POLICY:	**Reprocessing of Reusable Medical Devices**
Program Area:	**Medical Device Reprocessing**
Section:	**General**
Reference Number:	**CLI.5510.PL.008**
Approved by:	**Regional Lead – Acute Care & Chief Nursing Officer**
Date:	Issued 2025/Jan/09 Revised

PURPOSE:
To ensure reusable Surgical Instruments/Equipment are cleaned, disinfected and sterilized in compliance with Infection Control guidelines as recommended by Manufacturer's Instructions (MIFU).

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

POLICY:
To ensure manual cleaning, disinfection and sterilizing of Operating Room (OR) Surgical Instruments and Equipment complies with Infection Prevention Control (IPC) guidelines as recommended by Manufacturer's Instructions.

IMPORTANT POINTS TO CONSIDER:
- Staff document reprocessing activity using CLI.5510.PL.008.FORM.01 Boundary Trails Health Centre (BTHC) Manual Instrument Tracking System, CLI.5110.PL.008.FORM.02 Manual Instrument Tracking System, CLI.5110.PL.008.FORM.03 Inventory List of Reusable Medical Devices for Sterilizing.
- Point-of-use cleaning of surgical instruments/equipment is performed prior to being transported to the Medical Device Reprocessing Department (MDRD) for further manual or automated cleaning.
- Pre-Klenz is used to spray on soiled instruments having to wait for reprocessing. Pre-Klenz can be left on instruments up to 72 hours. Staff assigned to clean and disinfect surgical instruments/equipment:
  - Are trained and educated in infection prevention and control medical device reprocessing practices,
  - Wear appropriate personal protective equipment (PPE) as per routine practices,
  - Are immunized against Hepatitis B as per policy CLI.8011.PL.008 Occupational Health Immunizations for Health Care Workers and
  - Practice good hand hygiene.
- Cleaning is the first and most important step in Surgical Instruments/Equipment Reprocessing. Effective disinfection and sterilization are dependent on proper cleaning. Any residual debris, such as tissue, blood, or other body fluids, not removed from instruments/equipment prior to disinfection or sterilization result in contaminated instruments/equipment.
- Containers used for collection:
  - Used for collection of soiled items are sturdy, leak-proof, and capable of being sealed or covered to prevent the risk of disease transmission.
  - Containers indicate that they contain contaminated medical devices and be of a design to allow for effective decontamination after each use.
  - Single-use containers are disposed of according to the health care setting's waste management policy.

- Reusable containers and covers are decontaminated after each use.
- Contaminated items are transported in covered, fully enclosed containers or closed carts that are designed to prevent the spill of liquids and to protect personnel from harm and medical devices from damage. A cart/container exchange system is used for removal of contained items.
- If contaminated items are transported in an open cart, it is contained with a secured lid.
- All carts containing contaminated medical devices are identified according to the health care setting's Standard Operating Procedure (SOP).
- Carts containing contaminated medical devices are not left unattended during transportation.
- Follow CLI.5510.PL.002.FORM.01 Reprocessing Transportation Inventory List for satellite facilities or CLI.5510.PL.002.FORM.02 MDR Interdepartmental Instrument Tracking for interfacility use.
- For off-site transportation of contaminated medical devices follow the applicable regulations for transportation of biohazardous materials.
- Staff document reprocessing activity:
    - CLI.5510.PL.008.FORM.01 BTHC Manual Instrument Tracking System
    - CLI.5510.PL.008.FORM.02 Manual Instrument Tracking System
    - CLI.5510.PL.008.FORM.03 Inventory list of Reusable Medical Devices for Sterilizing

PROCEDURE:

1. PREPARE	**RATIONALE**
a) Perform hand hygiene.	According to IPC policy and prior to donning Personal Protective Equipment (PPE)
b) Put on PPE as recommended by Routine Practices and cleaning product manufacturer's recommendations.	Each worker is responsible for personal safety. Gloves, waterproof gown and eye/face protection may be required.
c) Clean sink in designated area with facility approved disinfectant.	Sink must be large and deep enough to immerse instruments/equipment completely.
2. SORT	**RATIONALE**
a) Separate instruments/equipment into groups of similar size. Keep sharp and/or delicate instruments/equipment together.	To prevent injury to personnel, damage to the instruments/equipment and ensure instrument tray sets are complete.
b) Be sure all instruments/equipment are: ➢ In "open" position. ➢ Disassemble/remove all parts as required.	To ensure all surfaces of instruments/equipment are cleaned and come in contact with the disinfectant cleaner.
c) Instruments/equipment that are grossly soiled are pre-rinsed with warm tap water to remove gross soil/debris. Immersible instruments/equipment that cannot be cleaned immediately after use are fully submerged in correct dilution of recommended detergent and water. For non-immersible instruments/equipment, use a separate clean cloth soaked with enzymatic detergent and water to wipe down each piece.	Failure of timely removal of soiled organic material, such as blood, feces, mucous or pus left on instruments/equipment may damage the items and will stop the action of disinfectants or sterilants.
d) Visually inspect all instruments/equipment for damage. i.e. cracks, defects, etc. and remove any residue, including adhesive prior to cleaning.	To identify instruments/equipment that are damaged and may require replacement. To remove debris where bacteria can live and grow.

3. CLEANING	RATIONALE
a) Manual manipulation and pre-cleaning is performed according to manufactures' instructions, including detergent type, water type, water temperature and cleaning methods. Use warm water, not hot water because hot water coagulates blood and makes it difficult to remove debris. DO NOT use saline solution for soaking as it damages medical instruments/equipment.	
b) Place dirty instruments/equipment to be cleaned in sink filled with water and enzymatic detergent.	
c) All instruments/equipment are kept completely under water during cleaning. ➢ Clean instruments/equipment with a soft bristle brush (inspected before use) using friction. ➢ Keep the brush and the instruments/equipment being cleaned under the surface of the cleaning solution and work from least soiled to most soiled. ➢ Clean all lumens and surfaces filling all lumens with detergent solution and ensure it flows through completely. ➢ Repeat cleaning of lumens and surfaces until brush does not show visible soil/debris. ➢ Soaking helps to soften residue and makes devices easier to clean.	To ensure entire instruments/equipment, including all internal lumens have contact with the cleaning solution. Friction action is important part of cleaning. To prevent contamination droplets from being sprayed into the air. To ensure no residual "dirty" particles remain and render instruments/equipment contaminated.
d) When cleaning heavily soiled instruments/equipment or many instruments/equipment, change cleaning solution frequently.	Avoids re-contamination
e) Ultrasonic cleaners may be used in addition to manual cleaning if manufacturer's instructions permit. Visible soil is removed before ultrasonic cleaning is performed. ➢ When loading an ultrasonic cleaner, all parts of the medical device are in complete contact with solution for the required contact time. Medical devices are immersed, and all trapped air removed. Note: Air removal and complete contact can be achieved by: a) Complete disassembly of the medical device according to the MIFU. b) Filling all lumens with cleaning solution and ensuring that fluid flows from the distal end. c) Positioning the medical device to allow trapped air to escape. d) Attaching the appropriate connectors for lumens, if required; and not overloading the baskets. e) Baskets of instruments are rinsed with tap water following ultrasonic cleaning and prior to putting into the washer/disinfector. ➢ Ultrasonic cleaners are tested for sonication performance at least weekly, or preferably each day it is used. The test	

results are documented on the site specific. The test and CLI.5510.PL.008.FORM.05 Ultrasonic Daily Testing Form is followed for appropriate testing protocols.	
f) Loading of automated washer/disinfector as described in manufacturer's instructions. ➢ Manufacturer's instruction is followed for routine cleaning and maintenance of automated washers. ➢ Complete disassembly of device according to MIFU. ➢ Proper positioning of device to ensure contact of cleaning solution. ➢ Attach appropriate connectors for lumens. ➢ Do not overload baskets. ➢ Test kits are used to check performance of washer/disinfector daily. ➢ Print out from the unit is verified and initial for all critical parameters of each cycle.	
g) Chemical residues and loosened soil are completely rinsed from the medical device before further reprocessing. ➢ Rinsing may be included as a final step in an automated cleaning process. If not, the medical device is rinsed manually. ➢ Non-immersible devices, including power equipment, are rinsed according to the MIFUs or with a water-dampened cloth to remove the cleaning agent and then dried. ➢ All medical devices are dried before disinfection and sterilization. Medical devices that will be further disinfected or chemically sterilized are dried unless the device is wiped with a new disinfectant wipe for low-/intermediate-level disinfection.	Water can dilute the action of the chemical disinfectant, and the presence of moisture during the beginning stages of many chemical sterilization processes could cause cycle cancellations. Drying also helps to prevent corrosion of certain materials such as stainless steel.
4. DISINFECTION OF SEMI- CRITICAL DEVICES	**RATIONALE**
➢ A semi-critical device is sterilized if it can be safely sterilized according to the MIFUs. If a semi critical device cannot be sterilized, then it, at a minimum, is high-level disinfected, thermally disinfected, or pasteurized according to the MIFUs between patient uses.	
5. LUBRICATION	**RATIONALE**
➢ Medical devices are clean and dry before they are lubricated. The lubricant used on the medical device is compatible and water-soluble and not impede the sterilization process to be used. ➢ Automated lubrication of instruments may be done as part of the washer-disinfector final rinse. Note: a) Not all medical devices require routine lubrication (i.e., implants). b) Use of single-use lubricant should be considered.	Pathogens can grow in lubricants that have been improperly mixed, handled, or stored. Care is exercised to avoid contamination of the lubrication source. Consult the lubricant manufacturer for preservative effectiveness testing information.

6. PREPARING MEDICAL DEVICES FOR STERILIZATION	RATIONALE
➢ Before sterilization, the device MIFUs is followed for assembly and disassembly. Note: ➢ Some medical devices require loosening or opening rather than disassembly. Consult the MIFUs. ➢ Printed content sheets are not included inside any packages due to the possibility of ink transfer to the contents. ➢ Package and load configurations ensure complete sterilizing agent penetration of packages and contact with all medical devices contained within. In addition, package and loads intended for steam sterilization are configured to ensure complete air removal and drying. ➢ Set configuration is based on the sterilizer MIFUs. Instrument trays are verified by performance qualification testing to ensure that a) sterilizing agent penetration occurs throughout the set; and b) for steam sterilization, air removal and adequate drying can also occur. Note: ➢ Even distribution of instruments in the set facilitates efficient sterilization. ➢ Each medical device and sterile barrier system (packaging) is validated and verified for the specific sterilization method and cycle parameters that is used. Note: ➢ Verification includes testing functionality, device conformance, materials compatibility, and microbicidal efficacy testing. Verification is unique to the device and sterilizer brands and models. ➢ In health care settings, reprocessed reusable medical devices are packaged using one of the following validated sterile barrier systems: a) pouches; b) wrappers; and c) rigid sterilization container systems. Note: ➢ Packaging is essential to maintaining the sterility and facilitating aseptic presentation of medical devices. ➢ Packaging for sterilization take the following considerations into account: o Weight limitations not to exceed 10 kg (22lbs) ➢ In addition to the Quality Management System (QMS) requirements, packaging policies and section 8 SOPs are based on the MIFUs from the device manufacturer, sterilizer manufacturer, and sterilization packaging	Some medical devices require disassembly for sterilization; those medical devices are reassembled for inspection in the MDRD and disassembled for sterilization. To ensure Occupational Health and Safety guidelines are met to allow personnel to use proper lifting technique.

manufacturer, as well as incorporating input of user departments as to arrangement of contents and aseptic presentation requirements. ➢ Each package for sterilization has a visible external chemical indicator for differentiating between processed and unprocessed packages. The indicator is appropriate for the sterilization process. ➢ Packages are labelled with at least the following information: a) package identification (package code or name); b) identity of the person who assembled the package (unless automatically recorded in the system). c) sterilizer load identification, including the sterilizer number, load number in that sterilizer and sterilization date. CLI.5510.PL.008.FORM.04 Sterilizer RESULTS Form	
7. STERILIZER TESTING	**RATIONALE**
Air Removal Test ➢ For dynamic air removal-type sterilizers (pre-vacuum cycles), an air removal test is performed every day the sterilizer is used. The Bowie Dick air removal PCD is placed in the chamber, which is typically on the bottom shelf above the drain in an empty sterilizer.	
Biological Indicators ➢ A biological indicator contained within a Process Challenge Device (PCD) is used to test the sterilizer for each type of cycle used (e.g., dynamic air removal, gravity) and at the shortest exposure time, according to the sterilizer manufacturer's recommendations. This test is done at least daily when the sterilizer is in use within a full load. CLI.5510.PL.008.FORM.04 Sterilizer RESULTS Form ➢ If a steam sterilizer is used for multiple types of cycles, each sterilization type used is tested daily. Note: Examples of multiple types of cycles include: a) gravity displacement at 132 to 135 °C; b) gravity displacement at 121 °C; c) dynamic air removal at 132 to 135 °C. ➢ For chemical sterilization, the sterilizer manufacturer identifies the cycles to monitor for the routine testing. ➢ Every load containing implantable devices is monitored using a biological indicator. ➢ Implantable devices are quarantined until the results of the biological indicator test are available. ➢ Early release of implants done in situations where there is an urgent, unplanned need (i.e., trauma-related devices). Early release of implants not used to compensate for inventory shortages or scheduling problems.	Due to the length of time that an implant is in contact with the patient, the risk of infection is greater than a typical medical device used during a typical surgical procedure.

Routine Monitoring includes: ➢ Physical parameters of sterilizer: time, temperature, and pressure and recorded on print out at end of each cycle. ➢ Chemical indicators ➢ Biological indicators ➢ Physical parameters of washer/disinfect ➢ Physical parameters of cart washer CLI.5510.PL.008.FORM.04 Sterilizer RESULTS Form ➢ If the testing cannot be explained by any cause other than sterilizer malfunction, complete CLI.5510.PL.008.FORM.06 Equipment Maintenance Form ➢ If recall is required complete the CLI.5510.PL.FORM.07 Regional MDR Recall of Goods Tracking Form. Refer to CLI.5510.PL.008.SD.01 Sterilization Failure Algorithm. ➢ The MIFUs for routine cleaning, maintenance and testing of all reprocessing equipment is followed and the documentation recorded on the CLI.5510.PL.FORM.08 MDR Daily and Weekly Check List	

EQUIPMENT/SUPPLIES:

- PPE (GOWN, gloves, mask, face shield, eye protection)
- Ultrasonic cleaner
- Sinks for cleaning and rinsing
- Soft bristle brush/appropriate size channel brushes
- Power channel irrigation or syringe
- Lint free cloths
- Approved enzymatic detergent
- Washer/disinfector
- Appropriate packaging material
- Chemical and Biological Indicators
- Steam Sterilizer
- Low Temperature Sterilizer
- Bowie Dick air removal test packs
- PCD Biological test packs

SUPPORTING DOCUMENTS:

CLI.5510.PL.008.FORM.01	BTHC Manual Instrument Tracking System
CLI.5510.PL.008.FORM.02	Manual Instrument Tracking System
CLI.5510.PL.008.FORM.03	Inventory List of Reusable Medical Devices for Sterilizing
CLI.5510.PL.008.FORM.04	Sterilizer RESULTS Form
CLI.5510.PL.008.FORM.05	Ultrasonic Daily Testing Form
CLI.5510.PL.008.FORM.06	Equipment Maintenance Report
CLI.5510.PL.008.FORM.07	Regional MDR Recall of Goods and Tracking Form
CLI.5510.PL.008.FORM.08	MDR Daily and Weekly Checklist
CLI.5510.PL.008.SD.01	Sterilization Failure Algorithm
CLI.5510.PL.002.FORM.01	Transportation Inventory List

CLI.5510.PL.002.FORM.02 MDR Interdepartmental Instrument Tracking

REFERENCES:

CSA Standards Reprocessing Medical Devices Z314:23 sections 11, 14,15 and 16

Best Practices for Cleaning, Disinfecting and Sterilization in all Healthcare Settings December 2011

CLI.8011.PL.008 Occupational Health Immunizations for Health Care Workers