

SAMPLE PROCEDURE

Routine Monitoring of STERRAD^{®1} Sterilization Systems with Celerity 20 HP Biological Indicators

Product Numbers:

LCB044 Celerity™ 20 HP Biological Indicator

LCB046 Celerity™ HP Incubator

This document contains sample procedures for the routine monitoring of STERRAD[®] 100S, STERRAD[®] NX and STERRAD[®] 100NX Sterilization Systems. The procedures contained in this document are only intended to provide a foundation for your development of 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, standards, or industry-recommended practices. 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.

Title: Routine Monitoring of STERRAD Sterilizers.

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 ST58:2013). A biological indicator does not verify that an item is sterile.

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 Indicators: System that reveals a change in one or more predefined process parameters based on a chemical or physical change resulting from exposure to a process (ANSI/AAMI/ISO 11140-1).

¹ STERRAD is the registered trademark of Advanced Sterilization Products, Division of Ethicon Inc., a Johnson & Johnson company

Routine Monitoring of STERRAD Sterilization Systems

POLICY:

Routine microbial challenges shall be conducted daily for each sterilizer listed below.

- STERRAD® 100S Sterilizer
- STERRAD® NX Sterilizer
- STERRAD® 100NX Sterilizer

PROCEDURE:

Prior to initiating a cycle examine the BI 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 magenta to orange/yellow.

Preparation and Placement:

1. Load the sterilizer with items to be processed according to the sterilizer's Operator Manual.
2. Take one Biological Indicator (BI), remove the lot label and place in record keeping documentation.
3. Place BI into the *(Insert name of sterilization pouch cleared for use with the STERRAD Sterilizer)*. Insert one *(Insert name of CI cleared for use with the STERRAD sterilizer)* into the pouch such that the indicator ink is visible through the clear side of the pouch. Ensure that the expiration date has not passed for the BI, CI or sterilization pouch.
4. Place the pouch at the back of the bottom shelf per the sterilizer's Operator Manual.

NOTE: Do not stack pouch directly on or beneath other items on the shelf.

5. Close the chamber door.
6. Initiate the appropriate sterilization cycle.
 - Default cycle of the STERRAD 100S Sterilizer
 - Standard or Advanced Cycles of the STERRAD NX Sterilizer
 - Standard, FLEX, Express, or DUO Cycles of the STERRAD 100NX Sterilizer

Upon completion of the cycle:

1. Review the cycle printout to ensure that cycle did not abort and follow directions for processing a sterilized load in the sterilizer's Operator Manual.
 - a. If cancellation messages show parameters were not met, the sterilization cycle was not successful. The processed items may not be released for use. Reject the cycle. Repackage and sterilize all items.
2. Put on gloves and remove the pouch from the shelf. Look for any leakage of the media onto the pouch or in the BI vial. If no leakage is detected, proceed to step 3.
 - a. Pouches which show leakage must be placed in a steam compatible container or pouch for disposal. Refer to the BI instructions for disposal recommendations.
3. Remove the chemical indicator strip. Observe the strip for a "Pass" color change per the CI's instructions for use.
 - a. If the chemical indicator shows passing results, continue to step 4.
 - b. If the chemical indicator shows failing results, follow departmental procedures for investigating suspected sterilization failures.
4. Remove the BI and check the process indicator on the BI vial label for a color change from magenta to orange/yellow.
 - a. If the process indicator is orange/yellow, proceed to step 5.
 - b. If the process indicator is not orange/yellow, determine the root cause of the cycle failure. Follow department procedures for investigating suspected sterilization failures.
 - c. Dispose of BI per manufacturer's instructions for use.
5. To activate the BI, twist the cap clockwise and transfer the media from the cap to the vial by holding the BI firmly by its cap and flicking the wrist down.
6. Label the BI with pertinent process information, ensuring the label is not placed on the side of the vial.
7. Place the activated BI in a Celerity HP Incubator and press the corresponding well number to start reading. The well light will blink red during incubation.

Control

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

1. Obtain an BI from the same lot used in the microbial challenge load.
2. Seal, activate, and incubate the SCBI as described in step 5 through 7 above.

Note: Use an unprocessed BI as the control.

Note: The process indicator on the label will remain magenta.

Interpretation of Biological Results

1. The Incubator will display results for the “Test” and “Control” BIs when incubation is completed (within 20 minutes).
 - a. A Negative response (no organisms present) is confirmed when the Celerity HP Incubator 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 with an audible signal.
2. Record the BI “Test” and “Control” results.
3. The test passes when the “Test” BI demonstrates a negative response (no increase in fluorescence signal) and the “Control” BI demonstrates a positive response (increase in fluorescence signal).
4. The test fails if the “Test” BI demonstrates a positive response (increase in fluorescence signal) and the “Control” BI demonstrates a positive response (increase in fluorescence signal). Follow departmental procedures for reporting and investigating suspected sterilization failures.
 - a. Recall sterilized loads back to the last negative BI.
5. The test is invalid whenever the “Control” BI 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 BIs.
 - a. Do not release the load
 - b. Repackage with all new materials and rerun the load.
 - c. Dispose of BI and Control per manufacturer’s instructions for use
 - d. Recall sterilized load back to the last positive control BI.