Alberta Health and Wellness

Standards for Single-Use Medical Devices:
As Applied to Critical and Semi-Critical Medical Devices

February 18, 2011

Government of Alberta

Reader Information

The Standards for Single-Use Medical Devices have been developed with input from experts including an infectious disease physician, infection prevention and control professionals, public health professionals and the Health Quality Council of Alberta. Information from various sources has been considered including the Canadian Standards Association, Accreditation Canada, the Canadian Agency for Drug Technologies in Health (CADTH) and the Newfoundland and Labrador Centre for Applied Research.[1]

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Scope	These Standards have been developed for use in all Health Care Facilities and Settings and apply to Critical and Semi-Critical Medical Devices.
Documents Updated/Replaced	The *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices*, February 18, 2011 update and replace the *Standards for Single-Use Medical Devices*, January 16, 2008.
Contact	This document can be found on the Alberta Health and Wellness (AHW) website: www.health.alberta.ca. For general information call AHW Central Reception at 780-427-7164 and your call will be directed to the appropriate personnel. Interpretation/implementation questions should be forwarded to Alberta Health Services (AHS) Zone Infection Prevention and Control contact. The Senior Medical Officer of Health at AHS can be contacted by e-mail at infectionpreventioncontrol@albertahealthservices.ca and the Chief Medical Officer of Health at AHW can be contacted by e-mail at ocmoh@gov.ab.ca.
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Definitions

Alberta Health Services (AHS)
The regional health authority established under the *Regional Health Authorities Act.*

Chief Medical Officer of Health
The person appointed by the Minister as the chief medical officer of health under the *Public Health Act.*

Client
A person receiving health care services.

Critical Medical Device
A Medical Device that:

- penetrates the skin or mucous membranes;
- 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. Examples include but are not limited to the following:

- needles (including acupuncture needles);
- lancets;
- syringes;
- suture removal kits;
- urinary catheters;
- biopsy forceps; and
- infusion supplies and devices such as catheters, needles, lines (e.g. IV administration tubing), and access ports.

Health Care Facility or Setting
A facility or setting in which a Client receives health care services including, but not limited to, the following:

- hospitals;
- surgical facilities;
- ambulatory care clinics;
- pre-hospital settings;
- public health clinics;
- nursing homes;
- designated assisted living facilities;
- extended and long term care facilities;
- hospice; and

- in the case of health care services provided through home care, private dwellings.

Intended Purpose

The use for which a Medical Device is intended according to the information supplied by the Manufacturer on the labeling, in the instructions and/or promotional materials for the Medical Device.[2]

Manufacturer

A person (including a partnership, firm or association) who sells a Medical Device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and with respect to the Medical Device, is responsible for the following:

- designing;
- manufacturing;
- assembling;
- processing;
- labeling;
- packaging;
- refurbishing;
- modifying; or
- assigning the Medical Device an Intended Purpose,

whether those tasks are performed by that person or on their behalf.[3]

Medical Device

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.[4]

Non-Critical Medical Device

A Medical Device which either touches only intact skin but not mucous membranes, or does not directly touch the Client. Examples include but

	are not limited to the following: • electrocardiogram (ECG) electrode patches; and • disposable non-sterile procedure gloves.
Opened but unused Single-Use Medical Device	A disposable Single-Use Medical Device whose: • sterility has been breached or compromised; or • whose sterile package was opened but the Medical Device has not been used on a Client, and has not come into contact with blood, tissue or bodily fluids.[5, 6]
Organization	An owner, operator or other person responsible for the management of a Health Care Facility or Setting, including the owner, operator or other person responsible for the management of health care services to a Client in the Client's own home, but excluding the owner of a private dwelling in the case of health care services provided through home care.
Point of Use	A specific point in time and place at which a Medical Device is used on a Client.
Senior Medical Officer of Health	The person appointed as a medical officer of health under the *Public Health Act* and designated by AHS as the Senior Medical Officer of Health.
Semi-Critical Medical Devices	A Medical Device that comes into contact with mucous membranes or non-intact skin, but ordinarily does not penetrate them. Examples include but are not limited to the following: • trans-rectal probes; • vaginal, nasal and rectal specula; and • respiratory therapy equipment (e.g. oral endotracheal tubes, airway devices, and suction devices).
Single-Client-Use Medical Device	A Critical or Semi-Critical Medical Device that is designated by its Manufacturer for use and reuse on a single Client but may not be reused on another Client. Examples include but are not limited to the following: • nebulizers; • metered dose inhaler spacers; • infant oxygen sensors; and • Yankauer suction tips.
Single-Use Medical Device	For the purpose of this Standard, a Critical or Semi-Critical Medical Device designated by the Manufacturer for single-use only[7] and may be indicated by, but not limited to, the following terms used for labeling by the Manufacturer: • Disposable;

- Consumable;
- Not for re-use or do not re-use;
- Discard after single-use;
- Do not use twice;
- Or a symbol such as: 

User

Any person employed, contracted or otherwise engaged by an Organization and who uses Critical or Semi-Critical Medical Devices in the course of his or her duties or in the provision of services to the Organization.

Validated

A documented procedure for obtaining, recording and interpreting the results required to establish that a process for cleaning, disinfection or sterilization of a Medical Device will consistently yield products complying with the Canadian Standards Association Standard Z17664.[8]

1. Single-Use Medical Devices

Medical Devices are assigned risk classifications based on the risk of infection involved with the use of the Medical Device on a Client. The three risk classifications are:

- Critical Medical Devices;
- Semi-Critical Medical Devices; or
- Non-Critical Medical Devices.[9]

Critical and Semi-Critical Medical Devices present a higher risk of infection and this Standard applies to these risk classifications.

1.1 Single-Use Medical Devices shall only be used on an individual Client for a single procedure and then must be discarded.

1.2 A Medical Device shall be treated as a Single-Use Medical Device in the event that:

1.2.1 the Medical Device is labeled as a Single-Use Medical Device by the Manufacturer;

1.2.2 the labeling of the Medical Device is unclear as to whether or not the Medical Device is a Single-Use Medical Device; or

1.2.3 there are no Manufacturer's Validated and written reprocessing instructions for the Medical Device.

1.3 Sterile Single-Use Medical Devices shall be maintained as sterile until Point of Use.

1.4 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 Manufacturers' Validated and written instructions (for example, dental burrs and orthopedic plates and screws).

1.5 Opened but unused Single-Use Medical Devices must be discarded or reprocessed according to the Manufacturers' Validated and written instructions.

1.6 Single-Client-Use Medical Devices shall not be reused on another Client.

1.7 For further clarity, a Single-Use Medical Device that has come into contact with blood, tissue or bodily fluids shall not be reprocessed or reused.

2. Written Policy

2.1 The Organization shall have a written policy regarding Single-Use Medical Devices that is consistent with the *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices.*

2.2 The Organization shall ensure its written policy regarding Single-Use Medical Devices is kept up-to-date.

2.3 The Organization shall make the *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices* and its written policy available to all Users and shall provide awareness training as required.

2.4 Users of Single-Use Medical Devices shall be familiar with their Organization's written policy regarding Single-Use Medical Devices and the *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices.*

3. Monitoring and Compliance

3.1 The Organization shall review and monitor Users' compliance with the *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices* in accordance with its written policy on monitoring and the results of such monitoring shall be documented.

3.2 Any non-compliance with the *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices* shall be reported and addressed promptly and effectively through the Senior Medical Officer of Health and to the Chief Medical Officer of Health.

References

[1] S. Bornstein, J. Butler & R. Kean, The Reprocessing and Reuse of Single-Use Medical Devices in Newfoundland & Labrador (St. John's, NL: Newfoundland and Labrador Centre for Applied Health Research, Memorial University, 2010).

[2] Adapted from Industry Canada, Canadian Medical Devices Industry Glossary (2009), online: http://www.ic.gc.ca/eic/site/md-am.nsf/eng/hi00043.html.

[3] Adapted from Medical Devices Regulation, S.O.R. 98-282.

[4] Adapted from Canadian Standards Association, Decontamination of Reusable Medical Devices (2008).

[5] Australian Government, Department of Health and Ageing, Australian Regulatory Guidelines for Medical Devices (2010), online: http://www.tga.gov.au/devices/argmd.pdf.

[6] U.S. Department of Health and Human Services Food and Drug Administration Centre for Devices and Radiological Health, Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospital (2000), online: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107172.pdf.

[7] Adapted from Canadian Standards Association, Decontamination of Reusable Medical Devices (2008).

[8] Adapted from Canadian Standards Association, Sterilization of Medical Devices: Information to be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices, (2006).

[9] Adapted from Canadian Standards Association, Decontamination of Reusable Medical Devices (2008).

