Alberta Health Services

POLICY

TITLE
MANAGEMENT OF LOANED AND REUSABLE MEDICAL DEVICES

SCOPE
Provincial

DOCUMENT #
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Clinical Operations Executive Committee

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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 medical devices** intended for use with a patient.

PRINCIPLES

Alberta Health Services is committed to ensuring that all loaned, reusable medical devices intended for use on a patient are received in a timely manner so that reprocessing and sterilization standards are met.

No medical devices and/or products shall be borrowed/leased/assessed/received, for use on a patient under any other arrangement that cannot be cleaned and reprocessed according to Alberta Health Services standards and capabilities.

No medical devices shall be accepted for use on a patient which has been used upon animals or cadavers.

No medical devices intended for use on a patient shall be loaned from Alberta Health Services 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 Loaner Medical Devices

1.1 All requests for loaned, leased or consigned medical devices shall be initiated through the Manager or designate, using a purchase requisition form, which will create a purchase order number.

1.2 For internal transfer of non-vendor items, follow site-specific, approved, internal processes for transferring and logging of medical devices.

1.3 The Manager, or designate, of the requesting department shall ensure that the vendor/site provides the following information in writing each time the medical device(s) are delivered to the facility:

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) as needed, education for staff on use, cleaning, and the correct reprocessing and sterilization of the medical devices.

1.4 The vendor shall provide the medical device(s) license number(s) to Contracts, Procurement and Supply Management.

1.5 Manufacturers/vendors shall confirm they are in compliance with Canadian Standards Association (CSA) standards (*Management of Loaned, Reusable Medical Devices Z314.22-16* section 4.1.5) that state loaner medical devices have not been used on animals, cadavers.

a) The manufacturer/vendor is required to have a system to track the medical devices.

b) For **adverse events**, and for tracing of adverse events, within Alberta Health Services sites or contracted facilities, this information shall be

supplied upon request to Product Quality & Safety, Contracting, Procurement & Supply Management Department.

1.6 Alberta Health Services Clinical Engineering shall review electrical medical devices to inspect, document, and test, where applicable, the medical devices for compliance with relevant industry and hospital standards.

1.7 Reprocessing and sterilization staff or departments shall receive the medical devices at least 2 business days before use. If this is the first time receiving the loaned, reusable medical device and/or if it requires an extended cycle, the minimum timelines shall be 3 business days allowing for verification that the health care setting can:

- follow the manufacturer's instructions for use (MIFU);
- have the resources available onsite; and
- complete performance qualification, if required.

a) No medical devices shall be accepted that do not arrive in sufficient time to allow reprocessing and sterilization staff or departments to follow their procedures for inventory, inspection and reprocessing.

b) All medical devices requiring processing shall be received in time to allow proper inspection, disassembly, cleaning, assembly and sterilization/disinfection.

c) In accordance with CSA standards, the weight, including an appropriate container, of individual instruments/trays of instruments shall not exceed 10 kilograms.

1.8 The Manager, or designate, of the requesting department shall ensure that following the procedure the loaned device is sent to the reprocessing and sterilization staff or departments for decontamination and reassembly.

1.9 Loaned medical devices shall be cleaned and either fully reprocessed or decontaminated, per hospital procedure, before returning it to the owner.

1.10 In the event the supplier does not provide confirmation in writing within 48 hours of receipt that loaned reusable medical devices have been received, and all components are complete, Alberta Health Services shall have no responsibility for items reported as damaged or missing (see Appendix A *Standard Language Excerpted from Contracts*).

DEFINITIONS

Adverse event means an event that could or does result in unintended injury or complications arising from health care management, with outcomes that may range from death or disability to dissatisfaction, or require a change in care such as prolongation of hospital stay.

Medical device(s) 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; or,
- control of conception;

and that does not achieve its principal intended action (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. (Alberta Health & Wellness, 2011)

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

Loaned, reusable medical devices means, for the purpose of this policy, a critical and semi-critical medical device that is used by a health care facility under an arrangement based on lending or trial use of new medical devices.

Note 1: Organizations that include more than one 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.

REFERENCES

- Appendix A: Standard Language Excerpted from Contracts
- Non-Alberta Health Services Documents:
  - *Infection Prevention and Control Standards* (Accreditation Canada, 2015).
  - *Management of Loaned, Reusable Medical Devices Z314.22-16* (Canadian Standards Association, 2016)
  - *Reprocessing of Reusable Medical Devices* (Accreditation Canada, 2017).
  - *Standards for Cleaning, Disinfection and Sterilization of Reusable Medical Devices for all Health Care Facilities and Settings* (Alberta Health and Wellness, 2012).
  - *Effective Sterilization in Health Care Settings by the Steam Process Z314.3-14* (Canadian Standards Association, 2014

VERSION HISTORY

Date	Action Taken
August 17, 2017	Revised
Click here to enter a date	Optional: Choose an item

APPENDIX A

Standard Language Excerpted from Contracts

The Supplier Representative shall 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 shall 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).