Purpose
A single-use device (SUD) is a disposable device, labeled as such by the original manufacturer, manufactured for single-use and not intended to be reprocessed or reused on another patient. Reprocessing of single-use medical devices involves regulatory, ethical, medical, legal and economic issues.

Policy Statement
Covenant Health Infection Prevention & Control is committed to patient safety at all levels of the organization by supporting and promoting an environment that prohibits the reprocessing and reuse of single-use medical devices.

Applicability
This policy applies to all Covenant Health facilities, staff, members of the medical staff, volunteers, students and to any other persons acting on behalf of Covenant Health.

Responsibility
Covenant Health staff, physicians, volunteers, and other service providers are responsible for creating and sustaining an environment that supports an infection control program that effectively prevents transmission of pathogens and healthcare-associated infections related to medical devices.

Principles
1. Background
   - Covenant Health adheres to Alberta Health & Wellness Standards (AH&W) for Single-Use Medical Devices (February 2011).
   - The Spaulding Classification system is used to classify infection risks for medical devices.
   - Covenant Health will not reprocess and reuse single-use devices that are classified as:
     - Critical—devices that enter sterile tissues, including the vascular system;
     - Semi-critical—devices that come in contact with mucous membranes or non-intact skin, but do not penetrate them.

2. Knowledge
   - Users of a medical device must know the risk class assigned to the device (critical, semi-critical or non-critical).
   - Users of a medical device must be knowledgeable of whether the device is a single-use medical device or if the device can be reused.

3. Use
   - A medical device shall be treated as a single-use medical device in the event that:
     - the medical device is labeled as a single-use medical device by the manufacturer
     - the labeling of the medical device is unclear as to whether or not the medical device is a single-use medical device; or
     - there are no manufacturer’s validated and written reprocessing instructions for the medical device.
• Single-use medical devices shall only be used on an individual client for a single procedure and then must be discarded.
• Single client-use medical devices may be reused on the same patient but shall not be reused on another patient.
• A single-use medical device that has come into contact with blood, tissue or bodily fluid shall not be reprocessed or reused.
• Sterile single-use medical devices shall be maintained as sterile until point of use.
• 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).
• Opened but unused single-use medical devices must be discarded or reprocessed according to the manufacturers’ validated and written instructions.
• Single-use devices must be disposed of in the appropriate waste receptacle at the point of use.

4. Monitoring and Reporting
• All staff strongly encouraged to report concerns related to the use of a semi-critical or critical single-use medical device to their manager and through Reporting and Learning System (RLS).
• Infection Prevention and Control leadership shall address all reports received on the use of single-use medical devices that are not in accordance with this policy. Such reports may include:
  • Summary reports from RLS
  • Internal review processes such as medical device reprocessing reviews conducted within Covenant Health facilities
  • External review processes such as those conducted by Accreditation Canada and Alberta Health & Wellness that include standards pertaining to single-use medical devices.
• All reports will be evaluated to determine if changes can be made of make patient care safer.

References

Revisions
- November 1, 2011
- November 1, 2010