Policy and Procedure Template for Steam Sterilization Failure

[Name of clinic, address, logo]

Date of Creation/Last revision:

Instructions for template use: This template is an example of a policy and procedure that can be adapted for use in a clinical office setting. You are responsible for ensuring that the information is up to date. Fill in the blanks with information specific to your clinic. Please review and delete items that are not relevant to your setting, and add items as needed. For more information about IPAC policies and procedures, refer to the resources below or visit the IPAC Information for Healthcare Professionals page on **halton.ca**.

Purpose:

This procedure is for the recall of improperly reprocessed medical equipment/devices following a failure of biological indicators.

The following steps must be taken in the event of a sterilization failure (positive Biological Indicator test):

1. Notify the person in the office responsible for reprocessing of medical equipment that you have had a positive biological indicator (BI)_____(name).
2. Do not use any items that were processed since the last negative test. Recall all items and set aside. Remove the sterilizer from service.
3. Review all records of physical and chemical indicators since the last negative BI, as well as all sterilization procedures to determine whether operator error could be responsible. In the absence of a mechanical failure, common reasons for a positive BI include overloading, failing to provide adequate package separation, and using incorrect or excessive packaging material.
4. Repeat the test using the same cycle that produced the failure. Consider using a BI with a different lot number. If this repeat test is negative, and there is no indication of a system malfunction, continue as normal.
5. If the repeated test indicates a failure:
    (a) Contact the sterilizer manufacturer. After repair and maintenance, re-challenge the sterilizer with 3 consecutive BI tests. All 3 BIs must be negative to return the sterilizer to service.
    (b) Re-sterilize the recalled items once the results of the sterilizer indicators are acceptable. This must include re-cleaning, rinsing, drying and fresh wrapping or packaging.
    (c) Notify Halton Region Public Health (call 311) if medical equipment that was reprocessed in a failed cycle was used on a patient. Public Health will assist in determining the risk of disease transmission and the need for a look-back of potentially affected patients.
    (d) Notify patients, other facilities and/ or regulatory bodies, as required.

If in doubt, consult with Halton Region Public Health by calling 311.

References:

1. Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Infection Prevention and Control for Clinical Office Practice. 1st Revision. Toronto, ON: Queen's Printer for Ontario; April 2015. https://www.publichealthontario.ca/-/media/documents/B/2013/bp-clinical-office-practice.pdf

2. Royal College of Dental Surgeons of Ontario (RCDSO), Infection Prevention and Control in the Dental Office, November 2018. https://az184419.vo.msecnd.net/rcdso/pdf/standards-of-practice/RCDSO_Standard_of_Practice_IPAC.pdf