STERILE PROCESSING PROCEDURE
STERILIZATION

Procedure SP3-4: **BI and integrator process for steam sterilization**

U T O L E D O HEALTH

Policy Number Superseded:

Responsibility: Operations Manager, Sterile Processing

Purpose of Procedure: To ensure the effectiveness of the sterilization process.

Effective Date:
December 2025

Initial Effective Date:
2010

Procedure:

A biological indicator test pack (BI) and chemical integrator test pack (CI) must be run every 24 hours after the Leaks Test and Bowie Dick Test, and in every sterilizer load after for the remainder of the workday and until 12 midnight when the test process begins again.

(A)   BI and integrator process.

Make sure that a CONTROL BI bearing a matching lot number to the BI being used has been activated and placed in an incubator. A new Control BI is activated every 24 hours.

(1)   Obtain a BI test pack and a CI test pack.

(2)   Check the lot number of BI test pack to assure that it matches the control lot number.

(3)   Place the BI test pack on bottom shelf, in front of cart (nearest to drain). Place the integrator test pack next to it.

(4)   Run the sterilizer load.

(5)   When load is complete:

    (a)   Remove BI and integrator test packs from sterilizer.

    (b)   Open integrator test pack and remove integrator.

    (c)   Tape integrator to SPM load printout.

    (d)   If integrator failed: load must be torn down, rewrapped and re-sterilized.

    (e)   Tape failed integrator to SPM load printout and detail the teardown procedure.

    (f)   Open BI pack, pick up BI and close cap by squeezing BI, holding top and bottom.

    (g)   Allow BI to cool for 2-3 minutes.

    (h)   Crush BI in incubator.

    (i)   Place the BI in an open incubator well. Log in SPM.

(6)   Fill out the BI reminder sheet IMMEDIATELY. Make sure reminder sheet is kept on the front table.

(7)   After 24 min., incubator should automatically indicate a "negative" reading on the BI. If at any time the incubator alarms and indicates a "positive" reading, immediately implement procedure #SP3-7.

(8)   *If the incubator and BI read "negative", enter the data in the BI reminder sheet and enter the following info into the SPM system.*

    (a)   Enter date (dd/mm/yy), time (AM/PM) **OUT** of incubator.

    (b)   Initials of person reading and removing BI.

    (c)   Under "Test Result", if auto reader alarms, enter "+" under "Test BI Results" and begin load recall process according to procedure #SP3-7

    (d)   If auto reader indicates negative, enter "**-**" under "Test BI Results". Implants may be released at this time.

If implants are requested prior to auto reader indicating negative, make sure that the yellow light is on, release instruments to OR and log in "Implant Logbook".

(9)   At this time, read control and fill out the Exception for Premature Release of Implants Form attaching a copy of the sterilizer load details. This form is in the Implant Logbook. (Additional copies available in the departmental shared drive.)

(10)   "Control BI Results" should be positive. If *CONTROL* is negative, contact the supervisor on duty or on-call.

(11)   Remove BI from incubator and place it in disposal bin.

Approved by: Initial effective date:
  Christopher Lehnert   2010
  Operations Supervisor, Sterile Processing

                                                          Review/Revision Date:
                                                            2014
Review/Revision Completed by: August 2018
  Operations Supervisor, Sterile Processing   December 2020
                                                            April 1, 2021
                                                            December 2025

                                                          Next review date:
                                                            December 2028