

## TITLE

**MANAGEMENT OF LOANED, REUSABLE CRITICAL AND SEMI-CRITICAL MEDICAL DEVICES**

## SCOPE

Provincial

## DOCUMENT #

PS-91

## APPROVAL AUTHORITY

Vice President, Cancer Care Alberta & Clinical Support  
Services

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## SPONSOR

Infection Prevention and Control

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Not applicable

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May 9, 2025

**NOTE:** The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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**OBJECTIVES**

- To set out the process, timelines, and requirements for management of all **loaned, reusable critical** and **semi-critical medical devices** intended for use on a **patient**.

**PRINCIPLES**

Alberta Health Services (AHS) is committed to ensuring that all loaned, reusable, critical and semi-critical medical devices intended for use on a patient are received by the Medical Device Reprocessing Department (MDRD) in a timely manner to meet reprocessing and sterilization standards.

**Medical devices** must not be borrowed/leased/assessed/received by AHS, or obtained by any other arrangement for use on a patient unless the devices can be cleaned and reprocessed according to AHS standards and capabilities.

Medical devices used on animals or cadavers must not be accepted for use on a patient.

Medical devices intended for use on a patient must not be loaned from AHS facilities for use upon animals or cadavers.

**APPLICABILITY**

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

## ELEMENTS

### 1. Requests for Loaned Medical Devices

- 1.1 Internal transfers of non-vendor medical devices must follow AHS provincial or site-specific, approved internal resources or processes (e.g., Standard Operating Procedures) to transfer, log, and track medical devices.
- 1.2 The following applies to vendor-supplied loaned, reusable medical devices.
- a) All requests for loaned, leased, or consigned medical devices must be initiated through the **Manager** or designate:
    - (i) in sufficient time to allow for delivery to the site within required timeframes; and
    - (ii) through a purchase requisition which creates a purchase order number, required for medical device tracking.
- 1.3 MDRDs must receive loaned, reusable medical devices within designated time frames in advance of use to ensure all required processes can be safely completed.
- a) Loaned, reusable medical devices that have been previously reprocessed at the site must be received by MDRD or designate a minimum of two (2) business days (48 hours) before use.
  - b) Loaned, reusable medical devices that have never been reprocessed at the site and/or for devices requiring a new cycle not usually used or programmed into the sterilizer, must be received by MDRD or designate a minimum of three (3) business days (72 hours) before use.
  - c) Loaned, reusable medical devices that are not received by MDRD or designate within the stated times to allow for required inventory, inspection and the reprocessing must not be accepted and the operating room must be notified.
  - d) Loaned, reusable medical devices received outside of the appropriate timeframe are considered a reportable hazard as outlined in Section 2 below.
- 1.4 The MDRD or designate must verify that the site follow required processes for inventory, inspection, and reprocessing before use of the loaned, leased, or consigned device(s), that include but are not limited to:
- a) confirming and following the manufacturer's instructions for use (MIFU) for reprocessing;
  - b) ensuring sufficient resources are available on site;

- c) completing **performance qualification**, if required; and
  - d) completing inspection, disassembly, cleaning, assembly, and sterilization/disinfection according to AHS requirements, Alberta Health requirements, and CSA standards.
- 1.5 The Manager or designate of the requesting department must ensure that the vendor/supplier provides the following information in writing each time the medical device(s) are delivered to the site:
- a) an accurate and itemized list of instruments or instrument set contents;
  - b) detailed pictures or diagrams of devices, instrument sets, and complex instruments;
  - c) the manufacturer's validated instructions for:
    - (i) disassembly (as necessary);
    - (ii) decontamination (cleaning and disinfection);
    - (iii) appropriate packaging;
    - (iv) the method and parameters of sterilization; and
    - (v) any additional special considerations for use and care of the device(s) (e.g., functionality testing).
  - d) education for MDRD as needed on the use, cleaning, and the correct reprocessing and sterilization of the medical devices.
- 1.6 MDRD must confirm manufacturers/vendors:
- a) are in compliance with *CAN/CSA Z314-18 Canadian medical device reprocessing* that state loaner medical devices have not been used on animals or cadavers;
  - b) have a system to track the medical devices;
  - c) have a Medical Device Active License, Special Access Program, or Investigational Testing Authorization number(s) for the loaned, leased, or consigned devices; and
  - d) weigh each loaned, leased, or consigned item (e.g., instrument tray and the appropriate container), and weight must not exceed 10 kilograms, in accordance with CSA standards.
- 1.7 AHS Clinical Engineering must review electrical components of loaned, reusable medical devices to inspect, document, and test, where applicable, the medical devices for compliance with relevant industry and hospital standards.

- 1.8 The Manager or designate, of the requesting department must ensure that after the procedure the loaned device is sent to the reprocessing and sterilization staff or departments for decontamination and reassembly.
- 1.9 Loaned reusable medical devices must be cleaned and either fully reprocessed or decontaminated, per AHS process, before returning it to the vendor/supplier.
- 1.10 AHS must not have responsibility for loaned, reusable medical devices reported as damaged or missing see Appendix A: *Standard Language Excerpted from Contracts*.

## 2. Documentation

- 2.1 Receivers and senders of loaned, reusable medical devices must maintain records for the purpose of traceability (e.g., manufacturer's serial number, date and time, and patient's identification number that can be used to link a patient with a device).
  - a) Documentation must include, but is not limited to, reprocessing details, device specific education, shipping records, damage during use, and appropriate replacement, and inventory records.
- 2.2 **Clinical adverse events, close calls, or hazards** should be reported according to the AHS *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events* Policy Suite, which includes but is not limited to:
  - a) the Reporting Learning System for Patient Safety with a copy to the **Accountable Leader** (e.g., Executive Director Surgery); and
  - b) completion of a Medical Device Incident or Problem (MDIP) report as per the AHS *Medical Device Safety* Policy Suite.
- 2.3 If the MDRD does not receive the medical devices at least two (2) business days (minimum 48 hours) before use, it is considered a clinical adverse event. Follow the process as outlined in Section 2.2 above.

## DEFINITIONS

**Accountable Leader** means the individual who has ultimate accountability to ensure consideration and completion of the listed steps in the *Management of Loaned, Reusable Critical and Semi-Critical Medical Devices* Policy. Responsibility for some or all of the components of management may be delegated to the appropriate level responsible administrative leader, but accountability remains at the senior level.

**Clinical adverse event** means an event that reasonably could or does result in an unintended injury or complications arising from health care management, with outcomes that may range from (but are not limited to) death or disability to dissatisfaction with health care management, or require a change in patient care.

**Close call** means an incident that has potential for harm and is intercepted or corrected prior to reaching the patient.

**Critical medical device** means a medical device that enters sterile tissues/vascular system, or enters normally sterile cavities and therefore presents a high risk of infection if the medical device is contaminated with any organisms, including bacterial spores.

**Hazard** means a situation that has potential for harm and does not involve a patient.

**Loaned, reusable medical devices** means a critical and semi-critical medical device that is used by a health care facility under an arrangement based on lending, lease, consignment, or trial use of new medical devices.

Note 1: Organizations that include more than one (1) health care facility and that follow common policies and procedures would not be considered to be loaning devices.

Note 2: Vendor-owned devices that are remaining within a facility for extended periods should be treated in the same manner as owned devices.

**Manager** means the individual(s) who has the delegated human resource authority for directly planning, monitoring, and supervising direct (employee) reports.

**Medical device** means any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for a human being for any of the following purposes:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiologic process;
- control of conception; and that does not achieve its principal intended purpose in or on the human body by pharmacological, immunological, or metabolic means, but that can be assisted in its function by such means.

**Patient** means an adult or child who receives or has requested health care or services from Alberta Health Services and its health care providers or individuals authorized to act on behalf of Alberta Health Services. This term is inclusive of residents, clients and outpatients.

**Performance qualification** means the process of obtaining and documenting evidence that the equipment, as installed and operated according to operational procedures, consistently performs according to predetermined criteria and thereby yields product meeting its specification.

**Reusable** means, through the selection of materials and/or components, designed by the manufacturer to be used again.

**Semi-critical medical device(s)** means a medical device that comes into contact with mucous membranes or non-intact skin, but does not penetrate them.

## REFERENCES

- Appendix A: *Standard Language Excerpted from Contracts*
- Alberta Health Services Governance Documents:
  - *Medical Device Safety Policy (#PS-103)*
  - *Medical Device Incident or Problem Reporting Procedure (#PS-103-03)*
  - *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy (#PS-95)*
- Alberta Health Services Forms:
  - *Medical Device Incident or Problem (MDIP) Report Form*
- Alberta Health Services Resources:
  - *Cleaning Medical Devices According to Manufacturer's Instructions Standard Operating Procedure*
  - *Pre-Process: Identification and Handling of Devices that are Difficult to Clean Standard Operating Procedure*
  - *Pre-Process: Inspection Identification and Disposal of Damaged/Defective Devices Standard Operating Procedure*
  - *Pre-Process: Transportation of Contaminated Items to Reprocessing Area Standard Operating Procedure*
  - *Reporting & Learning System for Patient Safety (RLS)*
  - *Reprocessing of Semi-Critical Reusable Medical Devices Standard Operating Procedure*
  - *Steam Sterilization Standard Operating Procedure*
- Non-Alberta Health Services Documents:
  - *CAN/CSA-Z314-18 Canadian medical device reprocessing*
  - *Infection Prevention and Control Standards (Accreditation Canada, 2019)*
  - *Reprocessing of Reusable Medical Devices (Accreditation Canada, 2019)*
  - *Reusable & Single-use Medical Devices Standards (Alberta)*

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**PS-91****APPENDIX A****Standard Language Excerpted from Contracts**

The Supplier Representative must confirm in writing to AHS that the Loaned Reusable Medical Device(s) have all been received and are complete (all required components are included in the set) within forty-eight (48) hours of receipt by the Supplier. If the Supplier does not provide such confirmation in writing within forty-eight (48) hours of receipt of the Loaned Reusable Medical Device(s), AHS must not be required to pay any charges or fees to the Supplier for Products that are missing or absent from the Loaned Reusable Medical Device(s).