BIOLOGICAL MONITORING STERILIZERS

POLICY:

Live bacterial spores are used daily and weekly to monitor the steam and sterrad sterilizers for a maximum level of sterility assurance.

PROCEDURE:

<table>
<thead>
<tr>
<th>Steps</th>
<th>Key Points</th>
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<tr>
<td>1. A steam biological culture of bacillus stearothermophilas shall be used every day if used, and with every implantable.</td>
<td>1. Culture is used to test sterility performance of steam sterilizers.</td>
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<td>2. Culture, identified with the appropriate lot and load information is put in the middle of an 16 towel pack taped together and placed on bottom rack above the sterilizer drain, according to AAMI standards.</td>
<td>2. Run in sterilizers 1 &amp; 2 to see if steam is penetrating the center of the pack. Run a regular cycle.</td>
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<tr>
<td>3. A steam biological culture is bacillus stearothermophilas shall be used every Sunday to challenge sterilizer #5. Sterilizer #6 and #7 are to be done every day that OR is not scheduled.</td>
<td>3. Sterilizer #5 is in decontam.</td>
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| 4. Steam culture identified with appropriate lot and load information is placed in metal tray unwrapped in sterilizers 6 & 7. Run sterilizers 6 & 7 for a 5 minute cycle. | 4. Run #6 for pre-programmed # of min  
Run #7 for 4 min                                                      |
| 5. Test pack for sterilizer 1, 2 & 5 consists of an 16 towel pack. |                                                                                 |
| 6. Place towel pack on bottom shelf over drain by door of sterilizer. | 6. Coolest area of sterilizer provides for greatest challenge.             |
| 7. Run a 45 minute cycle @ 250F.                                      | 8. Do the same for all sterilizers.                                        |
| 8. When cycle is completed, remove biological culture and place in incubator with control. Do the same for all the sterilizers. Only do one culture per day, we don’t need to do it with every load. | 9. Culture is checked after 1 hour and can usually be interpreted.         |
| 9. Results of biological culture is interpreted after 3 hours and recorded in sterilizer log book. |                                                                                 |
| 10. Positive biological culture must be reported immediately to the Director of OR. |                                                                                 |
| 11. Director of OR must contact hospital maintenance and sterilizer service personnel. |                                                                                 |
| 12. A recall of all processed items will occur.                        | 11. Determine cause of sterilization failure                              |
| 14. Sterilizer must be immediately rechallenged with a biological culture. | 14. Instruments may be run in the challenge load but should be quarantined until results are known. In case of an emergency, the physician on call may decide appropriate course of action. |
INDICATIONS FOR USE
The STERRAD CycleSure™ Biological Indicator is intended for use by healthcare providers for monitoring of the sterilization process in the STERRAD Sterilization System. STERRAD CycleSure is designed to accompany medical devices placed in the sterilizer. Note: Assure that the STERRAD CycleSure B1 is at room temperature before use. Package STERRAD CycleSure in a manner consistent with the items being sterilized. Place STERRAD CycleSure is the most challenging area for the sterilant to reach.

PLACEMENT AND PACKAGING:

BIOLOGICAL TEST
A. Set up a 55°C to 60°C biological incubator according to manufacturers instructions, allowing appropriate time for the incubator to heat up.
B. Immediately after the STERRAD Sterilization Cycle, remove STERRAD CycleSure from the sterilizer
   1. Check the chemical indicator for color change from red to yellow. See Interpretation of Results.
   2. Press the cap down until firmly seated in order to seal the vial.
   3. Using the tube crusher squeeze the STERRAD CycleSure vial until the media ampule has been crushed. DO NOT CRUSH THE MEDIA AMPULE BY HAND.
   4. Keep the vial in a vertical position after the ampule has been crushed. Note: Care should be taken not to puncture the vial in the crushing process in order to avoid false positive test results due to contamination entering the punctured vial.
C. Label the STERRAD CycleSure vial appropriately.
D. Incubate the processed STERRAD CycleSure vial in the 55°C to 60°C biological incubator.

USE OF CONTROLS
A. Positive Control: Crush an unprocessed STERRAD CycleSure vial and place in the same incubator used for the processed CycleSure vial.
B. Negative Control: An unprocessed and uncrushed STERRAD CycleSure vial can be used for comparison if desired.

This is typically on the shelf close to the rear of the sterilizer.

Note: If the cycle cancels, the STERRAD CycleSure B1 should be autoclaved. A new STERRAD CycleSure B1 should be used in the next cycle.

A positive control should be used with each STERRAD CycleSure.
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READOUT OF RESULTS
A. Observe each vial for color charge from purple to yellow and/or for turbidity of the media. Record results after 48 hours but prior to 7 days. After 7 days the color may revert to purple. Discard all vials immediately after final reading including the positive control STERRAD CycleSure vial. Prior to discarding, decontaminate any positive result vials and the positive control vials by autoclaving for at least 30 minutes at 121°C (250°F).

INTERPRETATION OF RESULTS
A. Compare the processed STERRAD CycleSure vial with the positive control vial.

1. The absence of a color change is the processed STERRAD CycleSure vial (i.e. the media remains purple) indicates that the sterilization conditions were achieved in the STERRAD Sterilizer.
2. If the processed STERRAD CycleSure changes color from purple to yellow (an in the positive control vial), and/or exhibits turbidity, this indicates that conditions necessary to achieve sterilization in the STERRAD Sterilizer have not been met.

B. If a positive result is observed, test the sterilizer with another STERRAD CycleSure B1.
C. If two consecutive positive results are observed in the processed STERRAD CycleSure vials, have the sterilizer checked by the manufacturer and follow the current hospital policy and procedures regarding retrieval of unused instruments and notification of the physician(s). If the second STERRAD CycleSure is negative, run a third STERRAD CycleSure to confirm sterilizer performance.

STORAGE OF STERRAD CycleSure BIOLOGICAL INDICATOR:
A. Store at 2°C to 25°C (35°F to 77°F) under dry conditions.
B. DO NOT store near any sterilizer, sources of ethylene oxide hydrogen peroxide acids, alkalis or volatile antimicrobials such as gultaralde-hyde or formaldehyde. STERRAD Cassettes, or any other oxidizers.
C. Do not use beyond labeled expiration date.