

TITLE

CRITICAL AND SEMI-CRITICAL SINGLE-USE MEDICAL DEVICESSCOPE

Provincial

DOCUMENT

PS-07

APPROVAL LEVEL

Alberta Health Services Executive

SPONSOR

Infection Prevention and Control

INITIAL EFFECTIVE DATE

May 01, 2012

CATEGORY

Patient Safety

REVISION EFFECTIVE DATE

July 08, 2016

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.

If you have any questions or comments regarding the information in this policy, please contact the Policy & Forms Department at policy@albertahealthservices.ca. The Policy & Forms website is the official source of current approved policies, procedures, directives, and practice support documents.

PURPOSE

- To provide direction for the use of critical or semi-critical **single-use medical devices** within Alberta Health Services to prevent the transmission of micro-organisms and injury to **patients**.

POLICY STATEMENT

Alberta Health Services supports patient safety and staff knowledge regarding appropriate use of single-use medical devices.

The contents of this policy are in accordance with Alberta Health *Standards for Single-Use Medical Devices*.

Note: this policy applies only to **critical** and **semi-critical medical devices**. **Non-critical medical devices** are excluded.

APPLICABILITY

Compliance with this policy 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).


POLICY ELEMENTS**1. Knowledge**

- 1.1 Users of a **medical device** must know if the device is a single-use medical device as outlined within this Policy or if the device can be reused.

- 1.2 Users of a medical device should know the **risk class** assigned to the device (critical, semi-critical or non-critical).

2. Use

- 2.1 A critical or semi-critical medical device shall be treated as a single-use medical device in the event that:

- a) the **manufacturer** has identified the device using labels that include, but are not limited to:
- (i) disposable;
 - (ii) consumable;
 - (iii) not for reuse or do not reuse;
 - (iv) discard after Single-Use;
 - (v) do not use twice; or 
- b) the labelling of the device is unclear; or
- c) there are no manufacturers' **validated** written **reprocessing** instructions for the device.

- 2.2 **Critical or semi-critical single patient-use medical devices** may be reused on the same patient, but shall not be reused on another patient.

- 2.3 Critical or semi-critical single-use medical devices shall only be used on an individual patient for a single procedure and then must be discarded.

- 2.4 Prior to using a critical or semi-critical single-use medical device that was purchased in a non-sterile state, the device shall be inspected and processed according to manufacturers' validated and written instructions (for example, dental burrs and orthopaedic plates and screws), and as per established site-based policy, procedure or standards.

- 2.5 Sterile critical or semi-critical single-use medical devices shall be maintained as sterile until **point of use**.

- 2.6 **Opened but unused** critical or semi-critical **single-use medical devices** must be discarded, unless the manufacturer provides **validated** and written instructions for reprocessing (e.g. orthopaedic plates and screws).

3. Monitoring and Reporting

- 3.1 To support continuous learning within Alberta Health Services, it is strongly encouraged to report concerns related to the use of a critical or semi-critical

single-use medical device through the Alberta Health Services Reporting and Learning System (RLS).

3.2 The **Infection Prevention and Control Executive** and the Senior Medical Officer of Health shall address all reports received on the use of critical or semi-critical single-use medical devices that are not in accordance with this policy. Such reports may include:

- a) summary reports from the Alberta Health Services RLS;
- b) internal review processes such as medical device reprocessing reviews conducted within Alberta Health Services health care facilities; and,
- c) external review processes such as those conducted by Accreditation Canada and Alberta Health that include standards pertaining to single-use medical devices.

3.3 Reports on the use of critical or semi-critical single-use medical devices received in accordance with Section 3 of this policy will be evaluated to determine if changes can be made to make patient care safer.

4. Exception

4.1 In rare cases, there may be a need to consider reprocessing or reuse of a critical or semi-critical single-use medical device. The exception process (see Appendix A) begins with the requesting department and requires information gathering, consultation, documentation and evaluation.

4.2 Exception requests shall be evaluated based on:

- a) patient safety and clinical effectiveness of the device to perform as originally intended by the manufacturer;
- b) Infection Prevention and Control standards and guidelines; and,
- c) medical device reprocessing capacities and capabilities.

4.3 Exception requests shall be evaluated using a multi-level approach. The decision to deny the request may occur at any level. The levels are:

- a) Provincial Infection Prevention and Control Committee;
- b) Infection Prevention and Control Executive and Senior Medical Officer of Health; and
- c) Alberta Health Services committees reporting to the Chief Executive Officer.

- 4.4 Upon approval, exceptions to this policy will be documented, communicated to staff and medical staff, reported to Alberta Health Chief Medical Officer of Health as approved and reviewed annually.

DEFINITIONS

Critical medical device means 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, infusion supplies and devices such as catheters, needles, lines (e.g., intravenous administration tubing), and access ports.

Infection Prevention and Control Executive means, for the purpose of this policy, a member of Alberta Health Services as defined in the Alberta Health (2011) Standards for Infection Prevention and Control - Accountability and Reporting.

Manufacturer means 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, labelling, packaging, refurbishing, modifying, or assigning the medical device an intended purpose, whether those tasks are performed by that person or on their behalf.

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; 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.

Non-critical medical devices means a medical device which either touches only intact skin but not mucous membranes, or does not directly touch the patient. 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 means 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 patient, and has not come into contact with blood, tissue or body fluids.

Patient means all persons who receive or have requested health care or services from Alberta Health Services and its health care professionals and also means, where applicable:

- a) a co-decision-maker with the person; or
- b) an alternate decision-maker on behalf of the person.

Point of use means, for the purpose of this policy, a specific point in time and place at which a medical device is used on a patient.

Reprocessing means, for the purpose of this policy, the steps performed to prepare a used medical device for reuse (e.g., cleaning, and sterilization or disinfection).


Risk Class means, for the purpose of this policy, the classification based on the risk of infection involved with the use of the medical device on a patient. The three risk classes are:

- critical medical devices;
- semi-critical medical devices; or
- non-critical medical devices.

Semi-critical medical devices means 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 patient-use medical device means a critical or semi-critical medical device that is designated by its manufacturer for use and reuse on a single patient, but may not be reused on another patient. 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 means for the purpose of this standard, a critical or semi-critical medical device designated by the manufacturer for single-use only and may be indicated by, but not limited to, the following terms used for labelling by the manufacturer:

- disposable;
- consumable;
- not for reuse or do not reuse;
- discard after Single-Use;
- do not use twice; or
- a symbol such as: 

Validated means, for the purpose of this policy, 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 Z17664-06.

REFERENCES

- Appendix A: *Single-use Medical Device Exception Process*
- Non-Alberta Health Services Documents:
 - Alberta Health (February 18, 2011). *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices*.
 - Alberta Health (May 12, 2011). *Standards for Infection Prevention and Control – Accountability and Reporting*.
 - Canadian Standards Association (2006). *Z17664-06 Sterilization of Medical Devices – Information to be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices*.

- o Canadian Standards Association (2014). *Z314.8-14 Decontamination of Reusable Medical Devices*.
- o Canadian Standards Association (2009). *Z314.3-09 Effective Sterilization in Healthcare Facilities by the Steam Process*.

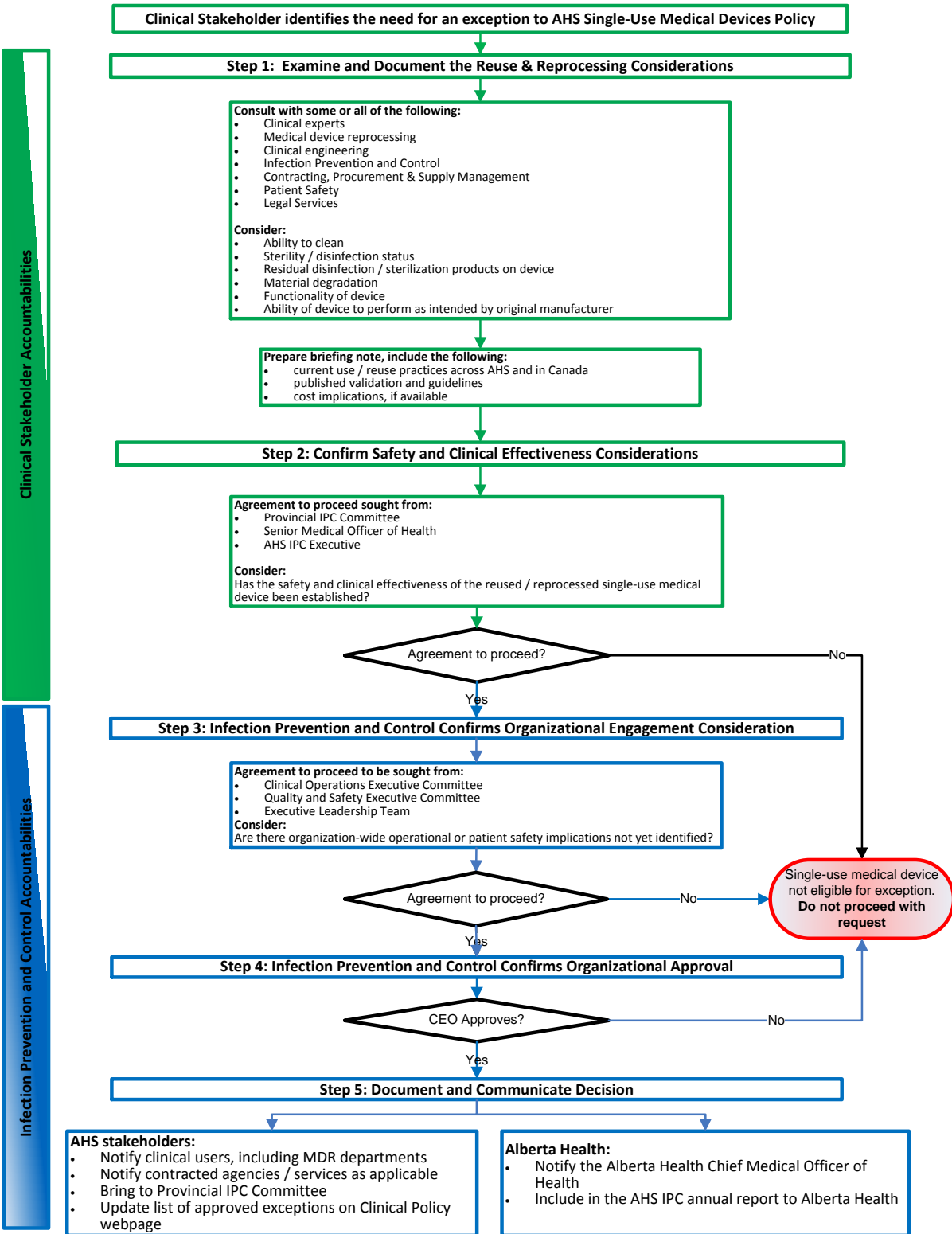
VERSION HISTORY

Date	Action Taken
May 01, 2012	Initial approval
May 01, 2012	Initial effective
July 08, 2016	Revised



Appendix A

Single-use Medical Device Exception Process



Clinical Stakeholder Accountabilities

Infection Prevention and Control Accountabilities