SAMPLE PROCEDURES
Routine Monitoring and Load Release of Immediate Use Steam Sterilization (IUSS) cycles with VERIFY® Assert™ Self Contained Biological Indicators

Product Numbers:
LCB032/LCB033
LCB030
PCC064/ PCC065
RK017

VERIFY® Assert™ Self Contained Biological Indicator (SCBI)
VERIFY™ Incubator for Assert™ Self Contained Biological Indicator
VERIFY STEAM Integrating Indicator
VERDOC® Exception Report

This document contains sample procedures for biological and chemical monitoring of immediate use steam sterilization cycles within sterile processing and by the OR. The procedures contained in this document are only intended to provide a foundation for developing specific policies and procedures for your facility. It is the responsibility of the health care facility to ensure compliance with applicable laws, regulations, standards and industry-recommended practices. The health care facility should seek expert advice and consultation for guidance with compliance issues. STERIS Corporation makes no representation, express or implied, with respect to compliance with local or federal laws, regulations, or standards. STERIS Corporation shall not be responsible for any loss, injury, damage, or claim arising from use of this document or the sample policies and procedures contained in it.

Definitions:

Mechanical Monitor: Sterilizer time, temperature, and pressure recording devices.

Biological Indicator: Test systems containing viable microorganisms providing a defined resistance to a specified sterilization process (ANSI/AAMI ST79:2013)

Biological Indicator “control”: An unprocessed biological indicator used to ensure viable organisms are present in the indicator lot and to monitor the operation of the incubator.

Chemical Indicator: System that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor the attainment of one or more of the variables required for sterilization process (ANSI/AAMI/ISO 11140-1)

Chemical Integrator: chemical indicators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in ISO 11138 series for BIs.

Process Challenge Device (PCD): Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

NOTE—For purposes of this recommended practice, a PCD is a challenge test pack or test tray that contains a BI and/or a Class 5 integrating indicator. A PCD containing a BI is referred to here as a BI
Routine Monitoring of Immediate Use Steam Sterilization Cycles

For routine monitoring of IUSS Steam Sterilization cycles, a representative Process Challenge Device (PCD) is constructed using a Biological Indicator and a Chemical Indicator (CI) within a containment device (tray, container system, etc.) that is routinely processed through IUSS cycles. Each type of tray configuration in routine use should be tested separately utilizing the validated exposure time for the biological indicator.

Procedure:

Table 1: List of Validated IUSS Cycles

<table>
<thead>
<tr>
<th>Sterilization Cycle Type</th>
<th>Sterilization Temperature and Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dynamic Air Removal-Prevacuum/SFPP (IUSS)</td>
<td>270 °F / 132 °C for 4 minutes</td>
</tr>
<tr>
<td></td>
<td>275 °F / 135 °C for 3 minutes</td>
</tr>
</tbody>
</table>

Prior to initiating a cycle examine the SCBI for expiration date, ensure media-filled cap is not fully seated on the top of the vial and the foil seal is intact. Verify there is no evidence of media in the vial and the process indicator has NOT changed from pink to brown.

Initiating the cycle:

1. Construct the PCD using a representative containment device containing the VERIFY Assert Self Contained Biological Indicator (SCBI) and the VERIFY Steam Integrator Strips.

   NOTE: Except for the inclusion of a chemical and biological indicator, the containment device should be empty.

2. Place the PCD in the most difficult area to sterilize as indicated by the sterilizer manufacturer (typically this is the lowest shelf above the chamber drain).

3. Close the chamber door.

4. Run the validated IUSS cycle.

Upon completion of the cycle:

1. Review the cycle printout to ensure that processing parameters were met (i.e., minimum time, temperature, pressure).

2. Open the chamber door and carefully remove the PCD. Remove the challenge pack from the cart or sterilizer shelf using thermal protective gloves to avoid thermal
injury. Once cool to touch, remove the SCBI and the chemical integrator (CI) from the PCD.

3. Interpret the CI as follows:
   a. The integrator demonstrates passing results when the dark bar has completely traveled through the “REJECT” area and has entered the “ACCEPT” area. Proceed to Step 4.
   b. The integrator demonstrates failing results when the dark bar is not visible in the “ACCEPT” area of the window. Dispose of the biological indicator test pack. Do NOT release the load. Follow departmental procedures for investigating suspected sterilization failures.

4. Remove the Self Contained Biological Indicator (SCBI) and peel off the lot label from the cap and adhere to load record documentation or cycle printout.

5. Check the process indicator on the SCBI vial label for a color change from pink to brown. If the indicator is brown, proceed to Step 6.
   a. If indicator has not changed to brown this should be considered a sterilization failure, the sterilized items may NOT be used. Dispose of the SCBI assuming it has not been sterilized. Follow departmental policy for reporting sterilization failure.

6. To activate the SCBI, twist the cap clockwise and transfer the media from the cap to the vial by the holding the SCBI firmly by its cap and flicking the wrist down.

7. Label the SCBI with pertinent process information, ensuring the label is not placed on the side of the vial.

8. Immediately place the activated SCBI in the VERIFY™ Incubator for Assert SCBI and press the corresponding well number to start the reading. The well light will blink red during incubation.

   **Control Biological Indicator:**

9. A control must be performed once each day that a test is performed and whenever the lot number of the test SCBIs changes.

10. Obtain an SCBI from the same lot used in the representative PCD. Seal, activate, and incubate the SCBI as described in Steps 7 through 9.

**Note:** The process indicator on the control SCBI will remain pink.

**Interpretation of Biological Indicator Test Results:**

11. The incubator will display results for the “Test” and “Control” SCBIs when incubation is complete (within 40 minutes).
   a. A Negative response (no organism present) is confirmed when the VERIFY Incubator for Assert SCBI demonstrates a solid green light with no audible alarm.
   b. A Positive response (organism present) is confirmed when the incubator demonstrates a solid red light and signals with an audible alarm.
12. Record the SCBI “Test” and “Control” results.

13. The test passes when the “Test” SCBI demonstrates a negative response (no increase in fluorescence signal) and the “Control” SCBI demonstrates a positive response (increase in fluorescence signal).

14. The test fails when the “Test” SCBI demonstrates a positive response (increase in fluorescence signal) and the “Control” SCBI demonstrates a positive response (increase in fluorescence signal). Follow departmental procedures for reporting sterilization failures.

15. The test is invalid whenever the control SCBI demonstrates a negative response (no increase in fluorescence signal). All tests performed since the last positive control must be repeated using a different box of SCBIs.

**Release of Immediate Use Steam sterilized items (implants)**

**IMPLANTABLE DEVICES SHOULD BE IUSS STERILIZED ONLY WHEN A DOCUMENTED EMERGENCY NEED HAS OCCURRED**

AAMI Statement: “IUSS of implantable devices is not recommended; however if it is unavoidable, full traceability to the patient should be maintained”.

**NOTE: AORN and AAMI do not recommend immediate use steam sterilization of implantable devices unless a documented emergency necessitates the process.**

**Procedure**

*Initiating the cycle:*

1. Identify the implant that must be immediate use steam sterilized. The Exception Form is to be filled out by the OR.

2. Ensure that the integrating indicator and SCBI are within expiration.

3. Place one integrating indicator (per level in multi-tiered trays) and one VERIFY Assert SCBI in the tray or container next to the item being sterilized. Place the tray or container into the steam sterilizer. (Insert immediate use steam sterilization container instructions for use here.)

4. Close the chamber door.

5. Process the load using a validated IUSS cycle. See Table 1

*Upon completion of the cycle:*

6. Review the cycle printout to ensure that processing parameters were met (i.e., minimum time, temperature, and pressure).
7. Open the chamber door and carefully remove the PCD (IUSS Tray/Container from the sterilizer:
   a. Immediately deliver the tray/container and Exception Form to the point of use, using appropriate PPE as the tray will be hot.
   b. As the items will be used as an IUSS, the appropriate early release paperwork should be completed, as the item will be used prior to the BI results.
   c. Open the tray/container.
   d. The Perioperative Scrub should examine the chemical indicator for passing results, if indicator shows a fail, the item cannot be used.
   e. If the indicator passes, the Perioperative Scrub should remove the SCBI and aseptically hand it off to an appropriate person for activation, incubation and documentation.
   f. The Operating Room will complete the Exception Form and return to Sterile Processing within 24 hours.

8. Interpret the CI as follows:
   a. The integrator demonstrates passing results when the dark bar has completely traveled through the “REJECT” area and has entered the “ACCEPT” area. Proceed to Step 10.
   b. The integrator demonstrates failing results when the dark bar is not visible in the “ACCEPT” area of the window. Dispose of the biological indicator test pack. Do NOT release the load. Follow departmental procedures for investigating suspected sterilization failures.

9. If all process parameters were met and the CI demonstrated passing results, the cycle was successful. Proceed to Step 11.
   a. If any process parameter was not met or the chemical indicator demonstrated failing results, the cycle was NOT successful. Follow departmental procedures for reporting sterilization failures.

10. Remove the top label (Lot Label) on the SCBI and adhere it to record keeping documentation.

11. Check the process indicator on the SCBI vial label for a color change from pink to brown. If the indicator is brown, proceed to Step 13.
    a. If the indicator is not brown, this should be considered a sterilization failure and the sterilizer may NOT be used. Follow departmental procedures for reporting sterilization failures.

12. To activate the SCBI, twist the cap clockwise and transfer the media from the cap to the vial by the holding the SCBI firmly by its cap and flicking the wrist down.

13. Label the SCBI with pertinent process information, ensuring the label is not placed on the side of the vial.

14. Immediately place the activated SCBI in the VERIFY™ Incubator for Assert SCBI and press the corresponding well number to start the reading. The well light will blink red during incubation.
**Control Biological Indicator:**

15. A control must be performed once each day that a biological test pack is used and whenever the lot number changes.

16. Obtain an SCBI from the same lot used in the biological test pack. Seal, activate, and incubate the SCBI as described in Steps 13 through 14.

**Note:** The process indicator on the control SCBI will remain pink.

**Interpretation of Biological Indicator Test Results:**

17. The incubator will display results for the “Test” and “Control” SCBIs when incubation is complete (within 40 minutes).
   a. A Negative response (no organism present) is confirmed when the VERIFY Incubator for Assert SCBI demonstrates a solid green light/no audible alarm.
   b. A Positive response (organism present) is confirmed when the incubator demonstrates a solid red light/audible alarm.

18. Record the SCBI “Test” and “Control” results.
   a. The test passes when the “Test” SCBI demonstrates a negative response (no increase in fluorescence signal) and the “Control” SCBI demonstrates a positive response (increase in fluorescence signal).
   b. The test fails when the “Test” SCBI demonstrates a positive response (increase in fluorescence signal) and the “Control” SCBI demonstrates a positive response (increase in fluorescence signal). Follow departmental procedures for reporting sterilization failures.
   c. The test is invalid whenever the control SCBI demonstrates a negative response (no increase in fluorescence signal). All tests performed since the last positive control must be repeated using a different box of SCBIs.

19. Upon completion of the surgery, the OR will forward the completed Exception Form to the sterile processing department immediately.

20. Complete the Implantable Devices Load Record when the biological results are known and file with the cycle records.