cpsa
COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Developing policies & procedures to support safe & effective medical device reprocessing in medical clinics

IPAC guidance

Infection Prevention & Control (IPAC) Program
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Background

To ensure that medical clinics provide consistent, high-quality outcomes, policies and procedures must be in place to align with the College of Physicians & Surgeons of Alberta (CPSA)'s Reusable & Single-Use Medical Device Requirements for Medical Clinics.

Policies describe the clinic's commitments and must align with regulatory requirements that set the overall goals for safe medical device reprocessing (MDR).

Procedures turn policy commitments into clear, step-by-step actions that guide staff in their daily work.

Strong policies and detailed procedures help ensure that staff understand what must be done, why it matters and how to do it correctly. This promotes consistent practice, supports staff competency, ensures regulatory compliance and protects patient safety.

Policies and procedures must be:

- Clinic-specific
- Dated with original development date and revision date
- Accessible to staff
- Reviewed for accuracy annually and when there has been a change in practice, product or equipment

Purpose

This guidance document outlines the minimum policies and procedures that must be in place at medical clinics to support safe and effective reprocessing of reusable medical devices.

This guidance document is intended to assist physicians and medical clinic staff in understanding:

- **Section 1.0:** Minimum policies required to perform MDR
- **Section 2.0:** Minimum procedures required to perform MDR
- **Section 3.0:** Procedures required for high-level disinfection for flexible endoscopes
- **Section 4.0**: Documentation
- **Section 5.0**: Storage

Each clinic must adapt the information in this document to fit its operations and ensure alignment with manufacturers' instructions for use (MIFUs) and applicable MDR requirements.

For assistance or more information, contact CPSA's IPAC program at ipac@cpsa.ab.ca or 780-969-5004.

1.0. Minimum policies required to perform medical device reprocessing (MDR)

- ☐ **Develop a policy for single-use medical devices** that is consistent with the verbiage described in *Part A: Single-Use Medical Devices* of the Reusable & Single-Use Medical Device Requirements for Medical Clinics. Single-use medical devices include, but are not limited to:
  - Syringes
  - Needles
  - Gauze
  - Disposable instrumentation
- ☐ **Develop a policy for retention of MDR records.** CPSA recommends a minimum retention period of 5 years. Records that must be retained include, but are not limited to:
  - Preventative maintenance of reusable medical devices and equipment
  - Installation, operational qualification and requalification of steam sterilizers
  - Sterilizer load records
  - Manufacturer's instructions for use (MIFU) for medical devices and equipment
  - High-level disinfection logs
- ☐ **Develop a policy for the education and training of staff** who perform medical device reprocessing. This should include, but is not limited to:
  - What training is required
  - Who will provide the training
  - What education is required
  - Frequency of training and education, e.g., after hire, annually, when there has been a change in products and equipment
  - Frequency of competency assessment, e.g., after hire, at least annually, when there has been a change in products and equipment
  - Who will conduct the competency assessment
  - How records of training and education will be retained
- ☐ **Develop a policy to track required occupational health and safety activities**, including the use of appropriate personal protective equipment (PPE) when performing MDR.

2.0. Minimum procedures required to perform medical device reprocessing (MDR)

2.1 Occupational health and safety

- ☐ **Describe how to don and doff PPE.** This may include an image for quick reference.
- ☐ **Describe how to perform hand hygiene** (soap and water, alcohol-based hand rub). This may include an image for quick reference.

2.2 Point-of-use cleaning and transport

- ☐ **Describe how to perform point-of-use cleaning** immediately after a medical device is used and prior to transport. This may include techniques such as wiping the device off with a disposable cloth or gauze moistened with water.
- ☐ **Describe where to place soiled devices for the purpose of transport after point-of-use cleaning, and what type of transport containers must be used.** Include the frequency of transport to the medical device reprocessing area or off-site location.

2.3 Sorting, disassembly, cleaning and rinsing

- ☐ **Describe how to sort medical devices** in a way that minimizes damage to instruments.
- ☐ **Describe which devices need to be disassembled for cleaning** and how to disassemble these devices.
- ☐ **Describe how to prepare cleaning solutions**, e.g., what solutions to use and the volume of solution to water. Define the recommended time for soaking a medical device in a solution prior to cleaning.
- ☐ **Describe how to brush soiled instruments to minimize aerosolization.** This should include brush selection, requirements for brushes, how to brush the reusable medical devices, how to reprocess reusable brushes and how to inspect brushes.
- ☐ **Describe where to rinse devices**, such as a dedicated sink or bin, and what kind of water to use, e.g., potable, reverse osmosis and how to perform rinsing.

Note: If using methods of automated cleaning, e.g., washer disinfector or ultrasonic cleaner, describe how to test the units, the requirements to document

the tests, how to perform routine and preventative maintenance of the units and when or how to use the units, including what solutions to use.

2.4 Inspection and drying

- ☐ **Describe when and how to inspect medical devices.**
- ☐ Describe what steps to take in the event that a device is found to have damage or residual soil.
- ☐ **Describe how to dry a medical device,** including which products to use when drying.

2.5 Packaging

- ☐ **Describe how to select the appropriate packaging material,** e.g., pouches, reels, wrappers.
- ☐ **Describe how to protect sharp instruments from damage when packaged**, and how to prevent perforations of the packaging material. Include which products to use for instrument protection, e.g., tip protectors.
- ☐ **Describe how to orient devices** in the packaging material to allow for aseptic presentation.
- ☐ **Describe how to package and seal packaging materials**.
- ☐ **Describe what chemical indicators to use** in packages and their placement within a package.

2.6 Labelling

- ☐ **Describe what product or products to use when labelling** a packaged medical device.
- ☐ **Describe what is required to be labelled** on a packaged medical device.

2.7 Testing of a steam sterilizer

- ☐ **Describe when to perform routine testing of a steam sterilizer,** e.g., biological indicator testing, chemical indicator testing, dynamic air removal test, leak test.
- ☐ **Describe when and how to perform** installation qualification (IQ), operational qualification (OQ) and requalification testing of a steam sterilizer.
- ☐ **Describe which cycles must be routinely tested.**
- ☐ **Describe how to appropriately construct a routine test,** e.g., pouched or wrapped biological indicator process challenge pack.
- ☐ **Describe where to place the tests** within the steam sterilizer.

- ☐ **Describe how to perform the test,** including how to interpret and document the results of a test.
- ☐ **Describe what to do in the event of a test failure,** e.g., a failed biological indicator test or a failed chemical indicator test**.**

2.8 Sterilizer loading, operation and documentation

- ☐ **Describe how to load a steam sterilizer**, e.g., orientation of packages.
- ☐ **Describe cycle selection and parameters,** e.g., time and temperature based on the devices and packaging materials used.
- ☐ **Describe what to do in the event that a sterilizer cycle fails.**
- ☐ **Describe what to document for steam sterilization cycles.**

2.9 Sterilizer unloading and inspection

- ☐ **Describe how and when to unload a steam sterilizer**.
- ☐ **Describe what to look for when inspecting sterilized packages,** e.g, moisture.
- ☐ **Describe the steps to take** if packages have not met the inspection criteria.

2.10 Storage

- ☐ **Describe where to store sterilized packages.**
- ☐ **Describe how to orient the sterilized packages** to ensure package integrity does not become compromised.

2.11 Routine and preventative maintenance

- ☐ **Describe the routine and preventative maintenance required** for the steam sterilizer.
- ☐ **Describe who is responsible** for performing routine and preventative maintenance.
- ☐ **Describe the frequency** of routine and preventative maintenance.
- ☐ **Describe how to perform** routine and preventative maintenance.
- ☐ **Describe how to document evidence of routine and preventative maintenance.**

3.0. Procedures required for high-level disinfection of flexible endoscopes

3.1 General procedures

- ☐ **Sections 2.1, 2.2, 2.3 and 2.4** are applicable for high-level disinfection of flexible endoscopes.

3.2 Leak testing, manual cleaning and rinsing

- ☐ **Describe how to perform leak testing** if required by the device MIFU.
- ☐ **Describe the specifics of brushing and flushing** the flexible endoscopes and accessories.
- ☐ **Describe the specifics of rinsing and flushing** the flexible endoscopes and accessories.

Note: If automated methods of flushing, e.g., automated endoscope flushing aid, describe how to test and use the unit as per the device MIFU.

3.3 High-level disinfectant selection and testing

- ☐ **Describe the high-level disinfectant product** to be used.
- ☐ **Describe how to perform the minimum effective concentration (MEC)** of reusable high-level disinfectants and how to document the results.
- ☐ **Describe when and how to perform quality assurance tests** of the test strips used for the MEC.
- ☐ **Describe what to do in the event of a failed MEC.**

3.4 3.4 Manual high-level disinfecting

- ☐ **Describe how to submerge the flexible endoscopes** in the high-level disinfectant.
- ☐ **Describe the minimum contact time and temperature of** the high-level disinfectant that must be achieved.
- ☐ **Describe how to monitor the minimum contact time and temperature** of the high-level disinfectant.

Note: If using an automated high-level disinfection system, describe how to use the system as per the system's MIFU.

3.5 Rinsing, drying and inspection

- ☐ **Describe what type of water is used** for rinsing the flexible endoscope.
- ☐ **Describe where and how to rinse** the flexible endoscope.
- ☐ **Describe how to dry** the flexible endoscope and what product to use.
- ☐ **Describe what to inspect** for on the flexible endoscope.
- ☐ **Describe what to do in the event of inspection** of the flexible endoscope failing, e.g., damage or residual soil.

4.0. Documentation

- ☐ **Describe what must be documented when performing high-level disinfection of flexible endoscopes.**

5.0. Storage

- ☐ **Describe where to store high-level disinfected endoscopes.**
- ☐ **Describe how to orient the flexible endoscopes in the storage location.**
- ☐ **Describe how long flexible endoscopes can be stored** before they must be reprocessed.
- ☐ **Describe the frequency with which the storage location of the flexible endoscopes must be cleaned** and how to document the cleaning frequency.

References and resources

1. College of Physicians and Surgeons of Alberta 2022 Medical-Device-Requirements-for-Medical-Clinics.pdf
2. College of Physicians and Surgeons of Alberta 2020 IPAC-Requirements-for-Medical-Clinics.pdf