agency of Canada/ 2011. Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy