Team Name: Infection Prevention and Control Team Lead: Regional Director, Staff Development, Infection Prevention & Control Approved by: VP - Human Resources	Reference Number: CLI.8011.PL.005 Program Area: Infection Prevention and Control Policy Section: Infection Prevention and Control Policies and Guidelines
Issue Date: August 16, 2017 Review Date: Revision Date: August 2, 2018	Subject: Single Use Medical Devices

POLICY SUBJECT:
Single use medical devices.

PURPOSE:
To provide Southern Health-Santé Sud staff with direction on the use of single use medical devices within health care settings to ensure patient safety by preventing transmission of microorganisms and injury to clients.

BOARD POLICY REFERENCE:
Executive Limitation (EL-02) Treatment of Clients
Executive Limitation (EL-03) Treatment of Staff
Executive Limitation (EL-07) Corporate Risk

POLICY:
Southern Health-Santé Sud is committed to patient safety at all levels of the organization by supporting and promoting an environment that prohibits the reprocessing and reuse of any single use or single client use medical device.

DEFINITIONS:
Cleaning: The physical removal of foreign material (e.g., dust, soil) and organic material (e.g., blood, secretions, excretions, microorganisms). Cleaning physically removes rather than kills microorganisms. It is accomplished with water, detergents and mechanical action.

Disinfection: The inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores. Medical equipment/devices must be cleaned thoroughly before effective disinfection can take place.

- **High-Level Disinfection (HLD):** The level of disinfection required when processing semi-critical medical equipment/devices. High-level disinfection processes destroy vegetative

bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores. Medical equipment/devices must be thoroughly cleaned prior to high-level disinfection.

- **Low-Level Disinfection (LLD):** Level of disinfection required when processing non-invasive medical equipment (i.e., non-critical equipment) and some environmental surfaces. Equipment and surfaces must be thoroughly cleaned prior to low-level disinfection.

Manufacturer: Any person, partnership or incorporated association that manufactures and sells medical equipment/devices under its own name or under a trade mark, design, trade name or other name or mark owned or controlled by it.

Medical device: Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap; investigation, replacement, or modification of the anatomy or of a physiological process; or control of conception.

Reprocessing: The steps performed to prepare used medical equipment/devices for use (e.g., cleaning, disinfection, sterilization).

Reusable medical device: A device that has been designed by the manufacturer, through the selection of materials and/or components, to be reused.

Risk class: The classification assigned to a device involved in client care based on the risk of infection involved with the use of the device. The classes are as follows and adapted from Spaulding (1971):

- **Critical medical devices** – Medical equipment/devices that enter sterile tissues, including the vascular system (e.g., biopsy forceps, foot care equipment, dental hand pieces, etc.). Critical medical equipment/devices present a high risk of infection if the equipment/device is contaminated with any microorganism, including bacterial spores. Reprocessing critical equipment/devices involves meticulous cleaning followed by sterilization.

- **Semi-critical medical devices** – Medical equipment/device that comes in contact with nonintact skin or mucous membranes but ordinarily does not penetrate them (e.g., respiratory therapy equipment, transrectal probes, specula). Reprocessing semicritical equipment/devices involves meticulous cleaning followed by, at a minimum, high-level disinfection.

- **Non-critical medical devices** – Equipment/device that either touches only intact skin (but not mucous membranes) or does not directly touch the client/patient/resident. Reprocessing of noncritical equipment/devices involves cleaning and may also require low-level disinfection (e.g., blood pressure cuffs, stethoscopes).

Single client use medical device: A term given to medical equipment/devices that may be used on a single client and may be re-used on the same client, but may not be used on other clients.

Single use medical device: A term given to medical equipment/devices designated by the manufacturer for single-use only. Single-use equipment/devices must not be reprocessed. Single use medical devices are usually labelled by the manufacturer with a symbol or ② may be labeled as disposable, consumable, not for re-use or do not re-use, discard after single use or do not use twice.

Sterilization: The level of reprocessing required when processing critical medical equipment/devices. Sterilization results in the destruction of all forms of microbial life including bacteria, viruses, spores and fungi. Equipment/devices must be cleaned thoroughly before effective sterilization can take place.

Validation: a documented procedure performed by the device manufacturer for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

IMPORTANT POINTS TO CONSIDER:

- All health care providers must have the understanding and knowledge of whether a medical device is a single use medical device, a single client use medical device or a reusable medical device according to Manufacturer's labeling, product information and instructions.
- A single use medical device is **not** validated for reuse and may be made in such a way that any reprocessing will damage or alter it to the extent of making it unsafe for reuse.
- Reusable medical devices are assigned a risk classification category based on the risk of infection involved with the use of the medical device on a client. The Spaulding Classification system defines three risk classifications of devices including critical medical devices, semi-critical medical devices and non-critical medical devices. Reprocessing of reusable medical devices must ensure the device can be used safely on another client and must be in compliance with Health Canada, provincial and regional policies and standards.
- A reusable medical device manufactured for reuse must work as well as it did on its first use every time that it has been reprocessed. The manufacturer must extensively test and validate the device and the process for reuse and provide adequate reprocessing instructions when the device is promoted for sale.

PROCEDURE:

Single Use Medical Devices

- Sterile single use medical devices must be maintained as sterile until point-of-care use.
- Opened but unused single use medical devices must be discarded.
- The health care provider will discard single use medical devices in the appropriate disposal container after a single procedure or intervention.
- Sharps and needles will be safely discarded in the facility approved sharps container closest to the point of use.

Single Client Use Medical Devices

- The health care provider will reuse the medical device on the same client only and the device will be discarded upon client discharge.
- The health care provider will follow the manufacturer cleaning instructions, in compliance with infection control guidelines and return the medical device for reuse on the same client only.
- The health care provider will discard grossly soiled or contaminated medical devices that cannot be adequately cleaned.

REFERENCES:

Alberta Health Services, *Critical and Semi-Critical/Single-use Medical Devices*, July 2016.

AORN Guidance Statement: *Reuse of single-use devices*, 2006.

Canadian Standards Association, Z314.0-13: *Medical Device Reprocessing – General Requirements* (2013).

Health Canada, *Archived – Reprocessing of Reusable and Single-Use Medical Devices*, 2004.

Prairie Mountain Health, *Single Use Medical Devices*, May 2016.

Provincial Infectious Diseases Advisory Committee (PIDAC), *Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in all Health Care Settings, 3rd edition,* May 2013.

Manitoba Health, Routine Practices and Additional Precautions: *Preventing the Transmission of Infection in Health Care*, April 2012.