SAMPLE PROCEDURE
Routine and Load Monitoring of Steam Sterilization Cycles with the VERIFY® Assert™ STEAM Process Challenge Device for Gravity Cycles

Product Numbers:
  LCB043  VERIFY Assert STEAM Process Challenge Device (PCD) for Gravity Cycles
  LCB030  VERIFY™ Incubator for Assert™ Self Contained Biological Indicator

This document contains sample procedures for biological and chemical monitoring of steam sterilization cycles within sterile processing. 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)

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 Type 5 integrating indicator. A PCD containing a BI is referred to here as a BI challenge test pack or BI challenge test tray. A PCD containing only a Type 5 integrating indicator is referred to as a CI challenge test pack.
Routine and Load Monitoring of terminally Steam Sterilization Cycles with the VERIFY® Assert™ STEAM Process Challenge Device for Gravity Cycles

Policy:
A biological indicator test pack shall be included with the first load of the day, minimally weekly, preferably daily, and with any loads that contain an implantable device. The implant load should be quarantined until the results are known.

Procedure:

Table 1: List of Validated Cycles

<table>
<thead>
<tr>
<th>Sterilization Cycle Type</th>
<th>Sterilization Temperature and Time</th>
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</thead>
<tbody>
<tr>
<td>Gravity</td>
<td>250 °F / 121 °C for 30 minutes</td>
</tr>
<tr>
<td></td>
<td>270 °F / 132 °C for 15 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. Load the steam sterilizer cart/racks or shelves (small chamber) with items to be processed.
2. Label the VERIFY Assert™ STEAM Process Challenge Device (PCD) with the appropriate load information, if needed. Ensure that the challenge pack is within expiration date.
3. 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).
4. Push the cart, if applicable, into the sterilizer.
5. Close the chamber door.
6. Perform appropriate, validated steam sterilization cycle.

Upon completion of the cycle:

1. Review the cycle printout to ensure that process parameters were met (i.e. minimum time, temperature, and pressure).
2. Carefully remove the cart, if applicable, from the sterilizer chamber.

3. Remove the challenge pack from the cart or sterilizer shelf using a thermal protective gloves to avoid thermal injury.

**NOTE:** Allow the PCD to cool prior to opening.

4. Confirm that the pack has been exposed to steam by viewing the integrator spot through the clear plastic

5. Peel open the BI test pack and remove the chemical integrator and interpret the integrator spot.

   a. The integrator demonstrates passing results when the indicator ink changes from yellow to blue/purple indicator color.

   b. The integrator demonstrates failing results if any yellow color remains or there is any color other than blue/purple. The critical sterilization parameters were not met. Dispose the test pack assuming the biological indicator is not sterile. Follow departmental procedures for investigating suspected sterilization failures, including not releasing the load, repackaging and resterilizing per facility policy.

6. 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.

7. Observe the process indicator on SCBI cap.

   a. If the indicator has changes from pink to brown, proceed to Step 8.

   b. If the indicator has not changed to brown this should be considered a sterilization failure, the sterilized items may NOT be used. Dispose the SCBI assuming it has not been sterilized. Follow departmental policy for reporting sterilization failure.

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

9. 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:**

10. A control must be performed once each day that a biological test pack is used and whenever the lot number changes.
11. Obtain an SCBI from the same lot used in the biological test pack. Seal, activate, and incubate the SCBI as described in Steps 8 through 9.

Interpretation of Biological Indicator Test Results:

12. The incubator will display results for the “Test” and “Control” SCBIs when incubation is complete.

   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.

13. Record the SCBI “Test” and “Control” results.

14. The test passes when the “Test” SCBI is sterile (negative response) and the “Control” SCBI is not sterile (positive response). The load may be released for use.

15. The test fails when the “Test” SCBI is not sterile (positive response) and the “Control” SCBI is not sterile (positive response). The load may NOT be released for use. Follow departmental procedures for reporting sterilization failures.

16. The test is invalid whenever the “Control” biological indicator is sterile (negative response). All tests must be repeated using a different box of PCDs.

17. Implants are quarantined until a negative BI result is obtained.

Emergency release of implants in quarantine

1. Identify the implant to be released from quarantine using the Implantable Devices Load Record.

2. Confirm that the chemical integrator within the PCD demonstrated passing results.

4. Deliver the implant and Exception Form to the Operating Room.

5. The Operating Room will return the completed Exception Form to the sterile processing department immediately.

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