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COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Offsite Reprocessing of Medical Devices

IPAC Program Guidance

Infection Prevention and Control (IPAC) Program

Last updated January 2024

Introduction

Adherence to requirements for medical device reprocessing can be challenging for some community medical clinics. CPSA has also heard that physicians may be unable to rely solely on single-use, disposable medical devices. Clinics may contemplate sending their contaminated reusable medical devices to another location to be cleaned and sterilized. This is known as "offsite reprocessing."

Offsite reprocessing is permissible. However, physicians at the originating clinic remain responsible for ensuring that their devices are handled, reprocessed and transported in accordance with CPSA requirements.

Purpose

This guidance is intended to assist physicians and medical clinic staff in understanding general obligations related to offsite reprocessing. This document should be considered a supplement to CPSA's Reusable & Single-Use Medical Device Requirements for Medical Clinics (January 2022) and may be used in conjunction with the Offsite Reprocessing Self-Assessment Tool.

For assistance or more information, please contact the CPSA IPAC Program at ipac@cpsa.ab.ca or 780-969-5004.

Glossary of Terms

Originating clinic: The clinic where the reusable devices are used on patients. In this context, the originating clinic sends their contaminated devices to another "offsite" location to be reprocessed. Once reprocessed, the originating clinic receives their reprocessed devices back from the offsite location.

Offsite location: The location that receives contaminated devices from the originating clinic for the purpose of reprocessing them and returning them to the originating clinic where they will be used. Offsite locations are typically other medical clinics or community hospital settings.

Offsite reprocessing: Sometimes referred to as "third-party reprocessing." This term refers to a partnership between two locations where contaminated devices are transported from one location to another so that cleaning and disinfection, or sterilization, of reusable devices can occur. Once reprocessing is complete, the devices are safely transported back to the originating clinic.

General Considerations

Medical clinics are expected to notify CPSA's Infection Prevention and Control (IPAC) program before engaging with another location to perform offsite reprocessing. It is essential that CPSA is aware of responsibilities and processes at both locations.

CPSA does not maintain a publicly-available list of offsite locations or businesses that perform offsite reprocessing. Physicians and clinic staff would take the lead in identifying potential offsite reprocessing locations.

Locations that typically partner with medical clinics to perform offsite reprocessing are:

- Medical Device Reprocessing and Central Sterile Reprocessing departments in AHS or AHS-contracted facilities (e.g., hospitals).
- Community medical clinics recently assessed by CPSA's IPAC Program.
- Medical Device Reprocessing areas within CPSA-accredited non-hospital surgical facilities.

A facility operated by another healthcare professional (e.g., dental clinic, podiatrist) may be considered suitable for offsite reprocessing. Offsite reprocessing at a location associated with animal care (e.g., veterinary settings) is not acceptable.

Administrative Requirements

CPSA will verify that both locations have an agreement in place for offsite reprocessing. Roles and responsibilities of staff at each location will be confirmed. All reprocessing steps set out in CPSA requirements must be accounted for between the two clinics.

Reusable medical devices must be stored, handled, reprocessed and transported in accordance with their manufacturer's instructions for use (MIFU). Both locations are expected to have a copy of MIFU for all devices being reprocessed.

Clinic staff at both locations must be appropriately trained and educated in the applicable steps of reprocessing and on specific details relating to the offsite reprocessing agreement between the two locations.

Written, clinic-specific policies and procedures covering the steps of reprocessing relevant to each location must be available. A written recall process must be in place between the two locations that addresses any failure of chemical and/or biological monitoring.

It is the responsibility of the physician at the originating clinic to ensure that processes are compliant at the originating and offsite locations. CPSA's Reusable and Single-Use Medical Device Requirements still apply to the originating clinic.

Responsibilities of the Originating Clinic

Even though most reprocessing activities do not occur at the originating clinic, staff still have an important role to play in handling the devices safely. The originating clinic will prepare and transport the contaminated devices and receive and store the reprocessed devices.

1. Preparing contaminated devices for transport

Sharps management

Sharps must always be discarded by staff at the originating clinic at the point-of-use in an appropriate sharps container. Used or contaminated sharps must never be transported between locations.

Pre-cleaning ("wiping") of devices at the point-of-use

Gross soil is to be removed at the point-of-use by staff at the originating clinic. This is typically done by wiping the used device with moistened, disposable gauze or a similar product.

Preventing soil from hardening

Soil and organic matter cannot be allowed to harden on the pre-cleaned devices. Devices are to be placed into a container and sprayed with an instrument gel, spray or foam. Moist towels may also be used for this step. Chemical products must always be used in accordance with their labelled instructions.

2. Transport of contaminated devices

Containers

Devices must be transported in a secure, rigid, cleanable and leakproof container.

Containers must be clearly labelled and designated specifically for the transport of contaminated devices (e.g., "contaminated devices only"). There must be no chance that the transport container opens accidentally during transport or that the contents within could be misinterpreted as clean or ready-to-use.

Containers must be cleaned and disinfected after each use. This is typically done by the offsite location.

Cleaning of devices

CPSA expects that cleaning (e.g., brushing immersed devices in a sink) occurs at the offsite location. Staff at both locations are to agree on who will be responsible for cleaning, rinsing and drying the soiled devices. There can be no doubt about which location is responsible for this critical step.

3. **Receipt of reprocessed devices**
   Sterilized devices will arrive back to the originating clinic via dedicated transport containers (i.e., labelled as "sterilized devices only"). Devices within transport containers will be wrapped or in peel pouches to preserve sterility.

   a. **Visual inspection**
      Each individual wrap or package is to be visually inspected to confirm that:
      - the entire expected inventory has arrived.
      - external and internal (where appropriate) chemical indicator results are verified and documented.
      - where peel pouches are used, devices within do not show signs of inadequate cleaning.
      - package integrity is intact (e.g., no perforations, broken seals or evidence of moisture contamination).

      Devices that show signs of inappropriate reprocessing or handling must not be used. They must be set aside for further reprocessing.

   b. **Storage**
      Sterilized devices must not be stored in their transport containers. Devices that pass visual inspection should be moved to a storage area that is protected from dust, moisture, vermin, temperature extremes and excessive humidity.

Responsibilities of the Offsite Location

Prior to agreeing to undertake reprocessing on behalf of the originating clinic, the offsite location must obtain, review and be capable of adhering to reprocessing instructions set out in the MIFU for the devices. Offsite reprocessing locations will be engaged by CPSA and must be deemed to be in compliance with CPSA requirements.

The offsite location is responsible for receiving, reprocessing, documentation and returning the devices.

1. **Receiving of the contaminated devices**
   Staff at the offsite location will receive the contaminated devices in a transport container. An inventory of devices will occur upon their arrival. The offsite location will then commence with the cleaning processes.

   The offsite location is then responsible for cleaning and disinfecting the interior and exterior of containers used to transport soiled devices.

2. **Reprocessing**

   The offsite location will clean, rinse, dry and disinfect, or sterilize, the devices and prepare them for safe transport back to the originating clinic.

3. **Documentation**

   Parameters of sterilization (e.g., sterilization time, temperature, biological indicator results) must be monitored, recorded and kept at the offsite location. Sterilization tracking information from the offsite location will be required by CPSA during assessments of the originating clinic. Load numbers from packages stored at the originating clinic will be reconciled against this tracking information.

   It is strongly suggested that the originating clinic be provided a copy of all pertinent reprocessing documentation. CPSA also recommends that the offsite location maintain a separate sterilization tracking record for each clinic they engage with.

4. **Transport**

   Reprocessed and packaged devices are to be secured in a dedicated and labelled transport container (e.g., "sterilized devices only"). The container used to transport reprocessed devices back to the originating clinic cannot be the same container used to transport contaminated items.

   Devices must be arranged and secured in a manner that preserves the integrity of the packaging and the sterile devices within. Devices cannot move around the container while in transport and are to be protected from damage that could arise from sudden stops, turns or collisions.

Transport Vehicles

Transportation may be conducted by staff of the originating clinic or the offsite location. Responsibility for this role must be clearly defined. Transport vehicles are to be routinely cleaned and in sound operating function. Drivers must be licensed and proficient.

Confidence in the sterility of reprocessed devices must be maintained throughout transportation back to the originating clinic. Containers and devices should remain under the supervision of the driver while in transport between locations.

To avoid compromising the activity of chemicals or the integrity of sterile packaging, transportation of devices must be done in a manner that prevents significant fluctuations in temperature or humidity.