POLICY:	**Sterilization Process Failures and Recalls**
Program Area:	**Medical Device Reprocessing**
Section:	**General**
Reference Number:	**CLI.5510.PL.005**
Approved by:	**Regional Lead - Acute Care &Chief Nursing Officer**
Date:	Issued 2025/Jan/29 Revised

PURPOSE:

To ensure appropriate sterilization of equipment has been performed for patient safety

BOARD POLICY REFERENCE:

Executive Limitation (EL-02) Treatment of Clients
Executive Limitation (EL-07) Corporate Risk

POLICY:

The Medical Device Reprocessing (MDR) staff identify circumstances that indicate failure in sterilization processes and take appropriate actions to prevent the use of questionably reprocessed items.

If there is doubt about the sterility of medical devices that have been released for use, a recall of those medical devices is carried out.

DEFINITIONS:

Air Removal Test (DART® or Bowie-Dick Test) - a diagnostic test run in dynamic air removal sterilizers to determine if any air has entered the chamber by means of a leak or if air is not removed because of malfunction of the vacuum pumping system.

Biological Indicator (BI) - a test system containing viable microorganisms providing a defined resistance to a specified sterilization process. A successful test result occurs when the BI processed through a cycle is negative for growth of the test microorganism following incubation: this indicates that conditions for sterilization were achieved during that cycle. It does not guarantee that the items in the load are sterile.

Chemical Indicator (CI) - a device that responds with a chemical or physical change when exposed to the sterilization cycle. A “pass” response indicates that certain conditions were achieved at the location of the chemical indicator. It does not necessarily indicate that a processed item is sterile.

Monitors - the means employed to check the efficacy of the sterilization process. Include chemical indicators, air detection tests, biological indicators, and the physical data.

Physical Monitors - data displayed on the sterilizer as each cycle progresses and recorded on a printout on completion of each cycle. These monitors provide information about conditions within the sterilizer chamber during and between cycles. The critical physical data monitored are time, temperature, and pressure.

Recall - the action of retrieving processed items that have been released for use when it is suspected that they are non-sterile.

PROCEDURE:

1. The MDR staff identify the following circumstances indicating a possible sterilization failure:
   1.1. Print-outs on reprocessing equipment exhibiting failure to reach correct physical parameters (i.e. temperature, pressure, exposure time),
   1.2. Positive (failed) biologic indicator (BI),
   1.3. External or internal chemical indicator(s) did not reach the desired endpoint,
   1.4. Failed air removal test and/or
   1.5. Incorrect reprocessing method was used.

2. The MDR staff immediately notify the manager, or designate responsible for MDR, in the event of a possible sterilization failure. The MDR staff provide the name of the employee who can provide current information about the sterilizer and recently processed loads. The manager or designate direct the investigation of the failure, and the recall of loads if needed, as described below.

3. In the event of a chemical indicator failure, biological indicator failure, physical monitoring failure, or dynamic air removal test failure; the manager or designate responsible for MDR:
   3.1. Quarantines the load,
   3.2. Removes sterilizer from service. Post an "Out of Service" warning sign on the sterilizer,
   3.3 Re-examines failed indicator to confirm it was properly used, handled, and interpreted according to manufacturer's instructions and
   3.4 Examines other related CIs, BIs, physical parameters, and last air detection test for abnormal results to determine the extent of the failure.

4 If cause of failure is immediately identified (usually operator error) and confined to one load (i.e., incorrect cycle used for the load) or one item within the load (i.e., internal CI failure in pack that was too dense to sterilize in the cycle parameters chosen):
   - If the load has already been released, recall the items (see Recall procedure below),
   - Correct the cause and
   - Rewrap the affected items with new chemical indicators and re- sterilize affected items.

   4.1 If cause of the failure is not immediately identified:
   - Recall all instrument sets and equipment pertaining to that load back (see recall procedure below).
   - If the failure involved a CI or physical monitors, investigate further for the root cause of failure (refer to 4.2 below).

   4.2 Determine the cause of the failure. Consult with Maintenance staff, the ICP, and the sterilizer service representative as appropriate.

   4.3 If the failure can be attributed to a cause **other than** malfunction of the sterilizer or attached utilities:
      4.3.1 Correct the error,
      4.3.2 Return the sterilizer to service and
      4.3.3 Rewrap the items from affected load(s) and re-sterilize.

   4.4 If the cause of the failure is attributed to malfunction of the sterilizer or attached utilities, or if no other cause can be found, ensure the sterilizer and utilities are evaluated and serviced by appropriate service personnel.

4.4.1 After service of the utilities or sterilizer, requalification of the sterilizer is necessary before returning sterilizer to service:

4.4.1.1.1 Requalification: Run BIs in three (3) consecutive cycles (dynamic air removal and gravity displacement gravity displacement sterilizers). Then run air removal tests in three (3) consecutive empty-chamber cycles in dynamic air removal sterilizers only.

4.4.1.1.2 If any of the BIs or air removal tests fail, further service of the sterilizer or utilities followed by requalification is required before returning the sterilizer to service.

4.4.1.1.3 If the BI and air removal tests pass, return the sterilizer to service.

5 Upon the discovery that an incorrect reprocessing method was used on medical devices, the manager or designate responsible for MDR:

5.1 Investigates to determine the duration of the error,

5.2 Recalls incorrectly reprocessed devices and notify the ICP and

5.3 Ensures affected items are rewrapped and reprocessed.

6 Recall procedure:

6.1 The manager or designate responsible for MDR completes the written Sterilization Failure Recall form identifying the following:

6.1.1 Sterilization load control label,

6.1.2 Departments or facilities that were issued the affected items,

6.1.3 Type and quantity of the medical devices to be obtained by the recall,

6.1.4 Person(s) responsible for destruction or return of items, and

6.1.5 Explanation of unrecalled items.

6.2 The manager or designate responsible for MDR completes the Sterilization Failure Recall identifying the following:

6.2.1 Circumstances that prompted the recall order,

6.2.2 Corrective action taken to prevent a recurrence and

6.2.3 Total number of items intended for recall.

6.3 The manager or designate sends copies of the completed Sterilization Failure Recall Order with any attachments and CLI.5510.PL.008.FORM.07 Regional MDR Recall of Goods and Tracking Form to the facility Infection Control Practitioner (ICP).

6.4 The Sterilization Failure Recall Order and any attachments and the CLI.5510.PL.008.FORM.07 Regional MDR Recall of Goods and Tracking Form is retained by the manager for 20 years according to Regional policy.

6.5 The manager or designate responsible for MDR completes ORG.1810.PL.001.FORM.01 Safety Event Report Form.

7 Assessment of risk to clients

7.1 The ICP or designate assesses the potentially exposed clients' risk for infection in collaboration with the physician(s), surgeon(s), Risk Management, Director, Health Services - Staff Development, Infection Prevention & Control, Director, Health Services/designate, and the Chief Medical Officer. Based on the results of this assessment and according to policy Disclosure Of Critical Incidents and Occurrences and Safety Event Report Form ORG.1810.PL.001.FORM.01, the clients may be notified of the occurrence if appropriate.

7.2 If the clients are deemed at risk for infection, the ICP/designate creates a list of potentially affected

clients and monitor them for infection. The duration of surveillance depends on the type of procedure performed with the medical devices and the degree of risk to the individual client.

SUPPORTING DOCUMENTS:

CLI.5510.PL.008.FORM.07	Regional MDR Recall of Goods and Tracking Form
ORG.1810.PL.001.FORM.01	Safety Event Report Form

REFERENCES:

Canadian Standards Association Z314:23 16.5.12